INTRODUCTION

Particle image velocimetry (PIV) has been used in regulatory submissions to the FDA for pre-clinical and post-market evaluations of flow fields in medical devices, such as artificial heart valves, blood pumps, and stents. The velocity and shear fields obtained from the PIV experiments are also used to validate computational fluid dynamics (CFD) data accompanying the submissions. However, previous studies have questioned the accuracy of PIV measurements in regions of high shear and low velocity (regions prone to hemolysis and thrombosis). Currently, there is no clear estimate of the amount of uncertainty involved in measuring various flow parameters in these high-risk regions. The objective of this study was to perform an inter-laboratory PIV study in a simplified nozzle model and quantify the uncertainties involved in measuring flow quantities relevant to blood damage, such as near-wall velocity, viscous and Reynolds shear stresses, size and velocity within recirculation regions, and for estimating an index of hemolysis.

MATERIALS AND METHODS

The simple benchmark nozzle model [Fig. 1a] used in this study produces flow fields similar to those occurring in some medical devices and consists of a gradual flow constriction, a narrow throat region, and a sudden expansion region where a fluid jet exits the center of the nozzle with recirculation zones near the model walls. PIV measurements of mean velocity, shear stress, and turbulent flow quantities were made in the benchmark device at 12 different cross-sections by three independent laboratories. The range of nozzle throat Reynolds numbers (Re_throat) from 500 to 6500 encompassed the laminar, transitional, and turbulent flow regimes. A standard operating procedure was developed to control the temperature and flow conditions during experiments, and to minimize systematic errors during PIV image acquisition and processing [1].

FLUID PROPERTIES: A Newtonian fluid composed of 50% sodium iodide (NaI), 20% glycerin, and 30% water by weight was used as the blood analog fluid. The dynamic viscosity and density of the blood-analog fluid ranged from 6.75 to 7.8 cP and 1.66 to 1.77 g/cc, respectively, depending on the operating temperature. The blood analog fluid was formulated to match the refractive index of the acrylic (~1.49) and make the model optically transparent to the laser and the camera. The flow was seeded using 10-micron hollow glass spheres (Lavision, Göttingen, Germany).

BOUNDARY CONDITIONS: A fully developed flow profile was attained at the model inlet for all laboratories for Re_throat ≤ 5000 [1].

PIV SYSTEM: The PIV system and the cross-correlation algorithm used for imaging the flow field and estimating the velocity were different for each laboratory (TSI Inc., Shoreview MN; LaVision Inc, Germany). The final PIV image resolution was 0.144-0.176 mm for Lab-1, 0.176 mm for Lab-2, and 0.11 mm for Lab-3. An error analysis estimated the cumulative uncertainty in the velocity measurements, due to differences in PIV algorithms, image resolution, inlet flow conditions, and fluid property measurements between labs, to be ~10% [1]. To estimate the viscous shear stress from the velocity data, a backward difference operator was used near the nozzle wall and a central difference scheme was used at the rest of the locations. No special curve fitting algorithms or wall-finding tools were used to estimate the wall shear stress. The inter-laboratory uncertainties in velocity and shear stress were expressed as one standard deviation divided by the mean value.
RESULTS

Figure 1 shows the axial velocity and viscous shear stress profiles at select radial locations for Re_{throat} = 3500. The flow was fully developed at the entrance region, and the peak velocity measured by each lab matched the theoretical maximum velocity for Poiseuille flow within about 5% [Fig. 1b]. The velocity profiles measured in the throat and sudden expansion regions [Figs. 1c and 1d] were similar among the three laboratories, with the inter-laboratory uncertainties in peak velocity estimated to be less than 10%.

Similarly, at the entrance region, the shear stress profiles from the participating labs matched well with the theoretical profiles for Poiseuille flow [Fig. 1e]. Ignoring the first four near-wall data points, the experimental shear data matched the theoretical solution within ~3%. However, near the wall (for radius > ~5.6 mm, i.e. three or four data points from wall), the shear stress values were inaccurate for all three labs and the inter-laboratory uncertainty in wall-shear stress was ~50%. In the throat region [Fig. 1f], where the pipe radius reduced from 6 mm to 2 mm, the maximum measured shear stress (wall shear stress) varied significantly (between 24 Pa and 75 Pa) among the three laboratories. While the peak velocity matched within ~10% at this location, the corresponding uncertainty in wall-shear stress was greater than 50%. However, downstream of the sudden expansion [Figs. 1d and 1g], where the maximum shear stress occurred at the shear layer and not at the wall, the inter-laboratory uncertainty in peak velocity and the peak shear stress was less than ~5% and ~17%, respectively.

Similar uncertainty analyses were performed for other flow variables, such as width and velocity of the re-circulation region [Fig. 2]. In addition, the uncertainty in the shear stress data was also used to estimate the error in predicting hemolysis using the empirical power-law correlation developed by Giersiepen et al. [2] [Fig. 2]. The error in measuring flow quantities such as center-line velocity and recirculation region size was small (< 9%, Fig. 2). However, the experimental uncertainties increased significantly (> 60%) while measuring quantities more relevant to blood damage, such as wall shear stress and the hemolysis index [Fig. 2]. A subsequent error analysis showed that the mesh resolution used for our PIV experiments, which was representative of the PIV resolution used in actual medical device evaluations, was not small enough to resolve the high shear and low flow regions near the vessel wall adequately.

DISCUSSION

Device manufacturers use velocity and shear-stress fields, estimated from PIV or PIV-validated CFD analyses, to quantitatively predict the safety of devices with respect to thrombosis and hemolysis. Our inter-laboratory study showed that uncertainties associated with measuring some of the flow variables, such as shear stress, could be very high and should be properly accounted for while making any device safety claims. Furthermore, the results indicate that special algorithms might be necessary for accurately measuring near-wall velocity and wall-shear stress, where localized blood damage occurs. Currently, no such algorithm is available in commercial PIV analysis systems. An industry-wide consensus standard that provides a methodology for minimizing these experimental uncertainties is essential to enhancing the reliability of PIV and PIV-validated CFD data in the evaluation of medical devices.

FUTURE WORK

Subsequent studies will focus on evaluating the uncertainties associated with measuring turbulent shear stresses, which can also influence the blood damage potential of a medical device.

ACKNOWLEDGEMENT

Financial support from FDA’s Critical Path Initiative (CPI) program is gratefully acknowledged.

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