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Innovations in supplementary IOLs

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Sulcoflex®: Supplementary vision in the sulcus

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In recent years, refractive outcomes have become a critical standard for success in cataract surgery; simply restoring vision is no longer enough. Patients who have received the highest quality cataract surgery may later desire multifocal implants. In addition, despite a surgeon's best efforts, refractive errors—whether residual to or otherwise following surgery as a result of any number of pathophysiological processes—are not always avoidable.

Supplementary IOLs provide a viable option in these and other cases, avoiding the trauma and increased risk of complications from IOL replacement. At the Asia-ARVO Meeting in January, five anterior segment ophthalmic surgeons and researchers gathered to discuss the Sulcoflex® (Rayner, East Sussex, U.K.), the first commercially available IOL designed specifically for supplementary sulcus implantation.

Dr. Chee: We are very excited to have this new option for cataract patients. Our biometry is not always perfect, and we are glad to have a lens that we can use as a piggyback lens to alter the power. You will see from this discussion that there are other ways to use this lens. Let's start off by asking Dr. Werner to introduce the topic.

Supplementary IOLs

Dr. Werner: Incorrect lens power is one of the most common reasons for explanting intraocular lenses. This is according to surveys done by **Nick Mamalis, M.D.**, and published every two or three years in the *Journal of Cataract & Refractive Surgery*. This survey is sent to members of the American Society of Cataract and Refractive Surgery (ASCRS) and the European Society of Cataract and Refractive Surgeons (ESCRS).

If you have a lens of incorrect power, what can you do? You can explant and exchange the intraocular lens; you can put in a piggyback intraocular lens; you can perform a corneal refractive procedure; and, of course, some surgeons prepare themselves for the bioptics procedure in cases of refractive lens exchange.

If you do a piggyback intraocular lens and you decide to use a pseudophakic intraocular lens, you cannot forget about the possibility of interlenticular opacification. This is the opacification of the opposing surfaces of piggyback intraocular lenses, and this has led to the explantation of many pairs of piggyback intraocular lenses that were sent to our lab. Interestingly, in all of the cases we analyzed, the lenses were hydrophobic acrylic lenses, basically AcrySof® lenses [Alcon, Fort Worth, Texas] because the AcrySof® material has an adhesive nature. All of the lenses were implanted inside of the capsular bag and via relatively small capsulorhexis. The lenses were fused together by this opacifying material, and there was a relatively large, central contact zone [Figure 1].

By knowing the pathology of the problem of interlenticular opacification, some surgical methods were proposed to prevent the complication. You can still implant both intraocular lenses in the capsular bag, but via a relatively large capsulorhexis. If you do that, there will be a fusion between the residual anterior capsule and the posterior capsule, and this is going to sequester the residual lens epithelial cells,

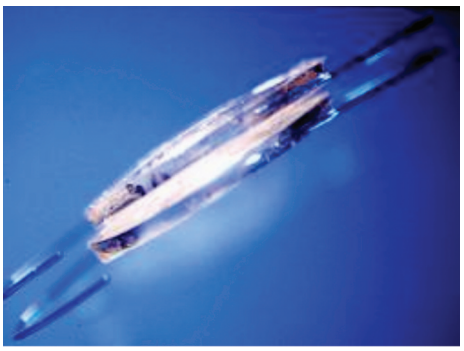

Figure 1. Interlenticular opacification fusing piggybacked IOLs
Source: Liliana Werner, M.D., Ph.D.

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and they are not going to be able to move to the interlenticular space [Figure 2].

The second option is to implant the first intraocular lens in the capsular bag via a relatively small capsulorhexis, and then the secondary lens is implanted in the sulcus. In this case, there will hopefully be a fusion of the anterior capsule to the anterior surface of the lens, and again the equatorial region of the bag is going to be sequestered so residual lens epithelial cells will not be able to move to the interlenticular space [Figure 3]. This method is very attractive to surgeons because of the ease of implanting a secondary intraocular lens in the sulcus.

If you choose to do that, you have to be very careful in the choice of intraocular lens to be placed in the sulcus. We published a case where there was a three-piece AcrySof® lens in the sulcus as a piggyback implant. This design has square and thick edges and unpolished side walls, and there was significant pigmentary dispersion leading to pigmentary glaucoma. The lens had to be explanted and exchanged.

Here you have a single-piece lens in which the edges are very square, the side walls aren't polished and the haptics are very thick; this lens is not recommended for sulcus implantation. Each time we analyze a lens of such design explanted from the sulcus, we observe significant pigmentary dispersion on the lens surface.

You have to keep all of that in mind; the lens to be implanted in the sulcus has to have specific characteristics [Table 1]. I think now is a good time for Dr. Amon to present on his design.

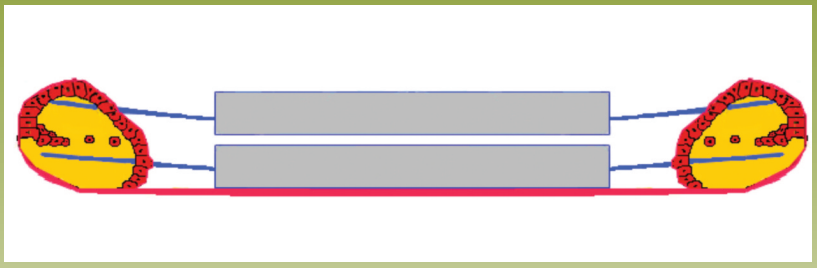

Figure 2. Method 1 for preventing interlenticular opacification: A relatively large rhexis allows the anterior capsule edge to fuse with the posterior capsule outside the implanted optic zones

Source: Liliana Werner, M.D., Ph.D.

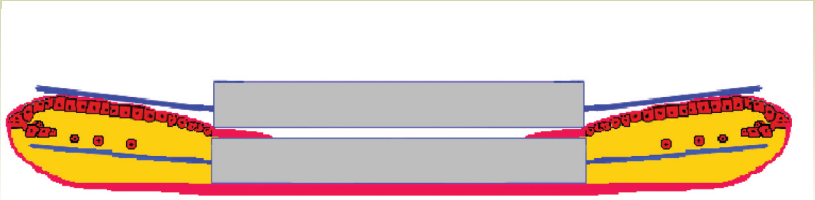

Figure 3. Method 2 for preventing interlenticular opacification: A relatively small rhexis allows the anterior capsule edge to fuse with the edge of the first IOL; the second IOL is inserted with the haptics in the sulcus

Source: Liliana Werner, M.D., Ph.D.

Sulcoflex: Specific characteristics

Dr. Amon: Here we have this lens, which is specially designed for sulcus implantation—that is very important [Figure 4].

There are a few important points to take into consideration in designing a lens for the sulcus. The first thing is we have to have an optic that has a concave posterior surface. If we have a biconvex surface, the center of the optics will touch, and in soft optics, they become plano or almost plano, and then you have hyperopic defocus. For that reason, there should be distance between them.

The second thing is we need a large optic to cover the entire optic area of the first lens to avoid glare or dysphotopsia. The Sulco*flex*® has a 6.5 mm optic, so it's quite large. The edges are round, which is also important; you get iris chaffing with sharp edges.

We have to have an angulation—this lens has a 10-degree angulation—so we get pupillary clearance, we get the distance between iris and lens optic. The haptics are angulated anteriorly so that the lens is located posteriorly to prevent iris chaffing and pigment dispersion.

Last but not least is the material. This lens is implanted in contact with uveal tissue. For that reason we need a material that has a high uveal biocompatibility. We have shown in several studies that uveal biocompatibility is high in hydrophilic lenses.

Haptic, size, rotational stability

Dr. Amon: The haptic is also very important. As the sulcus is quite large in some cases, you have to have a large haptic. This haptic is 14 mm in diameter, so it should fit in all eyes. It's very soft so that you don't erode vessels or tissues. The haptic has an undulation in order to preclude rotation. Rotational stability is also a big issue because when you use this lens for toric correction, you don't want to have any rotation. This lens is not going to be fixed by a capsular bag. Years later, you still have the option of rotating this lens. A lens might rotate spontaneously, so it's important to have a large undulating haptic to preclude this rotation.

I had a case where there was some rotation, so you never have a 100% guarantee that this lens will stay stable on the axis. Most do, but if it doesn't, you have the option to suture the lens to the sulcus.

One other factor is hydrophilic lenses have less adherence to silicone oil. If you have an eye filled with silicone oil, you have a change in refraction—and that's also an indication for this lens, to correct this change—and if you have some oil droplets, they won't stay on this lens' surface as much as with silicone lenses.

Dr. Chee: Dr. Amon, you mentioned that you had to suture one case for rotation. Tell us about the patient. Was the patient a high myope?

Dr. Amon: Yes, the patient was a myope and had quite a large eye. The lens was stable for about 6 weeks or so, and then the patient said he had blurred vision. We realized that there was a rotation of more

than 15 degrees—as you know, three degrees is about 10% of the correction. I first re-rotated it. For 2 weeks it was OK, and then it rotated again. It was just not fixating—showing that the lens was not ingrowing with the uveal tissue, which is good—but nevertheless there was that rotation, so I fixated it onto the sclera. I fixed it on one haptic very loosely, just to orient the lens. Maybe you can primarily suture the lens if you think that the eye is very big. But in all my other 80 cases, they were stable. It happens, you don't have 100% guarantee of rotational stability, but you can solve that problem.

Dr. Seah: Was the rotation in the same direction both times?

Dr. Amon: Yes, the lens went in the same position. The sulcus is not round, it is an oval shape, and the larger diameter usually is in the vertical and not the horizontal of the sulcus, so it was rotating to that position.

Neutral aspheric, aspheric, multifocal, and toric

Dr. Chee: Can you tell us a little more about the optics? Is this an aspheric optic?

Dr. Amon: It has an aberration neutral aspheric optic, which means it corrects the spherical aberration of the lens itself, but does not add or subtract aberrations to the pre-existing ocular or first lens aberrations.

Three versions of the optic are currently available: an aspheric monofocal version, a refractive multifocal version, with 3.5 D addition, and a toric version. I hope in the future we will also have an option that combines multifocality and toricity, that is to say, a multifocal-toric version.

Duet: "Primary" implantation of a supplementary IOL

Dr. Seah: I have mainly used the multifocal Sulco*flex*® lens. In the past, astigmatism was one of the contraindications for multifocal lenses. If there was more than one diopter of corneal astigmatism, I would not insert a multifocal implant. Also with very high myopia, it may be out of range. With the combination of two lenses, that means we can use a toric lens to correct the astigmatism, and we can add a multifocal on top of that. It becomes very versatile now; I can practically insert multifocal lenses in all patients.

Dr. Amon: I like to call that procedure a Duet Procedure. I do the same even without toric lenses; I perform Duet Procedures in order to have the reversibility, the option to take that lens out if that patient has dysphotopsia. I can tell the patient to wait for a few months for neuroadaptation, and if he doesn't neuroadapt, the lens is not grown in and fixated in the capsular bag, so we can easily take it out at any time. Or if a patient has some macular degeneration later on, in 10 years or so, and he has problems with multifocality, we can take that lens out at any time. I like to have this concept of Duet implantation: the first lens for emmetropia, and once the refraction is zero, the addition of a multifocal lens in order to give the patient multifocality. And it's reversible.

Dr. Seah: Has anyone done a study to compare a pure in-the-bag M-flex T multifocal toric (Rayner) and a Duet—do you think there's a difference in performance?

Dr. Amon: We are going to start a study comparing an M-flex, a bag lens multifocal refractive, with the Duet Procedure in the other eye. We've just started it, and I don't have any data yet.

Duet indications, reversibility, explantation

Dr. Chee: Are there any other indications for Duet implantation?

Dr. Amon: One indication is use of multifocal lenses. You can also do monovision—you try monovision and if the patient accepts, that's OK; if not, you take it out and he has binocular in the same correction.

Another indication is with children. As their eyes grow, there is a refractive change—a dynamic refraction, I call it. I calculate the first lens to be emmetropic when the child becomes an adult—you never know exactly, but you can approximate that—and then the second lens I add in order to make the patient emmetropic at the current age. Then I adjust it with time, depending on the change of refraction.

So these are also indications for Duet implantation: monovision, multifocality, and pediatric cases or dynamic refractive cases.

Dr. Chee: Has anyone explanted a Sulco*flex*® lens?

Dr. Seah: No, not even a regular multifocal.

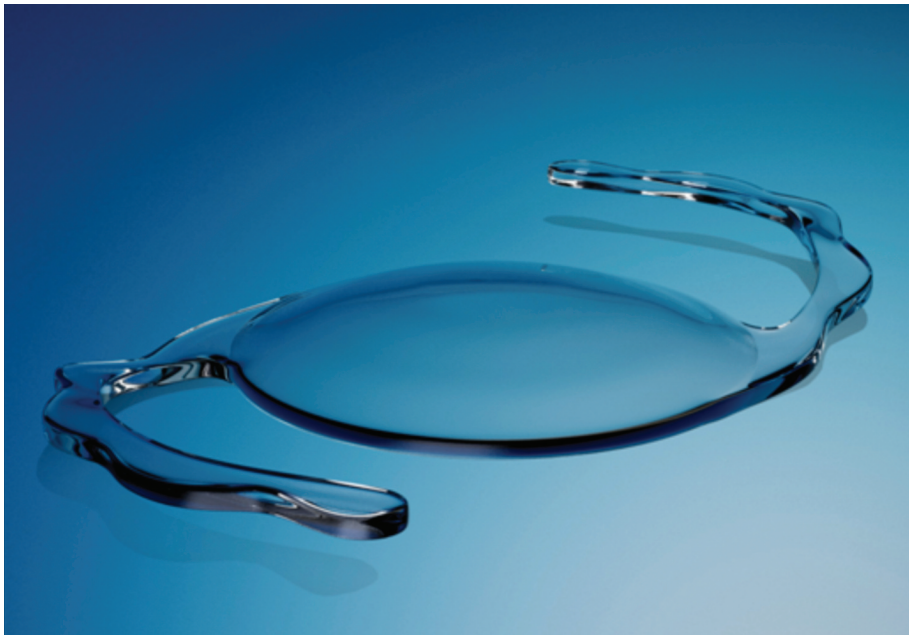

Figure 4. The Sulco*flex*® IOL

Source: Michael Amon, M.D.

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Dr. Amon: I have explanted one. It was loaded into the injector by a nurse, and she entrapped a haptic. It was broken but it was in already so there was a missing haptic. I took a forceps and pulled it out without folding it inside the eye. It's a very thin and soft material, so it's easy to explant the lens through a 2.4-mm incision.

I want to add one more indication for Duet, and this is very high myopia or hyperopia. When you don't have the stock lens, you can add on to adjust it. You can always get the right lens power with Duet.

Sulco*flex*® biometry

Dr. Seah: In all my multifocals for these Duet cases, they have been plano. I go with my regular biometry for the first lens implantation. I correct to plano, then add on the second lens. For the second lens, I don't need to do biometry. Basically, I just follow my refractions. If I'm at –1 after implantation of the first lens, I can use –1 +3.5.

Dr. Amon: It's a refractive vergence formula. If the diopter is between –7 and +7, I take the post-op ametropia, spherical 0.7 +2, and then multiply it by 1.5, which means a +3. Or if it's –2, I multiply it by 1.2, which means –2.5. Surgeons can easily calculate that. Rayner has a Raytrace Toric Calculator. It's very easy to calculate, and surgeons don't have to take any measurements; they just calculate the refraction, and that's very easy and straightforward.

Biocompatibility, inflammation

Dr. Liu: However biocompatible it is, in the long term, would the Sulco*flex*® actually dig in and get stuck? Over the years, and we don't have that experience yet, do you predict that it may become difficult to explant?

Dr. Amon: I have only explanted a lens right after implantation, so I can't tell. But in one case, after about 1 year, I did a rerotation of the lens because it was a keratoplasty case and the astigmatism changed. I had to re-rotate that lens—not to explant it, but to move it in the eye—and that was very easy. I didn't feel any resistance for rotation. I don't think that this lens will become fixed to some tissue. Maybe in a uveitic case, but in normal cases, it's hydrophilic material, and it's very biocompatible, and for those reasons there shouldn't be any reaction with uveal tissue.

Dr. Liu: What about flare? Have you studied flare formally?

Dr. Amon: Yes, we did laser flare cell measurements and objectively measured the flare values after implantation of that lens. The flare values were very low compared to phacoemulsification—if you take flare measurements after phaco, they're higher than the values after implantation of the Sulco*flex*® secondarily.

Dr. Chee: But does it normalize over time?

Dr. Amon: It comes back to pre-op values. As with phaco, it's about the same.

In two pediatric cases—I have done four now—we had some fibrin. There was poor compliance in those cases, but nevertheless, I think it's very important that, especially in children, you increase the dose of your nonsteroidal and steroidal anti-inflammatory treatment. Now I've started to inject some triamcinolone subconjunctivally because I think it's important to have quiet eyes especially in children. But this fibrin resolved, and their eyes are calm now after 1-year follow-up with my first patient.

Dr. Chee: I've had experience with a pediatric case as well. This patient needed an IOL power of –20, and of course we didn't have such a lens available. This patient was under 2 years old. What I routinely do when I do pediatric cataracts is give a small dose of intracameral dexamethasone—0.4 milligrams in 0.1 milliliters—and that usually prevents all fibrin formation.

Dr. Liu: Dr. Werner, I heard that you've conducted some cadaver eye studies. Do you have any data on long-term effects?

Dr. Werner: I cannot speak about the long-term effects because our study of the cadaveric eyes is to assess the fitting of the lens. I do not personally believe that it's going be an issue of the lens creating adhesions in the ciliary sulcus because of the nature of the material.

Secondary implantation

Dr. Chee: Has anyone had experience with secondary implantation?

Dr. Seah: For secondary implantation, the first group of patients is the previous pseudophakics who had a monofocal; they find out that there is such a thing as a multifocal and want one. The other group would be post-refractive surgery patients. As you know, biometry is a lot less accurate if the patient has had LASIK before, and if the patient requests a multifocal, I would not want to have just one procedure. I'd probably put in a simple toric or monofocal IOL and tell the patient we'll look at the refraction after surgery, and then add on the second lens.

Dr. Chee: Have you had to go back to take out a multifocal?

Dr. Seah: Not so far.

Dr. Chee: What is the patients' reading vision like? Do they have complaints of halos and glare?

Dr. Seah: I'm generally quite satisfied with this brand of IOLs. Reading vision has been good. Most of the patients are spectacle-independent, maybe some needing spectacle aid for smaller print. In terms of halos and dysphotopsia, we do get a few complaints here and there in the initial period, before neuroadaptation sets in. I don't have anyone who requested an explantation yet. As long as both eyes are done, I think they are OK. In the interim, when they are dependent on one side, then they have some complaints.

Dr. Liu: I have some cases of secondary piggybacks. Secondary Sulco*flex*® implantation can correct residual spherical and cylindrical error, and it can also add multifocality.

I had a challenging case of a 75-year-old female healthcare assistant who was intolerant of spectacles and contact lenses. I did bilateral hyperopic LASIK in 2002, which needed enhancement. Eventually she developed cataracts and had to have cataract surgery. Because of biometry error, the left eye IOL was exchanged. Afterward, she was not happy because she wanted monovision. She wanted her

right eye for distance and her left eye for near. So I added a Sulco*flex*® to give her unaided near vision.

Another example is a 60-year-old woman who wanted phaco and implants to emulate previously successful monovision contact lens wear. She was left eye dominant, but historically she's been corrected left eye for near, which she was happy with. So eventually I carried out phaco, with the left eye aiming for –1.37 and the right eye aiming for roughly zero or just verging toward very slight myopia. But the refractive outcome was not satisfactory, so she wanted something more done. I tried her with some toric contact lenses first and she was happy wearing +1.5/–0.75 at 180 in both eyes. I contacted Rayner and we did the calculations and ended up recommending bilateral Sulco*flex*® toric +1 with a +1 cylinder, which gave, more or less, emmetropia on the right and the minus that she wanted on the left. She's been stable, and she's very happy.

Refractive performance

Dr. Chee: This is a refractive lens, so do you have to look at pupil size before you offer patients this option?

Dr. Amon: This lens has a very large optical zone. For that reason, it's not as pupillary dependent as refractive lenses usually are. For that reason I feel very comfortable even with narrow pupils.

Dr. Liu: With secondary implantation, essentially, we're talking about a refractive procedure, so of course people want to know about the optical performance and the refractive predictability.

With refractive predictability, because we are looking mainly at small corrections, I don't think it's important exactly where the lens will sit within the sulcus and whether there's a large amount of Soemmering's ring or not. Because we're talking about low powers, that shouldn't be a problem.

Regarding the optical performance, I'd like to ask Dr. Amon, what have you built in to ensure the optical performance? Have you got a large enough lens, will it always sit stably, will it tilt, will it decenter, and does it matter if it tilts and decenters a little bit because you've built in zero asphericity?

Dr. Amon: Many studies need to be done to answer all these questions. One thing I can say is that centration is very good. It is stable compared to a capsular bag lens. Because of capsular contraction, you sometimes realize later on that the lens decenters with time. This won't happen with a sulcus lens. There is no contraction, this haptic has a good memory, so this lens will stay centered all of the time.

An interesting thing would be to measure the centration of a sulcus lens compared to the centration of a bag lens. When you look at the center, it's not totally aligned. I believe this has to be done. I think the sulcus lens has a better line of sight fixation as compared to the bag lens.

Dr. Seah: Since you say the sulcus is oval, what do you think is the ideal placement of the Sulco*flex*® toric lens?

Dr. Amon: I usually implant it with the haptics in the vertical position.

Dr. Chee: If you found that this eye on UBM prior to surgery had a big Soemmering's ring, would you place it along the same axis as the existing lens? Would it matter?

Dr. Amon: I don't think it would matter because the Soemmering's ring has the same thickness all over.

Dr. Chee: What if there is a plate haptic in the bag?

Dr. Amon: If there is a plate haptic, I would put it in at 90 degrees. And if there was, for instance, some zonular dialysis—that's not a good indication for that lens—but in some cases, I would risk implanting the lens 90 degrees to the dialysis.

Sulco*flex*® implantation

Dr. Chee: In terms of implanting the Sulco*flex*®, if you have a posterior capsule opacity, should you perform a YAG laser capsulotomy first?

Dr. Amon: I would usually first implant the lens and then YAG because otherwise you risk getting some vitreous during surgery, but both methods work. I've implanted secondary lenses in eyes that already had a YAG laser capsulotomy performed and it was no problem. Even if you get some vitreous because of a capsulotomy that is too large, you can do a formal anterior vitrectomy. So implantation is no problem either before or after YAG capsulotomy. I don't think the capsule opacity influences refraction that much.

Loading the injector

Dr. Liu: Using the same injector as used for other Rayner implants, it's recommended that you put a thin strip of viscoelastic on those grooves and then half fill the nozzle as well. The optic being slightly larger than the normal Rayner lenses, you do have to tuck it in underneath the ledge. Then you have to put the haptics in at the end. You're supposed to press the middle of the lens so that nothing catches. You hear a double click when you close the lid because there are two catches.

Behind the Sulco*flex*® is a soft-tipped, sponge-like material that pushes the Sulco*flex*® through. One important thing about the Rayner injector is because the plunger is a soft sponge, it's important not to push it through beyond the nozzle. Otherwise it forms a bulb and then you have difficulty pulling it back through a small wound.

Dr. Chee: What is the incision size this cartridge requires?

Dr. Amon: There are two injectors now. Usually with the older one, I use a 2.75-mm incision. With the newer one, you can come down to around 2.4, if you perform a corneal assisted injection. But I've implanted the lens through 1.8-mm incisions with other injectors. As it is very thin and soft, it would work with micro-incisions, too—sub-2-mm incisions.

Dr. Seah: I use the same incision as most of my phaco wounds [about 2.6 mm], so I know that it's no problem. I usually introduce the lens through the corneal wound.

When loading the injector, I think initially the trick is the lid. It tends to be a bit stiff, so initially, if you don't open it wide enough, you have to push the optic in. But later on I realized that I just push it a little bit more and the optic falls in place in the groove. It's a lot easier to push in with the forceps, and if it is nicely done, the haptics will also fall in nicely. So I think the initial learning curve will involve the trailing haptic as it can get caught.

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Table 1

Characteristics of an ideal sulcus add-on lens

- Soft, biocompatible material
- Large optic diameter and overall diameter
- Round, smooth optic and haptic edges
- Design configuration providing appropriate clearance with uveal tissue and in-the-bag IOL

Source: Liliana Werner, M.D., Ph.D.

Dr. Amon: The main thing is, it's a bit tricky, but you have to fold it under the microscope. You can't give it to the nurse to fold it on some other table. You have to control it under the microscope. Then it should work.

Dr. Chee: My very first case was a patient who was a high myope. He required a toric lens, so I used the Alcon toric lens. I made a 1.8-mm incision and put the lens in, wound-assisted. I was asked to use the Sulco*flex*® injector, but I wasn't going to open up the incision. I was using a toric lens and didn't want to affect the surgically induced astigmatism. Instead, I asked for an Alcon D-cartridge, the same kind I used for the toric lens, and I loaded it into the cartridge exactly the same way I would load an AcrySof® lens. I introduced the Sulco*flex*® through a 1.8-mm incision; it delivered it beautifully, no resistance, easily controlled.

Dr. Amon: I think this lens is a sub-2-mm incision lens. It depends on the injector. Off label, we have different injectors we can use. But Rayner has to provide us with a sub-2-mm injector.

Dr. Liu: I think wound creation is so important. On the one hand, you'd be stretching the wound and it may never come back properly, and there might be some risk of leakage. But the smaller it is, the better because it's a refractive procedure and you don't want to be introducing extra astigmatism or higher-order aberrations in order to introduce the lens.

Using viscoelastics

Dr. Chee: Which kind of viscoelastic would you use for secondary implantation?

Dr. Liu: I always use dispersive, apart from the most difficult phacos.

Dr. Amon: I always use cohesive; only in rare cases do I use dispersive, so it works with both. The preference is personal.

Dr. Chee: Is it very important to remove all the viscoelastic?

Dr. Amon: Yes, that's important, because otherwise we get some peaks in the pressure. If you have a toric especially you have to remove everything so that there's no re-rotation.

Most of my cases I use a kind of rock-and-roll technique to let the viscoelastic out. If it doesn't come out, I go between the lenses, in the interface, and remove everything. If you are performing a Duet Procedure, before you implant the second lens, remove all the viscoelastic from the capsular bag, then inject viscoelastic on top of the rhexis and the iris in between, and then implant the Sulco*flex*®. The viscoelastic in the bag is removed before the second implantation.

Dr. Seah: I think that the difficulty lies in the Duet cases where you find you're a bit off after you remove the viscoelastic and you have to adjust again. Some people find it difficult, but after a while, you know how to do it. You put your Sinskey hook just below the Sulco*flex*® and rotate from the optic-haptic junction of the first IOL and adjust it accordingly.

Dr. Chee: If you're using a toric Sulco*flex*®, can you rotate the lens counterclockwise?

Dr. Amon: After implanting the lens, later on, I think it can rotate in both directions. But during surgery, intraoperatively, I usually rotate it in the direction of the haptics: clockwise. If I'm too far, I go around again and it's not a problem.

Complications

Dr. Chee: Looking at the gap between the primary lens and the Sulco*flex*®, there are some cases where, because of Soemmering's ring, the iris is very close in proximity to the optic of the Sulco*flex*®. As a glaucoma surgeon, Dr. Seah, would you consider a PI [peripheral iridotomy] for such a case?

Dr. Seah: So far I have not performed a single PI in any of my patients. But I've heard of some colleagues finding a case of angle-closure glaucoma at first implant. So far I'm quite fortunate. I do glaucoma patients as well. In fact I do combine Sulco*flex*® with trabeculectomy in some cases, and so far I haven't had any problems.

Dr. Chee: I ask because Asian eyes are different from Caucasian eyes.

Dr. Amon: Definitely, and I don't have any results with Asian eyes. But with children, I do an iridectomy because their eyes are very small. With adults, we did OCT and UBM measurements, and there was a distance in all cases, in short eyes and in long eyes. But nevertheless, I had one case with a block. My suggestion is if you have a very short eye or an odd eye—you may have a long eye with a very shallow anterior chamber—then iridotomy is no problem. But in general, I don't do any iridotomies. I've had good results with that.

Dr. Werner: Have you had any cases of optic capture with this design?

Dr. Amon: No, there's an angulation and it's always behind. I don't use any miotic after surgery; others do to avoid capture, but there is no need to.

Dr. Chee: Have any of you experienced any other complications?

Dr. Amon: One rotation, in my 80 cases, one blockage, and two cases with fibrin in children due to poor compliance.

Dr. Werner: You don't see pigmentary dispersion at all?

Dr. Amon: No, no iris changes at all.

Dr. Seah: I did get one case of accelerated PCO. The patient was a high myope. Her distance visual acuity was 6/6, but near was quite bad. I put in a Sulco*flex*®, and then her best corrected vision dropped very quickly and it was due to PCO. After I performed a YAG laser capsulotomy, she was happy again because she was seeing very well. I'm not sure it's related.

Dr. Liu: High myopes have a high risk of PCO anyway, but I wonder, is it possible that when your viscoelastic went in, it separated the primary implant from the posterior capsule, creating space underneath it?

Dr. Seah: It's possible. She also had a shallow anterior chamber.

Dr. Chee: Do you all do an endothelial cell count before a secondary implant?

Dr. Amon: We did for investigational reasons, but I don't think there's a need. It's a posterior chamber lens, there's no need for that.

Dr. Liu: I think the flare studies and the endothelial counts should only be initial studies to prove the safety of the lens. Once that's been done, it's just like routine surgery. I don't think we need to perform that unless you think that there may be a problem beforehand.

Contraindications

Dr. Chee: It looks like this is a very safe procedure. Can you think of any contraindications to using this lens?

Dr. Amon: Right now, I wouldn't implant the lens in children younger than 1 year. I'll usually use IOLs in children after 1 year. I have some concerns with very small eyes. That's my contraindication.

I had one patient who had uveitis and I implanted because it was necessary and the eye stayed very calm and quiet. In general, uveitis may be a contraindication, but in this special case where I needed to use that lens, I did and it was a success, so no absolute contraindications. I think uveitis is a relative contraindication, but not absolute. It depends on the stage and the cause of uveitis.

Dr. Chee: How about pseudoexfoliation?

Dr. Amon: I've done it in pseudoexfoliation, but with pseudoexfoliation you may have zonular dialysis with or without a sulcus lens over time. For that reason, we may run into some problems later on. But then I wouldn't expect it to be a big problem to implant the sulcus lens and fix the second lens.

Dr. Werner: Have you implanted the lens in patients with glaucoma?

Dr. Seah: I have. No problems.

Dr. Chee: If you had intended to do a Duet Procedure and at the time of surgery you notice some zonular weakness, would that be a contraindication to proceed with the Sulco*flex*® lens as a Duet Procedure?

Dr. Amon: If I had a zonular dialysis I would use a CTR, and if it's not a big one, I would implant the sulcus lens 90 degrees to the dialysis. I think I would risk that if I really need that lens.

This lens is fixed in the sulcus and not on the zonules. It shouldn't, if it's properly implanted, interact with the zonules. If there is a small area of zonular dialysis but you are 90 degrees from that, I think you're safe. If it's a below 90-degree dialysis, I would do it.

Dr. Chee: We know how to check whether a lens is properly in the bag; do we know how to check whether this lens is properly in the sulcus?

Dr. Amon: I think it is impossible to check it. But to implant the lens in a way that it goes behind the iris, right in the sulcus, should happen in almost all cases because anatomically, it's one area where the lens should stay. Usually the haptics should glide over the processes into the sulcus.

Dr. Chee: I've seen patients who've had an extracapsular cataract extraction and who want something different, a multifocal add-on and so on. Some of these lenses are not in the bag, some of them are not perfectly centered and we have some adhesions. Would this be a contraindication?

Dr. Amon: There might be some risk that it doesn't work as well as it should. But, for instance, I had one patient where the first lens was in the sulcus, and I put the Sulco*flex*® lens on top in the sulcus, 90 degrees from the first one, and it worked. It's an off-label use, but it worked. You definitely run more risk of complication with that.

Dr. Seah: As Dr. Amon said, I think there's nowhere to go except into the sulcus. For Duet cases, there may be a tendency to have it go into the bag. You actually have to inflate the space, and then you have to angle the lens to make sure it goes above the capsular bag.

Dr. Amon: You first should remove the viscoelastic from inside the bag, then it collapses, then you put the viscoelastic on top and you don't have the risk.

Dr. Liu: The lens is safe, but I think when you're just starting out, don't do anything off label—stick to standard cases. Then when you become more experienced and you have other skills, be it glaucoma or vitreoretinal skills, you can do something off label. I'm really impressed because the previous problems with piggyback—the interlenticular opacification, the uveitis-glaucoma-hyphema [UGH syndrome]—they haven't really appeared with Dr. Amon's invention, so very well done to him.

Dr. Chee: This really is a useful addition to our armamentarium for correcting refractive surprises. What do you think are the future directions for this lens?

Dr. Amon: The next step should be a combination of the toric and multifocal lenses. I hope this will be available quite soon. I will try to have the first implantations this year. I would also like to design a lens for sulcus placement without the second implant, a sulcus lens as a standby lens in case of a posterior capsular problem, so you have a lens that is specially designed for complicated cataract cases.

Dr. Chee: That would be great especially if it's a multifocal lens.

Cadaver eye study at the John A. Moran Eye Center

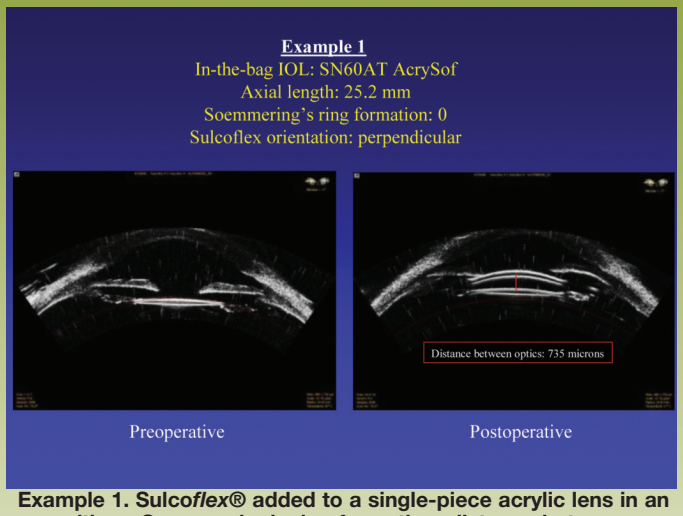
Dr. Werner, together with **Nick Mamalis, M.D.**, and other colleagues at the John A. Moran Eye Center, conducted cadaver eye studies to evaluate supplementary sulcus IOL placement in as wide a variety of scenarios as possible. By tapping into resources such as the Tampa and San Diego Eye Banks, the Moran researchers acquired large numbers of eyes of different sizes, with different IOL implants, zonular states, and degrees of Soemmering's ring formation.

"In all these cases, would the Sulco*flex*® behave in the same way?" Dr. Werner asked. "Would we still have the clearance between the optics?"

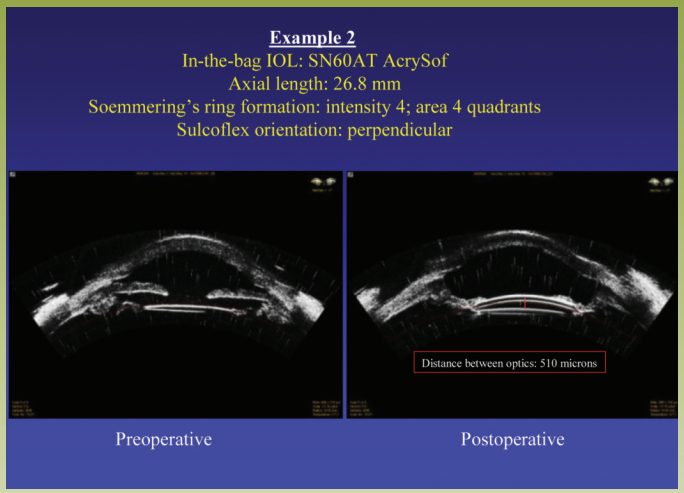
Using an Artemis high frequency ultrasound system (ArcScan, Morrison, Colo.), Dr. Werner and her colleagues took ultrasound biomicroscopy (UBM) studies before and after implantation of Sulco*flex*® lenses into the cadaver eyes.

Currently, the Moran researchers have data for 11 eyes. In all cases so far, the Sulco*flex*® optic was found to remain clear of the primary implant's optic. Moreover, analyzing the positions of the haptics has shown that they do not disturb the normal anatomy of the ciliary processes and surrounding structures.

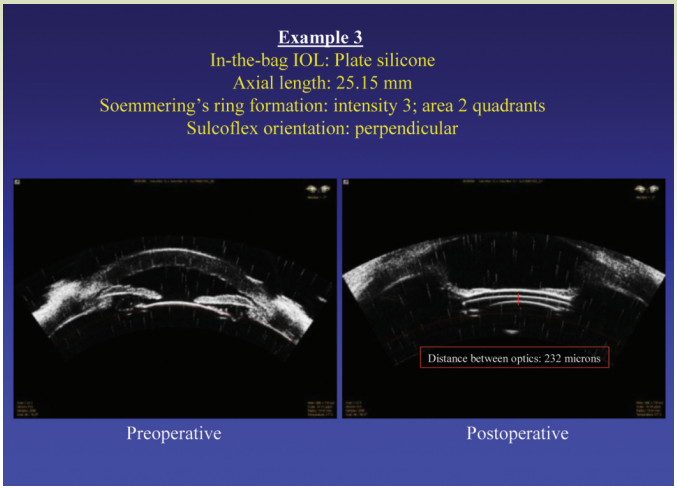
"We are continuing this study because we are hoping to get all of the size extremes," said Dr. Werner. "So far we have been quite impressed."



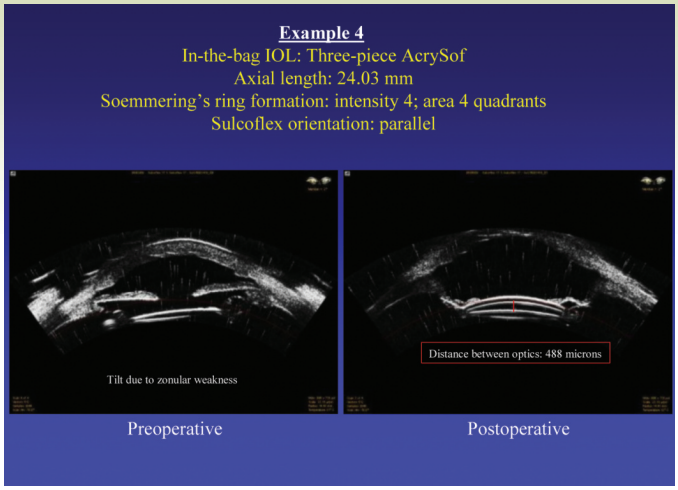
Example 1. Sulco*flex*® added to a single-piece acrylic lens in an eye with no Soemmering's ring formation; distance between optics: 735 microns



Example 2. Sulco*flex*® added to a single-piece acrylic lens in an eye with significant Soemmering's ring formation; distance between optics: 510 microns



Example 3. Sulco*flex*® added to a plate haptic silicone IOL in an eye with significant Soemmering's ring formation; distance between optics: 232 microns



Example 4. Sulco*flex*® added to a three-piece acrylic lens in an eye with significant zonular compromise resulting in tilt; in-the-bag lens tilt corrected during Sulco*flex*® implantation; clearance between optics: 488 microns

Source: Liliana Werner, M.D., Ph.D.

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