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Project Title:	Objective Refraction with Self-operable, Lightweight Autorefractor		
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Zip Code:	02139	**Congressional District:**	5
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Contact Monitor:		**Contact Phone:**	
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COI Name (Institution):	Nam, Ahhyun Ph.D. (PlenOptika, Inc.)		
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Task Description:	Industry Project Over a billion people worldwide suffer from poor vision, because they do not have access to eye care professionals. PlenOptika has developed the portable QuickSee system to automatically measure eye refractive errors and monitor changes over time, eliminating the need for an eye care professional to perform these tests. To improve access to eye care globally, PlenOptika proposes upgrading QuickSee by making it lighter and therefore easier for children and the elderly to use, and implementing a feedback system to help users take measurements faster and more reliably.		
Rationale for HRP Directed Research:			

Research Impact/Earth Benefits:

The goal of this work was to develop QuickSee Lite 2, an ultra-portable, self-operable version of QuickSee (handhold objective autorefractor) that retains the clinical accuracy of the current model that could be used to improved access to vision care for health disparity populations (e.g., children, elderly, special needs patients) terrestrially, and to be validated for detecting/monitoring long duration space flight-associated changes in hyperopic shift (surrogate for ocular axial length change) when self-operated by an astronaut.
Potential terrestrial impact

More than a billion people worldwide are impaired by poor vision due to poor vision from uncorrected refractive errors (UREs); uncorrected vision problems cost the global economy over $200 billion annually in lost productivity. A major bottleneck exacerbating this health care crisis is the global shortage of eye-care providers (ECPs), which is especially severe in low-resource settings. Whereas the USA has one ECP for every 5,500 people, parts of Africa have less than one ECP for every 1,000,000 people. Though many organizations are working to train additional ECPs, this approach is difficult and slow to scale. QuickSee Lite 2 will serve to increase ECP efficiency, reduce training requirements, and enable minimally-trained personnel to facilitate vision care. Lighter hardware, more intuitive user operation/experience, and more robust design are highly advantageous for screening vision in children, elderly patients, and patients with disabilities. By reducing access barriers, regular vision screening can become to prevalent and may the overall quality of life, opportunity for education and physical activities, and reduces the risk of serious ocular diseases later in life.

Potential space impact

Under long exposure to microgravity, hyperopic shift in the vision of astronauts is well documented, which affects near vision - a crucial ability needed to operate a space vehicle. Although the observed hyperopic shift can be corrected with eyeglasses, the time course of this progression is poorly understood and of high interest. A barrier to elucidating the phenomena is due to current approaches used to measure ocular axial length, such as high-frequency ultrasound, which have poor repeatability. Technologies that are highly repeatable are readily available in the clinic such as autorefractors and optical biometers, do not meet the portability (desktop form factors, 50 pounds) and durability (sensitive to shock and movement due to internal moving parts) requirements for space flights. QuickSee Lite 2 will help highlight the hyperopic shift and its time course under static and varying microgravity conditions such as long-duration space flight or stationing at a Martian/lunar outpost - data which has not been previously obtained. We are actively searching for potential Human Research Program (HRP) collaborators for this work.

Implementation pathway

The updated mechanical design, form-factor, and eyecup PD-alignment modifications (hardware), redesigned printed circuit boards (PCBs; electronics), and the on-board user interface for QuickSee and off-board user interface for QuickSee Lite 2 (software), have undergone both verification and validation, and are being directly implemented into production through our Quality Management System Engineering Change Order process. We plan for some of these improvements to be implemented into the existing commercial QuickSee during Q3-Q4 2020, and the substantial form-factor redesign to influence our future technology pipeline. PlenOptika is further developing and implementing these improvements through its own direct investments and through technology translation/commercialization grant applications. The final design of the QuickSee Lite 2 and it is intended use will be registered with the Food and Drug Administration (FDA) will be applied for, and it be folded into our marketing and sales efforts.

Task Progress:

1) Overview of this project and background unmet clinical need and potential impact
PlenOptika brings cutting-edge optical technology to front-line vision care professionals worldwide. To date, QuickSee, PlenOptika's flagship technology, is a handheld, low-cost, autorefractor that accurately measures refractive errors binocularly in 10 seconds, that has been used on > 1.5 M patients across 25 countries. This project's goal was to upgrade QuickSee to further enhance its adoption to address disparity in vision care in wider range of populations (children and elderly) by improving the usability and enabling self-operation. At the same time, these enhancements meet the stringent requirements needed for objective refraction testing and monitoring in long-duration space flight conditions. Over one billion people worldwide are impaired by poor vision, including 239 million children, because they do not have access to eye care professionals and/or prescription eyeglasses. A major barrier prolonging this major correctable health disparity is the critical need for tools that increase the accessibility of vision care globally such as handheld autorefractors. While QuickSee's current form factor and design offers advantages over competing approaches, there is potential to improve upon its features and to directly address feedback from clinical partners and customers which includes: (1) to reduce the weight of the device (currently, 1.1 kg or 3.3 lbs.) to make it easier to hold and use for children and elderly patients, and (2) to speed up the overall time-to-measurement (currently 30 seconds for alignment and measurement) by providing feedback during the alignment step. By reducing the weight of the device and implementing an interactive user interface to enable the user (patient, technician, or astronaut) to perform self-operation and measurement, the QuickSee Lite will be better suited for being used to screen and monitor childhood myopia progression (the worldwide myopia epidemic) and hyperopic shift during long-duration space flight.

2) Project aims/objectives and Expected outcomes

Deliverable 1. To develop QuickSee Lite, by reducing the weight of the QuickSee for improved use with children and transportation to space.

Expected outcome 1. Weight reduction of QuickSee by ~50%.

Deliverable 2. Incorporation of an alignment guidance system to facilitate easier alignment and self-operable refraction while maintaining the clinical accuracy of the current QuickSee.

Expected outcome 2. Develop an interactive user interface to guide the user and speed up alignment.

Deliverable 3. Validation of QuickSee Lite in measuring the induced hyperopic refractive error changes in the eyes of subjects in an Instituional Review Board (IRB)-approved clinical study at New England College of Optometry.

Expected outcome 3. Evaluate the accuracy and repeatability of QuickSee Lite in measuring induced hyperopic shift (surrogate for axial length changes) in 50 human subjects.

3) Key findings

(1) ~50% weight reduction, more robust industrial design, and better visual experience for the user (Deliverable 1);

(2) Substantially improved alignment mechanism that mass-manufacturing compatible, more intuitive operation due to simplified user interface (Deliverable 2);

(3) Preliminary data from the clinical study indicates that the QuickSee Lite 2 maintains the accuracy of the QuickSee and is able to accurately and reproducibly measure induced hyperopic-shifts as small as 0.25D (Deliverable 3).

4) Impact of key findings on technology requirements, objectives, and specific aims of the original proposal

The QuickSee Lite 2 developed for this project achieves the objectives and specific aims of the original proposal for both terrestrial and long-duration space flight applications. For terrestrial applications, the reduced weight and improved alignment enables improved usability for the patient, clinical technician, or astronaut to operate and obtain autorefraction measurements to meet the needs of children, elderly, and special needs patients. Therefore, the QuickSee Lite 2 innovations improve access to vision are for health disparity populations and are better suited for screening and monitoring childhood myopia progression (the worldwide myopia epidemic). For long-duration space flight applications, the reduced weight, potential self-operability by astronauts, and clinical accuracy for measuring induced hyperopic shifts, enables reduced cost-of-transportation to space and quantitative self-monitoring of hyperopic shifts by astronauts.

5) Proposed research plan for the coming year

Having completed the 1-year project, PlenOptika aims to translate the achieved innovations and deliverables to the market by incorporating them into the current commercial QuickSee product and future models. The improved alignment mechanism (eyecup modification) and user interface improvements are currently being incorporated into the company's regulatory system and upon completion, will be included in the product. In light of the COVID-19 related stoppages and delays to the clinical study subject recruitment, we aim to continue this study in collaboration with the New England College of Optometry, to complete data acquisition. The clinical data will be analyzed and we aim to disseminate the results as a clinical article in an appropriate medical journal. We are actively searching for potential Human Research Program (HRP) collaborators to continue this work within the NASA/Translational Research Institute for Space Health (TRISH) frameworks for technology evaluation and implementation.

Bibliography Type: Description: (Last Updated:)