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The Future Is Now: Latest Surgical Techniques for Anti-VEGF Delivery

Announcer:
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Dr. Arevalo:
New implantable technology that provides prolonged delivery of anti-VEGF therapy is now available. With it comes a new surgical technique for vitreoretinal surgeons. So how do we ensure a successful procedure?

This is CME on ReachMD. I am Dr. Fernando Arevalo and joining me for today's discussion is Dr. Lloyd Clark. Welcome to the program.

Dr. Clark:
Fernando, thank you so much for having me. What a pleasure.

Dr. Arevalo:
First, Lloyd, to get started, tell us about the port delivery system, the PDS. How is it implanted?

Dr. Clark:
Well, first of all the PDS is really a transformative technology. It's the only FDA-approved system for extended drug delivery for retinal diseases. In this case, a specialized formulation of ranibizumab is placed into this implant and then is extruded over a 24-week period. Really a complete game changer in terms of technology available to patients with age-related macular degeneration.

Today we're going to talk mostly about the techniques and the technical aspects of the implant. There is a parallel program on the efficacy of the PDS implant by Dr. Regillo and Dr. Baumal, that will also be available if you visit EyeHealthAcademy.org, and I would encourage you to do so.

In terms of the surgical steps involved in the implantation, you'll see, classically, them divided into 7 steps. Those steps in general are preparation of the ocular surface followed by implant preparation and loading the implant with the specialized formulation of ranibizumab. And then construction of the scleral wound, which is critically important in terms of size as well as hemostasis. Once the surgical wound is constructed, then we can place the implant. And then the important final step, which is a conjunctival closure.

So, here's a surgical video of PDS implantation. The wound’s already been marked to 3.5 millimeters. And we can see with a straight MVR blade the surgeon is doing a scleral cut down to create a choroidal bed. Once the choroid is exposed, a critical aspect of the surgery and one that can't be skipped is laser photocoagulation of the choroid with an endolaser probe. A little bit different procedure than what we're used to. Not used to using an endolaser probe outside the eye, but really takes care of the issue of vitreous hemorrhage very well. The endpoint here is actually return of liquefied vitreous through the large pars plana wound. That's really the clinical endpoint that we look for. From there, you'll use a 3.2-millimeter flat blade to enter and complete the incision of the choroid. From there, you've got a prepared surgical wound. We take the pre-prepared implant with the customized formulation of ranibizumab and put it into the

wound. Once it's inserted into the wound and seated up against sclera, we're then ready to close conjunctiva. And we'll talk about the specifics of conjunctival closure shortly.

Really an elegant surgical device with appropriate and careful surgical procedures is a real optimal treatment strategy for patients requiring long-term VEGF suppression.

Dr. Arevalo:
Lloyd, this is a very unique procedure. How steep is the learning curve? And what are the pitfalls that we should avoid as surgeons?

Dr. Clark:
Well, first of all, it's a procedure for retina specialists. And so, anyone that's done good surgical training in vitreoretinal surgery certainly has the skill sets to perform this procedure.

Now, that being said, there are some specific aspects of this procedure that are somewhat different than what we do on a regular basis. And most of those center on the handling of the conjunctiva. It's critically important to have very meticulous closure from not only conjunctiva but also Tenon's capsule in order to have adequate and consistent coverage of the implant. Remembering that we have these issues of conjunctival retraction and erosion, which have resulted in a boxed warning for the PDS. We had about a 3 times increased incidence in endophthalmitis in the patients who underwent PDS implant compared to the monthly ranibizumab arm in the registration trials. These increased cases of endophthalmitis have been clearly linked to cases of conjunctival erosion and conjunctival retraction. And so, a number of things are important for us to do in order to reduce the risk of conjunctival erosions and contracture.

Dr. Arevalo:
I totally agree. We have to learn from our glaucoma colleagues about management of the conjunctiva and Tenon's. Exposure, tears, and buttonholes are complications of glaucoma surgery, and their consequences are far greater than their size. They are difficult to treat and can lead to failure of the surgical procedure. The main reasons for their occurrences are poor visualization and poor instrumentation. We must learn from our glaucoma colleagues, and it is of utmost importance to handle the conjunctiva gently using non-toothed forceps. The risk of inadvertent buttonholes is greatest in previously operated eyes that have scars in the conjunctiva or scarring in the subconjunctival tissue and patients that have thin conjunctiva. Those are not good candidates for the PDS. In addition, efforts must be taken to avoid the cut edges of the conjunctiva touching the PDS.

Dr. Clark:
Fernando, those were all great points. And here's a case to illustrate some of those points. This is a case of conjunctival retraction where initially the closure was not brought up to the limbus. The scleral bites are posterior to the limbus, and they don't cover the entire surgical bed. And this gets us off to a bad start in this patient. What we're left with is a gap between the limbus and the peritomy due to some posterior-placed sutures. This gives us a laxity to the conjunctival peritomy, and that laxity, unfortunately, as we follow forward in the next slide, as you can see on your left, this is what the patient looked like at the time of surgery and just several months later due to remodeling of the surgical wound, conjunctival inflammation, suture inflammation. We see further contracture of the conjunctiva. Ultimately, this is one of the patients that we did have problems with conjunctival erosion and endophthalmitis.

And so, this allows us to look at these cases and understand that meticulous closure, as Fernando described, is critically important. So, these points are critical as we get started putting in the PDS.

Dr. Arevalo:
For those just tuning in, this is CME on ReachMD. I am Dr. Fernando Arevalo, and today I'm speaking with Dr. Lloyd Clark. We're reviewing the best practices that we, as retinal surgeons, need to use to ensure successful and safe implantation of the port delivery system.

Lloyd, let's talk about safety of the PDS. Can the implant be dislocated?

Dr. Clark:
Well, without a doubt, these implants can be dislocated. We saw a total of 6 dislocations in the registration trials that got the implant approved by the FDA. Most of these were put in early in the course of the clinical trial. And so, we learned some lessons associated with the surgical procedure that we believe will reduce the rate of implant dislocations. The biggest is the importance of wound construction. It's critical that we have a wound no larger than 3.5 millimeters. Five of the six implant dislocations were wounds that were greater than 3.7 millimeters. There was some variance early in the clinical trial that allowed us some variation in wound size. But after analyzing these dislocation patients, we found that as a common denominator, which is large wounds.

In addition, another important observation that was made during the clinical trials is that 5 of the 6 cases had a grayish discoloration around the implant underneath the conjunctiva. And what we believe that is, is exposed choroid. And so again, another example of

clues that demonstrate that the wound is too large.

Finally, it seems obvious, but these dislocations don't occur spontaneously. They occur at the time of refill-exchange. And that's due to some pressure on the implant.

So, it's important to make your wounds tight so that the implant is well seated in an appropriate-sized wound of 3.5 millimeters. And also, to use a moderate amount of pressure on the implant because overpressure on the implant can lead to a physical dislocation into the vitreous cavity, which is a difficult complication to manage.

Dr. Arevalo:
Well, now that you mention the refill-exchange of anti-VEGF with the PDS, this is also different. We're not used to it. What can you tell us about that? And what advice can you give our audience to make the process go smoothly?

Dr. Clark:
You know, I tell people I've done a number of these. I've done about 2 dozen implants, and I've probably done 75 or so refill-exchanges. I think the learning curve is actually a little more difficult with the refill-exchange than the surgery. As long as you're meticulous and follow the appropriate steps in the surgical procedure, I'm confident that that our colleagues will be able to do this very well.

But the refill is a little different. It's more of an art than necessarily a procedure. Some of the important things you need to do, first, you need to have good visualization of the septum, and that occurs through conjunctiva and Tenon's. You achieve that with, number one, good lighting, and number two, with magnification. I use a set of magnified – they're not loupes, but magnified lighted magnifiers on my head, and I don't typically use magnification for intravitreal injections. But for these implants, I think a higher level of visualization is of critical importance.

Secondly, you've got to have your orientation correct. You need to approach the implant perpendicular to the septum and basically insert the needle directly towards the optic nerve. It's a fairly small area to find the septum with the needle. But not only is it small, the actual shaft of the implant is quite small as well. So, you've got to have a 3-dimensional orientation very accurate prior to engaging the implant with a needle. You can't really engage the needle with the implant and then wiggle your hand too much. You really need to go straight in and straight out.

So, it takes some experience understanding sort of the 3-dimensional relationship of the implant with the eye. Once you get that down, it doesn't require a lot of force and becomes a reproducible procedure that's just a little more difficult than an intravitreal injection. But as you get started, it's considerably more challenging than an intravitreal injection, don't you think?

Dr. Arevalo:
Totally agree. Totally agree, Lloyd.

As we wrap up, Lloyd, what are your key take-home messages for our audience?

Dr. Clark:
Well, first, this is a transformational technology. We've never had anything like this in retina. It's our first sort of opportunity to really offer extended dosing for patients with a chronic disease – age-related macular degeneration. These patients do just as well with the implant as monthly therapy, and so the outcomes are outstanding, with significantly reduced treatment burden.

What comes with that is a careful attention to detail with the surgical procedure and a fairly long learning curve with the refill-exchange procedure with a needle. But with practice and patience and collaboration with your retina community and those who teach the procedure, I think it's really going to offer our patients a tremendous opportunity, a new treatment strategy that for some patients will be of tremendous benefit and preference.

Dr. Arevalo:
I will add that the PDS is a game changer. It will change the way we treat our patients with wet age-related macular degeneration. I think we have to learn from our glaucoma colleagues to handle the conjunctiva very gently.

And with that, we're out of time. I'd like to thank our audience for listening in and thank you, Lloyd, for joining me today. It was a great discussion.

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