Mechanical heart valve cavitation in patients with bileaflet valves*

Peter Johansen, Tina S. Andersen, J. Michael Hasenkam, Hans Nygaard, Peter K. Paulsen

Abstract— **Today, the quality of mechanical heart valves is quite high, and implantation has become a routine clinical procedure with a low operative mortality (< 5%). However, patients still face the risks of blood cell damage, thromboembolic events, and material failure of the prosthetic device. One mechanism found to be a possible contributor to these adverse effects is cavitation. In vitro, cavitation has been directly demonstrated by visualization and indirectly in vivo by registering of high frequency pressure fluctuations (HFPF).**

Tilting disc valves are thought of having higher cavitation potential than bileaflet valves due to higher closing velocities. However, the thromboembolic potential seems to be the same. Further studies are therefore needed to investigate the cavitation potential of bileaflet valves in vivo. The post processing of HFPF have shown difficulties when applied on bileaflet vavles due to asynchronous closure of the two leaflets. The aim of this study was therefore to isolate the pressure signature from each leaflet closure and perform cavitation analyses on each component.

Six patients were included in the study (St. Jude Medical (n=3) and CarboMedics (n=3); all aortic bileaflet mechanical heart valves). HFPFs were recorded intraoperatively through a hydrophone at the aortic root. The pressure signature relating to the first and second leaflet closure was isolated and cavitation parameters were calculated (RMS after 50 kHz high-pass filtering and signal energy). Data were averaged over 30 heart cycles.

For all patients both the RMS value and signal energy of the second leaflet closure were higher than for the first leaflet closure.

This indicates that the second leaflet closure is most prone to cause cavitation. Therefore, quantifying cavitation based on the HFPF related to the second leaflet closure may suggest that the cavitation potential for bileaflet valves in vivo may be higher than previous studies have suggested.

I. Introduction

Patients receiving mechanical heart valves must undergo lifelong anticoagulation therapy to counteract the increased risk of thromboembolic complications that follows post implantation [1]. One of the causes for the increased risk of thromboembolism may be cavitation, which has been demonstrated in several in vitro studies [2][3][4][5][6]. Most of these studies used visualization techniques to verify the presence of cavitation. Obviously, visualization is not applicable in vivo. It has therefore been a goal to develop methods capable of quantifying cavitation in vivo to investigate if findings in vitro also are presented in vivo. Today, the only technique that detect the direct action of imploding cavitation bubbles in vivo is based on recording of high frequency pressure fluctuations (HFPF)[7][8][9][10]. It has been shown that since cavitation occurs at valve closure these HFPF consist of both valve closing sound component as well as cavitation induced pressure oscillations [11]. The separation of these two components is rather difficult and a few approaches have been presented. Garrison et al. [11] found that the frequencies of the valve closing sound are limited to a confined range. It may therefore be removed through high pass filtering leaving only pressure signatures originating from cavitation. However, since this technique requires a proper selected cut off frequency, prior knowledge on particular valves closing sound bandwidths are required [12]. Another approach has been suggested which assumes that the closing sound components predominantly are deterministic and cavitation noise is mainly non-deterministic [13]. Hence, isolating the non-deterministic component gives a representation of the cavitation process. Those two approaches each have their advantages and disadvantages. The latter technique has difficulties handling signals from bileaflet valves due to an asynchronous closing pattern which makes time domain averaging very difficult. The RMS method can better handle such asynchronous closing signals. However, this technique will as default include the closing sound from both leaflets and produce an average number of those components. Since the last closing leaflet is most likely to close at a higher velocity [14], it could be speculated that the last closing leaflet is prone to cause more cavitation than the prior. If so, this could mean that the cavitation levels found earlier for bileaflet valves could have been underestimated, because the highest level of cavitation energy has not been evaluated in isolation. The aim of this study was therefore to isolate the pressure signature from each leaflet closure in a bileaflet valve intraoperatively in patients and perform cavitation analyses on each component.

II. Materials and Methods

The study comprised 6 patients who received a bileaflet mechanical heart valve in aortic position. Three patients had implanted a St. Jude Medical bileaflet valve (patient ID number 2, 4, and 5) and another three had implanted a CarboMedics bileaflet valve (patient ID number 1, 3, and 6). Inclusion criteria were age greater than 18 years, patient scheduled for elective heart valve surgery, and patients giving both oral and written consent.

The HFPF were measured intraoperatively using a miniature hydrophone (type 8103; Brüel & Kjær, Nærum, Denmark) with an upper frequency limit of 150 kHz. The hydrophone was connected to a preamplifier (Brüel & Kjær 2635) with a built-in HP filter at 20 Hz. Data were stored on

*Research supported by Arvid Nilssons Fond and Snedkermester Sophus Jacobsen og hustru Astrid Jacobsens Fond.

Peter Johansen is with the Department of Engineering, Faculty of Science and Technology, University of Aarhus (phone: +4541893234; e-mail: pj@eng.au.dk).

Tina S. Andersen, J. Michael Hasenkam, Hans Nygaard, and Peter K. Paulsen are with the Department of Cardiothoracic Surgery, Aarhus University Hospital, Skejby, and Clinical Institute, Faculty of Health Sciences, University of Aarhus

a computer equipped with a data acquisition card (AT-MIO16-E2; National Instruments, Austin, Texas) at a sampling rate of 500 kHz. Data acquisition and off-line signal analyses were accomplished using custom-made software developed in LabVIEW (National Instruments). The recorded signals were also visualized on-line on an oscilloscope. The measurements were performed when the patient had been hemodynamically stable for at least 2 minutes after being weaned from cardiopulmonary bypass. The sterilized hydrophone was placed near the aortic annulus at the low aortic and left atrial junction, and data were acquired for approximately 30 seconds.

The study was approved by the local Ethical Committee and complied with the Helsinki II declaration.

A. Data Analysis

The thirty seconds of continuous recorded data were analyzed off-line. The closing events were identified and the closing pressure signature for each leaflet was isolated using a three msec rectangular time window (Fig. 1).

Cavitation was quantified based on those recorded pressure signatures. The non-deterministic signal energy (Enon-det) [13][15] was calculated as well as the signal energy and the root mean square (RMS) value after 50 kHz high pass filtering [11] as measures for cavitation. Both the RMS and the non-deterministic signal energy approaches are well described in the literature. Briefly, the RMS value is calculated according to equation 1:

$$RMS = \sqrt{\frac{1}{n}\sum_{i=0}^{n-1}\left|x[i]\right|^2} \qquad (1)$$

where n is the number of samples (500 kS/s · 5 msec), and $x[i]$ are the HFPF samples.

The non-deterministic signal energy is calculated as the difference between the deterministic and the total signal energy. The deterministic signal is derived through ensemble averaging in time domain (reducing the variance, hence reducing the stochastic (non-deterministic) components). The energy in this component is calculated through integration of the energy density spectrum. The total signal energy is calculated as the integral of the energy density spectral ensemble average (Fig 2).

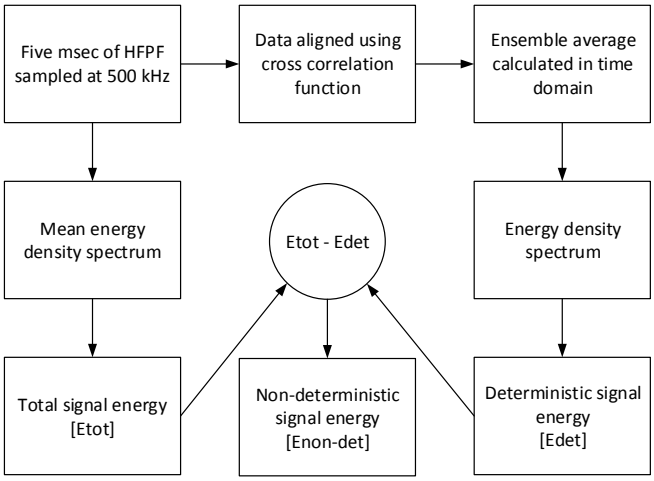

Fig. 2. After having sampled 5 msec of HFPF data alignment of individual valve closures is performed using cross-correlation. Subsequently, ensemble averaging is carried out representing the deterministic part of the signal. Parallel to this, the total signal energy is calculated after which the deterministic signal energy is subtracted leading to the non-deterministic signal energy.

III. RESULTS

The RMS pressure data for each patient is depicted in figure 3. It shows that all patients had higher RMS value for the second leaflet closure.

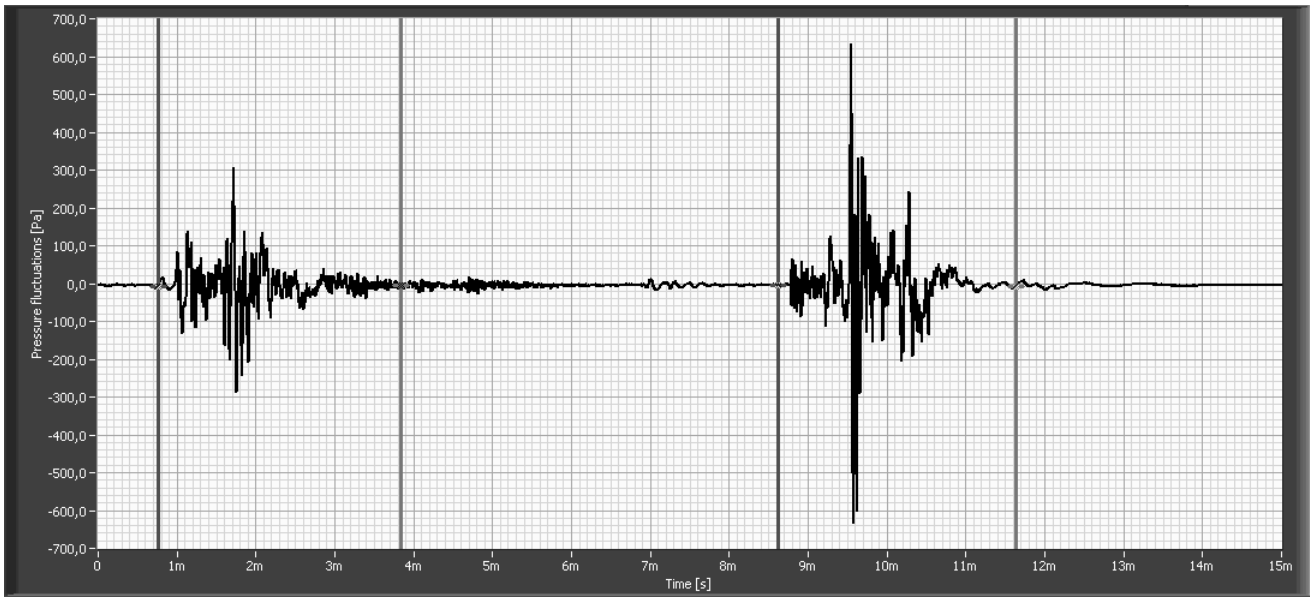

Fig. 1. Pressure signature recorded from a bileaflet valve. Each leaflet closing signature was isolated using a three msec rectangular time window (illustrated by the two set of cursors).

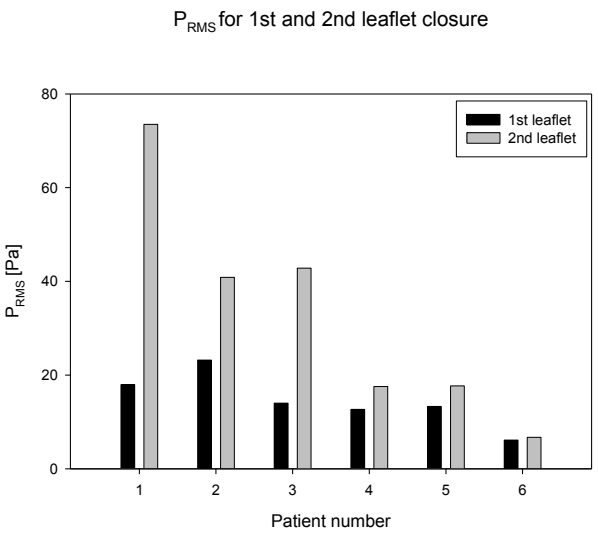

Fig. 3. The RMS pressure after 50 kHz high pass filtering for each patient. The black column shows the value for the first leaflet closing. The grey column represents the second leaflet closure.

The signal energy after 50 kHz high pass filtering for each leaflet closure is seen in figure 4. For all patients the second leaflet closure contained the highest signal energies.

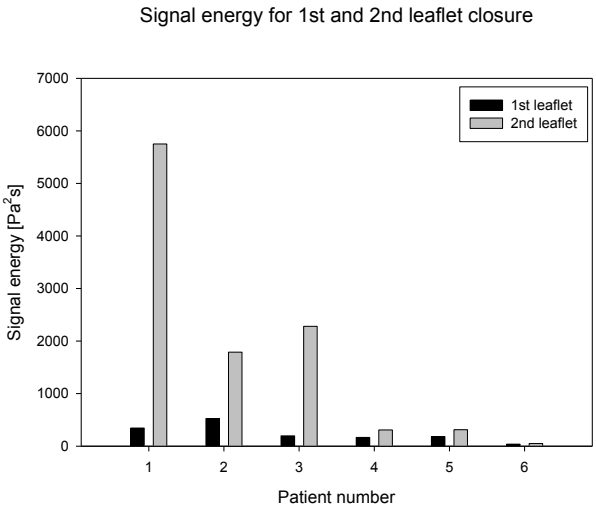

Fig. 4. The signal energy from the pressure signal for each patient after 50 kHz high pass filtering of the pressure signal. The black column shows the value for the first leaflet closing. The grey column represents the second leaflet closure.

The non-deterministic signal energy evaluated is illustrated in figure 5. Those data showed that for two patients (ID 2 and 4) the non-deterministic signal energy was highest for the first leaflet closure.

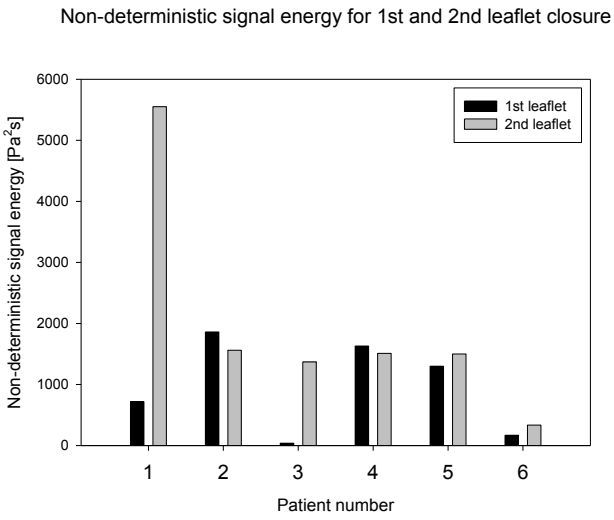

Fig. 5. The non-deterministic pressure signal energy for each patient. The black column shows the value for the first leaflet closing. The grey column represents the second leaflet closure.

Figure 6 shows the ratio between the cavitation parameters for the second and first leaflet closure. Note that the y-axis is a logarithmic scale. This graph summarizes that for all parameters in all patients the second leaflet closing had higher values than for the first leaflet closure except for the non-deterministic signal energy at patient 2 and 4.

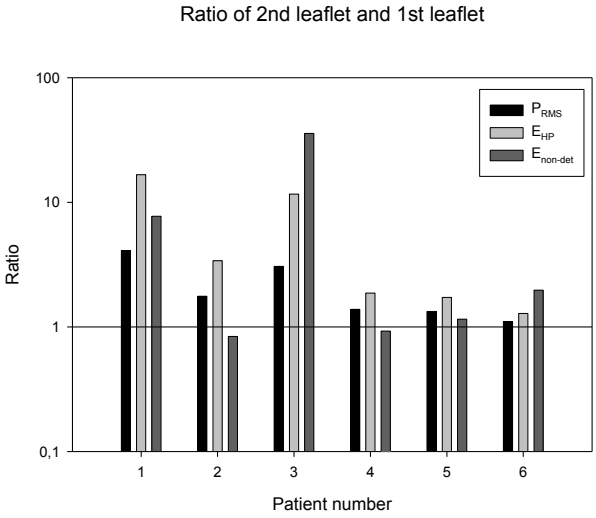

Fig. 6. The ratio between the cavitation parameters. Equality is marked with the line y = 1.

IV. Discussion

The results presented from intraoperative patient recordings demonstrate that caution should be taken when quantifying cavitation based on HFPF in vivo in bileaflet mechanical heart valves. All results, except the non-deterministic signal energy at patient 2 and 4 indicates that more cavitation may be present for the second leaflet closure in asynchronous mechanical bileaflet heart valves possible due to a higher leaflet impact. This suggests that when evaluating bileaflet

mechanical heart valve cavitation potentials in vivo the second leaflet closure should be analyzed in isolation. Since the degree of cavitation increases with valve load at closure [16] and the valve load (driving pressure) is higher for the second leaflet closure [14] this also makes sense; the aortic transvalvular pressure causing the mechanical leaflets to close increases with time during end systole, thus the second leaflet will experience the highest transvalvular pressure at closure.

However, there are still challenges when quantifying cavitation based on HFPF in the decomposition of the signal for assessing the non-deterministic signal energy. Minor misalignment prior to ensemble averaging as well as other stochastic components of the valve closing sound may add to the non-deterministic signal energy, which could explain the observation in patients 2 and 4. On the other hand, when applying the high pass filter approach closing sound components may still be present in the signature supposed to represent the cavitation signal. Therefore, further development of a robust in vivo applicable method for quantifying cavitation is still needed.

REFERENCES

[1] R. O. Bonow, B. A. Carabello, K. Chatterjee, A. C. de Leon, D. P. Faxon, M. D. Freed, W. H. Gaasch, B. W. Lytle, R. A. Nishimura, P. T. O'Gara, R. A. O'Rourke, C. M. Otto, P. M. Shah, J. S. Shanewise, 2006 Writing Committee Members, American College of Cardiology/American Heart Association Task Force, "2008 Focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons.," *Circulation*, vol. 118, no. 15. pp. e523–661, 07-Oct-2008.

[2] P. Johansen, "Mechanical heart valve cavitation.," *Expert Rev Med Devices*, vol. 1, no. 1, pp. 95–104, Sep. 2004.

[3] T. Graf, H. Reul, C. Detlefs, R. Wilmes, and G. Rau, "Causes and formation of cavitation in mechanical heart valves.," *J. Heart Valve Dis.*, vol. 3, pp. S49–64, Apr. 1994.

[4] D. S. Sneckenberger, D. R. Stinebring, S. Deutsch, D. B. Geselowitz, and J. M. Tarbell, "Mitral heart valve cavitation in an artificial heart environment.," *J. Heart Valve Dis.*, vol. 5, no. 2, pp. 216–227, Mar. 1996.

[5] C. S. Lee, K. B. Chandran, and L. D. Chen, "Cavitation dynamics of mechanical heart valve prostheses.," *Artif Organs*, vol. 18, no. 10, pp. 758–767, Oct. 1994.

[6] N. H. Hwang, "Cavitation potential of pyrolytic carbon heart valve prostheses: a review and current status.," *J. Heart Valve Dis.*, vol. 7, no. 2, pp. 140–150, Mar. 1998.

[7] T. S. Andersen, P. Johansen, P. K. Paulsen, H. Nygaard, and J. M. Hasenkam, "Indication of cavitation in mechanical heart valve patients.," *J. Heart Valve Dis.*, vol. 12, no. 6, pp. 790–796, Nov. 2003.

[8] T. S. Andersen, P. Johansen, B. O. Christensen, P. K. Paulsen, H. Nygaard, and J. M. Hasenkam, "Intraoperative and postoperative evaluation of cavitation in mechanical heart valve patients.," *Ann. Thorac. Surg.*, vol. 81, no. 1, pp. 34–41, Jan. 2006.

[9] P. K. Paulsen, B. K. Jensen, J. M. Hasenkam, and H. Nygaard, "High-frequency pressure fluctuations measured in heart valve patients.," *J. Heart Valve Dis.*, vol. 8, no. 5, pp. 482–6– discussion 486–7, Sep. 1999.

[10] C. M. Zapanta, D. R. Stinebring, D. S. Sneckenberger, S. Deutsch, D. B. Geselowitz, J. M. Tarbell, A. J. Synder, G. Rosenberg, W. J. Weiss, W. E. Pae, and W. S. Pierce, "In vivo observation of cavitation on prosthetic heart valves.," *ASAIO J.*, vol. 42, no. 5, pp. M550–5, Sep. 1996.

[11] L. A. Garrison, T. C. Lamson, S. Deutsch, D. B. Geselowitz, R. P. Gaumond, and J. M. Tarbell, "An in-vitro investigation of prosthetic heart valve cavitation in blood.," *J. Heart Valve Dis.*, vol. 3, pp. S8–22– discussion S22–4, Apr. 1994.

[12] P. Johansen, M. Lomholt, and H. Nygaard, "Spectral characteristics of mechanical heart valve closing sounds.," *J. Heart Valve Dis.*, vol. 11, no. 5, pp. 736–744, Sep. 2002.

[13] P. Johansen, K. B. Manning, J. M. Tarbell, A. A. Fontaine, S. Deutsch, and H. Nygaard, "A new method for evaluation of cavitation near mechanical heart valves.," *J Biomech Eng*, vol. 125, no. 5, pp. 663–670, Oct. 2003.

[14] Z. J. Wu and N. H. Hwang, "Asynchronous closure and leaflet impact velocity of bileaflet mechanical heart valves.," *J. Heart Valve Dis.*, vol. 4, pp. S38–49, Jul. 1995.

[15] V. Millette and N. Baddour, "Signal processing of heart signals for the quantification of non-deterministic events.," *Biomed Eng Online*, vol. 10, p. 10, 2011.

[16] K. B. Chandran and S. Aluri, "Mechanical valve closing dynamics: relationship between velocity of closing, pressure transients, and cavitation initiation.," *Ann Biomed Eng*, vol. 25, no. 6, pp. 926–938, Nov. 1997.