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Anatomical Outcomes from the LIGHTSITE III Trial

#### Announcer:

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## Dr. Do:

This is CE on ReachMD. I'm Dr. Diana Do, and I'm joined today by my friend and colleague, Dr. David Boyer, where we'll be reviewing the anatomic outcomes in the LIGHTSITE III clinical trial of photobiomodulation. David, welcome.

## Dr. Boyer:

Thank very much, Diana.

## Dr. Do:

It's very exciting now. We have photobiomodulation for the treatment of intermediate age-related macular degeneration. Can you share with us some of the post-hoc analysis looking at the anatomic outcomes in this clinical trial?

# Dr. Boyer:

Oh, my pleasure. One of the things that really stood out was the marked decrease in macular drusen volume that was seen. Unlike other studies, which we've seen can cause a loss of drusen, these patients did not seem to go on to developing iRORA or cRORA as drusen decreased, which is a kind of restriction to the natural history, with many times the large semi-soft drusen leave you with geographic atrophy.

There was also a ... Not only a reduction in drusen volume, but there was a reduction in the incident geographic atrophy. The disease progression to incident GA was significantly higher in the patients in the sham group compared to the active PBM treatment. I think this is a big distinction here when these patients began to improve.

# Dr. Do:

This is very interesting, David. We mentioned this is a post-hoc analysis. The original study was looking at visual acuity as the primary endpoint, but these anatomic analysis were after the fact and there are smaller numbers. Does it really means that photobiomodulation will truly decrease the rate of development of geographic atrophy?

# Dr. Boyer:





Well, Diane, I don't think we have enough information at this point to say that it will. I think, as you pointed out, these are all post-hoc analysis. These are small numbers. Compared to the large trials for geographic atrophy, there was less progression from iRORA to cRORA did not seem to progress in this study.

But those are things that were not part of the primary analysis. As you indicated, the primary analysis was an improvement of vision. I think these are opened for further evaluation. In larger trials, we may find that this actually improves the geographic atrophy from progressing either from iRORA to cRORA, which would be great, or the progression of cRORA to further evaluation.

But unlike the trials that we've had that have been approved for geographic atrophy, those trials were specifically meant to look at that, and did it in a prospective manner in a much larger trial. I think this is something that we should look at in the future. I think this is very ... It's encouraging results, as I'd like to look at it, but we really have to look at it in larger trials.

#### Dr. Do:

Yes, I think the educational points that you discussed are really key to understanding how this could benefit our patients. I also liked how when you discussed the reduction in drusen volume with the patients who received the active photobiomodulation, that the reading center also saw that this was accompanied by preservation of the photoreceptors. Maybe that's why the patients who received the active photobiomodulation were more likely to gain vision over the 2 years of the study.

Do you think that the photobiomodulation, does that mechanism translate to this improvement we see in both the anatomy and the vision?

## Dr. Boyer:

Well, I think that photobiomodulation works in a variety of ways. We have nitric oxide increase, so perhaps we're getting some vasodilation. It also has an effect ... It's an anti-inflammatory, and as you said, it increases mitochondria efficacy. I think there are a lot of different reasons. We haven't even gotten into things like heat shock protein, which may also be upregulated and may play a role in causing this improvement.

### Dr. Do:

Thank you, David, for sharing your insights on photobiomodulation. I learned a great deal. Thank you everyone for joining ReachMD.

### Dr. Bover

Thank you very much, Diana, for having me.

### Announcer:

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