An open-source, non-invasive, novel assembly for automated real-time monitoring of continuous bladder irrigation

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INTRODUCTION

Continuous bladder irrigation (CBI) is a common intervention following endoscopic manipulations of the genitourinary (GU) tracts to prevent clot retention in the early postoperative phase, or for patients with gross hematuria from other causes (benign prostatic hyperplasia, bladder tumor, etc.). During CBI, effluent color is assessed subjectively by attending staff, and adjustments are made to input flow rate to lighten the reddish hue to titrate an adequate irrigative force within the bladder to prevent excessive hemostasis and consequent clot formation; however, repeated subjective assessments tend to be labor-intensive, lack standardization, and may be unresponsive to changes in effluent color.[1] Tools such as Hemostick®[2] and the Hematuria Grading Scale (HGS)[3] offer one solution but still rely on manual assessments to make adjustments to CBI flow.

In this letter, we present an open-source, inexpensive assembly to construct an automatic CBI monitor, featuring 3D-printed enclosures and consumer-accessible hardware (*https://github.com/malyalar/CBI-monitor*). We secondarily validated the colorimetric function of the device in a clinical setting in 20 patients on CBI with agreement analysis vs. human raters. Other groups have developed automated CBI solutions,[4-6] but to our knowledge, none are available on-market and none have opened their designs for inspection and further development. Open-source medical devices carry several advantages over traditionally developed hardware, including but are not limited to: improved pace of innovation; modifiability for more specific uses; improved repairability; lower cost; and low potential for vendor lock-in.[7]

METHODS

The hematuria monitor (HM) is built with openness and expandability as core principles. The device uses the Arduino open-hardware platform, a popular, easy-to-use development environment that makes it ideal for prototyping devices. HM was also built with secondary goals of being easy to construct, and to keep potential cost-per-unit low. Instructions available on our published *github.com* page include editable CAD files for 3D-printable enclosures (Figure 1), circuit schematics, code, and data from validation.

The processing unit for HM is an Arduino Nano V3.0. The spectral sensing module is a white LED mounted opposite an AS7262 spectrophotometer, passing incident light through a catheter outflow tube latched inside the spectrophotometer shroud (Figure 2), resulting in a reading of transmitted light at the spectrophotometer inversely proportional to the level of hematuria.

The current implementation of HM uses a lookup table to estimate outflow color based on readings from the violet (450 nm) wavelength of light, as internal tests demonstrated the greatest sensitivity/reliability of this wavelength on the selected spectrophotometer to differentiate grades of hematuria (not shown). Flow rate is detected through rate-of-change calculations from a load cell, from which the catheter outflow bag is mounted. Readout data is displayed via a small screen.

We conducted initial laboratory validation of the HM with known serial dilutions of known-hematocrit pig's blood, sealed within portions of catheter outflow bag tubing (Figure 3). Eight dilutions were measured in quintuplicate, ranging from 0–1 mL in 10 mL saline. The range of these dilutions were corresponding to Lee et al's HGS values of 0–10.[3] A correlation coefficient analysis was undertaken. We also proceeded to validate the colorimetric function of the device in a

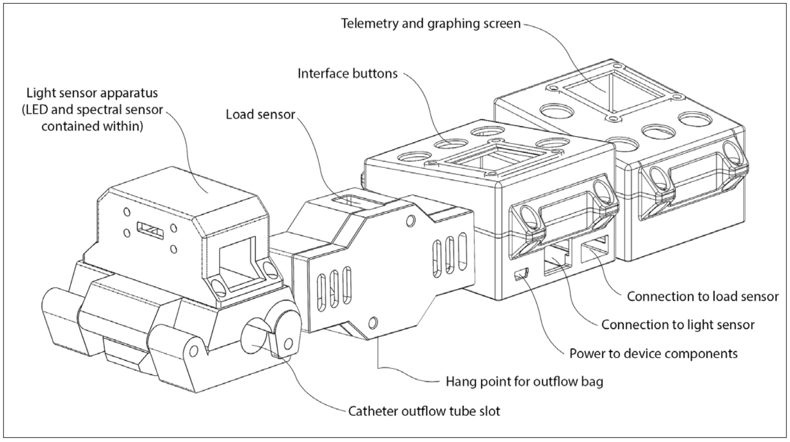

Figure 1. Wireframe diagrams of 3D printable enclosures of the base model, comprising three components. 1) A main body with the Arduino Nano microprocessor, with slots for three buttons, a switch, and a telemetry screen. Next, interfacing with the Arduino through wired connections; 2) a light sensor apparatus comprising a white LED and the AS7262x spectral sensing unit mounted opposite to each other within a folding shroud that clips over a catheter outflow tube; and 3) a bar-type load sensor (TAL220) with built-in HX711 load cell amplifier with a hang point for the outflow bag.

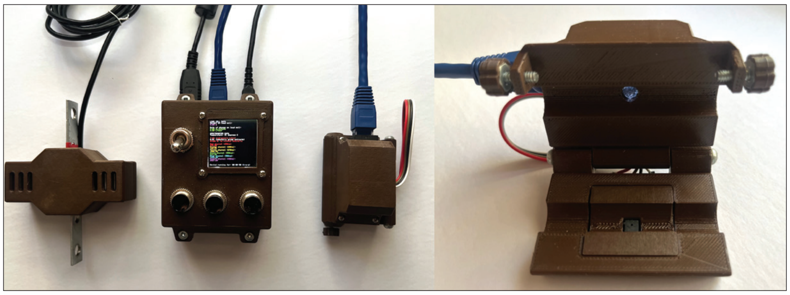

Figure 2. Demonstration of function of an example build. In view: spectrophotometer shroud and main processing unit.

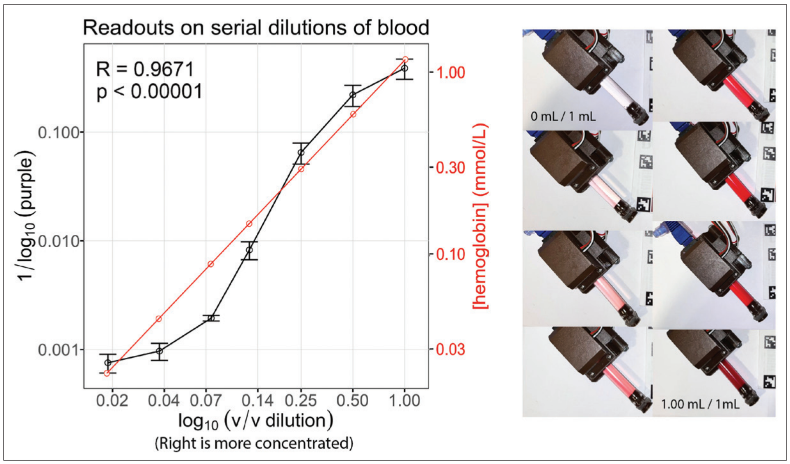

Figure 3. Validation of hematuria monitor across differing concentrations of blood in continuous bladder irrigation (CBI) effluent. Eight known volume/volume (mL blood to mL saline) dilutions of thawed, heparinized pig's blood in saline were prepared and placed within the spectrophotometer shroud. On the X-axis, values to the right correspond to higher concentrations of blood. Hemoglobinuria estimates from the spectrophotometer shroud were recorded and plotted alongside values of known dilutions. An image of the dilution tubes is included for reference to assess the subjective color range of the tubes.

KEY MESSAGES

- There is an opportunity in medical device development that may be addressed by open-source development strategies.
- Properly assembled consumer electronics-based sensors can be capable of differentiating grades of hematuria for research purposes in laboratory or clinical settings.
- We have demonstrated the development of an open-source device to monitor CBI that may serve as a platform for refinement or development of future adjuncts in the name of increasing patient safety.

ward setting on 20 patients undergoing CBI. Forty pictures were taken of the spectrophotometer shroud clamped on CBI effluent tubes beside a copy of the HGS, which were rated by three blinded raters on a scale of 0–10. These were simplified to an ordinal score from 0–5 to match the device readout. The mode of the three human-read grades was taken and compared with device readouts via weighted Kappa. Testing was done under The University of British Columbia Clinical Ethics Board (certificate H20-02012).

RESULTS AND DISCUSSION

The current iteration of the HM can be used completely externally to an existing CBI setup, and is notably compact. 3D print files are offered in varied formats for editability in different software. The device can continuously monitor flow rate. The total lowest-estimate cost for the HM is approximately $45 CAD at the time of writing (Table 1). Future implementations of the device would include components to control irritant flow rate and other modules that may increase the build cost. Figure 2 includes pictures of an exemplar build of the HM.

In laboratory testing, the HM achieved a correlation coefficient of 0.97 ($p<0.001$) (Figure 3). In clinical validation, the hematuria grade readouts from the HM (mean ± standard deviation [SD] 1.95/5±1.51) achieved a Kappa statistic of 0.822 ($p<0.001$) (Table 2), indicating high agreement with human raters (mean ± SD 1.62/5±1.14).

A hematuria monitor such as the one proposed may help increase patient comfort by reducing clot retention and catheter blockage during CBI, as well as potentially reduce the more significant complication of a perforated bladder from unrestricted inflow into an outflow blocked catheter. HM lends itself well to future CBI automation, as we have demonstrated its ability to distinguish grades of hematuria analogous to human readouts on standard scales. Further, providing a means to control the inflow rates to the CBI system based on HM readings may allow for improved patient safety, comfort, and reduction in complications, as well as a reduction in administrative burden by attending staff. The open-source nature of the device lends itself to easy extensibility, low cost, and feature-richness.

Regulatory approval challenges are a legitimate concern for open-source medical devices; however, during the COVID-19 pandemic, effort and interest in establishing pathways for open-source devices to play a larger role in healthcare flourished. Canadian examples of efforts in this space include Glia Medical's research-validated 3D-printable stethoscope,[8] and COSMIC Medical's Project Bubble Helmet.[9]

Future steps include the addition of a wireless communications module to output alarms to a user's cellphone, motor control of flow rate to automate the CBI process fully, and exploration of regulatory approval processes.

Table 1. Bill of materials (BOM)

	Component	Quantity	PPU
Central unit	Arduino Nano V3.0-based CH340 Chip Atmega328p Board, with USB Cable	1	$5.00
	Momentary push buttons (optional)	3	$1.00
	1.8" TFT display module ST7735	1	$9.00
Spectral sensor	AS7262 6-channel visible light spectral sensor breakout	1	$20.00
	White LED	1	$0.1
Load cell	TAL220 beam-type load cell	1	$5.00
	HX711 load cell amplifier	1	$1.00
Connectors, misc.	PLA filament for enclosures	100g	$1
	Resistors, Dupont connectors, solder, other consumables	n/a	$1
Total			$45.10

Table 2. Results of clinical validation

	Average ± SD (n=40 photos)	Kappa	p
Human grades (0–5)	1.62±1.14	0.822	<0.001
Machine grades (0–5)	1.95 ±1.51		

SD: standard deviation.

COMPETING INTERESTS: The authors do not report any competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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