

Essentials in Ophthalmology

Series Editor: Arun D. Singh

Jorge L. Alió

Joseph Pikkel *Editors*

Multifocal Intraocular Lenses

The Art and the Practice

 Springer

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Series Editor
Arun D. Singh

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Jorge L. Alió • Joseph Pikkell
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Multifocal Intraocular Lenses

The Art and the Practice

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*To my beloved wife and children, who escort and support me
in a lifelong effort of helping patients to save sight and in
my journey towards reaching the impossible*

Jorge L. Alio

To my wife Dvora, my copilot in flying towards my dreams

Joseph Pikkell

Preface

The quest for perfection is a great motivator for advances in life and in science. The rapid changes in modern life as well as the continuous extension of life expectancy raise the need for perfection of vision in all distances. This need is the reason for searching the ideal solution for multifocality.

At present, multifocal intraocular lenses provide the best available solution; however the more we implant these lenses, the more we learn about their advantages and disadvantages.

This book is dedicated to accumulation and refining of the current knowledge on this subject, and we hope it will serve as a practical tool for cataract surgeons.

Alicante, Spain
Safed, Israel

Jorge L. Alio, MD, PhD, FEBO
Joseph Pikkel, MD

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Multifocal Intraocular Lenses: The Challenges

1

Jorge L. Alió and Joseph Pikkell

The evolution of cataract surgery and intraocular lens (IOL) implantation over the last decade has been focused on improving quality of vision and quality of life of patients. Near vision and, more recently, intermediate vision have been acknowledged by patients as reasons for quality of life impairment. Today, we operate on younger patients, who have better visual acuity, even without cataracts, using refractive lens exchange procedures, which are growing in popularity among cataract and refractive surgeons. In such cases, patients are less tolerant of visual disabilities; moreover, the positive advances in refractive surgery, sometimes overestimating the potential outcomes of refractive surgical procedures, have informed their request for independence from spectacles. Nowadays, independence from spectacles can be successfully achieved, but in patients with presbyopia, obtaining good and stable near and intermediate vision is still a

problem. The restoration of accommodation is still a dream, and there is no chance in the short term of obtaining real and applicable techniques for the general presbyopic population. In this environment, we have to allocate clinically the role of and the opportunities for multifocal IOLs today.

The main challenge of multifocal lenses is to use a nonphysiological optical method to improve near vision. Multifocal lenses, by definition, divide light into different foci, and this causes a dispersion of the energy of the light entering into the eye and, consequently, distributing the light in different foci. This causes a change in the physiology of vision as the light follows a different focal performance at the level of the visual axis and, consecutively, at the level of the retina. It is necessary to activate neuroprocessing, the capability of the brain to adapt to changes, to adjust the neurophysiology to the changes that are induced in the quality of the retinal image by the dispersion of light. Moreover, the overlapping of different foci is neither physiological nor normal in the evolution of humans or animals. To the best of our knowledge, no visual system is multifocal in nature in any of the prominent mammal species, including humans, even through evolution. For this reason, neuroprocessing is the main challenge for multifocal IOLs. The new technologies emerging in recent years have been aimed at smoothing the changes in visual perception and making a much more

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physiological division of light, but even under these conditions, the efficacy of the technologies has to be demonstrated and confirmed by an improvement in the subjective quality of the patient's vision. The main issue of this book, therefore, is how the practical ophthalmologist and ophthalmic surgeon can select a suitable multifocal IOL, how to differentiate among the different technologies, how to identify the best available on the market, and how to use evidence in selecting what is best for the patients.

We have identified a lack of adequate medical education and an insufficient amount of independent, well-sustained information on this topic in recent literature. For this reason, we, as authors, have undertaken the commitment and task of gathering all the information available on the different technologies used in the multifocal IOL arena today, up until publication of this book. We not only show all the different technologies avail-

able, but also the most relevant clinical studies carried out and the experiences of distinguished, reputable, and independent clinical researchers in using the technologies within the scope of clinical research with adequate, standardized methods, independent opinion, and evidence-based clinical guidance. We hope that the reader will find this book useful for the purpose for which it was created: to raise independent opinion and credibility, and to provide unbiased information about modern multifocal IOLs. If we achieve these goals, the time dedicated to writing this book will have been well used.

Compliance with Ethical Requirements Jorge L. Alió and Joseph Pikkel declare that they have no conflict of interest.

No human studies were carried out by the authors for this article.

No animal studies were carried out by the authors for this article.

Part I

Historical Background and Clinical Indications

Kenneth J. Hoffer and Giacomo Savini

2.1 Introduction

Our patients teach us many things [1]. Often it is humility, but on rare occasions their clinical situation can spark an idea that leads to analytical thinking and a totally new concept. Such a patient appeared in my office over three decades ago on November 18, 1982 (Fig. 2.1). She was referred to me by a colleague, Dr. John Hofbauer, for the question of IOL removal due to bilateral IOL dislocation. She had received a Shearing style Iolab Hoffer Ridge posterior chamber intraocular lens (IOL) in each eye, and the implants had each decentered so that one covered only 50 % of the pupil OD (right eye) and the other only one-third of the pupil OS (left eye) (see hand-drawn diagrams in Fig. 2.1). In those days it was more difficult to get both stiff loops of the Shearing lens

in the bag resulting in one loop out of the bag causing decentration. I was evaluating her situation to determine whether one or both of these IOLs should be removed.

After personally refracting each eye at distance and near, there was a high cylinder in the left eye since she was 3 days PO with sutures still in. She corrected to 20/20 OD and 20/25 OS. Since so much of the pupil was aphakic, out of curiosity I then refracted each eye in an aphakic refraction range of about +10 diopters (D) and was astounded that she was also refractable to a 20/20 level with a full aphakic refraction. I wondered how is this possible?

Then I questioned this 65-year-old educated and intelligent lady regarding glare, halos, rings, and areas of blurred vision and she denied having any of these symptoms. I was astounded at how unaffected she was by the dislocated lenses. I told her that her eyes were perfect and sent her on her way. I told the referring surgeon that no intervention was necessary at least at this time.

The authors have no proprietary interest of any kind in the subject matter of this chapter.

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2.2 Inception of the Concept

That evening while enjoying a Guinness at Ye Olde King's Head in Santa Monica with colleagues, this lady's remarkable condition kept haunting me. How could her distance vision be 20/20 with and without aphakic correction while she was receiving only 50 % of the IOL refracted

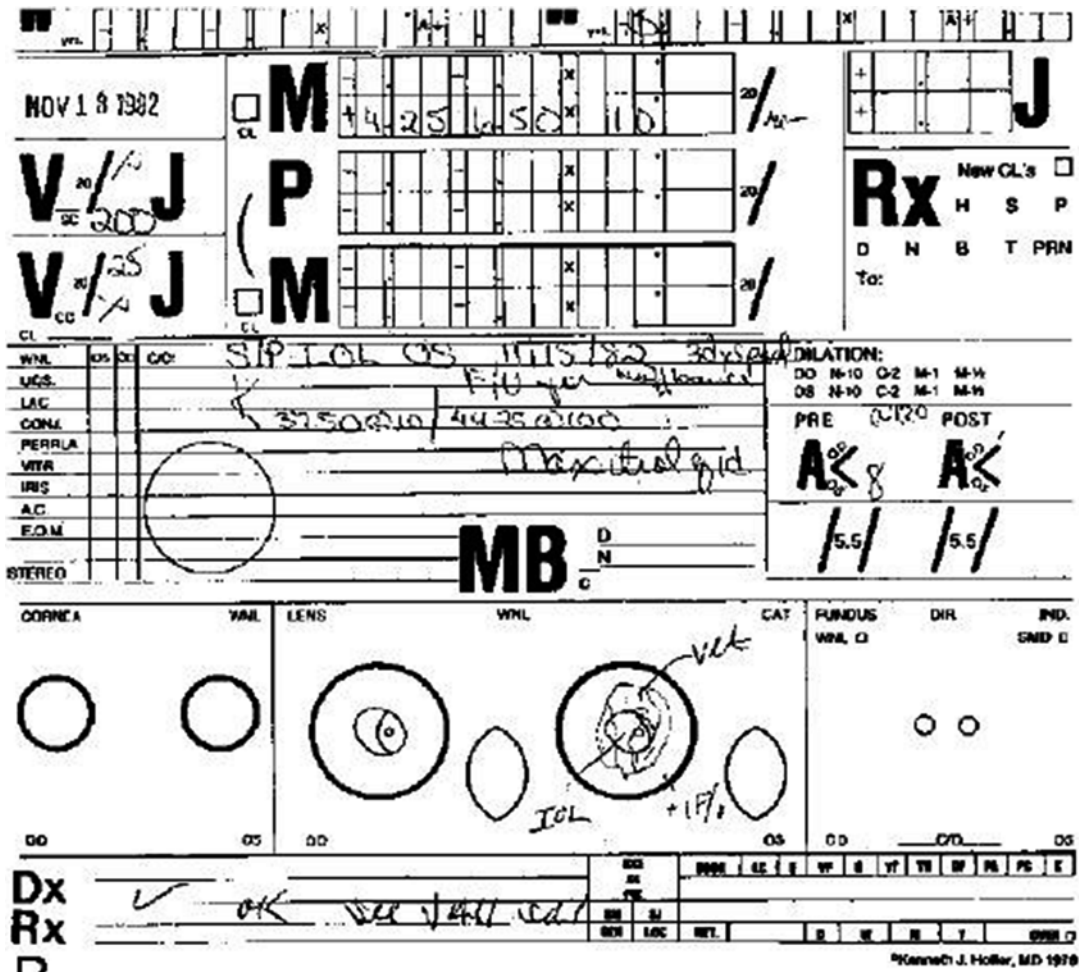


Fig. 2.1 Patient examination record from November 18, 1982, showing drawings of dislocated posterior chamber lenses; the left eye is 3 days postoperative

light (33 % in the other eye) without aphakic refractive aid and 20/20 while receiving 50 % (66 % in the other eye) of non-IOL refracted light. I analyzed the situation making the assumption that light was entering her pupils and being refracted by two different “lenses” simultaneously; one lens had a power of 20 D and the other was 0 D. If this assumption was true, then it had to follow that each “lens” (the 20 D and the 0 D) was creating its own image superimposed on the macula simultaneously. The 20 D lens created a perfectly focused image on the macula with the percentage of light it received and the 0 D “lens” created a hyperopic blurred image superimposed on the focused image (Fig. 2.2). From this I

deduced that the retina-brain had to be ignoring the blurred image completely, thereby accepting only the clear image she wanted to see. If this were not the case, she would have complained of some annoying visual symptoms. With the aphakic correction, the opposite was true; the 0 D “lens” image was now in clear focus and the 20 D lens image was completely blurred and thus the aphakic image was chosen by the brain and the other ignored.

Then it dawned on me that her pupil was actually holding a BIFOCAL lens! I then wondered, since she could tolerate a 20.0 D difference in the two segments of this “bifocal,” could she have tolerated a 3 D difference. I then proposed this to

Fig. 2.2 Depiction of the focal points of a split bifocal



the colleagues I was with and their response was, “You must be crazy.” Their lack of enthusiasm dampened my excitement but I finally concluded the concept should at least be tried. In November 1982 there was simply no such thing as a bifocal IOL. I realized that animal studies were completely out of the question because of the inability to get any feedback from them. Optical bench testing would also not answer the question of brain suppression. I hastily concluded that a human trial was the only way to find out if my theory would work at all, and if it did, whether it worked for everyone or only a select few. I could not do this alone. I needed an IOL manufacturer to fabricate the lens, if it was at all possible. From my decade of experience with IOL manufacturers, I knew they would be more receptive and feel more comfortable entertaining this possibility if the concept had patent protection prior to their spending time and money on a new lens design.

2.3 Intellectual Property Protection

I organized my thoughts and wrote down my concept of multifocality for IOLs with the retina-brain selectivity of clearest image and submitted it to my patent attorney Mr. Howard Silber on May 3, 1983 (Fig. 2.3a, b). In the document I theorized that the reason the bifocal IOL might work in a posterior chamber IOL better than it does in a contact lens was because the former is fixed and stationary and, more importantly, that it is located at the eye’s nodal point rather than on the front of the eye. I also considered and sketched as many possible configurations and combination of ways to include more than one optical power in the pupil (Fig. 2.4). Beside the simple Split

Bifocal, one of the possibilities was a central bullet for near or distance with the surrounding optic for the opposite. I didn’t feel this had much hope of success because of its dependence on pupil location and size and the possibility of IOL decentration. With this design I couldn’t decide whether to make the center bullet for near for accommodative pupil constriction or distance correction for outdoor light pupil constriction. A trifocal triangular configuration was proposed whereby one 33 % segment was for distance, the second for near, and the third for intermediate. Annular rings of alternating powers were considered which, of course, could be a diffractive lens. Other geometric shapes were considered but most of them could be affected by IOL decentration. The patent was then applied for with all these ideas.

I decided to proceed experimentally with my original concept of a simplistic Split Bifocal with a diameter line through the optical center. With this design the retina would always receive an equal amount of light (50 %) for both distance and near, never compromising one over the other regardless of the pupil size, accommodation, or lighting conditions. I specifically stipulated that the bifocal line be parallel to the axis of the loops. This was because the primary cause of posterior chamber IOL decentration (one loop out of the bag, one loop crimped) would cause the lens to decenter in the axis of the loops. Any minor to moderate decentration would still maintain the bifocal line through the center of the pupil. On the other hand, if the bifocal line was perpendicular to the axis of the loops, even a minor decentration would shift one of the focal zones entirely out of the pupil leading to either a monofocal lens for distance or one for near. One unanswered question remained. Would the patient notice the

Fig. 2.3 (a) Attorney work sheet for patent application dated May 11, 1983. (b) First page of multifocal patent application #1365

a NEW CLIENT/NEW MATTER DATA INPUT FORM (8/81)

Prepared by: HAS Date prepared: 5/11/83

ACTION REQUESTED: (check one) Matter Action Only Add Client
 Change Client Information Delete Client

CLIENT NUMBER: 021 (6)

CLIENT NAME: HOFFER, KENNETH J. (42)

ACTION REQUESTED: (check one) Add New Matter Delete Matter
 Change Matter Information

MATTER NUMBER: 018 (6) (circle one: PD FN C ID PD Tr 1)

MATTER NAME ONLY: BIFOCAL IMPLANT LENS (42)
 (NO MISC. INFO.)

MISC. INFO. (will not be displayed anywhere) _____ (30)

MATTER SERVICE TYPE: 027 (3) BILLING STATEMENT: _____ (1)

ORIGINATING ATTY: HAS (3) BILL ATTY: HAS (3) RESP ATTY: HAS (3)

SPECIAL RATE TABLE: 7

b PATENT APPLICATION 1365

TITLE: Multifocal Intraocular Lens Implant

PURPOSE: Provide simultaneous distance and near focus

NAME: Kenneth J. Hoffer, M.D.

Background

All optical systems function by using lenses to bring an object of regard into focus on a specific target or screen. The lens is either set at a fixed focus (measured in dioptric power) or is capable of being set at multiple focuses by changing either its position or its size. The human eye is such an optical system that has as multiple focus lens (human crystalline lens) that it capable of a multitude of focuses by an ability to constantly change its shape. This is accomplished because the human lens is a flexible semisolid enclosed in a flexible capsule. The capsule is attached to the inside

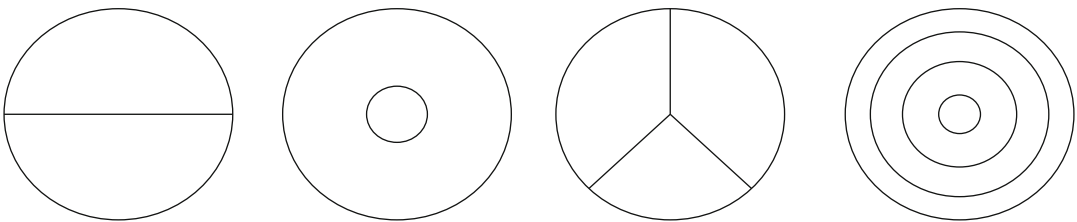


Fig. 2.4 Diagrams of possible configurations for multifocal lenses submitted in the patent application: L-R split bifocal, bullet bifocal, triangulate trifocal, and multiple rings

effect of the “line” through the center of the visual axis? This could only be answered by patient clinical trials. I never imagined in 1982 that it would take eight more years for me to accomplish it.

2.4 Making the First Split Bifocal IOL

With the legal protection the manufacturers would need in the works, I proceeded to present my idea to Mr. Peter La Haye (Fig. 2.5), the President and CEO of Iolab Corporation (now Bausch & Lomb). Their IOLs were injection molded and I thought it might be easier for them to do this. I knew Mr. La Haye very well because of his willingness to sponsor the Welcome Reception at the Annual Meetings of the American Intra-Ocular Implant Society for which I was the Chairman. Mr. La Haye had sold Iolab to Johnson & Johnson in 1980 but he was still in charge of the company for several years afterward. He told me it would be extremely expensive to fabricate an injection mold for this so I asked him to slice in half an 18 D and a 21 D IOL and then glue the opposite halves together. He promised me he would have it done in the company’s R&D department. I recently learned for the first time (11/20/13) from personal communication with Randall J. Olson MD (Chair, Department of Ophthalmology and Visual Sciences, John A. Moran Eye Center, Salt Lake City, UT) that he clearly recalls Mr. La Haye calling him in that year for advice as to whether to proceed with such a “wild idea.” Dr. Olsen remembers telling him that he had no idea whether it would work but that the only way it could be tested is to implant one in a patient’s eye. Perhaps if his advice were otherwise, La Haye might not have proceeded.

After several months, Iolab finally produced 10 samples for me to look at under the slit lamp (Fig. 2.6). Note in the figures that the split line is in the axis of the loops. Also the “circle” that appears in the center of the optic (Fig. 2.6a) is a drop of water on the back of the lens sitting on a flat surface and the peripheral curve of the water



Fig. 2.5 Mr. Peter La Haye, Founder and President of Iolab Corporation (circa 1990)

meniscus can be seen as different in the two segments reflecting the different radius of curvature of each segment. The lenses looked pretty good but I was told categorically that these lenses could not be implanted in a human patient since it would need protocols and FDA submission. Also the lenses were not clean or sterilized for implantation. Not long after that Mr. La Haye was scheduled to leave the company as is often the case in these buyouts and he no longer had any influence over it anymore. This was not good for me. I was soon to learn the corporate structure at Johnson & Johnson was far different from that of Iolab.

Those now in charge of such things at Iolab promised me it would be under consideration by a committee and so I waited many, many months. I was told I had to be patient. After a year, I finally pressured them for an answer I really didn’t want to hear. I was told they could not proceed with the Hoffer Split Bifocal because funds and efforts were needed for other more important IOL development projects. I later learned that the main project that took precedence over the bifocal was

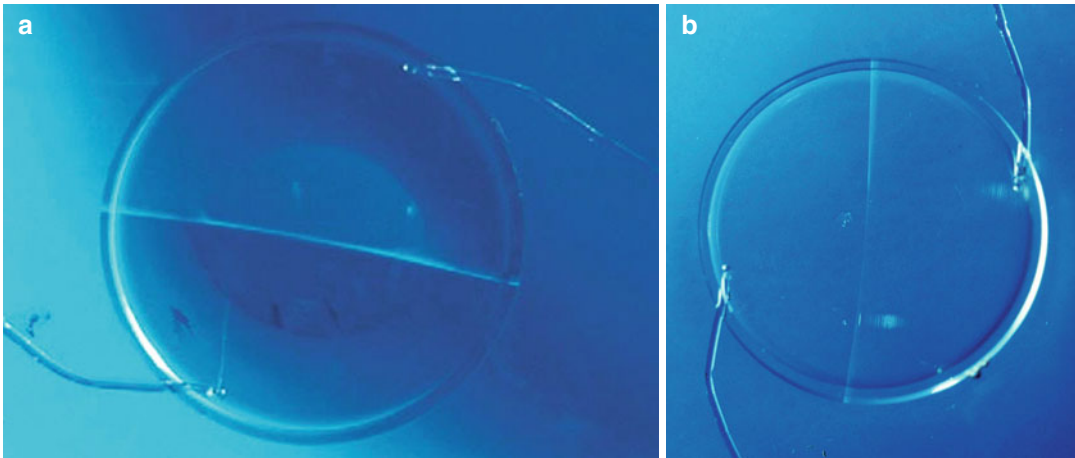


Fig. 2.6 Photographs of Hoffer Split Bifocal IOL made by Iolab in 1983 in their R&D department. (a) Note the water meniscus at the back of the IOL (b) shows a differ-

ent peripheral curvature due to the different radius of curvature of each half of the optic. Note the bifocal line is in the axis of the loops and the lens has a Hoffer Laser Ridge

“partial depth holes.” For those too young to remember, all IOLs had a series of two or four peripheral through and through holes in the optic to ease manipulating it in the eye with a hook. It was becoming evident that these holes were leading to glare and haloes especially with decentered lenses. They were hoping to eliminate the problem with holes that did not go completely through the optic. Eventually all positioning holes were eliminated from all IOLs, so this was a real wasted opportunity on their part. Because of my frustration and persistence, they told me that if I was that eager to do it I should take the lenses they had made for me and go to Mexico and implant them. I rejected that idea because I would not be able to explain to the patient appropriately what the experiment was (informed consent) or carefully interrogate a postoperative patient in Spanish. I would also need to monitor the patient on a continual basis and was not planning to move to Mexico. I spent another 6 months pleading with them but it was to no avail. I then went to Cilco (now Alcon Surgical), who also produced several prototypes in their R&D divisions by lathe cutting rather than injection molding. I could not find any specimens or photographs of these lenses. Delays by Cilco in further progress were similar to those by Iolab. I

had also gone to Precision-Cosmet and most all IOL manufacturers including my friend William Link at AMO but they all just turned me down completely. Things were at a standstill. I had a handful of bifocal IOLs but no way to implant them.

2.5 The First Bifocal IOL Implantation

Then came the surprising day in 1986 when I read a story in one of the throwaway ophthalmic newspapers that John Pierce MD had implanted bifocal IOLs for the first time in England. The lenses were manufactured by Precision-Cosmet. My initial reaction was ecstatic since I would finally find out whether my theory of brain suppression was real. On the other hand I was somewhat exasperated with Iolab and Cilco in that they could have pioneered this in the USA 3 years earlier and FDA studies would have been nearing completion by then. What is most amazing is that both companies had gained tremendous success with their Hoffer Ridge lenses and you might think they would consider that the inventor might also invent another reasonable idea.

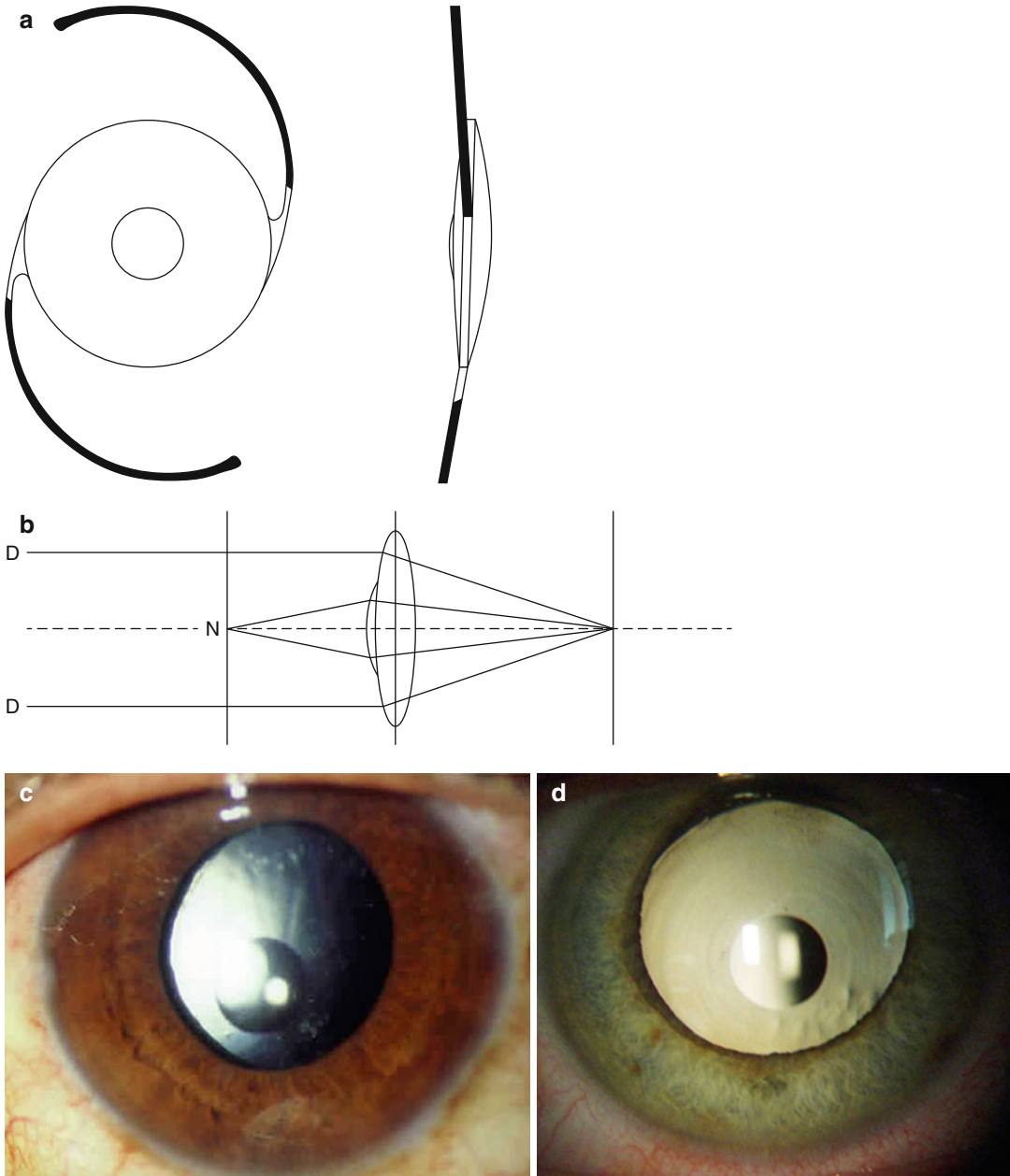


Fig. 2.7 (a) Diagram of Iolab NuVu lens. (b) Ray tracing of Iolab NuVu. (c, d) Photographs of postoperative eyes with the Precision-Cosmet (Iolab NuVu) bifocal IOL

implanted. Note the decentration of the central “bullet” zone in both eyes

I was sorry to hear that the central near bullet (Fig. 2.7) concept was the design chosen to be implanted because of the inherent problems I predicted above. Soon thereafter, Johnson & Johnson (Iolab) purchased Precision-Cosmet and

ironically inherited the mantle of the first bifocal IOL manufacturer. They ceased communicating with me in any way after this. Not long after, 3 M presented a diffractive bifocal meniscus lens (Fig. 2.8) followed by several manufacturers

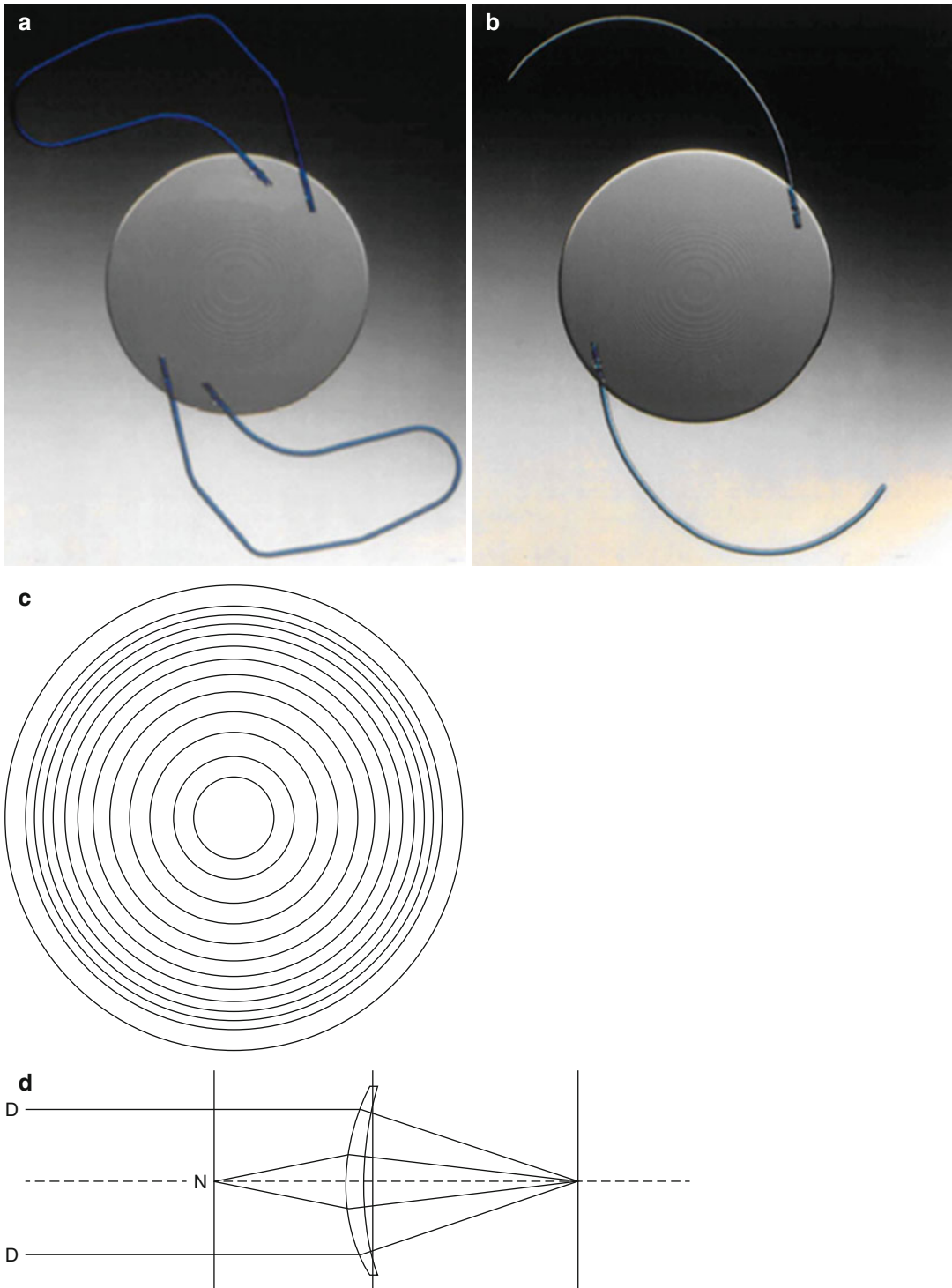
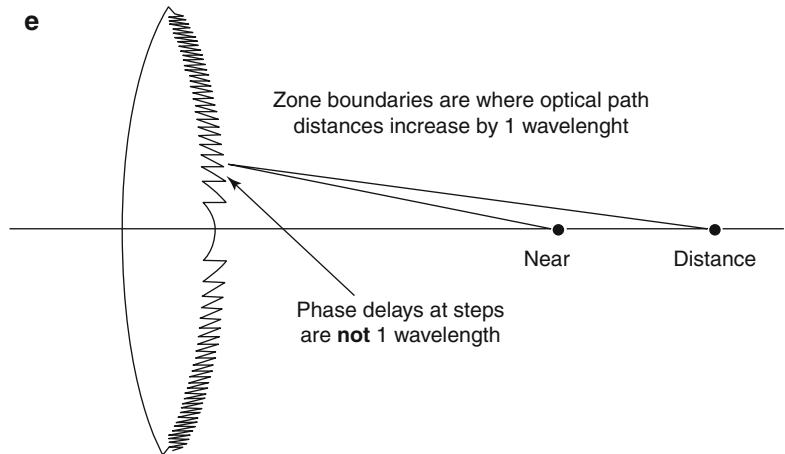


Fig. 2.8 Photographs of the early 3 M diffractive PMMA IOLs with closed (a) and open (b) loops. (c) Diagram of 3 M diffractive lens. (d) Diagram of ray tracing through the diffractive lens. (e) Diagram of diffractive process of 3 M lens

Fig. 2.8 (continued)



trying variations on the bullet and annular ring themes (see below). The data looked promising at that time but there were definite problems and compromises associated with all the various designs. I was pleased to see that my multifocal concept did seem to work.

The diffractive bifocal causes a complete loss of almost 20 % of the incoming light through the pupil leaving about 40 % of the light for distance and 40 % for near. Is this enough in contrast-compromised eyes such as those with macular degeneration? On the other hand, it is not subject to the vagaries of pupil size, position, or IOL decentration. All the other designs can be compromised by the pupil or IOL decentration and in the percentages of light available for each desired image position.

My patent application was ultimately turned down by the US Patent Office. They based their rejection on prior art based on an abandoned bifocal contact lens patent application by Dr. Jack Hartstein of Missouri several years earlier. No matter how much we protested, it was rejected. Things again were not going so well.

2.6 The First Hoffer Split Bifocal IOL Implantation 1990

By 1989 I was completely frustrated and decided to take things into my own hands. I had the lenses but they were not finished, clean, or sterile. Years

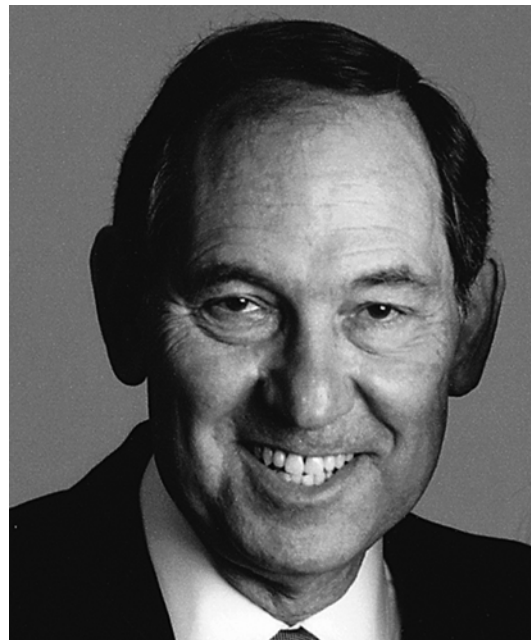


Fig. 2.9 Kenneth Rainin, President of Ioptex

earlier I had developed a working relationship with Kenneth Rainin (Fig. 2.9), the owner of Ioptex Research (bought by Smith & Nephew, later by Allergan). In the 1980s, I had lectured extensively on the benefits of their short C-loop lens. I went to Mr. Rainin and asked if he might do me a favor and check the dioptric power of the bifocals Iolab had made, clean, polish, and sterilize them for implantation in human patients. He told me he would only do it if I promised not

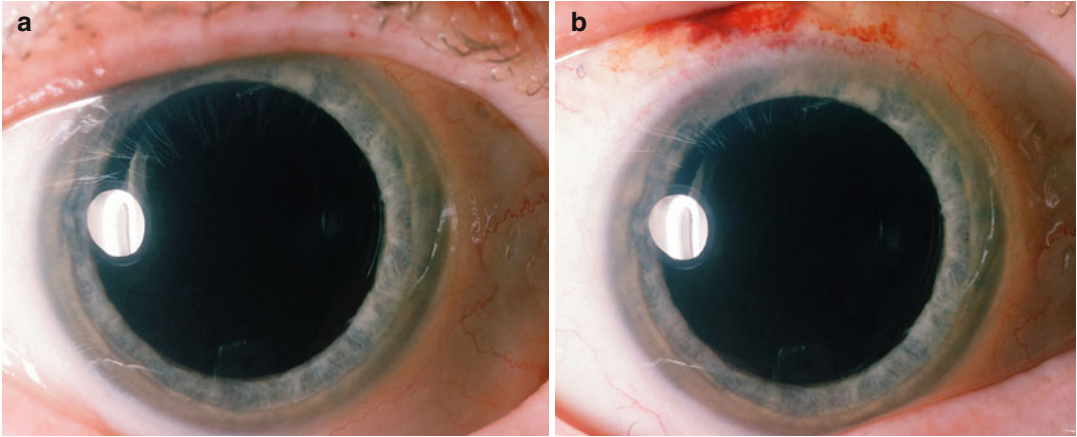


Fig. 2.10 (a) Clinical photograph of the first implanted Hoffer Split Bifocal dated October 18, 1990, labeled “PO 1 week OD” (Clannin.) (b) Another photograph taken the

same day. Note that even under high power, there is no bifocal line visible in this photo. It is obviously not visible when photographed in aqueous

to tell anyone it was done by Ioptex. He did this for me and I will always be grateful to him for doing so. Now with implantable lenses in hand, I wrote up an extensive informed consent and began discussing the idea with many of my cataract patients. I now had to offer the lens to only those patients whose emmetropic IOL power calculated to 18.0 D. Many patients were eager to try it.

After thorough informed consent, three patients agreed and were eager to have the Split Bifocal. I promised them they would be the first in history to receive such a lens and that if it didn’t work, I would immediately remove it and replace it with a normal lens at no charge to them for the surgery or hospital. For those unfamiliar with the US FDA, they only have jurisdiction over manufacturers but not over surgeons. If a surgeon has a specially made device, he may implant it without FDA approval. The surgeon’s only jeopardy is a malpractice action by the patient in civil court for implanting a non-FDA-approved device. I believe that this is still true today.

On my 47th birthday, October 10, 1990 (Fig. 2.10), I implanted my first lens in the right eye of 78-year-old Lenore Clannin (since deceased). Then less than a month later, on November 7, 1990, I implanted the second one (Fig. 2.11a) in the right eye of 71-year-old Jessica

Antonucci (since deceased). The operations records from the operating room document the names and dates of the implants (Fig. 2.12) showing implantations of IOLs labeled “Hoffer #002 Bifocal”. Both lenses were a Shearing posterior chamber lens with a Hoffer Ridge: 18.0 D distance power and 21.0 D near power. [Those powers I chose before I ever did the calculations.] To my great joy, both patients were able to see clearly at distance with a mild over-refraction and additionally see at near without an additional add. Note that even under high magnification (Fig. 2.10a, b), the bifocal line is not visible in aqueous.

My problem now was that because of the promises I made to Mr. La Haye (Iolab) and Mr. Rainin (Ioptex), I couldn’t publically talk about this or publish my results. I had proved my idea had worked to myself but could not publicize it in any way without going against the promises I had made to them. In October of 1991, Jessica Antonucci began to complain of symptoms of glare and, though she loved having distance and near vision without glasses, she asked me to remove the lens, which I did uneventfully. In Fig. 2.11a, the line of the bifocal was somewhat thickened and visible superiorly (at 11:30) the same way it looks in the unimplanted lens (Fig. 2.11b, c). Perhaps that may be the reason for the symptoms she experienced.

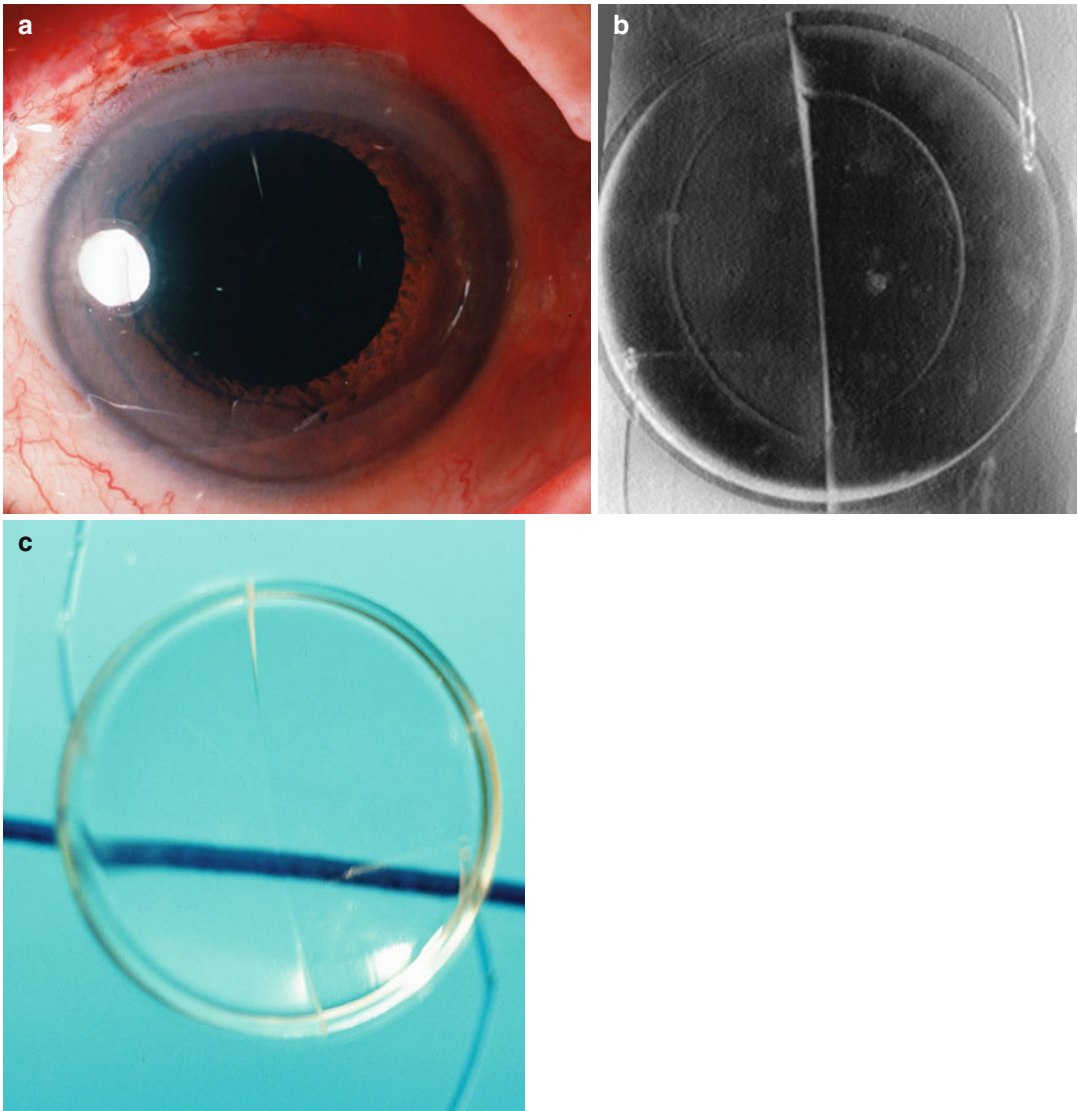


Fig. 2.11 (a) Clinical photograph of the second implanted Hoffer Split Bifocal dated November 7, 1990 labeled “PO 1 day OD; 20/100 J10” (Antonucci). Note the

thickened bifocal line visible superiorly at 11:30. (b) and (c) Photograph of a similar unimplanted lens showing the same obvious line thickness superiorly

In 1989, I was invited to present my original work at the first US meeting on multifocal lenses held in Fresno, CA, by Andrew Maxwell, MD. The presentations at that meeting were published in a book in 1991 entitled *Current Concepts of Multifocal Intraocular Lenses* [1]. The only reason I feel comfortable now relating the complete story is that Peter La Haye, Kenneth Rainin, and the implanted

patients have all passed away and the companies Iolab and Ioptex no longer exist as the entities they once were. Thus, the assurances I gave no longer exist. Mr. La Haye died in his private jet when it crashed in the Poconos Mountains in Pennsylvania on his way to New York City for an ORBIS Board of Directors meeting on December 12, 1999; Mr. Rainin died in 2006.

1990

a

NAME	AGE	EYE	DATE	SURG	1°/2°	STYLE	MF	POW	ENDUTH		VIS PRE
									PRE	POST	
<i>[Handwritten Name]</i>	63	OD	10/10	PIC CB 4.75	10	PC A	15.5	2300			50
<i>[Handwritten Name]</i>	55	OD	10/10	PIC CB 0.5	10	1802	18.5	2000			50
<i>Clara Clannin</i>	78	OD	10/10	PIC CB 4.25	10	1802	18.5	2000			60
<i>[Handwritten Name]</i>	90	OD	10/10	PIC CB 1.9	10	SPC	24.5	233			50

1990

b

NAME	AGE	EYE	DATE	SURG	1°/2°	STYLE	MF	POW	ENDUTH		VIS PRE
									PRE	POST	
<i>[Handwritten Name]</i>	76	OD	10/17	PIC CB 1.3	20	M3	A	1500			20
<i>[Handwritten Name]</i>	78	OD	11/7	PIC CB 1.3	10	JPC	A	20.5	465		50
<i>Jessica Antonucci</i>	71	OD	11/7	PIC CB 1.4	10	M3	A	18.5	24.5		80
<i>[Handwritten Name]</i>	86	OD	12/17	PIC CB 4.4	12	JPC	A	2000			45

Fig. 2.12 Operating room records documenting Split Bifocal implantations in 1990: (a) For the first implant, Lenore Clannin. (b) For the second implant, Jessica Antonucci

2.7 Evolution of Multifocal Refractive and Diffractive IOLs

The first multifocal IOLs marketed were manufactured in the late 1980s. Domilens (Lyon, France), Iolab (Claremont, CA), and Storz Ophthalmics (St. Louis, MO) developed refractive multifocal lens styles, whereas 3 M (St. Louis, MO), Pharmacia Upjohn (Kalamazoo, MI), and Morcher (Stuttgart, Germany) developed diffractive lenses. These were all polymethyl methacrylate (PMMA) lenses.

These earliest PMMA refractive IOLs had two (“bullet bifocal,” Iolab NuVue) (Fig. 2.7) or three zones such as the Storz TruVista (Fig. 2.13a) and Pharmacia (Fig. 2.13b). Ioptex developed a four-zone multifocal (Fig. 2.13c) and Wright Medical produced an aspheric zone multifocal (Fig. 2.13d). The Array (AMO, Irvine, CA), the first foldable silicon multifocal IOL (Fig. 2.14), had five refractive zones (zones 1, 3, and 5 were distance dominant; zones 2

and 4 were near dominant). This was the first multifocal to receive US FDA approval in 1997. AMO was willing to go through the rigorous testing that the FDA had put in place for multifocal IOLs, while all the others chose not to. The Array was later replaced by the ReZoom (AMO, Santa Ana, CA), a hydrophobic acrylic IOL that uses a refractive design with different zones within concentric rings for focusing at varying distances (Fig. 2.22).

The early diffractive IOLs, such as the 3 M, were rigid PMMA lenses with a full-optic diffractive design. They also featured a meniscus optic. The full-optic diffractive design, with constant diffractive step heights across the entire lens, leads to equal distribution of light for distance and near vision, without any influence of the pupil diameter or position. The compromise with this lens was a notable total loss of 20 % of the light, leaving just 40 % for distance and 40 % for near. This is not ideal in eyes developing macular degeneration or in dim-light situations. Several clinical studies of these various early

styles showed a degradation in color and contrast sensitivity [2, 3].

A slightly different approach has been followed by other manufacturers (e.g., Zeiss, Jena, Germany), which produce full-optic diffractive IOLs with unequal energy distribution. In this

case the step height changes. Lower steps send more light to distance and higher steps send more light to near.

A mixed refractive-diffractive design was introduced by the AcrySof ReSTOR (Alcon, Fort Worth, TX) which was approved in March

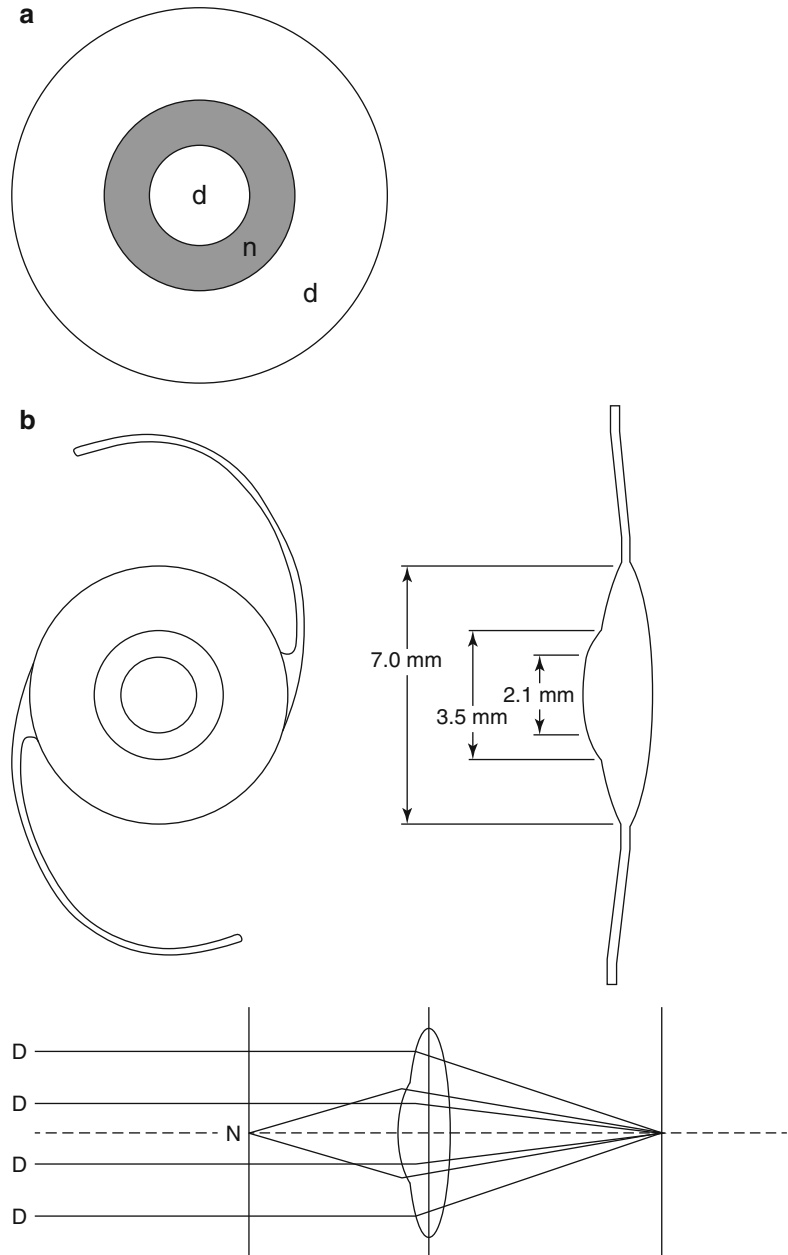


Fig. 2.13 (a) Diagram of the three-zone Storz TruVista lens. (b) Diagram of Pharmacia three-zone multifocal and ray tracing. (c) Diagram of the four-zone Ioptex lens and ray tracing. (d) Diagram of the Wright Aspheric Multifocal and ray tracing through Wright lens

Fig. 2.13 (continued)

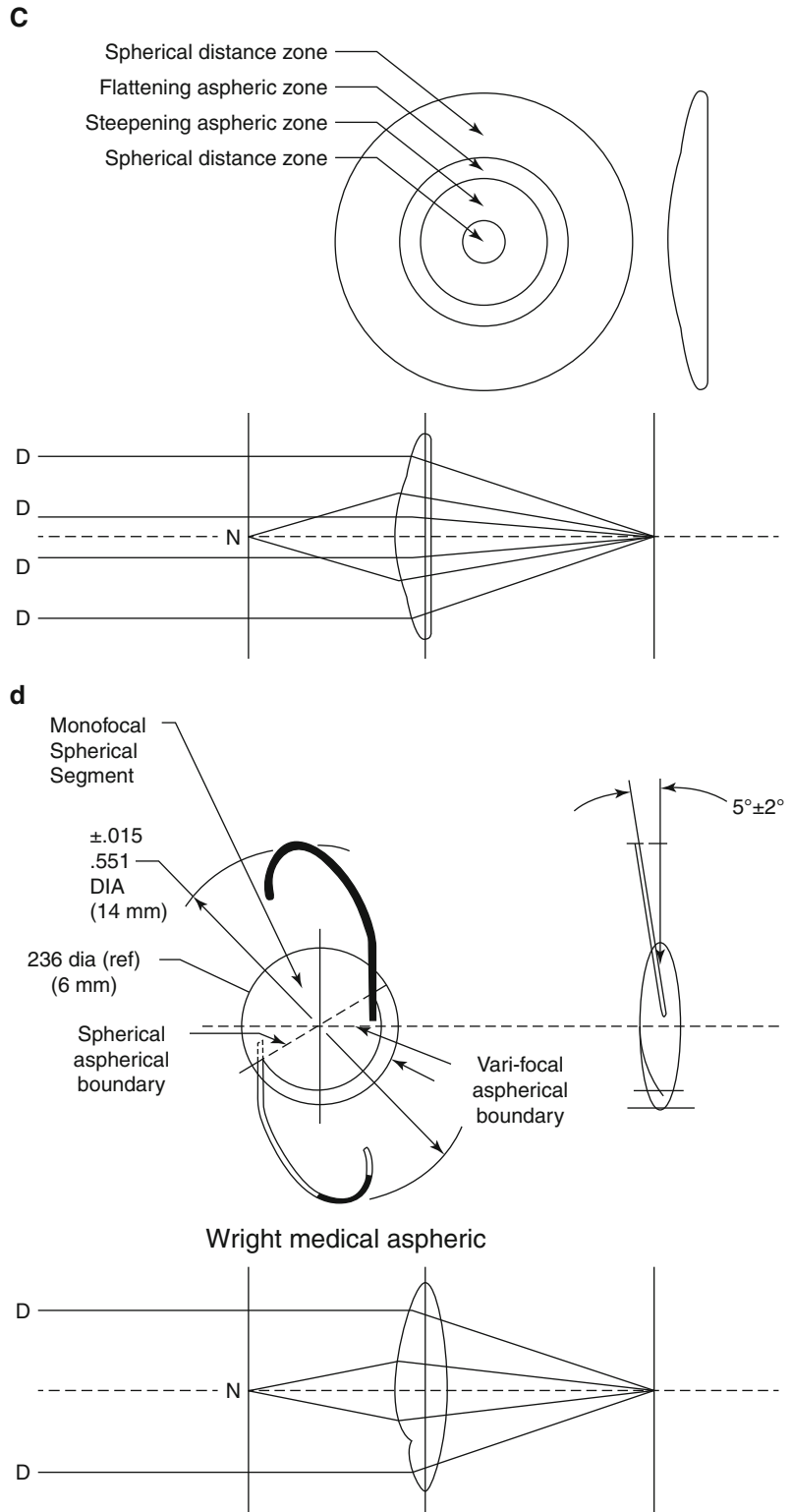
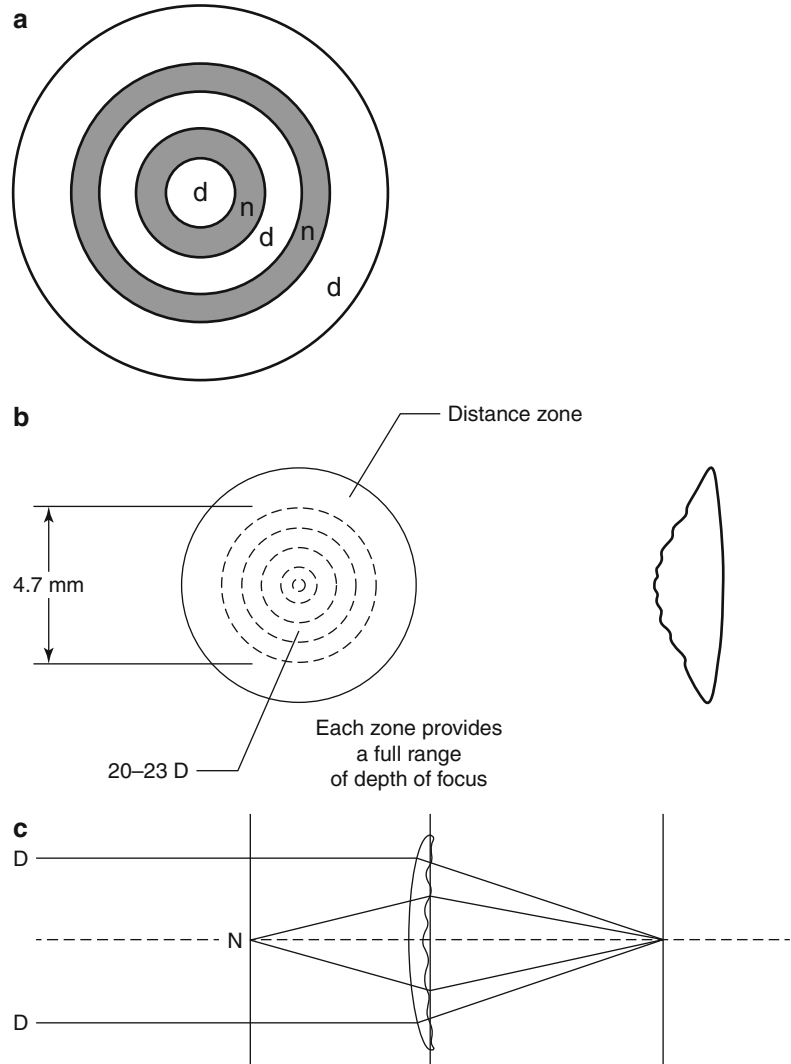


Fig. 2.14 Diagram of the AMO Array five-zone multifocal lens (**a**, **b**) and ray tracing (**c**)



of 2005 and combines the functions of both apodized diffractive and refractive regions (Figs. 2.15 and 2.21). In its original configuration, the single-piece hydrophobic acrylic lens has a central 3.6 mm optic zone (6.0 mm optic diameter), with 12 concentric steps of gradually decreasing step heights that allocate energy based on lighting conditions and activity. The largest diffractive step is at the lens center and sends the greatest proportion of the energy to the near focus. As the steps move away from the center, they gradually decrease

in size, blending into the periphery and sending a decreasing proportion of energy to the near focus. When the pupil is small (when reading), the lens maximizes near vision. In dim-light conditions when the pupil is enlarged, the lens becomes a distant-dominant lens. The refractive region of the optic surrounds the apodized area and is dedicated to distance vision. It has a +4.00 D add power for near vision. Subsequent developments led to lower add power for near vision (+3.00 D in late 2008 and +2.50 D since 2012).

2.8 Zoom Ahead 20 Years: Oculentis Mplus

Obviously over the next two decades, there was little I could do but watch all the newer multifocal lenses come and go in popularity but never see my Split Bifocal taken up by anyone. Then in 2010, I was attending the European Society of Cataract & Refractive Surgery (ESCRS) meeting in Paris, and one afternoon I had nothing to do, so I walked through all the exhibits. I came across the booth by Oculentis, a small IOL company based in Berlin, Germany, and did a double take when I looked at the design of their multifocal IOL (the Mplus) and lo and behold I see that it is a Split Bifocal (Fig. 2.16). The mistake made was the line of the split is perpendicular to the axis of

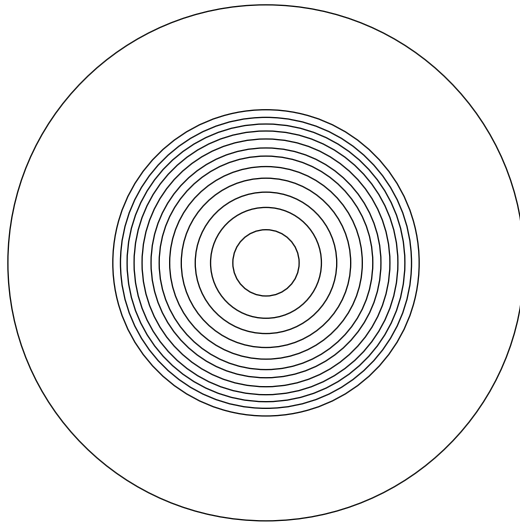


Fig. 2.15 Diagram of the Alcon ReSTOR multifocal lens

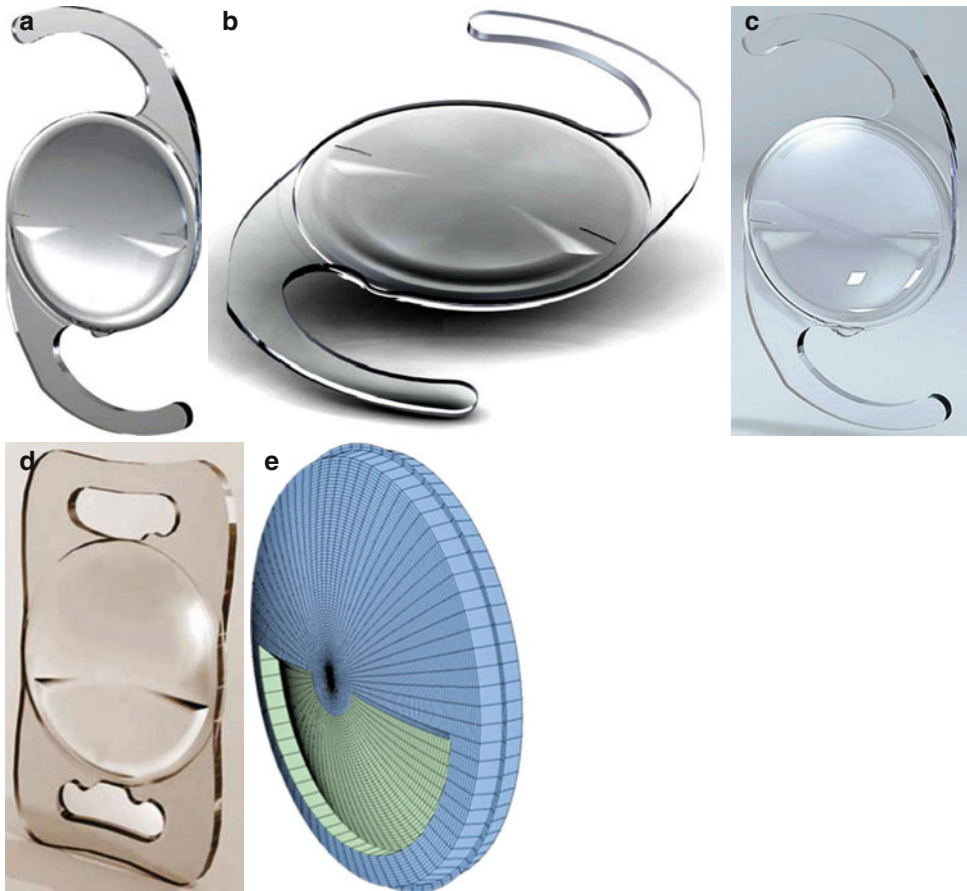


Fig. 2.16 Lentic Mplus LS-312 (Oculentis, GmbH): (a–c) Open loop design. (d) Plate haptic design. (e) Graphic depiction of the optic

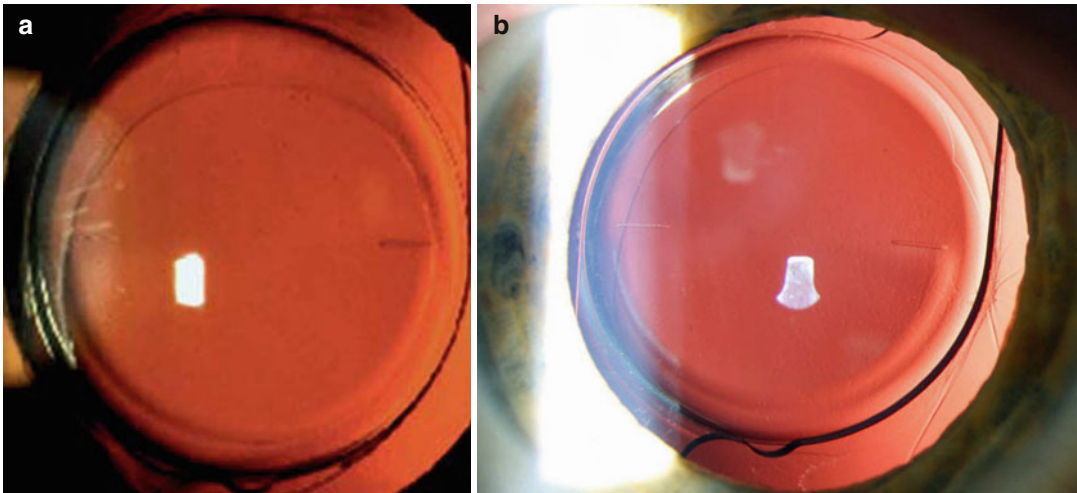


Fig. 2.17 Clinical photographs of postoperative Mplus Split Bifocal IOLs. Note that no lines are visible in aqueous

the loops allowing IOL decentration to more easily shift the near or far zone out of the pupil. In the newer models of the lens, there is a slight difference from the 50/50 split in that there is a slight angulation to each radius of the split and a tiny half-circle divot taken out of it in the center of the near zone.

The man at the booth started telling me all the names of the well-respected EU surgeons who have been using it with great success. At last my concept is being used and proven clinically acceptable for large numbers of patients. Later I contacted these surgeons (Alio, Aramberri, Carbonara, Mertens, et al.) that I knew personally as well as others and confirmed the successful published reports [4–13]. Interestingly enough, any patent I would have obtained would have expired by now.

There have been questions regarding the implanted position of the near add segment. The “common sense” position would be to place it inferiorly just as the bifocal add in spectacles. If one analyzes this situation carefully, it will become immediately obvious that the position of the IOL bifocal add makes absolutely no difference. Whether it is superior, inferior, or oblique, the near segment focus is superimposed over the distance focus and the brain selects the clear image of regard. With spectacles, the patient is looking downward (inferiorly) to read so the bifocal add needs to be in the inferior part of the

spectacle. This makes no difference when the two focal lenses are fixated behind the pupil.

Figure 2.17 demonstrates implanted Mplus lenses and that the optical transition zone of the Split Bifocal is not visible in aqueous. It is personally interesting that the Mplus lens also has a posterior annular “sharp edge” (or Hoffer Ridge) (Fig. 2.18a). Figure 2.18b shows the lens edge blocking the progression of Elschnig pearls.

2.9 Multifocal Optics Calculations

How strong should the power addition be in the near vision segment if the distance segment is set for emmetropia? I worked this out when first thinking through the development of the Split Bifocal IOL in 1982 but after I asked Iolab to make the lenses for me. These principles were presented at the multifocal meeting in Fresno which became a chapter in the book [14] as well as in a paper Holladay and I published in 1992 in the American Journal of Ophthalmology [15].

Several years later, other designers of bifocal IOLs concluded the necessary increase in IOL power for the near vision should be 2.75–3.00 D because that is what is needed for spectacle bifocals. This error can be directly linked to ignorance of theoretic formulas dealing with IOL

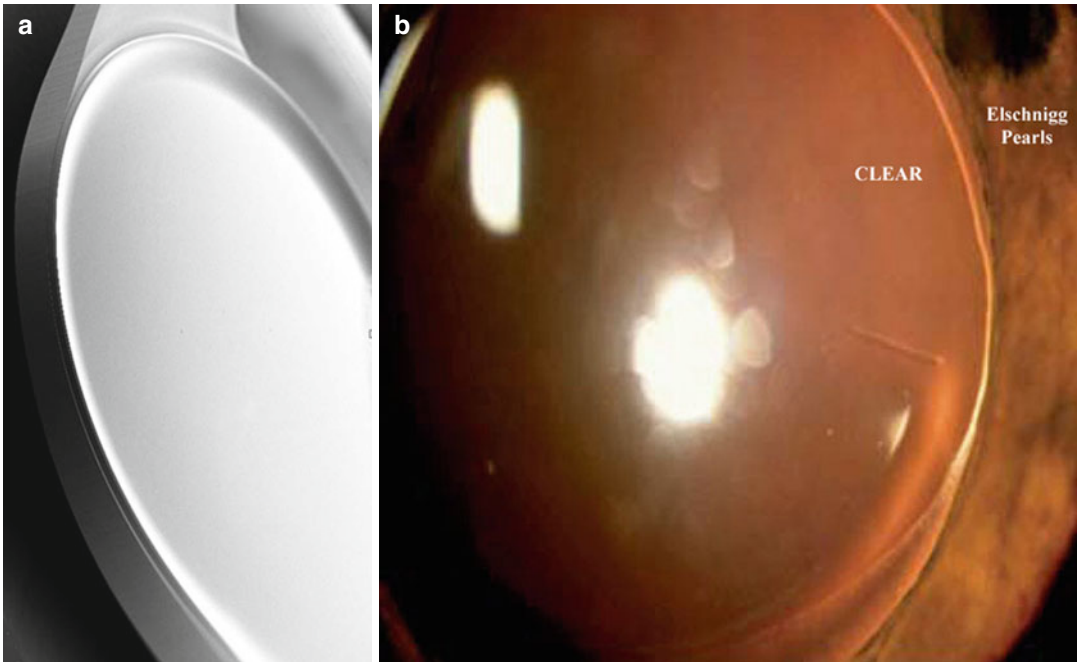


Fig. 2.18 (a) Electron photomicrograph of the “sharp edge” or “Hoffer Ridge” on the posterior surface of the Mplus lens. (b) Clinical photograph showing Elschnig pearls being blocked by the peripheral edge of the Mplus lens

power calculation. After early bifocal implantations with these lenses, it was realized clinically that this additional add in power was insufficient and that perhaps 3.50–4.00 D would be better. This error could have been easily prevented by simply calculating the theoretic formula for the predicted change in IOL power for a change in refractive error from 2.75 to 3.00 D of myopia. It would have been discovered that the IOL power would have to be increased by 3.50–4.00 D for a normal eye (AL 23.5 mm, K 43.50 D, ACD 4.0 mm). The mathematics are as follows (Table 2.1).

This phenomenon is due to the simple fact that the change in IOL power and the change in refractive error produced by that change is not a 1:1 relationship. Instead it is a 1.27:1 relationship in an eye with the above standard values. An important question to ask is whether this ratio is stable and constant throughout the range of all ALs, ACDs, and average Ks and whether 3.50 D is the constant we should add throughout the biometric range of eyes. To learn the answer, we must experiment mathematically by changing each parameter throughout their physiologic

Table 2.1 Normal eye

	Near	Distance	Bifocal add
AL	23.50	23.50	
ACD	4.00	4.00	
K	43.50	43.50	
PO Rx	−2.75	Plano	
IOL	22.08 D	18.58	3.50 D

Table 2.2 Extreme short eye

	Near	Distance	Bifocal add
AL	16.00	16.00	
ACD	4.00	4.00	
K	43.50	43.50	
PO Rx	−2.75	Plano	
IOL	65.19 D	61.69	3.50 D

range while holding all other variables constant. We can only do this using a second-generation IOL power formula such as the original Hoffer formula since third-generation formulas alter the ELP based on changes in other parameters.

First we can see what effect AL has on the bifocal add power in an extremely short eye of 16 mm (Table 2.2).

The above calculation using a short 16 mm eye reveals that the ratio of 1.27:1 (3.50/2.75) did not change. Now I give the calculation for an extremely long myopic eye of 39 mm (Table 2.3).

From these extreme examples, we can see that the ratio of 1.27:1 remains constant throughout the entire range of ALs, and we can conclude

Table 2.3 Extreme long eye

	Near	Distance	Bifocal add
AL	39.00	39.00	
ACD	4.00	4.00	
K	43.50	43.50	
PO Rx	-2.75	Plano	
IOL	-8.38 D	-11.88	3.50 D

mathematically that the AL does not influence the near add in a bifocal IOL. Figure 2.19a demonstrates graphically these changes.

Could a change in the average corneal power influence this ration in the otherwise normal eye? Here is the calculation for a very flat cornea of 35.00 D (with all other parameters normal) (Table 2.4).

Here we see a rise in the ratio to 1.41:1 with a very flat cornea. Now I give the calculations for a very steep cornea of 58.00 D (Table 2.5).

Here we see a drop in the ratio to 1.36:1 with an extremely steep cornea (Fig. 2.19b). So far we have shown that the ratio between the IOL bifocal and the spectacle add is not affected at all by changes in AL but is minimally affected by a

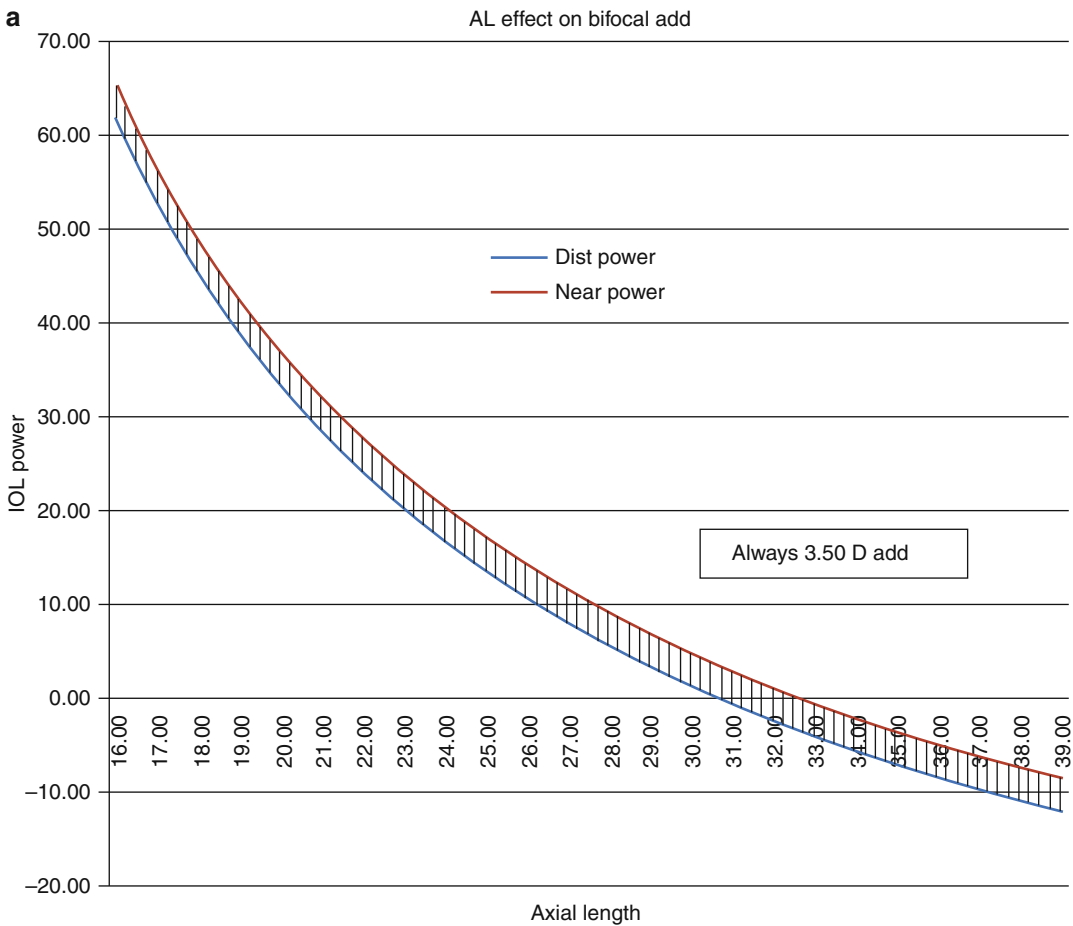


Fig. 2.19 Graphic depiction of changes in IOL power for distance and near with (a) changing axial length, (b) changing corneal power, and (c) changing IOL position (ACD)

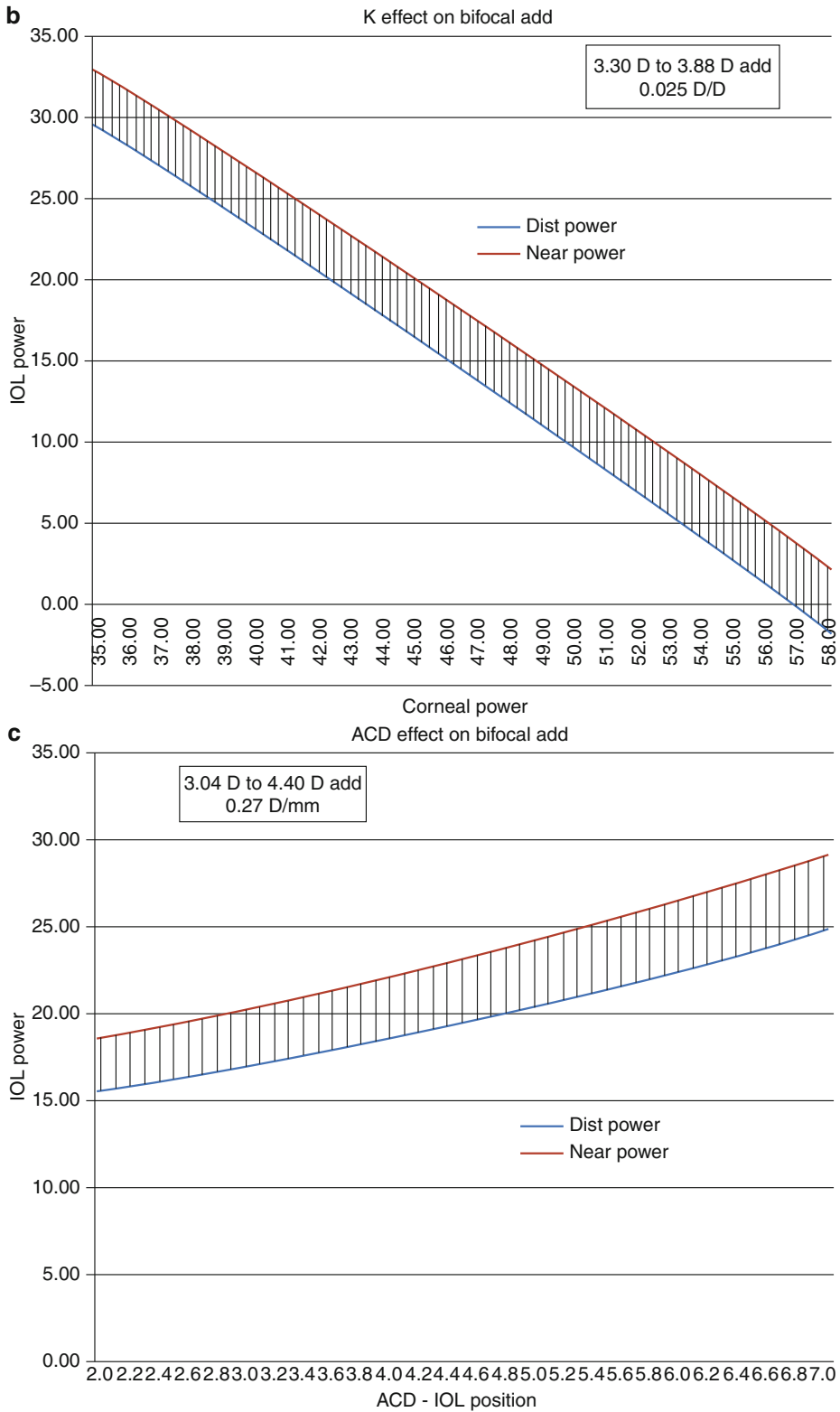


Fig. 2.19 (continued)

Table 2.4 Extreme flat cornea

	Near	Distance	Bifocal add
AL	23.50	23.50	
ACD	4.00	4.00	
K	35.00	35.00	
PO Rx	-2.75	Plano	
IOL	2.20 D	-1.62	3.88 D

Table 2.5 Extreme steep cornea

	Near	Distance	Bifocal add
AL	23.50	23.50	
ACD	4.00	4.00	
K	58.00	58.00	
PO Rx	-2.75	Plano	
IOL	16.25 D	12.52	3.73 D

Table 2.6 Extreme shallow ACD

	Near	Distance	Bifocal add
AL	23.50	23.50	
ACD	2.00	2.00	
K	43.50	43.50	
PO Rx	-2.75	Plano	
IOL	18.72 D	15.67	3.04 D

Table 2.7 Extreme deep ACD

	Near	Distance	Bifocal add
AL	23.50	23.50	
ACD	7.00	7.00	
K	43.50	43.50	
PO Rx	-2.75	Plano	
IOL	29.16 D	24.76	4.40 D

directly proportional relationship with the corneal power. This latter effect, however, only amounts to a total of 0.58 D over the entire range of human corneal powers from 35 to 58 D, and at 0.025 D/D, it can be considered essentially unimportant clinically.

The last biometric factor to analyze is the effect of change in the ACD or the position of the IOL postoperatively. First we calculate for a very shallow ACD of 2.00 mm (keeping all the other parameters normal) (Table 2.6).

With a very shallow ACD, we see the ratio drops to a low of 1.11:1. Now we calculate for a very deep ACD of 7.00 mm (Table 2.7).

But with an extremely deep ACD, we see the ratio rise to 1.60:1 and thus demonstrate a more significant directly proportional relationship to the depth of the anterior chamber, which can account for a 1.36 D change in bifocal add over this ACD range of 2–7 mm (Fig. 2.19c). This effect is 0.27 D/mm and is more significant clinically than that of the corneal power.

These facts should cause us to reassess the routine addition of 4.00 D for near vision in an IOL. If we can make the assumption that a 10.0 D IOL will be put into an eye with a long AL and that an eye with a long AL will probably have a deeper ACD, perhaps we should make the bifocal near add power stronger than we would for a 30.0 D IOL that will be put in a very short eye with a much shallower ACD. These calculations can easily be done in advance for the individual patient and the appropriate add chosen.

Conclusion

I look back over the past 33 years and ask myself what happened. What did I do wrong? An idea that many thought was crazy and improbable in 1982 is being successfully used today even though I tried my best to make it happen sooner. I am very happy to see this idea prove itself. The optical ray tracing of the Split Bifocal (Fig. 2.20) is shown to be superior to the two most popular multifocal lenses used in the USA: the ReSTOR lens (Fig. 2.21) and the ReZoom lens (Fig. 2.22). A lesson that can be learned from my experience is that if you have a new idea, don't take it to the largest most stable and successful manufacturers. Take it to a small company or get support from others and do it yourself.

Compliance with Ethical Requirements Kenneth J. Hoffer MD and Giacomo Savini MD have no conflict of interest in the topic of the chapter.

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 (5). Informed consent was obtained from all patients for being included in the study.

No animal studies were carried out by the authors for this article.

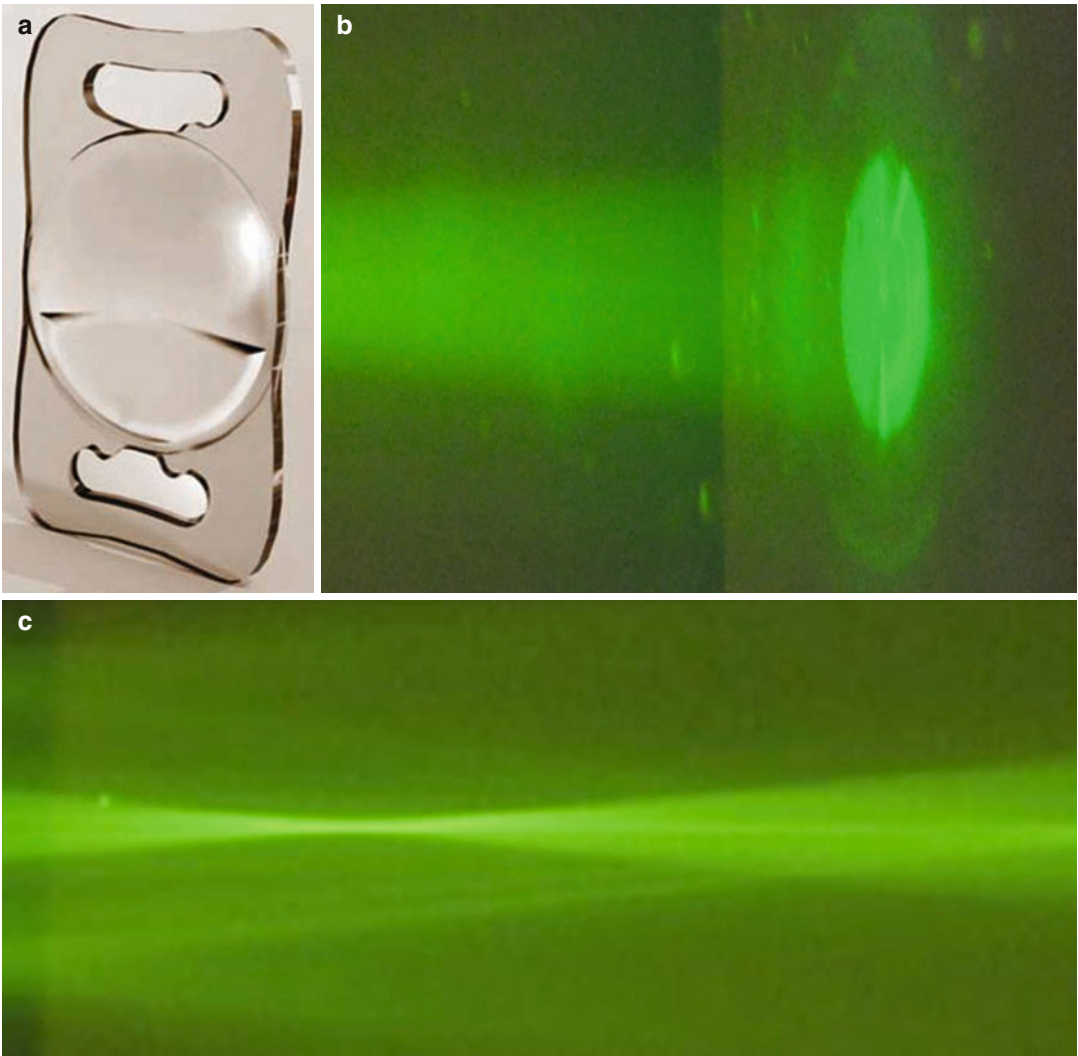


Fig. 2.20 The display of focal points (b, c) of the Oculentis Mplus (a)

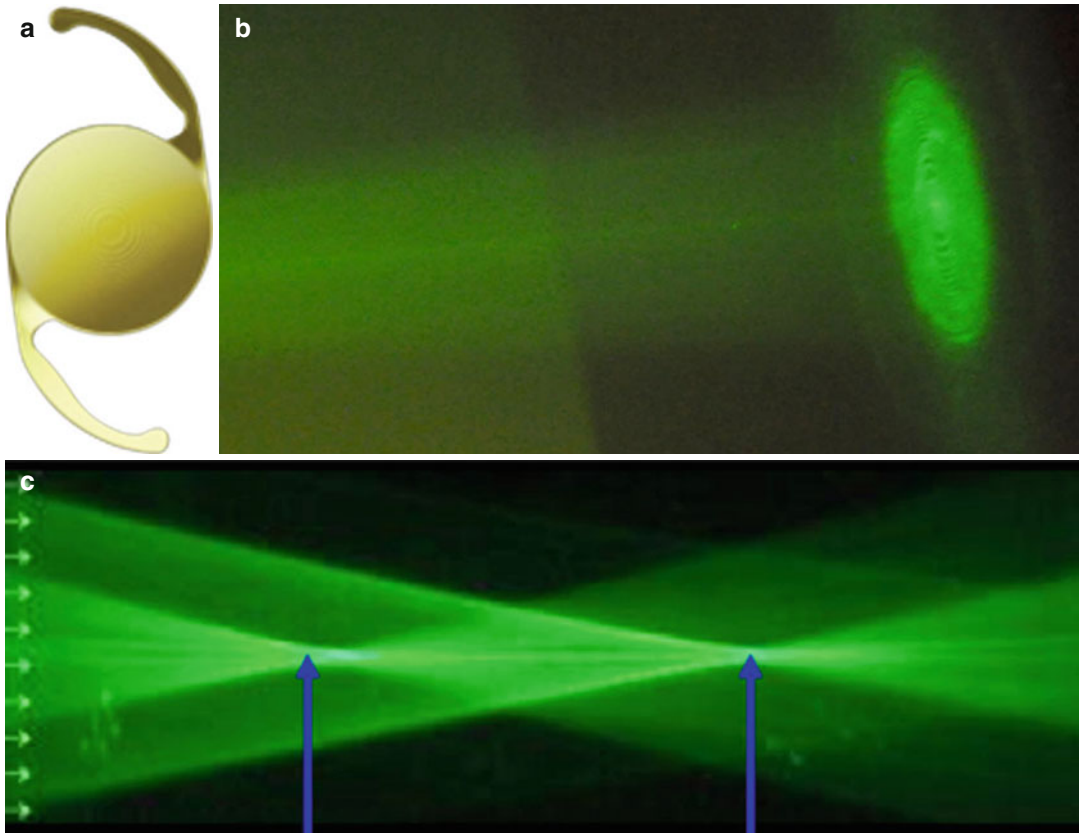


Fig. 2.21 The display of focal points (b, c) of the Alcon ReSTOR lens (a)



Fig. 2.22 The display of focal points (b) of the AMO ReZoom lens (a)

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Jorge L. Alió and Joseph Pikkell

3.1 Introduction

As in every surgery, cataract surgery with multifocal intraocular lens implant should be carefully planned. Though a variety of factors are to be considered in the planning of any surgery, while planning to implant a multifocal intraocular lens, special factors need to be taken into account. In this chapter we will describe the major factors to be considered.

3.2 General Considerations

A multifocal intraocular lens must incorporate some mechanism to focus light from distant objects and light from near objects at the same time. A redistribution of the light energy will happen, with no single focus receiving all the

energy as it happens in normal physiological accommodation. Unlike multifocal spectacle lenses, the multifocal intraocular lens refracts (or diffracts) light from any object for both near and distance vision at the same time. Thus there must always be some light that is not in focus with the light that is in focus. For distant objects, for example, the “add lens” steals some of the light that would have been focused and instead distributes relatively defocused light onto the retina, decreasing image contrast and reducing contrast sensitivity.

Multifocal intraocular lenses can obtain multifocality in different ways:

1. A combination of two or more different anterior spherical refractive surfaces for distance and near correction such as a combination of an anterior spherical and an anterior aspheric refractive surface for distance and near correction
2. A combination of a posterior spherical refractive surface and multiple anterior aspheric refractive surfaces
3. A combination of an anterior spherical refractive surface and multiple posterior diffractive structured surfaces for distance and near correction
4. A biconvex lens with longitudinal aberrations on the anterior surface (making it aspheric), providing near vision through the center of the lens, distance vision through the periphery, and intermediate vision in between

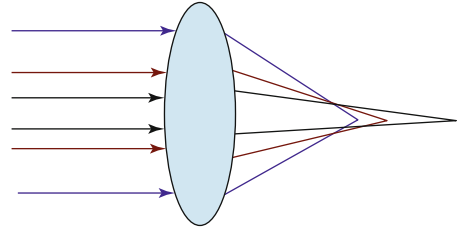
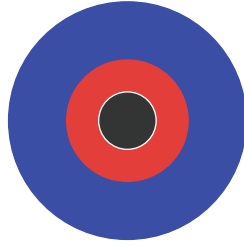
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Fig. 3.1 Refractive lens design: the outer zone (*blue*) for intermediate vision, the *red* zone for near vision, and the inner zone (*black*) for far vision



Multifocal intraocular lenses can be refractive, diffractive, or of a combined design. Refractive lenses use only differing areas of refractive power to achieve their multifocality. They function by providing annular zones of different refractive power to provide appropriate focus for objects near and far. Refractive bifocal/multifocal IOLs may be affected by pupil size and decentration, to a greater or lesser degree depending on the size, location, and number of refractive zones. The wavefront produced from the refractive lens is nonspherical, i.e., it does not have a focus. In these lenses the inner zone is powered for distance and the outer zone is powered for intermediate vision. The middle zone has an add zone for near vision (Fig. 3.1).

The refractive multifocal lens implant provides excellent intermediate and distance vision. The near vision is typically adequate but may not be sufficient to see very small print.

Limitations of refractive multifocal intraocular lenses are:

1. Pupil dependence design
2. High sensitivity for lens centration
3. Intolerance to kappa angle which varies from patient to patient
4. Potential for halos and glare due to more non-transition areas – rough areas between the zones
5. Loss of contrast sensitivity

Diffractive lenses are based on the principle that every point of a wavefront can be thought of as being its own source of secondary so-called wavelets, subsequently spreading in a spherical distribution (Huygens-Fresnel principle). The amplitude of the optic field beyond this point is simply the sum of all these wavelets. When a portion of a wavefront encounters an obstacle, a region of the wavefront is altered in amplitude or

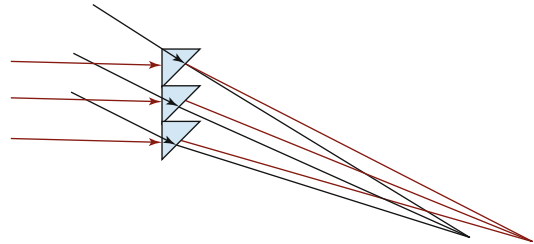


Fig. 3.2 Diffractive lens design: light travels slower on the side of the step of the lens compared to the speed of light that moves through the aqueous resulting in producing two foci, one for near vision and one for far vision

phase, and the various segments of the wavefront that propagate beyond the obstacle interfere and cause a diffractive pattern. As the spacing between the diffractive elements decreases, the spread in the diffractive pattern increases. By placing the diffractive microstructures in concentric zones and decreasing the distance between the zones as they get further from the center, a so-called Fresnel zone plate is produced that can produce optic foci. Thus the distance power is the combined optic power of the anterior and posterior lens surfaces and the zero order of diffraction, whereas the near power is the combined power of the anterior and posterior surfaces and the first order of diffraction (Fig. 3.2).

The diffractive multifocal lens implant provides excellent reading vision and very good distance vision. The intermediate vision is acceptable but not as excellent as the far and near vision. However, diffractive multifocal intraocular lenses are less pupil size dependent and are more tolerant to differences of kappa angle.

Diffractive bifocal/multifocal lenses only provide two focus points – far and near – and no intermediate foci; they have a high potential of producing halos and glare due to more non-transition areas,

and since they cause an equal distribution of light for both foci, they cause 18 % loss of light in transition. These disadvantages may decrease quality of vision especially in mesopic and scotopic conditions when more zones affect the incoming light rays to the retina. The modern diffractive trifocal IOLs, provided by different mechanisms that will be explained later in this book, are trying to provide intermediate vision by a redistribution of the diffracted light to other foci.

3.3 Considerations in Selecting the Multifocal Intraocular Lens

In recent years, we are witnessing an ongoing dramatic change and improvement in multifocal intraocular lenses. The use of multifocal intraocular lenses has become more common, and technological innovations as well as new designs have resulted in a constant improvement of these lenses. As a result, there is a large variety of multifocal intraocular lenses in the market and surgeons may be confused as to what lens they should choose [1].

The value added by multifocal intraocular lenses, in comparison to monofocal lenses, is the multifocal lens' optical function. A good multifocal intraocular lens design should give the surgeon the tool to adapt vision to the patient's lifestyle. To do that one should understand the optical principles needed in an optimal multifocal intraocular lens.

Multifocal intraocular lens' optics are either rotationally symmetric or rotationally asymmetric. Some multifocal intraocular lenses modify the index of refraction so that it changes from the periphery to the center of the lens, giving an adequate optical solution for different pupil sizes. Some multifocal intraocular lenses are designed aspherically in order to remove chromatic aberrations, thus improving near and intermediate vision.

In order for a multifocal lens to be efficient, astigmatism must be completely eliminated and therefore the ability to use toric multifocal intraocular lenses is of great importance. Since, in

most cases, multifocal intraocular lenses induce reduction of contrast sensitivity, this should be another concern when choosing a lens to implant. One should try to choose the multifocal intraocular lens that induces less reduction of contrast sensitivity. Multifocal intraocular lenses are contraindicated, because of the reduction of contrast sensitivity, in eyes with aberrated corneas or in patients that already suffer from limited contrast sensitivity such as in cases of maculopathy, retinal dystrophy glaucoma, or advanced senility [2].

In designing or in evaluating a new multifocal intraocular lens, we should follow some important facts to guide our decisions towards a successful outcome.

Following many years of clinical experience of implanting different multifocal IOLs that have appeared in the market during the last 2 years; we conducted on many clinical studies, most of them published in peer-reviewed scientific journals; and our present understanding on patients' needs, we postulate to follow these main principles as guidelines for the design and selection of a modern multifocal IOL:

- *The far focus should be dominant.* Humans are diurnal predators; therefore, our brain's dominant need is for distance vision. Another advantage of the dominance of far vision is the decrease of focus overlapping and reduction of glare and halos [3].
- *Adequate disparity between foci.* In order to produce an acceptable intermediate vision, some multifocal intraocular lenses are designed to have an overlap of the foci. However, while the intermediate vision is gained by this overlap, it also produces the disturbing phenomena of halos and glare. Therefore, the overlapping of foci should be minimized to decrease the incidence of halos and glare. In lenses where the near vision add is less than +3.00, the incidence of halos and glare will increase [4].
- *Aspheric design.* In our quest to achieve the best possible optical performance from the multifocal intraocular lens, one of our desires is that the lens should be free from aberrations. Aspheric lenses improve overall the optical performance of the lens. Asphericity is

even more important considering that about 20 % of patients do not have what is considered as a standard value of asphericity which is 0.27 μm . Lack of asphericity is even more common in patients that have previously undergone corneal refractive surgery [5].

- *Toricity available.* As mentioned before, for a multifocal intraocular lens to be efficient, astigmatism must be completely eliminated. If after the multifocal intraocular lens implant there is a residual astigmatism of more than 1.00 D, laser touch-up is required. About 4 % of patients have more than 3.00 D of corneal astigmatism and 70 % of patients have more than 1.00 D of corneal astigmatism; therefore, the ability to use toric multifocal intraocular lenses is of great importance [6].
- *Pupil independence/dependence.* Pupil size after cataract surgery is unpredictable, especially in cases in which the pupil was mechanically dilated. Pupil size is also affected by environmental conditions which are unpredictable as well. On the other hand, many of the multifocal intraocular lenses are designed so that the refractive power changes are according to the distance from the lens center and relay on a mean pupil size. Since the pupil size is unpredictable, the implanted lens should not depend on it to obtain adequate performance for far and near vision [7]. For this reason, while in some cases pupil independency may be the best option, in cases with normal pupil reactivity, pupil dependency may be a good alternative option.
- *Good optical performance at the optical bench and “in vivo.”* Lenses manufacturers are designing and testing multifocal intraocular lenses in order to produce the best available lenses; however, these efforts provide good performance at the optical bench in which conditions are not necessarily the same as inside the eye. Once a multifocal intraocular lens is implanted, intraocular conditions affect its optical performance and might decrease it as much as 50 % compared to the optical performance on the optical bench. There is no way to predict the IOL performance in vivo when a new lens is introduced to the market; therefore, the optical quality as well as unpredictable aberrations should be carefully looked for by the surgeon, and the first patients to be having the new lens implanted should be closely followed up, and optical performance and aberrations should be measured at least 3 months after lens implantation in order to study the real quality and performance of new multifocal intraocular lens designs [8].
- *Capsular bag stability.* The capsular stability is of great importance in achieving the best possible optical performance of the implanted lens. Instability of the capsular bag may cause tilt and decentration of the implanted lens, thus causing starbursts and preventing adequate focusing of light waves in different distances. A decentered or tilted lens may cause photic disturbances and a major inconvenience to the patient. Capsular stability is affected by the patient’s zonular stability and by the implanted lens. While one cannot affect zonular stability, the implanted lens should be designed in a way and also made by a biomaterial that does not reduce capsular stability [9].
- *Low posterior capsular opacity rate.* There is no doubt that the capsular bag should be cleaned as much as possible during cataract surgery; however, the implanted lens also has a major role in preventing posterior capsular opacity. Again, adequate lens design and biomaterial of the lens are major factors in preventing posterior capsular opacity. Light scattering and posterior capsular opacity significantly decrease the multifocal intraocular lens performance and may lead to the need for ND:YAG capsulotomy. Though ND:YAG capsulotomy may resolve this problem, it may lead to difficulties in case of a necessary replacement of the implanted lens [10].
- *Compatibility to microincisional surgery.* As cataract surgeries advance towards microincisional surgeries, the multifocal intraocular lens should be implantable through a sub-2-mm incision. The benefit of the practice of microincisional cataract surgeries is that they do not change the preoperative astigmatic or aberrometric corneal profile, while larger

incisions do. The need for a multifocal intraocular lens implantable through a sub-2-mm incision is therefore obvious. A lens implantable through a microincision helps the surgeon to control astigmatism and aberrations which are the two components necessary for optimal performance of these lenses [11].

- *Good far and adequate intermediate and near visual outcomes.* The quest for perfect vision in all distances is not achievable in current multifocal intraocular lenses. As mentioned before, the far focus should be dominant in order to give the patient a good far visual outcome. Nevertheless, the main aim of multifocal intraocular lenses is to free the patient from the need of using spectacles or contact lenses; therefore, not only should the lens provide excellent far vision, it should also provide adequate intermediate function such as for office and domestic tasks as well as adequate near functional vision for reading and other activities for which near vision is important [12].

3.4 Patient Selection

Other preliminary considerations are patient's lifestyle and primary clinical situation of the eye. Inquiring about the patient's hobbies and daily activities provides an important indication of his or her tolerance for nighttime dysphotopsia, and these should be taken into consideration by the surgeon when recommending a multifocal intraocular lens. Patient's personality is important in estimating the patient's ability to neuroadapt in cases of postoperative dysphotopsia, halos, and glare and the patient's ability to risk a small loss of contrast sensitivity or temporary glare in exchange for a broader range of vision and spectacle-free near vision. Patient's personality plays an important role in preoperative considerations – one should avoid patients with unrealistic expectations and those with overly critical personality [13].

Patients that suffer from night vision problems other than those that are caused by cataract and patients that work at night, drive at night, or

already suffer from night vision disturbances should be warned that postoperatively contrast sensitivity might be reduced and halos and glare may appear or worsen. In these cases, if a multifocal intraocular lens is to be implanted, the surgeon should choose a multifocal intraocular lens that is the least contrast sensitivity reducing [14].

Patient's needs and preferences also play a role in choosing the right lens. A patient that reads a lot but does not use a computer or watches television, for example, may benefit more from good near vision than from good intermediate vision, and hence a multifocal intraocular lens that provides better near vision and less intermediate vision might be a good choice in this case. The combination of a proper patient selection and a proper lens selection results eventually in a satisfied patient.

Postsurgically, vision degradation may result from surface dryness, blepharitis, basement membrane dystrophy, corneal scarring, corneal edema, intraocular lens tilt, decentration of the lens, posterior capsular opacity, macular edema, other retinal diseases, and residual refractive error or astigmatism. Out of these variables, those that exist prior to operation must be diagnosed and an effort should be made to predict the postoperative possible disturbances and to avoid them – surface diseases and blepharitis should be treated prior to operation and corneal scarring or diseases should be considered while planning the cataract operation. Among other things, the patient's ocular condition in addition to his or her personality and lifestyle is a factor that the surgeon should be aware of while choosing the specific multifocal intraocular lens that best fits the individual patient [15].

While the majority of patients, about 90 %, will be satisfied with the final result of the operation, some patients will not benefit from multifocal intraocular lenses. Surgeons should avoid patients who have ocular pathology that precludes normal visual potential or a chance of satisfactory multifocality free of spectacles.

Caution should be taken in patients that have long-standing history of monovision contact lens wear – implanting a multifocal intraocular lens is a different solution to the refractive error from

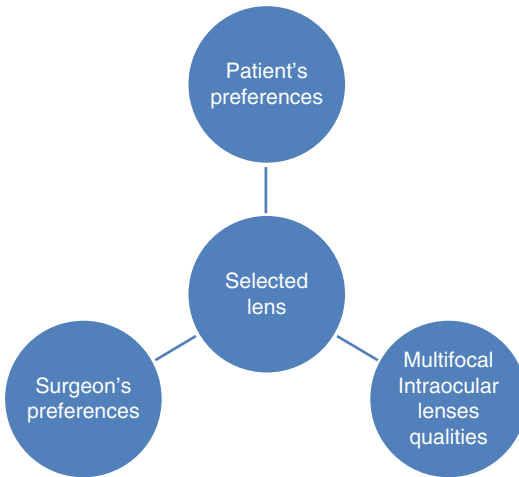


Fig. 3.3 Factors influencing lens selection

what the patient is already compatible with. That may cause a neuroadaptive problem.

Choosing the multifocal intraocular lens by taking into consideration the overall demands from an ideal lens and fitting it with the patient's needs, personality, and lifestyle, as in the previously discussed guidelines, can bring about beneficial result to the patient and the surgeon.

Though we described here possible complications of multifocal intraocular lens implant and a long list of preliminary considerations, overall, the value of multifocality for patients far exceeds the temporary discomfort of patients and surgeons and the short-term dysphotopsia that a few experience with multifocal intraocular lenses [16] (Fig. 3.3).

3.5 Multifocal Intraocular Lens Power Calculations

The aim of multifocal intraocular lenses is to free the postoperative patient from the use of spectacles or contact lenses. In order to achieve this goal, astigmatism should be eliminated and the refractive error should be ± 0.25 D of plane.

Several measurements are required for determining the proper multifocal intraocular lens power [17, 18]:

- Patient's age
- Central corneal refractive power (K readings)
- Axial length

- Horizontal corneal diameter ("white to white")
- Anterior chamber depth
- Lens thickness
- Corneal topography and corneal aberrometry
- Preoperative refraction
- Pupil size and pupil reactivity
- Ocular surface quality and dry eye
- Comorbidities

Though several formulas for intraocular lens power calculations have been suggested by different investigators, there are no significant differences between them and they vary in slight differences in assumptions of retinal thickness and corneal index of refraction. There are six variables that affect intraocular lens power calculations (K reading, axial length, lens power, effective lens position, desired refractive outcome, and vertex distance). The only unpredictable variable is the effective lens position which is defined as the distance between the corneal anterior surface and the intraocular lens position. The term effective lens position is used because it is more accurate than anterior chamber depth. The effective lens position is affected by the intraocular lens design as well as positioning of the lens by the surgeon, but by assuming that the lens will be properly positioned, the effective lens position prediction is important for calculating the intraocular lens power. The common practice is using, for intraocular lens power calculations, in patients with axial length of 22–25 mm, third-generation formulas such as the Holladay 1 [17], SRK/T [19], and Hoffer Q [20]. In cases outside this range, the Holladay 2 formula is considered to be more accurate.

Determining the desired multifocal intraocular lens power is slightly different than in intraocular monofocal lenses where a slight postoperative myopia may be beneficial. In implanting multifocal intraocular lenses, the refractive target should be exactly plano or the nearest to zero hyperopic outcome (dependent on the available lenses). The near vision with multifocal intraocular lenses is usually good and a slight myopia may cause an inconvenient near vision and reading vision [21].

As achieving the best available distance sight is the main goal, after measuring K readings and

axial length and using the known constant of the lens to be implanted, calculating the lens power for distant vision is possible by using one of the formulas mentioned above. Near-sight power should be calculated considering among other things patient's needs and lifestyle.

Although the lens design along with the other variables described earlier is the main factor influencing the desired refractive outcome, variations in surgery such as placement of the implanted lens, location and design of the incision and variations in calibrations, and types of axiometers and keratometers may also be important. Each surgeon should personalize the lens constant by the outcomes of the first 20–40 cases of implanting a specific lens. This is the only way to achieve superior results with multifocal intraocular lenses and accuracy within ± 0.25 D for 95 % of patients [21].

Accurate K reading, axial length measurement, anterior chamber depth measurement, corneal diameter, lens thickness, and preoperative refraction along with personalizing the lens constant and determining the correct refractive target are critical to ensure excellent results and patient's satisfaction with multifocal intraocular lenses.

3.6 Corneal Topography

There is an important role of corneal topography in preoperative cataract surgery considerations especially when implanting a multifocal intraocular lens. Since eliminating astigmatism is of great importance, corneal topography is important in planning the surgical incisions as well as in calculating the power of the implanted lens as described before. An accurate preoperative assessment of corneal shape provides understanding of preexisting corneal aberrations that might affect the visual outcome. Since overall visual function depends on each of the optical components along the visual axis, corneal topographic characteristics can significantly affect the visual performance.

An accurate preoperative corneal surface assessment provides understanding of corneal aberrations that might affect the final visual out-

come. Corneal topography is an important tool in planning the surgical incisions since small changes in corneal curvature can significantly influence the focus of light on the retina [22]. Surgical incision location is therefore of importance – surgical wound that is placed over the steep axis will reduce existing astigmatism [23]. Corneal topography is also important in estimating the amount of lenticular astigmatism, and as this component will disappear after operation, it should not be treated or affect the planning of the surgical incisions [24].

Corneal topography is even of more importance in patients that had prior corneal refractive surgery for accurate lens power calculation as well as for residual corneal astigmatism and aberrations assessment. Though these are still not the majority of patients who need cataract surgery, these patients are a group of patients that is rapidly growing [25].

3.7 Kappa Angle

One of the surgeon's concerns should be preventing postoperative glare and halos. For that, knowing the patients kappa angle is important. Kappa angle is the angular distance between the pupillary axis, which is an imaginary perpendicular line from the center of the cornea traveling into the eye via the center of the pupil, and the sight line which is the line representing the light ray that travels from the object to the fovea (Fig. 3.4).

If the kappa angle is large, the sight line, which is the light ray from the object, falls at a distance from the fovea, causing halo or glare. There are several ways of evaluating the kappa

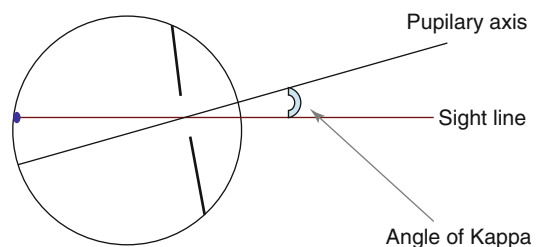


Fig. 3.4 Schematic eye and the kappa angle

angle; however, the simplest way to determine if the kappa angle exists is by a simple examination of the corneal light reflex. The patient should be instructed to fixate on a light source held directly in front of the patient. If there is a decentered corneal light reflex from one or two eyes, a cover test should be done. If there is a shift of the eye, manifest strabismus exists, and if no shift exists, kappa angle might exist. The next step is evaluating visual acuity and slit lamp examination of the pupil. Decentered corneal light reflex may manifest in cases of corectopia or coloboma or in cases in which visual acuity is abnormal due to macular pathology or eccentric fixation. If corneal light reflex is decentered and there is no pupillary abnormality, strabismus, or abnormal visual acuity, kappa angle exists. If the decentration is nasal, we call it positive kappa angle, and if the decentered reflex is temporal, we call it negative kappa angle. Estimating the amount of decentration is by estimating the distance from the corneal center to the corneal light reflex. Using instruments like Synoptophore and Orbscan was suggested too in order to measure kappa angle [26].

Recently, studies suggesting kappa angle as a contributor to photic phenomenon after multifocal intraocular lens implant were published, recommending evaluating kappa angle at the preoperative examination in order to avoid this disturbing outcome [27]. One of these studies suggested that patients with high kappa angle should be excluded from multifocal intraocular lens implant because of higher risk of postoperative photic phenomena [28].

As one can see, preoperative considerations are of most importance especially in cataract surgeries with multifocal intraocular lenses. Though many factors influence the final outcome, none should be ignored or overlooked. Selecting a proper multifocal intraocular lens which fits patients' condition, needs, and lifestyle is an essential part of a successful surgery. Planning ahead surgical incisions and strategy, according to clinical findings at the preoperative examination, helps to tackle possible problems during surgery and yet again to achieve the goal of patients' satisfaction.

Compliance with Ethical Requirements Jorge L. Alió and Joseph Pikkel declare that they have no conflict of interest.

No human studies were carried out by the authors for this article.

No animal studies were carried out by the authors for this article.

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4.1 Introduction

Multifocal intraocular lenses may open new horizons of treatment in patients that have special problems. The possibility of gaining good vision in different distances without the need of spectacles or contact lenses might be a solution for many challenging clinical situations. On the other hand, implanting multifocal intraocular lenses in certain situations might be useless and even causing reduction in visual function. Knowing the multifocal intraocular lenses advantages and limitations is a necessity while treating patients that have special clinical situations and needs. In this chapter we will deal with the most common special cases one might deal with and suggest some guidelines of how to use, or not use, multifocal intraocular lenses. However, the reader should be cautious about the

following conditions as they are to be considered as at the limit of the indication/contraindication clinical balance according to today's level of evidence in such borderline indications of multifocal IOLs.

4.2 Multifocal Intraocular Lenses in Children

Children that need to have a cataract surgery are prone to develop amblyopia unless they are vigorously treated in order to avoid it. Treatment for amblyopia in these children demands corporation and usually is difficult. The main reasons for developing amblyopia in these children is the changing of refractive power during the two first decades of life and the lack of multifocality due to the loss of accommodation after surgery. Allegedly the entrance of multifocal lenses to the market opened new options to tackle this problem; however, there are still some unclear issues while considering multifocal intraocular lenses implant in children. The first issue is the ongoing growing of the child resulting in a change of the refractive power of the eye hence raising the question of how to calculate the power of the implanted lens, when exactly does the eye become "adult eye"? Is the multifocal intraocular lens the best solution in children? What kind or type of multifocal intraocular lens should we implant in children? [1].

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There are just a few publications on this subject and implanting multifocal intraocular lenses in children is still in dispute. Advantages of using multifocal intraocular lenses are:

- Rapid rehabilitation of far, intermediate, and near vision
- Improved chance of binocularity
- Reduced risk of amblyopia
- No need for bifocals
- Better self-estimation of the child

While there is no doubt that these advantages are important, there are still some concerns. While implanting multifocal intraocular lenses, we might reduce contrast sensitivity and intermediate vision and exacerbate amblyopia [2]. While the visual world of a young child is primarily at arm's length, while growing his visual daily tasks become distant than that and the implanted lens might not fit anymore [3]. The growth of the eye between the ages of 10 and 20 may lead to a change of 4.0 diopters [4].

Cristobal et al. presented in 2010 their experience in multifocal intraocular lens implant in five children and reported of good postoperative visual acuity but less good results in postoperative stereoacuity [5]. Though their study was of limited number of patients and with no control group, their results do encourage the use of multifocal intraocular lenses in children. As multifocal intraocular lenses designs continue to improve and surgeon's experiences of implanting these lenses develop, there is a great promise for improving visual outcome and life quality of the pediatric cataract patient, especially in children 8–10 years of the age.

4.3 Multifocal Intraocular Lenses in Glaucoma Patients

The use of multifocal intraocular lenses in glaucoma patients is yet another subject that is relatively less discussed in the literature. Patients with glaucoma have a certain degree of contrast sensitivity reduction and mesopic visual function loss. Multifocal intraocular lenses reduce contrast sensitivity and mesopic visual function as well, and therefore multifocal intraocular

lenses implant might cause significant vision disturbances in these patients [6, 7]. Another consideration in glaucoma patients is small pupil and zonular weakness especially in pseudoexfoliative glaucoma patients. In patients that are candidates for combined operation (cataract and glaucoma), surgeons should take into consideration, while calculating the lens power, that the axial length of the eye and anterior chamber length change after the operation [8].

Glaucoma patients that have an intraocular multifocal lens will have difficulties in visual field tests due to the small pupil, reduction of contrast sensitivity, and defocus to near and intermediate distance. These undesired effects should be remembered and considered while evaluating visual field results in these patients [9, 10].

Ocular hypertension hence is not a contraindication for implanting multifocal intraocular lenses. Glaucoma patients, with no or slight visual field damage and controlled intraocular tension, are proper candidates for multifocal intraocular lens implant; however, patients with advanced glaucoma, significant visual field defects, or uncontrolled intraocular tension as well as patients with a glaucomatous damage in the other eye are not good candidates for this operation and will not benefit from multifocal intraocular lens implant, and in these patients, glaucoma is a contraindication for such a surgery.

4.4 Multifocal Intraocular Lenses in Patients with Maculopathy

There is no doubt that patients that suffer from diabetic maculopathy or from age-related macular degeneration may benefit from cataract surgery and intraocular lens implant. Though patients that suffer from maculopathy already have contrast sensitivity reduction which is additive to the contrast sensitivity reduction from the implanted lens, the overall result is beneficial to the patient. Most multifocal pseudophakes without an active retinal disease are satisfied from being free from spectacles and with trading some

of their contrast sensitivity for it. Patients with maculopathy and some visual loss are more tolerant to image defocus and might adapt more rapidly; however, in some of these patients, contrast sensitivity is an important measure of their reading ability. Therefore, patients that suffer from maculopathy should be carefully selected and preoperative assessed for multifocal intraocular lens implant [11].

Patients with maculopathy should be tested carefully in order to determine the maximal visual potential preoperatively and to be informed of the possible predicted visual outcome. These patients should be treated for the retinal disease, if needed and possible before the cataract surgery. If that is done and the patient's expectations correlate with the real predicted outcome, a multifocal intraocular lens implant will be of benefit for the patient.

Multifocal intraocular lenses were found to serve as an important visual aid in patients that suffers from age-related macular degeneration. In an article published in 2012, by Gayton, Mackool et al. reported their experience in implanting multifocal intraocular lenses in patients with age-related macular degeneration and concluded that for cataractous eyes with age-related macular degeneration, the multifocal lens serves as a low-vision aid. Targeting the implanted lens for a spherical equivalent of about -2.00 diopters yielded a $+5.20$ near addition. Replacing the crystalline lens with this myopia-targeted multifocal intraocular lens improved or maintained near vision without severely compromising distance vision [12].

4.5 Multifocal Intraocular Lenses in Patients with Amblyopia

Though implanting multifocal intraocular lenses reduces contrast sensitivity and intermediate vision, in adult patients, it does not exacerbate amblyopia. There are only two studies reporting multifocal intraocular lens implant in amblyopic patients in the current literature. In both studies multifocal intraocular lenses were implanted in both eyes – the amblyopic eye and the nonam-

blyopic eye – and both studies reported good results in far and near vision outcome, as well as slight improvement of binocularity in some of the patients [13, 14].

4.6 Multifocal Intraocular Lenses and Dry Eye

A healthy ocular surface is a key factor in achieving a successful result in multifocal intraocular lenses implant. Since the corneal tear film is actually the first refractive plane of the eye, its healthiness and integrity is important in reaching the aim of having the light rays uninterrupted focusing on the retina. A successful cataract operation with a multifocal intraocular lens implant but with interference in the tear film will result in an unfavorable refractive result and an unhappy patient. We use in daily practice the term dry eye, but actually the right term is inadequate tear film which might be due to small amount of tear production (dry eyes) or due to production of a proper amount but of poor-quality tears. No matter what the reason is, the result is a disruption of the ocular surface causing a disturbance in vision and interference with quality of life.

About 15 % of unsatisfied multifocal intraocular patients suffer from dry eyes reporting of blurred vision and photic phenomena in addition to irritation, redness, and excessive tearing [15]. The assessment of ocular surface problems such as dry eye is therefore essential as well as a thorough ophthalmic and systemic evaluation in order to diagnose, treat, and prevent dry eye syndrome. Dry eye signs include:

- Conjunctival erythema
- Decreased tear film strip test
- Decreased breakup time test
- Punctate epithelial staining

Categorization the dry eye into aqueous deficiency state or to poor tear quality is helpful in choosing the treatment strategy though frequently dry eye is a combination of the two [16].

Treatment of dry eye includes lubrication–hydration with tear supplements, lid hygiene, and in advanced cases punctal plugs installation. The use of topical cyclosporine 0.05 % twice daily

was found as an efficient treatment – reducing dry eye signs and improving visual quality – after multifocal intraocular lens implantation in patients that suffered from dry eye [17].

Dry eye should be diagnosed and treated preoperatively but should not prevent multifocal intraocular lens implant and the patients to benefit from it.

4.7 Multifocal Intraocular Lenses and Ocular Surface Diseases

As mentioned before, the healthy and integrated ocular surface is critical for cataract surgery to succeed however scholarly it is often overlooked at the preoperative examination. Proper mechanical lid function enables an equal and persistent tear spread all over the cornea thus preventing dry eye syndrome. In addition one should look for presence of any anterior or posterior blepharitis, since this condition does not only disturb vision but is of a potential risk for postoperative inflammation and even of infection.

Blepharitis increases the risk of antibiotic-resistant bacteria existence on the ocular surface and even of postoperative endophthalmitis [18]. Other diseases of the ocular surface such as seborrheic anterior blepharitis and meibomianitis should be diagnosed and treated since they are too a risk factor for postoperative infection and inflammation [19, 20].

Treatment of blepharitis includes:

- Lid hygiene
- Systemic doxycycline
- Antibiotic or steroid ointment (sometime combined therapy needed)
- Cyclosporine 0.05 % – topical
- Metronidazole cream
- Ketoconazole shampoo
- Omega-3 fatty acid supplementation – found to favorably alter meibomian gland secretions [21]

In addition to blepharitis and meibomian gland diseases, other surface conditions are important to diagnose and treat, such as anterior basement membrane dystrophy pterygia and Salzmann nodules which may cause significant astigmatism. In any case preoperative corneal

topography should be obtained in order to ensure that there is no astigmatism induced by these conditions.

Careful preoperative assessment and aggressive treatment of surface diseases combined with postoperative treatment for ocular surface diseases is obligatory and a must in order to ensure positive results from cataract surgery and multifocal intraocular lens implant.

4.8 Monocular Multifocal Intraocular Lens

As multifocal intraocular lenses reduce contrast sensitivity, in cases where only one eye is operated, the amount of light finely reaching the retina might be less compared to the unoperated eye. A difference in the image in each eye might cause inconvenience and might take time to get used to. Neuroadaptation to this difference is a time-consuming procedure, but eventually the brain neuroadapts and the perceived image from both eyes is clear and integrated in the vast majority of patients. Opponents to multifocal intraocular lenses warren from monocular suppression [22]; however, numerous reports are suggesting that multifocal intraocular lenses should be implanted in unilateral cataract patients and the overall outcome is satisfactory in these cases.

In order to help the process of neuroadaptation and overcome the difference in retinal image between the two eyes, it is recommended to perform cataract extraction and multifocal intraocular lens implant in two eyes. Nevertheless, some patients do have cataract only in one eye. Several reports on monocular multifocal lenses suggest that results in these cases are good and multifocal intraocular lenses in one eye provide better stereopsis higher spectacles independence rate and satisfactory functional vision compared to monofocal lens implant in unilateral cataract patients [23]. Although bilateral multifocal intraocular lenses implant is favorable, unilateral implantation of multifocal lenses also provided patients with high levels of spectacle freedom and good visual acuity without compromising contrast sensitivity [22]. In a recent study comparing

monofocal intraocular lenses implant to multifocal intraocular lenses implant in patients with unilateral cataract, the multifocal lenses provided better binocular near and intermediate vision and spectacles independence than the monofocal lenses, although distance contrast sensitivity was worse with the multifocal intraocular lenses [24].

Though bilateral multifocal intraocular lenses implant is favorable, in cases of unilateral cataract, patients gain more from these lenses compared to monofocal lenses, overcoming the reduction in contrast sensitivity. Though neuroadaptation might be more difficult or take longer even in unilateral cases, multifocal intraocular lenses implant is favorable.

4.9 Other Considerations

It is almost impossible to include the whole variety of preoperative considerations in one chapter; hence, there is no doubt that a thorough patient ophthalmic examination should be performed prior to cataract surgery and that issues as mentioned as well as others should be addressed and if needed treated prior to the cataract surgery; the patients general health and well-being should also be assessed.

Implanting multifocal intraocular lenses requires a personalized attitude since often patients present with multiple ocular, systemic, and psychological conditions that differ from one another. As many factors affect the final results, the surgeon must adopt a “wide angle” approach and be aware of the various conditions that eventually have an impact on it. If an unfavorable factor is diagnosed preoperatively, it should be treated and not ignored or postponed.

There is no doubt that in order to achieve the best possible results in multifocal intraocular lenses implant cataract surgery, there is a need to know the different factors that affect the final result and that this knowledge helps the patient in coping with them and the surgeon in targeting and achieving the aim of having a postoperative happy patient free of the need to use spectacles or contact lenses. Planning ahead the surgery in

view of these influencing factors is an essential step to perform a safe and fruitful surgery for the benefit of the patient and the surgeon as well. In multifocal intraocular lens implant operations, the “tailor made” approach, which means personal specific lens and surgery adaptation, should be taken especially in cases that are of treating challenge as described in this chapter. It is beyond the scope of any text to handle with the entire possible clinical situation; however, the reasonable surgeon can adopt the existing knowledge and the main considerations described here and imply it to the special clinical situation he deals with.

Compliance with Ethical Requirements Jorge L. Alio & Joseph Pikkell declare that they have no conflict of interest.

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Part II

Types, Models and Clinical Practice with Multifocal IOLs

Jorge L. Alió and Joseph Pikkell

5.1 Introduction

Neuroadaptation is a process in which our brain reacts to a sensory input and its ability to adapt to a change in the sensory input. How does the brain react when something disturbs our vision? How does our brain react to a new input and to an artificial component like a multifocal intraocular lens when it is implanted in the eye? In this chapter we will try to answer these questions and to explain the adaptation mechanism, called neuroadaptation, and how new technological developments may help to neuroadapt the visual change implemented by the implanted multifocal lens.

Our brain reacts to different sensory inputs such as the feeling of touch, heat, cold, pain, sounds, smell, or sight. The young person's nervous system is incredibly plastic and adjusts to disturbing sensory inputs as a “background

clutter,” so is, for example, our ability to adjust to background noise so that it does not interfere with our sleeping during flights or while going by train from one place to another. Neuroadaptation can occur within the visual system as well in response to visual disturbances, and it is neuroadaptation that enables us to cope with visual aberrations [1]. Such neuroplasticity decays with ageing, an issue that should be taken into consideration in the clinical use of multifocal IOLs.

As human beings, from the perspective of evolution, we are diurnal predators, this mechanism has assured our survival. Adaptation and plasticity of the visual system and the brain play a major role in providing us the ability to execute many important visual tasks [2].

Though our visual system may deal with visual aberrations, it cannot deal with a large amount of aberrations and it is important to understand what our visual system limit in that sense is. The ability to neuroadapt may be influenced by the state of mind, fatigue, age, etc., and further studies are done in order to find what makes us to better neuroadapt and what the limits of neuroadaptation of the visual system are [3].

The adult nervous system is remarkably plastic and its ability to modify input is quite rapid. Through this process of neuroadaptation, the brain modifies its sensory input to gain a survival advantage. It can take as little as a tenth of a millisecond or a few minutes to occur and is

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Fig. 5.1 On the left is the retinal image, on the right the perceived image after neuroadaptation

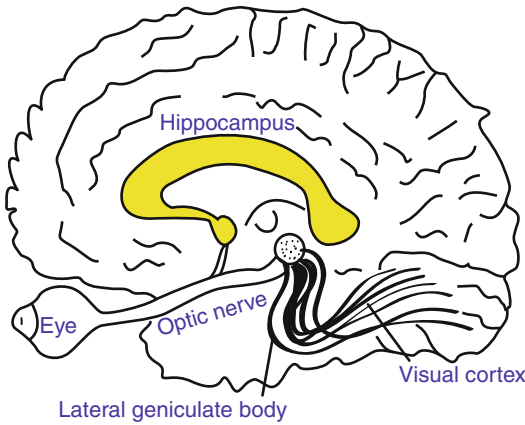


Fig. 5.2 The hippocampus and its anatomic relation to the visual system

experienced with regularity within the visual system. If an unclear image is projected to the retina, the process of neuroadaptation will “correct” it so that at the end of this process, our perceived image will be clear [4] (Fig. 5.1).

Neural adaptive roles in the consolidation of memory, emotion, addictive behaviors, navigation, and spatial orientation are all linked to the hippocampal region of the brain, and therefore it is believed that the hippocampus is where neuroadaptation occurs; however, virtually every area of the cerebrum, including the visual cortex, plays a part in neuroadaptation [5] (Fig. 5.2).

The study of neuroadaptation is based primarily on psychophysics. Neuroadaptation is a process in which the whole visual system from the retina to the high cortex is involved in. How neuroadaptation occurs and how the brain recruits the neurons to produce it are not fully understood yet and are just beginning to be clarified. Every processing point along the visual pathway contributes to the final clearly perceived optical image, and an interruption in the smooth flow of information anywhere in the visual stream can become problematic. Though neuroadaptation is not fully under-

stood yet, some of its aspects are known, and therefore, though multifocal intraocular lenses are a challenge for neuroadaptation, some steps can be taken by us to make neuroadaptation easier [6].

5.2 Contrast and Movement Perception

Unlike neuroadaptation which is a cortical neuron response, light adaptation occurs entirely in the retina, contrast adaptation begins at the earliest stages of the visual system in the retinal ganglion cells, and later it is finely processed in the cerebral cortex. Visual neuroadaptation is relatively quick, but it is actually a process that includes the whole visual system beginning in the retina up to the cortex, mainly in hippocampus. We have all experienced the situation of sitting in a standing car waiting for the traffic light to change, looking to the side, staring at another car. When the car next to us starts moving ahead, our perception is of us driving backward and it takes a few seconds for our brain to “correct” this perception and for us to understand that we are still standing at the same position while the other car moved forward. The process of having a stimulation input and a wrong primary perception and the correction of that perception so that the real situation is clear to us is in one word – neuroadaptation.

Models of visual motion processing suggest that some form of opponent processing is occurring where the response to stimuli moving in one direction is subtracted from those moving in the opposite. Contrast sensitivity and its relationship to motion occur within the same brain areas [7]. Multifocal intraocular lenses split the light rays to perform different foci and by doing that reduces contrast sensitivity. Contrast sensitivity reduction is one of the disadvantages of multifocal intraocular lenses and of a major concern while designing and producing these lenses. Neuroadaptation is the means of overcoming reduced contrast sensitivity. Though reduction of contrast sensitivity is the cause for some visual

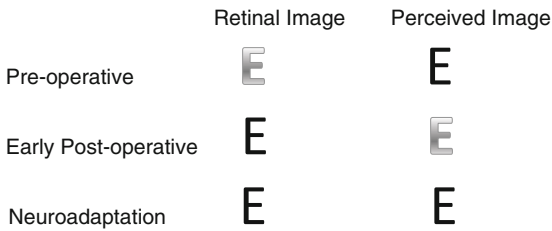


Fig. 5.3 The change in neuroadaptation

discomfort and disturbances, most patients neuroadapt to it within days to a few months.

5.3 Neuroadaptation and Multifocal Intraocular Lenses

As we described, neuroadaptation is a process in which the human nervous system adjusts to changes in neural inputs. Neuroadaptation is actually a process in which the brain learns how to “correct” the image so it will fit to the real one. As we all have aberrations due to the cornea and the crystalline lens, the image on the retina is not perfect and is somewhat blurred. Neuroadaptation is an acquired process and our brain gets use to correct the visual input according to what it already knows as the disturbances and aberrations. When implanting an intraocular lens, the aberrations of the cornea change due to the surgical incisions and the lens’ aberrations change as well. Multifocal intraocular lenses, due to their design, induce a further change since at least one focus (intermediate vision or near vision) is blurred, thus creating a more complex challenge for the brain to adapt to the new image on the retina [8]. At first the brain will correct the new image as it used to correct the previous (pre-operative) image. After the neuroadaptation to the new aberration will be completed, the perceived image will be similar to the real-world image. This is a time-consuming process and it is dependent on individual factors, some of which, such as age, are predictable while others are unknown. Many patients, even those that only change spectacles, complain of inconvenience

that during weeks or months disappears like a miracle. The “miracle” is actually neuroadaptation to the new situation, e.g., the new aberrations [9] (Fig. 5.3).

5.4 Multifocal Intraocular Lenses Design and Neuroadaptation

New technologies of multifocal intraocular designs and material are frequently introduced and launched to the market. As mentioned before, none of them is aberration-free, and they do differ from one another; nevertheless, there is no doubt that the major effect is due to the design of the lenses. Most multifocal IOLs in use today are either diffractive, refractive, or a combination of both principles. There is a difference in the aberrations induced by each of these designs [10].

Diffractive multifocal intraocular lenses are pupil independent and sacrifice intermediate vision by focusing incoming light rays at two points either near or far, while refractive multifocal intraocular lenses are pupil dependent, incorporating different refractive zones to create focal points at varying distances. Most of the patients that were having a refractive multifocal intraocular lens implant reported on good vision at intermediate and distance vision but had difficulty with near vision. On the other hand, patients that were having a diffractive multifocal intraocular lens implant reported on good vision at near and distance vision but had difficulties in the intermediate range. Lens manufacturers try to give a wide solution and produce, as much as possible, a multifocal intraocular lens that will provide good vision in all ranges; therefore, attempts to combine both optical principles have been made, such as in the combined apodized, diffractive-refractive IOL, and others are developing newer multizonal and progressive lens designs in an effort to address the current multifocal intraocular lenses limitations.

Asphericity also plays a large role in achieving fewer aberrations. Improvement in visual perception is induced due to the improved optics of the aspheric IOL, which corrects for the cornea’s positive spherical aberration. Kershner studied

the role of multifocal intraocular lenses optics in image contrast sensitivity. He compared the effects on retinal imaging and functional visual performance of an aspheric intraocular lens versus those of conventional spherical optics, with functional acuity contrast testing, and found that the use of an aspheric lens creates a measurable 38–47 % increase in photopic and a 43–100 % increase in mesopic visual performance. These findings emphasize the role of asphericity in reducing optical aberrations [11].

5.5 Multifocal Patients and Neuroadaptation

Since the multifocal intraocular lenses do not replicate the natural state, patients that undergo a multifocal intraocular lens cataract surgery have trouble adjusting to the new situation just as patients have trouble to adjust to their first pair of progressive add eyeglasses. Trying to explain to patients that it takes time to adjust to new situation almost always raises the question of how quickly and how well a given patient adapts to this change. As mentioned before the answer to this question depends on multifactors, some known to us and some still hidden from us. An active patient will probably want neuroadaptation to be as short as possible, but he should also understand that this process cannot be heisted. It is important for the surgeon to take the time to thoroughly discuss the implications of the post-operative visual change with the patient in respect to the patient's day-to-day needs before the patient undergoes surgery. In knowing the patient's needs and daily visual tasks, the surgeon can know what a patient is looking to improve by undergoing the surgery, and a most suitable intraocular lens for the individual patient can be chosen. An effort should be done to explain the process of neuroadaptation emphasizing that it takes time to reach good vision. Knowledge of what is ahead often calms the patient and at the end improves his satisfaction.

Patient education is of great importance not only in achieving patients' satisfaction but also for exposing the possible training techniques to

increase awareness and hence to expedite neuroadaptation. Patients have high expectations and demands, and if they are told ahead of time to expect a gradual adaptation period following their surgery, they will most likely accept this prospect. If the patient is impatient, it might be better to abandon the multifocal intraocular lens and propose another solution.

One of the options to try to hasten neuroadaptation is by training. These are sets of drills, visual tasks as forcing accommodative effort and relaxing drills, brief consistent visual stimuli, and other repetitive visual stimulations, in order for the patient to adjust to the new situation. Though some doubt the benefit of training, others advocate and recommend training as a possible solution to the non-adapting patients [12, 13]. The training method is usually a computer-based visual training, postoperatively, based on the concept of perceptual learning of discrimination line orientations. In one study visual performance after multifocal intraocular lens implantation was significantly accelerated by a specific 2-week training program. This effect was sustained over a 6-month period [14].

5.6 Monocular and Binocular Neuroadaptation

So far we discussed neuroadaptation as a monocular phenomenon; however, neuroadaptation can occur within the visual system in response to either a monocular or binocular visual disturbance. Neuroadaptation depends to a great extent on visual awareness. If one is not aware of a disturbance, he does not need to depress it or neuroadapt. In case of a monocular visual disturbance, the brain learns to compensate by altering its perception. So is in case of anisometropia when the brain's input from one eye disturbs the visual system and the neuroadaptive process is of ignoring one eye (usually the eye that produces a more blurry retinal image) that results eventually in amblyopia. Neuroadaptation has to solve not only monocular vision disturbances but also vision disturbances that occur due to the brain's attempt to produce a well-integrated binocular

image perceivment in order to provide an ability of depth perception and stereopsis. This need for binocular neuroadaptation is a key to understanding the need to implant a multifocal intraocular lens in both eyes rather than only in one and to implant the multifocal lenses in both eyes as close as possible – even at the same day. The need for a rapid neuroadaptation (and for neuroadaptation to occur at all) is the explanation as to why multifocality in both eyes is much better than in one eye only. Neuroadaptation is not a solution to all visual disturbances, monocular or binocular. As said before, though our visual system may deal with visual aberrations, it cannot deal with a large amount of aberrations and disturbances. Monocular multifocality might be “too much” for neuroadaptation to deal with. Given the time, the mind applies its negating effect to the undesirable pattern. If age and time works in the patient’s favor, the final image ultimately becomes acceptable. However, sometimes surgeons intentionally disrupt the “one-eye, one-image” perception that is required for successful merging of the images from two eyes, such as when implanting an IOL style for one eye that is different from the other. In this case, the brain is presented with a perceptive paradox that it is not wired to undo [15].

Each eye sends the visual input to the brain. Until the image signal hits the sixth order neurons, both images are monocular. It is here where ocular dominance and retinal rivalry exist. From the lateral geniculate bodies, the images begin to fuse. Flood these centers with retinal signals from multiple images and the deep centers of the brain that need to make sense of the chaos begin to fail. Like contrast, neural adaptation associated with both retinal rivalry and image crowding occurs at the earliest stages of visual processing.

Daily tasks as reading are also to do with binocular vision and neuroadaptation. When reading, our eyes move in spurts across the page. To meld the saccadic movement of our eyes into a smooth perception of letters and words requires higher cortical processing and neuroadaptation. Any disturbance to visual perception especially in a rapid process like reading should be depressed

quickly. The brain adapts to the information from both eyes images and combines them across glances [16].

Conclusion

Neuroadaptation is a major concern while implanting multifocal intraocular lenses since these lenses, in order to achieve multifocality, reduce contrast sensitivity and make at least one of the foci foggy. Knowing the patient’s needs, the lens’ qualities, and its advantages and disadvantages might help in choosing the most suitable lens for the individual patient. Explaining the phenomena to patients and, if needed, training them after surgery might be of great help and eventually lead to patients’ satisfaction.

At the same time that multifocal intraocular lenses are a challenge to neuroadaptation, neuroadaptation can serve us and related to as a tool to improve patient’s satisfaction and overcome the multifocal intraocular lenses problem of having one focus blurred and inducing aberrations. Neuroadaptation is a problem and a solution at the same time, and as most surgeons experience, the vast majority of patients experience visual improvement and enjoy doing visual daily tasks with no problem, usually within a short time after the operation, hence proving once again the superiority of the human mind and the brain’s flexibility which neuroadaptation is part of.

Compliance with Ethical Requirements Jorge L. Alio and Joseph Pikkell declare that they have no conflict of interest.

No human studies were carried out by the authors for this article.

No animal studies were carried out by the authors for this article.

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Multifocal Intraocular Lenses: Complications

6

Roberto Fernández-Buenaga and Jorge L. Alió

6.1 Introduction

Implantation of multifocal IOLs that offer full refractive correction at all distances is the ideal goal for cataract and lens-based refractive surgery. Overall, multifocal IOLs achieve high patient satisfaction; in a study comparing monofocal with two different models of refractive multifocal and one diffractive model, patients showed higher satisfaction with the multifocal model; in particular the diffractive model performed the best [1]. Other studies also show a high patient satisfaction after multifocal IOL surgery with the scores of 8.3 ± 1.6 (out of 10) and 8.5 ± 1.2 (out of 9), respectively [2, 3]. In a paper from our research group, we found correlations between some clinical parameters and the quality of life, such as driving (especially at night) and contrast sensitivity or eyesight quality and uncorrected distance visual acuity.

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In this chapter the multifocal IOLs' negative aspects are reviewed and discussed, as well as a strategy to prevent, detect, and treat these unwanted outcomes is offered.

6.2 Prevention

The first step to avoid problems when implanting multifocal IOLs is an adequate patient selection. A complete ophthalmological examination is mandatory before performing cataract surgery, and even more when multifocal IOLs will be implanted, as was discussed in Chap. 3 “Preoperative considerations.” A thorough medical, ophthalmic, and family history should be assessed, and special cases as glaucoma, AMD, and others should be considered (see Chap. 4 “Multifocal intraocular lenses in special cases”).

Meticulous slit lamp examination is necessary to rule out any corneal disorder, such as corneal scarring or corneal dystrophies (especially Fuchs dystrophy), and to check the zonule integrity in order to guarantee a stable capsular bag, thus avoiding decentrations or dislocations due to zonule of Zinn weakness.

Funduscopy is also essential to assess the optic nerve and the macula. Multifocal IOL implantation should not be performed in patients with previous pathologies that determine preexisting decreased contrast sensitivity as glaucoma, other neuropathies, or macular diseases. We

advocate performing macular OCT (optical coherence tomography) in every patient who is undergoing cataract surgery with multifocal IOL implantation.

Topography, corneal aberrometry, and pachimetry are necessary examinations with a dual purpose: to detect irregular or aberrated corneas (should be discarded for this surgery) and also to ensure that a laser enhancement could be performed in case it is needed after the cataract surgery to resolve a residual refractive error. Multifocal IOLs to perform well need both eyes with intact potential of vision; because of this, we do not recommend to implant these lenses in only eyes or in amblyopic ones. Binocular vision should be also carefully checked; these IOLs are suitable neither for patients with strabismus nor for those with high phoria because the decompensation could be facilitated.

Multifocal IOLs need a neuro-adaptation period; to accelerate and make this process easier, we recommend to implant multifocal IOLs in both eyes, in the same operation or in different ones with a very short interval lapsed between both eyes (less than 1 week). Postponing the second eye surgery is a risky strategy that may deteriorate patient satisfaction determining unnecessary IOL explantations in many cases.

Following the previous recommendations, the risk of dissatisfaction in our patients will be decreased; however, there will be some patients with several complaints that we need to know how to manage to turn dissatisfaction into full satisfaction.

6.3 Reasons for Patient's Dissatisfaction

6.3.1 Blurred Vision

Blurred vision is the leading cause of dissatisfaction among patients with multifocal IOLs [4]. Woodward, Randleman, and Stulting reported that blurred vision was the main complaint in 30 (41 eyes) out of 32 patients (43 eyes). 15 patients (18 eyes) reported photic phenomena and 13 patients (16 eyes) reported both blurred vision and photic phenomena. The etiology of blurred vision was attributed to ametropia and PCO in the majority of cases. Despite overall success

with less invasive interventions, 7 % of eyes required IOL exchange to resolve symptoms [4].

In a different study focused on the same issue, blurred vision (with or without photic phenomenon) was reported in 72 eyes (94.7 %) and photic phenomena (with or without blurred vision) in 29 eyes (38.2 %). Both symptoms were present in 25 eyes (32.9 %). Residual ametropia and astigmatism, posterior capsule opacification, and a large pupil were the three most significant etiologies. Intraocular lens exchange was performed in 3 cases (4.0 %) [5].

Dissatisfaction after multifocal IOL implantation is reported by patients who do not achieve the desired visual goals, have limited sharpness of vision, or have new visual aberrations. A Cochrane review about multifocal IOLs found that photic phenomena are 3.5 times more likely with multifocal IOLs than with monofocal IOLs [6].

Most of the time there is an identifiable reason. In a publication mentioned above, it was shown that the causes of blurred vision included ametropia (29 % of cases), dry eye (15 %), posterior capsule opacification (PCO) (54 %), and unexplained etiology (2 %). Regarding the photic phenomena, its causes included IOL decentration (12 %), retained lens fragment (6 %), PCO (66 %), dry eye (2 %), and unknown etiology (2 %). In this paper, the authors achieved an improvement in 81 % of eyes with conservative treatment [4]. In a similar study, 84.2 % of eyes were amenable to therapy, with refractive surgery, spectacles, and laser capsulotomy as the most frequent treatment modalities [5].

In a recent paper of more than 9,300 eyes implanted with a multifocal IOL, patient satisfaction was very high, 93.8 % of the patients reported to be satisfied or very satisfied, while only 1.7 % of the patients were dissatisfied or very dissatisfied [7].

6.3.2 IOL Decentration

Several clinical studies have determined the decentration of IOLs after cataract surgery [8–18]. In general, the mean decentration (after uneventful cataract surgery) in the studies is 0.30 ± 0.16 mm (range 0–1.09 mm). When a multifocal IOL is displaced from its center, it may lose its ability to achieve optimal optical

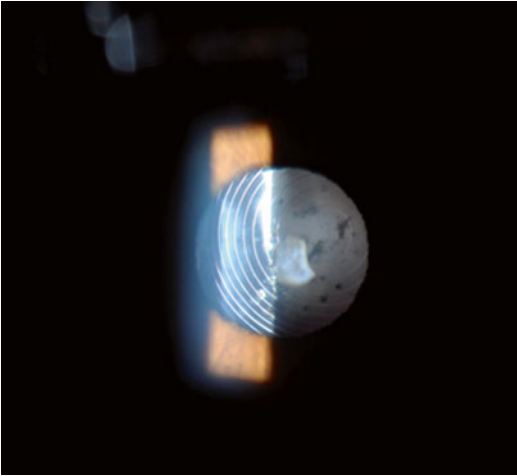


Fig. 6.1 This picture shows a diffractive IOL decentered nasally

properties, thus decreasing the visual function (Fig. 6.1). There are three main factors that determine how visual function is affected by IOL decentration:

- The degree of decentration
- The IOL design
- Pupil size

In a recent study, four different multifocal IOL model (two diffractive and two refractive) performances were studied at increasing degrees of decentration in an eye model with a 3 mm pupil. For the ReSTOR (+4), the near MTF (modulation transfer function) deteriorates with increasing degrees of decentration, while the far MTF tends to improve. This is explained by the specific design of this IOL with a monofocal design in its peripheral part. In other models like the ZM900, the entire optical surface has a diffraction structure; therefore, a slight decrease in both far and near MTF starting at decentrations of 0.75 mm was observed. For the refractive models (ReZoom and SFX-MV1), even when the decentration was 1 mm, the near MTF did not change however the far MTF decreased starting at decentrations of 0.75 and 1 mm, respectively. In conclusion, the MTFs and near images are affected, but clinical relevant effects are not to be expected up to a decentration of 0.75 using this eye model with a 3 mm pupil and the previously mentioned IOLs [19].

In a different study comparing refractive multifocal and monofocal IOL performance depending on the pupil size and decentration, it

was found that in the multifocal group smaller pupils correlated with worse near visual acuity while decentration was significantly correlated with worse distance and intermediate visual acuity. However, in the monofocal group, pupil size and IOL decentration did not affect the final visual acuity [20].

It has been also shown by other authors that the more sophisticated the IOL is, the more sensitive to decentration it is. In a paper comparing aberration-correcting, aberration-free, and spherical IOLs, after decentration, the performance of the IOL was more affected in the aberration-correcting group followed by the aberration-free IOLs, while the spherical IOLs were not affected by decentration at all [21].

Another interesting consideration is the angle kappa (see also in Chap. 3). Although it is not very common, some patients may have a large angle kappa. A large angle kappa should be suspected and checked in every patient with a perfectly pupil centered multifocal IOL but with poor vision complaint [22].

The main symptoms when multifocal IOL decentration occurs are the photic phenomena including glare and halo. A suboptimal visual acuity is also detected in these cases (Fig. 6.1).

6.3.2.1 Management

The first important message is that multifocal IOL decentration that occurs after an uneventful cataract surgery can be managed without IOL explantation in the majority of the cases. We advocate performing Argon laser iridoplasty as the treatment of choice. The Argon laser settings for the iridoplasty are 0.5 s, 500 mW, and 500 μ m. Other authors have also recommended this approach (E.D. Donnenfeld, MD, et al., “Argon Laser Iridoplasty to Improve Visual Function After Multifocal IOL Implantation,” presented at the ASCRS Symposium on Cataract, Intraocular Lens and Refractive Surgery, Chicago, Illinois, USA, April 2008).

6.3.3 IOL Tilt

The material and biocompatibility of the haptics have been shown to play a role in IOL centration [23, 24]. Hydrophilic IOLs have several

advantages because of its pliable and scratch resistance nature that allows to implant these IOLs through small corneal incisions. However, this malleable material may be a major drawback if capsular bag contraction develops. The combination of hydrophilic material with soft C-loop haptics may facilitate IOL decentration and tilt when capsule bag contraction starts to develop. Rotationally asymmetric refractive IOLs are sensitive to decentration and tilt because of their inherent design characteristics [25–27].

As a research group we have several recent publications on this issue especially regarding our experience with the Oculentis Mplus IOL [26–28]. To date, there are two different versions of the Lentis Mplus, the LS-312 and the LS-313. The former one was the first to be marketed and it has a C-loop design, while the latter one has a plate-haptic design (Fig. 6.2).



Fig. 6.2 C-loop design (LS-312) on the left and plate-haptic design (LS-313) on the right

Our research group published the first paper evaluating this IOL performance “in vivo” and comparing it with a monofocal spherical IOL [26]. We found that the Lentis Mplus LS-312 effectively restored the near visual acuity with also very good levels of intermediate vision showing a very good defocus curve (Fig. 6.3). It was discussed in this manuscript that it is intrinsic to this IOL design to induce primary vertical coma, and this could be related with the increased depth of focus found in this group of eyes. However, primary coma, especially in larger amounts, has a very negative impact on visual acuity because it induces optical blur. Furthermore, in this study, the multifocal IOL group had larger amounts of intraocular tilt (Fig. 6.4). This suggested that the Lentis Mplus LS-312 might be tilted and perhaps decentered in the capsular bag in a significant number of cases. We found a strong and significant correlation between IOL tilt and increased primary coma. Although, as previously commented, primary coma could have a positive effect on depth of focus, large amounts of this aberration due to the IOL tilting caused significant degradation of the retinal image. Therefore, the near vision outcomes seemed to be significantly limited by the increase of primary coma in cases of IOL tilt (Figs. 6.3 and 6.4).

Capsular tension rings (CTR) have been shown to inhibit posterior capsule opacification [29], play a role in the stability and positioning of IOLs [30], and prevent IOL movements caused by capsular bag contraction [31–33].

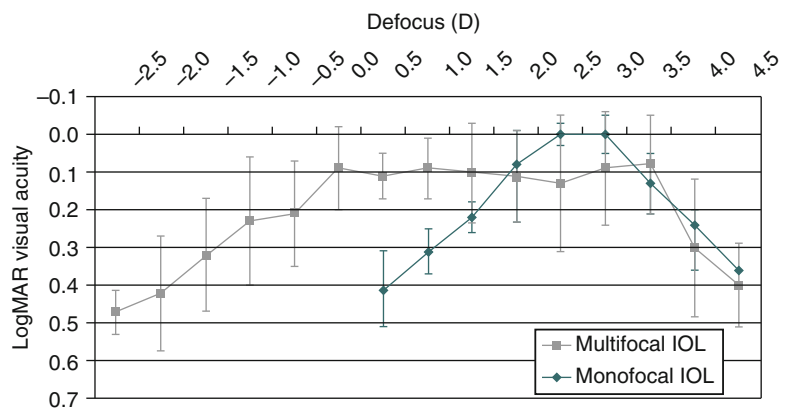


Fig. 6.3 Mean defocus curves (IOL intraocular lens)

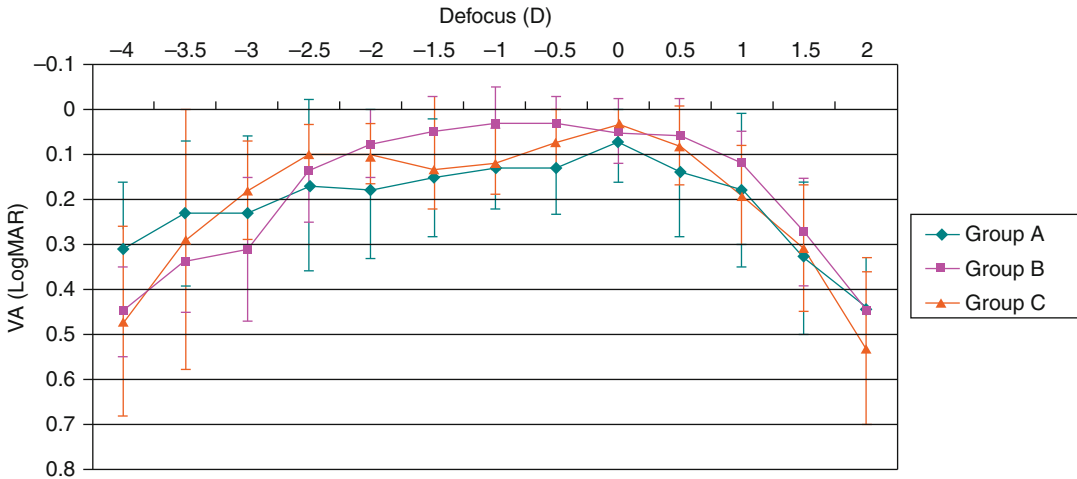


Fig. 6.4 Mean (\pm SD) postoperative intraocular aberrations with a 5.0 mm pupil (2nd coma secondary coma, HOA higher-order aberration, IOL intraocular lens, PSA

primary spherical aberration, RMS root mean square, SSA secondary spherical aberration)

Based on the outcomes showed in the previous paper, we decided to conduct another study to ascertain whether the use of a capsular tension ring positively affects the refractive and visual outcomes as well as the intraocular optical quality of eyes implanted with the rotationally asymmetric multifocal Lentis Mplus LS-312 IOL (Oculentis GmbH, Berlin, Germany). We compared two different groups of patients, one group with the Mplus LS-312 plus CTR and the second group implanted without CTR. It was found that refractive predictability and intermediate visual outcomes with the Lentis Mplus LS-312 IOL improved significantly when implanted in combination with a capsular tension ring. However, no significant differences were observed in the optical quality analysis between groups [28].

Due to all these inconveniences discussed above, Oculentis GmbH, Berlin, Germany, decided to introduce a new plate-haptic design for the Mplus IOL, the LS-313, in an attempt to achieve a greater IOL stability when capsular bag contracts. We conducted another study to check whether that purpose was achieved with the new design [27]. Significantly better visual acuities were present in the C-loop haptic with CTR group for the defocus levels of -2.0 , -1.5 , -1.0 , and -0.50 D ($P = 0.03$) (Fig. 6.5). Statistically

significant differences among groups were found in total intraocular root mean square (RMS), high-order intraocular RMS, and intraocular coma-like RMS aberrations ($P = 0.04$), with lower values from the plate-haptic group (Fig. 6.6). However, it is interesting to notice that when we analyzed the intraocular tilt aberrations, no significant differences between groups were detected. Thus, our findings indicate that it is unclear which IOL haptic design allows more effective control of IOL tilting.

To summarize, IOL tilt due to capsular bag contraction is more prone to occur in lenses made of soft materials especially in combination with C-loop haptics. IOL tilt determines increased high-order optical aberrations and, thus, poorer optical quality and limited performance also related to a worse refractive predictability. IOL tilt should be prevented using robust IOL designs resistant to the normally occurring capsular bag scarring.

6.3.4 Inadequate Pupil Size

Postsurgical pupil size is a very important parameter that definitely determines the IOL performance. The main challenge regarding this issue is that it is very difficult to predict the

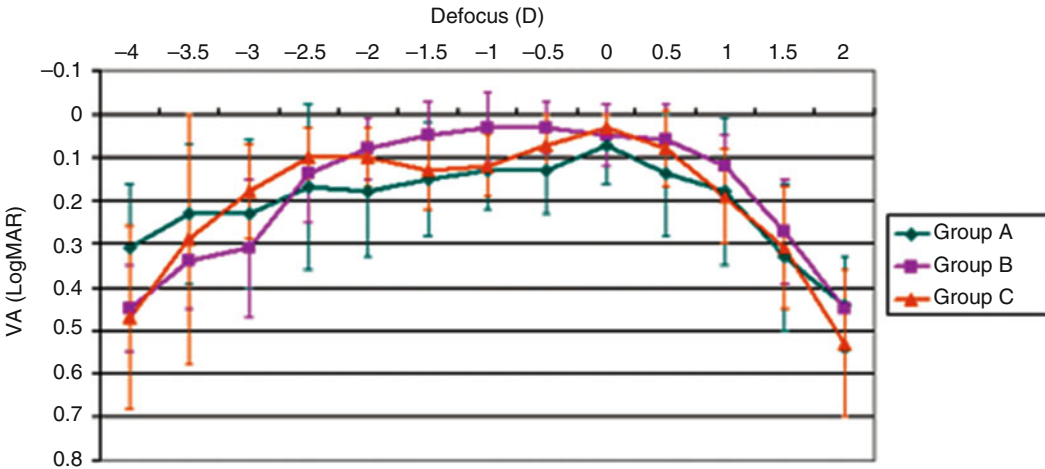


Fig. 6.5 Mean defocus curve in the three groups of eyes analyzed: *group A* eyes implanted with the C-loop haptic design of the refractive rotationally asymmetric multifocal intraocular lens (MIOL) without using a capsular tension ring (CTR) (*green line*), *group B* eyes implanted with

the C-loop haptic design of the refractive rotationally asymmetric MIOL using a CTR (*pink line*), and *group C* eyes implanted with the plate-haptic design of the refractive rotationally asymmetric MIOL (*orange line*)

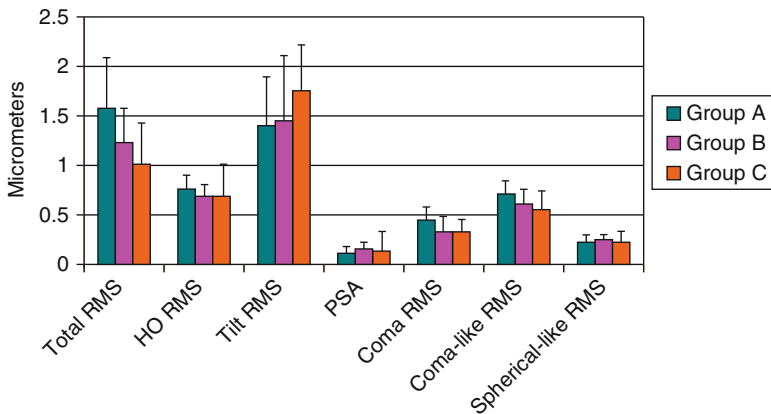


Fig. 6.6 Postoperative intraocular aberrations in the three groups of eyes analyzed: *group A* eyes implanted with the C-loop haptic design of the refractive rotationally asymmetric multifocal intraocular lens (MIOL) without using a capsular tension ring (CTR) (*green bars*), *group B* eyes implanted with the C-loop haptic design of the refractive rotationally asymmetric MIOL using a CTR (*pink bars*), *group C* eyes implanted with the plate-haptic

design of the refractive rotationally asymmetric MIOL (*orange bars*). RMS values (in micrometers) and standard deviation of total, higher-order, tilt, and spherical-like and coma-like aberrations. In addition, the primary spherical aberration is also reported with its sign. *RMS* root mean square, *HO* higher order, *PSA* primary spherical aberration, *SSA* secondary spherical aberration

pupil size that will be found after the surgery because it usually changes in comparison with the preoperative measurements. Thus a very small pupil after the surgery will limit the near vision performance of most of the multifocal lenses. On the other hand, large postoperative

pupils are associated with increased photic phenomena referred by the patients.

Visual acuity correlates with pupil size; a larger pupil permits greater use of the multifocal IOL optic with zonal models and improved contrast sensitivity with diffractive models [20, 34].

6.3.4.1 Management

- In patients with poor near vision outcomes due to very small pupils, we advocate the use of cyclopentolate to enlarge the pupil; if a clear improvement is noticed, the patient may keep using the cyclopentolate as described by other authors [4] or an 360° Argon iridoplasty (0.5 s, 500 mW and 500 μ m) can be planned.
- The other side of the spectrum is comprised of patients with too large pupils who complain of increased photic phenomena. In these cases, brimonidine tartrate 0.2 % to decrease mydriasis at night is a classical solution in refractive surgery that has been also recommended by other authors [4, 35, 36]. It decreases the pupil size, thus improving the photic phenomena at night.

6.3.5 Residual Refractive Error

As multifocal IOLs are more sophisticated lenses, they are also more sensitive to any residual refractive error.

Despite new advances in cataract surgery, unsatisfactory visual outcomes as a result of a residual refractive error occasionally occur. In a recent report analyzing refractive data from more than 17,000 eyes after cataract surgery, it was shown that emmetropia was only reached in 55 % of eyes planned for that goal [37]. These outcomes highlight that refractive error after cataract surgery is an important issue.

Postoperative refractive errors may be due to different causes, such as inaccuracies in the biometric analysis [38–40], inadequate selection of the IOL power, limitations of the calculation formulas especially in the extreme ametropia, or IOL positional errors [41].

Previous studies have shown good efficacy, predictability, and safety for myopic and hyperopic laser in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) enhancements after cataract surgery [42–48]. Lens-based procedures are also useful alternatives to consider [49, 50]. It should be noticed that some surgeons do not have excimer laser in their centers; thus lens procedures become the only possible

option in these cases. We have recently conducted a study which its aim was to present and compare the results assessing the efficacy, predictability, and safety of three different procedures to correct residual refractive error after cataract surgery: LASIK, IOL exchange, and piggyback lens implantation. Although this study only included monofocal IOLs, the outcomes could be extrapolated to multifocal IOLs. The results of this study showed that the three procedures were effective, but LASIK achieved the highest efficacy index, the best predictability with 100 % of the eyes within ± 1 diopters of final spherical equivalent, and 92.85 % of eyes showed a final SE within ± 0.50 D (Figs. 6.7 and 6.8). The LASIK also showed lower risk of losing lines of corrected vision compared with the other two procedures [51].

Regarding laser enhancement after multifocal IOL implantation, some authors have reported improvement in distance vision with limited effect on photic phenomena after PRK retreatments in patients implanted with refractive multifocal IOLs [43], while others have reported excellent predictability in patients implanted with apodized diffractive/refractive and diffractive IOLs [42, 52].

In another study performed by our research group, we evaluated efficacy, predictability, and safety of LASIK to correct residual refractive errors following cataract surgery, comparing the outcomes of patients implanted with multifocal and monofocal IOLs. We found that laser in situ keratomileusis refinement after cataract surgery with monofocal IOL implantation provides a more accurate refractive outcome than after multifocal IOL implantation. Predictability of LASIK correction is limited in hyperopic eyes implanted with multifocal IOLs (Figs. 6.9, 6.10, 6.11 and 6.12) [48].

In summary, residual refractive error is one of the most common reasons of patient complaints after cataract surgery with multifocal IOL implantation. Hence, it is extremely important to make sure prior to the cataract surgery with multifocal IOL implantation that the patient has normal topography and pachymetry that will permit a laser enhancement in case we need it.

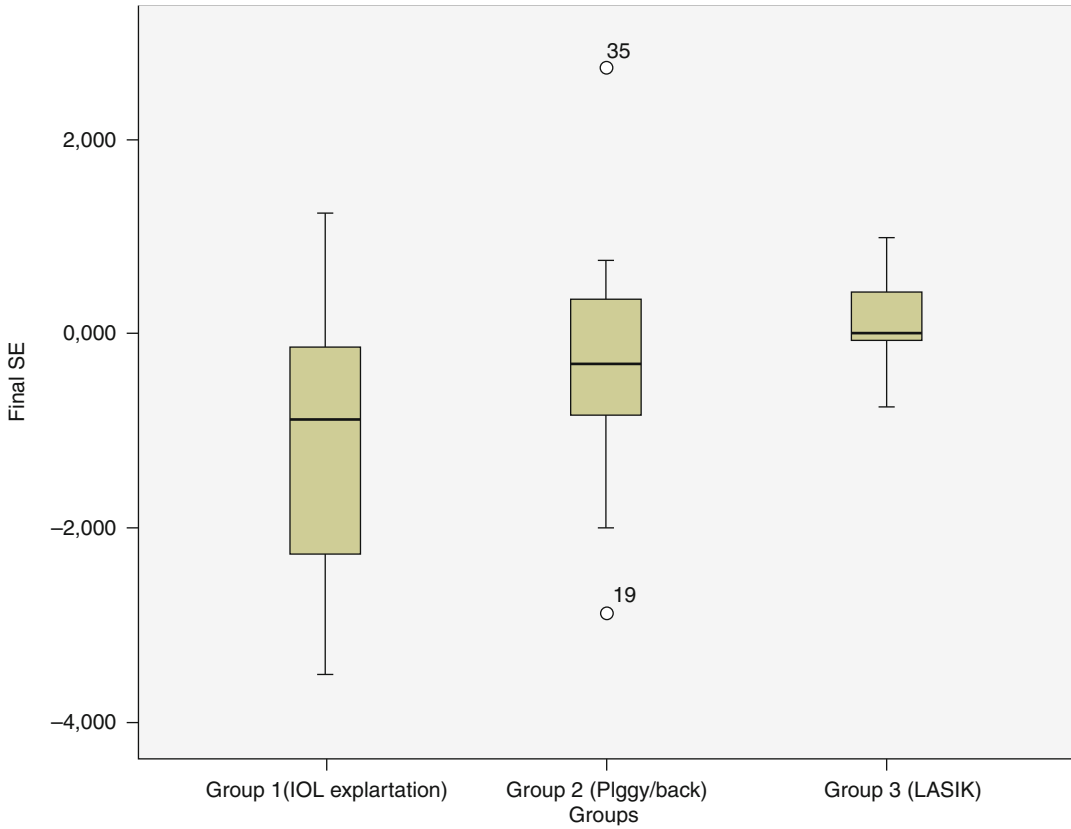


Fig. 6.7 Comparison of the final spherical equivalent (*SE*) among the three groups. Group 3 (*LASIK*) achieved the best outcome with the smallest results dispersion

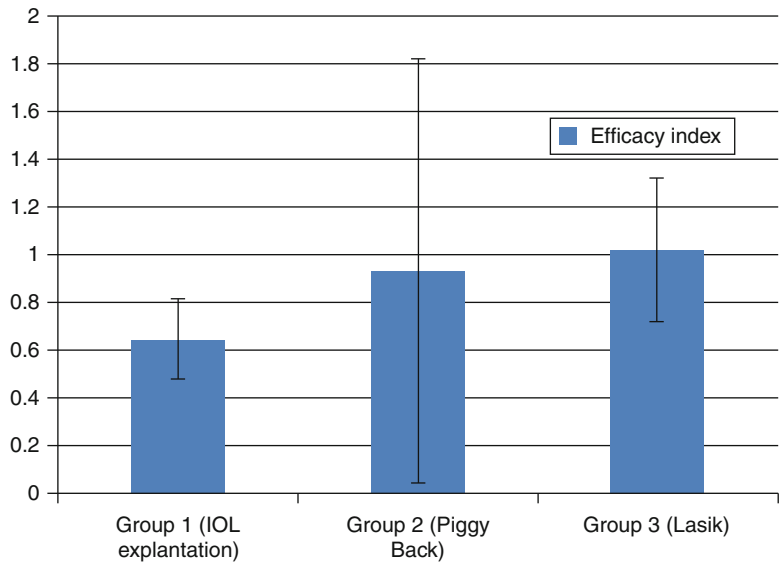


Fig. 6.8 The efficacy index mean and distribution among groups. The highest value was achieved by group 3 (*LASIK*)

Fig. 6.9 Distribution of postoperative uncorrected distance visual acuity outcomes (UDVA) (*white bars*) compared to preoperative distribution of corrected distance visual acuity (CDVA) (*grey bars*) in the multifocal group (50 eyes). Uncorrected distance visual acuity was 20/40 or better in 90 % of eyes and 20/25 or better in 44 % of eyes

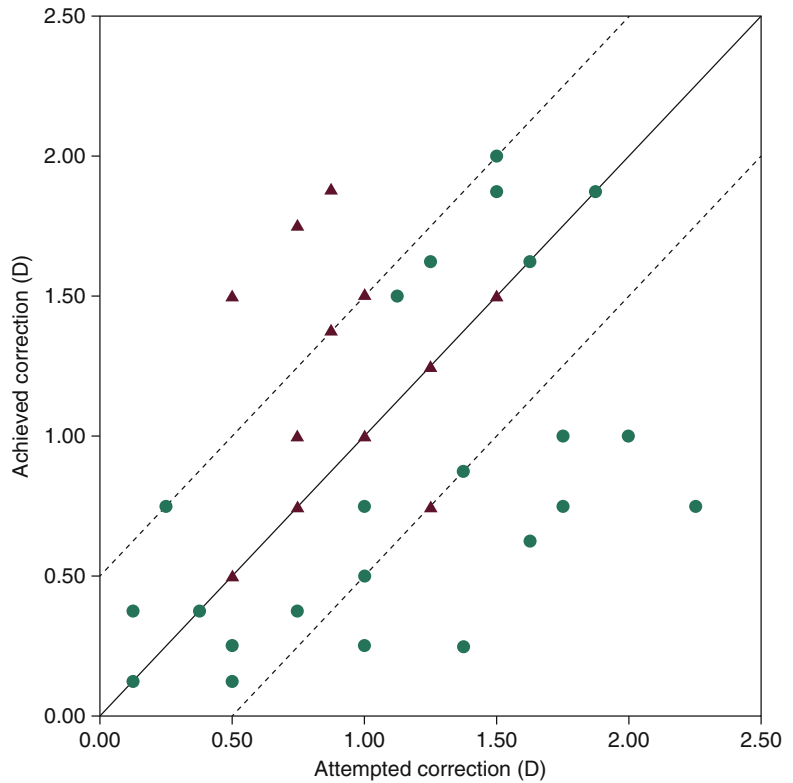
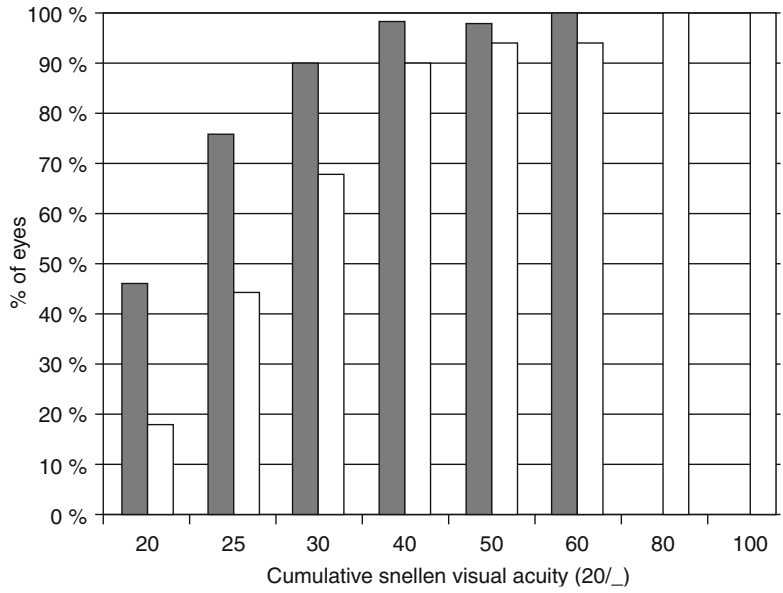


Fig. 6.10 Scattergram of attempted versus achieved correction for the multifocal group (50 eyes). *Green circles* represent hyperopic cases, whereas *red triangles* represent myopic cases. A tendency for undercorrection was noted in the eyes that underwent hyperopic LASIK after multifocal IOL implantation. *Dashed lines* represent ± 0.50 D from the 1:1 line

Fig. 6.11 Distribution of postoperative UDVA outcomes (*white bars*) compared to preoperative distribution of CDVA (*grey bars*) in the monofocal group (50 eyes). Uncorrected distance visual acuity was 20/40 or better in 94 % of eyes and 20/25 or better in 60 % of eyes

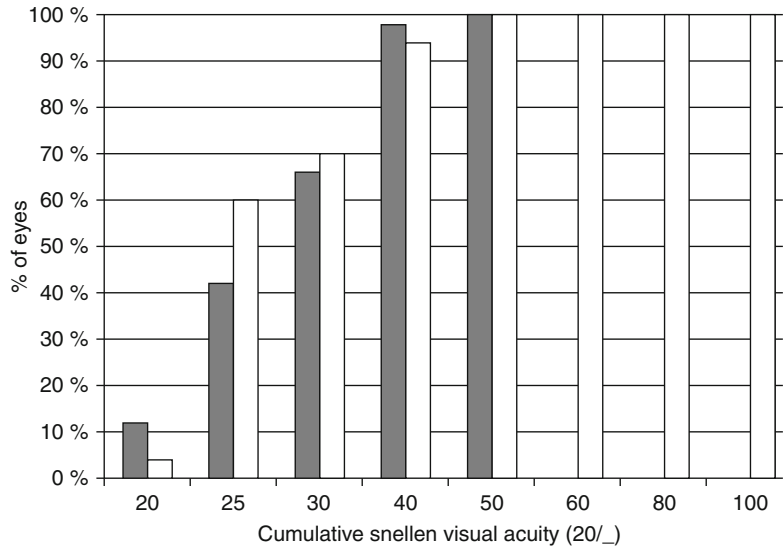
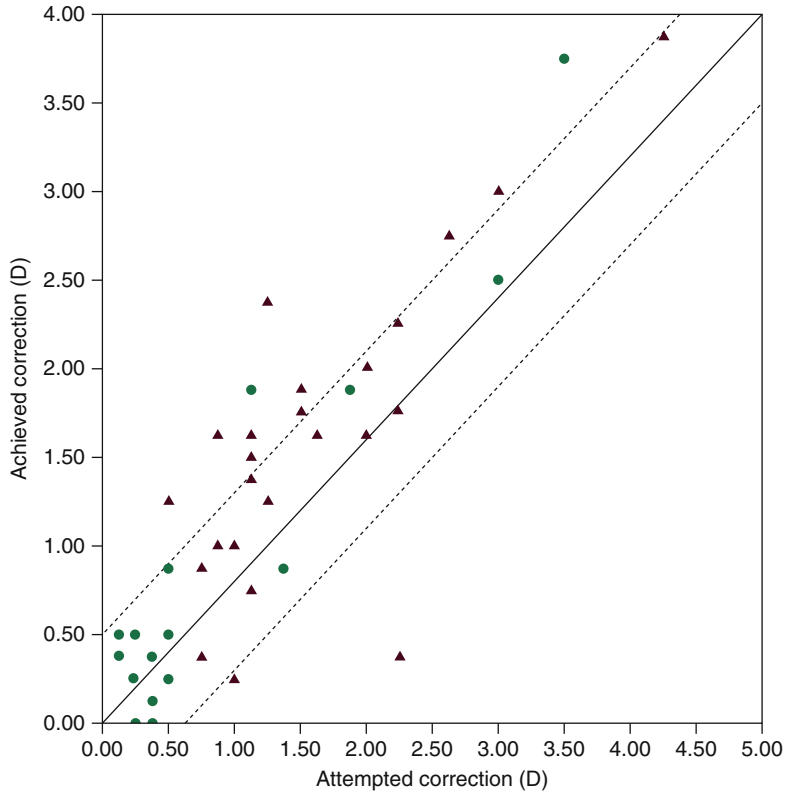


Fig. 6.12 Scattergram of attempted versus achieved correction for eyes from the monofocal group (50 eyes). *Green circles* represent hyperopic cases, whereas *red triangles* represent myopic cases. Predictability was good with almost all eyes within ± 1.00 D of spherical equivalent refraction. The *dashed lines* represent the ± 0.50 D range from the 1:1 line



6.3.6 Posterior Capsule Opacification

The most common long-term complication of IOLs implanted is posterior capsule opacification

(PCO) [53–55] Patients with PCO complain of decreased visual acuity, contrast sensitivity, and increased photic phenomena like glare. The treatment is fast and safe using the Nd:YAG laser. However, although rarely, there may be some

associated complications like optic IOL damage, intraocular pressure rise, cystoid macular edema, and retinal detachment increased risk [56]. Furthermore the procedure has a noticeable economical impact (250 millions of dollars/per year in the USA).

A Cochrane Review [57] showed significantly higher PCO rates after hydrogel IOL implantation than after implantation of IOLs of other materials, significantly lower PCO rates with IOLs with a sharp posterior optic edge than with round-edged IOLs, no difference between 1-piece and 3-piece IOLs, lower PCO rates with IOLs placed in the capsular bag than in the sulcus, and lower PCO rates in eyes with a small capsulorhexis than with a large capsulorhexis.

PCO is especially important in multifocal IOLs because due to more sophisticated design and higher visual demands, these lenses might be more sensitive to PCO than the monofocal ones. Indeed, in a study comparing the frequency of posterior capsulotomies in patients receiving a multifocal or monofocal intraocular lens (IOL) of a similar design, it was shown that the use of multifocal IOLs in clinical practice may result in more frequent Nd:YAG laser capsulotomies. After average 22-month postoperative follow-up (range: 2–41 months), 15.49 % of the eyes in the multifocal group underwent posterior capsulotomies compared to 5.82 % of the eyes in the monofocal group [58].

The main complaints in patients with multifocal IOLs implanted and PCO are blurred vision and increased photic phenomena [4]. In fact, in this study, blurred vision and photic phenomena were attributed to PCO in 54 and 66 % of the eyes, respectively.

Other authors have studied the capsulotomy rate after the implantation of different multifocal IOL models to see if there is a difference in this rate related to the IOL material or design. The authors compared a hydrophobic lens (AcrySof ReSTOR) with a hydrophilic IOL (Acri.LISA), and they found that 24 months after the surgery the capsulotomy rates were 8.8 % in the hydrophobic group and 37.2 % in the hydrophilic group ($P < 0.0001$). The eyes in the hydrophilic group

had a 4.50-fold (2.28 versus 8.91) higher risk for Nd:YAG laser capsulotomy ($P < .0001$) [59].

6.3.6.1 Management

It is evident that the best treatment to resolve a PCO is Nd:YAG laser capsulotomy. However, we encourage surgeons to reserve Nd:YAG capsulotomy until all other causes of patient complaints are treated or ruled out because IOL exchange is necessary in rare cases and is significantly more challenging and associated with higher risk of complications when the posterior capsule has been previously opened. Surgeons should be especially aware of patient complaints arising from elements intrinsic to IOL design, which should generate complaints in the immediate postoperative period before PCO formation.

6.3.7 Photic Phenomena and Contrast Sensitivity

In a very recent literature review about multifocal IOL benefits and side effects, photic phenomena was detected as one of the most important drawbacks after multifocal IOL implantation [60]. Halos and glare (Fig. 6.13) are more often reported by patients with a multifocal IOL than with a monofocal IOL [61, 62]. Refractive multifocal IOLs appear to be associated with more photic phenomena than diffractive multifocal IOLs [1]. Photic phenomena are among the most frequent reasons for dissatisfaction after multifocal IOL implantation [4, 5].

Multifocal IOLs are associated with lower contrast sensitivity than monofocal IOLs [1], especially in mesopic conditions [63]. In a very recent paper it has been demonstrated that patients with a diffractive multifocal IOL have a relevant reduction in contrast sensitivity as assessed with standard automated perimetry for size III and size V stimuli in comparison with phakic patients and with monofocal implanted patients [64] (Fig. 6.13).

An explanation for the lower contrast sensitivity could be that multifocal IOLs result in coexisting images, because the light is shared between

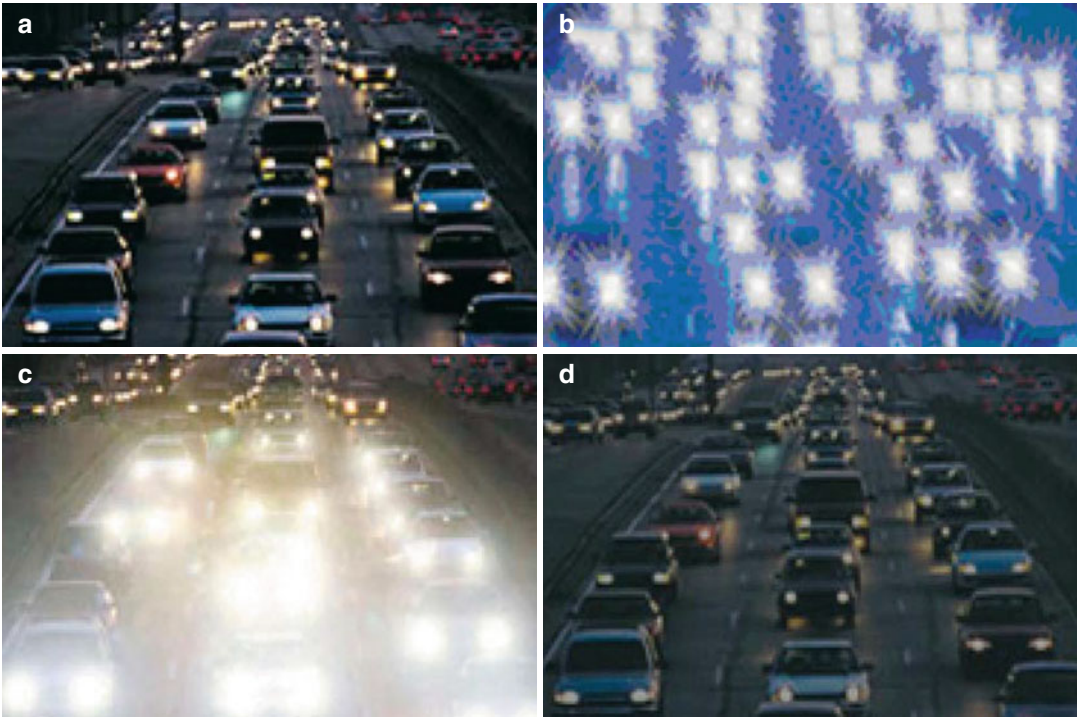


Fig. 6.13 (a) Normal image is shown on the left. (b) Image with glare is shown on the right. (c) Down on the left, halos. (d) Down on the right, contrast sensitivity loss

two different foci. Therefore, there are two images, one sharp and one out of focus, with the light from the latter reducing the detectability of the former image. Diffractive multifocal IOLs appear to be equal or superior to refractive multifocal IOLs with respect to contrast sensitivity [65–67]. Although contrast sensitivity in individuals with multifocal IOLs is diminished compared with individuals with monofocal IOLs, it is generally within the normal range of contrast in age-matched phakic individuals [34, 63].

6.3.7.1 Management

In our opinion, the photic phenomena management starts before the cataract surgery with the multifocal IOL implantation is performed. The preoperative patient education is very important and the patients should be told that they will notice glare and halos after the surgery (because they are inherent to the IOL design), although in most of the cases, the photic phenomena are mild to moderate and most of the patients get used to it with time (neuro-adaptation process). However,

we do not recommend to implant multifocal IOLs in night professional drivers, even more if the patient has a large scotopic pupil size which will increase the perception of halos and glare at night.

When the photic phenomena complaint is very prominent, all the causes that may exacerbate it (previously discussed in this chapter) have to be ruled out.

6.3.8 Dry Eye

Dry eye is a multifactorial disease of the tear film and the ocular surface that results in symptoms of discomfort, visual disturbance, and tear-film instability (see also Chap. 4 “Multifocal intraocular lenses in special cases”).

Dry eye and cataract formation are very common in the elderly population. In addition, cataract surgery can induce dry eye or exacerbate preexisting disease. The incisions created during surgery may damage the cornea’s

neuro-architecture, reduce corneal sensation, and induce dry eye disease [68]. A study found a significant increase in the incidence of dry eye in patients having cataract surgery [69]. In another study, patients with preexisting dry eye had decreased tear production and tear breakup time (TBUT) after cataract extraction, leading to ocular discomfort and irritation [70]. Given the inherent importance of the ocular surface and tear film to the quality of vision, dry eye may significantly degrade visual outcomes after multifocal IOL implantation [68].

Postoperative cataract surgery treatment may also play a role in triggering a dry eye or exacerbating a preexisting one. Therefore, in our opinion, it is mandatory to use preservative-free drops and to avoid very long and unnecessary antibiotic prescriptions.

6.3.8.1 Management

Dry eye treatment is not the purpose of this chapter, but as general guidelines we start the treatment by improving the eyelid hygiene and using artificial tears. In more resistant cases, cyclosporine has proven to be a very useful treatment in improving patient symptoms and tear breakup time and decreasing conjunctival staining [68]. Another alternative to consider is to implant punctal plugs, especially in those patients with aqueous deficiency and lack of associated inflammation. We have a very positive experience with the use of PRP (platelet-rich plasma) drops in patients presenting with severe dry eye. We have conducted several studies which show that platelet-rich plasma has very good outcomes in treating dry eye, dry eye after LASIK surgery, corneal ulcer, and even perforated corneas in its solid form [71–75].

6.4 Multifocal IOL Explantation

IOL explantation is the worst scenario possible after cataract surgery with multifocal IOL implantation because it may be associated with new complications and because it means that the aim of the original surgery is missed. Fortunately, it is only needed in very few patients of those

who complaint. Several studies show that the rate of multifocal IOL exchange among dissatisfied patients is 0.85 % [7], 4 % [5], and 7 % [4]. The main reasons that led to the IOL explantation were the photic phenomena, contrast sensitivity loss (inherent to the IOL design), and in other cases exacerbated by lens tilting [4, 5, 7]. In another study analyzing the main reasons for pseudophakic IOL explantation, the failure to neuroadapt in patients with multifocal lenses implanted was the fourth main cause of explantation after IOL dislocation (first cause), refractive error (second cause), and IOL opacification (third cause) [76]. Explantation surgery is always challenging; however, explantation of a multifocal lens is usually easier (especially with a capsular tension ring) than explantation due to the other causes. First, because the decision of explantation is made only few months after the cataract surgery, the scarring process has not occurred yet, and second because the ocular structures are undamaged, the surgery is less risky. In contrast, when performing IOL explantation due to other causes as dislocation or IOL opacification, the surgery is associated with more complications due to the ocular structure damage in the former and the presence of fibrotic tissue in the latter, especially, because in these cases the IOL explantation is performed long time after the original cataract surgery [77, 78].

Another consideration to be made is the design and material of the multifocal lens. C-haptic lenses are generally easier to remove by cutting a part of the lens, while plate-haptic lenses are sometimes more difficult to remove and require a bigger wound enlargement. Thus determining an astigmatic worsening [51].

6.5 Summary

The need of performing IOL explantation is very rare, and most of the complaints of dissatisfied patients are usually successfully managed with appropriate medical treatment (as described in this chapter). However, we encourage multifocal surgeons to implant capsular tension rings when the estimated risk of IOL explantation is higher

than usual (patients with problematic personality). Capsular tension rings make IOL explantation surgery easier. In our opinion, the neuro-adaptation process may last for up to 6 months; thus, if IOL explantation has to be performed, it should be done in the first 6 months after the surgery. Otherwise, waiting longer will make the surgery more challenging and difficult due to the scarring tissue, thus with higher complication risk.

Compliance with Ethical Requirements Roberto Fernández Buenaga and Jorge L. Alió y Sanz 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.

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7.1 Introduction

Whilst the use of multifocal IOLs has increased very greatly in the past decade as more and varied designs have come onto the market and increasing patient awareness and surgeon enthusiasm has driven demand, not every patient is happy with the result. This may, for example, be because of a suboptimal visual acuity result for either near or distance or due to the effects of the IOL design causing intolerable dysphotopsias. Very often these problems will be due to inadequate understanding by the patient of what is actually possible. This chapter will review the major causes of patient unhappiness and suggest solutions.

7.2 Avoiding Problems by Adequate Preoperative Discussions and Ocular Measurement

After having carried out a full ophthalmic examination to make sure that there are no comorbidities like tear film deficiency or macular problems which will not only compromise the visual result but are contraindications for multifocal IOL use, time needs to be spent talking

through what your patients are about to experience. Many of the issues which appear as a problem for these patients after their surgery would not occur with time spent in discussion prior to surgery. This includes an assessment by the surgeon and ancillary staff as to the character, patient's needs, lifestyle and expectations. It may be that unreasonable expectations for visual outcome or a particularly obsessive nature will be a contraindication for the use of these lenses. Never promise full spectacle independence but say that there is a good chance that a lot of the time glasses will not be needed. There are a number of useful questionnaires available to try to assist in this personality assessment.

From the surgeon's point of view, a well-developed knowledge of the characteristics of each style of lens they plan to use is mandatory. Do they, for example, give good distance vision at the expense of better reading vision like the Alcon ReSTOR +2.5 add or the Oculentis Comfort lens with a +1.5 add? Will reading require good light for the lens to work like most diffractive IOLs but most particularly the ReSTOR +3.0 add with a central diffractive area? In my practice we go to great lengths to emphasise such issues. All patients need to understand that whichever IOL is used, a compromise will need to be made as the available light is divided and some lost. There is simultaneous vision between near and distance resulting in a second blurred image which patients need to learn to

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ignore. This becomes even more important when trifocal lenses like the PhysiOL Fine Vision or the Zeiss Lisa Tri are being considered. Apart from these two, most multifocal IOLs are actually bifocal, and the relatively poorer intermediate vision available must be emphasised. Patients need to know that a computer screen may need to be moved closer or glasses used. All diffractive IOLs will lead to haloes at night, and patients need to know this in advance and preferably get some idea of what this means by a simulation. Many patients with cataracts will have been aware of these anyway. Patients should be informed that this phenomenon is a function of the design of the lens and that the vast majority of people get used to them very quickly. I also emphasise that when driving at night, it is important to look at the near side kerb where the dipped headlight beam falls.

Patients should have a clear idea of the process and time frame of adaptation to their new lenses. Although most patients will be comfortable with their near and distance vision within a week, some may take much longer, up to several months. I say to all my patients that they will be happy quicker if they do not try to deconstruct every aspect of their vision because this will lead to a much slower neural adaptation and potential dissatisfaction. All of the multifocal lenses available have a fixed reading distance which has a limited range on either side of the sweet spot. Patients need to realise that finding the focal length at an early stage postoperatively will lead to a quicker adaptation to their new visual status. I emphasise that from day one, they should try to find this distance and try to place whatever they are reading in the same position until it becomes second nature. One reason I like to carry out same-day surgery is that there is no opportunity to compare eyes and also because of the enhancement to vision of binocular implantation from day one.

Optimisation of A constants and careful biometry with an optical device like the IOLMaster or Lenstar will help to avoid refractive surprises. The Zeiss Lisa Tri has been optimised for the Haigis formula, but whichever formula is used, the surgeon must optimise from their refractive

outcomes. Using the calculator on Dr Warren Hill's website makes this a simple exercise. If it is not possible to use an optical device for biometry, it is preferable to use immersion A scan as this is more accurate than using the direct contact method.

It is critical that the corneal characteristics are also assessed. Using topography and aberrometry will not only pick up corneal abnormalities like forme fruste keratoconus and coma which will be contraindications for multifocal IOL implantation, but using a Scheimpflug device like the Pentacam enables the surgeon to determine the posterior corneal power. This last has been shown to be important in determining the amount of cylindrical error requiring correction by a toric IOL of any sort. With a multifocal IOL, astigmatism of 0.5 dioptres or more should be corrected. With very small amounts of cylinder, limbal relaxing incisions may be a better option than a toric lens.

Having made the patient aware of what they should expect from their new lens and given them a fully informed consent form to sign, it is now time to arrange their surgery. Be aware that despite the best efforts of you and your staff to prepare your patients for their surgery and recovery, they will forget most of what has been told them. It is thus very important that you give patients written information about their lenses. Most companies will have some patient literature available, but you may wish to create your own.

When the time comes for surgery, apart from the obvious need to make a central capsulorhexis overlapping the IOL, making every effort to place a toric lens accurately is even more important when using a multifocal. Even small inaccuracies of placement will result in degradation of the image for the patient.

7.3 Why Are Patients Unhappy?

Let us assume in the first instance that the surgery has gone well, the lenses are implanted as expected and the patient has come for their first postoperative visit. Despite all that you and your staff have told them, they are not happy. At this

point, it is important to try and assess what is disturbing them. What are the potential problems?

- Distance vision less than expected
- Distance vision “waxy”
- Reading vision less than expected
- Inability to read in poor light
- Poor intermediate vision
- Dark shadow in the temporal field
- Glare and haloes at night
- Poor night vision
- Foreign body sensation

Let us consider these in turn.

7.4 Distance Vision Less Than Expected or “Waxy”

I normally see my patients at 1 week postoperatively for their first visit by which time the effects of the surgery on ocular tissues are normally mostly gone. By this stage, the patient should be getting a fair idea of their distance vision. Complaints of poor distance vision at this point generally fall into three categories:

- Failure to adapt to the presence of both near and distance vision at the same time. Patients report that they can see a long way down the chart, but somehow it seems blurred. This is generally more of a problem in diffractive multifocals like the ReSTOR or TECNIS than zonal refractive lenses like the Mplus. If the spherical correction is accurate, i.e., less than 0.5 dioptres from the desired outcome, patients will generally adjust pretty quickly and learn to ignore the blur and concentrate on the clear image, although some may always complain that their vision seems “waxy.”
- Inability to see clearly down the chart beyond 20/40 or 6/12. This is due to two issues: either the biometry has been inaccurate or a toric lens has not been correctly placed or has shifted position. These patients will generally require some remediation, and this will be discussed below.
- The patient has a comorbidity in the eye which was not picked up preoperatively. For example, in cataract patients a preretinal membrane may not have been visible through the lens

opacity. If in doubt with the preoperative macular appearance, an OCT may make for caution in the use of MFIOLs. In the presence of an epiretinal membrane, referral to a vitreoretinal surgeon is required. A poor tear film is often missed and can have a profound effect on the vision with multifocal IOLs. Dosing with lubricants may improve things considerably.

7.5 Reading Vision Less Than Expected and Poor in Low Light

One of the main reasons that patients opt for a multifocal IOL is to be able to read without glasses. Thus, when they cannot even in good light, they are not happy. This may occur for several reasons.

- At 1 week post-op however one of the commonest reasons for less than expected reading vision is that the reading material is not being held in the optimal position. A little time spent demonstrating that reading is actually good when the right position is used generally solves the problem particularly when the patient has shown you that they have good unaided distance vision.
- It may be that the reading addition is not sufficient for the patient to resolve small print. It is for this reason, for example, that a new design of the optic has been incorporated into the M Plus as the M Plus X lens.
- The spherical correction is not correct. This will mean that if myopic, the reading distance may be too close or too far if the patient has ended up hyperopic. As for distance vision, a toric lens may be malpositioned. Solutions for this will be discussed below.
- As above ocular comorbidity may be present and will need to be dealt with as before. Reading in poor light is generally not very good with most multifocal lenses. When patients complain of this, they need to be reminded that they were told this before surgery. I normally suggest the use of the flashlight on a mobile phone if they need to read for short periods. For

extended reading, using a good halogen or LED light works very well.

Early and seemingly minimal posterior capsular changes can with MFIOLs lead to loss of reading vision and such patients will need a capsulotomy much sooner than in a monofocal implantee. A wide capsular opening is essential here to enable the IOL to function properly again.

7.6 Poor Intermediate Vision

As already stated most multifocal IOLs are in fact bifocals but whilst some with lower adds have good intermediate vision for most it is much poorer than near or distance. The usual complaint as far as intermediate vision is concerned relates to being able to use a computer. Although patients will have been warned about this they will still often complain. If a laptop is used this can generally be brought closer into the reading distance but a desk top computer may be more difficult. In this situation I suggest the use of a pair of +1.5 dioptre glasses.

7.7 Dark Shadows or Flickering Lights in the Temporal Field

The shadow is a common complaint in the early postoperative period due to a negative dysphotopsia, but there may also be a positive change in the temporal visual field as in shards of light. There are many theories as to why these occur, but no clear answers. The good news is that these usually disappear with time. Some say that it is when the anterior capsule covering the edge of the IOL opacifies others that the patient adapts. Others still say that it is the anterior capsule itself which causes the problem. It may be due to a space between the edge of the lens and the iris allowing stray light to create an internal reflection from the sharp edge of the IOL. In some patients it can persist because either they are unable to adapt to it or it just does not get better. In any event they complain bitterly leading to frequent office visits. Solutions will be discussed below.

7.8 Glare and Haloes

Inherent in the design of all MFIOLs whether they are diffractive or refractive is the likelihood of some unwanted optical effects like glare and haloes. However, some designs have been shown to have more problems in this regard than others. Diffractive designs, due to the concentric rings on their surface that enable near and distance vision to be achieved, will inevitably create haloes at night. The use of apodisation and an aspheric base lens does lessen the effect considerably, but despite this patients will complain. The good news is that in the vast majority of cases, time will allow them to adapt. However, if they feel they cannot manage, then lens exchange has to be considered. Make sure that no one has tried to improve the situation by carrying out a YAG capsulotomy as this will make any lens exchange much more hazardous. As above, a trial for the patient of loss of reading vision can help them to decide if it is a worthwhile price for getting less visual problems at night. It is important to distinguish between glare which may occur with any IOL for some patients and issues relating to their MFIOL. Unfortunately even after lens exchange, patients may still be troubled by unwanted glare. If lens exchange is contemplated, it is important to have warned the patient that there may be surgical complications which could worsen their vision and that they may still have some symptoms. I believe most patients will adapt in time, and as a result only 2 of my nearly 800 patients with MFIOLs have had lens exchanges. Only one of those was for glare and haloes (Fig. 7.1).

7.9 A Structured Approach to Provide Solutions for the Unhappy Patient

When the unhappy patient returns to see you it is best to have clear and logical approach to help both you and them. For the patients, their problem seems to them very real, and they want a solution. Often as we have seen above, this will be very obvious and straightforward. However,

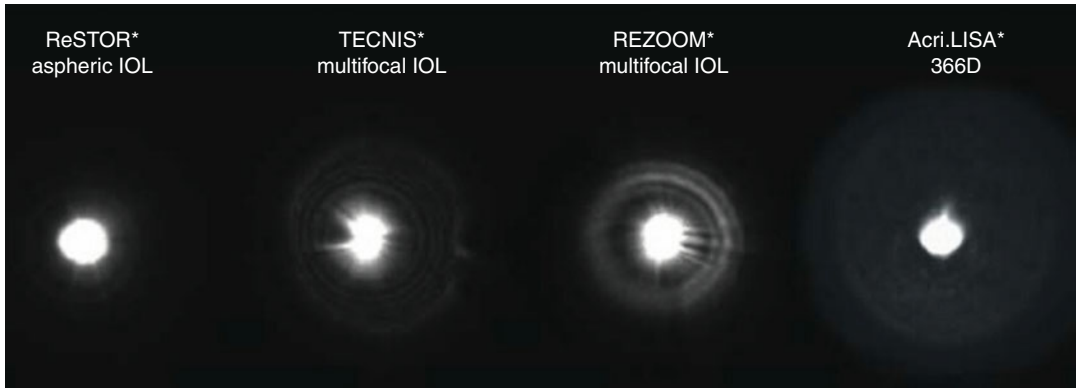


Fig. 7.1 Bench simulation of haloes with different MFIOLs

spending time listening to the complaints is very important in maintaining the patient's trust in you to deal with their issues as well as your understanding of how to make things better. Members of your staff need to know that this patient is not happy and thus be supportive.

- Less than hoped for far vision
- Less than hoped for near vision
- Less than hoped for intermediate vision
- Dysphotopsias whether negative or positive
- Glare and haloes

Many of these issues have already been referred to, but it is useful at this stage to review solutions.

7.10 Distance Vision Issues

With modern optical devices for biometry, refractive surprises are not a common problem, but with MFIOLs small errors of refraction can diminish the effectiveness of the lens. Normally being within 0.5D of intended refraction should ensure a good result. Many patients will tolerate up to 1D of spherical error, but at this level especially with diffractive IOLs, haloes at night are likely to be more troublesome and awareness of a second blurred image. Distance vision may also be affected by failure to correct astigmatism fully. Increasingly there are devices to help the surgeon place the lens more accurately in the correct meridian, but the corneal measurements are still not completely accurate. If the residual

astigmatism is less than 0.5D, patients will normally be happy.

What solutions can be offered to patients to enhance their distance vision? The need to do this depends partly on the degree of refractive error but also on the patient's expectation as far as spectacle independence is concerned. Thus, whilst some will accept a situation which means that for many tasks they do not need glasses, others will deem this unacceptable. Often this latter group have had unrealistic expectations from the outset despite preoperative discussions. It is important that this has been documented.

A number of patients implanted with diffractive MFIOLs initially have difficulty, even with a good refractive result, complaining that their vision seems not clear or "waxy." Almost all of these patients, given time, will adapt. Do not consider any action for at least 6 months. A problem may be here that only one eye has been implanted, and the patient is hesitant to have a similar lens in the second eye. One of the reasons I like to do same-day surgery for both eyes is that with both eyes open, this visual effect is much diminished. However, another solution is to use a lens in the second eye which has less effect on distance vision like an Mplus or ReSTOR +2.5 add.

Finally a good tear film is essential for MFIOLs to work properly. This is much more critical than with monofocal IOLs. This ideally should be picked up at preoperative examination and the patient advised accordingly. Checking tear film break-up time and performing

preoperatively a Schirmer test are very useful. If a patient with less than ideal tear film still wishes for an MFIOL, lubricants will be required.

Here is an algorithm for correction of post-op refractive errors:

- Counselling to assess the patients attitude with assurances, and if required, of solutions.
- Offer glasses for occasional use such as for driving or watching movies. For many people, being able to do most things around the house without glasses is a good result.
- Offer contact lenses because with full distance correction reading glasses usually are not needed. This may work for people who previously wore contact lenses.
- Surgical solutions to include excimer laser, piggyback sulcus lenses and toric lens adjustment.
- The advantage of excimer laser or piggybacking is that you are correcting a known error. Lens exchange unless the reason for the refractive error is a recognised lens error is not advised.

7.11 Near Vision Problems

The commonest difficulty that patients experience with their near vision is their failure to understand the limited range of focus that MFIOLs generally provide. Patients need to learn to find their ideal reading distance which may be different from that which they had preoperatively. We emphasise this preoperatively and especially in the immediate postoperative period. Once that has been dealt with the importance of good lighting with most MFIOLs must be highlighted. Making patients aware in advance of surgery of the capabilities of the proposed lens they are receiving helps greatly in avoiding disappointment. Some lenses like the ReSTOR +2.5 and the Lentis Comfort lens will give good distance and intermediate vision but only poor reading. Despite all of this, some patients are not satisfied, and this is generally due to residual refractive error either spherical or cylindrical. A myopic error may mean the reading distance is too close

and the opposite if the patient is left hyperopic. As above, tear film is also very important. If the poor reading is due to the actual lens design, the simplest solution really is reading glasses about which the patient has probably been warned anyway. It is possible that a patient would ask for different IOL with a stronger reading addition, but great care needs to be taken in this situation. The patient may swap their better reading vision for less clear distance vision. If the refractive error is either due to incorrect spherical power or failure to correct astigmatism, the solutions mentioned above for distance vision can be utilised.

7.12 Poor Intermediate Vision

One of the drawbacks until recently with MFIOLs is that they were actually bifocal with two distinct peaks on the defocus curve. With both eyes open, there was some intermediate vision, but not of very high quality and not good enough to see a computer screen without bringing it to the reading focus. Advising patients of the characteristics of their chosen MFIOL preoperatively is critical to avoid disappointment. Some patients surprisingly seem to do well for intermediate vision even with a bifocal IOL. There are now trifocal IOLs available that offer better intermediate vision, but the available light now needs to be divided three ways. Finding out in advance if intermediate rather than near vision is more important preoperatively is helpful. In patients that have opted for good reading vision, I normally say the use of a +1.5D pair of glasses for the computer or any intermediate task is the best approach. It means that most of the time, they will still be independent of spectacles.

7.13 Negative and Positive Dysphotopsias

As already mentioned, dysphotopsias are a common complaint in the early postoperative period. Fortunately for most patients, the reassurance that these will pass or seem to disappear will be

sufficient. However, some patients will be extremely disturbed by these phenomena. The cause is not by any means fully understood nor is it possible to predict which patients will have problems. Both negative and positive dysphotopias may have the same root cause. There is a general feeling that the sharp edge of a hydrophobic acrylic IOL is more likely to produce a problem, but there are many theories as to why. Miotics may help, but often do not. In patients that insist on some remedial action after allowing time for adaptation or resolution, there are two courses of action. The IOL can be removed and replaced with one of a different design and material. Often this may mean that they lose their multifocal lens in favour of a monofocal with a round edge. A trial for the patient by placing a -3 lens in front of them when they try to read will remind the patient what it is like not to have unaided reading vision. A better alternative is to implant sulcus lens like the Rayner Sulcoflex. This has a 6.5 mm optic and a round edge; it fills the space behind the iris and redirects the light away from the sharp edge of the multifocal lens. The Sulcoflex IOL can also be used to correct any residual refractive error if present. It has also been suggested that in fact prolapsing the IOL optic out of the capsular bag can help.

7.14 Glare and Haloes

MFIOLs by virtue of their complex designs are highly likely to produce some unwanted visual phenomena as we have seen already. These include glare and haloes. It is not unusual for any patient having lens implant surgery whether mono- or multifocal to experience some photophobia in the immediate postoperative period. There is greater light scatter with MFIOLs which may make this more prominent, but it generally

passes. Haloes are normally associated with MFIOLs because of their design whether diffractive or refractive. Patients should be made aware in advance of surgery that they will see this. Again almost all patients adapt to this and do not find that there is a permanent problem. Some patients feel relief of these symptoms when driving at night whilst the cabin light is on, causing a reduction in pupil size and hence a relief of glare and haloes. The later designs of lens have made haloes less obvious. However, some patients find these intolerable, and for them lens exchange is probably the only option. It is important that no one carries out a YAG laser capsulotomy which makes lens exchange surgery much more difficult and potentially hazardous. Remember to have a trial with each potential lens exchange patient of what losing their unaided reading vision will mean.

Conclusions

Multifocal IOLs of whatever design are a compromise with which most patients manage admirably provided that they have been suitably counselled in advance of their surgery. However, when the biometry has not yielded the desired result or the toric lens has not adequately corrected astigmatism, the visual result may be suboptimal, and patients are unhappy. Visual phenomena due to lens design and individual patient perception may also lead to patient dissatisfaction. By taking a measured and rational approach and making the patient understand that there are, in most cases, solutions which may be simply time or adjunctive surgery, long-term unhappiness may be averted.

Compliance with Ethical Requirements

Richard Packard declares that he has no conflict of interest.

No animal or human studies were carried out by the authors for this article.

María Luisa Durán-García and Jorge L. Alió

8.1 Introduction

In this chapter we present the pure technical details of the different types of multifocal lenses offered by the international market. Data which will be shown concerns the optical characteristics of the different lenses and their dimensional characteristics, refractive behavior, and refractive constants estimated by each manufacturer in order to find the most appropriate diopter power to meet the needs of a presbyopic patient. It should be indicated that each surgeon has always calculated his/her own customized constants according to their experience so that they can obtain a more accurate power. That is, the studies that support the efficiency of each lens are exposed by independent clinical investigators from commercial houses.

This information shown herein has been obtained through Web pages of each producer, directly contacting them, with the assistance of the company sales manager, and that one offered by

the different companies at the brochures distributed at international conferences such as the American Academy of Ophthalmology (AAO), European Society of Cataract and Refractive Surgeons (ESCRS), and American Society of Cataract and Refractive Surgery (ASCRS). The search limit is mainly based on the protocol of each company to provide information.

We want to highlight the fact that the information provided is the one offered by the manufacturing companies. Therefore, they are the only ones responsible for the accuracy of the data. Also, it may be incomplete due to that lack of information or limited release of it to us. In some cases, we cannot be sure whether the lens is original and is a marketing product with a different name of a lens manufactured by another company, but the data at hand do not allow us to clarify this fact.

These data are current as of December 31, 2013.

IOLs Described

1. AcriDIFF (Care Group)
2. Acriva Reviol MF 613 and Acriva Reviol BB MF 613 (VSY Biotechnology)
3. Acriva Reviol MFB 625 (VSY Biotechnology)
4. Acriva Reviol MFM 611 and Acriva Reviol BB MFM 611 (VSY Biotechnology)
5. Acriva Reviol BB T MFM 611 (VSY Biotechnology)
6. AcrySof IQ ReSTOR MN6AD1 (Alcon)
7. AcrySof IQ ReSTOR SN6AD1 and SN6AD3 (Alcon)

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8. AcrySof IQ ReSTOR SND1 T2-T5 (Alcon)
9. Add-On diffractive sPB and sPBY (HumanOptics)
10. Add-On toric-diffractive sPB and sPBY (HumanOptics)
11. AddOn progressive A4DW0N and A4EW0N (1stQ)
12. AF-1 iSii multifocal IOL PY-60 MB (HOYA Surgical Optics)
13. AlsioI 3D and AlsioI 3D toric (Alsanza)
14. AT LISA 809 M/MP (Zeiss)
15. AT LISA toric 909 M/MP (Zeiss)
16. AT LISA tri 839 MP (Zeiss)
17. AT LISA tri toric 939 MP (Zeiss)
18. Basis Z progressive B1EWYN (1stQ)
19. Bi-Flex M 677 MY (Medicontur)
20. BunnyLens multifocal (Hanita Lenses)
21. Diff-aA and Diff-aAY (HumanOptics)
22. Diff-sS and Diff-sSAY (HumanOptics)
23. EYECRYL ACTV IOLs DIYHS 600 ROH (Biotech, Moss Vision Inc.)
24. EYECRYL ACTV IOLs DIYHS 600 (Biotech, Moss Vision Inc.)
25. FineVision Micro F (PhysIOL)
26. FineVision Pod F (PhysIOL)
27. FineVision Toric (PhysIOL)
28. iDIFF Plus 1-P and 1-R (Care Group)
29. LENTIS Comfort LS-313 MF15 (Oculentis, Topcon)
30. LENTIS Mplus LS-313 MF and MplusX LS-313 MF30 (Oculentis, Topcon)
31. LENTIS Mplus Toric LU-313 MFT and LU-313 MTFY (Oculentis, Topcon)
32. M-flex 630-F and 580-F (Rayner)
33. M-flex Toric 638-F and 588-F (Rayner)
34. OptiVis multifocal (Aaren Scientific)
35. PreciSAL M302A, M302AC, PM302A, and PM302AC (MBI, Millennium Biomedical, Inc.)
36. Presbysmart Crystal Evolution (Micro Technologie Ophtalmique, MTO)
37. Presbysmart Plus PSP0, PSP1, and PSP2 (Micro Technologie Ophtalmique, MTO)
38. Preziol Multifocal Foldable (Care Group)
39. Preziol Multifocal PMMA (Care Group)
40. REVERSO (Cristalens)
41. Review FIL 611 PV (Soleko)
42. Review FIL 611 PVT (Soleko)
43. Review FIL 65 PVS (Soleko)
44. Revive SQFL 600DF (Omni Lens)
45. ReZoom NXG1 (Abbott)
46. SeeLens Multifocal (Hanita Lenses)
47. Sulcoflex Multifocal 653 F (Rayner)
48. Sulcoflex Multifocal Toric 653 T (Rayner)
49. TECNIS MF ZKB00, TECNIS MF ZLB00, and TECNIS MF ZMB00 (Abbott)

8.2 Technical Data of the Different Types of Multifocal Lenses

1. AcriDIFF (Care Group) [1]



Fig. 8.1 AcriDIFF (Care Group)

Type: one-piece diffractive-refractive multifocal IOL
 Optic: biconvex
 Pupil dependent: no
 Contrast sensitivity: decreased
 Material: hydrophobic acrylic
 Filter: UV
 Total diameter: 12.5 mm
 Optic size: 6.0 mm
 Haptic angulation: 5°
 Haptic style: modified C
 Edge design: square edge
 Implant location: bag

Refractive index: 1.525
 Diopter range: +10.0 D to +30.0 D (0.5 D increments)
 ADD IOL plane: +3.25
 Incision size: ≤2.0 mm
 Estimated A-constant: 118.8

MTF graph (near and far vision)

Corporate office:

Care Group India
 Block No. 310, Village Sim of Dabhasa
 Tal. Padra, Dist. Vadodara – 391 440
 Gujarat, India

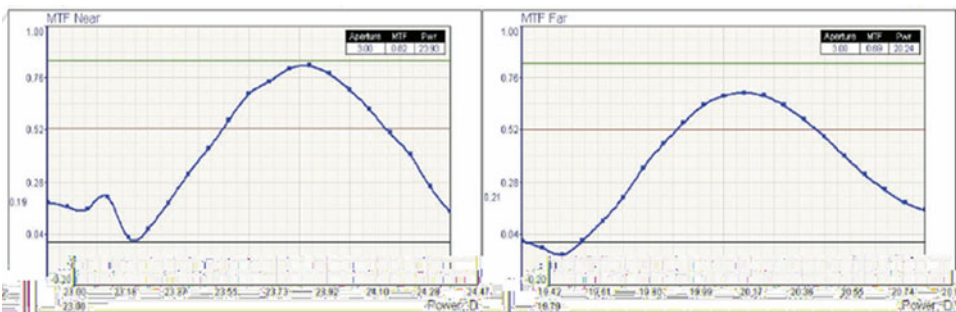


Fig. 8.2 MTF graph (near and far vision)

2. *Acriva Reviol MF 613 and Acriva Reviol BB MF 613 (VSY Biotechnology) [2, 3]*

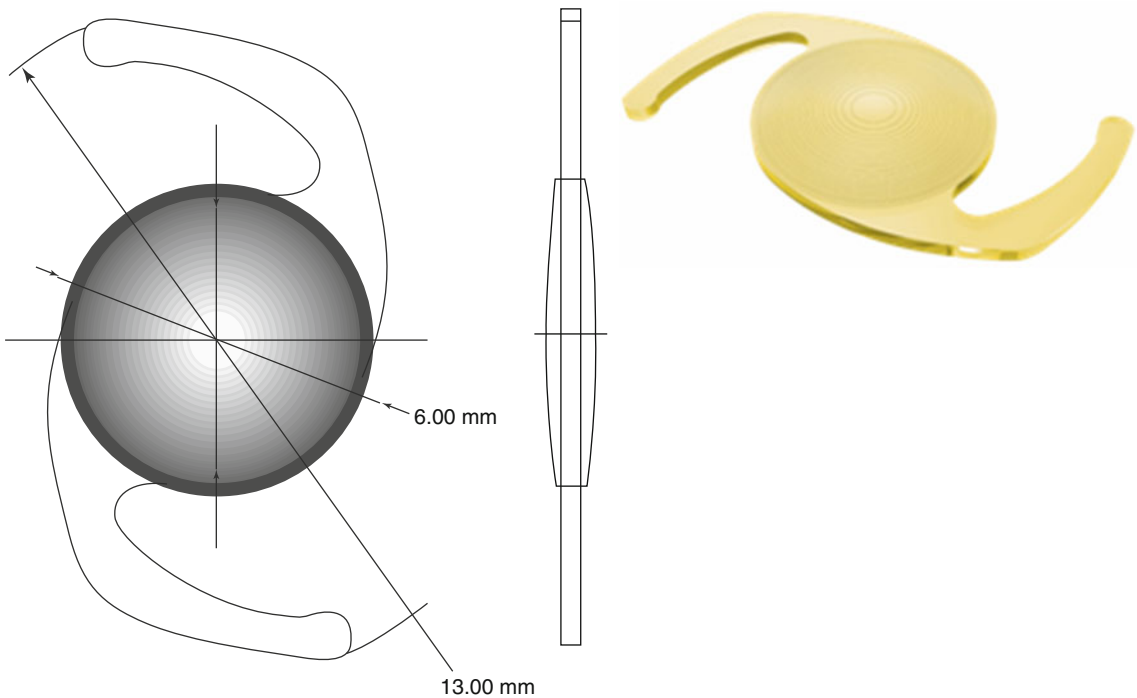


Fig. 8.3 Acriva Reviol MF 613 and Acriva Reviol BB MF 613 (VSY Biotechnology)

Type: one-piece diffractive-refractive aspheric multifocal IOL

Optic: biconvex, active-diffractive (polished special surface), aspheric

Pupil dependent: no

Contrast sensitivity: not affected

Material: hydrophobic surface, acrylic (25 % water content)

Filter: UV (MF 613) and blue filter (BB MF 613)

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: modified C

Edge design: all square 360° enhanced edge design

Implant location: bag

Refractive index: 1.509 (index dry), 1.462 (index wet)

Diopter range:

Acriva Reviol MF 613:

Standard: +0.0 D to +32.0 D (0.5 D increments)

Special: +32.0 D to +45.0 D (0.5 D increments)

Acriva Reviol BB MF 613: +0.0 D to +45.0 D (0.5 D increments)

ADD IOL plane: +3.75

Incision size: ≥ 1.8 mm (MICS) and ≤ 2.0 mm

Injector system recommended: AcriJet Blue injector and cartridge

Table 8.1

Estimated A-constant: 118.0		
	SRK/T	SRK II
Reviol MF 613	118.4	118.6
Reviol BB MF 613	118.1	118.3

Corporate office:

VSY Biotechnology BV

Strawinskylaan 1265

1077 XX Amsterdam (Netherlands)

3. Acryva Reviol MFB 625 (VSY Biotechnology) [4]

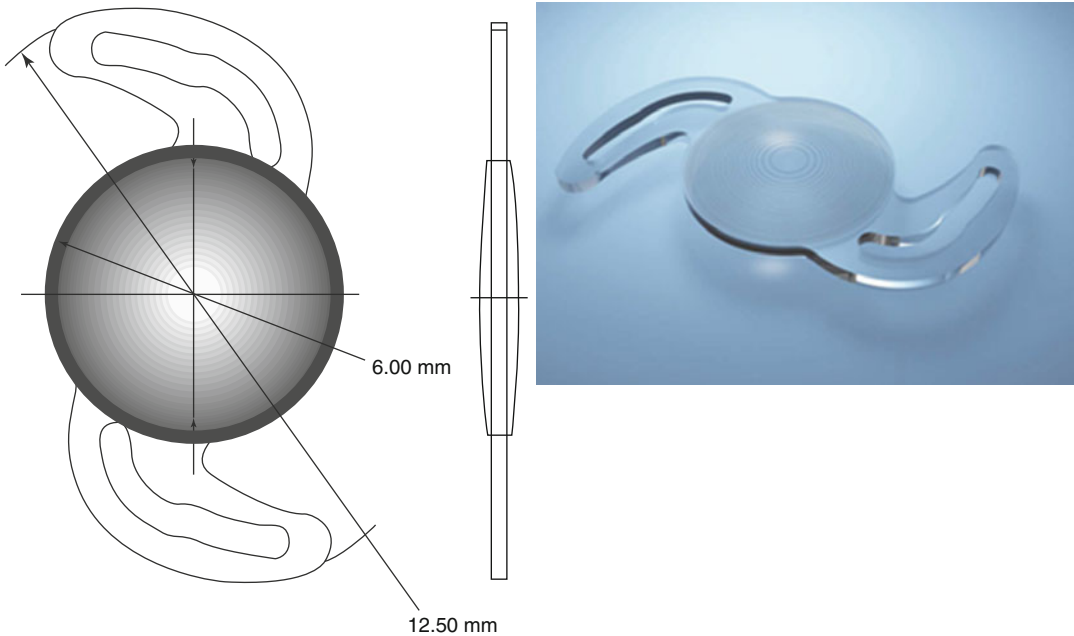


Fig. 8.4 Acryva Reviol MFB 625 (VSY Biotechnology)

Type: one-piece diffractive-refractive aspheric multifocal IOL

Optic: biconvex active-diffractive (polished special surface), aspheric

Pupil dependent: no

Contrast Sensitivity: not affected

Material: hydrophobic acrylic (25 %) surface

Filter: UV

Total diameter: 12.5 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: balanced modified C

Edge design: square 360°

Implant location: bag

Refractive index: 1.509 (index dry), 1.462 (index wet)

Diopter range:

Standard: +0.0 D to +32.0 D (0.5 D increments)

Special: +32.0 D to +45.0 D (0.5 D increments)

ADD IOL plane: +3.75

Incision size: ≤1.8 mm (MICS) and ≤2.0 mm

Injector system recommended: AcriJet injector and cartridge

Table 8.2

Estimated A-constant: 118.0	
SRK/T: 118.4	SRK II: 118.6

Corporate office:

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1077 XX Amsterdam (Netherlands)

4. Acriva Reviol MFM 611 and Acriva Reviol BB MFM 611 (VSY Biotechnology) [5, 6]

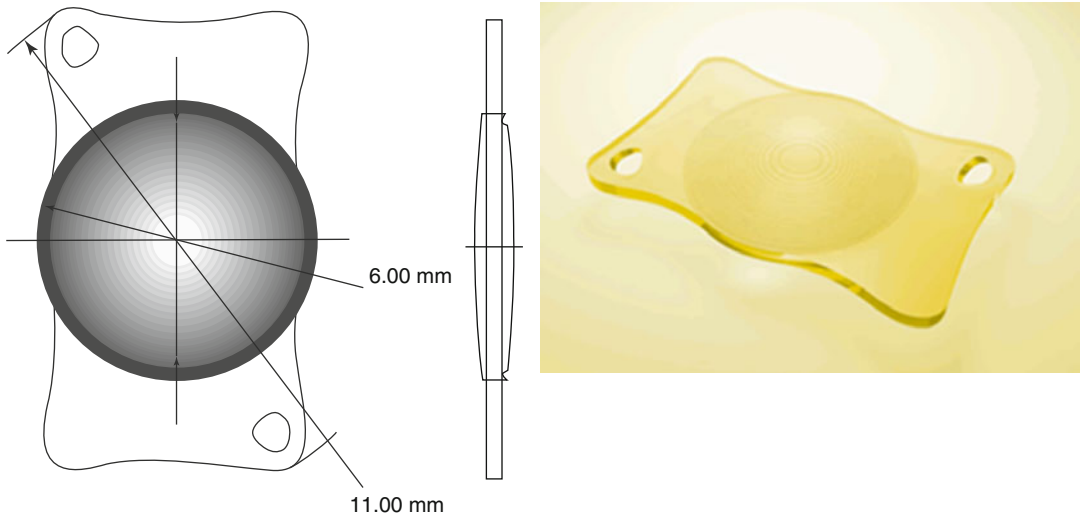


Fig. 8.5 Acriva Reviol MFM 611 and Acriva Reviol BB MFM 611 (VSY Biotechnology)

Type: one-piece diffractive-refractive aspheric multifocal IOL

Optic: biconvex active-diffractive (polished special surface), aspheric

Pupil dependent: no

Contrast sensitivity: not affected

Material: hydrophobic acrylic (25 %) surface

Filter: UV (MFM 611) and blue filter (BB MFM 611)

Total diameter: 11.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: plate haptic

Edge design: square 360°

Implant location: bag

Refractive index: 1.509 (index dry), 1.462 (index wet)

Diopter range:

Acriva Reviol MFM 611:

Standard: +0.0 D to +32.0 D (0.5 D increments)

Special: +32.0 D to +45.0 D (0.5 D increments)

Acriva Reviol BB MFM 611: +0.0 D to +45.0 D (0.5 D increments)

ADD IOL plane: +3.75

Incision size: MFM 611 ≤ 1.8 mm (MICS) and BB MFM 611 ≤ 2.0 mm

Injector system recommended: AcriJet injector and cartridge (MFM 611) and AcriJet Blue injector and cartridge (MFM BB 611)

Table 8.3

Estimated A-constant: 118.0	
SRK/T: 118.3	SRK II: 118.5

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VSY Biotechnology BV

Strawinskylaan 1265

1077 XX Amsterdam (Netherlands)

5. Acryva Reviol BB T MFM 611 (VSY Biotechnology) [7]

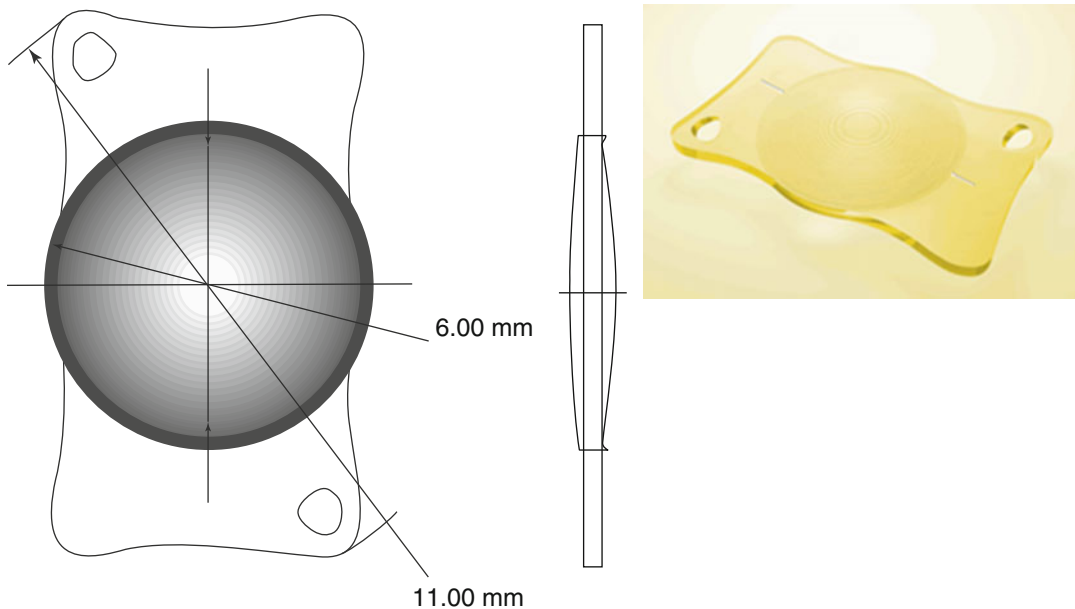


Fig. 8.6 Acryva Reviol BB T MFM 611 (VSY Biotechnology)

Type: one-piece diffractive-refractive aspheric toric multifocal IOL

Optic: biconvex active-diffractive toric multifocal

Pupil dependent: no

Contrast sensitivity: not affected

Material: hydrophobic acrylic (25 %) surface

Filter: UV and blue filter

Total diameter: 11.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: plate haptic

Edge design: square 360°

Implant location: bag

Refractive index: 1.509 (index dry), 1.462 (index wet)

Diopter range (custom-made):

Sphere: +0.0 D to +32.0 D (0.5 D increments)

Cylinder: +1.0 D to +10.0 D (0.5 D increments)

ADD IOL plane: +3.75

Incision size: ≤1.8 mm (MICS) and ≤2.0 mm

Injector system recommended: AcriJet blue injector and cartridge

Table 8.4

Estimated A-constant: 118.0	
SRK/T: 118.3	SRK II: 118.5

Corporate office:

VSY Biotechnology BV

Strawinskylaan 1265

1077 XX Amsterdam (Netherlands)

6. AcrySoF IQ ReSTOR MN6AD1 (Alcon) [8]

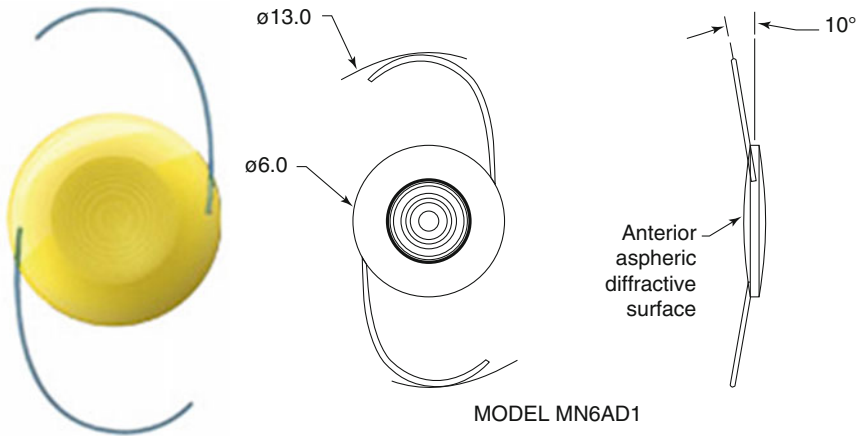


Fig. 8.7 AcrySoF IQ ReSTOR MN6AD1 (Alcon)

Type: three-piece multifocal hydrophobic acrylic IOL

Optic: symmetric biconvex with an anterior aspheric, diffractive, apodized surface

Pupil dependent: no

Contrast sensitivity: decreased

Material: acrylic copolymer

Filter: UV and blue light filtering

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 10°

Haptic style: Monoflex PMMA modified C

Edge design: square edge

Implant location: sulcus

Refractive index: 1.47

Diopter range:

+6.0 D to +30.0 D (0.5 D increments)

+31.0 D to +34.0 D (1.0 D increments)

ADD IOL plane: +3.0 D

ADD spectacle plane: +2.5 D

Incision size: ≥ 2.2 mm

Injector system recommended: single-use

Monarch D cartridge DK7797-2 and Loading

Forceps DK7717

Estimated A-constant: 119.2

Pupil dependence

Corporate office:

Alcon Laboratories, Inc.

6201 South Freeway

Fort Worth, TX 76134–2099 (USA)

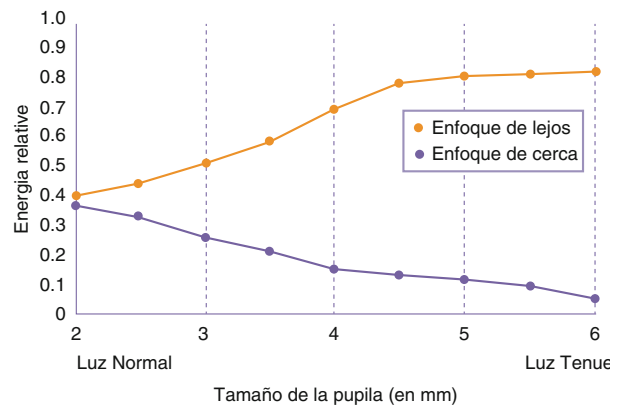


Fig. 8.8 Pupil dependence

7. AcrySoF IQ ReSTOR SN6AD1 and SN6AD3 (Alcon) [9, 10]

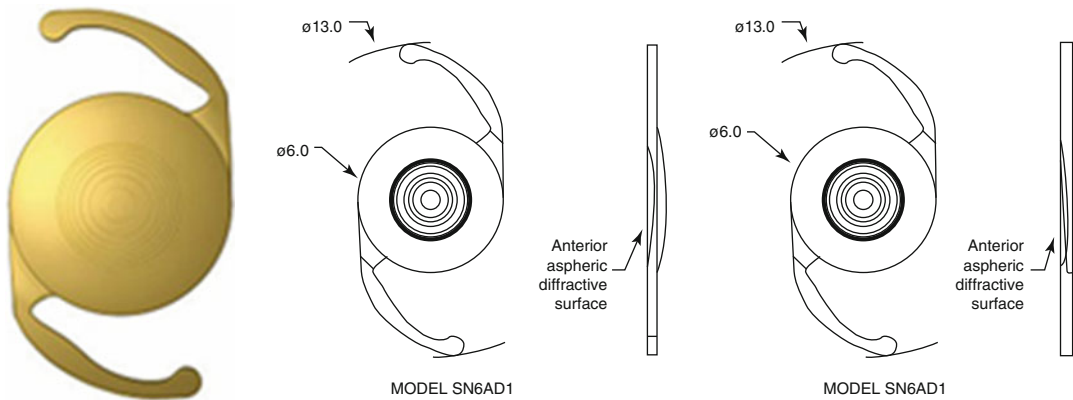


Fig. 8.9 AcrySoF IQ ReSTOR SN6AD1 and SN6AD3 (Alcon)

Type: One-piece multifocal hydrophobic acrylic IOL
 Optic: symmetric biconvex with an anterior aspheric, diffractive, apodized surface
 Pupil dependent: no
 Contrast sensitivity: decreased
 Material: hydrophobic acrylic
 Filter: UV and blue light
 Total diameter: 13.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°
 Haptic style: STABLEFORCE Modified-L
 Edge design: square 360°
 Implant location: bag
 Refractive index: 1.47

Incision size: ≥ 2.2 mm

Injector system recommended: single-use Monarch D cartridge DK7797-2 and Loading Forceps DK7717

Estimated A-constant: 118.9

Corporate office:

Alcon Laboratories, Inc.

6201 South Freeway

Fort Worth, TX 76134–2099 (USA)

Table 8.5

	SN6AD1	SN6AD3
ADD IOL plane	+3.0 D	+4.0 D
ADD spectacle plane	+2.4 D	+3.2 D
Number diffractive rings	9	12
Dioptric range	+6.0 D to +30.0 (0.5 D steps)	+10.0 D to +30.0 D (0.5 D)
	+31.0 D to +34.0 D (1.0 D steps)	+31.0 D to +34.0 (1.0 D steps)

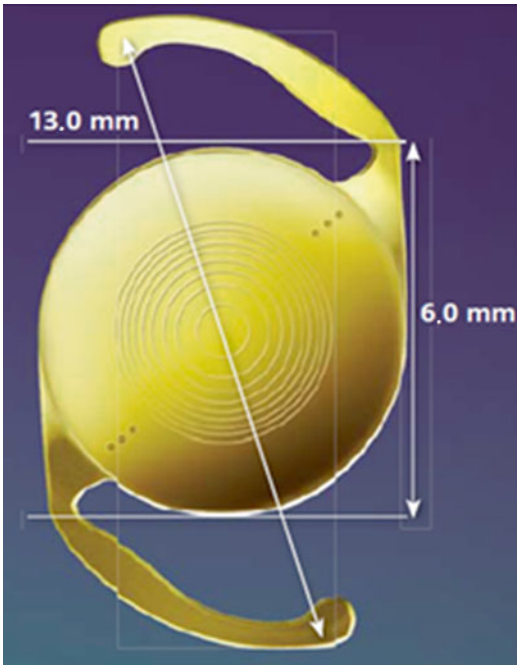
8. *AcrySoF IQ ReSTOR SND1 T2-T5 (Alcon)* [9, 10]

Fig. 8.10 AcrySoF IQ ReSTOR SND1 T2-T5 (Alcon)

Type: one-piece multifocal hydrophobic acrylic IOL

Optic: symmetric biconvex with an anterior aspheric, diffractive, apodized toric surface

Pupil dependent: no

Contrast sensitivity: decreased

Material: hydrophobic acrylic

Filter: UV and blue light

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: STABLEFORCE Modified-L

Edge design: square 360°

Implant location: bag

Refractive index: 1.55

Diopter range: +6.0 D to +30.0 D (0.5 D increments)

ADD IOL plane: +3.0 D

ADD spectacle plane: +2.4 D

Table 8.6

Cylinder power				
Models	SND1 T2	SND1 T3	SND1 T4	SND1 T5
Toric	0.68 D to 1.0 D	1.03 D to 1.5 D	1.55 D to 2.25 D	2.06 D to 3.0 D

Incision size: ≥ 2.2 mm

Injector system recommended: single-use

Monarch D cartridge DK7797-2 and Loading

Forceps DK7717

Estimated A-constant: 118.9

MTF graph of AcrySof IQ ReSTOR and AcrySof
 ReSTOR Toric
 AcrySof IQ ReSTOR Toric calculator: [http://
 www.acrysoftoriccalculator.com/](http://www.acrysoftoriccalculator.com/)

Corporate office:
 Alcon Laboratories, Inc.
 6201 South Freeway
 Fort Worth, TX 76134-2099 (USA)

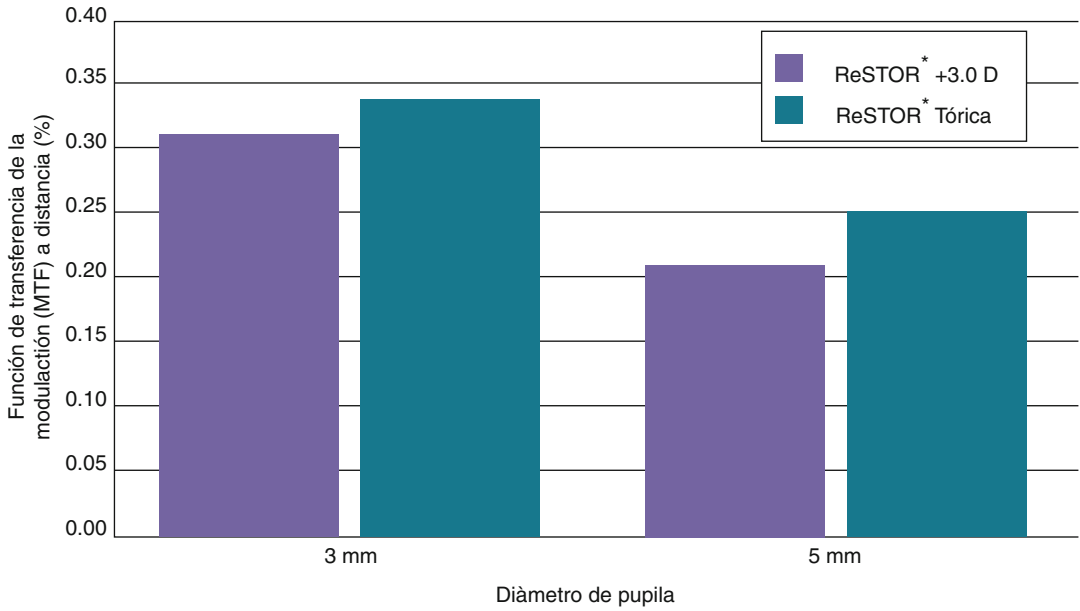
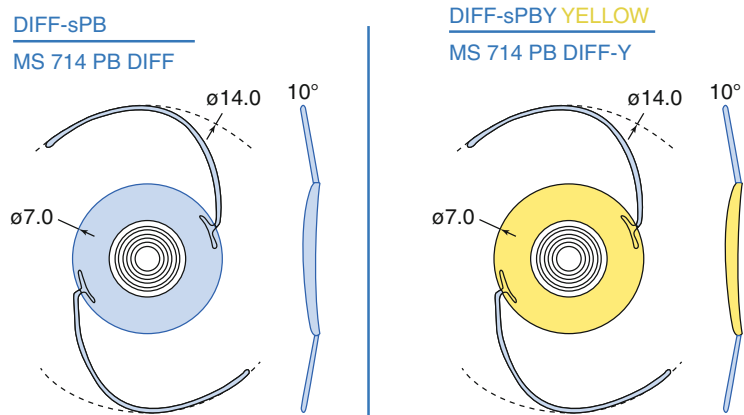
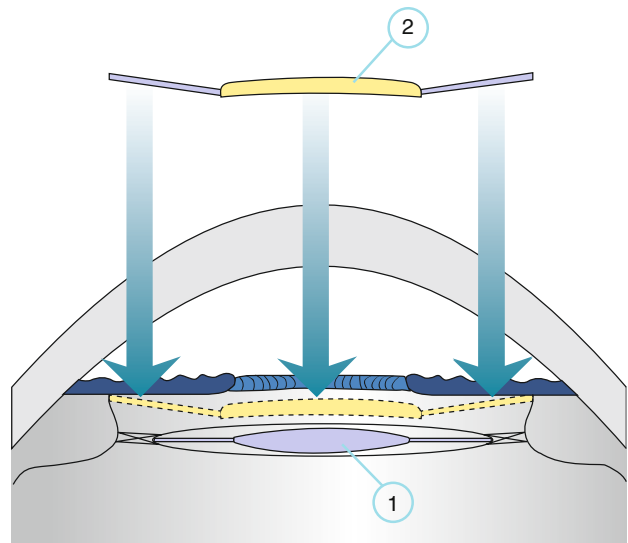


Fig. 8.11 MTF graph of AcrySof IQ ReSTOR and AcrySof ReSTOR Toric

9. Add-On diffractive sPB and sPBY (*HumanOptics*) [11]**Fig. 8.12** Add-On diffractive sPB and sPBY (*HumanOptics*)**Fig. 8.13** The *Add-On* concept illustrates one IOL located in the capsular bag and an additional *Add-On* IOL placed in the sulcus ciliaris

The *Add-On* concept illustrates one IOL located in the capsular bag and an additional *Add-On* IOL placed in the sulcus ciliaris.

Type: three-piece foldable multifocal *Add-On* IOL for sulcus fixation in pseudophakic eyes

Optic: convex-concave diffractive

Pupil dependent: yes

Contrast sensitivity: not affected

Material: hydrophobic MicroSil, high-molecular PMMA haptics

Filter: UV (Diff-sS), UV and yellow filter (Diff-sSAY)

Total diameter: 14.0 mm

Optic size: 7.0 mm

Haptic angulation: 10°

Haptic style: C loop

Implant location: sulcus

Edge design: round anterior edge

Diopter range:

Standard: +0.0 D

Special: -6.0 D to +6.0 D (0.5 D increments)

ADD IOL plane: +3.5 D

Incision size: 2.2 mm

Estimated A-constant: not applicable (by application principle)

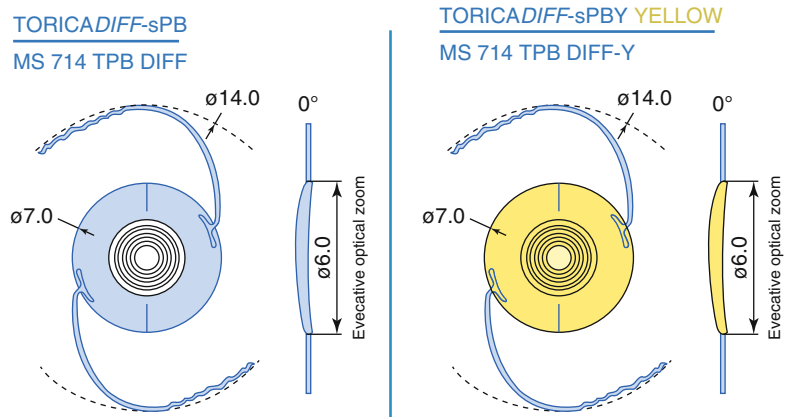
Corporate office:

HumanOptics AG

Spardorfer Str. 150

91054 Erlangen Deutschland

10. Add-On toric-diffractive sPB and sPBY (HumanOptics) [11]

Fig. 8.14 Add-On toric-diffractive sPB and sPBY (HumanOptics)

The *Add-On* concept illustrates one IOL located in the capsular bag and an additional *Add-On* IOL placed in the sulcus ciliaris.

Type: three-piece foldable toric multifocal Add-On IOL for sulcus fixation in pseudophakic eyes

Optic: convex-concave, diffractive anterior surface, toric posterior surface

Pupil dependent: yes

Contrast sensitivity: not affected

Material: hydrophobic MicroSil, high-molecular PMMA haptics

Filter: UV (Diff-sS), UV and yellow filter (Diff-sSAY)

Total diameter: 14.0 mm

Optic size: 7.0 mm (6.0 mm effective zone)

Haptic angulation: 10°

Haptic style: undulated extended C loop

Edge design: round anterior edge

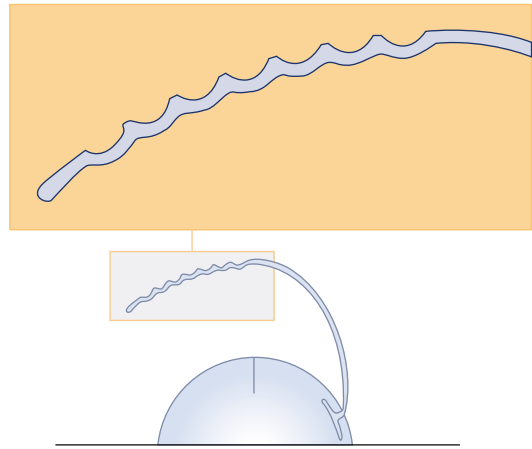
Implant location: sulcus

Diopter range:

Sphere: -3.0 D to +3.0 D (0.5 D increments)

Cylinder: 1.0 D to 4.0 D (0.5 D increments)

The haptics of the toric models have the well-proven undulations to prevent rotation.

**Fig. 8.15** Haptic style: undulated extended C loop

ADD IOL plane: +3.5 D
 Incision size: 2.2 mm
 Estimated A-constant: not applicable (by application principle)

Corporate office:
HumanOptics AG
 Spardorfer Str. 150
 91054 Erlangen (Deutschland)

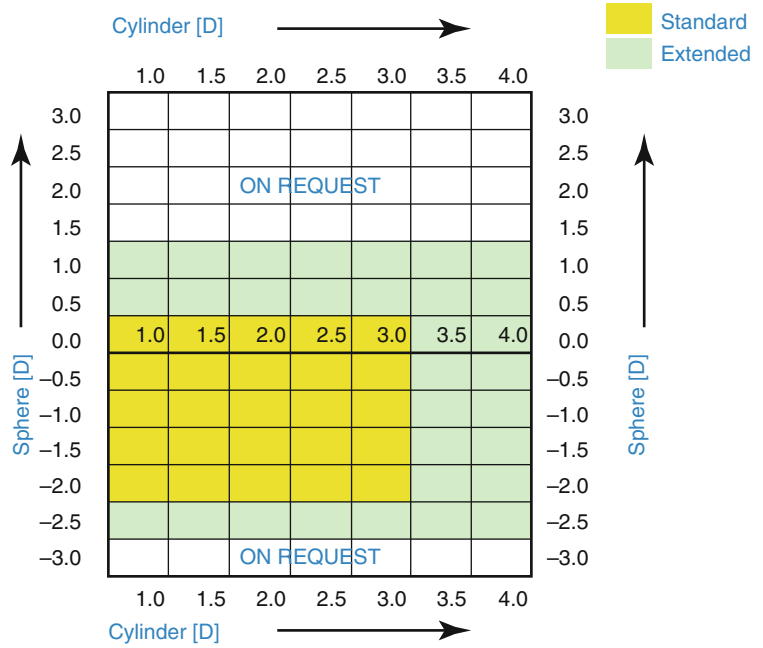


Fig. 8.16 Diopter range: sphere, -3.0 D to +3.0 D (0.5 D increments); cylinder, 1.0 D to 4.0 D (0.5 D increments)

11. AddOn progressive A4DW0N and A4EW0N (1stQ) [12]

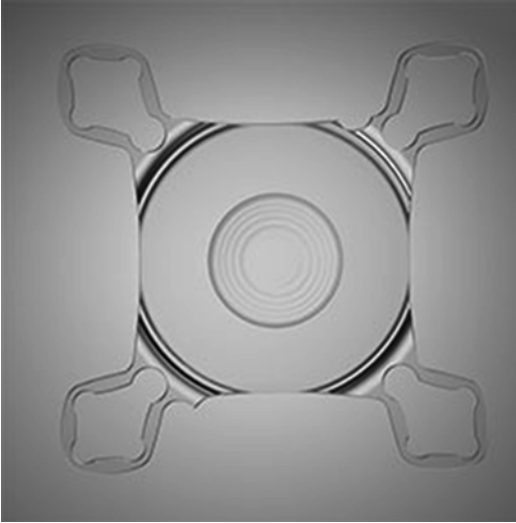


Fig. 8.17 AddOn progressive A4DW0N and A4EW0N (1stQ)

Type: one-piece foldable multifocal additional IOL for pseudophakic patients
 Optic: convex-concave multifocal
 Material: hydrophilic acrylic (25 % water)

Filter: UV and blue light filter
 Total diameter: 13 mm
 Optic size: 6 mm
 Haptic angulation: 0°
 Haptic style: 4 flex-haptics
 Edge design: square edge
 Implant location: sulcus
 Diopter range:

Table 8.7 *

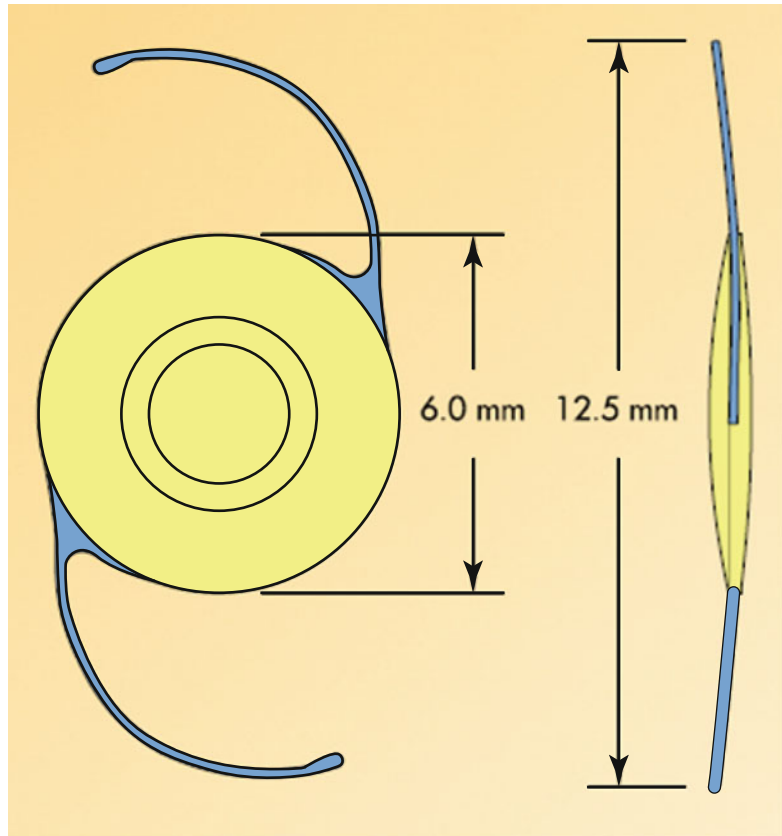
AddOn progressive	Spherical equivalent	Steps
A4DW0N	0.0 D	
A4EW0N	-3.0 D to -0.5 D	0.25 D
	+0.5 D to +3.0 D	0.25 D

*This IOL is available with individual features, upon request

ADD IOL plane: +3.5
 Corporate office:
 1stQ GmbH
 Harrlachweg 1
 68163 Mannheim (Germany)

12. AF-1 iSii multifocal IOL PY-60 MB (HOYA Surgical Optics) [13]

Fig. 8.18 AF-1 iSii multifocal IOL PY-60 MB (HOYA Surgical Optics)



Type: one-piece refractive multifocal IOL

Optic: three-zone refractive multifocal

Pupil dependent: yes

Contrast sensitivity: not affected

Material: hydrophobic acrylic, PMMA chemically bonded haptics

Filter: UV and blue light filter

Total diameter: 12.5 mm

Optic size: 6.0 mm

Haptic angulation: 5°

Haptic design: modified C loop

Edge design: square edge design and step edge

Implant location: bag

Diopter range: +14.0 D to +27.0 D (0.5 D increments)

ADD IOL plane: +3.0 (for near and intermediate vision)

Incision size: ≤ 2.5 mm

Injector system: iSert 230 and 231 preloaded injector system

Estimated A-constant: 118.4

MTF graph of 1-AF iSii MF

Corporate office:

HOYA Surgical Optics Global Headquarters

One Temasek Avenue

Millenia Tower, #35-03/04

039192, Singapore

Fig. 8.19 Haptic design: modified C loop

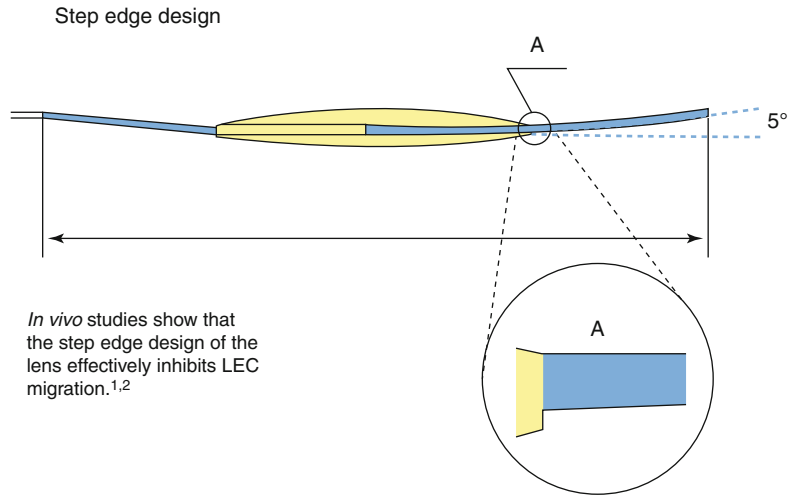
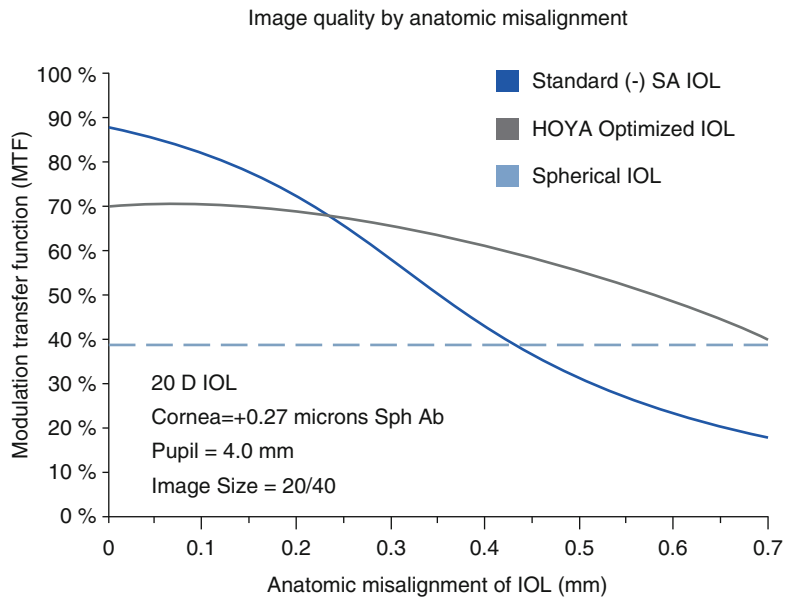


Fig. 8.20 MTF graph of 1-AF iSii MF



13. *Alsiol 3D* and *Alsiol 3D toric* (Alsanza) [14, 15]

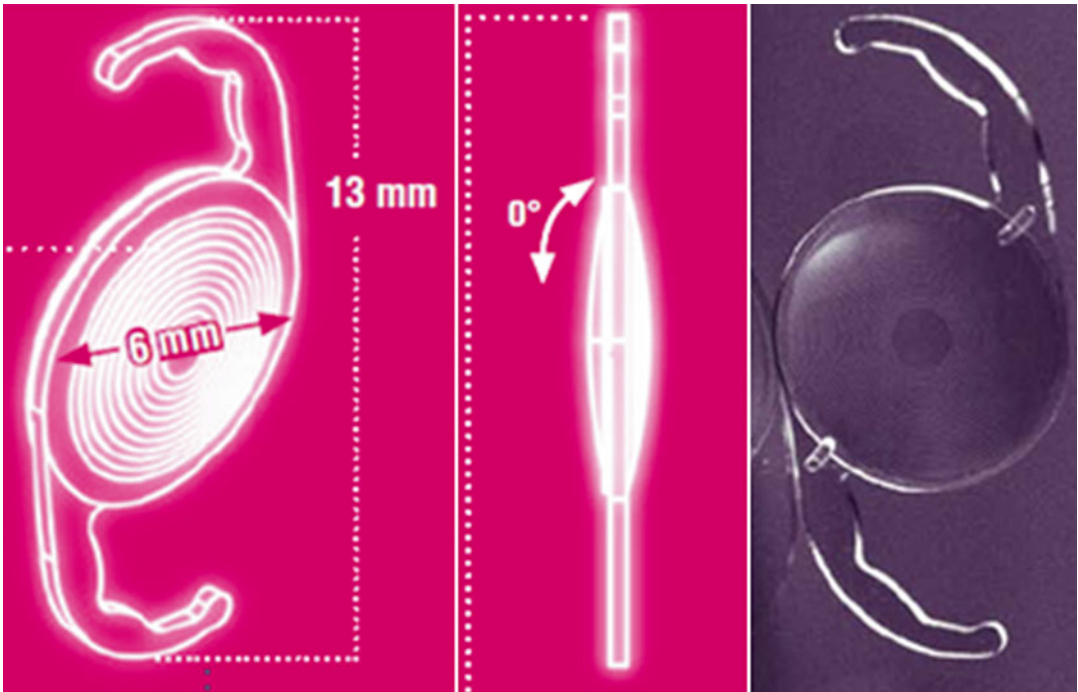


Fig. 8.21 *Alsiol 3D* and *Alsiol 3D toric* (Alsanza)

Type: one-piece biconvex aspheric diffractive 3D multifocal IOL

Optic: multifocal diffractive 3D

Pupil dependent: no

Contrast sensitivity: not significantly decreased

Material: hydrophilic acrylic biomaterial (25 %) with a non-coated hydrophobic surface

Filter: UV and violet light

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: modified C loops

Edge design: square 360°

Implant location: bag

Sphere diopter range *Alsiol 3D*:

Standard: +0 D to +32 D (0.5 D increments)

Customized: -20.0 D to +45.0 D (0.5 D increments)

Cylinder diopter range *Alsiol 3D toric*:

Standard: +1.0 D to +6.0 D

Customized: +6.0 D to +12.0 D

ADD IOL plane: +3.75 D

Incision size: ≥ 1.8 mm

Injector system recommended: MICS with Alsajet injector set

Estimated A-constant: 118.0

Theoretical ACD: 4.97

Alsiol 3D calculator: <http://alsatoriscan.com/>

Corporate office:

Alsanza GmbH

Hermann-Burkhardt-Straße 3

72793 Pfullingen (Germany)

14. AT LISA 809 M/MP (Zeiss) [16]



Fig. 8.22 AT LISA 809 M/MP (Zeiss)

Type: one-piece multifocal diffractive aspheric hydrophilic acrylic IOL
 Optic: multifocal, diffractive, and aspheric
 Pupil dependent: no
 Contrast sensitivity: decreased
 Material: hydrophilic acrylic 25 % with hydrophobic surface
 Filter: UV
 Total diameter: 11.0 mm
 Optic size: 6.0 mm

Haptic angulation: 0°
 Haptic style: plate
 Implant location: bag
 Refractive index: 1.46
 Diopter range: +0.0 D to +32.0 D (0.5 D increments)
 ADD IOL plane: +3.75 D
 ADD spectacle plane: +3.0 D
 Incision size: 1.5 mm AT LISA 809 M/1.8 mm AT LISA 809 MP
 Injector system:
 AT LISA 809 M, injector/cartridge set:
 AT.Shooter A2-2000/ACM2 (1.5 mm)
 Viscojet 1.8 injector set
 Single-use injector A6/AT, Smart Cartridge Set (1.8 mm)
 AT LISA 809 MP: preloaded injector BLUEMIXS 180 (1.8 mm)
 Estimated A-constant: 117.8
 Theoretical ACD: 4.85
 Corporate office:
 Carl Zeiss Meditec AG
 Goeschwitzer Str.51-52
 0.7745 Jena (Germany)

15. AT LISA toric 909 M/MP (Zeiss) [17]



Fig. 8.23 AT LISA toric 909 M/MP (Zeiss)

Type: one-piece multifocal diffractive aspheric hydrophilic acrylic IOL
 Optic: multifocal, diffractive, and aspheric
 Pupil dependent: no
 Contrast sensitivity: decreased
 Material: hydrophilic acrylic 25 % with hydrophobic surface
 Filter: UV
 Total diameter: 11.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°
 Haptic style: plate
 Implant location: bag

Refractive index: 1.46

Diopter range:

Sphere: -10.0 D to +32.0 D (0.5 D increments)

Cylinder: +1.0 D to +12.0 D (0.5 D increments)

ADD IOL plane: +3.75 D

ADD spectacle plane: +3.0 D

Incision size: 1.5 mm AT LISA toric 909 M/1.8 mm AT LISA toric 909 MP

Injector system:

AT LISA toric 909 M, injector/cartridge set (for IOLs from -10.0 D to +24.0 D with +1.0 D to +4.0 D cylinder):

AT.Shooter A2-2000/ACM2 (1.5 mm)

Viscojet 1.8 injector set

Single-use injector A6/AT, Smart Cartridge Set (1.8 mm)

AT LISA toric 909 MP (for IOLs from +6.0 D to +24.0 D with +1.0 D to +4.0 D cylinder): pre-loaded injector BLUEMIXS 180 (1.8 mm)

Estimated A-constant: 118.3

Theoretical ACD: 5.14

Corporate office:

Carl Zeiss Meditec AG

Goeschwitzer Str.51-52

0.7745 Jena (Germany)

16. AT LISA tri 839 MP (Zeiss) [18]

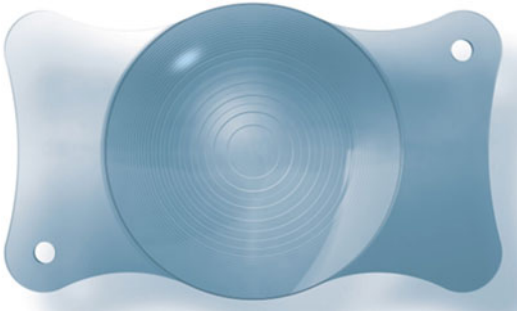


Fig. 8.24 AT LISA tri 839 MP (Zeiss)

Type: one-piece trifocal diffractive aspheric hydrophilic acrylic IOL
 Optic: multifocal, diffractive, and aspheric
 Pupil dependent: no
 Contrast sensitivity: decreased
 Asphericity: $-0.18 \mu\text{m}$
 Material: hydrophilic acrylic 25 % with hydrophobic surface

Filter: UV
 Total diameter: 11.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°
 Haptic style: plate
 Implant location: bag
 Refractive index: 1.46
 Diopter range: +0.0 D to +32.0 D (0.5 D increments)
 ADD IOL plane: +3.33 D for near vision, +1.66 D for intermediate vision
 Incision size: 1.8 mm
 Injector system: preloaded injector BLUEMIXS 180 (1.8 mm)
 Estimated A-constant: 118.6
 Theoretical ACD: 5.32
 Corporate office:
Carl Zeiss Meditec AG
 Goeschwitzer Str.51-52
 0.7745 Jena (Germany)

17. AT LISA tri toric 939 MP (Zeiss) [19]



Fig. 8.25 AT LISA tri toric 939 MP (Zeiss)

Type: one-piece trifocal bitoric diffractive aspheric hydrophilic acrylic IOL
 Optic: multifocal, diffractive, and aspheric
 Pupil dependent: no
 Contrast sensitivity: decreased
 Material: hydrophilic acrylic 25 % with hydrophobic surface
 Filter: UV

Total diameter: 11.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: plate

Implant location: bag

Refractive index: 1.46

Diopter range:

Sphere: +10.0 D to +28.0 D (0.5 D increments)

Cylinder +1.0 D to +4.0 D (0.5 D increments)

ADD IOL plane: +3.33 D for near vision, +1.66 D for intermediate vision

Incision size: 1.8 mm

Injector system: preloaded injector BLUEMIXS 180 (1.8 mm)

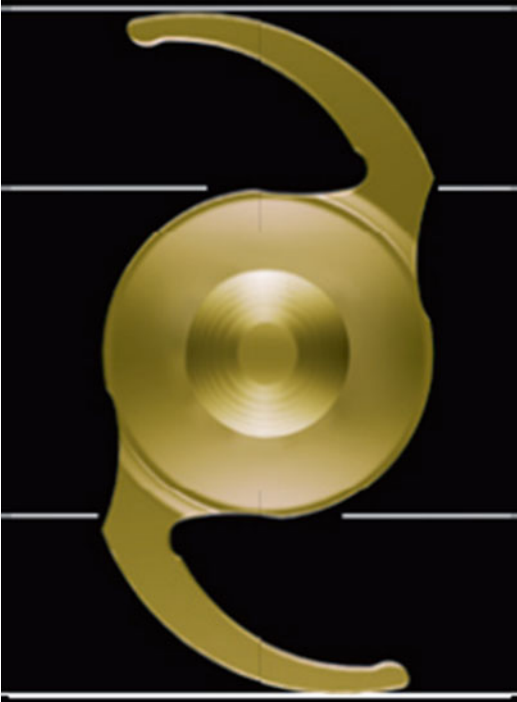
Estimated A-constant: 118.8

Theoretical ACD: 5.32

Corporate office:

Carl Zeiss Meditec AG
 Goeschwitzer Str.51-52
 0.7745 Jena (Germany)

18. Basis Z progressive BIEWYN (1stQ) [20]



Type: one-piece foldable multifocal IOL
 Optic: refractive, progressive, and aspheric
 Material: hydrophilic acrylic (25 % water) with hydrophobic surface
 Filter: UV and blue light filter
 Total diameter: 13 mm
 Optic size: 6 mm
 Haptic angulation: 0°
 Haptic style: Z-haptic
 Edge design: square edge
 Implant location: bag
 Diopter range:
 +0.0 D to +10.0 D (1.0 D increments)
 +10.0 D to +30.0 D (0.5 D increments)
 ADD IOL plane: +3.5 D
 A-constant estimated: 118.0
 Haigis: $a_0=0.39$; $a_1=0.242$; $a_2=0.153$
 Corporate office:
 1stQ GmbH
 Harrlachweg 1
 68163 Mannheim (Germany)

Fig. 8.26 Basis Z progressive BIEWYN (1stQ)

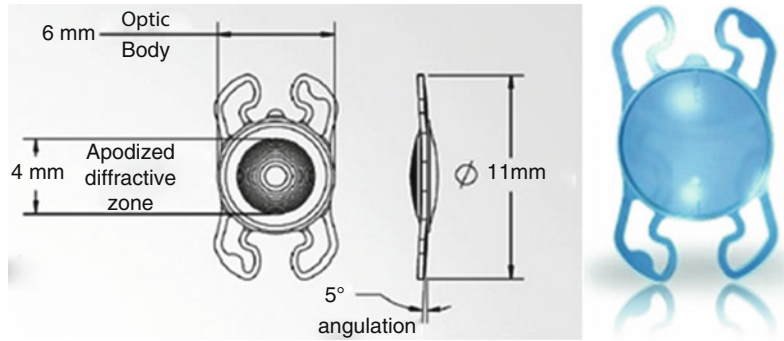
19. Bi-Flex M 677 MY (Medicontur) [21]



Fig. 8.27 Bi-Flex M 677 MY (Medicontur)

Type: one-piece biconvex multifocal diffractive aspheric hydrophilic IOL
 Optic: PAD technology, Progressive Apodized Diffractive; diffractive anterior surface, aspheric posterior surface
 Pupil dependent: no
 Contrast sensitivity: decreased
 Material: hybrid copolymer (hydrophilic and hydrophobic)
 Filter: UV and blue light filter
 Total diameter: 13.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°, asymmetric design with posterior vaulting
 Edge design: square 360°
 Implant location: bag

Edge design: 360° round square edge
 Refractive index: 1.46
 Diopter range: +0.0 D to +30.0 D (0.5 D increments)
 ADD IOL plane: +3.5 D
 Incision size: from 1.8 mm to 2.2 mm
 Injector system: single-use injector system MedJet MB 1.8
 Estimated A-constant: 118.6 (subject to changes to optimization)
 ACD: 4.8 mm
 Corporate office:
 Medicontur Medical Engineering Ltd
 Herceghalmi Road
 2072 Zsámbék (Hungary)

20. *BunnyLens multifocal (Hanita Lenses)* [22]**Fig. 8.28** BunnyLens multifocal (Hanita Lenses)

Type: one-piece foldable multifocal IOL for MICS

Optic: multifocal diffractive apodized aspheric

Pupil dependent: yes

Contrast sensitivity: decreased

Material: hydrophilic acrylic HEMA/EOEMA copolymer

Filter: UV and violet light

Total diameter: 11.0 mm

Optic size: 6.0 mm

Haptic angulation: 5°

Haptic style: 4-point haptic design

Edge design: square 360°

Implant location: bag

Refractive index: 1.46

Diopter range: +10.0 D to +30.0 D (0.5 D increments); +31.0 D to +35.0 D (1.0 D increments)

ADD IOL plane: +3.0 D

ADD spectacle plane: +2.4 D

Incision size: 1.8 mm

Injector system: single-use delivery system SoftJect 1.8

Pupil dependence

Corporate office:

Hanita Lenses R.C.A Ltd. Kibbutz Hanita, 22885

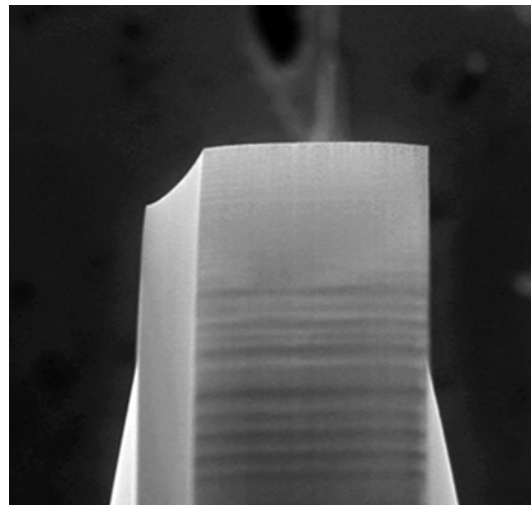
**Fig. 8.29** Haptic style: 4-point haptic design**Fig. 8.30** Edge design: square 360°

Fig. 8.31 Injector system: single-use delivery system SoftJect 1.8

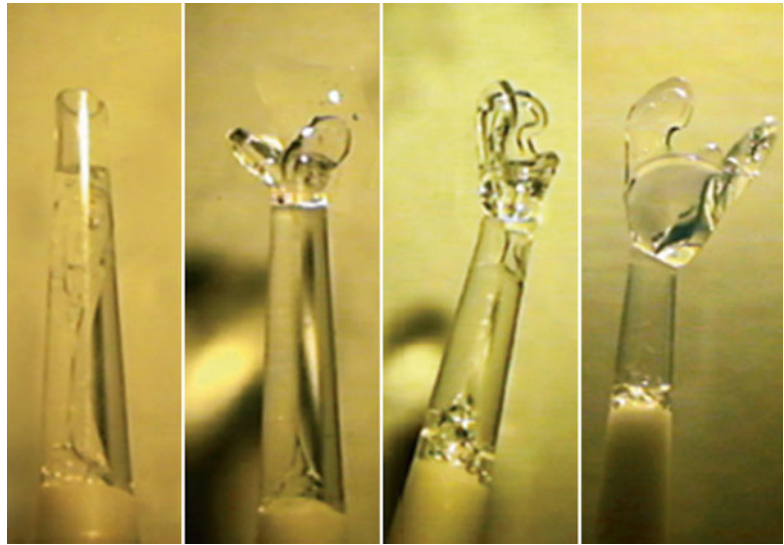


Table 8.8

Estimated constants		IOLMaster	US biometry
Hoffer Q	tACD	5.2	4.98
Holladay I	SF	1.42	1.2
SRK II	A	118.78	118.35
SRK/T	A	118.5	118.16
Haigis	a0	0.978	0.753
	a1	0.40	0.40
	a2	0.10	0.10

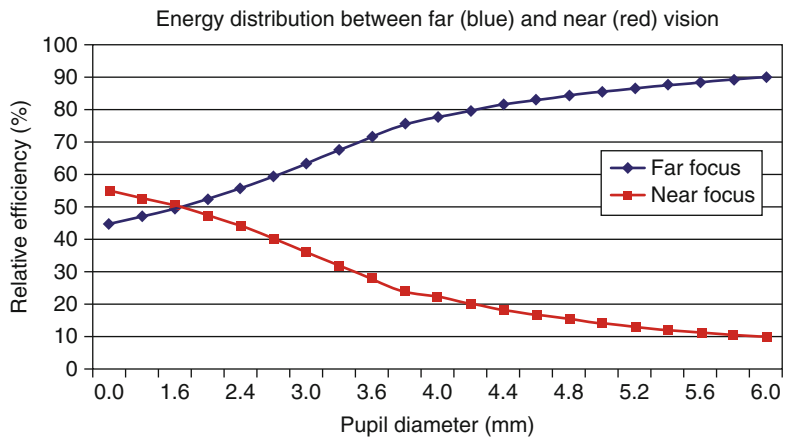
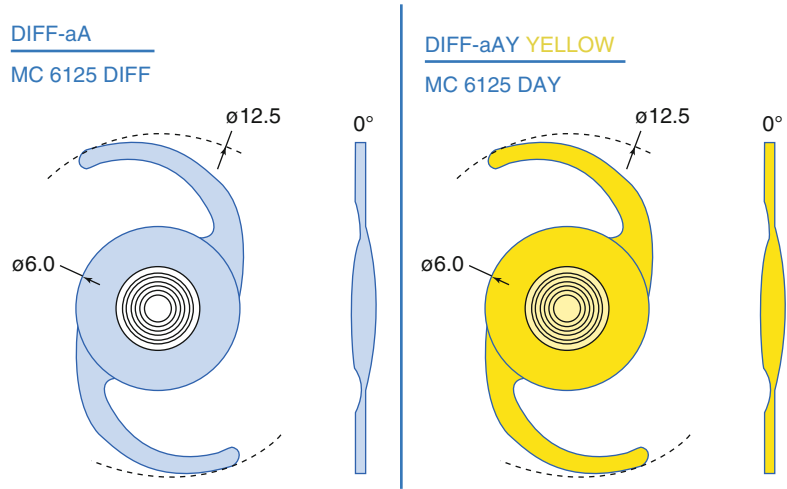


Fig. 8.32 Pupil dependence

21. Diff-aA and Diff-aAY (HumanOptics) [23]

Fig. 8.33 Diff-aA and Diff-aAY (HumanOptics)

Type: one-piece foldable multifocal IOL

Optic: diffractive aspheric anterior surface, spherical posterior surface

Pupil dependent: yes

Contrast sensitivity: not affected

Material: hydrophilic MicroCryl

Filter: UV (Diff-aA), AV and yellow filter (Diff-aAY)

Total diameter: 12.5 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: C loop

Implant location: bag

Diopter range: +10.0 D to +30.0 D (0.5 D increments)

ADD IOL plane: +3.5 D

Incision size: 2.2 mm

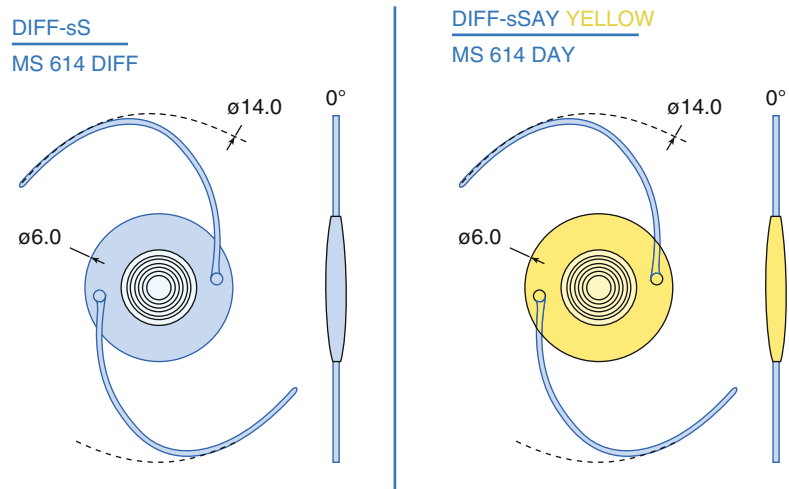
Estimated A-constant: 118.4

Corporate office:

HumanOptics AG

Spardorfer Str. 150

91054 Erlangen (Deutschland)

22. Diff-sS and Diff-sSAY (*HumanOptics*) [23]**Fig. 8.34** Diff-sS and Diff-sSAY (*HumanOptics*)

Type: three-piece multifocal hydrophilic acrylic IOL
 Optic: diffractive aspheric anterior surface, spherical posterior surface
 Pupil dependent: yes
 Contrast sensitivity: not affected
 Material: hydrophilic MicroSil
 Filter: UV (Diff-sS), UV and yellow filter (Diff-sSAY)
 Total diameter: 14.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°

Haptic angulation: C loop
 Implant location: sulcus
 Diopter range: +10.0 D to +30.0 D (0.5 D increments)
 ADD IOL plane: +3.5 D
 Incision size: 2.2 mm
 Estimated A-constant: 118.0
 Corporate office:
HumanOptics AG
 Spardorfer Str. 150
 91054 Erlangen (Deutschland)

23. EYECRYL ACTV IOLs DIYHS 600 ROH (Biotech, Moss Vision Inc.) [24]



Fig. 8.35 EYECRYL ACTV IOLs DIYHS 600 ROH (Biotech, Moss Vision Inc.)

Type: one-piece diffractive-refractive and aspheric hydrophilic acrylic multifocal IOL
 Optic: multifocal, diffractive, and aspheric
 Pupil dependent: no
 Contrast sensitivity: not affected
 Material: hydrophilic acrylic 25 % with hydrophobic surface
 Filter: UV
 Total diameter: 12.5 mm
 Optic size: 6.0 mm
 Haptic angulation: 5°
 Implant location: bag

Edge design: square 360°

Refractive index: 1.46

Diopter range: +10.0 D to +30.0 D (0.5 D increments)

Table 8.9

Estimated constants		
Fabricate A-constant = 118.0		
Hoffer Q	tACD	4.67
Holladay I	SF (surgeon factor)	0.93
SRK II	A	117.8
SRK/T	A	117.6
Haigis ^a	a0	0.56
	a1	0.40
	a2	0.10

^aUnoptimized

ADD IOL plane: +3.75 D

Incision size: ≤ 2.0 mm

Corporate office:

Biotech Vision Care

401, Sarthik II

Opp. Rajpath Club

S.G. Highway

Ahmedabad 380 054

Gujarat, India

24. EYECRYL ACTV IOLs DIYHS 600 (Biotech, Moss Vision Inc.) [25]



Fig. 8.36 EYECRYL ACTV IOLs DIYHS 600 (Biotech, Moss Vision Inc.)

Type: one-piece diffractive-refractive and aspheric hydrophilic acrylic multifocal IOL
 Optic: multifocal, diffractive, and aspheric
 Pupil dependent: no.
 Contrast sensitivity: not affected
 Material: hydrophilic acrylic 25 % with hydrophobic surface
 Filter: UV
 Total diameter: 12.5 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°
 Implant location: bag

Edge design: square 360°

Refractive index: 1.48

Diopter range: +10.0 D to +30.0 D (0.5 D increments)

ADD IOL plane: +3.0 D

Table 8.10

Estimated constants		
Fabricate A-constant = 118.5		
Hoffer Q	tACD	5.42
Holladay I	SF (surgeon factor)	1.63
SRK II	A	118.9
SRK/T	A	118.7
Haigis ^a	a0	1.24
	a1	0.40
	a2	0.10

^aUnoptimized

Incision size: ≤ 2.0 mm

Corporate office:

Biotech Vision Care

401, Sarthik II

Opp. Rajpath Club

S.G. Highway

Ahmedabad 380 054

Gujarat, India

25. *FineVision Micro F (PhysIOL)* [26]

Fig. 8.37 FineVision Micro F (PhysIOL)

Type: one-piece trifocal hydrophilic acrylic IOL
 Optic: diffractive FineVision anterior surface,
 aspheric posterior surface
 Pupil dependent: yes
 Contrast sensitivity: not significantly decreased
 Asphericity: $-0.11 \mu\text{m}$
 Material: 25 % hydrophilic acrylic
 Filter: UV and BlueTech
 Total diameter: 10.75 mm

Optic size: 6.15 mm
 Haptic angulation: 5°
 Edge design: double posterior square edge
 Implant location: bag
 Refractive index: 1.47
 Diopter range: +10 D to +35 D (0.5 D increments)
 ADD spectacle plane:
 +1.75 D intermediate vision
 +3.5 D near vision
 Incision size: ≥ 1.8 mm
 Injector system recommended: MICS
 Injector Medical Viscojet of ≥ 1.8 mm
 AccuJet of ≥ 2.2 mm for >25 D

Table 8.11

Estimated constants			
Fabricate A-constant = 118.5			
		<i>IOLMaster</i>	<i>US</i>
Hoffer Q	tACD	5.35	5.26
Holladay I	SF (surgeon factor)	1.6	1.48
SRK II	A	119.10	118.89
SRK/T	A	118.8	118.59
Haigis ^a	a0	1.36	1.04
	a1	0.40	0.40
	a2	0.10	0.10

^aUnoptimized

Corporate office:
PhysIOL s.a.
 Liège Science Park, Allée des Noisetiers, 4
 4031 Liège (Belgium)

26. *FineVision Pod F (PhysIOL)* [26]



Total diameter: 11.40 mm
 Optic size: 6.0 mm
 Haptic angulation: 5°
 Edge design: double posterior square edge
 Implant location: bag
 Refractive index: 1.46
 Diopter range: +6 D to +35 D (0.5 D increments)
 ADD spectacle plane:
 +1.75 D intermediate vision
 +3.5 D near vision
 Incision size: ≥ 2.0 mm
 Injector system recommended: MICS
 Injector Medical Viscojet of ≥1.8 mm
 AccuJet of ≥2.2 mm for >25 D

Table 8.12

Estimated constants		
Fabricate A-constant = 118.5		
Hoffer Q	tACD	5.59
Holladay I	SF (surgeon factor)	1.83
SRK II	A	119.31
SRK/T	A	118.95
Haigis ^a	a0	1.36
	a1	0.40
	a2	0.10

Fig. 8.38 FineVision Pod F (PhysIOL)

Type: one-piece trifocal hydrophilic acrylic IOL
 Optic: diffractive FineVision anterior surface, aspheric posterior surface
 Pupil dependent: yes
 Contrast sensitivity: not significantly decreased
 Asphericity: -0.11 μm
 Material: 25 % hydrophilic acrylic
 Filter: UV and BlueTech

^aUnoptimized

Pupil dependence

Corporate office:

PhysIOL s.a.

Liège Science Park, Allée des Noisetiers, 4
 4031 Liège (Belgium)

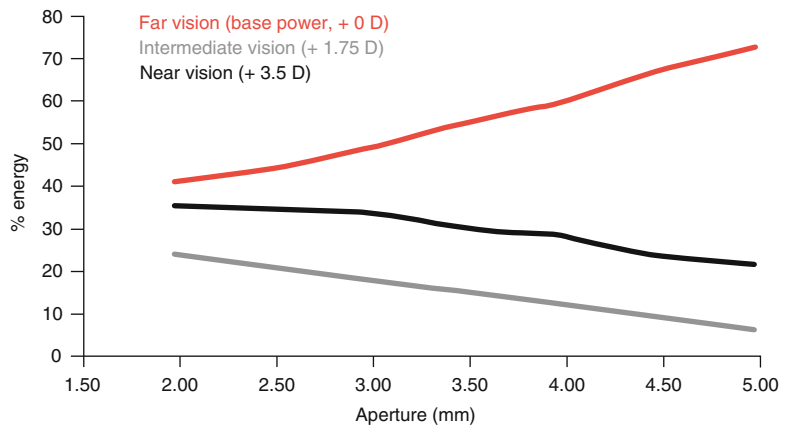


Fig. 8.39 Pupil dependence

27. *FineVision Toric (PhysIOL)* [26]

Fig. 8.40 FineVision Toric (PhysIOL)

Type: one-piece toric trifocal hydrophilic acrylic IOL

Optic: Biconvex, diffractive FineVision anterior surface, aspheric posterior surface

Pupil dependent: yes

Contrast sensitivity: not significantly decreased

Asphericity: $-0.11 \mu\text{m}$

Material: 25 % hydrophilic acrylic

Filter: UV and BlueTech

Total diameter: 11.40 mm

Optic size: 6.0 mm

Haptic angulation: 5°

Edge design: double posterior square edge

Implant location: bag

Refractive index: 1.46

Diopter range: +6 D to +35 D (0.5 D increments)

Cylinder power (on demand): 1.00 – 1.50 – 2.25 – 3.00 – 3.75 – 4.50 – 5.25 – 6.00 D

ADD spectacle plane

+1.75 D intermediate vision

+3.5 D near vision

Incision size: ≥ 2.0 mm

Injector system recommended: Medcel AccuJet 2.0

Table 8.13

Estimated constants		
Fabricate A-constant: 118.5		
		IOLMaster
Hoffer Q	tACD	5.59
Holladay II	SF	1.83
SRK II	A	119.31
SRK/T	A	118.95
Haigis ^a	a0	1.36
	a1	0.40
	a2	0.10

^aUnoptimized

FineVision Toric calculator: <http://www.physioltoric.eu/>

Corporate office:

PhysIOL s.a.

Liège Science Park, Allée des Noisetiers, 4
4031 Liège (Belgium)

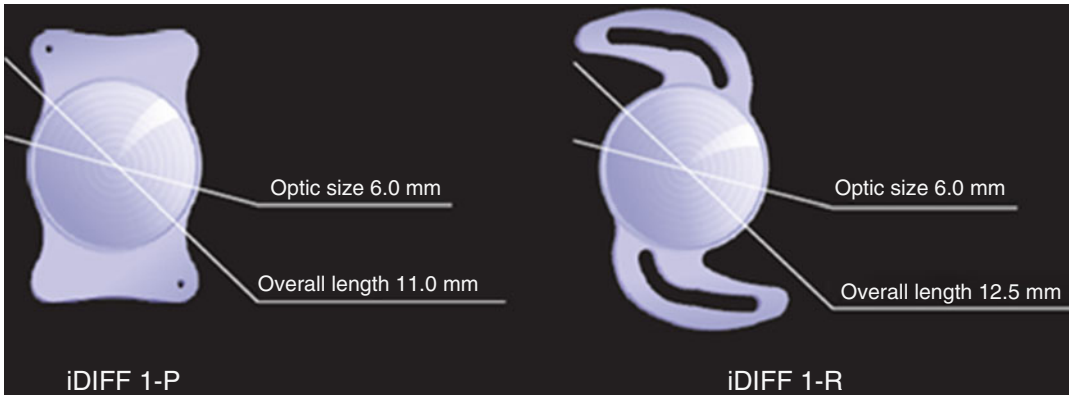
28. *iDIFF Plus 1-P and 1-R (Care Group)* [27]

Fig. 8.41 iDIFF Plus 1-P and 1-R (Care Group)

Type: one-piece diffractive-refractive multifocal IOL

Optic: modified diffractive-refractive and aspheric surface

Pupil dependent: yes

Contrast sensitivity: not affected

Material: hydrophilic acrylic

Filter: UV

Total diameter: 11.0 mm iDIFF 1-P, 12.50 mm iDIFF 1-R

Optic size: 6.0 mm both IOLs

Haptic angulation: 0°

Edge design: square 360°

Implant location: bag

Refractive index: 1.467

Diopter range: +11.0 D to +30.0 D (0.5 D increments)

ADD IOL plane: +3.0 D, +3.5 D, and +4.0 D

Incision size: ≥ 2.0 mm

Estimated A-constant: 118.0

MTF graph

Corporate office:

Care Group India

Block No.310, Village Sim of Dabhasa

Tal. Padra, Dist. Vadodara – 391 440

Gujarat, India

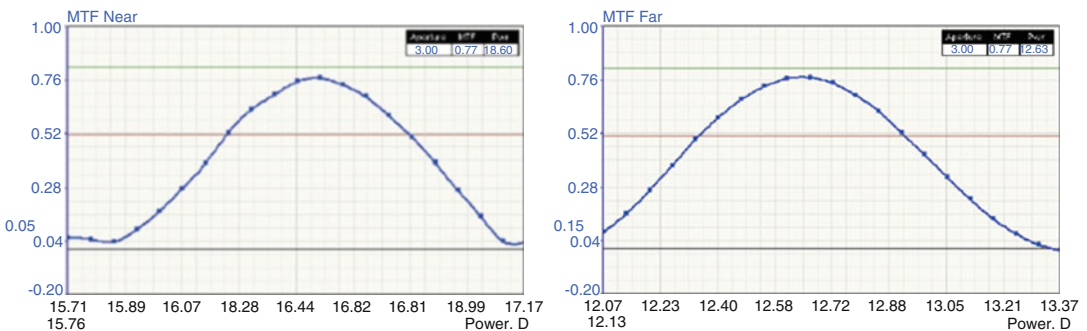


Fig. 8.42 MTF graph

29. LENTIS Comfort LS-313 MF15 (Oculentis, Topcon) [28]

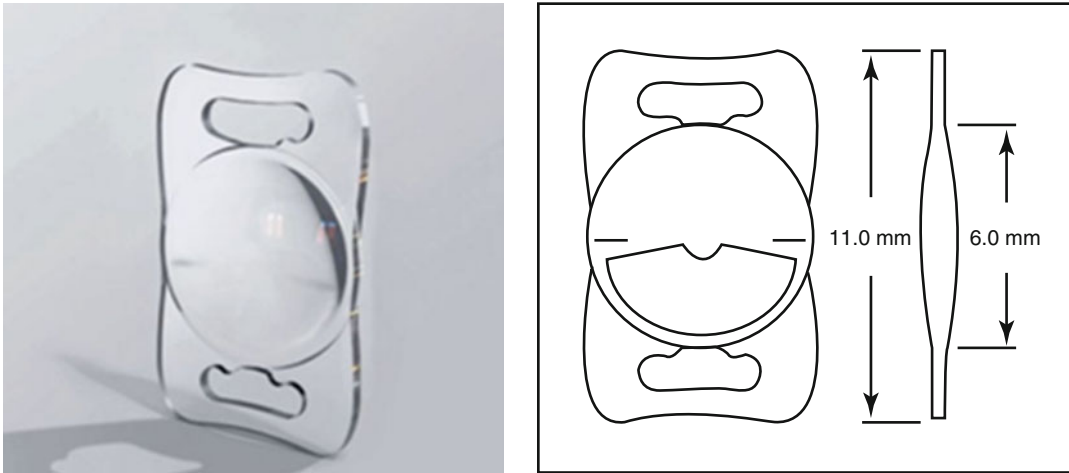


Fig. 8.43 LENTIS Comfort LS-313 MF15 (Oculentis, Topcon)

Type: one-piece foldable bifocal hydrophobic acrylic IOL to intermediate and far vision

Optic: biconvex, aspheric posterior surface; sector-shaped addition

Pupil dependent: no

Contrast sensitivity: not affected

Material: HydroSmart acrylate copolymer with hydrophobic surface

Filter: UV

Total diameter: 11.0 mm

Optic size: 6.0 mm

Central thickness: 0.97 mm (+22.0 D)

Haptic angulation: 0°

Haptic style: Monoflex PMMA modified C

Edge design: square edges, posterior 360° continuous barrier effect

Implant location: bag

Refractive index: 1.46

Diopter range:

−10.0 D to −1.0 D (1.0 D increments)

+0.0 D to +36.0 D (0.5 D increments)

ADD IOL plane: +1.5 D

ADD spectacle plane: +1.2 D

Incision size (recommended): 2.2/2.6 mm

Injector system:

Table 8.14

Recommended injector (reusable)	Injector:
	Viscoject-1-hand: L1604205 Viscoject-2-hand: L1604215
	Cartridges
	Viscoject BIO 1.8 Cartridge-Set: LP604205C (max. 25 D) Viscoject BIO 2.2 Cartridge-Set: LP604240C
Recommended injector sets (disposable)	Viscoject BIO 1.8 Injector-Set: LP604350C (max. 25 D)
	Viscoject BIO 2.2 Injector-Set: LP604340C

Table 8.15

Estimated constants (IOLMaster)		
Fabricate A-constant: 118.0/ACD, 4.97		
Hoffer Q	tACD	5.21
Holladay I	SF	1.47
SRK II	A	118.6
SRK/T	A	118.5
Haigis	a0	0.95
	a1	0.40
	a2	0.10

Corporate office:

Oculentis GmbH

Am Borsigturm 58

13507 Berlin (Germany)

30. LENTIS Mplus LS-313 MF and MplusX LS-313 MF30 (Oculentis, Topcon) [29]

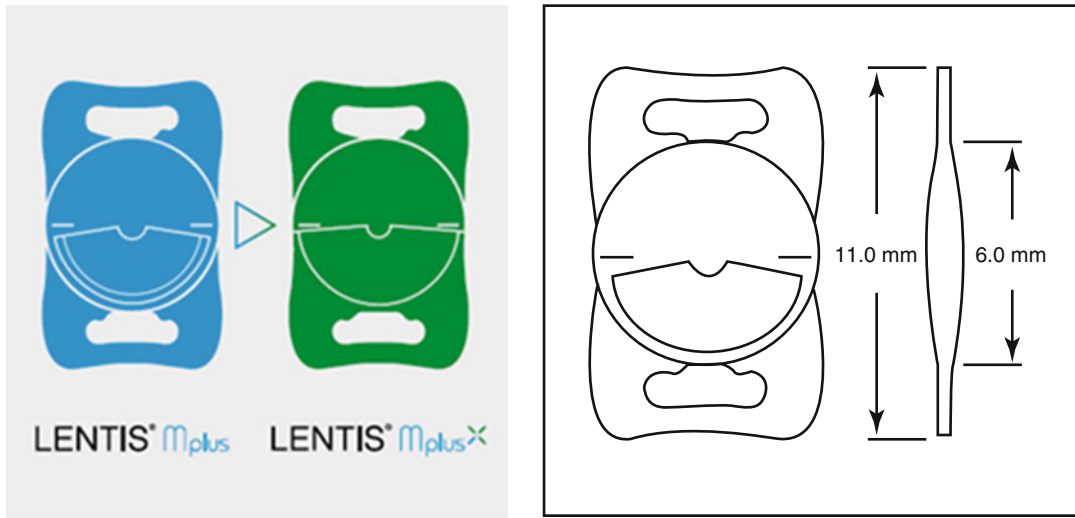


Fig. 8.44 LENTIS Mplus LS-313 MF and MplusX LS-313 MF30 (Oculentis, Topcon)

Type: one-piece multifocal acrylic IOL
 Optic: biconvex, aspheric posterior surface; sector-shaped addition of +3.0 D
 Pupil dependent: no; independently increased in MplusX, also for very small pupils
 Contrast sensitivity: not affected
 Material: HydroSmart acrylate copolymer with hydrophobic surface
 Filter: UV
 Total diameter: 11.0 mm
 Optic size: 6.0 mm
 Central thickness: 1.04 mm (+22.0 D)
 Haptic angulation: 0°
 Edge design: optic and haptics with 360° square edge
 Implant location: bag
 Refractive index: 1.46

ADD IOL plane: +3.0 D
 ADD spectacle plane: +2.5 D
 Injector system:

Table 8.17

Recommended injector (reusable)	Injector:
	Viscoject-1-hand: L1604205 Viscoject-2-hand: L1604215
Recommended injector sets (disposable)	Cartridges
	Viscoject 2.2 Cartridge-Set: LP604240M Viscoject injector + Viscoglide 2.2 Cartridge LP604340

Table 8.16

	LENTIS Mplus	LENTIS MplusX
Diopter range	+15.0 D to +25.0 D (0.5 D steps)	-10.0 D to +1.0 D (1.0 D steps) +0.0 D to +36.0 D (0.5 D steps)
Incision size	2.6 mm	2.2/2.6 mm

Table 8.18

Estimated constants (IOLMaster)		
Fabricate A-constant: 118.0 ACD, 4.97		
Hoffer Q	tACD	5.21
Holladay I	SF	1.47
SRK II	A	118.6
SRK/T	A	118.5
Haigis	a0	0.95
	a1	0.40
	a2	0.10

*Different areas of focus
Pupil dependent*

Corporate office:
Oculentis GmbH
Am Borsigturm 58
13507 Berlin (Germany)

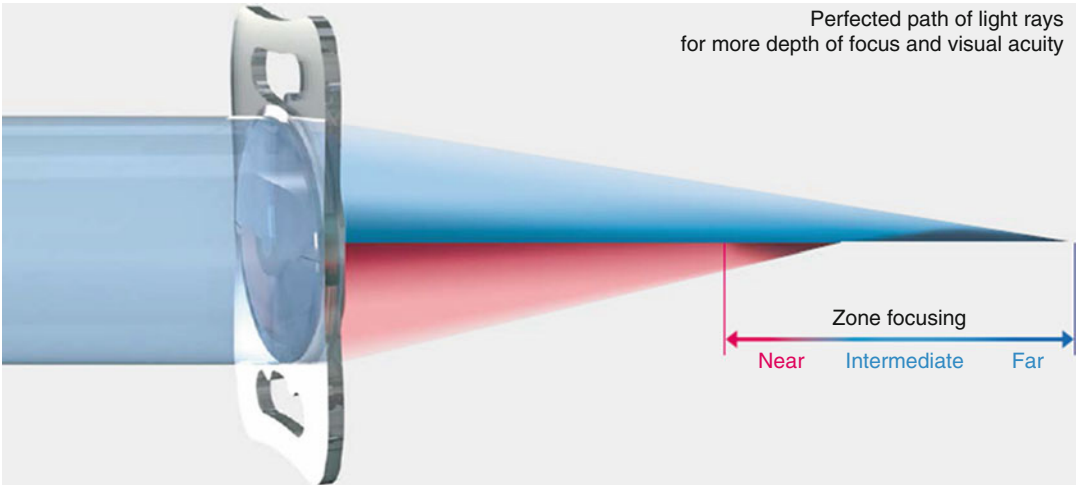


Fig. 8.45 Different areas of focus

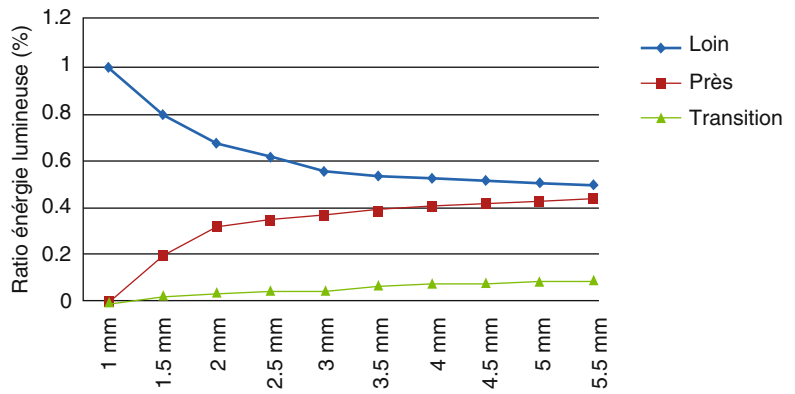


Fig. 8.46 Pupil dependent

31. LENTIS Mplus Toric LU-313 MFT and LU-313 MTFY (Oculentis, Topcon) [30]

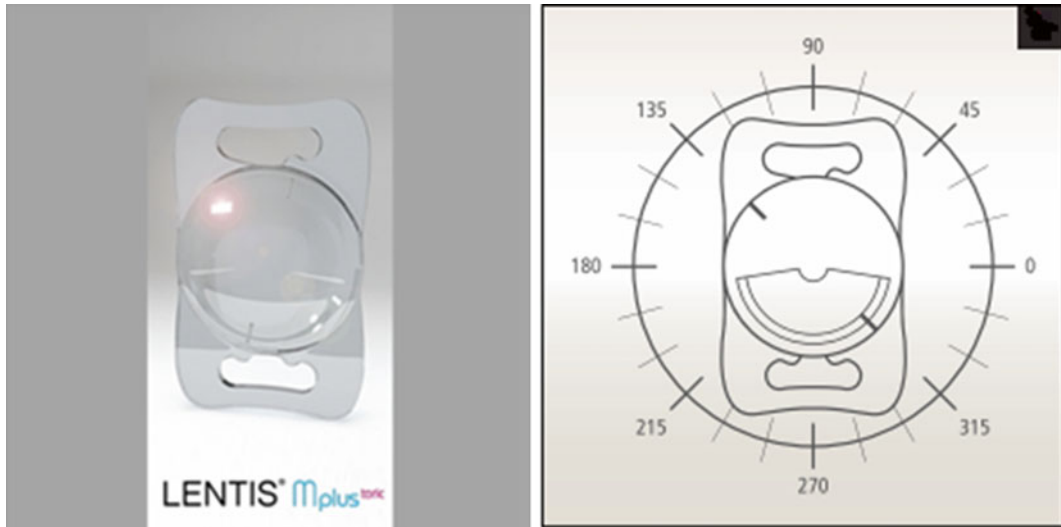


Fig. 8.47 LENTIS Mplus Toric LU-313 MFT and LU-313 MTFY (Oculentis, Topcon)

Type: one-piece multifocal toric acrylic IOL
 Optic: biconvex, aspheric, and toric posterior surface; sector-shaped addition of +3.0 D
 Pupil dependent: no
 Contrast sensitivity: not affected
 Material: HydroSmart acrylate copolymer with hydrophobic surface
 Filter: UV (LU-313 MFT) or UV with violet light filter (LU-313 MTFY)
 Total diameter: 11.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°
 Edge design: optic and haptics with 360° square edge
 Implant location: bag
 Refractive index: 1.46
 Diopter range: +0.0 to +36.0 D (0.01 increments)
 Cylinder: +0.25 to +12.0 (1° scale)
 Sph+Cyl <40.0 D
 ADD IOL plane: +3.0 D
 ADD spectacle plane: +2.5 D
 Incision size recommended: 2.6 mm

Injector system:

Table 8.19

Recommended injector (reusable)	Injector:
	Viscoject-1-hand: L1604205 Viscoject-2-hand: L1604215
Recommended injector sets (disposable)	Cartridges
	Viscoject 2.2 Cartridge-Set: LP604240M Viscoject injector+Viscoglide 2.2 Cartridge LP604340

Table 8.20

Estimated constants (IOLMaster)		
Fabricate A-constant: 118.0/ACD, 4.97		
Hoffer Q	tACD	5.11
Holladay I	SF	1.33
SRK II	A	118.2
SRK/T	A	118.2
Haigis	a0	0.87
	a1	0.40
	a2	0.10

Corporate office:

Oculentis GmbH
 Am Borsigturm 58
 13507 Berlin (Germany)

32. *M-flex 630-F and 580-F (Rayner)* [31]**Fig. 8.48** M-flex 630-F and 580-F (Rayner)

Type: one-piece multifocal hydrophilic acrylic IOL

Optic: multifocal refractive aspheric IOL, with 4 or 5 annular zones (depending on IOL base power)

Pupil dependent: yes

Contrast sensitivity: not affected

Material: hydrophilic acrylic

Filter: UV

Incision size recommended: 1.8 mm

Injector system: Rayner single-use soft-tipped injector

Table 8.23

Estimated constants		M-flex 630 F	M-flex 580 F
SRK/T	A	118.6	118.6
Hoffer Q	tACD	4.97	4.97

Table 8.21

	M-flex 630 F	M-flex 580 F
Optic size	6,25 mm	5,75 mm
Total diameter	12,50 mm	12,0 mm

Haptic angulation: 0°

Edge design: amon-apple enhanced square edge

Implant location: bag

Refractive index: 1.46

Table 8.22

	M-flex 630 F	M-flex 580 F	ADD IOL plane	ADD spectacle plane
Dioptric range	+14.0 D to +25.0 D (0.5 D steps)	–	+3.0 D	+2.25 D
	+14.0 to +25.0 D (0.5 D steps)	+25.5 D to +30.0 D (0.5 D steps)	+4.0 D	+3.0 D

33. *M-flex Toric 638-F and 588-F (Rayner)* [32]



Fig. 8.49 M-flex Toric 638-F and 588-F (Rayner)

Type: one-piece multifocal toric hydrophilic acrylic IOL
 Optic: multifocal toric aspheric IOL, with 4 or 5 annular zones (depending on IOL base power)
 Pupil dependent: yes
 Contrast sensitivity: not affected
 Material: hydrophilic acrylic
 Filter: UV

Table 8.24

	M-flex T 638 F	M-flex T 588 F
	Base powers ≤ 25 D	Base powers > 25 D
Optic size	6.25 mm	5.75 mm
Total diameter	12.50 mm	12.0 mm

Haptic angulation: 0°
 Edge design: amon-apple enhanced square edge
 Implant location: bag
 Refractive index: 1.46

Table 8.25

	Standard power range	Premium power range
Spherical equivalent ^a	+14.0 D to +32.0 D (0.5 D steps)	+14.0 D to +32.0 D (0.5 D steps)
Cylinder	+1.0 D, +2.0 D, +3.0 D	+1.0 D to +6.0 D (0.5 D increments)
ADD	+3.0 or +4.0	+3.0 or +4.0

^aSpherical equivalent is defined as sphere+(0.5 x cylinder)

Incision size recommended: 1.8 mm
 Injector system: Rayner single-use soft-tipped injector

Table 8.26

Estimated constants		M-flex T 638 F	M-flex T 588 F
SRK/T	A	118.6	118.6
Hoffer Q	tACD	4.97	4.97

Corporate office:
Rayner Intraocular Lenses Ltd.
 Sackville Road, Hove, East Sussex, BN3, 7AN (England)

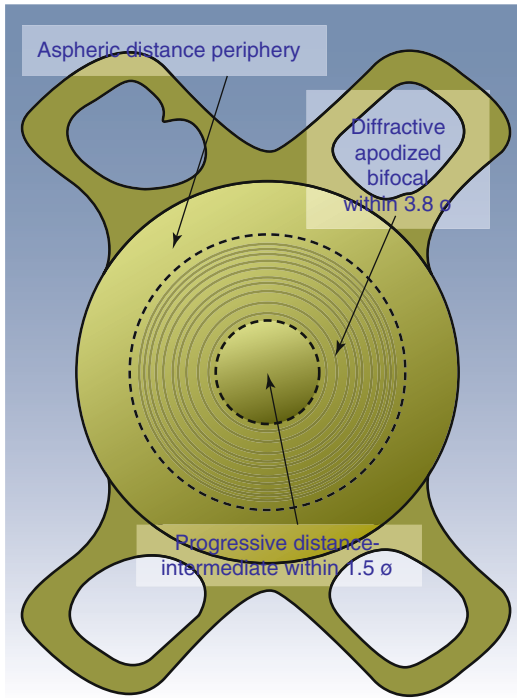
34. *OptiVis multifocal (Aaren Scientific)*

Fig. 8.50 OptiVis multifocal (Aaren Scientific)

Type: one-piece diffractive-refractive multifocal IOL

Optic: multifocal aspheric biconvex (radius optics). Refractive zone occupies central 1.5 mm diameter (far and intermediate vision). Diffractive zone occupies area between 1.5 mm and 3.8 mm diameters (far and near vision).

Pupil-dependent: no.

Contrast Sensitivity: decreased.

Material: hydrophilic acrylic.

Filter: UV.

Total diameter: 11.0 mm.

Optic size: 6.0 mm.

Haptic angulation: 5°.

Implant location: bag.

Refractive index: 1.46.

Diopter range: +10.0 D to +30.0 D (0.5 D increments).

Incision size: ≥ 2.2 mm.

Injector system: R28 Model IOL Delivery System (reusable titanium screw-style surgical instrument).

Estimated A-constant: 118.1.

Theoretical ACD: 4.46.

Corporate office:

Aaren Scientific Inc.

1040 South Vintage Avenue, Bldg. A

Ontario, CA 91761-3631 (USA)

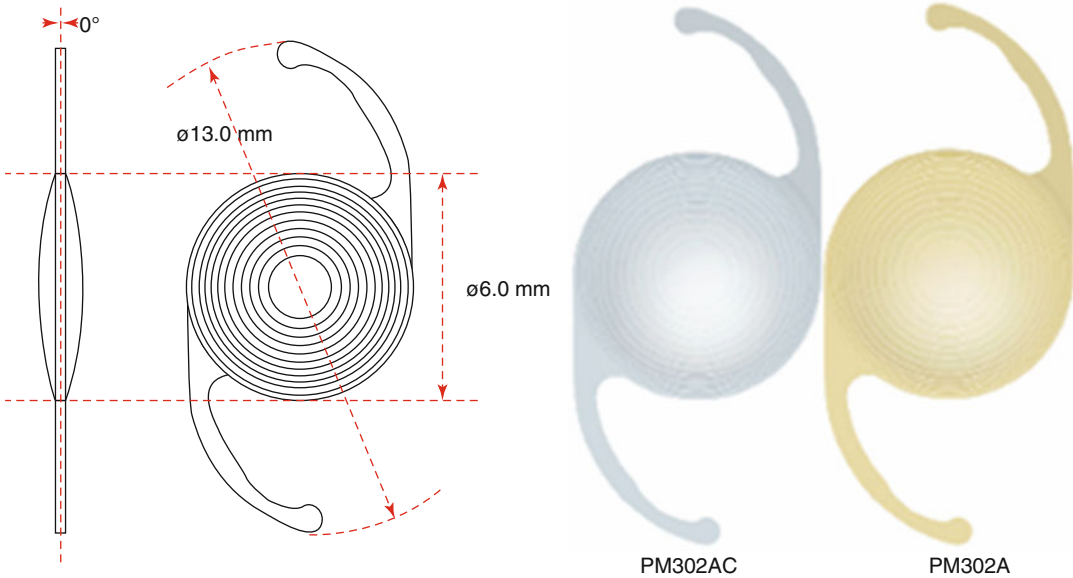
35. *PreciSAL M302A, M302AC, PM302A, and PM302AC (MBI, Millennium Biomedical, Inc.)* [33]

Fig. 8.51 PreciSAL M302A, M302AC, PM302A, and PM302AC (MBI, Millennium Biomedical, Inc.)

Type: one-piece hydrophobic diffractive and aspheric multifocal IOL

Optic: biconvex diffractive

Material: hydrophobic acrylic

Filter:

UV: M302AC, PM302AC

UV and blue light: M302A, PM302A

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: modified C

Edge design: square 360°

Implant location: bag

Refractive index: 1.5

Diopter range: +0.0 D to +10.0 D (1.0 D increments), +10.0 D to +30.0 D (0.5 D increments)

Incision size: ≥ 2.2 mm

Injector system: preloaded injector system
P302A and P302AC

Table 8.27

Estimated constants		
Fabricate A-constant: 118.7/ACD, 5.51		
Holladay I	SF	1.75
SRK II	A	119.2
SRK/T	A	118.9
Haigis	a0	1.32
	a1	0.40
	a2	0.10

Estimates only: surgeons are recommended to use their own values based upon their own experience

Corporate office:

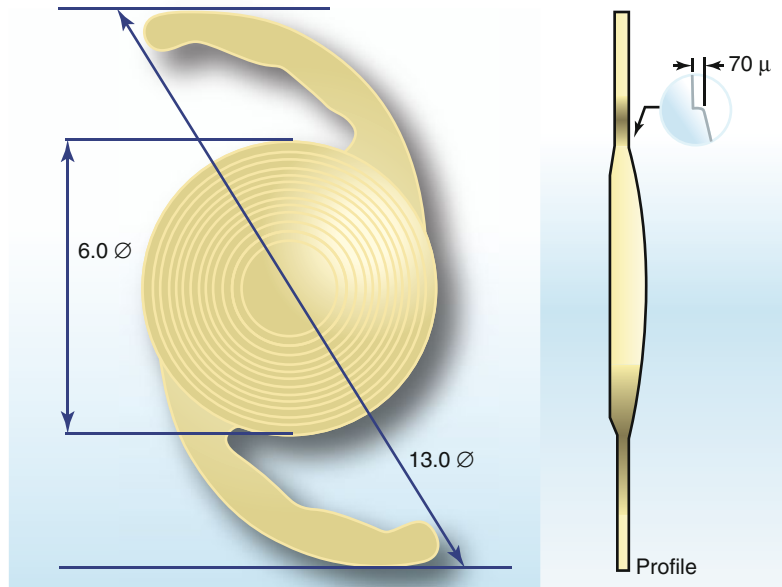
Millennium Biomedical Inc.

360 E. Bonita Ave. Pomona

CA. 91767 (USA)

36. Presbysmart Crystal Evolution (Micro Technologie Ophtalmique, MTO) [34]

Fig. 8.52 Presbysmart Crystal Evolution (Micro Technologie Ophtalmique, MTO)



Type: one-piece hydrophobic acrylic multifocal IOL

Optic: biconvex multifocal

Pupil dependent: yes

Contrast sensitivity: not affected.

Material: hydrophobic acrylic

Filter: UV and yellow

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: modified C loop

Edge design: square 360°

Implant location: bag

Refractive index: 1.49

Diopter range: +10.0 D to +30.0 D (0.1 D increments)

ADD IOL plane: +3.0 D/+3.5 D

Incision size: 2.2 mm

Injector system:

Injector Medical Viscojet of 2.2 mm

MTO Smartjet MICS of 2.2 mm

Table 8.28

Estimated constants		
Fabricate A-constant: US 118.5/IOLMaster 119.0/ACD, 4.96		
Hoffer Q	pACD	5.514
Holladay I	SF	1.739
SRK II	A	119.5
SRK/T	A	119.4
Haigis	a0	1.302
	a1	0.40
	a2	0.10

Estimates only: surgeons are recommended to use their own values based upon their own experience

MTF graph

Corporate office:

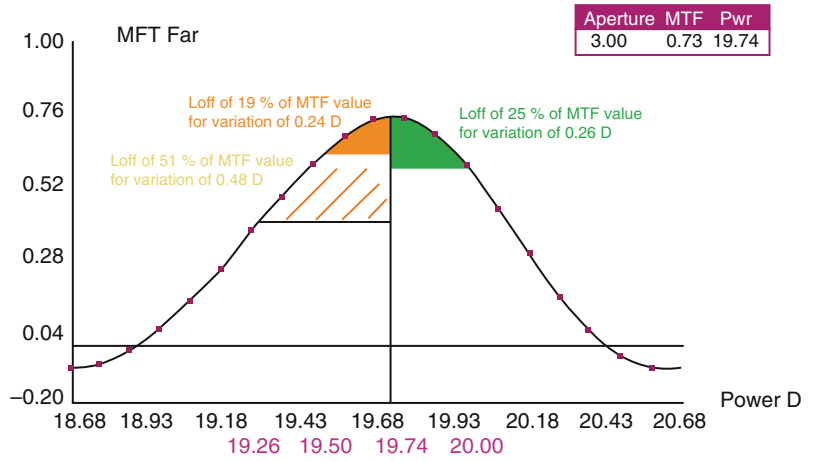
MTO Micro Technologie

Ophtalmique SA

Place de la gare 2

1950 Sion, Switzerland

Fig. 8.53 MTF graph



37. Presbysmart Plus PSP0, PSP1, and PSP2 (Micro Technologie Ophtalmique, MTO) [34]

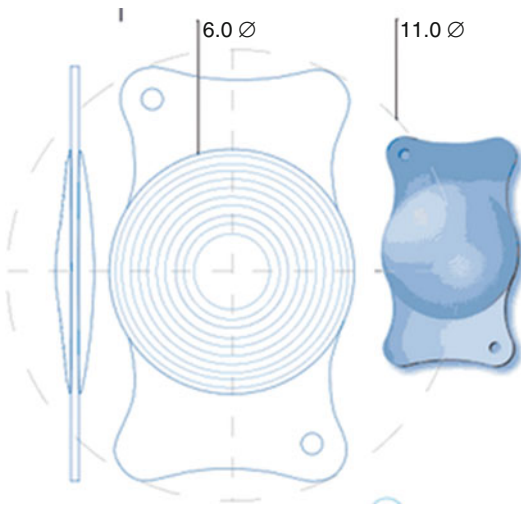


Fig. 8.54 Presbysmart Plus PSP0, PSP1, and PSP2 (Micro Technologie Ophtalmique, MTO)

Type: one-piece diffractive aspheric hydrophilic acrylic IOL
 Optic: biconvex diffractive multifocal
 Pupil dependent: no
 Contrast sensitivity: not affected
 Material: foldable hydrophilic acrylic (26 %)
 Filter: UV
 Total diameter: 11.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 0°
 Haptic style: plate edge
 Edge design: square 360°

Implant location: bag
 Refractive index: 1.465
 Diopter range: +0.0 D to +35.0 D (0.01 D increments)
 ADD IOL plane: PSP0: +3.0 D/PSP1: +3.5 D/PSP2: +4.0 D
 Incision size: ≥ 1.5 mm
 Injector system:
 Injector Viscojet Medical of 1.8 mm/2.2 mm
 MTO Smartjet MICS of 1.85 mm/2.2 mm

Table 8.29

Estimated constants		
Fabricate A-constant: US 118.2/IOLMaster 118.5/ACD, 4.8		
Hoffer Q	pACD	5.17
Holladay I	SF	1.39
SRK II	A	118.5
SRK/T	A	118.5
Haigis	a0	0.95
	a1	0.40
	a2	0.10

MTF graph

Corporate office:
 MTO Micro Technologie
 Ophtalmique SA
 Place de la gare 2
 1950 Sion (Switzerland)

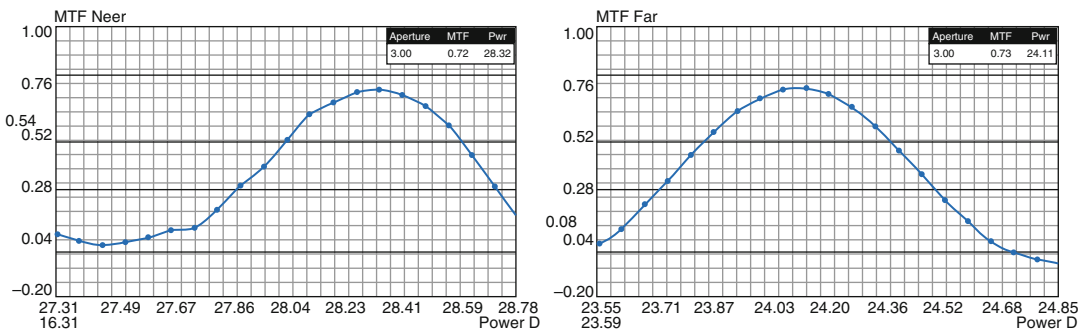


Fig. 8.55 MTF graph

38. *Preziol Multifocal Foldable (Care Group)* [35]

Fig. 8.56 Preziol Multifocal Foldable (Care Group)

Type: one-piece refractive aspheric multifocal IOL.

Optic: central zone for distance vision has diameter of 1.5 mm, second zone for near vision with diameter of 2.5 mm and peripheral zone for intermediate vision.

Pupil dependent: no.

Contrast sensitivity: decreased.

Material: acrylic.

Filter: UV.

Total diameter: 12.5 mm.

Optic size: 6.0 mm.

Haptic angulation: 0°.

Edge design: square 360°.

Implant location: bag.

Refractive index: 1.467.

ADD IOL plane:

Near vision +4.0 D.

Intermediate vision +1.0 over central zone.

Incision size: ≥ 2.8 mm.

Estimated A-constant: 118.0.

Theoretical ACD: 5.10.

Corporate office:

Care Group India

Block No.310, Village Sim of Dabhasa, Tal.

Padra, Dist. Vadodara – 391 440.

Gujarat, India

39. Preziol Multifocal PMMA (Care Group) [35]



Fig. 8.57 Preziol Multifocal PMMA (Care Group)

Type: one-piece refractive aspheric multifocal IOL.

Optic: central zone for distance vision has diameter of 1.5 mm, second zone for near vision with diameter of 2.5 mm and peripheral zone for intermediate vision.

Pupil dependent: no.

Contrast sensitivity: decreased.

Material: PMMA.

Filter: UV.

Total diameter: 12.5 mm.

Optic size: 5.25/6.0 mm.

Haptic angulation: 0°.

Haptic style: modified C.

Edge design: square 360°.

Implant location: bag.

Refractive index: 1.49.

ADD IOL plane:

Near vision +4.0 D.

Intermediate vision +1.0 over central zone.

Incision size: ≤ 2.8 mm.

Estimated A-constant: 118.2.

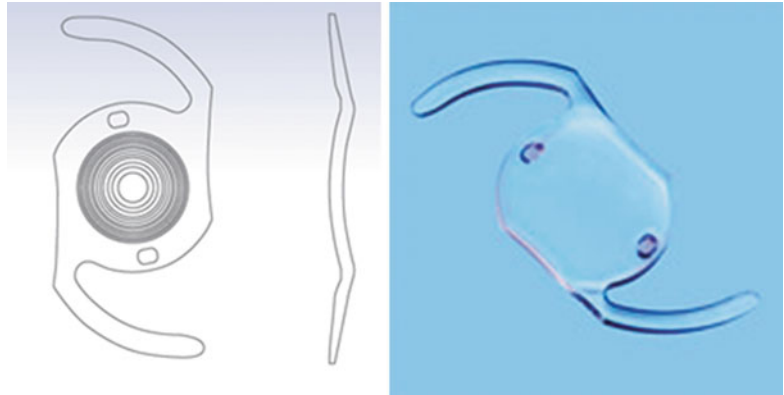
Corporate office:

Care Group India.

Block No.310, Village Sim of Dabhasa

Tal. Padra, Dist. Vadodara – 391 440

Gujarat, India

40. REVERSO (*Cristalens*) [36]**Fig. 8.58** REVERSO
(*Cristalens*)

Type: one-piece spherical IOL for implantation
in pseudophakic eyes

Optic: convex anterior surface, concave multifocal diffractive posterior surface

Material: hydrophilic acrylic 25 %

Filter: UV

Total diameter: 13.80 mm

Optic size: 6.5 mm

Haptic angulation: 10°

Haptic style: open-loop haptics

Edge design: round edge 360°

Implant location: sulcus

Refractive index: 1.46

Diopter range: standard, 0.0 D

On request: -3.0 D to +3.0 D (0.5 D increments)

ADD IOL plane: +3.0 D

Incision size: from 1.8 mm to 2.0 mm

Estimated A-constant: not applicable

Corporate office:

Cristalens

Hyde park – Bât Westminster

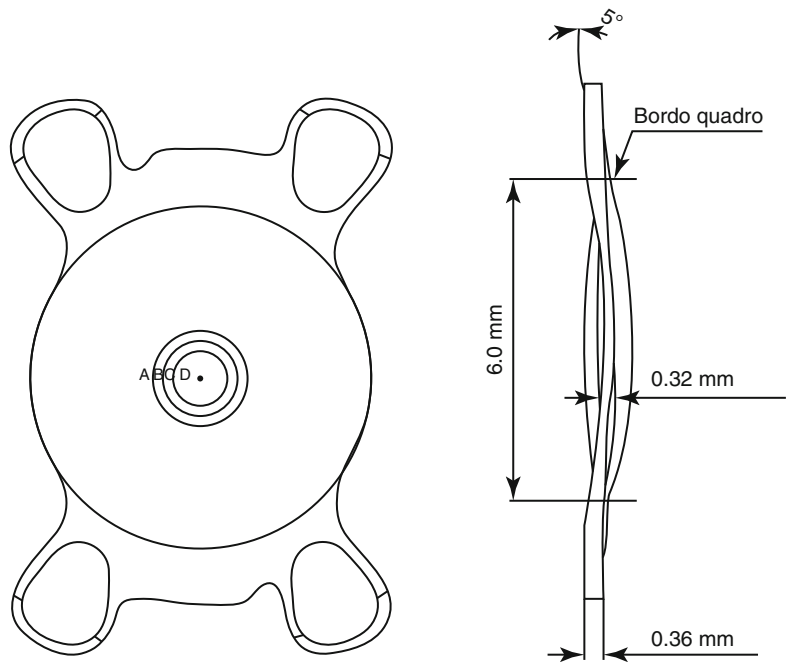
12 allée Rosa Luxemburg

BP 50240 Eragny

95615 Cergy Pontoise Cedex (France)

41. Review FIL 611 PV (Soleko) [37]

Fig. 8.59 Review FIL 611 PV (Soleko)



Type: one-piece refractive multifocal hydrophilic acrylic IOL
 Optic: central zone with different vision steps

Pupil dependent: no
 Material: foldable acrylic (25 %)
 Filter: UV
 Total diameter: 11.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 5°
 Edge design: square 360°
 Implant location: bag
 Refractive index: 1.461
 Diopter range: +9.0 D to +26.0 D (0.5 D increments)
 ADD IOL plane: +3.75 D
 Incision size: 2.0–3.0 mm

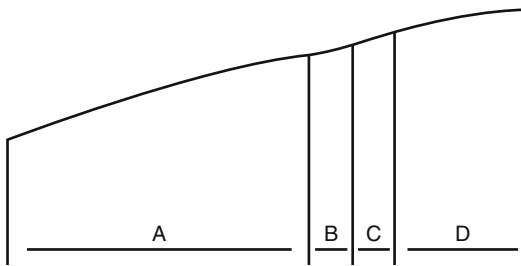


Fig. 8.60 Optic: central zone with different vision steps

Injector system recommended: Medical Viscojet or similar (2.2 for 2.0 mm incision, 2.0 for 1.8 mm incision)

Table 8.30

Zone	Additional power (IOL plane)	
A	0	Distance
B	0.9	Joint zone
C	2.1	Medium distance
D	3.75	Accommodation zone

Table 8.31

Estimated constants		
Fabricate A-constant: 118.5		
Hoffer Q	pACD	5.26
Holladay I	SF	1.73
SRKII/SRKT	A (IOLMaster/US)	118.5
Haigis	a0	1.044
	a1	0.40
	a2	0.10

Corporate office:

Soleko IOL Division

Via Aniene, 10

00198 Rome (Italy)

42. Review FIL 611 PVT (Soleko) [38]

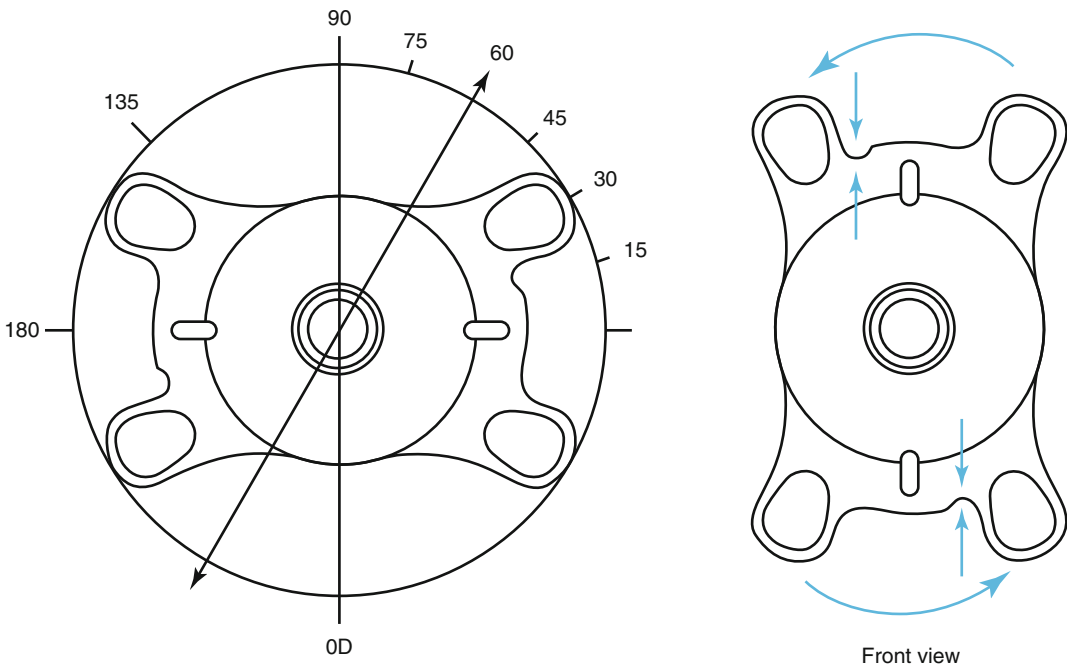


Fig. 8.61 Review FIL 611 PVT (Soleko)

Type: one-piece customized toric multifocal hydrophilic IOL. The axis marks of the cylinder are always positioned on the axis 0–180°.

Optic: refractive toric.

Pupil dependent: no.

Material: foldable acrylic.

Filter: UV.

Total diameter: 11.80 mm.

Optic size: 6.0 mm.

Haptic angulation: 5°.

Edge design: square 360°.

Implant location: bag.

Refractive index: 1.461.

Diopter range: +9.0 D to +26.0 D (0.5 D increments).

Cylinder range: +1.0 D to +6.0 D.

ADD IOL plane: +3.75 D.

Incision size: 2.0–3.0 mm.

Injector system recommended: Medcel Viscojet or similar (2.2 for 2.5 mm incision, 1.8 for 2.0 mm incision)

Table 8.32

Estimated constants		
Fabricate A-constant: 118.3		
Hoffer Q	pACD	5.26
Holladay I	SF	1.73
SRK II/SRKT	A (IOLMaster/US)	118.9/118.8
Haigis	a0	1.044
	a1	0.40
	a2	0.10

Corporate office:

Soleko IOL Division

Via Aniense, 10

00198 Rome (Italy)

43. Review FIL 65 PVS (Soleko) [39]

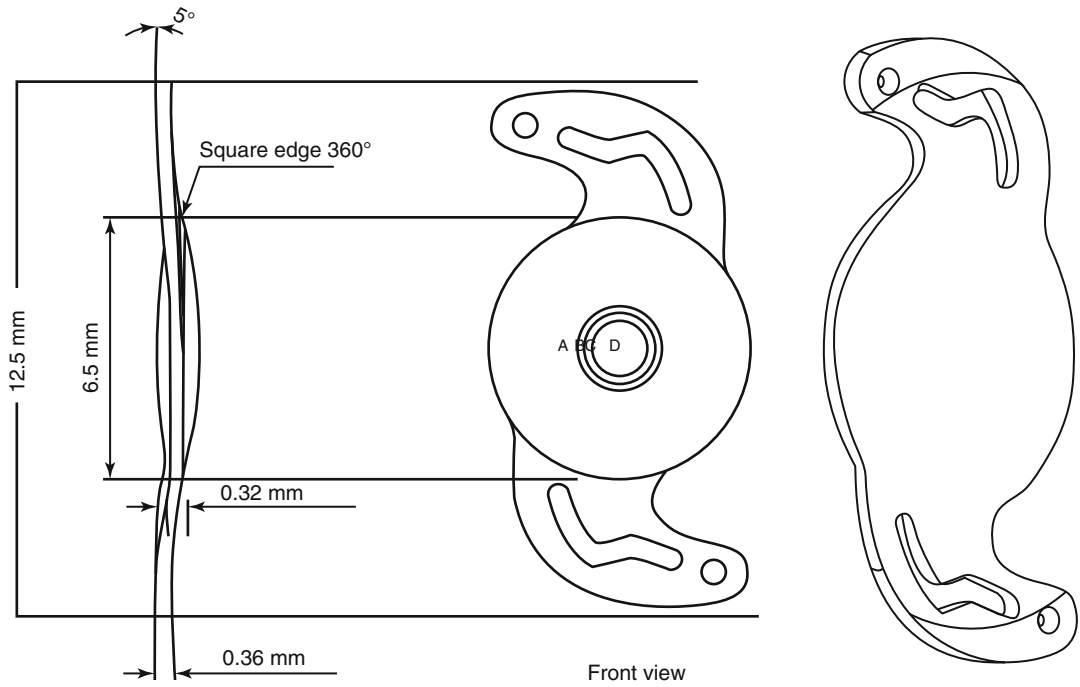
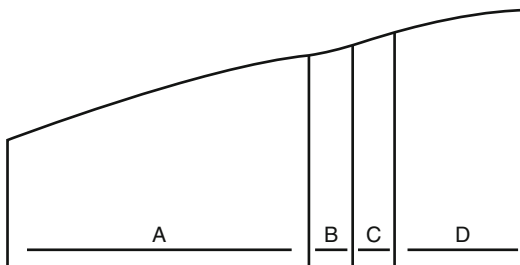


Fig. 8.62 Review FIL 65 PVS (Soleko)

Type: one-piece refractive multifocal hydrophilic acrylic IOL for paediatric patients
 Optic: central zone with different vision steps

Table 8.33

Zone	Additional power (IOL plane)	
A	0	Distance
B	0.9	Joint zone
C	2.1	Medium distance
D	3.75	Accommodation zone



Pupil dependent: yes
 Material: foldable acrylic
 Filter: UV
 Total diameter: 12.5 mm
 Optic size: 6.5 mm
 Haptic angulation: 5°

Fig. 8.63 Optic: central zone with different vision steps

Edge design: square 360°
 Implant location: bag, sulcus, or scleral fixation
 Refractive index: 1.461
 Diopter range: +18.0 D to +28.0 D (0.5 D increments)
 ADD IOL plane: +3.0 D
 Incision size: 2.0–3.0 mm
 Injector system recommended: Medical Viscojet (2.7 for 3.0 mm incision)

Corporate office:
Soleko IOL Division
 Via Aniene, 10
 00198 Rome (Italy)

Table 8.34

Estimated constants		
Fabricate A-constant: bag 118.7/sulcus 118.3/scleral fixation, 117.5		
Hoffer Q	pACD	5.26
Holladay I	SF	1.73
SRK II/SRKT	A (IOLMaster/US)	118.9/118.8
Haigis	a0	1.044
	a1	0.40
	a2	0.10

44. Revive SQFL 600DF (Omni Lens) [40]



Fig. 8.64 Revive SQFL 600DF (Omni Lens)

Type: one-piece apodized diffractive multifocal foldable IOL

Optic: diffractive multifocal optic with aspheric profile

Pupil dependent: yes

Contrast sensitivity: not affected

Material: hybrid acrylic (copolymer HEMA + EOEMA)

Filter: UV

Total diameter: 12.5 mm

Optic size: 6.0 mm

Haptic angulation: 5°

Haptic style: elastic band

Edge design: square 360°

Implant location: bag

Refractive index: 1.46

Diopter range:

From +8.0 D to +15.0 D and from +25.0 D to +30.0 D (1.0 D increments)

From +15.0 D to +25.0 D (0.5 D increments)

ADD IOL plane: +3.5 D

ADD spectacle plane: +2.8 D

Incision size: 2.2 mm

Injector system recommended: Aquaject Plus

Estimated A-constant: 118.2

Theoretical ACD: 5.08

Pupil dependence

Corporate office:

Omni Lens Pvt. Ltd.

5 “Samruddhi”, Opp.Sakar-III

Nr.Sattar Taluka Society, Navrangpura,
Ahmedabad-380014.

Gujarat (India)

Fig. 8.65 Haptic style: elastic band

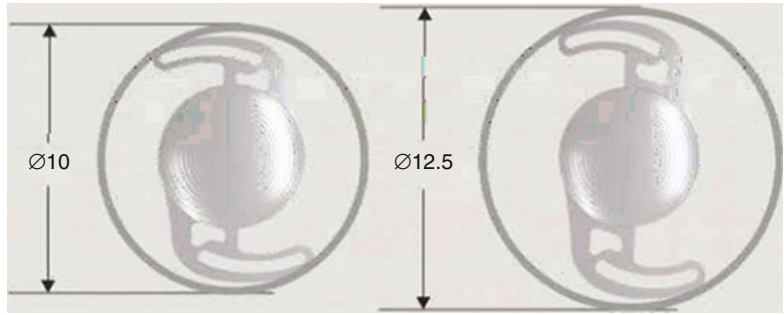
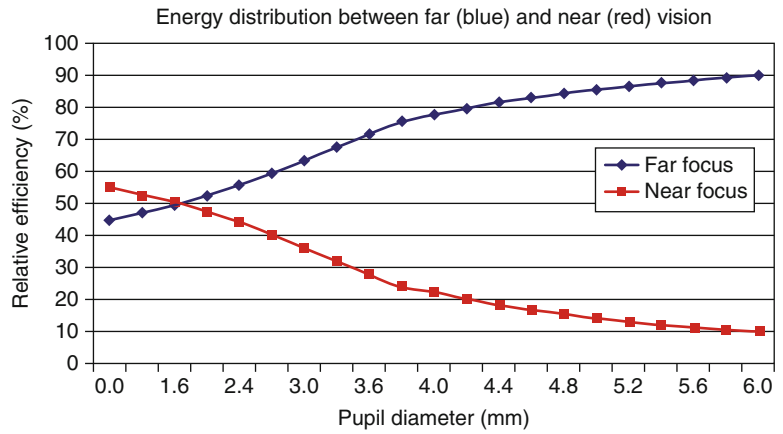
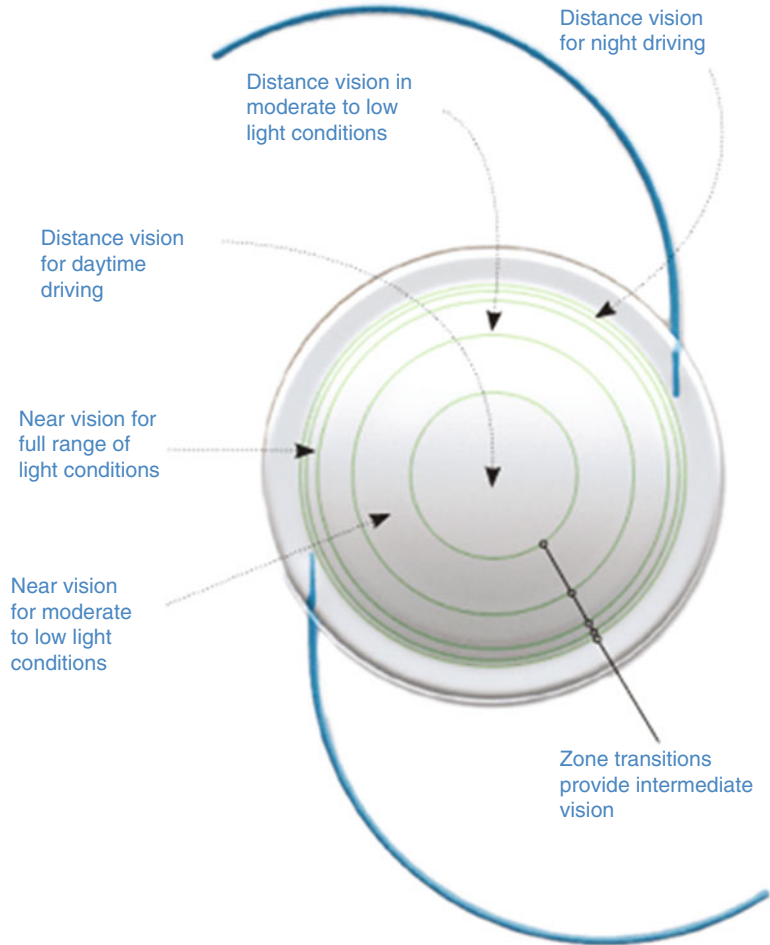


Fig. 8.66 Pupil dependence



45. ReZoom NXG1 (Abbott) [41]

Fig. 8.67 ReZoom NXG1 (Abbott)



Type: three-piece multifocal acrylic IOL
 Optic: biconvex with an anterior refractive zonal-progressive surface
 Pupil dependent: yes
 Contrast sensitivity: decreased
 Material:
 Optic zone: foldable acrylic
 Haptics: 60 % blue core PMMA monofilament
 Filter: UV
 Total diameter: 13.0 mm
 Optic size: 6.0 mm
 Haptic angulation: 5°
 Haptic style: modified C
 Edge design: square OptiEdge design

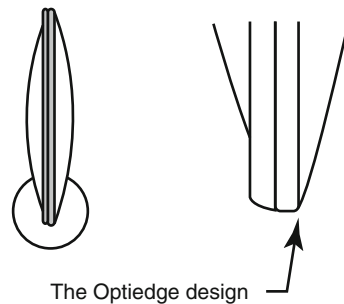


Fig. 8.68 Edge design: square OptiEdge design

Implant location: bag
 Refractive index: 1.47

Diopter range: +6.0 D to +30.0 D (0.5 D increments)

ADD IOL plane: +3.5 D

ADD spectacle plane: +2.4 D to +2.8 D

Incision size: ≥ 3.2 mm

Injector system recommended:

UNFOLDER Emerald series handpiece (EmeraldT)

UNFOLDER Emerald series cartridge (EmeraldC)

Corporate office:

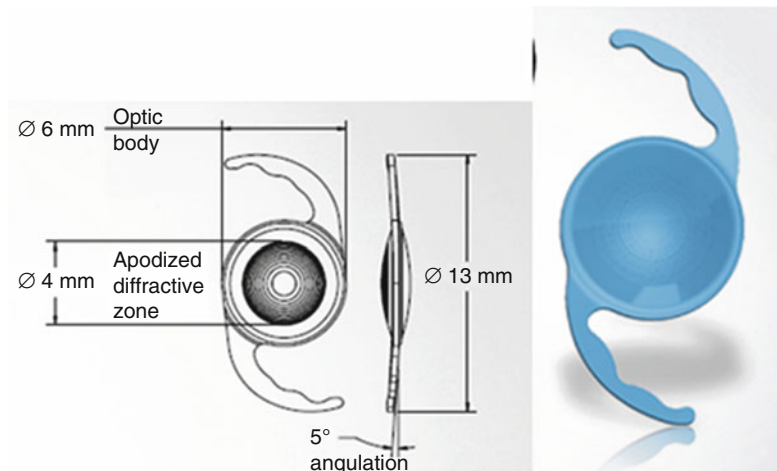
Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064
3500, USA

Table 8.35

Estimated constants		
Hoffer Q	tACD	5.2
Holladay I	SF	1.45
SRK/T	A	118.4

46. SeeLens Multifocal (Hanita Lenses) [42]

Fig. 8.69 SeeLens Multifocal (Hanita Lenses)



Type: one-piece foldable multifocal IOL for MICS

Optic: multifocal diffractive apodized aspheric

Pupil dependent: yes

Contrast sensitivity: decreased

Material: hydrophilic acrylic HEMA/EOEMA copolymer

Filter: UV and violet light

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 5°

Implant location: bag

Edge design: 360° double square edge

Refractive index: 1.46

Diopter range: +10.0 D to +30.0 D (0.5 D increments); +31.0 D to +35.0 D (1.0 D increments)

ADD IOL plane: +3.0 D

ADD spectacle plane: +2.4 D

Incision size: 1.8 mm

Injector system: single-use delivery system SoftJect 1.8

Table 8.36

Estimated constants		IOLMaster	US biometry
Hoffer Q	tACD	5.26	5.05
Holladay I	SF	1.48	1.27
SRK II	A	118.9	118.48
SRK/T	A	118.6	118.26
Haigis	a0	1.044	0.819
	a1	0.4	0.40
	a2	0.1	0.10

Estimates only: surgeons are recommended to use their own values based upon their own experience

Pupil dependence

Contrast sensitivity

Corporate office:

Hanita Lenses R.C.A Ltd. Kibbutz Hanita, 22885

Fig. 8.70 Pupil dependence

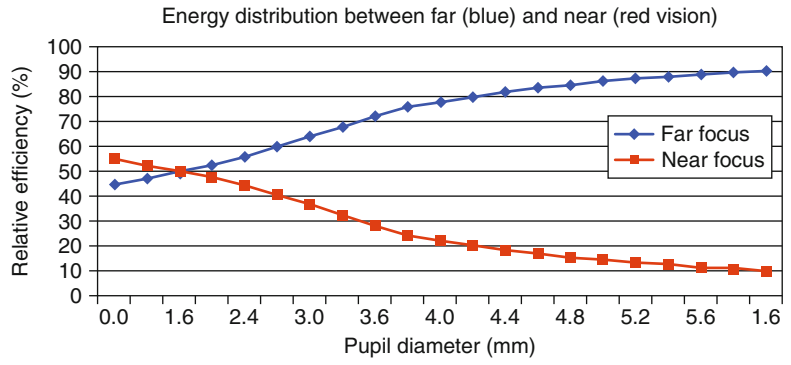
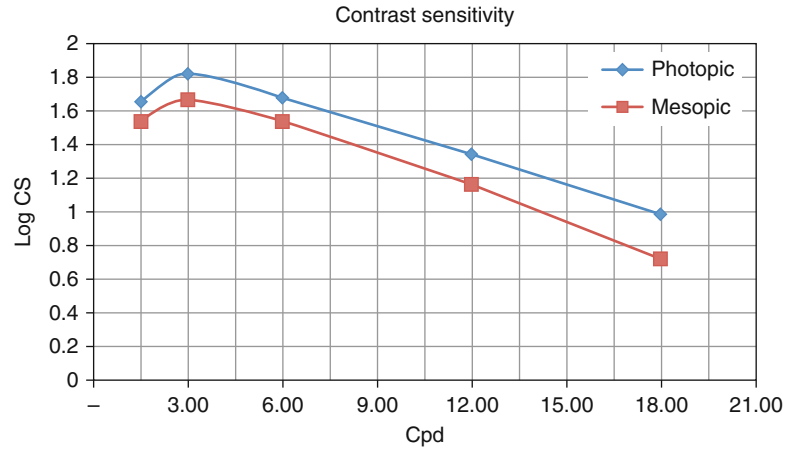


Fig. 8.71 Contrast sensitivity



47. *Sulcoflex Multifocal 653 F (Rayner)* [43]

Sulcoflex multifocal

Fig. 8.72 Sulcoflex Multifocal 653 F (Rayner)

Type: one-piece multifocal hydrophilic acrylic IOL for sulcus fixation in pseudophakic eyes
 Optic: convex anterior surface, concave posterior surface
 Pupil dependent: yes
 Contrast sensitivity: not affected
 Material: hydrophilic Rayacryl
 Filter: UV

Total diameter: 14.0 mm
 Optic size: 6.5 mm
 Haptic angulation: 10°
 Haptic style: undulating haptics
 Implant location: sulcus
 Diopter range: +3.0 D to -3.0 D (0.5 D increments)
 ADD IOL plane: +3.5 D
 ADD spectacle plane: +3.0 D
 Incision size recommended: 3.0 mm
 Injector system: Rayner single-use soft-tipped injector
 Estimated A-constant: 118.9
**Not approved for sale*
 Corporate office:
Rayner Intraocular Lenses Ltd.
 Sackville Road, Hove, East Sussex, BN3 7AN (England)

48. *Sulcoflex Multifocal Toric 653 T (Rayner)* [43]



Sulcoflex multifocal toric

Fig. 8.73 Sulcoflex Multifocal Toric 653 T (Rayner)

Diopter range:
Standard range:

Table 8.37

Equivalent sphere	−3.0 D to +3.0 D (0.5 D steps)		
Cylinder (1.0 D steps)	+1.0 D	+2.0 D	+3.0 D
Min. sphere	−3.5 D	−4.0 D	−4.5 D
Max. sphere	+2.5 D	+2.0 D	+1.5 D

Type: one-piece multifocal toric hydrophilic acrylic IOL for sulcus fixation in pseudophakic eyes
 Optic: convex anterior surface, concave posterior surface
 Pupil dependent: yes
 Contrast sensitivity: not affected
 Material: hydrophilic Rayacryl
 Filter: UV
 Total diameter: 14.0 mm
 Optic size: 6.5 mm
 Haptic angulation: 10°
 Haptic style: undulating haptics
 Implant location: sulcus

Premium range:
 ADD IOL plane: +3.5 D
 ADD spectacle plane: +3.0 D
 Incision size recommended: 3.0 mm
 Injector system: Rayner single-use soft-tipped injector
 Estimated A-constant: 118.9
**Not approved for sale*
 Corporate office:
Rayner Intraocular Lenses Ltd.
 Sackville Road, Hove, East Sussex, BN3 7AN (England)

Table 8.38

Equivalent sphere: −3.0 D to +3.0 D (0.5 D increments)												
Cylinder (1.0 D steps)	1.0 D	1.5 D	2.0 D	2.5 D	3.0 D	3.5 D	4.0 D	4.5 D	5.0 D	5.5 D	6.0 D	
Min. sphere	−6.5	−6.5	−7.0	−7.0	−7.5	−7.5	−8.0	−8.0	−8.5	−8.5	−9.0	
Max. sphere	+5.5	+5.0	+5.0	+4.5	+4.5	+4.0	+4.0	+3.5	+3.5	+3.0	+3.0	

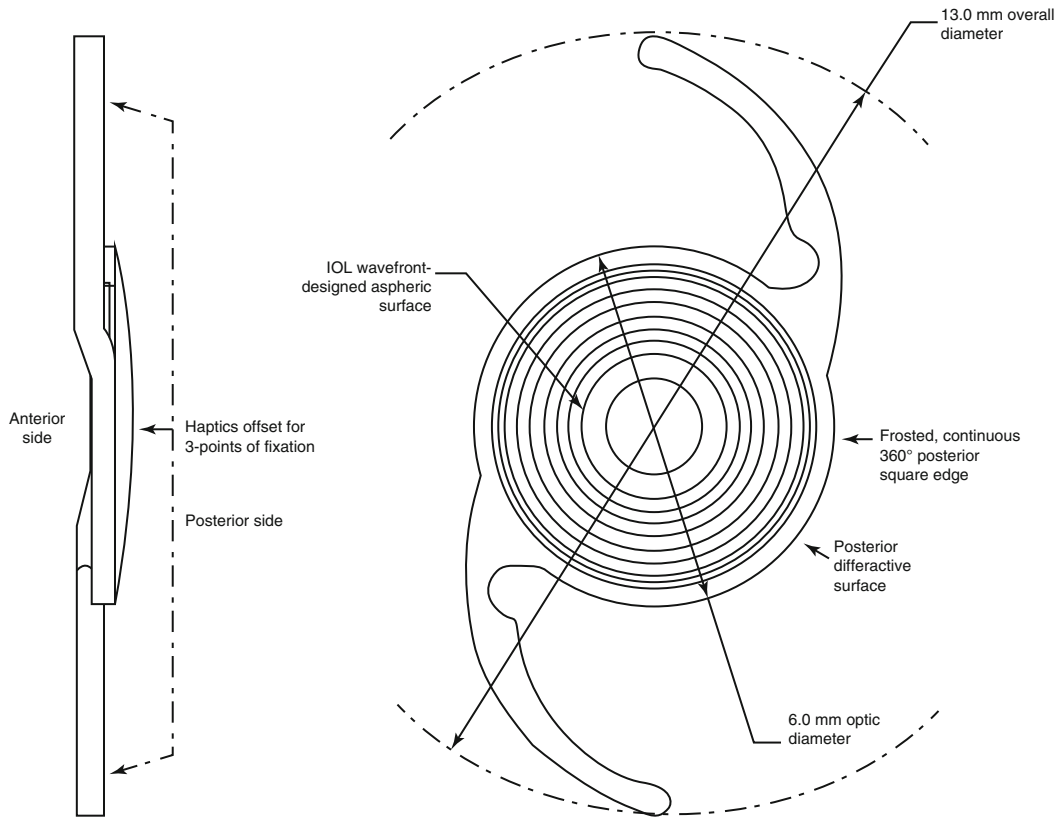
49. *TECNIS MF ZKB00, TECNIS MF ZLB00, and TECNIS MF ZMB00 (Abbott)* [44]

Fig. 8.74 TECNIS MF ZKB00, TECNIS MF ZLB00, and TECNIS MF ZMB00 (Abbott)

Type: foldable one-piece diffractive hydrophobic acrylic IOL

Optic: biconvex, aspheric anterior surface, diffractive posterior surface

Pupil dependent: no

Contrast sensitivity: decreased

Material: hydrophobic acrylic

Filter: UV

Total diameter: 13.0 mm

Optic size: 6.0 mm

Haptic angulation: 0°

Haptic style: modified C

Edge design: ProTEC frosted continuous 360° posterior square edge

Implant location: bag

Refractive index: 1.47

Diopter range: +5 D to +34 D (0.5 D increments)

Table 8.39

	ZKB 00	ZLB 00	ZMB 00
ADD IOL plane	+2.75	+3.25	+4.0
ADD spectacle plane	+2.01	+2.37	+3.0
Theoretical reading distance	50 cm	42 cm	33 cm

Incision size: ≥ 2.2 mm

Injector system recommended:

UNFOLDER Platinum set 1 injector thread (DK 7796)

UNFOLDER Platinum set 1 cartridge (1 MTEC 30)

One Series Ultra syringe injector (DK 7786)

One Series Ultra injector thread (DK 7791)

One Series Ultra cartridge (1 VIPR 30)

Table 8.40

Estimated constants		IOLMaster	US
Hoffer Q	tACD	5.72	5.40
Holladay I	SF	1.96	1.68
SRK II/SRK/T	A	119.3 ^a	118.8 ^a

^aA theoretical value derived from a typical lens of 20.0 D. AMO recommends that surgeons adapt the constant A according to the surgical techniques used and the team, experience with the model of the lens and postoperative results

Corporate office:

Abbott Laboratories
100 Abbott Park Road
Abbott Park, Illinois 60064
3500, USA

Compliance with Ethical Requirements *Conflict of interest*

María-Luisa Durán-García and J. L. Alió declare that they have no conflict of interest.

No human or animal studies were carried out by the authors for this article.

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Jorge L. Alió and Joseph Pikkell

9.1 Introduction

The advantages and disadvantages of the intraocular multifocal lens' performance have to fit patients' needs and the clinical situation. Knowing the difference between lenses is therefore crucial. Since no multifocal intraocular lens is perfect, choosing the lens to implant is actually doing a compromise, but while some compromise is good for one patient, it might be wrong for the other. This chapter does not claim to be an optimal guide in choosing multifocal intraocular lenses to implant, but merely to gather information available from different sources and to be a tool in helping the surgeon in his decision making. There is no substitute to personal experience and the best way to know how to do it is by doing it.

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9.2 Approach

After a thorough preparation and preoperative considerations, as described before, the surgeon has to choose a proper lens to implant.

The four most influencing factors in choosing a certain lens to implant are:

1. Patient's age, needs, lifestyle, and psychological profile
2. Patient's clinical ophthalmic condition
3. Pupil reactivity and size in different light environments
4. Evidence, published in peer review literature and independent from industry bias, supporting outcomes of the tentatively selected MFIOL, especially the defocus curve of the lens
5. Surgeon's prior experience

Patient's occupational and hobbies as well as his preferences (reading, watching TV, traveling, etc.) are to be taken into consideration. Matching the patients' needs with the lenses performance is essential. A surgeon will try to choose a lens that has less contrast sensitivity and produces less glare and halos for patients that drive a lot at night, for example, and on the other will not consider these qualities in patients that prefer to stay at home and concentrate on daily activities during day light hours. Patient's personality should affect these considerations as well.

The clinical ophthalmic situation has a major effect on the lens choosing procedure. Patients that

already suffer from degrees of reduced contrast sensitivity might suffer more from these phenomena compared to others and might adapt slower to the new situation. This is even more important in patients that suffer from glaucoma and already have contrast sensitivity reduction or in patients that suffer from AMD and contrast sensitivity is some time the aim of achieving reading ability. Implanting multifocal intraocular lenses in these patients might turn into a “too much” situation in terms of neuroadaptation and visual performance. In patients with AMD, a slight myopic shift might be a great reading aid as it is actually a magnifier, while in other patients the aim should be emmetropia. Treating these patients and choosing their lenses should be done with extra caution.

Another issue while choosing a lens is the surgeon’s prior experience with the lens and his confidence based on prior cases. It is not only personalizing the multifocal intraocular lens power calculation but also the ability to solve problems if they occur and the prior experience of the surgeon with the lens that gives him confidence.

On one hand there are the factors that affect the surgeon’s decision, and on the other hand there is a large variety of lenses available in the market. In this chapter we will summarize the qualities of the most common multifocal intraocular lenses available in the market today in an attempt to give the reader a simple tool or guide to choosing these lenses.

In comparing intraocular lens qualities, we have to define what should be compared and on what scale. It is widely accepted that these lenses should be compared for their performances in far vision, intermediate vision, and near vision. As to far vision we related it to performance of 6 m in distance and defined good far vision as 20/20–20/25 which is 0.8–1.0 decimal and 0.1 LogMAR. The intermediate vision is measured in different studies in different ways and is strongly related to habits and way of life of the studied population. Based on quality of life studies and our own opinion, we defined intermediate vision as vision for a distance of 80 cm that enables us to go to office and do domestic visual tasks such as computer working. Most of the

studies used this distance as the measured intermediate vision distance we defined good intermediate vision as 20/30 or 0.7 decimal or 0.2 in LogMar. Near vision was defined as the vision at a distance of 40 cm which is the acceptable near distance almost in all studies. Good vision was defined as Jaeger 2 or Radner 20/25 which is 0.8 or 0.2 LogMAR.

Contrast sensitivity, night vision, or disturbances were collected from patient’s satisfaction and quality of life questionnaires. This data was collected from the literature published on the subject. Our summary is based on these studies and on our own experience.

The data of the most common multifocal intraocular lenses in the market were collected and summarized in Table 9.1. Along with technical data about the lenses, you will find an evaluation of the lenses in terms of visual acuity performance to far distance, near distance, and intermediate distance as well as contrast sensitivity reduction and night vision photopic phenomena if existing. These evaluations are based on the literature on the subject as published in the English language as well as of our own experience. The last rows give direction to further reading. In each column under each lens name, you will find the row of more reading and numbers indicating sources of more reading material. *These numbers are the numbers of the references attached at the end of the chapter.* At the bottom of the table, you will find abbreviations. If we could not find information about a certain quality of the lens, the initial NA will appear which means “not available yet.”

9.3 Defocus Curves

Another way of comparing lenses’ performance is by using defocus curves. A defocus curve is a universally accepted measure of evaluating the subjective range of clear vision in presbyopia-correction techniques such as accommodating and multifocal intraocular lenses.

A defocus curve provides an indication of the level of vision a patient can expect at various distances, simulated using minus and plus lenses in

a phoropter to change the relative vergence of a distant eye chart. The first step in generating a defocus curve is by measuring the patients' far vision refraction. Using the patient's distance refraction removes the variability due to residual refractive error. The next steps are changing the power of lens in half diopter steps from slightly positive (+1.00 D or +2.00 D) to about -4.00 D. In each refractive correction vergence is measured. Defocus curves are graphs showing the relationship between lens vergence and distance focus. Usually the main interest is in three important points: infinite optical distance vision, intermediate distance at 80 cm, and a short-distance vision at 40 cm. These three points are actually representing the visual performance of the lens, as well as visual and optical quality of the patients in their daily lives.

If the patients' peak (best visual acuity) is at 0.00 diopters, it means that the intraocular lens provides good far vision. If the second peak is at around -2.50 diopters, it means that the lens provides good near vision ($100/2.50 = 40$ cm which is a comfortable reading distance). The height of the curve represents visual acuity in LogMAR, and the horizontal line is the additive lens power. Interpretation of defocus curve in brief is searching for the peaks and to what diopter do they match and the flatness of the curve. Peaks should be at the diopters where we expect good vision for far (0.00 D), intermediate (80 cm or -1.25), and near (40 cm or -2.50 D). Flatness of the curve means that the lenses' performance is similar in each correction. An ideal lens would produce a straight line at the height of LogMAR zero, but this is unachievable. In the following figure a typical defocus curve is represented (Fig. 9.1).

In a recent study done at VISSUM in Alicante, Spain, three multifocal lenses and two accommodative lens defocus curves were checked. The three multifocal lenses that were checked were the AT LISA tri 839 MP; the FineVision trifocal, single-piece, foldable aspheric intraocular lens; and the Bifocal AcrySof ReSTOR SN6AD1 (Alcon, Fort Worth, USA) and the Hanita

SeeLens multifocal. The defocus curves of these lenses are in the following figure and represents typical defocus curves (Fig. 9.2).

As can be seen the four lenses have a peak close to zero which means good far vision. Two of the lenses have a second peak near -2.50 diopters which means good near vision at 40 cm, while the other two have a better near vision by the distance of 50 cm. As a rule, the flatter the curve, the better the performance of the lens. The flatter the curve means that same vision is kept at different distances. However, the visual acuity is important too as the height of the curve's peak means better visual acuity. In the figure one curve is the highest, which means that visual acuity with all corrections was better.

Defocus curves are a useful method to evaluate the effectiveness and visual performance for specific IOL models using different levels of defocus (equivalent to different viewing distances). The problem with defocus curves is that there is no standardized methodology for their measurement; an assortment of different lens powers has been used to evaluate IOLs; for multifocal IOLs, however, defocus curves can be useful for comparing lenses. In a current literature search that we have done, defocus curves of most of the lenses that exist in the market can be found. Different studies use different additive steps; however, comparing these studies does not show a significant difference in terms of the overall performance of the lenses.

We recommend using the table and defocusing curves as good tools to compare different multifocal intraocular lenses, but as mentioned before there is no good substitute to self-experiencing the lenses' implant and learning from the visual outcomes and patients' impression.

Compliance with Ethical Requirements Jorge L. Alio and Joseph Pikkel declare that they have no conflict of interest.

No human studies were carried out by the authors for this article.

No animal studies were carried out by the authors for this article.

Table 9.1 Comparison between various multifocal intraocular lenses

Qual	Manfect									
	Oculentis GmbH		Alcon			Hanita Lenses		Physiol	Aaren	Abbott medical optics
Lens	LENTIS Mplus	LENTIS Mplus T	ReSTOR 2.5	ReSTOR 3	ReSTOR 4	SeeLens	BunnyLens	FineVision	OptiVis	Tecnis
Material	Hydrophobic acrylic	Hydrophobic acrylic	Hydrophobic acrylic	Hydrophobic acrylic	Hydrophobic acrylic	Hydrophobic acrylic	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophobic acrylic
Design	Ref. Sector-shaped near zone	Ref. Sector-shaped near zone	Diffra. 1 piece 9-step	Diff. +Ref.	Diff. +Ref.	Diff.	Diff.	Diff. trifocal	Diff.	Diff.
Optical diameter	6 mm	6 mm	6 mm	6 mm	6 mm	6 mm	6 mm	6.15 mm	6 mm	6 mm
Total diameter	11 mm	11 mm	13 mm	13 mm	13 mm	13 mm	11 mm	10.75 mm	11 mm	13 mm
Implant location	Bag	Bag	Bag	Bag	Bag	Bag	Bag	Bag	Bag	Bag
A constant	118.1	118.1	118.9	118.9	118.9	118.6	118.5	118.59	118.1	118.8
Diopter range	0 to +36	0 to +36	+6.0 to +34.0	+6.0 to +34.0	+6.0 to +34.0	+7.5 to +30.0	+10.0 to +30.0	+10 to +35	+10 to +30	+5.0 to +34.0
Near addition	+1.50,+3.00	+3.00	+2.50	+3.00	+4.00	+3.00	+3.00	+1.75 +3.50	+2.80	+4.00
Contrast sensitiv.	Not affected	Not affected	Decreased	Decreased	Decreased	Decreased	Decreased	Not significantly decreased	Decreased	Decreased
Incision size	2.2–2.6 mm	2.2–2.6 mm	2.2 mm	2.2 mm	2.2 mm	2 mm.	2 mm	1.8–2.2 mm	2.2 mm	2.2 mm
Asphericity	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pupil depend	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Va far	Good	Good	Good	Good	Good	Good	Good	Good	Good	Good
Va near	+3 Good +1.5 limited	Good	Limited	Limited	Limited	Limited	Limited	Good	Limited	Limited
Va intermed.	Good	Good	Good	Good	Good	Reduced	Reduced	Good	Reduced	Not good
Toric	No	Yes	Yes?	Yes	No	No	No	No	No	No
Night Vis	Sectoral halos	Sectoral halos	Halos	Halos	Halos	Halos + glare	Halos + glare	Halos	Halos	Halos +++
Addition. read	11–27		1–10			28		29–35	36	37–52

	Dr. Schmidt	Human	Hoya	Rayner			Carl Zeiss Meditec			Care group
ReZOOM	MS	Diffractive	iSi IOL	Mflex	Mflex T	SulcoFlex	Acrilisa Bi, Tri, T	AT Lisa	Gradiol	iDiff
Acrylic UV protect	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophilic acrylic	Hydrophilic acrylic		Hydrophilic acrylic
Deffr. + Ref.	Diff add on	Diff.	Diff.	Ref.	Ref.	Ref. Add on	Diffr. + Ref. T-Diffractive	Diff.		Ref. + Diff. + asph. surface
6 mm	6 mm	6 mm	6 mm	6.25 mm	6.25 mm	6.5 mm	6 mm	6 mm		6 mm
13 mm	11/06/13	12.5 mm	12.5 mm	12.5 mm	12.5 mm	14 mm	11 mm	809-909-11 MM 801, 802-12.5 mm		1-P: 11 mm 1-R: 12.5 mm
Bag	Sulcus	Bag	Bag	Bag	Bag	Sulcus	Bag	Bag		Bag
118.4	118.6	118.4	118.4	118.6	118.6	118.9	117.8 T -118.3& cyl. +1 to +12	809-117.8 909-118.3 801-118 802-118.1		
+6.00 to +30.0	-3.0 to +31.0	+10 to +34	+14.0 to +27.0	+14.0 to +25	+14.0 to +32.0	Toricity -3.00 to +3.00	-10.0 to +32 & cyl. +1 to +12	0.0 to +30.0		+10.0 to +34.0
+3.50	+3.50	+3.50	+3.00	+3.00,+4.00	+3.00, +4.00	+3.00 +4.00	+3.75	+3.75		+3.50
Decreased	Decreased	NA	NA	Not affected	Not affected	Not affected	Decreased	Decreased		NA
3.2 mm		2.2 mm	2.5 mm	1.8 mm	1.8 mm	2.6 mm	1.5 mm	801-2.2 mm, 802-2.8 mm, 809, 909-1.5 mmnMM		?
No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes		Yes
Yes	Yes	Yes	Yes	Yes	Yes	Yes	No			?
Good	Good	NA	NA	Good	Good	Good	Good	Good		NA
Limited	Limited	NA	NA	Good	Good	Good	Good	Good		NA
Reduced	Reuced	NA	NA	Reduced	Reduced	Reduced	Good	Good		NA
No	No	No	NA	No	Yes	Yes	Yes	Yes		No
Halos + Glare	Halos	NA	NA	Halos + Glare	Halos + Glare	Halos + Glare	Halos + Glare	Halos		NA
78-85	53-55	56, 57	58, 59	60-65			66-77			NA

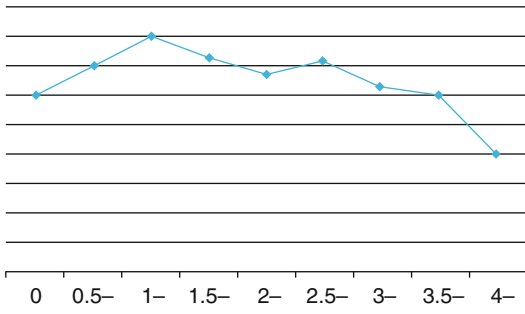


Fig. 9.1 Typical defocus curve: the highest peak is near-far vision. The second peak at near vision

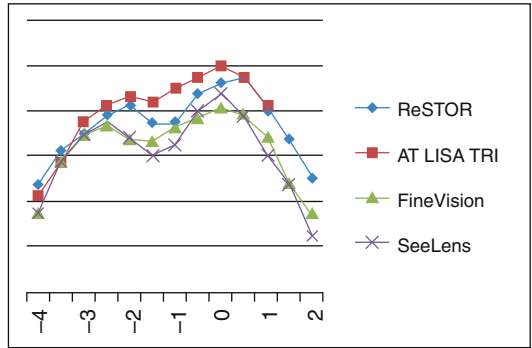


Fig. 9.2 Defocus curves of four multifocal intraocular lenses. The curves enable to quickly compare the performances of the lenses

Diffraction Multifocal IOLs: The Acriva^{UD} Reviol MFM 611 IOL and Acriva^{UD} Reviol MF 613 IOL

10

Minoru Tomita

10.1 Introduction

Multifocal intraocular lens (IOL) implantation, which was introduced more than 20 years ago, has been a popular procedure that achieves good visual acuity for both distance and near vision [1, 2]. In general, there are three types of multifocal IOLs: refractive, diffractive, and a combination of diffractive and refractive lenses' design [3, 4]. Multifocal IOLs with a diffractive optic design have been proven to provide a significantly better near vision and reading performance than refractive multifocal IOLs and monofocal IOLs [5]. With the addition of a +3.75 D near power, good intermediate distance visions from diffractive multifocal IOL models were also proven in previous studies [6, 7]. In this report I will describe our experience and two recent studies, one in which the visual and optical performances were evaluated and compared between two new-generation multifocal IOL models, both with a near addition power of +3.75 D but with different haptic designs, and the other study comparing these lenses' performance to other IOLs in the market with different near additions.

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10.2 Acriva^{UD} Reviol Multifocal IOLs

The diffractive multifocal IOL with a plate haptic design used in this study was the Acriva^{UD} Reviol MFM 611 IOL (VSY Biotechnology, Amsterdam, Netherlands) (Fig. 10.1, left). According to the manufacturer, this diffractive multifocal IOL has 3.75 D of addition power and can provide high-quality far, middle, and near visions. It has been verified to have smooth ridges at the diffractive ring transitions to increase the retinal image quality. It also has a 360° continuous square optic and haptic edge to reduce the PCO formation [6]. The Acriva^{UD} Reviol MF 613 IOL (VSY Biotechnology, Amsterdam, Netherlands) has the same optic design as the Acriva^{UD} Reviol MFM 611 IOL, but with a modified C haptic design (Fig. 10.1, right). The C haptic size is 13.00 mm with 0° haptic angle. Both multifocal IOL models are made of hydrophilic acrylic with a hydrophobic surface. Sixty percent of the intraocular light was allotted for far focus and 40 % for near.

10.3 Comparison of Acriva^{UD} Reviol MF 613 IOL with Acriva^{UD} Reviol MFM 611 IOL

In a prospective single-center study, cataract patients who underwent cataract surgery with diffractive multifocal IOL implantation from June

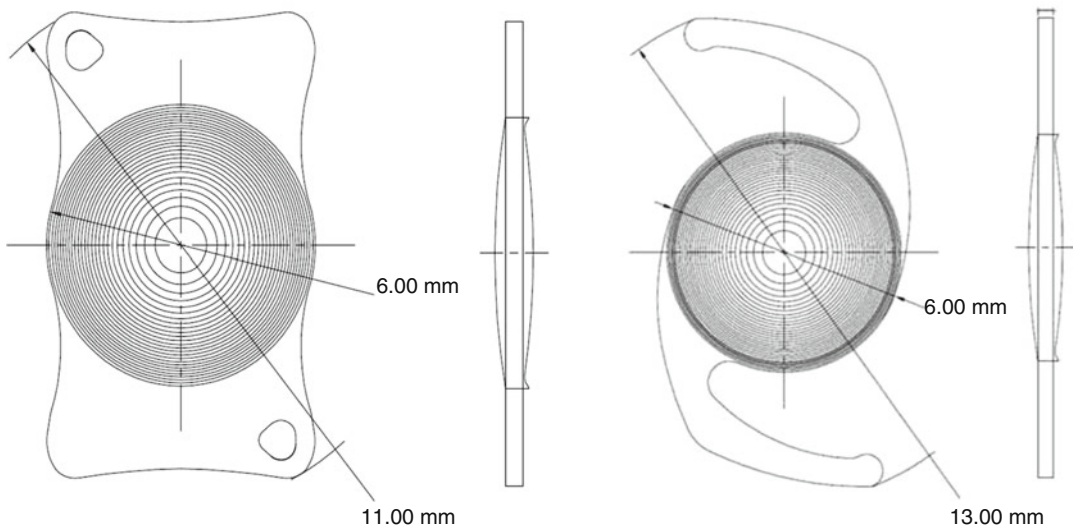
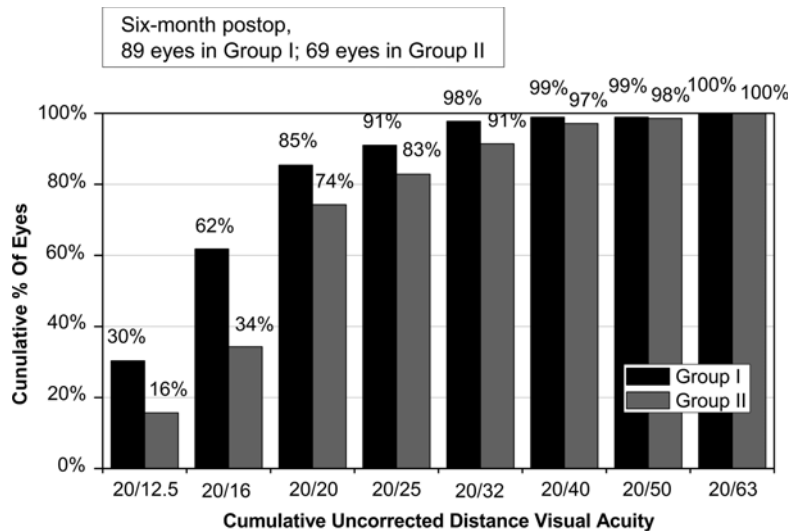


Fig. 10.1 A general view of the Acriva^{UD} Reviol MFM 611 lens (*left*) and the Acriva^{UD} Reviol MF 613 IOL (*right*)

Fig. 10.2



2012 to May 2013 at the Shinagawa LASIK Center, Tokyo, Japan, were assessed. A total of 158 eyes of 107 patients were included in this study. These eyes were randomly divided into two groups and implanted with multifocal IOLs: Acriva^{UD} Reviol MFM 611 for Group I and Acriva^{UD} Reviol MF 613 for Group II. Group I consisted of 89 eyes of 62 patients aged between 47 and 76 years (mean age, 60.74 ± 5.92 years) and Group II, 69 eyes of 45 patients aged between 45 and 73 years (mean age, 61.13 ± 5.46 years). All surgeries were performed by the same sur-

geon (M.T.) using femtosecond laser-assisted phacoemulsification [8]. After topical anesthesia and adequate dilation, femtosecond laser (CatalysTM Precision Laser System, OptiMedica Corp., Sunnyvale, California, United States) was used for the continuous curvilinear capsulorhexis (CCC) and lens fragmentation of all cataracts. The incision was created on the steepest corneal meridian. Viscoelastic material (ProViscTM, Alcon Corp., Fort Worth, Texas, United States) was injected, and the cut capsule was removed. Phacoemulsification was performed using the

Fig. 10.3

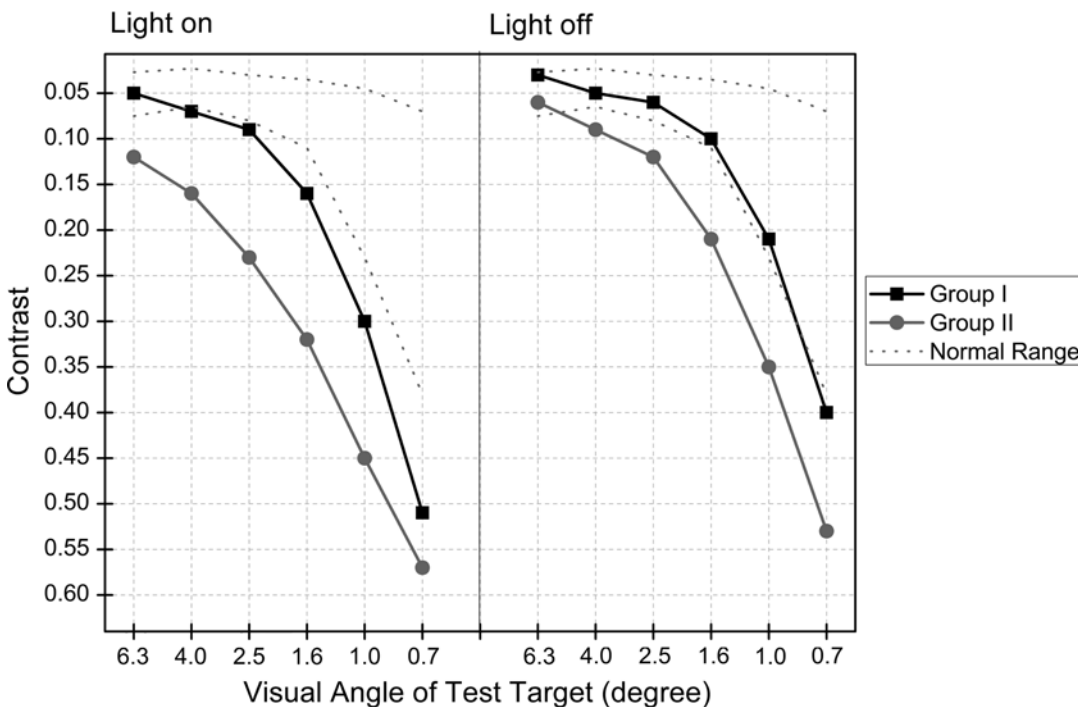
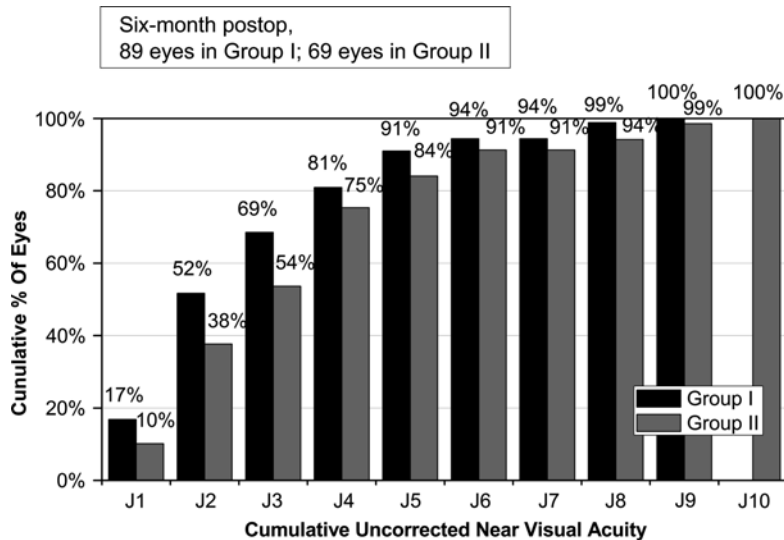
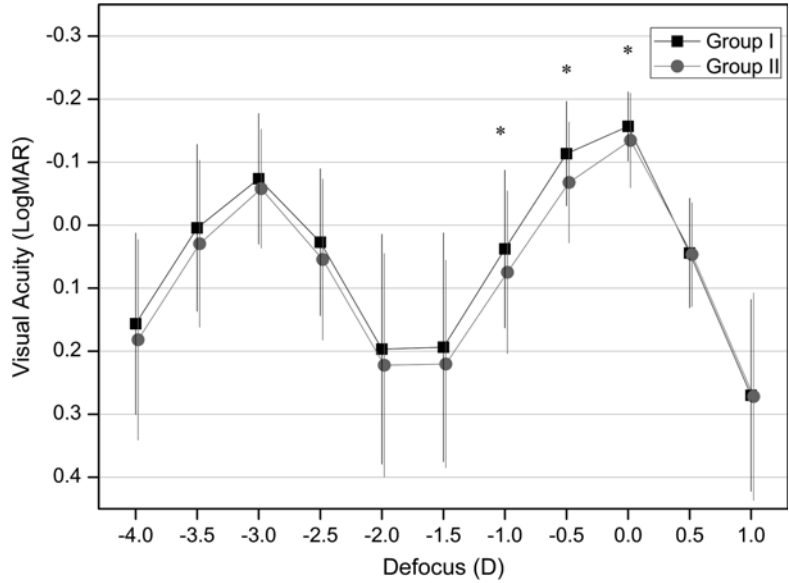
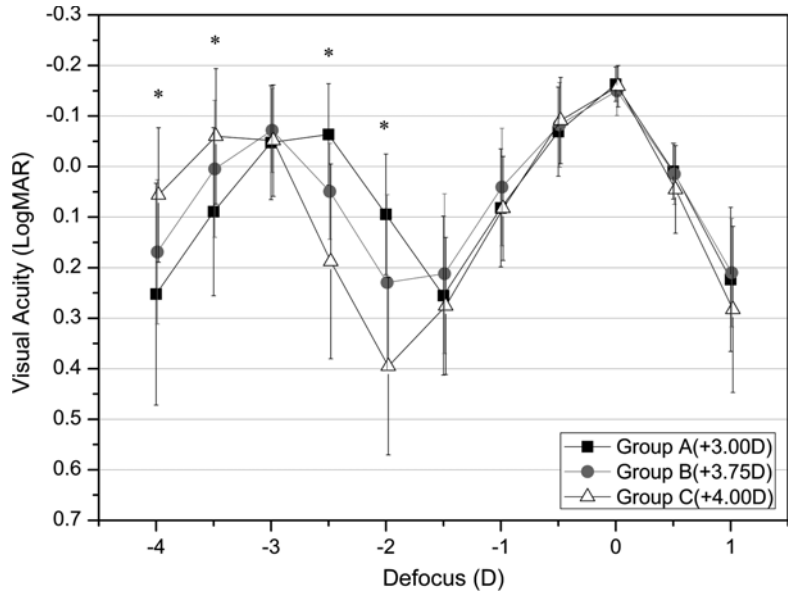


Fig. 10.4

INFINITI[®] Vision System (Alcon Corp., Fort Worth, Texas, United States). The foldable multifocal IOL was inserted and rotated into the intact capsular bag. The viscoelastic material was completely removed by irrigation and aspiration. All incisions were left sutureless.

No statistically significant differences in terms of age, visual acuity, and refractive parameters

were found between the two groups preoperatively ($P > 0.05$). At 6 months postoperatively, significant improvements in UDVA, CDVA, MRSE, UNVA, and CNVA were found in both groups ($P < 0.05$). Comparing the two groups, plate haptic multifocal IOLs (Group I) provided statistically better outcomes in UDVA, CDVA, and CNVA ($P < 0.05$).

Fig. 10.5 Defocus curves**Fig. 10.6** Defocus curves with near correction

In our opinion, these differences between the two diffractive multifocal IOL models might have been caused by their different positional stabilities within the capsular bags. Compared with monofocal and refractive multifocal IOLs, even a small misalignment of the central concentric rings can lead diffractive multifocal IOLs to provide significantly reduced results [9–13].

10.4 Comparison of Visual and Optical Performances of Multifocal Intraocular Lenses with Three Different Near Additions

In recent years, several kinds of multifocal IOL models with different near additions are available, such as +3.00 D, +3.50 D, +3.75 D, or

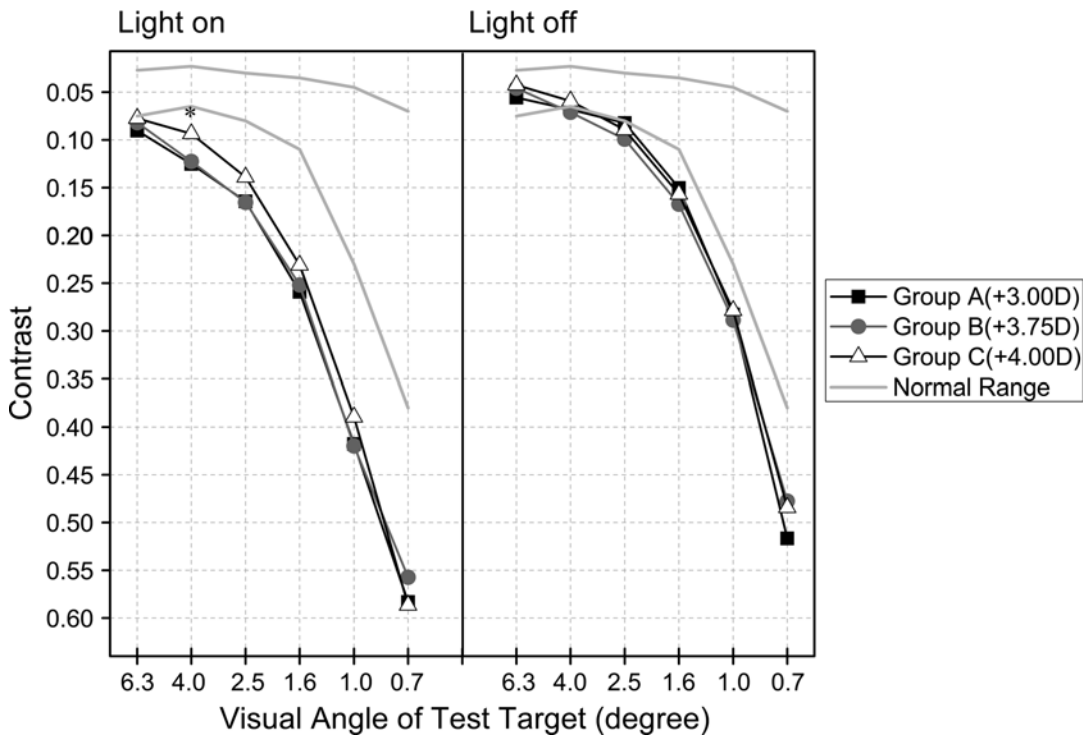
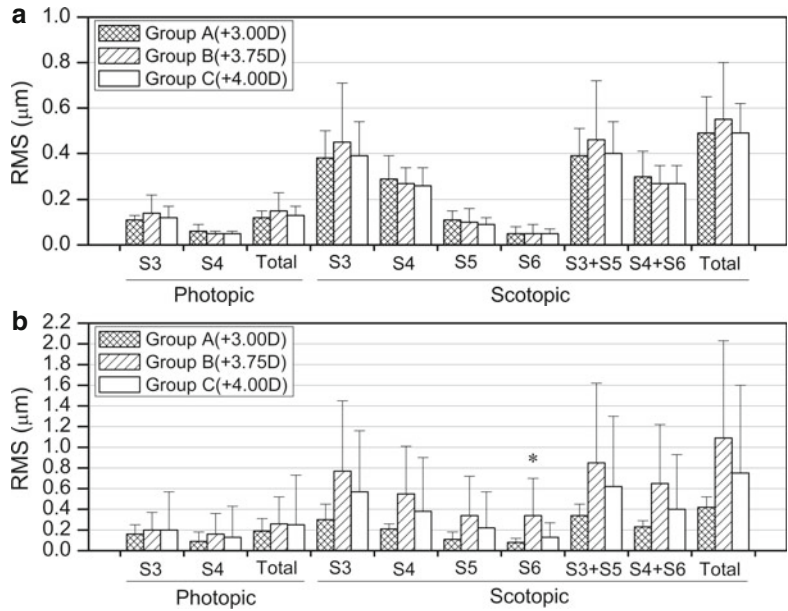


Fig. 10.7

Fig. 10.8 Photopic and scotopic performance



+4.00 D [5, 14]. The AcrySof® ReSTOR® SN6AD1 IOL (Alcon Corp., Fort Worth, Texas, United States) and AcrySof® ReSTOR® SN6AD3 IOL (Alcon Corp., Fort Worth, Texas, United States) have been proven in previous studies to two efficient aspheric IOL models with near additions of +3.00 D and +4.00 D [15, 16]. A more recent brand of diffractive multifocal intraocular lens is the Acriva^{UD} Reviol, which provides +3.75 D near addition for its two models, BB MF 613 and BB MFM 611. Having the same optic design, these two models claim to yield satisfactory far, intermediate, and near vision; the BB MFM 611 model had already been proven to provide effective visual acuities and contrast sensitivities [6]. The aim of the study is to evaluate and compare the visual and optical performances of the eyes after implanting these four multifocal IOL models with three different near additions, +3.00 D (AcrySof® ReSTOR® SN6AD1), +3.75 D (Acriva Reviol^{UD} BB MF 613 and BB MFM 611), or +4.00 D (AcrySof® ReSTOR® SN6AD3).

10.4.1 AcrySof® ReSTOR® SN6AD1 and SN6AD3

Both AcrySof® ReSTOR® SN6AD1 and SN6AD3 consist of a peripheral refractive zone and a central zone with a 3.6 mm apodized diffractive design. The apodized diffractive region is situated in the central 3.6 mm optic zone of the IOL. The corresponding diffractive structures of the AcrySof® ReSTOR® SN6AD1 and SN6AD3 have 9 and 12 steps, which provides near addition power of +3.00 D and +4.00 D.

10.4.2 Acriva Reviol BB MF 613 and BB MFM 611

The two +3.75 D multifocal IOL models, Acriva Reviol BB MF 613 and BB MFM 611, have a different diffractive ring distribution, which provides excellent far, middle, and near vision. Its special polished active-diffractive surface minimizes unwanted scattered light and halos and

offers the patient high contrast sensitivity even during night vision.

In a prospective single-center study comprised of cataract patients who had phacoemulsification with multifocal IOL implantation from January 2009 to December 2012 at the Shinagawa LASIK Center, Tokyo, Japan, 133 eyes from 88 patients (58 women and 30 men) were included. These eyes were randomly divided into three groups: Group A consisted of eyes implanted with multifocal IOLs with AcrySof® ReSTOR® SN6AD1 IOLs (+3.00 D); Group B had eyes with Acriva^{UD} Reviol BB MF 613 or BB MFM 611 IOLs (+3.75 D); and Group C eyes were implanted with AcrySof® ReSTOR® SN6AD3 IOLs (+4.00 D).

Surgical technique and postoperative treatments were the same as in the previous study described in this chapter.

There were no statistically significant differences in terms of gender, age, IOL power, UDVA, sphere, cylinder, MRSE, UNVA, intraocular pressure, or ECD among the three groups preoperatively ($P > 0.05$). The mean values of CDVA and CNVA in the eyes of Group B were statistically significantly better than the eyes of Group C ($P = 0.0258$ and $P = 0.0266$, respectively).

There were no statistically significant differences in UDVA, CDVA, sphere, cylinder, MRSE, intraocular pressure, or corneal endothelial cell density among the three groups ($P > 0.05$). The mean values of UNVA and CNVA in the eyes of Group C were significantly better than the eyes of Group A ($P = 0.0284$ and $P = 0.0062$, respectively).

Conclusions

The advantages of Acriva^{UD} Reviol BB MFM 611 IOL and BB MF 613 IOL are as follows:

- *Ideal additional power (+3.75 D)*

The mean highest near visual peak with Acriva^{UD} Reviol BB MFM 611 IOL and BB MF 613 IOL was found to be at 33 cm (−3.00 D) in our study. This distance was ideal for near acuity tasks such as reading books, using mobile phone, and checking the time on the wristwatch.

- *Provide excellent far, intermediate, and near vision*
Compared to other multifocal lenses, Acriva^{UD} Reviol series maintain less visual distortion and have a large range of accommodation, thus providing independence from spectacles.
- *High optic quality*
Acriva^{UD} Reviol series demonstrate high contrast sensitivity even during night vision. It is also designed to correct the positive aberration of the cornea as it has aspheric structure and aberration control which is termed the “ultra definition” technology.
- *Pupil independent*
With the IOL’s diffractive design, quality vision can be obtained independent of pupil size.
- *Premium material*
Acriva^{UD} Reviol series are made of an ultrapure acrylate monomer. It contains 25 % water and has a hydrophobic surface. With the hydrophobic surface, the risk for posterior capsule opacification remains at a minimal level.

Compliance with Ethical Requirements No animal studies were carried out by the authors for this article.

Dr. Tomita is a consultant for VSY.

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.

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and Esperanza Sala Pomares

11.1 Introduction

Diffractive multifocal intraocular lenses (IOLs) follow the Huygens–Fresnel principle. These IOLs generate interference patterns using multiple diffractive rings to create two primary focal points independent of the pupil size [1]. A side effect produced by this type of multifocal IOL is a reduction in contrast sensitivity compared to monofocal IOLs. To avoid this effect the apodized diffractive multifocal IOLs were designed. For apodized designs [1] the step height of the diffractive elements is reduced from the centre to the periphery. However, it should be noted that dysphotopsia, including halos and glare, is still observed with apodized multifocal IOLs.

The spherical AcrySof ReSTOR SN60D3 IOL incorporated an apodized hybrid diffractive–

refractive structure to create an IOL with two focal points. At present, three aspheric successors of this multifocal IOL are available: the AcrySof ReSTOR SN6AD3 IOL with a near addition of 4.00 diopters (D), the AcrySof ReSTOR SN6AD1 IOL with a near add of 3.00 D, and the AcrySof ReSTOR SV25T0 with a near add of 2.50 D. Aspheric IOLs provide negative spherical aberration [2] to improve contrast sensitivity [3], whereas spherical IOLs add to rather than counterbalance the positive spherical aberration of the cornea. Figure 11.1 shows a general view of the AcrySof ReSTOR SN6AD3.

The 3.00 D model was designed to provide better intermediate vision without compromising near or distance visual acuity. De Vries et al. [4] have demonstrated that the AcrySof ReSTOR SN6AD1 IOL gave better results than the AcrySof ReSTOR SN6AD3 IOL in intermediate vision without compromising near and distance visual acuity and contrast sensitivity. Therefore, the 4.00 D model is indicated for patients with a strong preference for a shorter working distance and lower visual expectations for intermediate vision. Recently, the AcrySof ReSTOR SV25T0 has been introduced into clinical practice. This IOL model has a near add power of 2.50 D, the goal of this IOL is to improve intermediate vision as previous studies report that low add multifocal IOLs improve intermediate visual acuity [4–6].

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Fig. 11.1 A general view of the AcrySof ReSTOR SN6AD3

11.2 AcrySof ReSTOR SN6AD3 IOL (+4.0 D Near Addition)

The AcrySof ReSTOR SN6AD3 IOL (4 D addition in the lens plane) is designed to provide quality near to distance vision by combining apodized diffractive and refractive technologies [7–10]. The centre of the IOL surface consists of an apodized diffractive optic (3.6 mm diameter) that focuses light for near through distance. The refractive region of the IOL is aspherical and it bends light as it passes through the lens to a focal point on the retina.

11.2.1 Results

11.2.1.1 Visual and Refractive Outcomes

A significant improvement after surgery in the uncorrected (UDVA) and corrected distance visual acuities (CDVA) was observed (Wilcoxon test; UDVA $p < 0.01$, CDVA $p = 0.05$) in a study of 40 eyes of 20 bilateral cataract patients with ages ranging between 49 and 80 years. In addition, a statistically significant improvement was observed postoperatively in UNVA and CDNVA (Wilcoxon test, $p < 0.01$). No significant changes were observed in the CNVA with the surgery (Wilcoxon test, $p = 0.65$). Regarding subjective refraction, no significant changes were observed in the manifest cylinder (Wilcoxon test; $p = 0.95$). In contrast, the sphere was significantly modified in those eyes implanted with the ReSTOR +4 IOL (Wilcoxon test, $p = 0.03$). As expected, a significant improvement in the distance visual outcomes was achieved after IOL implantation. This was consistent with previous findings reported by other studies [4–6, 10–13].

11.2.1.2 Contrast Sensitivity Outcomes

Figure 11.2 shows the postoperative contrast sensitivity outcomes after implantation of the AcrySof ReSTOR SN6AD3. As shown, photopic and low contrast sensitivity outcomes are within the normal range for the same age sample for all spatial frequencies. In a previous study [14] no differences were detected between this IOL model and a diffractive multifocal IOL; in this same study when the ReSTOR +4.0 D model was compared to a monofocal IOL, the monofocal IOL provided higher values of contrast sensitivity outcomes.

11.2.1.3 Defocus Curve Outcomes

Figure 11.3 shows the mean defocus curve for eyes implanted with the AcrySof ReSTOR SN6AD3. As shown in the defocus curve, this ReSTOR model provides two peaks of maximal vision with a trough for intermediate vision at -1.0 D defocus level. In a previous publication [13] when this model of ReSTOR IOL was compared to a diffractive multifocal IOL, no differences were observed in the defocus curve for any

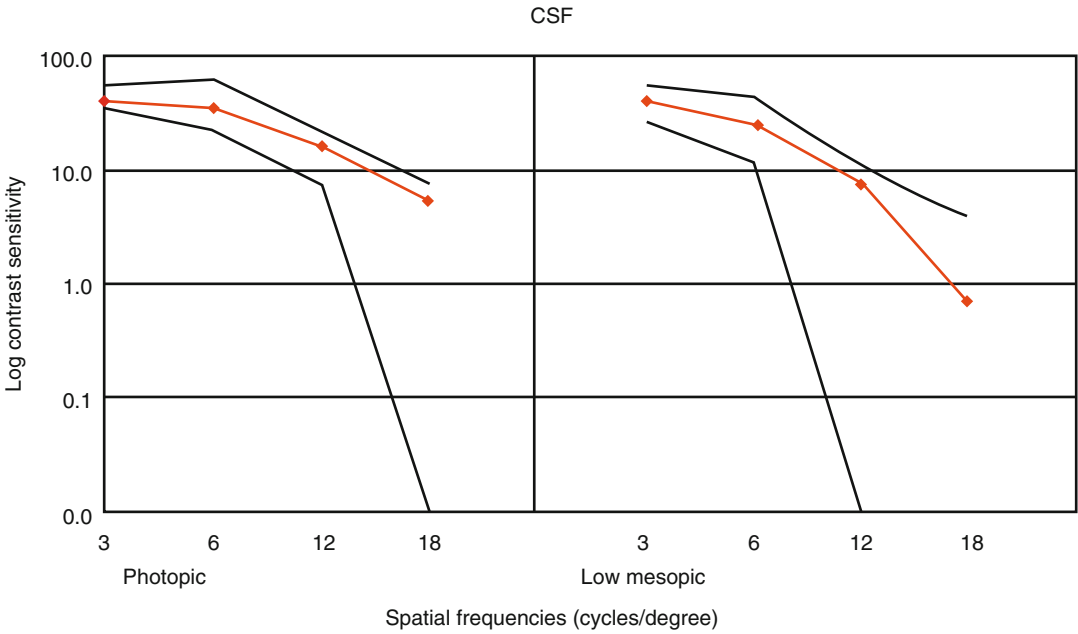


Fig. 11.2 Mean photopic and low mesopic contrast sensitivity of the AcrySof ReSTOR SN6AD3. Photopic and low mesopic contrast sensitivity are within the normal limits for all spatial frequencies. *Orange line*: contrast sensitivity obtained with the AcrySof ReSTOR SN6AD3, *grey lines*: normal values of contrast sensitivity for the same age sample

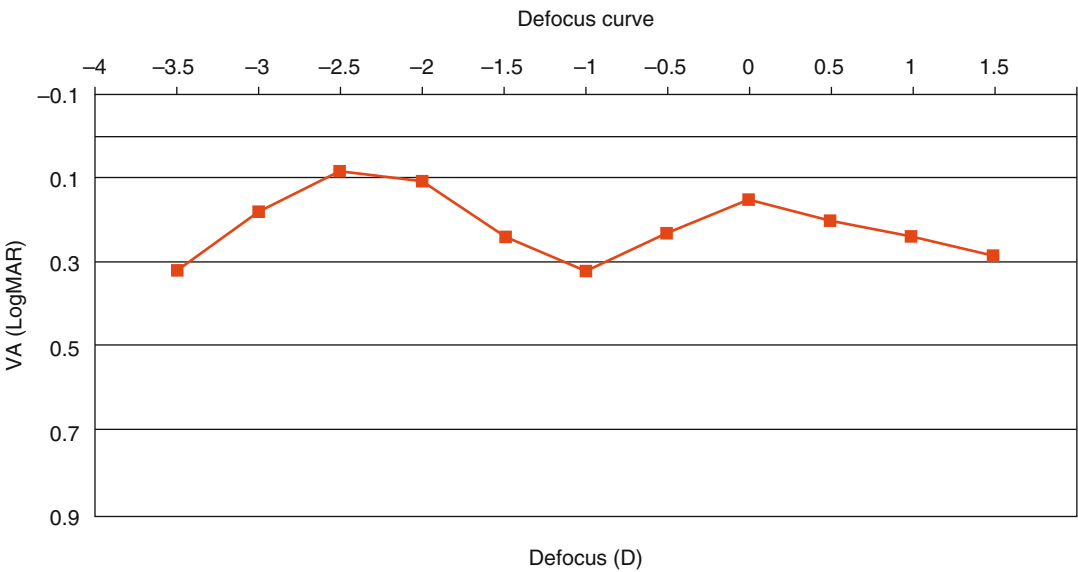


Fig. 11.3 Mean defocus curve of the AcrySof ReSTOR SN6AD3 multifocal IOL. This pattern shows a good distance and near visual acuity with a decrease in intermediate vision

defocus levels. In contrast, when the ReSTOR +4 IOL model was compared to a sectorial refractive multifocal IOL, the sectorial multifocal IOL

showed better visual acuity for the intermediate defocus levels than the AcrySof ReSTOR SN6AD3 [14].

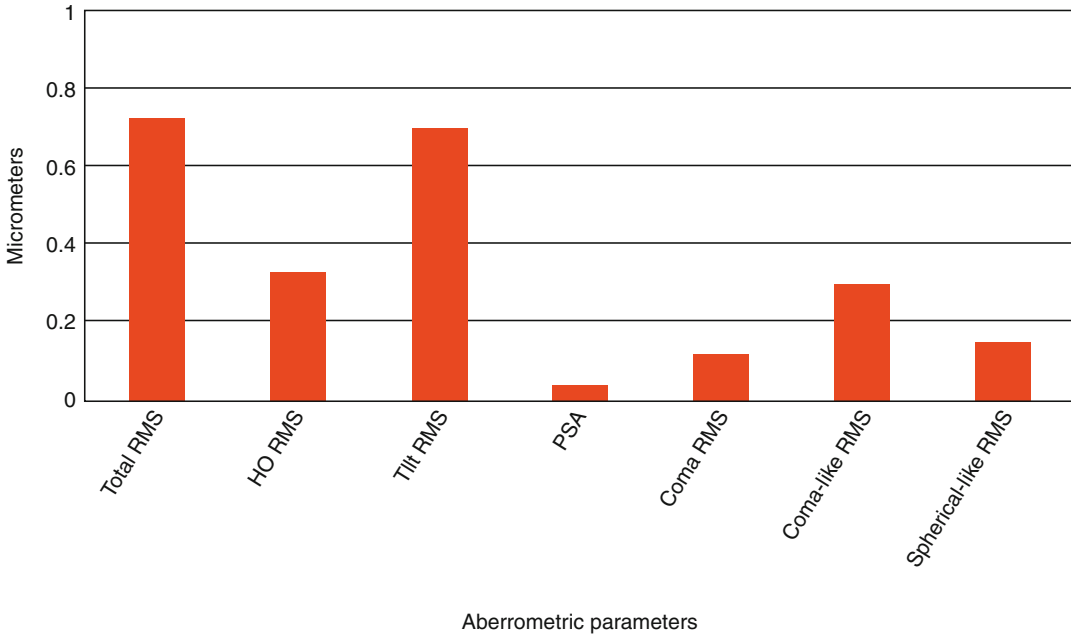


Fig. 11.4 Mean postoperative intraocular aberrations calculated by means of the VOL-CT software of the AcrySof ReSTOR SN6AD3. Total and tilt RMS have higher values

11.2.1.4 Optical Quality Outcomes

The postoperative optical quality measured with the OQAS system provided the following results: the Strehl ratio was 0.13 ± 0.03 and the cut-off MTF frequency was 20.68 ± 5.39 cycles/degree. Santiago et al. [6] have been demonstrated that there were no differences in these parameters between this model and the AcrySof ReSTOR SN6AD1. Also, in our prior investigation [15] when the AcrySof ReSTOR SN6AD3 was compared to a sectorial refractive multifocal IOL, no differences were detected. In contrast, in a previous study [14] the AcrySof ReSTOR SN6AD3 showed significantly lower values than a full diffractive bifocal IOL.

Regarding the postoperative intraocular optical quality, Fig. 11.4 shows the mean postoperative intraocular aberrations after implantation of the AcrySof ReSTOR SN6AD3 multifocal IOL. As shown, higher values were found for the total and tilt RMS, when the intraocular aberrometric parameters were compared to a monofocal IOL, lower values of total, spherical and spherical-like RMS were described for the AcrySof ReSTOR SN6AD3 multifocal IOL [14].

In addition, the intraocular Strehl ratio obtained with the ReSTOR +4 IOL model was 0.32 ± 0.05 ; no differences in this parameter were described previously [14] in comparison to a full diffractive IOL. Figure 11.5 shows a diagram with the analysis of the intraocular optical quality for a 5.0-mm pupil of one case implanted with the AcrySof ReSTOR SN6AD3.

11.3 AcrySof ReSTOR SN6AD1 IOL (+3.0 D Near Addition)

The AcrySof ReSTOR SN6AD1 IOL (3.0 D addition in the lens plane) is designed to provide quality near to distance vision by combining apodized diffractive and refractive technologies. The centre of the IOL surface consists of an apodized diffractive optic (3.6 mm diameter) that focuses light for near through distance. The refractive region of the IOL bends light as it passes through the lens to a focal point on the retina. This outer ring of the lens surrounds the apodized diffractive region and is dedicated to focusing light for distance vision.

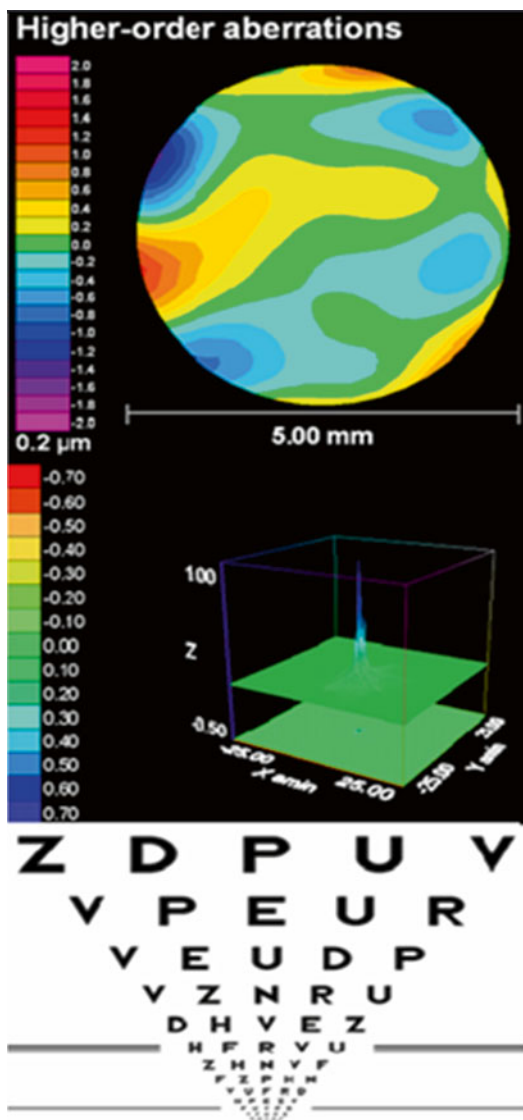


Fig. 11.5 Diagram showing the analysis of the in vivo intraocular optical quality for a 5.0 mm pupil of the AcrySof ReSTOR SN6AD3. *Top row:* intraocular wave front higher order aberrations. *Middle row:* 3-D PSF (point spread function). *Bottom row:* Snellen optotype simulation considering only the effect of higher order aberrations

11.3.1 Results

11.3.1.1 Visual and Refractive Outcomes

At 1 month after surgery, a statistically significant improvement was observed in the uncorrected

distance visual acuity (UDVA), in corrected distance visual acuity (CDVA), and uncorrected near visual acuity (UNVA) (Wilcoxon test, all $p \leq 0.03$) in 62 eyes of 37 cataract patients with ages ranging between 48 and 86 years. No statistical significant differences were detected in corrected near visual acuity (CNVA) after surgery ($p=0.18$).

Regarding manifest refraction, a significant decrease was found in the sphere and spherical equivalent 1 month after surgery (Wilcoxon test, $p=0.01$). In contrast, no significant changes in the manifest cylinder were detected (Wilcoxon test, $p=0.46$). As expected, a significant improvement in distance visual outcomes and in UNVA were achieved after IOL implantation. This was consistent with previous findings reported by other studies using the same IOL [4–6, 16–21], confirming the expectations on the safety of cataract surgery with the evaluated MIOL.

11.3.1.2 Contrast Sensitivity Outcomes

Figure 11.6 shows the mean postoperative contrast sensitivity function in logarithmic scale measured under photopic and scotopic conditions 3 months after surgery. As shown, photopic and low mesopic contrast sensitivity was within the photopic and low mesopic normal limits for the sample age for all spatial frequencies.

11.3.1.3 Defocus Curve

Figure 11.7 shows the mean defocus curve of the patients analysed. As shown, this multifocal IOL was able to provide two peaks of maximum vision, one at distance (around 0 D defocus level) and one at near (around -2.5 D defocus level). Between these two peaks an acceptable intermediate vision was maintained. Alfonso et al. [5] compared the intermediate vision between the AcrySof ReSTOR SN6AD1 and the AcrySof ReSTOR SN6AD3 and found better results with the $+3.0$ D model.

11.3.1.4 Optical Quality Outcomes

Figure 11.8 shows the optical quality outcomes through the mean corneal, internal and ocular wavefront aberration values 3 months

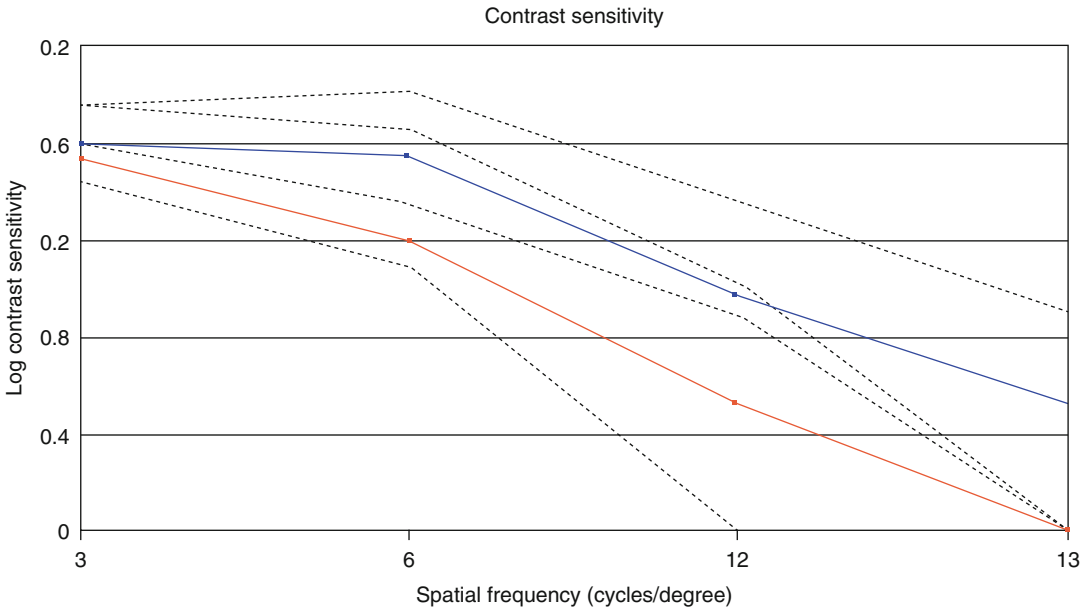


Fig. 11.6 Mean photopic and low mesopic contrast sensitivity of the AcrySof ReSTOR SN6AD1. Photopic and low mesopic contrast sensitivity are within the normal limits for all spatial frequencies. *Blue line*: photopic contrast sensitivity, *orange line*: scotopic contrast sensitivity, *black discontinuous lines*: normal values of photopic contrast sensitivity for the same age sample, *grey discontinuous lines*: normal values of low mesopic contrast sensitivity for the same age sample

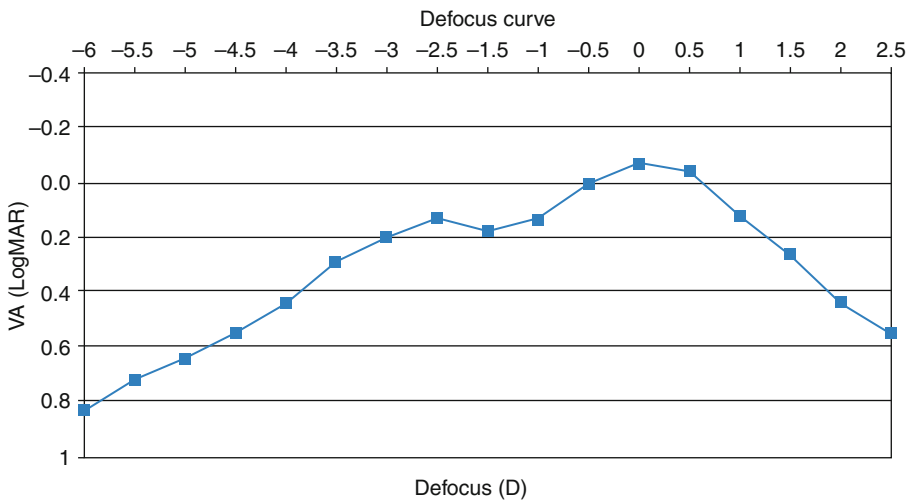


Fig. 11.7 Mean defocus curve of the AcrySof ReSTOR SN6AD1 multifocal IOL. This pattern shows a good distance and near visual acuity with an optimal intermediate vision

postoperatively. As shown, no larger values of these aberrometric parameters were observed after implantation of the AcrySof ReSTOR

SN6AD1 multifocal IOL. Toto et al. [22] demonstrated that the ReSTOR +3 model induced less spherical aberration than ReSTOR +4.

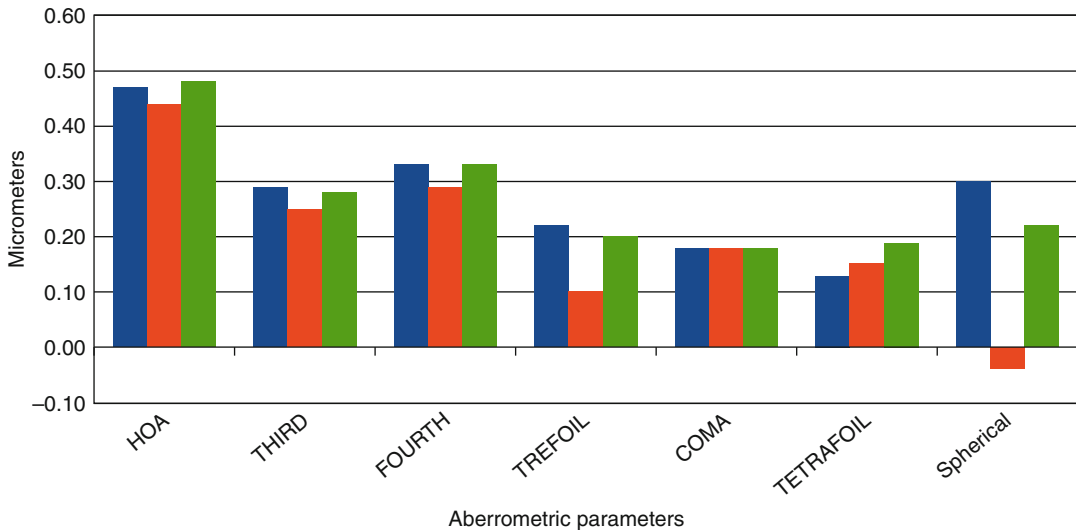


Fig. 11.8 Mean postoperative aberrometry measured by means of the KR-1 W aberrometer after implantation of the AcrySof ReSTOR SN6AD3. *Blue bars*: corneal aberrations, *orange bars*: internal aberrations, *green bars*: ocular aberrations

Conclusions

AcrySof ReSTOR SN6AD3 and AcrySof ReSTOR SN6AD1 provide good visual rehabilitation after cataract surgery with excellent visual outcomes for distance and near vision. Contrast sensitivity values are within the normal limits for the same age sample for both multifocal IOL models. However, the AcrySof ReSTOR SN6AD1 provides better intermediate visual acuity with a lower induction of spherical aberration.

Compliance with Ethical Requirements Ana Belén Plaza Puche, Jorge Alio and Esperanza Sala Pomares declare that they have no conflict of interest.

Informed consent:

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 article.

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Apodized Diffractive Multifocal Intraocular Lens: AcrySof ReSTOR SN6AD2 +2.5

12

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and Giorgio Marchini

12.1 Introduction

The AcrySof ReSTOR (Alcon Laboratories, Fort Worth, Texas, USA) line of multifocal intraocular lenses (MIOLs) were designed using three different but complementary optical principles (refraction, diffraction, and apodization) in order to obtain maximum visual acuity at a wider range of distances. The refractive portion of the optic functions like a standard intraocular lens (IOL). The optic periphery is dedicated to distance vision and designed to optimize night vision when the pupil is enlarged under scotopic conditions. The apodized diffractive optic region occupies the center of the lens and is formed by concentric rings that gradually decrease in step-height from the center of the optic to the periphery of the diffractive region. This affects the passing light by redistributing it into two focal points: one near and the other distant. As the

pupil dilates, the proportion of light directed to the near focal point decreases and the proportion directed to the distant focal point increases [1, 2].

The ReSTOR® SN6AD2 +2.5 diopters (+2.5 D) (Fig. 12.1 and Table 12.1) received the CE approval in Europe in 2012 but to date has not been approved by the FDA nor is available in the United States. This IOL was introduced as an option to the ReSTOR® SN6AD1 +3 D for use in cases where an intermediate vision (at distances between 0.4 and 0.7 m) is required. The apodized

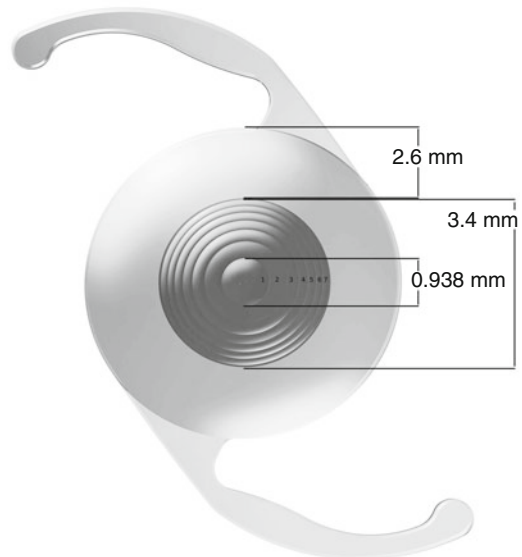


Fig. 12.1 An image of the ReSTOR® +2.5 D showing the technical characteristics and specifications

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Table 12.1 Technical characteristics of the ReSTOR® SN6AD2 +2.5 D

Material	Hydrophobic acrylate
Asphericity (microns)	-0.2
Additional power (D)	+2.5
Additional power to corneal plane (D)	+2.0
Number of concentric steps	7
Central region diameter (mm)	0.938
Optic diameter (mm)	6.0
Internal diffractive structure (mm)	3.4
External refractive structure (mm)	2.6
Refractive index	1.55

diffractive 3.4 mm central area of the SN6AD2 IOL consists of seven concentric steps that have a wider spacing than the nine steps of the SN6AD1 IOL and provides an addition of +2.5 D. The monofocal center and external regions are 9.6 and 8.3 % larger, respectively, than those of the SN6AD1 IOL, that is, 0.938 mm versus 0.856 mm for the center and 2.6 mm versus 2.4 mm for the periphery. These differences ensure the passage of a greater amount of light with a lower dispersion for distance vision. Given that this design incorporates fewer but wider concentric rings, the higher ratio of distant to near light should improve the quality of vision while decreasing side effects like halos and glare (Fig. 12.1 and Table 12.1).

12.2 Studies on ReSTOR® +2.5 D

Currently, there are only a limited number of studies that evaluated the effectiveness of the ReSTOR® SN6AD2 +2.5 D in terms of visual acuity and quality of vision. This is mostly due to the fact that the IOL was only recently available commercially.

Gudersen and Potvin [3] implanted 64 eyes with the ReSTOR® +2.5 D and showed that the best reading distance was at 50 cm with an important decrease of the visual acuity at 40 cm. The larger monofocal central area ensured that the patients achieved an excellent low contrast distance visual acuity, yielding results closer to a monofocal IOL when compared to the ReSTOR® +3 D even though this difference was not statistically significant. When evaluating the quality of

vision, the authors did not find significant differences between the +2.5 D and +3 D IOL, and the level of visual disturbances evaluated with the Quality of Vision Questionnaire was similar for both IOLs. In light of these results, they hypothesized that leaving the choice to the patient after an accurate explication of the lens options and of the possible side effects can increase the tolerance after surgery.

Costa et al. [4] conducted a comparative study about the optical quality of three different MIOLs: the ReSTOR® +3 D; the ReSTOR® +2.5 D; and a trifocal IOL, the AT LISA tri 839 MP (Carl Zeiss Meditec, Dublin, CA) [4]. They evaluated, *in vitro*, the Modulation Transfer Function (MTF) of these IOLs at different focal points. The MTF is an objective measurement of contrast sensitivity representing the loss of contrast produced by the optics of the eye on a sinusoidal grating as a function of spatial frequency [5]. The authors showed that the best quality of vision for distance was achieved from the +2.5 D IOL. This result was in accordance with expectations given that the IOL was designed to retain more light for distant objects. At intermediate distances, this IOL obtained better results than the +3 D IOL but lower if compared to the trifocal IOL. They concluded that the ReSTOR® +2.5 D could be indicated for patients who want a sufficient range of vision covering near and intermediate distances without compromising the outcome in terms of quantity and quality of distance vision.

12.3 Our Clinical Experience with ReSTOR® +2.5 D

The lack of studies evaluating the effectiveness of the ReSTOR® +2.5 D lens and of studies comparing this IOL to other MIOL models inspired us to assess visual outcome obtained with SN6AD2 +2.5 D in comparison to a previous ReSTOR® model (SN6AD1 +3 D). In our prospective study (Pedrotti E. et al. 2013, unpublished data), we assessed the visual outcome of these two MIOLs in terms of visual acuity, contrast sensitivity, and high-order aberrations. Here we report the preliminary results in patients with a 6-month post-operative follow-up.

12.4 Preoperative Planning and Surgical Approach

We calculated the IOL power with the IOL Master (Carl Zeiss Meditec, Jena, Germany), using the SRK-T formula (constant: 119.2). A comparison between the autokeratometry and the corneal topography was always performed. All eyes were targeted for emmetropia. In order to guarantee a maximization of patient satisfaction, astigmatisms higher than 1 diopter were excluded for the implantation of this lens. In included patients with a cylinder between 0.5 and 1 D, we routinely performed limbal relaxing incision or an incision on the deep axis when possible.

The ReSTOR® +2.5 is a foldable IOL designed for placement within the capsular bag at the time of phacoemulsification. In this study it was injected using a cartridge through the traditional clear corneal incision. A continuous curvilinear capsulorhexis smaller than the IOL optic (ideally with a 0.5 mm overlap) was executed in order to reduce the risk of tilting and decentration of the lens over time, which could produce subjective symptoms such as halos and glare. Ideally, a femtolasar-assisted capsulorhexis should be used for MIOL centration since this method has been shown to yield the most precise and reproducible capsulorhexis [6].

12.5 Visual Acuity Assessment

The previous models of the ReSTOR® line are the SN6AD3 +4 D and the SN6AD1 +3 D, available since 2005 and 2008, respectively. The higher visual acuity for near is about 32 cm for the +4 D IOL and 40 cm for the +3 D IOL [7, 8]. Several studies show how decreasing the additional power to the corneal plane gives a farther preferred reading distance [8–10]. The availability of different lens models permits the surgeon to customize the procedure according to the patient's needs and expectations.

For our patients, we evaluated the IOL properties in terms of monocular vision at 30, 40, 50, 60, and 70 cm. As expected, the ReSTOR® +2.5 D yielded better results at all intermediate distances, while for nearest vision the ReSTOR® +3 D gave better uncorrected visual acuity.

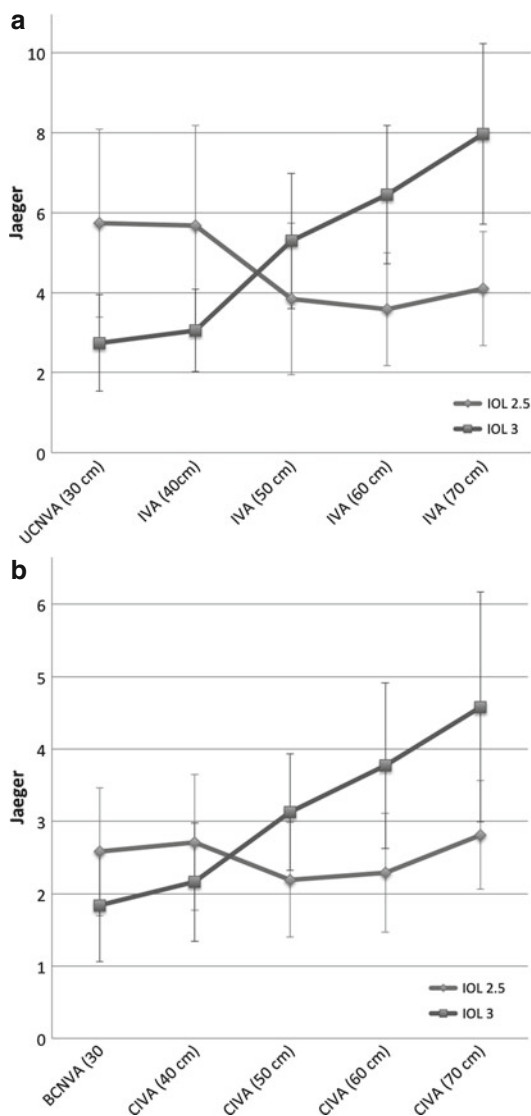


Fig. 12.2 Uncorrected visual acuity (a) and best corrected visual acuity (b) observed at a 6-month follow-up after implantation of ReSTOR® SN6AD2+2.5 D (diamonds) and SN6AD1 +3 D (squares) multifocal intraocular lenses. Error bars indicate standard deviation for group means ($N=25$ consecutive patients per group). Group differences were evaluated with an unpaired two-sided student's t-test with Bonferroni correction for multiple comparisons and yielded statistically significant differences at all distances. (UCNVA uncorrected near visual acuity, IVA intermediate visual acuity, BCNVA best corrected near visual acuity, CIVA corrected intermediate visual acuity)

Figure 12.2 and Table 12.2 highlight the visual trend inversion at about 45 cm. Furthermore, we studied the defocus curve and visual performance, assessment in terms of binocular vision.

Our results underlined how the ReSTOR® +2.5 D yielded better results at intermediate distances but also how matching IOLs with different additional power in fellow eyes gives a wider range of spectacle independence (Fig. 12.3). On the other hand, the preliminary

results suggest that this lens is not indicated for patients who require a nearer working distance: in fact, almost all patients required spectacles for adequate vision at 30 and 40 cm (Figs. 12.2, 12.3 and Table 12.2).

Table 12.2 Mean and standard deviation of uncorrected and best corrected visual acuity for ReSTOR® SN6AD2 +2.5 D and SN6AD1 +3 D multifocal intraocular lenses expressed in Jaeger

	ReSTOR® +2.5 D	ReSTOR® +3.0 D	<i>p</i>
UCNVA 30 cm	5.74±2.352	2.74±1.21	<0.001 ^a
IVA 40 cm	5.68±2.495	3.06±1.031	<0.001 ^a
IVA 50 cm	3.84±1.899	5.29±1.697	0.002 ^a
IVA 60 cm	3.58±1.409	6.45±1.729	<0.001 ^a
IVA 70 cm	4.1±1.423	7.97±2.258	<0.001 ^a
BCNVA 30 cm	2.58±0.886	1.84±0.779	0.001 ^a
CIVA 40 cm	2.71±0.938	2.16±0.82	0.017
CIVA 50 cm	2.19±0.792	3.13±0.806	<0.001 ^a
CIVA 60 cm	2.29±0.824	3.77±1.146	<0.001 ^a
CIVA 70 cm	2.81±0.749	4.58±1.587	<0.001 ^a

UCNVA uncorrected near visual acuity, IVA intermediate visual acuity, BCNVA best corrected near visual acuity, CIVA corrected intermediate visual acuity

^astatistically significant difference evaluated with unpaired two-sided student's t-test with Bonferroni correction for multiple comparisons

12.6 Visual Quality Assessment

An important parameter in the evaluation of a multifocal IOL is the quality of vision: the scotopic vision and the contrast sensitivity normally decrease after MIOL implantation. Furthermore, the higher amount of aberrations due to the lens structure may influence visual quality. Nevertheless, it is known that a certain percentage of side effects described as subjective symptoms can occur after surgery (e.g., halos, glare, and blurred vision) [11, 12].

12.7 Contrast Sensitivity and Wavefront Aberration Analysis

In our experience the assessment of binocular contrast sensitivity with a CSV-1000 chart (Vector Vision, Greenville, OH) showed comparable

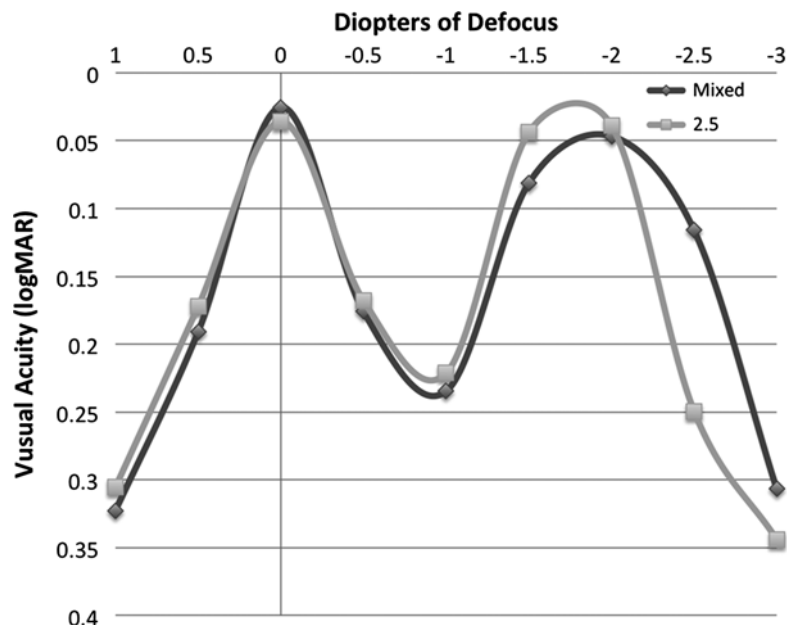
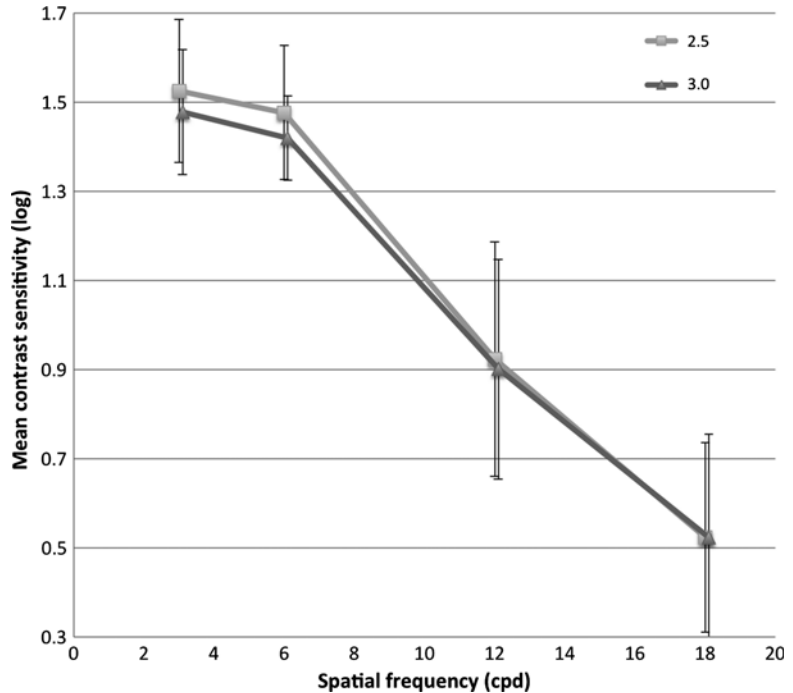


Fig. 12.3 Defocus curve: comparison between 15 patients binocularly implanted with ReSTOR® +2.5 D (squares) and 15 patients implanted with a ReSTOR® +2.5 D and a ReSTOR® +3 D in fellow eyes (diamonds) at a 6-month follow-up

Fig. 12.4 Binocular contrast sensitivity: comparison between 15 patients binocularly implanted with ReSTOR® +2.5 D (squares) and 15 patients binocularly implanted with ReSTOR® +3 D (triangles) at a 6-month follow-up. Error bars indicate standard deviation for group means. The between-group differences were not statistically significant



results obtained with the ReSTOR® +2.5 D and ReSTOR® +3 D (Fig. 12.4). Moreover, we measured the wavefront aberration using the Topcon wavefront analyzer KR-1 W (Topcon Medical Systems, Oakland, NJ) based on the Hartmann-Shack wavefront sensor technique. This instrument [13] calculates the internal high-order aberrations (HOA) induced by an IOL, excluding the corneal aberrations, expressed in root-mean-square (RMS) representing the average of the square root of the wavefront errors, measured in microns. The MTF was measured using the same instrument. While the MTF showed concordant results with the binocular contrast sensitivity (Fig. 12.5), we founded a statistically significant difference in terms of internal RMS between the two MIOLs with a lower amount of aberrations for the ReSTOR® +2.5 D. Since both IOLs have an aspheric profile and a very similar design, the lower value of the internal HOA could be due to the differences in distribution of light to distance and near foci with varying pupil size that are

induced by the lower and wider steps of the +2.5 D IOL [8, 14] (Figs. 12.4 and 12.5).

12.8 Side Effects

Subjective symptoms are the most common cause of dissatisfaction after a MIOL implantation. In accordance with the findings reported by Gudersen and Potvin [3], we founded that a careful selection of patients based on realistic expectations, especially based on their motivation, and a proper patient counseling can facilitate neuroadaptation within the first 6 months after surgery [3]. In our experience 70 % of the patients implanted with ReSTOR® +2.5 D did not refer any subjective visual disturbances, and none of the remaining 30 % required IOL exchange. Figure 12.6 shows the percentage distribution of frequency, severity, and overall discomfort of glare, halos, and starbursts among the patients in whom these IOLs were implanted.

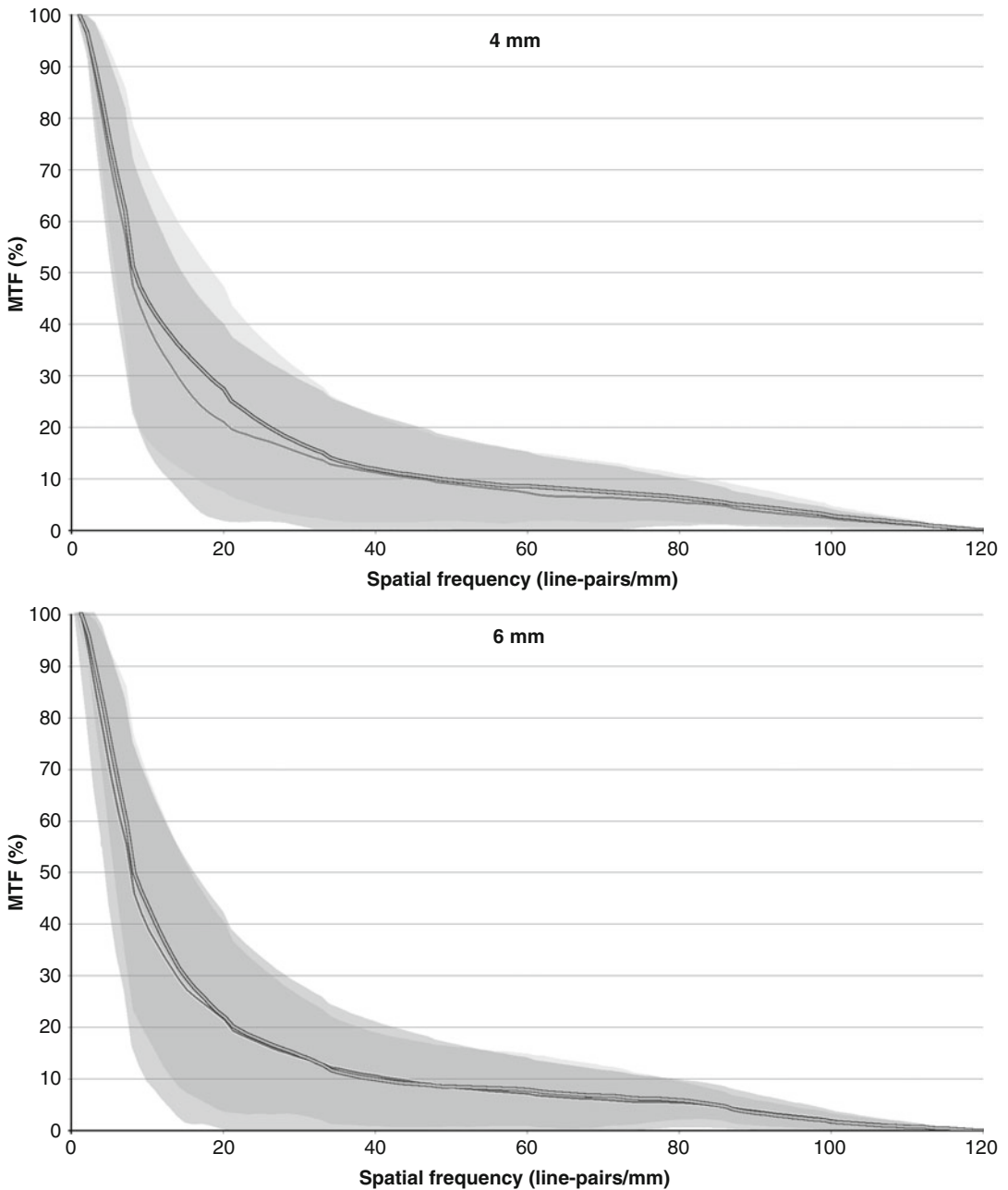


Fig. 12.5 Modulation Transfer Function (MTF) at 4 and 6 mm of pupil size. Comparison at a 6-month follow-up between two groups of 25 patients per group implanted with ReSTOR® SN6AD2+2.5 D (*double line*) and SN6AD1+3 D (*thinner line*) multifocal intraocular

lenses. Light gray and intermediate gray shaded areas indicate standard deviation for the two groups, respectively (*darker grey area indicates overlap*). The between-group differences were not statistically significant

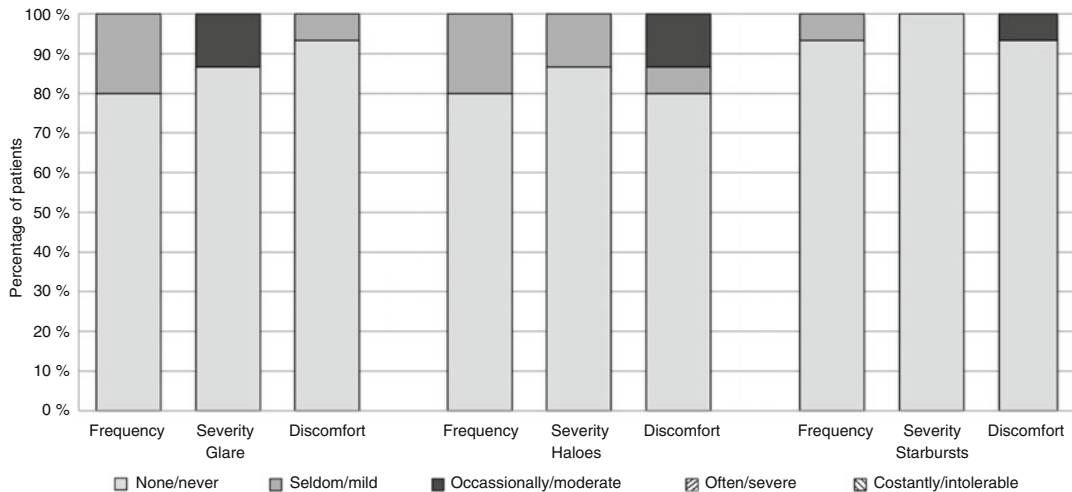


Fig. 12.6 The percentage distribution of frequency, severity, and overall discomfort due to glare, halos, and starbursts among the 15 patients binocularly implanted with ReSTOR® +2.5 D

Conclusions

The ReSTOR® +2.5 D provides a good visual acuity at all intermediate distances and a satisfactory quality of vision. It can be implanted in patients who need a preferred reading distance farther than the classic 30–40 cm, thus facilitating activities such as working at the computer or reading a newspaper or a watch. It is very important to explain to patients prior to surgery the theoretical compromise between spectacle dependence for near vision and a better visual quality for distance vision without conceding a good visual acuity at intermediate distances obtainable with this lens. This IOL should be considered among the options available for obtaining spectacle independence, thus increasing the number of patients suitable for the implantation of a MIOL.

Compliance with Ethical Requirements Rodolfo Mastropasqua, Emilio Pedrotti, and Giorgio Marchini 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 and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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13.1 Introduction

Multifocal IOL designs are based on diffractive and refractive optical principles [1–3] in order to enable postoperative far and near vision without spectacle dependence after crystalline lens or cataract extraction [4]. Diffractive IOLs are one specific type of multifocal (bifocal) lenses, which are based on the Huygens-Fresnel's principle. Specifically, a diffractive IOL presents concentric rings in its posterior surface that form two primary focal points independent of the pupil size [5]. This optical behavior of the lens allows an effective far and near visual restoration. The Acri.Lisa 366D is a multifocal IOL based on this diffractive principle [6].

The Acri.Lisa 366D [6–9] (Carl Zeiss Meditec AG) is a single piece, aspheric bifocal biconvex refractive-diffractive IOL. The optic diameter is of 6.0 mm, and the overall diameter is 11.0 mm. The surface is divided into main zones and phase zones; the phase zones assume the function of the steps of diffractive power of the main zones. The IOL power responsible for distance vision is refractive and diffractive at the same time. The two focal points are created by phase zones on the anterior surface of the IOL. The incident light is distributed with 65 % to distance focus and 35 % to near focus. The near vision add of this lens is +3.75 D over the distance power [6]. The technical details of this lens can be found in chapter: “Multifocal intraocular lens types and models” (Fig. 13.1).

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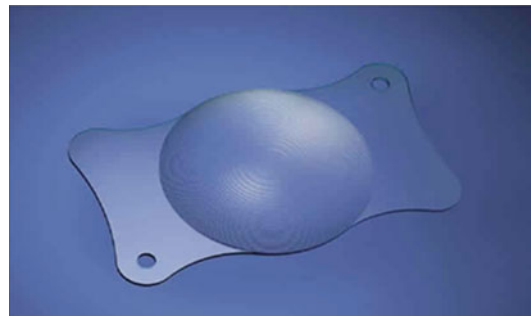


Fig. 13.1 Image of Acri.Lisa 366D bifocal

13.2 The Surgery with Acri.Lisa 366D

Surgery is performed using 1.8-mm sutureless with a coaxial approach or biaxial microincision (MICS) phacoemulsification. All patients receive topical anesthesia, and adequate dilation is obtained with intracameral mydriasis. The implant incision is placed on the axis of the positive corneal meridian. The lens is implanted using a specific hydraulic injector (Acri.Glide, Zeiss). Postoperative, topical therapy includes a combination of topical antibiotic and steroids. All surgeries were performed by the same surgeon (JLA).

Our experience was based on the outcomes of the lens in 48 eyes of 24 bilateral cataract patients with age ranging between 47 and 77 years that were implanted with Acri.Lisa 366D [10–12].

13.2.1 Preoperative and postoperative examinations

All patients had a full ophthalmological examination preoperatively, including the evaluation of the refractive status, distance and near visual acuities, slit-lamp examination, tonometry, and funduscopy. Distance visual acuity was measured with the Snellen charts, and the near visual acuity was measured with Radner Reading Charts [13, 14] (Spanish-validated version). The charts evaluate reading acuity in logRAD (equivalent to logMAR notation but for reading performance). Apart from these clinical tests, other specific examinations were also performed: corneal topography (CSO, Costruzione Research Institute), ocular aberrometry (COAS, Wavefront Sciences, Inc), biometry (IOL Master, Zeiss), endothelial cell count (Konan SP5500, Konan Camera Research Institute), contrast sensitivity (CST 1800, Vision Science Research), and quality of life (NEI VFQ 25 questionnaire, appendix NEI VFQ 39).

The analysis of the quality of life used the Spanish version of a validated questionnaire [15]. We used the quality of life questionnaire developed by the National Eye Institute (NEI) and called the “Native Visual Eye Institute Function Questionnaire (NEI VFQ).” This questionnaire was initially developed to evaluate the impact of

vision on different daily tasks and the quality of life. The NEI VFQ-25 consists of 25 items and a supplement of 14 additional items, all of which were taken from the original 52-item NEI VFQ. In six out of the 39 items in the NEI VFQ-25 plus supplement, patients are asked to grade their general health and vision, 20 rate difficulties with different normal life activities, and 13 ask about the level of agreement with statements describing the severity of problems associated with vision loss. The questions on difficulty with activities were rated on a 1–6 scale, with response choices including no difficult, little difficulty, moderate difficulty, extreme difficulty, stopping the activity because of eyesight, and stopping the activity for other reasons/not interested. A rating response of 6 was scored as missing data. The questions on level of agreement with statements describing role limitations due to vision loss were rated on a 5-point scale ranging from agree all of the time to agree none of the remaining eight items. Two items in the supplement rated overall health and vision on a 0 (worst) to 10 (best) scale.

Postoperatively, patients were evaluated at 1 day, 1 month, 3 months, and 6 months. The postoperative examination protocol at 1, 3, and 6 months was identical to the preoperative protocol, with the additional measurement of the defocus curve and the ocular optical performance with the OQAS system (Optical Quality Analysis System, Visiometrics SL). This is an instrument based on a double-pass technique and developed to perform an objective optical evaluation of the visual quality. The double-pass technique is based on recording images of a point source after reflection on the retina and a double pass through the ocular media. The data was processed so that the ocular point spread function (PSF) and the modulation transfer function (MTF) could be obtained. All the measurements were taken with a 5-mm pupil diameter size using phenylephrine 10 % for dilatation. The MTF cutoff point was analyzed and recorded, and it represents the point where the spatial frequency is maximal and has a theoretical relationship with the visual acuity (supposing a good macular and neuroprocessing function). In addition, the Strehl ratio was also analyzed, which is the ratio of peak focal intensities in the aberrated and ideal PSFs.

Table 13.1 Comparative table showing the preoperative and postoperative visual outcomes

Mean (SD) range	Preoperative	1 month	3 months	6 months	Comparison preoperative-6 months (<i>P</i> value)
LogMAR UDVA	0.61±0.39	0.11±0.11	0.09±0.11	0.12±0.16	<0.001
SPH (D)	2.61±2.42	0.13±0.48	0.16±0.56	0.32±0.38	<0.001
CYL (D)	-0.73±0.62	-0.60±0.40	-0.55±0.38	-0.55±0.36	0.35
LogMAR CDVA	0.03±0.09	0.02±0.06	0.01±0.03	0.03±0.09	0.75
LogMAR UNVA	0.82±0.33	0.12±0.11	0.09±0.11	0.16±0.13	<0.001
LogMAR DCNVA	0.59±0.21	0.08±0.10	0.11±0.10	0.14±0.13	<0.001
LogMAR CNVA	0.17±0.30	0.05±0.08	0.08±0.08	0.13±0.13	0.72

Abbreviations: SD standard deviation, D diopters, UDVA uncorrected distance visual acuity, CDVA corrected distance visual acuity, UNVA uncorrected near visual acuity, DCNVA distance corrected near visual acuity, CNVA corrected near visual acuity

13.3 Visual and Refractive Outcome Analysis of the Acri.Lisa 366D

Table 13.1 shows preoperative and postoperative visual outcomes with Acri.Lisa 366D. At 6 months after surgery, a statistical significant improvement was observed in the uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), and distance corrected near visual acuity (DCNVA) (Wilcoxon test; $p < 0.001$). These results confirm the efficacy of the IOL to obtain good visual acuity at all the distances. An improvement in the limit of the statistical significance was observed in the corrected near visual acuity 1 month after surgery (Wilcoxon test; $p = 0.053$). However, this visual parameter worsened significantly at the end of the follow-up (Wilcoxon test 3–6 months; $p < 0.01$). No significant changes were found in the corrected distance visual acuity (CDVA) (Wilcoxon test; $p = 0.72$). The spherical equivalent refraction reduced significantly after surgery (pre-op $+2.61 \pm 2.42$ vs. 6 months $+0.32 \pm 0.38$; Wilcoxon test; $p < 0.001$). The cylinder was not modified significantly by the surgery (Wilcoxon test; $p = 0.348$). The uncorrected distance and near visual acuities improvements confirm the

efficacy of the IOL for the correction of patient's aphakic ametropia. This results are consistent with various reports using the Acri.Lisa 366D [8, 9, 11, 16–18]. The CNVA experienced initially significant improvement, but at the end of the follow-up, it became significantly worse. A possible reason can be posterior capsular opacification that was detected in a significant number of patients at 6 months and reported in previous studies [19] (Table 13.1).

13.4 Contrast Sensitivity Function

At 1 month after surgery, contrast sensitivity improved significantly for all spatial frequencies under photopic and scotopic conditions (Wilcoxon test; $p \leq 0.007$). This was expected because of the cataractous crystalline lens extraction and replacement by a new transparent lens. During the rest of follow-up, significant changes were only found in photopic contrast sensitivity for the spatial frequencies of 3 and 6 cycles/degree in the postoperative period going from 3 to 6 months (Wilcoxon test; $p \leq 0.38$) and in the scotopic contrast sensitivity for 3 cycles/degree in the same period (Wilcoxon test; $p = 0.038$) (Fig. 13.2).

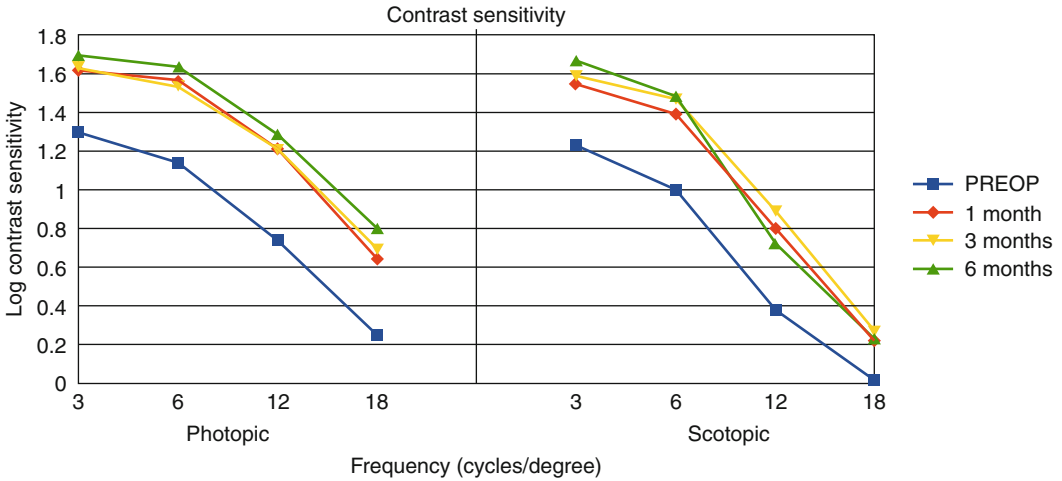


Fig. 13.2 Evolution of contrast sensitivity (preoperative, 1, 3, and 6 months) in photopic and scotopic conditions for all frequencies (3, 6, 12, and 18 cycles/degree). We observe that in photopic and scotopic conditions, contrast sensitivity improved for all spatial frequencies. *Blue line* represents preoperative values. Postoperative values are represented by the *orange line* (1 month), *yellow line* (3 months), and *green line* (6 months)

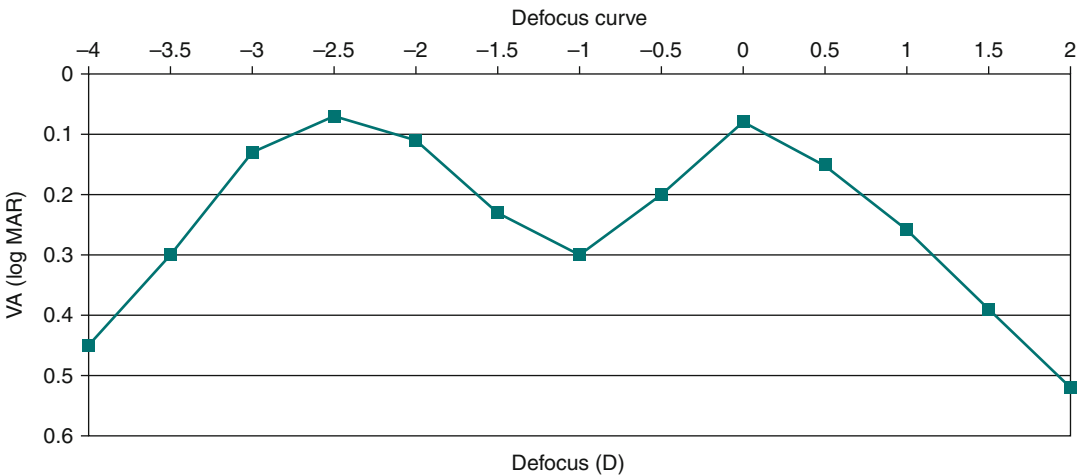


Fig. 13.3 Mean defocus curve for the Acri.Lisa 366D. We can observe that the best visual acuity values were obtained for defocus 0 D and -2.50 D. The minimum peak corresponds to defocus -1.00 D

13.5 Defocus Curve

Figure 13.3 shows the mean defocus curve for eyes implanted with Acri.Lisa 366D. The curve shows 2 peaks of maximum vision located at the far focus and the near focus, corresponding to 0 D and -2.50 D defocus, respectively, with reduced visual acuity at intermediate distance. We found that the results obtained for defocus

0 D corresponded to distance corrected visual acuity (DCVA). In the same case, visual acuity results in -2.50 D corresponding to distance corrected near visual acuity (DCNVA). The mean visual acuity was 0.3 logMar or better from +1.25 D to -3.50 D. This limit of 0.3 logMar is the most common criterion used in multifocal IOL studies [20] and matches the level of acuity defined as the driving standard across Europe [21] (Fig. 13.3).

Fig. 13.4 Evolution of total ocular root mean square (RMS total) and ocular higher-order aberrations (HOA) (Blue color, preoperative; orange color, 1 month after surgery; yellow color, 3 months after surgery; green color, 6 months after surgery). RMS total values were reduced after surgery. On the other hand, HOA values did not change after surgery

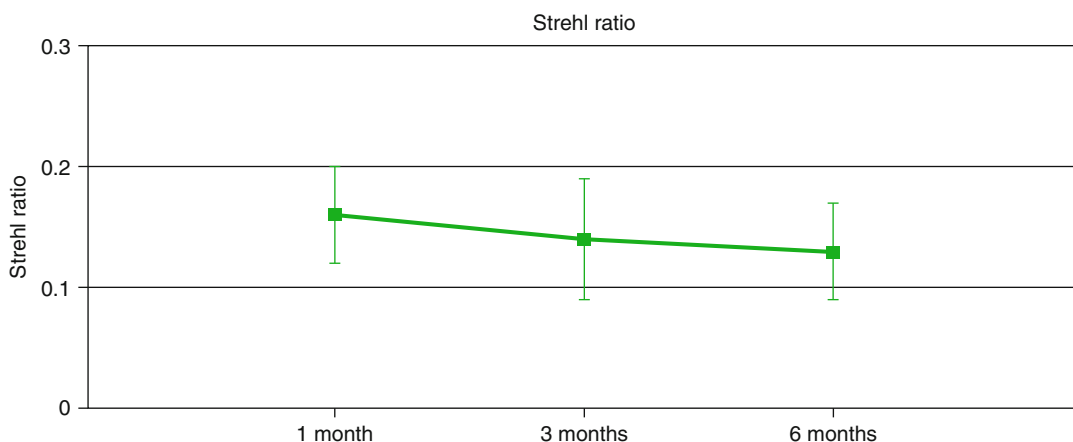
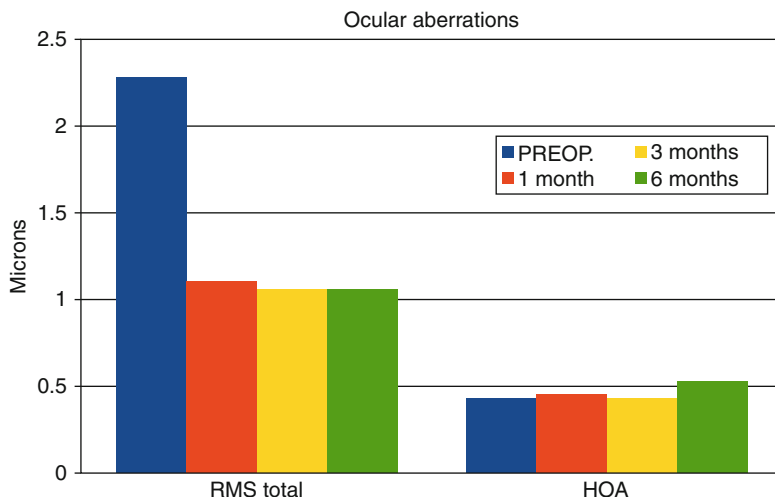


Fig. 13.5 Evolution Strehl ratio (1, 3, and 6 months). A reduction of the Strehl ratio was observed between 1 and 6 months

13.6 Optical Quality Analysis

Figure 13.4 shows the mean postoperative ocular aberrations. Global ocular aberrations were reduced significantly after surgery, mainly due to the correction of the spherocylindrical error. There was a significant reduction of the total ocular root mean square (RMS) 1 month after surgery (Wilcoxon test; $p < 0.001$). No significant changes were observed afterwards (Paired Student t and Wilcoxon test; $p \geq 0.060$). Preoperatively, the total ocular RMS mean value was $2.28 \pm 1.69 \mu\text{m}$. This value was reduced 1 month after surgery ($1.10 \pm 0.53 \mu\text{m}$). No changes in the 3 months ($1.06 \pm 0.43 \mu\text{m}$) and 6 months ($1.06 \pm 0.32 \mu\text{m}$)

follow-up visits were found. The RMS for ocular higher-order aberrations (HOA) did not change significantly during the follow-up (Paired Student t and Wilcoxon tests; $p \geq 0.15$). Preoperatively, the RMS for HOA mean value was $0.43 \pm 0.39 \mu\text{m}$ and after surgery remained the same value: 1 month $0.45 \pm 0.21 \mu\text{m}$, 3 months $0.44 \pm 0.18 \mu\text{m}$, and 6 months $0.44 \pm 0.18 \mu\text{m}$ (Fig. 13.4).

A significant reduction of the Strehl ratio was observed between month 1 [0.16 (0.04)] and 6 [0.13 (0.04)] after surgery (Paired Student t test; $p < 0.001$), although all the values were normal [22] (Fig. 13.5). Accordingly, the cutoff spatial frequency for the MTF also decreased significantly from month 1 [24.91 (7.19) cycles/degree]

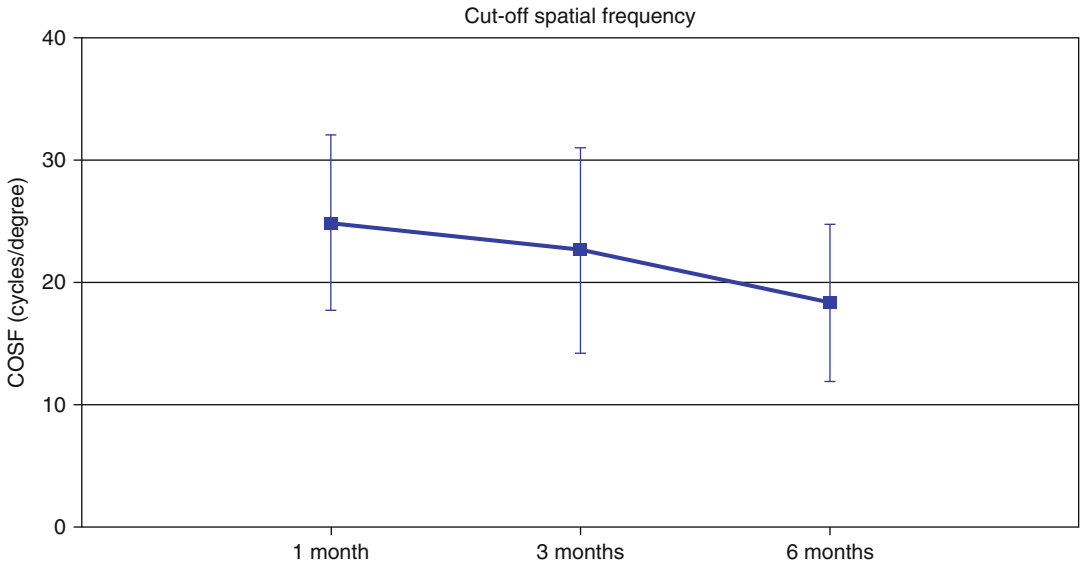


Fig. 13.6 Evolution of the cutoff spatial frequency for the MTF (1, 3, and 6 months). The cutoff spatial frequency for the MTF decreased from month 1 to 6

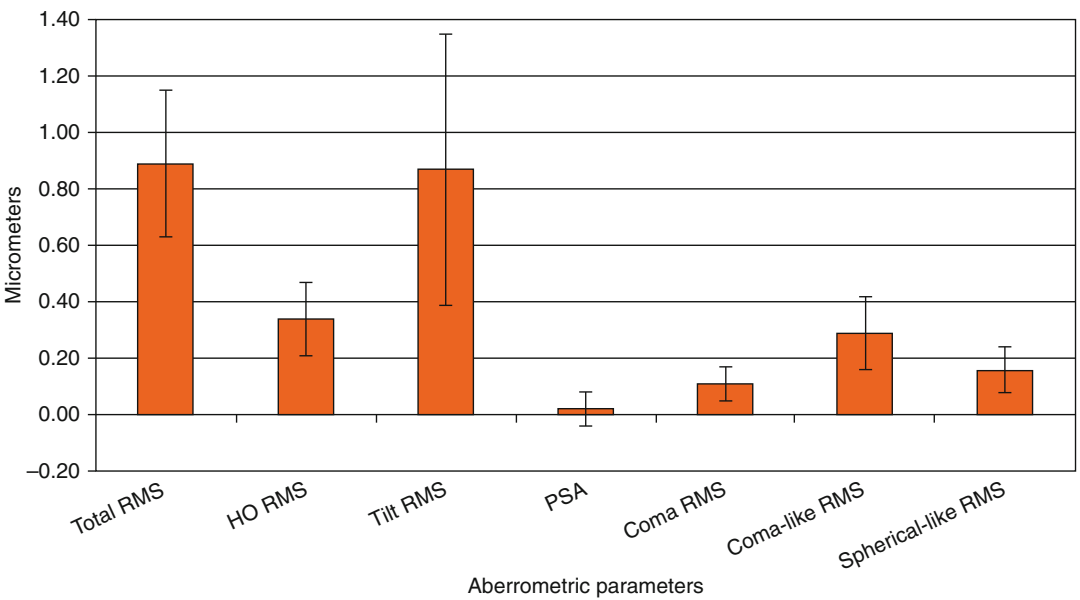


Fig. 13.7 Mean postoperative intraocular aberrations calculated by the VOL-CT software of the Lentis Comfort. There were no significant intraocular aberrometric values

to 6 [18.38 (6.43) cycles/degree] after surgery (Paired Student *t* test, $p < 0.001$) (Fig. 13.6) (Figs. 13.5 and 13.6).

Besides the postoperative intraocular optical quality, no significant changes in intraocular postoperative aberrations were detected. In a pre-

vious study [10], a monofocal IOL had a higher spherical-like RMS and primary spherical aberrations than the Acri.Lisa 366D. No differences were detected in the intraocular aberrometric parameters between the Acri.Lisa 366D and the ReSTOR SN6AD3 (Fig. 13.7).

Table 13.2 Summary of the achieved correlations between QOL index and clinical data

	Correl.1	Correl.2	Correl.3	Correl.4	Correl.5	Correl.6	Correl.7
T5 difficulty reading newspaper (1, none; 5, extreme)	-	-	-	-	-	-	-
T15c difficulty driving at day (1, none; 5, extreme)	CSF scotopic 6 cycles/degree $r = -0.615$ $p = 0.01$	-	-	-	-	-	-
T16 difficulty driving at night (1, none; 5, extreme)	CSF scotopic 6 cycles/degree $r = -0.632$ $p = 0.009$	-	-	-	-	-	-
T16a difficulty driving in adverse conditions (bad weather, rush hour) (1, none; 5, extreme)	CSF scotopic 6 cycles/degree $r = -0.646$ $p = 0.007$	-	-	-	-	-	-
Ta2a general vision (1, excellent; 5, very poor)	UDVA $r = -0.659$ $p = 0.002$	-	-	-	-	-	-
Ta3 difficulty reading small letters (1, never; 5, always)	UDVA $r = 0.538$ $p = 0.02$	UDVA $r = 0.538$ $p = 0.02$	UNVA, $r = 0.604$ $p = 0.001$	DCNVA $r = 0.548$ $p = 0.03$	NCVA $r = 0.620$ $p = 0.01$	-	-
Ta6 difficulty recognizing people		UNVA $r = 0.540$ $p = 0.03$	DCNVA $r = 0.539$ $p = 0.03$	UNVA $r = 0.576$ $p = 0.02$	-	-	-
Ta8 difficulty watching TV (1, none; 5, extreme)	RMS total $r = 0.523$ $p = 0.03$	CSF photopic 12 cycles/degree $r = -0.515$ $p = 0.054$	-	-	-	-	-

Conclusions

The Acri.Lisa 366D multifocal IOL provides good visual rehabilitation after cataract surgery as well as improvement in photopic and scotopic contrast sensitivity. This IOL provides a good vision for far and near distances and allows optimal vision for all distance tasks. For intermediate vision, the visual acuity decreases a limit that is defined as driving standard across Europe.

Compliance with Ethical Requirements Esperanza Sala Pomares, Ana Belen Plaza Puché, and Jorge Alio 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 article.

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Peter Mojzis, Pablo Peña-Garcia, and Jorge L. Alió

14.1 Introduction

The great prevalence of presbyopia and the importance of near and intermediate vision in modern society have resulted in the development of techniques to compensate this refractive condition. Moreover, as has been reported, the loss of reading skills can reduce the quality of life of presbyopic patients [1–4].

The use of multifocal lenses can improve near and distance uncorrected visual acuity reducing the spectacle dependence [5]. For this purpose, many designs have been developed by manufacturers of intraocular lenses (IOLs). The main types, multifocal IOLs available are: refractive, diffractive, refractive-diffractive and accommodative.

Each model has its own advantages and disadvantages, but in mean terms, all of them can improve near and distance uncorrected vision.

However, IOLs are still far from be perfect, and collateral effects such as halos, glare and loss of contrast sensitivity [6–9] have been reported after their implantation. Moreover, the results achieved in intermediate distance vision are not satisfactory in a great number of cases. Therefore, the improvement in intermediate vision is nowadays one of the most important challenges in this field. In this sense, the achievement of an intermediate focus in IOLs could be interesting to solve this problem.

In the present chapter the results of the AT LISA tri 839MP (Carl Zeiss Meditec), a new diffractive IOL model with a trifocal design, are analyzed in 60 eyes (30 patients operated bilaterally).

As will be seen along the chapter, the AT LISA tri is one of very few existing trifocal IOL [10–13], and what is more important, it has shown unbeatable results in improving near, intermediate and distance visual acuity in presbyopic patients [14].

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14.2 Surgical Technique

All surgeries were performed using a standard technique of sutureless micro-coaxial phacoemulsification. In all cases, instillation of topical anaesthesia drops was applied to the patient prior to the surgical procedure. The MICS incision was 1.6 mm and it was placed temporally. After capsulorhexis creation and phacoemulsification (Infinity Vision System, Alcon), the IOL was inserted into

the capsular bag using the single-use BLUMIXS 180 injector through the 1.6 mm incision. Postoperative topical therapy included a combination of topical antibiotic and steroid (Tobradex).

14.3 Preparation of the Lens Before Implantation

(Figs. 14.1, 14.2, 14.3, 14.4, 14.5, 14.6, 14.7, and 14.8)

14.3.1 Visual Outcomes and Contrast Sensitivity

Visual outcomes and their changes during the follow-up are shown in Table 14.1 and Fig. 14.9.

All visual parameters were measured with and without correction at different distances. Two near distances were considered: 33 and 40 cm.



Fig. 14.3 OVD application into the loading chamber

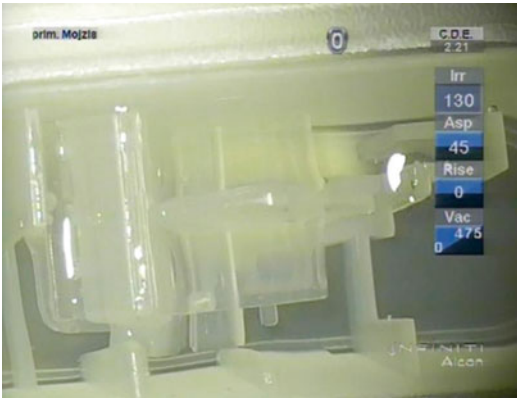


Fig. 14.1 Loading chamber with AT LISA tri is taken from water chamber

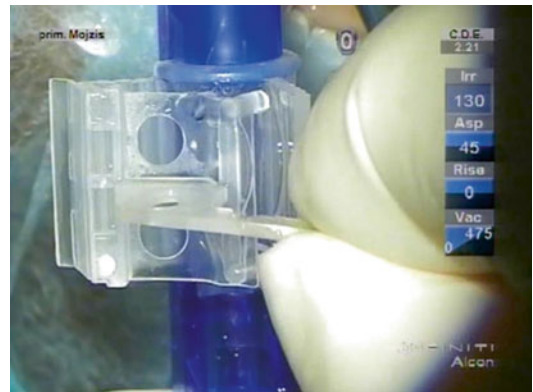


Fig. 14.4 Gently removal of lens holder

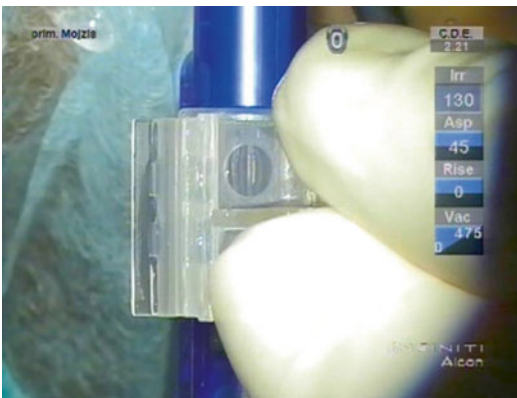


Fig. 14.2 Loading chamber is inserted in the BLUEMIXS injector



Fig. 14.5 Lens positioned at the bottom of loading chamber

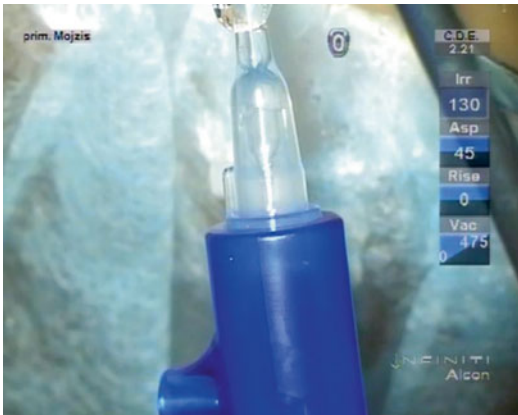


Fig. 14.6 Lens movement in the cartridge

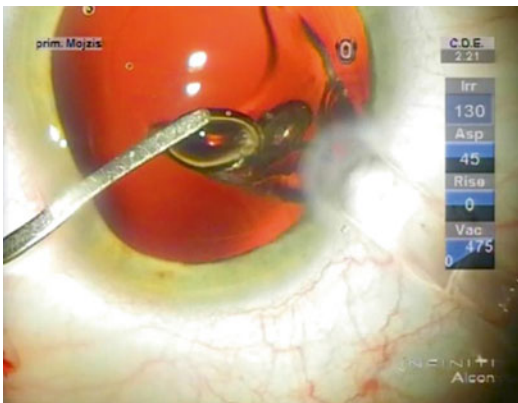


Fig. 14.7 AT LISA tri implantation through 1.6 mm CCI

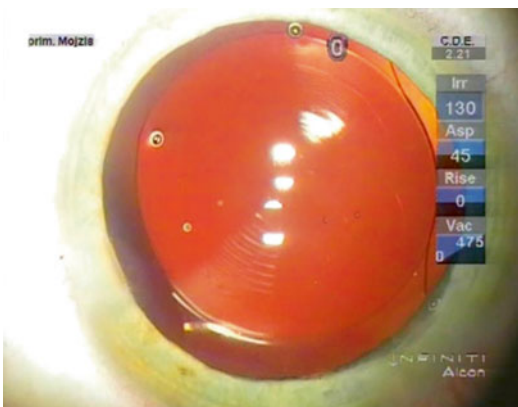


Fig. 14.8 Perfect centration

Also, two intermediate distances were considered: 66 and 80 cm (Table 14.1 and Fig. 14.9).

Best corrected near visual acuity (BCNVA) was slightly better 6 months after the surgery. The preoperative value was 0.17 ± 0.19 logRAD (-0.20 to 0.80), and the postoperative value was 0.13 ± 0.09 logRAD (0.00 to 0.40), but no significant improvement was detected ($p=0.230$). Best corrected intermediate visual acuity (BCIVA) also improved slightly from 0.13 ± 0.23 logMAR (-0.20 to 0.80) to 0.06 ± 0.11 logMAR (-0.10 to 0.40) but at the limit of significance ($p=0.050$). Comparisons at intermediate distance were performed at 66 cm, and comparisons for near vision were made at 33 cm.

We found statistically significant difference near VA comparing 33 and 40 cm (1 month $p=0.08$, 3 months $p<0.01$, 6 months $p=0.02$) (Figs. 14.10 and 14.11).

Regarding the postoperative intermediate VA, we observed no statistical significant difference between 66 and 80 cm (1 month $p=0.45$, 3 months $p=0.06$, 6 months $p=0.92$) (Figs. 14.12 and 14.13).

14.4 Defocus Curve

Defocus curve provides an objective measurement of expected vision at different distances; in simple words, it shows how the lens works in reality. The mean visual acuities (logMAR) and their standard deviations for different values of the defocus are shown in Fig. 14.6.

As can be seen from Fig. 14.6, for high values of the defocus (positive or negative), the visual acuity decreases as expected if the patients are properly refracted. This fact is compatible with the results found in the refractive analysis, with 100 % of the patients within the interval $+1.00$ to -1.00 D. The defocus interval between 0.00 and -3.00 D corresponds to distances from infinite to 33.33 cm. This is the most interesting zone of the defocus curve to evaluate the IOL efficacy for different tasks depending on the distance. In this case, the

Table 14.1 Changes in visual outcomes during the follow-up

	Preoperative	1 month	3 months	6 months
UDVA	0.53±0.47 (0 to 1.80)	-0.03±0.08 (-0.20 to 0.20)	-0.04±0.10 (-0.20 to 0.20)	-0.03±0.09 (-0.20 to 0.20)
CDVA	0.02±0.21 (-0.30 to 0.80)	-0.05±0.07 (-0.20 to 0.20)	-0.06±0.09 (-0.20 to 0.20)	-0.05±0.08 (-0.20 to 0.20)
UNVA (33 cm)	0.92±0.26 (0.10 to 1.40)	0.22±0.13 (-0.10 to 0.50)	0.19±0.11 (0.00 to 0.50)	0.20±0.12 (0.00 to 0.50)
BCNVA (33 cm)	0.17±0.19 (-0.20 to 0.80)	0.20±0.11 (0.00 to 0.50)	0.14±0.10 (-0.10 to 0.30)	0.13±0.10 (0.00 to 0.40)
DCNVA (33 cm)	0.68±0.19 (0.10 to 1.00)	0.20±0.11 (0.00 to 1.50)	0.17±0.10 (0.00 to 0.40)	0.17±0.11 (0.00 to 0.40)
UIVA (66 cm)	0.76±0.27 (0.00 to 1.40)	0.08±0.11 (-0.10 to 1.30)	0.11±0.10 (-0.10 to 0.30)	0.08±0.10 (-0.10 to 0.40)
BCIVA (66 cm)	0.13±0.23 (-0.20 to 0.80)	0.07±0.10 (-0.10 to 0.30)	0.08±0.10 (-0.10 to 0.30)	0.06±0.11 (-0.10 to 0.40)
DCIVA (66 cm)	0.43±0.26 (0.00 to 1.10)	0.07±0.10 (-0.10 to 0.30)	0.10±0.09 (-0.10 to 0.30)	0.08±0.10 (-0.10 to 0.40)

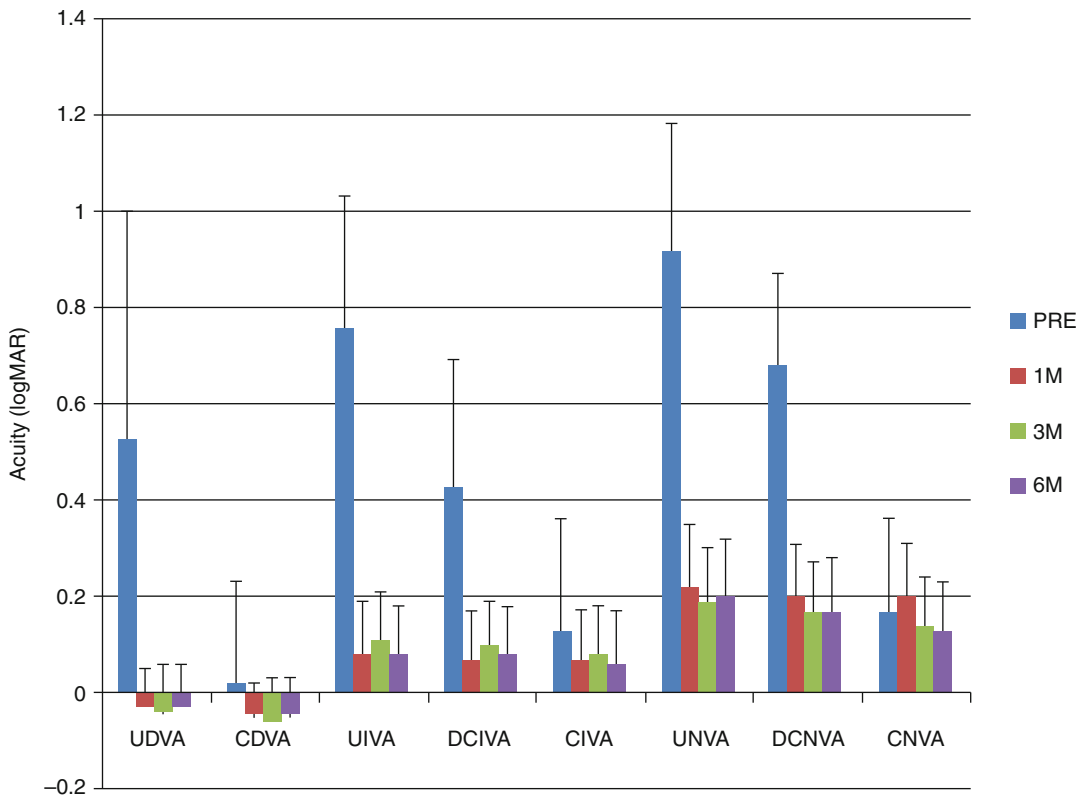


Fig. 14.9 There was a statistically significant improvement, comparing preoperative with postoperative at 6 months, for the next variables: uncorrected distance visual acuity (UDVA) ($p < 0.001$) (0.53 ± 0.47 to -0.03 ± 0.09 logMAR), corrected distance visual acuity (CDVA) ($p = 0.012$) (0.02 ± 0.21 to -0.05 ± 0.08 logMAR), uncorrected intermediate visual acuity (UIVA)

($p < 0.001$) (0.76 ± 0.27 to 0.08 ± 0.10 logMAR), distance corrected intermediate visual acuity (DCIVA) (0.43 ± 0.26 to 0.08 ± 0.10 logMAR) ($p < 0.001$), uncorrected near visual acuity (UNVA) ($p < 0.001$) (0.92 ± 0.26 to 0.20 ± 0.12 logRAD) and distance corrected near visual acuity (DCNVA) ($p < 0.001$) (0.68 ± 0.19 to 0.17 ± 0.11 logRAD)

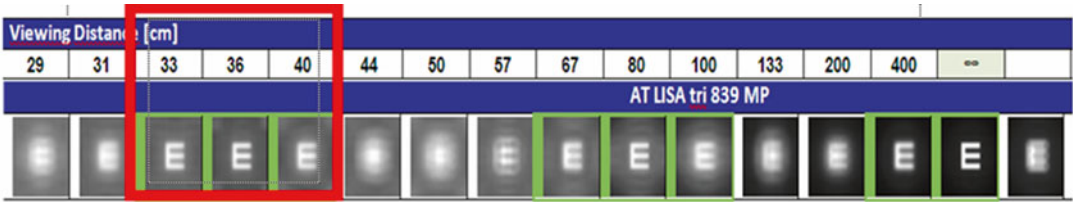


Fig. 14.10 Range of visual acuity with trifocal lens. AT LISA tri provides excellent near VA between 33 and 40 cm, the ideal distance for near vision is 36 cm

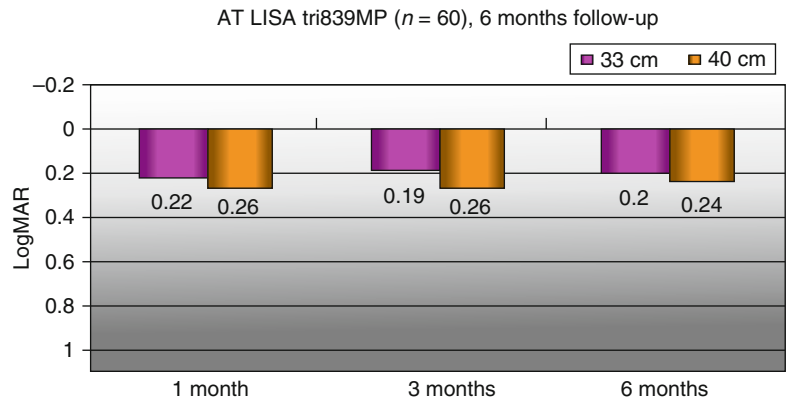


Fig. 14.11 Postoperative comparison of near VA at 33 and 40 cm

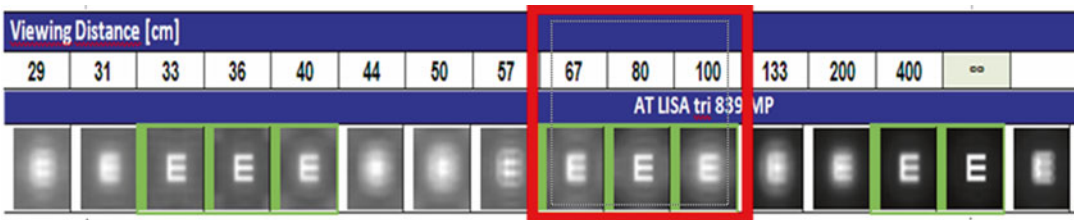


Fig. 14.12 Range of visual acuity with trifocal lens. AT LISA tri provides excellent intermediate VA between 67 and 100 cm; ideal distance to obtain high-quality image is 80 cm

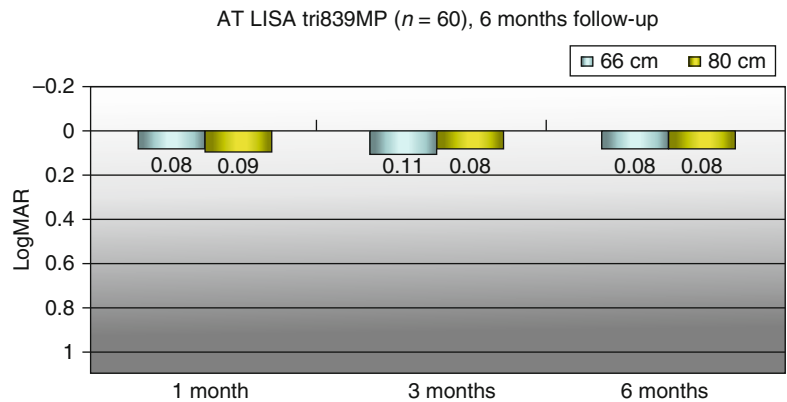


Fig. 14.13 Postoperative comparison of intermediate VA between 60 and 80 cm

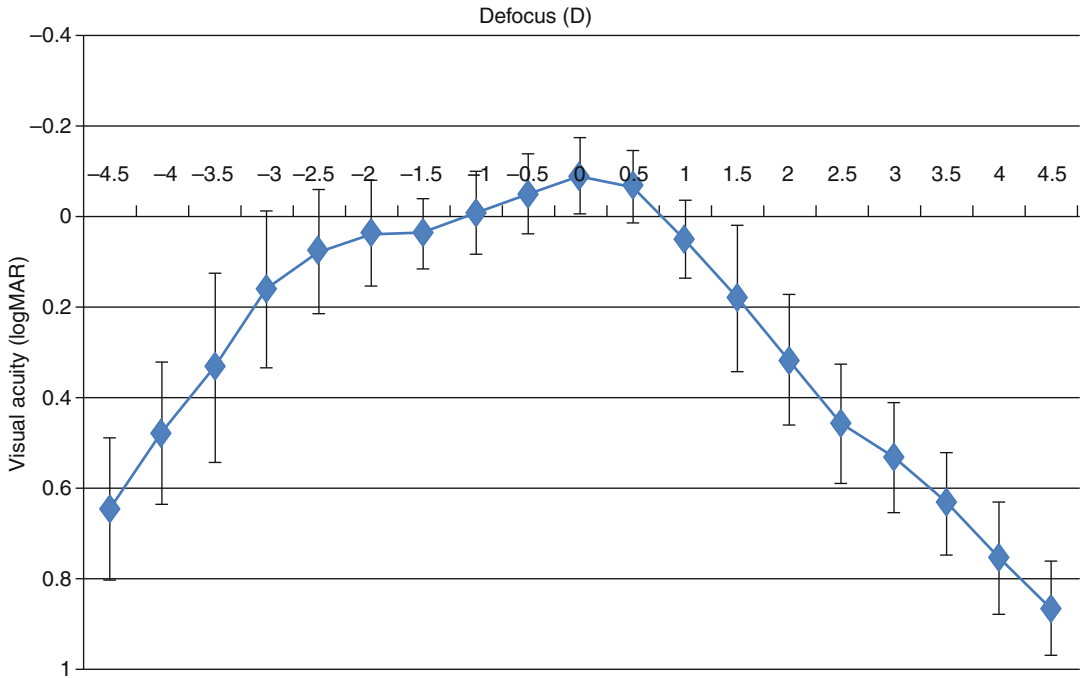


Fig. 14.14 Binocular defocus curve at 3 months

visual acuity values achieved ranged from -0.09 ± 0.09 logMAR (for 0 D) to 0.16 ± 0.17 logMAR (for 3 D). The defocus curve remained quite stable along this interval, providing a continuous and acceptable visual acuity for all distances. There were no statistical differences in visual acuity in the defocus range between +0.5 and -0.5 D ($p=0.180$). The values of visual acuity obtained for intermediate vision were especially stable: there were no significant differences in visual acuity in the range from -2 to -1 D (50 cm to 1 m) ($p=0.343$). The trifocal design, with the inclusion of a third focus for intermediate vision, seems to be the explanation for this behaviour. While other lenses present a clearly bimodal defocus curve, in the case of AT LISA tri 839MP, this curve remains almost constant in the interval from -1.5 to -0.5 D, corresponding to distances from 67 cm to 2 m. The mean change in visual acuity in this range is less than 0.1 units in logarithmic scale (from 0.04 to -0.05 logMAR). Moreover, variations along the defocus curve are very slight and continuous (Fig. 14.14).

14.5 Contrast Sensitivity Curve

The benefit of trifocal lens is improvement of intermediate vision. However, one major problem of any multifocal lens is impaired contrast sensitivity. Contrast sensitivity curve is present in Fig. 14.15. Changes in contrast sensitivity during the follow-up are also presented in Table 14.2. Comparing 1–6 months of the follow-up postoperatively, there was a slight but statistically significant improvement in the contrast sensitivity from the first month after surgery for low (1.5 cpd) frequencies ($p=0.034$), medium-high (12 cpd) ($p=0.019$) and high (18 cpd) frequencies ($p=0.001$). There was no significant improvement in contrast sensitivity for 3 and 6 cpd ($p=0.209$) and ($p=0.455$), respectively, when comparing 1 and 6 months postoperatively. Best levels of contrast sensitivity were achieved for medium (6 cpd) spatial frequencies ($p<0.001$). In terms of mesopic contrast sensitivity, we found values for all spatial frequencies in normal range (12 months after surgery) (Table 14.2 and Figs. 14.16, 14.17, and 14.18).

Fig. 14.15 Contrast sensitivity under photopic condition

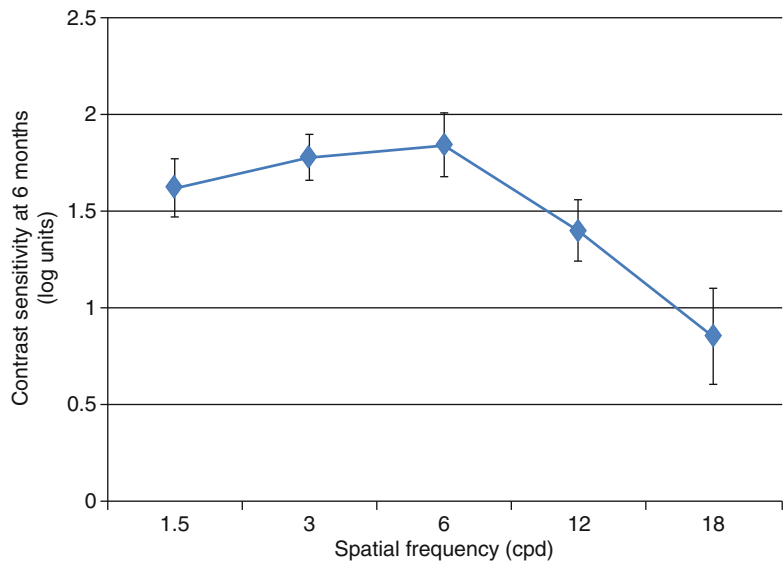


Table 14.2 Changes in contrast sensitivity during the follow-up

	1.5 cpd	3 cpd	6 cpd	12 cpd	18 cpd
1 month	1.57±0.13	1.76±0.11	1.82±0.16	1.35±0.15	0.73±0.22
3 months	1.61±0.14	1.78±0.12	1.85±0.16	1.39±0.18	0.78±0.24
6 months	1.62±0.15	1.78±0.12	1.84±0.16	1.40±0.16	0.85±0.25

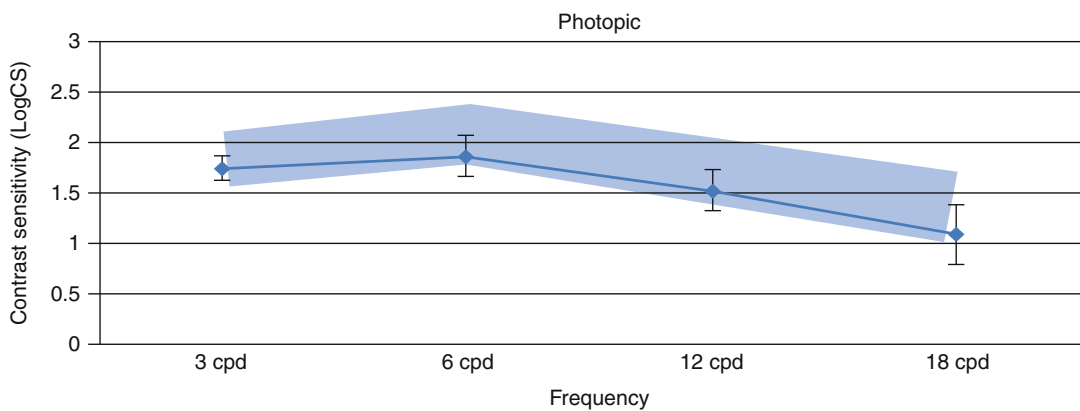


Fig. 14.16 CS values 12 months after surgery (50 eyes) under photopic conditions

14.6 Refractive Analysis

Refractive results for the whole group of patients (30 patients with bilateral implantation) are presented in Table 14.3. There were significant reductions in sphere ($p=0.009$), cylinder ($p<0.001$) and

spherical equivalent ($p=0.010$). The preoperative refractive status of the patients according to the type of ametropia was as follows: 42 eyes with hypermetropic astigmatism (spherical equivalent, $SE=1.78\pm 1.09$ from $+0.38$ to $+5.00$), 5 with mixed astigmatism ($SE=-0.08\pm 0.11$ from -0.25

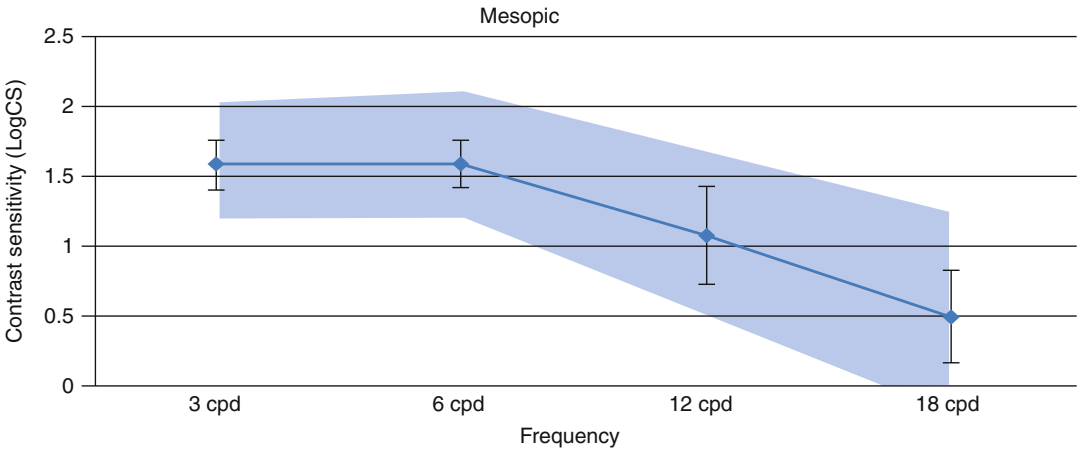


Fig. 14.17 CS values 12 months after surgery (50 eyes) under mesopic conditions

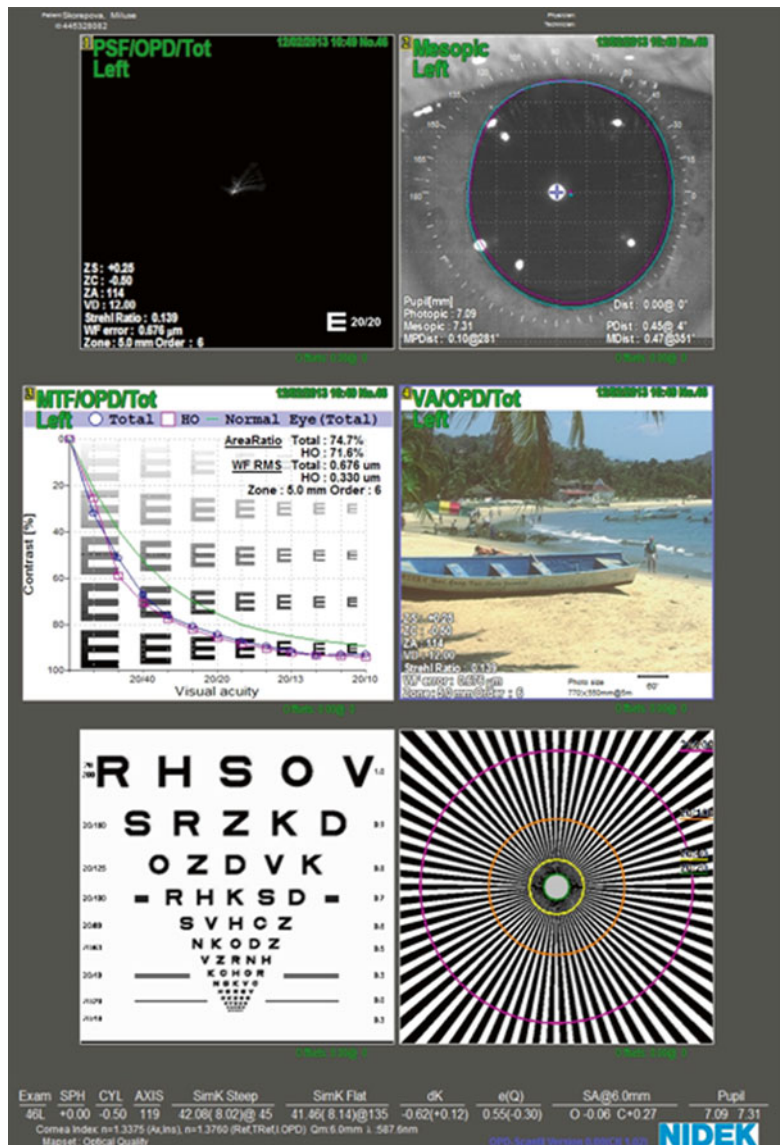


Fig. 14.18 Assessment of visual acuity and image quality in patient with AT LISA tri and large angle kappa, high Strehl ratio and MTF curve as well as perfect simulating images

Fig. 14.19 Spherical equivalent before and 3 months after surgery

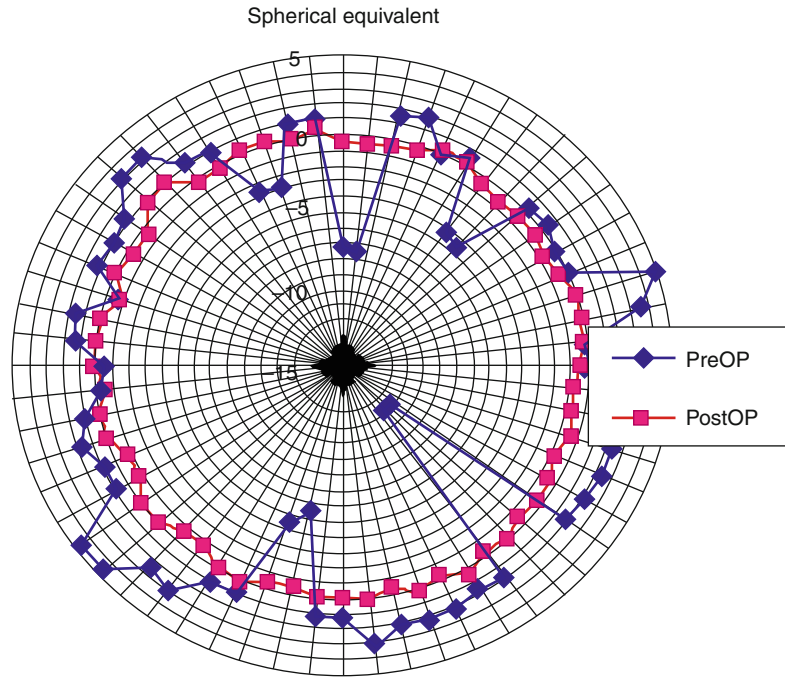


Table 14.3 Refractive changes during the follow-up

	Preoperative	1 month	3 months	6 months
Sphere (D)	0.42 ± 3.38	-0.12 ± 0.40	0.00 ± 0.36	0.02 ± 0.38
	(-12.00 to 5.25)	(-0.75 to 1.00)	(-0.75 to 0.75)	(-0.75 to 1.00)
Cylinder (D)	-0.47 ± 0.31	-0.33 ± 0.21	-0.28 ± 0.19	-0.28 ± 0.24
	(-1.25 to 0.00)	(-0.75 to 0.00)	(-0.75 to 0.00)	(-1.00 to 0.00)
Spherical equivalent (D)	0.18 ± 3.35	-0.28 ± 0.41	-0.14 ± 0.36	-0.12 ± 0.39
	(-12.25 to 5.00)	(-1.00 to 1.00)	(-1.00 to 0.50)	(-1.00 to 1.00)

to 0.00) and 13 eyes with myopic astigmatism ($SE = -4.88 \pm 3.83$ from -12.25 to -0.25).

Postoperatively, the spherical equivalent decreased significantly for hypermetropic patients to -0.12 ± 0.40 (-0.75 to +1.00) ($p < 0.001$) and for myopic patients to -0.13 ± 0.38 (-1.00 to +0.50) ($p = 0.003$). The postoperative spherical equivalent for mixed astigmatism patients was -0.15 ± 0.35 (-0.50 to 0.25); no significant change was detected ($p = 0.680$). The SE distribution 3 months after surgery was as follows: 8 eyes (13.33 %) within the interval -0.63 to -1.00 D, 34 eyes (56.67 %) in the interval -0.50 to 0.00 D and 18 (30 %) in the interval +0.13 to +0.50 D (Fig. 14.19). The efficacy index was 1.06, and the safety index was 1.10 at 6 months after surgery (Table 14.3 and Figs. 14.19 and 14.20).

14.7 Centration and Angle Kappa

Proper centration of MIOL is a crucial point to achieve perfect visual performance. Cataract surgeons usually centre the lens in the middle of the dilated pupil. Some surgeons recommend intraoperative instillation of Miochol to induce miosis. This is simple and effective method in patient with small angle kappa, where the visual axis is very close or identical with the pupillary axis. Angle kappa describes the distance between the pupillary axis (centre of pupil) and the visual axis. However, centration on pupil centre in patient with large angle kappa could lead to postoperative dissatisfaction. In this case, primary path of light passes through multifocal rings instead of the pupillary centre inducing coma and glare. Unfortunately, the surgeon is not able to influence angle kappa.

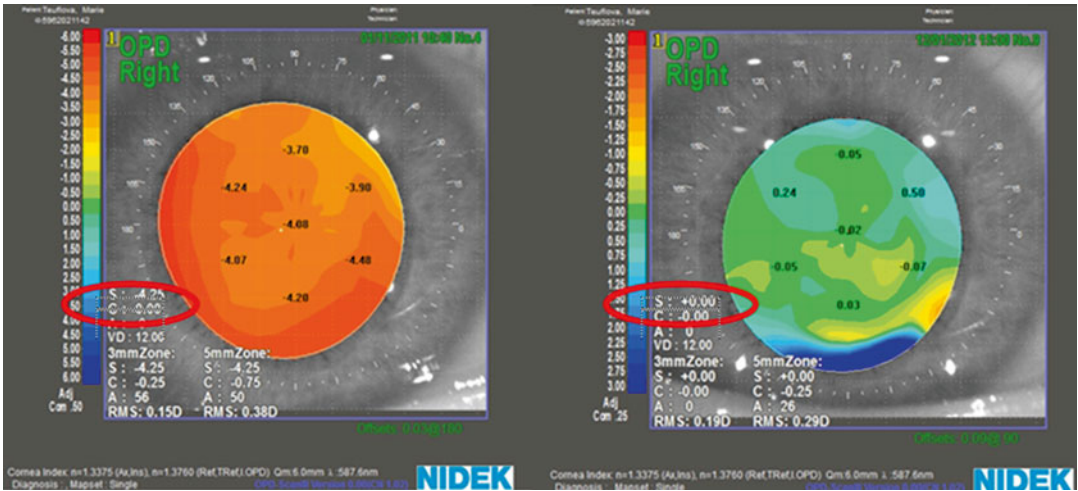


Fig. 14.20 OPD displays the distribution of refractive error before surgery (*left*) and after implantation of AT LISA tri (*right*). It shows correction needed at the each point within pupil to achieve emmetropia

In preoperative measurement, the angle kappa should be identified. In our study group of 30 patients, 60 eyes, we measured the mean angle kappa in myopes (10 eyes) of 0.2 ± 0.10 under photopic condition and 0.21 ± 0.10 under mesopic condition, in emmetropes (6 eyes) 0.34 ± 0.12 and 0.37 ± 0.13 and hypermetropes (42 eyes) 0.43 ± 0.18 and 0.41 ± 0.15 , respectively. In all cases, AT LISA tri were implanted. One of the very nice things of this lens is a central optical zone of 1.04 mm, and it could be implanted even in patients with large angle kappa (Fig. 14.1). It is hypothesized that the central optical zone should be half diameter greater than angle kappa. In addition, AT LISA tri is independent to pupil size resulting in very high postoperative satisfaction under mesopic condition and reduced visual phenomena.

The best location for MIOL centration is first Purkinje image. This point is very close to the visual

axis. Intraoperatively, coaxial light of microscopes is helpful to identify the correct position (first Purkinje image) for lens centration (Fig. 14.21).

Its plate-haptic design is suitable for MICS technique (Fig. 14.14). Plate haptic is centrated very well even in a case of broken haptic in the periphery (Figs. 14.22, 14.23, 14.24, 14.25, 14.26, and 14.27).

14.8 Posterior Capsule Opacification (PCO)

One of the main drawbacks of MIOLs is a higher rate of YAG laser capsulotomy compared with monofocal lenses. It has been shown that even low-grade PCO impairs significantly visual acuity.

Trifocal lens splits incoming light among 3 foci, far, intermediate, and near. Its delicate optic

Fig. 14.21 Preoperative measurement of patient with high angle kappa with AT LISA tri

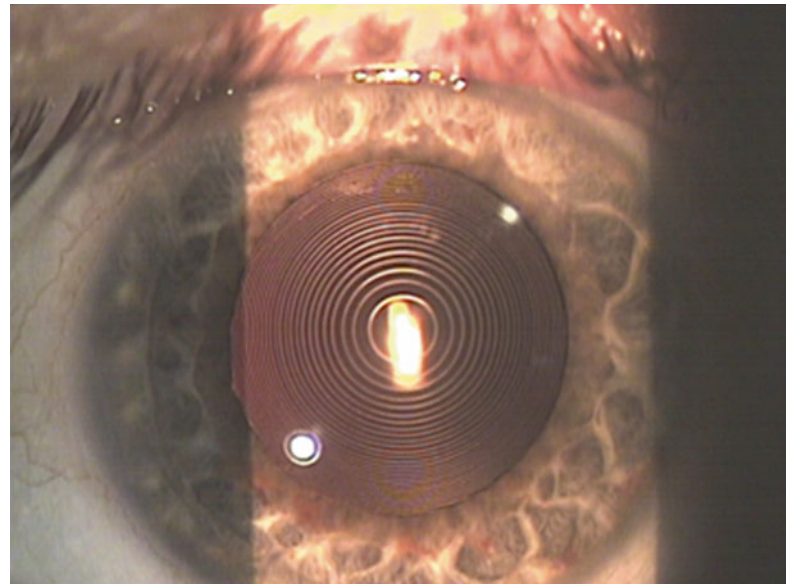
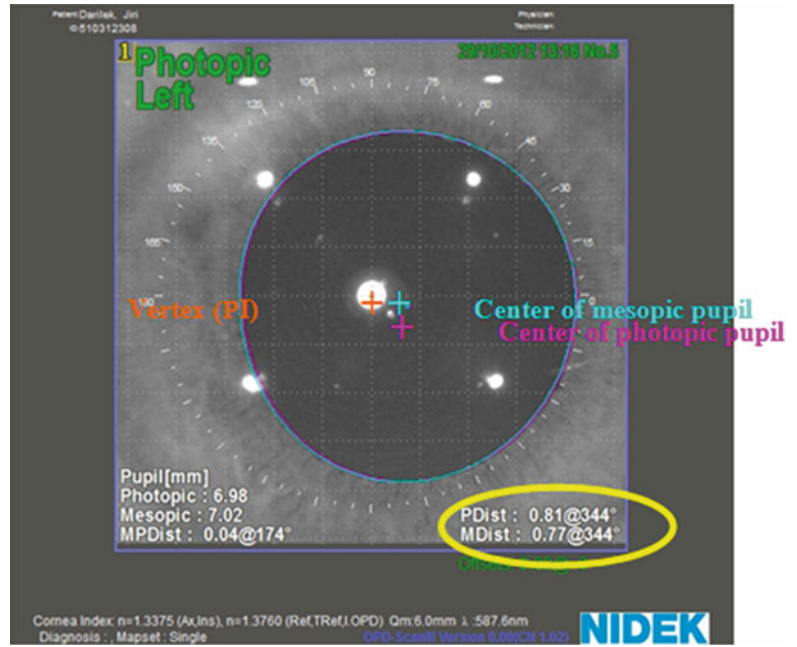


Fig. 14.22 AT LISA centration after surgery uncomplicated surgery

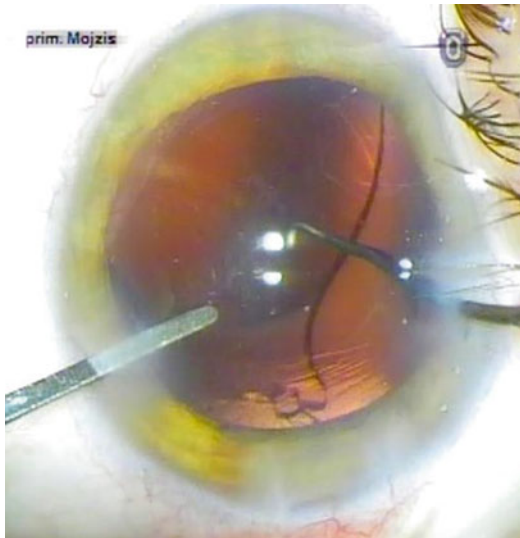


Fig. 14.23 Broken haptic after AT LISA tri implantation

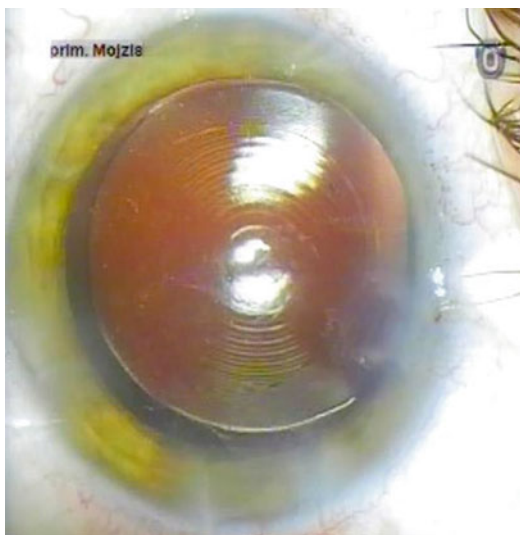


Fig. 14.24 Same patient – IOL positioned in the centre after OVD removal

is very sensitive to any capsular changes, especially in the central 4.34 trifocal zone, leading to deterioration of visual performance as well as to enhancement of disturbing visual phenomena

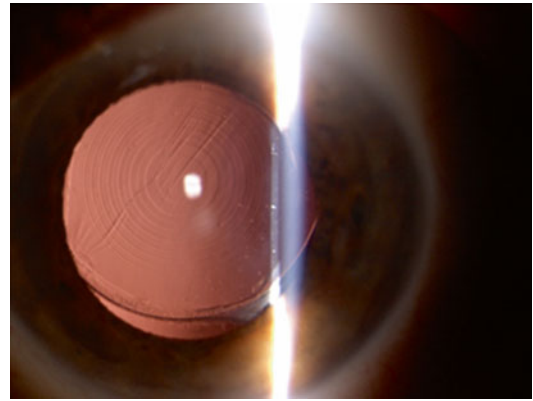


Fig. 14.25 Perfect centration of AT LISA tri with broken haptic 6 months after surgery

such as halos and glare. PCO is caused by epithelial cell proliferation and migration to the posterior capsule. It is classified into two forms: proliferative (Elschnig pearls) and non-proliferative (fibrosis). Proliferative PCO could be successfully treated using bimanual irrigation/aspiration cannulas (Figs. 14.20 and 14.21). Studies show that acrylic material and polishing of anterior and posterior capsule and square edge are associated with lower PCO rate. A new 360° square edge and hydrophobic surface of trifocal lens prevent early PCO formation (Figs. 14.28 and 14.29).

Fibrosis of posterior capsule should be treated with YAG laser capsulotomy to create opening in the posterior capsule. Although it is very effective and safe procedure, complications such as vitreous opacities, cystoid macular oedema, or retinal detachment were reported.

One year after surgery, in 30 patients with bilateral AT LISA tri, PCO type and grade in central 4.3 central zone were measured and evaluated using EPCO 2000. We found out an EPCO rate of 0.24 ± 0.33 , three YAG laser capsulotomies and two aspirations of Elschnig pearls were performed (Fig. 14.30).

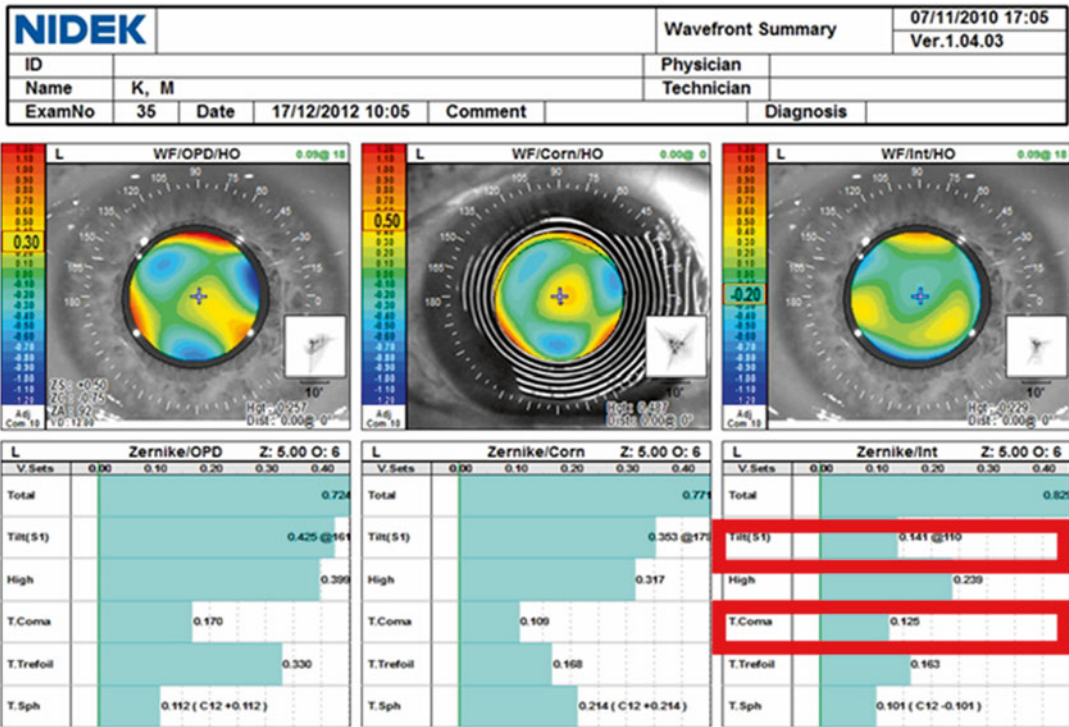


Fig. 14.26 Wavefront analysis in patient with broken haptic, low amount of internal aberrations tilt and coma

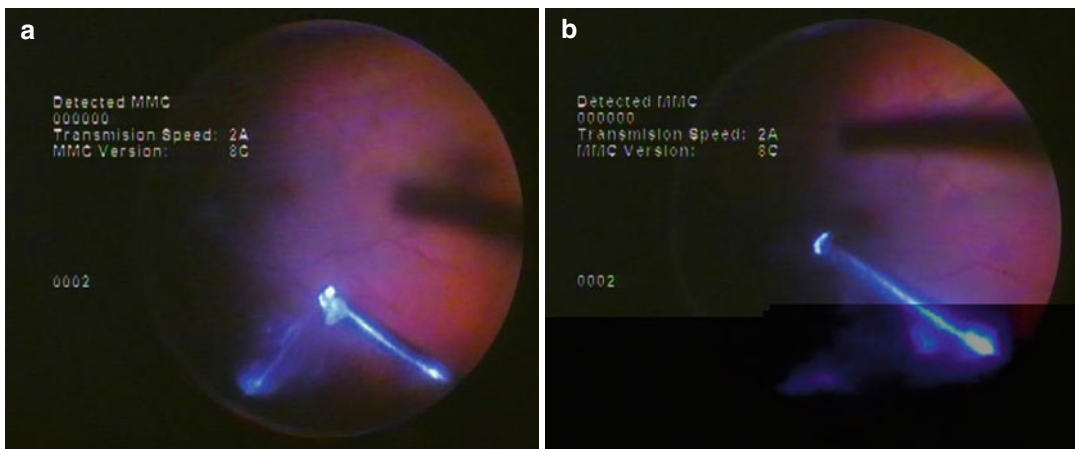


Fig. 14.27 a, b Pars plana vitrectomy to remove the vitreous opacity in patient with AT LISAtri

14.9 Optical Quality

The aim of multifocal lens exchange is to offer some degree of spectacle independence and to improve image quality. Emmetropic eye with the

pupil less than 3 mm is aberration-free, providing high image quality. However, when the pupil size increases, optical aberrations increase resulting in loss of optical image quality (Fig. 14.31).

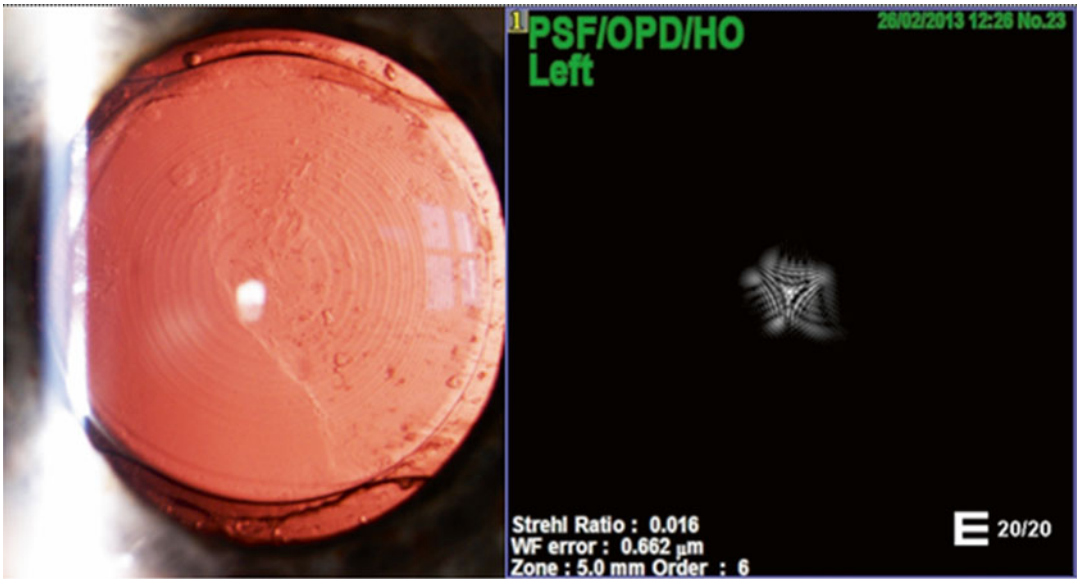


Fig. 14.28 Patient 14 months after AT LISA tri. *Left:* Elschmig pearls in central zone, VA. *Right:* very low Strehl ratio in 5.0 mm pupil

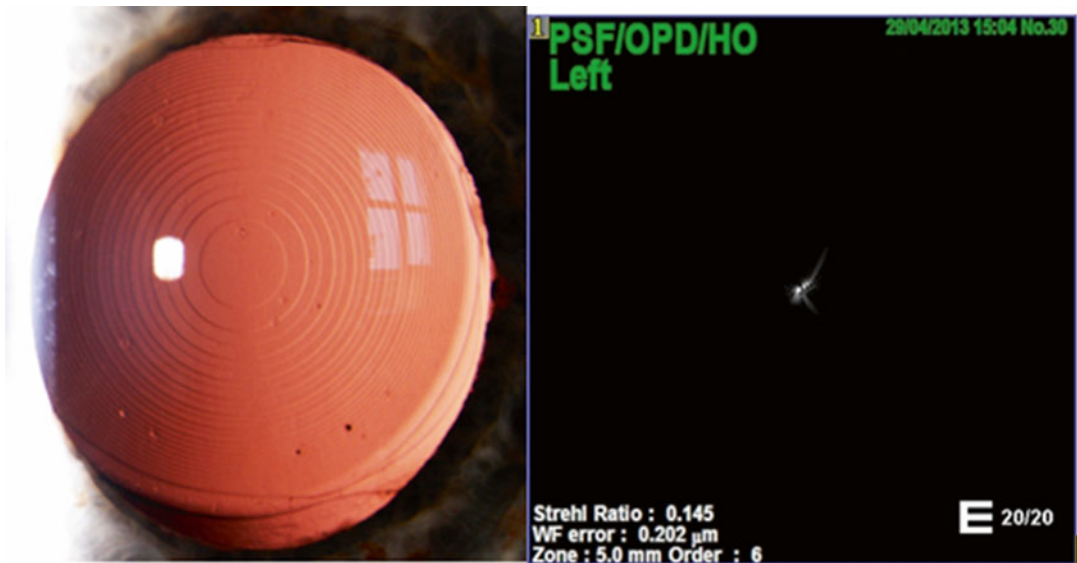


Fig. 14.29 The same patient after successful aspiration of Elschmig pearls (with very clear posterior capsule) and significant improvement of Strehl ratio and visual acuity in all distances

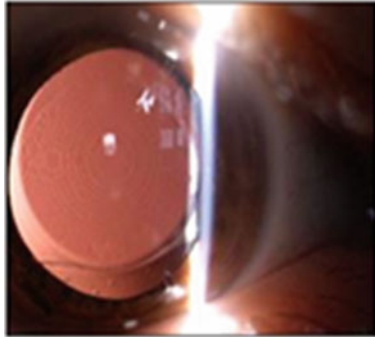
Fig. 14.31 Optical image quality in patient with AT LISA tri implantation in 3, 4, 5 and 6 mm pupil

EPCO 2000 evaluation report

08.03.2013 19:49:11

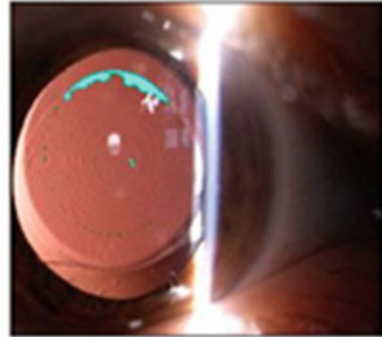
This copy of EPCO 2000 is not registered.

Native image



Kacirek, Petr OD.jpg

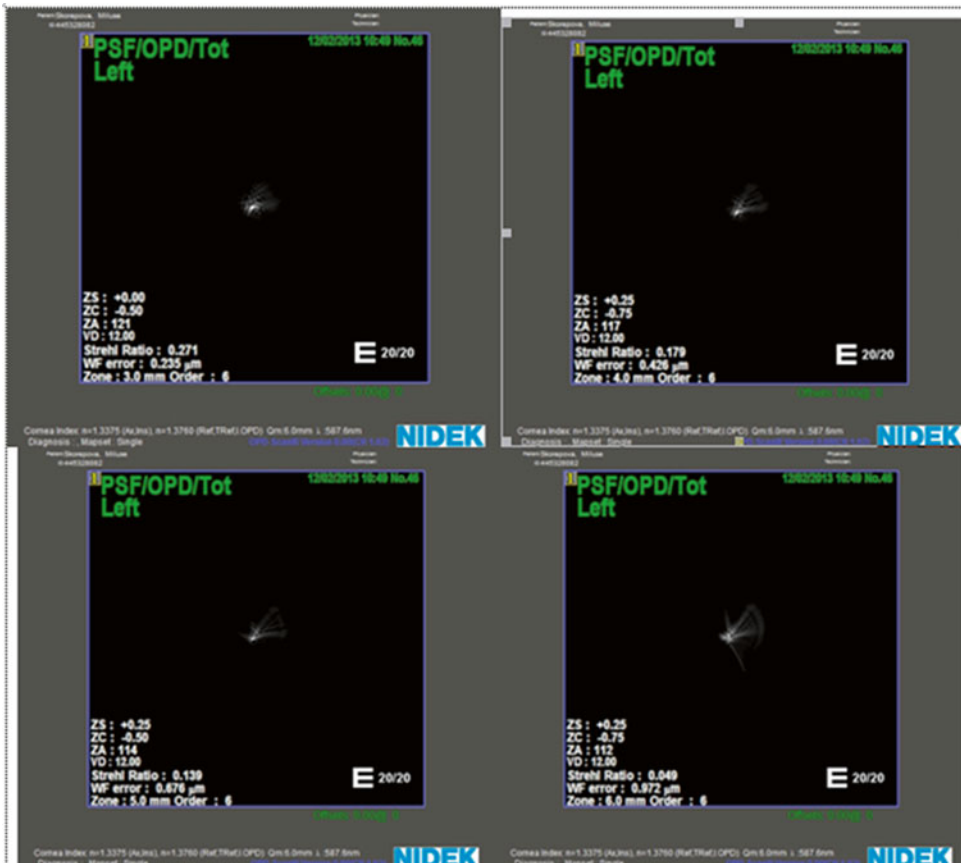
Evaluated image



Kacirek, Petr OD_eval.jpg

Area 1	0.045	Area 3	0		
Area 2	0	Area 4	0	Total	0.045

Fig. 14.30 EPCO 2000 evaluation report 12 months after surgery



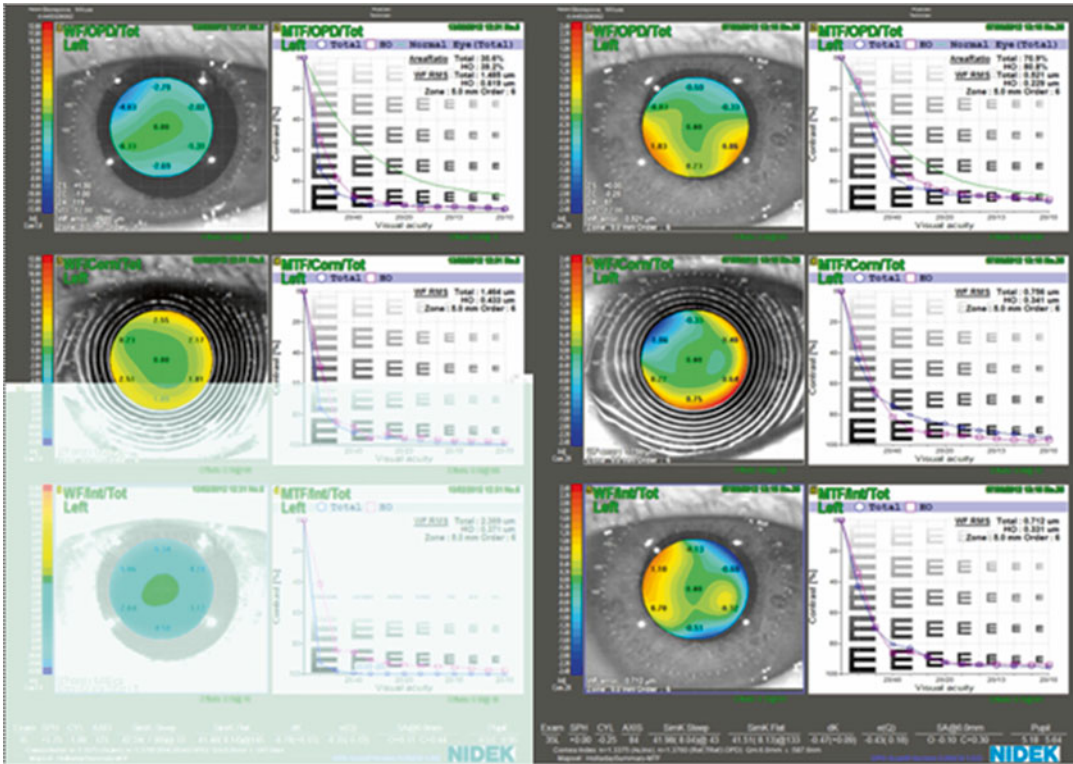


Fig. 14.32 MTF improvement of whole optical system (OPD total), cornea and intraocular lens (AT LISA tri), comparison of preoperative (left) and postoperative (right)

measurements. In postoperative period, MTF curves for total (blue) and HOA (purple) aberrations are closer to emmetropic eye (green curve) (5 mm pupil)

Modulation transfer function (MTF) is quantitative measurement of image quality. It measures loss of contrast sensitivity and image sharpness when light passes through the optical system. MTF is very sensitive to image degradation (Fig. 14.32). Perfect optical system is defined as an ability of the eye to produce a point image on the retina while watching at the point object. Point spread function (PSF) should be a highly localized bright spot, and its mathematical expression is Strehl ratio. It should be as close as possible to 1 which represents the ideal or perfect optical system (Fig. 14.33).

photoc phenomena such as halos and glare were mentioned by the patients as reported in previous studies of diffractive multifocal IOLs. Three patients (10 %) complained of significant halos; 3 patients complained of glare. Three patients also referred colour distortion (1 of them occasionally) for greens, but not disturbing and only temporary. During the follow-up period, the patients complaining of severe halos reported a significant improvement and overall satisfaction with the implantation (Figs. 14.31, 14.32, 14.33 and Table 14.4).

In our study group of 60 eyes, Strehl ratio and MTF cutoff frequency were evaluated in pupil under cycloplegy with a minimum diameter of 5 mm. All measures correspond to a 5 mm pupil. There was a significant improvement in the Strehl ratio from 0.01 ± 0.01 preoperatively to 0.07 ± 0.03 6 months after the surgery and an improvement in the cutoff frequency of the MTF ($p < 0.001$) from 25.61 ± 11.36 to 57.82 ± 12.00 cpd. Evolution of the MTF and Strehl ratio is presented in Table 14.4. However,

14.10 Corneal Astigmatism and Aberration Analysis

Corneal astigmatism greater than 1 dcyll leads to blurred vision and patient dissatisfaction. As mentioned before, AT LISA tri is a foldable model. The lenses were inserted using MICS technique with a very small incision of 1.6 mm. MICS allows better control of surgical-induced astigmatism as

Fig. 14.33 Strehl ratio (5 mm pupil): optical quality for whole optical system (OPD total), cornea and intraocular lens (AT LISA tri), comparison of preoperative (*left*) and postoperative (*right*) measurements. There are no appreciable changes of corneal aberrations and Strehl ratio

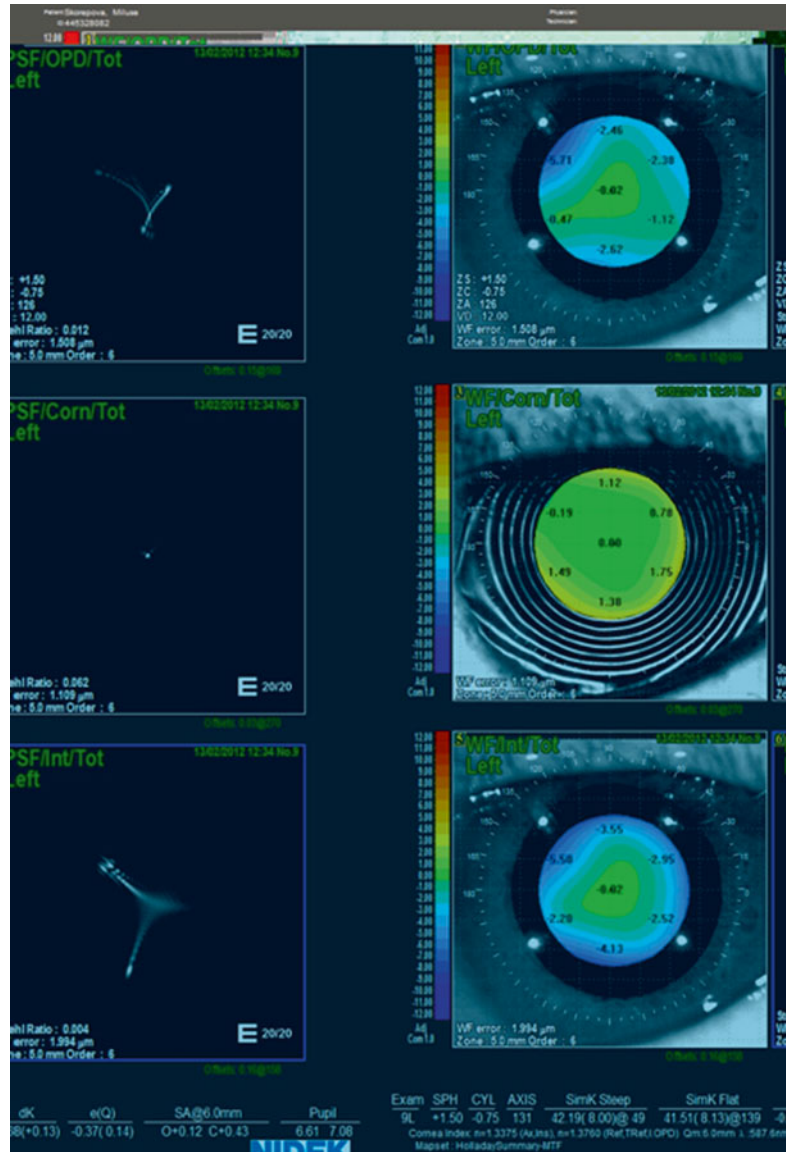


Table 14.4 Changes in Strehl ratio and in cutoff frequency for modulation transfer function (MTF)

	Preoperative	1 month	3 months	6 months
Strehl ratio	0.01 ± 0.01	0.06 ± 0.03	0.07 ± 0.03	0.07 ± 0.03
MTF cutoff frequency (cpd)	25.61 ± 11.36	53.59 ± 14.75	59.64 ± 13.50	57.82 ± 12.00

well as corneal aberrations. This fact is congruent with these keratometric results, which are summarized in Table 14.5. There were no significant differences in the comparison between preoperative and postoperative at 6 months for the flattest meridian (K_1) ($p=0.970$) or the steepest meridian (K_2) (0.769). There was also no significant change

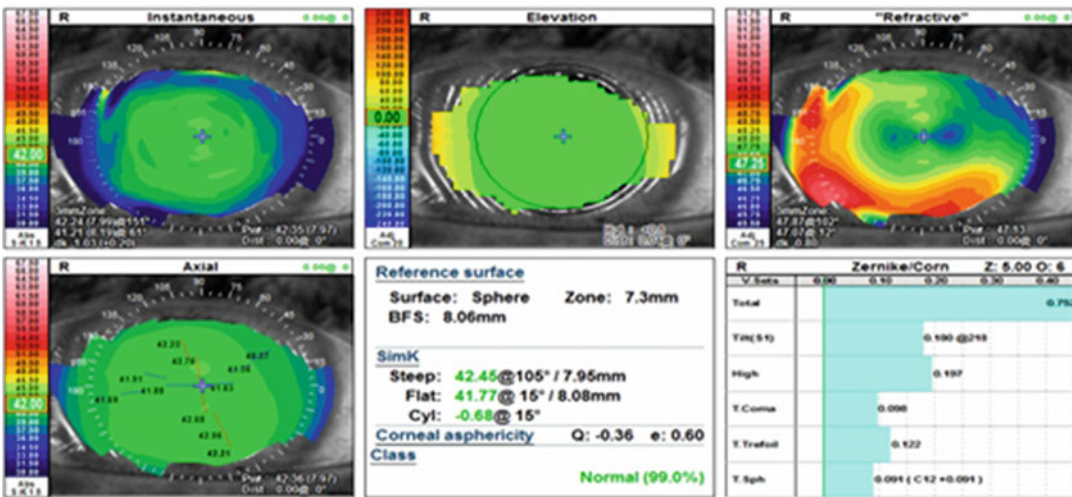
in corneal cylinder (K_2-K_1 in diopters) comparing preoperative and postoperative at 6 months ($p=0.611$) (Fig. 14.34 and Table 14.5).

No significant differences were found also in the comparison between preoperative and postoperative corneal aberrations: RMS total (pre-1 month $p=0.70$; 1–3 months $p=0.23$;

Table 14.5 Keratometric changes during the follow-up

	Preoperative	1 month	3 months	6 months
K ₂ (D)	43.55±1.23	43.60±1.23	43.59±1.26	43.54±1.21
(Steepest meridian)	(40.27 to 46.49)	(40.51 to 46.55)	(40.11 to 46.68)	(40.76 to 46.62)
K ₁ (D)	42.99±1.28	43.00±1.34	43.06±1.29	42.99±1.32
(Flattest meridian)	(39.62 to 45.86)	(39.76 to 45.96)	(39.85 to 45.92)	(39.52 to 45.86)
K ₂ -K ₁ (D)	0.56±0.23	0.58±0.28	0.54±0.26	0.54±0.31
(Corneal cylinder)	(0.16 to 1.13)	(0.11 to 1.43)	(0.05 to 1.15)	(0.00 to 1.32)

NIDEK		Cornea Summary		29/01/2012 09:00	
ID	5962021142	Physician		Ver.1.04.03	
Name	Teufova, Marie	Technician			
ExamNo	5	Date	18/11/2011 12:39	Comment	Diagnosis



NIDEK		Cornea Summary		29/01/2012 09:02	
ID	5962021142	Physician		Ver.1.04.03	
Name	Teufova, Marie	Technician			
ExamNo	9	Date	12/01/2012 15:00	Comment	Diagnosis

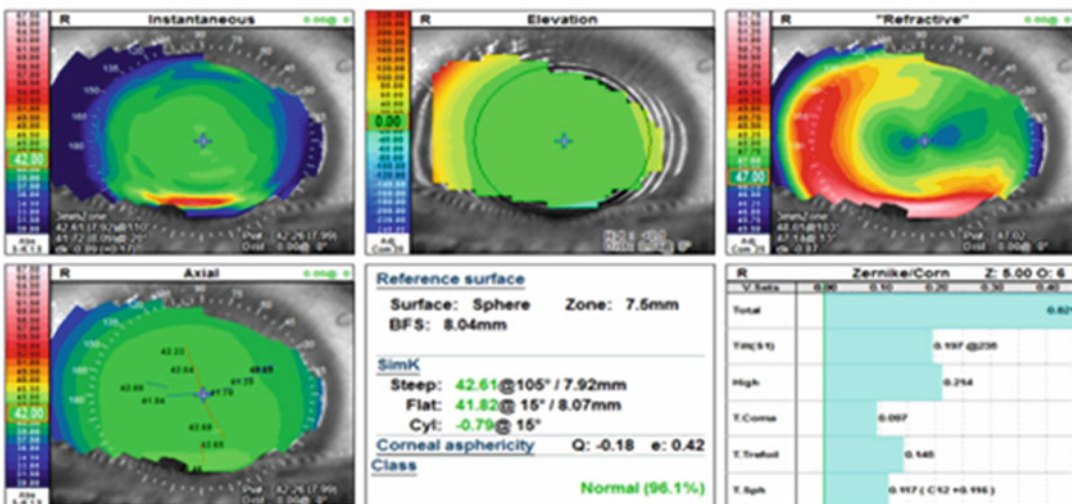


Fig. 14.34 Corneal cylinder and aberration changes pre-op, (a) 1 month, (b) 3 months and (c) 6 months after surgery

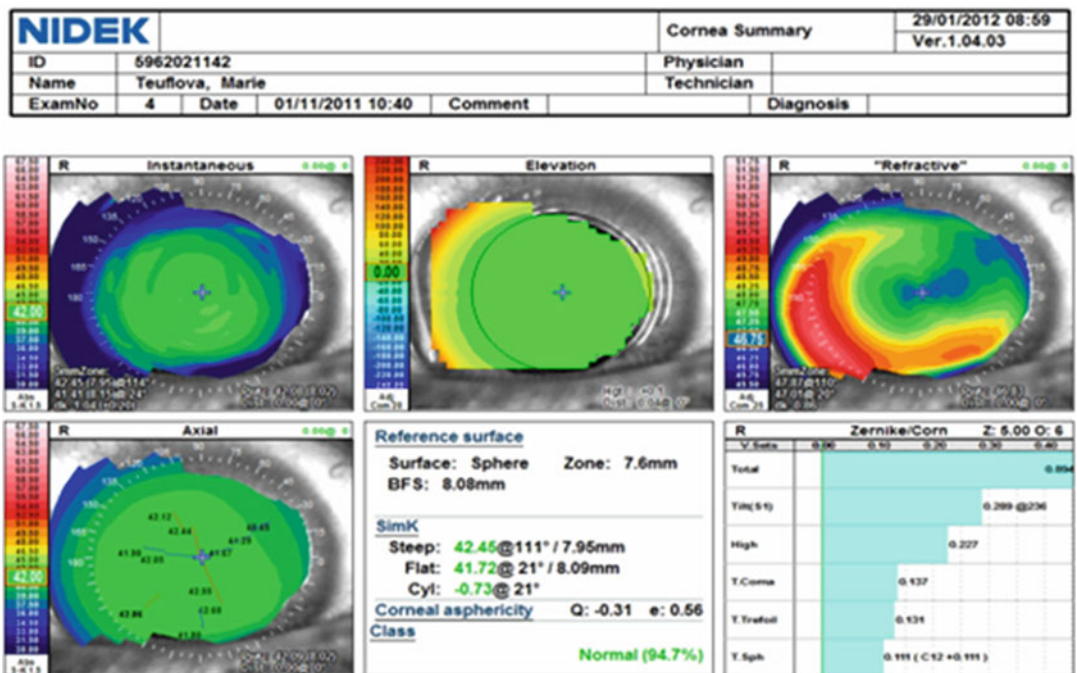
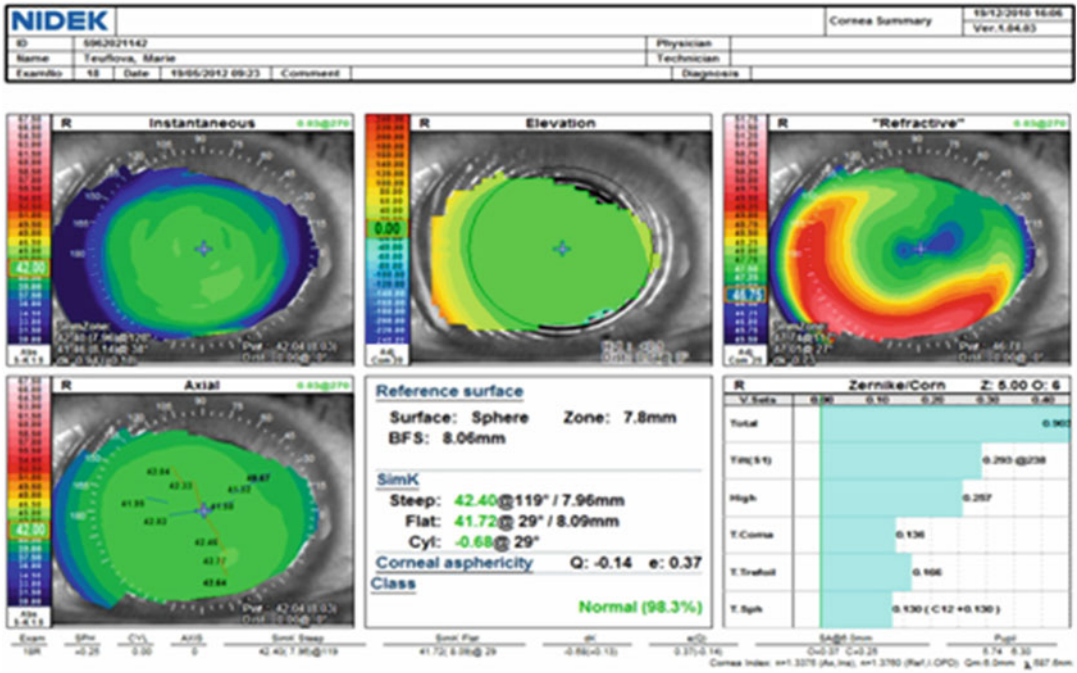


Fig. 14.34 (continued)

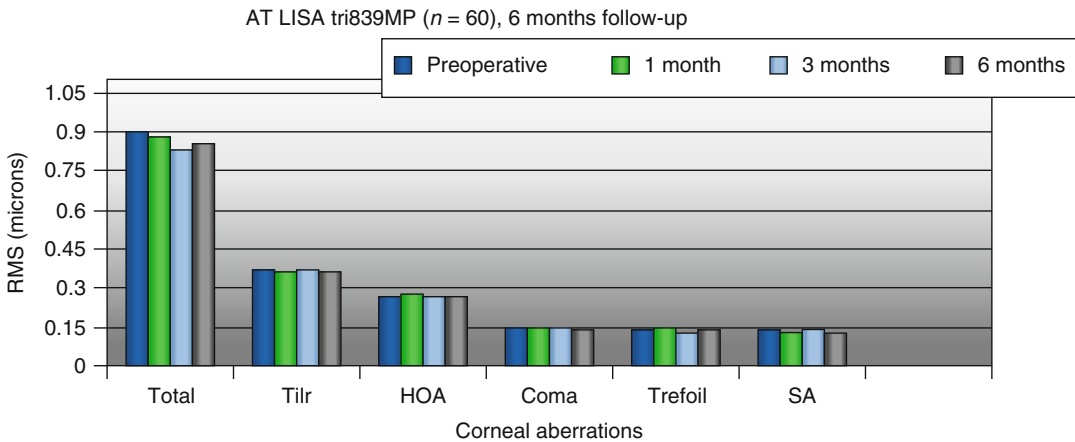


Fig. 14.35 Preoperative and postoperative corneal aberration values

Table 14.6 Changes in internal aberrations during the follow-up. Root mean square (RMS) is expressed in microns

RMS aberrations (μm)	Preoperative	1 month	3 months	6 months
Total	2.47 ± 1.77	0.69 ± 0.19	0.73 ± 0.19	0.76 ± 0.20
Tilt	0.33 ± 0.25	0.29 ± 0.14	0.28 ± 0.14	0.28 ± 0.14
Higher order	0.31 ± 0.30	0.26 ± 0.09	0.25 ± 0.05	0.26 ± 0.05
Primary coma	0.13 ± 0.10	0.11 ± 0.05	0.12 ± 0.05	0.12 ± 0.05
Trefoil	0.19 ± 0.16	0.14 ± 0.09	0.14 ± 0.05	0.15 ± 0.08
Spherical	0.09 ± 0.06	0.13 ± 0.04	0.13 ± 0.03	0.13 ± 0.03

3–6 months $p=0.09$; pre-6 months $p=0.55$), RMS tilt (pre-1 month $p=0.57$; 1–3 months $p=0.59$; 3–6 months $p=0.65$; pre-6 months $p=0.75$), RMS HOA (pre-1 month $p=0.06$; 1–3 months $p=0.22$; 3–6 months $p=0.35$; pre-6 months $p=0.70$), RMS coma (pre-1 month $p=0.83$; 1–3 months $p=0.53$; 3–6 months $p=0.23$; pre-6 months $p=0.86$), RMS SA (pre-1 month $p=0.31$; 1–3 months $p=0.19$; 3–6 months; $p=0.30$; pre-6 months $p=0.61$) and RMS trefoil (pre-1 month $p=0.05$; 1–3 months $p=0.03$; 3–6 months $p=0.23$; pre-6 months $p=0.31$). The lowest p value for the different comparisons was 0.310 for the comparison of the change in corneal trefoil aberration.

Regarding the aberrometric analysis, the corneal aberrometric profile remained almost unchanged, with no significant differences for any aberration (Fig. 14.35).

Furthermore, the analysis of ocular aberrations showed a significant decrease after the surgery in RMS total aberrations from 2.16 ± 1.89 to 0.60 ± 0.18 μm ($p < 0.001$), RMS tilt from 0.34 ± 0.22 to 0.24 ± 0.14 μm ($p = 0.002$), RMS

primary coma from 0.12 ± 0.08 to 0.10 ± 0.05 μm ($p = 0.019$) and RMS spherical aberration from 0.11 ± 0.13 to 0.04 ± 0.03 μm ($p < 0.001$). There was a minimal but nonsignificant improvement in RMS higher-order aberrations from 0.33 ± 0.16 to 0.29 ± 0.10 μm ($p = 0.075$).

The comparison of preoperative intraocular aberrations with postoperative at 6 months revealed a significant mean decrease in total internal aberrations ($p < 0.001$) from 2.47 to 0.76 μm. RMS spherical aberration increased significantly from 0.09 ± 0.06 to 0.13 ± 0.03 μm ($p < 0.001$) (Fig. 14.35). There were no significant changes in internal aberrations comparing 1, 3 and 6 months: total internal ($p = 0.144^*$), tilt ($p = 0.682^*$), higher order ($p = 0.583^*$), primary coma ($p = 0.247^*$), trefoil ($p = 0.190^*$) and spherical aberration (0.805^*) (Table 14.6 and Fig. 14.36). This means that the visual function of the patient was restored very rapidly, from the first month after the surgery (Table 14.6 and Fig. 14.36).

The analysis of internal aberrations showed a significant decrease in total aberrations and a

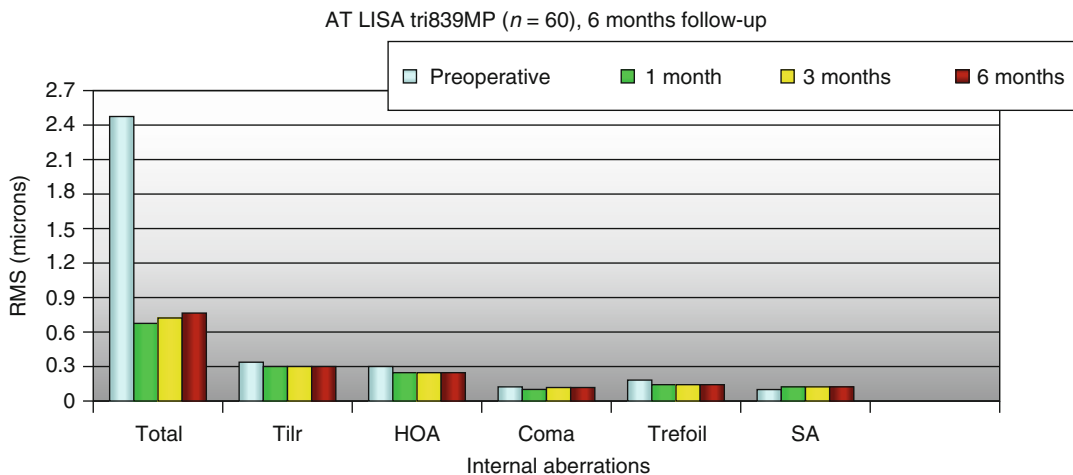
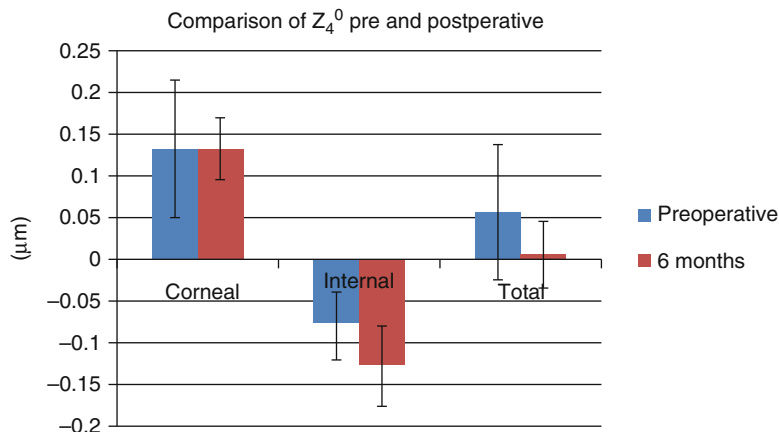


Fig. 14.36 The internal aberrometric changes

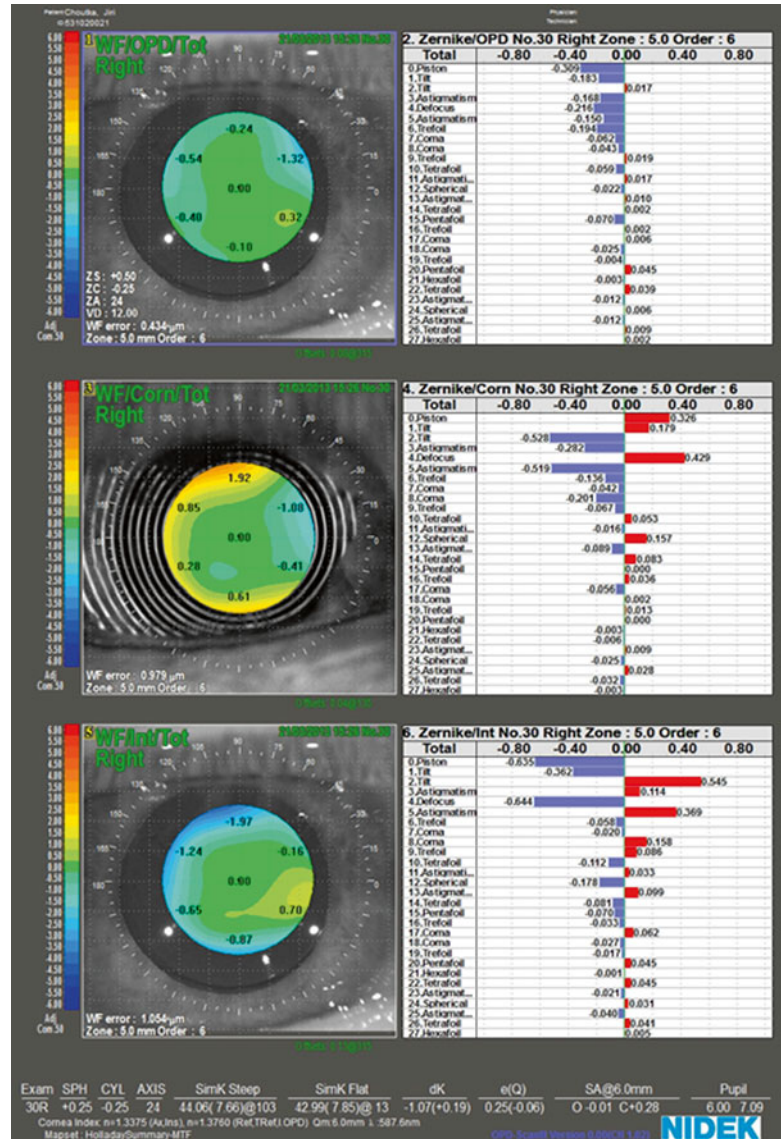
Fig. 14.37 Excellent compensation of corneal spherical aberrations by means of AT LISA tri resulting in very low total spherical aberrations close to 0



significant increase in the RMS spherical aberration postoperatively. The internal spherical aberration changed postoperatively to more negative values (although RMS values were higher) which resulted in lower RMS values of total spherical aberration. The explanation of this question seems to be related to the age of the patients, 57.90 ± 7.85 years. As reported by Artal, the internal spherical aberration in the young eye is, normally, negative and tends to compensate the usual positive aberration of the cornea. However, changes occur with age causing the internal spherical aberration to reach less negative values, and the effect produced is a decrease in the compensation of ocular spherical aberration.

Therefore, the aberrometric analysis revealed that the AT LISA tri induced negative values of the internal spherical aberration, and moreover the internal spherical aberration was more negative ($0.04 \mu\text{m}$ in mean) than that previously induced by the crystalline lens in the presbyopic patients operated with this IOL. The final result was a good compensation between corneal and internal spherical aberrations, obtaining low values of the ocular spherical aberration. The $Z_4.0$ Zernike coefficient was more negative in the postoperative and produces a better compensation of corneal spherical aberration. This effect resulted in lower values of ocular spherical aberration (Figs. 14.37 and 14.38).

Fig. 14.38 Example of excellent corneal/internal balance in spherical aberration. Postoperative measurement of wavefront aberrations (Zernike coefficient), aspheric profile of AT LISA tri (-0.178) compensates spherical aberrations of typical cornea (0.157) resulting in very low value of total spherical aberration (-0.022)



14.11 AT LISA tri 839MP

This lens is the first premium preloaded intraocular lens with 6.0 mm biconvex optic and overall length of 11.0 mm. It is made of foldable hydrophilic acrylate with a water content of 25 %, hydrophobic surface properties and a refractive index of 1.46. It has smooth diffractive structure covering the entire anterior optical surface. Aspheric optic corrects spherical aberration of typical cornea, and the asphericity of this lens is

- 0.18 μ m. It has a four-haptic design with an angulation of 0° and a new 360° square edge to prevent posterior capsule opacification. The lens is available from spherical power of 0.0 D to +32.0 D in 0.5 increments and is implanted with a single-use injector BLUEMIXS 180 through an incision less than 1.8 mm. The company-labelled A-constant for this lens is 118.6. Before starting the surgery, it is highly recommended to check updated A-constant on ULIB. The AT LISA tri is trifocal within a lens diameter of 4.3 mm, and

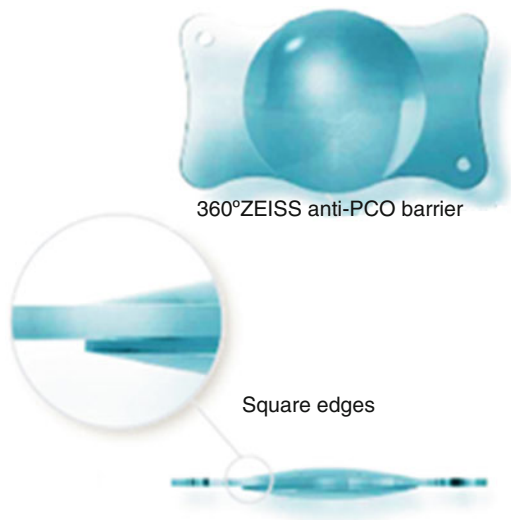


Fig. 14.39 AT LISAtri plate design with a new square edge to prevent PCO formation

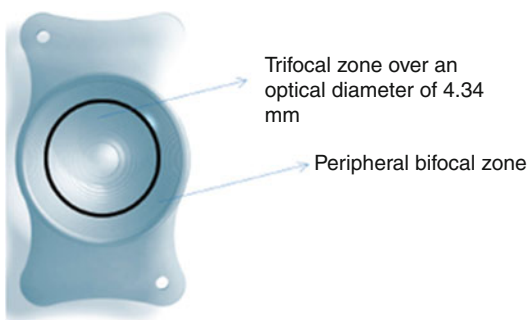


Fig. 14.40 Optics of AT LISAtri consists of two parts, central 4.34 mm trifocal zone and peripheral bifocal (like AT LISA)

between 4.3 and 6 mm diameter, it is bifocal. The add powers within the 4.3 mm diameter are 1.66 to intermediate and 3.33 diopters to near distance (Fig. 14.8). The add power between the 4.3 and 6 mm diameter is 3.75 diopters (equal to the AT LISA) (Figs. 14.39 and 14.40).

For large pupils (e.g. 6 mm), the adds of 3.33 diopters and 3.75 diopters, respectively, blend to result in a depth of focus in the near power. The relative intensity distribution is practically constant up to a diameter of 4.3 mm, with 50 % relative intensity for distance, 30 % for near and 20 % for intermediate. For pupils larger than 4.3 mm, the distance intensity increases, and the

intermediate intensity decreases while the near intensity remains constant (Fig. 14.41).

Total usable light intensity is 87 %, an amount which compares favourably with bifocal diffractive lenses with equal light distribution between distance and near, where it is 81 % (Fig. 14.42).

The trifocality is achieved exclusively by a modification of the main and the phase zones of the AT LISA. Unlike AT LISA, AT LISA tri consists of different phase zones in even and uneven zones (Fig. 14.43). Thus, the AT LISA tri does not require any additional lens zones. A detailed description of this zone modification is given in the patent application for the AT LISA tri (WO 2011/134948 A1). This modification is the result of advanced analysis of diffractive lenses. With fewer rings on the optical surface (29 diffractive steps for 0.0 D and 21 steps for +32.0 D IOLs), the AT LISA tri reduces the risk of visual disturbances (Figs. 14.43 and 14.44).

The AT LISA tri allows distance, intermediate and near vision in practical independence of pupil size. The images produced by the lens are in high resolution at every distance in all light conditions (Fig. 14.45).

AT LISA tri – technical specification (Fig. 14.46)

14.12 Patient Satisfaction

All patients were asked about their degree of satisfaction in different tasks. A clinician registered the scores to the following question: “describe, using a number, the quality of vision for these different tasks”. Tasks evaluated were: TV, theatre/concerts, at home, driving at daytime, driving at night (distance vision) and cooking, newspaper, computer, housework (intermediate and near vision). The possible scores were: excellent (1), very good (2), good (3), not completely satisfied (4), dissatisfied (5) and very dissatisfied (6). Results are presented in Table 14.1. As expected, the worst result was achieved in driving at night (2.57) (Table 14.7).

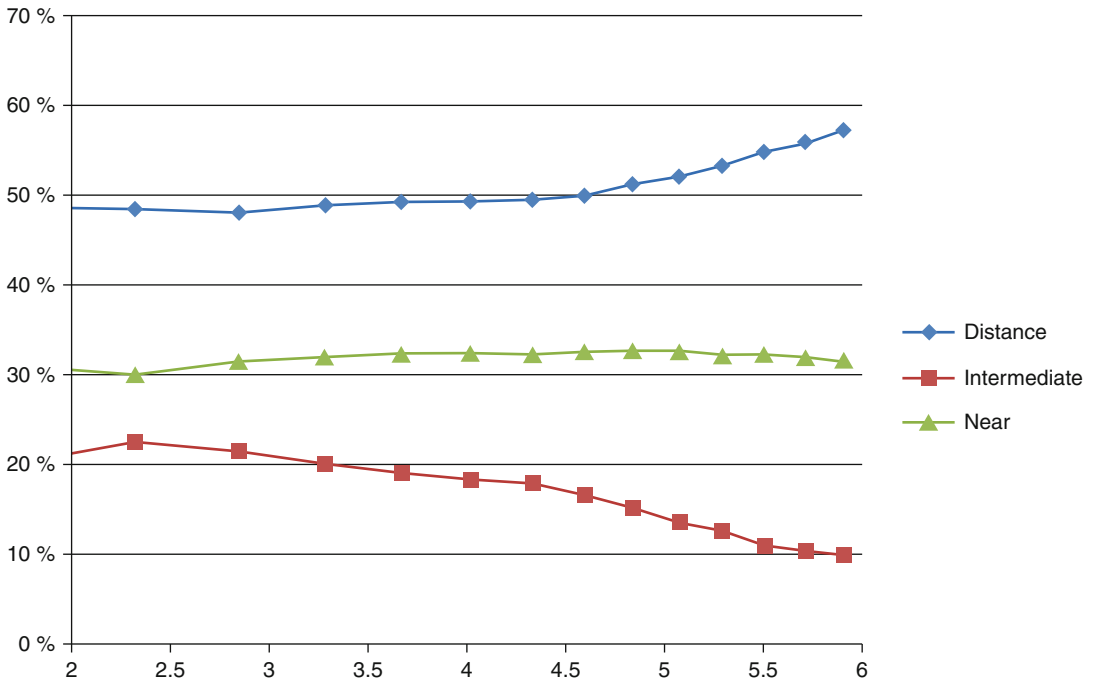


Fig. 14.41 Relative light distribution of the AT LISA tri for far, intermediate and near focus and sum of light intensities as absolute value in %

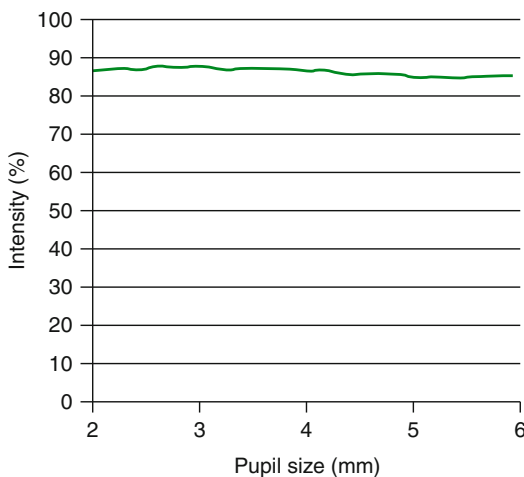


Fig. 14.42 Global light transmittance is close to 90 %

Correlations between these scores and visual outcomes were also investigated. The overall scores were highly correlated with the scores for the variable related to the household tasks ($r=0.512, p<0.001$). Overall scores were also

strongly correlated with the scores obtained for “reading newspaper” ($r=0.48, p<0.001$) and “driving at night” ($r=0.473, p<0.001$). So, these three questions had an important weight in the overall score assigned by each patient. Some of the most interesting correlations between the scores and visual outcomes are presented in Table 14.2. The results provided by the questions to evaluate patients’ subjective satisfaction revealed the importance of contrast sensitivity to medium/high spatial frequencies for different visual tasks. The correlation is negative since the higher the contrast sensitivity the lower the score (better results correspond to lower scores). The positive correlation of higher-order aberrations with the score achieved in the question “driving at night” explains the negative effect of HOAs on the retinal image quality and its major importance at night when pupil size increases. Specifically, the primary spherical aberration (fourth order) has been identified to be an important source of alteration in quality of vision at night.

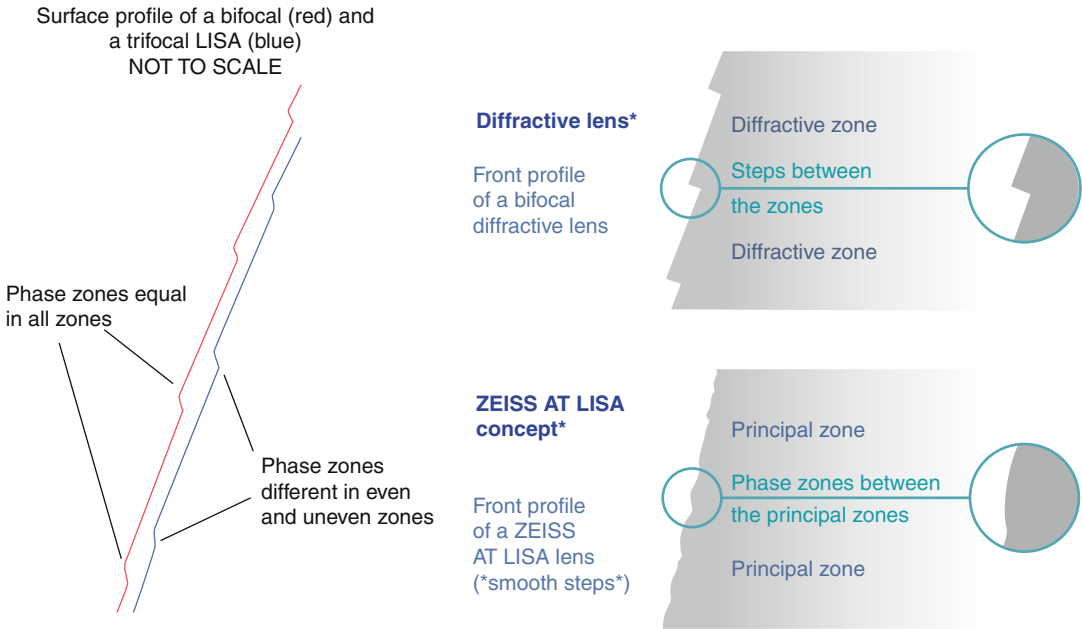
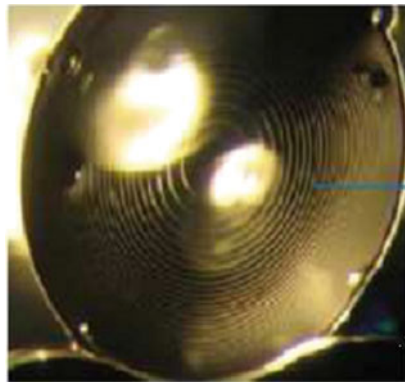


Fig. 14.43 Comparison of diffractive pattern of the bifocal and trifocal AT LISA

Fig. 14.44 AT LISA tri has fewer rings on its optic



- 29 diffractive steps for a 0.0D IOL
- 21 for a +32.0D

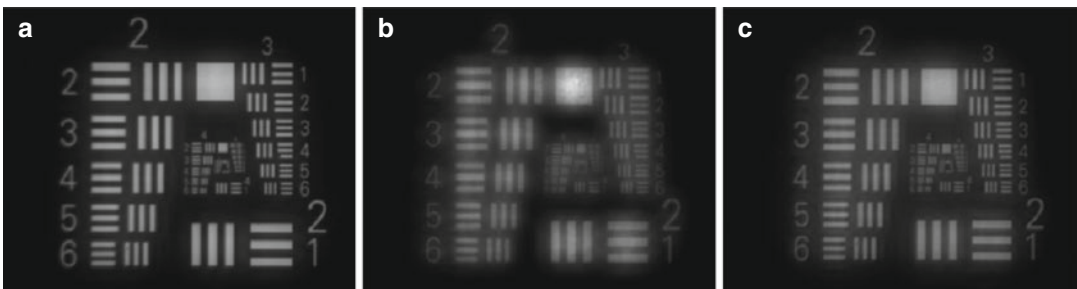


Fig. 14.45 United States Air Force Resolution Target Test (AFT). AT LISA tri at far (a), intermediate (b) and near (c) vision under photopic condition



AT LISA tri 839MP preloaded	
Optic Design	Trifocal, diffractive, +3.33 D near add and +1.66 D intermediate add at the IOL plane, aspheric (aberration correcting)
Material	Hydrophilic acrylic (25 %) with hydrophobic surface properties
Optic Diameter	6.0 mm
Total Diameter	11.0 mm
Haptic Angulation	0°
Lens Design	Single-piece, MICS
Incision Size	1.8 mm
Company Labeled A-Constant ¹	118.6
Diopter Range	0.0 to +32.0 D, 0.5 D increments
ACD	5.32
Implantation in	Bag
Injector / Cartridge Set ²	BLUEMIXS 180
Indications	presbyopia correction in patients with or without cataract (Prelex or CLE)

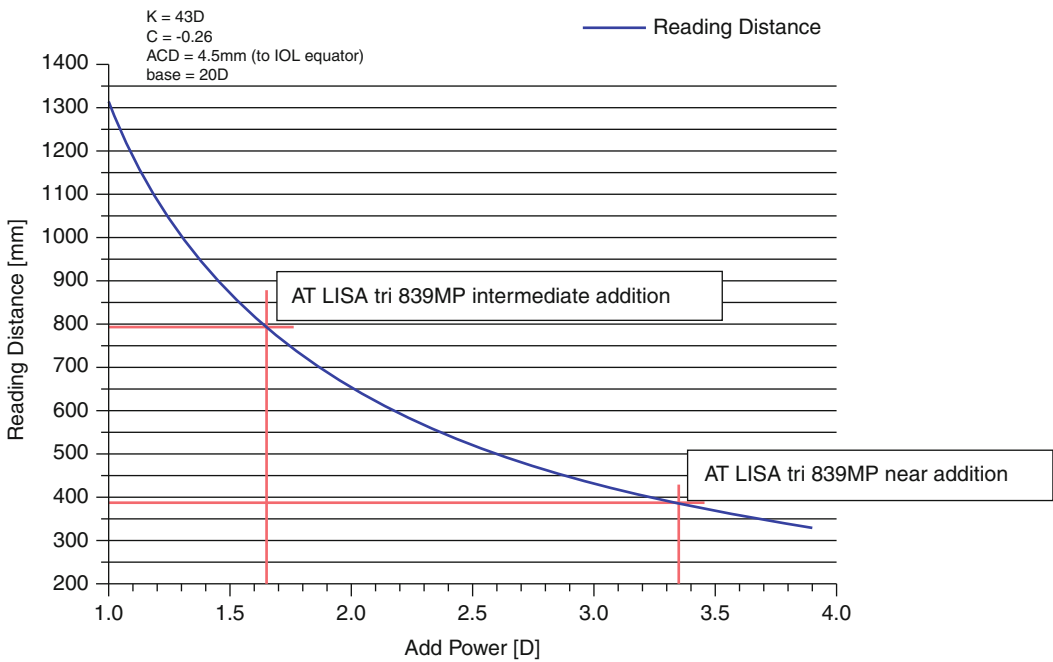


Fig. 14.46 Average reading distance for intermediate and near vision based on optical Raytrace calculation for the average eye. (a) Technical specification of AT LISAtri. (b) Relationship between reading distances and additions

The opinion of the users about this IOL implantation was very positive since all of them considered that the final result, as a whole, was excellent or very good (1 or 2 points). Moreover,

all of them referred that they were comfortable in intermediate distance tasks. Two additional questions were asked to the patients: “Would you choose the same lens again?” “Would you recommend this lens to other persons?” All the patients answered “yes”. This result reflects the excellent visual results achieved with this multifocal IOL model (Table 14.8).

Table 14.7 Satisfaction of the patients with working distances

Task	Score
TV	1.13±0.35 (1 to 2)
Theatre/concert	1.23±0.43 (1 to 2)
Driving at daytime	1.33±0.48 (1 to 2)
At home	1.17±0.38 (1 to 2)
Driving at night	2.57±0.77 (1 to 4)
Cooking	1.13±0.35 (1 to 2)
Newspaper	1.67±0.71 (1 to 3)
Computer	1.67±0.80 (1 to 4)
Homework	1.10±0.31 (1 to 2)
Overall	1.43±0.57 (1 to 2)

Compliance with Ethical Requirements Peter Mojzis, Pablo Peña, and Jorge Alió 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 article.

Table 14.8 Most important correlations between visual and refractive variables and scores to questions about degree of satisfaction in different visual tasks

	Overall	At home	Reading newspaper	Driving at night	Cooking
CS at 3 cpd					$r=-0.300$ $p=0.020$
CS at 6 cpd					$r=-0.362$ $p=0.004$
CS at 12 cpd	$r=-0.254$ $p=0.050$	$r=-0.274$ $p=0.034$	$r=-0.256$ $p=0.049$		$r=-0.345$ $p=0.007$
CS at 18 cpd	$r=-0.255$ $p=0.050$		$r=-0.357$ $p=0.005$		$r=-0.345$ $p=0.007$
SE					$r=0.348$ $p=0.006$
HOA aberrations				$r=0.291$ $p=0.024$	
Strehl ratio				$r=-0.246$ $p=0.058$	
UNVA at 33 cm		$r=0.317$ $p=0.014$	$r=0.297$ $p=0.021$	UNVA at 33 cm	
BCNVA at 40 cm			$r=0.278$ $p=0.031$	BCNVA at 40 cm	

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Roberto Zaldivar and Roger Zaldivar

15.1 Introduction

The goal of a multifocal IOL is to provide functional vision at different distances to minimise the use of glasses. Most studies support that these IOLs offer good distance and near visual acuity [1]. However, it is well known that traditional diffractive bifocal multifocal IOLs report poor scores for intermediate vision, which correlates with worse intermediate visual acuity and a high percentage of patients who wear glasses for seeing objects at intermediate distance [2].

The poor performance at intermediate vision is due to their optical design where light is distributed in two major peaks, zero order for far and first order for near vision. In other words, when patients are focusing on distant objects, the “near add lens” takes some of the light that would have been focused and distributes relatively defocused light onto the retina, decreasing image contrast sensitivity [3]. However, diffractive multifocal lens implant provides excellent reading vision and very good distance vision. The intermediate vision is acceptable but is definitely one of the

downsides of current bifocal designs since some patients who do lots of computer work find they need to sit closer to the computer, make the font size larger on the screen, or get a pair of intermediate vision spectacles to make intermediate work more comfortable. In addition, a considerable amount of patients note glare and halos around lights at night with bifocal diffractive multifocal IOL, a feature that is inherent to multifocal lenses [4]. These effects may interfere with ability to drive comfortably at night. However, most patients find that they get used to this phenomenon with time and the glare and halos become less obvious [5].

With the positioning of clear lens exchange as a widely performed refractive procedure, the age of patients that undergo lens surgery has decreased considerably. There is a clear need in this population to have an efficient intermediate vision to perform their daily tasks and to enjoy current technology [6]. New trifocals and full-range multifocal designs might be a solution to the higher expectations demanded by younger and more knowledgeable patients.

Recent advances in diffractive multifocal IOLs technology offer a new alternative for those desiring vision at distance, intermediate and near [7]. This chapter describes a new IOL based on 100 % diffractive technology, providing an extended range of clear vision at all distances (Figs. 15.1 and 15.2).

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Fig. 15.1 Decreasing steps height and increasing angulation from centre to edge ensures excellent light distribution for both focus point near and far with minimal chance of halos and scattering of light in dim conditions. $R0$ zero power, $dR1$ base refractive power, and $D1$ diffractive power

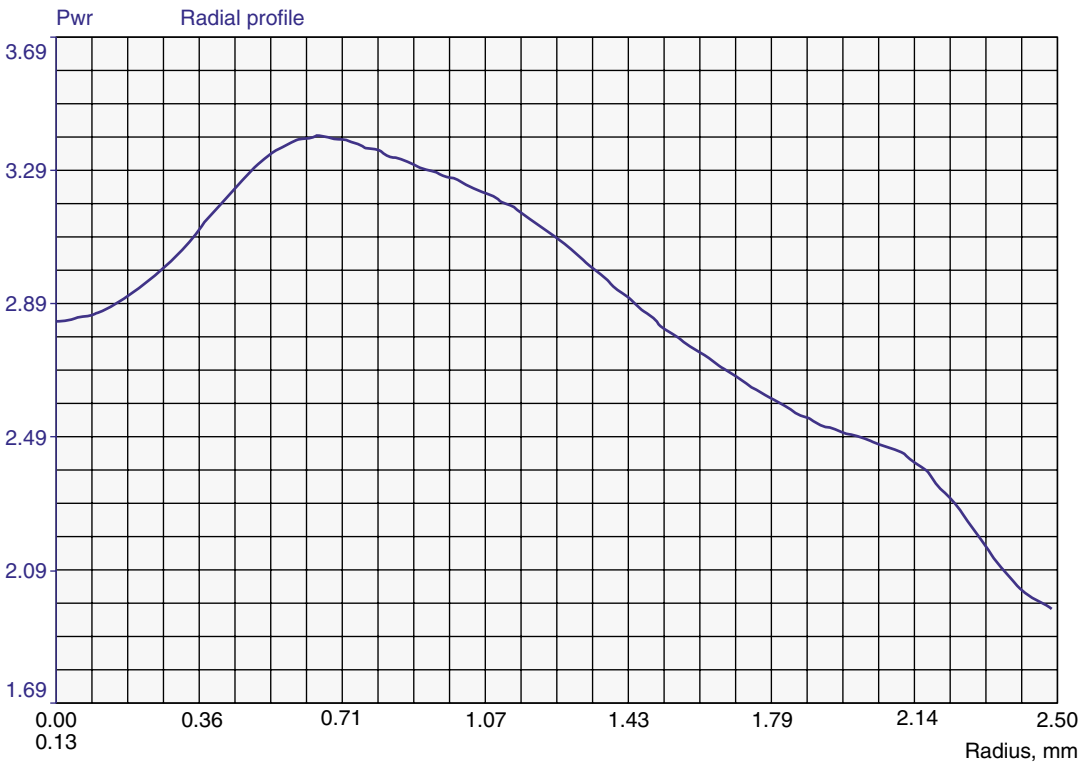
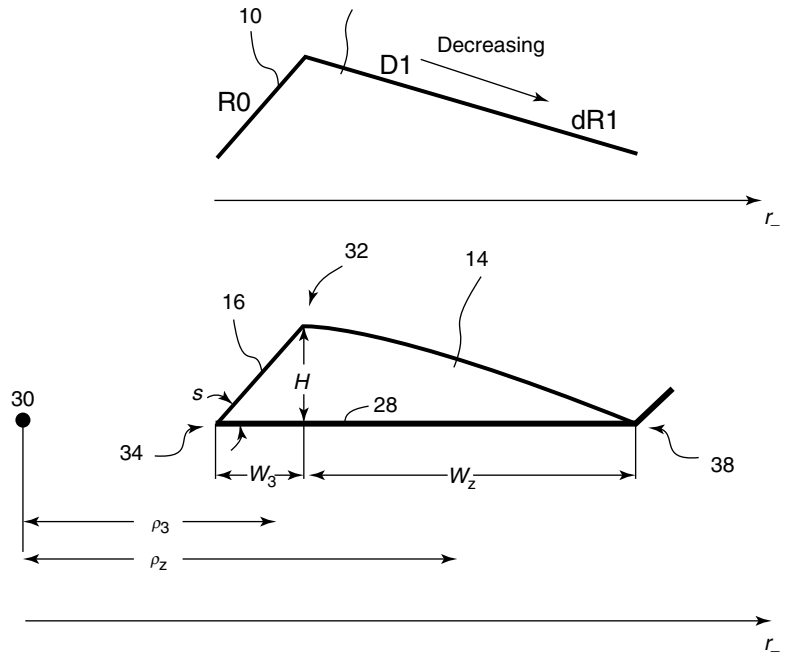


Fig. 15.2 Radial profile of additional power. The additional power is decreasing gradually from centre to periphery

15.2 EyeDIFF’s Patented Design

The full-range multifocal lens makes use of both refractive and diffractive optics. Consequently, the design of the lens is governed by refractive and diffractive considerations and their interrelations (Figs. 15.3, 15.4, and 15.5).

The lens comprising annular zones of alternating powers are shown. In the refractive-diffractive lens, the entire lens of optical diameter B is subdivided into N annular zones, and each of the zones exhibits the same area, e.g. in mm². Such a lens, as is known, produces two principal simultaneous powers with a power difference ΔD between these two powers of

$$\Delta D = \frac{8\lambda N}{B^2} \tag{15.1}$$

In terms of zone radii, this power difference is given by

$$\Delta D = \frac{2\lambda}{(r_2^2 - r_0^2)} \tag{15.2}$$

where r₂ is the outer bonding radius of a zone and r₀ is the inner bonding radius of this zone.

15.3 Results

In a prospective, single-arm, 3-month study conducted at two sites in Argentina, 40 patients (80 eyes) requiring bilateral cataract extraction or

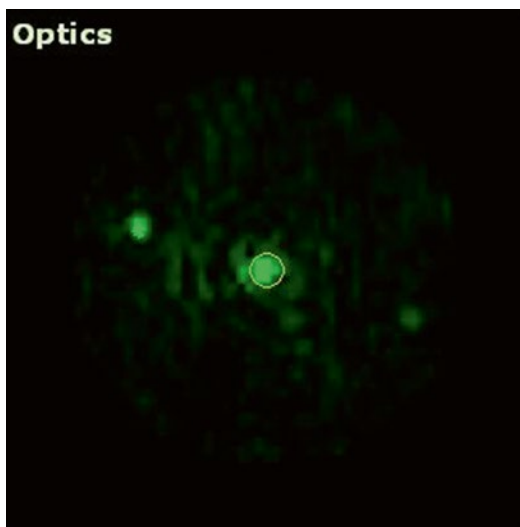


Fig. 15.3 Optical bench performance describing three main foci as a true trifocal and induces minimal halos and glare

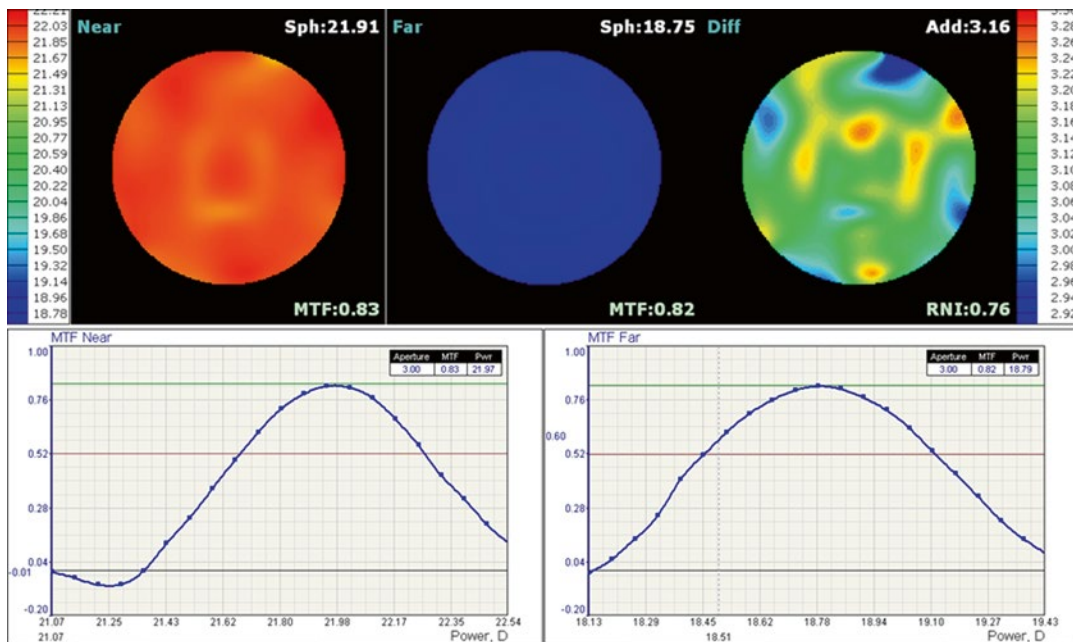


Fig. 15.4 MTF measurement is performed in every IOL, and the optical quality results are attached to each IOL

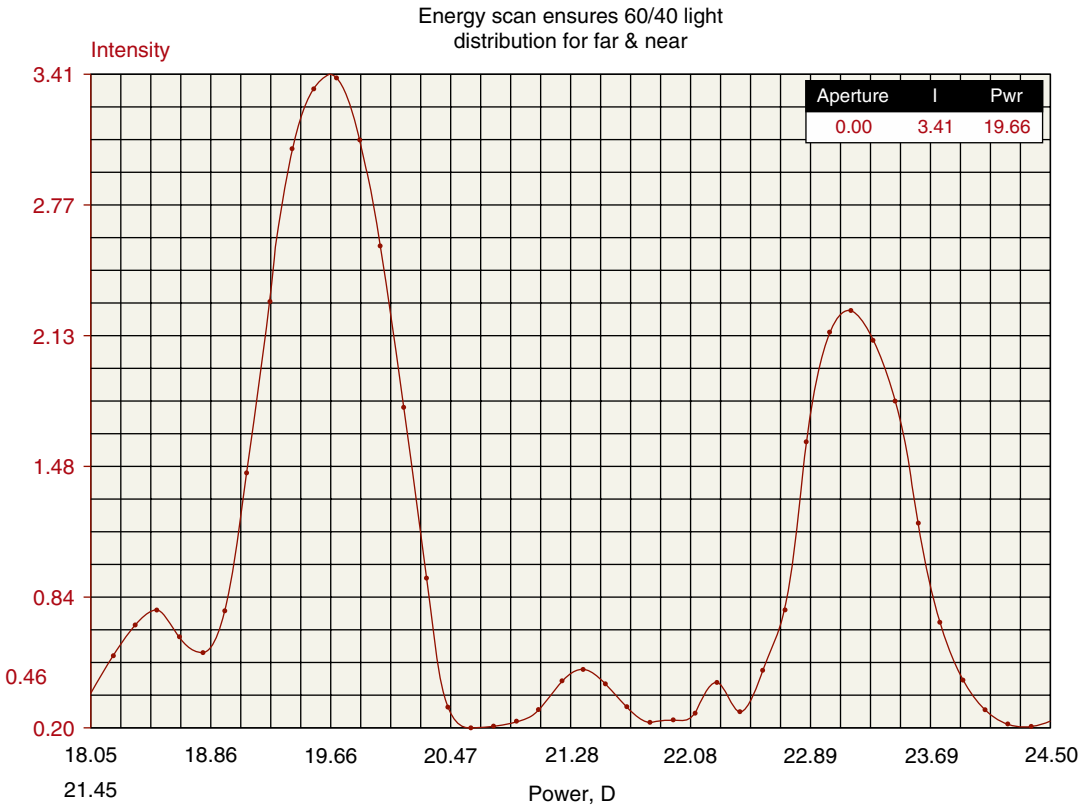


Fig. 15.5 Energy scan ensuring 60/40 light distribution

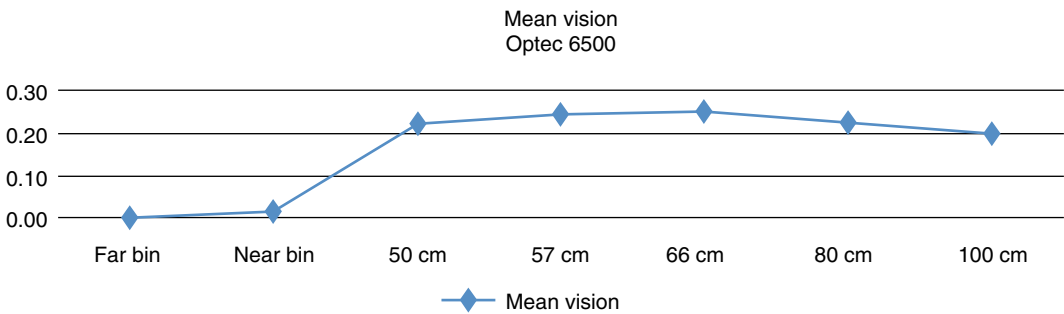


Fig. 15.6 Mean vision in the study describing a good performance at all distances (LogMar)

refractive lens exchange and IOL implantation in both eyes with preoperative regular corneal astigmatism of less than 0.75 D received bilateral EyeDIFF +3.5 D, IOL UK. The residual refractive absolute error was 0.33 D, 82.5 % within 0.5 D and 100 % within ±1.0 D. Uncorrected visual acuity was 0.00±0.2 logMAR at distance and 0.02±0.30 logMAR at near. The intermediate vision performance was tested with the Optec

6500, and it showed a flat defocus line with a 0.22±0.14 logMAR at 50 cm, 0.25±0.13 logMAR at 57 cm, 0.26±0.13 logMAR at 66 cm, 0.23±0.14 logMAR at 80 cm and 0.20±0.13 logMAR at 100 cm. Spectacle independence was achieved in 100 % of the patients for distance and near, with high levels of satisfaction reported. There were no minor adverse events described (Figs. 15.6 and 15.7).

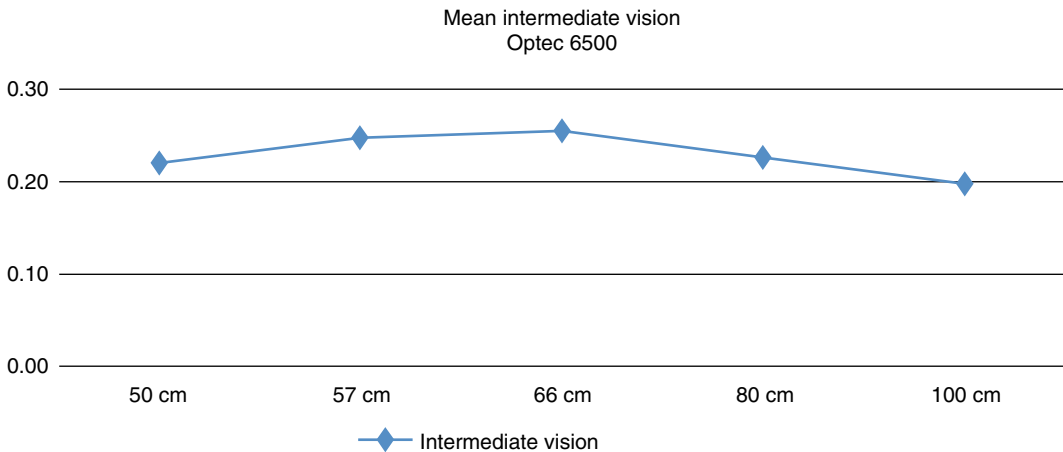


Fig. 15.7 Mean intermediate vision in the study describing a good performance at all distances

Conclusion

The EyeDIFF full-range multifocal IOL provides a good visual performance at all distances with minimal adverse effects.

Compliance with Ethical Requirements *Conflict of Interest*

Roger Zaldivar and Roberto Zaldivar hereby declare that they have no conflict of interest.

Informed Consent

No human studies were carried out by the authors for this article.

Animal Studies

No animal studies were carried out by the authors for this article.

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16.1 Introduction

Currently, the visual tasks of the patients are more exigent. They look for visual solutions for their lifestyle in a new information society. To satisfy the demands of a population with high life expectancy in developed countries, innovative intraocular lenses (IOLs) are appearing on the market. Frequently, the needs of different foci have been solved in many patients with a diffractive bifocal IOL. This kind of design of multifocal lens is made to control the percentage of light that arrives to each foci. A new multifocal intraocular lens (IOL) of recent commercialization is the FineVision trifocal IOL (PhysIOL, Liège,

Belgium). This IOL as shown in Fig. 16.1 integrates in the same optical body of two diffractive profiles to generate three different foci for distance, near, and intermediate vision [1] (Fig. 16.1).

In this chapter, the optical and visual outcomes of patients implanted with the Fine Vision IOL after cataract surgery are described. A description of the methods used and the results derived is developed below.

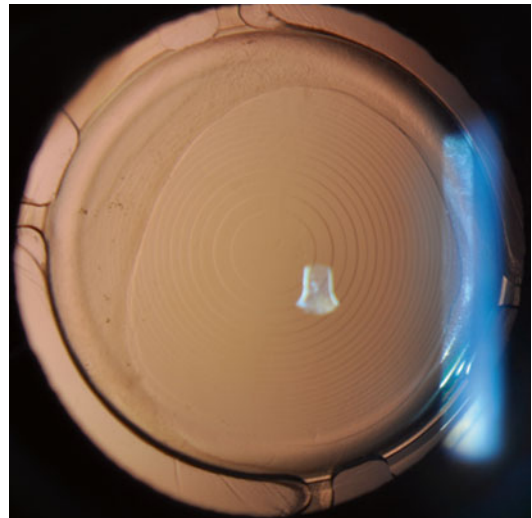


Fig. 16.1 Trifocal intraocular lens Fine Vision after 3 months of microincisional cataract surgery (MICS)

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16.2 Materials and Methods

16.2.1 Subjects

In this prospective consecutive interventional non-comparative study, we included 40 eyes of 20 bilateral cataractous patients with age ranging from 54 to 82 (mean age of 66.49 years old). The inclusion criteria of this study were patients with bilateral cataract, patients over 48 years old, and patients with corneal astigmatism of less than 1.50 D and uncomplicated surgery. The exclusion criteria were patients with previous ocular surgery, other ocular comorbidities, complications during surgery, and corneal astigmatism > 1.50 D. All patients were adequately informed and signed a consent form. The study adhered to the tenets of the Declaration of Helsinki and it was approved by the local Ethical Board Committee.

16.2.2 Surgery

All surgeries were performed by the same surgeon (JLA) using a sutureless microincision cataract surgery (MICS) phacoemulsification technique. All patients received topical anesthesia before surgery. Adequate dilation was obtained with intracameral mydriasis. The main incision was placed at the axis of the positive corneal meridian. The IOL FineVision was implanted in the capsular bag through a corneal incision of 1.8 mm. Postoperative therapy was prescribed including a combination of topical antibiotic and steroid agents.

16.2.3 Intraocular Lens

The Fine Vision IOL (Physiol, Liege, Belgium) is a trifocal, single-piece, foldable, and aspheric intraocular lens with two fully diffractive structures, one with +1.75 D addition for intermediate vision and another one with +3.5 D addition for near vision. It is made of 25 % hydrophilic material with yellow chromophore embedded in the matrix polymer. The theoretical light distribution for a 20 D diffractive IOL is 42 % for far focus, 15 % for intermediate focus, and 29 % for near with 14 % lost energy at 3 mm pupil diameter [1]. The distribution of light is variable with the pupil size.

The larger the pupil diameter, the greater the light distribution in far focus, which favors distance vision in dim light, while a smaller pupil diameter proportionally increases the amount of light on the near and intermediate focus [1]. The power range available is from 10 D to 35D (steps of 0.50 D). The IOL has a gradual decrease in the step height from the center to periphery to reduce halo symptoms at night [1].

16.2.4 Preoperative Examination

Preoperatively all patients had a full ophthalmological examination including the evaluation of the refractive status, distance and near visual acuities, slit lamp examination, tonometry, and funduscopy. The visual acuity was measured with the Early Treatment Diabetic Retinopathy Study (ETDRS) charts. Besides these clinical tests, other specific examinations were performed: corneal topography (CSO, Florence, Italy) and biometry by optical coherence interferometer (IOL Master v.4.3, Carl Zeiss Meditec). The target in the intraocular power lens calculation was plano in all cases included in the study.

16.2.5 Postoperative Examination

Patients were evaluated during the follow-up at 1 day, 1 week, 1 month, 3 months, and 6 months after surgery. The same independent experienced investigator (R.M.) performed all postoperative examinations using the same investigational protocol. The manifest refraction and visual acuity for distance, intermediate (80 cm), and near (40 cm) with and without corrected distance was evaluated at 1, 3, and 6 months with ETDRS charts. The visual acuity was evaluated in monocular and binocular photopic conditions. In addition, the distance-corrected visual acuity (CDVA) was measured in monocular with OPTEC 6500 (Vision Science Research Corp, Walnut Creek, California) in scotopic conditions (3 cd/m²). Monocular contrast sensitivity function (CSF) test was evaluated under scotopic conditions (3 cd/m²) with OPTEC 6500 at 1 and 6 months post surgery.

In addition, defocus curves were obtained at 6 months postoperatively. To generate defocus

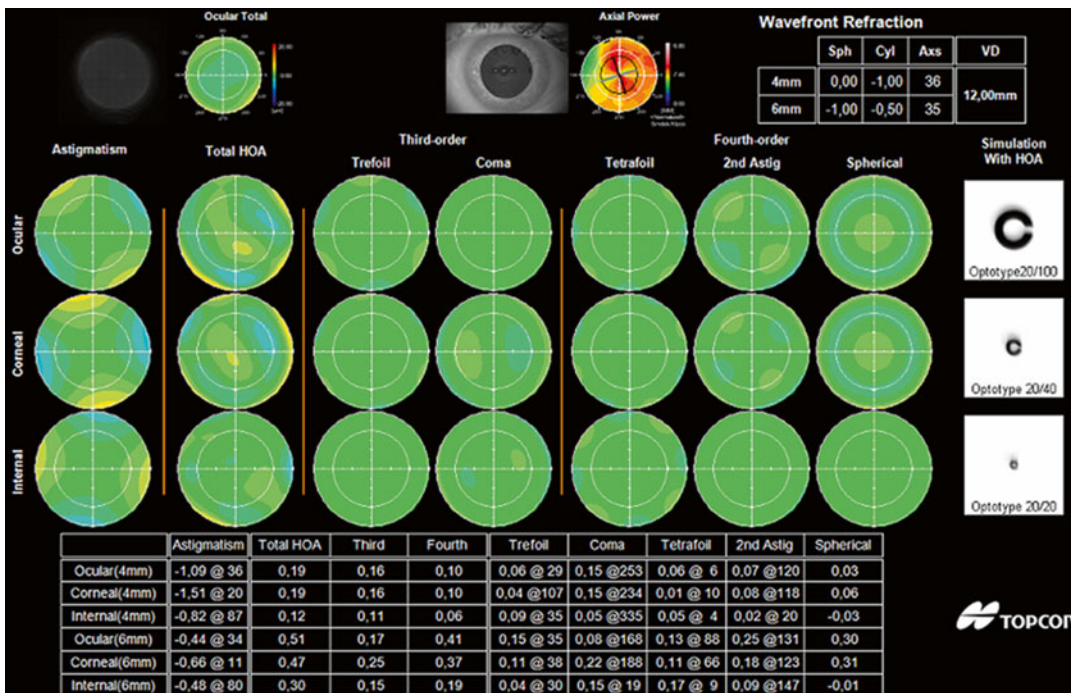


Fig. 16.2 Example of ocular, corneal and intraocular aberrometry measurements obtained with an integrated Hartmann-Shack aberrometer 6 months after implantation of a trifocal IOL (HOA high-order aberration)

curves, the visual acuity was measured with the ETDRS charts at 4 m. The defocus curve was obtained with monocular vision and with the best distance correction by adding plus lenses in 0.50 D steps and recording the visual acuity achieved by the patient with each type of blur. Following this, the procedure was repeated but with negative lenses [2]. The same protocol was followed to obtain the binocular defocus curve.

The following examinations were performed at 1 and 6 months post surgery using the ocular aberrometry with the KR1W device (Topcon Corp, Tokyo, Japan). This system incorporates three different technologies for the analysis of the optical performance of the human eye: wavefront aberrometry using the Hartmann-Shack principle, Placido-disk corneal topography, and standard autorefractometry. This system has the advantage of performing the measurement of corneal and global wavefront aberrations on the same axis, therefore, using the same reference for centration in a relatively short time [3]. Ocular, corneal, and internal aberrometric parameters were recorded and analyzed in each examination with KR1W system for a 6 mm pupil diameter: high-order root-mean-square (RMS) (computed for

third to tenth Zernike terms), primary coma RMS (computed for Zernike terms (Z3, ±1), Zernike coefficient for primary spherical aberration (Z4, 0), and astigmatism (in diopters). The pupils were dilated (phenylephrine 10 %) for the aberrometric study. Finally, the quality of the retinal image was analyzed by the Strehl ratio for a 4 mm pupil diameter, which provides objective information on optical quality performance at the retinal plane. A summary of results of a KR1W measurement was shown in Fig. 16.2.

16.2.6 Statistical Analysis

All statistical tests were 2-tailed, and *p*-values less than 0.05 were considered statistically significant.

16.3 Results

In a recent study about this IOL model developed by our investigational group, the visual, refractive, and aberrometric outcomes were reported

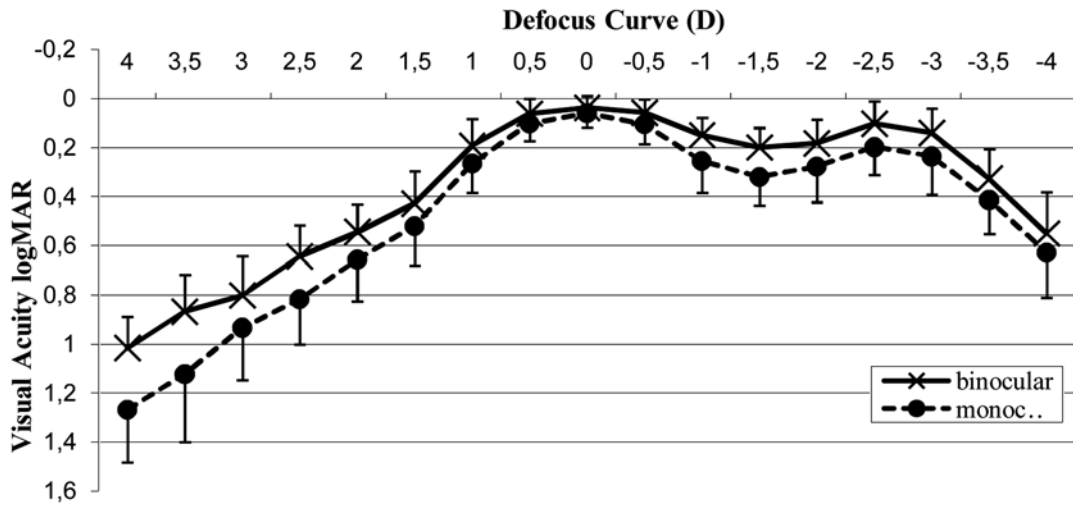


Fig. 16.3 Monocular and binocular mean defocus curve under photopic conditions. The error bars represent the range associated with each median value (D diopters)

[4]. The refractive result was as follows: the defocus equivalent (DE) changed significantly from 2.56 ± 2.00 (0.00–9.63) to 0.39 ± 0.27 (0.00–1.13) at 6 months ($p < 0.001$) and the DE at 6 months was less than 1.00 D in 95 % of the cases.

The visual monocular outcomes (logMAR) at 6 months postoperative were 0.05 ± 0.06 for corrected distance visual acuity and 0.16 ± 0.13 and 0.17 ± 0.09 for corrected-distance near visual acuity and corrected-distance intermediate visual acuity, respectively. Binocular defocus curve at 6 months shows a wide range of useful vision with 0.19 ± 0.08 logMAR at -1.50 D defocus as can be seen in Fig. 16.3. A detailed description of the cumulative Snellen visual acuity distribution obtained in this group of patients is presented in Fig. 16.4a–c.

A remarkable point about this lens is the contrast sensitivity achieved. The monocular contrast sensitivity under scotopic conditions (3 cd/m^2) was within the normal range for a population of over 60 years old [5] (see Fig. 16.5). This is an interesting finding because as has been reported previously [6–9], the implantation of diffractive lenses frequently results in the loss of contrast sensitivity and photic phenomena like halos and glare. In that group of

patients only one of them (2.5 %) reported halos in night driving (Fig. 16.5).

The ocular RMS HOA value analyzed at 6 mm pupil diameter with the integrated aberrometer KR1W (Topcon Corp, Tokyo, Japan) was $0.84 \pm 0.31 \mu\text{m}$ (0.40–1.56) at 1 month and $0.77 \pm 0.25 \mu\text{m}$ (0.33–1.43) at 6 months. This reduction of HOA at the end of the follow-up was not statically significant ($p = 0.108$). Figure 16.6 shows a summary of mean ocular aberration at 6 months. Other optical performance parameter analyzed was Strehl ratio (SR). The mean ocular SR for a 4 mm pupil diameter was 0.19 ± 0.10 (0.05–0.45) at 1 month postoperatively and 0.22 ± 0.11 (0.06–0.41) at 6 months. This difference was statically significant ($p = 0.03$, Student t test). Other authors have reported SR values of bifocal diffractive IOL AcrySof Restor (SN6AD1 add +3.00 D and SN6AD3 with add +4.00 D) measured with another aberrometer device based on dynamic retinoscopy ocular aberrometry (OPDScan aberrometer, Nidek Co, ltd) at 4 mm pupil diameter [10]. The SR for the both Acrysoft Restor obtained was 0.3. This result is better than that obtained for the Fine Vision, but the Acrysoft Restor is not trifocal (Fig. 16.6).

These differences should be due to a different diffractive design: on one hand, the Acrysoft

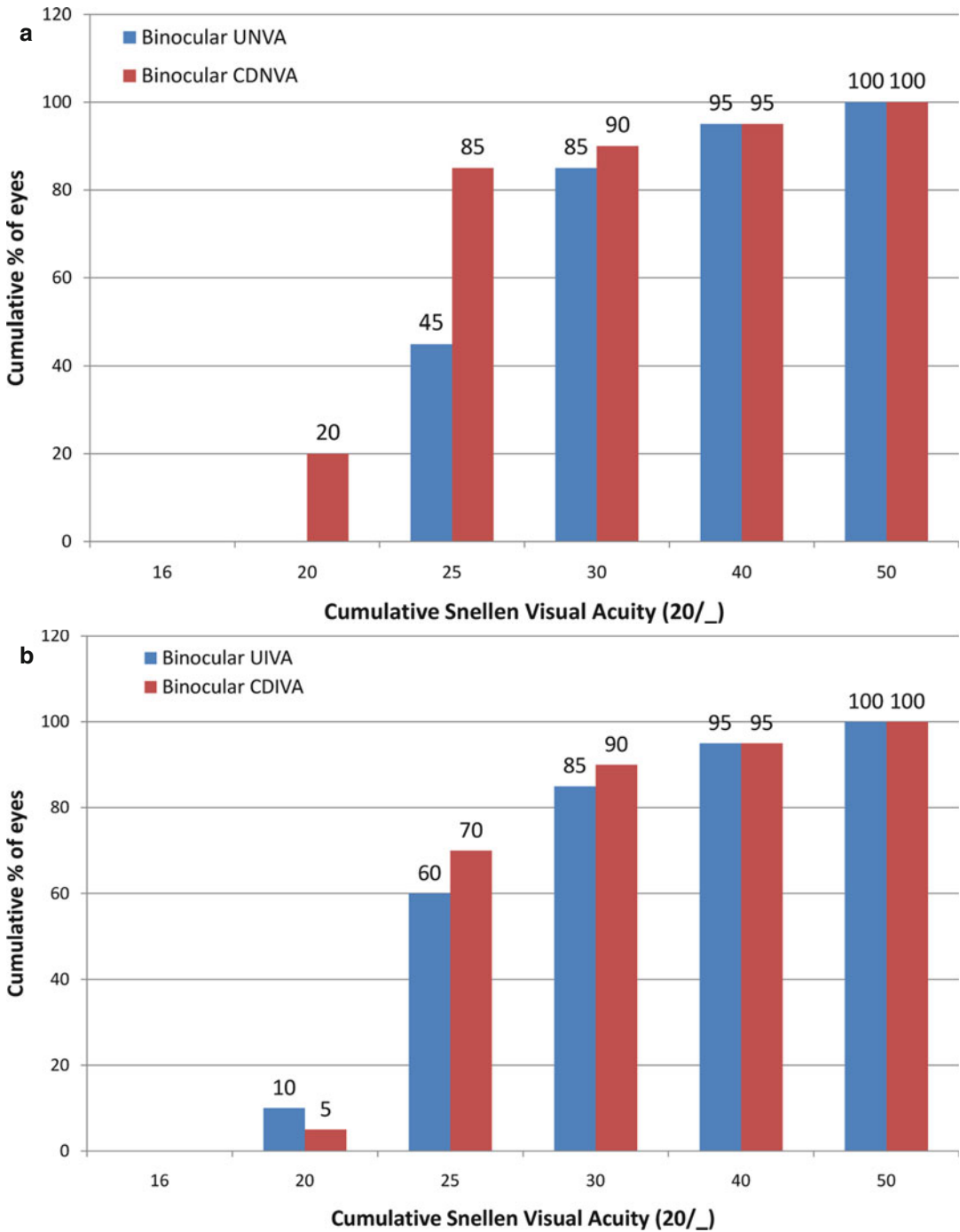


Fig. 16.4 (a) Cumulative bar graph for binocular near visual acuity at 6 months after cataract surgery (*UNVA* uncorrected near visual acuity, *DCNVA* distance-corrected near visual acuity). (b) Cumulative bar graph for binocular intermediate visual acuity at 6 months after cataract surgery (*UIVA* uncorrected intermediate visual acuity, *DCIVA* distance-corrected intermediate visual acuity). (c) Cumulative bar graph for binocular distance visual acuity at 6 months after cataract surgery (*UDVA* uncorrected distance visual acuity, *CDVA* corrected distance visual acuity)

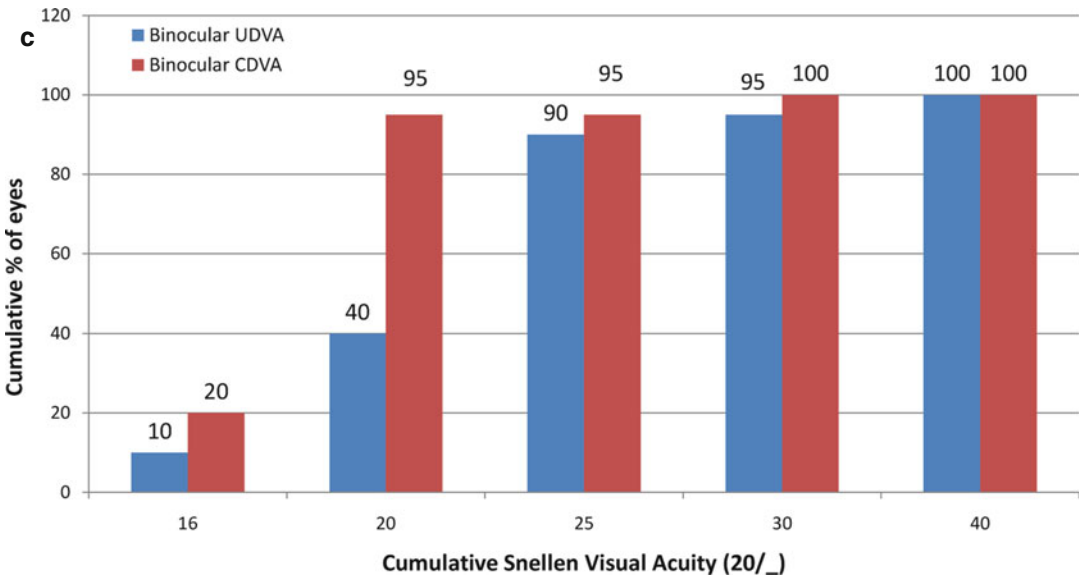
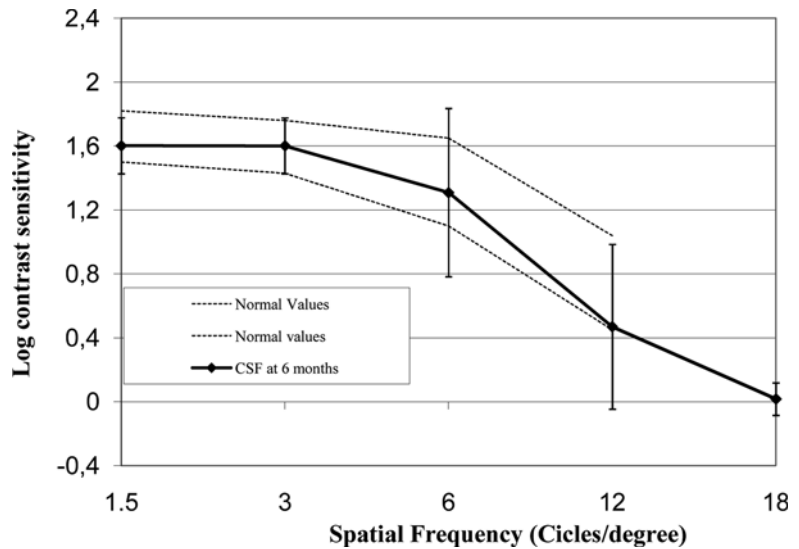


Fig. 16.4 (continued)

Fig. 16.5 Contrast sensitivity function. The dashed lines represent the normal range of contrast sensitivity for patients over 60 years old



Restor has been designed to provide negative spherical aberration in order to compensate the positive spherical aberration of the cornea, and on other hand, the aberrometer used in the Acrysoft study was not based in Hartmann-Shack sensor. It has been shown that the Hartmann-Shack aberrometer is limited when evaluating diffractive IOLs because several wavefronts are present at the same time in the pupil, and this can

interfere in the accuracy of the aberrometric measurement [11]. The energy distribution between foci is dependent on pupil aperture. With a 5 mm pupil diameter, over 60 % of the energy corresponds to the distance focus [1]. It is possible that with large pupil diameters the distance wavefront is the most brilliant and the interference with near and intermediate wavefronts could be minimal. However, more studies are necessary in this field

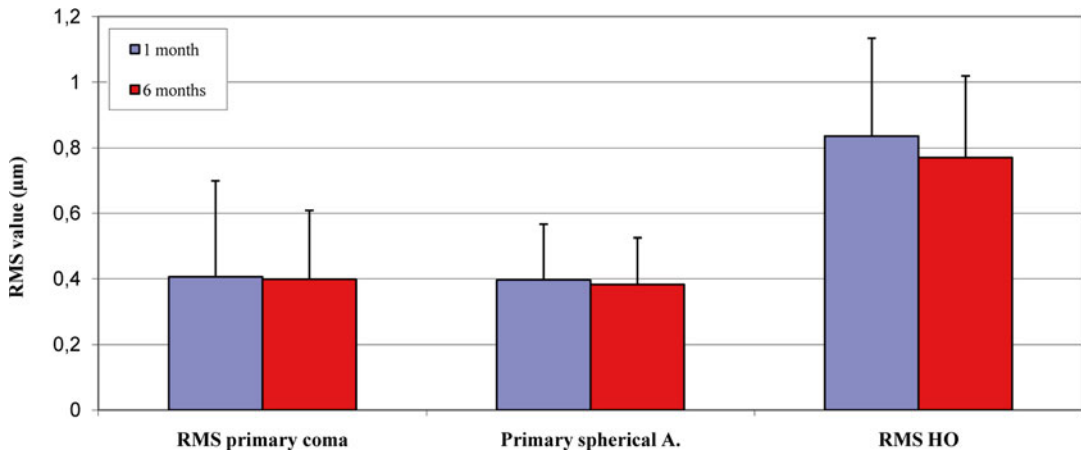


Fig. 16.6 Mean ocular aberration values \pm SD obtained with the Hartmann-Shack aberrometer (*RMS* root-mean-square, *RMS HO* higher-order root-mean-square)

to analyze in vivo the optical performance of multifocal IOLs.

Conclusions

The main conclusions that can be derived from the previous analysis can be resumed as follows:

Advantages

- The main advantage in our opinion is the addition of a third optical focus that results in efficient improvement of the intermediate vision.
- The contrast sensitivity in the patients implanted with this lens was not altered compared to the normal values in the general population of similar age (65 years in this study). This is congruent with a high rate of satisfied patients with this trifocal IOL.
- Another advantage is the possibility of inserting this lens through a small incision (1.8 mm). Therefore, it is insertable by microincisional cataract surgery (MICS).

Disadvantages

- This lens is pupil dependent because of its diffractive design.
- As any diffractive IOL, this model presents photic phenomena like halos and glare. This effect was detected not only in our study but in previous studies (Sheppard et al. [12]).

- Probably, other trifocal models like AT lisa tri have shown better visual performance, according to the studies of our investigational group. However, larger series are needed to confirm this point [13].

Indications and Contraindications

- Patients with corneal astigmatism less or equal to 1.50D
- Patients with an active lifestyle that demand good visual performance at any distance without the use of spectacles
- Not recommendable in patients with small pupil or bad papillary dynamic because of its pupil-dependent design

Compliance with Ethical Requirements Raúl Montalbán, Pablo Peña-García, and Jorge Alió 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 (5). Informed consent was obtained from all patients for being included in the study.

No animal studies were carried out by the authors for this article.

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Fyodorov Clinic Innovation GRADIOL: Gradient Refractive Index Optics Multifocal Intraocular Lens

17

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17.1 Introduction

Currently diffractive and refractive multifocal intraocular lenses (MIOLs) are often used for refractive lens exchange and presbyopia correction [1–12]. The principle of MIOLs involves subdividing incoming light into at least two components that form focal zones of specific depths. MIOLs represent an optical compromise between high-quality visual function in variable luminance conditions and the ability to see at various distances. Fundamentally, multifocal correction is a correlation between depth of focus and modulation transfer functions (MTFs) of the optical system. The MIOL design that provides better quality of vision and independence from spectacle correction continues to be still under debate.

Presently, the lenticular theory is the dominant theory of presbyopia. This theory

proposes that the main causes of presbyopia are the changes over time in optical and biomechanical parameters of the physiologic lens [13–22]. This theory incorporates well-established data including annual growth rate of the crystalline lens (0.02 mm/year) and changes in mean equivalent refractive index ($1.427 \div 1.418$) and surface refractive index ($1.386 \div 1.394$) [22–26].

Changes in the physiologic lens result in a decrease of negative spherical aberration towards positive spherical aberration in individuals of presbyopic age. This change in spherical aberrations and magnitude of the spherical aberration can have a number of optical consequences including changing the depth of focus. If depth of focus increases, it can result in a “passive” ability of the eye to see at various distances without an active change of lens power during accommodation [27]. We tried to emulate this physiologic process that can be modeled by gradient optics while developing a MIOL.

Currently available MIOLs have variable refractive power due to the complex shape of anterior and/or posterior surfaces; however, gradient optics is characterized by varying refractive power due to a change of refractive index in the inner structure of the IOL. This feature results in a number of optical and structural advantages. This design will likely improve functional results and diminish optical side effects in patients who undergo MIOL implantation.

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In addition to mimicking normal physiology, there are other potential benefits of gradient IOLs compared to other MIOL designs including:

- A smooth optical surface that decreases the possibility of mechanical damage to the optic lens during implantation.
- Postoperative functional vision is achieved over a wide range, including near and intermediate distances, which is of utmost importance for computer work and driving.
- Good visual functions under varying light conditions (photopic, mesopic, and scotopic).
- Better retinal image quality postoperatively.

The purpose of the current study was to use theoretical research to develop and clinically evaluate a MIOL with gradient refractive index optics. We tried to emulate this physiologic process that can be modeled by gradient optics while developing a MIOL. The goal of our study was to create an IOL with sufficient pseudoaccommodation (up to 5.00 D), which corresponds to the normal accommodation values of 40–45-year-old subjects [28].

17.2 Computer Modeling of Human Eye Optics with Implanted Multifocal Gradient Intraocular Lens

Original mathematical modeling software was developed based on fundamental optical principles. This software was used to optimize gradient IOL parameters in order to simulate the highest image quality possible. The software performs calculations for the optics of the human eye. This software can construct and analyze test object images by ray tracing in the axial and transverse planes, to model and visualize the color images projected on the retina. Additionally, comparative quantitative analysis can be performed on the optical characteristics of the IOL (modulation transfer and scattering functions) while changing varying parameters (diameter, surface curvature radius, and refractive index).

17.3 Theoretical Basis and Software Algorithm

The software is based on the calculation of light rays, each of which is incident to the lens surface at arbitrary point under variable angles. The only simplifying assumption fully fulfilled in all designs is the lens axial symmetry. The IOL surface can be modeled as spherical, ellipsoid, hyperbolic, or parabolic. The software calculates convex, concave, convex-concave, and concave-convex lenses. Calculation of each ray is performed according to the laws of geometric optics in a three-dimensional space.

To simulate an image of a point source of light, it is necessary to calculate the light ray data emitting from the given source and passing through the lens at different locations in a transverse fashion. Visualization of software simulation allows an understanding of the emission pattern and image type formed by the light rays. Mean focal distance calculation results in plotting a focal distance-principal optical axis distance diagram, which provides information on spherical aberration of the lens. This information is also garnered from the value of the standard deviation of the focal distance. Spherical and higher-order aberrations are calculated according to the software algorithm. The algorithm is easily extrapolated to the system of lenses and can be modified for calculation of lenses with complex surface structure including gradient optic lenses.

17.4 Software Windows

17.4.1 Determination of Optimal Optical Parameters for a Gradient Multifocal Intraocular Lens

The calculations were performed by software consisting of visual programming environment Borland C++ Builder (version 6) with the Windows XP operating system (Microsoft Corp., Redmond, WA, USA). The program operating window is presented in Fig. 17.1 that demon-

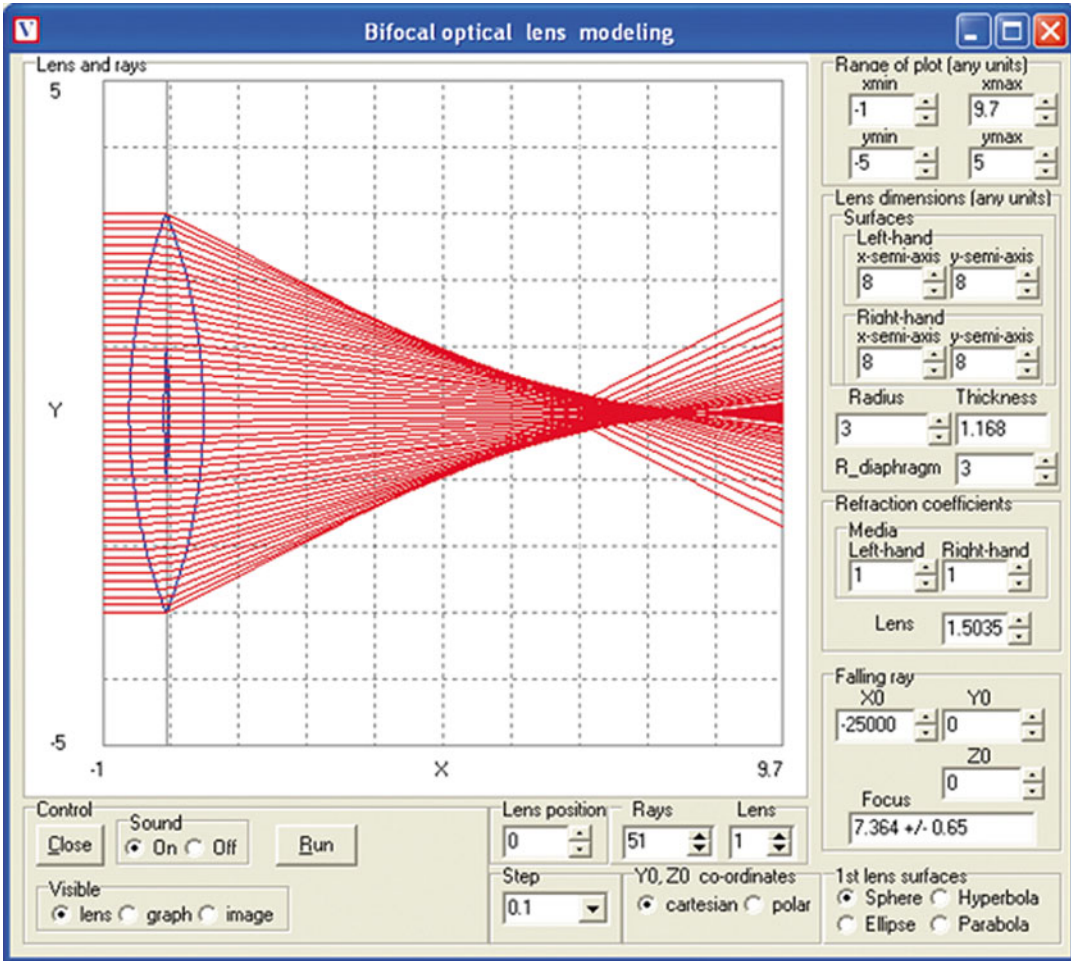


Fig. 17.1 Software window. Modeling rays pass through gradient lens, thus determining focal zone parameters

strates a software version for a particular gradient lens calculation, which consists of outer and inner components. The latter has a smaller diameter differing from the outer component by external surface radii and refraction index. The software accounts for a considerable number of optical system parameters including the cornea, aqueous humor, artificial lens, vitreous body, and retina. IOL parameters are set either as optical component diameter, curvature radius, refraction index, IOL thickness, lens sphericity in relation to the optical axis, or diaphragm diameter (i.e., pupil).

The human eye optical parameters include radius of curvature of the outer corneal surface (7.7 mm), inner corneal surface (6.8 mm), outer

corneal surface-retinal distance (24.0 mm), retinal curvature radius (12.0 mm), corneal refraction index (1.376), aqueous humor (1.336), and vitreous body (1.337).

Computer modeling software allowed analysis of the distribution of rays and ray patterns in the principal focus neighborhood and types of aberrations. Figure 17.2 demonstrates the ray transmission near multifocal gradient lens focus reflecting correlation to optimal lens parameters. The software plots focal distance-ray position to lens optical axis diagram (if the source is positioned at the principal optical axis and sufficiently distant from the lens) (Fig. 17.3). The diagram provides information on the spherical aberrations of a given lens. The focal distance

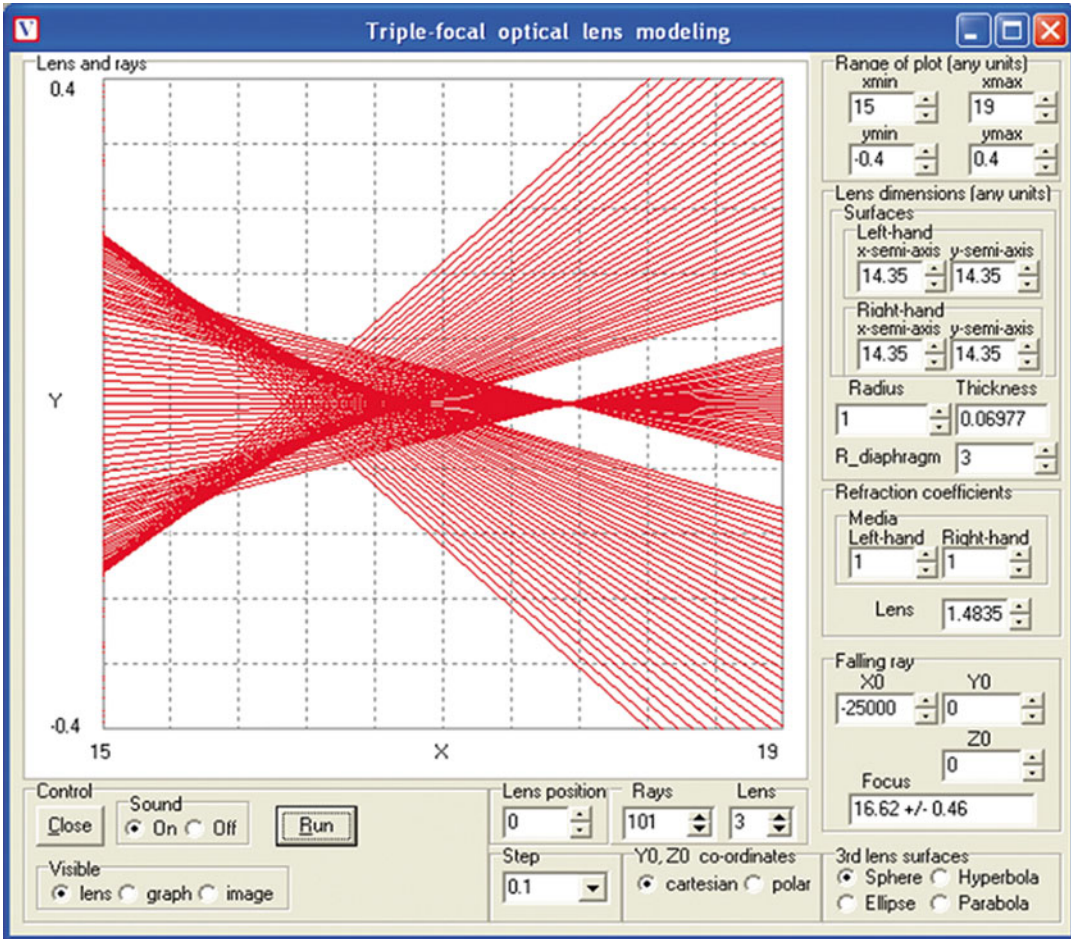


Fig. 17.2 Ray transmission nearby multifocal gradient lens focus. Outer lens component refraction index (RI) is 1.5035, and inner component RI is 1.4835

standard deviation value provides information on spherical aberration. All other lens aberrations are calculated according to the software algorithm.

The software enables simulation and analysis of point light sources located at various distances from principal optical axis of the lens. Figure 17.4 demonstrates the light scattering sources around the maximum concentration zone of the light beam that is attributed to one of the multifocal lens foci.

Simultaneous analysis and visualization of spherical and chromatic aberrations by the software allows simulation of color images of test objects formed on the retina of a pseudophakic eye. To obtain image quantitative estimation, the

computer modeling software calculates MTF and scattering function.

In order to calculate and select multifocal gradient IOL optimal parameters, we performed comprehensive computer modeling data evaluation. Additional optical power (difference in refractive power between zones for far and near) was specified by optimal distance for near vision (30/33 cm) and was determined by a refraction index (1.520 and 1.4795 for outer and inner components, correspondingly) and by component curvature radius (15.11 mm outer lens component, 13.66 mm inner). Optimal calculated value of refractive power difference for far and near (outer and inner components of the lens) was 3.0 D.

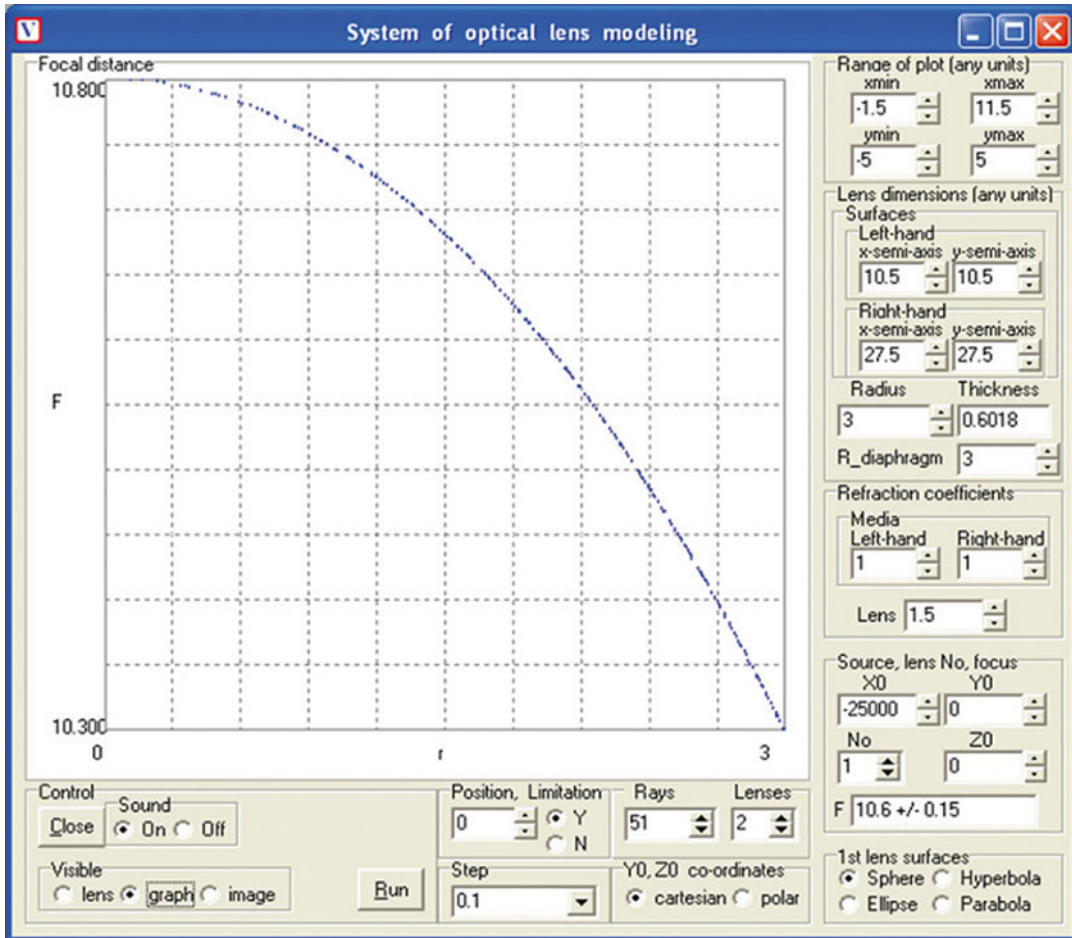


Fig. 17.3 Focal distance-ray radial coordinate diagram

For the retinal image computer modeling data, priority was placed on distance vision for pseudophakic patients, safe driving (especially for acute miosis under bright light), and the possibility of senile miosis. Hence, the central optical zone was designed for far vision. The diameter of the inner component was calculated with consideration of optimal redistribution of light rays under varying light conditions (variable pupil diameters) (Figs. 17.1, 17.2, 17.3, and 17.4).

The optimal calculated value of the inner component diameter was modeled for 2.0 mm (3.0 mm pupil diameter). Under photopic conditions the distribution of light rays between far and near zones was 45 and 55 %, respectively (inner component diameter 2.0 mm). Under bright light and 2.5 mm miosis, the redistribution

of light rays occurs at 65 and 35 %, respectively. Under mesopic conditions and 3.5–4.0 mm pupil diameter, the distribution of light rays for far and near zones was 30 and 70 %, respectively. The overall diameter of the optical zone is 6.0 mm. The inner component is placed in the center of the outer component on radius and thickness. The overall IOL thickness is 1.0 mm, and its central component is 0.4 mm.

A single piece foldable multifocal gradient IOL was manufactured with step-by-step polymerization technology in transfer molds of photohardening material (ultraviolet light) with various refraction indices (oligourethane-methacrylate). This technology can produce multifocal artificial lenses with gradient optics. The relative simplicity is an advantage of the manufacturing process;

Fig. 17.4 Point light source image formed by multifocal lens

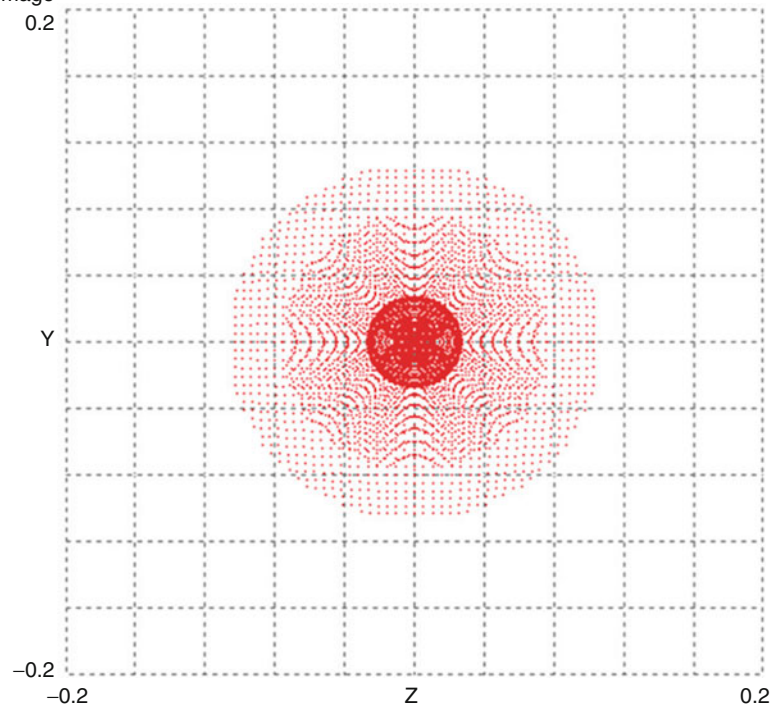


Fig. 17.5 General view of the multifocal intraocular lens with gradient optic (Gradiol)

hence, it is possible to combine stages of material polymerization with lens manufacturing concurrently. Additionally, polymerization in the mold determines better optical characteristics of the

lens in comparison to lens milling by achieving better surface quality and minimizing optical aberrations in the IOL.

The Gradiol IOL is a joint invention and the result of collaboration between the S. Fyodorov Eye Microsurgery Complex (B. Malyugin, T. Morozova) and REPER-NN (V. Treushnikov, E. Viktorova), a lens manufacturing company. Figure 17.5 demonstrates the general view of pseudoaccommodation with the Gradiol MIOL with gradient optics.

17.5 Clinical Studies

17.5.1 Patients and Method

This study was conducted according to the principles of the Declaration of Helsinki and was approved by the local ethical committee. All patients were adequately informed and signed a consent form.

Twenty-six patients (29 eyes) were prospectively enrolled with age ranging from 27 to

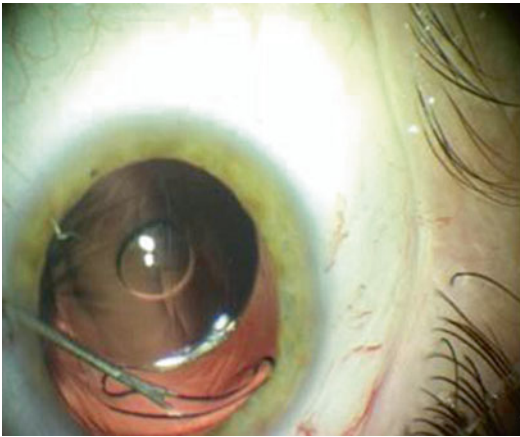


Fig. 17.6 Implantation of Gradiol trailing haptic element into the capsular bag

82 years. This non-comparative study included 11 males and 15 females. All patients had cataracts with mean visual acuity deterioration of 0.11 ± 0.09 . Exclusion criteria were astigmatism greater than 1.0 diopter and anterior segment pathology such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma, diabetic retinopathy, and age-related macular degeneration. Patients with previous anterior and posterior segment surgery and intraoperative or postoperative complications were also excluded. All eyes were targeted for emmetropia postoperatively using the SRK/T formula.

The surgical procedure included phacoemulsification through a 2.2 mm clear corneal incision under topical anesthesia. The IOL was implanted in the capsular bag with an injector (Fig. 17.6). At the end of the surgery, the incisions were hydrated.

All patients were discharged 1 h after surgery. Postoperative medications included topical moxifloxacin and dexamethasone 0.1 % QID for 3 weeks.

Patients were scheduled for clinical evaluation preoperatively and 1 day, 1 week, and 1, 3, and 6 months postoperatively. Additional visits were scheduled if necessary.

No major complications were observed during the early and late postoperative periods (Fig. 17.6).

17.5.2 Outcome Measures

A standard comprehensive ophthalmic examination, including manifest refraction, biomicroscopy, intraocular pressure measurement, and funduscopy, was performed at all visits.

Uncorrected and best corrected distance visual acuities were measured with decimal charts. Uncorrected and best corrected near visual acuities were measured with reading charts (Russian validated version). Uncorrected and best corrected distance visual acuities, monocular uncorrected and best corrected near visual acuities, and distance corrected near visual acuity acuities (NVA) were recorded at 5 m for distance measurements and 33 cm for near measurements in all patients. All visual acuity measurements were performed monocularly.

Refraction was measured with an autorefractor and retested subjectively.

Methods used for pseudoaccommodation testing included:

- Sphere addition-assisted defocusing with 1.0 D step at corrected visual acuity (VA) for far 0.8 using an accommodometer.
- Sphere addition-assisted defocusing with 0.5 D step at corrected VA 0.5 using conventional optotypes.
- Contrast sensitivity (CS) was measured with Optec 3000 (Stereo Optical Company, Inc., Chicago, IL, USA).

To perform a quantitative analysis of visual dysfunctions, we employed the VF-14 patient questionnaire (VF-14) [29]. To further assess functional needs and specific characteristics of multifocal correction, we included additional questions on the ability to use a computer without spectacle correction (to evaluate vision at intermediate distances) and details of optical disturbances (type and level).

17.6 Clinical Results

17.6.1 Distance Visual Acuity

Distance VA improved in all cases after phacoemulsification after implantation of gradient MIOL. Analysis of data on distance uncorrected

Table 17.1 Mean far visual acuity postoperatively

Mean VA	1 month	3 months	6 months
Uncorrected	0.73±0.16	0.72±0.20	0.73±0.18
With correction	0.77±0.19	0.88±0.13	0.89±0.15

and corrected visual acuity at various follow-up periods (1, 3, and 6 months) proves stability and good functional visual acuity (Table 17.1).

Better functional results were obtained in patients with slight hyperopia of ±0.5 D sphere, ±0.5 D of against-the-rule corneal astigmatism, and 1.0 D with-the-rule corneal astigmatism. Mean spherical equivalent was +0.09 D.

17.6.2 Near Visual Acuity

Data on uncorrected and best corrected visual acuity for near at various follow-up periods (1, 3, and 6 months) also proved stability and good functional visual acuity (Table 17.2). These data indicate full visual rehabilitation and high scores on the subjective evaluation postoperatively. Near VA outcomes indicated that reading could be performed without additional spectacle correction.

Evaluation of near VA with full distance correction is presented in Table 17.3. This measure assesses visual function specific to MIOLs. Additional distance correction in cases of residual myopic refraction decreases NVA compared to uncorrected near VA. Additional correction for far in cases of residual hyperopic refraction either increases or has no effect on near VA compared to near VA without correction. The latter determines residual hyperopic refraction postoperatively, which is more preferable.

17.6.3 Pseudoaccommodation Amplitude

The difference in power between optical zones should provide a calculated pseudoaccommodation amplitude of at least 3.00 D. The pseudoaccommodation after gradient IOL implantation was 4.75±0.50 D (Fig. 17.7).

Table 17.2 Mean far visual acuity postoperatively

Mean VA	1 month	3 months	6 months
Uncorrected	0.62±0.16	0.60±0.21	0.57±0.19
With correction	0.70±0.20	0.76±0.18	0.84±0.07

Table 17.3 Best corrected distance near visual acuity (VA; 16 cases) and patient’s postoperative refraction

VA for near without correction	VA for near with correction for far	Refraction
0.5	0.4	M
0.8	1	H
0.7	0.7–0.8	H
0.8	0/4	M
0.8	0.4	M
0.5	0.8	H
0.6	0.8	H
0.7	0.3	M
0.4	0.5	H
0.5	0.3	M
0.9	0.6	M
0.3	0.5	H
0.4	0.2	M
0.3	0.8	H
0.3	0.1	M
0.5	0.3	M

M myopia, *H* hyperopia

There was an even distribution of light energy among all optical zones (for far, near, and intermediate distances). The defocus curve was smooth with peak at the point of maximum corrected distance VA.

17.6.4 Contrast Sensitivity Testing

CS testing is one of the basic components of comprehensive clinical evaluation of postoperative visual outcomes. Previous studies have confirmed that CS and mesopic visual acuity (with/without glare) are diminished after MIOL implantation compared to normal values.

In the current study, there was no change in CS compared to normal values across all spatial frequencies after multifocal gradient IOL implantation (Fig. 17.8) (Tables 17.1, 17.2, and 17.3).

Fig. 17.7 Defocus curve after Gradiol implantation

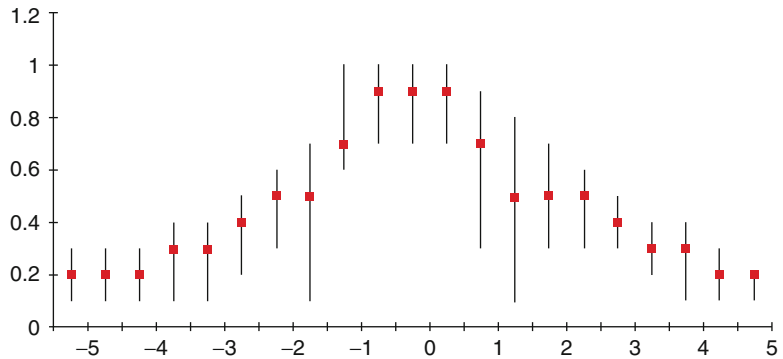
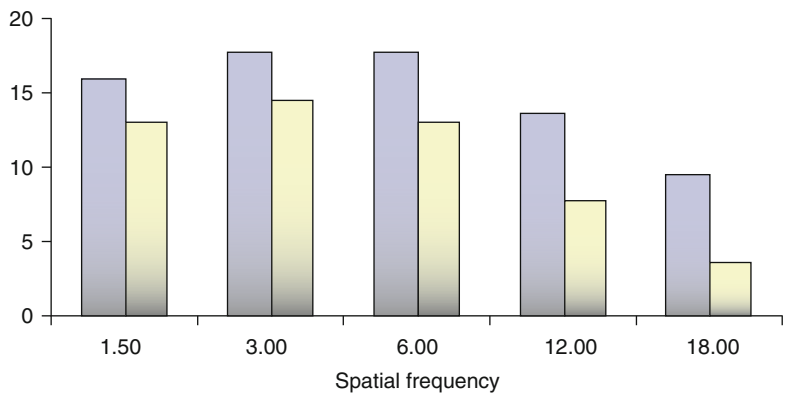


Fig. 17.8 Data on spatial contrast sensitivity testing after Gradiol implantation. Three months postoperatively



17.6.5 Optical Disturbances

Optical disturbances included light streaks, halos, flare, flashes, and glare [30]. Halos and glare were the most frequent complaints.

The grades varied from subtle to pronounce (Table 17.4). There was no tendency for these optical disturbances to decrease over long-term follow-up.

The cause of the optical disturbances is likely the separation of light at the focal zones as well as the presence of distinct borders between the inner and outer optics. The majority of patients (57.1 %) noted optical disturbances during history taking, and only 10.7 % of cases were functionally significant.

Mostly patients complained of halos under scotopic conditions and a “blinding” effect from oncoming headlights while driving at night. None of the patients required MIOL explantation due to night vision disturbances.

Of all the patients with optical disturbances postoperatively, 81.3 % had residual myopic

Table 17.4 Optical phenomena

Type	Total (abs)	Total (%)
Pronounced (halos only)	3	10.7
Moderate	–	–
Subtle (halos, glare)	13	46.4
Total	16	57.1
Halos	13	46.4
Glare	3	10.7

refraction. Residual myopia increases light scattering resulting in an increase of the optical disturbance and decreasing patient’s quality of life (Table 17.4, Figs. 17.7 and 17.8).

17.6.6 Subjective Questionnaire

The mean VF-14 score was equivalent to 100 indicating high subjective satisfaction after Gradiol implantation. Postoperatively, 86 % of patients were able to perform near tasks without

spectacle correction, including prolonged work at near, small print text reading, as well as computer work under varying light conditions (bright and dim light).

17.7 Discussion

It is possible to theoretically calculate the light beam distribution in optical models of the human eye, including the modulation transfer and scattering functions, and perform retinal image quality modeling. However, simulation of the effect of neural processing on visual functions after MIOL is not possible. Hence, the final conclusion on the efficacy of a specific MIOL can only be reached after clinical trials. The functional outcomes for far and near vision and pseudoaccommodative amplitude indicate that the Gradiol is efficacious.

The outcomes for distance visual acuity after Gradiol implantation are comparable to diffractive and refractive MIOLs. For example, after ReSTOR® IOL implantation (diffractive/refractive; Alcon Inc., Fort Worth, TX, USA), the uncorrected distance VA was 0.8 in 54 % cases and uncorrected near VA of 0.5 was achieved in 100 % of the cases and 0.8 was achieved in 52 % of the cases [31, 32]. A multicenter trial of the AMO Array® (refractive IOL) reported that distance uncorrected VA of 0.7 or better was achieved by 73 % of cases and near VA of 0.5 or better was achieved by 85 % of cases. Another study [33] reported that mean binocular uncorrected distance VA after ReZoom® refractive MIOL implantation was equal to 1.0 and 0.5 for near.

Patients who have undergone refractive and gradient IOL implantation have better intermediate vision (from 40 cm to 1.0 m) compared to patients who have undergone diffractive IOL implantation. Intermediate vision is important for driving (dashboard control) and computer work. Results of CS testing of the current study was comparable with previous outcomes from diffractive MIOLs and refractive AMO Array [34]. In previous studies CS in both groups at low and high spatial frequencies was identical to the normal values [34]. Compared

to refractive MIOLs, CS in patients with diffractive MIOLs was lower at mid-spatial frequencies [34]. Glare testing CS in the first group was significantly lower than normal values [34].

We consider subtle decrease in CS at all spatial frequencies as an important specific feature of multifocal gradient IOLs. We believe this characteristic enables visual work under varying light conditions and adequate functional rehabilitation of patients postoperatively. The comparison of CS in our study and other studies seems to show that gradient and refractive MIOLs have advantages over diffractive MIOLs as the latter result in impaired CS and increased glare.

Postoperative optical disturbances are important for functional assessment of the MIOL implantation. We found clinically significant disturbances in only 10.7 % of cases. However, there was no regression of symptoms with long-term follow-up. Often neural processing adapts to these disturbances, ignoring them over time. Therefore, most of the patients noted optical disturbances only after meticulous discussion (57 %). Theoretically, these disturbances can be explained by light reflection from the transition zone and IOL surface and light diffraction at the border of the optical components.

Comparative analysis of our data to other studies of optical disturbances indicated similar outcomes for different types of MIOLs. Haring et al. [30] reported optical side effects in 9 % of patients after monofocal IOL implantation and in 41 % of cases after refractive multifocals. Halos and glare are the most frequent complaints in patients after MIOL implantation compared to monofocal IOLs. Takhtayev and Balashevich [31] studied symptoms after AcrySof ReSTOR (Alcon Inc., Fort Worth, Tx, USA) implantation and observed visual impairment in twilight conditions in 8 % cases, optical side effects near point sources of light in 11 % of cases, and impairment on glare testing in 14 % of cases. The symptoms were of moderate severity [31]. To reduce the symptoms or optical disturbances reported by the current study, refinement of the IOL design is required such as relatively homogeneous transition zones or elimination of transition zones.

Conventional visual acuity testing is the most widely used test for evaluation of functional outcomes. However, this test does not reflect patient satisfaction and does not provide information on the effects on work or quality of life. Subjective testing in all MIOL groups demonstrated high patient satisfaction postoperatively. Previous reports of patient satisfaction vary considerably indicating a range of 32–81 % of patients who did not require additional spectacle correction [4, 35–39]. In our study, 86 % of patients did not use spectacle correction for work at distance and near including during prolonged activity and driving [40].

Based on these results, the current clinical trial proved safety, efficacy, and stability of results determining adequate visual rehabilitation and high patient satisfaction. These results are encouraging and provide the impetus for further design enhancements to existing MIOLs or the creation of new models.

Our initial results are essential in the development of optics with gradient change in refraction index. The most significant disadvantage of the Gradiol MIOL is the postoperative optical disturbance, which has also been reported with other multifocals. Refined designs may mitigate these symptoms. We are currently conducting a clinical trial of a new generation of gradient MIOLs with no transitional border between the two optical zones.

Compliance with Ethical Requirements Boris Malyugin, Tatiana Morozova, and Valentin Cherednik 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.

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18.1 Introduction

All multifocal IOLs developed until now with reported clinical outcomes are based on the concept of rotational symmetry and the principles of diffraction, refraction or a combination of both. With these three technologies, incoming light rays are distributed onto two principal focal points (near and distance foci) or onto several foci. The designs of these IOL technologies are concentric circles that produce images in several foci over the entire surface of the lens. The images are generated in an area of 360°, and the light is scattered on the foci over the entire lens surface. These designs produce several consequences such as loss of light reducing contrast sensitivity, permanent overlapping images generating halos and glare and loss of image quality, enhanced by the diffraction and pupillary rim causing a reduction of MTF and PSF.

The concept of refractive rotational asymmetry has been developed and introduced in the

clinical practice. The Lentis Mplus (Oculentis GmbH, Berlin, Germany) is a multifocal intraocular lens (IOL) model based on this concept of refractive rotational asymmetry. The design of this lens includes an inferior surface-embedded segment with the optical power required for near vision and seamless transitions between the near and far vision zones. This type of design theoretically makes this multifocal IOL independent of pupil size and ensures optimum adjustment of near and distance vision acuity. With this design, the light is refracted to other foci only in a specific sector; the rest of the lens has a monofocal lens behaviour. This principle should have advantages as more light on the furthest focus that increase the contrast sensitivity, less duplication of images reducing halos and glare and better picture quality, without the effect of scattering of light by diffraction with higher values of MTF and PSF. These principles could produce the following improvements: increased patient satisfaction, easier to adjust for binocular vision and increased spectacle independence.

There are two different designs of this type of multifocal IOL, a truly bifocal lens with near add of +3.00 D which provides an acceptable intermediate vision and the Lentis Comfort LS-313 MF15 which has a near addition power of 1.5 D with the aim of providing distance and intermediate visual rehabilitation after cataract surgery with a lower incidence of optical side effects. This multifocal IOL is one of the few multifocal

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IOLs with low near add with the aim of generating less photic phenomena, reducing neuroadaptation time and the CSF lost, thus increasing patient satisfaction.

In this chapter, the visual outcomes and optical quality results obtained with the Lentis Mplus LS-313 and the Lentis Comfort LS-313 MF15 are explained in detail.

18.2 Surgical Technique

The surgical technique to implant these lenses is performed using a standard technique of sutureless microincision 2.2 mm or biaxial MICS phacoemulsification. It requires adequate dilation as the lens is better injected directly inside the capsular bag and the surgical manoeuvres may be traumatic if straightforward injection is not achieved. An adequate capsulorhexis of about 5 mm is necessary for the same reason. We use intracameral mydriasis for this purpose which may be enhanced just before the implantation. The incision for the implantation is placed on the steepest corneal meridian. The Lentis Mplus is then implanted using a specific injector (Viscoject 2.2 Cartridge-Set LP604240M, Oculentis GmbH). The capsular bag is better filled using cohesive viscoelastic. Then the injector tip is inserted into the anterior chamber until it is located inside the capsular bag. Then, the injection manoeuvre is performed, and the distal edge of the haptic is released into the capsular bag. The injector is slowly retracted while the lens is ejected. Then, the haptic is released into the capsule while pushing the lens backwards with a second instrument to assist in the intracapsular location of the lens. We only recommend using the plate-haptic model of these lenses.

18.3 Sector Rotational Asymmetrical Refractive Multifocal IOL: The Lentis Mplus Ls-313 Model

C-loop haptic design: The initial model was the Lentis Mplus LS-312 MF30, which has been the subject of several studies by our group, with

preliminary excellent visual outcomes and low incidence of photic phenomena [1]. However, larger amounts of intraocular tilt were detected, suggesting that this model of IOL within the capsular bag can become tilted and probably decentred. A probable reason for this phenomenon is the haptic design which does not seem to be effective for stabilising the lens. The use of a capsular tension ring may be a potential solution for this situation. Although, in a previous study [2] a capsular tension ring (CTR) was implanted jointly with Lentis Mplus LS-312 MF30 IOL to study the optical and refractive stability provided by CTR. In this study the refractive predictability improved when the Lentis Mplus LS-312 IOL was implanted in combination with a CTR and improved the optical stability of this model of IOL.

Plate-haptic design: Despite the use of a capsular tension ring, a different haptic design was suggested to be probably more adequate to stabilise the sophisticated optic of this IOL within the capsular bag. Then, the Lentis Mplus LS-313 was introduced to improve the stability of the Mplus optic with a plate-haptic design. Our research group has compared both models of the Lentis Mplus [3] and found better refractive predictability and intraocular optical quality with the plate-haptic design than with the C-loop haptic model, even in combination with a CTR. With the plate-haptic design, better optical and visual outcomes were obtained with this MIOL model due to a better IOL stability.

18.3.1 Methods

18.3.1.1 Patients

Forty-five eyes of 25 patients (age ranging between 47 and 82 years) were implanted with the Lentis Mplus LS-313 (plate-haptic model).

18.3.1.2 The Lentis Mplus LS-313

The Lentis Mplus LS-313 is a refractive rotational asymmetric multifocal IOL containing an aspheric distance vision zone combined with a 3.00 D posterior sector-shaped near vision zone and plate-haptic design (Figs. 18.1 and 18.2).

Fig. 18.1 A general view of the Lentis Mplus LS-312 MIOL (*left*) and the Lentis Mplus LS-313 MIOL (*right*)

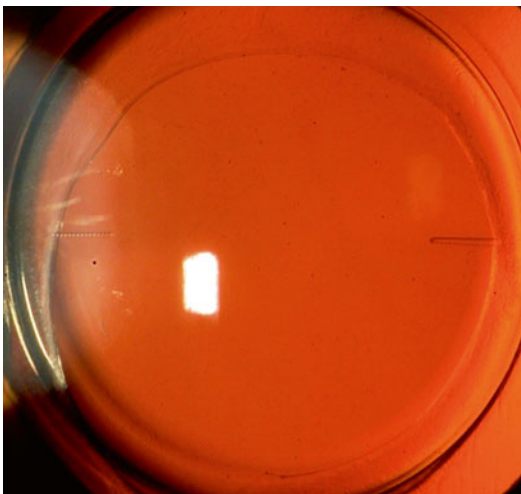


Fig. 18.2 The Lentis Mplus LS-313 in the human eye. The *horizontal marks* indicate the correct orientation of the near sector

18.3.1.3 Preoperative and Postoperative Examinations

Preoperatively all patients had a full ophthalmologic examination including evaluation of the refractive status, the distance and near visual acuities, slit lamp examination, tonometry and funduscopy. Distance visual acuity was measured with the Snellen charts and the near visual acuity

with the standardised Radner reading charts. Besides these clinical tests, corneal topography and biometry were performed. The postoperative examination protocol was identical to the preoperative protocol, with the additional measurement of the ocular optical performance with the OQAS system (Optical Quality Analysis System, Visiometrics SL), the calculation of the intraocular optical aberrations and intraocular Strehl ratio using VOL-CT software and the measurement of the defocus curve and contrast sensitivity.

18.3.2 Results

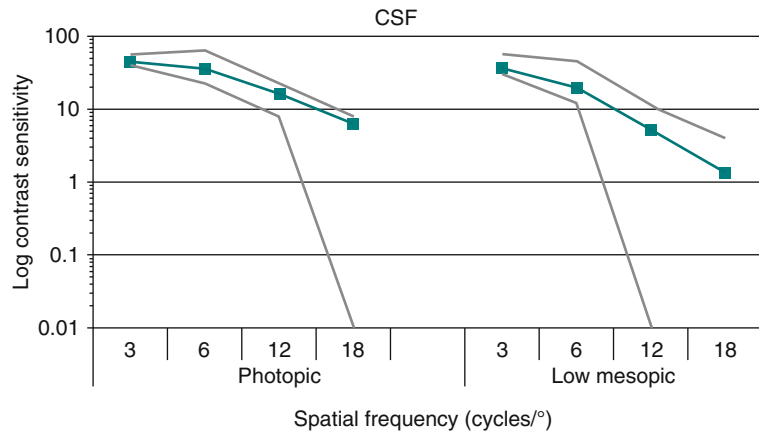
18.3.2.1 Visual and Refractive Outcomes

Table 18.1 shows preoperative and postoperative visual outcomes with the Lentis Mplus LS-313. A significant improvement after surgery was observed in the uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected near visual acuity (UNVA) and corrected near visual acuity (CNVA) (Wilcoxon test; $p < 0.01$). Regarding subjective refraction, a significant reduction in the manifest sphere and cylinder was observed (Wilcoxon test; $p \leq 0.02$). With the Lentis Mplus LS-313, patients obtained a good distance and near visual acuity after cataract surgery

Table 18.1 Comparative table showing the preoperative and 3 months postoperative. Distance and near visual acuities improved significantly when this IOL is implanted

Mean (SD)	Preoperative	Postoperative	P-value (statistical test)
Range			
LogMAR UDVA	0.69 (0.53) 0.02 to 2.00	0.16 (0.11) 0.00 to 0.52	<0.01 Wilcoxon test
Sphere (D)	+1.15 (3.24) -8.50 to 6.00	+0.16 (0.40) -1.00 to +1.25	0.02 Wilcoxon test
Cylinder (D)	-0.86 (0.67) -3.00 to 0.00	-0.39 (0.49) -2.00 to 0.00	<0.01 Wilcoxon test
LogMAR CDVA	0.13 (0.19) -0.08 to 0.82	0.03 (0.06) -0.08 to 0.30	<0.01 Wilcoxon test
LogRAD UNVA	0.78 (0.38) 0.10 to 1.40	0.20 (0.13) 0.00 to 0.52	<0.01 Wilcoxon test
LogRAD DCNVA	-	0.17 (0.13) 0.00 to 0.52	-
LogRAD CNVA	0.17 (0.22) 0.00 to 1.00	0.07 (0.08) 0.00 to 0.30	<0.01 Wilcoxon test

Fig. 18.3 Mean contrast sensitivity function in eyes implanted with the Lentis Mplus LS-313. Under photopic conditions (85cd/m²). Under mesopic low conditions (3 cd/m²). Contrast sensitivity obtained with the Mplus LS-313, (Green line) normal values of contrast sensitivity for the same age sample (Grey lines)



which confirms the efficacy of this IOL designed for patient visual rehabilitation. Previous studies [1–4] have confirmed these visual outcomes after implantation of these types of IOLs.

18.3.2.2 Contrast Sensitivity Outcomes

Regarding contrast sensitivity as shown in Fig. 18.3, photopic and low mesopic contrast sensitivity was within the normal range for the age sample for all spatial frequencies [5].

18.3.2.3 Defocus Curve Outcomes

Figure 18.4 shows the mean defocus curve for eyes implanted with the Lentis Mplus LS-313. As

shown in the defocus curve, the Lentis Mplus LS-313 provides two peaks of maximum vision, one at 0D defocus level which corresponds to the CDVA and the second peak at -2.5 D defocus level which corresponds to the distance corrected near visual acuity (DCNVA). Also, the defocus curve of this multifocal IOL offers a range of optimal vision within -3.0 D and +1.0 D of defocus levels (0.2 LogMAR or better) providing a good intermediate visual acuity in spite of the bifocal design.

18.3.2.4 Optical Quality Outcomes

Besides optical quality, the mean ocular Strehl ratio estimated with the OQAS system was 0.09

Fig. 18.4 Mean defocus curve CSF of the Lentis Mplus LS-313. This pattern shows an optimal distance, intermediate and near visual acuity

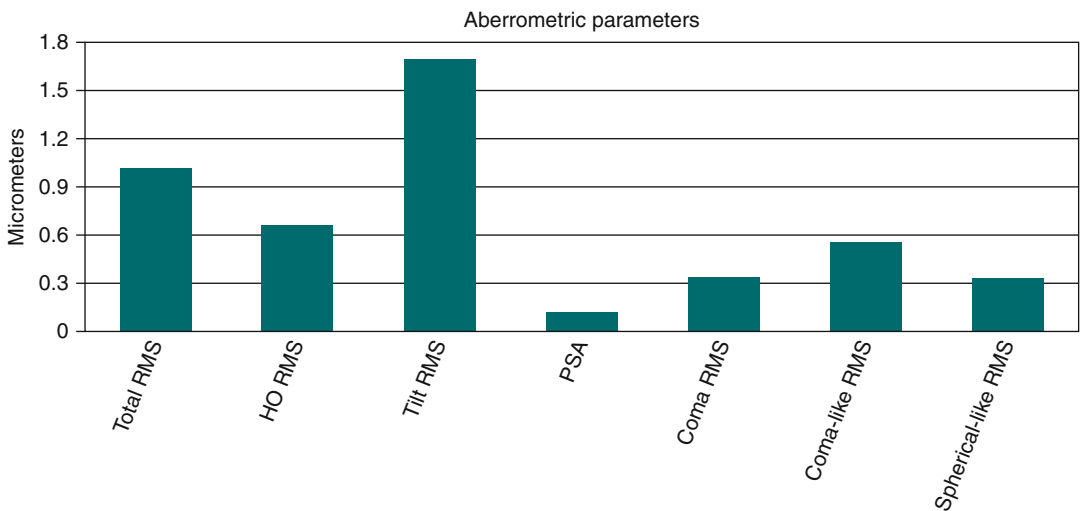
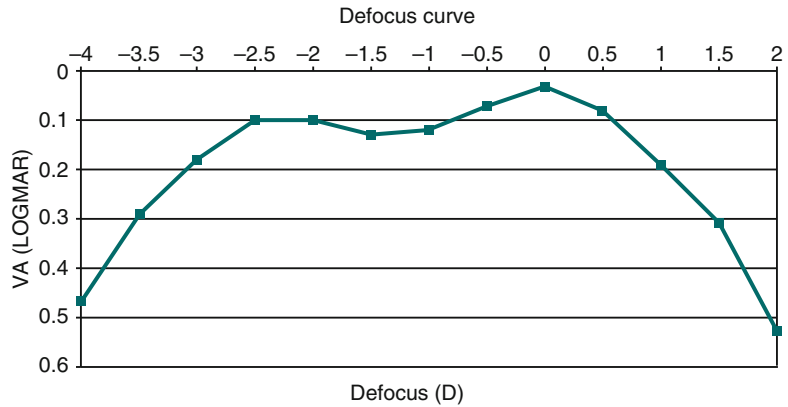


Fig. 18.5 Mean defocus curve CSF of the Lentis Mplus LS-313. This pattern shows an optimal distance, intermediate and near visual acuity. *RMS* Root mean square, *HO* high order, *PSA* Primary spherical aberration

(SD 0.03), and the mean cutoff spatial frequency for the ocular MTF was 13.62 (SD 6.38). Furthermore, the mean ocular high-order RMS aberrations was 1.05 (SD 0.59), and the intraocular Strehl ratio mean value was 0.29 (SD 0.05).

Figure 18.5 shows the mean postoperative intraocular aberrations, and Fig. 18.6 shows a diagram with the analysis of intraocular optical quality for a 5.0 mm pupil of one case implanted with the Lentis Mplus LS-313. Due to the geometrical asymmetry [6] of the IOL analysed in a previous study, the postoperative intraocular optical analysis shows the presence of primary coma and coma-like aberrations with higher magnitude in eyes implanted with the C-Loop haptic design.

If we consider that optical, refractive and visual performance provided by multifocal IOLs are related to IOL rotational stability, previous studies [1, 2] with the C-loop haptic IOL design have demonstrated poor stability of the IOL within the capsular bag and suggested a new plate-haptic design to improved this issue in accordance with results provided by other authors [7–9], but when the intraocular tilt aberrations were analysed, no significant differences among groups in these values were detected; otherwise, all groups presented large amounts of this aberration. These findings indicate that it is unclear which haptic IOL design allows a more effective control of IOL tilting.

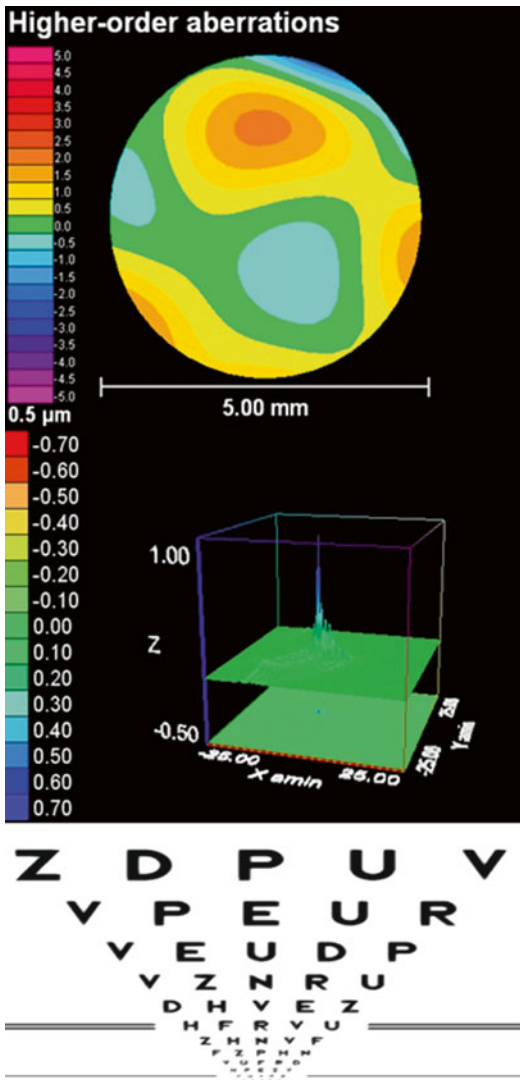


Fig. 18.6 Diagram showing the analysis of the in vivo intraocular optical quality for a 5.0 mm pupil of the Lentis Mplus LS-313. *Top row:* intraocular wavefront higher-order aberrations. *Middle row:* 3-D PSF (point spread function). *Bottom row:* Snellen optotype simulation considering only the effect of higher-order aberrations

18.3.3 Conclusions of the Sector Rotational Asymmetrical Refractive Multifocal IOL: Lentis Mplus-LS313 with +3 Near Vision Add

The rotationally asymmetric multifocal IOL, the Lentis Mplus LS-313, allows a near, intermediate

and distance visual restoration in pseudophakic eyes providing better refractive predictability and intraocular optical quality than with the C-loop model. The C-loop haptic model shows instability due to the design and haptic material which was solved with the plate-haptic model providing a high IOL stability in the capsular bag. This multifocal IOL technology provides a wide range of focus and good contrast sensitivity outcomes for the age sample with no degradation of the optical quality.

18.3.4 Sector Rotational Asymmetrical Refractive Multifocal IOL: The Lentis Comfort LS-313 MF 15 with Low (+1.5) Near Vision Add

The patient's visual performance after cataract surgery is highly dependent on the type of intraocular lens (IOL) implanted. The introduction of new optimised models of IOL aimed at restoring not only the visual function for distance but also in intermediate and near conditions [10, 11]. These latest generation multifocal IOLs have been demonstrated to provide good distance and near functional vision without the use of corrective lenses [12].

The Lentis Comfort has been included in clinical practice to improve intermediate visual acuity and provide a lower incidence of optical side effects after cataract surgery due to an addition for near of +1.5 D. This type of design may provide an optimal visual outcome for near and intermediate distance and an excellent distance visual acuity, with an even lower incidence of optical side effects.

18.3.5 Methods

18.3.5.1 Patients

Thirty-one eyes of 18 patients (ages ranging between 64 and 81 years old) underwent cataract surgery with implantation of the rotationally asymmetric multifocal IOL Lentis Comfort.

Table 18.2 Comparative table showing the preoperative and postoperative conditions of patients implanted with the Lentis Comfort

Mean (SD)					
Range	Preoperative	1 month	3 months	6 months	<i>P</i> -value (statistical test)
LogMAR UDVA	0.61 (0.28)	0.22 (0.23)	0.27 (0.26)	0.20 (0.14)	<0.01
	0.15 to 1.30	0.00 to 0.82	0.00 to 1.00	0.01 to 0.40	Wilcoxon test
Sphere (D)	+0.85 (2.00)	+0.06 (0.39)	-0.17 (1.12)	-0.13 (0.61)	0.83
	(-2.75 to +3.75)	(-0.50 to +1.00)	(-3.50 to +1.00)	(-1.50 to +0.50)	Wilcoxon test
Cylinder (D)	-1.11 (0.80)	-0.91 (0.93)	-0.96 (0.57)	-0.77 (0.59)	0.06
	-3.00 to 0.00	-3.00 to 0.00	-2.50 to 0.00	-1.50 to 0.00	Wilcoxon test
LogMAR CDVA	0.27 (0.24)	0.09 (0.12)	0.11 (0.17)	0.06 (0.08)	<0.01
	0.00 to 0.70	0.00 to 0.40	0.00 to 0.70	0.00 to 0.22	Wilcoxon test
LogRAD UNVA	0.76 (0.27)	0.41 (0.14)	0.43 (0.20)	0.45 (0.19)	0.07
	0.30 to 1.40	0.22 to 0.70	0.00 to 0.70	0.10 to 0.62	Wilcoxon test
LogRAD DCNVA	-	0.35 (0.12)	0.40 (0.16)	0.47 (0.13)	-
		0.19 to 0.52	0.19 to 0.70	0.22 to 0.62	
LogRAD CNVA	0.36 (0.26)	0.13 (0.11)	0.11 (0.07)	0.11 (0.08)	<0.01
	0.00 to 1.00	0.00 to 0.40	0.00 to 0.22	0.00 to 0.22	Wilcoxon test
LogMAR UIVA (80 cm)	-	0.19 (0.11)	0.14 (0.07)	0.19 (0.11)	-
		0.10 to 0.40	0.00 to 0.22	0.00 to 0.40	
Near addition (D)	2.88 (0.17)	+1.61 (0.60)	+1.61 (0.34)	+1.67 (0.22)	<0.01
	+2.50 to +3.00	0.00 to +3.25	+1.00 to +2.50	+1.50 to +2.50	Wilcoxon test

The corresponding *p*-values for the comparison between groups are shown for each parameter evaluated. Distance visual acuities improved with the surgery, and the near addition was reduced significantly after surgery

18.3.5.2 The Lentis Comfort

The Lentis Comfort is a refractive rotationally asymmetric multifocal IOL containing an aspheric distance vision zone combined with a 1.50 D posterior sector-shaped near vision zone and plate-haptic design.

18.3.5.3 Preoperative and Postoperative Examinations

Preoperatively, all patients had a full ophthalmological examination including the evaluation of the refractive status, the distance and near visual acuities, slit lamp examination, tonometry and funduscopy. Distance visual acuity was evaluated with the Snellen charts (4 m) and the near visual acuity (40 cm) with the Radner reading charts. Besides these clinical tests, other specific examinations were performed, such as corneal topography and biometry. Postoperatively, patients were evaluated during the follow-up at 1 day, 1 month and 3 months after surgery. The postoperative examination protocols at 1 and 3 months were identical to the preoperative protocol, with two additional clinical tests: ocular

aberrometry and the evaluation of the ocular optical performance with the OQAS system (Optical Quality Analysis System, Visiometrics SL). In addition, defocus curves and contrast sensitivity were obtained at 3 months postoperatively.

18.3.6 Results

18.3.6.1 Visual and Refractive Outcomes

Table 18.2 shows the visual and refractive outcomes at 1, 3 and 6 months after surgery. A significant postoperative improvement in uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) and CNVA was observed (Wilcoxon test; $p \leq 0.01$). Regarding the UNVA, no significant differences were found postoperatively (Wilcoxon test; $p = 0.07$).

Figure 18.7 summarises the percentage of eyes with UDVA, UNVA and uncorrected intermediate visual acuity (UIVA) of 0.3 LogMAR or better during the follow-up. As expected, a significant improvement in distance visual outcomes

Fig. 18.7 Percentage of eyes with UDVA, UNVA and UIVA of 0.3 LogMAR or better with the Lentis Comfort during the follow-up; 1 month after surgery (blue bars) and 6 months after surgery (orange bars). 70 % of eyes had a UDVA of 0.3 LogMAR or better and 90 % of eyes had a UIVA 0.3 LogMAR or better. UDVA uncorrected distance visual acuity, UNVA Uncorrected near visual acuity, UIVA Uncorrected intermediate visual acuity

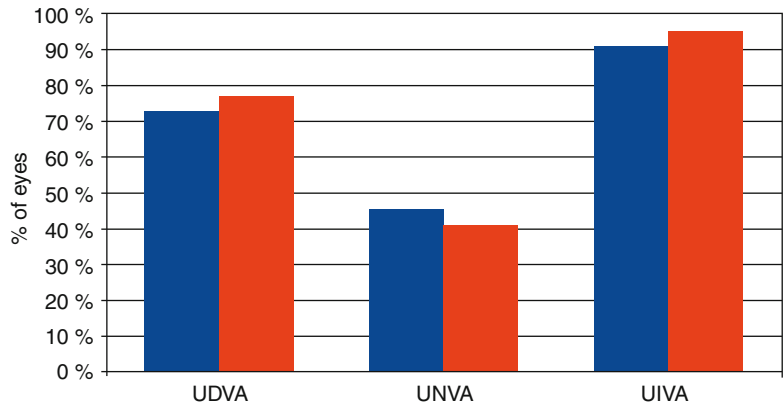
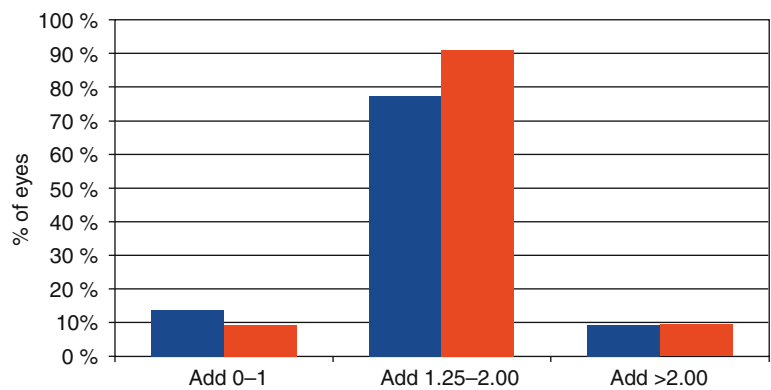


Fig. 18.8 Near addition data distribution of eyes implanted with the Lentis Comfort. Approximately 90 % of eyes had a near addition between 1.5 and 2.0 D at 6 months postoperatively. Blue bars: 1 month postoperatively, Orange bars: 6 months postoperatively



was achieved after IOL implantation. Therefore, this IOL is able to restore the distance visual function. As shown, a limitation in the UNVA was present with this IOL.

Regarding subjective refraction, no significant changes in manifest sphere and cylinder were found during the whole follow-up (Wilcoxon test; $p \geq 0.07$) (Table 18.2). Postoperative spherical equivalent was within ± 0.50 D in 14 eyes (63.64 %) at 1 month and in 11 eyes (50.0 %) at 6 months. Figure 18.8 summarises the near addition data distribution postoperatively, which was reduced significantly after surgery (Wilcoxon test; $p \leq 0.01$). The limitation in near vision with the +1.5 D addition IOL was associated to a better visual outcome for intermediate vision. This finding is consistent with the design of the IOL evaluated and follows the trends observed in

previous series also comparing other multifocal IOLs with different levels of near addition [13].

18.3.6.2 Contrast Sensitivity Outcomes

Besides contrast sensitivity, as shown in Fig. 18.9, postoperative photopic and low mesopic contrast sensitivity was within the normal range for the age sample for all spatial frequencies. In a previous report [14], no differences were found in contrast sensitivity between the Lentis Comfort and the Lentis Mplus LS-312 MF30.

18.3.6.3 Defocus Curve Outcomes

Figure 18.10 shows the mean defocus curve. As shown, an optimal intermediate visual acuity was obtained with this IOL for defocus levels between 0 and -1.5 D with visual acuity better than 0.20 LogMAR. Previously the defocus

Fig. 18.9 Mean photopic and low mesopic contrast sensitivity with the Lentis Comfort. Photopic and low mesopic contrast sensitivity was within the normal limits except for the spatial frequency of 18 cycles/degree in low mesopic conditions. *Orange line:* Contrast sensitivity obtained with the Lentis comfort, *Grey lines:* normal values of contrast sensitivity for the same age sample

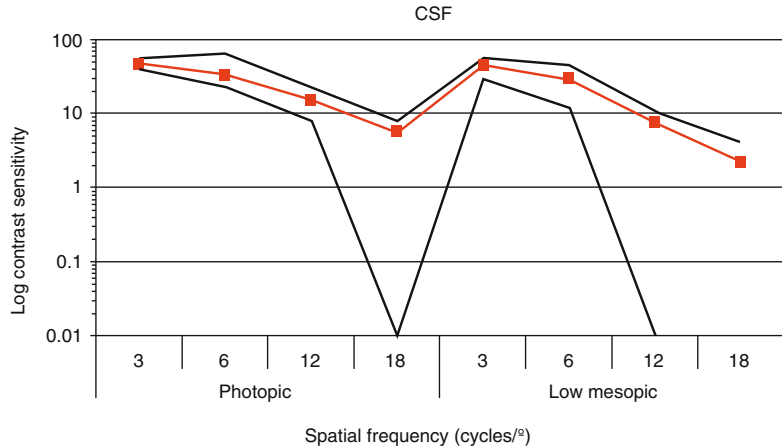
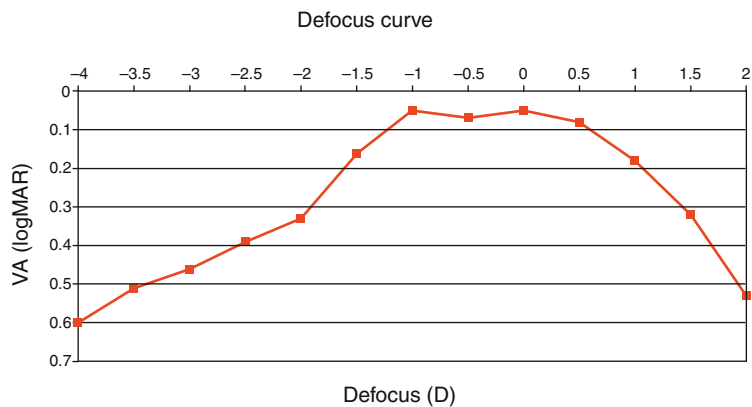


Fig. 18.10 Mean defocus curve of the Lentis Comfort. Visual acuity of 0.3 LogMAR or better was observed between -1.5 and +1.0 D of defocus levels



curve of this IOL model was compared with the Lentis Mplus LS-312 MF30 [14] and the Crystalens HD [15] accommodative IOL with the Lentis Comfort providing better results for intermediate vision.

18.3.6.4 Optical Quality Outcomes

Besides optical quality, the mean ocular Strehl ratio estimated with the OQAS system was 0.10 (0.04), and the mean cutoff spatial frequency for the ocular MTF was 13.44 (5.41). Furthermore, the mean ocular high-order RMS aberrations was 0.77 (0.08), and the mean value of the intraocular Strehl ratio was 0.24 (SD 0.03). Figure 18.11 shows the mean postoperative intraocular aberrations, and Fig. 18.12 shows a diagram with

the analysis of the intraocular optical quality for a 5.0 mm pupil of one case implanted with the Lentis Comfort. As expected, we have demonstrated that the IOL with lower addition is associated to a poorer visual outcome in near vision, but we did not know if this could have a potential benefit on the visual quality. However, in a previous [14] study, no significant differences in these optical parameters were detected between the low and high addition power models of the Lentis Mplus. The analysis of postoperative intraocular optical aberrations revealed significantly larger amounts of intraocular tilt. This finding was previously reported [1] with the +3.00 D addition power of multifocal refractive IOL with rotational asymmetry.

Fig. 18.11 Mean postoperative intraocular aberrations calculated by means of the VOL-CT software of the Lentis Comfort. High values of tilt RMS were detected with this IOL model. *HO* high order, *PSA* Primary spherical aberration, *RMS* Root mean square

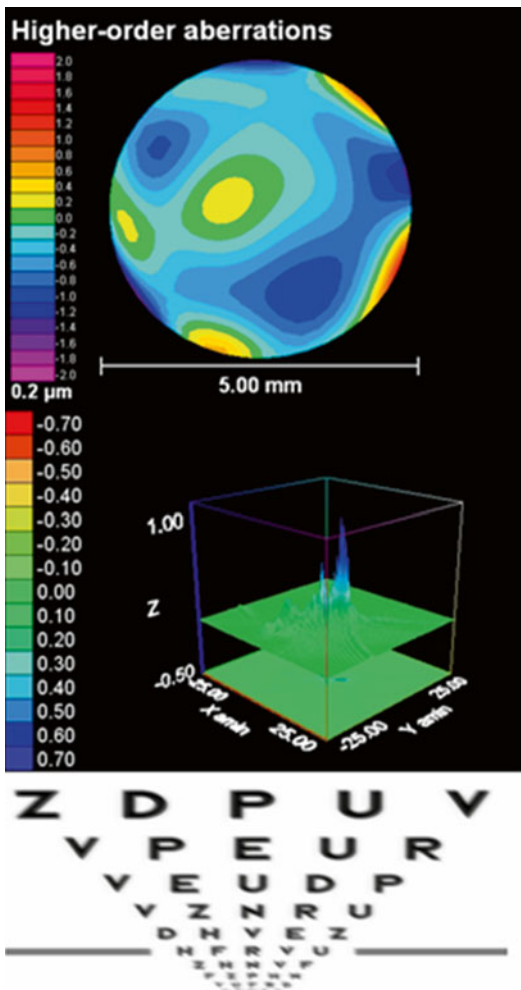
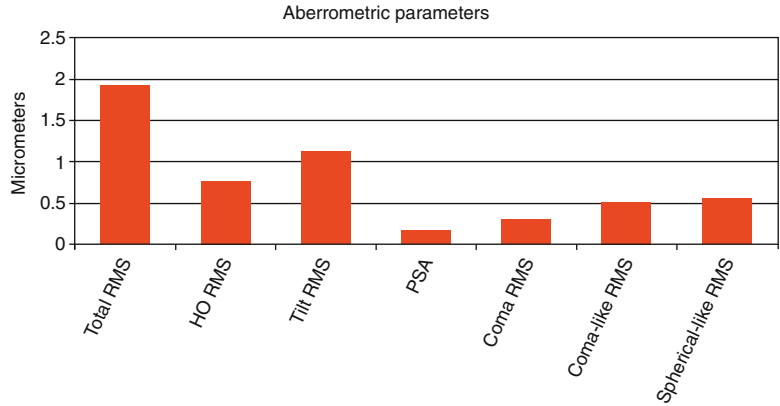


Fig. 18.12 Diagram showing the analysis of the in vivo intraocular optical quality for a 5.0 mm pupil of the Lentis Comfort. *Top row*: intraocular wavefront higher-order aberrations. *Middle row*: 3-D PSF (point spread function). *Bottom row*: Snellen optotype simulation considering only the effect of higher-order aberrations

Conclusions

The rotationally asymmetric multifocal IOLs allow a distance visual restoration in pseudophakic eyes. These IOLs are bifocal IOLs; the Lentis Mplus LS-313 provides better near visual outcomes and an optimal intermediate visual acuity with high stability than the C-loop haptic model. Also, the Lentis Comfort provides better intermediate visual acuity after cataract surgery than the Lentis Mplus LS-313. This kind of multifocal IOLs allows the surgeon to choose either model depending on the visual needs of the patient.

The low near add concept of the Lentis Comfort is able to successfully restore the distance visual function after cataract surgery and provide an improvement in near vision. In addition, the low addition power of multifocal refractive IOL with rotational asymmetry provides a wide range of focus especially in the intermediate vision conditions with a limitation in providing a complete near visual rehabilitation. Possibly, Lentis Comfort IOL could be a good option for patients with significant demands in intermediate vision.

Compliance with Ethical Requirements Ana Belén Plaza Puche and Jorge Alió 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 article.

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The Rayner Multifocal IOL Family: State-of-the-Art Technology from the Original Manufacturer of IOLs

19

Bitá Manzouri and Charles Claoué

19.1 Introduction

One of the major advances in the field of ophthalmology began with the first successful implantation of an intraocular lens (IOL) by Sir Harold Ridley on 29 November 1949. This first IOL implantation marked a culmination of events that began when Sir Harold, who was serving as a military surgeon at the time, observed that Royal Air Force pilots who sustained eye injuries and retained intraocular foreign bodies (mainly involving the fighter cockpit windshield material polymethyl methacrylate) did not show any significant foreign body reaction. Deducing that the transparent material was inert and potentially useful for implantation in the eye, Sir Harold approached John Pike, an optical scientist at Rayners of London, to provide important technical assistance and practical advice for the design and manufacture of an IOL [1]. The resulting Perspex C.Q. (clinical

quality) lens was used in the first IOL operation at St Thomas' Hospital in London, marking the beginning of what has now become one of the most common and most successful of all eye operations.

19.2 Rayner: The Original IOL Manufacturer

Established in 1910, Rayner Intraocular Lenses Ltd. (Hove, East Sussex, United Kingdom) is the only IOL manufacturer in the UK and is focused entirely on the development of hydrophilic acrylic injectable IOLs and associated instruments for the treatment of cataracts.

Rayner multifocal IOLs are based on one of two platforms for either capsular fixation or sulcus placement and are notable for using refractive optics with two add powers. The logic behind refractive optics is that all available light is used for images that can be visualised (unlike a classic diffractive bifocal which loses approximately 22 % of light to higher-order images that can never be visualised) [2]. Since reduced contrast sensitivity is one of the arguments against the use of multifocal IOLs [3], it does seem logical to use a design that does not waste light. Further, published data shows that the contrast sensitivity of eyes with refractive multifocal IOLs is the same as monofocal IOLs [4] suggesting that,

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for well-designed refractive multifocal IOLs, the loss of contrast sensitivity is below most patient's threshold of appreciation. The Rayner *M-flex*, a capsular-fixated lens, was originally manufactured with only a +3 add (at the IOL plane, equating to a +2.25 add at the spectacle plane) since this would be expected to minimise haloes. However, the subsequent introduction of a +4 version (equivalent to +3 at the spectacle plane) was not associated with any noticeable increase in the already very low incidence of haloes, leading to the hypothesis that the particularly low index of refraction (1.46) of "Rayacryl", the material used to manufacture the IOLs, is a major contributory factor.

19.3 *M-flex* and *M-flex* T

The capsular-fixated *M-flex* and *M-flex* T are based on a closed-loop haptic system platform. This design, called "anti-vaulting haptics" (or AVH), is used for its good centration. These haptics have zero angulation, meaning that for the monofocal IOL variants, there is no "front" or "back". This is not the case for toric or multifocal versions which must be injected to give a reverse-S configuration to preserve the vergence power of the toric or multifocal surface (Fig. 19.1). An additional feature of the Rayner capsular-fixated platform is the 360° square edge. This was the first single-piece IOL platform with this feature, several other IOL manufacturers having neglected to put the square edge at the haptic-optic interface leaving an "Achilles' heel" for posterior

capsular opacification (PCO) to approach the visual axis (Fig. 19.1).

The *M-flex* and *M-flex* T have concentric rings which provide a refractive bifocal lens with either 4 or 5 annular zones (depending on IOL base power) and +3.0 or +4.0 D of additional refractive power at the IOL plane (equivalent to +2.25 or +3.0 D at the spectacle plane). The power additions have been selected for a minimal incidence of halo or glare [5]. Further, while standard multifocal IOLs are often contraindicated for patients with >1.5 D of corneal astigmatism, the combination of multifocal and toric optical components found in the *M-flex* T offers the potential benefit of reduced spectacle dependence to be extended to patients with significant corneal astigmatism. The Rayner *M-flex* T multifocal toric IOL has small marks indicating the steep meridian of the torus and was the first commercially available foldable toric IOL. These IOLs can be used to treat cataract or for refractive lens exchange (presbyopic lens exchange or PRELEX). In both situations, the refractive error to achieve both emmetropia and presbyopia is treated. Since presbyopia is the only universal refractive error, there is considerable interest in IOLs able to address this problem.

The *M-flex* lens is available in two models that differ in the diameter of the optic body and overall length to accommodate different ocular sizes, outlined in Table 19.1; the powers available for the two models of the *M-flex* lens are outlined in Table 19.2. The *M-flex* T lens also comes in two models; the models and corrections available for this lens are outlined in Tables 19.3 and 19.4, respectively.



Fig. 19.1 The *M-flex* (left) and *M-flex* T (right) multifocal lenses with the closed-loop haptic design positioned in a reverse-S configuration. Note the small grooves on the

edge of the optic of the *M-flex* T to allow correct alignment of the lens (Figures by kind permission of Rayner Intraocular Lenses Ltd.)

Table 19.1 Physical parameters of the Rayner *M-flex* lens

	Model number	
	<i>M-flex</i> (630F)	<i>M-flex</i> (580F)
Optic body diameter	6.25 mm	5.75 mm
Overall length	12.50 mm	12.00 mm
Estimated SRK/T A-constant	118.6	118.6
Theoretical ACD	4.97 mm	4.97 mm

Table 19.2 Power availability of the Rayner *M-flex* lens

	Power availability	
	<i>M-flex</i> (630F)	<i>M-flex</i> (580F)
+3.0 D add far dominant	+14.0 to +25 D in 0.5 D increments	
+4.0 D add far dominant	+14.0 to +25 D in 0.5 D increments	+25.5 to +30.0 D in 0.5 D increments

Table 19.3 Physical parameters of the Rayner *M-flex* T lens

	Model number	
	<i>M-flex</i> T (638F) base powers ≤ 25.0 D	<i>M-flex</i> T (588F) base powers > 25.0 D
Optic body diameter	6.25 mm	5.75 mm
Overall length	12.50 mm	12.00 mm
Estimated SRK/T A-constant	118.6	118.6
Theoretical ACD	4.97 mm	4.97 mm

Table 19.4 Power availability of the Rayner *M-flex* T lens

	Power availability	
	<i>M-flex</i> T (588F and 638F) standard power range	<i>M-flex</i> T (588F and 638F) premium power range
Spherical equivalent	+14.0 to +32.0 D in 0.5 D increments	+14.0 to +32.0 D in 0.5 D increments
Addition	+2.0, +3.0, +4.0 D	+1.0 to +6.0 D in 0.5 D increments
Cylinders	+3.0 or +4.0 D	+3.0 or +4.0 D

19.4 Clinical Evidence

The first *M-flex* injectable multifocal lens was implanted on 31 August 2005 by Charles Claoué at Queen's Hospital in London. Since then,

several published studies have reported on the number of patients who have experienced improved visual outcomes, in many cases becoming spectacle-free, as a result of bilateral implantation with this multifocal IOL.

In a prospective study, Cezón et al. evaluated visual outcomes after cataract surgery with the Rayner *M-flex* 630F +3 IOL over a 12-month follow-up period [5]. They recorded monocular and binocular uncorrected and corrected distance, intermediate and near visual acuities, distance contrast sensitivity under photopic and mesopic conditions, subjective dysphotopic phenomena (unwanted visual effects that occur with multifocal IOLs when the distinct-focus image at 1 dioptic power is overlapped by out-of-focus images at other, lower dioptic powers) and subjective spectacle dependence.

This study enrolled 32 eyes of 22 patients. At the 12-month postoperative assessment, their mean monocular corrected distance acuity was 0.03 ± 0.05 LogMAR and mean corrected near acuity was 0.04 ± 0.05 LogMAR. At 6 months, the binocular uncorrected and corrected near acuity was 0.25 ± 0.08 LogMAR and 0.03 ± 0.02 LogMAR, respectively, with no change thereafter. None of the patients reported any dysphotopic phenomena at the 12-month visit, and of the patients having binocular IOL implantation, 90 % were spectacle independent for distance vision and 70 % for near vision at 6 months [5]. The authors conclude that the *M-flex* 630F C3 refractive multifocal IOL is an effective alternative to monofocal IOLs and provides excellent distance and intermediate vision, sufficient functional near vision, good contrast sensitivity and a low incidence of visual disturbances.

In another study by Aslam et al. [6], 20 eyes of 19 patients were observed following uneventful phacoemulsification with implantation of the *M-flex* 630FIOL. A mean improvement in Snellen equivalent distance visual acuity was noted from between 0.48 LogMAR uncorrected visual acuity (UCVA) and 0.30 LogMAR best corrected visual acuity (BCVA) preoperatively to between 0.18 UCVA and 0.00 BCVA postoperatively. Additionally, 13 eyes (65 %) had uncorrected near visual acuity of J6 or better after surgery

(median J4, range J1–J8), which improved to 16 eyes (80 %) with correction. Three eyes with near visual acuity measuring J1–2 improved to J1 with a +1.0 D spherical addition. Notably, no patient reported dysphotopic symptoms, including glare or haloes, during follow-up.

These specific studies complement the author's and others' experience that the *M-flex* IOL is a good IOL for correcting presbyopia with our without cataract. It seems to be a “friendly” tool with remarkably few patients disturbed by haloes or glare.

19.5 The Sulcoflex Multifocal and Sulcoflex Multifocal Toric

Rayner's sulcus-placed IOLs are the *Sulcoflex* Multifocal and *Sulcoflex* Multifocal Toric (the latter produced to order) and are the work of Professor Michael Amon from Vienna, Austria. The long undulated 14 mm haptics of the *Sulcoflex* platform (Fig. 19.2) are designed to be gentle so as not to erode into the delicate choroidal tissue, while the undulations provide rotational stability. It is worth stressing the importance of meticulous removal of any ophthalmic viscoelastic device (OVD) from behind the iris when using the *Sulcoflex* Multifocal Toric; if it is left behind, there is a risk of rotation when the OVD finally resorbs. The *Sulcoflex* haptics have a gentle anterior angulation (i.e. the optic is retroplaced) in order to minimise the risk of

pupil block. The optic has an anterior convex and a posterior concave configuration, and does not have a square edge (since this is of course not required for PCO prevention) but a round edge to minimise the risk of dysphotopsia and iris chaffing with pigment dispersion. Rather fortuitously, this allows these IOLs to be used as a treatment for negative dysphotopsiae. The concave posterior surface of the optic means that there is no chance of optic-optic contact with deformation and subsequent hyperopic defocus with image degradation, such as occurs when two biconvex IOLs are used.

The *Sulcoflex* optics are essentially the same as for the *M-flex* and *M-flex* T but of much lower spherical power (although the adds are the same) as they are designed as supplemental IOLs to correct residual refractive error in pseudophakic eyes. The *Sulcoflex* Multifocal (653F) is available in spherical powers ranging from –3.0 to +3.0 D in 0.5 D increments with +3.5 D add (equivalent to +3.0 D at the spectacle plane) (Fig. 19.2).

Typically, a *Sulcoflex* IOL is used in one of three scenarios:

1. Primary duet procedure – While primary duet procedures (the simultaneous implantation of a capsular-fixated and a sulcus-placed IOL) are typically for extremes of refractive error, PRELEX can be performed as a primary duet procedure with a capsular-fixated monofocal IOL targeted on emmetropia and a plano multifocal *Sulcoflex* to provide presbyopia correction. The two advantages of this over a single multifocal IOL are that in eyes with extreme refractive error (when biometry is least accurate), any refractive surprise can be treated by simply exchanging the multifocal *Sulcoflex*. The other advantage is for patients who are concerned by stories of “haloes” but who still wish to have their presbyopia treated. Performed as a “presbyduet” procedure, the patient has the opportunity to experience multifocal vision. If this is not tolerated after a suitable period of neuroadaptation (which should be at least 3 months), then it is easy to remove only the *Sulcoflex*. In this case, the eye has then effectively had a monofocal refractive lensectomy. It should be noted that this is the only effective reversible surgery for presbyopia that we know of.



Fig. 19.2 The *Sulcoflex* lens, showing the undulating haptics with the anterior angulation to allow retroplacement of the optic to minimise the risks of pupil block (Image by kind permission of Rayner Intraocular Lenses Ltd.)

2. Secondary duet conversion procedure – This is likely to be the most common scenario for *Sulcoflex* lens use. The “conversion” refers to the eye being converted from monofocal to multifocal optics by the insertion of a multifocal *Sulcoflex*. Clearly appropriate IOL powers are also used to correct any residual spherical refractive error and any significant astigmatism.
3. Duet implantation with a conventional lens and the *Sulcoflex* in paediatric cataract surgery – In children over 1 year of age, IOL implantation is an accepted procedure with the IOL being implanted in the capsular bag with emmetropia the aim of the postoperative refraction. However, as the child’s eye grows with age, it becomes increasingly myopic. In this instance, duet implantation can be used to avoid this myopic shift. Professor Michael Amon has performed this procedure on four children following a strict protocol for *Sulcoflex* implantation in paediatric cases [7]. He states that the child must be between the ages of 1 and 5 years and that a peripheral iridectomy is mandatory. Follow-up must include amblyopia therapy so that the eye has the best possible chance to grow correctly. Finally, it is best to perform surgery as early as possible in a paediatric patient since the earlier the cataract exists, the more severe the amblyopia will be. In paediatric duet implantation, the power of the first lens (placed in the capsular bag) is calculated to ensure the child is emmetropic once the eye is fully grown. The *Sulcoflex* is then implanted in the sulcus on top of the conventional lens to provide an opportunity for the child to reach emmetropia immediately after surgery. As a result, the child has good refraction both immediately following surgery and as the eye grows. In order to keep the refraction stable as the eye grows and becomes more myopic, the *Sulcoflex* can either be explanted or exchanged for another lens. Although duet implantation is very new, it may be the answer to myopic shift in the growing eyes of children. Such use is clearly “off-label”.

19.6 *Sulcoflex* Outcomes and Considerations

Khan and Muhtaseb have examined outcomes following the use of the *Sulcoflex* piggyback IOL in five of their pseudophakic patients who had postoperative astigmatism, postoperative ametropia or pseudophakic presbyopia [8]. Four eyes received a *Sulcoflex* Multifocal IOL, and one eye received a *Sulcoflex* Toric IOL. All patients achieved uncorrected distance visual acuity of 0.1 LogMAR or better, and those who received the *Sulcoflex* Multifocal IOL achieved uncorrected near visual acuity of N6 (Jaeger 4) or better [8]. They conclude from their work that the placement of a *Sulcoflex* IOL may be a safe and effective method for enhancing the refractive outcome following phacoemulsification with good distance and near visual acuities able to be achieved with the use of the multifocal lens.

One of the recognised late complications of piggyback lens insertion is interlenticular opacification. However, this complication is only seen with the implantation of both IOLs in the bag through a small capsulorhexis [9]; implantation of one lens in the bag and the other in the sulcus along with improvements in IOL design and material has resulted in a reduced incidence of this complication.

Finally, it is important to mention the ways of aligning toric IOLs on insertion into the eye since accurate alignment is critical for correction of the astigmatism. Invariably, a degree of cyclotorsion occurs when a person changes from an upright to a supine position. Consequently, it is important to accurately mark the eye or record distinguishing landmarks in the upright position so that the proper meridian of astigmatism can be identified during surgical treatment, especially if a general anaesthetic is envisaged. Methods for toric intraocular lens alignment include iris fingerprinting, limbal registration and intraoperative wavefront aberrometry, although many surgeons employ much simpler techniques such as using a needle to mark the cornea at the slit lamp. Intraoperatively, it is recommended that the alignment marks on the lens be left at least 10–15° short (counter-clockwise) of the final meridian so if the IOL

rotates slightly during OVD removal it will still remain short of its final resting position to facilitate a slight clockwise rotation into the correct position as the final surgical manoeuvre. Otherwise, if the lens overshoots the final meridian, it will require a large amount of rotation.

The author has a number of years' experience with the *Sulcoflex* platform and finds it extremely easy to use. In general terms, the fact that it is injected using the injector device common to all Rayner IOLs mean that there is a minimal learning curve. Rayner also has an online ordering system which simplifies obtaining the correct IOL, and drawings of the intraoperative positioning make alignment planning easy. As with all toric IOLs, meticulous removal of OVD immediately prior to dialling the IOL to the final 10° is mandatory to avoid postoperative rotation. By adhering to this precept, we have not seen any *Sulcoflex* rotation. The opportunity to do a duet conversion procedure, that is converting an existing pseudophakic monofocal eye to multifocal optics, is a real advance. Previously, this would have required explanting the monofocal IOL, potentially damaging the zonulocapsular apparatus and leaving the eye aphakic at the end of surgery. In comparison, implanting a supplemental multifocal IOL is immensely more attractive. We believe that there is an increasing demand for this surgery which is likely to grow further still as patients become aware of the possibility.

19.7 Summary

In conclusion, Rayner multifocal IOLs are notable for their hydrophilic acrylic material, for using a single injector for all models and for their capsular-fixated or sulcus-positioned platforms.

The decision to use refractive rather than diffractive technology appears to be based on rational analysis of physical optics and results in an extremely high proportion of satisfied patients with an exceptionally low level of unwanted visual effects.

Compliance with Ethical Requirements No animal or human studies were carried out by the authors for this article.

Mrs. Bitá Manzouri declares no conflict of interest.

Professor Charles Cloué is a paid consultant to Rayner Intraocular Lenses Ltd.

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20.1 Introduction

Improved visual quality and therefore quality of life in cataract surgery patients have increased in recent years with the improvements in IOL technology, including multifocal designs, improving refractive and optical quality outcomes to give high visual expectations for intermediate, near, and distance vision [1–4]. These type of intraocular lenses can produce different visual complications, such as a reduction in contrast sensitivity due to the different distributions of the incidence of light and a loss of image quality by the presence of halos and glare produced by the dependence of these lenses on pupil size. Other disadvantages are the offset of the lens, causing a

decrease in efficiency, and the presence of other higher-order aberrations, such as coma and trefoil.

In this chapter, we present a new model of apodized diffractive IOL with an asymmetrical light distribution: the SeeLens MF (Hanita Lenses R.C.A Ltd., Kibbutz Hanita, Israel). This lens has concentric rings located at 4 mm from the middle, allowing good adaptation to any pupil size. With this design, an optimal distribution of energy is produced in different light conditions, minimizing spherical aberrations. The apodization concept refers to a property of the diffractive steps, in which the height of these is gradually reduced from the centre to the periphery, providing a distribution of light energy dependent on the 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 and improving contrast sensitivity.

Many studies [5–7] have reported visual outcomes and optical quality with several models of diffractive IOLs, but this clinical trial included 20 cases of patients who underwent cataract surgery and were implanted bilaterally with the SeeLens MF.

We have evaluated the clinical outcomes of this new multifocal diffractive IOL taking into account the visual and optical quality and quality of life in patients implanted with the new SeeLens apodized diffractive multifocal IOL after cataract surgery.

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20.2 Surgical Technique

All surgeries were performed by the same surgeon (JLA) using a standard technique of sutureless microincision (MICS) phacoemulsification. All patients received topical anaesthesia before surgery. The main incision was placed on the axis of the positive corneal meridian. The IOL was 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) administered for 1 week. In addition nonsteroidal anti-inflammatory drops (Diclofenaco Alcon Cusí Inc, Barcelona) were administered for 6 weeks.



Fig. 20.1 The SeeLens MF

20.3 Methods

20.3.1 Patients

Twenty eyes of 10 bilateral cataract surgery patients (between 58 and 71 years old) were implanted with the SeeLens MF. The patients chosen for this surgery presented different criteria, bilateral visually significant cataract, older than 50 and with corneal astigmatism lower than 1 D. The exclusion criteria were patients with active ocular diseases, visually significant corneal scars and known retinal disorders.

20.3.2 The SeeLens MF

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 incidence of light is distributed with 65 % to distance focus and 35 % to near focus for a 3-mm-diameter pupil. This IOL generates +3.00 D additional power for near vision equivalent to 2.4 D in the spectacle plane (Figs. 20.1 and 20.2).

20.3.3 Preoperative and Postoperative Examination

Before cataract surgery all patients underwent a complete ophthalmic examination, including the evaluation of the refractive status, the distance and

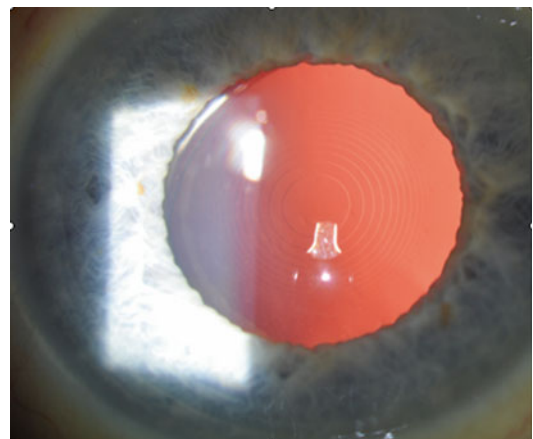


Fig. 20.2 The SeeLens MF implanted in one eye

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 1 day, 1 week, 1 month, and at the third and sixth month after surgery. The examinations were identical to the preoperative protocol but at the third and sixth month adding measurements of contrast sensitivity in photopic (85 cd/m²) and scotopic (3 cd/m²) conditions with CST

1800 (Vision Sciences Research Corp) and the defocus curve. In order to generate defocus curves, the visual acuity was measured with the ETDRS (charts at 4 m).

At the sixth month after surgery, functional visual impairment and quality of life were assessed by performing the Visual Functioning Index (VF-14) questionnaire. Each question had five possible answers graded from 0–4.

20.4 Results

20.4.1 Visual and Refractive Outcomes

Table 20.1 shows the visual and refractive outcomes at the first, third and sixth month after surgery with the SeeLens MF. A statistically significant improvement was observed in the first month in the uncorrected distance visual acuity (UDVA), in the corrected distance visual acuity (CDVA), in the uncorrected near visual acuity (UNVA) and in the corrected near visual acuity (CNVA) (Wilcoxon

test, all $p < 0.01$), but in the following months, these parameters remained constant, without showing significant changes ($p \geq 0.16$). There were no significant changes in DCNVA between the first and third month ($p = 0.35$); however, an improvement was observed between the third and sixth month ($p < 0.01$). In intermediate vision, UIVA and DCIVA, no significant changes were observed during the first, third and sixth month ($p \geq 0.09$).

With respect to the manifest refraction, no significant changes were found in the sphere and cylinder 1 month after surgery ($p \geq 0.23$), but between the first and third month, there was a slight trend towards a positive sphere ($p = 0.03$), with no significant modifications afterwards ($p = 0.89$).

These results are similar to those reported by other authors, who also observed a significant improvement in the different ranges of vision that were evaluated using the SeeLens MF IOL. Although most patients achieved functional visual acuity for distance and for near with different models of diffractive IOLs, the main limitation of this technology is the poor intermediate vision that it provides [8]. In the design of this

Table 20.1 Comparative table showing the preoperative and postoperative visual condition of patients included in this table

Mean (SD)						P value
Range		Preoperative	1 month	3 months	6 months	Pre-1 month
LogMAR UDVA		0.73 (0.38) 0.30 to 1.50	0.21 (0.15) 0.00 to 0.62	0.22 (0.17) 0.00 to 0.70	0.22 (0.20) 0.00 to 0.93	<0.01
Sphere (D)		-0.41 (2.52) -5.00 to +3.50	-0.04 (0.59) -1.00 to +1.50	0.16 (0.65) -0.75 to +2.00	0.10 (0.98) -3.00 to +2.00	0.53
Cylinder (D)		-0.78 (0.54) -1.75 to 0.00	-0.55 (0.47) -1.25 to 0.00	-0.70 (0.55) -1.50 to 0.00	-0.81 (0.54) -2.25 to 0.00	0.23
LogMAR CDVA		0.33 (0.31) 0.00 to 1.00	0.04 (0.05) 0.00 to 0.12	0.07 (0.16) 0.00 to 0.70	0.04 (0.06) 0.00 to 0.20	<0.01
LogMAR UNVA		0.69 (0.22) 0.40 to 1.00	0.24 (0.12) 0.00 to 0.40	0.31 (0.22) 0.00 to 0.90	0.24 (0.15) 0.00 to 0.60	<0.01
LogMAR DCNVA		-	0.22 ± 0.12	0.26 ± 0.18	0.15 ± 0.09	$p = 0.35$ (1–3 month) $p < 0.01$ (3–6 month)
LogMAR CNVA		0.36 (0.26) 0.10 to 1.0	0.13 (0.08) 0.00 to 0.30	0.14 (0.14) 0.00 to 0.60	0.08 (0.08) 0.00 to 0.30	<0.01
Addition		2.73 (0.24) 2.50 to +3.00	0.75 (0.61) 0.00 to +1.75	0.88 (0.81) 0.00 to 2.50	0.81 (0.65) 0.00 to +1.50	<0.01
Log MAR UIVA	63 cm	-	0.20 ± 0.13	0.24 ± 0.14	0.27 ± 0.15	$p \geq 0.09$
	100 cm	-	0.22 ± 0.12	0.25 ± 0.17	0.30 ± 0.15	$p \geq 0.09$
Log MAR DCIVA	63 cm	-	0.23 ± 0.10	0.25 ± 0.14	0.24 ± 0.10	$p \geq 0.09$
	100 cm	-	0.22 ± 0.10	0.23 ± 0.18	0.26 ± 0.12	$p \geq 0.09$

The corresponding p values for the comparison between preoperative and postoperative follow-up are shown for each parameter evaluated

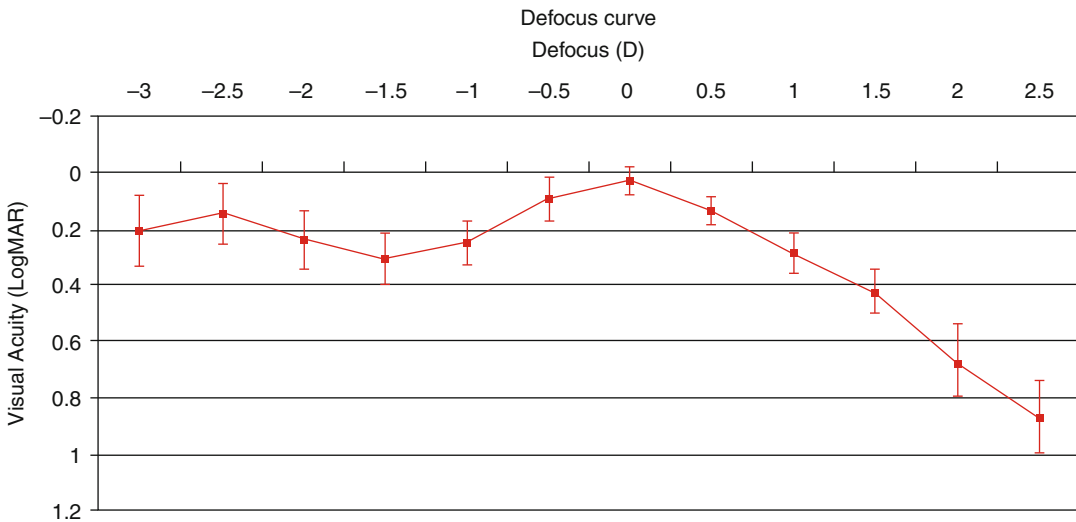


Fig. 20.3 Mean defocus curve of the patients analyzed in this graphic. We can observe two peaks of maximum vision, one at distance (around 0 defocus level) and one at near (around -2.5 D defocus level). Between these two

peaks, defocus of approximately -1.5 D was deemed to provide acceptable intermediate vision (better than 0.3 LogMAR). VA Visual Acuity

intraocular lens, we observed an improvement in the functional intermediate vision [5, 9].

20.4.2 Defocus Curve

Figure 20.3 shows the mean defocus curve for eyes implanted with the SeeLens MF. As shown, this multifocal IOL provided 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 was deemed to provide acceptable intermediate vision (better than 0.3 LogMAR). The slight slope between these two peaks means that patients can achieve adequate and functional intermediate visual acuity. One of the reasons that could explain this behaviour may be related to the fact that the new design of this IOL is based on an aspheric refractive-diffractive apodized profile.

20.4.3 Contrast Sensitivity

Postoperative contrast sensitivity function (CSF) is shown in Fig. 20.4, in logarithmic scale under photopic and scotopic conditions at 3 and 6 months after surgery. A significant increase in scotopic

contrast sensitivity was detected for 6 cycles/degree spatial frequency during follow-up ($p=0.04$), but no significant changes were observed for the rest of the spatial frequencies ($p \geq 0.06$). When the photopic CSF was compared with the normal population of the same age, the results obtained with the SeeLens MF are within physiological levels, but in scotopic conditions, a reduction in CSF after surgery was found with respect to the same values for the same age of normal population. This decreased [10, 11] sensitivity is due to the great dispersion of light energy being more pronounced in low light, scotopic. Another reason that explains the reduction of CSF with this type of multifocal IOL is the relationship that exists between the optical quality and the near visual performance of the IOL. Despite this reduction, there is a tendency to achieve a better perception of image contrast between the third and sixth month of follow-up which could be related to the neuroadaptation process observed in patients implanted with multifocal IOLs [12].

20.4.4 Optical Quality Outcomes

Figure 20.5 shows the internal aberrometric outcomes. At 6 months after surgery, there was a significant reduction in the RMS of the internal high-order

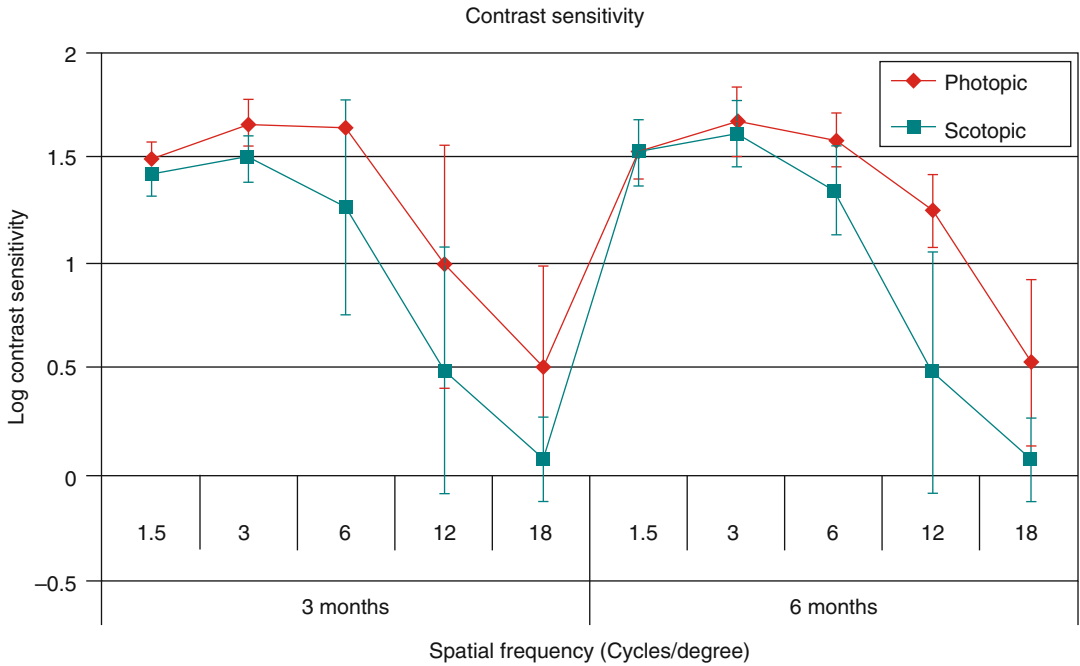
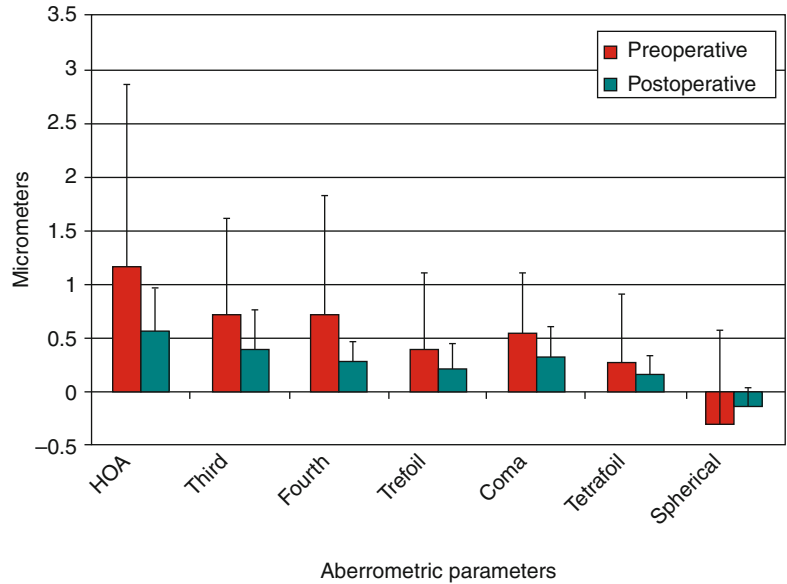


Fig. 20.4 Mean postoperative contrast sensitivity function (CSF) in logarithmic scale under photopic and scotopic conditions at 3 and 6 months after surgery

Fig. 20.5 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



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

spherical aberrations (both $p \geq 0.41$) where a change towards a more positive spherical aberration was found. This might be related to the aspheric profile of the SeeLens MF, which introduces a negative aspheric factor within the optic of its design.

On the other hand, the optical quality analysis showed a significant increase in the ocular Strehl ratio from 0.11 ± 0.06 preoperative to 0.19 ± 0.11 6 months after surgery ($p=0.02$). Also, 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 previously published by our research group with other types of diffractive IOLs [13, 14], but we must be cautious with these results because they were evaluated with Hartmann-Shack aberrometer.

20.4.5 Quality of Visual Life Outcomes

Table 20.2 shows the mean *quality of visual life outcomes* obtained with the Visual Functioning Index (VF-14) questionnaire 6 months after surgery.

Table 20.2 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 mah-jong	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 a little difficulty, 2 moderate difficulty, 3 quite difficult, 4 impossible to be performed

Patients found more difficulty reading small print, such as medicine bottle labels, a telephone book or food labels, and driving at night. In spite of finding more difficulty in reading small print, most of the responses to the questionnaire showed high levels of satisfaction about carrying out their daily tasks.

Conclusion

The SeeLens MF IOL can restore distance and near vision in presbyopic patients undergoing cataract surgery. The lens profile minimizes spherical aberration and generates +3.0 D additional power for near vision, providing better optical and visual quality than other multifocal IOLs. Patients implanted with this diffractive IOL report a high level of satisfaction from the results of the questionnaire mentioned previously.

This new IOL also provides functional intermediate vision with an adequate intraocular optical quality performance which leads this IOL to be a suitable choice within the different alternatives of diffractive multifocal IOL.

Compliance with Ethical Requirements Jorge Alió, MD, PhD; Pablo Sanz, MSc; Ana Belén Plaza-Puche, MSc; and Alfredo Vega-Estrada, MD, 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 (5). Informed consent was obtained from all patients for being included in the study.

No animal studies were carried out by the authors for this article.

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Jorge L. Alió and Joseph Pikkell

21.1 Introduction

Patients that either had refractive laser enhancement or cataract surgery with multifocal intraocular lens implant have high expectations for good vision free of the need to use any other visual aid like spectacles or contact lenses.

The eye is actually an optical system of two refractive plains, the cornea and the intraocular lens. These two refractive organs concentrate light rays from infinity to a certain focal point. If we want to change the focal point, we can do it either by changing the corneal refractive power, by changing the lens power, or by changing both. As our aim is to free the patient from the need to use spectacles or contact lenses, it is only reasonable to use all the tools we have – changing the refractive power of the cornea, lens, or both.

While discussing multifocal intraocular lens implant and laser refractive surgery, there are two

possible clinical conditions – multifocal intraocular lens implant after refractive laser (or radial keratotomy) treatment or refractive laser enhancement after multifocal intraocular lens implant. These two possible conditions raise different issues to be considered such as timing of procedures, corneal topography, aberrations, lens power calculations, amount of the needed refractive power change, etc.

21.2 Multifocal Intraocular Lens Implant After Radial Keratotomy or Corneal Excimer Laser Surgery (LASIK in PRK)

Radial keratotomy and refractive laser treatment on the corneal surface have been widely done for the last three to four decades. Therefore, it is no surprise that the number of patients needing cataract surgery after having previously refractive surgery on the cornea is in incline and will continue to rise in the future. There is, however, surprising paucity of the literature on this topic, and the greatest concern of what was published so far deals mainly in what the proper intraocular lens power calculations are. In a study assessing safety, efficacy, and predictability in eyes that had refractive lens exchange with implantation of spherical diffractive intraocular lens after previous hyperopic laser in situ keratomileusis, published in

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2009, this procedure was found to be safe, effective, and predictable [1]. A review, published in 2013, found that the use of hybrid refractive-diffractive multifocal intraocular lenses in eyes with previous myopic or hyperopic laser in situ keratomileusis can result in good refractive results but there may be possible refractive surprises that may require further intervention [2].

The main three concerns while planning to implant an intraocular lens after laser in situ keratomileusis or after radial keratotomy are as follows:

- Stability of the corneal refractive power. This is an important limitation for previous radial keratotomy cases and one of the reasons to contraindicate the multifocal IOL in the aging patient.

Corneal topography and corneal aberrometry: The corneal topography pattern should be mostly regular. Severe or moderate corneal irregularity as measured by corneal aberrometry is to be considered a contraindication for multifocal IOLs. In general, patients with corneas affected by more than 1 μm of higher corneal aberration (HOA), especially if they are caused by high levels of coma, should not be considered as good candidates for multifocal IOL implantation. A very important consideration in the analysis of the eye with total eye aberrometry is to ascertain if the aberration's origin is in the cornea or the lens and accordingly to plan the next stage. Operating and replacing the lens while leaving the corneal aberrations untreated will result in an unsatisfactory visual outcome.

Several factors should be considered:

- Lens power calculation. Difficult to perform as its precision is affected by multifactorial clinical and anatomical variables.
- Quality of the retinal image following multifocal IOL implantation. It depends mainly on the anterior corneal surface and, to a lesser extent, on the posterior corneal surface.
- Corneal aberrometry is, in our opinion, of major help in making the decision. Patients with more than 1 μm of higher-order aberrations are not good candidates for multifocal IOLs.

There is no logic in operating the cataract in an eye with an unstable corneal refractive power. Luckily enough, most patients that need cataract surgery had the corneal refractive treatment long ago and while needing a cataract surgery have a stable cornea and a non-changing corneal refractive power. In the minority of patients that do not show corneal stability or developed cataract in a short time after the corneal refractive treatment, surgery must be postponed, if possible until the cornea reaches a steady state and a steady refractive power. If such stability is not achieved prior to cataract surgery, refractive surprise may occur and the patient might have to have another procedure such as a lens exchange or another refractive laser treatment.

An attention to corneal topography and possible existence of corneal aberration is important in planning cataract extraction and multifocal intraocular lens implant. Not all corneal topography instruments are able to detect delicate corneal changes and aberrations, and one should know the limitations of the current machinery in use. If the corneal surface is not regular and a further laser treatment can repair this irregularity, such a treatment should be considered prior to the cataract operation. If the previous treatment was not properly centered, one should consider performing another corneal laser treatment. If it is possible, the corneal surface should be made as regular and without aberrations as could be since eliminating astigmatism and corneal aberrations is a key to success in multifocal intraocular lens implant. Laser enhancement and afterwards recovery and corneal stability are a time-consuming process but inevitable if we want good refractive results and patient satisfaction.

Calculating the power of the intraocular lens to be implanted, after corneal incisional refractive treatment, is not always accurate, and hyperopic shift after cataract surgery might occur. Power of the implanted lens is calculated by formulas that use the A constant of the lens, the axial length of the eye, and the corneal refractive power (K readings). The reasons for the miscalculations lie in the inability of keratometers to measure accurately K readings of

the corneal center area (approx. 2 mm diameter) after corneal refractive treatment and in the fact that the outer and inner surfaces of the cornea may change in an unpredictable way after these treatments. As a rule, patients that had previously corneal refractive treatments (laser in situ keratomileusis, photorefractive keratomileusis, or radial keratotomy) have to be informed that the intraocular lens power calculations are not always accurate and that a further operation for exchanging the lens may be needed in the future.

There are a few ways to calculate the lens power in these patients, but none of them is 100 % accurate. The most accurate way of calculating the lens power is the *clinical history method*. To use this method, we need to have the refractive error and the K readings before the refractive treatment and the refractive error after the treatment. In this method we calculate the change in the spherical equivalent (the data after the corneal refractive treatment has to be that of a stable refractive power, long enough after the treatment, and unaffected by the cataract which might cause a myopic shift) [3].

Example

If the average K reading before the refractive treatment was 44.00 D and the spherical equivalent was -8.00 , the spherical equivalent before the refractive treatment at the corneal plain was $-8.00/[1.00-0.012 \times (-8.00)] = -7.30$ (vertex distance is 12 mm)

If the spherical equivalent after the treatment is -1.00 , we can calculate the new spherical equivalent at the corneal plain the same way:

$$-1.00/[1.00-0.012 \times (-1.00)] = -0.98$$

The change of the refraction at the corneal plain is therefore $-7.30 - (-0.98) = -6.32$.

Now we can calculate the correct average reading by reducing the change of corneal power from the prior corneal power: $44.0 - 6.32 = 37.68$ D.

If we have only the K reading and the refraction prior to the treatment, we have to assume that after the treatment, the refractive error was zero. By using the SRK formula:

Lens power = A constant $- 2.5$ Axil length $- 0.9$ K reading. Assuming that there was no change

in the spherical equivalent since the treatment, we can calculate the lens power:

Example

A constant = 118.4, axial length = 25.00 mm, prior average K reading = 44.00, and the refraction was -8.00 .

The new K reading is $44.00 - 8.00 = 36.00$ and the lens power is

$$118.4 - (2.5 \times 25.00) - (0.9 \times 36.00) = 23.50$$

If we know the refraction before and after the treatment but we do not have any information of the previous K reading, we reduce 20 % of the K reading that we measure.

Example

If before treatment the refraction was -8.00 and now it is -1.00 , then the change is $-8.00 - (-1.00) = -7.00$.

20 % of that change is -1.40 . If the measured K reading is 40.00, we have to reduce 20 %, which means that the correct corneal power is $40.00 - 1.40 = 38.60$.

If we know only the refraction before treatment, we can use the Feiz-Mannis method in which we calculate the IOL power using the pre-treatment keratometry. This calculation is then increased by the amount of refractive change at the spectacle plain divided by 0.7 [4].

Another calculating method was originally outlined by Holladay. In this technique a *contact lens* is used in order to measure the accurate corneal power. This method is very accurate but is actually impractical, takes a lot of time, and requires an experienced examiner. Best corrected visual acuity has to be 6/24 or better. At first, we measure the existing refraction. Then we put a hard contact lens whose power and base curve are known and we measure the refraction with the contact lens.

If there is no refractive change, the corneal power is similar to the lens power.

If there is a myopic shift, the contact lens has more power than the cornea by the amount of the myopic change.

If there is a hyperopic shift, the cornea has more power than the contact lens by the amount of the refractive change.

Another formula considered as accurate in these patients is the Haigis-L formula in which

$$\text{Corrected radius} = \frac{331.5}{-5.1625 \times \text{measured radius} + 82.2603 - 0.35}$$

For practical use, some of the modern keratometers have a built-in calculating system for patients after refractive treatment, and there are some Internet sites that provide online calculators which are quite accurate. Anyhow, the patient should know that intraocular lens power calculations after refractive treatment may eventually bring an undesired refractive surprise and a lens exchange might be needed.

At the present moment and confirming recent reported evidence [6], our preferred methods for MfIOL calculation following previous myopic LASIK are the “Flat K” method of the Holladay II consultant formula and the ASCRS-min method available at the ASCRS calculator.

If the three influencing factors, stability of the corneal refractive power, corneal topography, and proper lens power calculation, are considered, the outcome of the cataract surgery with multifocal intraocular lens implant in patients that previously had corneal refractive surgery should be good and no different than in those that did not have a previous corneal refractive treatment.

21.3 Laser Refractive Surgery After Multifocal Intraocular Lens Implant

The high rate of success of multifocal intraocular lens implant and satisfied patients rose patients' expectations for good visual acuity in all distance without the need to use spectacles or contact lenses. Though intraocular multifocal lenses design improved, related glare and halos were reduced and surgeons experience and confidence in these lenses increased, there are some cases in

the measured corneal radius is “corrected” and the IOL power calculation is accurate. The Haigis-L formula is [5]:

which the final visual outcome is not satisfactory [7, 8]. Out of these patients, the vast majority have some residual refractive error – myopic or hyperopic shift or residual astigmatism.

Since our aim is to give the patient a good all distances visual acuity free of the need to use any other correction, we can use laser refractive surgery (or keratotomy) to correct this residual refractive error. Previous studies showed that laser refractive surgery, mainly laser in situ keratomileusis, particularly with femtosecond laser flap creation is a safe and effective treatment in correcting this refractive error [9].

There are some considerations that must be addressed prior to performing a secondary laser in situ keratomileusis treatment in these patients [10]:

- Refractive stability. After cataract surgery, a few healing procedures take place as adherence of the intraocular lens to the lens capsule which may take 2 months after operation and corneal changes which may take 6 months. After 6 months, dehiscence of the corneal self-sealed incisions is unlikely to occur during the flap creation [11]. Due to these healing processes and the refractive stability, it is wise to wait for 6 months after the cataract operation before proceeding with the laser treatment. Waiting, in this case, and restraining from treatment until the time is right is a good thing to do.
- Refractive evaluation. Autorefractometers and wave front refractive error measurements may be incorrect in these patients. A careful evaluation of the refractive error is obligatory in these patients. Retinoscopic evaluation in addition to autorefractometer measurements is recommended in these patients as well as a

manifest refraction conformation just prior to the laser treatment.

- Preoperative exam should include comparison of current findings with the cataract preoperative findings in order to determine if the laser treatment will be beneficial to the patient and if it is safe. Corneal thickness, corneal diseases, pupil problems, intraocular lens position, and clarity of the posterior capsule should be evaluated. If there is any pathological finding, an alternative treatment should be considered. Last but not least important is a thorough funduscopy examination to detect any retinal problems.
- Is the residual refractive error the cause of the unsatisfactory visual outcome, or is something else the cause for it? There is no use in laser treatment if other things like lens position and aberrations, posterior capsule opacity, or a retinal disease are the cause of the problem.
- Glare, halos, and reduced contrast sensitivity can occur after multifocal intraocular lens implant. Most of these symptoms get better within a few months possibly due to neuroadaptation [12]. It would be therefore wise to wait for a few months until we are sure that the manifest refraction is stable and neuroadaptation has finished before planning and performing a secondary laser treatment.
- Surface eye diseases and especially dry eye should be looked for and evaluated since corneal laser treatment tends to exacerbate these diseases. Dry eye should be one of the major concerns while considering corneal refractive laser treatment. About 33 % of the population report of some dryness filling in their eyes. Since dry eye is known to be a common problem after LASIK, it would be wise to assess this problem and try to solve it prior to the laser treatment. Preventive treatment with lubricants after the laser treatment might be a good practice in patients that already have the tendency towards dry eyes.
- Choosing the adequate laser treatment. There are different types of corneal refractive laser treatments. The surgeon should choose what kind of treatment he should recommend based on the patient's refractive error, clinical situa-

tion, corneal thickness and configuration, and the patient's needs.

- Residual refractive errors cannot always be treated by one treatment alone. Sometime there is a need for more than one procedure. The patient should be explained that such a possibility exists and be prepared for it.

If these pretreatment considerations are made, laser refractive treatment would be a safe and effective modality in treating cases of residual refractive error after multifocal intraocular lens implant. Treatment of these residual refractive errors requires however experienced and knowledgeable refractive surgeons.

Compliance with Ethical Requirements Jorge L. Alio and Joseph Pikkel declare that they have no conflict of interest.

No human studies were carried out by the authors for this article.

No animal studies were carried out by the authors for this article.

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