

Industry Insider is a timely chat with an ophthalmic industry thought leader.

Guardion Health Sciences

David Evans

David Evans, PhD, MBA, is CEO and director of Guardion Health Sciences, a manufacturer of medical foods and diagnostic devices. Dr. Evans also serves as Guardion's chief science officer and was founder of Guardion's subsidiary VectorVision. He is the inventor of VectorVision's flagship product, the CSV-1000 contrast sensitivity vision test, and its successor, the CSV-2000, which was introduced this year.



David Evans, PhD, MBA

Ophthalmology

Management: What role do medical foods play in eye health?

David Evans, PhD, MBA: A medical food is nutritional therapy that treats a specific disease or condition that cannot be managed by a patient's modification of diet and that must be taken under the supervision of a physician. What our medical foods target are the underlying conditions associated with various eye diseases.

For example, we know the macular pigment is often depleted in patients with visual loss from macular degeneration; that's why our product Lumeza-Z is constructed specifically to enhance and restore the macular pigment. Another of our products, GlaucoCetin, focuses on reversing underlying mitochondrial dysfunction disorders. Recent studies have shown, for example, that glaucoma and other long-term vision disorders stem from underlying mitochondria dysfunction.

There has been a dogma in eye health care related to degenerative ocular diseases, which is "let's make sure patients don't get worse." I've felt for many years that if we can catch the

diseases early, we should focus on ways to help patients get better, not just prevent them from getting worse. Data from macular degeneration and glaucoma patients suggests our medical foods may be able to do just that in certain patients.

OM: Why be involved in both medical foods and diagnostics?

DE: For many medications and treatments for eye health, there are efficacious ways to treat and track the disease. For example, visual fields are used to determine if patients are progressing for glaucoma; in diabetic patients, spreading of the retinopathy is an indication of progression.

But for many conditions, visual acuity is the primary metric to determine the status of the disease and the response to treatment.

The problem with visual acuity is that it is very insensitive to losses in vision for eye diseases like AMD and glaucoma. For example, by the time an AMD patient loses a line or two of acuity, the battle to save their eyesight is already being lost. Contrast sensitivity, when it is tested in a standardized format, provides a way to detect and measure the earliest vision loss and a rapid method to track

treatment. When we combine the contrast sensitivity testing of our CSV-1000 and CSV-2000 with our medical foods, it allows us to detect the disease at an earlier state and then measure the response to treatment over relatively short time periods. We call this our evidence-based protocol.

The two go hand-in-hand — that way, when a physician recommends one of our medical food for his or her patient, the doctor and patient can validate its effect by changes in contrast sensitivity.

OM: After positive results from a study this May, what's next for Lumeza-Z?

DE: In several studies published over the last year, we were able to demonstrate our formula's high level of bioavailability and efficacy, and the stabilization of visual function. Now that we have proven results, our next step is to get the word out.

Lumeza-Z has been in use by several dozen eye-care practices for six years but has only been widely available commercially for a little more than a year. Over time we have had many doctors tell us anecdotally that switching patients to Lumeza-Z

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Industry Insider, continued from page 40 has yielded better outcomes than other nutritional therapies for AMD. Now that we have published research to support these anecdotal care studies, we want to educate physicians on the benefits of our formula.

OM: You were the inventor of the CSV-1000 for VectorVision. Tell us about the creation of this device.

DE: The development of the CSV-1000 was based primarily on my experience in the Air Force. I remember evaluating the vision of pilots, some of whom could detect an enemy aircraft at 20 miles but others with the same 20/20 or 20/15 acuity could only detect the enemy aircraft at 10 miles away. That detection distance makes a big difference when flying at about 600 miles an hour.

Medically, we have known for decades that contrast sensitivity is a better overall measure of vision than acuity. The first such paper was published in 1972. So it was no surprise that when I transitioned the technology from pilot testing into the clinic, we found it was a very good technology for measuring and monitoring disease state in the eye. Visual acuity, on the

other hand, was originally conceived of as means to prescribe glasses by correcting optical blur. But eye diseases, such as macular degeneration, do not affect optical blur, which means that a different method would be needed to fully evaluate vision in these patients. When an AMD patient is tested with a standardized contrast sensitivity test, eye doctors achieve a much better measure of the status of the disease.

To be used clinically, contrast sensitivity has to be tested in a standardized format because it is very sensitive. What was unique about the CSV-1000 was that it was the first self-standardized contrast sensitivity vision test that could ensure a doctor would get accurate results. This is very important for early detection of vision loss and tracking the efficacy of treatment over time.

We just launched the CSV-2000, the computerized version of the vision test. It is the first fully standardized computer vision testing system that allows for a wider range of vision testing, including visual acuity, color and astigmatism, as well as contrast sensitivity and glare. A patented technology, called AcQviz, automatically calibrates the monitor light level. **OM**

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