Available online at www.sciencedirect.com

ScienceDirect

Physics Procedia 70 (2015) 1181 – 1184

Physics Procedia

2015 International Congress on Ultrasonics, 2015 ICU Metz

Automatic emboli detection system for the artificial heart

T. Steifer[a], M. Lewandowski[a,*], P. Karwat[a], M. Gawlikowski[b]

[a] *Institute of Fundamental Technological Research, Polish Academy of Sciences, Warsaw, Poland*
[b] *Foundation of Cardiac Surgery Development, Zabrze, Poland*

Abstract

In spite of the progress in material engineering and ventricular assist devices construction, thromboembolism remains the most crucial problem in mechanical heart supporting systems. Therefore, the ability to monitor the patient's blood for clot formation should be considered an important factor in development of heart supporting systems. The well-known methods for automatic embolus detection are based on the monitoring of the ultrasound Doppler signal. A working system utilizing ultrasound Doppler is being developed for the purpose of flow estimation and emboli detection in the clinical artificial heart ReligaHeart EXT. The system will be based on the existing dual channel multi-gate Doppler device with RF digital processing. A specially developed clamp-on cannula probe, equipped with 2 – 4 MHz piezoceramic transducers, enables easy system setup. We present the issues related to the development of automatic emboli detection via Doppler measurements. We consider several algorithms for the flow estimation and emboli detection. We discuss their efficiency and confront them with the requirements of our experimental setup. Theoretical considerations are then met with preliminary experimental findings from a) flow studies with blood mimicking fluid and b) in-vitro flow studies with animal blood. Finally, we discuss some more methodological issues - we consider several possible approaches to the problem of verification of the accuracy of the detection system.

Peer-review under responsibility of the Scientific Committee of ICU 2015

Keywords: microemboli; embolism; Doppler ultrasound; ventricular assist device;

1. Introduction

The ReligaHeart EXT is an extracorporeal, pneumatic ventricular assist device (VAD) that is a part of a Cardiac Assist System currently developed in the Foundation of Cardiac Surgery Development, Poland. The system utilize results from the existing extracorporeal heart supporting system POLCAS, which was applied in more than 300 cases, mostly in Poland. ReligaHeart EXT VAD has been successfully tested during in-vitro investigations on blood as well as in animal trials and it is ready for the second stage of clinical trials.

One of the most important issues in VADs is thromboembolism. Blood pumps may activate the coagulation system in several ways, e.g. blood contact with artificial material (biocompatible polymer or titanium covered by biocompatible layers), excessive shear stress, intermittent cavitation, excessive speed of pressure changes, blood stagnation or turbulent flow. To avoid these complications, the coagulation system should be partially blocked by pharmacological treatment. But the higher the blocking of coagulation system, the higher the risk of bleeding, especially bowels

* Corresponding author.
E-mail address: mlew@ippt.pan.pl

Peer-review under responsibility of the Scientific Committee of ICU 2015
doi:10.1016/j.phpro.2015.08.254

bleeding or intracerebral hemorrhage, leading even to death. Routinely monitored blood coagulological parameters (e.g. INR, ApTT) give information only about the degree of coagulation system blocking but not about its ability to counteract clots forming. Therefore, a better way to adjust the anticoagulant medication seems to be observing the effect of anticoagulation. Thus it was proposed to monitor the VAD via an automatic microemboli detection system based on the principles of Doppler ultrasound.

2. Detection system

The backscattering of the ultrasound wave on a sufficiently large particle moving in the vessel is observable in a form of characteristic Doppler signals, known as high-intensity triansient signals (HITS). An aalysis of these changes may provide partial information about the physical properties of the particle. One could distinguish four problems here: (a) detection of HITS; (b) classification of HITS into two groups: data containing microembolic signal and data free from microembolic signal (noise and artifact changes); (c) distinction between signals from gaseous and solid microemboli; (d) estimation of the solid microemboli size. We assume that in our target experimental situations only solid emboli are present. Other advantages over other clinical Doppler measurement situations are the constant diameter of the cannula and the fixed position of the probe.

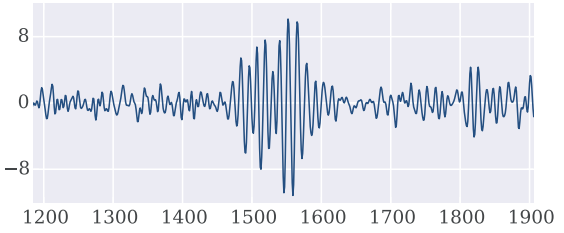

Fig. 1. An example of HITS.

2.1. Doppler system

The ultrasonic probe is to be connected to the extracorporeal plastic tubing. During preliminary studies it was observed that the rounded shape of the tubing caused a lensing of the ultrasound wave and in effect, a reduction of the effective sample volume. Therefore, a special clamp-on probe was designed to flatten the tubing. Two tranducerds (2 and 4 MHz respectively) were used - potentially allowing for the implementation of emboli sizing algorithms. The Doppler I/Q data aquisition is performed using the digiTDS - a multigate Doppler ultrasound system developed in the Institute of Fundamental Technological Research of Polish Academy of Sciences.

3. Validation

It is generally assumed that HITS are audible as a characteristic sound when audio representation of the Doppler data is considered. Thus a subjective analysis of audio Doppler data by a human expert was established as a *gold standard* for diagnosis of the thromboembolism in various clinical applications. For this reason, the automatic detection systems are usually validated via comparison with human expert findings. However, this approach is flawed. Firstly, it is not clear what the limits of the human perception in this matter are, i.e. what part of HITS present in the whole signal are detectable by a human expert. Secondly, such validation gives no information about the general sensitivity of the given Doppler system - i.e. what kind of emboli are detectable in the signal as HITS.
Thus a more objective method of validation should be sought. In our studies we consider an in-vitro method of validation via optical measurement. The aim of the validation was to establish a minimal size of the particle measurable in our Doppler ultrasound system. The experiments were performed on a calibrated flow phantom supplied with the same type of tubing as the one used in the target VAD (E-3603 flexible plastic tubing, Tygon, France). A commercially

available blood mimicking fluid Model 046 was used (CIRS, Norfolk, Virginia, USA) to acquire a realistic Doppler data.
The main idea was to collect optical images from a high-speed camera placed near the ultrasonic probe in a way that ensured that a moving particle will pass in a short time through both the camera and the Doppler sample volumes - thus allowing for a comparison of both types of data collected. Two methods for optical measurement combined with two types of calibrated particles were considered: a) measuring the laser light scattered on the particles moving through the sample volume and b) using the fluorescent particles and measurement of the light emitted by the particles. The first approach was ineffective due to high scattering of the light on the particles constituting the blood mimicking fluid. The second method involved using fluorescent particles emitting light which wavelength was significantly different from the wavelength of the laser light that was triggering the fluorescence. Therefore, it was possible to separate the useful signal from the background with use of an optical filter of matched bandwidth. Consequently, the second method was chosen for further measurements.
Calibrated green fluorescent microspheres (Microgenics Corporation, Fremont, California, USA) were used. One hundred images per second were collected via a high-speed camera. An averaged brightness of the images could be used as a parameter for detection of the activated fluorescent particle. However, in a cloudy medium such as the used blood mimicking fluid the changes in the average brightness were hardly distinguishable from noise. A sum of the pixels that were brightened at least by a certain factor appeared to be much more specific indicator of the activated fluorescence.
Additionally, two preliminary studies were performed on a percine blood circulating in a system connected to the target VAD. The possibility of applying an optical method in such study is limited. However, the study of embolic material formed during the experiment provided an additional insight into the subject.

3.1. HITS detection

Three methods based on different estimators were tested on the data collected. In every method the detection procedure consists of comparing the instantaneous value of the estimator to the threshold (fixed or adaptive).
An embolus causes an increase in the signal energy [**?**]. Thus, the simplest estimator under consideration is the absolute value of the Doppler I/Q signal filtered with a moving average filter.
The second estimator, reported in [**?**], is based on the assumption that the filtered blood signal may be modelled as a stationary signal, while the embolic signals are non-stationary. The autoregressive models (AR) are fitted to the fragments of signal and two values may be used as the estimator - the model prediction error or the AR coefficients. The first coefficient of the AR model seems to be a more stable estimator than the prediction error.
The third approach was proposed in [**?**] using the instantaneous frequency estimator. It is assumed that HITS are narrow band signals (in relation to wide frequency band of the blood signal with no emboli present) and that this difference in frequency bandwidth should be observable as a change in the deviation of the instantaneous frequency estimator.

4. Discussion

All estimators tested are sensitive to embolic changes in the Doppler signal as seen on Fig 2. Data sets consisting of 25 seconds of measurements were collected and analysed. Manual fitting of the detection thresholds allowed even for 100% sensivity as compared to the optical findings - however these thresholds were not consistent among different data sets.
A manual analysis of Doppler data revealed up to 110% more HITS per data set as compared to the optical findings. It was observed that the blood mimicking fluid particles spontaneously formed conglomerates that apparently were detectable as emboli. Consequently, the exact mapping of optical data to the Doppler signal was not possible.
The most problematic aspect of the validation is the issue of emboli shapes. In the in-vitro study spherical particles were used (e.g. Fig. 3). Similarly, the popular model describing the energy increase in embolic signal - the emboli-to-blood ratio (EBR), introduced in [**?**] - is based on the assumption that the emboli are spherical. However, the examination of clot samples collected from the porcine blood experiment shows that the real emboli tend to manifest

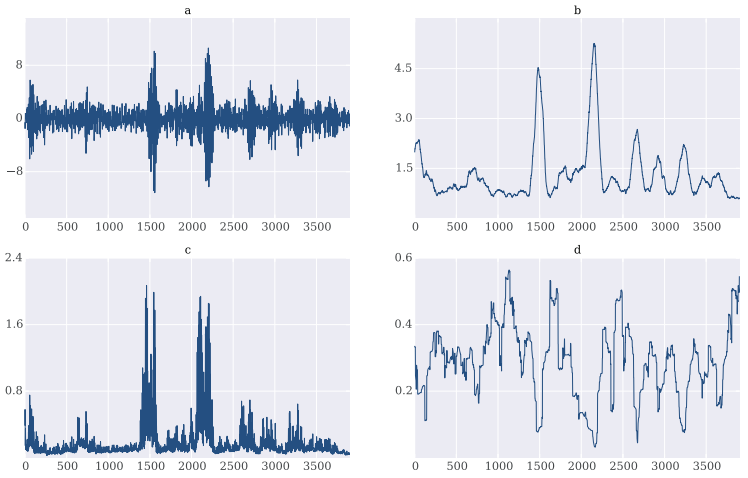

Fig. 2. (a) Doppler data; (b) absolute values of Doppler signal with moving average filter; (c) AR coefficients; (d) instantaneous frequency with moving average filter.

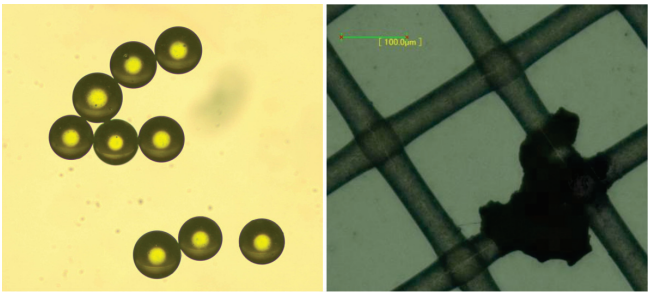

Fig. 3. (a) 140μm fluorescent particles; (b) blood clot collected during in vitro study.

in various shapes that are unlikely to cause the same ultrasound backscattering as a spherical particle of the same volume. A plausible evaluation of any automatic detection system will not be possible without further studies into the subject of uncertainty resulting from the shapes of emboli.

Acknowledgements

This work is supported by The National Centre of Research and Development, PBS1/A3/11/2012.