

The WaveDyn Vision Analyzer from WaveFront Dynamics: a new tool for Optometrists and Ophthalmologists; measuring more ocular detail for optimal treatment



**Daniel Neal PhD
Founder & CEO**

WaveFront Dynamics Inc.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEO CFO Magazine**

CEO CFO: *Dr. Neal, the first thing I see on the Wavefront Dynamics website is "Elevating Vision with Dynamic Precision." Would you tell us what your plan is for doing that?*

Dr. Neal: My team and I have worked together for the last 25 years to build instruments to measure the eye. We developed, and then slowly improved, the technology to measure more & more aspects of the eye, and we use these instruments & techniques for various types of treatment. When we say *dynamic precision*, we mean accurately measuring the eye as a function of time. Each measurement is a movie instead of a snapshot. That gives us a much fuller picture of how the eye is responding and how it may change over time. We then use this information to *elevate vision* by giving patients a better prescription or customized correction.

Rather than using the old method ("which is better, one or two?"), we measure dynamically and select the best measurement for refraction and treatment. Ultimately, we can also take that information and then make a customized correction; for example, a LASIK procedure or customized contact lens. This process can bring everybody to high quality vision.

CEO CFO: *Would you explain how an eye changes second by second?*

Dr. Neal: The eye, just like everything in the body, is continuously moving. The fixation (direction of gaze) constantly changes. Every time you blink, the tear film gets smoothed out by the eyelid, and then it starts to evaporate, thereby changing the vision. A poor tear film can cause a reduction in vision.

Depending on the age of the person, the internal structure of the eyes also changes in different ways. Younger people might change their focus several times in a second. By measuring all aspects of the eye, we can collate information together to provide the right measurement to drive a treatment.

CEO CFO: *What is the state of this concept today?*

Dr. Neal: This technology is like many technologies in many different fields. It results from the slow evolution of improvement over many years. My team has been working on this since about 1999. We have made five generations of instruments. The WaveD̄yn is the latest one. At each stage in the development, you find ways to improve the technology.

We now measure multiple aspects of the eye *dynamically*, which gives us increasing confidence in the results. Prior instruments gave information, but with no way to verify clinically. Building in the subjective comparison increases the confidence and provides a time savings for the optometrist/technician.

It is a pretty new technology. We have had the WaveD \ddot{y} n Vision Analyzer released for about a year and a half. With any new technology there is a slow adoption curve at first. We just released the wavefront corrected contact lens and are working with our first customers. Some people have a distorted lens or cornea, either from prior surgery or some disease, such they are not able to focus light properly. It may just result in just a little blurriness, or it could be so bad that they cannot see an image. For these cases we measure the eye, and then make a correcting contact lens. It is kind of like noise-cancelling headphones. Where the cornea is thin, the lens is thick, and vice versa, so it cancels out the wrinkles, providing good vision. We take people sometimes from 20/400 to 20/20 vision. This improves and *elevates* their vision.

CEO CFO: *Do you see this being used in standard exams as time goes on or more for specialization?*

Dr. Neal: You can do these measurements quickly. In a minute you can measure both eyes and have a complete refraction. Some clinics are using this to speed up their process. The current process can take ten or fifteen minutes, so we can save 5-7 minutes per patient. Not every site needs this efficiency gain by itself but may use other tools to assess the health of the eye, the retina, and overall vision. We don't eliminate optometrists; we just give them a new tool to improve their efficiency.

"The ability to accurately measure all aspects of the eye leads directly to better treatments. This accurate measurement is a paradigm shift for the whole ophthalmic community. The WaveD \ddot{y} n Vision Analyzer measures every important ocular detail; quickly, dynamically and accurately. This measurement allows an eye care practitioner to select the best kind of treatment, whether eyeglasses, contact lenses, custom contact lenses, Lasik surgery or cataract surgery. We are still at the starting point in developing new applications. Already we've improved the vision of hundreds of patients with highly aberrated eyes. In future, I expect more and more eye doctors to use this tool to make eye care more efficient and to provide better vision for more patients." Daniel Neal PhD

CEO CFO: *How does cost come into play?*

Dr. Neal: Anytime you have a new technology, especially in the beginning, it is expensive. The instruments themselves are expensive. We are working on various business models to reduce the cost for the patients and the eye doctor. Some of these things have recently been put in place.

CEO CFO: *Could you explain more about how the technology works?*

Dr. Neal: Several aspects of the eye are measured simultaneously. We project a dim dot of light onto the retina to create a small spot. This scattered light is collected by the eye itself and then re-imaged onto a Shack-Hartmann sensor. The sensor has an array of little lenses on it, kind of like a fly's eye. It is not just one lens; it is a whole grid of lenses.

The lenslet array creates a pattern on the camera. The shape of that pattern and how it moves and fluctuates is a measurement of the optics of the eye. Now instead of a snapshot on the camera, we record a movie, each frame having 2800 to 3000 individual measurement points. Each point provides a refraction measurement, so the grid provides a map of the refraction of the eye, also known as the wavefront map.

CEO CFO: *What is involved in reading the results?*

Dr. Neal: Like any new technology, you need to learn how to use it. We provide training, and there is quite a bit of resource material available. The information is presented in a color map so that if everything is smooth, it is green. However, if it is irregular, it becomes many different colors to provide quick interpretation. You can see whether there is a region that might have a problem or whether one eye is more aberrated than another. Various metrics and parameters also give you an idea of the quality of vision. You can simulate what an eye chart looks like to a patient, thus allowing the doctor to "see through the patient's eyes."

CEO CFO: *Are there similar ideas or products?*

Dr. Neal: With anything, there is always competition. Competition forces everyone to do better. This is the highest resolution and highest speed sensor, giving the most accurate results. As our competition evolves, we must make ours better to remain competitive.

We were the first ones to introduce an aberrometer in the year 2000, but now there are ten to fifteen instruments on the market. We have had to keep getting better over time to be competitive.

The WaveD \ddot{y} n Visual Analyzer gives us the most advanced instrument available in the US market.

CEO CFO: *How do you get attention for Wavefront Dynamics?*

Dr. Neal: Through trade shows, social media, direct to customers, and word of mouth. We haven't done much actual advertising, yet we will slowly try to expand our reach. Word of mouth is very powerful, as there is a small community of specialists in this field. Once our instrument is successful for one person, then they tell other doctors about us.

CEO CFO: *How do you stand out at a conference?*

Dr. Neal: That is challenging. There are lots of companies with all different products at these conferences. We stand out by publishing and presenting at conferences. We often partner with an eye doctor to make a technical publication and give a talk or a poster. That allows people to get to know us through the technical aspects. The actual booth at a trade show will be a place where they can come to see what the instrument does and to get a demonstration. They can have their eyes measured to gain an understanding of the process. With booth graphics and displays alone it is hard to gain much attention, but if you participate in the whole scientific process, it can be effective.

CEO CFO: *Would you tell us about the manufacturing and inventory?*

Dr. Neal: We manufacture all in-house currently. We have about 10,000 square ft. of space and about half of that is dedicated to manufacturing. We can make about eight of these units a month, which is low volume at the moment. If that increases, we will have to get more space.

It takes a team of trained technicians, but they do not have to be PhDs, they just have to have the appropriate training. We can train just about anyone who has some technical skills.

There are also always improvements we are making to the instrument and the process. Mostly these are software things; the mechanics of the instrument are fairly stable at this point.

CEO CFO: *Are you seeking funding, partnerships, or investment as you move forward?*

Dr. Neal: Absolutely! We are seeking funding. We've invested a lot of money and effort to develop a product and now are trying to get into the market. We need funding to find the right sales venues, to hire salespeople, improve our product delivery infrastructure and other commercialization activities. We could use some investors, partners, distributors, contact lens companies or other treatment connections.

CEO CFO: *Is the investment community looking at eyes?*

Dr. Neal: There is a good community of people who invest in ophthalmic products. I have found it was easier for me to find early-stage investors than those who will help us to get it launched in the market.

CEO CFO: *Where does the FDA or any regulation come into play for you?*

Dr. Neal: You must be registered with the FDA to sell a medical device product. There are different classifications of that. We met with the FDA and concluded together it was a Class 1 510(k) Exempt device, which means there is no formal approval required but we do have to follow a good manufacturing process. We follow all the design-controls, which means keeping a record of every change and detail of the design process. Our device is registered with the FDA, but it does not require approval from the FDA.

CEO CFO: *What do you see a year down the line?*

Dr. Neal: I am seeing a lot of interest in the treatment with our wavefront guided scleral lenses. There is a disease called Keratoconus which is caused by a thin spot in the cornea. The internal pressure of the eye causes that region of the cornea to bulge out, creating a distorted cornea. This disease turns out to be a sweet spot for our technology; it is

straightforward to measure and within the capabilities of the contact fabrication technology. Most people who have Keratoconus, who start with 20/100 or 20/80 vision, can be corrected to 20/20 and sometimes 20/15. That is a real win for these patients. In some cases, these patients go from not being able to drive or read to being functional in every area.

Several specialty clinics are treating these patients, and the tools that they have had to date have been somewhat compromised. With this new tool, I see us being able to help this whole segment. Over a year I expect that this is the area that will have the biggest growth. I also expect more sites to recognize the benefits of the speed and accuracy of automated refraction and to replace the methods that have been around for the past 200 years. We will see this pick up as people start recognizing the value of improved efficiency.

CEO CFO: *How does Wavefront Dynamics stand out?*

Dr. Neal: The ability to accurately measure all aspects of the eye leads directly to better treatments. This accurate measurement is a paradigm shift for the whole ophthalmic community. The WaveD \ddot{y} n Vision Analyzer measures every important ocular detail; quickly, dynamically and accurately. This measurement allows an eye care practitioner to select the best kind of treatment, whether eyeglasses, contact lenses, custom contact lenses, Lasik surgery or cataract surgery. We are still at the starting point in developing new applications. Already we've improved the vision of hundreds of patients with highly aberrated eyes. In future, I expect more and more eye doctors to use this tool to make eye care more efficient and to provide better vision for more patients.