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## NEWS RELEASES

Monday, September 27, 2021

# NIH-funded study shows screening device accurately detects amblyopia (lazy eye)

A handheld screening device that detects subtle misalignment of the eyes accurately identifies children with amblyopia (lazy eye), according to a study published in the *Journal of the American Association for Pediatric Ophthalmology and Strabismus*.

“The findings suggest that pediatricians and other primary care providers could use the device to catch amblyopia at an early age when it’s easier to treat,” said Michael F. Chiang, M.D., director of the National Eye Institute (NEI), which supported research and development of the device. NEI is part of the National Institutes of Health.

Amblyopia is impaired vision in one eye and it is the leading cause of preventable monocular (single eye) vision loss, affecting three of every 100 children in the U.S.

During early childhood, our developing brains learn how to take images from each eye and fuse them into a single image to produce vision. Amblyopia develops when misalignment of the eyes (strabismus) or decreased acuity in one eye interferes with the brain’s ability to process visual information from both eyes, causing it to favor one eye. Once a child is visually mature, vision lost in the weaker eye cannot be corrected with glasses or contact lenses.



Within seconds of the screening, the pediatric vision screening device calculates a binocularity score based on foveal alignment and provides a “pass” or “refer” result to the clinician. *Andrew Schuman, M.D.*



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Children with amblyopia can suffer from poor school performance and impairments in depth perception and fine motor skills such as handwriting and other hand-eye coordinated activities.

Treatment of amblyopia generally involves placing a patch over the good eye to improve vision in the weaker eye. Patching is less successful as children get older, making early detection crucial. However, this depends on timely diagnosis by the child's doctor, and most pediatricians are equipped only for basic eye chart vision screening tests, which are not useful for detecting amblyopia in very young children.

The screening device works by assessing the eyes' ability to fixate together. Held 14 inches from the eyes, the child fixates on a smiley face while the device simultaneously scans both retinas. The scan involves a polarized laser that probes nerve fibers in an area of the light-sensing retina called the fovea, which is important for central vision. Even a subtle misalignment of the foveas — called small-angle strabismus — can interfere with the brain's ability to integrate images from both eyes. The device calculates a binocularity score that indicates whether the child requires referral to an eye health physician for further investigation.

For the study, 300 children, ages 2 to 6 years, with no known eye disorders were recruited during previously scheduled visits to two Kaiser Permanente Southern California pediatric clinics.

Two non-ophthalmic research associates who were trained how to use the device screened each child, and the results were compared against those from an eye examination performed by a pediatric ophthalmologist who was unaware of the device's results. The device detected all six cases (100% sensitivity) of amblyopia and/or strabismus that had been confirmed by the professional eye examination. The device also flagged an additional 45 children as possibly having amblyopia and/or strabismus who were later determined by the eye examination to be normal (85% specificity).

"In the hands of a trained user, it takes 28 seconds to sit the child down, perform the test, and record the results – provided that the child cooperates — which is an important consideration for its adoption in busy pediatric care settings," said the study's co-lead investigator, Shaival S. Shah, M.D., a pediatric ophthalmologist at Kaiser Permanente based in Tustin Ranch, California. The test itself requires just 2.5 seconds of a child's attention.

A key limitation of the study was that the device was not compared with currently available photo-screening devices. Such devices detect differences in light reflexes in each eye and produce images that can help detect risk factors for amblyopia, but not amblyopia itself, which can result in both over and under detection of amblyopia.

By contrast, the pediatric vision scanner detects the presence of amblyopia as opposed to the risk factors of amblyopia, which may lead to fewer unnecessary referrals to pediatric ophthalmologists.

The pediatric vision screener tested in the study is a prototype of blinq.®, a device that was cleared by the U.S. Food and Drug Administration in 2016.

The clinical trial identifier is NCT02536963. The study was supported by NEI grant R44EY025926 to Rebiscan, Inc. (doing business as Rebion), the Boston-based firm that markets blinq.®. Support was provided under the Small Business Innovation Research (SBIR) program, a funding mechanism that helps independently owned companies with 500 or fewer employees bring biomedical technologies to the market.

Co-founder of Rebion, David Hunter, M.D., Ph.D., ophthalmologist-in-chief at Boston Children's Hospital, co-invented blinq.® with support from NEI grant R01EY012883.

For more information, visit the [amblyopia page](#) on the NEI website. To learn more about the screening device, see [Vision screening device improves detection of "lazy eye"](#).

NEI leads the federal government's research on the visual system and eye diseases. NEI supports basic and clinical science programs to develop sight-saving treatments and address special needs of people with vision loss. For more information, visit <https://www.nei.nih.gov>.

The Small Business Innovation Research (SBIR) program is a competitive awards-based funding mechanism that supports U.S.-based small businesses engaged in research and development that has the potential for commercialization. The NEI SBIR program specifically provides funding to companies developing technologies and innovations relating to blinding eye diseases, visual disorders preservation of sight, and addressing the special health problems and requirements of individuals with impaired vision.

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## Reference

Shah SS, Jimenez JJ, Rozema EJ, Nguyen MT, Preciado M, and Mehta AM, "Validation of the Pediatric Vision Scanner in a normal preschool population". Published in J AAPOS Volume 25, Issue 4, August 2021, Pages 216.e1-216.e4. <https://doi.org/10.1016/j.jaapos.2021.03.010>

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