Design of new trileaflet heart valves: 
computational mechanics study

S. Mantero, a E. Di Martino, a R. Sesana, b R. Pietrabissa a
a Dipartimento di Bioingegneria, Politecnico di Milano, Milano, Italy
b Dipartimento di Meccanica, Politecnico di Torino, Torino, Italy

Abstract

In this study differently shaped trileaflet valves have been designed and structurally examined by FEM-analysis. Aim of this preliminary work is to choose the valve geometry for the prototyping of a valve in a polyurethane polymer. Mechanical fatigue properties of polyurethane polymers do not provide a good valve durability. We developed new design features, a semi-open configuration at rest for the leaflets and a wireframe-like expansible stent, in order to improve valve durability by means of better stress distribution.

For a comparative evaluation three different leaflet geometries and two stents have been modelled. The leaflet geometries at zero stress condition are: spherical surface (valve in semiopen configuration); spherical surface (valve in close position); interpolation surface between two arcs (valve in semiopen position). The stents are a classic rigid ring stent and an expansible one.

Results indicate that the best valve performance is achieved when the expansible stent is coupled with the non-spherical surface leaflets.

1 Introduction

Performance requirements for a prosthetic heart valve are basically four: the valve must provide mechanical reliability, good haemodynamics, blood compatibility, and maintain these functions for the life expectancy of the patient.

Polymeric trileaflet valves have been developed to match good performances of mechanical and biological valves. These devices, similar in shape to natural aortic valve, show proper haemodynamics and good haemocompatibility.
Their limit is early failure due to tearing and calcification of the valve cusps. While calcification is not related to valve design, mechanical failure can be reduced through modification of stent and cups geometry [1,2,3,4,5,6].

It is generally believed that structural failure of polymeric trileaflet valve is mainly due to the cyclic tensile stresses developed during valve closure. Up to now no polymeric material has been found which can resist the fatigue cyclic load acting on a cardiac valve (about $38 \cdot 10^6$ cycles per year).

As the cusps geometry and the stent design influence stress patterns and local concentration on the leaflet, we compare the closure mechanics of six valve models characterized by different leaflet geometry and stent design.

In particular our aim is to verify if the use of pliable and expansible mounting frame, which follows natural expansion of aortic root, can significantly reduce stress concentration at the commissures, providing better valve durability.

2 Materials and Methods

Design characteristics of the new prosthetic valves include enhanced geometry of leaflets and stent.

The stents designed are a classical rigid ring stent and another pliable and expansible which allows the valve to follow aortic root movements during cardiac cycle. The geometries of the leaflets studied are, with reference to zero stress conditions: spherical surface (valve in semiopen position); spherical surface (valve in close position); interpolation surface within two arcs (valve in semiopen position). Six valve models, resulting from the combination of the two stents and the three leaflets, have been structurally analyzed, using a numerical method, in order to evaluate the closure mechanism in terms of stress levels, stress patterns and concentrations as well as displacements under static pressure load. Figure 1 shows the six valve models.

The study has been performed using CAD techniques, involving solid modelling (Pro/ENGINEER), mesh creation (P3/Patran), solution of the static analysis with FEM (ABAQUS) and post-processing of results.

Due to valve symmetries the analysis contemplates just 1/6 of the valve itself. To restrict the analysis to 1/6 of the valve we modelled a monolateral contact with rigid surfaces which simulate the coaptation of the cusps during closure.
Figure 1: the first line shows the solid models for the three different leaflets mounted on traditional stent; the second line shows the leaflets mounted on expansible stent.

The hypotheses for the mechanical model used to perform the FEM analysis are: linear elastic isotropic material (E=10 MPa), symmetries constrains. We used shell elements for leaflets and traditional stent, beam elements for expansible stent. The load is a static pressure load of 120 mmHg.

Figure 2 shows the mesh obtained on a leaflet for the FEM analysis.

The FEM solution is a direct solution obtained using RIKS algorithm for non linear analysis which calculates step by step the incremental load to apply.

Figure 2: example of mesh for spherical surface leaflet (half leaflet, valve in semiopen position at rest)
3 Results and Discussion

The results of the mechanical analysis show that all valves come to closure within 40% of applied load. Figure 3 shows the evaluation parameters (displacements and stresses) chosen to identify best valve performance.

Natural aortic valve motion studies show that in the closing phase the axial height diminishes, the commissures moving downwards to the centre of the aorta and the base moving outwards [7].

![Figure 3](image)

Figure 3: (a) $U_{1-1}$ evaluates the semiopen configuration at rest (the effective valve closure); the other displacements measure the rigid rotation of the stent posts.
(b) localization of Von Mises stresses on the leaflet.

Figure 4 shows base and commissures displacements for the six valves models.

The expansible stent confirms the prediction about the 'rigid rotation' of the stent post. The classical stent reaches closure by means of a flexion of the posts inwards, while the expansible stent couples the inward displacement of the posts with an outward displacement of the base. Figure 5 shows a deformed configuration obtained from the analysis of a semiopen configuration valve. Note the base displacement ($U_{1-3}$) and the stent post displacement ($U_{1-2}$) which account for the effective rotation of the post.

Closed spherical geometry implies a sort of shape resistance opposite to the pressure load and causing stress concentration localised at the separation line between spherical and flat surface (coaptation surface). The difficulties in deforming the sphere to a flat surface causes the leaflet to bulge in the centre under the pressure load.
Figure 4: Radial and axial displacements of the commissures and axial displacements of the base:
A: Non spherical leaflet, rigid stent and semiopen conf. at rest
A1: Non spherical leaflet, expansible stent and semiopen conf. at rest
B: Spherical leaflet, rigid stent and semiopen configuration at rest
B1: Spherical leaflet, expansible stent and semiopen conf. at rest
C: Spherical leaflet, rigid stent and close configuration at rest
C1: Spherical leaflet, expansible stent and close conf. at rest
Comparing the valves with open configuration at rest, the non-spherical geometry appears to have the better behaviour in terms of stress distribution and of displacements of base and commissures. This is probably due to the geometry itself. The non-spherical geometry comes evenly and gradually in contact with the rigid surface. It also benefits from the expansible stent more than the other leaflets.

Figure 5: Deformed configuration of half leaflet, the original configuration is visible underneath the deformed one in lighter grey. Pressure direction is normal to the sheet plane.

Figure 6: results from the static analysis; Von Mises stress variable for (a) non-spherical leaflet geometry and expansible stent (b) non-spherical leaflet geometry and completely rigid stent.
To confirm our hypotheses we modelled a valve with completely rigid stent. The leaflet mounted on this valve is a non-spherical one. The results of this analysis show that there is a stress concentration at the commissures which value is higher than the maximum stress in all the previous models.

Figure 6 shows the comparison between non spherical leaflets mounted on expansible stent and on completely rigid stent in terms of stress levels.

4 Conclusions

Critical characteristics of polymeric valves are briefly: closed valve configuration at rest. It guarantees no valve leakage, but induces flexion stresses on material which compromise valve durability; a flexible but non-expansible stent. It prevents significant radial displacement thus implying a global rigidity and cyclic inward flexion of the stent posts.

A solution to these problems has been committed to an expansible wire frame-like stent and a semiopen configuration at rest more similar to the natural configuration.

The spherical leaflet geometry close at rest do not benefit from the expansible stent as it opposes a shape resistance to the external pressure and develops flexion stresses in the area of initial contact between the leaflets. The spherical semiopen leaflet shows less radial displacements compared to the valves with non spherical leaflet.

Comparing the performance improvements obtained substituting the rigid ring stent with the expansible one, we observed that leaflet which benefits the most from the expansible stent is the non spherical one.

References


