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Numerical analysis for the structural strength comparison of St. Jude Medical and Edwards MIRA bileaflet mechanical heart valve prostheses †

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Abstract

This paper presents a numerical analysis for the structural strength comparison of the St. Jude Medical bileaflet mechanical heart valve prosthesis with flat leaflet and the Edwards MIRA bileaflet mechanical heart valve prosthesis with curved leaflet. Computer aided engineering systems are used in the analysis. The blood fluid pressure is applied to both flat and curved leaflets of the bileaflet mechanical heart valve prostheses for the rigid body dynamic analysis to confirm the almost same dynamic characteristics of both flat and curved leaflet motions. Thereafter, using the same blood fluid pressure and dynamic characteristics of leaflet motions, structural mechanic analyses for both flat and curved leaflets of the mechanical heart valve prostheses are carried out to show quite different stress and deformation results, respectively. Conclusively, from the viewpoint of stress, it is revealed that the St. Jude Medical bileaflet mechanical heart valve prosthesis is structurally stronger and better than the Edwards MIRA bileaflet mechanical heart valve prosthesis. Computer aided engineering systems used in this comparative structural analysis are ADAMS for the rigid body dynamic analysis, and NISA for the structural mechanic analysis.

Keywords: Numerical analysis; Structural strength comparison; Bileaflet mechanical heart valve prosthesis; Rigid body dynamic analysis; Structural mechanic analysis; Computer aided engineering system

1. Introduction

A normal heart valve performs an amazing mechanical function, opening and closing with each beat of the heart, about 38 million times per year for an entire lifetime. There are times when heart valves may not work properly. In children there may be congenital defects at birth that sooner or later result in valve malfunction. Certain diseases, such as rheumatic fever, can damage the valves enough that they will eventually need to be repaired or replaced. Age can also result in stiffening or deposition of calcium on the valve, which may also require repair or replacement. Representative heart valve diseases are stenosis, regurgitation (or insufficiency), and a combination of stenosis and regurgitation. Today, valve surgery can correct these problems and restore the function of diseased valves. For some patients the existing natural valve will need to be replaced by a prosthetic valve (manufactured heart valve).

The new replaced prosthetic heart valve can be either a biological heart valve (BHV) or a mechanical heart valve (MHV). Biological heart valves (also called tissue or bioprosthetic heart valves) are manufactured using several different methods. Mechanical heart valves (also called synthetic heart valves) are made totally of mechanical parts, that are tolerated well by the body. Despite the care given to heart valve design and patient welfare, problems may arise. Some complications of valve surgery include prosthetic valve failure, reoperation of pig or cow tissue valve due to tissue failure, pannus (scar tissue) ingrowth, stuck leaflets (impingement), anticoagulant-related bleeding (hemorrhage), thrombotic complication (thrombus, thromboebolism), prosthetic valve infection, and hemolytic anemia (hemolysis). These problems do not occur in most patients, but awareness of them can increase the likelihood of success with the new valve.

The third generation prosthetic valve was developed in the late 1970s and became the valve of the 1980s [1]. This was the St. Jude Medical bileaflet mechanical heart valve prosthesis. Leaflet opening was more complete, the hemodynamics was improved, and the incidence of thromboembolism was reduced. Nowadays, bileaflet mechanical heart valves like the St. Jude Medical bileaflet mechanical heart valve prosthesis, the Edwards MIRA bileaflet mechanical heart valve prosthesis,

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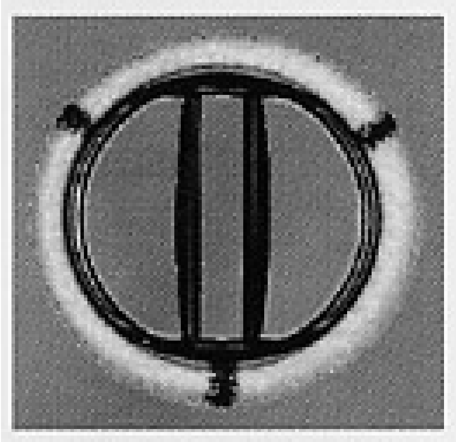
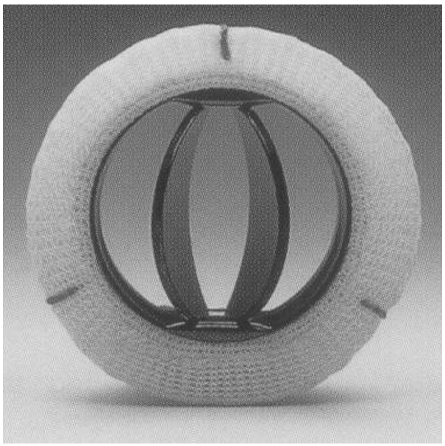
and the On-X bileaflet mechanical heart valve prosthesis (the newest brand name of bileaflet mechanical heart valve prosthesis) etc., are the most commonly and widely implanted prosthetic heart valves, with over 130,000 implants worldwide each year. Since the report [2] of the in vivo leaflet fracture in the Edwards Duromedics bileaflet valves, clinically structural failure of a bileaflet mechanical heart valve is very rare. Bileaflet mechanical heart valve prostheses have been available commercially from early 1980s and have had no structural problems and they function in the human body for some decades without structural failure. Hence, there is very little interest in the comparison of the deformation and stress on the leaflets from a clinical point of view. The major problem with implanted mechanical heart valves is the initiation of thrombus and the detailed fluid mechanical analysis is more of interest to study the relationship between fluid-induced stresses and thrombus initiation. However, the modern cardiac valve prosthesis must be capable of continuously regulating blood flow in “hostile” physiological environments for patient lifetimes. The bileaflet mechanical heart valve prosthesis developed so far has either a flat leaflet geometry or a curved leaflet geometry. The St. Jude Medical bileaflet mechanical heart valve prosthesis and the On-X bileaflet mechanical heart valve prosthesis have the flat leaflet geometry, whereas the Edwards MIRA (previously named as Edwards Duromedics) bileaflet mechanical heart valve prosthesis has the curved leaflet geometry. Nowadays, the St. Jude Medical bileaflet mechanical heart valve prosthesis and the On-X bileaflet mechanical heart valve prosthesis are widely and clinically implanted in the human heart, while the Edwards MIRA MHV prosthesis is rarely used and moreover not available commercially now. The main reason why the curved bileaflet MHV prosthesis is not used now may be due to the report of the in vivo leaflet fracture [2] in the Edwards Duromedics bileaflet MHV prosthesis. On the contrary, such in vivo leaflet fractures have never been reported in the St. Jude Medical and even in the newest brand On-X bileaflet MHV prostheses. Hence, the bileaflet MHV prosthesis with flat leaflet geometry seems to be structurally stronger than the bileaflet MHV prosthesis with curved leaflet geometry. However, this clinically accepted axiom has not been proved analytically as yet. Only one reference [3] showed that the curved leaflet geometry used in the Edwards Duromedics MHV prosthesis does not provide any fluid dynamic advantage. Hence, the purpose of this paper is to analytically prove and/or justify that the bileaflet MHV with flat leaflet geometry is structurally stronger than the bileaflet MHV prosthesis with curved leaflet geometry by using the numerical analysis method (i.e., FEM). That is, this paper presents the numerical analysis for the structural strength comparison of St. Jude Medical and Edwards MIRA bileaflet mechanical MHV prostheses.

Since the stresses are very difficult to measure experimentally or through the in vivo experimental investigation for transient systems with complex three-dimensional geometries, the computational numerical methodology can enhance the understanding of the biological and mechanical heart valve behaviors under different patho-physiological conditions. Hence, most of the structural analyses for the stress measure in the valve leaflet have been performed through the numerical method, i.e., finite element method (FEM). Structural failures of biological and mechanical heart valves have been shown to occur as a consequence of high stresses in the leaflets during opening and closing [4-12]. These structural analysis studies for the stress reduction in the valve leaflet are important and very required for the design of the biological and mechanical heart valves. Recently, a computational numerical approach method considering fluid-structure interaction between blood flow and leaflet behavior and using computer aided engineering systems has been developed for a better understanding of the opening and closing behaviors of a synthetic heart valve, i.e., the bileaflet mechanical heart valve [13-19]. Hence, from this point of view, in the present study, a numerical analysis on the behaviors of flat and curved leaflets of the bileaflet mechanical heart valve prostheses is executed to compare the structural strength of the leaflets for the better design of the bileaflet mechanical heart valve prosthesis. At first the rigid body dynamic analyses for the leaflet motions of the flat and curved bileaflet MHV prostheses are carried out to compare the dynamic characteristics of the flat and curved leaflet motions and make sure the leaflet position where the maximum stress and strain may occur in the flat and curved leaflets. These rigid body dynamic analyses are not directly related to the structural strength of the leaflets. However, these rigid body dynamic analyses are very necessary and required for the structural mechanic analysis of the leaflets for the structural strength comparison, because constraint conditions such as boundary condition and the external load condition which are very essential for the structural mechanic analysis are determined through these rigid body dynamic analyses. Otherwise, difficult and bothersome structural dynamic analyses of the leaflet motions should be carried out instead of simple structural mechanic analyses, and structural dynamic analyses are not useful just for the structural strength comparison of the leaflets. Once the constraint conditions such as boundary conditions are determined through the rigid body dynamic analyses, thereafter the structural mechanic analyses are performed. The multidisciplinary analysis (MDA) technique adopted in this paper, where several analyses like rigid body dynamic analysis, fluid mechanic analysis, and structural mechanic analysis are carried out simultaneously and related to each other, is a noble and emerging new technology in the numerical structural analysis and design [20]. Nowadays, multidisciplinary analysis and design optimization techniques are efficiently applied to a large complicated scale structural analysis problem [21-22]. Fatigue fracture analysis due to the alternating stress [23-25] and the fracture analysis due to the cavitation [26-27] are not treated in this paper, because the in vivo leaflet fractures of the bileaflet MHV prostheses due to these kinds of phenomena have not been reported even though some BHV prostheses have been reported to have these kinds



(a) St. Jude Medical mechanical heart valve prosthesis with flat leaflet (Courtesy of St. Jude Medical)



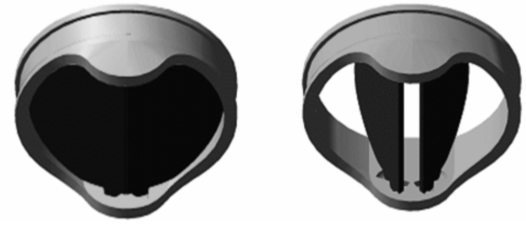
(b) Edwards MIRA mechanical heart valve prosthesis with curved leaflet (Courtesy of Edwards Lifescience LLC)

Fig. 1. Flat and curved bileaflet mechanical heart valve prosthesis models used in the analysis.

of fracture problems. Nonetheless, many researches [23-27] have been carried out under the assumption of the possibility of the leaflet fracture due to these phenomena. Computer aided engineering systems like ADAMS and NISA are used for the present study. The flat bileaflet mechanical heart valve model used in the present study is the St. Jude Medical bileaflet mechanical heart valve prosthesis and the curved bileaflet mechanical heart valve model is the Edwards MIRA bileaflet mechanical heart valve prosthesis (Fig. 1).

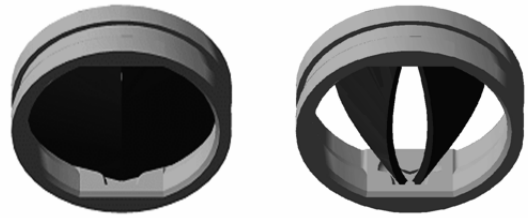
2. Rigid body dynamic analyses of the leaflet motions

In this section, reaction force and torque variations with time at joints of the valve during the leaflet motion are computed to understand the dynamic characteristics of leaflet motions of the bileaflet mechanical heart valve prostheses and to determine the leaflet movement position at which the structural mechanic analysis is carried out. As mentioned in the previous section, these rigid body dynamic analyses are very



Opening angle θ = 25 °   Opening angle θ = 65 °

(a) St. Jude Medical mechanical heart valve



Opening angle θ = 20 °   Opening angle θ = 60 °

(b) Edwards MIRA mechanical heart valve

Fig. 2. Solid models of the bileaflet mechanical heart valve prosthesis generated using ADAMS (completely closed and opened configurations, respectively).

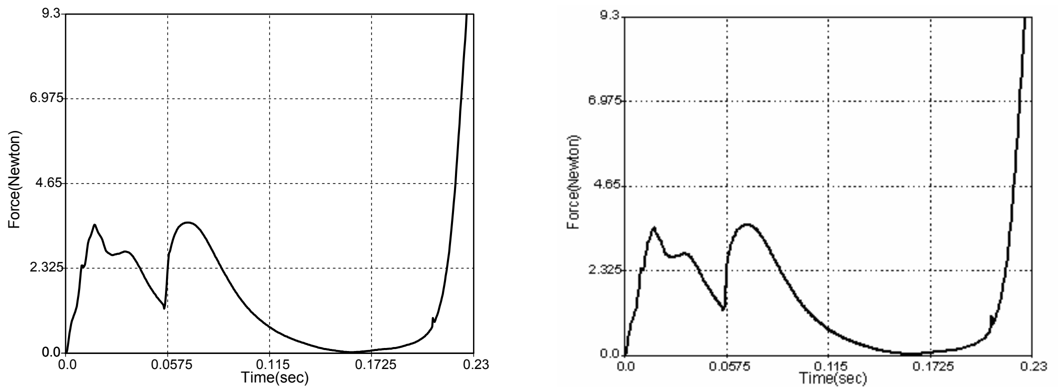
important and required to determine the constraint conditions needed for the structural mechanic analyses of the deformed leaflets. ADAMS, a commercial code, is used for the rigid body dynamic analyses of the leaflet motions.

2.1 The kinematical model for rigid body dynamic analysis

The bileaflet mechanical heart valve prosthesis consists of three parts : two leaflets which control the blood reverse flow, the orifice ring which supports the leaflets and the sewing cuff which attaches and fixes the orifice ring to the tissue of the heart muscle. A rigid body dynamic analysis of the leaflet of the mechanical heart valve prosthesis is performed to get the reaction force and torque at each joint (hinge). The kinematical model of the mechanical heart valve prosthesis consists of three links and four joints. And the mobility of the leaflet movement is two. The solid model generated by ADAMS is shown in Fig. 2.

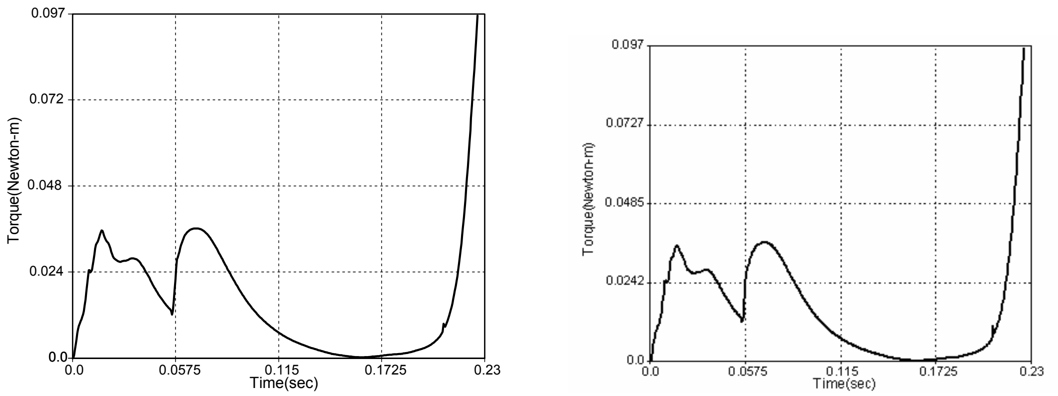
2.2 Analysis results and discussions

Fig. 3 and Fig. 4 indicate the reaction force and the torque occurring at joints during the valve movement, respectively. The reaction force and the torque change very roughly while the leaflets keep opening up to 80° for the St. Jude Medical bileaflet mechanical heart valve prosthesis and up to 85° for the Edwards MIRA bileaflet mechanical heart valve prosthesis. The reaction force and the torque at joints increase rapidly after t=0.2 seconds when the leaflets start to close for both flat and curved leaflets and become the maximum value at the completely closed leaflet movement position. Hence, structural deformations in the leaflets are expected to become the maximum value at the completely closed leaflet movement



(a) St. Jude Medical mechanical heart valve (b) Edwards MIRA mechanical heart valve

Fig. 3. Transient variation in reaction force occurring at joints of the bileaflet mechanical heart valve prosthesis (computed through the rigid body dynamic analysis).



(a) St. Jude Medical mechanical heart valve (b) Edwards MIRA mechanical heart valve

Fig. 4. Transient variation in torque occurring at joints of the bileaflet mechanical heart valve prosthesis (computed through the rigid body dynamic analysis).

position for both flat and curved leaflets at which the maximum reaction force and torque occur at joints. Consequently, both flat and curved leaflets have the almost same dynamic characteristics, and structural mechanic analyses for both leaflets are carried out only at the completely closed leaflet movement position instead of all leaflet movement positions. This result agrees very well with other research work [6, 8, 11, 12], but it is derived logically through the rigid body dynamic analysis of the valve movement in this study (while it was just intuitively assumed in other research work). These constraint conditions shall be used for the structural mechanic analysis of bileaflet mechanical heart valve prostheses in the next section.

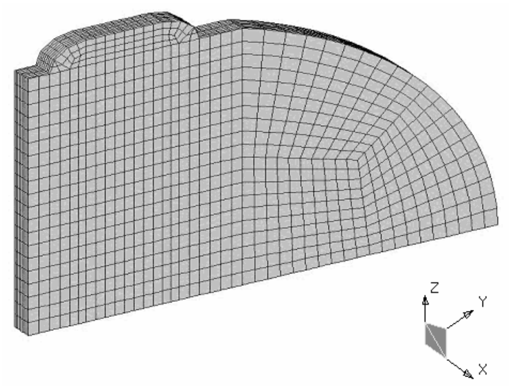
3. Structural mechanic analyses for deformed leaflets

The movement position of the leaflet and fluid forces acting on the leaflet at a time when the maximum structural deformation may occur in the leaflet should be known for the execution of the structural mechanic analysis of the deformed leaflets, because the boundary and constraint conditions to be imposed on the leaflets for the structural mechanic analyses of the leaflets depend on the leaflet movement position.

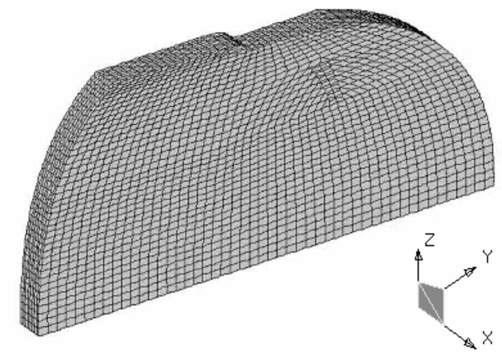
The movement position of the leaflet when the blood fluid force acting on the leaflet and the reaction force occurring at valve joints become the maximum value was computed as the completely closed leaflet movement position through the previous rigid body dynamic analyses. Hence, structural mechanic analyses for the deformed leaflets are carried out at the completely closed leaflet movement positions of the opening angle 25° for the St. Jude Medical bileaflet mechanical heart valve prosthesis and of opening angle 20° for the Edwards MIRA bileaflet mechanical heart valve prosthesis to get the structural strength variations of valves as the leaflet thickness changes. NISA, a commercial finite element analysis code, is used for the structural mechanic analysis and the linear structural analysis technique of NISA is adopted.

3.1 Analysis model and boundary conditions

Finite element models of leaflets for the structural mechanic analysis for the deformed leaflets are shown in Fig. 5. Half of the leaflet is used as a model for each valve due to the geometric symmetry. Finite element models consisting of eight node hexahedron elements and eight elements are meshed in the direction of the leaflet thickness.



(a) St. Jude Medical mechanical heart valve



(b) Edwards MIRA mechanical heart valve

Fig. 5. F.E. models of leaflets.

Table 1. F.E. model data for the leaflet of the St. Jude Medical bileaflet mechanical heart valve prosthesis.

Parameters		Data	Units
Model data	Element type	Eight node hexahedron solid element	None
	No. of nodes	9,754	None
	No. of element	6,432	None
	Yield stress	407.7	MPa
Leaflet material properties	Young's modulus (E)	30.5	GPa
	Poisson's ratio (ν)	0.3	None
	Density (ρ)	2,116	Kg/m^3

Table 2. F.E. model data for the leaflet of the Edwards MIRA bileaflet mechanical heart valve prosthesis.

Parameters		Data	Units
Model data	Element Type	Eight node hexahedron solid element	None
	No. of nodes	15,489	None
	No. of element	13,136	None
	Yield stress	407.7	MPa
Leaflet material properties	Young's modulus (E)	30.5	GPa
	Poisson's ratio (ν)	0.3	None
	Density (ρ)	2,116	Kg/m^3

The orifice ring is neglected in the analyses, because it does not affect the analysis result. The orifice ring is assumed as a rigid body. Three degrees of freedom (u_x, u_y, u_z) are constrained at the hinge point and on the outer end surface of the leaflets that contact the rigid orifice ring. The symmetric boundary condition (u_y=0) is applied on the symmetric surface (y=0), since both leaflets contact each other on this symmetric surface, and also the symmetric boundary condition (u_z=0) is applied on the symmetric surface (z=0). The blood fluid pressure that is the external force acting on leaflets is exerted onto the leaflet surface as a normal uniform blood pressure. Blood pressures varying from 24,050.59 Pa to 104,050.59 Pa increasing by 20 KPa are applied on the leaflet surface. Besides the blood pressure, the impact force as a reaction of the torque (Fig. 4) may exert on the leaflet at the moment when the leaflet closes completely and hits the orifice ring. But this impact force does not affect the structural deformation analysis of the leaflet, because the leaflet contact surface exerted by the impact force as a reaction force is constrained as fixed at the completely closed position of the leaflet movement. The material of the leaflet is assumed to be Si-Alloyed PyC. Table 1 and Table 2 show the finite element and node numbers of models, and the material property values [28] of the leaflet material (Si-Alloyed PyC) for flat and curved leaflets, respectively.

3.2 Analysis results and discussions

Structural deformation and stress distribution results obtained from the structural mechanic analyses are shown in Fig. 6-Fig. 8 and Table 3~Table 4. Maximum stresses occur at the upper central part of the symmetric plane (y=0) of the flat leaflet (Fig. 6(a)) and at the hinge of the curved leaflet (Fig. 8(b)), respectively. Large stresses are also found at the lower sharp corner part of the leaflet end surfaces that contact the orifice ring for both flat and curved leaflets (Fig. 6 and Fig. 8). Table 3 indicates variations of the computed maximum deformation, and Table 4 indicates variations of the computed maximum von Mises stress as the leaflet thickness varies from 0.5 mm to 0.75 mm and the applied blood pressure varies from 24,050.59 Pa to 104,050.59 Pa.

As indicated in Table 4, the maximum von Mises stresses occurring in the leaflets are smaller than the yield stress 407.7 MPa of the material for each leaflet thickness and applied blood pressure. Hence, the leaflet seems to be structurally strong enough in all cases, but the internal stress and deformation values increase as the leaflet thickness decreases. Therefore, the leaflet becomes structurally weaker as the leaflet thickness decreases. As shown in Fig. 9 and Fig. 10, as the blood pressure increases, stress and deformation also increase for all leaflet thickness. However, slopes of lines representing von Mises stress and deformation changes with respect to blood pressure slightly increase as the thickness becomes smaller than 0.60 mm. This phenomenon may suggest that the leaflet structure becomes much weaker as the leaflet becomes thinner than 0.60 mm. This argument can be reasoned and justified from the fact that since the leaflet opens and closes periodically and countlessly for the lifetime, even slight change in the strength of the leaflet structure may cause a little damage to the bileaflet mechanical heart valve prosthesis.

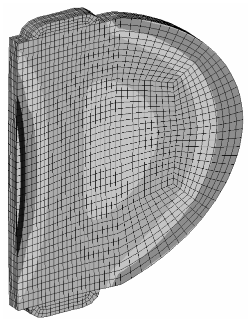
Comparing structural analysis results of flat and curved leaflets, the deformation occurring in the flat leaflet is larger as two or three times as that of the curved leaflet (Table 3), whereas the stress occurring in the curved leaflet is higher as about three times as the stress occurring in the flat leaflet (Table 4). Consequently, the structural mechanic analyses show quite different stress and deformation results for flat and curved bileaflet mechanical heart valve prostheses, respectively, even though they have the almost same dynamic characteristics. Hence, conclusively, this study shows that from the viewpoint of stress the St. Jude Medical bileaflet mechanical heart valve prosthesis is structurally stronger and better than the Edwards MIRA bileaflet mechanical heart valve prosthesis. The structurally weak part of the Edwards MIRA bileaflet mechanical heart valve prosthesis is revealed to be the hinge part that coincides with the in vivo leaflet fracture part reported by Klepetko [2]. And the structurally weak part of the St. Jude Medical bileaflet mechanical heart valve prosthesis is the upper central part of the symmetric plane (y=0) of the flat leaflet, but the stress value of this part is very low. Hence, this structurally weak part of the St. Jude Medical bileaflet mechanical heart valve prosthesis is not so much significant, and a structural failure may not occur. This result agrees very well with the fact that the in vivo structural failures (or fractures) of the St. Jude Medical MHV prosthesis have never been reported so far. Hence, it is analytically justified the axiom that the St. Jude Medical bileaflet MHV prosthesis with flat leaflet geometry is structurally stronger than the Edwards MIRA bileaflet MHV prosthesis with curved leaflet geometry. This result is derived without the analyses of fatigue fracture due to

Table 3. Computed maximum deformations occurring in leaflets of the bileaflet mechanical heart valve prostheses (unit : $\times 10^{-6}$ m).

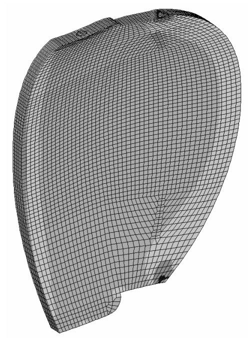
Leaflet thickness (mm) \ Blood pressure (Pa)		24,050.59	44,050.59	64,050.59	84,050.59	104,050.59
0.5	St. Jude Medical heart valve	4.89	8.951	13.00	17.10	21.10
	Edwards MIRA heart valve	1.63	2.99	4.35	5.71	7.07
0.55	St. Jude Medical heart valve	3.71	6.80	9.87	13.00	16.10
	Edwards MIRA heart valve	1.40	2.57	3.73	4.90	6.06
0.6	St. Jude Medical heart valve	2.90	5.30	7.71	10.10	12.50
	Edwards MIRA heart valve	1.21	2.22	3.22	4.23	5.23
0.65	St. Jude Medical heart valve	2.31	4.23	6.15	8.07	9.99
	Edwards MIRA heart valve	1.05	1.93	2.80	3.68	4.55
0.7	St. Jude Medical heart valve	1.88	3.44	5.00	6.56	8.12
	Edwards MIRA heart valve	0.92	1.69	2.45	3.22	3.98
0.75	St. Jude Medical heart valve	1.55	2.84	4.13	5.42	6.71
	Edwards MIRA heart valve	0.81	1.48	2.16	2.83	3.51

Table 4. Computed maximum von Mises stresses occurring in leaflets of the bileaflet mechanical heart valve prostheses (unit : MPa).

Leaflet thickness (mm) \ Blood pressure (Pa)		24,050.59	44,050.59	64,050.59	84,050.59	104,050.59
0.5	St. Jude Medical heart valve	8.008	14.67	21.33	27.98	34.64
	Edwards MIRA heart valve	21.84	40.01	58.17	76.33	94.50
0.55	St. Jude Medical heart valve	6.76	12.38	17.98	23.62	29.25
	Edwards MIRA heart valve	18.77	34.38	49.99	65.60	81.21
0.6	St. Jude Medical heart valve	5.70	10.44	15.18	19.92	24.66
	Edwards MIRA heart valve	16.33	29.92	43.5	57.08	70.67
0.65	St. Jude Medical heart valve	4.94	9.065	13.18	17.30	21.41
	Edwards MIRA heart valve	14.37	26.33	38.28	50.24	62.19
0.7	St. Jude Medical heart valve	4.33	7.93	11.53	15.13	18.73
	Edwards MIRA heart valve	12.78	23.41	34.04	44.67	55.29
0.75	St. Jude Medical heart valve	3.83	7.02	10.21	13.40	16.59
	Edwards MIRA heart valve	11.47	21.01	30.55	40.08	49.62



(a) St. Jude Medical mechanical heart valve



(b) Edwards MIRA mechanical heart valve

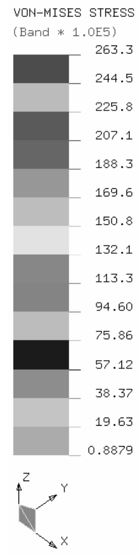
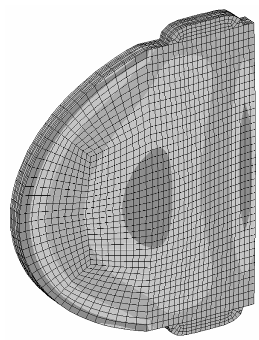
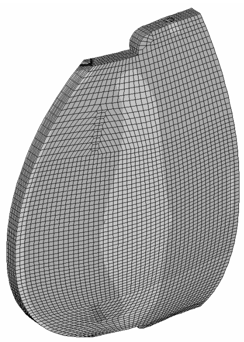


Fig. 6. von Mises stress distribution contour in the leaflet of the bileaflet mechanical heart valve prosthesis (top view, thickness = 0.65 mm, pressure = 44,050.59 Pa).



(a) St. Jude Medical mechanical heart valve



(b) Edwards MIRA mechanical heart valve

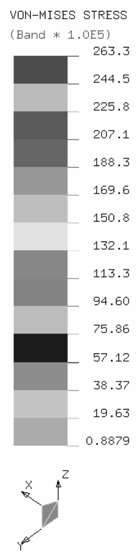
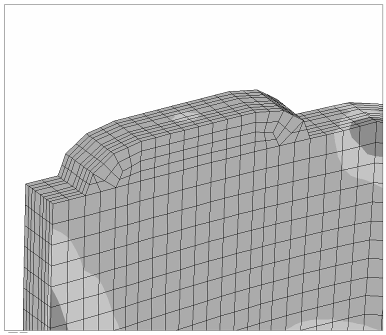
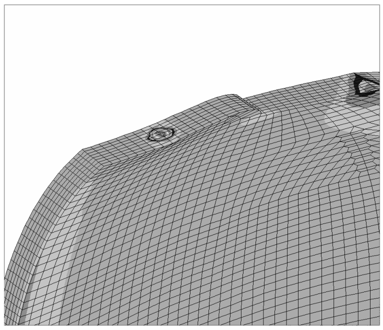


Fig. 7. von Mises stress distribution contour in the leaflet of the bileaflet mechanical heart valve prosthesis (bottom view, thickness = 0.65 mm, pressure = 44,050.59 Pa).



(a) St. Jude Medical mechanical heart valve



(b) Edwards MIRA mechanical heart valve

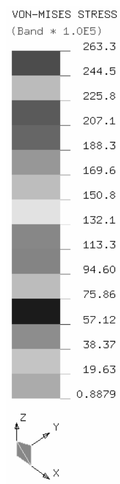
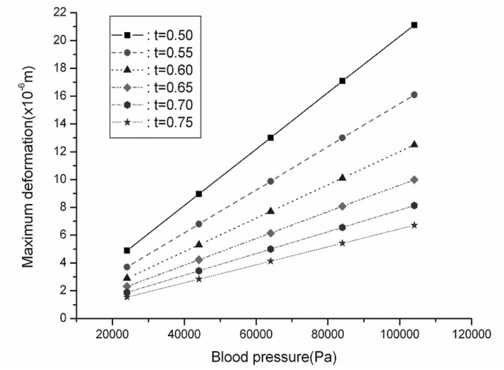
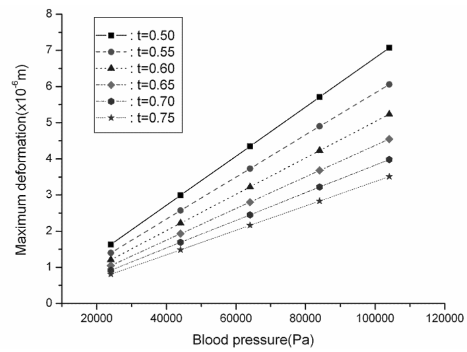


Fig. 8. von Mises stress distribution contour around the hinge of leaflet of the bileaflet mechanical heart valve prosthesis (thickness = 0.65 mm, pressure = 44,050.59 Pa).

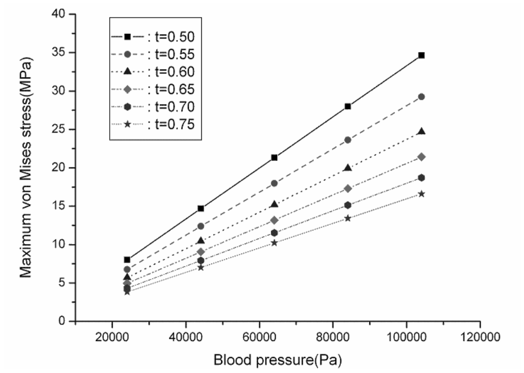


(a) St. Jude Medical mechanical heart valve

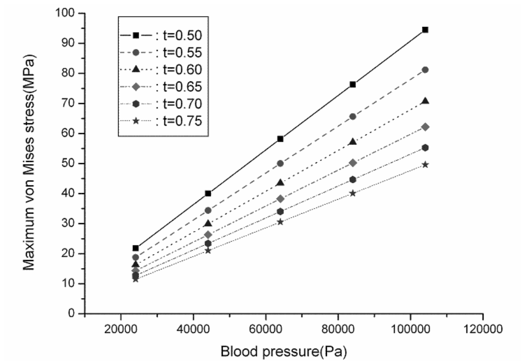


(b) Edwards MIRA mechanical heart valve

Fig. 9. Maximum deformation variation in the leaflet according to the blood fluid pressure change (t : leaflet thickness).



(a) St. Jude Medical mechanical heart valve



(b) Edwards MIRA mechanical heart valve

Fig. 10. Maximum von Mises stress variation in the leaflet according to the blood fluid pressure change (t : leaflet thickness).

the alternating stress and the fracture due to the cavitation. Hence, these leaflet fracture analyses are not needed in the numerical analysis just for the structural strength comparison of the St. Jude Medical and the Edwards MIRA bileaflet MHV prostheses and not treated anymore in this paper.

4. Conclusions

In this paper a numerical analysis for the structural strength comparison of the St. Jude Medical bileaflet mechanical heart valve prosthesis with flat leaflet and the Edwards MIRA bileaflet mechanical heart valve prosthesis with curved leaflet is presented. Blood fluid pressure forces are used as the external load constraint in the rigid body dynamic analysis for the leaflet motion to get the reaction force at the hinge of the leaflet and in the structural mechanic analysis for the deformed leaflets. The movement position of the leaflet when the reaction force at the hinge becomes the maximum value is identified through the rigid body dynamic analyses for the leaflet motions. The completely closed position of the leaflet movement is identified as the optimum leaflet movement position when the reaction force at the hinge becomes the maximum value. Hence, the leaflet in the completely closed movement position is used for the structural mechanic analysis to get the deformation and stress that may occur in the leaflet on which the blood pressure is applied. Consequently, this paper adopts a very noble and state-of-the-art technique, i.e., multidisciplinary analysis (MDA) technique. A structural mechanic analysis is performed as the leaflet thickness varies from 0.5 mm to 0.75 mm and the blood pressure varies from 24,050.59 Pa to 104,050.59 Pa by adopting the linear structural analysis technique.

Comparing the structural mechanic analysis results of flat and curved leaflets for all applied blood pressures, the deformation occurring in the flat leaflet is larger as two or three times as that of the curved leaflet, whereas the stress occurring in the curved leaflet is higher as about three times as the stress occurring in the flat leaflet. This means that the St. Jude Medical bileaflet mechanical heart valve prosthesis is structurally stronger than the Edwards MIRA bileaflet mechanical heart valve prosthesis. Consequently, structural analyses presented in this paper show that flat and curved bileaflet mechanical heart valve prostheses have quite different stress and deformation results respectively, whereas they have the almost same kinematic and dynamic characteristics. Hence, conclusively, from the viewpoint of stress, it is revealed that the St. Jude Medical bileaflet mechanical heart valve prosthesis is structurally stronger and better than the Edwards MIRA bileaflet mechanical heart valve prosthesis. Moreover, it is analytically justified the axiom that the St. Jude Medical bileaflet MHV prosthesis with flat leaflet geometry is structurally stronger than the Edwards MIRA bileaflet MHV prosthesis with curved leaflet geometry. And also it is concluded that the analyses of fatigue fractures due to the alternating stress and fractures due to the cavitation are not necessarily required for the structural strength comparison of the bileaflet MHV prostheses.

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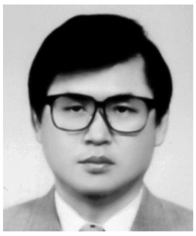

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