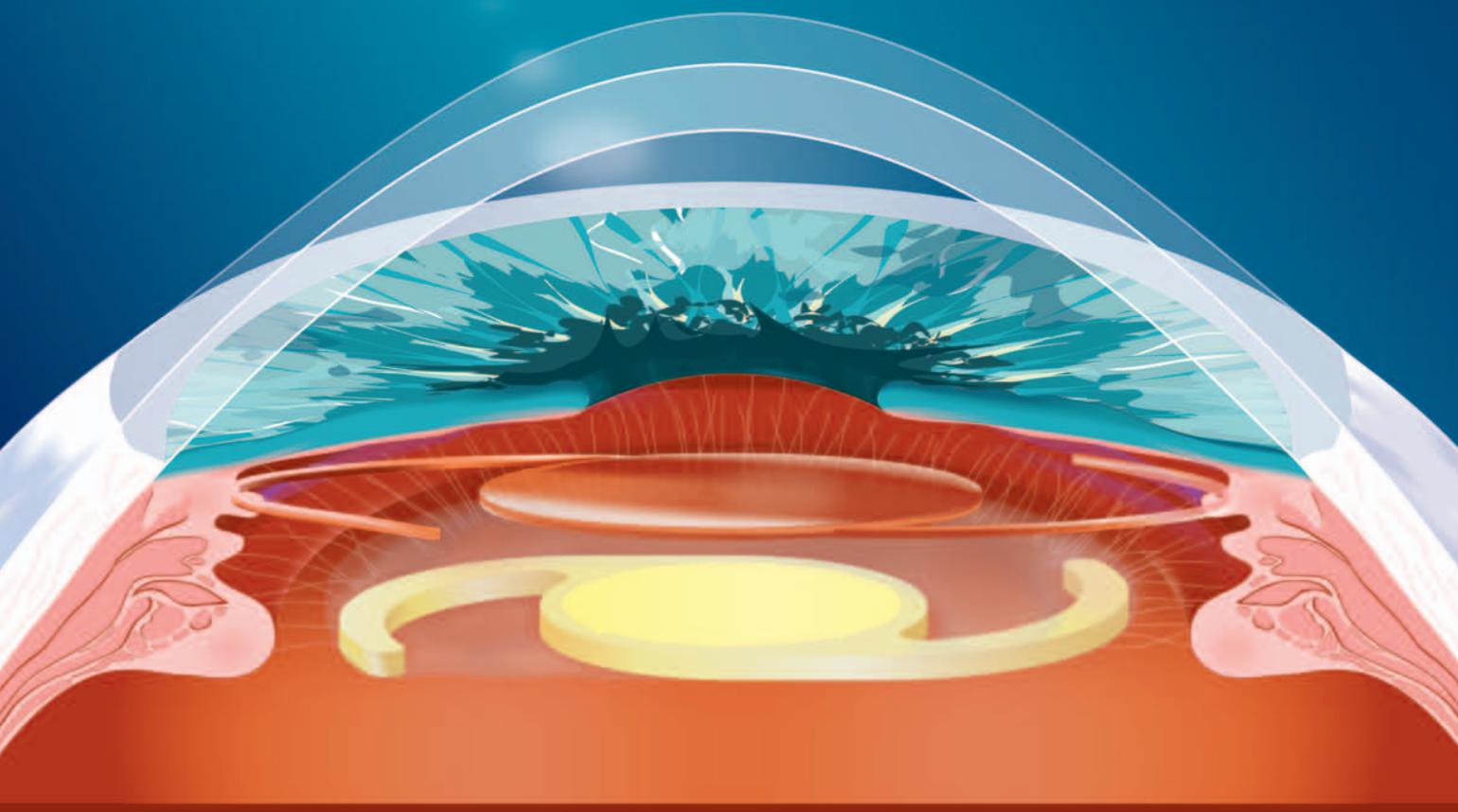


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The Add-On Principle: Two Lenses in One Eye

The Add-On IOL: My First Choice for Sulcus Fixation, by Hans-Reinhard Koch, MD
Evaluating Long-Term Safety and Stability of the Add-On, by Gerd Auffarth, MD
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The Add-On IOL: My First Choice for Sulcus Fixation

I have been using this three-piece design for more than 9 years.

BY HANS-REINHARD KOCH, MD

In today's ophthalmic practice, it is important to have regimented fine-tuning options for patients. One option I extend is the MicroSil Add-On IOL (HumanOptics AG, Erlangen, Germany; Dr. Schmidt Intraocularlinsen GmbH, St. Augustin, Germany). This IOL may be implanted in either a one- or two-session strategy. In the one-session strategy, the Add-On is implanted into the ciliary sulcus during cataract surgery, after implantation of a standard IOL in the capsular bag. The purpose of implantation in these cases is to extend the power range of the standard IOL. Alternately in the two-session strategy, the Add-On is implanted, again in the ciliary sulcus, in an already pseudophakic eye. The purpose of implantation in these cases is to correct residual refractive error—spherical or astigmatic—after previous IOL implantation.

The Add-On IOL is designed with a concave posterior surface to ensure a safe distance, approximately 0.5 mm, between it and the standard IOL (Figure 1A). In this sense, you can avoid interlenticular opacification, a common occurrence when piggybacking two IOLs in the capsular bag. The lens' overall diameter is 14 mm, with a large degree (45°) of sulcus contact area. The diameter of the optic is 7 mm, which avoids glare and iris capture (Figure 1B).

Another characteristic of its design is the enlarged c-loop haptics, which ensure secure and stable placement in the sulcus compared with more flexible haptics. The latter may cause an anterior-posterior shift in IOL placement and lead to pigment dispersion and secondary pigmentary glaucoma.^{1,2} The thin filament PMMA haptics of the Add-On fit the natural anatomy of the sulcus to prevent induction of any irritations, such as pigment dispersion, that might occur with single-piece acrylic IOLs placed in the sulcus.³ These unique haptics enable the IOL to adjust with the morphologic conditions of the ciliary process (Figure 2). This is important because the sulcus has a high range of metabolic activity.

TWO-STEP PROCEDURE

I am fond of using the Add-On IOL, which is available in

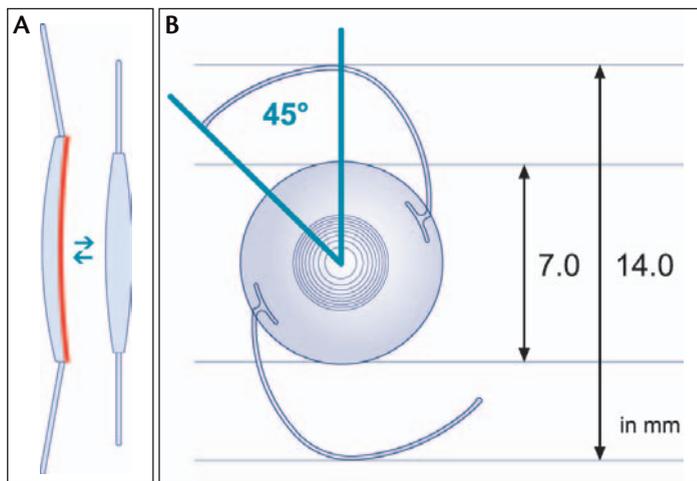


Figure 1. (A) There is approximately 0.5 mm between the Add-On and the standard IOL. (B) The overall diameter of the Add-On is 14 mm, providing 45° of contact area with the sulcus. The diameter of the optic is 7 mm.

spherical, toric, and multifocal models, as a two-step procedure. In these cases, the patient is unhappy with the IOL power currently implanted. Because this power is typically aimed at correcting distance vision, the patient most likely needs glasses for near and intermediate vision. Instead of explanting the IOL, the modern diffractive Add-On IOL can then be implanted secondarily, in front of the standard IOL, providing the patient with clear vision at near and intermediate distance as well. If done soon after cataract surgery, I simply reopen the original incisions. If implanting the Add-On several months or more after cataract surgery, I make new incisions for insertion. After successful surgery, the patient will have sharp vision at all distances, without the need for correction.

I find it easier to implant a second IOL than to replace the existing IOL. For starters, you have to make a tear in the capsule to remove the original IOL. Additionally, figuring out the exact positioning of the new IOL is complicated, and a slight refractive error may result. If you leave everything as is, meaning keeping the original IOL in place and adding the missing power with the Add-On IOL, you have the best chance and predictability for good results.

In my experience, most patients with residual refractive

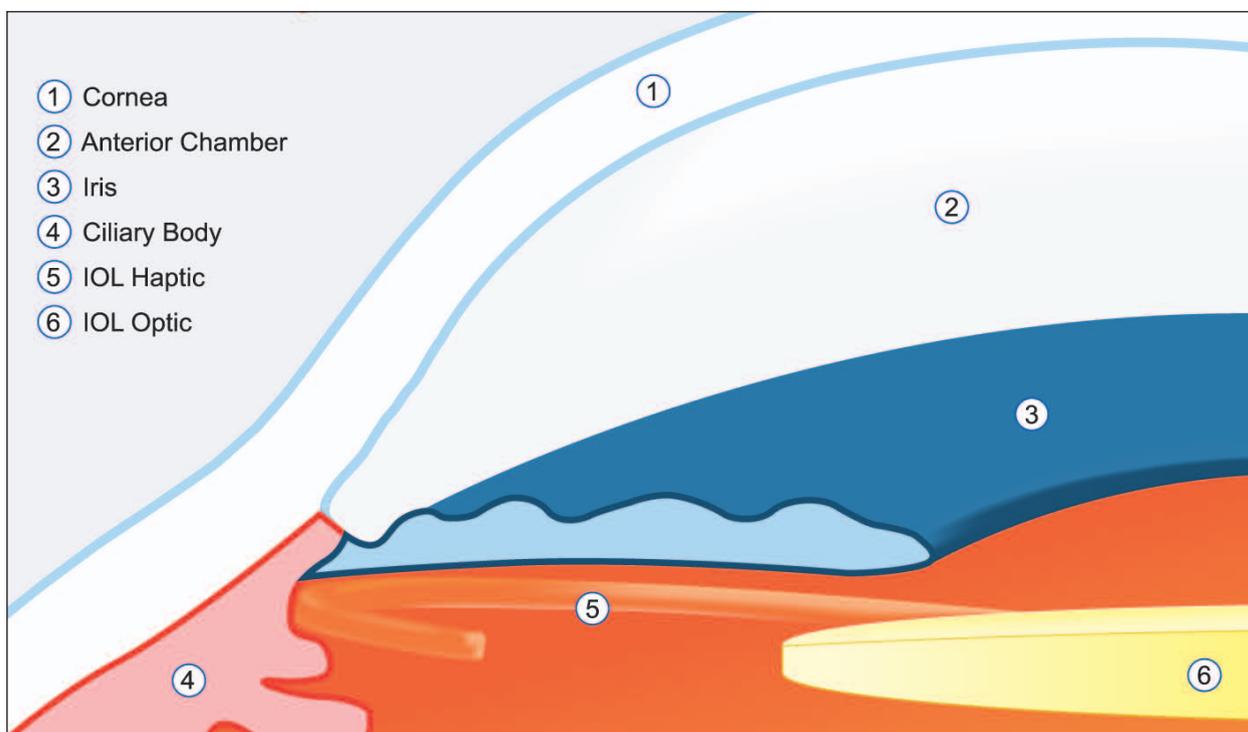


Figure 2. The filament PMMA haptics fit the natural anatomy of the sulcus.

errors require an addition 1.00 to 2.00 D of correction. If the patient has residual astigmatism after cataract surgery, the toric IOL is a great option; for residual spherical error, the spheric model is the best option. I have used this Add-On technique in the large proportion of my cases for the past 9 years, with high patient satisfaction.

ONE-STEP PROCEDURE

When used in the same session as cataract surgery, the Add-On IOL is just as easy to implant as the standard IOL. Generally, I will implant Add-On when the power range of the standard IOL needs extending. This is especially helpful in patients with high hyperopia. Combining two lower-powered IOLs is advantageous because they are thinner than one higher-powered IOL; both are easily inserted into the respective portions of the eye, the standard IOL into the capsular bag and the Add-On IOL into the ciliary sulcus.

Multifocal and toric Add-On models may also be used in the same respect. The benefits of these lenses can easily be combined with an unlimited variety of standard IOLs to further enhance outcomes of cataract surgery. One thing that I have found helpful is to keep several toric Add-On IOLs in stock. Therefore, if I am unaware of a patient's astigmatism before surgery, I can quickly rectify the situation by implanting the toric Add-On in addition to the IOL in the capsular bag.

In my experience, the MicroSil line of IOLs produce excellent results, with good centration, axial stability,

and almost negligible posterior capsular opacification. Additionally, this IOL offers retinal protection because of its blue-light-filtering property and does not cause glisterings.

The Add-On procedure is suitable at any time after cataract surgery, even years afterward. Therefore, I implant the Add-On IOL in the majority of my patients who have a postoperative refractive result that does not meet his expectations. Although there are several choices for enhancing the refractive outcome, including LASIK and refractive lens exchange, I find the best solution is to keep the existing IOL in place and implant the Add-On IOL into the ciliary sulcus. In this respect, the patient will have the best possible outcome with the least amount of damage to the capsule. ■

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Evaluating Long-Term Safety and Stability of the Add-On

With resounding long-term data, there is a bright future of applications for this IOL.

BY GERD AUFFARTH, MD

Approximately 6 or 7 years ago, a patient visited my clinic with a -7.00 D residual refractive error after cataract surgery. He had seen several other surgeons, none of whom wanted to explant the original IOL. Although I agreed with the other surgeons that explantation was not the answer, I did agree to treat him. This was my first patient implanting the Add-On IOL (HumanOptics AG, Erlangen, Germany; Dr. Schmidt Intraocularlinsen GmbH, St. Augustin, Germany).

Using the Add-On lens in the patient's eye proved to be very telling of my repeated experiences with this IOL. Postoperative results were beautiful, and the patient was pleased with his outcome. He returned to normal life and enjoyed spectacle independence, which was his wish. Since that time, I have used all three available Add-On IOLs, including the toric, spherical, and multifocal models (Figure 1). In general, results are excellent.

At the beginning, I only used the Add-On lens to

correct drastic errors of refraction. In one case, I even treated a patient with a 14.00 D residual error. After my comfort with the lens grew and I was convinced of the safety of the procedure, I gradually increased my treatment zone to include patients with smaller errors. Now, I have no problem treating patients with as little as 1.00 or 2.00 D of residual refractive error.

LONG-TERM SAFETY AND STABILITY

I am currently an investigator in a long-term, multicenter study on the safety and stability of the Add-On IOL. At the moment in the study, I have 11 patients included with follow-up of up to 7 years. Two patients received the spherical Add-On for corrections of -6.00 and -12.00 D, seven patients received the toric Add-On (Figure 2) for cylinder corrections between 2.00 and 19.00 D, and two patients received the multifocal Add-On.

In this population of 11 patients, there was no interlenticular cell deposits or lens opacifications, no elevation of

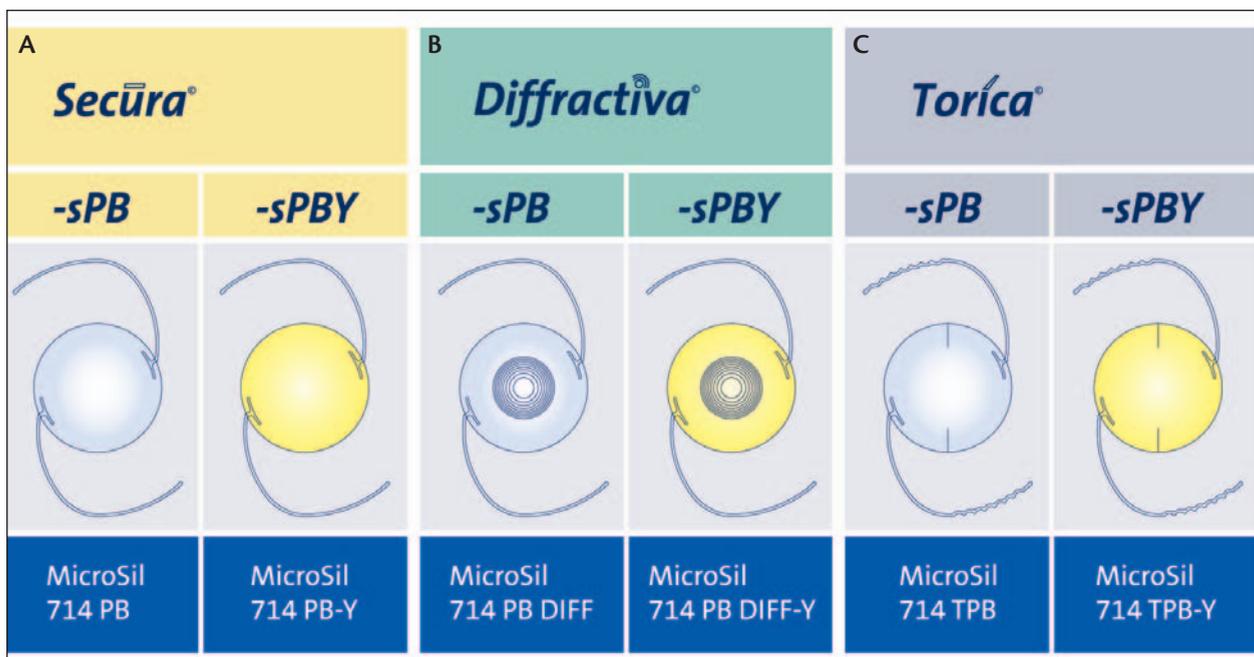


Figure 1. The Add-On IOL is available in three models: (A) spherical, (B) multifocal, and (C) toric.

intraocular pressure, no pigment dispersion, and no irritation or inflammation. Additionally, the lens position of the Add-On was stable, with a safe distance between it and the IOL in the capsular bag. This Add-On concept is promising because it may be combined with all possible lens materials, including hydrophobic and hydrophilic acrylic, silicone, and PMMA. In our clinical observations, the material of the other IOL had no impact on the Add-On IOL.

Safety with this lens is excellent. These patients go through less trauma than what cataract surgery patients go through. The Add-On is implanted under topical anesthesia by reopening the clear corneal incision made during cataract surgery, when possible. It is also safe to create a temporal incision to treat astigmatism. No lenses required re-rotation, and 100% of the eyes were within ± 0.50 D of intended correction when the target was emmetropia. Thus far in the study, we have concluded that the Add-On IOL is safe, with no shift in lens position.

The principle complication associated with the use of the Add-On, which rarely occurred, was pupil capture; however, it is only a threat in very small eyes, with very few cases reported. In 2007, in order to avoid the risk of pupil capture, HumanOptics/Dr. Schmidt Intraocularlinsen increased the optic diameter from 6 to 7 mm. In the eyes with the larger optic, no iris capture was seen.

MANY INDICATIONS

One of the benefits of the Add-On is its large range of indications. In addition to use in pseudophakic patients, I also use this lens as an alternative to the excimer laser for touch-ups or refractive fine-tuning after refractive lens exchange. It is also useful to implant the Add-On in keratoplasty patients. The reversibility of the implantation is ideal because you can implant the toric Add-On based on the patient's current astigmatism and then explant the IOL in the event that another keratoplasty is needed. Afterward, you can safely implant another toric IOL with the updated astigmatic correction.

Another interesting subset of patients is the case of pediatric cataract. As the child's refraction changes with growth of the eye, you can update the refraction with an Add-On IOL. This avoids explanting the fixated IOL in the capsular bag. In patients with previous retinal detachment where silicone oil was used, the Add-On IOL will actually compensate for the hyperopic effect of the silicone oil. Then, after the silicone oil is removed, the lens is explanted, thus returning the patient to emmetropia. As a general rule of thumb, I look to use the Add-On IOL any time there is a dynamic change in refraction. I think in the near future, we will start to see more surgeons implanting

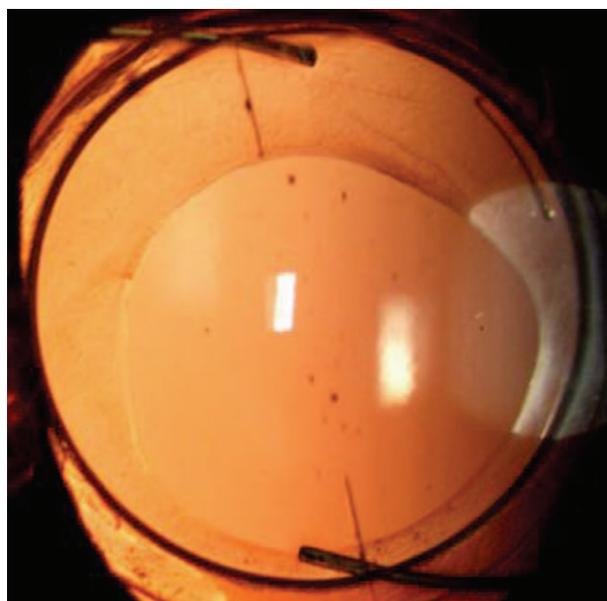


Figure 2. Toric Add-On IOL.

the Add-On IOL and uncovering even more indications for its use.

CONCLUSION

One nice thing about incorporating the Add-On into our practice is that there is no need for a large investment, such as is required for excimer laser surgery. Second, this is a reversible procedure. In the case of a multifocal IOL patient who is not satisfied with his correction or cannot adapt to the multifocality, it is fairly easy to remove the lens from the sulcus.

I have noticed that the Add-On principle has been creating a gradual buzz in the industry. I suspect it will be the hot topic at the next few ophthalmic conferences. As the indications for Add-On IOLs continue to broaden, so will the constituents who use them. The possibilities of using IOLs in refractive surgery will multiply with this type of lens. In addition to the numerous premium lenses on the market, the Add-On can be implanted to compensate for any residual refractive errors. The possibilities are endless; you can satisfy almost any type of patient with the combination of a premium IOL and the Add-On lens. ■

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Correction of Pseudophakic Presbyopia With the Add-On Lens

Approximately 90% of patients will achieve spectacle independence.

BY GEORG GERTEN, MD

Although the MicroSil Add-On IOL (HumanOptics AG, Erlangen, Germany; Dr. Schmidt Intraocularlinsen GmbH, St. Augustin, Germany; Figure 1) is available in spherical, multifocal, and toric models, I have the most experience implanting the multifocal design. I prefer this method of refractive correction in my pseudophakic presbyopic patients; compared with implanting a multifocal IOL in the capsular bag, using the multifocal Add-On only takes two additional minutes but provides unlimited benefits.

To patients, these benefits include the lens' reversibility. With the Add-On IOL, if a patient is unhappy with his vision or cannot adjust to the multifocal principle, we simply explant the IOL. (However, I have never had an unhappy patient and I have never had to explant the IOL.) If the lens does need to be explanted, it can be done without touching the capsular bag. This provides added protection to the patient's eye.

To the surgeon, the benefits provided by the Add-On IOL include sanity in the operating room. This Add-On approach leads to simplification of logistics and stock-keeping, because I do not have to house a full range of IOL powers in multiple lenses or double stock standard capsular bag IOLs and multifocal capsular bag IOLs. I simply need to make sure that I have enough standard IOLs to pair with the 0.00 D diffractive Add-On lens. This IOL carries the near addition only.

Because pseudophakic eyes often have small residual ametropias for distance, we also keep some Add-On IOLs with small amounts of additional distance correction in our stock, for example 1.50 D for distance combined with 3.50 D diffraction for near. Diffractive Add-On IOLs can be produced with a distance power in the range of -6.00 to 6.00 D to correct ametropia at the same time.

PSEUDOPHAKES, CATARACT PATIENTS

The Add-On IOL can be used in pseudophakic as well as cataract patients. In my experience, which includes approximately 58 pseudophakic patients and 150

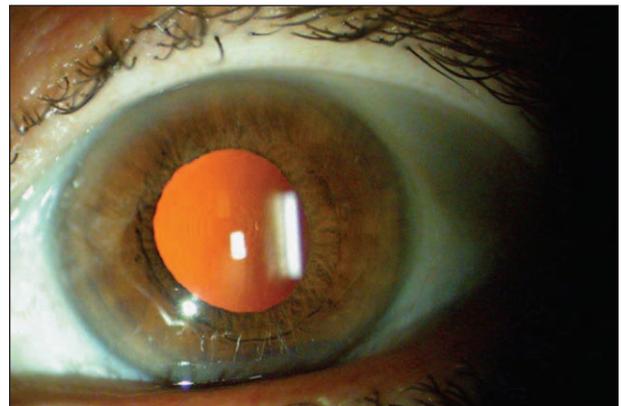


Figure 1. Implantation of a posterior chamber IOL and an Add-On IOL in the sulcus on the first postoperative day.

cataract patients, 90% never use glasses. Only 7% use correction for special tasks, like computer work, and a mere 3% of patients use glasses all the time. Therefore, I tell my patients that they have a 90% chance of achieving spectacle independence (Figure 2).

I define a pseudophakic patient as someone who has already had a cataract operation but wants to optimize his results. The multifocal Add-On is a great option for these pseudophakic patients because the near add, 3.50 D, provides comfort in daily life. The majority of patients (96%) are satisfied with the lens and do not require reading glasses. Intermediate vision is also outstanding with the Add-On. At 1 meter, patients have a mean UCVA of 0.8.

INITIAL CASE

I decided to use the Add-On IOL in my pseudophakic presbyopic patients after treating a husband and wife at my clinic. Although the wife had undergone cataract surgery 5 years prior and received a monofocal IOL, I had performed the husband's cataract surgery recently, implanting a standard multifocal IOL. His results were excellent, and he was spectacle independent postoperatively. The wife visited my office to inquire about the possibility of receiving the same multifocal IOL as her husband. However, it is difficult

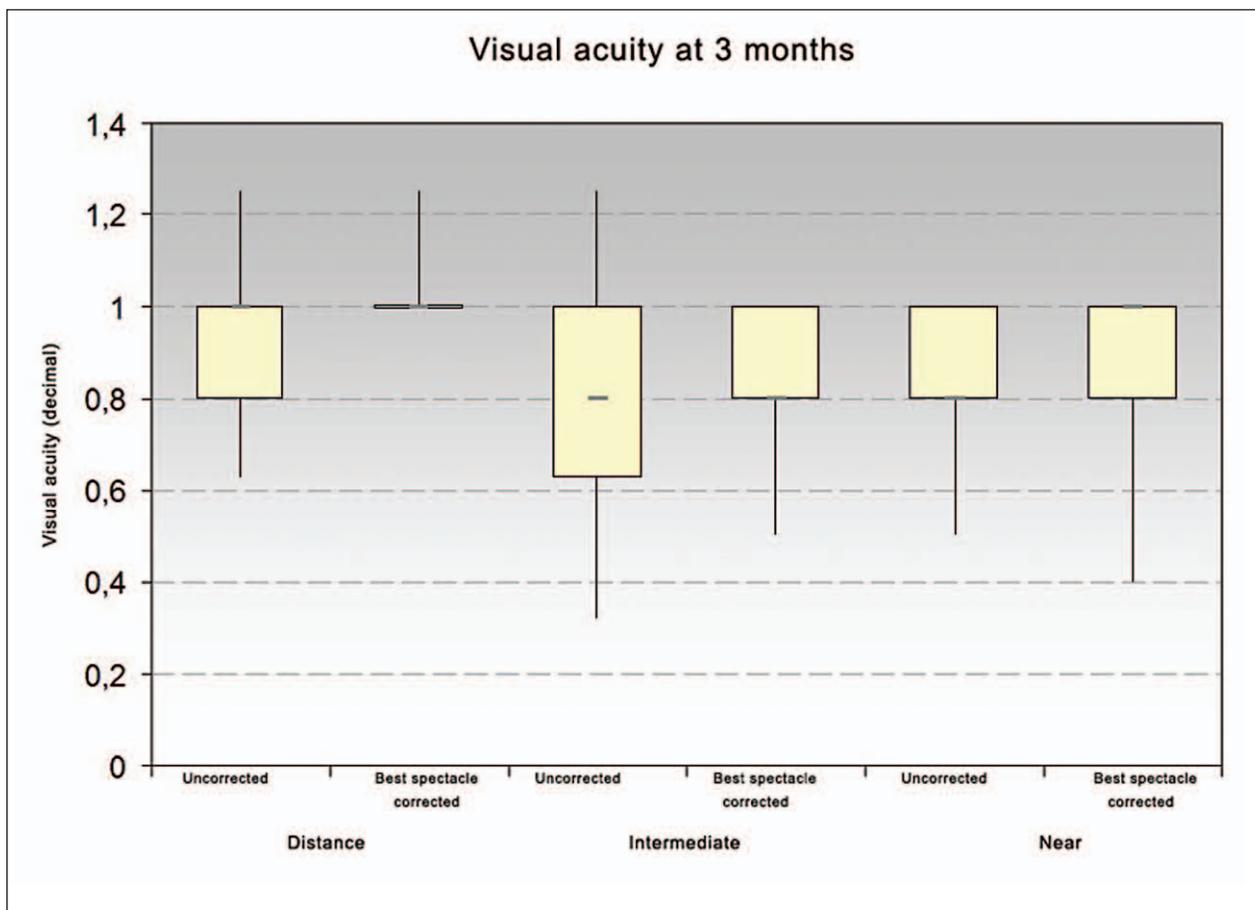


Figure 2. UCVA and BCVA at all distances, 3 months postoperatively in Dr. Gerten's cases.

to exchange an IOL after such a long period of time. There is too much risk of damaging the capsular bag or causing a capsular rupture. Therefore, I chose to implant a second IOL, the multifocal Add-On, to optimize distance visual acuity (she was 1.00 D) and at the same time give her the chance to see at near with a diffractive optic (Figure 3). She was incredibly happy with the outcomes, and I have since decided to continue using Add-On IOLs as my primary lens choice in pseudophakic patients.

The nice thing about the Add-On IOL is that it works with all materials in the capsular bag. Therefore, I do not have to be concerned with the standard IOL design. However, you must ensure that the patient's astigmatism is less than 1.00 D. Anything more is a problem for all diffractive optics, leaving laser refractive surgery or bioptics as the two remaining options for correction. In my experience, most of the patients I treat are in the range of emmetropia and want to see at near and far without corrective lenses, whether that be spectacles or contacts. In these typical patients, I order the Add-On

IOL with 1.00 D for far and 3.50 D for the diffractive optic.

PEARLS

Endothelial cell count and fundus exams. We noticed that all diffractive IOL patients are sensitive to anything that adds stray light to the optical path, including corneal guttata, Fuchs' dystrophy, vitreous floaters, and capsular opacification. All diffractive optics stress the optical system; however, there is a certain point where the brain can no longer adapt, and the optical system is overwhelmed. Therefore, we do an endothelial cell count to rule out corneal guttata with endothelial dystrophies as well as a fundus exam to check for macular degeneration and vitreous floaters.

Corneal refraction, structure, and astigmatism—regular and irregular (what we call higher-order aberrations today)—must be evaluated preoperatively with topography, Scheimpflug photography (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany; Figure 4), or Orbscan (Bausch & Lomb, Rochester, New York) exami-

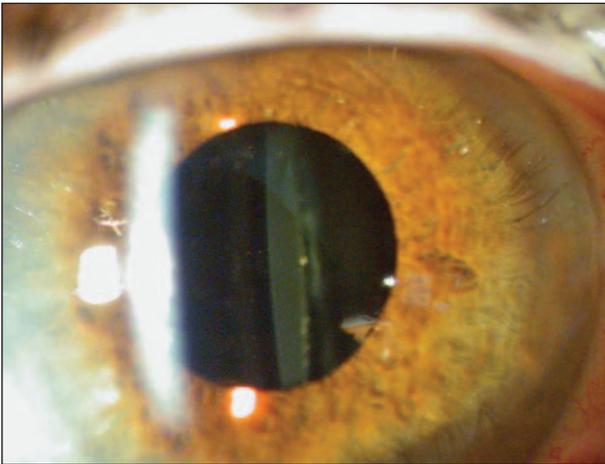


Figure 3. One week postoperatively, there is sufficient distance between the anterior Add-On IOL and the posterior chamber IOL at all sites.

nation. Corneal thickness is also mandatory to know in advance, especially in cases where the need for bioptics surgery is likely.

IOL insertion. Be sure to use an ophthalmic viscosurgical device (OVD) made from hyaluronic acid and not methylcellulose. This will help create adequate space in the anterior chamber. Also use the OVD in the sulcus to enlarge the space enough for placement of the oversized haptics. The haptics of the Add-On IOL must be long (14 mm) for sulcus fixation.

The lens may be inserted with forceps or an injector. With forceps, create a 2.6- to 2.7-mm incision.

Although slightly larger than many incisions today, it is still astigmatically neutral. Combined with its 7-mm optic, this lens is big enough to avoid optic capture with the iris and remain stable in the sulcus.

THE IDEAL PATIENT

The unilateral monofocal pseudophake who comes in for cataract surgery in the second eye is an ideal candidate for the Add-On IOL. Patient satisfaction is high in these cases because you can implant the Add-On IOL in both eyes. Diffractive optics work best when implanted bilaterally. Although it is impossible to decipher the patients who will adapt to halos from those who won't, the ideal strategy is to implant two lenses. That way, in the event the patient

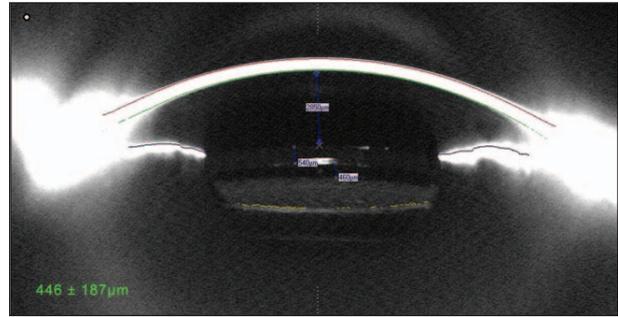


Figure 4. A Scheimpflug image showing the distance between the monofocal IOL in the bag and the multifocal IOL in the sulcus, with no sign of lens epithelial cell ingrowth between the two lenses.

is unhappy with the multifocal IOL, the anterior lens can be removed—even 6 months to 1 year after surgery.

Because the Add-On can be combined with any lens, it can be used in patients whose diopter range is not covered by standard capsular bag IOLs. For example, we operated on a patient with a refraction of -15.00 D, using a 2.00 D IOL in the capsular bag plus the Add-On IOL in the sulcus. I don't know of any other company who can provide you with a 2.00 D diffractive multifocal capsular bag lens.

CONCLUSION

This specific IOL is advantageous over other lenses because the diffractive optic is very close to the pupil. Whereas there is approximately 1 mm between the iris and the diffractive element of a capsular bag IOL, the diffractive optic of the Add-On IOL sits close to the nodal point of the eye as well as the iris opening. It is close enough to provide added benefit to the patient's optic system but far enough away from the iris to protect from iris pigment loss, iris shaving, and iris capture. We have also not experienced any decentration or glaucoma as a result of using the Add-On. ■

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I am Convinced of the Add-On Principle

Compared with piggybacking IOLs, implanting a second posterior chamber IOL in the ciliary sulcus is safer.

BY MICHAEL KÜCHLE, MD

There are many viable IOLs on the market for use in cataract surgery, and more recently, for refractive lens exchange. With each option come particular advantages and disadvantages. In my own experience, I have found great benefit in using the Add-On IOL (HumanOptics AG, Erlangen, Germany; Dr. Schmidt Intraocularlinsen GmbH, St. Augustin, Germany) in many of my patients.

Although I have used the Add-On occasionally for approximately 8 years, I have been using it with increasing frequency over the past year. So far, we have more than 100 patients implanted, with excellent results in all cases.

This IOL provides flexibility in treatment options. You can use it during cataract surgery as a second IOL, implanted in the ciliary sulcus. But you can also use it any time after cataract surgery to correct residual refractive errors. In these cases, it is used instead of exchanging the problematic IOL in a pseudophakic eye. You can use it to correct pseudophakic presbyopia, including unwanted hyperopia or myopia, or you can use it as a toric IOL to correct astigmatism.

REVERSIBILITY

As I mentioned, there are many IOLs to choose from, and selecting the proper IOL must be done on a case-by-case basis. However, there are many advantages to using the Add-On. The first, and biggest, is its reversibility. For example, if you have a patient with a corneal graft and high astigmatism, you can correct the astigmatism with a toric Add-On IOL. If the patient has another graft later, I can simply exchange it for another Add-On IOL. We have excellent results, very happy patients, and also it is quite easy and safe to implant.

In addition to the toric model, the Add-On is also available as a spherical or multifocal IOL. Many surgeons are moving toward lens-based options for refractive errors. I think we should also be moving toward the use of additional IOLs in pseudophakic patients. For example, you would not want to perform a refractive lens exchange in a pseudophakic patient who had a

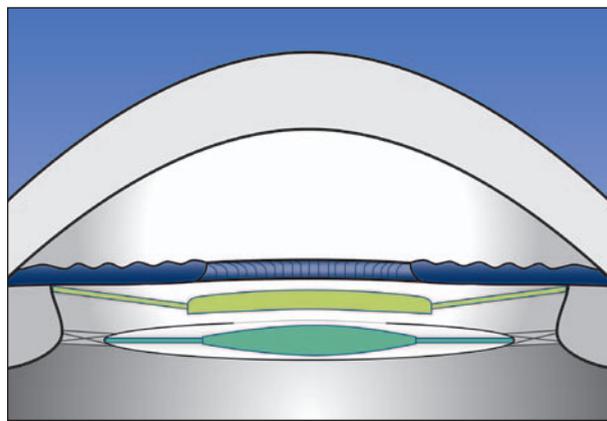


Figure 1. The IOLs remain at a safe distance from each other when using the Add-On with another lens.

Nd:YAG laser capsulotomy. In this case, I would implant the multifocal Add-On on top of the primary posterior chamber IOL.

Another classic example is patients with unwanted hyperopia. The quality of the LASIK procedure in these patients is probably questionable. Implanting the Add-On IOL is an ideal option because the IOL calculation is easy, and the unwanted refractive change after implantation is low. Additionally, the regression experienced after LASIK is obsolete. The many advantages of using the Add-On IOL are clear.

INDICATIONS

There are several indications for Add-On IOLs. At this time, the most frequent use in my practice is the multifocal Add-On IOL. However, the toric IOL is also important to have on hand. I typically have at least five toric Add-On IOLs (MS 714 TPB) in stock, ranging from 2.00 to 6.00 D of cylinder because it gives me the option to easily combine the toric Add-On with a standard aspheric IOL in the capsular bag. I typically use this IOL in cases where no advanced planning is possible, such as in patients who are referred to me for same-day surgery. I also use the toric Add-On in

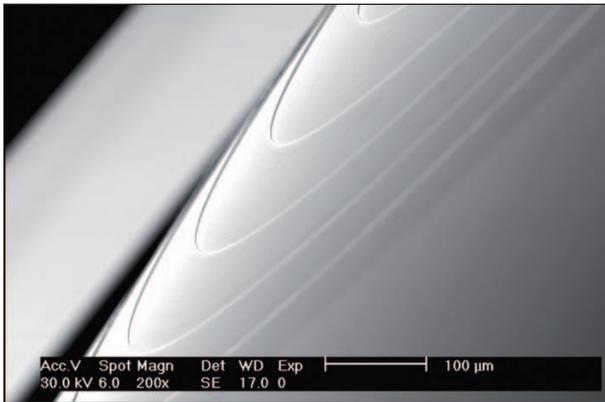


Figure 2. SEM-photography of the diffractive surface.

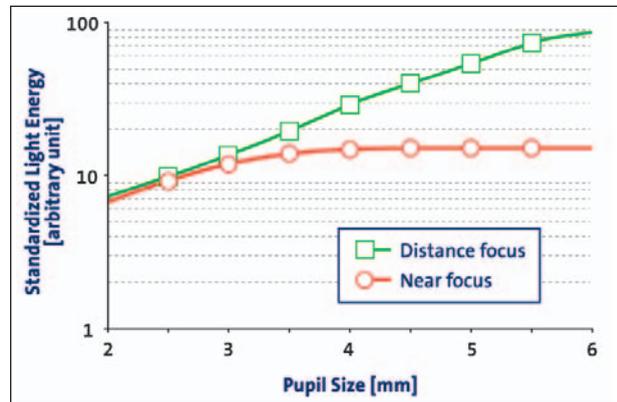


Figure 3. Light distribution of the diffractive Add-On IOL in relation to pupil size measured with the photometer.

pseudophakic patients who require a secondary correction for residual astigmatism.

I use the multifocal Add-On during routine cataract surgery when the patient does not like reading glasses and is interested in the multifocal IOL. I am taking part in a current prospective study evaluating the diffractive multifocal Add-On (MS 714 PB Diff). Initial results with now 10 eyes having completed the 3-month follow-up examinations are promising, with a stable position of the optic compared with the IOL in the capsular bag. The mean distance between the two IOLs was $570 \pm 167 \mu\text{m}$. At 3 months, the following results for binocular UCVA were measured: all patients were at least 0.8 or better for far distance, 0.5 or better for intermediate (1 m), and 0.8 or better for near (40 cm). Subjective patient satisfaction was high, with 80% of patients judging the results as excellent and 20% as satisfying. Additionally, contrast sensitivity under mesopic and scotopic conditions was within the normal range.

LOGISTICAL CHOICE

Some surgeons ask me why I choose to use the Add-On multifocal IOL in the ciliary sulcus in addition to a standard IOL in the capsular bag. The truth is that most surgeons opt to implant one IOL, a multifocal in the capsular bag. However, my method is much easier to handle in the operating room. We do not need to make our patient wait for surgery until the correct multifocal IOL power (from 10.00 to 30.00 D) is available. By using the multifocal Add-On IOL, you just need one type of multifocal, which provides a 0.00 D distance correction and 3.50 D near addition. The standard IOL is implanted in the capsular bag for the distance correction. It makes logistics easier, providing more flexibility for your patients, especially those who prefer same-day surgery.

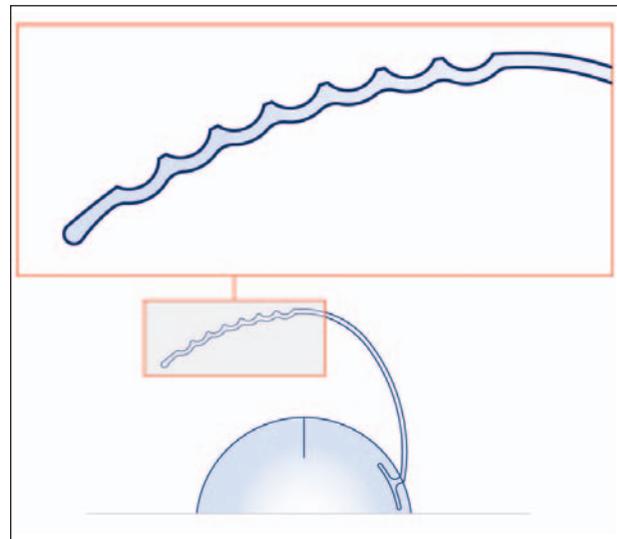


Figure 4. The haptics of the Add-On toric have the well-proven undulations to prevent rotation.

Patients have responded beautifully to the Add-On IOL. I can remember one occasion specifically: A patient came to me with a corneal graft, high anisometropia, and high astigmatism. Her eye with the graft was pseudophakic and highly myopic; the other eye was hyperopic. I suggested the toric Add-On. After surgery, she was very happy because she was able to function normally again and enjoy binocular vision for the first time after many years.

I present the Add-On IOL to my patients in any case where I believe it is a good option. If a patient is referred to our clinic for problems after cataract surgery, I always suggest the Add-On is a good solution. However, in the regular cataract patient, IOL choice is much more situational. When we talk about the surgical process, we simply inform the patient that the

Add-On IOL is a good option if he wants to get rid of glasses or correct preexisting astigmatism.

PIGGYBACKING IOLS

Another alternative is the piggyback principle. In this situation, you implant two IOLs into the capsular bag. Compared with the Add-On principle, piggybacking IOLs has several problems. The first complication associated with piggyback implantation is interlenticular opacification.¹⁻⁶ These cases are quite difficult to treat because you cannot use the Nd:YAG laser; you need surgery to remove it. Another common complication with piggybacking IOLs is hyperopic shift.⁷ Because the position of the two IOLs may change over time, the refraction may shift.

Whereas both IOLs are placed together during piggybacking, the Add-On lens gets implanted into the ciliary sulcus, thereby safely separating the two IOLs (Figure 1). Thus far, we have not encountered any complications and have not seen other problems, including elevated intraocular pressure, inflammation, or melanin dispersion after implantation of Add-On IOLs.

CONCLUSION

Why should surgeons be convinced of the Add-On principle? It is a great new technology offering a whole

new world of options for individualized treatments. It is very flexible, allowing you to use it in many ways—during or after cataract surgery. You can correct almost anything from a refractive point of view. This new IOL concept (Figures 2 through 4) has a promising future in ophthalmology. ■

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