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Advances in Glaucoma Treatment: MIGS (Part 1)

Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCME curriculum.

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Dr. Grover:

Hi, this is CME on ReachMD, and I'm Davinder Grover. We're going to talk today about bleb-forming MIGS because they are an option to decrease a patient's dependency on drops and improve pressure, in patients with glaucoma. We're going to look at 2 microshunts, the XEN Gel Stent, and the PreserFlo Microshunt. I'm going to start first with the XEN Gel Stent, which has an inner diameter of 45 µm. Now there are a large number of studies on outcomes with XEN. There's truly too many to kind of overview in just this short episode. But I want to talk first on the the Reitsamer, et al., study, which published 3 years' data. And it was a retrospective study based in Europe where a mean IOP [intraocular pressure] was 20.7 on 2.5 meds. And at 3 years, they reported a mean IOP of 13.9 on 1.1 meds.

Now most of these patients were of European descent, and they tended to use a lower amount of mito [mitomycin C], which was somewhere between 10 and 20 µg – much lower than other studies. And the needling rate was actually much higher than what's usually published. Their needling rate was about 43%, where usually the needling rates are around 20%. Now 12.3% of these eyes did require additional glaucoma surgery, but overall at 3 years, the success rate was 65.8% – slightly higher in the XEN alone group, a higher success rate than in the phaco XEN group, but there were no safety concerns. And, as you know, the XEN gel stent can be implanted through a bunch of different techniques. Ab interno, ab externo, with or without a conjunctival peritomy. When you look at all the studies published on those different techniques, the outcomes are actually quite similar for each technique, so I think it really shows that you stick with the technique you're most comfortable with.

Now when it comes to the PreserFlo Microshunt, this has an inner diameter of 70 µm, and it's a little bit longer, at 8.5 mm. It's approved in Europe and in Canada, but not in the United States. The FDA trial is complete, and it was a prospective, randomized, multicenter, interventional trial which showed no significant safety concerns, and both groups had significant decrease in IOP and a decrease in dependence on glaucoma drops. But at 1 year, the probability of success was lower in the microshunt group compared to the trabeculectomy group – 53.9% compared to 72.7%. Now in the microshunt group, the mean IOP decreased from 21.1 mmHg on 3.1 medications to 14.3 on 0.6 meds at 1 year. The trabeculectomy group – their mean IOP decreased from 21.1 mmHg on 3 meds, down to 11.1 on 0.3 meds. So the trial group had a lower overall IOP, but both groups did well. Now the incidence of hypotony was higher in the trabeculectomy group. If this was a noncomparative study, similar to the pivotal trial that got XEN approved, with a 510(k) pathway, I think PreserFlo would have been approved. But it's just hard to beat trabeculectomy, and that was one of the major endpoints. And because PreserFlo did not beat trabeculectomy, I think that's one of the reasons it was not approved. And trabeculectomy is hard to study, right? The floor is much lower, so you can get much lower pressures, whereas these microshunts really protect against hypotony, and that's actually why we like them. Now also with the microshunts, you typically need to get higher dose – you need to use higher doses of mitomycin C, which is what we see in the studies published out of Europe and in Canada. Much higher than it would ever be approved by an FDA trial.

Now overall, you know, I envision these microshunts and these techniques for delivering microshunts to continue to evolve and improve,

and while I don't think we're there, to say that microshunts should completely replace trabeculectomy, I do envision sometime in the next couple years, once we get even better with these microshunts, to be able to make that statement.

Well, that's all we have for today. Thank you for joining me.

Announcer:

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