



# XEN45:

Seven respected surgeons offer perspective on patient selection, surgical technique, and postoperative follow-up with the gel stent implant.

## The Next Generation of MIGS

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# XEN45:

## The Next Generation of MIGS

Seven respected surgeons offer perspective on patient selection, surgical technique, and postoperative follow-up with the gel stent implant.

*In the treatment of glaucoma, surgical approaches have historically been reserved for severe cases or in instances where progression has been confirmed. That mindset shifted somewhat with the introduction of microinvasive glaucoma surgery (MIGS), which is associated with modest IOP reduction but a better safety profile compared with tube or trabeculectomy. There are now several MIGS options on the market that target different outflow mechanisms, which serve to provide a more complete set of options for reducing IOP. The latest MIGS device to obtain clearance by the FDA is a gel stent implant (Xen45; Allergan) that targets subconjunctival drainage and is implanted ab interno. It offers IOP-lowering efficacy comparable to trabeculectomy, but with the promise of an improved safety profile due in large part to the outflow resistance of the device and less tissue manipulation during the surgery.<sup>1,2</sup>*

*For the discussion contained in the following pages, we invited a group of leading surgeons, many of whom were involved in the clinical trials with the gel stent implant—and all of whom have experience using the device—to offer perspective on patient selection, surgical technique, and postoperative follow-up. It is hoped that the perspective herein can serve as guidance to peers and colleagues using this device or considering incorporating it into their practice.*

—Robert N. Weinreb, MD, moderator

### BACKGROUND: WHEN TO CONSIDER SURGERY

**Robert N. Weinreb, MD:** *There are a number of factors that could potentially influence when and how a patient with glaucoma is managed. There is a definite need to tailor the approach to the needs of the individual, but there are core principles that can help guide our approach. For example, we need to safely and effectively gain control of IOP, the only known modifiable risk factor for glaucoma progression, while also considering how treatment might impact a patient's quality of life. That is often a tricky balance to achieve. What factors do you use to determine if you need to intervene more aggressively, and how much do you think about safety, efficacy, and quality of life issues?*

**Inder Paul Singh, MD:** Medical therapy has traditionally formed the basis of treatment for most forms of glaucoma, although there are certainly shortcomings to that approach. Aside from the issues associated with compliance and cost, the use of topical medications also has a limit on how effectively it can control IOP.<sup>3</sup> When patients are on multiple drops and still not optimally controlled, we have to make a decision about whether to add more medication or think about turning to a procedure. In the past, it made much more sense to maintain patients on medical therapy as long as possible because some of the surgical options were associated with significant short- and

long-term risks. That is what jumps to my mind when you mention quality of life. The long recovery after trabeculectomy or tube shunt surgery is inconvenient, and it carries well-known risks, such as loss of vision, hypotony, choroidal effusion, cataract, flat or shallow anterior chamber, and tube-related complications, including tube blockage, erosion, and endothelial cell loss.<sup>3-5</sup> The introduction of selective laser trabeculoplasty, and later the entire MIGS class of glaucoma devices, really changed that. Those modalities led me to rethink my treatment paradigm over the years. Because of the better safety profile of MIGS versus trabeculectomy or drainage tubes, and because they are generally as or more effective than laser options, my bar for moving to surgical management is now much lower.

**Davinder S. Grover, MD, MPH:** Even when I moved to procedural-based glaucoma management, I really preferred to do so in a step-wise fashion and always in the interest of preserving or returning natural outflow mechanisms. In practical terms, that meant if I were going to offer a patient a surgical option, I would start with procedures that open the trabecular meshwork (TM) to provide direct access to the collector channels. Later, if that did not work, I would consider ways to create a new drainage mechanism, which meant either a trabeculectomy or tube shunt.

**Dr. Weinreb:** That would certainly be a logical progression, considering that some of the ab interno procedures may result in tissue damage of the canal of Schlemm.<sup>6</sup> Even the most delicate ab interno surgery focused on the TM may wind up limiting future surgical approaches, which is why the risk-benefit analysis is complicated, especially for someone with milder glaucoma. That becomes doubly important when we consider that the TM constitutes less than 60% of total resistance outflow<sup>7</sup>—if a large pressure reduction were needed, a TM-based procedure may be insufficient for lowering IOP, and other means of achieving outflow may be needed. One of the historical problems with trabeculectomy or tube surgeries is that while they may get the desired pressure reduction, they result in trauma to the conjunctiva that limits future options.

**John Berdahl, MD:** I think that paradox informs why there has been so much interest in the MIGS category and how the class has evolved significantly. I operate in a rural area, and some of my patients do not have a glaucoma surgeon within a 4-hour commute, so they need something that is low maintenance but highly effective. I think we can all agree that topical medications are not ideal for that kind of patient, nor is an incisional surgery really a great option because of the requirements for follow-up. When the MIGS category came along, it was a revelation, a way to offer a moderate degree of pressure reduction with an improved safety profile over incisional surgeries. With the gel stent implant, what we are seeing is really the next logical step in that progression for more severe glaucomas.

**Steven D. Vold, MD:** It is interesting to take a step back and appreciate how the MIGS class has evolved. The earliest entries to the market fit very nicely with cataract surgery, and so in addition to improving on the safety of glaucoma surgery offerings, they also offered convenience. The next step was devices that targeted different outflow mechanisms, but they still could only be used during combined procedures. Now, with the gel implant, we have the next generation of MIGS. This is a stent that offers comparable effectiveness as trabeculectomy, but because it is introduced via an ab interno approach, the safety profile and the postoperative recovery are improved.<sup>1</sup> Although it is approved for refractory glaucoma procedures here in the United States, I envision it is a device that can be used in a variety of cases where we need to yield a high amount of IOP reduction.

**Steven R. Sarkisian Jr, MD:** The label indication is important. My personal opinion is that ophthalmologists are granted a license to practice medicine and surgery, and we are not limited to strictly following the FDA label. Instead, there should be an element of judgment in how we use

As we continue to learn more about the procedure we will be operating earlier with the device, and it is interesting that a room full of surgeons can all have a different yet positive response to the potential around the implant.

—Robert N. Weinreb, MD

the treatments at our disposal. There is an emerging preference in our field to treat glaucoma as a surgical disease, and that philosophy really follows from the safety profile of MIGS devices. Ultimately, we can be assured by the safety of MIGS, and by the gel implant in particular, as we use our judgment to interpret the label and carefully select patients we believe will succeed with these procedures.

**Dr. Grover:** The introduction of the gel implant has changed how one might answer the question of when to go to surgery. In the past, if I had a patient who was borderline controlled on maximum medical therapy, the next step would be to think about trabeculectomy or placing a tube, balancing the potential to achieve the IOP target against the risk of both surgical failure and any complications that might arise. Because of the safety and quality of life concerns, I would often wait for definitive progression before moving to surgery in those cases. In my hands, though, based on what is currently available in the United States, I have found the gel stent to be the safest and most predictable way of creating a new drain, and it is also less likely to induce complications. The gel stent, then, becomes a viable option if the pressure is not where I think it needs to be. Overall, the gel stent has lowered my threshold to intervene surgically.

## DEFINING MAXIMUM MEDICAL THERAPY

**Dr. Weinreb:** *The gel stent implant is approved for use in the United States for patients with refractory glaucoma who failed previous surgical treatment or in patients with primary open-angle glaucoma, pseudoexfoliative, or pigmentary glaucoma with open angles that is unresponsive to maximum tolerated medical therapy.<sup>8</sup> It is that last part that is intriguing, as there could be several different interpretations of maximum medical therapy. How are some of you defining that clinically?*

**Dr. Vold:** In my practice, maximum medical therapy is two bottles of medication, and that is usually a prostaglandin

plus a combination medication. The data on how much additional IOP-lowering efficacy is gained with a third or fourth medication is not overwhelmingly positive,<sup>9</sup> and when you add the fact that compliance decreases as the daily regimen becomes more complex,<sup>10</sup> it really makes sense to move to surgery earlier in the treatment course.

**Dr. Berdahl:** The limitations placed by the label can certainly be viewed as restrictions, but I would submit that they could be an opportunity to individualize the approach to the needs of the patient. It is specifically because “maximum tolerated therapy” is ill defined that we can apply our own clinical definition and also adjust the definition based on the needs of the patient. In my experience, two bottles or three medications is typically the limit for most patients, although there are those rare individuals who are doing fine with three bottles or four medications and their glaucoma is controlled. In those situations, we do not necessarily have to rush a patient to the OR.

**Dr. Weinreb:** In some cases, maximum tolerated therapy may even mean one or no medications. Perhaps the strict definition is less important than being able to document in the medical record the inability to control pressure with medication before opting for surgery with the gel implant.

**Dr. Grover:** It is well known that patients are generally not ideally compliant with medical therapy, so what is reported during an examination has to be taken with a grain of salt. I think compliance/adherence to medical therapy becomes a factor especially in patients with an active lifestyle, where there is a greater chance for missing a dose, or in patients who no longer have the ability or dexterity to place their own drops. And so, as we search for a definition of maximum medical therapy, perhaps we need to think about what is best for that individual patient and what is most realistic for that patient.

**Dr. Singh:** I would add that we should also consider quality of life as we document in the chart which patients are intolerant to or whose pressure cannot be controlled with medical therapy. My definition of “uncontrolled glaucoma” has now changed; it now includes patients who state they cannot afford medications, forget to take medications, or just do not like to take medications, regardless of whether the IOP is at target or the stability of the ocular nerve head and visual fields. These are similar to the patient experiencing side effects or discomfort taking the medication—in either scenario, the prescribed medical therapy is not having its intended effect, albeit for different reasons.

**Dr. Weinreb:** *Within the context of maximum tolerated*

*medical therapy, how important is the lens status and whether the patient is scheduled to undergo cataract surgery?*

**Dr. Singh:** I personally believe that if patients have a cataract that is clinically significant and they have any type of glaucoma disease for which they need medication, they are getting some type of MIGS device. For me, it has become standard of care to offer some device for them—and now, depending on disease severity and how many medications the patient is taking, the more likely I am to consider a filtering type of procedure, such as a gel implant.

### CONSIDERATIONS FOR SURGICAL MANAGEMENT OF GLAUCOMA

**Dr. Weinreb:** *When you do decide to move to a surgical option, there are several different approaches to choose from. What criteria are useful for choosing which MIGS procedure to use?*

**Dr. Berdahl:** One of the factors I consider is how much the IOP needs to be lowered versus the risk for complications. For example, a trabecular bypass procedure is associated with a favorable safety profile, but the efficacy is not as robust as, say, drainage to the suprachoroidal space, which requires closer follow-up due to a higher risk of complications. In my experience, subconjunctival drainage with either trabeculectomy or a tube drainage device would yield the greatest IOP lowering but with high risk of complication. However, the introduction of the gel stent will likely change the paradigm.

**Dr. Weinreb:** *When new MIGS options come to market, like the gel stent, how do you decide if it is something you will adopt?*

**Dr. Berdahl:** The first thing I do is study the data, especially if I was not involved in the clinical trials, and then I seek input from colleagues whose opinions I respect. Then, if it seems to make sense, I look for opportunities to get trained and use it, because I do not think it makes sense to make a determination until you have tried the procedure yourself. Industry has done a very good job in recent years of providing training for their new devices, and the gel stent is no exception to that.

**Dr. Singh:** Formal training programs are important, but there are other opportunities to learn about new procedures in less structured ways as well. I have always found it useful to visit my colleagues’ ORs who are using a device or technology I am interested in learning to see how it is used and the postoperative requirements. That tends to get me more comfortable as I integrate the new technique into regular practice.

**Dr. Vold:** The training element really extends to staff as well. If I determine that a new MIGS device will help me provide better care for patients, and do so safely, then it becomes important to ensure that we use that device correctly. Because, we always have to remember, our patients are depending on us to provide a flawless surgery, and so our first time in the OR using that device has to be successful. For me, the best way to increase the odds of success are to thoroughly research all the data and train the staff, but also to talk to others who are using the device to gain some familiarity before it is used.

## PATIENT SELECTION CRITERIA AND SURGICAL PLANNING

**Dr. Weinreb:** *Generally speaking, what criteria are helpful in determining that a surgical approach is likely to achieve the desired outcome?*

**Iqbal “Ike” K. Ahmed, MD, FRCSC:** Historically, surgery has been reserved for patients with severe and advanced glaucoma, but, because of the availability of several MIGS options, there is strong rationale for introducing surgical options earlier in the disease course, especially if the individual has a coexisting cataract. The stage of the disease is important for two reasons: (1) for determining the ideal target pressure, and, related to that, (2) factoring how aggressive one should be to reach that target pressure in the interest of preserving the visual field. The presence of a cataract would make me more likely to intervene surgically with a MIGS procedure. In a standalone procedure, the rationale is specifically to gain IOP control, and so the risk-safety profile is slightly different.

**Dr. Grover:** It is interesting that we are talking about how aggressively we should be going after the IOP target. In the past, when we talked about aggressive interventions, we were largely referring to tube shunts and trabeculectomy, with attendant risk for complications. With the introduction of the gel stent, however, we have an option to yield a larger quantity of IOP lowering but with much less tissue manipulation and an improved safety profile.<sup>1,2</sup> In a sense, this option allows us to be moderately aggressive in getting the patient to the target IOP, but without the consequences of a fully invasive ab externo surgery.

**Dr. Weinreb:** *Does that thinking at all inform who you consider to be a candidate for glaucoma surgery and for the gel stent specifically?*

**Dr. Grover:** The short answer is yes, it does. The fact that we are not burning real estate on the conjunctiva while implanting the gel stent is an advantage. I think the

patient type for whom this device is appropriate is very broad, and about the only situations I might hesitate with are patients with uncontrolled uveitis or someone with long-standing and uncontrolled diabetes. Additionally, I would not use the gel stent in patients with excessive conjunctival scarring, ICE syndrome, or angle-closure glaucoma with broad peripheral anterior synechiae.

**Dr. Weinreb:** *What about a patient with previous glaucoma surgery that was unsuccessful?*

**Dr. Berdahl:** That may be a more difficult situation in which to implant the gel stent, but I do not think that previous glaucoma surgery is an absolute contraindication. It depends on how healthy the conjunctiva is in the desired target quadrant. I look for how taut the conjunctiva is, and I also look under the slit lamp and ask the patient to blink and assess how much conjunctival mobility is maintained with eye movements.

**Dr. Grover:** It may be useful to characterize what is meant by “unsuccessful” and also to clarify what was the previous surgery. For instance, prior trabeculectomy that led to aggressive scarring is an indication that the patient may not tolerate subconjunctival filtration, and so it may be prudent to think about other surgical approaches, such as a glaucoma drainage device, in that kind of patient. I have done gel stent implantation in patients who failed prior trabeculectomy, but how and why they failed is important for us to think about.

**Dr. Weinreb:** Agreed. Prior unsuccessful or failed trabeculectomy should not preclude a patient from receiving a gel implant, but maybe other factors of the previous surgery should enter into our thinking. What kind of incision was used? Was it a small periotomy or a large limbus-based flap? Where is the incision? Is it placed at 12:00 o’clock, making it difficult to place the gel implant where it will be most effective? There may be other patient characteristics or comorbid conditions that might be worth considering as well.

**Dr. Sarkisian:** Another way of asking this question may be: “In what kinds of patients is it prudent to take extra precautions before going forward with gel stent implantation?” The health of the conjunctiva is an important component of successful implantation, and it does take some experience to know when the conditions are right. Yet, there are some things that surgeons can look for, including previous glaucoma surgery, which we have already discussed, but also things that may affect healing, including blepharitis, ocular surface disease, and other conjunctival insults.<sup>11</sup>

**Dr. Weinreb:** *Are there other factors that are important in determining the health of the conjunctiva?*

**Dr. Vold:** In addition to the overall mobility of the conjunctiva, I also look at the vascularization to see how much injection is occurring. I have found that patients who have been on long-term topical therapy may not have a healthy conjunctiva, which may have implications for gel stent surgery. In my experience, long-standing medication use may induce inflammation on the conjunctiva, and it may contribute to thickening of the Tenon tissue layer—neither of those are a contraindication for gel stent implantation, but they may make the surgery more difficult.

**Dr. Weinreb:** *Are there any objective parameters that are useful for judging the thickness of the Tenon tissue? Does it matter for the purposes of implanting a gel implant?*

**Dr. Ahmed:** The thickness of the Tenon layer may influence the success of an implantation procedure, but there is currently no validated means to assess that in the clinic. One thing we do look for in the clinic is a thin-appearing conjunctiva at the desired implant location, which is an indication that the Tenon layer is probably not thick in that area. Otherwise, we have to look at epidemiologic data as a guide in some cases. For example, older patients typically have a thinner Tenon tissue layer, and individuals of African ancestry have a thicker Tenon compared to other ethnicities.<sup>12</sup> Where that becomes important is if there is significant intratissue resistance, it could contribute to bleb contraction. If the surgeon suspects that a particularly thick Tenon tissue layer may cause increased intratissue resistance distal to the implant, it may make sense to avoid an intra-Tenon placement. This was not an issue with trabeculectomy, because the Tenon tissue was dissected during the ab externo approach. With the gel stent, on the other hand, because we are approaching placement ab interno, the tissue is preserved. To avoid interstitial resistance that may obstruct flow through the 45- $\mu$ m lumen of the implant, it may be necessary to aim for a supra-Tenon placement.

**Dr. Weinreb:** *Are there other anatomic features a patient may have that would necessitate an adjustment to the surgical approach or that would disqualify them from getting a gel implant?*

**Dr. Ahmed:** In my experience, surgery in patients with high brows or very deep-set sockets is more difficult, and those kinds of cases may be especially difficult as the surgeon is working through the learning curve with the gel stent. Another anatomic feature that might give me pause

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**—John Berdahl, MD**

is a tight palpebral fissure where it may be hard to maneuver safely around the globe and to place the device where I think it will be most effective. On the other hand, after the first initial cases and after the surgeon is comfortable with the technique of implanting, there are steps to help manage difficult anatomic features. For a deep-set eye, for instance, choosing the correct speculum is an obvious consideration, but less obvious is to inject retrobulbar fluid. Adjusting to the patient with a tight palpebral fissure is a little bit trickier; in that setting, I might aim for placement of the stent a little more superonasally than I typically would, because visualizing 12:00 o'clock becomes very difficult in those patients.

**Dr. Weinreb:** *We have established that previous glaucoma surgery does not preclude the use of the gel stent implant. What about the other way around? Does an unsuccessful gel stent implant obviate future interventions?*

**Dr. Singh:** One of the benefits of the gel stent is that it does leave future options available, should they become necessary. There are still other mechanisms of aqueous drainage to target, and the conjunctiva is much more intact than it would be after a trabeculectomy.

## THE LEARNING CURVE AND SELECTING EARLY CASES

**Dr. Weinreb:** *We have discussed that the gel implant is appropriate for a diverse set of patients, but that some patient and clinical features may make some cases more difficult. Are there cases surgeons should look for as they work through the learning curve?*

**Dr. Grover:** My experience has taught me that it is easier to perform surgery on the same side as your dominant hand, and so a right-handed surgeon may wish to start with surgeries on a right eye and vice versa. Other features that might make the procedure a little more straightforward are to avoid

combined surgeries while you are learning the techniques. A pseudophakic eye presents less challenging anatomy.

**Dr. Sarkisian:** I think it is valuable to do more than one case during your first OR experience. In my experience training surgeons, I have found that the most successful trainees are those who are committed prior to going into the OR. They may fumble during some of the steps, but that mindset of wanting to get it right is truly important for learning any technique and for gaining a level of confidence to keep learning. A surgeon can quickly get through this learning curve if they do about two to five cases a day and 15 to 20 cases in the first few weeks.

**Dr. Weinreb:** *Do you have any advice for surgeons new to gel stent implant surgery?*

**Dr. Singh:** Using the injector is likely to be new for most surgeons, so it might be helpful to get some experience in the wet lab before going to the OR. Try over- and under-hand delivery techniques; try it in your left and right hand and really figure out what is going to be most comfortable for you personally. That may seem like a pretty perfunctory piece of advice, but using the injector properly will actually help to avoid damaging the implant during delivery and help better place the stent in the subconjunctival space as well as the anterior chamber.

Something else I learned in my early cases was about positioning the implant and how to approach the angle. We would try to place the implant right on that 12:00 o'clock position to make sure the bleb was forming superiorly. For me, that meant entering the eye on a perpendicular plane. Over time, I realized you could use a temporal incision and enter tangentially very close to 12:00 o'clock, but with an exit point that was supranasal. I think that still yields a superior bleb, which is desirable, but eliminates the need to reach all the way across the eye to achieve that.

**Dr. Ahmed:** In early cases, especially, it helps tremendously to have good visualization of the field and a clear path to the gel stent location. And so, I would encourage surgeons learning the techniques to avoid complicated anatomy that can obstruct the injector, such as high cheekbones, or that make it difficult to maneuver around the globe, such as deep-set eyes.

**Dr. Sarkisian:** In standalone procedures, do you make your incision at the limbus or more anteriorly?

**Dr. Ahmed:** I make it the limbus. There are a couple of theories why the incision might want to be more on the anterior cornea, but I am not convinced they are plausible.

For instance, some argue that an anterior incision gives better access over the lid, but if access is a concern, a temporal incision works just as well. The other argument I hear is that an anterior cornea incision will result in the implant sitting away from the iris. However, that does not make a lot of sense to me. The angulation of the implant in the anterior chamber depends on the scleral tract not where you enter the eye.

**Dr. Grover:** Part of the learning curve for me was learning to relax my hand and the patient's eye while delivering the implant at the angle, especially when the needle is being retracted into the injector. During this moment, if one is placing traction with the second hand, there is a high risk of a "flick." This sudden movement can dislodge the implant or damage the intraocular structures.

**Dr. Berdahl:** While nothing substitutes for proper training in how to implant the gel stent, the surgeon new to the procedure should practice the various steps in a model and/or cadaver eye first.

Also, safely simulate all the gonioscopy, hand positioning, and angles of approach in the OR after a routine cataract surgery. Be aware of the size of the injector and how to avoid the cheekbone.

## PREOPERATIVE WORKUP AND PATIENT EVALUATION FOR GEL STENT SURGERY

**Dr. Weinreb:** *So far we have discussed how to evaluate whether surgery is the best option for the patient and how the introduction of an ab interno mechanism for affecting subconjunctival drainage expands our options. Once you determine that a patient is a candidate for the gel implant, what are the next steps? How does the preoperative workup compare with trabeculectomy and are there any similarities?*

**Dr. Berdahl:** There are studies showing that using preoperative topical corticosteroids may be beneficial for eyes undergoing a filtration procedure, especially if there is significant inflammation.<sup>13</sup> That may be a practice we can consider.

**Dr. Weinreb:** *How do you present the gel stent to patients?*

**Dr. Grover:** I tell patients that we are creating a new drainage mechanism for them using the gel implant. I also discuss the safety profile of the gel implant and that this option represents the most predictable and safe mechanism for lowering IOP (when discussing subconjunctival filtration), but in case it does not work, we have more aggressive procedures we can try in the future.

**Dr. Berdahl:** I frame the conversation with patients around the risk-benefit profile of the various options at our

disposal based on the clinical need. For the patient with mild glaucoma, one may tend to err on the side of a safer approach, but that conversation changes with the patient with more advanced glaucoma who needs aggressive IOP lowering to preserve vision. I explain that trabeculectomy and tube shunts are certainly an option, but they may involve a degree of compromise. If the patient is a candidate for the gel stent implant, I explain that it is a good option for balancing efficacy and safety when we need to target low to mid-teens for the pressure.<sup>1</sup>

**Dr. Weinreb:** In my experience with the gel implant, the postoperative recovery is faster compared with trabeculectomy or tube shunts, which may be a crucial factor for individuals who are still working and cannot take a lot of time off from work. That is something I try to impress on my patients.

**Dr. Ahmed:** My experience has been similar, with patients regaining vision faster and with less irritation to the eye in the postoperative period. There is also a lesser chance of inducing astigmatism during the procedure because we are not performing a full cutdown of the conjunctiva. Anecdotally, I would also say that we are seeing less bleb dysesthesia with the gel implant compared with trabeculectomy.

**Dr. Singh:** In our clinic, we surveyed patients at day 1 and again at 1 week and 1 and 3 months after receiving a gel implant, and we have not had any reports of bleb dysesthesia or foreign body sensation (unpublished data). Most of my traditional glaucoma surgery patients would

often complain of some irritation from surgery, whether immediately postoperatively or after many months. We were also surprised to see visual acuity return to baseline in 90% of our patients by postoperative week 1.

**Dr. Weinreb:** *Does the fact that there is less surgically induced astigmatism suggest a potential role for toric lenses in patients with astigmatism?*

**Dr. Ahmed:** There is no reason I can think of to withhold a toric lens simply because you are implanting a gel stent. If it is a combined surgery, the surgically induced astigmatism is going to come from the cataract portion of the procedure. I would say that for surgeons who have a good sense of how much astigmatism their operations induce that toric IOLs would be an option given the appropriate circumstances.

**Dr. Berdahl:** Just because you have glaucoma does not mean you should be excluded from having your astigmatism fixed. A trabeculectomy procedure is going to make that difficult to accomplish, but the gel stent may be a different story. There is some anecdotal evidence that low postoperative IOP is a risk factor for IOL rotation, although this has not been shown in any published studies. If that were true, though, it would seem that a more stable postoperative IOP and anterior chamber, like we see after gel stent implantation, would be a benefit when using a toric lens.

#### ADJUNCTIVE ANTIFIBROTICS

**Dr. Weinreb:** *It has become common practice to use anti-fibrotic agents when performing a trabeculectomy. Is that a practice that should be adopted when implanting the gel stent?*

**Dr. Sarkisian:** I inject 0.1 cc of 0.4 mg/cc of mitomycin C (MMC) 10-12 mm posterior to the limbus with a 30-gauge needle for every case in which I implant the gel stent. After injecting, I massage the fluid posteriorly to make sure it will not obstruct my view in subsequent steps and to avoid avascularity at the limbus while encouraging posterior bleb formation.

**Dr. Weinreb:** *Is anyone else using a different concentration of MMC?*

**Dr. Vold:** I inject 0.2 ml of a 50/50 mixture of 1% MPF lidocaine and 0.2 mg/mL MMC into the superior subconjunctival space prior to implantation of the gel stent. I have been very pleased with this formulation thus far.

**Dr. Singh:** I also use 0.1 cc of 0.2 mg/cc MMC injected around 6.0 mm behind the limbus and use Weck-Cel sponges

## WATCH IT NOW

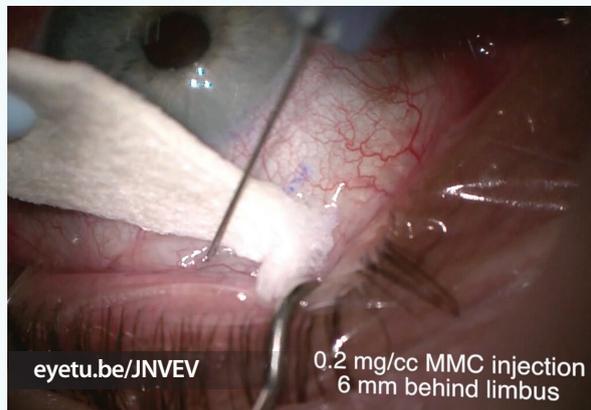
Inder Paul Singh, MD, interviews patients about their experience following gel stent implant surgery.



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## WATCH IT NOW

Inder Paul Singh, MD, demonstrates his MMC injection technique.



(Beaver-Visitec International) to keep the MMC posteriorly, away from the limbus. This helps decrease the chance of ischemia near the limbus and helps to create a posterior-flowing bleb.

**Dr. Ahmed:** When I started with the gel implant, I was using the same MMC dose and concentration that I was for trabeculectomy, but my protocol has changed over time, moving eventually to a lower concentration. I am currently using 0.2 mg/cc and I inject a little bit less than 0.1 cc. I have found that using a higher volume of MMC has a greater chance of reaching the limbus and causing avascularity there, in turn affecting bleb formation. The injection technique and placement are also important. In my practice, I favor an intra-Tenon injection, and I aim as far posterior as I can to avoid any chance of pooling at the limbus, and I use a wet cotton swab to roll and keep the fluid back. Ultimately, the patient will have the greatest chance for success if the bleb forms posteriorly, and so one thing I have found useful is to have the patient look down while I am injecting. In some cases I even place a traction suture on the cornea when the patient has difficulties looking down. I then wait about 2 to 3 minutes, as MMC binds quickly, do some irrigation, and then proceed with surgery.

### POSTOPERATIVE MANAGEMENT

**Dr. Weinreb:** *There has been some suggestion that the bleb that forms after implanting a gel stent is morphologically or functionally different than a bleb after trabeculectomy. This is difficult to quantify, but does anyone have any experience with this phenomenon?*

**Dr. Ahmed:** With trabeculectomy, the bleb can at times be large, diffuse, and avascular with thin walls. With the gel implant, about the only time I see those bleb characteristics is when my needle track was too short, which may result in peritubular flow around the implant. It may also be caused by pooling of MMC at the limbus. The majority of eyes are not like that, however, especially as the techniques for implantation and MMC injection have evolved.

**Dr. Weinreb:** *Have you seen any cases of infection?*

**Dr. Ahmed:** In our experience, we have not.

**Dr. Weinreb:** I assume there is a possibility of endophthalmitis after gel stent surgery. However, the bleb characteristics that Dr. Ahmed was talking about, and how they differ from a bleb after trabeculectomy, would lead me to believe that the risk of infection is lower.

**Dr. Ahmed:** I would be less concerned about infection after implanting a gel stent than I would be about ensuring proper flow dynamics. We are discussing theoretical risks, and things that, if they occur at all, would be very rare. I think that lowering infection after surgery comes down to meticulous surgical technique and good habits that have already been learned.

**Dr. Weinreb:** *Do you ever find there is a need to perform needle revision after implanting the gel stent to ensure that optimal flow you are referring to? If so, what is your protocol?*

**Dr. Ahmed:** We do, on occasion, have to perform needle revision in the postoperative period. We do it in the office.

**Dr. Sarkisian:** I do gel implant revisions in my ambulatory surgical center, where I find the patient is more comfortable, and I can be more aggressive. Also, I feel better that other patients are not waiting while I perform an unscheduled procedure in the office.

**Dr. Grover:** If I have to needle, I do it at the slit lamp using a 30-gauge needle.

**Dr. Weinreb:** *What are other people using? I have experienced some bending of the needle using 30-gauge. Does anyone use a larger size?*

**Dr. Ahmed:** The flexibility of the instruments is one reason why we have moved to a 27-gauge needle for postoperative revision. In my hands, I have better control with 27-gauge versus 30-gauge.

## ADVICE FOR NEW SURGEONS

**Dr. Vold:** Patients who have been on long-term topical therapy may not have a healthy conjunctiva. Mobility of the conjunctiva and presence of vascularization and injection can help assess the health of the conjunctiva.

**Dr. Sarkisian:** Previous glaucoma surgery is not an absolute contraindication, but requires additional planning and preparation during the preoperative phase. Treat blepharitis and ocular surface disease before moving to surgery, as they may affect outcomes.

**Dr. Ahmed:** The thickness of the Tenon layer while difficult to assess, may influence the success of an implantation, if there is significant intratissue resistance, it could contribute to bleb contraction. Thin conjunctiva at the desired implant site may indicate a thin Tenon layer.

**Dr. Sarkisian:** Schedule more than one case during the first OR experience with the gel implant. The surgeon new to implanting the gel stent may fumble during some of the steps, but the mindset of wanting to get it right is truly important for learning any technique.

**Dr. Singh:** Get experience with the injector in the wet lab before going to the OR. Try over- and underhand delivery techniques; try it in your left and right hand and really figure out what is going to be most comfortable.

**Dr. Berdahl:** While nothing substitutes for proper training in how to implant the gel stent, the surgeon new to the procedure should practice the various steps in a model and/or cadaver eye first.

**Dr. Grover:** I have found it easier to perform surgery on the same side as my dominant hand, and so a right-handed surgeon may wish to start with surgeries on a right eye and vice versa. In early cases, a pseudophakic eye presents less challenging anatomy.

**Dr. Ahmed:** While getting through the learning curve, it helps tremendously to have good visualization of the field and a clear path to the gel stent location. Avoid complicated anatomy that can obstruct the injector, such as high cheekbones, or that make it difficult to maneuver around the globe, such as deep-set eyes.

**Dr. Singh:** The bleb should ideally be in a superior position and as far posterior to the limbus as possible. In my surgeries, I use 0.1 cc of 0.2 mg/cc MMC injected around 6.0 mm behind the limbus and use Weck-Cel sponges (Beaver-Visitec International) to keep the MMC posteriorly, away from the limbus to create a posterior-flowing bleb.

**Dr. Grover:** Part of the learning curve for me was learning to relax my hand and the patient's eye while delivering the implant at the angle, especially when the needle is being retracted into the injector.

**Dr. Berdahl:** Safely simulate all the gonioscopy, hand positioning, and angles of approach in the the OR after a routine cataract surgery. Be aware of the size of the inserter and how to avoid the cheekbone.

**Dr. Ahmed:** The surgeon's judgment in choosing appropriate patients, skill in education and preparing the patient, skills in the OR, and knowledge of postoperative protocol are all important for success.

**Dr. Grover:** When you are needling a bleb, are you trying to separate the gel stent from the tissue as much as possible? What is your technique? I typically try to mobilize the implant as much as possible and like to see it moving freely. Ideally, I try to reposition the implant anterior to the pocket of scar tissue, directly in the subconjunctival space.

**Dr. Ahmed:** I like to slide the needle under the implant and then sweep toward the fornix and go on top of the implant as well to really make sure that we free up any obstruction. The goal is to achieve a free and mobile implant, so it may be necessary to repeat the steps. We also inject Healon GV (Johnson & Johnson Vision) viscoelastic

after the needling is done under the subconjunctival space at the distal end of the implant, because it stays longer than balanced salt solution. I do that because I think it works as a spacer and prevents recurrence of obstruction. In extreme cases, if we are not able to get the bleb to elevate after needling, we will intentionally cut the implant slightly at its distal end to make sure there is no blockage.

**Dr. Grover:** I sometimes use Healon during needling to gain that extra space around the lumen in some instances. I aim the needle for the base of the gel implant where it exits the sclera and pull upward (anteriorly) to free as much adjacent tissue as possible. Following that, I inject the viscoelastic to maintain the space that I have created with the needle pass.

**Dr. Vold:** I, too, prefer a 27-gauge needle for bleb needling. In my experience, bleb needling is most successful when performed within the first 2 to 3 weeks after surgery. Furthermore, bleb needling should be considered for more than just postoperative IOP, but also for potentially repositioning of the gel stent to a more ideal position and also ensuring the patient achieves the desired bleb configuration as well.

**Dr. Weinreb:** *Has anyone noticed any differences in postoperative needle revision after gel stent implantation versus after trabeculectomy?*

**Dr. Ahmed:** Needling a bleb after trabeculectomy usually takes multiple needle sticks and is prone to puncturing the flap, leading to fluid egress all over the field. It would have more distribution forces and flow, whereas with the gel implant, there is only one needle pass above and one below the site of the implant and one exit point of fluid at the distal end of the implant.

**Dr. Singh:** I find needling a gel stent bleb a little less stressful than needling a trabeculectomy bleb. There tends to be less avascularity with the bleb that forms after a gel stent is implanted, less of a fibrotic membrane, and the conjunctival vessels are usually healthier, which allows for less fear of causing a buttonhole. The motion of the needling is more of a swiping back and forth motion rather than poking in and out of the bleb.

**Dr. Weinreb:** *MMC is frequently used during needle revision, but there has been some thought that using anti-VEGF agents might have a benefit. Does anyone use anti-VEGF for this purpose?*

**Dr. Ahmed:** To my knowledge, there have not been any published reports of anti-VEGF agents in this setting; that said, it would seem that anti-VEGF agents would have the greatest effect during the early phase of postoperative wound healing, when the eye is typically still inflamed. If I notice a lot of injection in the early postoperative period, I will inject an anti-VEGF agent directly into the bleb, which is something I would do for a bleb after trabeculectomy as well. However, generally speaking, those cases are the exception rather than the rule, and I prefer to use MMC.

## POSTOPERATIVE PROTOCOLS

**Dr. Weinreb:** *After a trabeculectomy, I tell my patients to avoid any bending, lifting, or straining for up to 2 weeks. Is the same kind of guidance applicable after gel stent implantation?*

**Dr. Grover:** In my experience, the recovery after gel stent is faster compared with trabeculectomy. I do tell

I am still surprised as to how much of a positive impact on patients' quality of life removing even a single drop can have.

—Inder Paul Singh, MD

patients to exercise caution, but I usually tell them they can resume life activities after about 1 week.

**Dr. Ahmed:** Some patients may be able to resume normal activities as soon as the first postoperative day, but those may be exceptional circumstances. To be safe, I advise patients to be careful for the first week. I follow the same protocols as far as telling patients to avoid eye rubbing and to avoid getting the eye intentionally wet after surgery.

**Dr. Weinreb:** *What are some important clinical markers to look for at each postoperative visit?*

**Dr. Ahmed:** The gel implant achieves a very predictable IOP range right after proper implantation, which means the postoperative protocol can be guided by IOP measurements at each visit. The bleb morphology and function are less predictive of long-term success, although they are each related to whether the target pressure is achieved. The underlying philosophy is to start low, stay low with respect to IOP.<sup>11</sup> Day 1, most patients have an IOP between 3 to 10 mm Hg, which is optimal, although IOP above or below this range is not necessarily a failure, either. Nevertheless, whether the target pressure is achieved, and how well that pressure is maintained over time, are good markers for the degree of physiologic outflow that is occurring as a result of the surgery. At the week 1 follow-up visit, surgeons should be looking at whether there has been a change in IOP—something we refer to as *Week 1 Delta*, or the difference between Day 1 and Week 1 IOP. If the Week 1 Delta is greater than 10 mm Hg, meaning the pressure has gone up unexpectedly, that is an indication that outflow is not occurring. There are a couple of different reasons why that may be happening, but the core concept is to use IOP as guidance to direct the need for intervention as well as how aggressively to intervene.<sup>11</sup>

**Dr. Weinreb:** *Does anybody use digital massage during the postoperative period?*

**Dr. Grover:** I do not tell patients to digitally massage the eye, because I think the inherent resistance of the device mitigates the effectiveness of massage.

**Dr. Singh:** I think it is a matter of surgeon preference. If a patient has not achieved single digit IOP on the first day, or if there is a significant increase in IOP (often greater than 8-10 mm Hg) at the 1-week follow-up, I will attempt digital compression at the slit lamp to determine flow, and I will tell patients to do that at home as well. I feel early flow is key to prevent long-term fibrosis.

**Dr. Ahmed:** There are questions regarding the benefit of digital compression in the setting of trabeculectomy. However, it is probably different with the gel implant. For the patient experiencing a change in IOP at 1 week, there is likely some resistance beyond the implant, which I believe in many cases is due to Tenon tissue resistance. In my experience, digital ocular compression will expand Tenon tissue and reduce resistance, especially if it is performed in the first month during the critical healing period. I have seen this in OCT images showing the hydroexpanded Tenon tissue before and after.

#### POSTOPERATIVE CORTICOSTEROID USE

**Dr. Weinreb:** *One thing that might be different after gel implant surgery compared with trabeculectomy and other glaucoma surgeries is how corticosteroids are used and tapered. Does anyone use steroids any differently with the gel implant than with other surgical interventions?*

**Dr. Ahmed:** There are two components to why corticosteroid use after gel implant surgery may be different. First, while steroids are effective at addressing inflammation, a lot of the protocol around the implant is predicated on reducing inflammation, and so there may not be a great need for further reduction. After trabeculectomy, bleb contraction is often a byproduct of an inflammatory response, whereas that is minimized after the gel implant, to the point where mechanical factors leading to contraction become much more relevant to consider. The second reason we may want to consider a different corticosteroid protocol is that they are largely effective during the vascular, inflammatory, and proliferative phases of wound healing, but they may be detrimental during the remodeling phase.<sup>14,15</sup> There is evidence to suggest that corticosteroids down regulate glycosaminoglycans that are important for bleb maturation and permeability.<sup>16</sup>

**Dr. Grover:** I typically use difluprednate (Durezol; Novartis) six times a day for the first week and then reduce that to four times a day for the first few weeks. However, reducing steroids can be tricky in some patients because of the variable healing

response. I feel comfortable slowly tapering steroids as soon as the anterior chamber is quiet and the conjunctiva is white.

**Dr. Weinreb:** *When does remodeling typically occur and does that influence how you use steroids?*

**Dr. Ahmed:** My protocol for corticosteroid use has evolved. I have found that most remodeling occurs around 4 to 6 weeks.<sup>11</sup> Practically speaking, then, I will use corticosteroids every 2 hours for the first week—and the specific type of steroid may be important. I prefer to use prednisolone acetate (Pred Forte; Allergan) or dexamethasone 0.1%, and I tend not to use difluprednate, because I believe its use may increase the risk of encapsulation. After that, I reduce the dose to four times a day for the next 2 to 3 weeks, and then cut it down by one drop a week. By about 7 to 8 weeks maximum, the steroid is usually stopped. Patients need the steroid coverage during the inflammatory and early healing phases, but I want to have it ceased by the remodeling phase.

**Dr. Weinreb:** *Does that thinking change if there is active inflammation in the eye?*

**Dr. Ahmed:** Yes, it does. What I am discussing is a general guidance, and there may be a need to tailor the regimen to the needs of the patient.

**Dr. Weinreb:** I look for cells in the anterior chamber and for signs of hyperemia, which I use as an indication of whether the steroid can be tapered. The choice of agent may play a role as well.

#### POSTOPERATIVE EVENTS

**Dr. Weinreb:** *We previously discussed that the ab interno approach of a MIGS procedure reduces tissue damage during the surgery. This less invasive approach is one reason why MIGS options have a more favorable safety profile relative to tube and trabeculectomy procedures, the other being the reduction in postoperative complications. That said, like any intervention used in medicine, there are potential postoperative events the surgeon should be aware of. For example, encapsulation has been described to occur in rare cases after implanting a gel stent. Does anyone have any experience with this and how do you manage it?*

**Dr. Ahmed:** It is a rarely occurring event and it can be avoided with careful surgical technique. In cases where encapsulation does occur, my first option would be to treat it medically, because if you needle too soon, there is an increased chance of recurrence. I think it is reasonable to stop any steroid use if encapsulation occurs, as it may be a contributing factor.

**Dr. Sarkisian:** I had one case of encapsulation, but it was a fairly innocuous occurrence caused by a Tenon cyst. Four months after the event, the patient has a pressure of 12 mm Hg on one medication.

**Dr. Weinreb:** *Another complication that has been described is conjunctival erosion. Has anyone encountered that?*

**Dr. Ahmed:** We saw a few cases in our early experience with the gel stent, and they were all attributable to the scleral tunnel being too short. We realized that an exit point around the limbus might be suboptimal to avoid the risk of erosion. As we refined our technique and approach, the incidence of erosion in our cases has gone down. The other important factor is whether a bleb is forming over the implant, and the success of the gel implant is really predicated on the bleb forming posteriorly. If the surgery is performed correctly, the risk of erosion should be very minimal.

**Dr. Weinreb:** *Does the fact that you might be placing the implant supra-Tenon have any influence on risk of implant erosion?*

**Dr. Ahmed:** In my opinion, no, as long as the bleb is elevated above the implant.

**Dr. Grover:** A supra-Tenon placement might result in a thin, less vascular tissue layer above the implant. If the length of the implant in the subconjunctival space is short, or around 1 to 1.5 mm, I think the implant can occasionally stick anteriorly and place the patient at a higher risk for erosion. I switched to targeting around 2 to 3 mm length in the subconjunctival space, which I think allows the implant to lay flat against the eye, further reducing the relatively low risk of erosion. I also think placing the implant under the eyelid improves safety.

**Dr. Ahmed:** The eyelid does play a role in causing erosion, however, a fluid layer above the site of the implant may act as a cushion.

**Dr. Weinreb:** Nevertheless, erosion is still a rarely occurring complication with this procedure, and what we are talking about here are situations the surgeon should be prepared for to maximize the potential for a successful outcome.

**Dr. Grover:** It is also important to highlight that in addition to erosion being rare, not all cases have to result in implant removal. We had one case where we were able to use some viscoelastic to push the implant down, under a pocket of conjunctiva and Tenon tissue.

The predictable IOP range after patients receive the gel implant is an intriguing aspect of this particular device.

—*Iqbal “Ike” K. Ahmed, MD, FRCSC*

### CONCLUSION

**Dr. Weinreb:** *The gel stent implant may be new to the United States, but it has actually been used in Europe for a few years now. It will be interesting to track how use of the implant might change as more users get access to using it in their surgeries. Based on your early experiences, how do you envision that the gel stent implant might impact your approach to managing glaucoma?*

**Dr. Berdahl:** The gel stent has already become an important part of my practice because it is causing us to rethink the approach not only to the more severe cases, but also to aggressive moderate glaucoma. With the gel stent, there are opportunities to intervene earlier because of the favorable risk/benefit ratio compared with a tube or trabeculectomy.

**Dr. Grover:** In my experience, the gel stent is the safest, easiest, and most efficient way to create a new drain that is available in the United States. If it gains acceptance in the marketplace, I foresee that we may be performing fewer trabeculectomies in the future. One thing I can say is that it makes postoperative management more predictable and blissful.

**Dr. Vold:** I am discovering that many of our patients who are on two or more bottles of medication are extremely receptive and often excited about the possibility of getting off their glaucoma medications with this procedure. The word of mouth in our practice from our patients has resulted in many patients asking if they potentially may be a candidate for the gel implant procedure as a means to get off glaucoma medications. This is a significant paradigm shift for me in approaching my patients with more moderate to advanced glaucomas.

**Dr. Singh:** There is a concept in anterior segment surgery where 20/20 vision is not the only goal; rather surgeons

should also strive to achieve a 20/happy patient. In a lot of ways, we have not had that opportunity in glaucoma. But things have changed now that we can get patients off of drops, offer them the potential for faster vision recovery, yet maintain an effective drainage that helps control the IOP. I am still surprised as to how much of a positive impact on patients' quality of life removing even a single drop can have.

**Dr. Sarkisian:** In my own practice, I have historically been very cautious about moving to bleb-forming procedures. To me, I would usually wait until there was great potential to lose vision because of the risk of complications. That often meant waiting until the glaucoma got severe, but the problem is there is a limited window to intervene before structural damage with permanent visual consequence has occurred. And so, what the gel stent represents is a chance to intervene sooner than I had previously.

**Dr. Ahmed:** The predictable IOP range after patients receive the gel implant is an intriguing aspect of this particular device, and it could expand indications for surgery. It may allow us to shift our IOP target lower for patients who are not yet indicated for a trabeculectomy. The ability to maintain patients at lower pressure, and potentially while being off medications, would be a significant change for how we manage glaucoma.

**Dr. Weinreb:** For me, the most important aspects are that the gel stent procedure is safer than trabeculectomy or tube with a faster rehabilitation. I think as we continue to learn more about the procedure we will be operating earlier with this device. But that is also what is interesting about this gel implant, that a room full of surgeons can all have a different yet positive response to the potential around the gel implant.

**Dr. Grover:** With any new procedure, the initial wave of learning and interest is typically around the surgery itself. The experience from our European colleagues and ongoing research has helped refine the technique and figure out the nuances. We are in a phase now where we can focus on improving the postoperative management of patients after receiving the implant. This is really a crucial aspect of achieving a successful outcome.<sup>11</sup>

**Dr. Singh:** One aspect that has been reassuring to me with regard to the gel stent surgery is that there are not a lot of intraoperative variables. With trabeculectomy, for instance, you have to determine where you make your conjunctival incision, the size and shape of the scleral flap, whether to perform an iridotomy, what kinds of incisions to use, where to place sutures and how tight you make

them, etc. The minimalist approach to surgery with the gel implant is an advantage when it comes to the healing process for the patient, but for the surgeon, it means greater consistency of intraoperative flow and overall control over the case.

**Dr. Sarkisian:** I would make the case that preparing a patient properly and setting reasonable expectations is also important. We do not have cures for glaucoma, but the gel implant does add an option for getting better control of the pressure. We cannot overpromise, and we should prepare patients for the possibility of needing future interventions to gain full control of the glaucoma, and that may include a discussion about the possibility for needle revision.

**Dr. Ahmed:** If the gel implant is placed properly, it directs flow of aqueous humor from the anterior chamber to an external bleb. But that is an admittedly simplistic summary of the factors that lead to a successful outcome. If you place an intraocular lens incorrectly, it will not perform as desired, and it is the same thing with the gel implant. The surgeon's judgment in choosing appropriate patients, skill in educating and preparing the patient, skills in the OR, and knowledge of postoperative protocol are all important for success.<sup>11</sup> ■

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A large, faint, light blue graphic of a human eye is centered in the background of the page. The eye is rendered in a simple, clean style, showing the iris, pupil, and eyelids. The overall background is a gradient of light blue, transitioning from a slightly darker shade at the top to a lighter shade at the bottom.

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