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https://reachmd.com/programs/cme/the-future-is-now-a-closer-look-at-implantable-anti-vegf-technology/13987/

Released: 09/15/2022
Valid until: 09/15/2023
Time needed to complete: 15 minutes

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The Future Is Now: A Closer Look at Implantable Anti-VEGF Technology

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Dr. Kitchens:
Prolonged delivery of anti-VEGF is now possible with the port delivery system, or PDS. How can we best integrate its use into our day-to-day practice?

This is CME on ReachMD, and I'm Dr. John Kitchens.

Dr. Sadda:
And I'm Dr. SriniVas Sadda.

Dr. Kitchens:
Vas, let me start by asking you, as a medical retina specialist, are you at all worried about losing patient volume to the surgical retina folks who are going to be implanting port delivery?

Dr. Sadda:
Well, that's a great question, John, and I have to tell you, I'm not worried about that at all. I think we've all got our hands full with injections up to our ears, so many patients needing injections really, I think, pushing the capacity limits of our system as it stands, and we can anticipate, with the imminent approval of treatments for geographic atrophy, that burden and that challenge is only going to increase. So we really need more durable treatment strategies in order to better manage our patients. And so I think being able to refer patients to the vitreoretinal surgeon for this implantation, I'd be very happy to do so, and I'm not at all worried about the volume issues.

Now, the good thing is that I do think that with regards to the port delivery system, I think these patients still need to be monitored at an interval. I certainly, after the first implantation, would want to see them within 6 weeks and possibly at that frequency, depending on how they're doing, or at the very least, 1 interval visit between the 6-month refills. And so that'll give me an opportunity to maintain that patient connection and in between when the patient sees the vitreoretinal surgeon for that initial implantation and possibly the refills as well.

Dr. Kitchens:
You know, Vas, you hit on a great point, and I really think that's going to be crucial, is a lot of these patients who are the best candidates for a port delivery system are the frequent flyers, the patients that we've seen for years and years, require frequent injections, and they get so attached. I'm sure that they're going to be like, "Dr. Sadda, I don't want to go to another doctor," and when you can reassure them that, "Hey listen, I'm going to get you to an excellent surgeon, a good friend of mine, and they will do your surgery, but then you're going to come back to me for the routine monitoring and the refills." I think that can really be the best of both worlds.

Now, Vas, we have other injectable treatments. We have – brolucizumab's been out for a couple of years. Faricimab is very new on the scene. How are you deciding between these emerging treatments and PDS?

Dr. Sadda:
Yeah, John, you know, it's really great that we're in this era where we have multiple options. I think both you and I can recall a time when we had no treatment options, really, for these patients with subfoveal neovascularization. And so, really, as with most medical decisions, it comes down to the risk-benefit profile. Obviously, surgical intervention will have some additional risks compared to just an intravitreal injection, and so it really depends on balancing sort of the treatment burden versus all of these issues that go into the risk-benefit calculation. And for me personally, how this computes, in terms of this calculation, is that the kind of patients that I think we're going to be really – the candidates for the PDSare patients who I can't extend beyond 12 weeks. With longer-acting agents, such as faricimab or brolucizumab, you know, that's our expectation now, that maybe we can get our patients out to that kind of interval.

And for patients you can't achieve that, that's when I think it's reasonable to consider the PDS, because I think quarterly injections – that's not overly burdensome. I'd want to monitor the patient at least at that frequency anyways, and so it's for those patients who can't get there that I think PDS is very useful. Certainly, though, there are other considerations. Because it involves surgery, because you involve disturbing the conjunctiva, patients with a history of glaucoma surgery may not be great candidates. Patients who have a history of recurrent or frequent conjunctival or lid infections, maybe not a good idea to have a device there. And certainly, patients who have dry eye disease. I mean, you can imagine how disturbing – the conjunctiva might only disturb such a patient further. So I think it's certainly reasonable for most patients to consider trying them on faricimab, see how they do with at least 1 injection, and see if you can get them out to 12 weeks before you might consider using the PDS.

Dr. Kitchens:
For those just tuning in, you're listening to CME on ReachMD. I'm Dr. John Kitchens, and here with me today is Dr. SriniVas Sadda. We're looking at the ins and outs of integrating the port delivery system into practice for patients with neovascular AMD.

And that's a really great summary, Vas. Now what about our patients that present with a submacular hemorrhage or have some hemorrhagic component to their wet AMD [age-related macular degeneration]? Is that something that would be a contraindication for PDS? Are those good patients for PDS? What do you think?

Dr. Sadda:
Well, my opinion, John, I mean, you know, one of the best studies that I've seen on this topic of submacular hemorrhages and their connection to anti-VEGF therapy was really the study that was published out of the Wills Eye Hospital, and their study didn't really seem to show a tight connection between a long duration between the last anti-VEGF injection and the development of submacular hemorrhage. In fact, many of the patients who developed a significant hemorrhage had recent anti-VEGF therapy. So for me, just because a patient develops hemorrhages does not mean that they can't ever receive a PDS, and a PDS might be a very good method, in fact, to control those individuals. In fact, you might even argue that perhaps continuous VEGF delivery as opposed to episodic delivery, perhaps that actually could better control such patients. So certainly don't view it as a contraindication, but certainly such patients probably would warrant more careful monitoring.

Dr. Kitchens:
Yeah, it's really where we need to have this in the real world and get some experience with it to see how those patients do.

Now speaking of the frequent flyer patients, I'd love to show you and get your thoughts on one of my patients. In fact, this is the first patient that we put the device in when it was commercially available. She is a feisty 84-year-old patient who actually presented to me when she was 80 with new-onset wet AMD in her right eye. She kind of had this lumpy, bumpy, kind of low-lying drusenoid RPE [retinal pigment epithelium] elevation, but just a thin layer of subretinal fluid. 20/40, and she was very specific about the distortion that she was having. So she responded to anti-VEGF therapy, and so we knew that this was not only a therapeutic trial of an anti-VEGF, but also a bit of a diagnostic trial because of that subretinal fluid improving. And, you know, even though she presented with very mild disease – very early onset – I just could not extend her out beyond monthly injections. When we would go 5 weeks after an injection, she would have new subretinal fluid and, more importantly, she would be symptomatic. And she'd come in and say, "I told you I couldn't go 5 weeks."

And her vision would drop a line to 20/50, and so when we first learned about the pending approval of port delivery, I asked her – I said, "You know, you've been on this monthly therapy for 4 years. Would this be something that you're interested in? And you might well be one of the first people in the world to have it put in, post approval." And she said, "Sign me up." So we did. We treated her about a week and a half, 2 weeks before the implantation with an anti-VEGF injection. She underwent uncomplicated surgeries. Great surgery. She had a little hypotony after her surgery, and we treated her with some topical Durezol, or steroids, and that really kind of helped quell things. But what was so interesting is, is 1 week after the implantation, she was drier than I really had ever seen her in the last couple of years, and she was 20/25. And the best she had ever really been during her monthly visits was 20/40. And she told me, she said, "You

know, listen, I can see better than I've seen in 2 years. I can sit at my kitchen table, and I can read the clock on my stove, and I haven't been able to do that for 2 years."

Now, what was really interesting – and I always tell people when putting in the port delivery system, expect the unexpected. And so 7 weeks after implantation, I brought her back for a follow-up visit, and sure enough, she had some new subretinal fluid. Not under the fovea, but new subretinal fluid. What was really interesting, she was not symptomatic with this subretinal fluid, and before, she always had been. So I thought perhaps we were going to have to give her a rescue treatment, but calmer heads prevailed and, basically, we just followed her, and that subretinal fluid resolved. And 4.5 months after her port delivery system implant, she looked as dry as she had ever been. She settled in about 20/40 at that point, and we refilled her at 6.5 months, and she's happy. It's kind of funny, because I want to see her more often, but she said, "Why did I get this thing? I got it so I wouldn't have to come back." So we negotiated, and I'm going to see her back in 4 months after her refill, and she knows she can call me if she has any issues. She knows to watch for any signs of exposure and whatnot. But this is a patient that I really was worried, you know? She's a frequent flyer. Is she going to do well with PDS? And it turned out that at least so far, she has done exceedingly well.

Dr. Sadda:
Wow. John, that's a really instructive and great case. I think it highlights some really important issues because it, you know, one might think, well, the kind of patient that you might consider for a PDS is someone you can get completely dry, and that's, you know, the kind of patients I might prefer. But your patient is a really great case that illustrates that there could be significant differences between, as you – I think you alluded to, between bolus dosing versus kind of continuous delivery. So you might have patients who might even have some persistent fluid, but with continuous delivery, they could actually get dry, which I think is potentially exciting in thinking about how we use the PDS. You know, for me specifically, you know, I think in a patient like this who maybe even they have some fluid even after you've put in the PDS, I think that the circumstance may be a little bit different than in patients who don't have a continuous delivery system in place.

Generally, you know, my opinion is you treat to dry. You try to get the retina completely dry. We know that long term, having persistent exudation leads to vision loss, but you can imagine, maybe, a patient who has a little bit of fluid outside the fovea, and you don't see significant fluctuations, because we know that significant fluctuations can be associated with a loss of vision. But that might be somebody who you might be able to hold off on giving a bolus dose, as you were able to. As you said, cooler heads prevailed, and you were able to ride it out. And I think in that regard, your case is very instructive but, you know, again, that's where, if you have a patient who has some persistent fluid, as you get your sort of feet wet, you might watch them. Bring them back at very short intervals to make sure things aren't worsening, they're not developing additional hemorrhage, and you might be able to sustain them through that 6 months, which obviously would be pretty exciting for the patient.

Dr. Kitchens:
And, Vas, we could go on for an hour about this. You've spoken about it. You've written about it. But, you know, location of fluid. Will the location, intraretinal fluid versus subretinal fluid, will that play any role in your decision to use PDS or recommend PDS?

Dr. Sadda:
Maybe not on the initial decision-making, John, although I do think that a patient who has fluid that's outside the fovea, I'd be maybe a little bit less concerned about than somebody who's got fluid right under the fovea, so perhaps that could be a factor. But fundamentally, I think that the big thing is if somebody has relatively small amounts of fluid, they're not people who develop big fluctuations, I think that even if there's a little bit of fluid outside the fovea, I think it'd be very reasonable to consider the PDS, as I think, actually, your case beautifully illustrates that you were able to dry the fluid with continuous therapy. I was very impressed by that.

Dr. Kitchens:
You know, Vas, it's really important by the way – and I looked into this with this patient – is not to refill the PDS before 6 months. The labeling indicates really only 6-month refills. It is different than monthly, or interval dosing, as you alluded to, and there's a lot we don't know, and we're going to learn from patients like my patients and your patients as we start to utilize this more and more. And I think realizing, once again, expect the unexpected with this and don't overreact when you see somebody that develops something, new subretinal fluid or new intraretinal fluid. Maybe take a pause and wait a couple weeks and see if that doesn't resolve, because that's what I've been so surprised with in some of my study patients and in this patient.

Well, this has been a wonderful conversation. Vas, as we wrap up here today, what's 1 or 2 take-home messages for our audience?

Dr. Sadda:
Absolutely, John. I really enjoyed having this discussion with you, and I guess one thing I would say as a takeaway is really, I think, don't be afraid to use all of the tools in your arsenal. We're lucky to be in this era where we have these different options. Ultimately, the most

important thing is getting control of the exudation for your patient.

If they're a patient who can't make it for their visits, can't maintain that follow-up schedule, then clearly, you know, the PDS, I think, can play a very valuable role there. The other thing I think is that you want to really avoid, I think, fluid fluctuations. I think the data is really quite compelling that patients who have big fluctuations, oscillations in their fluid, they tend to have the worst visual outcomes. So this is where I think it's exciting to have a strategy that can give you continuous therapy that may aid in minimizing these types of fluid fluctuations.

Dr. Kitchens:
And, Vas, for me, I really think the bit of advice I would have is, these patients are already there. If you're injecting a patient very frequently, you've seen them for years, you already have a relationship – think about PDS for that patient.

Well, that's all the time we have today. I want to thank our audience for tuning in, and I really want to thank you, Vas, for joining me. It was a pleasure speaking with you.

Dr. Sadda:
Thanks so much, John. It's always a pleasure to speak with you, and I really enjoyed this.

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