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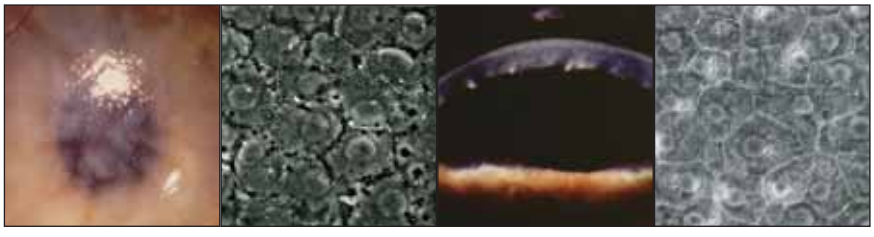
Corneal Protection

IN CATARACT SURGERY

Safeguarding the cornea against disease elements and environmental challenges.



Featuring:

Nick Mamalis, MD (Moderator)

Henry F. Edelhauser, PhD

Rudy M. M. A. Nuijts, MD, PhD

Abhay R. Vasavada, MBBS, MS, FRCS

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Safeguarding the cornea against disease elements and environmental challenges.

Ophthalmic surgery has been made safer and more efficacious for the patient through a variety of advances in surgical techniques and medical device technologies. Nevertheless, a growing body of research into a variety of new disease elements and environmental sensitivities has increased the need for surgeons to take even simple steps to protect their patients' health. In response to these developments, numerous regulatory bodies have issued new guidelines and requirements for medical manufacturers and practitioners in an effort to ensure that patients are given every possible advantage toward the goal of maximizing outcomes. Considering these factors alongside patients' increasing expectations regarding outcomes, it is vital that every ophthalmic surgeon use products and procedures aimed at the greatest possible level of protection in both routine and premium procedures.

—Nick Mamalis, MD

PANEL

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Dr. Mamalis: This panel has convened to discuss examples of recent disease and environmental issues that have had an impact on patient safety in the cataract surgical arena. Primary among these concerns is toxic anterior segment syndrome (TASS), but we will also discuss prion disease, manufacturing variability, issues with facilities' processing, and the concerns about plastic DEHP, among other considerations.

TASS

Two-Year Experience

Let's begin by discussing TASS. In 2006, Dr. Edelhauser and I created an adhoc task force in conjunction with the ASCRS to study the major TASS outbreak in the United States. In an effort to uncover the source of this outbreak, our task force created two questionnaires that we send to affected clinics. One questionnaire contains questions about instrument processing, cleaning, and sterilization, and the other questionnaire asks about products and medications used during surgery. We also send ophthalmic nurses to visit and study affected sites. Let me summarize our 2-year data from our analysis of these questionnaires and clinical visits.

In the past 2 years, personnel from 76 ophthalmic centers have filled out the questionnaires, and our task force nurses have visited 54 sites. We have data from 909 cases of TASS out of approximately 50,000 cataract surgeries that these reporting centers have performed during this time. Interestingly, we did not find a particular product to be the culprit in any of the TASS outbreaks, but rather multiple factors, especially with the cleaning and sterilization of instruments. The most common problems include inadequate flushing of the phaco and I/A handpieces, the wrong concentrations of enzyme cleaners and detergents, problems with ultrasonic baths (such as endotoxin contamination [*see sidebar*]), the use of preserved versus unpreserved medications such as epinephrine, and the reuse of single-use products. What has been the panel's experience with TASS? Have you seen any trends in the past 6 to 12 months?

Irrigating Solutions

Dr. Vasavada: TASS has been a nagging problem for years in many parts of the world, including India and Asia Pacific. Although the TASS Task Force clearly showed that the cleaning of surgical instruments is the primary issue, there have been cases of TASS linked to the variability of the quality of intraocular irrigating solutions and ophthalmic viscosurgical devices (OVDs) that local manufacturers produce. These solutions often have different pHs and concentrations. Also, similar issues arise with methylcellulose and hydroxypropylmethylcellulose (HPMC), which are used quite frequently in many parts of the world. However, I have seen a marked improvement in these same clinics since many surgeons switched to better viscoelastics and solutions, like Viscoat and BSS PLUS (both manufactured by Alcon Laboratories, Inc., Fort Worth, Texas), following the reports published by the TASS task force.[1-3]

CLEANING ULTRASONIC BATHS

Ultrasonic baths need to be replaced with clean water as well as ultrasonic cleaner. Some baths need to be deionized and rinsed with 70% alcohol to remove endotoxins that may coat their sides.

Dr. Edelhauser: You are right about the quality of irrigation solutions in India. Years ago, before the emergence of TASS, I evaluated an intraocular irrigating solution produced in India that contained benzalkonium chloride (BAK).[4] I was told at that time that there was no way to recall the contaminated product. Obviously, there were many cloudy corneas based on the use of that solution.

Dr. Mamalis: Even intraocular irrigating solutions such as balanced salt that are produced under good lab conditions can have problems. One of the first outbreaks of TASS I studied in 2005 was related to endotoxin contamination of the intraocular irrigating solution.[1] This product was produced by a single manufacturer but labeled by multiple companies who then distributed the solution throughout the eastern United States. Endotoxin contamination can still occur in intraocular irrigating solutions produced without preservatives.

Dr. Vasavada: I do not think there is appropriate concern for this issue among clinicians or patients worldwide. The issue of safety in intraocular irrigating solutions should be top priority, because it affects millions of patients internationally.

Dr. Edelhauser: I agree; none of the phacoemulsification surgical units function without an irrigating solution. When BSS PLUS was first released, most European surgeons and hospitals were reluctant to use it because of its higher cost. Some hospital pharmacies were mixing a BSS PLUS lookalike, which led to a number of surgical infections that

resembled the TASS we see today. At the time, surgeons did not understand the ramifications of TASS.

Cleaning and Sterilization

Dr. Mamalis: Our task force found that the proper cleaning and sterilization of instruments is critical in preventing TASS. We must emphasize the need for disposable instruments, especially small-bore cannulas. We have linked outbreaks of TASS to the difficulty in cleaning residual OVDs or other surgical materials out of small-bore cannulas and other instruments. Surgeons must be very careful to use disposable instruments only once. Has anyone else had a similar experience?

Dr. Vasavada: I have only been using disposable instruments exclusively for the last few years. These instruments are not very expensive; it is a shame surgeons are not using them more. It is challenging to remove methylcellulose and other OVDs from small tubes, in particular.

Dr. Edelhauser: This is not a new observation. Dr. J. H. Kim published the first article recommending disposable cannulas in the mid-1980s.[5] He was the first to notice that OVD left in a reusable cannula would absorb the detergent before being flushed into the anterior chamber. I think a bigger issue, however, is I/A tips. I suspect that surgeons do not bother to read the directions for use (DFU) of these devices, which state that cleaning them should take 5 minutes. Surgeons must allow enough time for the instruments to be cleaned properly. This may be more of an issue in large-volume practices, which need to maintain a certain number of cleaned trays that include I/A tips and cannulas.

Dr. Mamalis: The TASS task force devised guidelines for cleaning and sterilizing ophthalmic instruments, and I think it is critical for surgeons to work with their staff to ensure that they follow these guidelines. The inadequate flushing of I/A tips and phaco handpieces is the single most common factor we found to be associated with TASS. Dr. Vasavada, have you seen issues with the cleaning and sterilization of instruments aside from the flushing? Have you had problems with detergents, enzymes, or ultrasound equipment?

Dr. Vasavada: My staff and I randomly check our instruments once every week under high magnification, and I would say that one out of 20 instruments has some residue or deposits from surgical materials. We still see this problem, despite the care we take to clean our instruments thoroughly. I agree that the problem is most significant with I/A tips and phaco handpieces, which are the only reusable parts of the machinery. I would like the manufacturers to consider developing disposable I/A tips. A different material would be more cost effective.

> "Although the TASS Task Force clearly showed that the cleaning of surgical instruments is the primary issue, there have been cases of TASS linked to the variability of the quality of intraocular irrigating solutions and OVDs."
>
> —Abhay R. Vasavada, MD

Dr. Edelhauser: The I/A tips are always an issue because they have a very small bore, and their interiors have a lot of nooks and crannies that can trap solutions and OVDs.

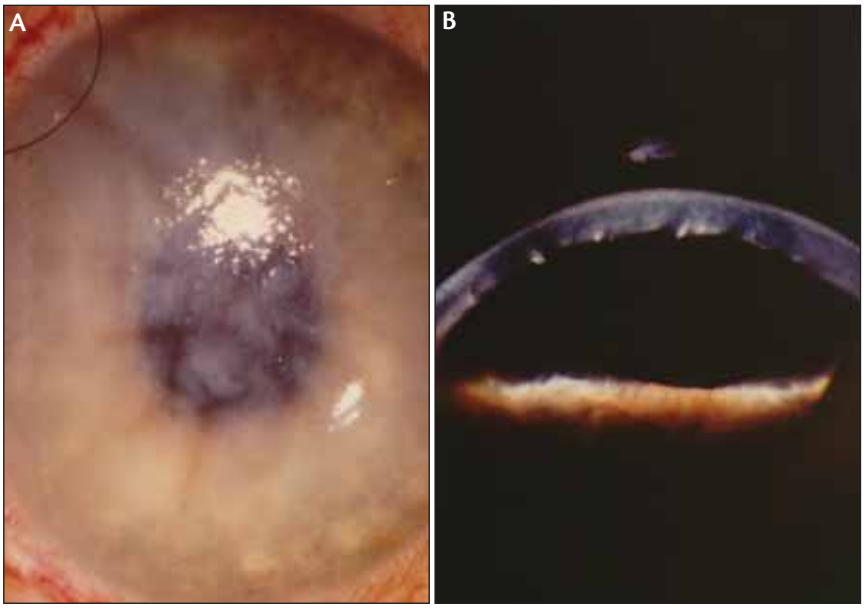
Dr. Vasavada: The I/A cannulas are surprisingly friendly to bacterial growth. Their tiny aspiration ports are made of metal, which grabs bacteria. Again, I think we need disposable cannulas, perhaps made from a synthetic material.

Dr. Edelhauser: IOL injectors' cartridges are swimming in viscoelastic, which gets into the instrument. This fact makes it especially important to clean this instrument in order to minimize the risk of bacterial growth. I have heard of cases in which there was so much dried viscoelastic around the mechanism of an injector that the surgeon could not advance it. Obviously, those injectors are not being cleaned.

Dr. Mamalis: I think surgeons forget that the plunger of IOL injector systems is not disposable. Cleaning the plunger can be very difficult and must be done properly.

Dr. Edelhauser: When I get calls about TASS, I always ask the surgeon if he or she has observed an I/A tip becoming plugged. If the answer is 'yes,' I know the practice has an issue with cleanliness. The response is usually 'yes'.

Dr. Vasavada: I have learned to flush out the I/A tip with the phaco machine's reflux mode before I perform



(Courtesy of Rudy M. M. A. Nuijts, MD, PhD.)

Figure 1. An eye that suffered corneal decompensation after remnants of cleaning detergent were flushed into it (A and B).

irrigation/aspiration. It is another step I take to make sure any remnants from the previous procedure are flushed out. This technique is simple to run on modern phaco machines and takes about 20 seconds to perform. I think the manufacturers could stress it more.

Dr. Edelhauser: Dr. Nuijts, you conducted one of the first studies that proved OVDs can absorb detergents and thereby affect the corneal endothelium.

Dr. Nuijts: Like most complications, this is one of human error. Between 1988 and 1989, the department of ophthalmology of the Academic Medical Center in Amsterdam experienced an outbreak of ocular infections.[6] Approximately 22 patients developed acute endothelial decompensation that caused them to lose 50% to 70% of their endothelial cells. My colleagues and I found that reusable cannulas were not being cleaned thoroughly and contained residual OVD material.[7] This residual material then mixed with the detergent in the ultrasonic bath and created a toxic combination that was infused into the patient's eye in the next surgery (Figure 1A, B). The source of the error was a new crew in this laboratory's sterilization/cleaning department who were not following the sterilization guidelines. We have since revised these guidelines to prevent this problem. Now, this practice prohibits the reuse of all small-lumen cannulas, syringes, etc., whenever possible. I am convinced that most cases of TASS are related to cleaning issues, and I agree that there is a great need for disposable I/A instruments in our field.

Dr. Mamalis: I think this example again highlights the importance of using disposable cannulas and of not reusing small-bore cannulas, because even when cleaned properly, they may still retain material. We should be working toward using disposable tips for I/A needles.

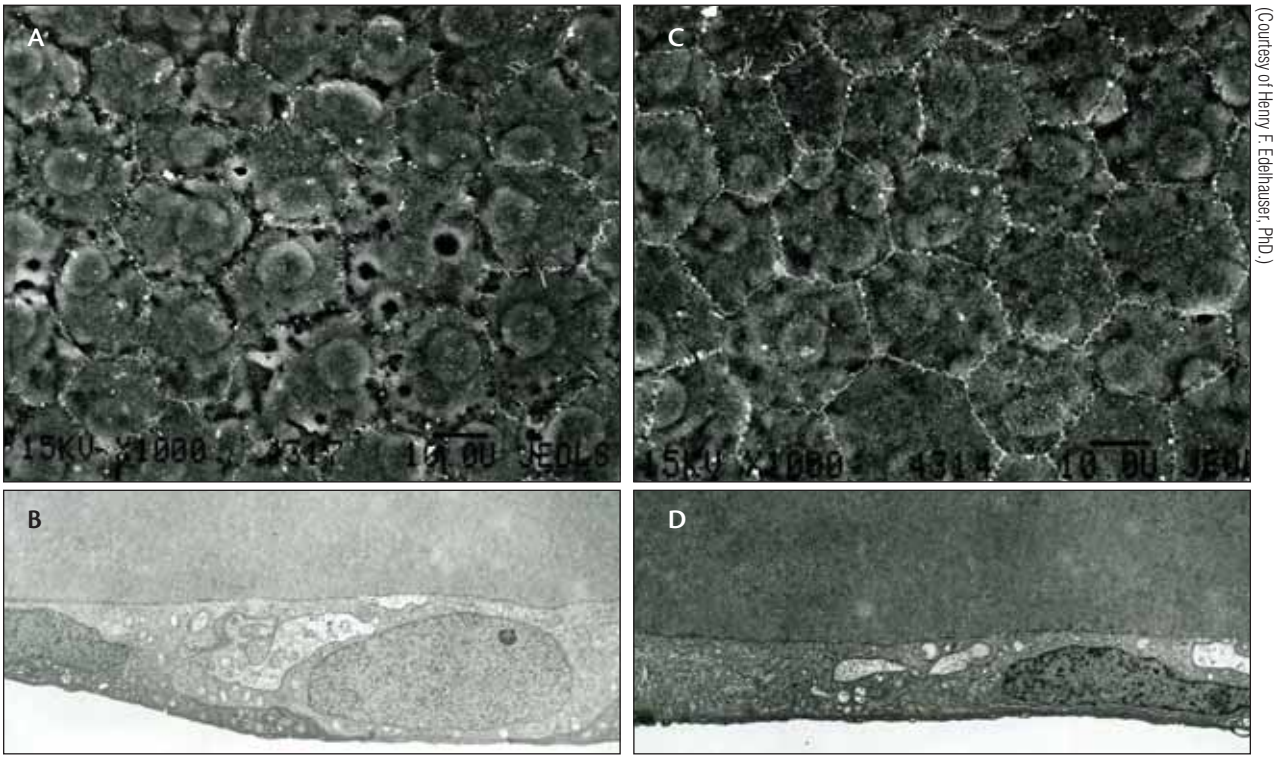
Dr. Edelhauser: The Simcoe I/A tip (multiple manufacturers) is particularly difficult to clean, because it has a lot of tubing as well as a small-bore cannula. I know of five or six practices that eliminated future cases of TASS after either cleaning or eliminating the Simcoe.

Dr. Nuijts: This is no longer an issue, because there are effective disposable versions of Simcoe cannulas available now.

Dr. Edelhauser: Another source of bacterial contamination is reusable tubing on phaco machines. Some phaco machines can use these tubes up to nine times, and hospitals are requiring this number of uses in an effort to contain costs.

STEAM STERILIZATION

Dr. Mamalis: In the US, the Joint Commission on Allied Health Personnel in Ophthalmology recently examined the procedures involved in the cleaning and sterilization of surgical instruments.[8] Many surgical centers use short-cycle steam sterilization (10-minute cycles) to clean their instruments between cases, and we have found this practice to be quite safe in terms of endophthalmitis. In fact, studies conducted at the John A. Moran Eye Center (Salt Lake City, Utah), the Bascom Palmer Eye Institute (Miami, Florida), and the Aravind Eye Hospital in India, showed that short-cycle steam sterilization techniques do not increase patients' risk of endophthalmitis.[9,10] In Europe and elsewhere, however, there has been a push to use the longer sterilization cycle instead of the short cycle to ensure the instruments' cleanliness. Dr. Vasavada, have you found this to be an issue in your center?



(Courtesy of Henry F. Edelhauser, PhD.)

Figure 2. Scanning and transmission electron micrographs show human corneal endothelium exposed to Hartmann's solution (A and B) and BSS PLUS (C and D) for 15 minutes. Note the edema in response to the Hartmann's solution. (SEM photos [A,C] magnification X1000; TEM photos [B,D] magnification X4930.) Reprinted with permission.[11]

Dr. Vasavada: We used to use long-cycle sterilization, but we have been using the short-cycle version for the past 5 or 6 years and have had no problems with endophthalmitis. I do not think properly controlled and monitored short-cycle sterilization contributes to TASS. As I said, I think contamination occurs from improper cleaning and/or the non-standard manufacturing of irrigation fluid and OVDs.

Dr. Nuijts: We have not seen an epidemic of TASS related to short-cycle steam sterilization in our country. Very few practices in The Netherlands use short-cycle sterilization, and all hospitals use the long version. Furthermore, many private practices outsource their sterilization to centralized companies.

INTRAOCULAR IRRIGATING SOLUTIONS

Dr. Mamalis: The US FDA has stopped companies from marketing unapproved intraocular irrigating solutions, and only two manufacturers are currently approved to market these solutions, Alcon Laboratories, Inc., and Akorn, Inc. (Buffalo Grove, Illinois).

Dr. Vasavada, what issues have you seen with the manufacturing of intraocular irrigating solutions?

Dr. Vasavada: The issues have been numerous. As I mentioned previously, there were short outbreaks of TASS in India and Asia Pacific, where I have served as a consultant for a few clinics. Because these incidences were usually related to the quality of a particular batch of fluid, I think regulation of the manufacturing process is essential to ensuring patients' safety. I think the concept of worldwide coordination or even a worldwide regulatory body to oversee surgical manufacturing operations is an interesting idea.

Dr. Edelhauser: Keeping irrigating solutions sterile and properly balanced requires a certain amount of pharmaceutical scientific evaluation.

Dr. Nuijts: Also, many hospital pharmacies do not realize the importance of maintaining the original balance and that mixing these solutions is an off-label practice.

Dr. Vasavada: Many centers still use lactated Ringer's and Hartmann's solutions.

Dr. Edelhauser: Lactated Ringer's solution varies widely in pH, and the plasticizers in the solution's bags

can leach into the intraocular irrigating solution. Many surgeons do not realize that after cataract surgery, the reformed anterior chamber will retain any solution for 4.5 to 5 hours.

Dr. Nuijts: Not all surgeons see the benefits of using an irrigating solution, because many do not see their patients on the first postoperative day, but only at 1 to 4 weeks. Some surgeons may send their patients to a comanaging optometrist postoperatively and may not see early postoperative problems with corneal clarity. Published studies have shown that various irrigating solutions affect the cornea differently at 1 day postoperatively. Dr. Edelhauser, you conducted studies comparing preoperative human corneas that were temperature reversed with intraocular irrigating solution and then exposed to BSS, BSS PLUS, or lactated Ringer's solution, and you found that the corneas exposed to lactated Ringer's solution experienced stromal swelling, endothelial cell edema, and poorer vision than those exposed to BSS or BSS PLUS (Figures 2A-D and 3A, B).[11]

Dr. Vasavada: My group also published a study on lactated Ringer's solution.[12] We found that corneal edema is apparent within 12 hours.

Dr. Nuijts: If the surgeon only sees the eye days later, the cornea will hopefully have recovered from the solution. Surgeons must be educated that there is a better option than a lactated Ringer's irrigating solution. It is particularly important that corneas with endothelial dystrophy or low endothelial cell counts not be subjected to these solutions.

Dr. Edelhauser: Or glaucoma patients—any eyes with a stressed endothelium.

Dr. Mamalis: The corneal endothelium is exquisitely sensitive to fluctuations in pH and any constituents in the solution. This fact underscores the importance of good manufacturing practices for the irrigating solution.

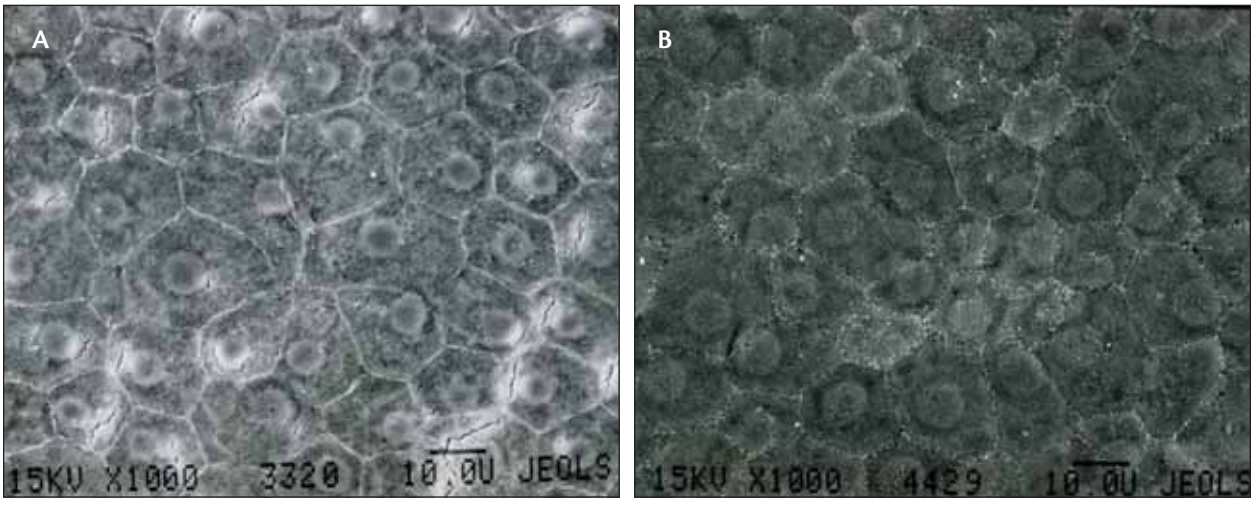
Dr. Mamalis: Dr. Nuijts, do you think physicians are starting to see more of their premium IOL patients on the first postoperative day, or no?

Dr. Nuijts: Yes, there are certain patients whom we want to see more quickly after surgery. For example, we want to make sure toric IOLs are properly aligned. With multifocal lenses, we want to check for any visual issues before implanting the second eye. However, I still use the same irrigating solution for all my patients. I would not want to see surgeons begin to use a "better" irrigating solution only for premium IOL patients.

Dr. Edelhauser: Surgeons who see a patient 7 days after surgery will not be able to identify TASS. TASS usually manifests in the first 12 to 24 hours.

ADDITIVES

Dr. Edelhauser: Two areas we have not touched on are the off-label additives used in intraocular irrigating solutions and the use of intracameral drugs in ocular surgery. For example, when James Gills, MD, of Tarpon Springs, Florida, conceived of delivering lidocaine intracamerally, it revolutionized the use of anesthetics for phacoemulsification.



(Courtesy of Henry F. Edelhauser, PhD.)

Figure 3. Scanning electron micrographs (magnification X1000) of human corneal endothelium perfused for 35 minutes with Hartmann's solution (A) and BSS PLUS (B).[11]

Dr. Mamalis: Again, the intracameral delivery of drugs underscores the notion that we need to know exactly what is going into the eye and how it will affect the anterior segment in general and the corneal endothelium in particular. Any drug delivered intracamerally must be free of preservatives, must be the proper pH and the proper dosage, and it needs to have undergone rigorous testing for safe use on the endothelium.

Dr. Nuijts: Something I would like to see developed is beneficial additives to irrigating solutions that could assist with postoperative complications like cystoid macular edema. I think such a solution could have great potential.

Dr. Mamalis: I agree. If the protection of the corneal endothelium is our primary concern, we do not want to do anything differently with a premium IOL than we would with a standard implant.

> "It takes only a small amount of endotoxin to damage the cornea endothelium, and the current testing for endotoxins may not be sensitive enough to detect low levels of contamination."
>
> —Nick Mamalis, MD

PLASTICS

Dr. Mamalis: A newer issue that has arisen is the safety of the plastics used in these solutions' bottles and phaco tubings. The European Union recently issued guidelines regarding the type of plastic allowed in surgical products.[13] One of the nonapproved materials is the plasticizer di-(2-ethylhexyl)phthalate (DEHP), which is now present in the bags in which irrigating solutions are delivered. Dr. Nuijts, has the use of this material been an issue in Europe?

Dr. Nuijts: It has not been an issue for me personally, because my colleagues and I use irrigating solutions in glass bottles. I am not aware of other colleagues in The Netherlands having problems with these kinds of plastics. Most surgeons I know use BSS or BSS PLUS.

Dr. Mamalis: Fortunately, Alcon is manufacturing a new plastic bag for BSS that does not contain DEHP.

Dr. Vasavada: It is not just plastics; the quality of glass containers can make a difference, too. Many of the cheap intraocular irrigating solutions come in a glass bottle that is not type 1, and they have contaminants or particles of glass delaminates.

Dr. Edelhauser: The glass bottles that BSS comes in are made of number 1 silica. One of the early TASS outbreaks in the US occurred when a company made a lookalike intraocular irrigating solution and placed it in non-Type 1 glass. As the glass broke down, the pH of the solution rose quite high. The eyes that received that contaminated solution experienced cloudy corneas. Also, there were more cases of TASS associated with that manufacturer than bottles used, which meant that some of the bottles were used multiple times.

QUALITY CONTROL

Dr. Nuijts: I was surprised that the US manufacturers that experienced endotoxin contamination of their intraocular irrigating solutions did not detect the problem in their quality controls.

Dr. Mamalis: The difficulty is that it takes only a small amount of endotoxin to damage the cornea endothelium, and the current testing for endotoxins may not be sensitive enough to detect low levels of contamination. The contaminated cytosol solution[1] that caused the outbreak in the Eastern United States was manufactured by a single company but branded under multiple brands. Our task force evaluated multiple cases of TASS before we realized that a single solution was the culprit.

Dr. Nuijts: Again, I feel it is important that hospital pharmacies be aware of these issues, because some manufacturers sell their solutions directly to these pharmacies. The pharmacies do not realize that these solutions, which look exactly like the ones marketed to clinics, may not have been tested in vitro or in vivo. I feel that irrigating solutions should be regulated before they are introduced into the market, just like OVDs. Surgeons know that there is testing behind any OVD they choose to use.

Dr. Mamalis: The US has guidelines in place for regulating irrigating solutions, which is why the FDA has publically announced that only two manufacturers are making the intraocular irrigating solutions according to these guidelines. I agree that it is important for manufacturers to follow these guidelines to ensure the safety of these products.

Dr. Edelhauser: In the late 1960s and early 1970s, ophthalmologists did not have intraocular irrigating solutions. The only solution available was a 15-mL balanced salt solution made by Alcon Laboratories, Inc. It took 7 years to get BSS PLUS developed and FDA approved. Meanwhile, the fields of phacoemulsification and vitreoretinal surgery were expanding. So, Alcon was able to modify the 15-mL irrigating solution and develop a 500-mL bottle for these purposes. That solution filled the gap during the 7 years that BSS PLUS was being finalized.

> "We showed that BSS and BSS PLUS are superior to lactated Ringer's solution in terms of corneal tissue safety and integrity."
>
> —Rudy M. M. A. Nuijts, MD, PhD

CORNEAL PROTECTION

Dr. Mamalis: What role do intraocular irrigating solutions play in protecting the corneal endothelium during cataract surgery? How do these solutions contribute to postoperative outcomes and corneal clarity? I know that both Drs. Edelhauser and Nuijts have performed work in this area.

Dr. Nuijts: I conducted part of my doctoral work in Dr. Edelhauser's laboratory. We performed an in vitro study of different irrigating solutions using human corneas that were not suitable for transplantation. We mounted these corneas in the in vitro corneal specular microscope, which allowed us to infuse these solutions directly to the corneal endothelium. We then measured the effect of increased corneal thickness and the impact on the corneal endothelial cell layer. We conducted paired experiments on corneas that came from the same donor, and then we compared the outcomes to the control corneas. We first deturgesed these corneas using a profusion of BSS PLUS. After they were temperature reversed, we exposed them to the test solution. We saw the most swelling in the corneas exposed to the lactated Ringer's solution as opposed to BSS and BSS PLUS. Thus, we showed that BSS and BSS PLUS are superior to lactated Ringer's solution in terms of corneal tissue safety and integrity.[14]

Of course, it is much more difficult to calculate an effect in phacoemulsification patients (in vivo studies), because there are so many different variables involved, such as the hardness of the cataract, the viscoelastic being used, the surgeon's experience, etc. The most accurate way to assess the safety and efficacy of intraocular irrigating solutions is to measure the patient's corneal thickness on postoperative day 1. Personally, I want to use the solution that has been proven superior in vitro, no matter the cost. I would not want to settle for an inferior solution for my patients. Besides, BSS and BSS PLUS have well-proven safety track records.

Dr. Edelhauser: Surgeons should understand the difference between BSS and BSS PLUS. BSS is the older solution and contains a buffer of acetate citrate. Although this buffer has been proven safe and efficacious, no tissue in the body uses acetate citrate as a buffer. The buffer in BSS PLUS is bicarbonate, which is secreted by the ciliary body to form aqueous humor. Additional components of BSS PLUS are glucose and oxidized glutathione, the latter of which can act as an antioxidant.[15] Studies have shown that corneal endothelial cells do indeed take up glutathione.[16]

Questions have been raised about the inclusion of oxidized glutathione in BSS PLUS. Adding reduced glutathione to a salt solution would convert the glutathione to the oxidized form in about an hour. However, the tissues inside the eye are lined with an enzyme called *gamma-glutamyl transpeptidase*, which can easily break down the oxidized glutathione into a tripeptide, which the cells can absorb. My group has published studies that confirm this process.[17] The cells use glutathione to mitigate the turbulence stress (oxidative) in the anterior

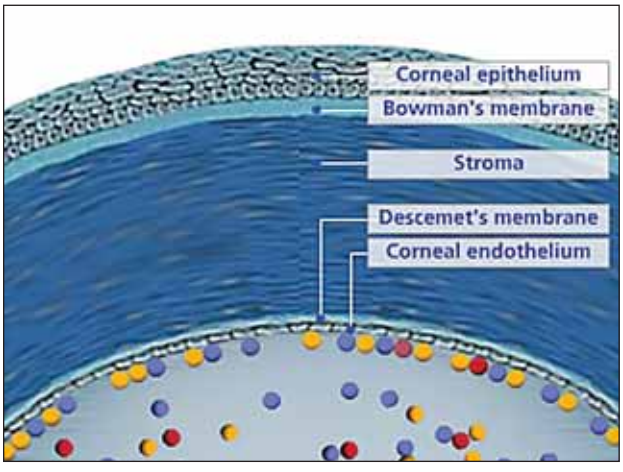


Figure 4. Glutathione maintains the junctional complexes of corneal endothelial cells[16] and protects the integrity of the blood-aqueous barrier.[18] Ocular tissue is highly sensitive to depletion of cellular glutathione levels. Depletion of cellular glutathione can result in cell apoptosis.[19] BSS PLUS Solution has the ability to deliver a continuous supply of glutathione to the surgical site.

chamber during phacoemulsification (Figure 4). The anterior chamber contains 250 µL of vitreous. Many of the new phaco machines use a flow rate of 40 to 60 mL/min, which infuses approximately 150 to 170 times this volume through the anterior chamber during phacoemulsification. When surgeons perform this step, their eyes are fixated on the phaco tip; they are not thinking about what is flowing through the anterior chamber.

> "The cells use glutathione to mitigate the turbulence stress (oxidative) in the anterior chamber during phacoemulsification."
>
> —Henry F. Edelhauser, PhD

Dr. Nuijts: Today's fluidics replace the total fluidic volume of the anterior chamber three times per second, which is not natural. A flow rate of 40 to 60 mL/min = 0.67 mL/sec and an anterior chamber volume of 0.25 mL. The flow rate per second is three times the anterior chamber's volume.[20]

Dr. Mamalis: The protective effects of the fluid are very important because of what Drs. Edelhauser and Nuijts just stated. In addition to the flow and turbulence of phacoemulsification, there is now a question of free-radical formation in the eye.[21] So, I think it behooves us as surgeons to do everything we can to protect the endothelium during cataract surgery from the potential damage of these forces.

Dr. Vasavada: The new OZil Torsional ultrasound technology on the INFINITI Vision System (Alcon Laboratories, Inc.) allows surgeons to use low fluidic parameters, which should reduce the damage you mention. I think the combination of using BSS PLUS with the OZil Torsional phacoemulsification is much safer for the corneal endothelium than other technologies and solutions.

Dr. Nuijts: My group is running a randomized clinical trial with patients who have Fuchs' dystrophy. Half the patients are receiving conventional longitudinal phacoemulsification, and the other half are undergoing surgery with OZil Torsional ultrasound. Both groups are receiving DuoVisc (Alcon Laboratories, Inc.) with BSS PLUS. Our preliminary outcomes are showing that torsional ultrasound is advantageous; these eyes are showing less corneal edema compared to the longitudinal eyes. So, I think this new technology is benefitting cataract patients in terms of the endothelial pump and corneal physiology.

CORNEAL PROTECTION IN CHALLENGING SURGERIES

Dr. Mamalis: What is the panel's opinion about the ability of irrigating solutions to protect the corneal endothelium in complicated surgeries, such as in eyes with harder nuclei or pathological diseases?

Dr. Vasavada: Certainly, corneal protection during cataract surgery is even more important in these eyes, because the endothelium is more vulnerable to nuclear fragments and fluidic turbulence. I appreciate the additional protection I get from the chondroitin sulfate in Viscoat OVD (Alcon Laboratories, Inc.). There is a distinct difference between Viscoat and any other viscoelastic agents. I have tried several different OVD formulations, but I feel that Viscoat offers the best protection for the cornea in eyes with dense cataracts.

I would also like to comment on removing the nucleus. I think surgeons should approach nuclear extraction from the posterior plane. The low fluidics of OZil can be very helpful in allowing us to fragment and remove the lens away from the endothelium. Attempting this technique with longitudinal ultrasound poses too great a threat to the posterior capsule (or the iris, in the case of a small pupil). Low fluidic parameters enable surgeons to work away from the endothelium without fearing any ill effect from the aspiration. This is where I think the OZil technology shines: the ability to use low parameters without sacrificing efficacy.

Dr. Nuijts: To increase endothelial protection during cataract surgery, Alcon and other companies are looking at ways to improve their irrigating solutions so that they can scavenge for free-radical formation. This feature should protect the endothelium even more from increased flow of 40 mL/min.

With high fluidic rates, cohesive viscoelastics aspirate quickly from the eye and therefore cannot protect the corneal endothelium. We have to look at other dispersive solutions that can cover the endothelium better, like those with chondroitin sulfate. These OVDs stay in the eye for a longer period of time. If we could transfer that characteristic to the irrigating solutions, I think it would be beneficial in cataract surgery.

SUMMARY

Dr. Mamalis: We have all stressed the importance of promoting corneal clarity after cataract surgery. This goal

has become critical with the advent of premium refractive IOLs and the possibility of performing refractive lens exchange with IOLs to enhance near and distance vision. We have seen a marked increase in patients' as well as surgeons' expectations, so we need to do everything possible to maintain the health and clarity of the corneal endothelium after the procedure.

Do you panelists feel that heightened patient expectations has put more emphasis on the quality of your outcomes, and do you think that is affecting surgeons' choice of surgical products?

Dr. Nuijts: Surgeons in private practice of course weigh cost versus performance in surgery. However, if surgeons are not able to measure the superiority of one product versus another, they will not realize they need to switch. Moreover, I fear that the constant emphasis on cost reduction, such as less frequent postoperative patient visits, lessens postoperative controls and prevents surgeons from knowing what is happening in the eye in the early postoperative period. This makes it difficult for some surgeons to realize the beneficial effects of all the products they use. Therefore, it is clear that surgeons need to be continually educated about the benefits of certain products over others, especially in eyes that have a compromised endothelium. ■

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