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THE EFFECT OF BILEAFLET MECHANICAL HEART VALVE DESIGNS ON BIOMECHANICAL BEHAVIOURS – A FINITE ELEMENT ANALYSIS

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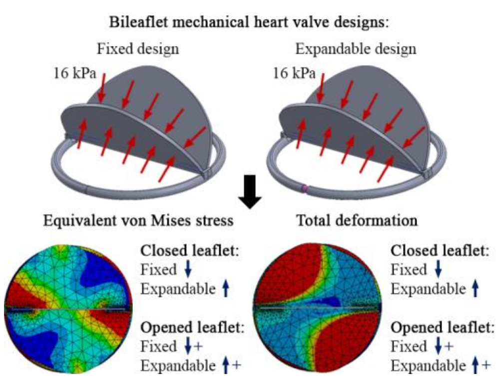
Graphical abstract



Abstract

Heart valve replacement is a popular treatment modality for patients with valvular heart disease. One of the prominent issues of mechanical heart valve is blood clotting around the valve that could lead to operation failure. Different valve design affects the valve structural behaviour differently which could be associated to the valve leaflet movement and its attachment to the housing. This study aimed to analyse the stress and total deformation of a fixed and expandable heart valve designs under a closed and opened leaflet conditions using three-dimensional (3-D) finite element analysis (FEA). Geometrical valve models were created in SolidWorks 2020 and then exported into Ansys 2022 R2. All models were assigned with linearly elastic, isotropic, and homogenous properties. A pressure of 16 kPa was applied on the top (closed condition) and bottom (opened condition) surfaces of the leaflets. The results exhibited that the expandable design recorded about 98% and 8.6% higher stress than the fixed design under the closed and opened conditions, respectively. The expandable valve was also observed to generate approximately 186% and 182% greater total deformation compared to the fixed valve under the closed and opened conditions, respectively. Of the valve designs evaluated, the fixed valve was found to be more satisfactory. However, the expandable valve could also be of interest with relevant modifications imposed if the adverse functionality impacts are concerned.

Keywords: Bileaflet, finite element analysis, heart valve, stress, total deformation

Abstrak

Penggantian injap jantung merupakan satu mod rawatan terkenal bagi pesakit yang mempunyai penyakit injap jantung. Salah satu isu utama bagi injap jantung mekanikal ialah penggumpalan darah di sekeliling injap yang boleh membawa kepada kegagalan operasi. Reka bentuk injap yang berbeza boleh mempengaruhi tingkah laku struktur injap secara berbeza yang boleh dikaitkan dengan pergerakan penutup dan pautannya terhadap perumah. Kajian ini bertujuan untuk menganalisis tegasan dan perubahan bentuk keseluruhan reka bentuk injap jantung tetap dan boleh dikembangkan di bawah keadaan penutup tertutup dan terbuka menggunakan analisis unsur terhingga tiga dimensi. Model injap geometri telah dihasilkan di dalam SolidWorks 2020 dan kemudian dieksport ke Ansys

2022 R2. Semua model telah diberikan dengan sifat anjal linear, isotropik dan homogen. Tekanan 16 kPa dikenakan pada permukaan atas (keadaan tertutup) dan bawah (keadaan terbuka) penutup. Keputusan menunjukkan bahawa reka bentuk boleh dikembangkan masing-masing mencatatkan tegasan 98% dan 8.6% lebih tinggi daripada reka bentuk tetap di bawah keadaan tertutup dan terbuka. Injap boleh kembang juga diperhatikan masing-masing menghasilkan kira-kira 186% dan 182% perubah bentuk lebih tinggi berbanding injap tetap di bawah keadaan tertutup dan terbuka. Daripada reka bentuk injap yang dinilai, injap tetap didapati lebih memuaskan. Walau bagaimanapun, injap boleh dikembangkan juga boleh menarik minat dengan pengubahsuaian yang berkaitan dikenakan jika kesan kebolehfungsian yang buruk dibimbangkan.

Kata kunci: Dwipenutup, analisis unsur terhingga, injap jantung, tegasan, perubahan bentuk keseluruhan

1.0 INTRODUCTION

Cardiovascular disease is widely known as a disease that related to the heart and its corresponding blood vessels. According to World Health Organization (WHO), the disease is a leading killer to death for most of the human population. Ischemic heart disease is the most common type of the cardiovascular diseases which usually then followed by stroke and chronic obstructiveness with a total death estimation of 11% and 6%, respectively. Besides, another disease that associated with the heart but hardly known is valvular heart disease [1, 2]. This disease is associated with aortic and mitral roots enlargement that affects blood flow. Little is aware on the importance of the heart valve function where the problematic heart valve could result in regurgitation by which the blood flows backward in the heart. Further to that, stenosis may also occur [2]. Stenosis is a condition when the opening of blood flow is narrowed or stiffened causing the blood to be accumulated and pressurised [3]. The combination of regurgitation and stenosis effects can lead to blood clotting.

The unwell or problematic heart valve could not play its role efficiently and it must be replaced. The replacement of the heart valve should be realised with something that is natural and having a long-life span. Literatures reported many researchers had come out with various designs of the prosthetic arterial valve [4]. The first replacement of the heart valve on human was performed in 1961 [5]. Generally, the prosthetic heart valve can be categorised into two main groups which are the bioprosthetic and mechanical types [2, 6]. In comparison to the bioprosthetic valves, the mechanical valves have a higher risk of blood clot formation and severe bleeding due to mandatory anticlotting medication [7]. This valve also unsuitable for pregnant mother or women who plan to have a baby as there is a necessity to take warfarin which could cause fetal malformations [8]. However, the mechanical valve is suitable for younger patients as they usually need subsequent reoperations to replace the degenerating tissue valve [9]. The valve also provides several advantages over the bioprosthetic one that includes freeing from structural valve degeneration and having better effective orifice area [5, 10]. The effective orifice area is the standard parameter for the clinical assessment of aortic stenosis severity. Moreover, the mechanical valves also offer a lower profile that making them to easily be implanted in patients with smaller hearts [11].

The main purpose of heart valve prosthesis is to restore the affected function of the real human valve [4]. Higher pressure from the inside of the heart pushes the leaflet to open and allow the blood to flow out to the aorta. The pressure is then decreased, and the leaflet is sucked to be closed. This situation forms a separation to prevent the blood from flowing backward [12]. A basic mechanical heart valve design comprises three main parts which are the leaflet, housing, and sewing ring. In general, a heart valve prosthesis has the inner diameter (housing) of 22.5 mm and the leaflet thickness of 0.65 mm [13]. The leaflet is normally in a thin and curved shape, and the housing is made of carbofilm coated titanium alloy. This combination is intended to optimise hemodynamic performance via a larger orifice, complementing the natural blood flow pattern and minimizing turbulence. The sewing ring is used to attach and fix the orifice ring to the heart tissue [14]. Three classifications of mechanical heart valve available which are caged-ball, single-tilting disk, and bileaflet-tilting disk valves [10, 15]. The bileaflet valve is found to be the most common implanted mechanical valve that introduced to provide a better blood flow, low jet velocity, small pressure drops, and large effective orifice area [16]. This valve is highly secured as the leaflets are hardly stuck out from the housing even at the maximum velocity during opening. However, a few previous studies reported that the bileaflet valves produced a lower closing velocity than the monoleaflet valves. On the contrary, in the squeezed flow, the valve closing velocity and stop areas were increased to avoid blood cells damage [17]. The housing of traditional mechanical valve is fixed, meaning that its circumferential length cannot be adjusted. As development of medical technology is advanced, new valve with expandable housing was created. The expandable valve can be grouped as balloon-expandable, self-expandable, and mechanically expandable types. The mechanically expandable design is developed with the ability to reposition and retrieve in the final position [18]. However, this valve has rarely been found in clinical practice although the balloon- and self-expandable ones demonstrated a higher rate of vascular and bleeding complications [19].

The prediction on the mechanical behaviours of the biological tissues such as stress and strain are currently well accepted through the use of computational simulation [20, 21]. This approach is more flexible and less complex than the real experimental or clinical works. Finite element analysis (FEA) is an extensively known computational method that utilised to elucidate the mathematical modelling problems in numerous fields of science and technology. The examples of technical analysis covered in FEA scope are structural, thermal [22], heat transfer [23], biomedical, fluid flow [24], and vibration analyses.

A number of studies has been conducted to evaluate or predict the performance of the mechanical heart valves in terms of different geometrical designs, features, and properties. This includes the analysis on different number of the leaflet [25], curvature of the leaflet tip [26], and potential of new leaflet material [27]. Based on past findings, the main hiccup of the mechanical heart valve is the need of anticoagulation medication to prevent blood clots around the valve [5, 9]. During the maximum opening and closing of the valve leaflets, blood with high velocity jets through the gap between the leaflet and the housing attributing the mechanical stress to elevate and may subsequently cause red blood cell damage and platelet activation. On top of that, an increase in the coagulation due to blood stagnancy with the artery wall may lead to thrombosis and thromboembolism which should be avoided for cardiac patients [28]. Countless cyclic leaflet motions could reduce the structural strength of the heart valve, develop inhomogeneous mechanical properties of the leaflet, and initiate the cavitation phenomenon to occur [29]. These consequences are among the keys of cardiac patients' death due to cracking and fracture of the valve leaflet leading to operation failure [13]. Thus, the leaflet movement plays a vital role which significantly related to the mechanism of width configuration (opening) of the housing. To date, limited available data could be discovered on the comparative evaluation of different mechanical heart valve types on their structural strength that makes this matter still uncertain and inconclusive. With regard to the scope of our study, only a few works were observed reporting the effect of the fixed and adjustable housings of the heart valve. Many of which have only discussed the findings from clinical perspective, without clearly emphasising on mechanical characteristics. Critical grasp on the structural performance of the mechanical heart valve is important to well understand the force transfer within the valve assembly.

Concerning all the aforesaid matters, the present study was thus aimed to investigate the biomechanical responses in terms of equivalent von Mises stress and total deformation between the fixed and expandable bileaflet mechanical heart valve housings under a closed and opened leaflet conditions through three-dimensional (3-D) FEA. The null hypothesis set in this study was that the fixed and expandable valve designs exhibit inconsiderable difference in the result data. The novelty of our study was to provide clinicians with suggestions and important insights of quantitative mechanical response data that may be applied in the treatment or preoperative planning of cardiac patients. Besides, this study may also highlight the force transfer within the heart valve, thus addressing the unpredictability of some mechanical heart valve issues.

2.0 MATERIALS AND METHODS

2.1 Three-Dimensional Development of Mechanical Heart Valve Models

Two different housing designs of the bileaflet mechanical heart valve model – fixed and expandable – were developed using a computer-aided design software, SolidWorks 2020 (SolidWorks Corp., Concord, Massachusetts, USA). Both valve designs are different in terms of the housing structural configuration in which the circumference of the expandable design can be expanded up to 0.8 mm at one side, compared to the fixed one. This length indicates the maximum extension that can be achieved during expansion of the housing. However, both valve designs have the same basic dome-shape leaflets that were slightly modified from the standard flat-surface bileaflet valve design. The modification imposed was at the tips of the leaflet where they were slightly curved. This modified feature was also considered in a past numerical study by Hafizah Mokhtar *et al*., 2018 [26]. The valve models were fully created using the 3-D solid geometry tools and features provided in the software such as revolve, shell, extrude, extrude cut, and/or loft. The region of interest of the 3-D heart valve models developed only covers the leaflet and housing parts. As a result, the completed valve models are 25 mm in the inner diameter (the length of a straight line passing through the center of the opening), 28 mm in the annulus diameter (the diameter of the basal ring), 14 mm in the leaflet circumference, and 0.6 mm in the thickness. These dimensions were parallel with the ones considered in several previous related works that using the same region of interest. It was noted that the inner diameter and leaflet thickness of the commercial valve is 22.5 mm and 0.65 mm, respectively, as mentioned earlier [13]. These dimensions being our main reference in the modelling stage as they are the standard configuration of a commercial mechanical heart valve prosthesis.

In order to verify the accuracy of model construction, the created valve models were then matched and compared with the virtual heart model from 3-D human anatomy software, Complete Anatomy from 3D4Medical, Elsevier. Besides, the verification was also made by considering the allowable dimensions and tolerances suggested by implant manufacturers to substantiate the model correctness. Figure 1 shows the constructed 3-D fixed and expandable mechanical heart valve models.

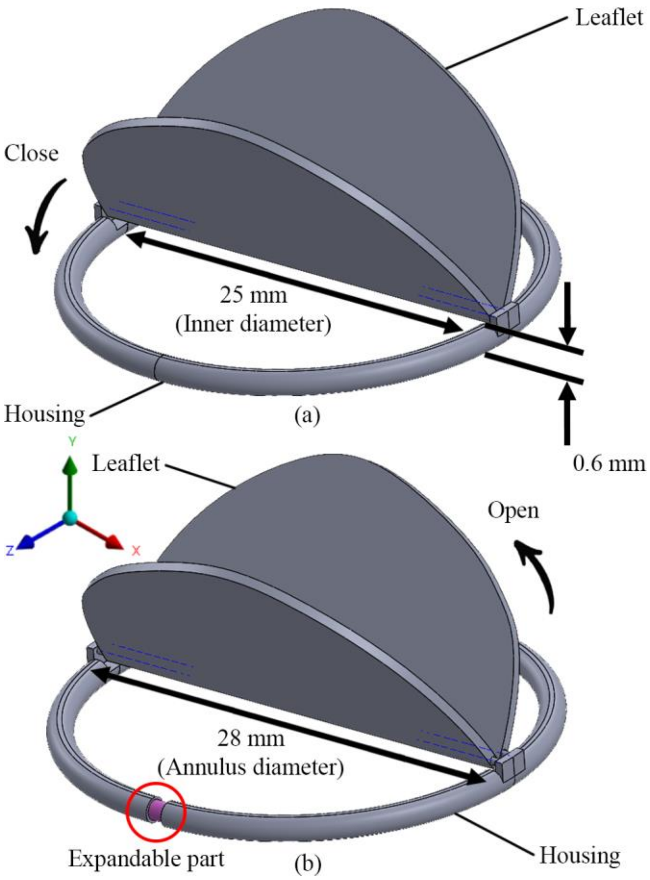


Figure 1 Three-dimensional model of the (a) fixed and (b) expandable mechanical heart valves

2.2 Pre-Processing of Finite Element Analysis

To model the heart valve design as closely as possible with the actual one, its behaviour was characterised as pyrolytic carbon material. This material has good hemocompatibility, durability, and biological and mechanical properties [30]. Valves made of pyrolytic carbon with graphite coated surfaces, benzylalkonium chloride, and heparin could resist the formation of thrombus when exposed to blood for a long time. Linear static finite element analysis was selected as the type of analysis of interest by which all material properties were assumed to be isotropic, linearly elastic, and homogenous. Therefore, the properties of pyrolytic carbon were interpreted in terms of Young's modulus, E and Poisson's ratio, v in the analysis as shown in Table 1. All the material properties were kept constant throughout the analysis.

Table 1 Material properties of pyrolytic carbon used in the analysis [31]

Material Properties	Value	Units
Young's Modulus	4800	MPa
Poisson's Ratio	0.28	-
Yield Strength	120.6	MPa

Since the assembly model of the heart valve configuration comprises more than one individual part, the contact modelling must therefore be defined at the interfacial surfaces. In total, there is four contact surfaces existed for the opened condition (leaflet does not touch the housing), while six contact surfaces existed for the closed position (leaflet touches the housing). All the contact surfaces were assumed to be completely bonded indicating a strong attachment. Relative movement was hindered at the interfaces by adopting direct contact method. The algorithm applied was Augmented Lagrange and the contact detection occurred at Gauss integration point.

The simulation of mechanical loading exerted on the heart valve during opening and closing conditions was realised by applying a uniform pressure in different directions. The pressure of 16 kPa indicating a systolic of 120 mmHg, was subjected to the top surface of the leaflets for the closed condition. Whilst, the same value of pressure was applied at the bottom surface of the leaflets to represent the opened condition. For the boundary condition, the outer surfaces of the housing were fixedly constrained for the fixed valve design. In addition, as the expandable valve design allows the change in the housing circumference; therefore, the distance for the expansion of the housing was controlled or restricted by using displacement constraints. This was executed by setting a fixed distance of at least 1 mm for the left and right movements of the housing. The purpose of this displacement constraint is to prevent the leaflet part models from overlapping with the surrounded housing which could lead to inaccurate realistic configuration. Besides, the outer surfaces of the housing were also set with frictionless support to let the displacement constraints function possible. Figure 2 exhibits the loading and boundary conditions imposed on both valve designs.

2.3 Meshing and Verification of Finite Element Model

The results of FEA must be independent of all purely numerical factors which could be achieved by performing mesh sensitivity analysis. All the geometrical models were turned into four-node solid tetrahedral elements with three degrees of freedom in a finite element analysis software, ANSYS Workbench 2022 R1 (ANSYS Inc., Houston, TX, USA). In total, there were six different sets of valve finite element model prepared with different mesh sizes which are 2.0 mm (Tet-A: ~6,450 elements), 1.6 mm (Tet-B: ~7,110 elements), 1.4 mm (Tet-C: ~8,110 elements), 1.0 mm (Tet-D: ~7,860 elements), 0.8 mm (Tet-E: ~8,660 elements), and 0.6 mm (Tet-F: ~11,110 elements). The meshing process was performed by using automatic solid meshing tool provided in ANSYS software. The span angle center of the element was set to "Fine" regardless of mesh sizes in order to produce a high quality of discretised models. The fixed heart valve design in the closed condition was considered and assigned with the material properties, contact type, loading, and boundary condition as stated earlier. The maximum equivalent von Mises stress value recorded in the model was evaluated for all trials of the mesh sensitivity test. The findings showed that there was a significant difference in the stress magnitude among the model sets where the coarsest model resulted in a lower stress compared to the more refined ones. The optimum mesh size was selected to be used if the variation of the stress results among the sets is less than 5%. The model seemed to converge at the mesh size of 1.0 mm (Tet D) after three refinements with the percent deviation of 1.2%. The total number of nodes and elements are about 17,650 and 7,860, respectively. Figure 3 depicts the plot of the maximum equivalent von Mises stress value versus mesh density for all trials in the sensitivity analysis.

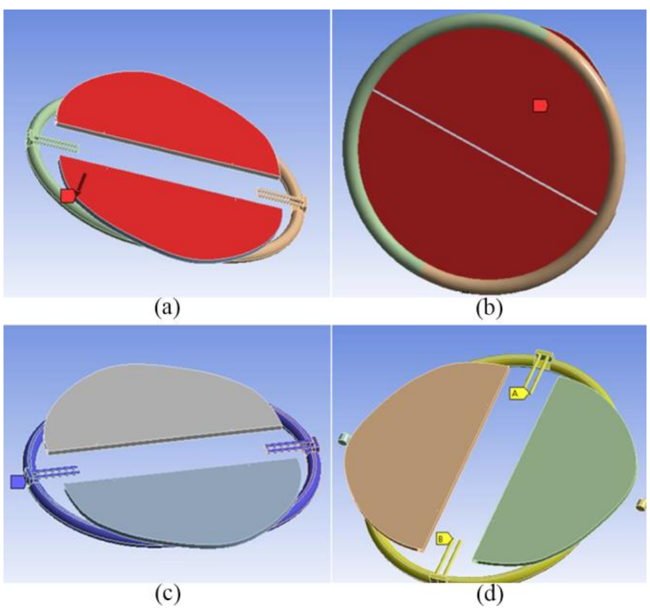


Figure 2 The pressure applied on the top surface for (a) closed condition, and on the bottom surface for (b) opened condition. (c) The fixed support applied on the outer surfaces of the housing for the fixed design. (d) The displacement constraints set on the outer surfaces of the housing for the expandable design

3.0 RESULTS AND DISCUSSION

Two main mechanical response parameters were analysed in this study – equivalent von Mises stress and total deformation – in terms of their maximum level. The findings were also presented in spectrum colouring scale where the red colour designating high stress and deformation, whilst the blue colour designating low magnitude. Table 2 and Figure 4 show the summary of the analysis results for each heart valve design under the closed and opened leaflet conditions.

Table 2 Maximum values of the stress and deformation recorded in the analysis models

Valve Design	Condition	Equivalent von Mises Stress (Pa)	Total Deformation (m)
Fixed	Closed	21.18×10^{9}	54.2×10^{-6}
	Opened	59.80×10^{9}	213.5×10^{-6}
Expandable	Closed	61.91×10^{9}	1471.3×10^{-6}
	Opened	65.18×10^{9}	4546.3×10^{-6}

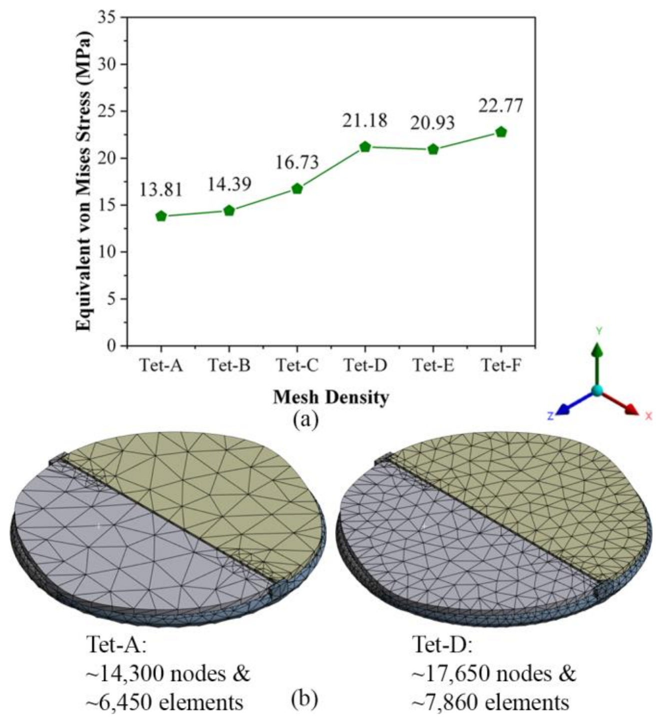
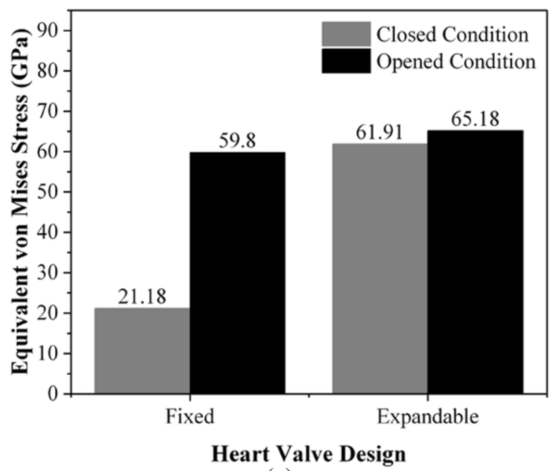
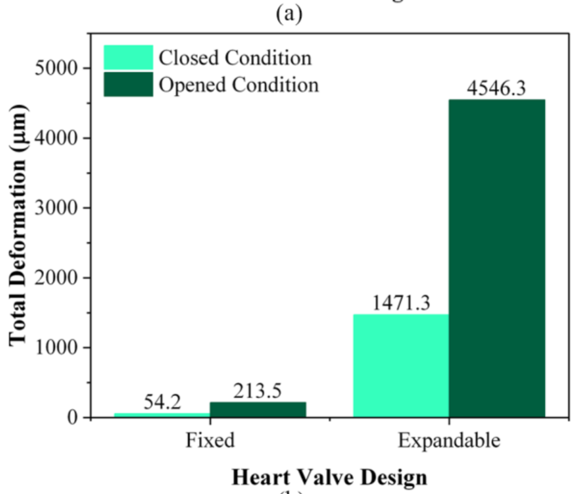


Figure 3 (a) The plot of the maximum equivalent von Mises stress in different mesh sizes (Tet-A – Tet-F). (b) Tetrahedral element distribution in Tet-A set (before refinement) and Tet-D set (after three refinements)

As far as the maximum equivalent von Mises stress within the valve was concerned, our findings showed that the expandable design recorded a greater stress value than the fixed design regardless of the condition of the leaflets. The percentage differences were about 98% and 8.6% for the closed and opened conditions, respectively. It appears that the stresses in the expandable design were 61.91 GPa (closed) and 65.18 GPa (opened) compared to those in the fixed design which were 21.18 GPa (closed) and 59.80 GPa (opened). The critical stress area was more significant and pronounced in the expandable design under closed condition that located surrounding the hinge connection region of the housing relative to that of the fixed design as illustrated in Figure 5a. This is consistent with the higher stress magnitude generated in the expandable design as explained earlier. However, a contradict stress distribution was found for the opened leaflet condition where the fixed valve model attributed the vicinity of the hinge with more excessive stress albeit its maximum value was slightly lower than the expandable model (Figure 5b).



(a)



(b)

Figure 4 Comparison of maximum (a) stress and (b) total deformation values for both heart valve designs under the closed and opened conditions

In terms of total deformation, the results were seen to be parallel with the stress findings where the value of total deformation increased in the expandable design compared to the fixed design irrespective of leaflet conditions. It was evident that the expandable model recorded a total deformation of 1471.3 μm and 4546.3 μm which was considerably higher than the fixed model that were 54.2 μm and 213.5 μm, for the closed and opened conditions, respectively. This contributes about 186% displacement increase under the closed condition, whilst 182% increase under the opened condition. A larger deformation concentration area was created at the tip of the leaflet towards the central region with insignificant displacement distribution difference between both valve designs under the closed condition (Figure 6a). For the opened leaflet condition, the highly displaced region appeared to be more widespread in the expandable design relative to that in the fixed design (Figure 6b). More satisfactory deformation was found on the central area of the leaflet in the fixed model, indicating a lower possibility of the leaflet to displace at that particular part.

The present study evaluated the effect of two different mechanical valve designs on the stress and total deformation under two different leaflet working conditions using 3-D linear static FEA. The main objective was to analyse whether changing the valve housing design may affect the structural integrity of the valve body under the closed and opened leaflet conditions. The perseverance of a heart valve prosthesis is secured by good primary stability and motion of the leaflets during opening and closing mechanisms. An adequate fitting between the leaflet and the housing is important in order to obtain efficient blood flow in the heart. Considering this, different housing designs of mechanical heart valve were analysed.

Our findings exhibited that a higher stress magnitude was generally recorded for the expandable design compared to the conventional or fixed design. The stress in the fixed design was approximately 2.9- and 1.1-fold lower than the expandable design for the closed and opened leaflet conditions, respectively. With regard to the value of the stress generated, the results of the analysis were inconsistent with a previous work by Kiang-ia *et al*., 2013 [25] that investigated the mechanical behaviours of the fixed valve. They reported a significantly lower stress value in the bileaflet mechanical valve model which was merely about 14 MPa that approximately 1513-times lower than our recorded value (21.18 GPa) for the fixed-type valve. This deference could be explained by different detailed geometrical features and material properties of the valve model used. The rationale behind the relatively minimal stress sustained in the fixed valve model either in the closed or opened leaflet condition was due to a better structural integrity of the housing attained in resisting the pressure. As the housing of the valve is fixed or its circumferential length could not be adjusted, this has maintained the configuration of the housing to well adapt with the applied loading especially during the closed leaflet position. The expandable valve design, on the other hand, possesses an adjustable circumferential length that resulting in a larger diameter of the housing. However, the presence of the expandable housing could not help in tolerating the loading effectively, particularly when the leaflet is closed. This design might be advantageous if the leaflet opening is of high concern because the dissipation of the mechanical stress was slightly improved and reliable within the leaflet structure.

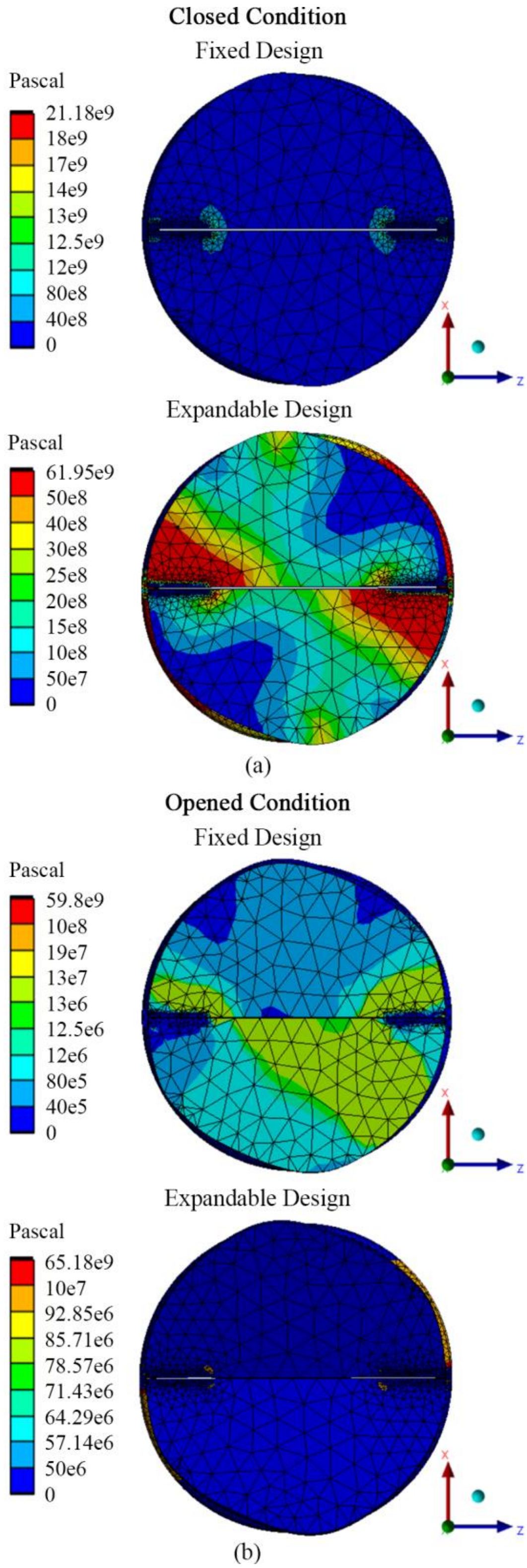


Figure 5 Distribution of equivalent von Mises stress in the fixed and expandable valve designs under (a) closed and (b) opened conditions from top view

To the extent that the working mechanism of the leaflet was of interest, a greater stress value was generally produced in the opened leaflet condition compared to the closed one irrespective of the valve designs. A possible explanation for this is due to the increase in the retention strength of the housing to secure the position of the leaflets in place. The reverse was observed for the closed configuration where the leaflet structure is more stable and well supported underneath by the surrounding housing in counteracting the applied pressure in the opposite direction. Overall, the maximum stress generated in the analysis for all cases was higher than the yield strength of pyrolytic carbon (120.6 MPa), the material assigned for the valve model. This may predict the tendency of failure of the respected structures.

Total deformation of the mechanical heart valve is another vital response parameter for consideration to scrutinise the issue apart from the mechanical stress. The result was congruent with the valve stress findings wherein the total deformation was increased if the expandable housing structure is employed. It is noteworthy that the housing part of the expandable design was highly deformed relatively compared to the one of the fixed designs. The vicinity of the hinge connection in the expandable model also seemed to highly deform as a larger widespread of the critically dislocated area was noticeable. The findings are probably due to the increased circumferential length of the housing that leading to the decrease in the bending strength of the part in sustaining the loading imposed. As a result, the expandable design tends to have more undesirable deformation that could lead to the unexpected destruction.

Based on literatures, the mechanical heart valve that experienced with high stress and deformation were greatly prone to damage as discussed by Hafizah Mokhtar *et al*., 2018 [26]. This agrees well with an earlier study by David Merryman *et al*., 2006 [6] which stated that a small change in the tensile stress may cause a large deformation of the expandable housing of the bileaflet heart valve in both closed and opened conditions. Furthermore, according to Gloeckner *et al*., 1999 [32] the continuous repetitive cyclic stress from the complex combination of stretch, flexure, and shear may cause delamination of the layered leaflet structure through flexion, which may then lead to calcification and eventual failure of the valve leaflets. Calcification is a condition where the leaflet becomes stiff, and the structure finally being narrowed or stenotic [33]. The stenotic heart valve could increase the heart work in which subsequently increase the resistance towards blood flow [3]. The present study exhibited that the width of the hinge gap owing to the expansion of the valve housing plays a vital role in the structural integrity and fluid flow. This seems to be parallel with a past investigation by Jun *et al*., 2014 [34] where the hinge gap size may significantly affect the flow field.

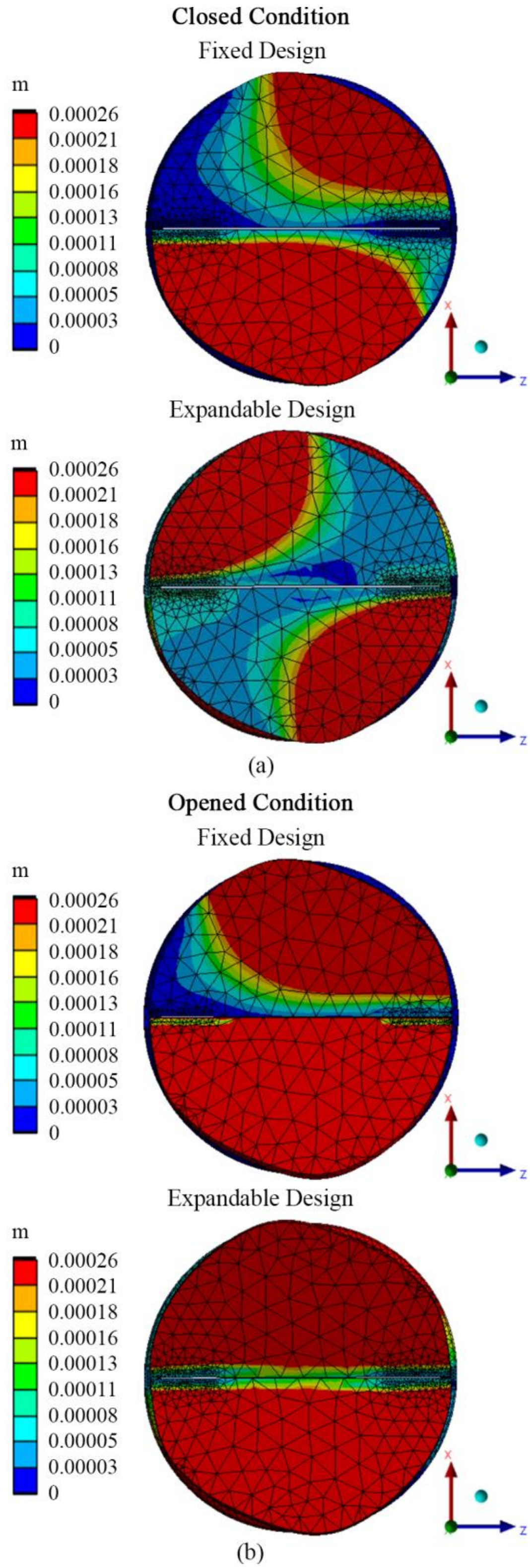


Figure 6 Distribution of total deformation in the fixed and expandable valve designs under (a) closed and (b) opened conditions from top view

Apart from calcification, the occurrence of cavitation in a mechanical heart valve should also be prevented. Cavitation is defined as the transient appearance of bubbles on the heart valve surface during closure. The bubble formation is caused by abrupt pressure changes in the vicinity of the valve [35]. This situation yields a formation of undesirable effect such as erosion and pitting, and loss of performance [36]. On top of that, cavitation may result in wear and tear of the heart valve over a period of time that ultimately initiating crack development. This corresponds well with the findings by Lee *et al*., 2006 [17]. They stated that the presence of cavitation on the heart valve surface has caused fracture triggering failure of the structure. Cavitation does not only create high levels of noise and vibration, but it may damage the blood cell as well. Albeit the expandable valve design has increased the mechanical stress and deformation values as revealed in this study, it was however predicted to lessen the time of impact of the leaflet with its housing, and reduce squeeze jet ejected from the gap space according to Wu *et al*., 1994 [37]. As the blood flows through the valve, the housing of the expandable valve will enlarge to allow maximum blood flows into the other chamber of the heart. During the closing position, the expandable housing slowly returns to its actual size corresponds with the closing of the leaflets. Another rationale of the introduction of the expandable heart valve is associated with pressure distribution. The pressure tends to be increased when the blood rushed through a smaller size of the housing due to high restriction. Butterfield *et al*., 2001 [38] stated that higher pressure gradient and energy loss across the valve signify an increased force level to open the leaflets thus indicating poor valve function. Instead, a wider housing may slow down the blood flow and recover the pressure accordingly. As a result, the velocity of the heart valve is decreased, and this could minimise the occurrence of cavitation.

Inadequate part configuration of the expandable heart valve might leave adverse effect to patients. Travis *et al*., 2008 [39] in their experimental work claimed that viscous stress was significantly affected by a large hinge gap where this situation may contribute to more damages to the blood cell and increase the risk of thromboembolic complications. Besides, the retraction mechanism of the expandable housing that allows the part to move back into its original position gives a potential of blood backflow and thrombosis to occur [28]. Blood backflow may impose harms to patients namely shortness of breath which attributes the heart to be dilated and pumped vigorously. Too small gap, on the contrary, could trap and scratch the red blood cell disk. The affected red blood cell can induce further related consequences such as hemolytic anemia. This red blood cell disorder would ineffectively hold and bring oxygen throughout the entire body. For the fixed heart valve design, no opening or gap is present between the leaflets and its housing, therefore minimising the risk of calcification and cavitation.

Despite the substantial results of the analysis, several aspects of the study can further be enriched. This includes the evaluation of different heart valve materials with viscoelastic properties, application of different loading configurations and models, and optimisation of the expandable housing feature characteristics. The limitations of the present study are: (1) the properties of material assigned in the analysis were assumed to be isotropic and linearly elastic, while a more realistic one having viscoelastic behaviour, and this argument could somewhat affect the findings; (2) the study only examined a single thickness of the leaflets, therefore the results were ascribed to this geometrical part dimension; (3) the applied loading was static in a linear structural analysis, thus disregarding the influence of fluid flow domains surrounding the heart implant; and (4) the heart valve responses is limited to a single loading type which may further be explored by having a variety blood flow metrics during different physical activities such as walking, running, etc. Real biological or clinical condition could not directly be related based on the results of analysis. However, at least, the present study may determine the difference in the biomechanical behaviours through computational approach. Further *in vivo* and/or *in vitro* works should be included to verify the analysis findings even at low level. The study rejected the null hypothesis. The fixed and expandable bileaflet heart valve designs exhibited a considerable difference in the mechanical stress and total deformation generated.

4.0 CONCLUSION

The results of linear static analysis on the fixed and expandable bileaflet mechanical heart valve designs support the following conclusions. The expandable valve design exhibited an increased stress value for approximately 98% and 8.6% under the closed and opened conditions, respectively, compared to the fixed design. Also, the expandable valve design promoted about 186% and 182% greater total deformation magnitude than the fixed design. Although the expandable valve demonstrated less promising mechanical stress and total deformation, the valve design could be macro- and micro-geometrically improved and optimised to produce a mechanical heart valve with optimal performance particularly if the calcification and cavitation implications are of concern.

It is believed that an improved preoperative treatment planning in terms of patient's heart valve condition is anticipated. This is achieved by having a mechanical heart valve with optimal performance that may subsequently reduce the risks of implant failure.

Conflicts of Interest

The author(s) declare(s) that there is no conflict of interest regarding the publication of this paper.

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