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The Future Is Now: What We've Learned About Implantable Anti-VEGF Technology

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Dr. Weng:
It's exciting that we now have the technology to deliver anti-VEGF therapy for up to 6 months in patients with neovascular age-related macular degeneration [AMD]. But which patients are eligible for the port delivery system [PDS], and what are the nuances that we as surgeons need to know about for successful implantation and refill?

This is CME on ReachMD, and I'm Dr. Christina Weng.

Dr. Chang:
And I'm Dr. Margaret Chang.

Dr. Weng:
Margaret, it's always great to have the chance to speak with you. I'd like to kickstart our discussion today with a real patient of mine.

This is a 71-year-old female with a new diagnosis of wet AMD in her left eye. Her vision is 20/30 minus at presentation, and her OCT [optical coherence tomography] shows this pocket of subretinal fluid and drusen. So I initiated anti-VEGF therapy, and she responds very well. Following 3 injections, her fluid had completely resolved with visual acuity improved to 20/20 minus. But early on, she already started mentioning the difficulty of frequent visits, especially since she lives an hour away from the medical center, and like many of our patients, she serves as a caretaker for an ill spouse at home. So I decided to extend her to every 6 weeks, but then when she returned you can see that her fluid recurred with concurrent drop in vision. So we contracted back to every 4 weeks, and again her fluid completely resorbed. Given all of these social challenges, even though I usually extend and contract in 2-week increments, I decided to try extending her to every 5 weeks, but again her fluid comes back and then goes away as soon as we revert back to monthly treatment.

And so this is an example I wanted to start off with. It's a patient who responds well to anti-VEGF but is unable to extend beyond every 4 weeks, and it's not an uncommon scenario, as we've learned from our treat-and-extend studies.

Margaret, I want to ask you, is this someone for whom you'd consider port delivery system or faricimab? And would your approach differ if the patient was, for example, stable on every-12-week injections of anti-VEGF?

Dr. Chang:
Well, Christina, I think this patient is perfect for port delivery system or faricimab, and it is really going to be up to the patient to decide which one they would prefer. So the PDS patients who enrolled in the ARCHWAY study really did prefer the PDS over injections. As you know, the patients who enrolled in that study are probably going to be more likely to want something surgical in nature, and every patient is going to be different. So some of my patients absolutely want a surgical procedure to try and decrease their need for injections, and

they would be great candidates for the PDS. And then there's some patients who absolutely say, "I don't want to go into the operating room." And so for that patient, the faricimab choice would be better.

For the patient who is stable on q12-week treatment, I would say there's less need and probably less of a desire on the patient's standpoint to try and change therapy at that point. Most of my patients who are stable on q12-week treatment don't really want to change what they're doing. What about yours?

Dr. Weng:
Yeah, I feel the exact same way, and I think that there's so many different potential applications for the port delivery system. One of them is like this patient. This is somebody that I definitely think about for offering this option. But I also think that patients who potentially aren't able to extend beyond every 6 weeks or 8 weeks may also be candidates, and like you said, it really comes down on a per-patient basis and what their particular desires are. And this is just great that we have another option to help them achieve those goals.

Dr. Chang:
Absolutely.

Dr. Weng:
So I wanted to ask. You know, I think one of the uniquely beneficial parts of the PDS launch is that the manufacturers have implemented a training program to ensure that surgeons are appropriately trained to implant the PDS since it's new to all of us. And I've gone through the entire training course now for the port delivery system, but I have not yet performed my first case in the operating room. Hopefully soon.

Margaret, you've done many of these cases – probably more than most retina surgeons in the country. What are some of the nuances to implanting the port delivery system that I should be thinking about in the operating room when my turn comes?

Dr. Chang:
Well, you know, the PDS procedure is relatively straightforward, but it really does necessitate attention to detail and meticulous planning, and this starts with patient selection. And it continues with careful conjunctival handling with non-toothed forceps. So you have to plan out the implant location so that future refills are easily performed, and you have to locate the implant so that conjunctival sutures are not overlying the implant, which can increase the risk of later erosion. So in this surgical video that I'm showing here, you can see that you start by carefully measuring a 6 x 6 mm conjunctival peritomy. You take care to undermine under both Tenon's and conjunctiva to relax the tissues as much as possible. Carefully maintaining hemostasis of the field will make sure that you can see your scleral marks later on when you're measuring how long the incision needs to be. And again, using non-toothed forceps is absolutely critical.

And then, you do carefully prepare the implant, making sure that there are no bubbles in the implant that measure more than a third of the implant width, otherwise you need to start all over again. So you do want to be very careful when you're measuring that scleral incision length. We've found, going backwards, that incisions that were longer than 3.5 mm were associated with a higher risk of implant dislocation. And then carefully apply laser to the choroids to make sure that the choroid is thin enough to make sure that there's no vitreous hemorrhage. And of course, this is to be done very carefully so that the sclera is not burned or distorted, which can lead to later scleral changes long term in these PDS patients. You do need to remeasure that scleral incision to 3.5 mm. Then it's an in-and-out stab incision with the slit knife. The implant is seated, and any excess vitreous is trimmed with the vitreous cutter. And then, the conjunctiva, of course, needs to be very carefully reapproximated, with 3-1-1 anchoring sutures with an 8-0 Vicryl suture, taking care to have limbal sutures that are parallel to the limbus and with some limbal overhang. We've found that conjunctival closure is the key to success with the PDS because any conjunctival complications can lead to an increased risk of endophthalmitis. And so making sure that the conjunctiva is properly closed is really going to make this a necessity in this procedure.

Dr. Weng:
For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Christina Weng, and here with me today is Dr. Margaret Chang. Together, we're discussing what you need to know for a successful surgical implantation and refills of the port delivery system.

So, Margaret, those are some great points that you made about the potential for implant dislocation, which can happen very rarely. But one of the other things that we've been hearing about is that the implant septum can also dislodge during that refill-exchange process. And in fact, there was recently a case report published just last month in *JAMA Ophthalmology* by Timmons and colleagues, where this occurred on the patient's third refill-exchange. What are some of the subtleties of the PDS refill-exchange process that we need to watch out for to mitigate this?

Dr. Chang:
I think that the refill-exchange is not going to be like your standard, run-of-the-mill intravitreal injection, and we just need to keep in mind that really good task lighting, making sure the patient is properly positioned – so as supine as possible, and standing contralateral to the

patient, these are all tips that are going to help making visualization of that septum more successful.

So you really need to make sure that you are perpendicular to that septum. There's a very small target to look for, and if you aren't completely perpendicular, then you are not going to be successful in that refill-exchange. So if you are in the correct space, the needle will pass through the silicone overmold really smoothly at first, and then it'll take a little bit more pressure to get into the right space to do the refill. What some people have been doing is doing a lot of twisting to try and get into the right space. That is what's going to lead to a higher risk of implant dislocation or septum dislocation, because the septum is really only held to the implant by some of the epoxy adhesive, and so really making sure that you're perpendicular is really going to be the key to a successful refill-exchange.

Dr. Weng:
Yeah, I've heard that. I think those are great pearls, and also just making sure that you're really just perpendicular upon entry. And there's just such a learning curve to all of this, but I heard that it's really rapid, and so I think that we will see those less and less frequently as we share tips across the field like this.

One of the interesting questions that arises with these longer durability agents is how often we should follow these patients. Margaret, how are you monitoring your patients who have received the port delivery system, and what are you doing if fluid is present prior to the 6-month refill-exchange time point?

Dr. Chang:
So, you know, I usually see the PDS patients on a routine postoperative surgical schedule, so, you know, that's going to be a day, a week, a month after surgery. And then I would want to see them about 3 or 4 months later, you know, prior to their next refill-exchange. The question of fluid, I think, is an interesting one. You know, just because there is fluid doesn't mean necessarily that the patient needs to have a supplemental treatment. So, you know, the supplemental treatment criteria in the ARCHWAY trial required a 150-µm increase in central subfield thickness from the lowest measurement, or a drop in vision of 15 or more letters from the best recorded visual acuity, or a combination of 100 µm increase in central subfield thickness and a drop in 10 or more letters. So just having fluid doesn't necessarily mean that you need to do a supplemental treatment. And in fact, I actually had a patient in the Ladder study who developed a little bit of fluid, and when I first saw it, my knee-jerk response was, "This person needs a supplemental treatment." But she didn't actually meet supplemental treatment criteria, and in fact, she never met supplemental treatment criteria. And so she actually didn't ever need a refill-exchange through 31 months in the study and maintained 20/25 vision with a little, tiny bit of subretinal fluid.

Dr. Weng:
Yes, I think there's so much to learn about the pharmacokinetics of this system and that we may be able to tolerate fluid a little bit more than perhaps we're used to doing with our bolus approaches that we're taking now.

If there were a significant amount of fluid that you saw before the refill-exchange was due, would you ever consider supplementing with a different anti-VEGF, say aflibercept or faricimab, for example, for a patient who didn't have the response that you were looking for?

Dr. Chang:
Yeah, I think that that's certainly an option that could be thought of. You know, when we have patients in our current practice who don't maintain good enough control with q4-week treatment, we'll often supplement, you know, q2 with another agent, so I think that would be perfectly reasonable. What do you think?

Dr. Weng:
Yeah, I think that's something that I would definitely consider. We know that there are patients who respond differently to different types of agents, and although it's important to ensure that patients are responsive to ranibizumab before putting in a port delivery system, I think that, you know, things change over time and the disease is dynamic. And so I think the most important thing is to make sure that the patient is cared for, and so I would consider potentially injecting something else in between. But I haven't heard that that's been necessary. You know, for a lot of my colleagues who have already treated patients with PDS, they seem to do quite well for the 6-month intervals, and I bet you that we will eventually try to reach for even longer.

So this has been really a very informative discussion. Before we go, Margaret, what's your one take-home message for our listeners today?

Dr. Chang:
You know, I think PDS is a ground-breaking new treatment modality for patients with macular degeneration. You know, it is a great, durable, long-lasting treatment option for our patients, and I think it's really preferred over injections for a vast majority of patients with PDS, so I do think that careful patient selection is going to be key to success in this treatment, and maintaining meticulous surgical technique is also going to be the key to success as well.

Dr. Weng:
Yeah, great points. And I'll add that the port delivery system certainly offers a huge leap forward, like you said, in terms of durability for our wet AMD patients, and while any surgical intervention will inherently have some associated risks, it's really reassuring to know that the learning and sharing of best practices has already proven to mitigate many of these.

I really appreciated the tips that you offered around the refill-exchange particularly, and I look forward to putting these into action for my own patients, hopefully in the near future.

Dr. Chang:
Thanks for having me, Christina.

Dr. Weng:
Well, that's all the time that we have today. For more information, feel free to visit EyeHealthAcademy.org. I want to thank our audience for tuning in, and thank you, Margaret, for joining me today. It was a pleasure speaking with you.

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