Scientific Validation of MRI Blood Flow Analysis Packages from MedVoxel Systems Inc.

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Scientific Validation of MRI Blood Flow Analysis Packages from MedVoxel Systems Inc.

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I. OBJECTIVES:

To evaluate a commercially available medical imaging software package from MedVoxel System Inc. for blood flow analysis in cardiovascular applications.

II. INTRODUCTION:

Blood flow measurement based on phase-contrast magnetic resonance imaging (PC-MRI) has been recognized as a valuable and accurate technique to assess hemodynamics in vascular and valvular diseases. Noninvasive cardiac imaging protocols commonly include evaluations of heart anatomy, assessments of performance of myocardial contractility, and analysis of blood flow to help early diagnosis and management of patients with heart conditions. Recent developments on rapid cine imaging techniques provide a continuous depiction of heart motion, which is widely used for evaluation of myocardium contractility, cardiac function, and valve abnormalities. However, the multi-frame cine technique requires timely effort for image segmentation and post data processing, which significantly reduces the overall utilization rate of MRI scans in the clinical environments. Thus, dedicated, time-efficient cardiac MRI analysis software could extensively improve patient throughput of the conventional cardiac MRI and eventually reduce the heavy financial burden of capital expenditure of MRI facilities. The objective of this technical report is to perform comprehensive software evaluations on a small population of human MRI data by using the blood flow analysis package from MedVoxel System Inc.

III. EVALUATION CRITERIA:

All image acquisitions were performed with a clinical MRI system (Siemens Healthcare, Erlangen, Germany). The FDA-approved commercial cardiovascular application software (Argus, Siemens Healthcare, Erlangen, Germany) was used and compared to the blood flow analysis package from MedVoxel (hereinafter referred to as “HeartPro Flow”). Cardiac flow images from six human subjects were uploaded to the web-based Digital Imaging and Communications in Medicine (DICOM) database. In each MRI dataset, post image analysis was performed by using both Argus and HeartPro Flow software. In this report, the evaluation criteria were classified into (i) software utilization, (ii) measurement accuracy and (iii) software functionality. Software performance evaluation of HeartPro Flow was compared to the standard flow analysis software (i.e., Siemens Argus) at the Institute for Biodiagnostics, National Research Council.

Specific function evaluations are listed as below:

(i) **Utilization:** speed and workflow of flow image analysis, design of user interface, and study reporting system;
(ii) **Accuracy:** peak flow velocity, positive/negative/net flow volume, and location-dependent concomitant phase error; and
(iii) **Functionality**: in-plane flow measurement, multi-directional flow measurement, beat-to-beat real-time flow measurement, automatic segmentation algorithm, and phase unwrapping capability.

IV. SUMMARY:

HeartPro Flow is one of the first web-based medical image analysis software packages with a specialty of cardiovascular MRI. The goal of the software design was to optimize workflow of the post processing steps after the conventional MRI flow scans. Simple user interface and the reliable algorithm of segmentation and phase unwrapping are the major advantages of HeartPro Flow compared to existing software packages. HeartPro Flow also minimizes prerequisite training to conduct blood flow analysis and reduces imaging processing time in daily work. Also, several minor software improvements or potential joint research projects will make this product more successful in the current and future clinical cardiovascular setting.

Strengths:

1. Novel web-based database and software applications provide a 24/7 working environment for cardiologists and radiologists, who have internet access and a standard personal computer.
2. Automatic and straightforward user interface reduces post processing time and avoids possible man-made mistakes

Weaknesses:

1. Limited or no software validation reports have been published in major international journals (e.g., Journal of Cardiovascular Magnetic Resonance, Radiology, Journal of Magnetic Resonance Imaging and Magnetic Resonance in Medicine). A long-term multi-center and multi-vendor trial will be essential to collect valuable information for future product promotion.
2. Performance of web-based analysis software might be delayed by the narrowed internet bandwidth and network stability between the server and client's personal computer.
3. The functionality of customized image brightness and contrast control is required for most medical imaging software to adopt the preference of individual users.
4. Lack of function to analyze multiple regions of interest (ROI) in one slice (Note: This is commonly used to quantify flow volume inconsistency between the ascending and descending aorta.)
5. Additional acquisition details are stored in the Dicom header section. The function to read and modify Dicom information is strongly recommended. Furthermore, the function to anonymousize patient information will be useful for protecting their privacy.

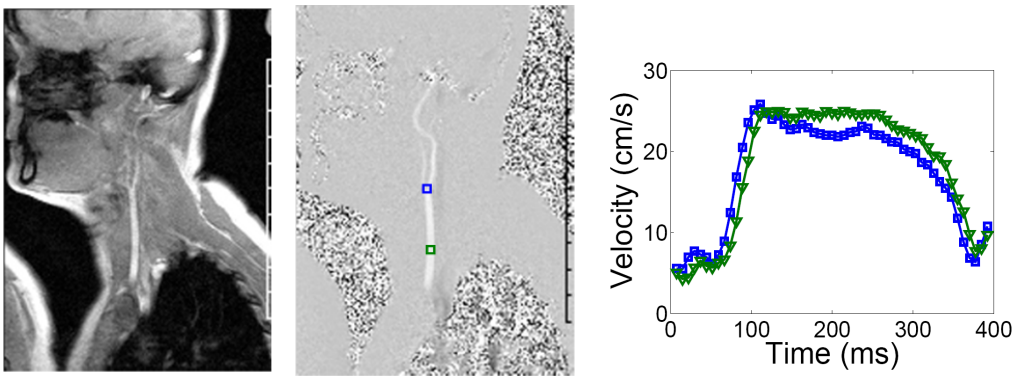
Opportunities and Possible Joint Research Projects:

1. Development of the post processing function to calculate pulmonary-to-systemic (Qp/Qs) shunt ratios for diagnosis of congenital septal defects

   Motivation: Quantification of left-to-right cardiac shunt ratios is critical to diagnose septal defects in patients. Invasive cardiac catheterization with oximetric technique is commonly performed in clinical practice (1). Recent developments of PC-MRI have been recognized as a noninvasive alternative to diagnose septal defects by calculating the ratio of pulmonary and systematic circulations (1-3). To our best knowledge, no commercial software is able to efficiently analyze pulmonary-to-systemic shunt ratios using PC-MRI flow data.

2. Development of a post processing function to estimate arterial stiffness using the pulse-wave velocity (PWV) measurement technique

   Motivation: The stiffness and thickness of carotid arteries are well known clinical indicators of atherosclerosis and cerebrovascular diseases. Local pulse wave velocity (PWV), measured by PC-MRI (left and center), provides a noninvasive method to estimate the stiffening of the elastic arteries that corresponds to an increase in aortic blood pressure (4, 5). The standard analytic method is described below: At each location along the artery of interest, two or more data points are required on the leading edge of the velocity waveform to differentiate between arrival times of pulse wave. The quotient of transit time-delay between arrivals of pulse wave and distance represents the estimated PWV in local measurement (right).



3. Quantification of Area at Risk of myocardial infarction region using the T_2 or T_2* mapping technique

   Motivation: Acute myocardial infarction (also known as heart attack) is injury of the myocardium caused by the sudden blockage of a coronary artery. The presence of myocardial edema has been clinically proved as a precursor of myocardial infarction. The T_2 or T_2* relaxation characteristics

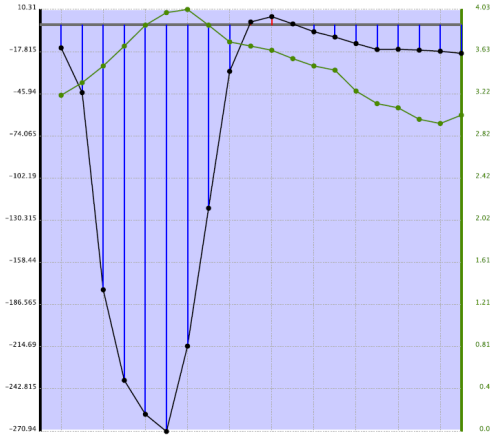
are essential for detecting the increase of water content in “Area At Risk” of myocardial infarction (6, 7). However, there is a lack of T_2 or T_2* mapping commercial software packages available in the current market.

4. Development of flow measurements on in-plane flow to characterize flow regurgitation

   Motivation: Mitral and aortic valve regurgitations can be accurately diagnosed using PC-MRI that encodes blood flow along in-plane direction. The major advantage of this technique is to quantify regurgitant flow volume and visualize the endpoint of regurgitant flow, which provides significant clinical diagnostic tools on valvular disease patients. Existing commercial blood flow analysis software is normally focused on through-plan MRI flow measurements. Post processing of in-plane PC-MRI flow results will be useful for market penetration and to differentiate from current competitors. Furthermore, multi-directional velocity encoding technique will be extremely useful to accurately assess flow jet in the mitral regurgitation and stenosis.

5. Improve software compatibility for MRI real-time flow analysis using HeartPro Flow

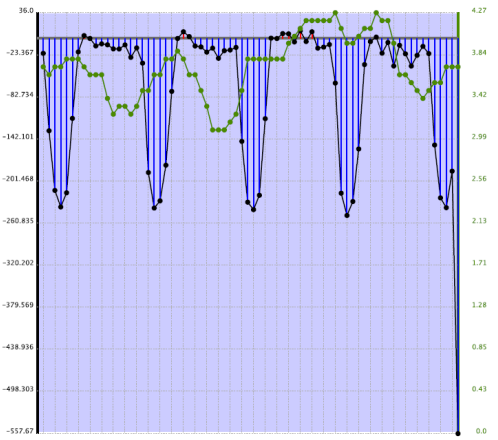
   Motivation: Conventional PC-MRI requires reliable cardiac gating, regular cardiac rhythm, and either signal-averaging, respiratory gating, or breath-holding to suppress respiratory motion artifacts. Therefore, novel beat-to-beat blood flow quantification method, which is capable of real-time monitor hemodynamics without cardiac gating and breath-holding, has a great potential to improve accuracy and reliability of MRI flow measurements (3, 8, 9). We collaborated with the MedVoxel software team to perform preliminary beat-to-beat flow measurements (right) using HeartPro Flow software compared with conventional segmented methods (left), as shown below. Further investigations will require optimizing segmentation algorithm, improving large data handling and specializing user interface to characterize beat-to-beat blood flow results.



Scan Interval: 43.5 ms, R-R Interval: 870.0 ms, Heart Rate (beats/min): 69.0

Positive Volume = 0.356 ml | Negative Volume = -64.55 ml | RF = 0.6 % (0.356 / 64.55)

Net Volume = -64.18 ml | Flow Rate = -4.4 (L/min) | VENC = 150.0 cm/sec



Scan Interval: 52.5 ms, R-R Interval: 3780.0 ms, Heart Rate (beats/min): 15.9

Positive Volume = 2.56 ml | Negative Volume = -297.299 ml | RF = 0.9 % (2.56 / 297.299)

Net Volume = -294.625 ml | Flow Rate = -4.7 (L/min) | VENC = 150.0 cm/sec

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