In Vitro Characterization of Bileaflet Mechanical Heart Valves Closing Sound

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Abstract

Due to the asynchronous closure of the leaflets [1], the closing sound of a bileaflet Mechanical Hearth Valve (MHV) is characterised by the presence of two peaks in the time domain. The closing sounds of four commercial MHVs have been acquired in vitro using the Sheffield Pulse Duplicator, under different working conditions to simulate as many physiological ones. The MHVs closing sounds were detected by a commercial apparatus (Myotis 3c, Cardiosignal GmbH). Closing sound spectra (10-22 kHz) have been statistically analysed and compared. A preliminary classification of the tested MHVs is herewith presented; differences in their phonographic behaviour are briefly discussed. This work would allow moving towards the early phonocardiographic diagnosis of bileaflet MHVs malfunction due to endothelial pannus deposition and/or thrombosis.

1. Introduction

In the wake of a previously published paper [2], which analyses the hydrodynamic performances of bileaflet mechanical prostheses, the present work aims at characterizing the *in vitro* behaviour of four MHVs with respect to the features of their closing sounds. Signals were acquired by the Myotis 3C (CardioSignal GmbH, Hamburg, Germany), a device specifically designed for phonocardiographic analyses, which checks the presence of two peaks in the signal over the time domain, each one belonging to the closing sound produced by a single leaflet of a bileaflet valve. The presence of vortices that breaks the symmetry of the flow downstream the leaflets [3] is considered as the main cause of the asynchronous closure of the leaflets (besides possible manufacture imperfections). Despite that, in this study the Myotis 3C was only used to register the closing sounds of the valves *in vitro* and considerations on the splitting of the signal will be taken further on. Signals were then converted from the time-domain to the frequency-domain by means of the Welch method, using the Nuttall window to avoid redundant information. Therefore, the closing sound spectra were statistically analysed to compare the behaviour of the tested valves and to classify them from a bioengineering point of view.

2. Methods

The following bileaflet mechanical heart valves were considered for *in vitro* testing: 1) On-X 19 mm (Medical Carbon Research Institute, Austin, Texas, USA); 2) CarboMedics Top Hat 21 mm (CarboMedics Inc, Austin, Texas, USA); 3) Sorin OverLine 18 mm (Sorin Biomedica, Saluggia, Italy); 3) St. Jude Regent 19 mm (St. Jude Medical, St. Paul, Minnesota, USA). The valves were mounted over the same 21 mm holder in the aortic chamber of the Sheffield Pulse Duplicator (Department of Medical Physics and Clinical Engineering, University of Sheffield, UK), which allows testing prosthetic heart valves under pulsatile hydrodynamic regime [4]. The system was filled with saline solution (0.9%). The hydrodynamic conditions applied to test the mechanical valves are summarized in Table 1: they reproduce a number of physiological conditions by changing the stroke volume and the beat rate. Four measurements were acquired for each valve under each hydrodynamic set of the Pulse Duplicator.

All the signals acquired were analysed off-line after filtering out components below 10 kHz, to clean the digitalised signals from breathing murmurs and native valve tones. Thereafter, data were exported and processed with an original software specifically developed in the Matlab® language. Signal spectra in the frequency-domain were calculated from the closing sounds over the time-domain for each valve and for each set of experimental conditions. The conversion from the time-domain to the frequency-domain was carried out by the Welch method [5[5]]. Since the closing sounds of MHVs should be treated as non stationary signals, the original signals were divided into sections: the corresponding periodograms were mediated to reduce the variance of the spectral estimation. The Nuttall window [6] was used to avoid redundant information in the regions of sections overlapping.

Table 1. Experimental conditions for testing the mechanical valves with the Sheffield Pulse Duplicator.

#	Stroke volume [ml]	Beat rate [bpm]	Flow rate [l/min]
1		60	3.0
2		70	3.5
3	50	80	4.0
4		90	4.5
5		100	5.0
6		60	3.6
7		70	4.2
8	60	80	4.8
9		90	5.4
10		100	6.0

The spectra of the investigated valves were statistically compared by means of the Kruskal-Wallis test: it is a nonparametric version of the classical one-way ANOVA, and an extension of the Wilcoxon rank sum test to more than two groups. The Kruskal-Wallis test compares the medians of the samples, and returns the p-value for the null hypothesis (all samples are drawn from the same population); if the p-value is near zero, this casts doubt on the null hypothesis and suggests that at least one sample median is significantly different from the others. A result is usually considered significant if the p-value is less than 0.01.

3. Results

For each valve and for each experimental set, two variables were measured: the frequency (Hz) of the highest peak of the spectra; the amplitude of the highest peak (a.u.). It was noticed that the spectra of all the valves are centred on ± 12 kHz, but one: the St. Jude Regent valve spectra are centred on ± 17 kHz. For all the tested valves, the frequency of the highest peak is not affected by changes in the beat rate and in the stroke volume (data not shown).

As to statistical purposes, all the spectra acquired under different conditions were compared; each curve represents the mean values of the spectra and its standard deviation at a specific beat rate (60, 70, 80, 90, 100 bpm). The spectra of the On-X and St. Jude Regent valves are depicted in Figure 1 and Figure 2, respectively; Table 2 summarizes the statistical results: it specifies the frequency ranges where the signals are statistically comparable, thus indicating if and where the closing sounds can be considered reproducible.

4. Discussion and conclusions

By comparing the amplitudes of the highest peaks detected in the closing sounds spectra of all the tested valves, it is possible to state that the St. Jude Regent is the least noisy; it is also characterized by the highest frequency of the maximum peak (± 17 kHz), which is close to the upper limit of the audibility range.

As it is likely to see from the spectra, different valves are differently reproducible as to the closing sound spectra. Since closing sounds ultimately depend on the mechanical impact of the leaflets against the housing of the valve, different closure reproducibility can reveal differences in the valve mechanical design and structure: moreover, these latter can influence the hydrodynamic performances of the prosthetic devices. Therefore, we speculate that the current analysis can be exploited for the functional evaluation of bileaflet mechanical heart valves.

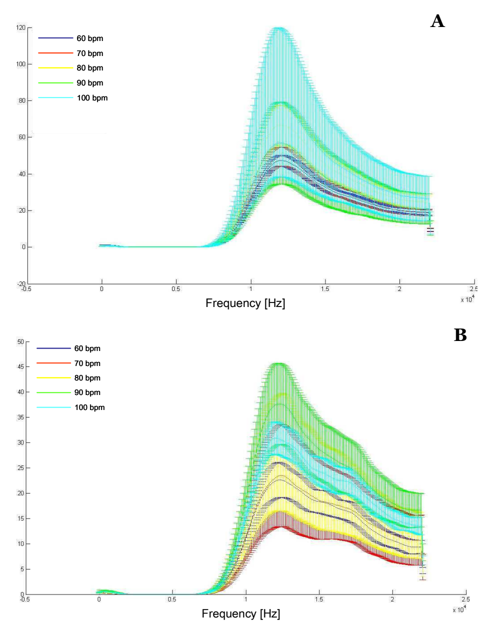

Figure 1. Spectra of the closing sound signals of the On-X valve: different colours indicate different beat rate (60, 70, 80, 90 and 100 bpm); in A the spectra acquired with stroke volume 50; in B the spectra acquired with stroke volume 60.

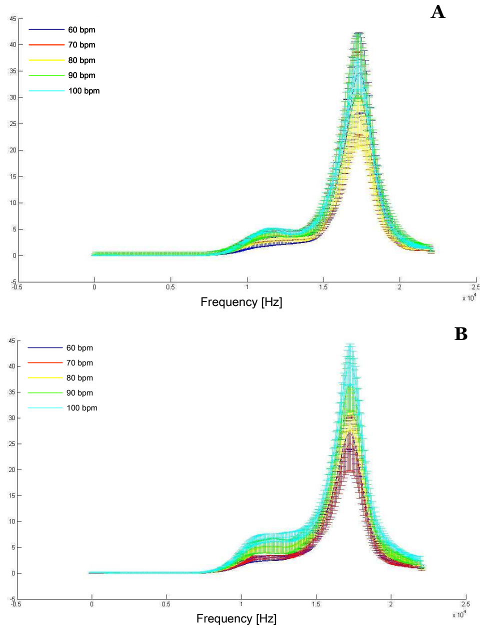

Figure 2. Spectra of the closing sound signals of the St. Jude Regent valve: different colours indicate different beat rate (60, 70, 80, 90 and 100 bpm); in A the spectra acquired with stroke volume 50; in B the spectra acquired with stroke volume 60.

Table 2. Detailed results of the statistical analysis (Kruskal-Wallis test) applied to the spectra of the closing sound signals: Null Hypothesis (NH) is refused (R) in one or more frequency ranges, if at least one sample median significantly differs from the others; Null Hypothesis is "accepted" (A) in one or more frequency ranges, if no sample median significantly differs from the others. The threshold used for the p-value was 0.01. Valves are indicated as it follows: 1, On-X; 2, Carbomedics Top Hat; 3, Sorin OverLine; 4, St. Jude Regent.

<table>
<tr><th></th><th colspan="2">SV 50</th><th colspan="2">SV 60</th></tr>
<tr><th></th><th>NH</th><th>Frequency [Hz]</th><th>NH</th><th>Frequency [Hz]</th></tr>
<tr><td rowspan="2">1</td><td>A</td><td>1292-2929
4307-22050</td><td>A</td><td>4134-22050</td></tr>
<tr><td>R</td><td>0-1206
3015-4221</td><td>R</td><td>0-4048</td></tr>
<tr><td>2</td><td>R</td><td>0-22050</td><td>R</td><td>0-22050</td></tr>
<tr><td rowspan="2">3</td><td>A</td><td>3531-4479</td><td rowspan="2">R</td><td rowspan="2">0-22050</td></tr>
<tr><td>R</td><td>0-3445
4565-22050</td></tr>
<tr><td rowspan="2">4</td><td rowspan="2">A</td><td rowspan="2">0-22050</td><td>A</td><td>0-8010
14729-15246
18174-18260</td></tr>
<tr><td>R</td><td>8096-1463
15332-18088
18346-22050</td></tr>
</table>

The analysis of the spectra of the closing sound produced by bileaflet MHVs can be combined with the more traditional phonocardiographic monitoring carried out by the Myotis 3C. The early diagnosis of valve malfunction based on the search for "double clicks" in the signal acquired *in vivo* over the time-domain, can be improved by the analysis of the corresponding spectra in the frequency-domain: if the phonocardiographic signal lacks double clicks, or a sufficient number thereof, it might be useful to compare the corresponding spectrum with a library of pre-registered ones. Thus, the *in vitro* classification of MHVs behaviour by means of statistical tools might improve the phonocardiographic diagnosis *in vivo*.

Further studies are in progress to extend the range of frequency above 20 kHz and increase sampling frequency to improve the classification performances.

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