Creating vision
beyond what we see

Ora IVAD

Ora's IVAD (Inter-blink Interval Visual Acuity Decay) technology provides a clinically relevant endpoint measurement of visual function. Thus, providing our sponsors with an innovative way to demonstrate therapeutic impact on ocular surface degradation.

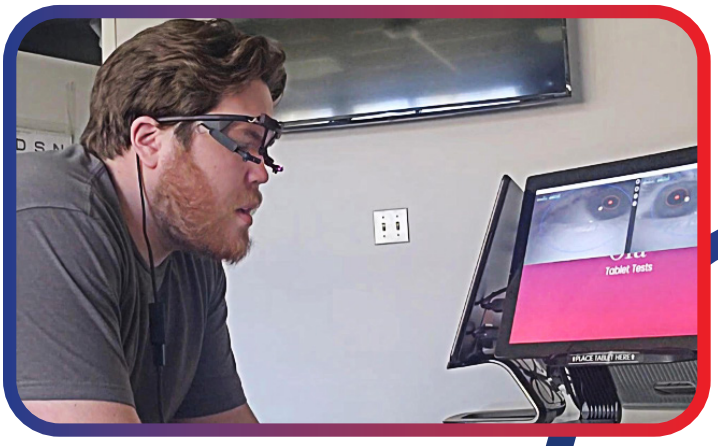
- The Ora IVAD test is a novel diagnostic tool developed by researchers at Ora R&D to demonstrate the objective therapeutic benefit of visual function improvement in a clinical trial.
- The IVAD test has been validated by Ora as a primary/secondary endpoint in the US and as a secondary endpoint in Europe and Latin America.
- Visual function as measured by IVAD is a clinically relevant and meaningful endpoint, directly impacting everyday quality of life.

Dry Eye Disease (DED) is a chronic and debilitating condition of the ocular surface that affects millions worldwide. A more recent area of study in DED is the implications for visual function. People often experience a decreased blink rate during visual function tasks, which can exacerbate DED symptoms. Ultimately, the patient will experience some degree of limited visual functioning capabilities.

The effects of DED symptoms on visual function can be assessed by testing the visual acuity degradation during the inter-blink interval (IBI). Previously, it has been difficult to quantify the decay of visual acuity within the IBI. However, the Inter-blink Interval Visual Acuity Decay (IVAD) test is a novel diagnostic tool developed by researchers at Ora Clinical Research and Development (R&D) to evaluate functional visual acuity between blinks.

IVAD is a computer-based visual task which involves the identification of landholt 'c's at individualized best-corrected visual acuity (BCVA) between blinks and measures parameters based on patient responses. During the IVAD test, the rotating optotype 'c' is presented, and the subject verbally indicates the direction of the 'c' and a technician records the response.[1] The test stops when the subject blinks.

By using a standardized task for all DED patients before and after treatment, the IVAD test is designed to establish an accurate representation of the effects of dry eye treatments on visual function. A shorter test time represents a loss of BCVA. While a greater time indicates prolonged maintenance of BCVA, thus sustained visual function[2].



Above: *IVAD tablet display along with the Landolt "C" Orientation Options*

With Ora's novel diagnostic tool IVAD, our customers stand to benefit in several ways:

1. Visual function as measured by IVAD is a clinically relevant and meaningful endpoint measurement, directly impacting everyday quality of life.
2. IVAD is a precise and sensitive tool that can reproducibly monitor real-time maintenance of BCVA between blinks. Thus, providing a subjective endpoint measured in an objective manner.
3. IVAD can evaluate both immediate therapeutic benefit (e.g., a single eyedrop of an artificial tear) and long-term treatment/disease modification (e.g., prescription product).

Additionally, the IVAD test can provide evidence of product superiority in competitive 1:1 comparison. A recent Alcon Phase 4 study, looking at the artificial tear (Systane) was performed in the US. The study investigated patients suffering from DED symptoms. Ora's IVAD technology, study design, and execution supported the sponsor's marketing and messaging campaign to promote a leading artificial tear. As a result, Systane was shown to significantly improve the maintenance of visual acuity (data from IVAD technology) allowing Alcon to suggest that their product helps patients "see better longer" after a single eyedrop when compared to a direct competitors' eyedrop.

Above: *Example of IVAD testing options showing subjects eye tracking.*

The Ora IVAD diagnostic test is a perfect example of one of the Ora R&D team's innovative tools that proves Ora is at the forefront of matching the best endpoints for each sponsor's potential therapy.

Previous studies have shown eye dryness and discomfort directly impact vision in everyday activities. By including the Ora IVAD technology as a clinical endpoint to assess visual function, our sponsors will be able to prove their therapeutic performs in a way that will improve debilitating symptoms for patients suffering from DED.

References

1. Walker P, Ousler GW III, Workman DA, et al. Visual function in normals compared to patients diagnosed with dry eye as measured by the inter-blink interval acuity decay (IVAD) test. Invest Ophthalmol Vis Sci. 2007;48: E-abstract 422.

2. Chin J, Jones S, Bensinger E, Ousler G. Does an ocular lubricant with hydroxypropyl guar and sodium hyaluronate prolong maintenance of best corrected visual acuity, measured objectively by the Interblink Visual Acuity Test (IVAD) in Dry Eye Disease patients? The Association for Research in Vision and Ophthalmology (ARVO); 2024.

Ora

Ora is a global full-service ophthalmic drug and device development firm with vast capabilities through all steps of clinical research, including preclinical, clinical, CMC & regulatory, and patient and site evaluations. Through Ora's 40+ years of experience, the company has assisted in bringing more than 80 products to market. Ora's team of experts utilizes global regulatory strategies, integrated research operations, and extensive site and patient engagement to accelerate product development in anterior and posterior segment, as well as ophthalmic devices.