3-D Simulation of the St. Jude Medical Bileaflet Valve Opening Process: Fluid-Structure Interaction Study and Experimental Validation

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Background and aim of the study: **Simulation of the opening and closure dynamics of a mechanical valve through a moving deforming mesh algorithm presents a challenge because of the large rotations of the leaflet and of the small gaps between the housing and the leaflets, which make remeshing a critical issue. The present study offers a computational approach to the simulation of valve leaflet motion during the opening process, together with an experimental set-up for validation of the model.**

Methods: **A fully 3-D simulation of the 27 mm St. Jude Medical Hemodynamic Plus mechanical valve was performed using the computational code, Fluent. Interaction between the leaflet and fluid was simulated through customized user subroutines which, according to a weakly coupled approach, update the leaflet velocities through subsequent time steps by means of an under-relaxation procedure. A parallel, experimental test was defined to collect data for the set-up of simulations and for validation purposes.**

Results: **The computed leaflet velocity and angular displacement compared well with experimental data. The model captured the main features of the opening process, and did so also from a quantitative viewpoint. Nonetheless, some discrepancies were observed, including a delay of ~7 ms in the computed leaflet displacement and an underestimation by ~7% of the maximum computed leaflet velocity.**

Conclusion: **The weakly coupled approach adopted here limited computational costs, thus allowing the simulation of a fully 3-D realistic mechanical valve within 154 CPU hours at minimal computational costs. No significant drawbacks were raised in comparison with the fully coupled approach. The opening process delay was similar to that reported previously, and cannot be ascribed to the weakly coupled approach adopted here.**

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The use of computational fluid dynamics (CFD) to investigate heart valve mechanics presents a considerable challenge because of the large rotations that leaflets encompass, and the fully coupled fluid-structure interaction features of the phenomenon. Currently adopted approaches may be divided into two classes: in the first class, the fluid-structure boundary movement is loosely calculated through interpolation techniques without deforming the mesh of the fluid domain; in the second class, the fluid mesh deformation is actually accounted for.

In the first case, the fluid mesh does not move, or it is only perturbed with respect to its initial configuration, the leaflet profile is superimposed on the fluid mesh, and interpolation schemes are adopted to assign the proper boundary conditions at the fluid-structure interface. For this purpose, different computational methods have been proposed, including the immersed boundary method (1), the fictitious domain method (2), the marker and cell method (3), the Chimera grid-embedding method (4), and the operator-split method implemented in the LS-Dyna code (5). These methods have the advantage of avoiding mesh movement treatment and are also versatile; however, they are inaccurate at the interface between the fluid and the leaflets. With the exception of the immersed boundary method, they are fully coupled approaches requiring a bi-directional communication between the fluid solver and the structural solver.

In the second case, the fluid-structure interaction at the boundary is highly consistent. The computational grid moves accordingly to the fluid-structure bound-

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ary, and different techniques can be used in order to couple the flow field and structural equations. The most popular technique is the arbitrary lagrangian eulerian (ALE) approximation, which incorporates grid velocities in the momentum and continuity equations of the fluid domain. This approach has proved to be valid for simulating ventricle and vessel hemodynamics (6,7). Nonetheless, it is problematic where valve simulations are concerned, as the large mesh deformations resulting from the leaflet's rotations are critical for mesh adaptation, and remeshing is in most cases required at least in some regions of the fluid domain. In fact, ALE-based models are more accurate, but present two drawbacks: (i) local numerical diffusion may still occur in the regions where remeshing is needed; and (ii) simulations are extremely demanding in terms of computational costs due to mesh handling requirements. Consequently, published studies of mechanical heart valve motion (8,9) are limited to the two-dimensional (2-D) domain. To the present authors' knowledge, the only three-dimensional (3-D) model accounting for grid deformation deals with a bioprosthetic valve, and was created by Makhijani et al. (10) using the implicit influence coefficient technique. However, bioprosthetic valves models are less demanding in terms of mesh deformation and allow the use of structured grids without remeshing. In fact, this approach cannot be used for mechanical valves where the large leaflet rotations and the small gaps between the housing and the leaflets do not permit the use of purely deforming structured grids.

Most of the above-mentioned studies have focused on the feasibility of simulating the opening or closure process of a heart valve. Experimental validation is not taken into account, with the exception of the investigations of Makhijani et al. (10) on bioprosthetic valves, and Cheng et al. (8) on 2-D mechanical valves.

The present study investigated the 3-D numerical

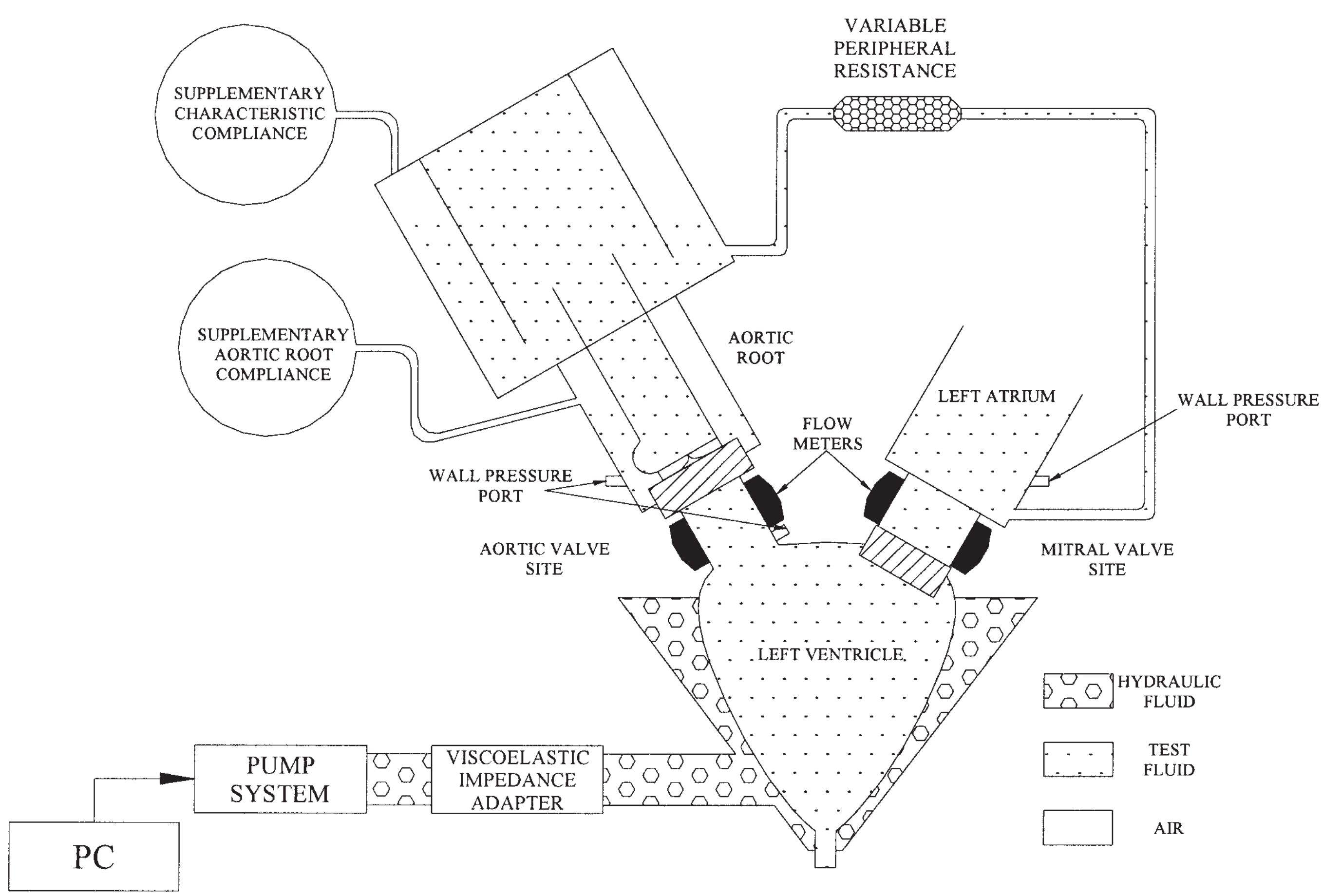

Figure 1: Diagrammatic sketch of the pulsatile, open loop, mock circulatory system (MCS) - VSI (Vivitro Systems Inc.). The MCS consists of a pump system controlled by a PC for waveform generation and data acquisition and a physical model of the left heart system (left ventricle and atrium). The left ventricle chamber consists of a left ventricle model made of polyurethane, a glass model for the aortic root and an entrapping air system for aortic compliance. The atrium consists of an open ceiling reservoir. The left ventricle and the atrium are connected by a circuit with a variable peripheral resistance. The St. Jude HP valve is located in the aortic valve site; the aortic flow measurements were performed by two electromagnetic flow meters.

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and experimental simulation of the opening process of a bileaflet mechanical heart valve. The moving deforming mesh method implemented in the CFD commercial software Fluent (Fluent Inc., Lebanon, IL, USA) was used in conjunction with a customized subroutine for the calculation of the leaflet center of mass motion. In order to reduce computational costs, a loose coupling algorithm was adopted, which calculates the force acting on the leaflets at the end of each time step and forecasts the leaflet motion in the subsequent time step through an under-relaxation scheme. Simulations of a 27 mm St. Jude Medical Hemodynamic Plus mechanical valve (St. Jude HP) were performed at the Department of Bioengineering at the Polytechnic University of Milan; technical drawings of the valve were provided by St. Jude Medical. The Laboratory of Biomedical Engineering of the Italian National Health Institute carried out in-vitro experimental simulations with the same valve mounted in a Vivitro (Vivitro Systems Inc.) mock loop, thus providing the experimental counterpart of the study.

Materials and methods

Experimental simulation

The experimental session was performed with a pulsatile, open loop, mock circulatory system (MCS) - the VSI (Vivitro Systems, Inc.) mock loop - which was properly modified in order to create a thin glass window located on top of the aortic site, thus allowing the monitoring of the valvular function with a camera (11,12). The MCS pulse duplicator consists of a piston-in-cylinder pump head driven by a low-inertia electric motor, and a physical model of the left heart system, which consists of a hydraulic chamber containing a transparent and compliant left ventricle model made of polyurethane, an atrial chamber simulated by means of an open ceiling reservoir and a glass model of the aortic root (including the Valsalva sinuses), together with an entrapping air system modeling the aortic compliance. A diagrammatic sketch of the MCS is shown in Figure 1.

The mechanical bileaflet prosthetic valve was located in the aortic valve site, while a mechanical reference valve (e.g. no-leakage valve) was inserted in the mitral site (13).

Ventricular, atrial and aortic pressure measurements were performed through wall pressure ports, with instrumentation composed of three pressure transducers (for clinical use, pt. 43-604; 0.5 μV/V/mmHg ± 2% sensitivity) and three bridge amplifiers (AM-PACK AP9991). Aortic and mitral flow measurements were made with two electromagnetic flow meters (FM501; Carolina Medical, Inc.) located in the aortic and mitral valve positions, respectively (Fig. 2).

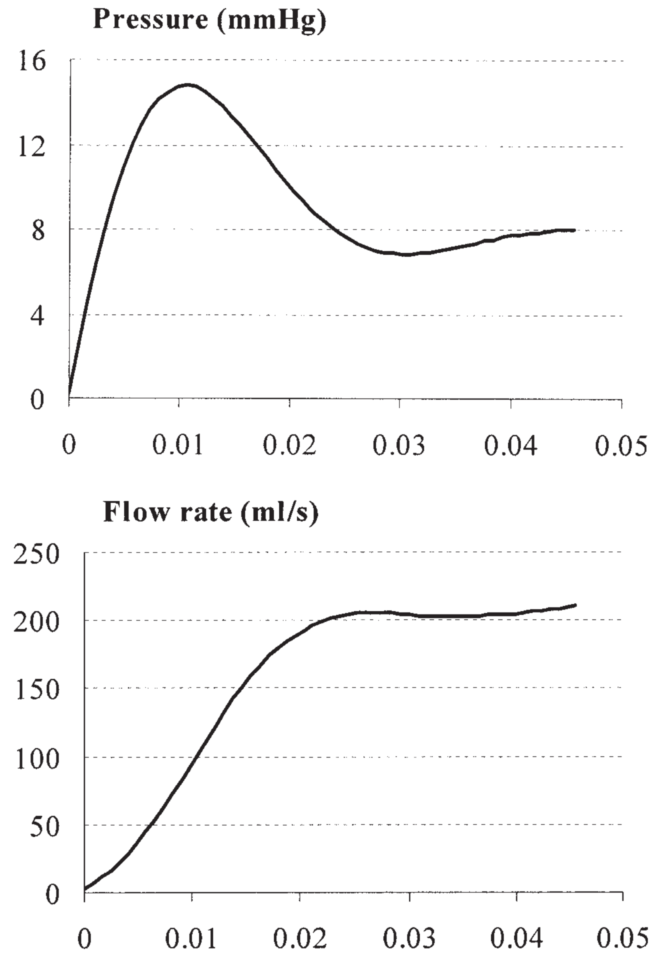

Figure 2: Transvalvular pressure drop and flow rate measurements at the aortic valve site. The pressure was used as input waveform in the numerical calculations, while the flow rate data were recorded for comparison with numerical results.

The hydrodynamic behavior 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 3.7×10^{-3} Pa·s, which is similar to that of blood.

A PCI-MIO-16E-4 (National Instruments, Austin, TX, USA) I/O board, controlled by PC (Pentium III, 64 MB RAM) was adopted for data acquisition and pump drive waveform generation. A custom-made software program developed in a LabVIEW® environment (National Instruments) made it possible to drive and control the MCS, since it can generate several pump drive waveforms, as well as acquire, analyze and display experimental data (a more detailed description of the software can be found in Grigioni et al. (12)). The implemented pump drive waveform is a standardized flow waveform for the mean function of a patient's heart, in accordance with FDA guidelines.

A cardiac output of 2 l/min, with a mean arterial pressure of 100 mmHg and a heart rate of 72 beats/min were the working conditions for the prosthetic valve used in this investigation. This quite unrealistic fluid dynamic condition was chosen in order to attain laminar flow throughout the cardiac cycle. This was considered a main concern of the present study, the primary aim of which was the comparison of simulated and experimental leaflet dynamics in order to validate the numerical approach. Consequently, a flow rate was adopted which was equal to 2 l/min according to experimental evidence which showed, in preliminary tests, that the onset of turbulence occurs at the physiological cardiac output in the present experimental set-up.

Studies of the kinematics of the prosthetic valve were performed using an ultrafast cinematographic technique (Kodak Ektapro) (14). The Ektapro camera, which is located on the other side of the thin glass window, records 239 × 192 pixels images at a frequency of f_c = 1000 frames per second. Once the calibration has been performed by acquiring the image of a reference object, this experimental set-up makes it possible to follow the tidal evolutions of characteristic points of the leaflets, thus recording specific features both in the opening and in the closing phases of the valve.

Splitting of the Ektapro screen into 12 parallel slices produced an image of the central piece of the prosthetic valve B-Datum (Fig. 3) at a rate of 12,000 frames/s (i.e. 12 × f_c) (14). With a backlighting system, the position of the innermost points P_l and P_r was recorded at the internal left and right leaflet edge respectively, thus making it possible to measure the width of the gap between the leaflets (B-Datum), as shown in Figure 3. In this way, leaflet motion in time could be followed in detail.

The light intensity of the camera lens was set to minimize diffractive phenomena; likewise, the backlight system was arranged for uniform illumination without blooming effects.

The original Labview code controlling the MCS caused the synchronization of the Ektapro recording and the cardiac cycle; 16 beats were acquired and averaged.

In this way, the displacement of the leaflet in the valve plane was measured. Since the coupling between the housing ring and the leaflet designed for St. Jude HP allows only a purely rotational motion to the leaflet (rigid motion), knowledge of the planar displacement alone was sufficient to fully describe leaflet kinematics (15).

Numerical simulation

Numerical simulation was performed with the finite volume commercial software Fluent 6.1. Although it was not designed for fully coupled fluid-structure interaction problems, Fluent software provides a number of features which are well-suited for handling the specific problem of rotating boundaries according to the following: (i) the implemented moving deforming mesh module allows robust mesh deformation handling by assuming that the tetrahedral edge behaves

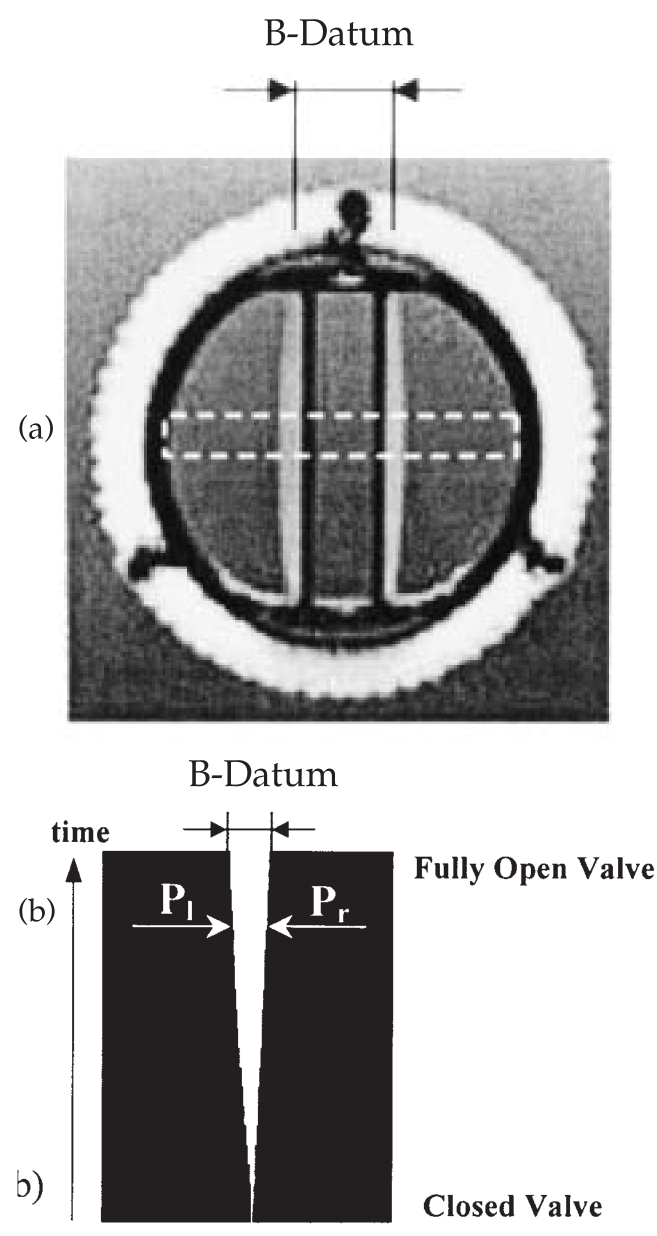

Figure 3: a) Image of the prosthetic valve; the dotted white line outlines the central slice of the Ektapro screen (1/12 of the camera screen) where images are captured at a rate of 12,000 frames/s. b) Temporal evolution of the gap between the leaflets (B-Datum) during the beat, from the completely closed valve configuration (bottom) to the fully open one (top). The position of the innermost points P_l and P_r, at the internal left and right leaflet edge respectively, is shown for a generic timeframe.

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like a spring; (ii) the moving deforming mesh module can be used in conjunction with a remeshing algorithm to properly treat degenerated cells; and (iii) Fluent uses the ALE formulation, which provides an accurate solution for the Navier-Stokes equations for deforming meshes.

Geometry

The valve seat and leaflet geometries (Fig. 4a) were constructed from data provided by St. Jude Medical. Similarly, the aortic and ventricular conduits were modeled from MCS 2-D technical drawings; only the ducts located between the MCS pressure sensors were taken into account (see Fig. 1). The valve seat and leaflet geometries were slightly modified in order to attain a high-quality mesh throughout the valve opening phase. A 0.07-mm gap was created between the leaflets in the closed position so as to put two rows of cells in between. The butterfly hinges were scaled by a factor of 1.06 and transformed into spherical hinges to avoid contacts between the seat and the leaflet. The action of the butterfly hinges was simulated by limiting the leaflet rotation between 24° (fully closed position) and 84° (fully opened configuration), with respect to the valve orifice plane. Finally, as far as the MCS is concerned, the model was simplified and the sinuses of Valsalva were approximated with a surface of revolution. The whole fluid domain is shown in Figure 4b.

The valve region was discretized with tetrahedral elements according to the moving deforming mesh module requirements. The mesh was refined at the valve edges by means of a size function in order to accommodate for leaflet movement (Fig. 5a). In the aortic and ventricular ducts, a hexahedral mesh was used in order to limit the numerical diffusion. The number of cells used in the simulation was equal to 309,000 tetrahedral cells and 31,000 hexahedral cells.

Fluid-structure interaction method

As previously stated, Fluent does not provide a fluid-structure algorithm for fully coupled interactions as it does not include a bi-directional communication capability between the fluid dynamics solver and the structural solver. In the present study, the moving deforming mesh module was used in conjunction with two user-defined subroutines called *MDM* and *cg_motion* (center of gravity motion). At the beginning of each step, the first one calculates and updates the kinematics of the leaflets on the basis of the moment applied to them, which is calculated by the second subroutine at the end of the previous step once the time step convergence has been achieved. In fact, the two subroutines work together iteratively through consecutive steps.

More precisely, at the end of the *n-th* step, the moment M_P acting on the leaflets due to blood pressure is calculated by the *MDM* subroutine as:

$$M_P = \sum_{i=1,n_b} \left(p_i A_i \mathbf{n}_i\right) \wedge \mathbf{r}_i \quad (1)$$

where n_b is the number of the leaflets' boundary faces, the subscript i refers to the *i-th* face, p_i is the pressure acting on the face whose versor is indicated with n_i, A_i is the area of the face and r_i is the distance from the rotation axis.

Once the value of M_p is known, at the beginning of the next step *(n+1)-th*, the *MDM* subroutine calculates the leaflet kinematics by means of three equations. Under the hypothesis of pure rotation (as in the case of the St. Jude HP valve), the first equation describes the leaflet dynamics and makes it possible to calculate the angular acceleration:

$$I \frac{d^2\theta}{dt^2} = M_P \quad (2)$$

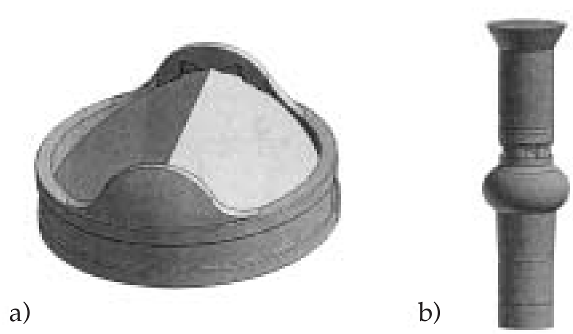

Figure 4: Model geometry. a) 27 mm St. Jude HP valve; b) overall model including the inlet ventricular duct and the outlet aortic duct.

Figure 5: Discretized model. a) 27 mm St. Jude HP valve surface discretization; b) overall fluid domain.

where I is the moment of inertia and θ is the rotation angle. This formulation does not take shear or gravitational forces into account.

The second equation is introduced in order to update the acceleration value for the subsequent time step through an under-relaxation scheme as in the form:

$$\ddot{\theta}_{n+1} = \ddot{\theta}_n + w\,(M_{P,n}/I - \ddot{\theta}_n) \qquad (3)$$

where the under-relaxation factor w reduces the change of acceleration produced during each iteration. The value of w was set equal to 0.01 according to preliminary 2-D simulations (unpublished data); values greater than 0.01 were observed to cause instability or divergence throughout the simulation.

The third and last equation makes it possible to calculate leaflet velocity and displacement on the basis of the acceleration values using the Newmark method:

$$\begin{aligned} \dot{\theta}_{n+1} &= \dot{\theta}_n + (1-\gamma)\,\Delta t\,\ddot{\theta}_n + \gamma\,\Delta t\,\ddot{\theta}_{n+1} \\ \theta_{n+1} &= \theta_n + \Delta t\,\dot{\theta}_n + (\frac{1}{2} - \beta)\,\Delta t^2\,\ddot{\theta}_n + \beta\,\Delta t^2\,\ddot{\theta}_{n+1} \end{aligned} \qquad (4)$$

where the parameters β and γ were set equal to 1/4 and 1/2. With this choice, the Newmark method is unconditionally stable and second order accurate in time (9,16).

The above-described procedure implies two simplified assumptions concerning the fluid-structure interaction. First, a delay of one time step occurs in the communication between the fluid and the leaflet solvers since the mesh is updated at the beginning of the time step and the updated flow patterns are available at the end of the time step. Second, the under-relaxation scheme described by Eq. (3), which was used in order to reduce the simulation computational costs, introduces a further delay in the information exchange between the solvers.

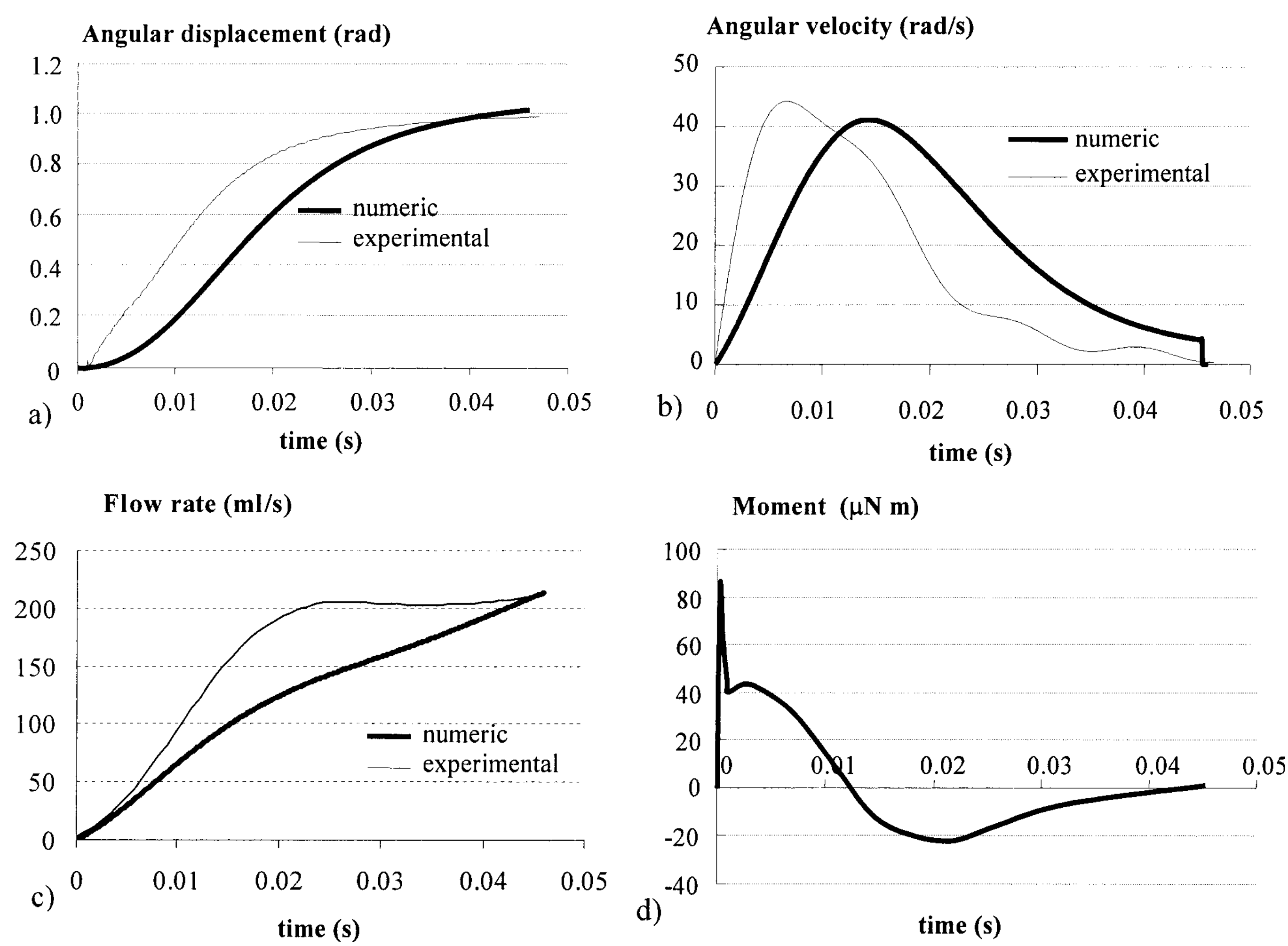

Figure 6: Comparison between experimental and computational results. a) Angular displacement; b) velocity; c) flow rates; and d) moment resulting from the blood pressure.

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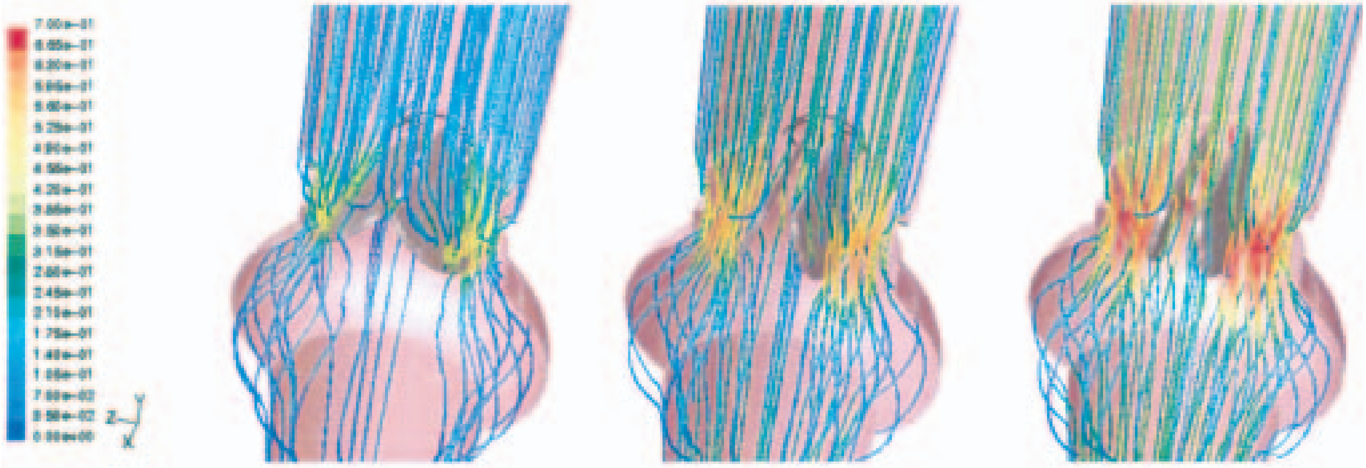

Figure 7: Left to right: stream lines colored by velocity magnitude calculated at the beginning of the opening process (37.5°), in an intermediate phase (63°), and with the valve fully opened (84°).

Simulation set-up

Blood flow was assumed to be isothermal and laminar, and blood was treated as an incompressible, Newtonian fluid. The density of the fluid was set at 1,060 kg/m^3 and its viscosity at 3.7×10^{-3} Pa·s to match the characteristics of the fluid used in experimental simulations.

The density of the leaflet was set at 2,000 kg/m^3 in accordance with data (provided by St. Jude Medical) for pyrolytic carbon obtained with the fluidized bed coating process at high temperatures. Under this assumption, the leaflet moment of inertia was calculated by means of the structural code ABAQUS (HKS) and is equal to 9.51×10^{-9} kg·m^2.

A no-slip condition was set on the walls. At the outlet, a constant pressure of 0 Pa was assumed. At the inlet, a harmonic function that corresponds to the pressure drop measured in the experimental session between the inlet and outlet was applied.

The simulation was run on a single processor Intel Pentium 4, 1.7 GHz computer with 2 GB RAM. The time step was determined as equal to 0.02 ms, and each timestep required 4 min for the simulation to converge. The complete opening of the valve was obtained in 154 h.

Results

Figure 6 demonstrates the comparison between numerical and experimental results in terms of valve kinematics, flow rate and moment acting on the leaflets. Numerical results relating to valve angular displacement and velocity showed a good, although approximate, agreement with experimental measurements. The opening angle process was delayed by ~7 ms. This value was considered acceptable with respect to the opening phase time lapse of 46 ms. Angular velocity was slightly underestimated (7%). Due to the delay in the opening process, the flow rate was underestimated; the maximum deviation from the experi-

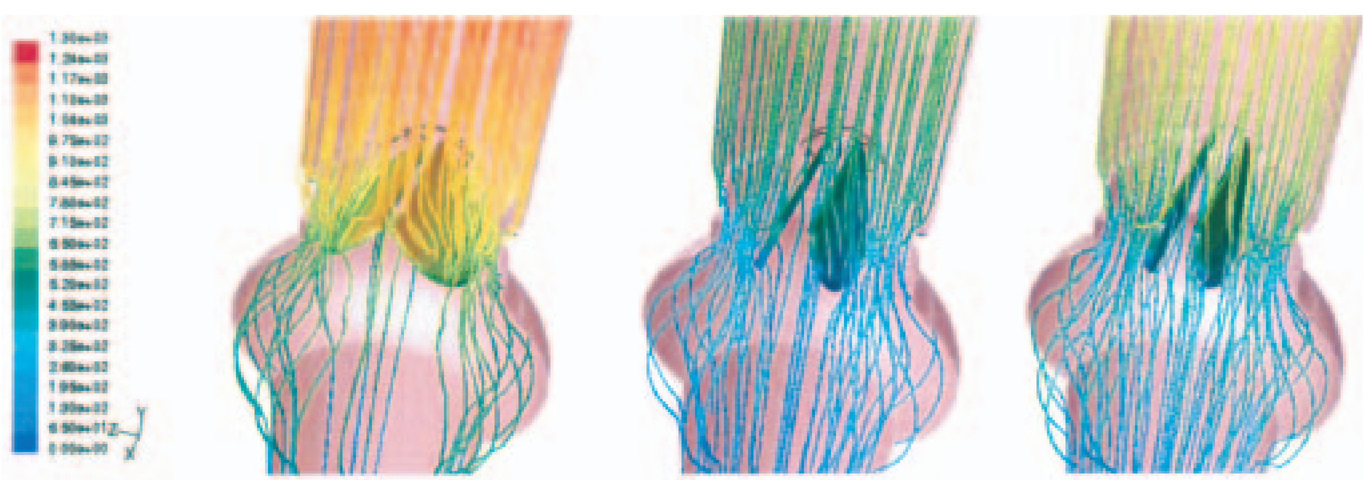

Figure 8: Left to right: stream lines colored by pressure at opening angles of 37.5, 63 and 84°.

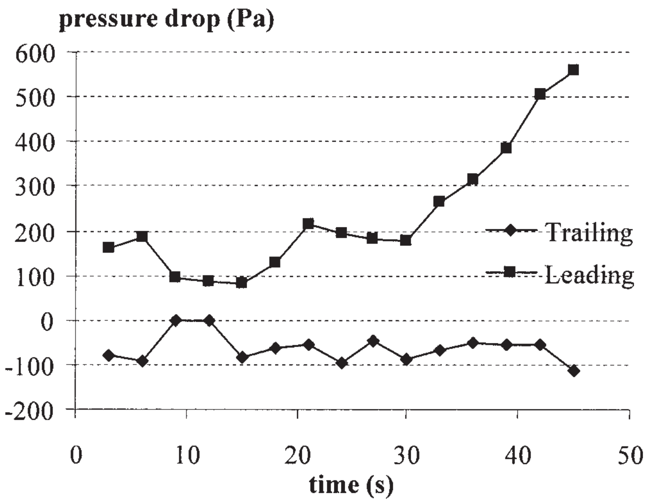

Figure 9: Pressure drops at the mid-point of the leading and trailing edges of the leaflets. Pressure drops were calculated as the difference of the pressure between the outer and inner surfaces of the leaflets.

mental data was ~25% and occurred at 0.02 s. The overall flow rate underestimation was equal to 19% after 46 ms. The moment showed an unnatural spike at the very beginning of the opening process and a positive value in the first 0.12 ms of the opening process; it became negative afterwards, when the leaflets decelerated.

Figure 7 shows the streamlines colored by velocity magnitude. No vortices were observed during the opening process of the valve. The maximum velocities were calculated in the central region between the leading edges of the leaflets, where the Reynolds number was equal to 2,430 at the end of the opening process.

Figure 8 shows the streamlines colored by pressure. The pressure remained almost constant in the transverse plane, except near the leaflets.

Figure 9 indicates the time course of the transvalvular pressure drop calculated as the difference between the pressure measured at the outer and inner surfaces of the leaflets in the middle of the leading and trailing edges. The maximum pressure drop was equal to 560 Pa (4.2 mmHg) and occurred at the leading edge when the valve was fully opened and the flow rate reached its maximum.

Discussion

The present study describes a method to measure the fluid-structure interaction between blood and the valve leaflets of a commercial bileaflet mechanical valve during its opening process. The method couples the moving deforming mesh module of Fluent, which handles large mesh deformations, and two user subroutines for the leaflet kinetics calculation. The method was first refined by means of a 2-D model (unpublished data) and then applied to a 3-D case. In the present authors' opinion, the moving deforming mesh module proved to be efficient in handling large deformations, thus confirming previous 2-D studies (9,16). The major concerns were the 3-D features of the valve, boundary conditions and experimental comparison. In fact, only minor modifications were made with respect to the original technical drawings provided by St. Jude Medical, and a specifically developed experimental protocol was designed in order to provide realistic boundary conditions for the simulation set-up and for validation purposes. In previous studies dealing with mechanical valves, the leaflet geometry and experimental apparatus were either simplified (3) or bidimensional (1,4,8,9). Transvalvular pressure drops and flow rates were, in most cases, simulated with simplified analytical functions (3,9). Moreover, only Cheng et al. (8) reported detailed experimental data for validation purposes as far as mechanical valves are concerned.

The present approach applies a loose coupling between the fluid and the leaflet. The major advantages of this include a consistent reduction in computational costs and a simpler computational scheme. The major drawback is a delay in the leaflet response with respect to the fluid forces. Hence, a very small time step (0.02 ms) was used in order to limit the delay, and at the same time, it maintained the advantages of the weakly coupled approach. With regard to the present results, the initial spike of the moment time course, which occurred in the first 0.2 ms (Fig. 6d), was probably due to the delayed response of the leaflets. In turn, the 7 ms delay of the opening angle and the related lower flow rate calculated during the opening process were not necessarily due to the calculation scheme, as similar results were reported when a tight fluid-structure coupling algorithm was used. Shi et al. (3) obtained a consistent delay of 18 ms for the valve motion with respect to the fluid velocity onset, while the computed angular displacement was delayed by 7-10 ms with respect to the pressure onset in the study by Cheng et al. (8). The cause of the delayed valve opening was probably due to an overestimation of the fluid inertia. Before the onset of the systolic phase, the fluid is expected to move because of the compliant aortic root (not taken into consideration in the simulation), the valve static leakage and the previous diastolic filling. In the simulation, the fluid is assumed to be quiescent at the beginning of the systolic phase, and this implies a larger inertial load contrasting the onset of the opening process.

It is interesting that, in the present study, the moment profile was similar to data relating to the intraventricular pressure drops reported in previous studies (6).

The transvalvular pressure drop increased throughout the opening process up to 570 Pa. The calculated value was consistent with the value attainable under stationary conditions at the maximum flow rate (213 ml/s) and with the valve fully opened (542 Pa), thus indicating that the inertial non-convective term plays a minor role in determining the overall pressure drop.

In the present study, some simplified assumptions were made, and further investigations are necessary.

The Reynolds number has been limited to about 2,400, and according to experimental observations this guaranteed laminar flow. Nonetheless, the study of the transient and turbulent conditions is of great interest for valve design. Unfortunately, no single turbulence model is universally accepted, especially when dealing with low-Reynolds-number effects. Currently, Fluent software offers two options for this kind of flow, the modified K-ω model and the RNG K-ε model, the name of which is derived from a rigorous statistical technique (renormalization group theory). Future plans involve the evaluation of both models by comparison with proper experimental tests.

The flow pattern validation may also be improved through the use of particle image velocimetry, once it is developed for 3-D valve fluid dynamics visualization. This technique, currently used at the Laboratory of Biomedical Engineering of the Italian National Health Institute for 2-D valve fluid dynamics visualization (17) and under development for 3-D application, requires careful implementation due to the inherent difficulties related to the optical access offered by the MCS set-up. In fact, the MCS used in the present study must be properly modified for this application. In addition, the experimental set-up must be further improved with respect to the triggering of the different measurements at the onset of the actual opening process (when the evidence of a gap between the leaflet may not correspond), as well as a more detailed evaluation of the flow patterns at that phase.

Finally, the fluid-structure interaction algorithm can be improved. In particular, two options are feasible in order to avoid the delay in fluid-structure coupling. The first option is the introduction of a variable under-relaxation parameter. The 1% value of w was used in order to guarantee the algorithm stability in the first time steps. However, a larger value is probably not critical for the subsequent time steps, thus improving the convergence and the response of the leaflet with respect to the fluid forces acting on the leaflets, once the leaflet inertia becomes negligible. Alternatively, a tightly coupling algorithm like that used in the present authors' previous studies and by Verdonck's group (6,9,16,18) may be adopted. This approach requires an external batch subroutine, which manages multiple fluid dynamics simulations for each time step in order to identify the simulation that satisfies the fluid-structure interaction problem. In 3-D studies, this procedure is extremely time-consuming and would require the use of a parallel solver. This solution was not adopted in the present study as the use of user-defined functions currently abates the solver parallel efficiency. The elimination of this bug will consistently speed up the simulation process and improve the efficiency of Fluent software as a tool for the design of mechanical valves.

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