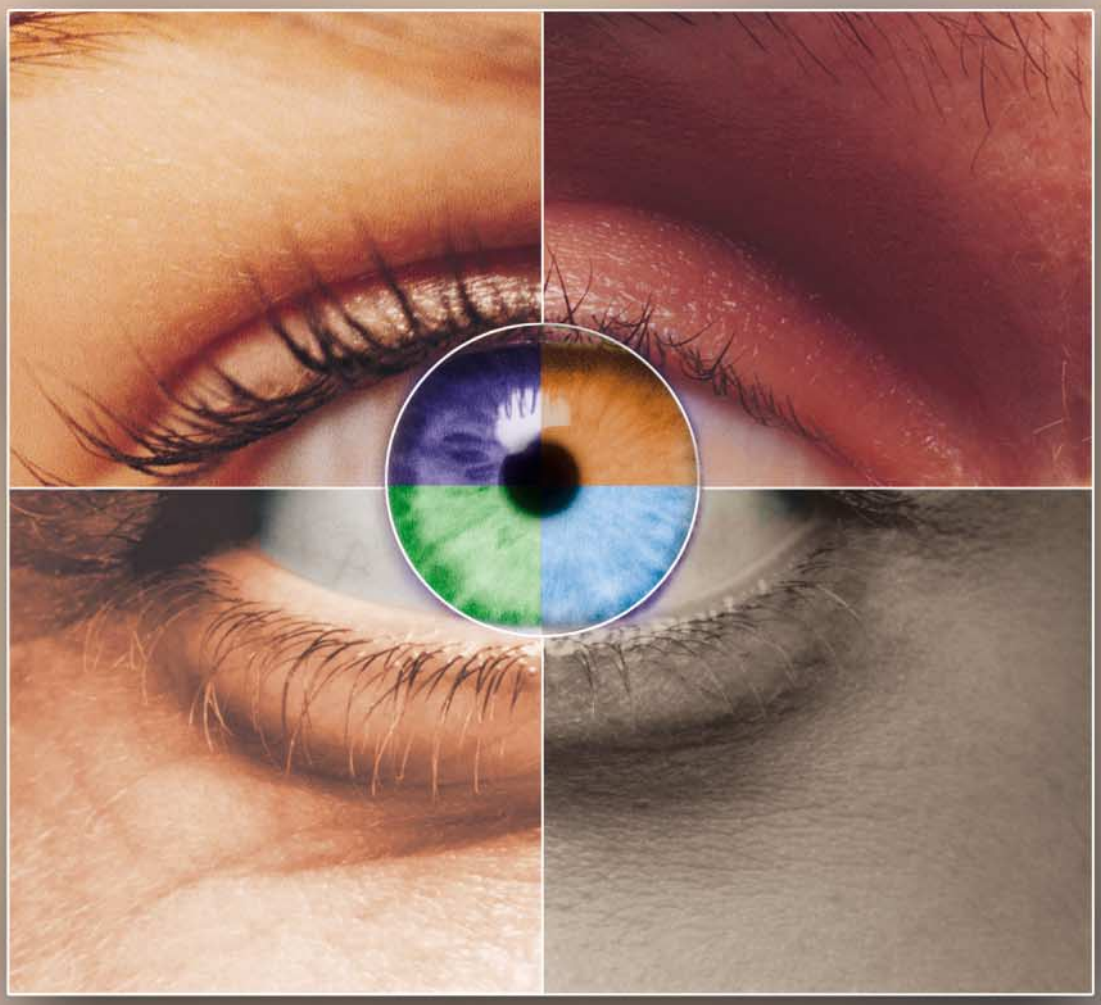
OCULAR SURGERY NEWS
EUROPE/ASIA-PACIFIC EDITION

November 2001

# The Impact of Design & Material on ACRYLIC LENS PERFORMANCE



Sponsored by Allergan Surgical

# Introduction

Design and material play important roles in IOL selection. The new acrylic IOLs that are becoming available to ophthalmic surgeons throughout the world offer more choices than ever before. These IOLs have been designed to help minimize and prevent optical side effects and create easier, safer procedures to benefit both the surgeon and the patient.

OCULAR SURGERY NEWS Europe/Asia-Pacific Edition has assembled a panel of seven ophthalmologists from the United States, Thailand, Korea, Australia, India, and Indonesia to discuss their experiences with various IOL designs. This discussion will include consideration of the impact of IOL design and material on the incidence of side effects, as well as the effects of implantation technique and incision size.

I would like to thank the faculty for their participation in this important discussion and Allergan Surgical for sponsoring this OCULAR SURGERY NEWS Europe/Asia-Pacific Edition symposium and monograph project.

Richard L. Lindstrom, MD
Chief Medical Editor
OCULAR SURGERY NEWS Europe/Asia-Pacific Edition

**David Chang, MD, Moderator,**
*is a member of the OCULAR SURGERY NEWS editorial advisory board and is clinical professor at the University of California, San Francisco, U.S.A.*

**Stephen Bambery, FRACO, FRACS,**
*is a surgeon at the Southern Eye Centre, Day Surgery and Laser Clinic in Frankston, Australia.*

**Dr. Sri Ganesh,**
*is a surgeon at the Nethrahama Eye Clinic and Surgical Center in Bangalore, India.*

**Choun-Ki Joo, MD, PhD,**
*is a professor in the Department of Ophthalmology & Visual Science at the College of Medicine, The Catholic University of Korea in*

**Seung Jeong Lim, MD, PhD,**
*is director of the Seran Eye Center and clinical professor of ophthalmology at Yonsei University in Seoul, Korea.*

**Pannet Pangputhipong, MD,**
*is a surgeon at the Mettapracharak Hospital in Nakornpathom, Thailand.*

**Istiantoro Soekardi, MD,**
*is a surgeon at the Jakarta Eye Center in Indonesia.*

## Introduction

**David Chang, MD:** Until recently, the only acrylic IOL available was the three-piece AcrySof (Alcon Laboratories, Fort Worth, U.S.A.). However, a variety of acrylic lenses are now available, so we must be specific in terms of what class and design of acrylics we are discussing. For example, there are currently three different models of the standard hydrophobic lenses: the single-piece AcrySof SA30AL (Alcon Laboratories), the three-piece AcrySof MA60BM (Alcon Laboratories), and the Sensar Posterior Chamber Acrylic IOL (Allergan Surgical, Irvine, U.S.A.). Additionally, lenses made of hydrophilic acrylic are now available, such as the MemoryLens (CIBA Vision Ophthalmics, Duluth, U.S.A.), the HydroView (Bausch & Lomb, Claremont, U.S.A.), and the Collamer lens (STAAR Surgical, Monrovia, U.S.A.).

Dr. Pannet, what is your lens of choice?

**Pannet Pangputhipong, MD:** When I first began performing cataract surgery 10 years ago, I used the SI30 (Allergan Surgical). In 1994, the first three-piece acrylic lens, the AcrySof MA60BM, became available and I began using that lens.

Since that time, the ophthalmologists in my hospital have implanted 8,500 acrylic IOLs. In 1997, approximately 39% of the lenses that we implanted were acrylic. This figure increased to approximately 71% in 1998, 89% in 1999, and in 2000, approximately 99% of the lenses that we implanted were acrylic.

I first used a hydrophilic hydrogel IOL in 1997. This lens accounted for approximately 2% of the lenses implanted in my hospital in 1997. Although the percentage increased to 9% in 1998, we stopped using the hydrophilic hydrogel completely because of the poor results that it achieved in patients. In almost 90% of cases, epithelial downgrowth appeared on the lens surface, outside of the visual axis.

The Sensar IOL became available in our hospital 1 year ago, and the results have been at least as favorable as the results of the AcrySof lenses.

**Seung Jeong Lim, MD, PhD:** In the past 10 years, I have performed more than 10,000 cataract procedures. In those 10,000 procedures, I have used approximately 7,000 to 8,000 silicone IOLs and 2,000 to 3,000 acrylic IOLs. I currently prefer acrylic lenses to silicone lenses. Approximately half of the acrylic lenses I use are AcrySof and half are Sensar IOLs. However, I must note that I still prefer the silicone Array Multifocal IOL (Allergan Surgical) for patients who would benefit from a multifocal lens.

The first-generation silicone lenses possess polypropylene haptics, which can become deformed in the capsular bag and cause posterior capsular opacification (PCO). PCO is caused not only by the optic material, but also by the configuration of the haptic material.

**Choun-Ki Joo, MD, PhD:** I have implanted approximately 10,000 IOLs — 50% of which have been acrylic and 50% silicone.

If the smallest possible incision is indicated for surgery, I tend to prefer silicone. However, since I began implanting the Sensar acrylic lens, I have used the Unfolder Sapphire Implantation System (Allergan Surgical) and have been pleased with the smaller incision that this device allows over forceps insertion.

Another concern that I have had in the past with acrylic lenses is astigmatism. The rate of postoperative astigmatism at 1 week is lower using the Unfolder Sapphire to implant the Sensar, compared to implanting the AcrySof with a forceps folding technique.[1]

When implanting an IOL in a patient who has diabetes or a history of uveitis, I prefer an acrylic IOL to a silicone IOL, because of better biocompatibility.

*… since I began implanting the Sensar acrylic lens, I have used the Unfolder Sapphire Implantation System and have been pleased with the smaller incision that this device allows over forceps insertion.*

**Choun-Ki Joo, MD, PhD**

*The Sensar can be implanted through a smaller incision than the AcrySof and the edge glare and unwanted images are not as prevalent.*

**Stephen Bambery, FRACO, FRACS**

**Stephen Bambery, FRACO, FRACS:** I implant approximately 700 IOLs each year, primarily silicone lenses.

In the past, I primarily implanted silicone plate-haptics lenses, but I switched to the PhacoFlex II Model SI40 (Allergan Surgical) with PMMA haptics because of problems of damage to the plate haptics during implantation.

Currently, two-thirds of the IOLs I implant are silicone and one-third are acrylic. The acrylic lenses that I am using are evenly split between the AcrySof and the Sensar lens. The Sensar can be implanted through a smaller incision than the AcrySof and the edge glare and unwanted images are not as prevalent.

In my experience, it is too early to compare the PCO rates of the AcrySof with the Sensar because of the debate over whether edge design or material plays a role in PCO rates.

**Dr. Sri Ganesh:** I have been performing cataract surgery in India for 7 years, during which time I have implanted more than 6,000 IOLs. When I first began performing cataract surgery, I was implanting 5.5-mm PMMA lenses. I started implanting foldable silicone IOLs with forceps. However, I found this technique to be difficult because the first-generation silicone lenses tended to slip out of the forceps during implantation.

When the Unfolder became available, I used it to implant more than 3,500 silicone lenses. Recently, I have begun using AcrySof and Sensar lenses but I prefer the Sensar because I can use the Unfolder Sapphire, which I prefer to forceps.

I switched to acrylic IOLs because 60% to 70% of my patients have diabetes and may require future retinal procedures. I also have found that postoperative uveitis is less frequent and biocompatibility is better with acrylic IOLs.

**Istiantoro Soekardi, MD:** I practice ophthalmology in a private hospital and teach in a university. I first performed cataract surgery 12 years ago using PMMA lenses. The first foldable IOL that I used was the STAAR AA series plate haptic lens (STAAR Surgical) implanted with an injector. I found that there were many complications with this lens, such as anterior capsule contraction, so I switched to the PhacoFlex II Model SI30 (Allergan Surgical) and SI40 implanted with the Unfolder implantation system.

In the past, for patients with diabetes, I implanted the three-piece AcrySof. But 6 months ago I began using the Sensar with the Unfolder Sapphire because I prefer to create a standard-sized incision. With forceps, a larger incision is often required to correctly center the lens. I also prefer the clearer optic of the Sensar.

## Biocompatibility

**Chang:** There are many factors affecting postoperative inflammation. Some of these factors are surgical, such as the amount of operative trauma, prolonged surgical time, and retained cortex. Some factors are related to patient characteristics, such as the presence of diabetes or glaucoma. Finally, many surgeons are concerned about how different IOL materials react in higher risk patients with diabetes, glaucoma, uveitis, or those who have undergone combined procedures. For these patients, our goal is to seek the most immunologically inert material that minimizes any potential inflammation related to the IOL.

What is the definition of biocompatibility? Why is it an important consideration when choosing an IOL?

**Ganesh:** Biocompatibility is how the body's immune system reacts to foreign material. For example, it has been found that when an acrylic IOL is introduced into the eye, many patients' eyes react with only a low incidence of giant cell formation and uveitis.

Many patients who have diabetes have developed postoperative uveitis after implantation with silicone IOLs. I find that the rate of postoperative uveitis is lower when I use acrylic IOLs for such patients. The patient can discontinue

steroids earlier and will be more comfortable.

**Joo:** I performed laboratory studies several years ago that tested the capacity of different lens materials for holding giant cells. In this research, silicone was shown to hold more cells than PMMA or acrylic by maintaining a stronger adherence to the cells. This was only shown to be true in the early postoperative period.

**Lim:** Cell deposition on lens material is only a small part of the biocompatibility issue. We cannot state that silicone is the least biocompatible material based only upon the fact that most inflammatory cells adhere to silicone.

**Chang:** I agree with Dr. Lim. Overall, the biocompatibility of all lens materials that we are currently using is good, which is the reason why IOL problems are so rare. The problem with many anecdotal reports regarding biocompatibility is that it is hard to know how much anterior chamber inflammation relates to the IOL versus the surgical technique itself. Early postoperative inflammation is a normal result of any surgery, and cannot be attributed to the IOL. I believe IOL biocompatibility is best evaluated by specular microscopic measurements of giant cell deposits at 30 days or later, when the anterior chamber is otherwise quiet. Furthermore, because there are so many factors affecting inflammation, randomized studies are necessary to isolate the IOL material as the variable.

There are several randomized studies that meet this criteria. Giuseppe Ravalico, MD, published a study in 1997 comparing PMMA, heparin-surface modified PMMA, and second-generation silicone (SI30). He found that the material with the highest incidence of giant cell formation was PMMA, the next highest was heparin-surface modified PMMA, and the material associated with low to no incidence of giant cell formation was the second-generation silicone.[2]

Emma Hollick, MD, and David Spalton, MD, conducted a study in order to compare the HydroView, PMMA, and the second-generation SI40 lenses. Again, PMMA had the highest incidence of giant cell formation, but no cells appeared on the SI40 or the HydroView lenses.[3]

From these randomized studies of giant cell deposits, we can conclude that the AcrySof acrylic, the HydroView hydrogel, and the second-generation silicone SI30, SI40, and PhacoFlex II Model SI55 (Allergan Surgical) lenses had the best biocompatibility. Each of these excelled in at least two different studies. Second-generation silicone was superior to first-generation silicone, and PMMA was consistently the worst material.

Please discuss your experience with hydrophilic acrylic lenses.

**Bambery:** I have used the H60M (Bausch & Lomb), but no longer use this lens. I was impressed by how easy this lens is to fold and handle and that it requires only a slightly larger incision than silicone lenses. However, I stopped using the H60M because I found that patients implanted with the lens had higher rates of PCO, as well as recurring PCO.

**Chang:** Did you observe anterior membranes developing through the visual axis?

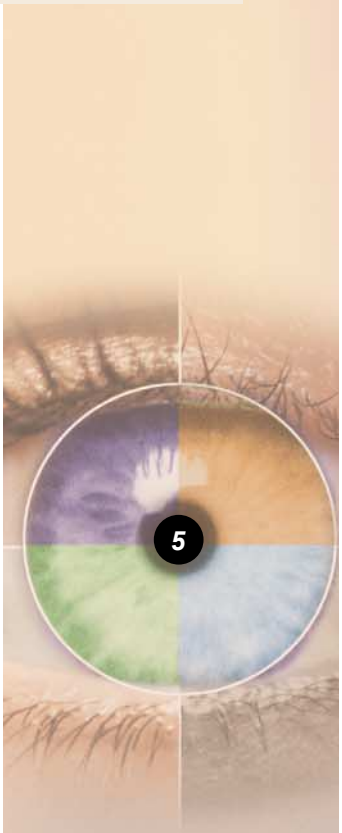
**Bambery:** I observed deposits that were scattered over the anterior surface of the IOL, many of which required a YAG procedure.

**Pannet:** I have seen epithelial ingrowth on the anterior surface of the HydroView lens beginning at the capsulorrhexis, but it has not extended into the visual axis. The incidence of cell proliferation and higher PCO rates have been unsatisfactory, so we are reducing the use of the HydroView lens.

**Ganesh:** I have used both the HydroView and the Centerflex (Rayner Intraocular Lenses, East Sussex, Great Britain) hydrophilic IOLs. When viewed under a slit lamp, these lenses have a cloudy

*The problem with many anecdotal reports regarding biocompatibility is that it is hard to know how much anterior chamber inflammation relates to the IOL versus the surgical technique itself.*

**David Chang, MD**



*A capsulorrhexis covering the edge of the IOL, good cortex aspiration, posterior and anterior capsular polishing, and placement of the IOL are some of the factors that reduce PCO rates.*

**Pannet Pangputhipong, MD**

appearance in the optic zone. I have also observed rainbow shadows after dilating patients' pupils and viewing them under the slit lamp. I believe that the high water content of these lenses causes these rainbows, but it does not affect visual acuity.

I have had no cases of uveitis or membranes on the lenses with either the HydroView or the Centerflex IOLs. However, some patients implanted with these lenses have had PCO and required a YAG procedure.

**Chang:** Majid Koch, MD, reported on the incidence of anterior membranes in a prospective series of 200 HydroView cases. One-third of patients implanted with the HydroView IOL developed epithelial cell membranes on the anterior IOL surface. When vision was affected, these eyes required YAG treatment or even surgical membranectomy in 4 cases.[4]

Drs. Hollick and Spalton have shown that the PCO rate for HydroView is also the highest among all of the materials. The higher water content of the hydrophilic lens may actually make them too biocompatible. This might explain why lens epithelial cells (LECs) grow so readily across the anterior and posterior surfaces of these lenses.[5]

The theoretical advantage of hydrophilic acrylic lenses is the increased biocompatibility in high-risk patients, such as those with uveitis, glaucoma, or diabetes. However, if this is accompanied by a higher PCO rate, then these patients are better off with a hydrophobic acrylic or a second-generation silicone lens. Both of these foldable materials are associated with low PCO rates and an intact posterior capsule is advantageous for these high-risk eyes.

## PCO rates

**Chang:** What factors affect PCO rates?

**Pannet:** There are several factors that affect PCO rates. A capsulorrhexis covering the edge of the IOL, good cortex aspiration, posterior and anterior capsular polishing, and IOL placement are some of the factors that reduce PCO rates. Additionally, the lens design affects PCO rates.

Patient factors such as age also contribute to the formation of PCO. Younger patients have higher rates of PCO.

**Bambery:** I am familiar with the studies on rabbit eyes by Okihiro Nishi, MD, that show that square edges result in an interrupted, discontinuous bend, which serves as a barrier for PCO.[6]

**Lim:** A square edge of an IOL is unable to prevent PCO. This design only delays its incidence. I have found that the amount of trauma and the extent to which the lens material is removed affect PCO rates. The configuration of the optics is also important; a biconvex, larger optic helps to prevent PCO. The capsulorrhexis must be smaller than 6 mm, and the edge of the capsulorrhexis must cover the anterior surface of the optic 360º.

**Soekardi:** In terms of PCO, is there any difference between a 5.5-mm and a 6.0-mm optic?

**Lim:** A larger optic is better. I have no data on the PCO rates of 5.5-mm acrylic lenses versus 6.0-mm acrylic lenses, but I have data on 5.5-mm and 6.0-mm optic PMMA lenses. The PCO rates of the 6.0-mm PMMA lens are lower than the PCO rates of the 5.5-mm PMMA lens.

**Ganesh:** In my practice, I have seen that there is a lower incidence of PCO in patients who receive 6.0-mm or 6.5-mm PMMA lenses than in patients implanted with 5.0-mm or 5.5-mm lenses.

Another important factor in PCO prevention is the haptic design. J-shaped loops cause striae in the posterior capsule, forming a gutter where LECs can grow. C-shaped haptics, such as those of the Sensar, do not produce striae, so no gutter exists and PCO rates are lower.

The tackiness is also relevant.

Hydrophobic acrylic lenses such as the Sensar are tacky and the posterior capsule adheres to the posterior surface of the lens. This tackiness and adhesion prevent the LECs from growing between the posterior surface of the lens and the posterior capsule, thus reducing the PCO rate.

The capsulorrhexis must be smaller than the optic. I prefer to do a 5-mm capsulorrhexis when I am inserting a 6-mm lens to allow for a secure overlap of the lens' anterior surface. If the overlap does not exist, there is a chance that the lens may peapod out, setting the anterior and posterior capsules at opposition. This allows LEC migration, increasing PCO.

I have also used capsular tension rings to lower the PCO rate. Capsular tension rings may cause necrosis of the LECs in the equator and also reduced posterior capsule striae. Capsular tension rings stretch the capsular bag and prevent striae in the posterior capsule. The capsular bag is also stretched, pushing the posterior capsule forward for better opposition of the posterior and anterior capsule.

**Chang:** Dr. Nishi first hypothesized that the creation of a kink in the posterior capsule, such as with a capsular tension ring, can serve as a barrier for LECs. He has demonstrated this in cell culture and in rabbits. He now also believes that having the optic edge indent the posterior capsule in the early postoperative period is important. An "all on" capsulorrhexis, angled stiff haptics, and a sharp posterior edge all combine to create this early kinking of the posterior capsule.

**Lim:** Dr. Nishi may have initially advocated the use of a capsular tension ring to stop PCO, but he eventually found the results of his study to be disappointing. His final results showed that the square-edge optic delays PCO, but that the capsular tension ring cannot permanently prevent PCO.

**Chang:** The issue of PCO prevention is complex and multifactorial. Anecdotal reports of YAG rates are therefore not useful. Because the IOL is one of many variables and because the indications for performing a YAG capsulotomy vary, randomized studies with objective measures of PCO, such as digital photography, are needed. Only through randomization can the IOL be isolated as the study variable.

Fortunately, several such studies have been conducted. Randall J. Olson, MD, and Alan S. Crandall, MD, compared the SI30 to PMMA at 3 years and found lower PCO with the SI30 using a lens opacity meter.[7] Drs. Hollick and Spalton found the AcrySof three-piece to be superior to PMMA and a first-generation silicone at 3 years.[8] However, they subsequently studied second-generation silicone (SI30) using the same study approach. Here they found that the SI30 PCO rate was similar to the AcrySof rate from their earlier study. Hydrogel and PMMA PCO rates were worse in this study.

In a large randomized study reported in the *Archives of Ophthalmology*, Ken Hayashi, MD, used Scheimpflug photography to compare PCO rates for PMMA, SI30, and three-piece AcrySof MA60BM. Although both were superior to PMMA, the SI30 and three-piece AcrySof were statistically equal.[9]

These four randomized studies were amazingly consistent in their conclusions regarding PCO advantage. Three-piece AcrySof, SI30, and SI40 are not statistically different. However, they are all statistically superior to PMMA, hydrogel, and first-generation silicone.

## Additional considerations

**Joo:** If a patient being treated for a cataract has cells of grade 2 to 3 inflammation, I would prescribe a topical steroid and oral medication. If the inflammation remains, I would recommend a heparin-coated PMMA lens because PMMA has achieved good results for more than 50 years. What IOL would you recommend?

*Hydrophobic acrylic lenses such as the Sensar are tacky … this tackiness and adhesion prevent the LECs from growing between the posterior surface of the lens and the posterior capsule, thus reducing the PCO rate.*

**Dr. Sri Ganesh**

*I do not implant PMMA IOLs in patients with uveitis because incision sizes smaller than 5.5 mm are required to reduce trauma.*

**Seung Jeong Lim, MD, PhD**

**Ganesh:** I have successfully implanted several acrylic lenses for patients with cataracts and inflammation. My patients tolerate the acrylic lenses well, including the Sensar and the AcrySof. I have implanted Sensar and AcrySof lenses in 25 to 30 eyes with cataracts associated with uveitis.

**Pannet:** When acrylic IOLs first became available, I avoided using acrylic for patients with uveitis or diabetes. However, the limitations of acrylic IOLs are diminishing. Now, I implant acrylic IOLs in almost every type of patient, including children older than 18 months old.

**Lim:** I do not implant PMMA IOLs in patients with uveitis because incision sizes smaller than 5.5 mm are required to reduce trauma.

**Chang:** The SI30/40 and the three-piece AcrySof MA60BM stand out in terms of biocompatibility and low PCO rate, the most important IOL factors for patients with uveitis.

Thomas W. Samuelson, MD, performed a randomized, single-surgeon study comparing giant cell deposits on different foldable IOLs following combined phaco-trabeculectomies. These were high-risk patients who were often taking miotics and required pupilloplasties. The first-generation plate haptic silicone IOLs had the highest rate of giant cell deposits. The second-generation SI30 and SI40 had the lowest rate. AcrySof was in between, but there was a statistically significant benefit to the SI30/40 in this study of combined procedures.[10]

**Lim:** What is the difference between the optic of the first- and second-generation silicone IOLs?

**Chang:** The main difference is the center thickness. The second-generation silicone IOL has a higher refractive index, so the optic is thinner. Also, the material formulation in order to achieve the high refractive index is different.

What are some important considerations when implanting the one-piece AcrySof IOL?

**Ganesh:** There is a potential problem with the one-piece AcrySof that stems from the haptic being from the same material as the optic. If the haptic gets inverted behind the optic and comes in contact with the optic during insertion, it may adhere to the optic because of the tackiness of the material. This creates a situation in which the lens is not easily manipulated. This does not happen with the three-piece IOL because the different materials do not readily adhere to each other.

**Pannet:** When implanting the one-piece AcrySof SA30, I use a viscoelastic to lubricate inside the optic fold. I have not experienced problems with sticky haptics, but I still prefer the haptics to be tucked in such a way that they do not fall out of the capsular bag during implantation. The AcrySof's overall haptic size is smaller, so it cannot be implanted if the posterior capsule is ruptured. I believe that the only advantage of the one-piece AcrySof over the three-piece is that striae within the capsule are reduced.

**Ganesh:** There is a difference between the one-piece and three-piece AcrySof lenses because the three-piece haptics are in a J-shaped configuration. The C-shaped configuration of the three-piece Sensar IOL results in minimal stretching of the capsular bag, lower tension on the equator, more capsular contact, and thus good centration.

**Chang:** Dr. Bambery, how often do you use the one-piece AcrySof in cataract surgery?

**Bambery:** I have implanted approximately 75 one-piece AcrySof IOLs, but found that they have a tendency to produce a more myopic result than predicted. This should be corrected by adjusting the

surgeon factor in the IOL calculation formula.

Another disadvantage of the one-piece acrylic lens is that both the haptics and optics are tacky, and implantation can be difficult in cases where there is positive vitreous pressure. Specifically, movement of the lens can be retarded if the lens sticks or catches on the posterior capsule.

**Chang:** David J. Apple, MD, and colleagues have looked at the clinical consequences of anterior capsule fibrosis and contraction. In comparing three different silicone IOL designs, they found that the amount of decentration varied with the haptic design. Plate haptic IOLs had the highest incidence of decentration. Three-piece silicone IOLs with polypropylene haptics were better. However, the most stable centration was the PMMA haptics. This suggests that the stiffness of the haptic is most important for IOL centration.[11]

## Optical side effects

**Chang:** Another important consideration when selecting lenses is unwanted optical effects — collectively called dysphotopsias.

We have discussed the advantages of square-edge IOLs for PCO prevention. However, Jack Holladay, MD, has used ray tracing to show how a straight edge on an IOL can focus an oblique source of light sharply onto the macula in an arc shape. The result is that a patient may see a fleeting flash of that reflection in the macula, compared to the more diffuse reflection noted with round-edge IOLs.[12]

What is your experience with the edge glare from the AcrySof lens?

**Pannet:** A more widely dilated pupil and anterior capsule fibrosis may cause dysphotopsias, so I do not subscribe to an glare phenomenon. In the initial postoperative period, some patients complain about the light from an oblique source. This light may be related to the surface reflectivity, because during the examination when the pupil is dilated, the illuminating light reflects onto corneal endothelium. I am not sure if the reflection is prevalent in the early postoperative period and whether it improves with time.

**Joo:** I have had patients who complained of edge glare, especially with the 5.5-mm AcrySof IOL. At night, if a patient's pupils dilate, the result is an arc-like effect that is somewhat disturbing, but does not require lens explantation. I have never explanted a lens because of edge glare.

**Bambery:** I have had patients who were unhappy with edge glare effects with acrylic, plate haptic, and 6-mm silicone IOLs. Edge glare is more common with acrylic IOLs because of the reflection from the square edge and the high refractive index. However, I also have not explanted any lenses because of edge glare.

**Pannet:** Convexity of the anterior surface of the lens also reduces reflectivity. I have had some patients in whom I implanted a silicone lens in one eye and an AcrySof MA60BM, which has a flat anterior surface, in the other eye. A few days after surgery, the patient noticed a difference between the two lenses because of the reflection, not the edge glare.

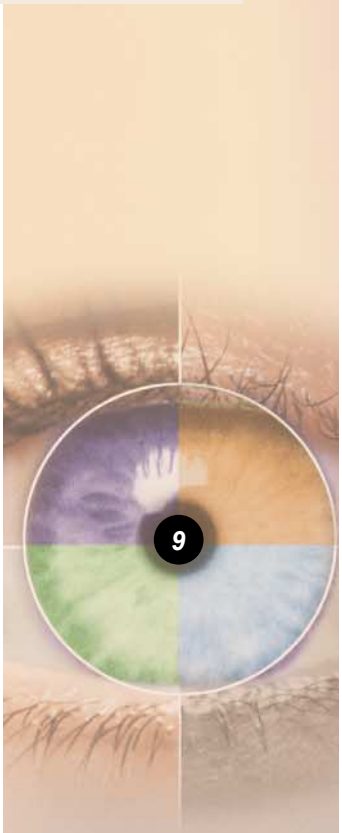
**Ganesh:** AcrySof is a planoconvex lens, so the anterior surface is flat and it reflects light like a mirror.

**Chang:** The three-piece AcrySof has the highest refractive index of any foldable IOL (1.55), and as a result, the anterior surface is virtually flat. This not only creates the external pupillary reflection, but ray tracing shows that it also creates an internal reflection back onto the patient's retina.[13]

This explains why pilocarpine does not relieve the dysphotopsias noted by some patients with the AcrySof IOL. A convex anterior IOL surface avoids this problem, and it is a feature of both the Sensar and the one-piece AcrySof.

*I have had patients who complained of edge glare, especially with the 5.5-mm AcrySof IOL. At night, if a patient's pupils dilate, the result is an arc-like effect that is somewhat disturbing, but does not require lens explantation.*

**Choun-Ki Joo, MD, PhD**



*The advantage of a square-edge design is a lower rate of PCO, but glare is more common. An ideal lens would have a sharp posterior edge and a rounded anterior edge.*

**Dr. Sri Ganesh**

**Lim:** Some of my patients who are younger than 40 to 50 years of age have complained of edge glare because if the pupil dilates more than 6 mm, a 6-mm capsulorrhexis will not be sufficient to cover the 360º optic. In this case, the patient may have some edge glare, especially with the square-edge IOLs. Comparatively, the round-edge IOLs cause less edge glare.

I have implanted 2,000 to 3,000 AcrySof lenses, but have only had one complication related to the AcrySof square-edge design. Several months after IOL implantation, the pupil was caught on the edge of the AcrySof lens. I am unsure if the iris was also caught by the sharp edge of the AcrySof lens.

What are the advantages of round-edge IOLs as compared with square-edge IOLs?

**Ganesh:** Both designs have advantages and disadvantages. The advantage of a square-edge design is a lower rate of PCO, but glare is more common. An ideal lens would have a sharp posterior edge and a rounded anterior edge. Allergan has recently introduced the Sensar OptiEdge, which combines these two edge features. The OptiEdge is now available throughout the Asia-Pacific region.

Some patients complain of a dark shadow or a dark arc in their temporal vision with the AcrySof lens. These arcs may be caused by the destructive interference of light by the square edge.

**Chang:** Robert Tester, MD, published a large survey in which 50% of pseudophakic patients reported dysphotopsias when specifically questioned about this. AcrySof had the highest incidence of dysphotopsias, but these complaints were present with all IOL styles.[14]

Michael A. Farbowitz, MD, reported a series of nine cases in which three-piece AcrySof IOLs were exchanged because of intolerable dysphotopsias.[15]

James A. Davison, MD, and Mark Ellis, MD, have also reported that their AcrySof cases required explantation for dysphotopsias.[16,17] Many of the patients who underwent explantation and those with severe edge dysphotopsias had the same 5.5-mm optic AcrySof, and were younger patients between 40 and 55 years of age.

There are two important conclusions that can be drawn from these case reports and ray tracing studies. While we tend to dismiss such complaints if the patient sees 20/20, IOL-related dysphotopsias are common and occasionally severe and these symptoms must be explained to the patients. Secondly, lenses with smaller optics should not be implanted in younger patients and in eyes with larger pupils. The 5.5-mm optic has been the most popular AcrySof model in the United States because of the smaller incision size required. However, this may be producing an ill-advised tradeoff with increased dysphotopsias for significant numbers of patients.

Another issue of optical quality is glistenings. Dr. Joo, what is your experience with glistenings?

**Joo:** Usually, patients do not complain of glare or a decrease in visual acuity. But upon observation, I see vacuoles or glistenings inside the optic area of the AcrySof lens. The optic of the Sensar is clear.

**Chang:** When have you noticed these vacuoles in the AcrySof? Do they change over time?

**Joo:** My experience has been that no vacuoles are present before 6 months postoperatively, but that vacuoles are present 1 to 2 years postoperatively. I generally see patients at 1 week postoperatively, then 2 months, 6 months, 1 year, and annually thereafter.

**Pannet:** Approximately 67% of my patients implanted with the AcrySof IOL develop vacuoles after 2 ½ years, but they

are minimal, with no inflammation or visual deficit.

Vacuoles may be related to the lens manufacturing and packaging process, or may be due to humidity, residue, or material variation. I keep the lens at room temperature before it is implanted in order to prevent vacuole formation.

**Chang:** The 1996 recall of AcrySof IOLs in the United States was because of glistenings related to the AcryPak packaging, and the issue was thought to have been resolved.

These are minute water vacuoles that form in the acrylate matrix. More recently, Katsuya Mitooka, MD, reported at the 1999 American Society of Cataract and Refractive Surgeons meeting that he observed the delayed appearance of glistenings in nearly 60% of AcrySof lenses. The majority were mild, but 11% were severe and they were more common in diabetic patients. A minority of patients had a measurable decrease in contrast acuity.[18]

Dr. Olson and colleagues reported that 36% of AcrySof patients had some glistenings.[19] Thus, both of your findings, Dr. Joo and Dr. Pannet, are in line with the published data.

**Ganesh:** Is there any difference between the incidence of glistenings in the single-piece AcrySof and the three-piece AcrySof lenses?

**Chang:** The material, the refractive index, and the source of the lenses are the same. If glistenings were a manufacturing problem, the vacuoles would appear immediately. There appear to be more factors involved in the formation of vacuoles.

**Lim:** I have been implanting AcrySof lenses since 1999. Prior to implantation, I used to warm the lens to room temperature. After hearing reports of temperature changes having an effect on glistening formation, I discontinued this procedure.

**Chang:** Allergan maintains that the Sensar material does not permit the formation of these water vacuoles. In a lab setting, glistenings can be created in the AcrySof lens by first heating and then cooling the IOL. I have observed no glistenings on the Sensar, and I understand that this is due to differences in the manufacturing process of the Sensar.

Because glistenings appear to be a delayed phenomenon, eventually there will be enough data to compare the incidence of glistenings in the AcrySof with the Sensar.

## Implantation technique

**Chang:** Are there any differences in implantation procedures for the AcrySof and the Sensar?

**Ganesh:** The AcrySof lens must be heated prior to implantation, whereas the Sensar does not require warming. Also, in my opinion, the AcrySof is more difficult to fold than the Sensar.

The Sensar does not soften after heating because there is a difference in the glass transition temperature. The glass transition temperature of the AcrySof lens is 18.5º C, whereas the Sensar's is 13º C.

**Pannet:** I have tried to fold the Sensar lens with forceps, but it is not a good technique because the Sensar is stickier than the AcrySof lens. I find that the Unfolder Sapphire is the best method for implanting the Sensar.

**Joo:** Using forceps to fold an IOL can also create marks on the lens surface.

**Chang:** Is incision size important when choosing a method of IOL insertion?

**Soekardi:** Yes. Using forceps often requires a larger incision because the lens is not always folded in the middle of the optic, as it is with an injector.

**Ganesh:** I am able to insert the Sensar IOL with the Unfolder Sapphire using a

*Using forceps often requires a larger incision because the lens is not always folded in the middle of the optic, as it is with an injector.*

**Istiantoro Soekardi, MD**

*The Unfolder Sapphire offers control because there is a rail on both sides of the cartridge for centering the lens.*

**Pannet Pangputhipong, MD**

3.2-mm incision. Implanting the 6-mm AcrySof lens with forceps requires a 4-mm incision.

**Lim:** Would you recommend a 3-mm incision before the implantation with the Unfolder Sapphire?

**Ganesh:** I usually widen the incision to 3.2 mm. Otherwise, it is difficult to insert the IOL and some patients have discomfort. The cartridge for the Unfolder Sapphire is different from that of the Unfolder for the silicone SI30 and SI40 IOLs. The Unfolder Sapphire has a split at the tip, creating friction in smaller incisions.

**Lim:** In Korea, most physicians prefer injection systems because they are more convenient for implanting an IOL. Folding with forceps is more difficult.

However, I am concerned that using an injection system may compromise the strength of the haptic.

**Ganesh:** I have implanted approximately 300 lenses with the Unfolder Sapphire and have had only two cases of a broken or a trailing haptic where the lens had to be explanted. Forceps can cause damage to the IOL, such as marks on the lens, and if the IOL has not been preheated, stress fractures may result. I have had cases in which I have induced lines on the AcrySof with forceps.

**Pannet:** The Unfolder Sapphire offers control because there is a rail on both sides of the cartridge for centering the lens. If the lens is not centered between these rails, it cannot be folded. The folding process is easy and I have had no complications with 50 cases — no haptics have been damaged and no optics have been torn.

**Ganesh:** The speed at which the Sensar unfolds in the eye can also be controlled with the Unfolder Sapphire.

**Chang:** Dr. Bambery, you use both silicone and acrylic lenses. What is your preferred method of implantation?

**Bambery:** I prefer to use the Unfolder implantation systems. Difficulties with implantation have been overcome by avoiding viscoelastic at the proximal end of the cartridge and keeping the Unfolder tip dry. The surface of the optic that faces the surgeon must be kept dry so that the Unfolder pushes the IOL rather than slipping over the IOL.

Also, the Unfolder is more convenient because a nurse or surgical assistant can preload the IOL while I perform surgery. The overall incision is smaller and the implantation is sterile.

**Chang:** Nick Mamalis, MD, and Thomas Kohnen, MD, performed separate studies comparing incision sizes after implantation with different styles of lenses and implantation techniques.[20,21] Each surgeon used Steinert-Deacon calipers to measure the size of the incision after the IOL was implanted. In all instances, the incisions that were used for implanting with lens injectors were slightly smaller than the incisions for forceps implantation. Does a slightly smaller incision make a difference in surgery?

**Lim:** Yes. For example, if I perform phaco with a 3-mm incision, I do not want to increase the incision to 3.2 mm or 3.5 mm because enlarging the incision may cause distortion. I prefer to make a larger incision for phaco, so that I do not have to enlarge it for IOL implantation. Currently, I use a 3-mm incision for phaco and silicone lens implantation.

**Bambery:** My 3-mm incision induces 0.25 D of astigmatism. A smaller incision would not lead to a significant reduction of induced astigmatism.

A 3-mm keratome is the most convenient and accurate way to create such an incision. However, for some IOLs, I need a larger incision which I create freehand.

**Chang:** With scleral pocket incisions, the radial length is such that a small difference in wound width is not clinically significant. However, when performing clear corneal incisions, we are limited to 1.5 mm to 2.0 mm of radial length. In this context, a difference in width of several tenths of a millimeter becomes significant in terms of wound integrity. Minimizing incision size is particularly important with hydrophobic acrylic lenses, because these lenses always require larger incisions compared with silicone. A retrospective study of incision integrity performed at the University of Utah compared 100 consecutive SI40 cases with 100 consecutive MA60BM AcrySof cases. There was a statistically significant superiority to the silicone lens group in terms of demonstrable wound leak either intraoperatively or on the first preoperative day.[22]

However, with acrylic IOLs, it is far better to reduce the incision size by using an injector than to downsize the optic diameter.

**Bambery:** I have found that the incision tends to be enlarged approximately 0.2 mm after lens implantation with the Unfolder Sapphire. However, the Sensar IOL has a 6-mm optic, thus allowing the smallest incision possible for an acrylic IOL.

**Chang:** Compared to the longer scleral pocket incisions, minimizing incision width is more important with clear corneal incisions where tenths of a millimeter make a difference. Injector systems not only reduce the incision width, but also provide perfect consistency because the cartridge tip is always the same size and shape. When manually folding a lens, there are many variations in the position of the forceps blades and the exactness of the fold. These variations can change the clear corneal incision requirement by several tenths of a millimeter.

**Pannet:** Occasionally when I am inserting the Sensar IOL with the Unfolder Sapphire series, I have found that as I attempt to turn back the plunger, the trailing haptic can get trapped between the rod tip and the wall of the cartridge. The result is that the trailing haptic can be damaged. To avoid this situation, I recommend that a surgeon or nurse carefully follow the loading instructions and ensure the trailing haptic is in the correct position before initiating the delivery. If a surgeon encounters this situation, I recommend that the surgeon remove the Unfolder and dial in the trailing haptic. Instead of trying to turn back the plunger, I reinsert the plunger into the anterior chamber, freeing the haptic and then allowing the plunger to safely retract.

**Joo:** However, the Sensar is not a lens that unfolds quickly. In order to avoid damaging the optic or haptics, surgeons must wait until the lens has fully unfolded before pulling out the injector. Retracting the plunger and trying to push in the optic is difficult.

## Future

**Chang:** In this discussion, we have described our ideal lens based upon all of the evidence-based studies. The lens should be of a biocompatible material — either hydrophobic acrylic or second-generation silicone — and preferably without glistenings. Stiff, angled PMMA haptics resist decentration and may enhance the posterior push from the contracting capsulorrhexis that indents the posterior capsule with the optic edge. The IOL should have a convex anterior curvature to minimize external and internal reflections. To decrease PCO, it should have a sharp posterior edge for the entire optic circumference. However, to minimize edge reflections and dysphotopsias, the edge should be slightly angled and rounded on the front surface. Allergan has responded to this challenge by developing the new Sensar OptiEdge, which, as previously mentioned by Dr. Ganesh, has this optic edge design. Ray tracing indicates that

*… with acrylic IOLs, it is far better to reduce the incision size by using an injector than to downsize the optic diameter.*

**David Chang, MD**

*I would like to see an injector with a volume larger than 6 mm that is capable of implanting an IOL through a smaller incision with better control of the haptics.*

**Seung Jeong Lim, MD, PhD**

because the edge is angled, rather than perpendicular to the optic plane, the amount of internal edge reflection is even lower than with the original round-edge Sensar.

**Ganesh:** Will a modified injection system also be available to accommodate the new lens design?

**Chang:** The Sapphire injector will be the same. What other improvements in lens design would you like to see?

**Lim:** I would like to see an injector with a volume larger than 6 mm that is capable of implanting an IOL through a smaller incision with better control of the haptics.

**Ganesh:** I would like to see a smaller lens in the extended range. For patients who have myopia and require low diopter lenses, a 6.5-mm lens with a 14.5-mm haptic to prevent capsular contraction would be ideal.

**Chang:** I am currently involved with Calhoun Vision (Pasadena, U.S.A.) in the development of a laser-adjustable IOL, where one would be able to change the power of the optic several weeks after implantation. The technology involves photoreactive polymers that can diffuse within a silicone matrix. Following irradiation, the diffusion of this molecule can be initiated and titrated in a way that results in precise changes in the optic curvature, thereby modifying the power. Both spherical and astigmatic refractive errors could be adjusted. Toric adjustments could be delayed until the capsular bag has already contracted, avoiding the problem of IOL rotation during the first week or so. Being able to assure emmetropia would be a tremendous advantage, whether dealing with a toric IOL, a multifocal IOL, an accommodating IOL, or a phakic IOL.

We have discussed why foldable IOLs have overtaken PMMA IOLs in popularity. Modern IOL preference is based upon four main criteria — biocompatibility, PCO rates, optical quality, and incision size. Although modern foldable IOLs as a group are excellent, we have seen that different IOL materials and designs hold advantages or disadvantages with respect to each of these four areas. Finally, in the past few years, a tremendous number of important, randomized clinical studies in this area have been reported. As a result, we can now use an evidence-based approach, rather than an anecdotal approach in selecting IOLs.

I would like to thank the faculty for their participation and Allergan Surgical for sponsoring this OCULAR SURGERY NEWS Europe/Asia-Pacific Edition symposium and monograph project. OSN

## References


1. Joo CK, Kim HH. Compatibility of intraocular lenses with blood and connective tissue cells measured by cellular deposition and inflammatory responses in vitro. *J Cataract Refract Surg.* 1992;18:240-246.
2. Ravalico G. Postoperative cellular reaction in various intraocular lens material. *Ophthalmology*. 1997;104:1084-1091.
3. Hollick EJ, Spalton DJ, Ursell PG. Surface cytologic features on intraocular lenses: Can increased biocompatibility have disadvantages? *Arch Ophthalmol*. 1999;117(7):872-878.
4. Koch MU, Kalicharan D, van der Want JJ. Lens epithelial cell layer formation related to hydrogel foldable intraocular lenses. *J Cataract Refract Surg*. 1999;25:1637-1640.
5. Hollick EJ, Spalton DJ, Ursell PG, et al. Posterior capsular opacification with hydrogel, polymethylmethacrylate, and silicone intraocular lenses: Two-year results of a randomized prospective trial. *Am J Ophthalmol*. 2000;129:577-584.
6. Nishi O, Nishi K. Preventing posterior capsular opacification by creating a discontinuous sharp bend in the capsule. *J Cataract Refract Surg*. 1999;25(4):511-526.
7. Olson RJ, Crandall AS. Silicone versus PMMA IOLs with regard to posterior capsular opacification. *Ophthalmic Surg Lasers*. 1998;24:55-58.

8. Hollick EJ, Spalton DJ, Ursell PG. The effect of polymethylmethacrylate, silicone and polyacrylic intraocular lenses on posterior capsule opacification three years after cataract surgery. *Ophthalmology*. 1999;106:49-55.
9. Hayashi K, Hayashi H, Nakao F. Quantitative comparison of posterior capsule opacification after polymethylmethacrylate, silicone, and soft acrylic intraocular lens implantation. *Arch Ophthalmol*. 1998;116:1579-1582.
10. Samuelson TW, Chu YR, Krieger RA. Evaluation of giant cell deposits on foldable intraocular lenses after combined cataract and glaucoma surgery. *J Cataract Refract Surg*. 2000;26(6):817-823.
11. Werner L, Pandey SK, Escobar-Gomez M, Apple DJ, et al. Anterior capsule opacification: Correlation of pathologic findings with clinical sequelae. *Ophthalmology*. 2001;108:1675-1681.
12. Holladay JT, Lang A, Portney V. Analysis of edge glare phenomena in intraocular lens edge designs. *J Cataract Refract Surg*. 1999;25(6):748-752.
13. Erie JC, Bandhauer MH, McLaren JW. Analysis of postoperative glare and intraocular lens design. *J Cataract Refract Surg*. 2001;27:614-621.
14. Tester R, Pace NL, Samore M, Olson RJ. Dysphotopsia in phakic and pseudophakic patients: Incidence and relation to intraocular lens type. *J Cataract Refract Surg*. 2000;26(6):810-816.
15. Farbowitz M, Zabriskie NA, Crandall AS, Olson RJ, Miller KM. Visual complaints associated with the AcrySof acrylic intraocular lens. *J Cataract Refract Surg*. 2000;26(9):1339-1345.
16. Davison JA. Positive and negative dysphotopsia in patients with acrylic intraocular lenses. *J Cataract Refract Surg*. 2000;26(9):1346-1355.
17. Ellis M. Sharp-edged intraocular lens design as a cause of permanent glare. *J Cataract Refract Surg*. 2001;27:1061-1064.
18. Mitooka K. Incidence of glistenings in acrylic IOLs. Poster presented at the American Society of Cataract and Refractive Surgery meeting, April 10-14, 1999; Seattle, U.S.A.
19. Christiansen F, Durcan FJ, Olson RJ, Christiansen K. Glistenings in the AcrySof intraocular lens: Pilot study. *J Cataract Refract Surg*. 2001;27:728-733.
20. Mamalis N. Incision width after phaco with foldable intraocular lens implantation. *J Cataract Refract Surg*. 2000;26(2):237-241.
21. Kohnen T. Incision sizes with 5.5-mm total optic, 3-piece foldable intraocular lenses. *J Cataract Refract Surg*. 2000;26:1765-1772.
22. Olson RJ. Is there truly a clinical difference in intraocular lenses available today? *Comp Ophthalmol Update*. 2000;1:19-28.

*Being able to assure emmetropia would be a tremendous advantage, whether dealing with a toric IOL, a multifocal IOL, an accommodating IOL, or a phakic IOL.*

**David Chang, MD**

# The Impact of Design & Material on ACRYLIC LENS PERFORMANCE

Sponsored by Allergan Surgical

SLACK INCORPORATED
*An innovative information, education, and management company*

6900 Grove Road
Thorofare, NJ 08086
856-848-1000
www.slackinc.com