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DESIGN OF A PORTABLE VENOMANOMETER SYSTEM FOR EPISCLERAL VENOUS PRESSURE MEASUREMENT

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ABSTRACT

Traumatic brain injury (TBI) has been considered a precarious health issue especially within the military population. Research has shown that early treatment of TBI could reduce possible neurocognitive injury. However, the nature of military triage has created challenges for early TBI detection. Intracranial pressure (ICP), which is used as a biomarker of outcomes in TBI, is not only expensive to measure but is also invasive and requires specialized surgical and procedural skills. Episcleral venous pressure (EVP) was proven to be a good alternative biomarker to ICP. However, the current technology in measuring EVP is not portable, and requires a skilled operator with a slit-lamp for testing. Moreover, the measurement is highly subjective and depends on the operator's skill and technique. Therefore, there is a critical need for alternative technology for non-clinical TBI diagnosis. In this paper, we present an improved venomanometer design for measuring EVP in the field.

Keywords: traumatic brain injury (TBI), intracranial pressure (ICP) measurement, episcleral venous pressure (EVP) measurement, venomanometer, military personnel, triage

1. INTRODUCTION

"Traumatic brain injury (TBI) has been referred to as the 'signature wound' of U.S. troops that served in the Afghanistan and Iraq wars" [1]. This physical injury to the brain has affected 1 in 5 deployed veterans, if not more in recent years [2]. In this century, TBI was reported to account for a higher percentage of deaths than in other recent U.S. wars.

To date, vast effort has been expended into designing body protection systems for military personnel [3]. Moreover, the advancement in medical knowledge and technology also contributed to the reduced number of deaths among combat forces. The result of these developments is believed to contribute to the decline of mortality rates [3]. However, closed brain injuries or injuries around the face and neck that are equivalently damaging are still unavoidable in these dangerous environments [2].

Research [4-6] has shown that early intervention or treatment of TBI reduced deaths from head injuries. In fact, trial data has shown that every 20 minutes of delay will result in a 10% reduction in treatment effectiveness [5]. However, the military encountered many challenges in the early diagnosis of TBI that are required for the early treatment of TBI both in-theater and in-garrison. For instance, the nature of the environment of the combat zones presents obstacles for the early detection of TBI. The combat theaters are often chaotic, loud, and usually take place in remote locations that do not have immediate access to medical facilities. Moreover, the diagnostic apparatus that are used in current TBI detection are impractical to be used in non-clinical settings due to their initial design objectives and size constraints. Additionally, accurate, precise, and sensitive TBI evaluation methods are lacking. Currently, the "Military Acute Concussion Evaluation (MACE)" and the "3 Question DVBIC TBI Screening Tool" are used to screen TBI in the field [1]. These have proved to be unreliable due to the subjective questions presented [7] and insufficient sensitivity and specificity to be clinical helpful [8], particularly for the MACE screening method.

In recent years, there is an increase in attention to the application of biomarkers for TBI triage. Intracranial pressure (ICP) is a marker for severe TBI, which is useful for triage decisions [9]. However, the current preferred and recommended methods for ICP monitoring techniques (lumbar puncture and intraparenchymal bolts) not only require specialized surgical and procedural skills, but they are also invasive and involve the use of expensive medical equipment. Meanwhile, non-invasive ICP monitoring techniques are neither accurate nor reliable [9].

Ocular biomarkers, namely intraocular pressure (IOP), episcleral venous pressure (EVP), and retinal vein diameter

(RVD), are some of the more dependable methods found that could allow ICP monitoring to be non-invasive. Although IOP has shown promising results as an alternative of ICP biomarkers [9], a recent study [10] suggested that EVP would be a better bioindicator than IOP since EVP has a more direct relationship to ICP through intracranial venous pressure changes and is a more robust quantitative marker [11].

Episcleral venous pressure (EVP) is the pressure of the episcleral veins found on the surface of the eye; this measurement is used routinely in aqueous humor dynamics glaucoma research [10]. This is described by the modified Goldmann equation:

$$IOP = EVP + F/C \quad (1)$$

where F is the aqueous humor flow rate, and C is the outflow facility. The relationship between EVP and IOP is that for every increment of pressure change in the EVP, an equal change in IOP would occur [10].

Currently, non-invasive EVP measurements via venomanometry require a slit-lamp or an operating microscope along with the commercially available episcleral venomanometer (EyeTech EV-310). With that being said, the setup of the current venomanometry technique clearly does not meet all the logistic constraints of military triage. In previous research [14], a portable and automated measurement for EVP was designed to allow automatically recorded measurement while reducing the potential for uncertainty in the measurements. Nevertheless, the lack of fine movement control for approaching the instrument to the episcleral vein, insufficient camera resolution, and the absence of autofocus feature were among the design limitations which have prevented its application as a reliable device for non-invasive EVP measurement. In this paper, an improved prototype that is compatible with TBI detection at the point of injury and in prolonged and en route care in the combat zone is to be designed and proposed. The design requirements are as follows, in order of priority:

a) Able to make fine adjustment
b) Stable
c) Sufficient illumination
d) Sufficient magnification
e) Able to deliver reproducible results
f) Portable/ Easily transported
g) Compact
h) Simple set-up procedure
i) Capable of automated readings
j) Autofocus capability
k) Rugged

2. METHODS

2.1 General Concept of EVP Measurement

In general, non-invasive EVP measurement is based on the concept of venous compression where once "an episcleral vein is identified, a force is applied to the vein until it collapses, and venous pressure is determined from the pressure required to collapse the vessel to a predetermined endpoint" [11] (see FIGURE 1).

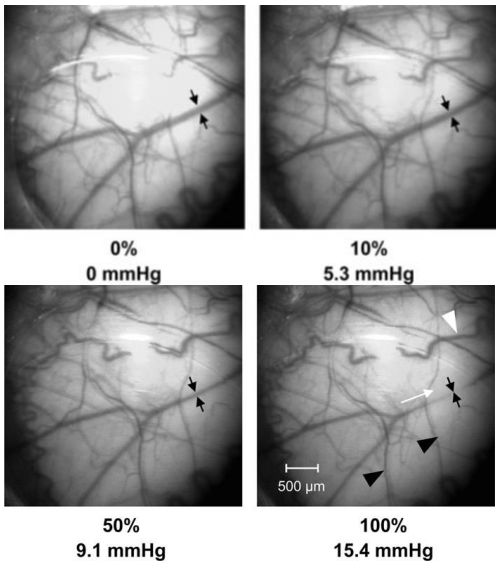

FIGURE 1: PROCESS OF BLANCHING OF AN EPISCLERAL VEIN. IN THIS CASE, THE VEIN IS SHOWN TO BE "HALF" COMPRESSED WHEN THE PRESSURE IS AT 9.1 MMHG, CAUSING THE EPISCLERAL VESSEL TO BE LESS VISIBLE [11].

EVP is measured using an episcleral venomanometer (FIGURE 2) that utilizes an air chamber and a rotatable knob for driving pressure changes through a piston. A transparent and flexible silicone membrane (General Electric RTV 615A) that has a 3mm diameter indicator ring at its center is connected to the end of the air chamber and inflates or expands according to the rotation of the pressure knob. The design of the venomanometer allows an EVP measurement of up to 30 mmHg.

FIGURE 2: IMAGE OF AN EPISCLERAL VENOMANOMETER (EyeTech EV-310) THAT IS COMMERCIALLY AVAILABLE [13].

2.2 Standard Clinical EVP Measurement Method

In the routine clinical setting, the episcleral venomanometer is mounted directly on a slit-lamp or an operating microscope (Haag-Streit 900 or Zeiss). The subject of the test is required to sit in an upright position (90° posture) or lie in an inclined position (45° on their stomach; FIGURE 3). The eye of the test subject is aligned with the slit-lamp before the ophthalmologist

observes it through the silicone membrane attached to the venomanometer. At this point, the measuring tip is barely touching on the sclera. Once an episcleral vein is chosen, the pressure knob of the venomanometer is rotated accordingly, increasing the pressure of the system until the silicone bulb causes the preselected episcleral vessel to diminish to 50% of its original intensity in the image (i.e., the vein is half-blanched). The pressure value achieved is considered as the episcleral venous pressure of the subject. Most of the time, each measurement is repeated three times and the mean of the values would be recorded and used.

To allow a more suitable application of the measurement of the EVP in the assessment of feasibility of the proposed prototype, the EVP measurement is tested two times. A third measurement will be conducted if the difference between the first two measured readings has a difference of more than 2 mmHg. For both two and three repeated measurements, the median value is considered the real EVP of the test subject.

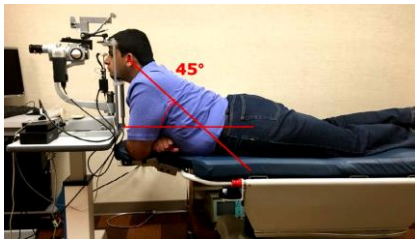

FIGURE 3: SUBJECT IS POSITIONED TO A 45° POSTURE FOR EVP MEASUREMENT USING A SLIT-LAMP [15].

When a subject is in a supine position, the EVP measurement is conducted through a standard operating microscope (FIGURE 4). A similar measuring concept is applied where the observer holds the venomanometer by hand and places the silicone bulb near the eye of the subject. By observing through the venomanometer viewing pane, the dial of the venomanometer is rotated once an episcleral vein is selected. As the vessel turns half-blanched, the pressure value obtained is recorded as the EVP of the subject.

2.3 Proposed Portable Venomanometer System for EVP Measurement

In order to better suit the environment setting and constraints found in military triage, a new EVP measurement system was designed. Additional hardware and software were integrated into the design to reduce measurement errors and broaden the application of the venomanometer.

A commercially available venomanometer (EyeTech EV-310) was used in this prototype along with other customized attachable parts such as the venomanometer holder, a specialized phone case, and an electrical component housing (FIGURE 5). All of the customized components were 3D printed with polylactic acid (PLA) filament (Hatchbox). The design of the venomanometer holder not only holds the venomanometer, but the sliding dovetail joint at the back of it also allows the attachment of the electrical component case that houses the microcontroller.

FIGURE 4: A RABBIT IS IN A SUPINE POSITION, AND THE EVP MEASUREMENT IS CONDUCTED THROUGH A STANDARD OPERATING MICROSCOPE.

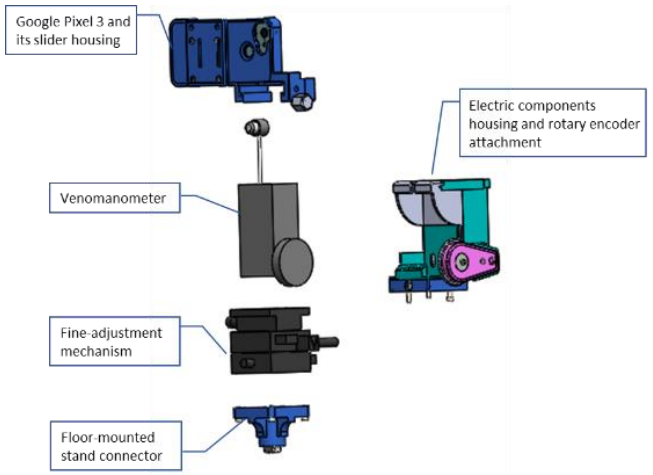

FIGURE 5: AN EXPLODED VIEW OF THE PROTOTYPE SUBASSEMBLY.

The specialized phone case mentioned was created to hold the Google Pixel 3 smartphone in place, where its camera is aligned directly with the venomanometer viewing pane. The phone case also has a sliding dovetail design at its side to enable a forward-backward single degree of freedom sliding motion. This feature enables position adjustment (which relates to focal point adjustment) of the smartphone in order to attain the best view of the targeted vein. In this research, the Google Pixel 3 smartphone was chosen as a user interface due to its superior camera and image processing ability. Between the smartphone and the venomanometer viewing pane, lenses (0.36x super wide-angle lens stacked with a 20x macro lens) are attached to the phone case to further enhance the magnification capability in visualizing the episcleral veins.

An ESP32 microcontroller housed in the electrical component housing is used to connect the smartphone to the venomanometer pressure knob. The pressure value from the venomanometer knob is transmitted via a rotary encoder connected to the microcontroller. The processed value is then sent to the customized smartphone application in real-time by a

USB-C serial adapter and processed to be overlaid with the view displayed on the screen. Wi-Fi and Bluetooth Low Energy (BLE) were considered as options for communication with the smartphone but were dismissed after several iterations due to considerations of possible data breach or signal transmission interference that could occur on the battlefield. Furthermore, communication through the serial adapter also eliminated the need for an extra power supply needed for the operation of the microcontroller, and it could now be powered by the smartphone.

To achieve the requirement of having the ability for fine movement, a commercially available fine-adjustment mechanism (TOAUTO) designed for microscope stages was integrated as part of the measuring system. The ability of fine-tuning could be considered as the most crucial aspect for EVP measurement which the previous design [14] failed to achieve. This added component enabled steady 3-axis direction changes with a minimum increment of 0.01mm for up to 10mm. The incorporation of this mechanism was to replicate the fine-adjustment function found in slit-lamps used in a clinical setting.

After several tests and changes in design, a cymbal stand (DW 9700) was retrofitted to be used as a floor-mounted stand that holds the venomanometer. This floor-mounted stand has a height adjustment from 30 inches to 46 inches tall and includes several other manually adjustable joints (FIGURE 10). One of the two horizontal boom arms was constrained with a hard-stop mechanism to reduce complexity for the user. With the shorter adjustable boom arm, a 270° change in angle is made possible for coarse positioning of the venomanometer. It was observed that stability was a significant issue that prevented a steady EVP measurement. To ensure better stability, a 5-lb counterweight was added to the end of the long boom arm (FIGURE 6). With the changes of the floor-mounted stand and the addition of a counterweight, the characteristic deflection of the whole system was successfully decreased by 70%.

The issue of stabilizing the venomanometer was further addressed through the addition of a flexible arm (BZE; FIGURE 6) designed as a small camera tripod mount. The soft and deformable arm was designed to be mounted on the front of the venomanometer assembly in such a way that it can brace against a support surface (e.g., exam table surface). Furthermore, the strategic location of the attachment permitted a safer measuring condition by preventing accidental drop of the second angle-adjustable arm. Finally, the addition of the flexible arm managed to decrease the deflection of the system to less than 1 mm, thus improving the accuracy and usability of the device.

A commercially available dolly (Ravelli) which was initially designed for the use of sound systems or cameras on tripods was retrofitted to be added on the main supporting stand of the prototype (FIGURE 7). In an EVP measurement procedure, it is typical for both the left and right eye of the subject to be tested. This dolly allows easier maneuvering of the venomanometer assembly and the supporting stand, particularly from one side of the bed to the other. This feature also further supports the design goal of permitting the portable venomanometer system to be operated effortlessly by only one operator without additional skills required.

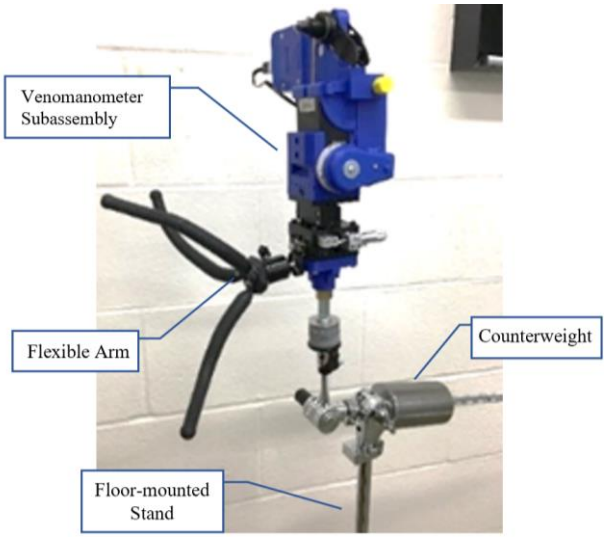

FIGURE 6: IMAGE OF THE VENOMANOMETER DEVICE ASSEMBLY WITH A BLACK FLEXIBLE ARM ATTACHED IN FRONT OF THE DEVICE AND A COUNTERWEIGHT INTEGRATED INTO THE VERTICAL BOOM ARM OF A FLOOR-MOUNTED STAND.

FIGURE 7: A COMMERCIALLY AVAILABLE DOLLY (RAVELLI) WAS RETROFITTED TO BE INTEGRATED INTO THE PORTABLE VENOMANOMETER SYSTEM. IT IS FOLDABLE WHICH ALLOWS THE PROTOTYPE SYSTEM TO BE COMPACT.

To ameliorate the usability of the flexible arm that was intended to provide extra support and stability to the venomanometer device, a 3-inch tall, waterproof, rugged cushion was included to make up for a height difference between the flexible arm and the examination table (FIGURE 8). The cushion has an inverted "U" shape to accommodate the shape of the human head. By locating the cushion right above the subject's head, the flexible arm is able to rest on it to provide additional backing.

Lastly, a flashlight that was attached to a flexible gooseneck (Sarhan-Tech) was incorporated with the floor-mounted stand to provide additional illumination (FIGURES 9-10). The built-in camera flashlight that was intended to act as the light source was located right behind the venomanometer pole that directs the air to the silicone bulb, causing unwanted shadows and glare in the image and negatively affecting the EVP measurement process. With a flashlight that is integrated into a flexible gooseneck, the light source can adjust accordingly in the effort of attaining a clear image.

FIGURE 8: A WATERPROOF SOLID CUSHION WAS FABRICATED TO PROVIDE EXTRA HEIGHT FOR THE FLEXIBLE ARM.

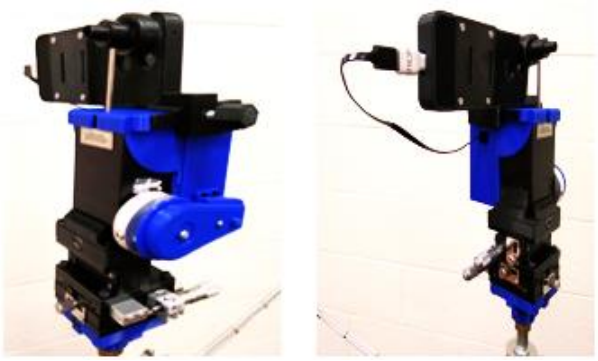

FIGURE 9: SIDE VIEWS OF THE VENOMANOMETER DEVICE ASSEMBLY.

FIGURE 10: A COMPLETE ASSEMBLY OF THE PORTABLE VENOMANOMETER SYSTEM.

A smartphone application was developed on top of existing open-source code for Android image and video capture to fulfill the simultaneous implementation of the smartphone as a user interface, viewing device, camera, and data logger. The smartphone application has specifically been designed to allow the user to control where the camera is focused, with the intent of feeling similar to a microscope. This feature is shown as the red slider bar in FIGURE 11. The smartphone application's user interface has been designed with the goal of allowing the user to have the most control possible without needing to change screens. The application also allows the user to see the amount of pressure applied without looking at the dial on the venomanometer. In addition to a single layer user interface, the application processes the image of the microscope and eye with computer vision to determine the center of the image and adjust the view to maintain optimal visibility for the user.

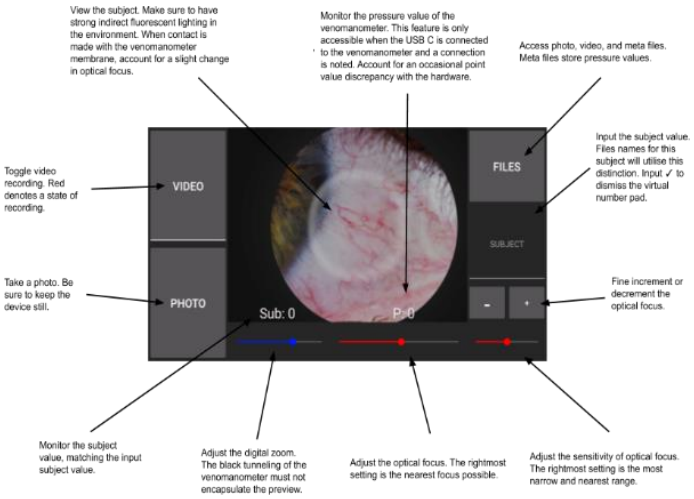

FIGURE 11: A SCREENSHOT OF THE CUSTOMIZED ANDROID APPLICATION AND ITS FUNCTION DESCRIPTIONS.

As a whole, the full system has a total weight of 29.1 lb (see TABLE 1) with most of the weight contributed by the floor-mounted stand (14.2 lb). The venomanometer and its attachment weigh 3.9 lb and the other one-third of the weight is from the other equally crucial hardware parts. The weight can be thought of as a necessary compromise between improving the stability of the EVP measurement (stiffness) and the portability of the whole system. The prototype fits into two bounding boxes with dimensions of 33" x 18.5" x 5.5" and 19" x 9.5" x 7.5" respectively. By using wheeled boxes, the dissembled portable venomanometer system could be considered compact and portable. Meanwhile, the venomanometer assembly only requires a minimum space of 36" x 36" x 54" at a full setup situation to make measurements, opening up the possibilities for the use of venomanometry anywhere, even in places with limited space. By having a total prototype cost of $1858.23 which includes the $975 commercially available venomanometer, the proposed portable system is more cost-effective ($883.23) as compared to its counterpart method that uses a slit-lamp (Haag-Streit 900 or Zeiss) which costs more than $3500.

TABLE 1: LIST OF COMPONENTS OF THE PORTABLE VENOMANOMETER SYSTEM WITH THEIR WEIGHT, SIZE WHEN COLLAPSED, AS WELL AS THE TOTAL WEIGHT AND TOTAL BOUNDING SPACE OF THE SYSTEM.

Components	Weight (lbs.)	Bounding Box Dimension (in)
Venomanometer and 3D attachments (phone and fine-adjustment mechanism included)	3.9	12 x 7.5 x 6
Supporting components:		
I) Floor-mounted stand + attachments	14.2	33 x 10 x 5.5
II) Height cushion	1	19 x 7.5 x 3.5
III) Counterweight	5	2.5 (d) x 4.5 (l)
Others:		
Dolly	5	23 x 8.5 x 5.5
Total	29.1 lbs.	3951.089 in^3 (2.3 ft^3)

2.3 Portable EVP Measurement Method

The main venomanometry concept has remained similar to the standard venomanometry method since the same venomanometer is used in the measurement of EVP. Following the upgrades made to the portable venomanometer system design, the setup and device handling procedure has been altered.

Instead of holding the venomanometer by hand, the portable system is rolled close to the subject followed by the positioning of the height of the floor-mounted stand and the angle of the venomanometer device. By observing through the Google Pixel 3 screen, the image of the episcleral vein is chosen and aligned for EVP measurement. The appropriate feature (video recording or image capturing) is selected in the software interface if the process involves more than just pure real-time observation. Next, the light source, magnification, and focus of the image are adjusted through the software until a clear color fundus image is shown. The standard venomanometry concept can then be applied where the knob of the venomanometer is rotated accordingly until the vessel turns half-blanched. Lastly, the displayed value on the screen and the fundus image photographed are saved for further analysis using the smartphone application.

3. RESULTS AND DISCUSSION

Throughout the process of designing the prototype, several tests were executed to test its feasibility. The early iterations of the prototype were tested on standard Jaeger reading cards and phantom wooden eyes for different measurement positions and magnification as well as illumination capability. A more robust design of the prototype was further proceeded to undergo three tests using a rabbit model for its overall performance evaluation. All animal studies were reviewed and approved by the Institutional Animal Use and Care Committee of UNMC. Dutch-belted rabbits were used in this research and were sedated with ketamine and xylazine as per standard technique. Standard venomanometry in animal experiments includes immobilization of the venomanometer in a clamp with the observer moving the venomanometer manually for the fine adjustments and stabilization of the silicone membrane on the eye during the measurement. Values obtained using this technique were used to compare with the measurement recorded using the prototype (FIGURE 12).

The first rabbit test was conducted on two rabbits by two glaucoma experts. The research did not continue with the third rabbit due to the poor images seen from the phone screen which prevented a proper EVP measurement. The comparison between the standard and proposed prototype method shows significant difference for their mean EVP readings. Since the prototype was still at its early stage, both the hardware and software development were not mature enough to provide quality EVP measurement, where issues such as insufficient focus and poor stability of the prototype system were detected. Furthermore, one of the reasons for the imperfect EVP measurement process was also due to users not being familiar with the operation of the prototype portable venomanometer system.

TABLE 2: COMPARISON OF THE MEAN AND STANDARD DEVIATION OF EVP VALUES BETWEEN RABBIT TEST 1 AND RABBIT TEST 2 FOR THE EVP MEASUREMENT USING THE PROPOSED PROTOTYPE.

	EVP Mean ± SD (mmHg)	
Subject	**Rabbit Test 1**	**Rabbit Test 2**
Rabbit #719	9.8 ± 2.6	9.0 ± 0.0
Rabbit #819	-	10.7 ± 2.5
Rabbit #919	11.3 ± 2.0	12.0 ± 1.6

After Rabbit Test 2 was conducted, the recorded values were analyzed and compared with the performance of the prototype from Rabbit Test 1. The EVP values recorded were from three different rabbits, namely Rabbit #719, Rabbit #819, and Rabbit #919 by the same two glaucoma experts as in Rabbit Test 1. As seen in TABLE 2, the EVP mean values for Rabbit Test 2 have a smaller standard deviation as compared to Rabbit Test 1, with one of the rabbits (Rabbit #719) having consistent EVP values measured for all 4 observations (1 rabbit x 1 eye each x 2 measurements by each observer x 2 total observers = 4). Moreover, the EVP readings obtained in the Rabbit Test 2 show two out of three measurements having readings less than 2 mmHg difference from their means, indicating the repeatability of EVP measurement using the proposed prototype.

Besides quantitative feedback, user experience and qualitative feedback were collected to allow necessary changes to the current prototype iteration. For instance, an important observation was reported where cleanliness of the silicone bulb and other attached lenses play a significant role in providing good quality images for EVP measurement.

In short, the reduction in standard deviation between each rabbit in Rabbit Test 2 reflects the improvement in performance for the proposed prototype. Despite the increases in performance achieved, conclusive assertions regarding the reliability of the prototype and the quality of data collected should not be made

since the sample size in both of these experiments was small (n=3).

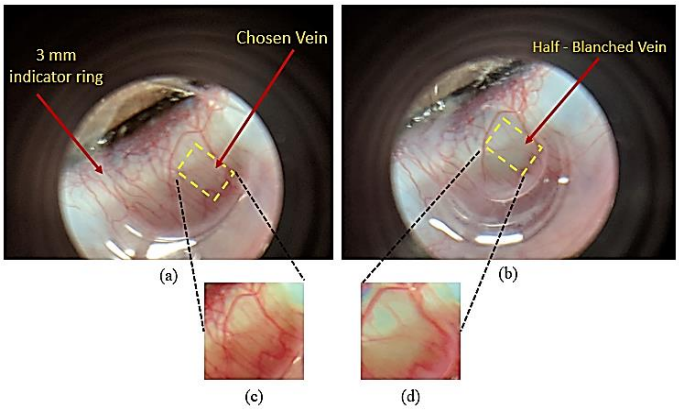

FIGURE 12: (A) AN EPISCLERAL VEIN WAS SPOTTED THROUGH THE SILICONE MEMBRANE. (B) THE VEIN TURNED HALF-BLANCHED AS THE OBSERVER ADJUSTS THE PRESSURE KNOB OF THE VENOMANOMETER. (C) A 200% SATURATION INCREASED OF A CLOSER VIEW OF THE CHOSEN VEIN FOR BETTER ILLUSTRATION. (D) A 200% SATURATION INCREASED IN THE CLOSER VIEW OF THE COLLAPSED VEIN.

TABLE 3: COMPARISON OF THE MEAN AND STANDARD DEVIATION OF EVP VALUES BETWEEN THREE RABBITS FOR THE EVP MEASUREMENT USING BOTH THE STANDARD METHOD AND THE PROPOSED PROTOTYPE IN RABBIT TEST 3

	EVP Mean ± SD (mmHg)	
Subject	**OLD**	**NEW**
Rabbit #719	9.7 ± 5.9	11.5 ± 4.0
Rabbit #819	10.3 ± 1.7	10.6 ± 3.0
Rabbit #919	14.3 ± 4.9	10.3 ± 4.6

TABLE 3 shows the data obtained from Rabbit Test 3 by 2 observers. EVP values with random differences were observed in both the standard method and the proposed prototype. There should not be a large discrepancy in EVP values observed via the standard method since it is a well-established method. This indicates that there were errors occurring in some other aspect apart from the venomanometer measurement system. Therefore, the values via the standard method could not be a reliable dataset for t-test comparison with the proposed prototype method in order to dictate the capability of the prototype.

One of the hypotheses made regarding the unexpected results in this experiment is that there might be effects from lighting that hindered the observers from detecting the vein and from observing its half-blanching point properly. This experience had been reported by both observers throughout the testing procedure. Moreover, the silicone bulb was not cleaned every time after each testing. According to previous animal testing, the clarity of the silicone bulb could affect the testing procedure tremendously.

Another reason for this phenomenon could be due to the cooperation between the hardware and the software. The phone camera may not have been aligned perfectly with the viewing pane and the silicone bulb of the venomanometer, especially when it was zoomed in. An offset of less than 1 mm was assumed between the center of the phone on-board camera and the center of the viewing pane. Since the customized smartphone application was built to have the most focus in the middle of the screen, the phone application might have encountered challenges in focusing at the vein since the focal point of it is not on the vein.

Due to the limited accuracy of the in-house 3D printer used (Afinia), it is difficult for the prototype to be perfect in terms of component dimensions since the 3D printer has a printer nozzle of 0.4 mm and accuracy of ± 0.5 mm. Over time, the 3D printed components can also warp according to temperature differences, creating unavoidable manufacturing defects.

In view of this, additional testing is needed to determine the system robustness and eventually find out the exact source(s) of issues of inconsistent EVP readings.

4. CONCLUSIONS

The design of this prototype can provide fine venomanometer adjustment, sufficient stability, magnification, illumination and autofocus feature for clear image detection, along with improved portability, compactness, set-up procedure, and image processing ability. It has also simplified the redesigns and ruggedization process that is necessary for FDA and military standard (MIL-STD 810) in the future. Meanwhile, the smartphone application established has managed to lay out the groundwork for future automated reading of episcleral veins. Therefore, the design of the portable venomanometer system for EVP measurement could be considered a significant advancement. Future work includes manufacturing refinements and subsequent re-validation of the accuracy of EVP measurements.

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