

Investigating Fatigue of Three-Dimensional Flow Phantom Model of the Carotid Artery of Preterm Infants

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ABSTRACT

This study aimed to examine phantom fatigue and perform flow volume measurements with Doppler ultrasound using 3D printed flow phantom models of carotid artery in preterm infants. 3D printed Doppler flow phantom model with three different vessel diameters; 0.158 cm, 0.196 cm and 0.244 cm and varying characteristics that were 18 to 24 months old were used for these experiments. Leading edge to centre was used to measure vessel diameter. Two observers performed flow volume measurements using continuous and pulsatile flow.

Agreement between observers was examined using Bland-Altman plots. 36 measurements were performed. 9 (50%) measurements were performed using continuous flow. Pulsatile flow measurements were performed using physiological rates. Bland-Altman analysis for continuous flow diameter measurements for observer 1 and 2 were -0.004 (95%LOA -0.012 to 0.005) cm and -0.006 (-0.022 to 0.010) cm. Bias for pulsatile flow diameter measurements were smaller both observers. Bias for continuous flow measurements for observer 1 and 2 were 0.382 (95%LOA -5.306 to 6.070) ml/min and 3.516 (-4.030 to 11.06) ml/min respectively. Bias was smaller for pulsatile flow measurements. Inter observer reliability was excellent for majority of measurements. The coefficient of variation for all diameter measurements for both observers ranged from 0.29% to 4.47%. 3D printed flow phantom that were nearly 2 years old maintained their structural integrity and produced ultrasonographic images similar to when they were first used. Validity and reliability studies between observers showed acceptable results. Researchers and clinicians can use this model for further training and simulation in the long term.

Keywords: 3-dimensional, 3D printed, flow volume measurements, flow phantom fatigue, carotid artery, preterm infant, ultrasound.

INTRODUCTION

Haemodynamic monitoring including cerebral blood flow when used in conjunction with clinical examination has shown to improve care provision in the neonatal intensive care.[1] Doppler ultrasound, a readily available modality, has been used to measure cerebral blood flow in term and preterm infants.[2, 3] Flow phantom models provide an excellent resource for training clinicians and researchers[4, 5] since a degree of operator skill and proficiency is required before cerebral blood flow measurements can be undertaken with minimal handling of the sick newborn infant. We previously produced realistic flow phantom models of the carotid artery of the preterm infant using different materials [6] including 3D printed materials[7] which produce echogenicities similar to biological tissues. We have also examined ideal measurements points to interrogate vessel diameter, an important parameter in flow volume measurements, using ultrasound which provided accurate and reliable measurements of lumen diameter.[8]

Flow phantoms, like any other equipment, are prone to wear and tear following repeated use and deterioration occurring over time. The diameter of the vessel lumen is around 2 mm which may lead to issues with turbulent flow and altered velocities over time due to breakdown of lumen wall. Flow phantoms of the carotid artery produced using 3D printed materials are novel and therefore there is lack of data on the long-term effect of time and multiple use on the quality and functionality of the 3D printed materials.

The aim of this work was to examine flow measurements using 18 to 24 months' old 3D printed phantom models of the carotid artery of preterm infants using Doppler ultrasound and to examine the reliability of measurements between observers.

METHODS

The phantom was designed and produced in the Clinical Physics Department of Barts Health NHS Trust.

Data collection for designing flow phantom

In order to determine the physical characteristics of the right common carotid artery in human preterm infants, data was collected from twenty-one randomly selected infants who were admitted to the tertiary level neonatal intensive care unit. As part of standard routine care, cerebral blood flow measurements were also performed in some infants as part of haemodynamic assessment when functional echocardiography and cranial ultrasound scans were performed. Some of the scans were obtained from infants who were recruited to a blood pressure study that had ethics committee approval (reference 12/LO/1553).[9]

Data used for designing flow phantom

From images obtained with a transducer placed over the anterior triangle of the neck, the following data were collected about the physical characteristics of the right common carotid artery:

d – cross sectional diameter of the blood vessel (cm)

Tp – proximal depth of the blood vessel from skin surface (cm)

Td – distal depth of the blood vessel from skin surface (cm)

L – distance between Tp and Td measuring points

Φ – angle formed between blood vessel and skin surface, calculated using the following formula;

$$\Phi = \tan^{-1} (Td - Tp) / L$$

Flow phantom production

Flow phantom design

All 3D printed components were developed using SolidWorks 3D CAD drawing software (Standard, SP1.0, 2018: Waltham, MA, USA) and printed on an Objet 260 Connex 3D printer (Stratasys, Eden Prairie, MN, USA).

Three 3-chamber models were developed as previously described with each chamber having a vessel of different Φ and d.[6, 8] The phantom model encasement was 3D printed using VeroWhitePlus, which is a rigid general-purpose material. The dimensions of the phantom (150 x 55 mm, 90 mm height) were compatible with typical transducers used in neonatal intensive care. Vessel supports protruded from either side of the chambers, with a central channel to hold the 3D printed neonatal carotid artery. These supports maintained the vessels at the correct position, relative to the phantom surface. Various phantom vessel internal diameters were used (0.158, 0.196 and 0.244 cm) at a Φ of 10°, 15° and 20°. The internal base of the phantom, consisted of an angled and soft surface made from Agilus30Black (rubber like material), to minimise reflections of the ultrasound energy back to the transducer.

Each vessel was 3D printed using a digital material mixture of VeroWhitePlus and Agilus30Black. The digital material was the result of combining these two materials, in specific concentrations to create a composite material with hybrid characteristics. The vessels used in this study had a Shore-A: 95 hardness value on the Durometer Shore hardness scale, with a wall thickness of 0.5mm. The Shore A scale measures the hardness and flexibility of a wide range of materials.

The vessels were encased in an agar and glycerol-based tissue mimicking material (TMM).[10] The phantom vessel was embedded in the TMM at a depth of 10 mm from the phantom surface to the upper point of the tubing. The top of the phantom was sealed with a 1.0 mm layer of low-

density polyethylene (LDPE) plastic (PSG Group Ltd, London, UK), this minimised desiccation, and thereby increasing phantom lifetime. Each vessel was printed with two removable formers (made from VeroWhite) which were positioned centrally in the vessel. The formers could be carefully removed from each vessel. The purpose of the formers was to minimise the quantity of support material to be removed after printing. Subsequently, precision ground rods of increasing diameter were inserted through the vessel, to provide assurance that no residual material was left in the vessels. Additionally, the rods provided assurance the vessel lumens were of the correct specified dimensions.

Testing the flow phantom

The flow phantom was set up in the neonatal unit where the ultrasound scanner was housed. Blood mimicking material (Model 707, ATS Laboratories, Norfolk, VA USA) with a density of $1004 \pm 10 \text{ kg/m}^3$ was run through the model. The flow was adjusted by varying the height of the reservoir containing the blood mimicking fluid or by adjusting the outflow valve attached to the end of the line. This produced continuous flow through the circuit. Pulsatile flow, simulating physiological flow, was achieved by incorporating a peristaltic pump (Watson Marlow, model MHRE 72) into the circuit. The pump was run at speeds that produced a pulsatile flow of 120–150 pulses per minute in keeping with the physiological heart rates in premature infants.

The Clinical Physics data were used wherein the measurement of the flow was achieved by independently measuring the accumulation of the mass of the blood mimicking fluid as follows. The fluid was collected in a container placed on a sensitive load cell (Compression Load Cell, model 1004, Tedea Huntleigh) that acted to dynamically measure the accumulative mass of the blood mimicking fluid. The load cell output was measured as one arm of a classical resistance bridge circuit set within a full bridge module (National Instruments NI 9237). The module was connected via a USB link to a monitoring laptop that was running data acquisition and visualisation software LabVIEW real-time software (v. 14.0.1, National Instruments, Newbury, UK).

Ultrasound image optimisation used for diameter measurements

After placing an adequate amount of water-based ultrasound jelly on the flow phantom, the cross-sectional view of the vessel was obtained represented by the presence of 2 echogenic areas in the vessel wall (Figure 1). The zoom function in the ultrasound machine was utilised to increase image size. Focus range was adjusted to include the whole vessel and the midpoint of the focus was aligned to the midpoint of the vessel. The scanner gain settings were adjusted to an appropriate level to visualise the vessel lumen. The image was frozen and scanner calipers were used to measure the vessel diameter.

Measurement points for diameter measurements

Diameter is an important parameter as measurement errors can square when calculating flow. Flow volume (Q) was calculated using the following formula;
 $Q = IWMV * (\pi d^2 / 4)$ in ml/min

where $IWMV$ is intensity weighted mean velocity (cm/s) and d is cross-sectional diameter of the vessel lumen (cm).

Therefore, diameter is an important parameter as measurement errors can square when calculating flow. Based on our previous work, we used the leading edge to centre for measuring the diameter (Figure 1). All diameter measurements were performed with a 7-15 MHz 'hockey-stick' linear array probe using the Phillips iE33 ultrasound system (Bothwell, USA). Diameter measurements were performed by two observers; SSP (observer 1) and ASA (observer 2) who were blinded each other's measurements and to the characteristics of the chamber (vessel diameter and Φ).

Measurement of flow

The ultrasound probe was placed parallel to the flow phantom vessel after placing an adequate amount of ultrasound gel wedge. The wall filter was set to a minimum. Care was taken to ensure that the lowest angle of insonation practically possible and a clear Doppler spectral signal was obtained. The ultrasound machine's automated function was used to acquire a time average peak velocity and time average mean velocity, both of which were recorded along with the angle of insonation. Flow measurements were performed by calculating half of the time averaged peak velocity.

Preparation of the flow phantom

The flow phantom was examined for structural integrity prior to repeated measurements 18 to 24 months since production. One of the phantoms had a small amount of discolouration on the underside of the LDPE surface, which was in contact with the agar glycerol based TMM. The top outer casing was removed, and the LDPE surface cleaned to reduce potential interference with measurements. The TMM and the vessel were not disturbed.

Statistical analysis

Data was summarised using mean (standard deviation) for normally distributed data. The validity of measurements was examined using Bland-Altman plot and expressed as difference in percentage.[11]. Flow volume measurement by both observers were compared with flow measurements measured using clinical physics data. Reliability between observers was checked using intra class correlation (ICC) using 2-way mixed ANOVA with observers being fixed factors and measurements being random factors.[12, 13] The coefficient of variation (CoV) (mean SD/Mean)*100 was also calculated as an additional measure of agreement and results expressed as percentage. The grading of strength of correlation was assessed using previously described methods.[14] All statistical analyses were performed using IBM SPSS v22 (Chicago, IL, USA) and GraphPad Prism version 9.1.0.

RESULTS

A total of 36 measurements were carried out on multiple flow phantoms with varying characteristics. 9 (50%) measurements were performed using continuous flow and 50% measurements using pulsatile flow. Doppler signals using continuous and pulsatile flow produced patterns mimicking physiological flow (Figure 3-4). The flow phantom did not show any obvious signs of wear and tear externally. Echogenicities obtained were similar to those obtained when the 3D printed flow phantom was first examined. There was no obvious evidence of deterioration of the vessel lumen wall on ultrasound examination. (Figure 2).

Vessel diameter measurements

The mean (SD) diameter measurements performed by observer 1 and 2 were 0.196 (0.033) cm and 0.193 (0.032) cm respectively using continuous flow measurements, table 1. The mean (SD) diameter measurements performed using pulsatile flow measurements for observer 1 and 2 were 0.196 (0.036) cm and 0.194 (0.035) cm respectively. The CoV, for continuous flow measurements, for observer 1 for phantom 1, 2 and 3 were 0.63%, 2.09% and 0.65% respectively whereas that for observer 2 were 1.94%, 0.78% and 4.47% respectively. For pulsatile flow measurements, the CoV for observer 1 for phantom 1, 2 and 3 were 1.33%, 0.29% and 0.96% respectively whereas that for observer 2 were 2.09%, 4.00% and 0.43% respectively.

Bland Altman analysis for continuous flow diameter measurements showed a mean bias (95% LOA) of -0.004 (-0.012 to 0.005) cm for observer 1 and -0.006 (-0.022 to 0.010) cm for observer 2 (Figure 5 A-B). Bland Altman plot analysis for pulsatile flow diameter measurements demonstrated a mean bias (95% LOA) of -0.003 (-0.007 to 0.001) cm for observer 1 and -0.005 (-0.017 to 0.006) cm for observer 2 (Figure 5 C-D).

Flow volume measurements

A mean bias (95% LOA) of 0.382 (-5.306 to 6.070) ml/min for observer 1 and 3.516 (-4.030 to 11.06) ml/min for observer 2 for continuous flow measurements on Bland-Altman analysis (Figure 6 A-B). For pulsatile flow measurements, the mean bias (95%LOA) for observer 1 was -0.908 (-7.422 to 5.605) ml/min and that for observer 2 was -2.155 (-7.580 to 3.270) ml/min (Figure 6 C-D).

Inter observer reliability

Inter observer reliability for diameter measurements using continuous flow with ICC(3,1)[12, 14] was 0.983 (95% CI 0.928 to 0.996); resulting in an 'almost perfect' [13] grade (Table 1). For pulsatile flow diameter measurements, inter observer reliability using ICC(3,1)[12, 14] was 0.986 (95% CI 0.983 to 0.997); resulting in an 'almost perfect' [13] grade (Table 1).

Continuous flow measurements showed a lower ICC (3,1)[12, 14] 0.212 (95% CI -0.485 to 0.774) but reliability was much higher for pulsatile flow measurements with an ICC (3,1)[12, 14] 0.827 (95% CI 0.409 to 0.958).

DISCUSSION

We performed flow volume measurements using 3D printed flow phantom model of the carotid artery of preterm infants that were 18 to 24 months old. The structural integrity of the flow phantoms was preserved and there was no evidence of vessel wall breakdown on ultrasound imaging. This study found flow volume measurements to be within acceptable limits and excellent inter observer reliability for the majority of parameters that were measured, results mimicking those when this flow phantom was first studied.[7]

Echogenicities produced using the 3D printed material were similar those seen with biological tissues after adjusting for gain. There were no changes in the echogenicities observed when compared to ultrasound images obtained when the flow phantom was first studied. The vessel diameter echogenicities were very similar to our previous flow phantom model using polytetrafluoroethylene (PTFE),[6]. In addition, 3D printed materials also had preserved elastic

properties when a peristaltic pump was used to mimic physiological blood flow. The vessel lumen on long axis view did not have any obvious irregularities representing degradation of the inner lumen walls nor were there any visible acceleration of TMM with the different velocities studied.

Intensity weight mean velocity was used to perform flow measurements in our previous work.[6] For this work, the ultrasound scanner did not measure low velocity flow despite adjusting the wall filter settings to the minimum level. As a result, intensity weight mean velocities were higher resulting in overestimation of flow volume measurements. Therefore, we took the average of the time averaged peak velocities for flow volume measurements in this work.

We found excellent inter observer reliability for the majority of diameter measurements performed in this study with CoV values being similar to our previous work[2, 6, 7, 15] and lower than those performed in newborn infants.[2, 3] Our values were similar to other studies that used 3D printed vascular models for different purposes.[16, 17] The inter observer reliability for diameter measurements using pulsatile flow was comparatively higher when compared to pulsatile flow. One possible explanation for this could be due to the pulsatile flow measurements being performed after continuous flow measurements which meant that the observers were more used to the technique resulting in between reliability and lower CoV values for both observers.

Validity studies for flow volume measurements for both observers fell within the acceptable limits of $\pm 30\%$ for cardiovascular measurements[18] for almost all measurements. Observer 1 measurements had lower variance when compared to observer 2 which could be accounted for by operator experience. Further evaluation of the outliers for observer 2 showed that for the flow measurements, the measured value was 15.9 ml/min and the actual volume was 23.8 ml/min. This may be a one-off recording as the other two recorded values were much closer. (first measured volume of 16.6 ml/min and actual volume 20.1 ml/min and second measured volume 18.9 and actual volume 19.7 ml/min). The second outlier was for diameter measurements with continuous flow measurements. The lumen diameter was measured as 0.221 cm with the actual lumen being 0.244 cm. However, on repeat measurements with pulsatile flow, there were no outliers. One plausible explanation is that with more measurements, the operators became more proficient and the chance of errors reduced. This is supported by the finding of narrower 95% limits of agreement for both observers with pulsatile flow measurements which were performed after continuous flow measurements. Reassuringly, the same operators who performed the initial measurements carried out these repeat measurements. This way, the operators could compare the physical characteristics of the flow phantom and the ultrasound images. This also reduced the chances of operator related variation that one would have encountered if different operators carried out the experiments.

This study has a few limitations. We did not examine 3D printed materials of varying ages for identifying other problems of phantom fatigue. The vessel lumen that was studied did not have obvious evidence of deterioration that was found using ultrasound. Small degrees of lumen wall wear and tear occurring at a physical level could not be ruled out as when did not open up the flow phantoms and physically inspect the vessel lumen wall. We examined physiological flow rates and did not investigate the integrity of the flow phantoms using very high flow rates.

Lastly, we did not investigate intra observer reliability but have carried out multiple such studies previously.

This study examined flow (both continuous and pulsatile flow) volume measurements, using flow phantoms models of the carotid artery in preterm infants with varying characteristics. We found minimal bias and excellent inter observer reliability for the majority of measurements. The integrity of the walls remained intact with no leakage from the walls. A prolonged phantom lifetime improves the cost effectiveness of the phantom and demonstrates the repeatability of measurements between users over time. This is a valuable resource which can be used in the long term for simulation and training batches of clinicians and researchers.

CONCLUSION

The structural integrity of the 3D printed flow phantoms was preserved when repeated measurements were carried at 18 to 24 months of phantom age. Flow volume measurements were within acceptable limits with good inter observer reliability. These 3D printed flow retained their structure and ultrasound properties and phantoms are a very valuable and useful resource for training researchers and clinicians in the long term. Further work should consider examining phantom fatigue after several years of use.

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TABLES AND FIGURES

Table 1. Vessel diameter measurements by all observers with flow phantom characteristics and descriptive analyses. Unless specified, all figures represent cms. Absolute difference derived as actual lumen difference minus mean diameter of both observers. SD – Standard deviation.

Type of flow	Parameter	Observer 1 Mean (SD, 95% CI)	Observer 2 Mean (SD, 95% CI)	Inter observer reliability ICC (95% CI)
Continuous (n=9)	Vessel diameter (cm)	0.196 (0.03, 0.17 to 0.22)	0.193 (0.03, 0.17 to 0.22)	0.983 (0.928 to 0.996)
	TAPV (cm/s)	38.7 (16.9, 25.7 to 51.6)	42.4 (15.5, 30.5 to 54.4)	0.977 (0.903 to 0.995)
	Angle of insonation (degrees)	49.6 (6.1, 44.9 to 54.2)	52.7 (4.5, 49.2 to 56.1)	0.523 (-0.163 to 0.868)
	Calculated flow (ml/min)	31.5 (3.4, 28.9 to 34.1)	34.3 (3.0, 32.1 to 36.6)	0.212 (-0.485 to 0.774)
Pulsatile (n=9)	Vessel diameter (mm)	0.196 (0.04, 0.17 to 0.22)	0.194 (0.03, 0.17 to 0.22)	0.986 (0.983 to 0.997)
	TAPV (cm/s)	27.7 (15.6, 15.7 to 39.8)	27.6 (15.1, 16.0 to 39.2)	0.953 (0.807 to 0.989)
	Angle of insonation (degrees)	43.8 (6.1, 39.1 to 48.5)	43.6 (4.9, 39.8 to 47.3)	0.552 (-0.123. to 0.878)
	Calculated flow (ml/min)	21.9 (5.0, 18.1 to 25.7)	21.2 (4.8, 17.5 to 24.9)	0.827 (0.409 to 0.958)

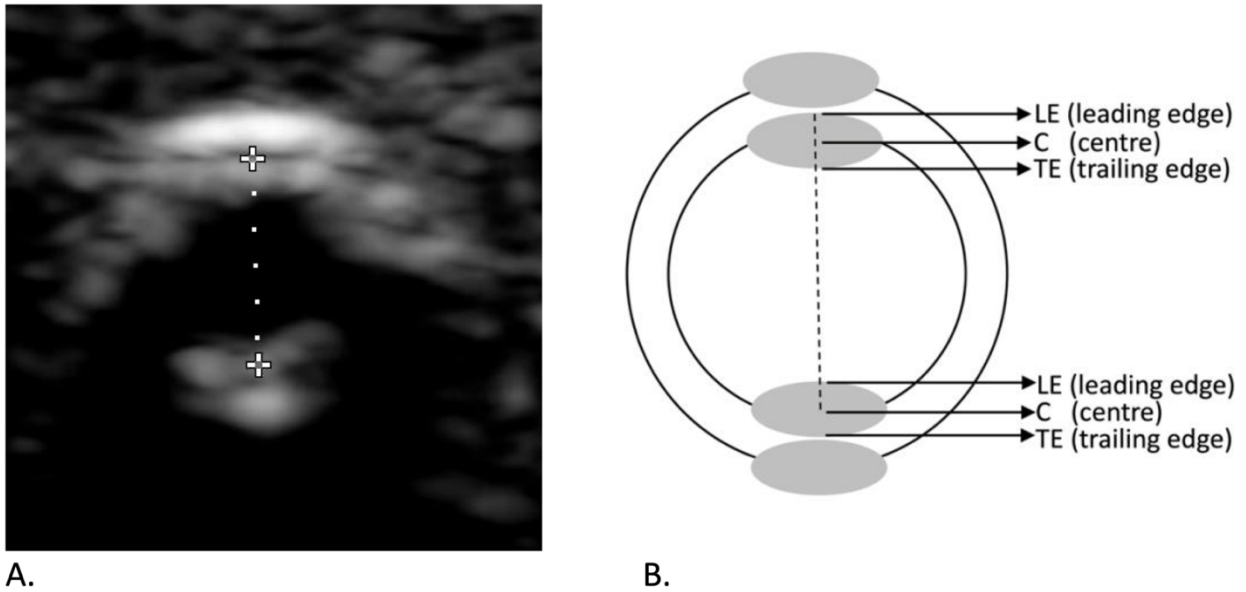


Figure 1. (A) Cross section of the vessel in the flow phantom. (B) Schematic illustrating the leading edge (LE), centre (C) and trailing edge (TE) of the echodensity from where measurements are taken.

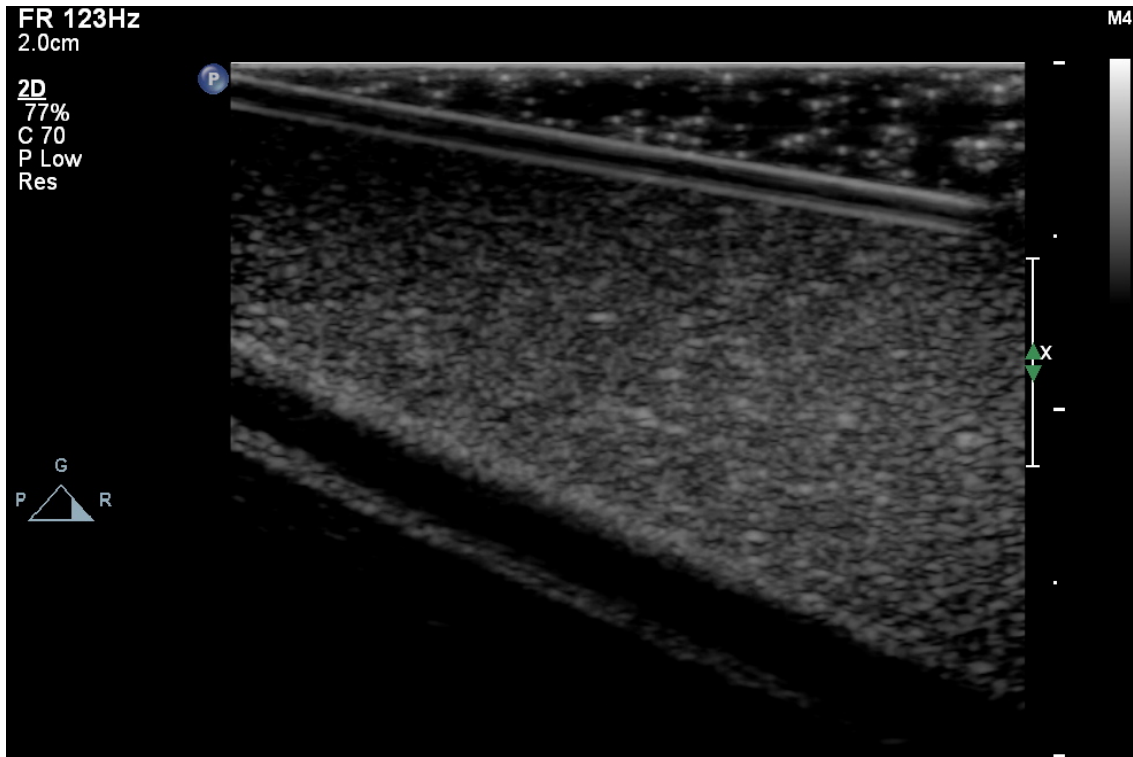


Figure 2. Ultrasound of the length of the vessel in the flow phantom illustrating continuity with regular margins and no obvious defects.

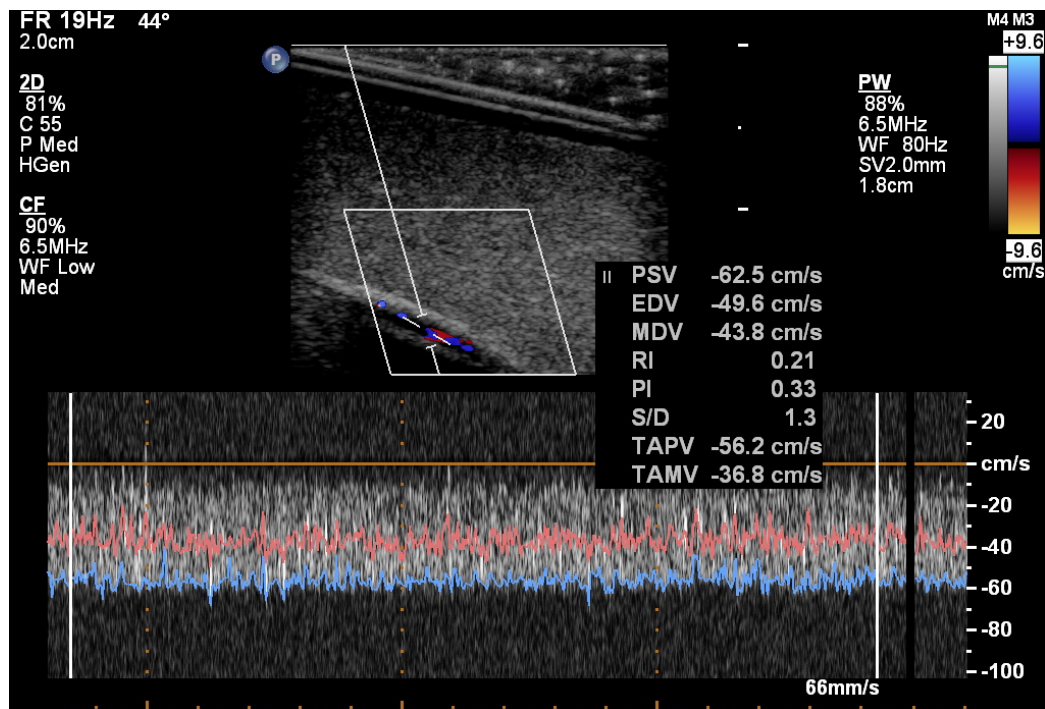


Figure 3. Continuous flow automated measurements of various parameters.

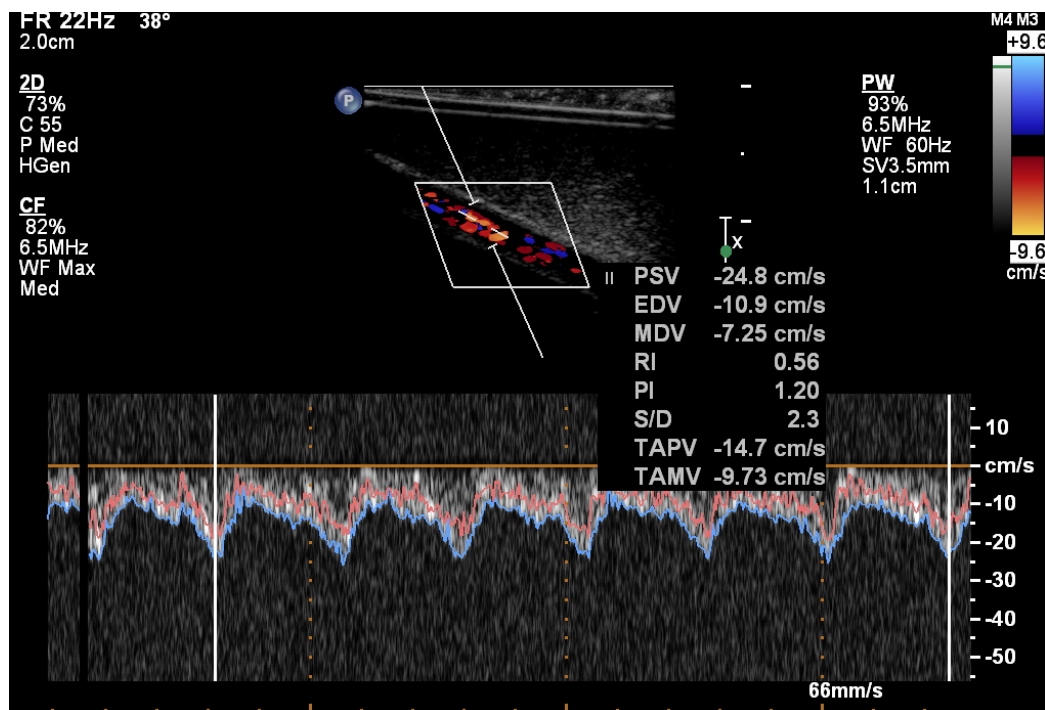
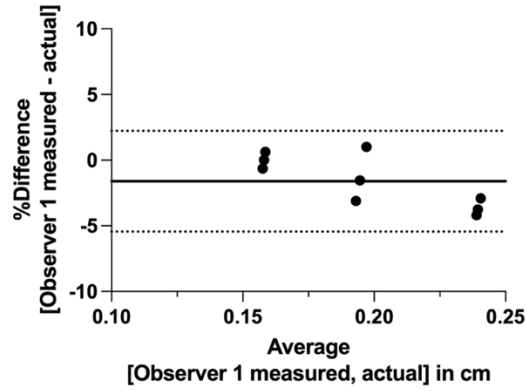
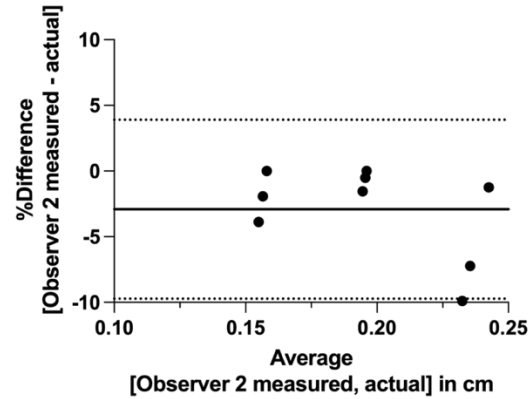


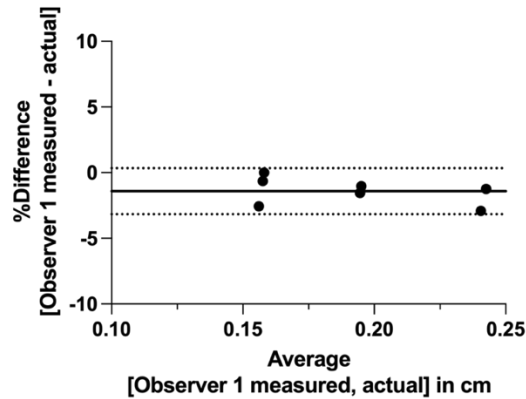
Figure 4. Pulsatile flow automated measurements of various parameters.



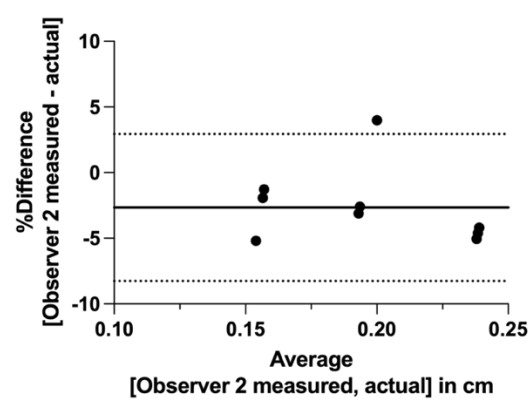
A.



B.



C.



D.

Figure 5. Comparison of Bland-Altman plots between observer 1 and 2 for continuous flow vessel diameter measurements (A,B) and pulsatile flow vessel diameter (C,D). Solid lines represent mean bias and dashed lines represent upper and lower 95% limits of agreement respectively.

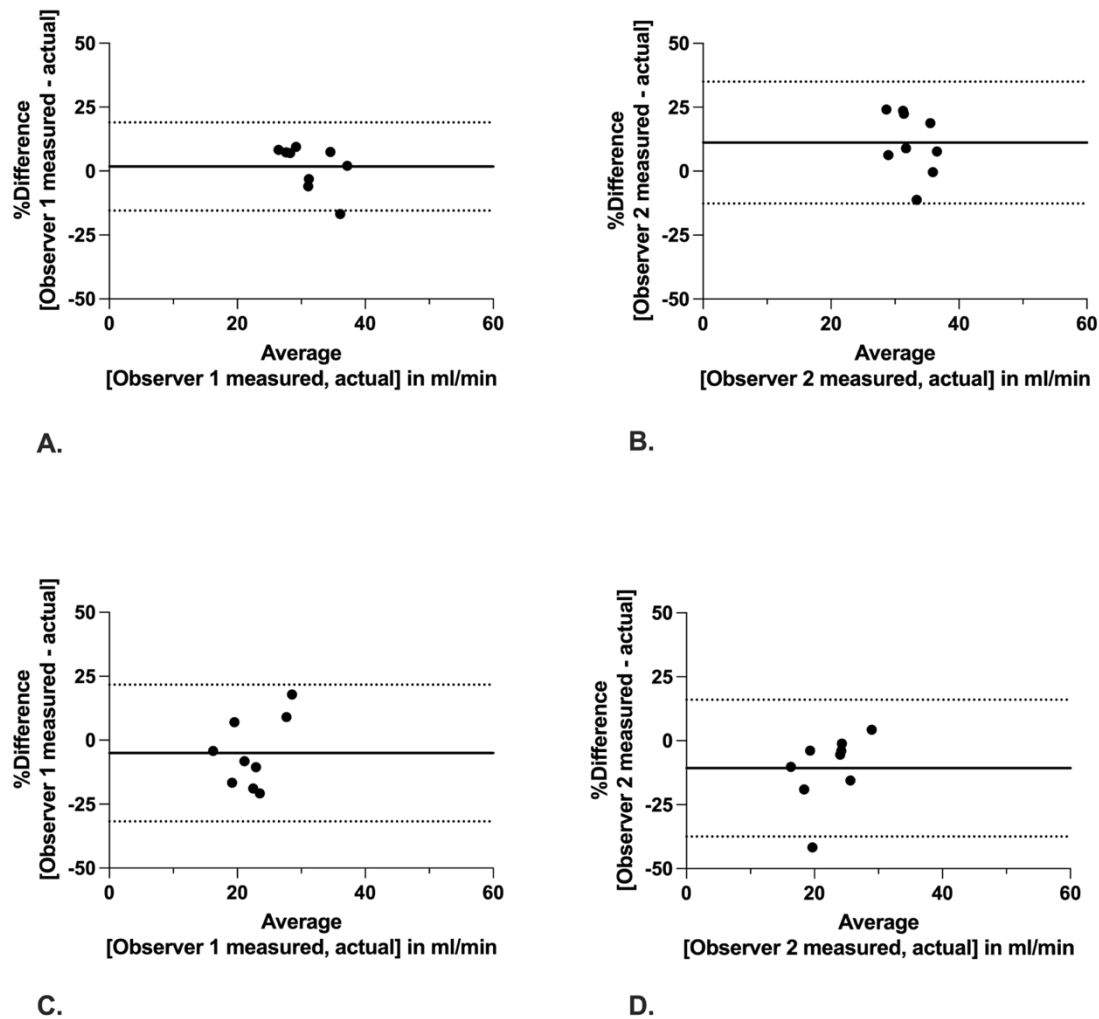


Figure 6. Comparison of Bland-Altman plots between observer 1 and 2 for continuous flow measurements (A,B) and pulsatile flow measurements (C,D). Solid lines represent mean bias and dashed lines represent upper and lower 95% limits of agreement respectively.