2 Multifocal Intraocular Lenses: Historical Perspective

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, John Hofbauer MD, for the necessity 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 couldn't understand how this was 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.

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 light (only 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"

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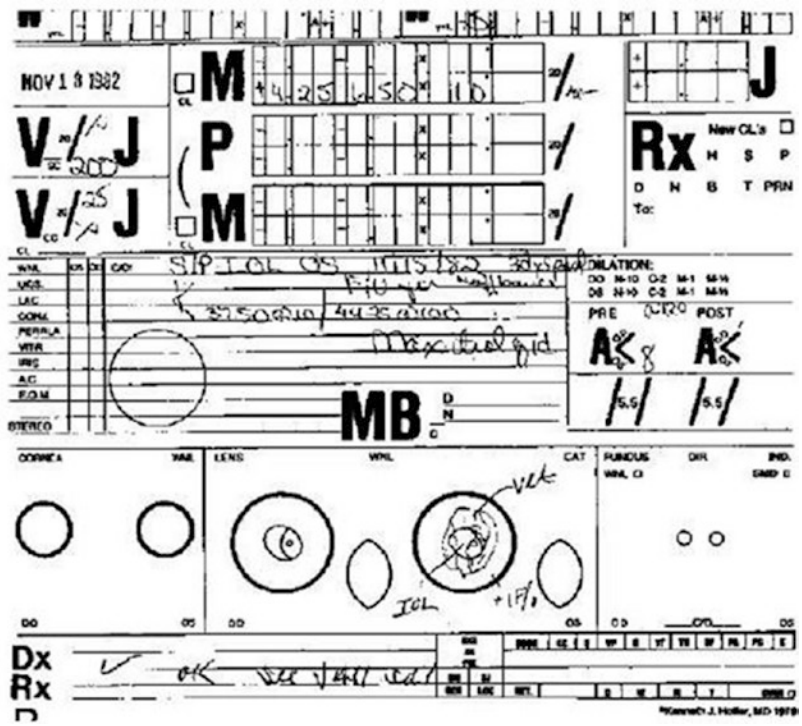


Fig. 2.1 Patient examination record from November 18, 1982, showing drawings of dislocated posterior chamber lenses; the left eye is 3 days postoperative

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, after my second Guinness, 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 the colleagues I was

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

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

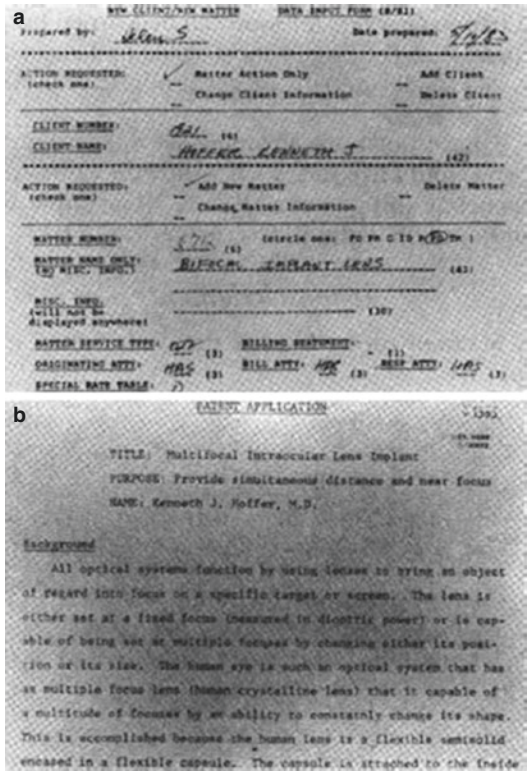


Fig. 2.3 (**a**) Attorney work sheet for patent application dated May 11, 1983. (**b**) First page of multifocal patent application #1365

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). Besides 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. *In the patent application, 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

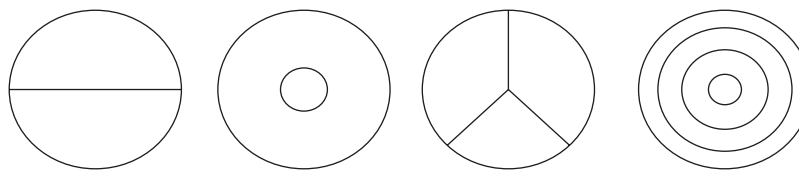


Fig. 2.4 Diagrams of possible configurations for multifocal lenses submitted in the patent application: L-R split bifocal, bullet bifocal, triangulate trifocal, and multiple rings

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 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 (now ASCRS) 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.

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

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 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

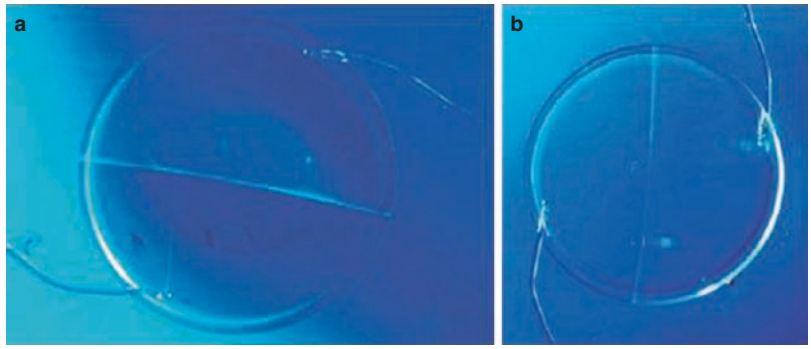


Fig. 2.6 Photographs of Hoffer Split Bifocal IOL made by Iolab in 1983 in their R&D department. (**a**) Note the water meniscus at the back of the IOL (**b**) shows a different peripheral curvature due to the different radius of curvature of each half of the optic. Note the bifocal line is in the axis of the loops and the lens has a Hoffer Laser Ridge

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 "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. They did make some for me, but 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.

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

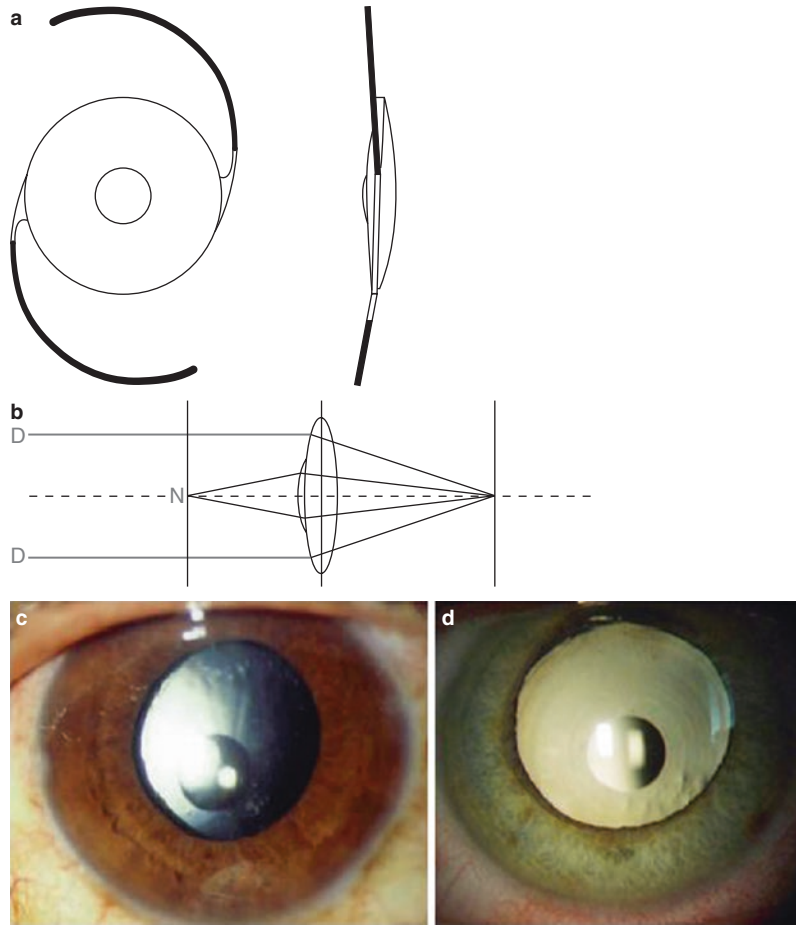


Fig. 2.7 (**a**) Diagram of Iolab NuVu lens. (**b**) Ray tracing of Iolab NuVu. (**c**, **d**) Photographs of postoperative eyes with the Precision-Cosmet (Iolab NuVu) bifocal IOL implanted. Note the decentration of the central "bullet" zone in both eyes

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 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 Jack Hartstein MD of Missouri several years earlier. In discussing a contact lens manufacturing process, he mentioned "this could also be done with IOLs" which had nothing to do with a bifocal IOL No matter how much we protested their incorrect reasoning, it was rejected. The cost to fight this was estimated at $200,000 ($486,720.63 in 2019). Things again were not going so well.

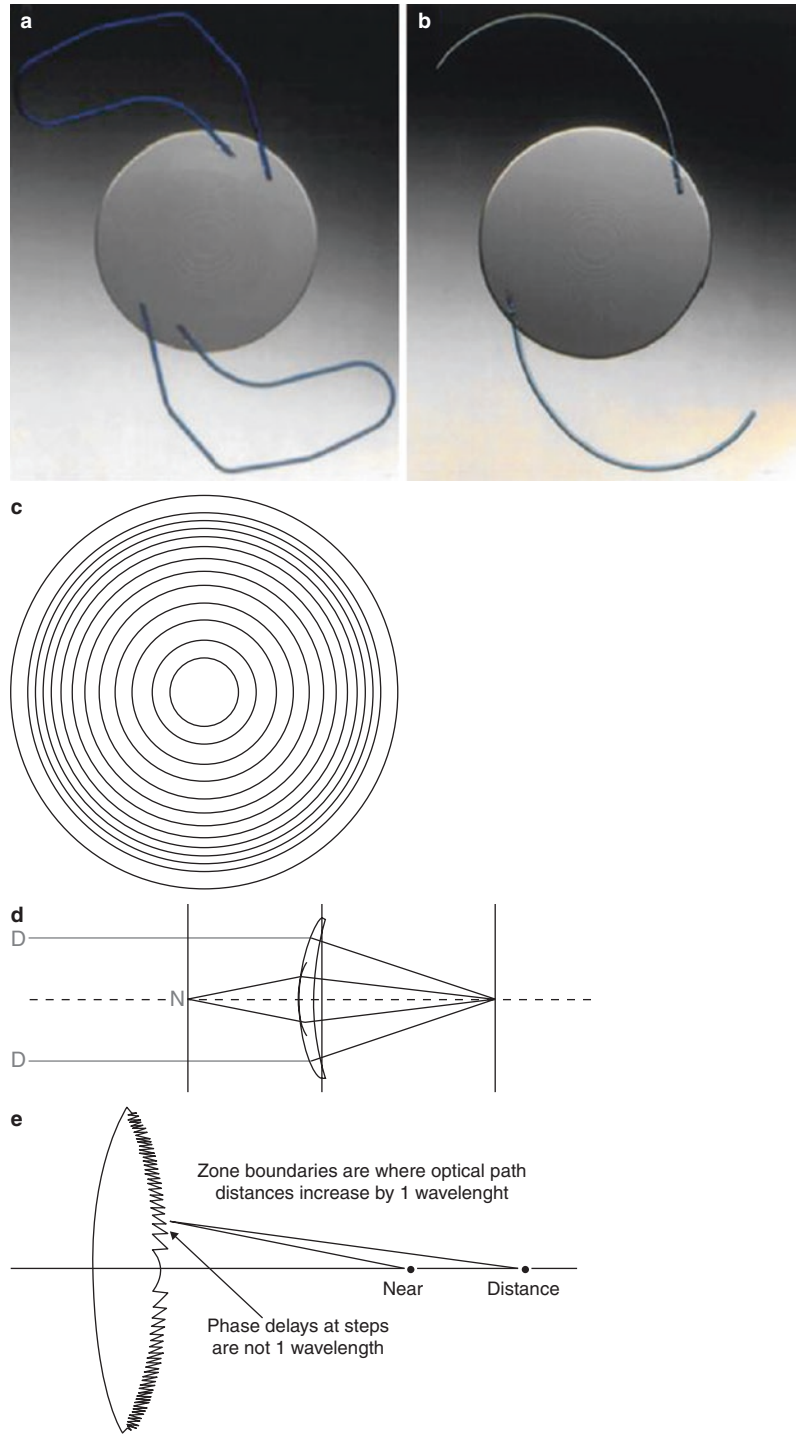


Fig. 2.8 Photographs of the early 3 M diffractive PMMA IOLs with closed (**a**) and open (**b**) loops. (**c**) Diagram of 3 M diffractive lens. (**d**) Diagram of ray tracing through the diffractive lens. (**e**) Diagram of diffractive process of 3 M lens

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 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, which I used exclusively at the time. 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 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 Split Bifocal 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.

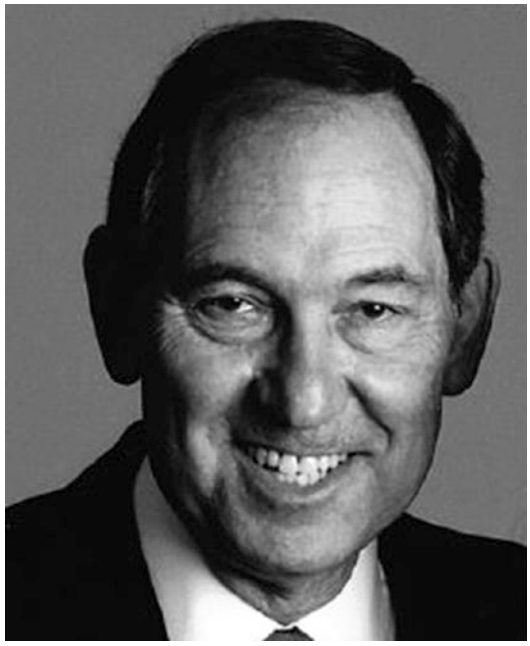


Fig. 2.9 Kenneth Rainin, President of Ioptex

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 Split Bifocal lens in the right eye of 78-year-old Lenore Clannin (since deceased). Then less than a month later, on

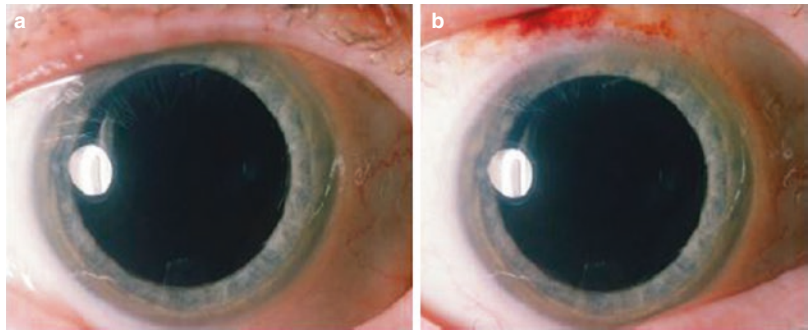


Fig. 2.10 (**a**) Clinical photograph of the first implanted Hoffer Split Bifocal dated October 18, 1990, labeled "PO 1 week OD" (Clannin.) (**b**) Another photograph taken the same day. Note that even under high power, there is no bifocal line visible in this photo. It is obviously not visible when photographed in aqueous

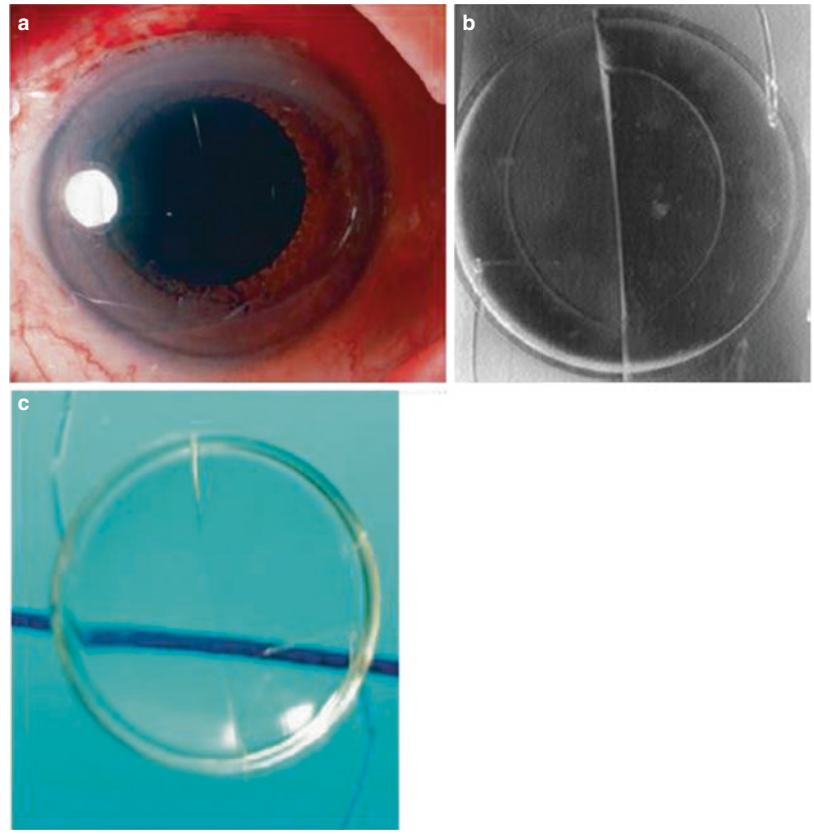


Fig. 2.11 (**a**) Clinical photograph of the second implanted Hoffer Split Bifocal dated November 7, 1990 labeled "PO 1 day OD; 20/100 J10" (Antonucci). Note the thickened bifocal line visible superiorly at 11:30. (**b**) and (**c**) Photograph of a similar unimplanted lens showing the same obvious line thickness superiorly

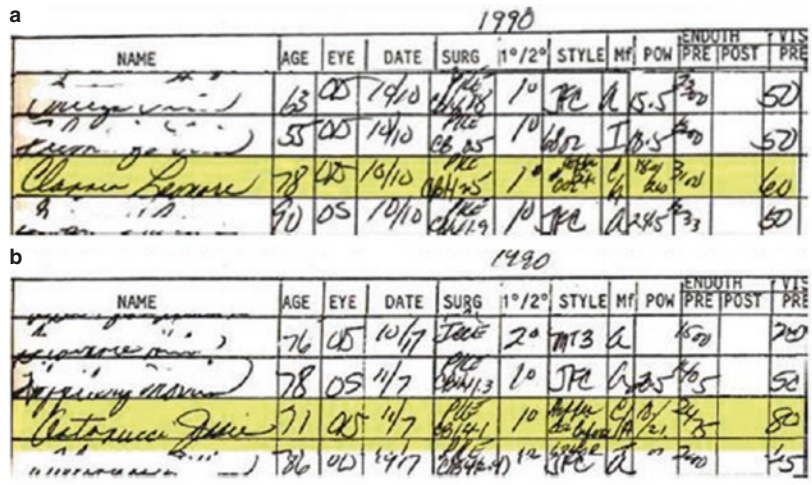


Fig. 2.12 Operating room records documenting Split Bifocal implantations in 1990: (**a**) For the first implant, Lenore Clannin. (**b**) For the second implant, Jessica Antonucci

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 both of 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.

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.

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 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

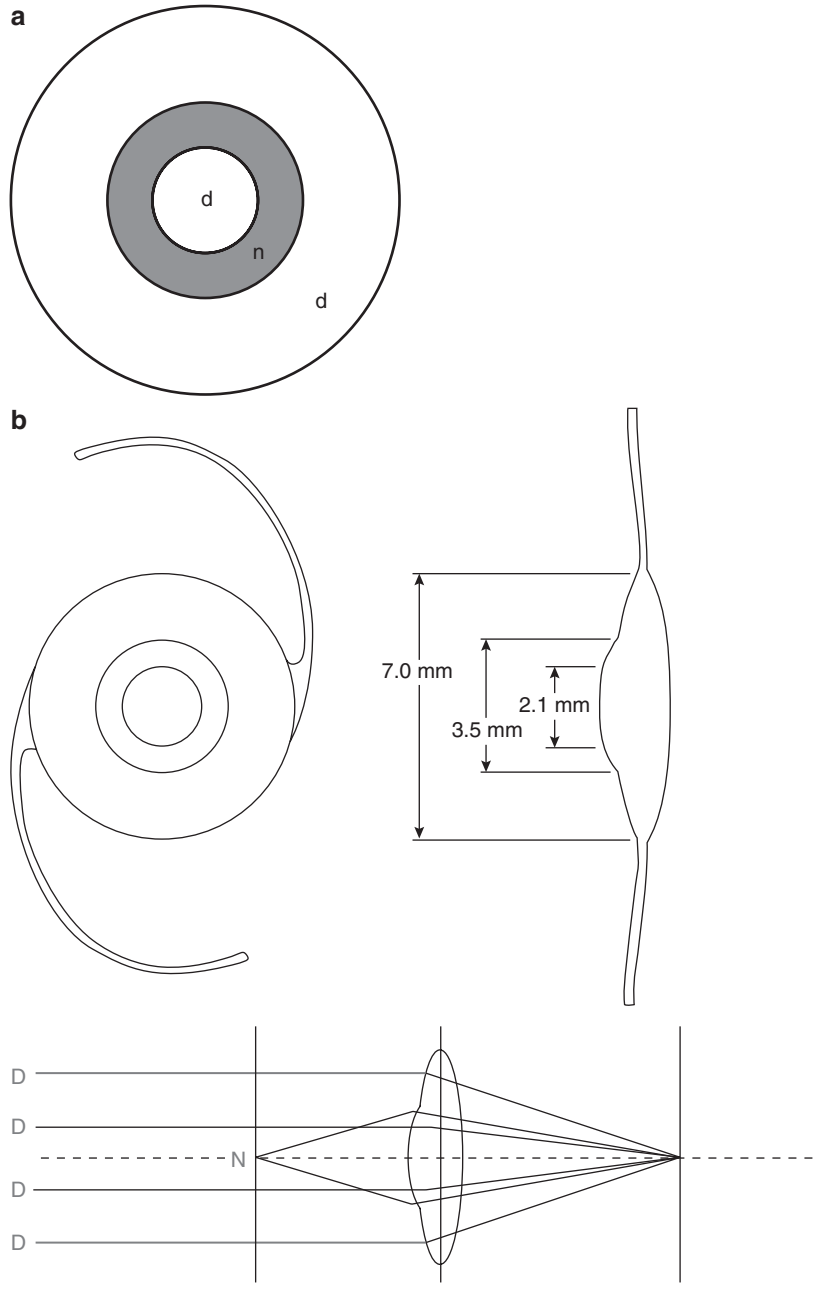
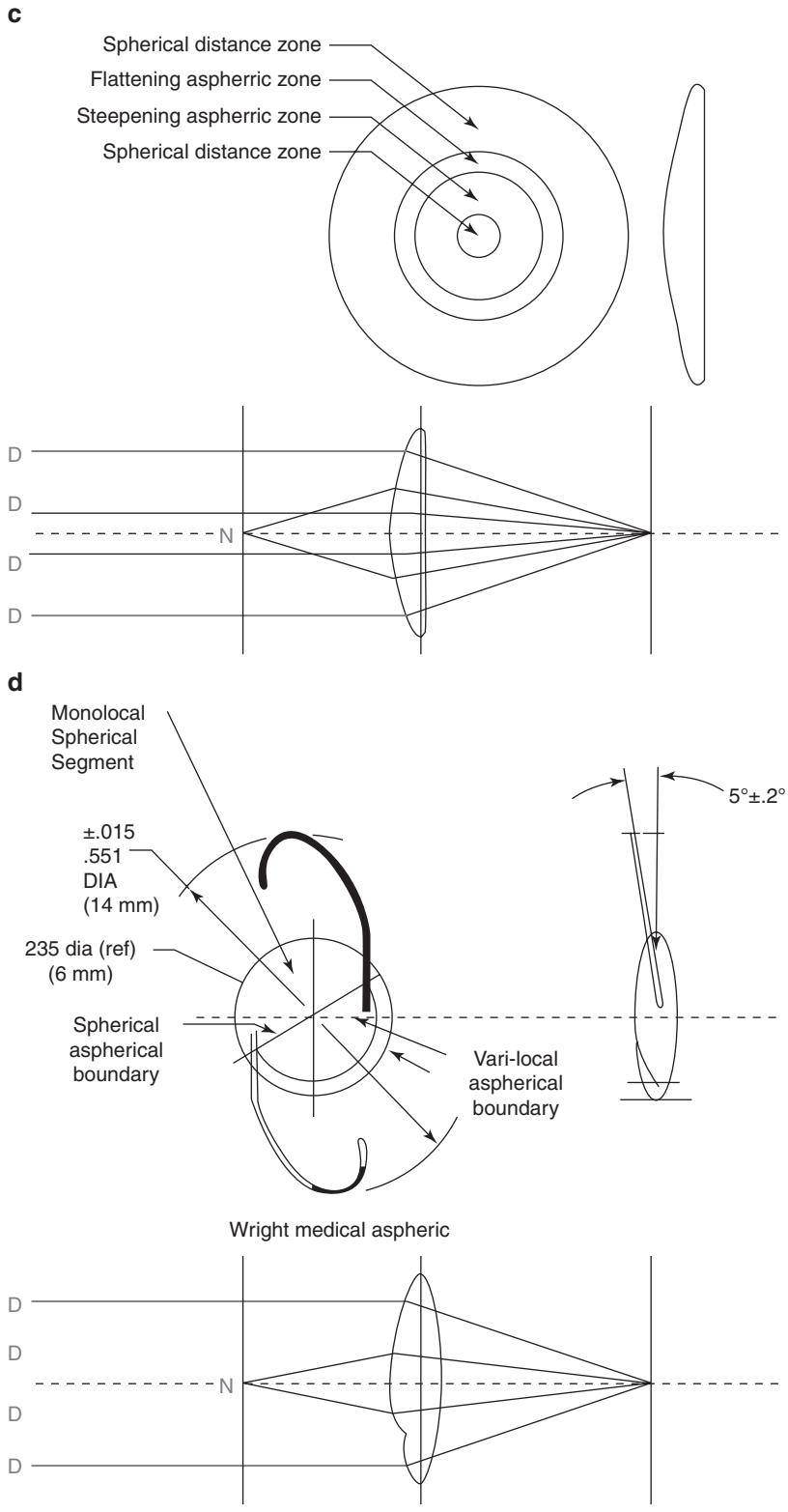


Fig. 2.13 (**a**) Diagram of the three-zone Storz TruVista lens. (**b**) Diagram of Pharmacia three-zone multifocal and ray tracing. (**c**) Diagram of the four-zone Ioptex lens and ray tracing. (**d**) Diagram of the Wright Aspheric Multifocal and ray tracing through Wright lens



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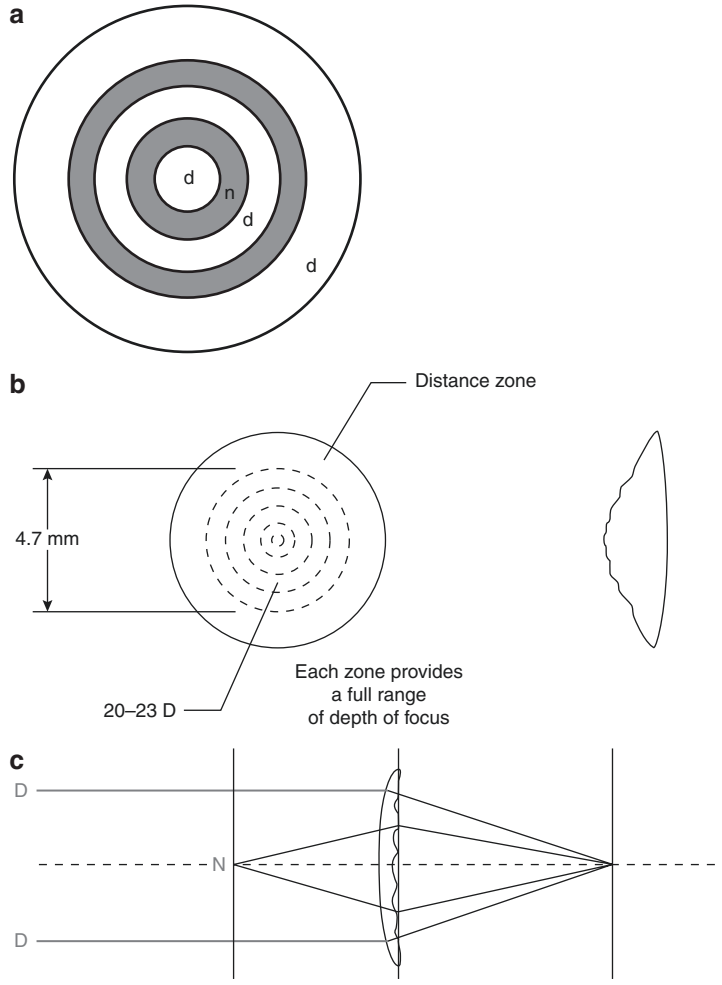


Fig. 2.14 Diagram of the AMO Array five-zone multifocal lens (**a**, **b**) and ray tracing (**c**)

Fig. 2.15 Diagram of the Alcon ReSTOR multifocal lens

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 they made (and still do) was the line of the split is perpendicular to the axis of the loops allowing IOL

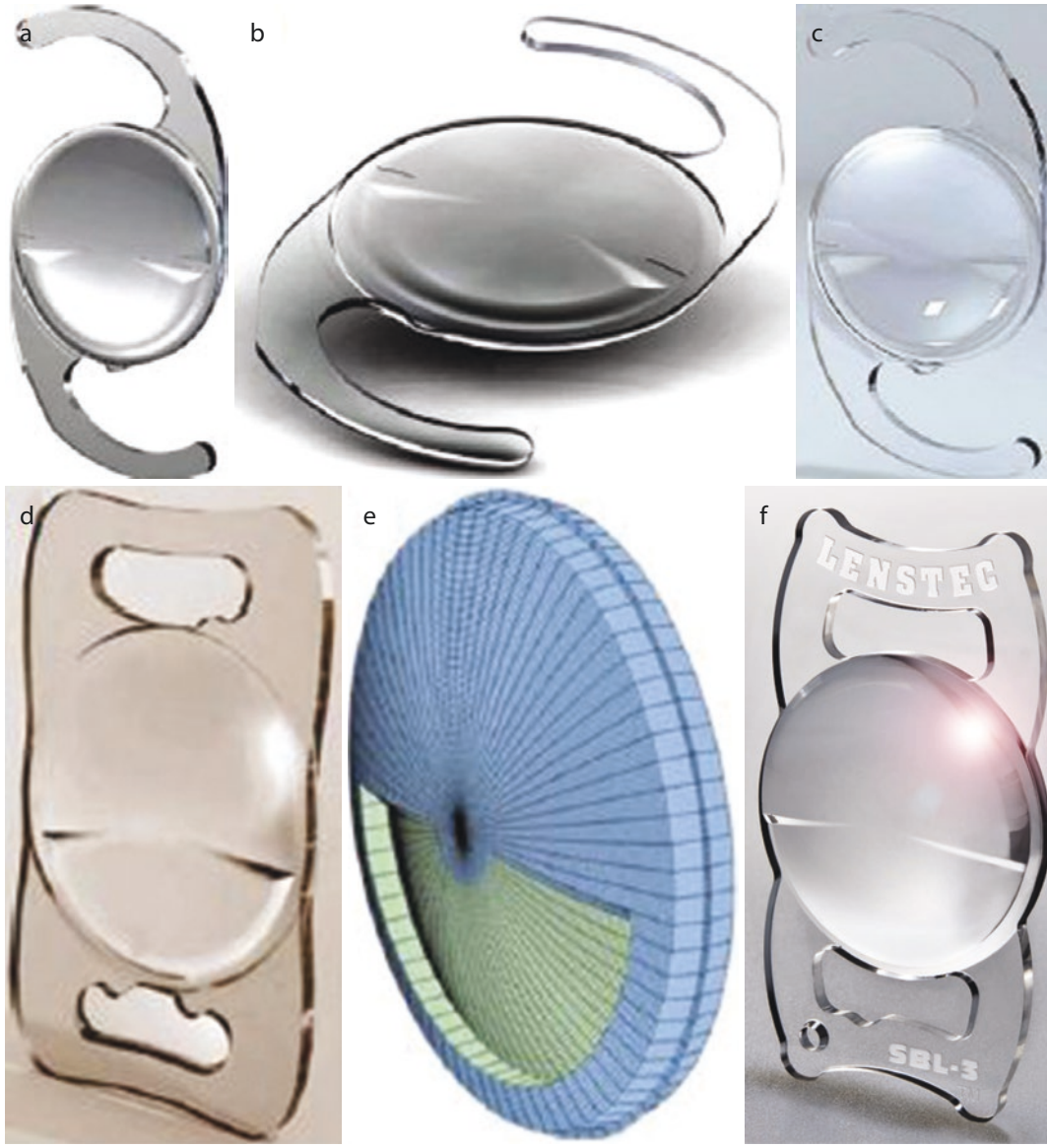


Fig. 2.16 Lentis Mplus LS-312 (Oculentis, GmbH): (**a–c**) Open loop design. (**d**) Plate haptic design. (**e**) Graphic depiction of the optic. (**f**) LensTec SBL-3 Split-Bifocal

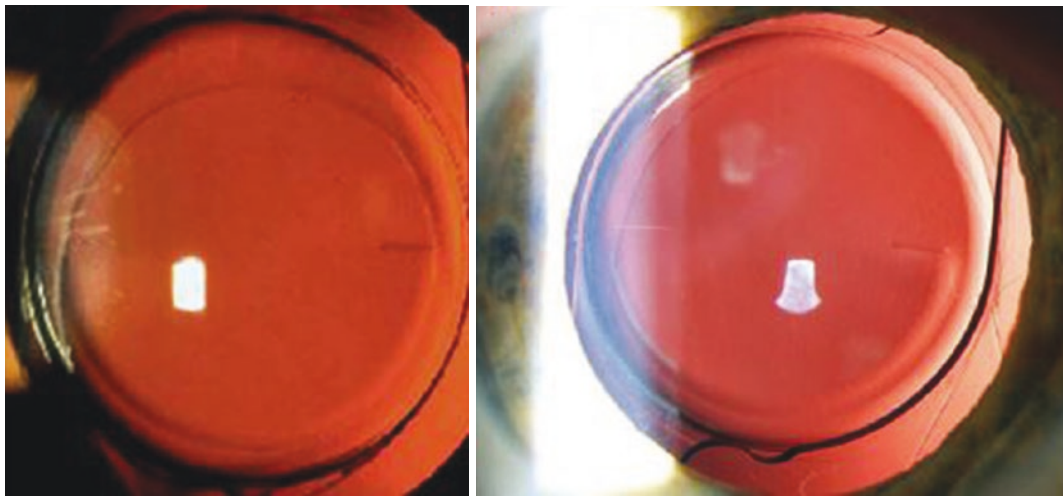


Fig. 2.17 Clinical photographs of postoperative Mplus Split Bifocal IOLs. Note that no lines are visible in aqueous

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, by this time, 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 as was the case with my original 1990 implantations. 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.

In 2013, LensTech (St. Pete Beach, FL) began making their SBL-3 Split-Bifocal (Fig. 2.16f) making the same mistake Oculentis did by placing the haptics perpendicular to the bifocal line. They have CE mark approval for implantation in Europe and report great success with it there. In 2019, their Split-Bifocal lens is slated for FDA approval in the U.S.

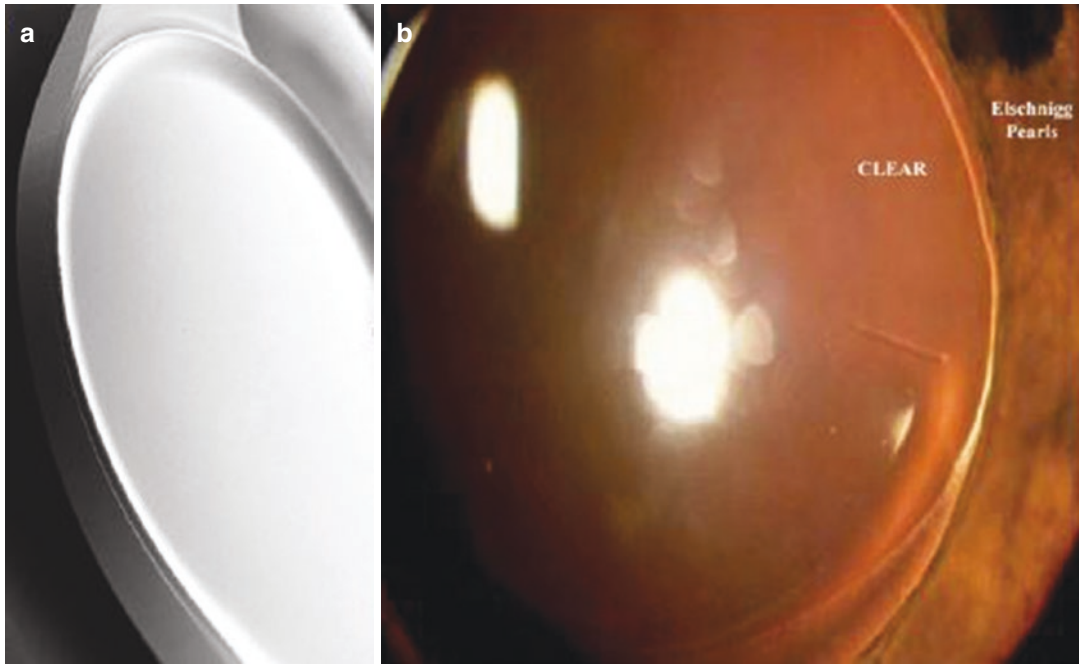


Fig. 2.18 (**a**) Electron photomicrograph of the "sharp edge" or "Hoffer Ridge" on the posterior surface of the Mplus lens. (**b**) Clinical photograph showing Elschnig pearls being blocked by the peripheral edge of the Mplus lens

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 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 to obtain 2.75 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).

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

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 range

while holding all other variables constant. We can only do this using a second-generation IOL power formula such as the original 1974 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. Here is 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 mathematically that the AL does not influence the near add in a bifocal IOL. Figure 2.19a demonstrates graphically these changes.

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

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

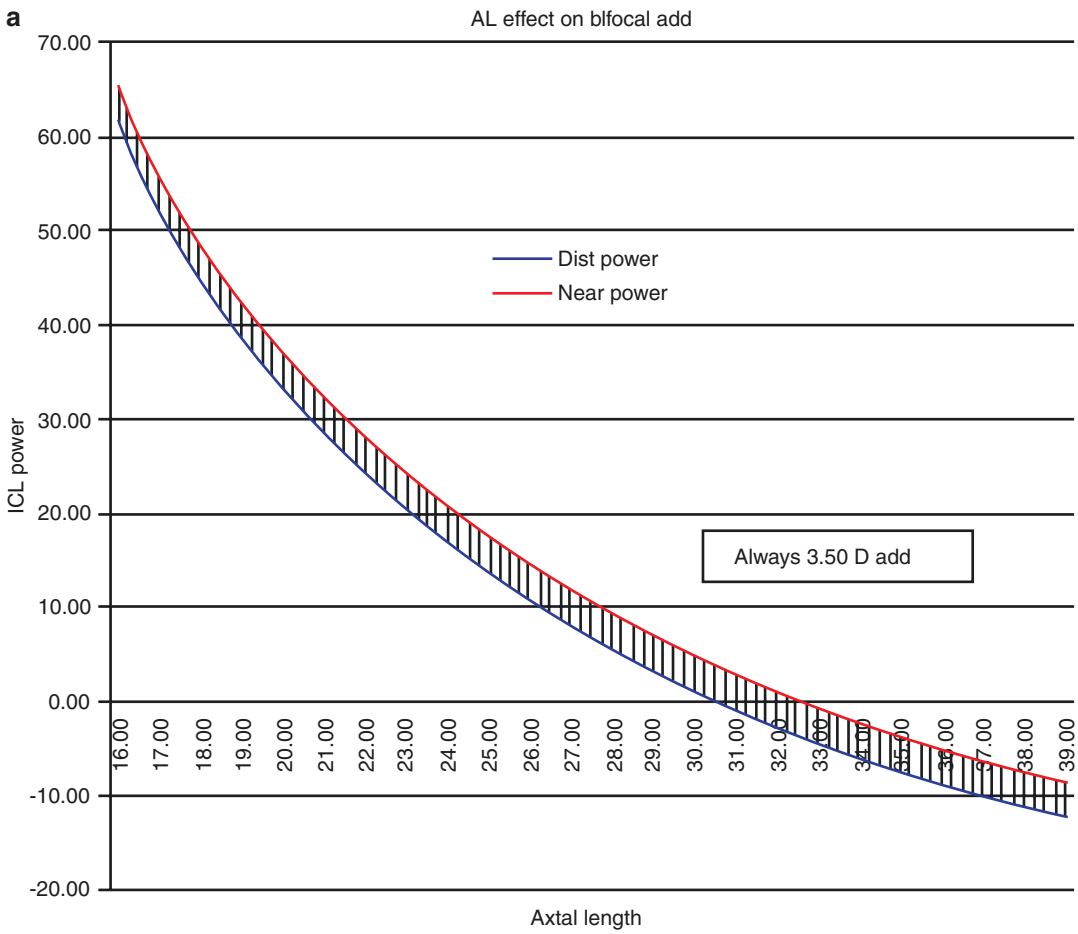
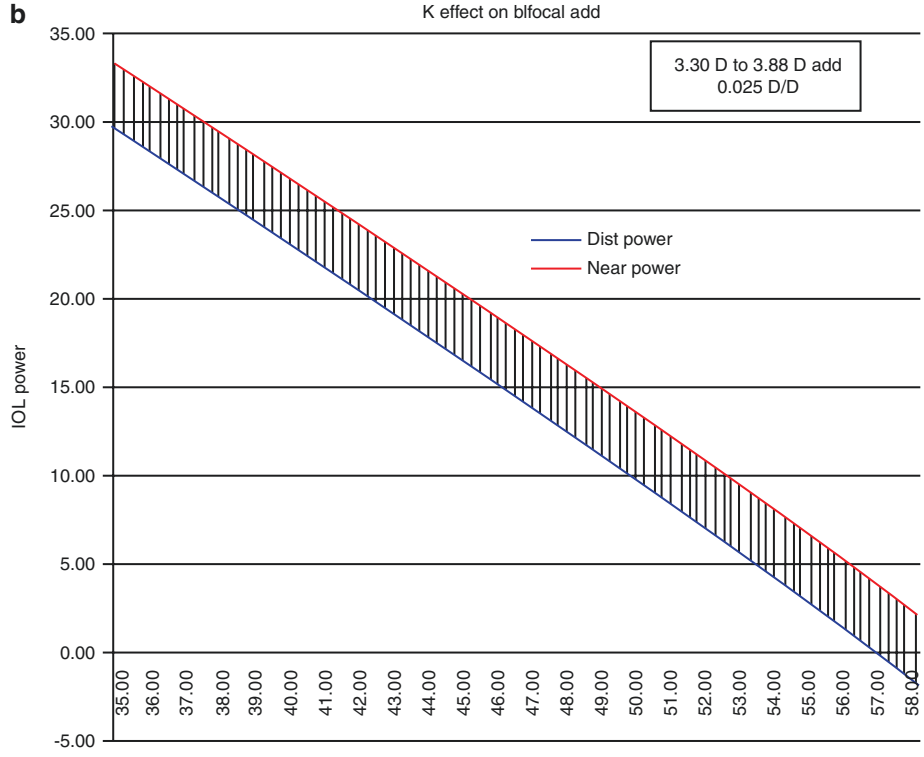


Fig. 2.19 Graphic depiction of changes in IOL power for distance and near with (**a**) changing axial length, (**b**) changing corneal power, and (**c**) changing IOL position (ACD)



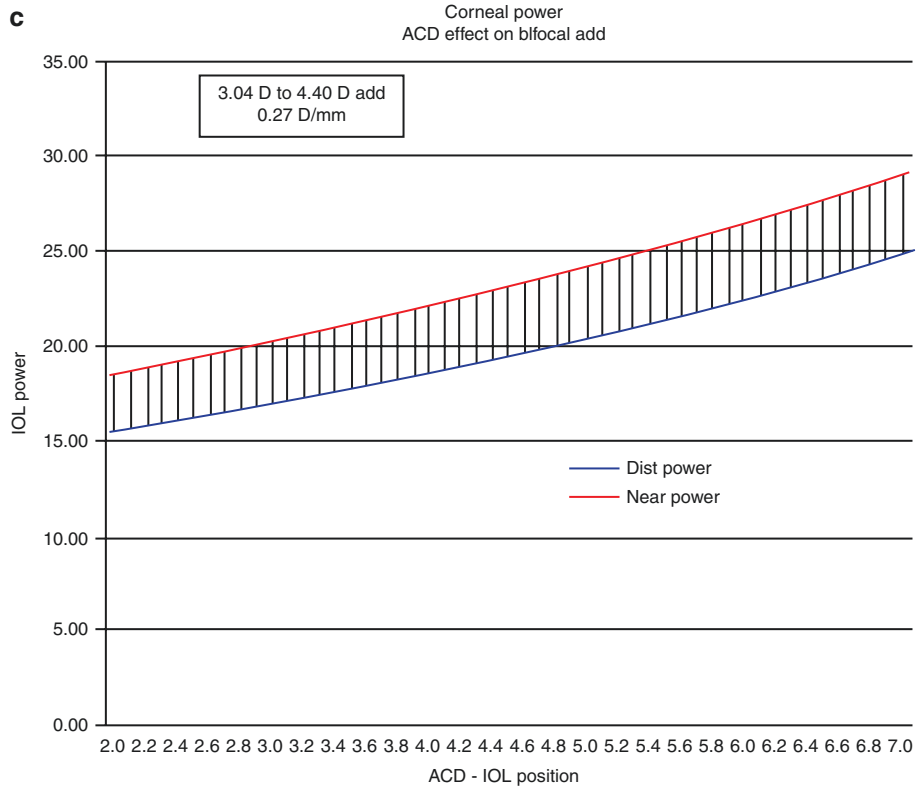


Fig. 2.19 (continued)

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

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

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

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 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 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. Here, 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

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

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 any one value 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.

2.10 Conclusion

I look back over the past 37 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 very popular multifocal lenses used today: 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.

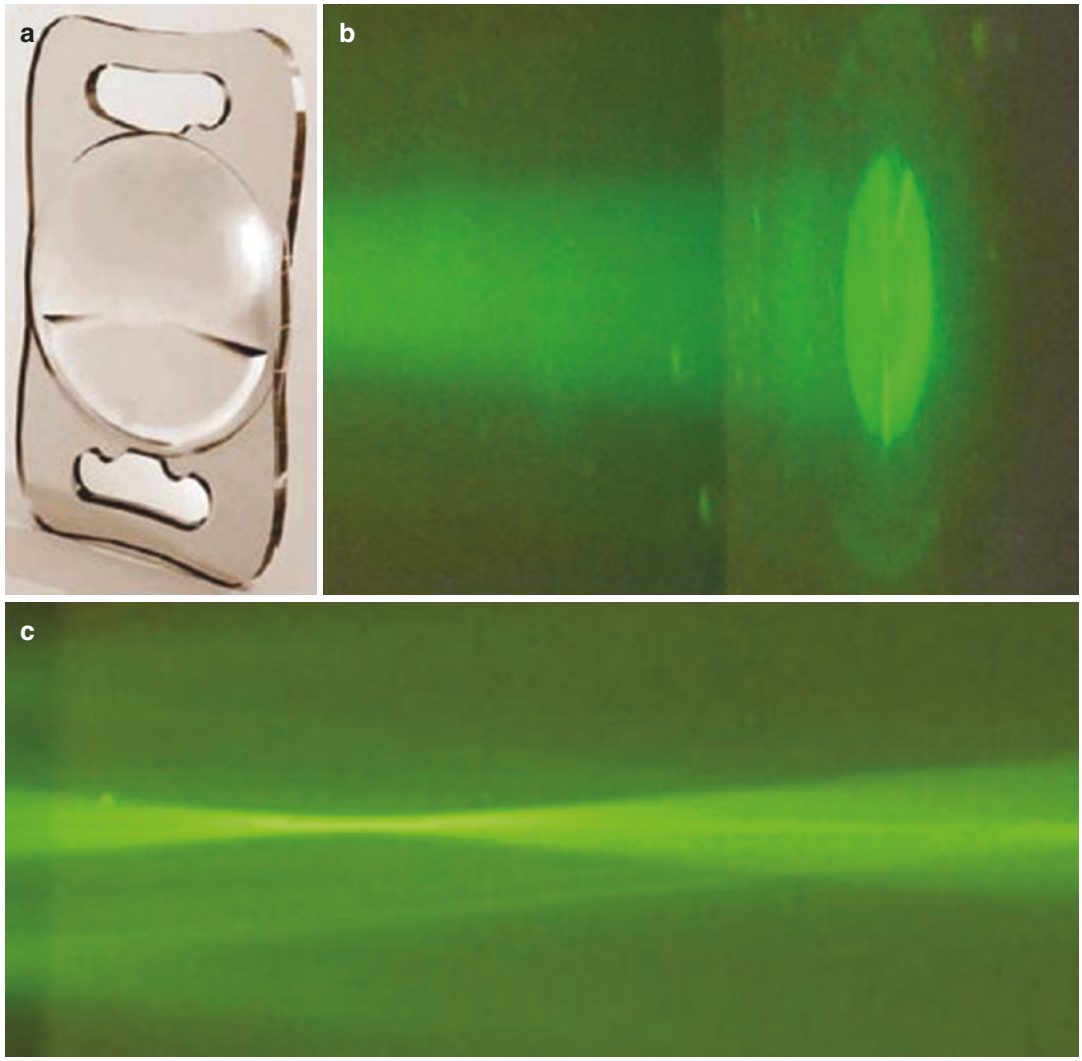


Fig. 2.20 The display of focal points (**b**, **c**) of the Oculentis Mplus (**a**)

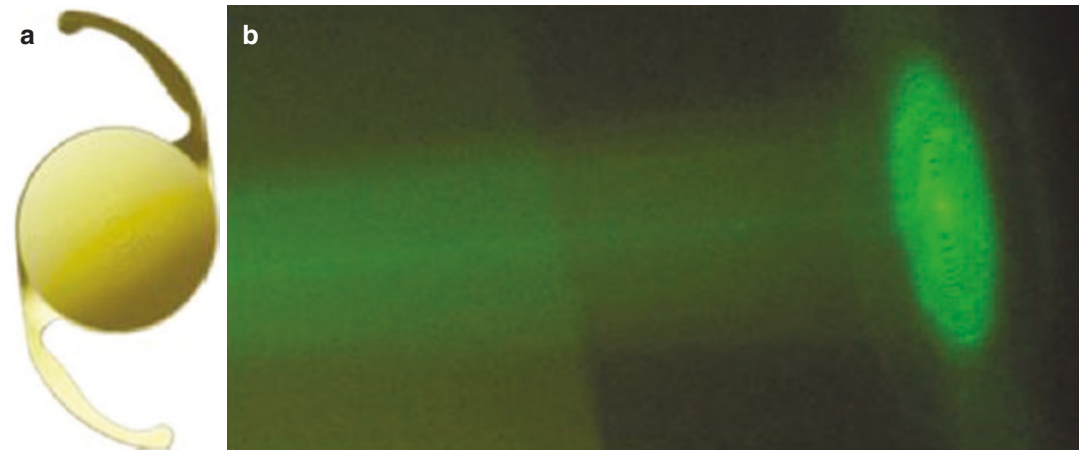


Fig. 2.21 The display of focal points (**b**, **c**) of the Alcon ReSTOR lens (**a**)

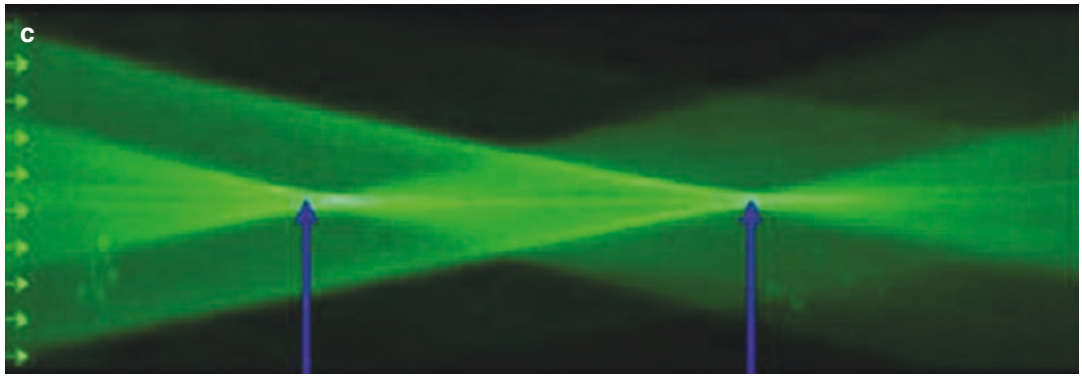


Fig. 2.21 (continued)

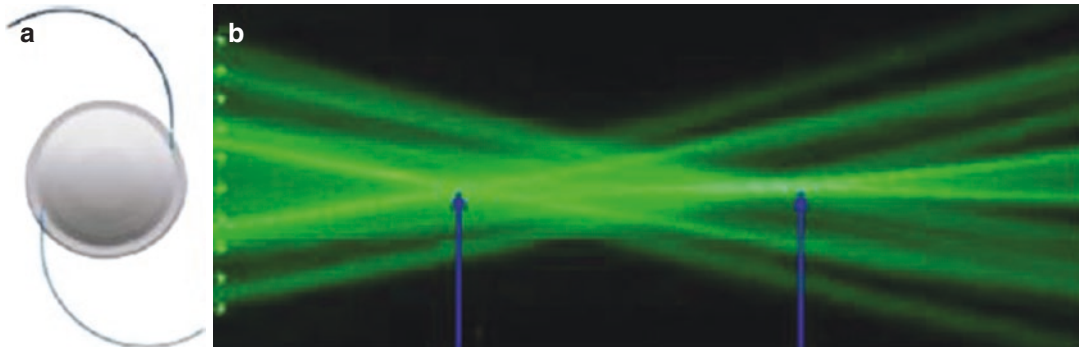


Fig. 2.22 The display of focal points (**b**) of the AMO ReZoom lens (**a**)

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.

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