

Laser Vibrometry as investigational tool for mechanical heart valves kinematics: preliminary investigation

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Abstract

Vibration measurement is of primary interest in many fields. Due to the non-contact nature of the optical probe and the unparalleled characteristics offered by the use of coherent monochromatic laser light as primary carrier of information, laser techniques for vibration measurement have a series of undoubted advantages, offering interesting perspectives of progress for vibration measurements in terms of innovative applications.

In virtue of the above mentioned offered advantages, laser techniques could be an interesting alternative investigational tool to be tested in biomedical and clinic fields, especially as evaluation method in design and quality control of artificial organs. The laser vibrometry technique applied on prosthetic heart valves could be regarded as an useful tool in order to analyse the mechanical features of these devices for a detailed comprehension of their working conditions. Due to the activity of surveillance of the market carried out by the Istituto Superiore di Sanità, aim of this study is to investigate the kinematics of mechanical heart valves in-vitro, with an ad hoc set-up: the behaviour of the prosthetic valve was investigated in an open loop pulsatile mock circulatory system (VSI, Vivitro Systems). A solution of water and 35% glycerol, 0.9% NaCl, was used as test fluid (viscosity of the solution was 3.7 mPas, similar to blood viscosity). The implemented pump drive waveforms are representative of an instantaneous ventricular volume signed as FDA waveform by VSI. A cardiac output of 2 l/min, with a mean arterial pressure of 100 mmHg and a heart beat of 70 beats per minute were the investigated working conditions for the prosthetic valve.

The study of the kinematics of the prosthetic valve was performed using heterodyne laser Doppler vibrometry system (Polytec), which allows the measurement of both the vibrational velocity and displacement. The VSI mock circulatory loop allows to approach the vision of the valvular function in the aortic site by means of a glass window, through which the laser light has been oriented.

Mechanical valves kinematics is dependent on the characteristic coupling hinge-pivot: in order to catch specific features both in the opening and the closing phase of the valve, on each leaflet the kinematics of a point near the hinge-pivot coupling was investigated.

Three of the most commonly implanted mechanical bileaflet heart valves were investigated (St. Jude HP, Sorin Bicarbon, Carbomedics, tissue annulus diameter 27 mm).

The power spectra of the position signals from laser measurements, relative to the three valves under investigation, are compared in terms of spectral components and associated power; the spectra are obtained using basically the fast Fourier transform (FFT) technique. Starting from that analysis a comparison could be made to investigate frequency patterns and to discriminate between normal and malfunctioning devices. The proposed method could furnish a typical "fingerprint" characterizing each valve behaviour in repeatable experimental conditions. The critical points and difficulties to build up experimental studies in this field will be clearly pointed. The present investigation can be considered as a feasibility analysis.

Introduction

Vibration measurement is of primary interest in many fields. Due to the non-contact nature of the optical probe and the unparalleled characteristics offered by the use of coherent monochromatic laser light as primary carrier of information, laser techniques for vibration measurement have a series of undoubted advantages, offering interesting perspectives of progress for vibration measurements in terms of innovative applications.

In virtue of the above mentioned offered advantages, laser techniques could be an interesting alternative investigational methodology to be tested in the study of biomedical devices for the cardiovascular system, especially as evaluation method in design and quality control of artificial organs. The laser vibrometry technique applied on prosthetic heart valves could be regarded as an useful tool in order to analyse the mechanical features of these devices for a detailed comprehension of their working conditions.

The study of the kinematics of prosthetic valves by means of ultrafast cinematographic technique, a skill of the Laboratory of Biomedical Engineering of the ISS (1), allows to reconstruct the trajectory of a leaflet as a whole, under specific, simplifying assumptions: nothing can be said about the tidal evolutions of characteristic points such as the ones near the couplings hinge/pivot, in order to catch specific features both in the opening and the closing phase of the valve.

Due to the activity of surveillance of the market carried out by the Istituto Superiore di Sanità (ISS), aim of this study is to investigate the kinematics of mechanical heart valves in-vitro, with an ad hoc set-up: the behaviour of the prosthetic valve was investigated in an open loop pulsatile mock circulatory system with a laser Doppler vibrometer.

The applicability and accuracy of laser Doppler measurement technique depends on the conditions in which the system operates, i. e., the level of the signal available, the environmental conditions, the characteristics of the surface observed, the presence of other shifts in addition to the ones pointed out, as reported in (2).

Aim of the present study is to verify if notwithstanding the interfering inputs due to the operative conditions of mechanical prosthetic heart valves, a simplified approach could furnish on valves' kinematics informations reliable to their specific design features. The proposed method could furnish a typical "fingerprint" characterizing each valve behaviour in repeatable experimental conditions. The critical points and difficulties to build up experimental studies in this field will be clearly pointed out. The present investigation can be considered as a feasibility analysis, a first step to evaluate the chance of extending the use of laser vibrometric measurement systems to a case, the evaluation of implantable cardiac devices, in which the applications of the technique proves to be difficult.

Materials & Methods

The experimental session was performed with a pulsatile, open loop, mock circulatory system (MCS), the VSI (Vivitro Systems Inc.), properly modified (3): in it, the hydrodynamic and kinematic behaviour of three of the most commonly implanted mechanical bileaflet heart valves were investigated, all of them with a tissue annulus diameter of 27 mm: a St. Jude HP (SJ27), Sorin Bicarbon (SB27), Carbomedics (CM27). The MCS pulse duplicator consists in a SUPERPUMP (Vivitro Systems Inc., (VSI)), i. e., a piston-in-cylinder pump head driven by a low inertia electric motor and a linear actuator which converts rotary motion of the motor to linear displacement of the piston.

As physical model of the left heart system, the SUPERDUP'R (VSI) was adopted, consisting in: 1) an hydraulic chamber containing a transparent and compliant model left ventricle made of polyurethane, 2) a

Delrin valve mounting block lodging both aortic and mitral valves, on the top of the hydraulic chamber, 3) an atrial chamber simulated by means of an open ceiling reservoir, 4) a glass model of the aortic root (including the Valsalva sinuses) together with an entrapping air system modelling the aortic compliance, 5) a systemic impedance, reproduced with two-stage models, including adjustable peripheral resistance and systemic characteristic compliance. The ventricular distensibility was simulated with the insertion of the viscoelastic impedance adapter between the pump head and the model of the ventricle. A sketch of the MCS is showed in figure 1.

The mechanical bileaflet prosthetic valves were located in the aortic valve site, while a mechanical reference valve (e. g., no-leakage valve) was inserted in the mitral site. Ventricular, atrial and aortic pressure were recorded through wall pressure ports, Aortic and mitral flow measurements were performed with two electromagnetic flow meters (FM501, Carolina Medical Inc.) located in the aortic and mitral valve position, respectively. The hydrodynamic behaviour of the prosthetic valve was investigated with a solution of water and 35% glycerol, 0.9% NaCl, test fluid; the viscosity of the solution was approximately 3.7 mPas, similar to blood viscosity. A PCI-MIO-16E-4 (National Instruments, Austin, Texas, USA) I/O board, controlled by PC (Pentium III, 64MB RAM), was adopted for data acquisition (8 channels) and pump drive waveform generation (1 channel). A custom made software program developed in the LabVIEW® environment (National Instruments, Austin, Texas, USA) allowed to drive and control the mock circulatory system (a more detailed description of the software can be found in (3)). The implemented pump drive waveforms are representative of an instantaneous ventricular volume signed as FDA waveform by VSI. A cardiac output of 2 l/min, with a mean arterial pressure of 100 mmHg and a heart beat of 70 beats per minute are the investigated working conditions for the prosthetic valve.

The study of the kinematics of the prosthetic valve was performed using a laser Doppler vibrometric system (Polytec, DE), based on the principle of heterodyne interferometry (4, 5), which allows the measurement of both the vibrational velocity and displacement. A laser Doppler vibrometer is based on the principle of the detection of the Doppler shift of coherent laser light (frequency order of magnitude, 10^{14} Hz), scattered from a small area of the vibrating specimen. The relationship of the Doppler frequency shift f_D and the phase change Φ introduced into the measurement beam, with the vibrational velocity v and displacement d , respectively, are expressed by:

$$f_D = 2 \frac{v(t)}{\lambda} \qquad \Phi = 4\pi \frac{d(t)}{\lambda}$$

with λ being the wavelenght of the laser light. Therefore, vibrational velocity and displacement can be obtained from Eq. (1) and Eq. (2), respectively. A clear description of a an optical system of a typical heterodyne interferometer can be found in Ngoi *et al.* (4). The VSI mock circulatory loop allows to approach the vision of the valvular function in the aortic site by means of a glass window, through which the laser light has been oriented (as showed in figure 1). The laser beam was not kept at a fixed point on the specimen: a scanning of four characteristic points on the leaflets surface (two for each leaflet), very close to the couplings hinge/pivot, was carried out in the attempt to catch specific features both in the opening and the closing

phase of the valve. A sketch of the location of the measurements points, together with the nomenclature chosen for their identification, is showed in figure 2.

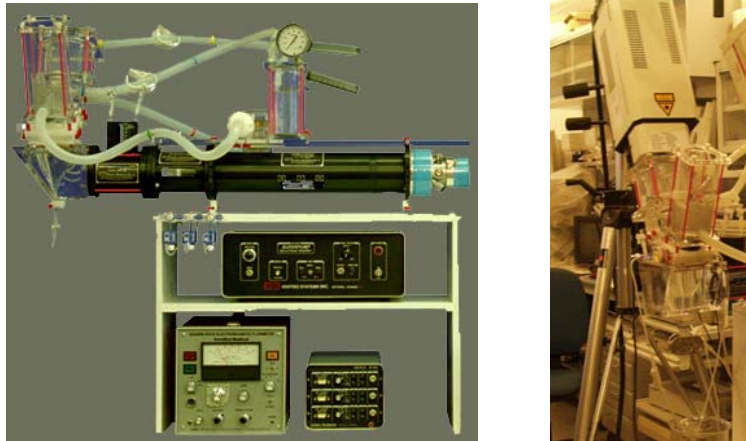


Figure 1

It must be pointed out that the approach adopted to the kinematic measurement allowed to follow the tidal evolutions on a position, not of a point on the leaflet (only components of the kinematic quantities perpendicular to the optical axis are measured).

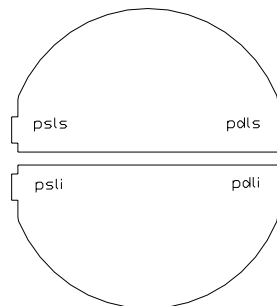


Figure 2

The proper own Labview code controlling the VSI system provided the trigger to synchronize the vibrometry system recording with the cardiac cycle. Each signal was sampled at 10240 Hz for about 14 seconds. The position signals, describing the mechanical valve kinematics, were successively segmented with a time period equal to the duration of a beat, averaged and normalized with respect to root mean square of the averaged waveform itself (6), before to proceed with the analysis in the frequency domain. The power spectra of the averaged position signals from laser measurements, relative to the three valves under investigation, are compared in terms of spectral components and associated power; the spectra are obtained using basically the fast Fourier transform (FFT) technique.

Results

As an example of the acquisition strategy followed in the present study, the recordings of position signals for the SB27, relative to the four sites of measurement on the leaflets, are shown in figure 3, where the synchronous trigger and the ventricular pressure waveforms (in volts) are also reported.

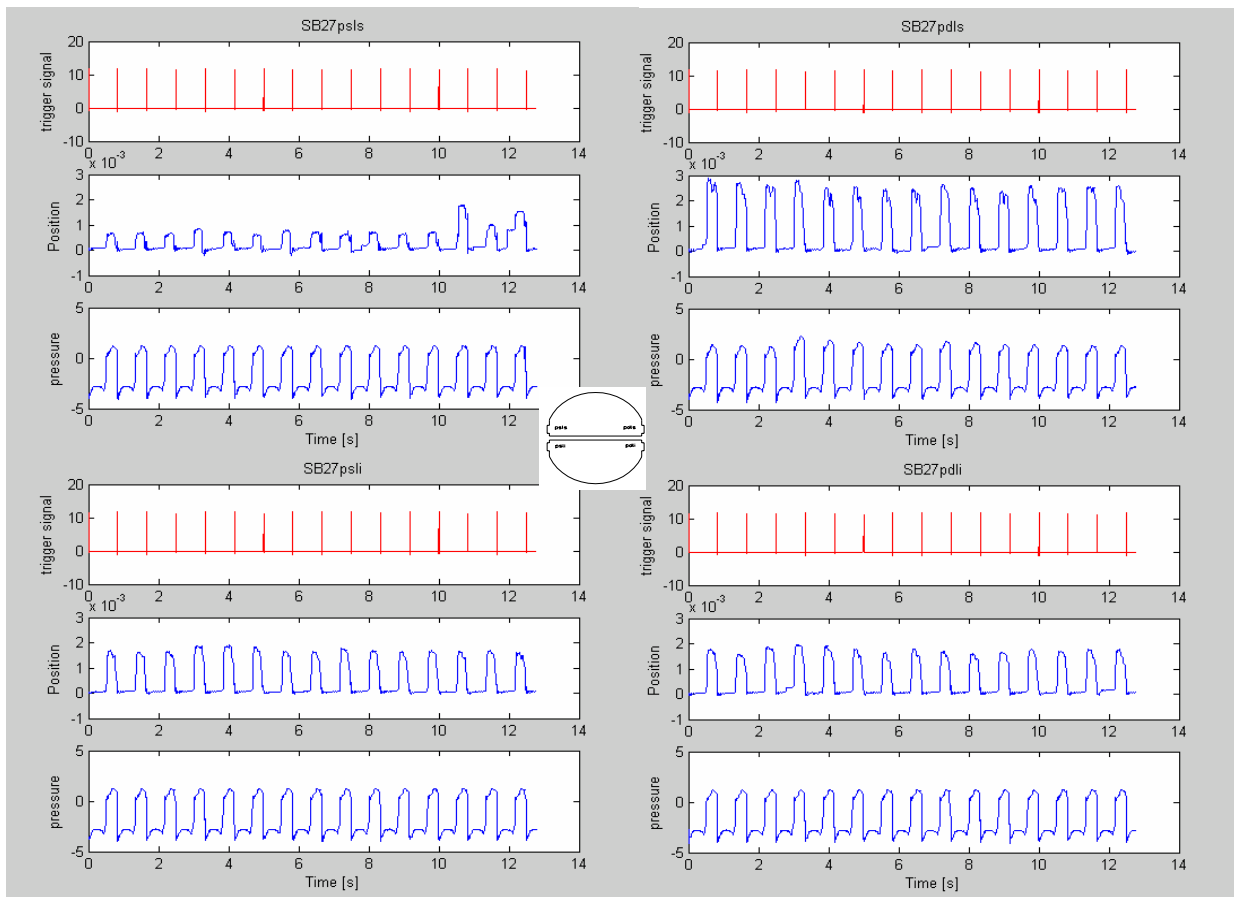


Figure 3

It can be noticed, from figure 3, how the kinematics on the superior leaflet (ls) show a less regular behaviour with respect to the inferior leaflet (li) in the SB27. The position signals describing the averaged beat in all the measurements valve sites are shown in figures 4, 5 for the SB27, and CM27, respectively. The averaged waveforms have been normalized with respect to their root mean square value; the averaged ventricular pressure waveforms are also shown in those figures, in order to correlate the kinematics of the points on the valve to the different phases in the cardiac cycle. As can be seen from figure 5, the CM27 shows a behaviour significantly different from the other two valve models both in the velocity and the position signals: the position waveforms for example shows a characteristic super-elongation in the opening phase, and a trend in the closing phase that may be related to a rebound of the leaflet on the hinge after the closure impact; for the CM27 this phenomenon seems to be more significant in the ls and, even if less pronounced, it is also present in the ls of the SJ27 (data not shown). In figure 6 the root mean square (rms) values of the averaged position signals, for the three valves under investigation, are compared: it can be pointed out the greater values for the SB27 with respect to the other two valves, with a great difference in the behaviour observed in the two sites of measurement on the ls; the SJ27 also shows a light difference in the ls.

On the contrary, the three valves show similar rms values in the two sites of measurements, on the inferior leaflet (li). The normalized power spectra of the position signals from laser measurements, relative to the

three valves under investigation in one site of measurement on the superior leaflet (pdls), are compared in figure 7: it can be noticed how the CM27 power density spectrum is characterized by a power fraction distributed on spectral components higher than the other two valve models: also in this case the observed behaviour seems to be a less pronounced tendency in the inferior leaflet (data not shown).

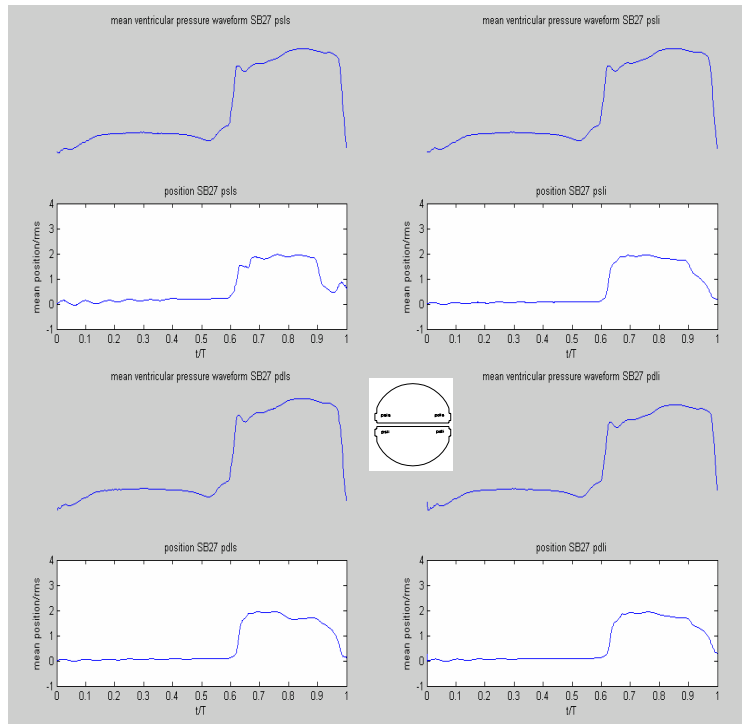


Figure 4

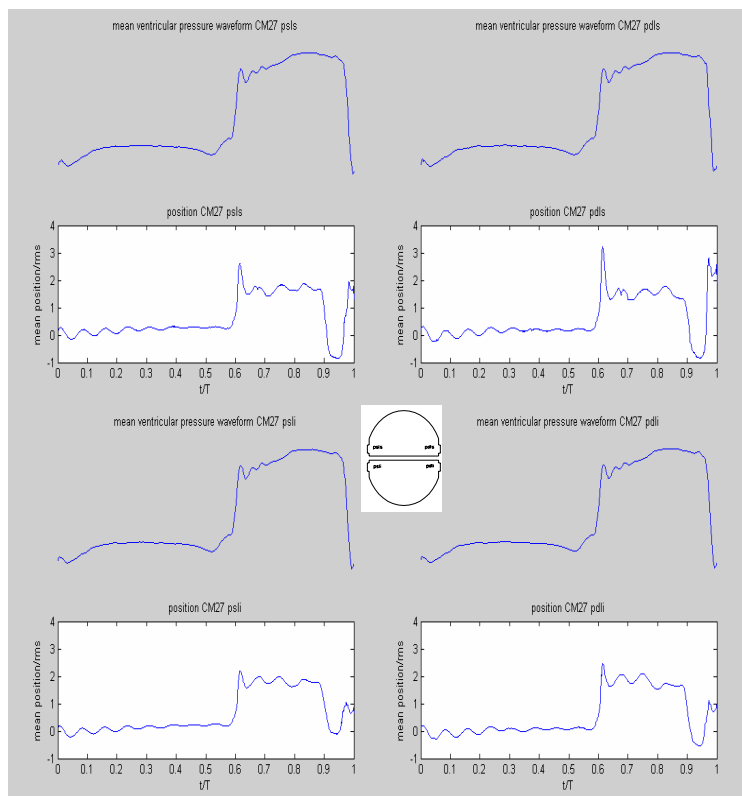


Figure 5

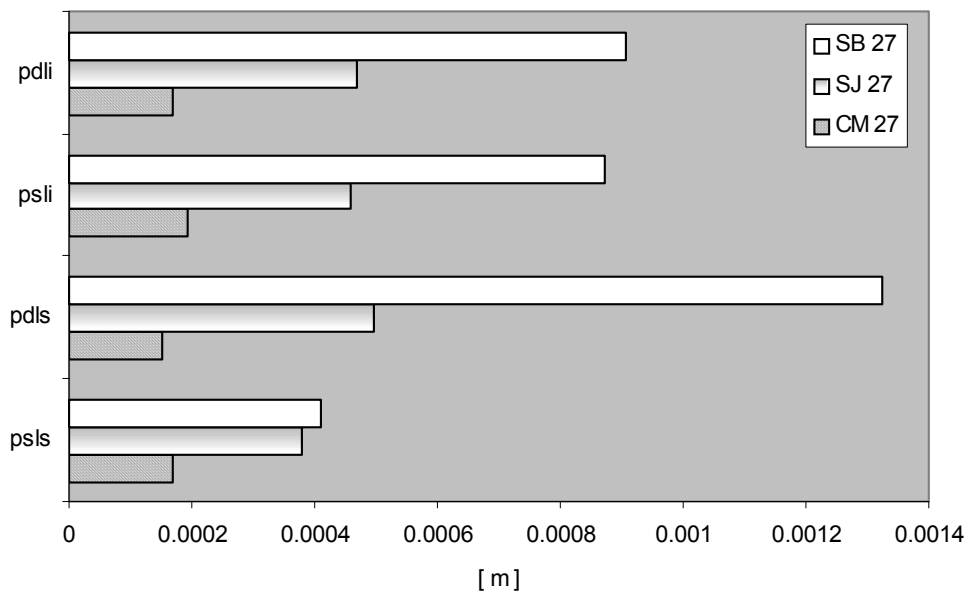


Figure 6

Discussion

The current standard of in vitro and in vivo preclinical heart valve testing has recently been questioned because of its failure to reveal the wear and fracture events potential of the prosthetic valve (for example, (7)). The evaluation of the mechanical behaviour of the prosthetic heart valves is of fundamental importance to discriminate on the correct functionality of these devices.

The hinge behaviour of bileaflet valves should be evaluated in relation to the long-term durability characteristics not only in the design phase, but also in the pre-market one, when an accurate quality control is needed to intercept tolerance related interferences. It is shown that structural integrity, especially for brittle materials, is not just a function of design, but involves the entire manufacturing process (8, 9). An in-vitro study of the leaflets kinematics and related frequency patterns seems to be necessary as a preliminary step in this direction. Operating in this way it is possible to achieve a detailed spectral pattern for each prosthetic valve, taking into account leaflet/housing coupling and being possible to provide a comparison among the several valves investigated. To date, the study of the kinematics of prosthetic valves has been performed by means of ultrafast cinematographic technique (1), which allows to reconstruct the trajectory of a leaflet as a whole, under specific, simplifying assumptions: nothing can be said about the tidal evolutions of characteristic points such as the ones near the couplings hinge/pivot, if not by modeling, in order to catch specific features both in the opening and the closing phase of the valve. Due to their non-contact nature, laser techniques for vibration measurement offer themselves as auxiliary investigational tool to be tested in the field of biomedical devices, especially as evaluation method in design and quality control of artificial organs. The applicability and accuracy of this measurement technique depend on the conditions in which the system operates, that in the case of the study of mechanical prosthetic heart valves are: 1) the characteristics of the measurand surface of the leaflet, which is poorly cooperative with respect to the usage of laser Doppler systems with its alternance, during the motion, of reflective and badly diffusive areas. This effect brings to a

deterioration of the signal-to-noise ratio; 2) the level of the signal available, and the laser beam loss when the measure is carried out in points of the leaflet with the widest dynamics of the motion, i. e., on leaflets' tip; 3) the environmental conditions, because the valve is tested in a mock loop in presence of a fluid simulating blood viscosity, which has to be passed through by the laser beam together with the glass window allowing the optical access to the valvular function.

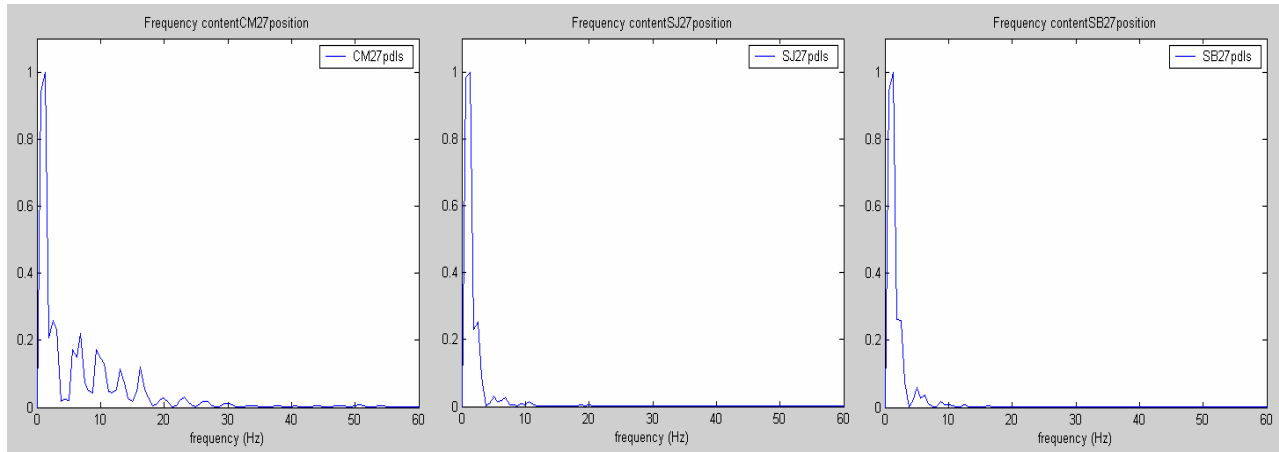


Figure 7

A partial matching of refraction indices may contribute to further compromise the signal-to-noise ratio; 4) the presence of other shifts in addition to the ones pointed out (the vibrations of the whole system) (2). Therefore, this methodology needs particular care in the interpretation of the results being affected by the specific conditions of each experimental set up that could be result in a difficult attempt for a correct classification of the functionality of these devices. The unequal behaviour exhibited by the three valve models under investigation may be related to the different design choices for the coupling between the housing ring and the leaflets. The Bicarbon valve uses a spherical coupling, thus free body motion should have to be considered for the leaflet rigid body. Moreover, design allowances entail a basculating motion of the leaflet, that makes leaflet closure to be different cycle by cycle, which results in a different final position inside the housing ring. On the contrary, the coupling between the housing ring and the leaflet used by St Jude HP and Carbomedics allows a pure rotational motion only to the leaflet (rigid motion, the knowledge of a sole measured component of the motion is sufficient to fully describe leaflets' kinematics): the design difference between the two models in the coupling lies in the capability, for the St Jude HP, to maintain the leaflets fixed when in fully open position, while for the Carbomedics the presence of a fluttering phenomenon is widely well-grounded in literature (for example, (10)). Globally, mechanical valves produced a characteristic velocity signal within the bandwidth up to 500 Hz (data not shown), and a characteristic position signal within the bandwidth up to 50 Hz with different power frequency distribution: the CM27 power density spectrum, characterized by a power fraction distributed on spectral components higher than the other two valve models (see figure 7), may be related to its typical fluttering behaviour. The different behaviour between the two leaflets observed in all the valves under investigation may be strictly related to the presence of the sinuses of Valsalva in the physical model of aortic root mounted on the mock circulatory

loop, which make the region immediately downstream of the valve asymmetric, with remarkable consequences in the flow field conformation. Position signals from vibrometric measurements, relative to the three valves under investigation, are compared also in terms of spectral components and associated power. Starting from that analysis a comparison could be made to investigate frequency patterns and to discriminate between normal and malfunctioning devices. The proposed method could furnish a typical “fingerprint” characterizing each valve behaviour in repeatable experimental conditions. The critical points and difficulties to build up experimental studies in this field have been pointed out. The present investigation can be considered as a feasibility analysis.

Future aim is to verify if a non invasive measurement technique such as laser Doppler vibrometry could be applied for the preclinical evaluation of mechanical heart valves, and to assess the ability of this methodology to identify mechanical heart valve critical design features and manufacturing process steps that may be valve-related structural failure.

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