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Comparison of Hemolysis With the Second Heart Assist Whisper and Impella CP pMCS devices: An FDA-Mandated Study

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Abstract:	Percutaneous mechanical circulatory support (pMCS) devices sometimes cause hemolysis. The US FDA mandates comparative in vitro testing for new devices to evaluate the risk of hemolysis. This study compared the degree of hemolysis caused by the Second Heart Assist (SHA) Whisper at its maximum pump speed with that of the Impella CP, following ASTM standards. SHA Whispers were tested at 10,000 RPM; Impella CP was operated at 44,133 ± 606 RPM to match the SHA Whisper's flow rate in two identical in vitro blood circulatory loops using citrated bovine blood. Hemolysis was analyzed by the tetramethylbenzidine method. The change in plasma free hemoglobin (ΔpfHb) was significantly greater with the Impella CP than with the SHA Whisper ($p < 0.01$). Both devices caused a steady increase in pfHb, with significant differences after 60 minutes ($p < 0.01$). For SHA Whisper and Impella CP, there were significant difference in NIH (0.088 ± 0.022 versus 0.194 ± 0.029 g/100, $P < 0.01$), and MIH (9.72 ± 2.4 versus 20.83 ± 3.5, $P < 0.01$). Thus, the SHA Whisper was more hemocompatible than the Impella CP under the same hemodynamic conditions. These benchmark values will aid future in vitro blood testing for pMCS devices.

Sep 7, 2024

Pramod Bonde, MD
Editor-in-Chief
ASAIO Journal

Dear Dr. Bonde:

On behalf of my colleagues, I would like to introduce to you our manuscript, **Comparison of Hemolysis With the Second Heart Assist Whisper and Impella CP Percutaneous Mechanical Circulatory Support Devices: An FDA-Mandated Study**, which we have submitted to be considered for publication in the *ASAIO Journal* as an Original Research Article.

Hemolysis is a risk associated with the use of mechanical circulatory support (MCS) devices; however, there are limited data on the comparative rates of hemolysis among different percutaneous MCS (pMCS) devices. For all new devices for which an investigational device exemption is sought, the FDA mandates comparative in vitro testing with an FDA-approved device, and the Impella CP is the only pMCS device currently approved as a comparator. In this study, we evaluated the effect of the maximum pump speed of the Second Heart Assist (SHA) Whisper device on hemolysis, using the Impella CP as a comparator. The SHA showed greater hemocompatibility than the Impella CP under identical hemodynamic conditions.

The contents of this manuscript are our original work and have not been submitted or published elsewhere, in whole or in part, prior to or simultaneous with the submission of this manuscript to the *ASAIO Journal*. All listed authors were fully involved in the study and agree with the content of the manuscript.

Thank you for taking your time in reviewing this submission. I am very interested in receiving your comments after the *ASAIO Journal*'s review of this manuscript.

Yours Sincerely,

Chris Hoi Houng Chan, PhD

The Texas Heart Institute

Comparison of Hemolysis With the Second Heart Assist Whisper and Impella CP Percutaneous Mechanical Circulatory Support Devices: An FDA-Mandated Study

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Short Title: Hemocompatibility of SHA Whisper and Impella CP

Keywords: Percutaneous mechanical circulatory support; hemolysis; in vitro testing; SHA; Impella CP.

Conflicts of Interest: Zvonimir Krajcer, Sejal Chaudhari, Alex Richardson, and Leslie Miller are employees of Second Heart Assist.

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Author Contributions:

CHHC, YW, and AR conceptualized and designed the study. CHHC, AF, PP, SK, and HA conducted the experimental procedures and conducted biological sampling and processing. CHHC drafted the manuscript. AF conducted statistical analyses. All authors provided critical revision of the article.

Comparison of Hemolysis With the Second Heart Assist Whisper and Impella CP Percutaneous Mechanical Circulatory Support Devices: An FDA-Mandated Study

Abstract

Percutaneous mechanical circulatory support (pMCS) devices sometimes cause hemolysis. The US FDA mandates comparative in vitro testing for new devices to evaluate the risk of hemolysis. This study compared the degree of hemolysis caused by the Second Heart Assist (SHA) Whisper at its maximum pump speed with that of the Impella CP, following ASTM standards. SHA Whispers were tested at 10,000 RPM; Impella CP was operated at 44,133 ± 606 RPM to match the SHA Whisper's flow rate in two identical in vitro blood circulatory loops using citrated bovine blood. Hemolysis was analyzed by the tetramethylbenzidine method. The change in plasma free hemoglobin (Δ*pf*Hb) was significantly greater with the Impella CP than with the SHA Whisper ($p < 0.01$). Both devices caused a steady increase in *pf*Hb, with significant differences after 60 minutes ($p < 0.01$). For SHA Whisper and Impella CP, there were significant difference in NIH (0.088 ± 0.022 versus 0.194 ± 0.029 g/100, $P < 0.01$), and MIH (9.72 ± 2.4 versus 20.83 ± 3.5, $P < 0.01$). Thus, the SHA Whisper was more hemocompatible than the Impella CP under the same hemodynamic conditions. These benchmark values will aid future in vitro blood testing for pMCS devices.

Introduction

Conventional left ventricular assist devices (LVAD) are large and complex. The invasive surgical procedures required to implant them are associated with high morbidity and mortality rates and prolonged recovery times. Alternatively, percutaneous mechanical circulatory support (pMCS) devices may be easier and quicker to implant, are less invasive, and could reduce surgical risk. They can also be used in less critically ill patients, who are more likely to recover cardiac function.[1-3]

The Second Heart Assist Whisper (SHA, Second Heart Assist, Inc, South Salt Lake, UT; Figure 1) is a 13.5 Fr impeller-driven pump mounted on a driveshaft within a stent cage. It is delivered percutaneously through the femoral artery into the descending aorta, where it is positioned 10 cm above the renal arteries. This device stands out as the most efficient pump in its field, operating at only 7,500 RPM. It provides significant benefits to both the heart and kidneys by improving cardiac output and reducing cardiac filling pressures. This is primarily achieved through afterload reduction, as the rotation of the impeller blades pulls blood down through the pump. The SHA Whisper can augment cardiac output by generating an additional > 2.5 L of pulsatile flow over what the native heart produces. This additional output increases renal blood flow by up to 50% over baseline and thus helps counteract the intrarenal vasoconstriction associated with low cardiac output in patients with heart failure. The resulting increase in blood flow improves kidney function, increases urine output, and accelerates decongestion. The catheter-based SHA device can be inserted and the stent and impeller blades fully deployed in less than 2 minutes, without crossing any valve.[4] It is designed to provide support for up to 24 hours for patients admitted with acute decompensated heart failure who develop

significant diuretic resistance. When support is terminated, the catheter handle controller can be used to collapse the propeller blades and stent for easy removal.

For all new devices seeking an investigational device exemption, the US Food and Drug Administration (FDA) mandates comparative bench testing with both an FDA-approved device and a legally marketed comparator device. Numerous standard in vitro hemocompatibility tests have been developed and tested for LVAD[5-7] and extracorporeal membrane oxygenation.[8-10] However, there are minimal data on the comparative rates of hemolysis among pMCS devices. In this study, we compared the hemolytic performance of two types of pMCS devices: the SHA Whisper device, operating at its maximum pump speed, and the Impella CP (Abiomed, Inc., Danvers, MA), the FDA-approved pMCS device, adjusted to match the flow rate and pressure head conditions.

Materials and Methods

The study was conducted in compliance with ASTM standards for blood selection (ASTM F1830-19)[11] and in vitro blood pump evaluation (ASTM F1841-19).[12] Five repeated in vitro blood tests were conducted with five new, sterile SHA Whisper devices and one new, sterile Impella CP device under the constant hemodynamic conditions outlined in Table 1. Pressure and flow curves (H-Q curves) for SHA and Impella CP devices at various pump speeds and a wide range of pressures are shown in Figure 2.

Preparation of Test Blood

For each test, 1800 mL of blood was obtained from live cows (Animal Technologies, Inc., Tyler, TX) by venipuncture and collected into an anticoagulated blood

bag containing 200 mL 3.8% trisodium citrate solution. The blood was passed through a 40-μm blood transfusion filter (SQ40; Haemonetics, Boston, MA) to remove microaggregates, clots, and contaminants such as animal fur and skin tissue. Blood hematocrit levels were then adjusted to a target of 35 ± 2% by hemodilution with phosphate-buffered saline (21-031-CM, Corning Life Sciences, Durham, NC) or hemoconcentration (by 15 min centrifugation at 2250×g and 6 °C) as necessary to reduce variation between samples. An antibiotic solution (50 mg/L gentamycin; Sigma-Aldrich, St. Louis, MO) was added to prevent bacterial contamination. The total time elapsed between blood collection and the initiation of test procedures was less than 48 hours. Baseline blood samples were measured for plasma-free hemoglobin (*pf*Hb) to ensure there was no potential blood damage (initial *pf*Hb < 50 mg/dL) before the trial began.

Blood Circulatory Loops

Two identical blood circulatory loops (BCLs) were built (Figure 3). The BCLs were modified to better accommodate pMCS devices. These modifications included using two 1-inch inner diameter latex rubber tubing as flexible blood reservoirs instead of a single blood reservoir, and adding a device insertion port, three 1-inch inner diameter clear acrylic tubes, and 3/4-inch inner diameter Tygon tubing for flow probe connection. The volume of blood in each loop was 450 ± 30mL. Pump flow was monitored with an ultrasonic flow meter (ME16PXL1153; Transonic Systems Inc., Ithaca, NY), while inlet and outlet pressures were monitored with piezoresistive pressure probes (PREPS-N-000, PendoTECH). Temperature was monitored with a temperature probe (TEMPC-N-999, PendoTECH). After each experiment, the used Impella CP and parts of the BCLs were

rinsed with saline and then immersed in 2 L of detergent solution (EmPower Dual-Enzymatic Detergents, 10-4100; Metrex Research, Orange, CA) for at least 60 min. This gentle cleansing process is intended to remove any traces of protein, blood, and other protein-rich bodily fluids. After air drying overnight, the Impella CP device and parts of the BCLs were thoroughly disinfected with an 80% ethanol spray and washed with deionized water five times before the next test.

Hemodynamics and Data Acquisition

The two identical BCLs were filled with normal saline to wet the blood-contacting surfaces (Figure 3). Both pMCS devices were then started, and the saline was allowed to circulate for at least 20 minutes. After the saline was removed from the circuits, the prepared blood was gently syringed into each circuit, ensuring the elimination of air bubbles before the evaluation started. The two BCLs were then placed in an air temperature-controlled incubator box (UX-01110-04, Cole-Parmer Instrument Co., Vernon Hills, IL) and were maintained at 37±1 °C for the 6-hour duration of the in vitro blood testing. The remaining bovine blood was kept in a blood bag and warmed in a water bath (EW-14576-08, Cole-Parmer) at 37±1 °C as a static control.

Once per hour, blood samples were drawn from each circuit via a sampling port for *pf*Hb measurement. The first 2 mL was discarded, and 6-mL blood samples were collected for analysis. The SHA Whisper and Impella CP circuits were purged with saline solution at the same purge infusion rate of 7.9 ± 1.8 mL/hr. Blood count (Table 2) and blood gases (Table 3) were measured at baseline (0 min), 10 min, 180 min, and 360 min. The static control blood bag gently rocked once per hour before the specimen was drawn

to prevent separation of the blood cells from plasma. Constant hemodynamic parameter data were recorded hourly from the two pump circuits throughout the 6-hour testing period (Table 1).

Hemolysis Assay

For hemolysis analysis (or *pf*Hb measurement), triplicate blood samples were collected into heparin tubes and centrifuged at 2,000×g for 15 minutes. Plasma was isolated and re-centrifuged at 13,000×g for 15 minutes. The centrifuged plasma samples were immediately stored at −80 °C and subsequently sent to IDEXX BioAnalytics, a Good Laboratory Practice–compliant laboratory in West Sacramento, California, for *pf*Hb measurement. Hemolysis was measured by the tetramethylbenzidine method. Triplicate complete blood counts were measured with a hematology analyzer (VETSCAN HM5, Abaxis, Inc., Union City, CA), and triplicate blood gas analyses were performed with an i-STAT machine with CG4+ and CHEM 8+ cartridges (i-STAT 1, Abbott Laboratories, Chicago, IL) at the time points of 0, 10, 180, and 360 min.

From the determined Δ*pf*Hb, the normalized index of hemolysis (NIH) and modified index of hemolysis (MIH) were calculated using equations (1) and (2), respectively, where Hct is the hematocrit (%), V is the blood volume in the loop (mL), Q is the measured flow rate in the SHA Whisper and Impella circuits (L/min), ΔT is the sampling time point (min), and Hb is the total blood hemoglobin concentration at baseline (g/dL):

$$NIH\ \left(\frac{g}{100\ L}\right) = \frac{\Delta pfHb \times V \times \frac{(100-Hct)}{100}}{Q \times \Delta T \times 1000} \quad (1)$$

$$MIH\ = \frac{\Delta pfHb \times V \times \frac{(100-Hct)}{100}}{Q \times \Delta T \times Hb} \quad (2)$$

Statistical Analysis

Microsoft Excel (2023; Microsoft Corp., Redmond, WA) was used for all statistical analysis and graphic representation. A two-way repeated-measures analysis of variance was conducted to compare the changes in hemolysis between the two conditions (SHA Whisper vs Impella CP) over the 6-hour study duration. A two-tailed paired t-test was performed to compare the hemolysis levels between the SHA Whisper and Impella devices. Paired t-tests were conducted to compare hemolysis levels at each time point against the 10 minutes time point for each device. To account for multiple comparisons, a Bonferroni correction was applied, adjusting the alpha value to 0.00833. The NIH and MIH were compared between the two devices and analyzed with two-tailed paired t-tests.

Results

Hemolysis increased significantly over time for both SHA Whisper and Impella CP, but not in the static control (Figure 4). Δ*pf*Hb in the SHA Whisper and Impella CP conditions increased significantly from 10 min to 60-360 min ($p < 0.01$). There were significant differences in *pf*Hb between SHA Whisper and Impella CP from 60 to 360 min ($p < 0.01$). For SHA Whisper and Impella CP, there were significant difference in NIH (0.088 ± 0.022 versus 0.194 ± 0.029 g/100, P < 0.01), and MIH (9.72 ± 2.4 versus 20.83 ± 3.5, P < 0.01) (Figure 5).

Discussion

The development of minimally invasive pMCS devices has lagged behind LVAD technology, with the Impella device being the only FDA-approved pMCS device for partial support and recovery in non-end-stage heart failure patients. Incidences of hemolysis have been reported in patients using the Impella devices.[13-15] The SHA Whisper catheter-based pump device might be a better option because it causes less hemolysis and therefore may produce better outcomes during and after pMCS support. In this FDA-mandated study, we evaluated the effect of the maximum pump speed of the SHA Whisper device on hemolysis, using the Impella CP as a comparator device.

In the development of a pMCS device, hemocompatibility is one of the most critical elements to assess. In the development of a pMCS device, assessing hemocompatibility is crucial. In vivo evaluations of VADs in animals are labor-intensive, costly, and may yield variable outcomes. Therefore, a valid in vitro test in a recirculating loop can save time and money while providing a much simpler means of evaluation. Shear stress encountered by blood in transit through the pump system can affect both cells and large proteins in the plasma. Understanding the impact of currently available pumps on a wider range of blood cell types and plasma proteins will lead to further improvements in pump design.

In the present study, the SHA Whisper was operated at 10,000 RPM to pump 8.4 L/min, while the Impella CP had to be run at > 44,000 RPM to match this flow rate. Because the SHA Whisper's lower pump speed exerts less mechanical shear on the red blood cells,[16] the SHA Whisper was nearly 47% less hemolytic than the Impella CP, according to the MIH results. We assume that in clinical situations, when the SHA Whisper device would be used at its normal operating pump speed of 7,500 RPM, hemolysis levels

would be expected to be even lower. The observed increase in total platelet count (Table 2) at the 360-minute time point during the in vitro tests, particularly in the Impella CP circuits, was anomalous. The hematology analyzer may have mistakenly counted small particles, such as destroyed, fragmented erythrocytes and leukocytes, resulting in a slight but incorrect increase in measured platelet counts during the pumping process.[17]

The current catheter-based first-generation device, SHA Whisper, is powered through a driveline and is designed to provide short-term support. In contrast, the next-generation SHA device, the SHA Freedom, is designed to provide long-term support and uses completely wireless power, eliminating the need for a driveline. This device's subcutaneous inductive coil has been miniaturized to fit on the distal tip of the catheter, while the motor and battery are housed in a titanium case on the driveshaft. After the stent and pump are deployed in close proximity to the kidneys, the driveshaft can be detached by demagnetizing a ball at its end.[4]

Conclusion

We conducted hemolytic performance testing for the SHA Whisper device, at maximum pump speed, and compared it to the Impella CP device. Our in vitro model, using citrated bovine blood under ASTM standard testing conditions, showed a higher hemolysis profile for the Impella CP, which is FDA-approved for adult systemic use, than for the SHA Whisper. These results can serve as hemocompatibility performance benchmarks for the future development of pMCS devices.

Acknowledgment

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Figure Legends

Figure 1. Overview of the Second Heart Assist Whisper system (Second Heart Assist Inc), which consists of a pump head (**A**), catheter handle controller (**B**), an external motor (**C**), and a compact ambulatory controller (**D**). **E:** Schematic shows the Second Heart Assist Whisper system in place in a patient. The catheter-based, impeller-driven pump is delivered percutaneously through the femoral artery into the descending aorta and positioned approximately 10 cm above the renal arteries. The device features a protective open-frame stent cage to secure its position.

Figure 2. Pressure and flow curves (H-Q curves) at various pump speeds of the SHA Whisper (3,000-10,000 RPM) and Impella CP (23,000-46,000 RPM) in 20 ± 2°C glycerol/water solution (40/60 by weight, viscosity of 2.6 cP).

Figure 3. Photographs of the blood circulatory loops. **A:** Second Heart Assist Whisper. **B:** Impella CP. **C:** Flexible blood reservoir. **D:** Pressure probe. **E:** Sampling port. **F:** Temperature probe. **G:** Air temperature-controlled incubator box. **H:** Flow probe. **I:** Thermometer. **J:** Device insertion port.

Figure 4. Evaluation of hemolysis in the SHA Whisper, Impella CP, and static control. Levels of plasma free hemoglobin (*pf*Hb) were compared after exposure to varying conditions over 360 min of in vitro pump circulation. The *pf*Hb was significantly greater in the Impella CP loop than in the SHA Whisper loop after 60 min (*$P < 0.01$). Data are presented as mean ± standard deviation.

Figure 5. Comparison of normalized index of hemolysis (NIH) (**A**) and modified index of hemolysis (MIH) (**B**) between the SHA Whisper and the Impella CP. Both NIH and MIH were significantly higher in the Impella CP than in the SHA Whisper ($P < 0.01$). Data are presented as mean ± standard deviation. *Statistically significant difference between SHA Whisper and Impella CP.

Table 1. Constant hemodynamic parameters of the Second Heart Assist (SHA) Whisper and Impella CP devices

Hemodynamic parameters	SHA Whisper	Impella CP
Blood flow rate (L/min)	8.4 ± 0.2	8.3 ± 0.3
Pump speed (RPM)	10,000 ± 0	44,133 ± 606
Purge fluid infusion rate (mL/hr)	7.9 ± 1.8	7.9 ± 1.8
Pump inlet pressure (mmHg)	1.0 ± 2.7	3.9 ± 7.0
Pump outlet pressure (mmHg)	4.6 ± 3.0	7.1 ± 7.2
Pressure changes across the pump (mmHg)	3.6 ± 0.3	3.2 ± 0.6
Temperature (°C)	37.4 ± 0.6	36.8 ± 0.3

These parameters were maintained during a 6-hour in vitro hemocompatibility test. Data are presented as mean ± standard deviation.

Table 2. Blood counts over time for each circuit condition

	Baseline	SHA Whisper (n=5)			Impella CP (n=5)		
Time (min)	0	10	180	360	10	180	360
Total hemoglobin (g/dL)	10.3 ± 0.70	9.5 ± 0.56	9.1 ± 0.39	8.6 ± 0.44	9.5 ± 0.57	9.0 ± 0.50	8.7 ± 0.50
Hematocrit (%)	33.2 ± 0.50	30.9 ± 1.60	29.4 ± 1.35	27.8 ± 1.37	31.2 ± 1.29	28.6 ± 1.40	25.8 ± 1.12
RBCs (10^{12}/L)	7.4 ± 0.80	6.7 ± 0.50	6.3 ± 0.48	5.9 ± 0.46	6.7 ± 0.52	6.2 ± 0.45	5.5 ± 0.47
WBCs (10^{9}/L)	4.7 ± 0.36	4.4 ± 0.32	3.5 ± 0.26	2.6 ± 0.37	4.3 ± 0.52	3.1 ± 0.48	2.2 ± 0.39
Platelets (10^{9}/L)	192 ± 76.5	185 ± 26.0	162 ± 25.6	168 ± 41.5	192 ± 33.3	181 ± 34.1	225 ± 66.7

Data are presented as mean ± standard deviation.

RBCs, red blood cells; WBCs, white blood cells; SHA, Second Heart Assist.

Table 3. Blood gas measurements over time for each circuit condition

	Baseline	SHA Whisper (n=5)			Impella CP (n=5)		
Time (min)	0	10	180	360	10	180	360
pH	7.38 ± 0.02	7.43 ± 0.01	7.39 ± 0.01	7.36 ± 0.01	7.38 ± 0.01	7.37 ± 0.01	7.33 ± 0
pCO_2 (mmHg)	43.8 ± 3.27	39.6 ± 3.44	39.2 ± 2.17	39.0 ± 3.87	41.2 ± 3.83	40.6 ± 2.30	38.4 ± 2.88
pO_2 (mmHg)	40.0 ± 6.04	41.0 ± 3.08	42.4 ± 2.30	41.2 ± 4.09	41.0 ± 2.92	40.8 ± 3.63	41.8 ± 2.95
Glucose (mg/dL)	90.6 ± 9.94	83.8 ± 8.96	63.4 ± 8.91	42.8 ± 7.82	83.8 ± 10.06	56.4 ± 10.06	33.0 ± 5.70
Lactate (mmol/L)	2.88 ± 1.38	3.04 ± 1.38	4.14 ± 1.25	5.02 ± 1.14	3.16 ± 1.40	4.76 ± 1.26	5.54 ± 0.94

SHA, Second Heart Assist. Data are presented as mean ± standard deviation.

Figure

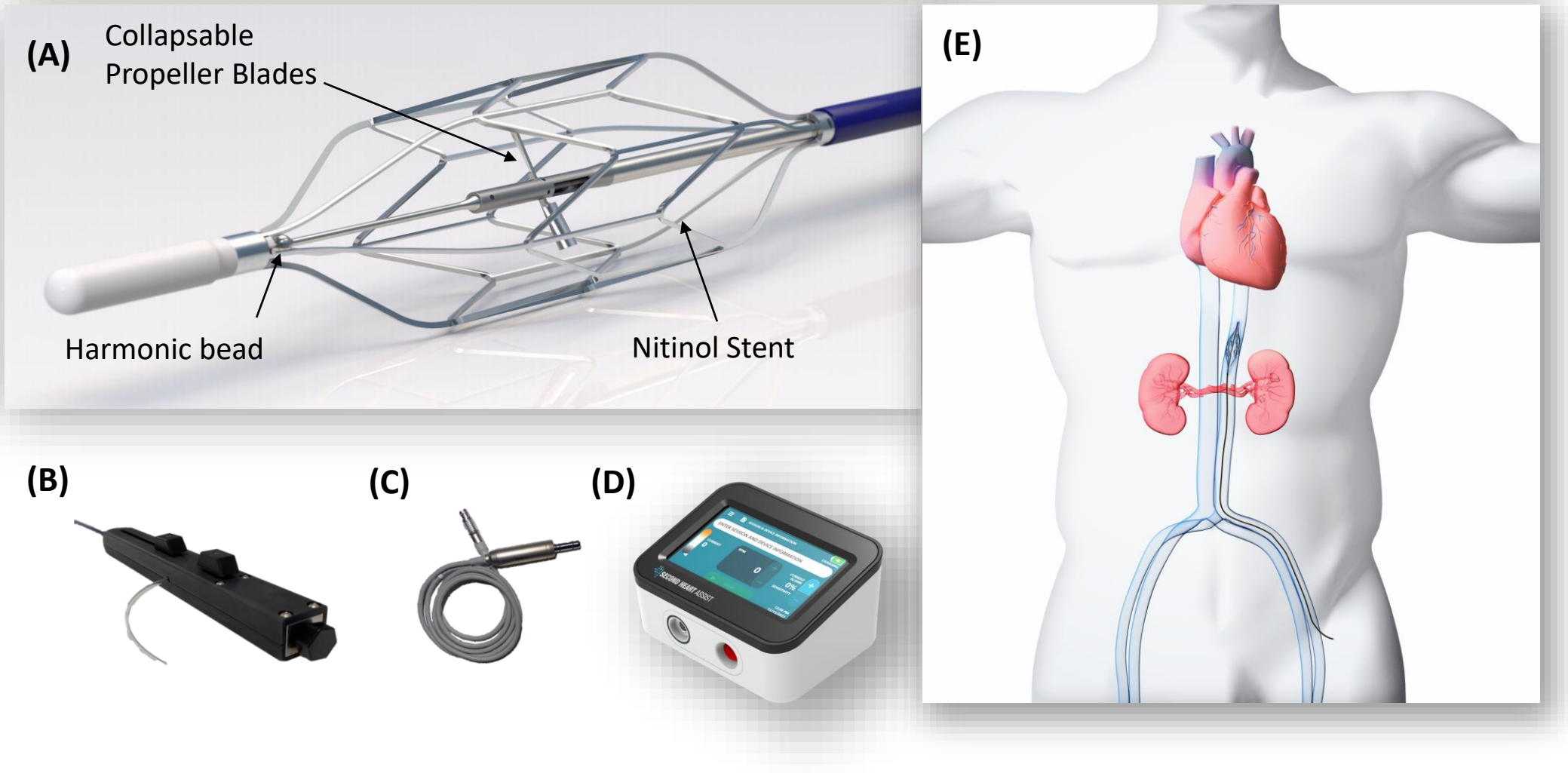
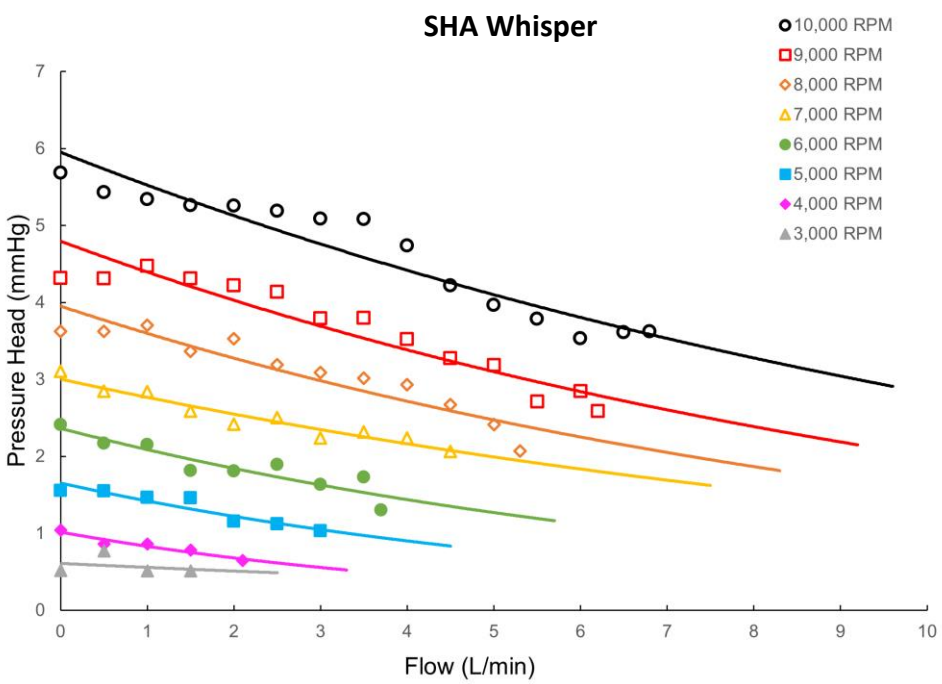


Figure 1.


SHA Whisper
10,000 RPM
9,000 RPM
8,000 RPM
7,000 RPM
6,000 RPM
5,000 RPM
4,000 RPM
3,000 RPM
Pressure Head (mmHg)
Flow (L/min)

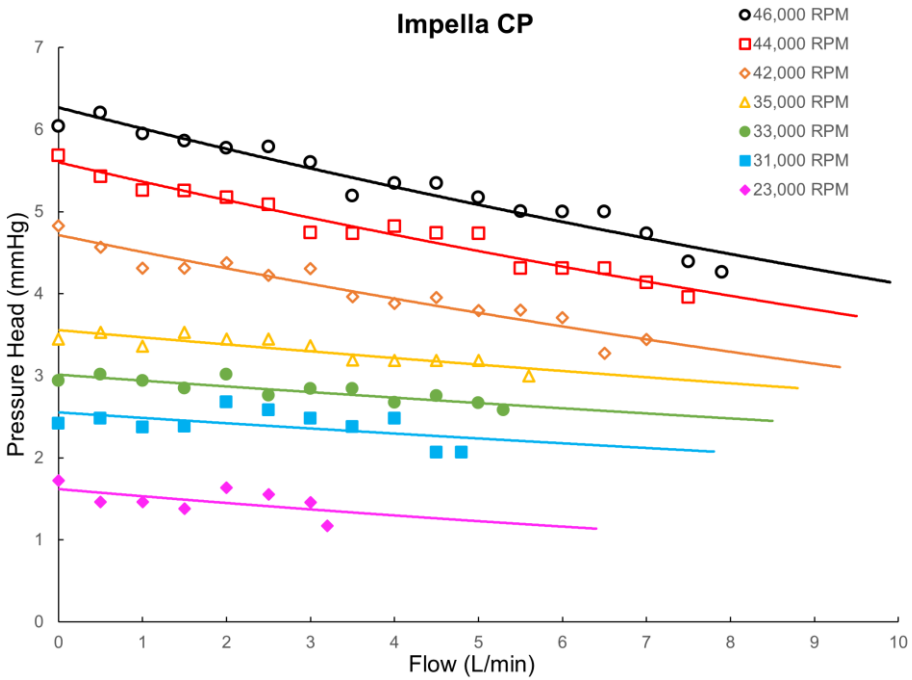

Impella CP
46,000 RPM
44,000 RPM
42,000 RPM
35,000 RPM
33,000 RPM
31,000 RPM
23,000 RPM
Pressure Head (mmHg)
Flow (L/min)

Figure 2.

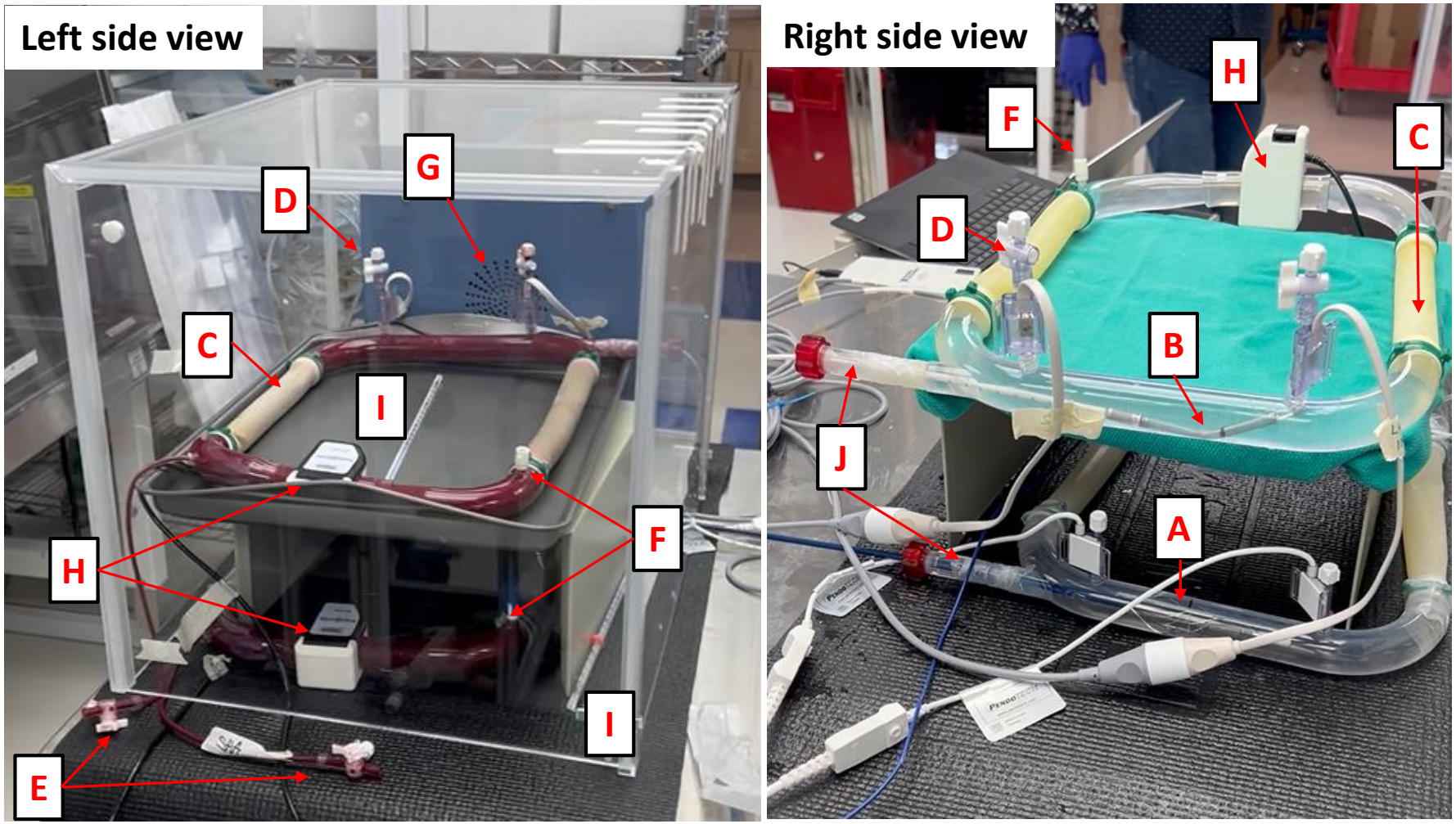


Figure 3.

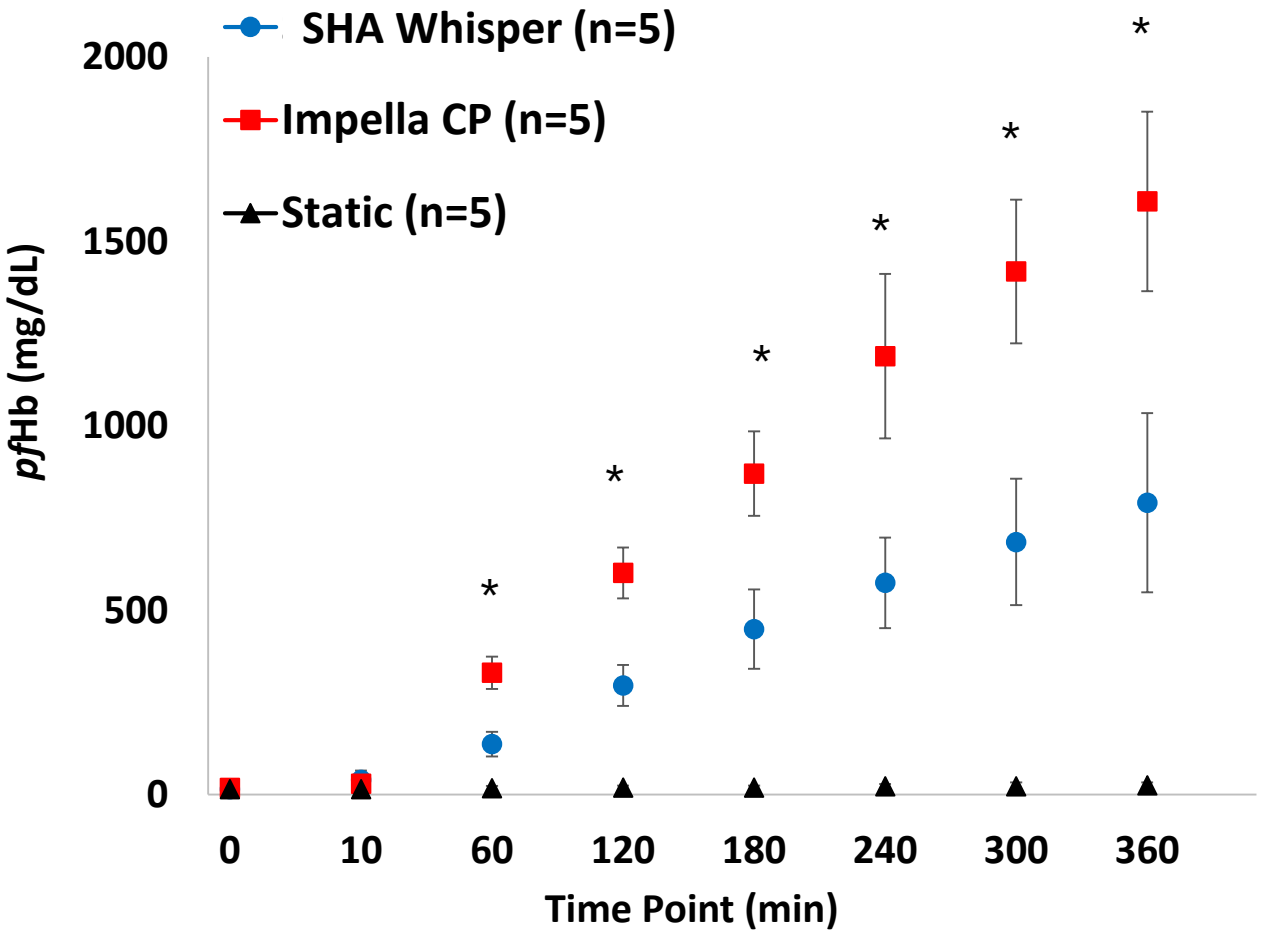

SHA Whisper (n=5)
Impella CP (n=5)
Static (n=5)
2000
1500
1000
500
0
pfHb (mg/dL)
0
10
60
120
180
240
300
360
Time Point (min)
*
*
*
*
*
*

Figure 4.

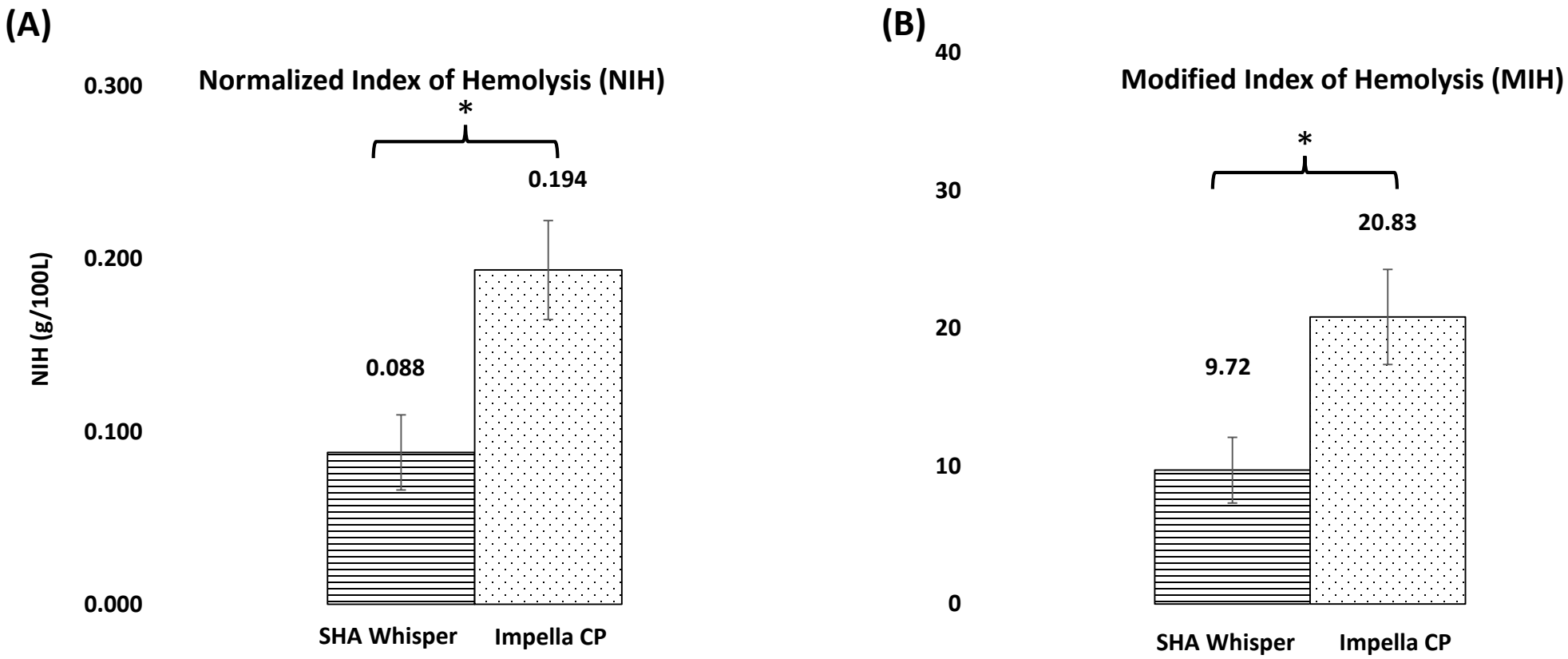

(A)
Normalized Index of Hemolysis (NIH)
NIH (g/100L)
0.300
0.200
0.100
0.000
*
0.194
0.088
SHA Whisper
Impella CP
(B)
Modified Index of Hemolysis (MIH)
40
30
20
10
0
*
20.83
9.72
SHA Whisper
Impella CP

Figure 5.