



AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

Summary – 04-Mar-2024

Attendees: Brian Fowlkes, Jim Zagzebski, Haylea Weiss (AIUM), Michelle Robbin, Jonathan Rubin, Kunio Hashiba, Jing Gao, Stephen Pinter, Paul Carson, Megan Russ, Ted Lynch, Rimon Tadross

The team discussed a variety of topics related to their project. They began with a review of Lizbeth Dominguez's (U. Wisc.) summary about phantom fluids, followed by a conversation about the feasibility of measuring backscatter coefficients from blood mimicking fluids. The team also discussed the impact of blood flow on power readings in color flow imaging and the need for additional specifications of the fluid. The meeting concluded with a discussion about the impact of the backscatter level of blood mimicking fluid on the performance of Doppler ultrasound systems.

Summary by Chapters: Phantom Fluids Formulation Discussion

The meeting commenced with a roll call and a review of the previous meeting's minutes. The focus of the discussion shifted to a summary on specifications for phantom fluids. The team discussed the formulations and their properties, with Ted confirming that their current formulation follows a variant of the Ramnarine formula. The conversation also touched on potential supply issues and the equivalence of properties to human blood.

Backscatter Coefficients in Blood Mimics: Feasibility and Collaboration

The team discussed the feasibility of measuring backscatter coefficients from blood mimicking fluids. Ted expressed concerns about the limitations of their current setup, while Jim suggested exploring the possibility of collaboration with other labs. The team also debated the importance of measuring true backscatter properties versus just ensuring a similar integrated backscatter. The discussion concluded without a clear decision but with several ideas to be explored further.

Blood Flow Effect on Medical Imaging Power Readings

Brian and Michelle discussed the effect of blood flow and its influence on the power readings in medical imaging. Brian explained that the slowing of blood flow can lead to increased echogenicity and subsequently, higher power readings. However, this only becomes a complication if the backscatter coefficient is not constant with the type of blood flow, i.e. Rouleaux formation. There was also a discussion about the difficulty in achieving a 100% blood estimate in small vessels but that shear in such vessel would prevent Rouleaux. Despite this, they concluded that the technique is unlikely to be significantly affected in normal clinical situations, particularly when there is always a high amount of shear, and that it could still be useful in situations such as fistulas.

Specifying Backscatter Coefficient Requirements

The team discussed the need for additional specifications of the fluid and phantom, particularly concerning the backscatter coefficient. There was a consensus that avoiding aggregation was already addressed in the profile. Ted suggested the possibility of integrating the backscatter

coefficient across a range of frequencies. However, he emphasized that while a precise scientific specification might be challenging to measure, a quality check to ensure proper mixing and absence of aggregation would be more practical and important from a manufacturing standpoint. The current specification for the fluid backscatter level, at least 30 dB lower than that of a background material, was also referenced.

Color Power Sensitivity Testing Protocol

The team discussed the importance of testing the sensitivity of color power, with a focus on ensuring that the amount of color power returned is representative of what would be expected in vivo. They also emphasized the need for a more sensitive test than just visually confirming blood under bmode. The idea of using a protocol for color power and checking its consistency was proposed. The team agreed on the need to verify that their current testing methods meet the proposed criteria and suggested using a good Doppler power meter for this purpose.

Backscatter Level Impact on Ultrasound Systems

The team discussed the impact of the backscatter level of blood mimicking fluid on the performance of Doppler ultrasound systems. They considered the potential issues if the backscatter level was lower than expected, such as giving a false sense of the depth range over which measurements could be reliably made. The team agreed that the current specification of a minimum 30 dB lower backscatter level might be problematic and suggested a need to revisit this. They also considered the impact of changes in the backscatter level over time due to factors like clumping, and the need for a protocol to check and compare backscatter levels. The team concluded that understanding the context of the specification, such as whether it's for system certification or QA/QC, might influence the required tolerance level.

Data Collection and Analysis Improvements for Next Profile Stage

Brian discussed the needs related to achieving next stage for the profile, specifically in terms of data collection and analysis. A potential solution was considered, which involves setting up a system to process data offline and maintaining proprietary information. The next meeting was scheduled for May 6th, with the decision made to skip the April meeting due to other commitments. There were also some uncertainties about the recording of the meeting.

Next Steps

1. Brian will reach out to Lizbeth and Ivan to discuss the feasibility of measuring backscatter coefficients from blood mimicking fluids.

2. Brian will consider a possible protocol to help people evaluate their relative backscatter for their blood mimicking fluid.

3. Brian will look over the information from the RSNA on how the spreadsheet works and consider its potential use for future testing.

4. Brian will work on developing a standalone software package for offline data processing.