Notes from a surgeon roundtable discussion

Moderator: I want to thank you all for taking the time to meet with me here in Brisbane, Australia. As you know, I am interested in your experiences with the Hydrus Microstent, the Schlemm’s canal scaffold from Ivantis (Irvine, California). I would like to begin by sharing some data collected from Ivantis’ global online registry. That will be our starting point, but more importantly, I’d like you to share your thoughts regarding the use and efficacy of the Hydrus Microstent in your practices. The panel in this room is arguably one of the most experienced groups in the world regarding the length of time you’ve used the device and the volume of surgeries completed with the device, either in combination with cataract surgery or as a standalone procedure. Your insights will be helpful to surgeons around the world as they obtain access to the Hydrus Microstent. I know any advances in this new paradigm in glaucoma treatment, often referred to as microinvasive glaucoma surgery (MIGS), will be of considerable interest to your colleagues worldwide.

Dr. Healey: It’s worth pointing out that MIGS is a convenient term, but not very specific. Perhaps it is time to search for another. A short tube put through the wall of the eye may be considered MIGS, but such procedures must always be treated as a type of external drainage procedure, with all its attendant benefits and risks. Such a risk/benefit profile is different from canal-based procedures such as the Hydrus Microstent or indeed suprachoroidal procedures. Terminology that differentiates these may be required.

Moderator: That’s an interesting observation. The differences you note will likely be raised again later when we discuss the technology in more detail.

continued on page 2
To begin our discussion, I’d like to present some of the data available from a global registry that tracks clinical outcomes with the Hydrus Microstent. While recognizing that such a registry is not a controlled clinical study, it has considerable value in terms of representing “real world” results. The data set as of the time of this discussion consists of more than 1,500 eyes treated at 48 centers in 17 countries and was analyzed to assess the performance of this novel MIGS device. It should be noted that the majority of these patients fall within the moderate to advanced glaucoma classification, as more than 69% of patients are on two or more medications and 41% of patients are on three or more medications. Where patients fall on the disease severity scale will have an impact on how measures such as IOP and medication reduction should be interpreted. Patients with a higher baseline medication count, for example, will generally be less likely to be medication-free compared to a patient on one medication at baseline.

Figure 1 shows 12-month clinical data for combined cataract surgery and Hydrus implantation. In nearly 600 eyes at 12 months, there is both a statistically significant pressure reduction (18%) and a substantial medication reduction (59%) in eyes that have received the Hydrus Microstent compared to preoperative levels (both p<0.05). While overall the number of patients on 0 medications at 12 months was 53%, Figure 2 shows for those patients on one medication preoperatively, 83% were medication-free at 1 year, and for those on two medications at baseline, 63% were medication-free at 1 year.

Figure 3 shows IOP and medication reduction in a consistent cohort of 84 patients from the data set with 1-, 2-, and 3-year follow-up available, again for combined cataract surgery with Hydrus implantation. The reduction in IOP and number of medications appears stable across that time period, indicating that the Hydrus is a durable long-term option for pressure management in patients with glaucoma.

Finally, I would like to compare these data to a publication from Pfeiffer et al, which reported on a multicenter randomized controlled study with 2-year follow-up. He and his colleagues randomized 100 eyes with mild to moderate glaucoma (mean baseline IOP 18.9 mm Hg on 2.0 medications, with a diurnal washout pressure of 21 to 36 mm Hg) at the time of cataract surgery to the Hydrus Microstent compared to cataract surgery alone. This study reported mean IOP of 16.0 mm Hg on 0.5 average medications at 12 months with 77.5% of eyes medication-free, and 16.4 mm Hg on 0.5 average medications with 75% medication-free at 24 months in the Hydrus Microstent group, all significantly superior to cataract surgery. While the study population was primarily mild to moderate glaucoma, the results from the “real world” data appear consistent with those found in this controlled clinical trial, especially among patients with similar baseline characteristics. The implication of these data is that the IOP values from our clinical practices were similar to those observed in a controlled study, but the magnitude of medication reduction will vary by baseline severity. This is important because I know several of you have tertiary care practices, where you are managing more severe glaucoma in many cases.

Dr. Lim: The results you’ve shown here look similar to my experience. The majority of patients I’ve treated with the Hydrus Microstent were mild/moderate glaucoma patients, similar perhaps to the study cohort. While I don’t have a large number of patients at 2 years, my 1-year data shows a pressure drop of about 25% in my patients, even as most of them were able to discontinue at least one medication. I’ve noticed
numbers, but my patients want to know, “How will this impact my life?” My patients with a Hydrus Microstent who have been able to decrease their medications are happy people.

Dr. Cronin: Allergy is not the only issue either. Prostaglandin analogs can change the appearance of the patient’s eyes, and glaucoma medications have known negative effects on quality of life. Those are tolerated because of the need for pressure control. However, if the Hydrus can control the pressure in the absence of or with a reduction of medications, patients may experience a quality of life improvement.

Dr. Chiang: If patients are entirely free of drops, and this appears possible in a reasonable percentage of cases, I have found it has a significant effect on their quality of life. In fact, even eliminating one medication can improve quality of life for many patients.

Dr. Hay-Smith: That is one reason I consider the Hydrus for implantation in my elderly patients, some of whom have not had their glaucoma appropriately managed for decades. In some of these patients, drop compliance can be a major challenge, and the Hydrus Microstent can be helpful.

Dr. Lim: This discussion points to the value of health economic studies that include quality of life issues to

Dr. Lim: This can be important. We often concentrate on the
demonstrate the cost effectiveness of the Hydrus over and above expected savings on chronic medical therapy.

Moderator: Earlier comments suggest that the use of Hydrus at the time of cataract surgery in cases from mild to refractory glaucoma appears viable. Is that your experience?

Dr. Chiang: As a glaucoma referral center, I did not start using the Hydrus with the mindset of using it only for mild to moderate glaucoma. I use it in a wide variety of cases, including refractory glaucoma, so my spread of data is higher than might be typical. With data from 40 patients at 1 year and 21 patients at 2 years, results in my broader data set match those above—about 25% lower IOP and a reduction in the number of drops. At 1 year, 40% of my patients receiving the implant were no longer using drops. The pressure drop I achieved at 24 months with the Hydrus was still high because I treat advanced patients conservatively and perhaps left them on drops for longer than required.

I have implanted the Hydrus in a number of patients who were on maximum medication therapy. Some were cataract plus Hydrus as a “staged” procedure, as I expected to need a trabeculectomy or other filtering procedure down the road. Results and patient response to these cases has been exciting. Patients often ask if their fellow eye can be treated in the same way. I would say that Hydrus is a viable alternative for maximally medicated patients who are unsuitable for or unwilling to have a trabeculectomy. Early data suggests a reduction in the number of medications is possible. Interestingly, I have implanted Hydrus Microstents in cases of angle closure, when after cataract surgery I can see the angle and get around any synechiae. In these patients I have seen a much larger pressure drop, part of which is no doubt achieved as a function of the cataract surgery.

Dr. Healey: It is likely that with patients who have higher pressures, the effect of the stent will be good, provided the collector channels are viable. Preoperative pressure is a likely predictor of the effectiveness of any canalicular stent.

Dr. Lim: I have noticed that. I’ve seen average pressure drops of 34% at 1 year for my patients with a starting IOP >21 mm Hg, with a drop of about 23% in patients with a starting IOP <21 mm Hg.

Dr. Hay-Smith: Some patients who are maximally medicated and who are still not at their target pressure are often not suitable for a trabeculectomy. In several of these cases I’ve implanted the Hydrus Microstent and been pleasantly surprised by the results—the pressure drop has been sufficient to avoid the trabeculectomy. As a consequence, I will now look at putting the stent in instead of performing a trabeculectomy in more of my patients.

Dr. Chiang: The Hydrus can work well in refractory cases, and it is often the best alternative when there are no other viable surgical options or when you want to delay more complex surgery. For instance, in the case of a red-eyed patient with a poor ocular surface who might be presenting for a trabeculectomy, I introduce the Hydrus as a possible interim step. If the Hydrus provides a sufficient pressure drop, great, but the patient does have to understand that a trabeculectomy may still be necessary.

Dr. Lim: Like you, I will use the Hydrus in cases where medical therapy is failing. I use it as a staged procedure, looking for a delay in the need for a filtering procedure.

Dr. Lee: I would concur. I think I am doing fewer trabeculectomies now but using more tubes. For complex glaucoma cases I find that I am working more with tubes and stents now.

Dr. Healey: I have a similar approach in my practice. I tell patients that in advance of a trabeculectomy a Hydrus Microstent may be helpful. If it works, it may offer the chance to avoid the trabeculectomy and the necessary follow-up with that procedure.

Dr. White: Older pseudophakic patients account for a large proportion of my candidates for the Hydrus. In many cases I think they would not stand up to more complex surgery. Increasingly, those in whom in the old days I might have performed a phaco-trabeculectomy are being offered the Hydrus Microstent.

Dr. Yuen: My typical patients for the Hydrus have mild to moderate glaucoma. However, I’m happy to use the Hydrus for cases outside that, particularly those that are on maximal medical therapy and are facing the prospect of a tube or trabeculectomy. In cases of cataract, the use of Hydrus at the time of cataract surgery is a “no brainer.”

Moderator: You mentioned implanting the Hydrus in pseudophakic patients. Much of the discussion to this point has related to Hydrus implantation at the time of cataract surgery. Is a standalone surgery also an option, and when do you consider it?
Dr. Cronin: I do both the standalone surgery and the combined cataract surgery as required. The patient demographics for both groups, at least in my practice, are about the same.

Dr. Lim: I would say that pseudophakes with mild/moderate glaucoma are one group of patients in my practice that I would suggest the Hydrus Microstent to, in a standalone procedure.

Dr. Lee: The candidate for a standalone procedure with the Hydrus Microstent in my practice is a patient on maximal tolerated medical therapy. In these cases, I am hoping the Hydrus will avoid the need for a trabeculectomy. Other standalone surgery candidates are those who have already had a trabeculectomy or tube implanted but who still have a higher than desired pressure. In these cases, I will also implant a Hydrus.

Dr. Green: Standalone surgery represents one of two general patient groups for me. When I am performing cataract surgery on a patient with mild to moderate glaucoma I look at implanting the Hydrus as an important adjunct for the patient to consider; that is my first group. The second group is those patients with ocular surface disease who are looking for more comfort and less redness. That group drives my standalone surgeries.

Dr. Chiang: I find standalone surgery highly effective.

Moderator: Can you characterize some of the patients you are implanting with the Hydrus Microstent? How are you deciding to move forward with the stent? How do patients react?

Dr. Healey: Most of my candidates are those with poorly controlled pressures, with a small subset of patients where alternative surgeries are extremely high risk (of failure or complications). From both groups there is a high rate of acceptance. A patient with a trabeculectomy in one eye and a Hydrus in the other is a strong spokesperson for the stent.

Dr. Hay-Smith: I find myself using the Hydrus as an alternative to a trabeculectomy in many cases, hoping to avoid the need for the latter if the stent provides sufficient pressure lowering. The morbidity of trabeculectomy, with 20% of patients returning to the OR within a few years even when a skilled surgeon performs the original procedure, argues strongly for trying the stent first.

Dr. Lee: If I’ve got glaucoma patients presenting for cataract surgery and if I’m not offering them a stent, I think I am missing an opportunity to lower their pressure, reduce medications, or both.

Dr. Yuen: There are patients who, for various reasons, you’d like to have avoid a major surgery. The Hydrus can be a good interim solution for those patients. I’ve had a patient with advanced glaucoma who did have a trabeculectomy in the first eye, but wasn’t happy with the experience. Such patients are pleased to learn that there is an alternative that may avoid the need for a trabeculectomy.

Dr. Healey: You mentioned patient response. Happy patients are the best advertisement for the Hydrus. Some of my patients tell me the Hydrus has changed their life.

Moderator: Dr. Lee, I understand you’ve recently completed a clinical study of the short-term results from implantation of the Hydrus Microstent. I’m sure the group would be interested in your findings.

“\nThe scaffold dilation of Schlemm’s canal, the bypassing of the trabecular meshwork, and the 90-degree coverage area to reach several collector channels constitutes the ‘trimodal action’ of the Hydrus Microstent and is unique to this device.\n”
Moderator: What are some of the things that you like about the Hydrus? How have you decided on the Hydrus as a procedure of choice? How does it compare to other surgical devices you have used for the management of glaucoma?

Dr. Green: A big advantage of the Hydrus device to me is its low risk profile. I don’t think that there is much of a downside to implanting the Hydrus, while there is a high upside.

Dr. Lim: To me, the beauty of the Hydrus is that when it is in, you know it is in—I think of it as “verifiable.” In my experience with an alternative stent, I haven’t felt as confident about the procedure. It was sometimes difficult to tell if it was in the correct location. In general, I think we are lucky to have a canal-based choice such as the Hydrus in our surgical approach now.

Dr. White: There is a shorter alternative stent, but I’ve found that it is possible to get the placement “wrong” with that device. With the Hydrus it is difficult to get the placement wrong.

Dr. Yuen: I would agree. I’ve found with an alternative stent that placement and/or depth of insertion can be difficult to control, and it can also be hard to tell if the stent is in the correct position. I’ve had no such issues with the Hydrus.
Dr. Lee: I think the challenge with the smaller stents and their smaller surface area is that the friability of the trabecular meshwork can make it difficult to place properly. I used a different stent before the Hydrus but I found that with the smaller design I wasn’t getting enough pressure lowering consistently, often a function of how close I implanted it to a patent collector channel. I’ve had more consistent pressure lowering with the Hydrus.

Dr. Cronin: You have in Hydrus a device that from a model perspective is safe, effective, and easy to get right. It has no real competition in this regard. Ethically, it is something I think I should be using.

Dr. Chiang: It is reassuring in that you can see it is there, you know it is in, and you can see it is working.

Dr. Hay-Smith: I am driven by published data. To date, comparative articles suggest the Hydrus is the most effective stent on the market. I’ve found it easy to use, and I’ve had a lot of success with it. It is unlikely I will use any alternative stent unless or until there is published data to change my opinion.

Dr. Green: As noted, there is little data in the literature comparing the various stent options at present, so one must consider other factors. The 90-degree scaffolding and the dilatory effects of the Hydrus on Schlemm’s canal give it what I call a higher “biological plausibility” of lowering pressures relative to other devices I’ve considered.

Dr. Yuen: I like Dr. Green’s concept of “biological plausibility.” With a 90-degree coverage area and the canal dilation, it is hard to imagine that there won’t be a patent collector channel available to the Hydrus. It would be much harder to make that claim with a smaller stent. I think Hydrus is superior to other stents available at present, based on the results I’ve achieved. It is my “go to” device for any open angle glaucoma.

Moderator: As an aside, that 90-degree coverage area, which is likely to include several collector channels, the scaffold dilation of the canal, and the bypassing of the trabecular meshwork is often referred to as the “trimal” action of the Hydrus Microstent, and is unique to this device.

Dr. Healey: The Hydrus Microstent fits well into the current range of treatments and offers a canal-based procedure that does not preclude or jeopardize later fistulizing procedures. Hydrus has demonstrated a high level of patient acceptability and an easy postoperative course. A successful stent can delay or eliminate the need for fistulizing procedures, where postoperative management is half the battle. This is a strong argument for use of the Hydrus.

Dr. Green: In terms of choice of procedure, it should always come down to clinical data. Early data is limited for a lot of the new MIGS devices. Numbers are so small that it is hard to know what to make of them.

Dr. Healey: I mentioned earlier my discomfort with the term “MIGS.” Fistulizing, canal-based and suprachoroidal approaches should be considered different procedures despite all being called MIGS. The former will always be a trabeculectomy-type surgery with all the required follow-up and scarring issues. It should not be considered the same as the insertion of a Hydrus. Suprachoroidal approaches have their own benefits and challenges that have been recognized from our experience with cyclodiagnosis.

Dr. Yuen: A canal-based procedure is more physiological, and if the patient has a cataract, using a stent first seems to make more sense than going directly to a tube to access the subconjunctival space. At the end of the day all the fistulizing procedures are still a bleb, even if referred to as a MIGS procedure, with possible scarring and requirements for needling. Saving the subconjunctival procedures for later is a better way to go.

Dr. Chiang: I would agree. Most glaucoma surgeons would like to avoid the subconjunctival space, which means that implants such as the Hydrus have significant advantages.

Moderator: There are surgeons around the world who would benefit from your early experience with the Hydrus Microstent. Are there pearls you could share with them, in terms of technique and use?

Dr. Green: Wet labs and even standard cases provide a great opportunity to practice gonioscopy skills before using the Hydrus. This will help with recognizing structures and gain familiarity with the anatomical variation in angles.

Dr. Hay-Smith: It is worth reiterating that the anatomy of the angle is highly variable; the spread of what a “normal” angle looks like can be a challenge for surgeons.
who have not done a lot of gonioscopy. Practice will help in this regard.

**Dr. Chiang:** Positioning will be something that new surgeons will want to become familiar with as well. Gonioscopy skills aside, the positioning to perform the surgery will feel new and is worth practicing. Overall, it won’t be too hard to make the adaptations. As to results, it is reasonable to expect a 25% or so drop in pressures.

**Dr. Cronin:** As with all new surgical techniques, it will be a transition. Implanting the Hydrus requires a bit of an unnatural position, but a few cases getting familiar with the patient position and the gonioscopy prism will pay off. With a little practice, surgeons can expect to get their first case right. After 10 to 20 cases they should be comfortable with the procedure.

**Dr. White:** A lot of the issues will be, as noted, related to intraoperative gonioscopy and positioning. The microscope will have to be tilted, for instance. Some of the new instruments that are attached to the microscopes, such as intraoperative aberrometers, may make this a bit more difficult.

**Dr. Lim:** Most ophthalmologists will have the necessary surgical skills to adapt their cataract surgery to implant the Hydrus; they need only to have the interest in doing so.

**Dr. Yuen:** The learning curve isn’t too long. If you are comfortable with intraoperative gonioscopy, that shortens it. Like all surgery, it has its nuances, but it is not that difficult to learn to implant the Hydrus.

**Dr. Healey:** The techniques of insertion do matter, as does eye preparation. Pressure changes affect the geometry of Schlemm’s canal, and these changes are more problematic in glaucomatous eyes. The canal lumen is smaller and more discontinuous in cases of open angle glaucoma, and the lumen will be smaller with higher IOP. As such, higher IOP can make the Hydrus more difficult to insert, as resistance to insertion will increase and it will be harder to locate the canal. On the other hand, low pressure can introduce tissue distortion, which also makes insertion problematic. Dropping the IOP initially will encourage blood reflux, then keeping the IOP between 10 and 20 mm Hg (depending on scleral rigidity) will facilitate insertion of the Hydrus. In terms of geometry, it is important to remember that the wall of the eye is not perpendicular to the iris plane. The inferior wall is more peripheral than the superior. Considerations such as these will affect where and how the Hydrus is implanted.

**Moderator:** We’ve covered a lot of material today. I would welcome any parting thoughts.

**Dr. Chiang:** Something that did not come up earlier was the use of more than one Hydrus Microstent. I have implanted a second Hydrus device in one eye. The first stent did not drop the pressure sufficiently, but I achieved an additional drop in IOP with the second Hydrus, which was sufficient. There was, however, a diminishing return in that the pressure drop with the second stent was not as high as with the first. This is perhaps not surprising.

**Dr. Lim:** We also didn’t mention whether there were indicators that might help us determine which eyes will see maximum benefit from the Hydrus, outside of the fact that higher pressure is likely to improve performance. Research into this question is worthwhile, looking at aqueous veins, for instance.

**Dr. Chiang:** That’s an interesting thought. I have used video footage to look at the reflux of aqueous into veins after applying then releasing finger pressure on the globe. However, I have not yet quantified the results.

**Dr. Hay-Smith:** With a device such as the Hydrus, where the safety profile is so good, it brings up the question of when to surgically intervene in glaucoma cases. Earlier surgical intervention may be more helpful in younger people.

**Dr. Chiang:** I would agree. There is some likelihood that earlier intervention may have advantages in terms of further influencing pathological development.

**Moderator:** Doctors, I want to thank you for your time and your insights regarding the use and effectiveness of the Hydrus Microstent. It is clear from our discussion that the Hydrus Microstent marks a major step forward in the surgical management of glaucoma.

**Reference**