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Clinical and Safety Outcomes from the LIGHTSITE III Trial

Announcer:
Welcome to CE on ReachMD. This activity, titled Clinical and Safety Outcomes from the LIGHTSITE III Trial is provided by Evolve Medical Education.

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Dr. Boyer:
This is CE on ReachMD, and I'm David Boyer, and I'm pleased to be joined by Diana Do to discuss photobiomodulation. Diana, we just had a recent LIGHTSITE III trial. What was the primary efficacy endpoint?

Dr. Do:
Great to join you, David. Yes, it's very exciting to talk about multiwavelength photobiomodulation as delivered in the LIGHTSITE III randomized clinical trial.

This trial looked at eyes with intermediate age-related macular degeneration. The primary endpoint was the change in best-corrected visual acuity at month 21. It compared active photobiomodulation compared to an active sham treatment group.

What the study showed was that photobiomodulation met its primary endpoint in that those eyes that received this multiwavelength light therapy gained on average 6.2 letters at month 21, compared to a smaller gain in the active sham group.

At month 24, this improvement in visual acuity on average was sustained with a gain about 5.6 letters in the active treatment group. Of course, these results were statistically significant and led to this device being FDA cleared. What do you think about these results, David?

Dr. Boyer:
Well, they're impressive. I think that it also demonstrated less loss of vision. When you looked at the patients who were in the sham group, they had a much higher incidence of losing vision. I think that this gives us an opportunity to treat intermediate AMD, which we've never been able to treat previously.

There was a definite improvement in 5, 10, and 15 letter gains in this trial, and much less vision loss, as I indicated. The most important thing I think when we have a new treatment is safety. Diana, do you want to discuss the safety?

Dr. Do:
Yes, I'd be happy to. As you said, it's very important not only to have efficacy, but also to demonstrate safety. Remember that

photobiomodulation is a noninvasive light therapy. When we looked across the hundreds of eyes that were enrolled in the clinical study, there were no serious adverse events related to photobiomodulation.

Some of the common safety events were just dry eye, a little irritation on the eyelids, but no damage in the retina, no thermal damage at all. David, what about development of neovascular age-related macular degeneration? How did that evolve in the study?

Dr. Boyer:
Well, as you know, previous treatments for geographic atrophy with several agents demonstrated a marked increase in the number of patients who went on to developing neovascular AMD. In this study, the sham group and the treated group remained about the same. There was really no increase.

I think it's also important we have efficacy, we have safety, but how do the patients perceive this? I think it's important to realize that when we looked at quality of life, there were definite improvements in the quality of life measurements in these patients. They actually not only had a visual improvement, they also perceived a visual improvement that improved their quality of life.

Dr. Do:
Yes, I think it's very important because this is a noninvasive light therapy that's delivered over 9 sessions over a 3 to 4-week period, and then repeated 3 times over the year. It seems to act at the cellular level, iin the mitochondria to prevent oxidative damage and degeneration over time. Clearly we're seeing this efficacy signal. What are you telling your patients when they're asking you about the efficacy and their likelihood of improving vision when you employ this light therapy?

Dr. Boyer:
Well, I think it's important to realize ... In this trial, they actually had patients that had excellent levels of vision. 20/25 was, I think, the lower limits. The patients who were 20/40, 20/60 even had a larger improvement. When I speak to the patients, and they're coming in and I feel they're good candidates, and let's say they have 20/40, 20/60, I'm very optimistic that they will see perhaps a bigger improvement. When they're 20/25, I'm just basically saying that we want to maintain your present level of vision and prevent you from developing iRORA or cRORA, other changes that can cause visual decrease.

Dr. Do:
I think that advice is spot on because, as you said, in a population, there's a range of responses. Some patients will improve vision, some will develop stabilization. I think that's important to be realistic when we decide to recommend this light therapy to our patients.

Dr. Boyer:
Diana, thank you very much for your comments. Thank you very much to the audience for participating in this CE event. I hope that you've learned something about both the safety and efficacy of this new photobiomodulation.

Dr. Do:
Thank you, David, for allowing me to participate.

Announcer:
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