

Q3D: Quantitative Three Dot Device



Organization

University of Missouri–St. Louis

Industry:

Medical device, optometry/vision care

Researchers:

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Status of Intellectual Property:

- US Patent #[7,686,452](#) entitled “Apparatus and Method for Assessing Visual Suppression”
- Canadian Patent #2676122

Next Steps:

Working prototypes available. A commercial partner is needed for manufacturing and marketing/sales.

Wanted

Experienced leader to commercialize the Q3D, a novel device that quantitatively measures the depth of visual suppression. This capability does not currently exist on the market and is critical to save the sight of children with conditions such as amblyopia.

Customer Problem

The target application for the Q3D is patients with amblyopia, the loss of vision in an eye that occurs when the brain “suppresses” information from that eye. Amblyopia is the most common cause of vision impairment in children, young and middle-aged adults. The National Eye Institute (NEI) estimates that up to 3% of children in the US with amblyopia (incidence in European countries reaches nearly 4%). If not detected and treated early enough, it can cause permanent vision loss. However, amblyopia can be difficult to recognize early because the suppressed eye can appear normal. The screening technology currently on the market (Worth 4 Dot test) is a “blunt” instrument that can measure only qualitatively and only when significant suppression is already present, most often when it is too late to prevent or reverse the condition. A sensitive testing device that can detect very small changes in visual suppression is needed.

Potential Market Uses

The Q3D device is reliable, simple to use, and accessible to all levels of vision care professionals (optometrists, ophthalmologists, technicians, volunteers, etc.). It has the potential to identify more cases of visual dysfunction much earlier, with the potential to move visual screening into the hands of non-clinical personnel, and significantly improve rates of clinical intervention and overall patient outcomes worldwide. The Q3D test can be administered rapidly (< 1 minute) and is able to detect extremely small changes in suppression, flag possible cases of amblyopia very early and monitor the efficacy of therapies. Screening all children early is critical to improve health outcomes; the Q3D can be part of normal vision screening of all patients in the clinic and can easily be used outside of the clinic to expand the pool of patients who benefit.

Note: other potential applications include detection of optic nerve abnormalities such as optic neuritis and TBI.

Market Size

The primary addressable market for the Q3D device consists of optometrists, ophthalmologists, and pediatricians in the United States and Europe. There are an estimated 40,000 practicing optometrists, 18,000 ophthalmologists, and 92,000 pediatricians in the U.S. Approximately 20% of optometry and ophthalmology professionals have a major focus on pediatric issues, which commonly require screening and assessment of visual function. Optometrists serve as the sole primary eye care provider in more than 4,300 communities across the United States. There are more than 400,000 combined eye care professionals (optometrists and ophthalmologists) worldwide.

Innovation

The Q3D is a simple, inexpensive, non-invasive device that provides an immediate and accurate quantified measurement of visual suppression (in 0.1 to 3.0 log units) in patients as young as 3 years old. The first and only such device, the Q3D is a hand-held, battery powered electronic device that presents visual stimuli to a subject through the use of calibrated light emitting diodes (LEDs).

The Test. Visual stimuli of varying brightness are selectively presented to each of the subject's eyes, enabling a direct comparison of the level of visual function in each eye. The patient wears anaglyph (red/green) glasses and looks at the Q3D from three feet away. Three lights (one green, one yellow and one red) should be seen by the subject and should appear of equal brightness. However, visual suppression in the right eye (covered by the red filter) will cause the patient to see two green lights; suppression in the left eye (covered by the green filter) will cause the patient to see two red lights. The intensity of light being viewed by the suppressed eye is increased until it matches the brightness of the light as seen by the other eye. The suppression is quantified using log units, a numeric scale of the amount of suppression. The entire test takes less than a minute.

The current version of the Q3D is designed to be manufactured inexpensively as a stand-alone device; however, previous versions were developed as possible add-on to fit standard power handles found in most clinics (e.g., Welch Allyn and Keeler).



Clinical Trials. After an initial small study conducted at UMSL, a clinical trial of the Q3D was performed at Cardinal Glennon Children's Hospital with more than 300 patients in collaboration with Dr. Oscar A. Cruz, M.D., Chairman, Department of Ophthalmology and Bradley Davitt, M.D. at the Saint Louis University Eye Institute (SLU Medical Center). Results from the clinical trial at Cardinal Glennon indicated that the Q3D is a significantly more sensitive predictor of visual suppression than current methods and can be used on patients as young as three years of age. **The Q3D detected 4x the number of impairments in patients with amblyopia as the existing screening tool.**

Stage of Development

3rd-Generation Prototype: The inventors were awarded a \$50,000 University of Missouri System "FastTrack" award for the Q3D project to fund optimization of the device's LED optics, improved form factor of the Q3D device, optimization of the Q3D schematics and design to improve reliability and reduce manufacturing cost per device. Ten (10) working prototypes with hardware, software and circuit design documentation were produced.

Competitive Advantages

Currently, the Worth 4 Dot Test is administered to determine the **presence** of suppression in patients. The Q3D is the first and only device that quantifies the **depth** of visual suppression. The Q3D detects small changes/impairments in visual suppression (0.1 log unit steps up to 3 log units); the Worth 4 Dot only detects dense suppression >2 log units. The Q3D can detect suppression much earlier than the Worth 4 Dot, which allows for higher treatment success rates.

The test is fast to perform (< 1 minute) and easily administered by clinicians, nurses, technicians or other trained personnel. Quantifying depth of suppression allows for the selection of appropriate treatments and monitoring of outcomes over time, which is not possible with the Worth 4 Dot.

Initial evaluation has determined that the device will likely be FDA Class I exempt.