August 2019 Short Report on Globe Biomedical's Blindness Prevention System (BPS) Research & Development Effort

Project Timeline: Feb 2019 – Oct 2019

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Introduction

This report summarizes the progress made to-date for Globe Biomedical's alpha-version of its Blindness Prevention System (a-BPS). The a-BPS is an early R&D effort aimed at developing a cloud-based, wearable intraocular pressure (IOP) monitor using eyeglass frames embedded with imaging sensors that photograph the exposed sclera of the eye - mainly near the limbus. This early R&D effort is supported through a 9-month NSF Phase I SBIR grant that began in February 2019 and ends in October 2019. This report is a summary of activities through the first six months of the project.

The BPS (planned to be marketed as Cure™ frames – www.cureframes.com) collects images and uses an algorithm to track physical spacing between features in order to quantify tissue expansion as a percentage, i.e. scleral strain. One key aim of the testing in this project is to capture images of a pig eye under various anatomical pressures on a benchtop and develop computer code to calculate pressure based on the mechanical strain (tissue expansion) observed in the imagery. Preliminary results from the first two eyes yield a strong correlation between the calculated IOP using the a-BPS and the true IOP as measured from a benchtop water column with a digital pressure sensor. In addition, significant progress has been made with regard to the development of the support electronics.

Feasibility Experiments and Software Development

The key milestones for the Phase I work are shown in Fig 1. Milestones P1 and P2 were completed as expected and we are currently working toward milestone P3 with a revised completion target of the middle of Month 8. In this report, we present the data for the first two eyes to undergo the completed testing protocol. In brief, the proposed glaucoma simulator shown in Fig. 2(a) has been constructed (milestone P1) and implemented, which is shown in Fig. 2(b) and 2(c). The custom 3D printed parts include a head, the frames, and custom elastic molded nose and ears. The pig eye under test is placed in the left eye socket. The camera used is one of a seven CMOS models researched and selected as part of this project and meets the design criteria for the product -- see Fig. 5(a) for an illustration of the size expectation. A few key elements to the experiment:

- The eyes are used within approximately 72 hours post-mortem
- Graphite powder was added to the eye as needed for image tracking
- A liquid microflow sensor insured the inflation was steady
- A computer monitor was used to provide consistent, realistic illumination - Fig 2(c)

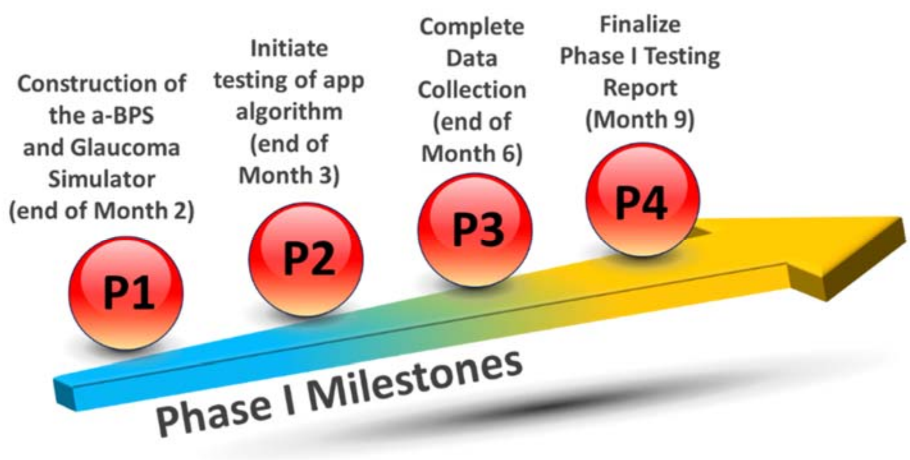
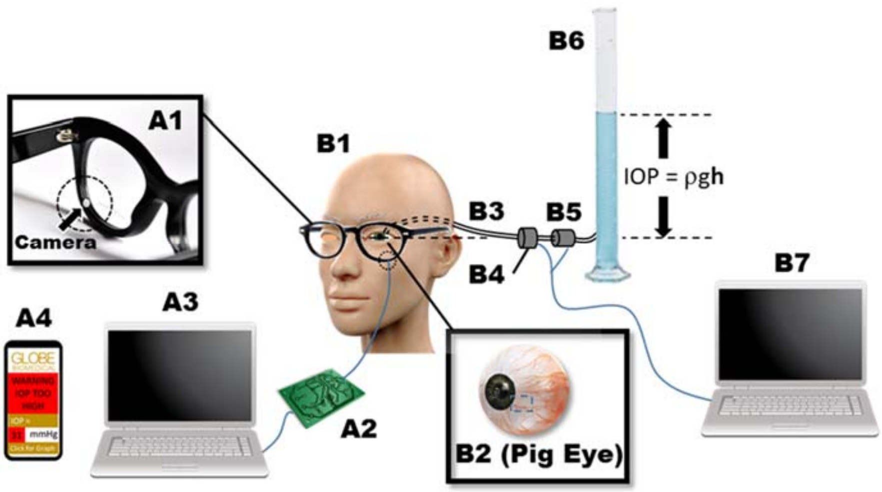


Fig 1: Milestones presented in the Phase I proposal

Custom software was developed that (1) calculates IOP from changes in imagery due to mechanical strain of the tissue, (2) communicates and sends high IOP alarms to a mobile device, and (3) alerts the user if the glasses have slid to far off the nose. The results for the IOP calculation based on the strain imagery are shown in Fig 4 for two eyes, which are the first and only eyes to-date to have been through the completed protocol. For each run, a calibration curve was created using the lower pressures – either 12 through 24 mmHg at steps of 2 mmHg, or 13 through 22 mmHg at steps of 3 mmHg. Using this lower IOP calibration data, a mathematical relationship (best-fit polynomial) was created between the true (lab) IOP and an a-BPS output signal based on the strain imagery. The fit was then used to extrapolate pressures up to 30 mmHg ("extrap" in Fig 4). This simulates the expected use case in which a patient is calibrated in the office during the initial fitting. Following this event, the patient then experiences high IOP during daily life. As evident in Fig 4, this initial software code provided (1) a consistent and monotonic trend in all five calibration sets, and (2) a reasonably good prediction of elevated IOP – within 1.5 mmHg. We are working to improve the code with a goal of reducing the tolerance of the prediction to within 0.5 mmHg by end of the Phase I effort.



(a)

(b) (c)

Fig 2: Benchtop Glaucoma Simulator (a) the proposed system; (b),(c) the constructed system currently in use (August 2019)

Fig 3: Sample image of inflated porcine globe

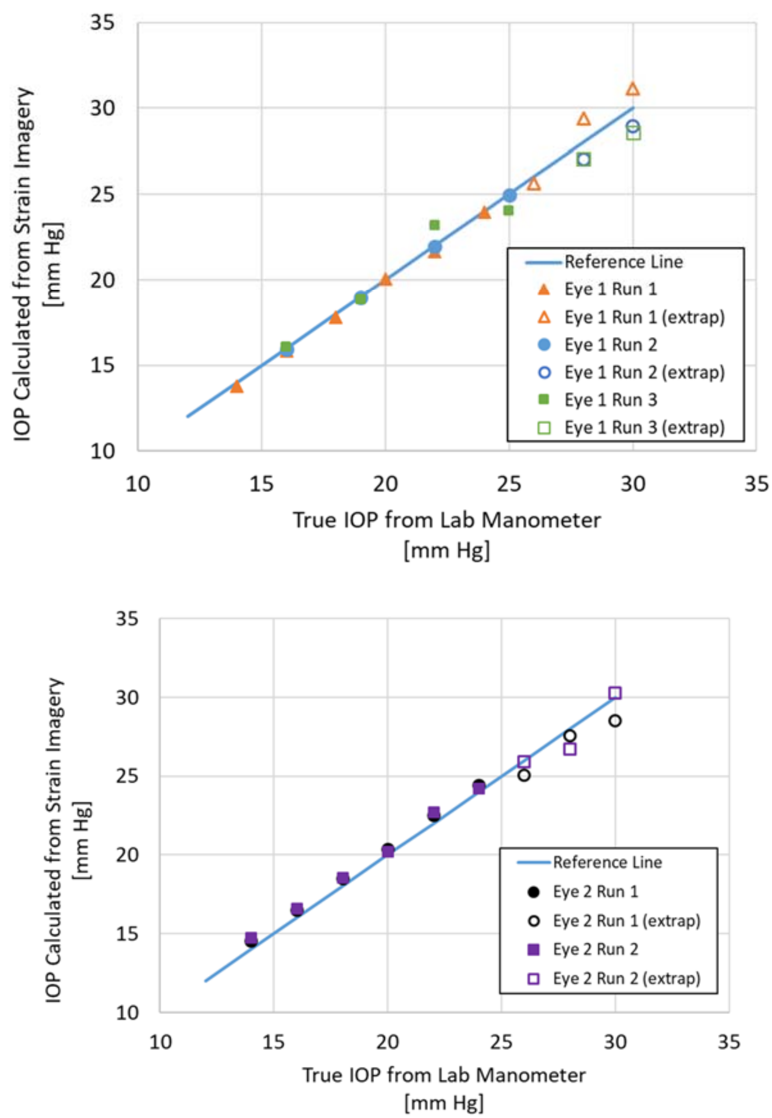


Fig 4: First analyzed data set for the aBPS using the Glaucoma Simulator

Development of Frame-Integrated Supporting Electronics

Two printed circuit boards (PCB's) have been designed, fabricated, and are currently being tested. The PCB designs include a detailed layout for all the necessary electronic components for operating the cameras. The PBC's form factors can be seen in Fig 5 and work within the strict design requirements associated with the temples of the frames.

(a) (b) (c)

Fig 5: Conceptual prototype of the technology. The electronics and cabling show have been developed and are currently under evaluation.

Next Steps

We will continue to collect data using our alpha prototype, a-BPS, and Benchtop Glaucoma Simulator and document the results prior to the end of this Phase I project (October 2019). We will attempt to repeat our results with additional eyes, variations in lighting, and small changes in eye position. We are also improving the code's output at higher IOP levels and have a goal of reducing the tolerance of the prediction to within 0.5 mmHg for an elevated IOP (25 to 30 mmHg). For the supporting electronics, we expect to have fully tested our first PCB design by the end of the project.

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