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The Road Ahead – Integrating Research Into Practice

Dr. Wykoff:
Hello, This is CME on ReachMD. I'm glad you're here with us, virtually. I'm Charles Wyckoff, and it's great to be here today with Dr. Dean Elliott.

So, Dean, it's an exciting time in retina. We now have a new FDA approval. There is a new encapsulated cell-based implant, which is available for patients with idiopathic macular telangiectasia type 2, or Mac-Tel. And a key question is, how should this treatment be integrated into our clinical practices?

Dr. Elliott:
Great to be here. Thank you, Charlie. The question on everyone's mind is who is best suited for treatment.Study participants were between 21 and 80 years of age and in the Phase 3 trial, patients had to have an ellipsoid zone breakdown between 0.16 and 2 millimeters squared. The BCVA was greater than 54 ETDRS letters, or about 20/80, and no evidence of subretinal neovascularization.

The odds of achieving treatment response were more likely with smaller area of ellipsoid zone loss, specifically, less than 0.5 millimeters squared, younger age, less than 65 years, and lack of foveal involvement.

Dr. Wykoff:
Dean, super important background. And I'm just going to briefly highlight how we implant these devices, and then I will walk through a patient of my own.

So, the device comes in the operating room in culture media, as shown in this image here. It is then implanted inside of the eye and fixated to the overlying sclera through the pars plana, as we will show in this next surgical video.

So, here are baseline images for a patient of mine that I enrolled in the Phase 3 clinical trial. This is a patient that I had been following for a while, with macular telangiectasia type 2. They had progressive scotomas and metamorphopsias just off of the center in their left eye, and they were bothered by this. It was affecting their activities of daily living and they decided to enroll in this Phase 3 clinical trial.

So, here's a surgical video of the implantation procedure. First, you're making a full-thickness sclerotomy, 3-millimeters wide, about 3.75-millimeters posterior to the limbus. You're now, inserting the NT-501 implant into the vitreous cavity, leaving the titanium loop with pre-placed Prolene suture exposed. And then, once you fixate that Prolene suture to the titanium loop, you're now passing that double-arm 9-O polypropylene suture at a 90 to 99% scleral depth, to really fixate that suture on the far inside of the sclera, so that the Prolene suture dangles into the vitreous cavity. You don't want that titanium loop rubbing into the scleral wound.

Once that Prolene suture is placed, I'm now closing the wound with interrupted nylon sutures.

So, here are typical post-operative images. These are images from this patient. You can see, on the right, the implant in good intraocular position. It is not obscuring the visual access. And then on the left, you can see that the Prolene suture is visible post-operatively. Remember, the idea is that the Prolene suture will be durable, holding that implant to the inside of the sclera but not pulling that titanium loop into the scleral wound. That's key. The key is that you want to tie that Prolene suture knot gently and not pull it firm. You don't want to pull that titanium loop into the scleral wound. The wound closure knots are performed with the nylon interrupted sutures on either side of the Prolene suture.

Dr. Elliott:
Great case and nice video, Charlie. My experience has been similar, in that the most important part of the procedure is really, proper placement of that titanium clip, as you mentioned, 90 to 95.9 percent depth of a scleral bite with the Prolene suture. I think that's critical. And you hit all the high points of the surgery.

So, the take-home messages here are, younger patients who are early in the disease course with more preserved anatomy and better vision tend to do well. Complications can arise. Most of them are related to improper suturing of the titanium clip, but also patients have delayed dark adaptation and meiosis, roughly between 15 and 20% for each of those. Ideally, patients will have active treatment with the implant for many years.

Dr. Wykoff:
Dean, that was a great summary of the surgery. I agree, been great going over these cases with you, Dean. Thank you.

Dr. Elliott:
Thank you.