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Abstract

Existing methods for measuring functional vision in low-vision individuals may not capture clinically meaningful outcomes. By assessing an individual's ability to identify objects up close in various lighting conditions, we can derive meaningful and comprehensive measures of an individual's visual capabilities in day-to-day tasks. This evaluation offers valuable insights into the functional aspects of vision, shedding light on a person's visual acuity and performance when engaging in tasks that require proximity to objects. Here, we report the development and evaluation of the MLSDT (Multi-Luminance Shape Discrimination Test), including considerations of object sizes, shapes, spacing/organization, and the required number of objects. We also provide assessment of the suitability of the MLSDT in low-vision patients and comparison of its functional performance with low-vision best-corrected visual acuity (BCVA) measurement using Freiburg visual acuity. The MLSDT test performance in subjects with different BCVA showed improved object recognition when the size of the objects is increased and/or the luminance level is enhanced.

Keywords: MLSDT (Multi-Luminance Shape Discrimination Test); Best-Corrected Visual Acuity (BCVA); Freiburg Visual Acuity

Introduction

As regenerative medicine, notably gene and cell therapy, continues to advance, the focus on targeting diverse cell types to halt degeneration, re-functionalize cells, or integrate new cells becomes more prominent [1]. The exploration of innovative methodologies to assess functional vision in these subjects is gaining significance, as it opens new avenues for understanding the impact of these cutting-edge treatments. This growing interest stems from the potential these therapies hold for addressing the complex challenges faced by individuals with very low vision. The limitations of the sight charts including early treatment diabetic retinopathy study (ETDRS) chart [2] become particularly evident when confronted with patients whose visual acuity falls below the established testing range. Therefore, in cases of low-vision patients with best corrected visual acuity worse than 20/800 including counting fingers (CF) and hand movements (HM) [3], it is often challenging to accurately assess and quantify the vision. Thus, monitoring of natural history and effective treatment planning is hindered in the ever-growing population of blind patients. Further, sight charts have limited ability to fully comprehend the functional implications of vision loss in patients with such severe visual impairments [4]. This is especially important for patients suffering from loss of light sensitivity due to loss of rod and cone functions [5-7]. The currently approved mobility test evaluated the performance at multiple luminance levels, thus enabling measurement of improvement or deterioration based on lowest passing luminance level [8]. However, the mobility test may be limited, and results may be confounded by physical impairment, caused by various comorbidities in the

aging population. Mobility assays are also limited by the requirement of physical space and lighting environment. Further, the testing time is extended over several hours which can hinder the suitability of mobility assays in everyday clinics. These intricacies underscore the need for alternative assessment tools and methodologies for patients with vision impairments exceeding the conventional testing limits of the sight charts and mobility tests.

The pursuit of novel assessment tools for low-vision patients is becoming equally important as the search for effective therapies for retinal degenerative conditions that impact light sensitivity as well as image-forming abilities. Therefore, the intended test must be suitable to evaluate the patient population for which the therapy is intended. For example, due to the heterogeneous nature of abnormal retinal morphology changes in maculopathy, it is suggested that individuals with maculopathy may encounter greater challenges in tasks requiring the global integration of visual stimuli across a substantial retinal area compared to tasks focused on localized aspects, such as visual acuity [9]. Thus, shape discrimination hyperacuity tests with perfect and distorted circular contours as visual stimuli have been developed to evaluate patients with maculopathy, who are known to see distortion in visual targets [10]. By precisely measuring changes in vision and its improvement post-treatment, researchers can effectively evaluate the therapeutic efficacy and tailor interventions to optimize outcomes.

Unlike mobility assay, the functional vision assessments should be portable to be deployed in everyday clinics. Further, the testing time must have a short execution time to allow the clinician and patient to go through other clinical examinations and consultations. By assessing an individual's ability to identify objects up close in various lighting conditions, one can derive meaningful and comprehensive functional vision measures of an individual's ability in day-to-day tasks such as reaching for and grabbing a desired food item from a refrigerator, identifying and processing food on a chopping board, picking up an object from a shelf or under a night lamp, and interactions with their immediate environment. Grasping the capacity for recognizing nearby objects across diverse light levels is crucial for gaining a deeper understanding of visual impairments, effectively addressing them, and optimizing visual interventions. Here, we provide assessment of the suitability of the MLSDT in low-vision patients and a comparison of its functional performance with low-vision best-corrected visual acuity (BCVA) measurement using Freiburg visual acuity [11]. This development would significantly contribute to advancing low-vision research by enabling the evaluation of patients through sight charts/mobility tests during the natural course of disease progression as well as after therapeutic interventions.

Materials and Methods

Ethics statement

The evaluation of the multi-luminance shape discrimination test (MLSDT) and Freiburg acuity (FrACT) was conducted on sightimpaired individuals and normal volunteers following the execution of informed consent. The study using human subjects reported in the manuscript was conducted according to the principles of the Declaration of Helsinki.

Measurement of best corrected visual acuity (BCVA)

BCVA of normal vision and vision-impaired subjects was assessed using the Freiburg acuity. The Freiburg visual acuity test was designed to assess visual acuity, particularly in low-vision patient populations. Freiburg visual acuity can provide quantifiable, and reproducible visual acuity assessments for visual acuities even worse than CF and has been validated to correlate with ETDRS and Snellen visual acuity measures [3,12]. Visual acuity is measured in "logarithm of the minimal angle of resolution" (LogMAR) units by Freiburg Acuity measurements. A lower LogMAR score denotes better visual acuity.

The lateral size of position sensors-array based on visual field

Since the objective of MLSDT is to measure shape discrimination without requiring excessive head or eye movement, providing accurate insights into the subject's visual capabilities, it is essential to ensure that the size of the row and placement of objects take into

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consideration the subject's visual field. The object of ~ 6 cm size at 30 cm (optimum viewing distance for near activities) subtends an angle of ~ 11 degrees. Patients suffering from severe retinal degenerative conditions such as Retinitis Pigmentosa, having vision worse than 20/800, have constricted visual fields less than 45 degrees [13,14]. Since MLSDT is intended to evaluate such low-vision patients, the lateral size of the position sensors-array in the controlled illumination box was limited to 25 cm (equivalent to 45 degrees visual angle at a distance of 30 cm). Further, it is reasonable to assume that the objects are appropriately spaced (minimum: 3 cm) to allow picking up the object without hitting adjacent objects. Therefore, as shown in figure 1, two rows were created to position 6 objects.



Figure 1: Multi-luminance shape discrimination test (MLSDT) set up. (A) MLSDT 3x2 set up configured with an assortment of 6 large-sized real-life objects (pyramid, donut, brick, cube, cylinder, and sphere). (B) MLSDT 3x2 set up configured with an assortment of 6 large-sized objects (mimicking real-life objects) with the software interface showing automated detection of picked-up objects.

Selection of shapes based on familiar objects

Assessing functional vision through object recognition in individuals with severe and long-standing vision loss presents challenges, as reliance on senses like touch becomes crucial, known as the Molenyux Paradox [15]. Therefore, the evaluation of shape discrimination by the MLSDT requires a careful selection of objects that the subject may have encountered and touched before losing vision. Initially, six common everyday objects-sphere, cylinder, cube, donut, brick, and pyramid-were chosen, as depicted in figure 1A. This approach prevents overwhelming individuals with very low vision with too many diverse stimuli. Figure 1B shows casted versions of these selected geometric shapes. The size of the objects, approximately 6 - 7 cm, mirrors that of real-life grabbable objects like apples, oranges, or baseballs. The testing aimed to identify shape-object combinations that were recognizable under low-lighting conditions and closely resembled real-world objects. Following this evaluation, the final device design streamlined the selection to incorporate only three objects. This decision was influenced by the identification of potential issues with the donut, brick, and cylinder shapes during the testing phase.

MLSDT system description

The MLSDT involves placing 3D objects of different shapes onto pressure sensors in the controlled-luminance box (Figure 1). The 3D shape discrimination of objects that are illuminated at different luminance levels emulates different lighting conditions while performing activities of daily living. An example of a 3D shape discrimination test setup is shown in figure 1. The equipment list includes a calibrated

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laptop with software, a light meter, an apparatus (testing box) for 3D shape discrimination, the multiple object shapes and sizes. Figure 1A shows the MLSDT 3x2 setup configured with an assortment of 6 large-sized real-life objects (pyramid, donut, brick, cube, cylinder and sphere). MLSDT 3x2 setup configured with an assortment of 6 large-sized objects (mimicking real-life objects) is shown in figure 1B. The depicted software interface allows automated detection of picked objects. Supplementary figure 1 shows MLSDT 3x2 set up with a backrow raised platform mimicking a rack.



Supplementary Figure 1: Difficulties in MLSDT 3x2 set up with back-row raised platform. (A) MLSDT 3x2 set up configured with an assortment of 6 large-sized objects (pyramid, donut, brick, cube, cylinder, and sphere) in a rack. (B) Knocking off the incorrect object (pyramid) while reaching for the correct object (sphere) in the back row.

Supplementary figure 2 shows the MLSDT setup with a 3x1 configuration of 3 large-sized objects (pyramid, cube, and sphere). The 3D shape discrimination apparatus has a flat LED panel mounted at the top of the apparatus. The LED panel is set to pre-calibrated light intensity levels to illuminate different objects placed on the base of the MLSDT unit. The pressure sensors that are attached to the base of the set-up, detect change in the pressure when the objects are placed or displaced. Supplementary figure 2B shows the schematic of the MLSDT illustrating the spatial relationships among objects, lights, enclosure, electronics, and their connection to the computer. The control board is responsible for adjusting LED light settings and communicating with pressure sensors. Additionally, a PC interface communicates with the control board to receive user inputs and displays the picked-up object based on pressure sensor readings. This comprehensive integration of components and the MLSDT configuration enables precise control, accurate object discrimination, and reliable data collection for assessing the visual capabilities of individuals with severe vision impairment.

Supplementary figure 3 shows the physical dimensions of objects and spacings between objects in MLSDT. Height-dependent spacings between sphere and cube, pyramid and cube, as well as pyramid and sphere are shown. While the cube to sphere gap varies from 36 - 71 mm, the pyramid to cube gap varies from 40 - 61 mm and that between the pyramid to sphere varies from 41 - 97 mm.

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Supplementary Figure 2: MLSDT is set up with a 3x1 configuration of 3 large-sized objects (pyramid, cube, and sphere). (A) The MLSDT 3x1 enclosure is connected to a laptop with software open. (B) The schematic of the MLSDT illustrates the spatial relationships among objects, lights, enclosure, electronics, and their connection to the computer. Key components include the LED light panel (1001) with user-settable intensity, the base of the 3D shape discrimination unit (1002), object slots 1 to 3 with integrated pressure sensors (1003-1005), and the three objects (1006-1008). The control board (1009) is responsible for adjusting LED light settings and communicating with pressure sensors. Additionally, a PC interface (1010) communicates with the control board to receive user inputs and displays the picked-up object based on pressure sensor readings.



Supplementary Figure 3: Physical dimensions of objects and spacings between objects in MLSDT configuration. (A) Physical dimensions of the 3 large-sized objects and the spacings between them. Height-dependent spacing between (B) Sphere and Cube, (C) Pyramid and Cube, and (D) Pyramid and Sphere.

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MLSDT measurement procedure

A measuring string was used to position the subject with respect to the MLSDT device. The subject occludes one eye with an eye patch before beginning the test, thus allowing the performance of monocular measurements in individual eyes. The test was conducted in a dark room (<= 1 lux) with the subject seated to have an eye positioned at 30 ± 5 cm in front of the MLSDT device. The normal and vision-impaired participants were tasked with accurately identifying and retrieving the specified object. The precision of object recognition was assessed across various luminance levels as part of the evaluation process. The system randomizes the target object for the user to pick up or select, as well as the position of objects within the box to remove bias. The test was performed under different lighting conditions to gain a comprehensive understanding of the object recognition capabilities of the participants.

While the proctor of the test sitting on the opposite side of the subject had easy access to the graphical user interface (GUI) displayed on the monitor screen, the subject did not have access to the GUI and the display on the monitor screen. The display monitor light intensity was dimmed to maintain a controlled low luminance (e.g. < 1 lux ambient room light) level environment for the testing. The GUI displayed the orders in which objects need to be placed in the MLSDT platform. Once the objects were arranged on the platform by the proctor, the test began with an announcement of the target object (by the proctor according to the procedure, or by automated voice in the GUI). The pressure sensor ensured that the 3D objects were placed in the correct order. To ensure that automated scoring by the pressure sensor is accurate, we conducted a systematic evaluation comparing the accuracy of object-displacement detection by the piezo sensors (that is reported by the computer interface) with that of a proctor's observation.

During the test, the subject and proctor were positioned facing each other at a table, with the MLSDT device situated 30 cm away from the subject. The proctor oversaw connecting and operating the device's software, which, in turn, guided the proctor in arranging objects in proper order and issued audible instructions to the subject regarding the target object to pick up within a 15-second timeframe. The subject was instructed to pick up the target object within a time cut-off (15 sec), and not allowed to change his/her decision once (s) he touched an object (as the texture of the object can influence the decision). The trial concluded when the subject picked up any object regardless of correctness. The pressure sensor in the MLSDT apparatus provided feedback to the software and recorded the shape that was picked up in that trial. The proctor rearranged the objects based on subsequent randomized order prompts. The test was repeated at the same luminance level 3 times before moving on to a higher luminance level until reaching the highest level. The best possible score is 100% (e.g. 3 out of 3 trials consecutively) and the worst possible score is 0% (0/3) for a given luminance level. A higher score indicates better shape discrimination ability. After the final trial conducted at the highest luminance level, the test was complete. The subject then occluded the other eye and repeated the process.

Results

The MLSDT involves the identification and picking up of objects by the subject, simulating everyday activities like picking up a fruit from a table and picking up a can of soda from the refrigerator. Thus, the 3D object identification task in a controlled multi-luminance environment is designed with the intent to evaluate useful functional vision in low-vision patients. Multiple parameters such as object size, number of objects, and multiple luminescent levels were tested to investigate their effect in evaluating vision.

Reducing object size for better-seeing subjects

Subjects with normal vision were able to perform all the tests within the MLSDT system without difficulty. The 3D objects in the MLSDT are based on their distinct shapes, and these objects were chosen to challenge the subject's visual discrimination ability, especially for low-vision patients with limited capacity to differentiate shapes. However, moderate vision loss individuals (20/800 or better) were able to see and discriminate medium (\sim 3 cm) and even small (\sim 1.5 cm) sized objects. The medium and small-sized objects retained the same shape and aspect ratios compared to their large (\sim 6 cm) counterparts. The sensitivity of the piezo sensors in the MLSDT device allowed

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automated detection of displacement of small and medium-sized objects (Figure 2). While 6 small objects could be fitted within 25 cm length with adequate gaps between objects, it was not possible to provide adequate separation between medium-sized objects in the limited lateral dimension. Figure 2D illustrates object size-dependent accuracy score in MLSDT using a 3x2 MLSDT setup configured with an assortment of 6 objects (pyramid, donut, brick, cube, cylinder, and sphere). Small object sizes were approximately ~15 mm, the size of medium objects was approximately 30 mm and the large size objects were ~60 mm. For both groups of tested eyes with BCVA ranging from 1.3 to 1.8 logMAR and BCVA ranging from 0.8 to 1.3 logMAR, the accuracy score in recognizing the target object increased as the size of the object became larger (Figure 2D).



Figure 2: Object size-dependent accuracy score in MLSDT. MLSDT 3x2 set up configured with an assortment of 6 objects
(pyramid, donut, brick, cube, cylinder, and sphere) of size: (A) small (~15 mm), (B) medium (~30 mm), and (C) large (~60 mm).
(D) Variation of % accuracy in determining target object for different sizes of the objects in MLSDT performed by individuals with different BCVA. N = 5, Av± SEM.

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Accuracy of object recognition in multi-row MLSDT

Since MLSDT is intended to be an automated scoring method (avoiding bias by the proctor), the placement of 3D objects within the multi-luminance enclosure needed to be spaciously arranged to avoid inadvertent knocking-off of the adjacent objects. A 3x2 configuration was implemented to fill a greater number of objects (size ~ 6-7 cm) within a 25 cm lateral dimension (i.e., 45 degrees visual field) with adequate spacing (~3 cm). This arrangement ensures that the subjects' responses are solely based on their discrimination ability and not influenced by unintended contact with nearby shapes as shown in figure 3. Figure 3 illustrates the test complications by having multiple row objects while accessing objects in the back row in the MLSDT 3x2 setup as well as incorrect registration by the software due to inadvertent hitting large objects during pick up of target objects in the back row. As shown, the subject knocked off the incorrect object (brick) while reaching for the correct object (cylinder) in the back row of the MLSDT 3x2 setup configured with an assortment of 6 large-sized (~ 60 mm) objects. In addition to the physical and visual hindrance of the front row objects while identifying and reaching for the back row, the back row objects are inadvertently farther than the front row objects to the subject's eye, thus, resulting in a smaller visual angle. Figure 3B shows the variation of % accuracy in determining the target object in the front and back row of MLSDT, performed by individuals with different BCVA.

The MLSDT system with 3x2 large objects was refined to (i) avoid blocking the visualization of back-row objects by the front-row objects, and (ii) minimize the likelihood of unintended hitting of adjacent objects. Raising the back row platform higher by ~ 6 cm than the front row platform reduced the difference in visual angles created by objects in the front and back rows. This also allowed a better path for a sight (Supplemental figure 1A). However, the illumination of back-row objects was found to be higher than that of the front-row objects owing to the varied distance from the roof-top lighting. Further, the incidence of inadvertent hitting of the front-row objects while reaching for target objects in the back-row persisted (Supplementary figure 1B). Supplementary figure 1B shows the mishit of the incorrect object (pyramid) while reaching for the target object (sphere) in the back row. Even subjects with less severe vision loss were found to occasionally bump their hands with the front row objects. From the above observations during development, it was decided to finalize the design with three large objects in a single-row configuration to assess the functional vision of subjects with severe vision loss (vision worse than 20/800).



Figure 3: Difficulty to avoid hitting large objects inadvertently in MLSDT 3x2 setup. (A) Knocking off the incorrect object (brick) while reaching for the correct object (cylinder) in the back row of the MLSDT 3x2 setup configured with an assortment of 6 large-sized (~ 60 mm) objects. (B) Variation of % accuracy in determining target object in front and back row of MLSDT, performed by individuals with different BCVA. N=5, Av ±SEM.

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Selection of shapes for MLSDT 3x1 setup

The subject with vision as good as 20/200 reported that the brick (rectangular prism) and cylinder front view resembles close to that of the cube. Therefore, only a cube was selected to be included among the 3 objects to be used in the 3x1 configuration in MLSDT. Further, the donut was not stable in a vertical position. Therefore, sphere, cube, and pyramid were selected for MLSDT. These 3 object shapes are distinct and can be easily discriminated from one another. Supplementary figure 4 shows time-lapse images of MLSDT 3x1 performance of a moderate vision loss subject (vision 20/200) in 3 consecutive trials when the setup was configured with an assortment of 3 large-sized objects (pyramid, cube, and sphere).



Supplementary Figure 4: Performance of moderate vision loss subject in MLSDT (3x1) setup. Time-lapse images of subject with vision 20/200 tested in 3 consecutive trials in MLSDT 3x1 set up configured with an assortment of 3 sized-objects large-sized objects (pyramid, cube, and sphere).

Illumination range of MLSDT based on real-life environments

To evaluate the functional vision of discriminating shapes under various lighting conditions, ranging from very low to moderate luminance levels, luminance levels in MLSDT were varied. The chosen equally spaced (semi-log) luminance levels (0.2 lux, 0.7 lux, 2.1 lux, 7 lux, and 21 lux, at the subject's eye level) represent scattered light intensity (4% Fresnel reflection coefficient, of incident light) at near-vision distance (30 cm). This corresponds to a wide range of lighting scenarios, including outdoor parking lots at night (3 lux) to relatively well-lit office environments (~500 lux). Figure 4A shows the MLSDT setup at a low luminance level (0.2 lux), while figure 4B shows the setup at a high luminance (21 lux), without any room light. The nominal luminance values (0.2 lux and 21 lux) were measured at 30 cm from the device at the subject's eye level. Figure 4A and 4B show the software interface for randomization of placement of objects (sphere, pyramid, and cube) and automated detection. During MLSDT measurement, the laptop screen is turned away from the subject and only visible to the proctor.

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Figure 4C demonstrates the output data file (automatically generated by the software) displaying the first few responses, including light level, order of object arrangement, target object, picked-up object, and accuracy as well as time taken by the subject to pick the object. Figure 4D illustrates the variation of % accuracy in determining target object in MLSDT, performed by individuals with normal and impaired vision. As expected, the normal vision subject's accuracy was 100% across all light levels ranging from 0.2 to 21 lux. The individual with BCVA of 0.36 logMAR had ~ 60% accuracy at the lowest luminance level (0.2 lux), which increased to 100% at a luminance level of 1 lux. In contrast, the subject with poor vision (0.975 logMAR) could not achieve 100% accuracy in recognizing the objects even at the highest luminance level, i.e., 21 lux. However, the % accuracy increased gradually when the luminance level was increased from 0.2 lux (level 1) to 21 lux (level 5) as shown in figure 4D. Figure 5 shows the MLSDT development decision tree summarizing the appropriateness of different MLSDT configurations and parameters to provide meaningful evaluation of functional vision in low-vision subjects.





Figure 4: Shape discrimination in multiple luminance settings of the MLSDT 3x1 setup. (A) Low-luminance (0.2 lux); (B) High luminance (21 lux) measured at 30 cm from the device at the subject's eye level. Also shown is the software interface for randomization of placement of objects (sphere, pyramid, and cube) and automated detection. The laptop screen is turned away from the subject and only visible to the proctor. (C) Output Data file displaying the first few responses, including light level, order of object arrangement, target object, picked up object, and subject's accuracy. (B) Variation of % accuracy in determining target object in MLSDT, performed by individuals with normal (BCVA: 0 logMAR) and impaired vision (0.36 and 0.975 logMAR). Levels 1-5: 0.2, 0.7, 2.1, 7, and 21 lux, measured at the subject's eye level, 30 cm from the MLSDT setup.



Figure 5: MLSDT development decision tree summarizing the appropriateness of different MLSDT configurations to provide meaningful evaluation of functional vision in low-vision subjects. LP: Light perception without projection; HM: hand motion at 1', CF: Count Fingers at 1'. NA: Not applicable (Floor), L: Large Objects (~ 60 mm); M: Medium-size objects (~ 30 mm) and S: Small objects (~ 15 mm).

Discussion

In the context of low-vision patients, there is a lack of reliable measures for functional vision that emulates activities of daily living. The Multi-Luminance Shape Discrimination Test (MLSDT) was designed to simulate real-world scenarios of object recognition, such as reaching for and getting a food item from a refrigerator, and identifying and picking up an object from a shelf. In MLSDT, near vision (objects within hand reach distance) of visually impaired subjects is evaluated via discrimination of three-dimensional (3D) objects of varying shapes (and/or different sizes) at multiple luminance levels. The MLSDT employs an automated detection and scoring system to quantify accuracy in discriminating 3D object shapes without the need for graders and thus avoiding inter-rater variability. By assessing accuracy at different luminance levels and using a scoring system based on the lowest luminance level the subject can pass, the test ensures that the overall score accurately reflects the subject's ability to discriminate shapes. The MLSDT design ensures that it is sensitive, reliable, and reflective of the subject's visual capabilities in different lighting conditions.

The cognitive load on the proctor and low vision subjects was found to be optimal with the use of three objects (sphere, cube, and pyramid). The addition of a greater number of objects increased the complexity of the test significantly, potentially overwhelming the proctor and the subject with a larger number of random assortments to position and process. This could lead to increased mental fatigue leading to non-vision-related errors and reduced test performance. Limiting the number of objects to three reduced the potential for interference between objects. In the MLSDT, the subjects are asked to pick up the target object within an allocated time and having only three objects decreases the likelihood of visual clutter, making it more reasonable task for the subjects. More objects would require creating multiple rows with unequal distance and /or height, leading to different visual angles as well as illumination conditions. This variability would complicate the test, as it becomes challenging to control for these factors. With only three objects also allowed for consistent comparisons among the shapes. Each shape can be compared directly against the other two, making it easier for subjects to focus on the differences and similarities between them. With a large number of objects, the comparison process becomes more intricate, and the ability to discern between each shape may become convoluted for severe vision loss patients. The use of three objects ensured that the MLSDT remains feasible to be conducted within a reasonable testing time while maintaining reliability. As the complexity of the test increases with more objects, the test administration and data collection could become more challenging and time-consuming.

Scoring the MLSDT becomes more straightforward and robust by enforcing accurate selection from three objects consecutively. Each correct identification, which is repeated multiple times, can be assigned a predefined score, and the overall test results are easier to interpret. Overall, three objects in the MLSDT strike the right balance between providing a challenging test that assesses shape discrimination abilities in low-vision subjects and maintaining test feasibility, consistency, and reliability. This approach enables researchers to obtain meaningful insights into the subjects' visual capabilities without overwhelming them with excessive stimuli or complicating the evaluation process. Due to the limitation on the number of objects in MLSDT for severe vision loss patients, stringent pass criteria must be implemented to avoid false positive outcomes (picking up a correct object by chance). Requiring subjects to pass all consecutive trials at each light level sets a stringent pass criterion. Even if a subject were to guess correctly on one trial, the chances of consistently guessing correctly on all trials are significantly reduced. For example, in a 3-trial test scenario, success is measured by 3/3 consecutive choice of correct shapes, such that the probability of passing by chance is $(1/3)^*(1/3)^*(1/3) = 1/27$ (i.e., 3.7%). This criterion is 3x more stringent than performing a single test of selecting a correct object from an assortment of 9 objects (probability =1/9, i.e. 11%). Further, to reduce Type-I error, the test can also evaluate the subject's ability to recognize all objects in the row and ask to pick up objects in a sequence instead of picking up a single target object. Asking the patients to identify the three objects in front of them before reaching them may further demonstrate the accuracy of their choice.

The spatial arrangement of objects in a strictly two-dimensional context establishes distinct silhouettes with visual significance. Uniform spacing plays a crucial role in creating a structured order for recognition, akin to the process of learning letters in a language. Significance is conferred not only by the spaces between objects but also by the individually recognizable features of their silhouettes. However, a challenge arose when considering the brick and cylinder from a two-dimensional front-facing perspective, as they exhibited significant visual similarity, posing difficulties for individuals with visual impairments. Moreover, the Donut's distinctive feature—its central hole—granted it an unfair advantage in terms of selection and identification, leading to its exclusion from the final MLSDT 3x1 design. Following an optimization of kerning to align with the objects' dimensions of 6-7cm, the spacing was adjusted to approximately 4-6 cm, achieving an improved visual and functional balance. Still, objects can be difficult to identify due to "change blindness", especially in low-vision subjects with low light when the objects are swapped out of the line of sight. Slow rotation of the objects may be used to accentuate the silhouette of the objects, thus giving another tool for detection by low vision subjects.

MLSDT is an automated low-vision measurement test, that minimizes the learning effect of repeated testing. The system randomizes the requested object that the user must pick up or select. Further, the position of the objects on the screen (for the proctor) and within

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the box are randomized to remove bias. This automated approach ensures objective and consistent scoring, reducing the potential for human biases and errors during the evaluation process. For ultra-low vision patients (BCVA worse than CF@1'), the larger size (60 mm) objects were easier to recognize and discriminate from each other. For subjects with moderate vision loss (BCVA ~ 20/200), it was meaningful to perform the test with small (15 mm) and moderate-size (30 mm) objects. While the MLSDT performance improved with increasing luminance, for some subjects, 21 lux (measured at the eye level) was too bright which blinded them from performing the shape discrimination task. Therefore, 21 lux as the upper luminance limit should be sufficient to evaluate the efficacy of any therapeutic intervention. The inclusion of too many objects posed a significant challenge for severe vision loss subjects as (s)he had to discriminate the correct object from the others, rather than identifying an object by itself. 3D Shape Discrimination evaluated by MLSDT emulates real-world scenarios. There is potential for broader use of an MLSDT variant in subjects with less severe vision loss, especially considering there is not a minimum size constraint on the size of objects.

Conclusion

In conclusion, MLSDT was designed to evaluate vision restoration by testing object recognition in moderate to low-vision subjects. The test employs multiple illuminance levels, 3D objects with distinguishable shapes, and automated scoring to quantify shape discrimination ability in a robust and unbiased manner, without requiring graders. MLSDT provides functional relevance, by simulating real-life scenarios of selecting a specific shape from an assortment of objects at multiple luminance levels. MLSDT was able to distinguish subjects with different levels of visual impairment and normal vision subjects. Validation of MLSDT in low-vision subjects will provide a measure for clinically meaningful change to evaluate therapies intended for patients with vision loss.

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