

SURGICAL EDITION

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Glaucoma Surgery: Today and Tomorrow

Glaucoma Today held a roundtable discussion on glaucoma surgery at the 2006 AAO Annual Meeting. Participants shared their views on the procedures, technologies, and problems of today, and they looked forward to the possibilities of the future.

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PARTICIPANTS

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THE TUBE VERSUS TRABECULECTOMY STUDY

Lewis: The Tube Versus Trabeculectomy (TVT) Study is considered a landmark, and its data will have a profound effect on our approach to glaucoma surgery.^{1,2} How has the study impacted your practice?

Goldberg: One problem facing readers of the TVT Study is that they may not have many patients who fit the study's criteria for inclusion and exclusion. That means that the conclusions of the study may not be applicable to many of their patients.

Also, many of the conclusions from the TVT Study are based on a remarkably high complication rate for trabeculectomies. I have been using tube shunts since 1984. They also have many potential complications. For example, regardless of how you cover them, in time, the tissues will thin and become avascular, and the tubes eventually will erode. Tubes can migrate anteriorly and cause epithelial changes. It would be an oversimplification to conclude from the TVT Study that tube shunts are a superior option to trabeculectomy.

Ahmed: The trabeculectomy group required less medication, but the success rates of the two modalities were pretty similar. It was a large study, some 200 patients, and comprised a diverse population. Someone whose first trabeculectomy failed is very different than someone who has undergone phacoemulsification and needs glaucoma surgery. The results that I am most interested in are patients who had failed trabeculectomy with mitomycin C (MMC), and they composed a small group. Based on my experience, tubes definitely come into play with these patients.

Lewis: What I think was so dramatic about the TVT Study was that the complication rates were so high.

Condon: It would be a bold move for ophthalmologists to switch completely to tube shunts or trabeculectomy based on the TVT Study. The results are short term at this point, and, as Ike noted, the groups were diverse. I agree that a patient with a failed trabeculectomy is completely different from one who has undergone clear corneal phacoemulsification and has virgin conjunctiva. The TVT Study has reaffirmed my belief that trabeculectomies have a solid role in glaucoma management. The data on complications also have made me feel a lot better about my trabeculectomies and my technique. The study has not really changed my mix, if you will, in terms of tubes and trabeculectomies.

Crandall: I am involved in residency approval. Because of the TVT Study, residents could not get enough hands-on experience at VA or university hospitals to qualify for trabeculectomy.

Condon: It is surprising that the TVT Study is already affecting how many trabeculectomies residents are performing during their training. In that regard, the TVT Study may propagate the complications of trabeculectomies that were reported.

Brown: We have put all of our intellectual and inventive efforts into procedures that do not create holes, so no one has really assessed how to make trabeculectomy better. When you break down a trabeculectomy, it is just a hole. The main issue is that we cannot control aqueous flow as we would like. In London, Peng Khaw, PhD, FRCS, has made creating a hole into a very large operation, because he is trying to control the flow. A tubular device not made of metal that could titrate aqueous flow and direct it posteriorly to produce a posterior bleb would make trabeculectomy a much safer procedure and a much smaller operation.

Lewis: Has the TVT Study changed what you are doing?

Brown: No, because I have the same concerns that everybody else has about tubes.

Ahmed: I always worry about the corneal issue. It is evident to me that there is a regurgitation of aqueous with the ocular pulse back through the tube. I have seen it come right back into the anterior chamber. This, along with intermittent tube/cornea touch, may result in an increased risk of corneal decompensation. I worry about creating more problems with our procedures that are not necessarily glaucoma related.

Lewis: Is the complication of a tube (particularly its effect on the endothelium and its potential for erosion) better or worse than the long-term complications of a bleb—the dysesthesia, thinning, and infection?

Condon: Again, the data from the TVT Study are short term. I agree with Ivan that we are likely to see long-term complications in the tube group. I do believe that a tube placed in the pars plana as opposed to the anterior chamber

can greatly reduce the risk of late problems like erosion of the tube and eliminate associated corneal problems.

Ahmed: I should note that I have been really pleased with my tubes. To me, they have an important role in eyes with failed trabeculectomies, previous conjunctival mutilations, scleral buckles, major extracapsular or intracapsular cataract surgeries, or previous filters.

Lewis: No one has talked about the amount of pressure lowering. In my hands, tube shunts tend to produce IOPs in the high teens or low 20s.

Goldberg: That is my experience as well with the two-plate Molteno Implant (Molteno Ophthalmic Limited, Dunedin, New Zealand), which provides 270 mm² of drainage area. If you need a lower IOP, often the patients require supplementary aqueous outflow suppressants.

Lewis: So, you are on medication plus?

Goldberg: Many patients are. Pleasingly, many patients respond well to timolol once daily.

Lewis: Nothing beats trabeculectomy for reducing medication.

Brown: I liken the treatment of glaucoma patients to moving them out on a limb. You have a certain number of branches and opportunities, and you cannot go back. Once you have placed a tube, it is very difficult then to do additional surgical procedures. You have put them in a situation where their only remaining options are a second tube, an inferior tube, or cyclodestruction. Glaucoma surgeons must always ask, what is my next operation?

IMPACT OF SLEEP DATA ON THE DIURNAL CONTROL OF IOP

Lewis: Robert Weinreb, MD, has reported that patients' IOPs are significantly higher when they are recumbent and sleeping and that prostaglandins seem to decrease pressure the most at this time point.³ No glaucoma medication lowers the IOP adequately in certain high-risk patients. When you look at diurnal curves, check IOP while patients are recumbent, and compare them on medications, no medications, and surgery, the only ones who have a flat curve, who have well-controlled pressures, are the surgical patients (R. N. Weinreb, MD, unpublished data, October 2005). Shouldn't surgery therefore be the solution to noncompliance, poor diurnal IOP control, and a lack of target pressure?

Brown: Wouldn't surgery be a better way to control pressure? The answer, I think we would all agree, is yes. It is just a matter of having an operation that is safe and effective.

THE EYEPASS GLAUCOMA IMPLANT

Goldberg: Reay, with the Eyepass Glaucoma Implant (not available in the US; GMP Companies, Inc., Fort Lauderdale, FL), you have been disappointed with your results. Why do you think that is?

Crandall: No, the pressures were not as low as we had hoped, but it is a great procedure, very safe. I think it is a good start on a Schlemm's canal procedure.

Goldberg: What percentage of the patients ended up needing a secondary procedure, probably a trabeculectomy?

Brown: About 50%. That is too high.

Condon: An operation that has a very low risk and only works half the time might be a pretty reasonable operation.

Brown: I think that is true, but a 50% success rate probably occurs because we do not understand exactly how it is

working—or not working. If we understood outflow and how these devices may promote it, we would probably be able to increase the 50% success rate greatly.

Goldberg: Any procedure that buys the patient more time is worthy of consideration.

THE AquaFlow COLLAGEN GLAUCOMA DRAINAGE DEVICE

Lewis: Ivan, what are some of the pluses and minuses of the AquaFlow Collagen Glaucoma Drainage Device (STAAR Surgical Company, Monrovia, CA)? How many of these have you done?

Goldberg: My group has done 13 only, and we had one long-term success. The 12 others failed, and they all went on to receive trabeculectomies augmented with antifibrotics.

Lewis: Alan, do you still use the AquaFlow?

Crandall: I use the AquaFlow for individuals with whom I follow up quite frequently. For the many out-of-state patients sent to me for glaucoma procedures for whom I will not do the follow-up, I will usually choose a standard trabeculectomy with MMC. I am very comfortable with the AquaFlow, and I don't mind modifying it—everything that I might do for a trabeculectomy. My results are good.

Lewis: Do you get a bleb with that?

Crandall: Almost always.

Lewis: Can you describe your procedure?

Crandall: It is nonpenetrating, but I use MMC. I do modifications maybe 50% of the time. People say, if you modify it, it is a trabeculectomy, but it is not, because the holes are a different size.

Lewis: Is there any operation today that you are confident works well for glaucoma and that actually relies on fluid's getting outside the scleral wall and into the subconjunctiva?

Condon: I am mainly performing trabeculectomy with a smattering of nonpenetrating deep sclerectomy AquaFlow.

CANALOPLASTY

Condon: I have performed five canaloplasties (iScience Interventional, Menlo Park, CA) with the 360° suture in Schlemm's canal. The predictability has not been there for me. One is a booming success. Two other patients are on medications, and two others have had trabeculectomies. These were all primary surgeries.

Ahmed: By putting a suture there, do you think you are creating an effect like pilocarpine or holding the canal open?

Lewis: The viscodilation part of the study showed some pressure reduction without that. They viscodilated at the same time they did the deep sclerectomy without putting the suture in. So, they still enhanced fluid flow across the membrane into the scleral lake.

Condon: You have deep sclerectomy data. We now have 360° viscodilation data, which showed it did not get the pressure low enough. Now, we add the third component, which is a tension suture in the canal. How long that is going to last and whether suture tensioning is the answer we do not really know. Is there any chance that multicenter data, stratified, would suggest which type of patients will have successful outcomes? What are we going to know other than the overall success rate with this operation?

Lewis: Surgical studies are difficult to recruit for and interpret. Some of the patients had combined surgery, some had argon laser trabeculoplasty, and some were on medication. This mixed bag of diagnosis and prior treatments is a problem in surgical studies, partially explaining why some patients do well and some patients do poorly (see Formatting Surgical Reports).

Condon: Also, what component of that procedure is the most important? I cannot figure that out.

Brown: It is also difficult to improve when you do not understand why it works in the first place.

Lewis: It is going to take a broadening of this field. We seem to get a reduction of IOP. What happens when we get some more surgeons who are adequately trained doing this procedure?

Brown: You are passing a huge device through a very delicate structure with viscoelastic. Maybe it helps, but maybe it creates inflammation.

Condon: Rick, which patients do you think are not good candidates for the canaloplasty suture surgery?

Lewis: I would say patients who have causes of secondary glaucoma. My most obvious failure was someone with a 35-year history of diabetes. Although I did not see diabetic retinopathy, she ended up having ischemic disease. Something was going on in the way her eye reacted to the surgery. I did not see much inflammation. That is what is so remarkable about these patients. Postoperatively, their vision is remarkably good, there is no bleb, and there is no anterior segment inflammation. The eyes look really good on the first day.

Ahmed: With ischemic diseases, that is a major problem.

Lewis: Yes, I totally did not recognize it. But, the postoperative care of these canaloplasty procedures is light years better than everything we have to do with trabeculectomy. I do not have to work with a bleb, perform laser suture lysis, or see patients every couple of days for the first few weeks. The key is selecting which patients are good candidates.

Condon: Assuming patients have open angles, whom are you excluding?

Lewis: Secondary open-angle glaucoma patients such as those with ischemic disease or a history of trauma are not good candidates. The challenge is understanding the anatomy. Once surgeons learn to find the canal, canaloplasty is not very difficult. iScience Interventional has an imaging system that helps beginners identify the canal (Figure 1). The other challenge is the tension of the suture. The more distension of the canal, the greater the pressure drop. The biggest complication of our study is Descemet's detachment.

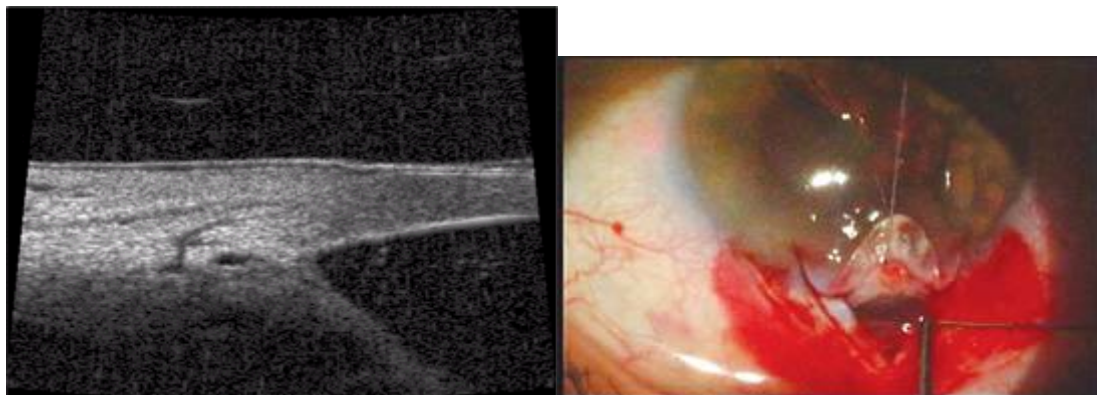


Figure 1. The canal of Schlemm and collectors are viewed with the iUltrasound (iScience Interventional) (left). Lifting the scleral flap reveals the canal (right).

Goldberg: Is it too early to tell if the suture is going to erode into the anterior chamber?

Lewis: It has not been a problem but theoretically could be. If the suture is too tight, you can remove it. If it is not tight enough, you can replace it through the original flap.

SOLX GOLD MICRO-SHUNT

Ahmed: I do not think that simply trying to bypass the meshwork or trying to enhance the canal is going to get the pressure down. There may be functional blockage, not just structural blockage, in glaucoma. We seem to be stuck at 16 to 17 mm Hg with these procedures that attempt to bypass the meshwork. I am intrigued by the suprachoroidal space. There is a huge potential for IOP lowering without the bleb.

Implanting the Solx Gold Micro-Shunt (not available in the US; OccuLogix, Inc., Mississauga, Ontario, Canada) is an attempt to control and titrate the traditional cyclodialysis procedure. It is a very thin—50 μm or so—wafer made of gold with two plates on it. The head sits in the anterior chamber, and the tail sits in the suprachoroidal space (Figure 2). Fluid passes through and around the shunt into the suprachoroidal space.

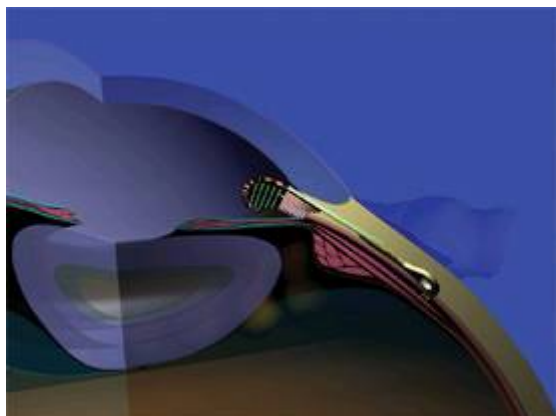


Figure 2. The Solx Gold Micro-Shunt reportedly uses the eye's natural pressure differential to move aqueous from the anterior chamber to the suprachoroidal space. No bleb is created.

There have been over 150 to 200 worldwide, but, as far as the study versus the Ahmed Glaucoma Valve (New World Medical, Inc., Rancho Cucamonga, CA), there are about 60 patients in that study. The early results, again only 6 months, are promising.

Lewis: Did you check them for lasers?

Ahmed: None of these has lasers. These are patients that have at least one failed trabeculectomy or tube. These are pretty sick eyes. I have often seen IOPs in the low teens. It is still early in terms of suprachoroidal instruments and devices, but I think this area has great potential. What I am doing is basically making a scleral cutdown, 3 to 4 mm to the limbus to 95% depth and then entering the anterior chamber, keeping to the angle as much as I can through the spur. I place the head of the implant through that dissection. Then, I make that cutdown all the way to the choroid and then tuck the tail of the implant back into the suprachoroidal space. I like to have a bit of an anterior shelf there. When you make a large incision, you see a fishmouth of that internal incision around the head of the shunt. I really aim to have some lateral flow around the implant. I also think of it like a stent.

Lewis: Do you have hypotony problems?

Ahmed: In the early postoperative period, a minority of patients had transient hypotony, but no one has had a persistent choroidal effusion.

Condon: The beautiful thing about this procedure is that the likelihood of choroidal infusion is slim, because there is no pressure gradient across the insertion of the choroid and the sclera once the device is in place.

Lewis: Is the device stable across the angle?

Ahmed: Surprisingly, it is.

Lewis: Why do you think the device failed in some eyes?

Ahmed: I think it was multiple issues. Fluid may enter the suprachoroidal space, but then it may be localized beyond that. Alternatively, there may be fibrosis in the suprachoroidal space. If the fluid is only going through that shunt, then maybe that is insufficient for some patients. Finally, there may be an obstruction at the head of the implant in the anterior chamber if it is placed too close to the cornea.

Brown: Because it is too big?

Ahmed: I do not think that it is big enough. I think that you need to have openings bigger than 40 μm .

ENDOCYCLOPHOTOCOAGULATION

Ahmed: During the last year, I have been combining endocyclophotocoagulation (ECP) with phacoemulsification. In a current, ongoing study, my colleagues and I are prospectively comparing phacoemulsification with combined phacoemulsification and ECP. I do not generally favor external cyclodestructive surgeries because of the risk of hypotony and complications. I have been fairly impressed, however, with the lack of major problems with ECP and the reasonable reduction of IOP in patients whom I have selected. Typically, they are in for cataract surgery, they have mild-to-moderate glaucoma, and their IOP is borderline controlled (20 to 21 mm Hg) on a couple of medications.

Lewis: You take the cataract out?

Ahmed: The tip of the scope is placed just anterior to the zonule into the sulcus. Space is created with the use of viscoelastic. Everything is visual, so the ciliary process is seen during ablation. When it whitens and contracts, there is a visual endpoint. Thus, the damage to muscle and deeper tissue is minimized while the effect is to the aqueous-producing ciliary epithelium.

Lewis: How many areas do you treat?

Ahmed: I do at least 270°. I like the endoscope for other things. I use it for sutured IOLs and other intraocular suturing. I was treating aggressively and using a lot of steroids. Overall, it has been reasonable. Pressure spikes had been a problem.

Lewis: Because you have no outflow at all. You cannot win the game by shutting down outflow.

NONPENETRATING GLAUCOMA SURGERY

Condon: Nonpenetrating surgery has advantages over trabeculectomy, so why isn't it more popular? It is harder to do and takes too long.

Lewis: It does take a little longer than a trabeculectomy, but postoperative care is shorter. So, the overall time commitment (intraoperatively plus postoperatively) is probably less when performing nonpenetrating surgery.

Condon: I do not think my postoperative care for a well-performed trabeculectomy is any more intense than for a nonpenetrating procedure in a routine case.

Lewis: My incidence of shallow chambers or hyphema in nonpenetrating surgery versus trabeculectomy was not different.

Condon: Let's return to the question of why, despite the well-documented studies showing that nonpenetrating surgery is potentially safer than trabeculectomy,^{4,5} it is not more popular. In the beginning, the success rates were not duplicated outside of certain parts of the world. That reduced surgeons' enthusiasm. I also think that residency programs in the US do not teach residents how to get into the canal.

Goldberg: Nonpenetrating surgery involves too much of a learning curve. It was too hard for the glaucoma faculty as a whole to master, so there was no way the general ophthalmologist was going to pick it up.

Brown: With cataract surgery, you can trace the progression from intracapsular to extracapsular, 7- to 6- to 3.5-mm phacoemulsification. The goal is pretty obvious. That is not true yet for trabeculectomy surgery. It is an issue of convergence.

Lewis: You don't think that lower pressure is the goal?

Condon: We do not know what to converge on. If we knew that our goal was something that directed fluid directly to the ostium of a collector channel, we could solve that problem.

Brown: If locating Schlemm's canal allowed patients to see well up close and far away, I guarantee you that manufacturers would have devices to find Schlemm's canal in about a week.

TRABECTOME

Lewis: Let's turn our attention to the Trabectome (NeoMedix Corporation, Tustin, CA) (Figure 3).

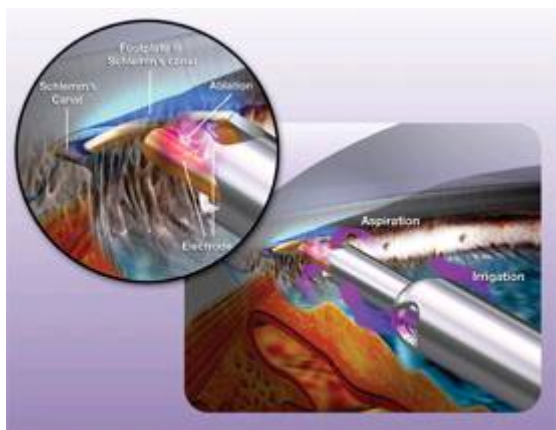


Figure 3. The Trabectome applies microelectrocautery ablation in Schlemm's canal.

Ahmed: I am looking at it right now with my hospital.

Lewis: The Trabectome is an expensive device. The machine plus each of the probes costs around \$2,000.

Brown: Cost is an important issue, but we need to consider our patients. What do we want for them? What would we want for ourselves? If the Trabectome had a 50% success rate that was long lasting, it would be a pretty

tempting procedure. I am interested in it, because, if I am not going to hurt the person, then doing that as a combined procedure would seem to be of great benefit to the patient.

Condon: You certainly still maintain the option of a trabeculectomy.

Goldberg: I do not find the concept of the Trabectome very attractive. I think it is conceptually akin to ciliary body destruction, except it is targeting outflow as opposed to inflow rates. Although, theoretically, this is certainly better, it seems to me rather gross tissue destruction. We have to try to refine it.

Brown: We don't know that it is any more traumatic to the trabecular meshwork and the angle than a trabeculectomy. I think the recommended treatment is only 30°. So, it is a very short amount of treatment, and that raises the question, would 60° be better than 30°? Or, would it be better to remove two 30° segments from nonadjacent areas?

Lewis: Does anybody have histopathology at 1 or 2 years? What does the tissue look like? Is it all fibrotic?

Brown: Why would you want to see histopathology? It would seem to me that what you would really want is outflow.

Lewis: We need long-term data on efficacy and histopathology to ensure we are not jeopardizing outflow.

IMAGING

Goldberg: When you have all these parallel streams of surgical research heading in a number of different directions, it means nothing is optimal. Currently, with all of our techniques, we cannot reliably control the rate of outflow in the immediate postoperative period reliably. We have techniques that err on the side of ocular hypertension rather than hypotony, and then we fiddle with stitches in all sorts of ways to encourage drainage. We cannot predictably do an operation, however, and know the rate of flow is going to be so many microliters per minute. We just do not have that technology.

Should we be trying to design a way of imaging the outflow pathway for an individual patient? If we could do that, then maybe we could actually think about the different methods and their physiologic effects, and this might help us to achieve our goal to reduce IOP reliably and predictably.

Lewis: That capability is so relevant in cardiovascular surgery. They do angiography catheterization. They can determine which are not operable situations and which would benefit from coronary bypass surgery.

Goldberg: What if we could identify where the blockage was in glaucoma? Then we could say, we need to put in a stent, or we need to do a trabecular bypass surgery.

Lewis: The point is cardiovascular surgeons can see what procedure is most appropriate. What if we could see that a patient's outflow system was never going to work or determine that a canal-based procedure had a good shot at working?

Goldberg: Could we design an imaging technique that identifies the outflow pathology of a particular glaucomatous eye?

Brown: I think we all agree that a better understanding of outflow is critical to moving forward in canal surgery.

PANELISTS' CHOICES

Lewis: If you were newly diagnosed with glaucoma and had cupping, visual field loss, and uncontrolled pressure, would you opt to have surgery or medication?

Condon: I would have selective laser trabeculoplasty (SLT) or maybe a drug. I certainly wouldn't have surgery first.

Crandall: I would probably not have surgery first but have a short trial on medications and SLT. I would proceed quickly to surgery, however, if my IOPs were not controlled.

Goldberg: If I had chronic open-angle glaucoma, I would try medications and SLT before invasive surgery.

Ahmed: I would actually probably go with SLT first and then proceed to nonpenetrating surgery.

Goldberg: You would not even try a medication?

Ahmed: Not if I had significant cupping.

Lewis: There is no question that a good surgical outcome really stops the disease.

Brown: This brings me back to my point about trabeculectomy with a device. With nonpenetrating surgery, you are controlling the outflow to a relatively low flow rate so that you do not have to perform an iridectomy. You do not have to worry about hypotony. I am saying I agree. Let's have a device that you just slip in so you get the same well-controlled pressure outflow characteristics that you get with nonpenetrating surgery by finding Schlemm's canal and using that barrier to control outflow. But, with the right device, you do not need to find Schlemm's canal, because you are creating a "hole" by placing a device that has reduced outflow characteristics built into it. The device's placement would be a much easier operation than finding Schlemm's canal, and it would be a much smaller operation. So, it would save options for the future.

Condon: Your point is well taken, Reay, but it is a little bit hypothetical.

Lewis: To the question of what we would do—medication, laser, surgery—there is no consensus.

Brown: When I was in Germany, I was watching colleagues perform cataract surgery. They were using the same implants, the same procedure, just a little tweaking here and there. There was a convergence of technology and technique. In glaucoma, we do not have a platform where you can say we are converging. But, we are taking steps down the road, and eventually I know we are going to get there.

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