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Aspheric IOL Design

*and Clinical
Implications*

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Introduction

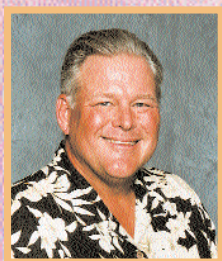
Currently, standard-optic IOLs are able to correct visual error at high levels and many patients who undergo cataract surgery enjoy better vision without glasses than they experienced for the majority of their adult years. The new aspheric IOLs are an improvement on the standard-optic IOLs because they improve contrast sensitivity. One of these new aspheric IOLs, the SofPort AO IOL (Bausch & Lomb, San Dimas, Calif.) has the additional advantage of being an aberration-free IOL. This IOL induces no aberrations that cause night vision symptoms such as glare and halos.

There are several factors that must be considered by ophthalmologists when selecting an IOL, such as cost, insertion techniques and clinical performance.

This SLACK Incorporated monograph, sponsored by Bausch & Lomb, will focus on the faculty's experiences with various IOLs, important considerations in choosing an IOL and the pros and cons of the new aspheric IOLs.

Richard L. Lindstrom, MD
Moderator

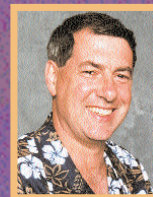
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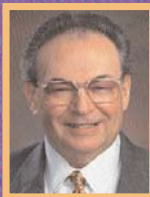
Richard L. Lindstrom, MD, is clinical professor of ophthalmology at the University of Minnesota and managing partner, Minnesota Eye Consultants.



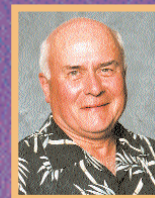
Rosa Braga-Mele, MD, is assistant professor of ophthalmology in the Department of Ophthalmology and Vision Sciences at the University of Toronto, Canada.



Eric D. Donnenfeld, MD, is the medical director of the TLC Laser Center in New York. He is also a partner with Ophthalmic Consultants of Long Island and Connecticut.



I. Howard Fine, MD, is clinical professor of ophthalmology, Oregon Health and Science University, Portland. Dr. Fine is also in private practice in Eugene, Ore.



John D. Hunkeler, MD, is the founder and medical director of the Hunkeler Eye Institute, Kansas City, Kan.



Louis "Skip" Nichamin, MD, is medical director of the Laurel Eye Clinic in Brookville, Pa.



Stephen G. Slade, MD, is national co-director, The Laser Center, Houston, Texas.

Aspheric IOL Design and Clinical Implications

The science of aberration-free IOLs

Richard L. Lindstrom, MD: What has nature taught us about the impacts of spherical aberration and coma on the human crystalline lens as it ages?

Eric D. Donnenfeld, MD: The visual system is dependent upon the integration of the refractive surfaces of the cornea and the lens. These integrated systems work hand-in-hand with the normal positive spherical aberration of the cornea being canceled out by the normal negative spherical aberration of the crystalline lens, which is the optimal system for achieving maximal contrast sensitivity and Snellen visual acuity. Visual peaks are reached early in life, and, due to the normal aging processes that occur, the cornea remains fairly static throughout, but the crystalline lens thickens to the periphery. This thickening induces positive spherical aberration as we age, so the canceling effect of the lens at a younger age is negated and increasing spherical aberration is added. The result is that as the eye ages, contrast sensitivity is significantly decreased and glare and halos enter the visual system.

Lindstrom: At what age do most patients have the highest quality vision?

Donnenfeld: The highest quality of vision usually is present at approximately 20 years of age. At that time, the cornea and the lens almost perfectly cancel one another out, resulting in minimal higher-order aberrations, best contrast sensitivity and best Snellen visual acuity.

Lindstrom: Can spherical aberration have a positive effect on the visual system?

Stephen G. Slade, MD: Positive spherical aberration provides depth of field. Spherical aberration and coma can interact to where they lessen one another. I would prefer to keep the visual system as neutral as possible, but a moderate amount of positive spherical aberration can be an advantage.


Lindstrom: For patients who develop visually significant cataracts, ophthalmic surgeons have traditionally performed cataract extraction and have implanted standard IOLs with positive spherical aberration. Patients have been satisfied with the results that are achieved in these procedures. However, aberration-free aspheric IOLs are now available, potentially allowing for even better outcomes that can mimic the vision of a younger patient.

John D. Hunkeler, MD: In today's world, patients are no longer willing to tolerate with increased spherical aberration

that comes with aging. Because of this, ophthalmologists must be able to provide optimum unaided functional vision for their patients. The IOLs that are available today will help in counteracting the positive corneal and lenticular spherical aberration with a negative spherical aberration or aberration free IOL and, in effect, will optimize the overall quality of vision.

Lindstrom: Currently, several types of IOLs are available to clinicians. One is a regular spherical IOL, which leaves the patient with some positive spherical aberration. The second is a modified-prolate IOL, which neutralizes the cornea's positive spherical aberration. The third is an aberration-free aspheric IOL, which induces no spherical aberration.

Dr. Nichamin, can you tell us exactly how the



Aberration-free aspheric IOLs are now available, potentially allowing for even better outcomes that can mimic the vision of a younger patient.

— *Richard L. Lindstrom, MD*

aberration-free SofPort Advanced Optics (AO) aspheric IOL (Bausch & Lomb, San Dimas, Calif.) is designed?

Louis D. Nichamin, MD: The SofPort AO IOL is similar to a handheld aspheric lens that is used in conjunction with an indirect ophthalmoscope. Both the anterior and posterior surfaces of the IOL are truly aspheric, and have even power distributions from the center of the IOL to the periphery. The SofPort AO can be considered a neutral IOL because it will impart neither positive nor negative spherical aberration.

The SofPort AO is more forgiving than a spherical IOL or an IOL with negative spherical aberration with regard to centration and tilt. Any IOL with either positive or negative spherical aberration will induce other higher-order aberrations such as astigmatism and coma should they not be aligned with the visual axis. This IOL is unique in that it induces no additional aberration to the optical system.

One approach to improving upon the quality of vision in the pseudophakic eye is to employ negative spherical aberration in an IOL to combat positive spherical aberration in the cornea. However, a relatively broad distribution of corneal spherical aberration is found within the general population. One of the advantages to the SofPort AO is that it does not require selectivity in regard to pre-existing higher-order aberration.

Lindstrom: Dr. Fine, what is your experience with the modified-prolate Tecnis Z9000 IOL (Advanced Medical Optics [AMO], Santa Ana, Calif.) and how does it compare with the SofPort AO?

I. Howard Fine, MD: I was one of the investigators for the Tecnis Z9000 IOL. In the Food and Drug Administration study for Tecnis, a group of patients who were 20 to 30 years of age and had no cataracts were compared to patients who had received the Tecnis IOL.¹ Mesopic contrast sensitivity for the Tecnis was at least as good as the mesopic contrast sensitivity for younger patients studied. In this sense, the Tecnis restores youthful vision. Senior citizens implanted with the Tecnis had better mesopic contrast sensitivity than

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— *Louis D. Nichamin, MD*

spherical IOL implanted seniors had photopic contrast sensitivity. In a sense the Tecnis provides day for night vision.

The Tecnis has a negative spherical aberration built into its anterior surface, which is designed to address positive spherical aberration in the eye. However, not all patients have positive spherical aberration, so the Tecnis has the potential to worsen spherical aberration in this small subset of patients.



When implanting the Tecnis IOL, a surgeon must use a small capsulorrhexis and be certain that there is symmetrical overlap at the anterior capsule. This is because the advantage of the Tecnis deteriorates once there is more than 0.4 mm of decentration and 7° of tilt.

Conversely, The SofPort AO allows the surgeon more leeway for a less-than-perfect surgery and a greater margin of error for decentration or tilt because this IOL does not induce spherical aberration. Therefore, no problems occur when the SofPort AO is decentered or tilted.

Lindstrom: One possible disadvantage to a standard or a negative spherical aberration IOL is that when decentered, it will induce coma in most cases. If the IOL tilts, astigmatism will be induced. What is known about the effect of IOL centration on the visual axis?

Rosa Braga-Mele, MD: Most IOLs that I implant are initially well centered. However, in cases of either pseudoexfoliation or a traumatic case that results in zonular dehiscence, an IOL may shift over time. Also an IOL can also shift and tilt if it is implanted in the sulcus. For example, when implanting any IOL either with positive or negative sphericity, slight decentration or tilting is possible, and these IOLs would result in a higher likelihood of coma and astigmatism.

The advantage of an aberration-free IOL is that no harm is done with this lens, no spherical aberration is added or subtracted — the IOL allows the eye and the cornea to function with some positive spherical aberration and added depth of field. If the IOL tilts or shifts, nothing happens.

Lindstrom: The surgical techniques used for IOL implantation have improved, but data suggest that the typical IOL decentration off the visual axis is still approximately 0.35 mm, mainly because the lens capsule is not perfectly lined up with the visual axis. The standard deviation is between

0.12 mm and 0.25 mm, meaning that at least 5% to 20% of IOLs are most likely decentered to at least 0.5 mm. Is this amount of decentration enough to affect the performance of aspheric IOLs with negative spherical aberration?



From a refractive surgery standpoint, an

aberration-free lens would seem to be the best type of IOL to combat night vision symptoms and avoid adding aberrations to the visual system.

— *Stephen G. Slade, MD*

Braga-Mele: I believe that decentration above 0.4 mm makes a difference because it can affect contrast sensitivity. Any difference in contrast sensitivity affects visual outcome and performance.

Lindstrom: Dr. Donnfeld, if pupil size changes in a patient with a mildly decentered IOL, what are the potential consequences?

Donnfeld: The normal physiological pupil moves during the course of dilation and constriction. With constriction of the pupil there is a

superior and nasal movement, which is normal. Visual acuity may change significantly depending upon the state of pupillary dilation.

The normal pupillary shift in patients undergoing refractive surgery has been documented as 177 μm .² Among the outliers, 10% of patients had a 300- μm or more shift. These data show that significant visual disparity exists between different levels of illumination. Pupillary movement can cause induction of higher-order aberrations with an IOL with negative or positive spherical aberration built into the optic. If there is normal variability of IOL positioning in the eye and normal pupillary movement, a large number of patients may have induced higher-order aberrations. Coma is caused by IOL decentration and results in glare and halos.

Hunkeler: Would IOLs shift similarly in pseudophakic eyes? With current IOL designs that rest in either the posterior chamber or capsular bag, the iris is planar.

Donnfeld: There is no evidence to suggest pupillary movement is different in phakic vs. pseudophakic eyes, but this should be investigated.

Hunkeler: In my experience, the movement is restricted in pseudophakic eyes because the iris vaults over the natural lens.

Lindstrom: Night vision symptoms can create a challenge for an ophthalmologist. Many patients have 20/20 Snellen visual acuity but do not see as well as they would like at night. What have we learned from our refractive surgical experience about ghosting, halos and glare in night vision?

Slade: From a refractive surgery standpoint, an aberration-free lens would seem to be the best type of IOL to combat night vision symptoms and avoid adding aberrations to the visual system.

Lindstrom: Imagine that an ophthalmologist has many kinds of IOLs available, so that, after measuring the patient with some form of corneal-surface aberrometry and calculating for age, the appropriate IOL could be chosen. If the surgeon is unable to perform a perfect capsulorrhexis or has a tear in the anterior capsular rim, a quick switch could be made to an IOL appropriate for these situations.

In your opinion, how many ophthalmologists would switch out IOLs this way compared to how many will use the same IOL for every situation because of its successful track record?

Slade: Too many variables or “built-in” aberrations would hinder an ophthalmologist’s ability to select an IOL that is able to take a preemptive strike on induced aberrations. An IOL with no spherical aberration power or that is neutral across the eye makes the most sense to me.

Patient criteria

Hunkeler: What is the ideal IOL for a patient who has undergone previous refractive surgery?

Lindstrom: This is a good question. Some patients who have had previous refractive surgery often complain of clinical symptoms that include ghosting and night vision problems. Preoperative measurements may help when

deciding what type of IOL to use in these patients to achieve better functional vision after surgery. However, if a patient has serious symptoms that are related to aberrations, it is worth trying to find an IOL that can improve the patient’s vision.

Donnenfeld: The situation depends on the type of refractive surgery the patient has had, but in cases where photoablation was used prior to the availability of custom treatments, tremendous amounts of positive spherical aberration were induced. For those patients, an aspheric or aberration-free IOL is the best choice. To implant a conventional IOL in this type of patient would be a mistake and would actually make the vision worse, except in cases of hyperopia. In patients who have had previous hyperopic photoablations, negative spherical aberrations have been induced in the cornea, so in these cases, a conventional IOL is most likely the best choice. The second

most common choice is an aberration free IOL followed by an aspheric IOL, which is chosen in rare cases.

Nichamin: In my practice, we have mostly stopped performing LASIK in patients older than 50 years of age for both hyperopia and myopia. These older patients, especially those with myopia, have some degree of nuclear sclerosis and changes taking place in their crystalline lens. We learned this through experience after performing initially successful LASIK for patients in this age group and having some come back with complaints. We originally thought that we had induced higher-order aberrations with LASIK, but soon learned that it was the changes in the lens that were causing problems.

Hunkeler: Where is the center of the optical zone on the cornea after previous refractive surgery and can it be matched to the center of the IOL?

Lindstrom: The center of the optical zone will be different for every patient because the center of



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—*Rosa Braga-Mele, MD*

treatment in a refractive procedure is often decentered in any of the 360° meridians. The pupil usually moves nasally and inferior as it constricts, but there is no way to determine where the center of the ablations will be prior to implanting an IOL.

Lindstrom: Are there any contraindications for implanting the SofPort AO IOL?

Braga-Mele: Overall, I cannot think of any patient for whom it would be unsafe.

Fine: The aberration-free SofPort AO is appropriate for all patients. It would be hard to find patients who are not good candidates for the SofPort AO because this IOL does no harm.

Hunkeler: As Dr. Donnenfeld stated earlier, I would avoid implanting an negative-aberration aspheric IOL in patients who have previously had refractive surgery to correct hyperopia.

Braga-Mele: I agree that an aspheric IOL with negative spherical aberration would not be a good choice for this patient because it would add to the sphericity of this cornea, but the aberration-free design of the SofPort AO would have no negative effects.

I would recommend to any surgeon that keeping the aberration-free SofPort AO IOL in their inventory is a good idea.

procedure. Because of this, it is important that cataract surgeons correctly measure their preoperative spherical aberration and work to correct it with an IOL. I believe that the SofPort AO will achieve this correction for many patients.

Lindstrom: The typical surgeon has traditionally used standard IOLs with positive spherical aberration and has achieved good results. How does a surgeon need to adjust his or her workup for patients who are receiving the SofPort AO?

Donnenfeld: I do not think the workup needs to be adjusted. Surgeons can just expect better visual results with this IOL.

Lindstrom: Would you consider a patient with keratoconus a candidate for the SofPort AO?

Donnenfeld: I would have reservations about implanting the SofPort AO in a patient with keratoconus because they have high negative spherical aberration. A conventional IOL would decrease the aberration, a SofPort AO would keep it the same and an aspheric IOL would increase the aberrations. More research must be performed for how the IOL performs in these patients.

Lindstrom: Dr. Braga-Mele, you said earlier that this

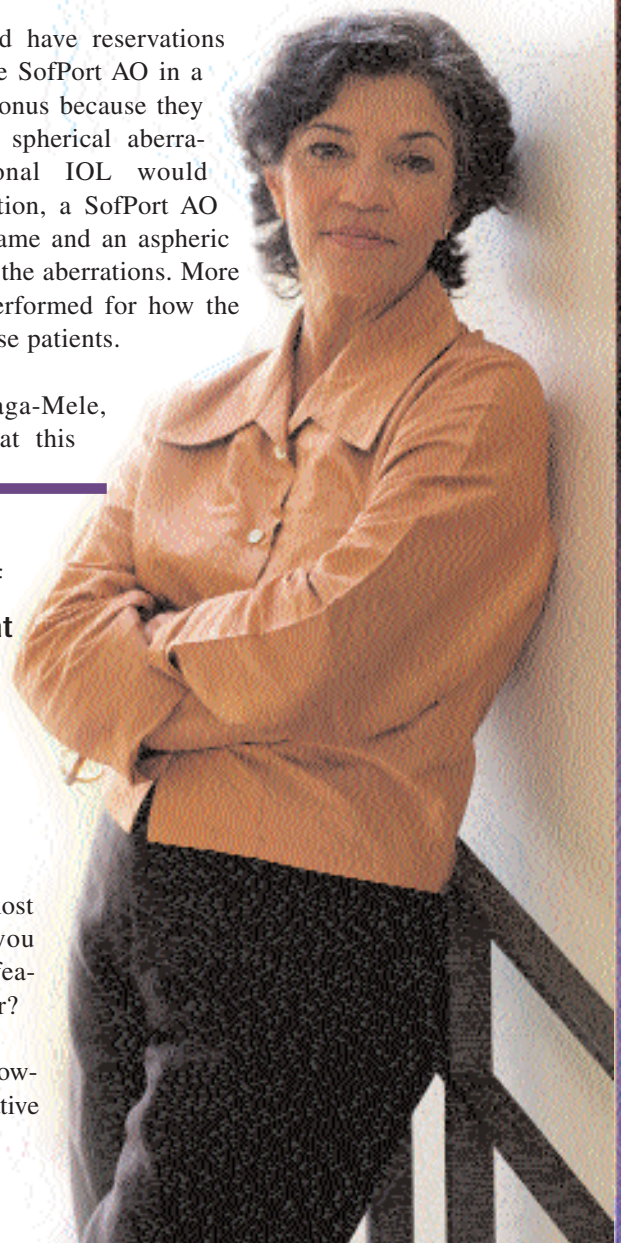
Ophthalmologists are quickly filling the world with patients who have had some kind of refractive procedure and many of these patients will develop cataracts ... there is no reason that they will not also expect improved vision from a cataract procedure.

— *John D. Hunkeler, MD*

Hunkeler: Ophthalmologists are quickly filling the world with patients who have had some kind of refractive procedure and many of these patients will develop cataracts. These are the same patients who demand LASIK enhancements and there is no reason that they will not also expect improved vision from a cataract

IOL is safe for most patients. Would you change any design feature to make it better?

Braga-Mele: No. However, if the postoperative



visual acuity is not exactly what was desired, bioplastics can be performed to correct any aberration on the cornea, because the SofPort AO is not designed to correct any aberration.

I agree that the aberration-free aspheric IOL may not be the most appropriate IOL for cases of keratoconus and perhaps patients who have had hyperopic LASIK because of the possibility negative spherical aberration exists in their corneas.

Nichamin: The aberration-free IOL is a more forgiving platform than standard or other aspheric IOLs.

Slade: I agree. A surgeon can implant the SofPort AO IOL and not worry about the pupil or how the capsular bag will be affected during surgery. The lens itself does not add aberrations which would be influenced by the size of the pupil or capsular contractions.

Lindstrom: Medicare or hospital settings often demand that when a new technology is adopted, the old one must be discarded. In other words, inventory is limited outside of an ambulatory surgery center (ASC). Should a surgeon be comfortable giving up his or her inventory of standard IOLs and replacing them with aberration-free aspheric IOLs?

Hunkeler: I think that most surgeons will happily change their inventory when they see the benefits that these IOLs have for their patients. Surgeons will also enjoy the benefits of the insertion system for the SofPort AO, the Mport SI IOL delivery system (Bausch & Lomb), as it is extremely user-friendly.

Lindstrom: When calculating IOL power, what is the A constant for the SofPort AO?

Nichamin: For the SofPort AO, I use an A constant of 118.0 with ultrasound and 118.76 on the IOLMaster (Zeiss Humphrey, Dublin, Calif.) Axial lengths measured with the IOLMaster tend to be roughly 0.2 mm longer than lengths measured with traditional A-scans.

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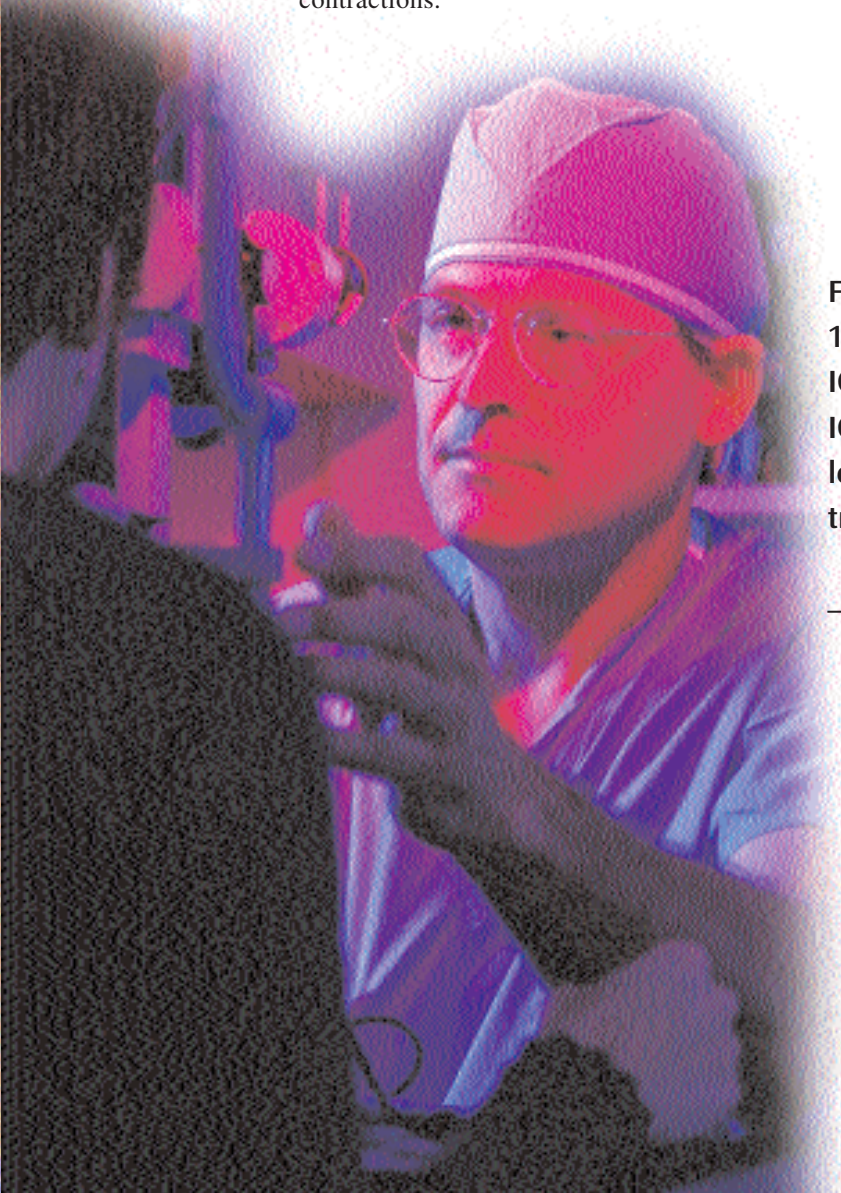
— *Louis D. Nichamin, MD*

Braga-Mele: I have personalized mine, so I use 118.1 when using ultrasonic biometry and 118.7 on the IOLMaster.

Surgical techniques

Lindstrom: How would you describe the SofPort AO and the surgical procedure for implantation to a physician who has never used a Bausch & Lomb IOL before?

Nichamin: The SofPort AO (figure 1) is comprised of third-generation silicone elastomer



material and has a 6-mm truncated optic with a 13-mm haptic to haptic length. To my knowledge, this is the only silicone IOL that gently releases in the eye without snapping open, even if implanted with forceps.

In addition, the SofPort AO has a slightly lower refractive index than the other available silicone IOLs, which may be one of the reasons that there have been no significant complaints of dysphotopsia as there has been with other truncated silicone lenses.³ The posterior capsular opacification (PCO) rates with this IOL are comparable to all of the other leading IOLs, made of both hydrophobic acrylic or square-edged designed silicone.

The haptics of the SofPort AO are made of fairly robust PMMA and hold up nicely to the Mport SI (Bausch and Lomb) delivery system (figure 2). The SofPort AO has more power distributed on its anterior surface than its posterior surface (1.3:1), a feature that lowers the incidence of dysphotopsia.

The Mport SI delivery system allows the surgeon to implant the SofPort AO through an unenlarged 2.8-mm incision. The transition to using the injector system is short, even for the novice surgeon in that the injection process is very straightforward. Once the IOL is properly loaded into the injector, the implantation procedure is a single-handed planar delivery that includes the trailing haptic.

Hunkeler: Initially, loading of the IOL can be challenging for a surgeon who is accustomed to having a technician load IOLs into injector systems. The new Easy-Load delivery system will make the SofPort insertion system unique with a planar delivery of the lens implant through a sub 3-mm incision into the capsular bag and with the spring-loaded automatic retraction of the plunger and a second push effectively placing the trailing haptic into the capsular bag as well, which is essentially a push-push maneuver to get the entire lens implant into the capsular bag. This is a very efficient and effective lens implant insertion that requires no further instrumentation in that the lens is completely delivered into the capsular bag and ready for irrigation and aspiration of the residual viscoelastic. The new Easy-Load delivery system will maintain the quality of planar insertion of the SofPort system and enhance the effectiveness of loading for the presbyopic

Bausch & Lomb AO IOL and MPort SI IOL Injector

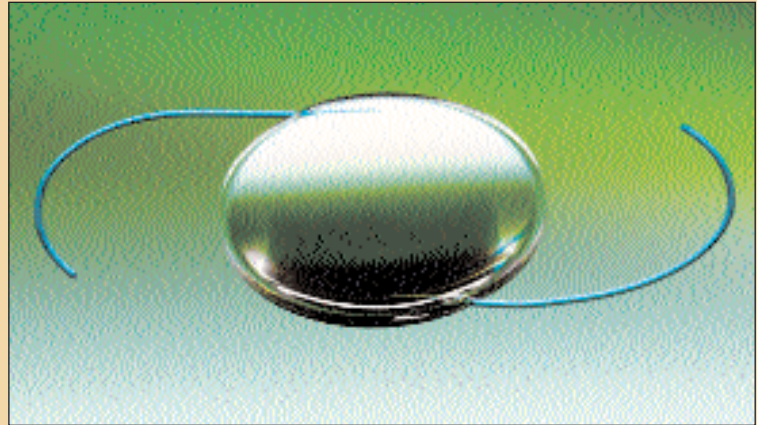


Figure 1. The SofPort AO is comprised of third-generation silicone elastomer material and has a 6-mm truncated optic with a 13-mm haptic to haptic length.

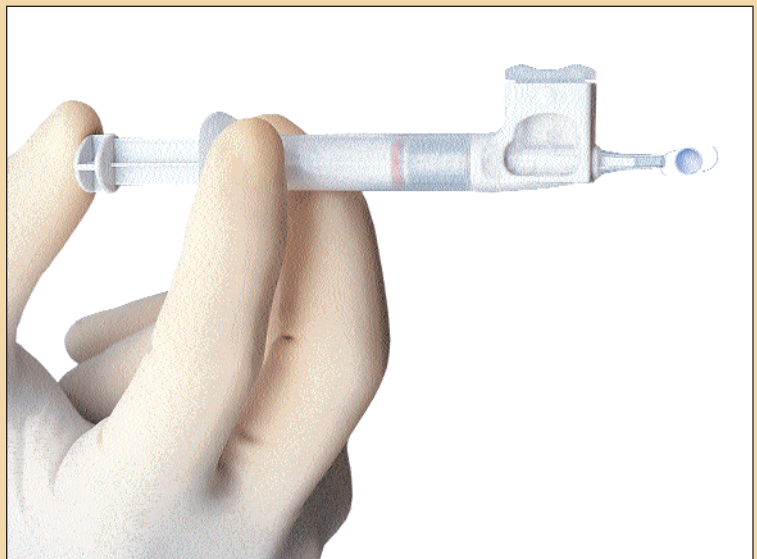


Figure 2. The MPort SI delivery system allows a surgeon to implant the SofPort AO through an unenlarged 2.8-mm phaco incision.

(All Figures courtesy of Bausch & Lomb.)

surgeon or assistant attempting to load the current SofPort cartridge.

Braga-Mele: When implanting the IOL through a 2.8-mm incision, there is no tension or fraying of the IOL edges and no postoperative wound leakage. An attractive feature on the Mport SI is that which allows the surgeon to insert the trailing haptic with the plunger, making this a true closed-system delivery.

because movement of this IOL in the sulcus is less critical due to the aberration free optic.

Lindstrom: In our practice, we consider the current generation silicone used in the SofPort AO to be good material for use in high-risk cases where patients have mild inflammation. However, many retinal specialists are still resistant to using silicone. I have many patients who have undergone retinal surgery and subsequently developed cataracts, and have been referred by a retina specialist. These patients tend to be more resistant to my using an IOL made of silicone because of what they have been told by their retinal specialists.

Nichamin: We have an unusual practice in that we specialize in both anterior and posterior segment ophthalmology. As such, we must entertain retinal considerations frequently and it is actually rather rare to find a patient that has a true contraindication for a silicone IOL. I am finding that, slowly and steadily, more vitreoretinal specialists are changing their view on silicone implants. The literature is now replete with documentation that the latest generation of silicone elastomers are just as biocompatible as those that are acrylic. The only real contraindication for silicone is in an eye that has both an open posterior capsule and one that requires a silicone oil tamponade.

The SofPort AO IOL also has wide utility in that it can be implanted in the sulcus, has a 6-mm haptic diameter, and is comprised of a material that does not cause iris chafing and once again is extremely forgiving in regard to decentration.

Donnenfeld: When implanting any IOL in an eye with a torn capsule, the surgeon must be concerned with centration. A decentered conventional IOL or a negative aspheric lens can induce significant high order aberrations. In these cases an aspheric lens offers a significant advantage.

Lindstrom: Dr. Hunkeler, many of the patients on

whom you perform cataract surgery are referrals from other ophthalmic specialists. Is there a group of patients for whom you select an acrylic IOL, or are you comfortable using silicone for all of your patients?

Hunkeler: I agree that some retinal specialists are adamant that patients with a history of diabetic retinopathy with vitrectomies receive acrylic IOLs, but most referring ophthalmologists do not object when I implant a silicone IOL in a patient who has undergone macular hole surgery. The good results that I have achieved in the past have helped to ease resistance to silicone.

In regard to surgical technique, surgeons must be aware that if they are using Healon5 (AMO), the process is slightly different. Normally, the closed implantation system that the Mport SI offers will initiate IOL rotation clockwise once the IOL is injected. However, if the surgeon is using Healon5, the IOL will not rotate, so if he or she tries to jam it into the eye, the IOL may come out the other side of the capsule. A dial-in technique is best in this situation.

Braga-Mele: What Dr. Hunkeler refers to happened to


me the first time I used Healon5 with the SofPort AO. A surgical pearl that will help with implanting this IOL correctly is that the injector should not be too far inside the eye because it may push the lens completely through the capsule, but it must be far enough inside so that the IOL delivers into the capsular bag.

Also, surgeons must be careful not to overfill the capsular bag with Healon5, as is done with other types of viscoelastic.

Clinical results

Lindstrom: What have the clinical results been with the SofPort AO IOL?

Slade: Clinically, I have found that the SofPort AO injects more quickly and easily than any other IOL I have used.



Younger patients may prefer the SofPort AO because they have not undergone the changes to the crystalline lens that occur naturally with age and they are accustomed to a higher degree of contrast sensitivity.

— Eric D. Donnenfeld, MD

I first implanted SofPort AO IOLs in patients who had another IOL in their fellow eye. The reaction that I received from these patients has typically been that they are happier with the SofPort AO and that their quality of vision is better with this IOL. The patients usually offer these comments spontaneously.

Fine: I have had good results with the SofPort AO, but my experience remains limited with this IOL in that I have not had the opportunity to test all of my patients who received it. Additionally, a comparative study between the SofPort AO and the Tecnis IOL is being planned in which contrast sensitivity of the two IOLs is studied.

I have not had any problems with the SofPort AO after implanting 25 to 30 of these IOLs. The SofPort AO is easy to implant and the eyes look good postoperatively.

Nichamin: Physicians in my practice have implanted several hundred of these IOLs and randomly interviewed patients who have a standard IOL in one eye and the SofPort AO in the other. Anecdotally, no patients preferred the standard IOL, and a fair number of patients, particularly older individuals, voice no particular preference. There are, however, a number of patients who do report a preference for the SofPort AO. These patients tend to be younger, more articulate and discriminating patients.

A prospective, randomized trial is currently underway that will add clinical support to these anecdotal findings.

Donnenfeld: Younger patients may prefer the SofPort AO because they have not undergone the changes to the crystalline lens that occur naturally with age and they are accustomed to a higher degree of contrast sensitivity. Older patients have had peripheral thickening of the lens and have lost contrast sensitivity so they will not see any difference between their crystalline lens and a conventional IOL. Younger patients with mild cataracts and minimal glare, halo and contrast sensitivity loss will appreciate aspheric IOL technology the most.

Lindstrom: In my experience with refractive surgery, patients reported a better quality of vision when I added wavefront-driven customization to LASIK and induced less spherical aberration. However, this improvement was subjective and particularly involved mesopic and scotopic vision, not Snellen acuity.

Nichamin: I agree. Snellen acuity versus quality of vision, especially in regard to night vision and contrast sensitivity, are two separate measures.

Lindstrom: Has anyone had to explain the SofPort AO due to severe visual dysfunction or dysphotopsia?

Nichamin: The incidence of explantation is zero in more than 5,000 IOLs implanted.

Lindstrom: An incidence of zero explantations supports that the SofPort AO does not seem to induce any negative visual effects. The explantation/exchange rate across IOLs is between 0.5% to 1.0%, with a slightly higher rate — 2% to 3% — for multifocal IOLs.⁴


Have any of your patients complained about ghosting or trouble driving at night?

Nichamin: No. With other higher-index IOLs I implant, I occasionally have patients who have routine, successful surgery and while the IOL looks fine in their eye upon examination and their Snellen visual acuity is satisfactory, they continue to complain of multiple side effects.

Lindstrom: Have you implanted the SofPort AO in any patients who have had previous LASIK?

Nichamin: Yes. I have implanted the SofPort AO in a number of post-RK and LASIK eyes. I believe that this implant is specifically indicated in these challenging eyes.

Reimbursement/economic concerns
Lindstrom: An important factor in considering which IOL to use for patients is cost. For Medicare purposes, is the SofPort AO IOL



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— *Richard L. Lindstrom, MD*

considered a standard or a new technology IOL?

Hunkeler: In order to receive new technology IOL (NTIOL) status for Medicare reimbursement in an ASC for this IOL, Bausch & Lomb must apply to Centers for Medicaid and Medicaid Services (CMS) with documentation as to why this lens yields superior outcomes to standard IOLs. This can only be done after a clinical trial is completed. The application for the Tecnis Z9000 IOL is currently under review by Medicare, and whether AMO receives approval will have a significant impact on if Bausch & Lomb receives approval for this additional \$50 reimbursement.

Fine: In an ASC setting, the added cost of the IOL to the surgeon is compensated for by the added reimbursement to the surgeon. I am not sure what the prevailing opinion of hospital administration will be with respect to higher-priced IOLs. In our ASC, we use all technologies that are proven to have an advantage for patients in terms of enhanced outcomes.

Lindstrom: Would you pay more for the SofPort AO lens compared to the cost of a standard IOL?

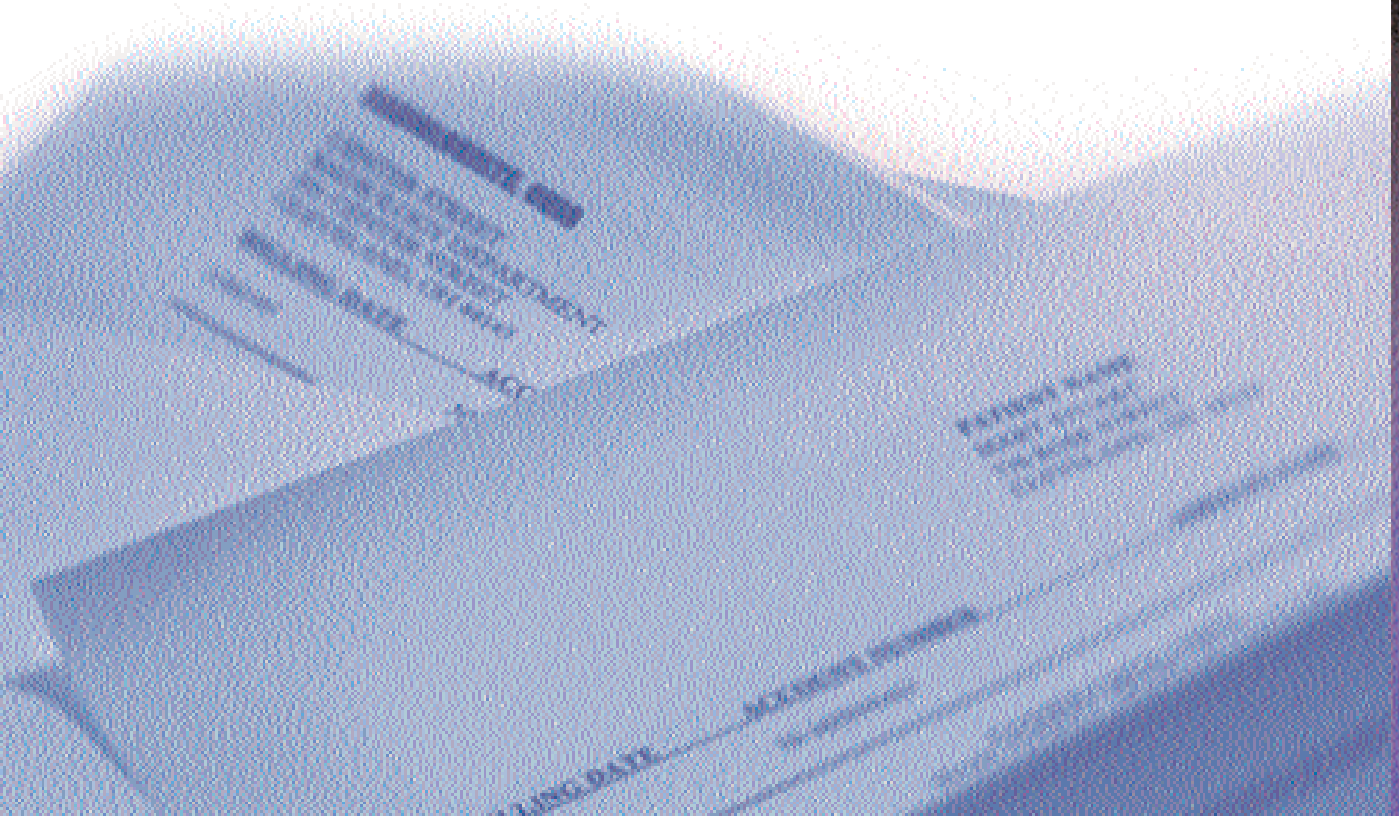
Hunkeler: Yes. New technology is worth the added cost and research and development (R&D) is not free. If surgeons want low costs, plenty of PMMA IOLs can be inserted through large incisions that cost less.

Lindstrom: The majority of my patients who undergo cataract surgery appreciate whatever kind of vision I can restore for them. However, it is worth the added cost to be able to improve quality of vision and not induce any new aberrations and night vision symptoms.

Slade: I agree with Dr. Hunkeler. Those in the ophthalmic industry must get over the issue of higher prices for better technology. We know that R&D costs money and so we can pay the added costs ourselves, have the patients pay or lobby CMS for reimbursement. Ophthalmologists are not helping themselves or their patients if they fight rising R&D costs.

In an ASC setting, the added cost of the IOL to the surgeon is compensated for by the added reimbursement to the surgeon. In our ASC, we use all technologies that are proven to have an advantage for patients in terms of enhanced outcomes.

— *J. Howard Fine, MD*



Donnenfeld: As a surgeon and an owner of an ASC, my primary concern is always going to be what is best for the patient. Having said that, there is cost-effectiveness to implanting an IOL that will offer better quality outcomes. With better results, a surgeon will grow his or her practice and increase patient satisfaction, resulting in more profitability in the long-term.

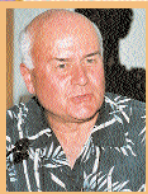
It is important for surgeons to understand that, while they might lose some money per case implanting more expensive IOLs, in the broader picture, the financial bottom line will be better overall if the quality of patient care improves.

Lindstrom: I own an ASC and also work in a not-for-profit ASC, as well as a small, privately owned community hospital. In my own ASC, I have already traded out my IOL inventory for the SofPort AO, but I have not been able to convince the not-for-profit ASC or the private hospital to do the same, even though the outcomes are better with this IOL.

Nichamin: Ophthalmologists will see similarities in how the situation evolves with the SofPort AO and in how customized ablation ended up fitting into our practices. The SofPort AO is better technology and it costs more. Cutting-edge ophthalmologists will adopt this technology initially, and others who want to grow their practices and establish themselves as leaders in the ophthalmic community will follow. Just as a certain percentage of ophthalmic surgeons became early adopters of customized ablation, we will see a percentage of leading surgeons quickly embrace this IOL. More users will then enter the market as the technology's benefits are further substantiated.

Slade: Patient perspective is also important to consider when discussing the cost of advanced technology. Two technologies on which patients have been well educated by the media and Internet are accommodative IOLs and LASIK. Patients come

into my office and ask specifically for the Crystalens accommodative IOL (eyeonics, Aliso Viejo, Calif.) by name as well as customized ablation. I would not be surprised if patients were also to ask directly for an aberration free IOL. If patients are well educated on new technologies, they demand them.



I see no reason to go back to using standard-optic IOLs.

The SofPort AO adds significant value to what ophthalmologists can offer their patients and I expect this technology to continue to improve visual outcomes.

— *John D. Hunkeler, MD*

Braga-Mele: Clinical data to support the fact that aberration-free IOLs are superior and worth the extra cost must be made available. Hospitals are always concerned about budgets, so suspicion naturally arises from the administration if the cost of a new IOL is higher than what they have been paying for other technology. However, if the SofPort AO is clinically proven to provide better patient outcomes, acceptance will be more likely.

Donnenfeld: In many cases, cataract surgeons are dealing with patients who are elderly and we are seeking to improve their quality of life. If a patient

has the ability to see at night under low-contrast scotopic conditions, they will be able to drive and lead a more productive visual life — the standard-optic IOLs do not provide that degree of freedom.

In refractive surgery, it is general practice to listen to patients to assess their visual needs. With the aspheric IOLs that are available, we now have the ability to do the same for our cataract patients. Listening to my refractive surgery patients' needs for better vision and fewer side effects convinced me to switch from conventional to customized ablation and the same will be true with the new aspheric IOLs.

Future impact of aspheric IOLs

Lindstrom: Are you convinced that aspheric IOLs are the new direction in IOL technology?

Nichamin: I see no reason not to be fully committed to aspheric IOL technology. As was said earlier in this discussion, unless there is a distinct contraindication for silicone, the SofPort AO can

be used for every patient undergoing implant surgery.

Slade: I would be more hesitant to commit to the SofPort AO if it were not an aberration-free IOL. However, as it is, this IOL is neutral, safe and effective.

Hunkeler: I see no reason to go back to using standard-optic IOLs. The SofPort AO adds significant value to what ophthalmologists can offer their patients and I expect this technology to continue to improve visual outcomes.

I would like to see additional features added to the aberration-free IOL such as a multifocal component.

Lindstrom: I agree. An accommodating component to the SofPort AO IOL would also be interesting to investigate.

Braga-Mele: I also think this IOL may be the ideal design for adaptation into dual-optic IOLs because if the two optics shift laterally over one another or tilt there would be less induction of aberrations.

Fine: IOL technology is rapidly expanding and now includes accommodative and light-adjustable IOLs. Ophthalmologists will see a cross-licensing of technologies that will allow for extremely precise, customized IOLs.

Donnenfeld: Not only do I plan to switch to aberration-free aspheric IOLs exclusively, I also plan to tell my partners that these are the best IOLs to use for most cataract surgeries. Our reputation in the community is to provide the highest quality of

care and this is another step in the right direction.

Moving forward, the ability to control aberrations, possible chromatic aberration and improve quality of vision will significantly raise the bar in cataract surgery by visually rehabilitating patients to a new level.

Lindstrom: Dr. Braga-Mele, how hard do you think it will be for surgeons in Canada to be able to use the SofPort AO?

Braga-Mele: Although I have no doubt there will be a certain degree of pushback from health care administrators in Canada, my hope is that this IOL becomes the standard of care.

Lindstrom: I am looking forward to the results of the prospective clinical trial on the SofPort AO so that ophthalmologists will have more introduction regarding its clinical outcomes.

I would like to thank the faculty for participating in this informative discussion. I would also like to thank Bausch & Lomb for its sponsorship and continued dedication to improving patient care and SLACK Incorporated for organizing this symposium and monograph project.

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