Numerical Simulation Transcatheter Aortic Valve Implantation and Mechanics of Valve Function

M.S. Hamid, Ph.D.
Advanced Computational Systems LLC
Rochester, MI 48306
acssah027@gmail.com

Abstract

As the older population increases, age-related diseases such as aortic stenosis is a common heart condition in which there is a thickening and calcium deposition in the aortic root and aortic valve leaflets. This results in a host of symptoms like angina, embolism, stroke and sudden death. Current default treatment for severe aortic stenosis is surgical aortic valve replacement. Mechanical and bioprosthetic heart valves are common choice for surgical replacement of the diseased valves. However, surgical intervention is extremely risky for a large population of frail patients. Transcatheter Aortic Valve Implantation (TAVI) is being used selectively as a percutaneous alternative to surgical aortic valve replacement. This is a very complex procedure and involves very coordinated team work. This procedure involves steps from valve crimping to implantation and monitoring. Computational simulations of the TAVI help evaluate the valve functioning. In present study, a step-by-step complex numerical simulations of the TAVI procedure including the stent crimping and balloon inflation are presented. The stent frame is assumed as stainless steel and the outer skirt is assumed as polyethylene material. The stent frame is modeled with 3D hexagonal finite elements and the skirt is modeled as thin shell elements with fabric material property. The valve leaflets are modeled as Mooney-Rivlin material. The results of valve crimping and blood flow during ejection phase are presented. The SPH technique is used in modeling the flow through the aortic valve. The stent deformation and the stresses induced due to crimping are presented. The normal and calcified leaflets opening are presented.. The LS-DYNA® multi-physics capabilities of fluid structure interaction is presented..

Introduction

As the older population increases, age-related diseases such as aortic stenosis is a common heart condition in which there is a thickening and calcium deposition in the aortic root and the valve leaflets. The aortic stenosis affects 3 to 5% of USA population over 75 years old and thus becoming the most common valvular heart disease [Ref 1]. The position of aortic valve in the heart, the normal and valve with aortic stenosis are shown in Figure 1 [2]. Under severe conditions, usually surgical intervention is common treatment in which the diseased valve is replaced with artificial heart valves. The artificial valves evolved from mechanical to biological or bioprosthetic aortic valves (BAV) that are used to replace the diseased ones by surgery to transcatheter aortic stent valve which are implanted (TAVI) without surgery as shown in Figure 2. [3].

The bioprosthetic valves are used extensively from 80's onwards due to its biocompatibility and better hemodynamic performance. However, these valves have host of problems like thinning, thickening, calcium deposit, tissue tear etc. Extensive studies were conducted by both clinical research and computer simulations [4-9]. Surgical replacement of the diseased valves are sometimes high risk and also expensive. The older patients may not withstand the ordeal of surgery and new interventional technologies are being developed using stented valves as shown in Figure 2c and 2d. These valves are being implanted in very frail patients.

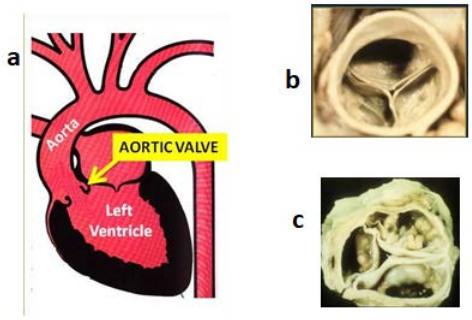
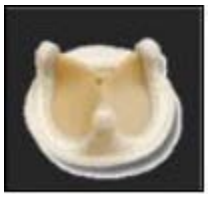
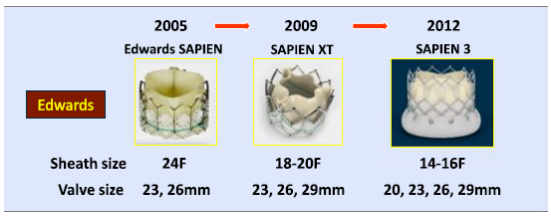


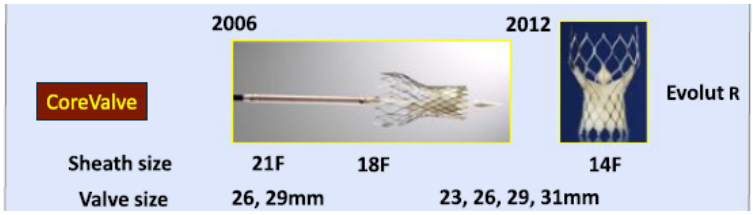
Figure 1. **a)** Aortic valve in heart **b)** Normal **c)** With aortic stenosis [Ref. 2]

a) Mechanical Valve



b) Bioprosthetic valve





c) Advanced valve and delivery systems [Ref. 3]

d) New models of TAVI approved in Europe [Ref. 3]

Figure 2. Development of artificial heart valves.

TAVI Procedure: TAVI in position is shown in Figure 3 [10]. Basically, the valve is placed in existing diseased aortic valve and is sometimes called valve in valve implantation. The valve can be implanted through multiple access as shown in Figure 4. The following steps are used in the procedure.

Step 1. The valve is crimped to 6 to 8mm diameter using a crimping device shown in Figure 5.
Step 2. The crimped valve is attached to a delivery system with a balloon inflator (Fig 5.)
Step 3. The delivery system is placed in the aortic valve position and inflated (Fig. 3,4).

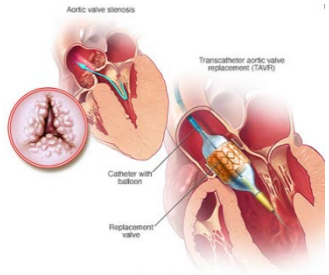
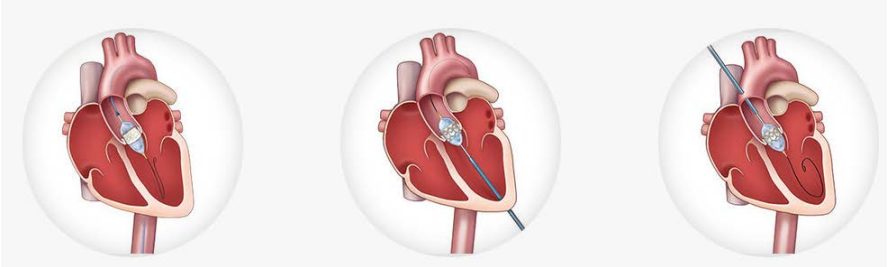


Fig. 3 TAV in position



A B C

Fig 4. A) Transfemoral B) Transapical C) Transaortic Approach.

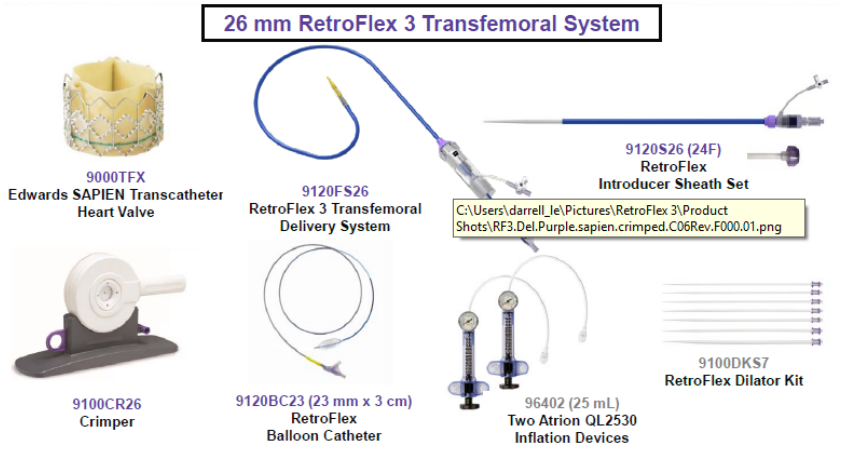


Figure 5. TAVI Procedure [Ref. 11]

The purpose of this study is to numerically simulate some of these steps in order to understand this complex TAVI implantation technique using LSDYNA capabilities.

Model Development

The finite element model developed for this study is shown in Figure 6. The model consists of 1) left ventricle (LV), 2) natural aortic valve, 3) aortic arch and 4) transcatheter aortic valve (TAV).

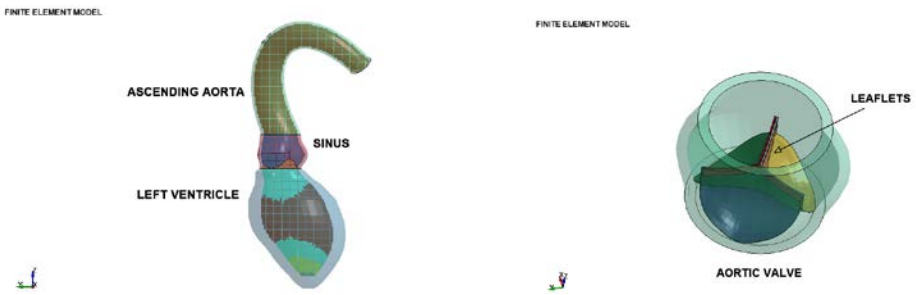


Figure 5. Finite Model of LV and Aortic Valve

1. Left Ventricle : The left ventricle is a thick vessel of thickness 8mm in diastole and 12mm in systole. The ventricular muscle thickens as it contract and the orientation of the fiber generate enough force to propel the blood through the aortic arch against aortic pressure. LV is approximated as an ellipsoid based on cross section of the geometry using single plane cineangiocardiogram [12,13]. Modelling the boundary condition for left ventricle is challenging due to thickness changes during systole and the LV is surrounded by other three chambers. In this study, it is assumed that apex of the LV is fixed in space. The material property of the LV is assumed to be isotropic since the focus is aortic valve.

.

2. Native Aortic Valve: The native aortic valve was developed using the geometry and relative dimensions of aortic valve region given in Figure 2 of Ref. 14. The finite element model is shown in Figure 5.

3. Stent Model: The stent model developed is shown Figure 6. **This particular stent design does not represent any commercially available stent as shown above in Figure 2.** The stent was modeled with 3D elements. The stent thickness was assumed as 0.2mm.

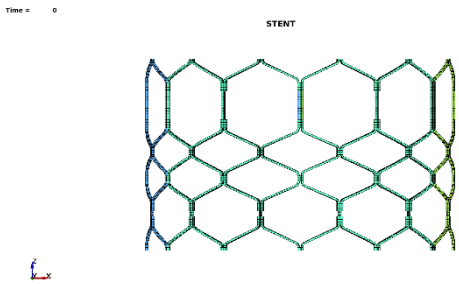


Fig. 6. Stent FE Model

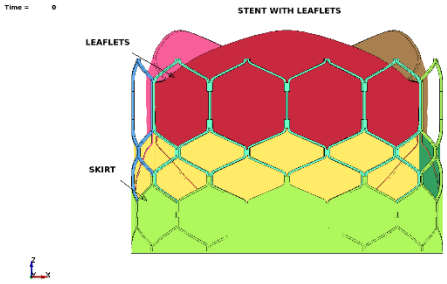


Fig. 7. Valve FE Model

4. Stent Valve Model: The stent valve model is shown in Figure 7. It consists of biocompatible leaflets which are sutured to skirt cloth. The cloth was attached to the stents by suturing along the solid stent frame.
This finite modeling used tied contact surface keywords of LSDYNA in order to approximate the attachment of the valve leaflets and skirt to stent frame.

5. Flow Model : The blood is modeled using SPH particles. The particle size is 1mm and it filled the system as shown in Figure 5 above.

Analysis and Results

1. Crimping of the Valve: The crimping device was represented by strips of cylinders which were allowed to radially move in order to induce radial compression. The model set up is shown in Figure 8.

Figure 8. Crimping Device Approximation and radial movement of the strips.

The valve material was assumed as stainless steel with Young's modulus of 200GPa, yield stress (sigy) equal to 250MPa and its failure plastic strain of 47%. *MAT_PIECEWISE_LINEAR_PLASTICITY model was used for the stent. The leaflet were assumed as nearly incompressible material and was modelled using hyperelastic material model *MAT_MOONEY_RIVLIN. The constants used were A=5.50E-04 and B=1.38E-04 GPa, the Poisson's ratio was 0.498 and the density of the tissue as 1200 Kg/m**3. The thickness of the leaflets is assumed as 0.2mm constant throughout even though the leaflet thickness varies. The skirt cloth was assumed as fabric material. *MAT_FABRIC model was used. The thickness was assumed to be very small since the fabric tends to resist the free movement of the stent along longitudinal direction while radial compression was applied. This resulted in buckling of stents and very low thickness was assumed to circumvent this numerical instability.

The crimped valve is shown in Figure 9. The stresses and plastic strain induced in the stent are shown in Figure 10 and 11.

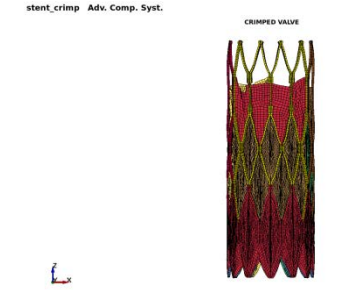


Fig 9. Crimped Shape

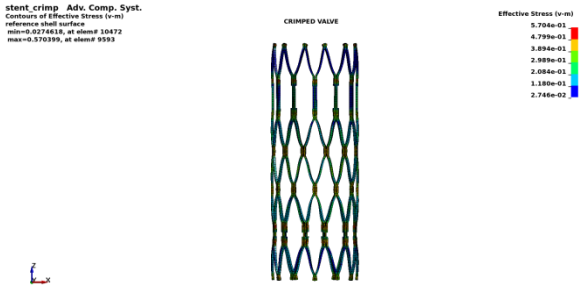
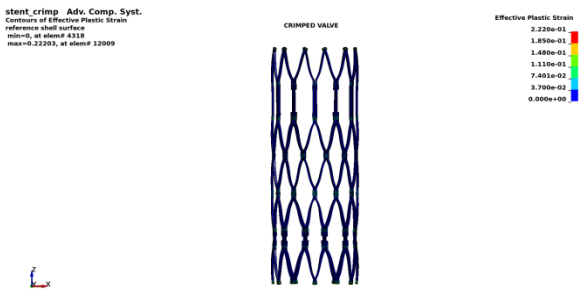


Fig. 10. Equivalent Stresses in the Stent.



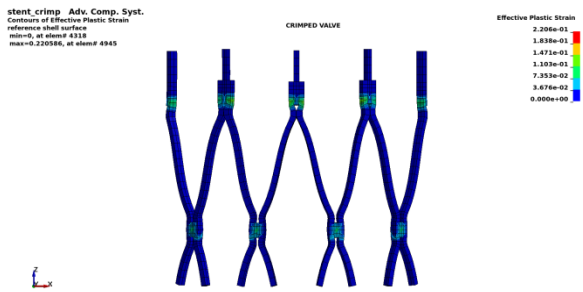
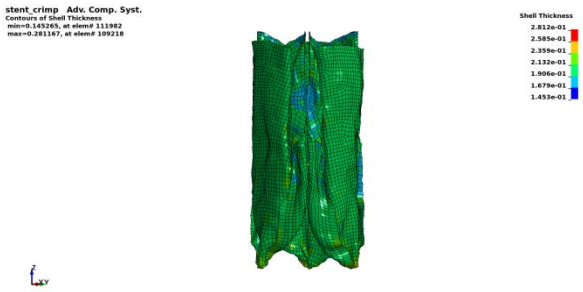


Fig. 11 Plastic Strain Distribution.

The leaflet thickness change and percentage leaflet thickness changes are shown in Figure 12. The leaflet thickness varied from 0.14 mm to 0.28 mm. The percentage reduction was -40.7% to 27.3%.



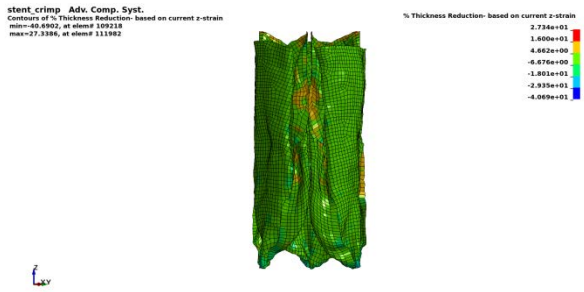


Figure 12. Leaflet Thickness Variation and % shell thickness reduction.

2. Natural and Calcified Valve Opening During Systole: The Fluid Solid Interaction(FSI) during ejection was simulated to understand the normal valve opening using SPH method. The model of the LV and aortic arch filled with blood using SPH particles is shown in Figure 5 above. The blood was modelled as fluid with density and viscosity of 1060 Kg/m**3.and 0.004 Pa.s. The material model *MAT_ELASTIC_FLUID was used where the equation of state (EOS) built in. This representation showed initial pressure as zero. To introduce average aortic pressure of 80mm Hg, the material model *MAT_NULL with *EOS_GRUNEISEN was used to represent the initial pressure.

```
*EOS_GRUNEISEN_TITLE
blood_initial_pressure
$#   eosid         c         s1         s2         s3      gamao          a         e0
         3    1483.0     1.794        0.0        0.0     0.4934       0.02.16300E-5
$#      v0
       0.0
*MAT_NULL_TITLE
blood_approximat
$#     mid        ro        pc        mu     terod     cerod        ym        pr
         61.06000E-6       0.04.00000E-9       0.0       0.0       0.0       0.0
```

The blood was injected from LV by using *BOUNDARY_SPH_FLOW. The value of the velocity was used from the published results given in Ref. 15.

Both normal and randomly calcified aortic leaflets were used to simulate the valve opening. The results are shown in Figures 13 and 14. The LV ejection is shown in Figure 15.

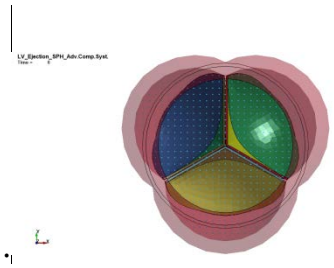


Fig. 13 a) Normal Leaflets

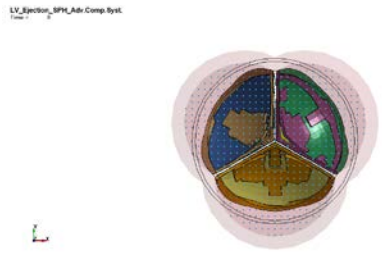


Fig. 13 b) Calcified Leaflets.

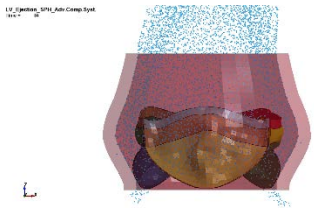


Fig. 14. a) Normal Leaflets Opening

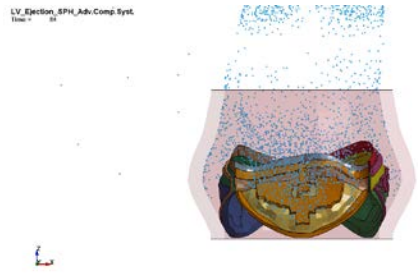


Fig. 14 b) Calcified Leaflets Opening.

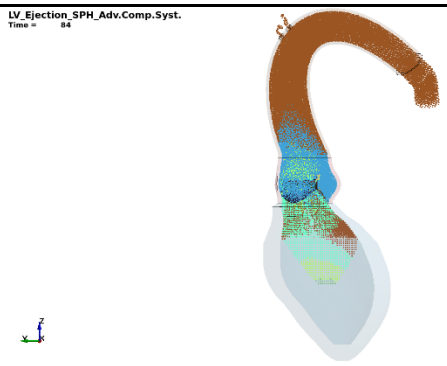


Figure 15. LV ejection.

3. Balloon Inflation of Crimped Valve: The balloon inflation is the last step once the device is placed in the aortic valve position. In this study, the balloon is shown in Figure 16. The stresses and plastic strain are induced in the valve due to crimping. Even though some time is allowed for recoiling after crimping, the valve is not stress relieved. In balloon inflation simulation the initial stress and plastic strain induced due to crimping is taken into account by introducing *INITIAL_STRAIN_SOLID and *INITIAL_STRESS_SOLID. The thickness variation in the leaflet was also taken into account in the input. The balloon was assumed as Mooney-Rivlin material. The limited result available is shown in Figure 16. The stent is expanding more in the upper portion compared to lower portion. This may be due to unequal stiffness of the bottom portion due to presence of skirt cloth.

Figure 16. Balloon Inflation of Crimped Valve.

Discussion and Concluding Remarks

The crimping simulation showed plastic strain induced in the stent material due to crimping forces. Also, the valve thickness distribution is changed. The valve leaflet may be damaged due to crimping. The effects of crimping on valve leaflets are discussed in detail in Ref. 16-19.
Calcification of the leaflets is common in older generations. As the valve gets thicker and calcified, the opening of the valve leaflets may not provide enough flow orifice area to pump the blood. Also, insufficient closure of the valve leaflets might lead to backflow to ventricle during diastole which might create further complications.

Application of SPH method provide easier way of flow modeling and analysis, However, dealing with boundary conditions for complex structures such as heart is challenging task. The SPH solution seems to be the future in biomechanics applications [Ref. 20].

In modeling of biological structures, many assumptions are made. Some of these assumptions may be justifiable while others are tenuous. For example, the left ventricle is not exactly ellipsoid, but these assumptions were made by many researchers. However, numerical simulations provide insight to the problem.

Disclaimer

This work was not intended to evaluate any product in the market. The sole purpose of this work is to show the application of numerical techniques in biomechanics.

Acknowledgement

The author wishes to thank Mr. Dilip Bhalsod of LSTC for his help during this work and Mr. Philip Ho for helping out in modeling of complex structure. Also, thanks to cardiologist Dr. Zakir Sahul, M.D. for explaining the complex TAVI procedure.

References

1. B.A. Carabello, 'Introduction to Aortic stenosis', Circulation Research, Vol 113, pp 179-185, 2013.
2. A. Cribier, 'The Odyssey of TAVI: From Concept to Clinical Reality', Engineers Ireland, May 15, 2014.
3. A. Cribier, 'The Development of Transcatheter Aortic Valve Replacement (TAVR)', Global Cardiology Science and Practice, 32, pp 1-15, 2016
4. G. Hoffmann, G. Lutter and J. Cremer, 'Durability of Bioprosthetic Heart Valves', Dtsch Arzteblatt, 105(8), 143-148,2008.
5. M.S. Hamid, H.N. Sabbah and P.D. Stein,. 'Large Deformation Analysis of Aortic Valve Leaflets During Diastole', J. of Engineering Fracture Mechanics, 22: 773-785, 1985.
6. M.S. Hamid, H.N. Sabbah and P.D. Stein, 'Vibrational Analysis of Bioprosthetic Heart Valve Leaflets using Numerical Models: Effect of Leaflet Stiffening, Calcification and Perforation', Circulation Research, 61,5: 687-694, 1987
7. H.N. Sabbah, M.S. Hamid, and P.D. Stein, 'Mechanical Stresses on Closed Cusps of Porcine Bioprosthetic Valves: Correlation with Sites of Calcification', Ann. Thoracic Surgery, 42: 93-96, 1986
8. H.N. Sabbah, M.S. Hamid and P.D. Stein, 'Estimation of Mechanical Stresses on Closed Leaflets of Porcine Bioprosthetic Valve: Effects of Stiffening, Focal Calcification and Focal Thinning', American Journal of Cardiology, 55: 1091-1096, 1985
9. M.S. Hamid, H.N. Sabbah and P.D. Stein, 'Influence of Stent Heights upon Stresses on the Cusps of Closed Bioprosthetic Valves', Journal of Biomechanics, 19: 759-769, 1986.
10. Transcatheter Aortic Valve Replacement (TAVR), Mayo Clinic https://www.mayoclinic.org/tests-procedures/transcatheter-aortic-valve-replacement/about/pac-20384698
11. J.A. Southard, 'TAVR : It's a Career, Not Just a Procedure, Cardiology, May 5, 2012.
12. D..N. Ghista and M.S. Hamid, 'Finite Element Stress Analysis of the Human Left Ventricle whose Irregular Shape is Developed from Single Plane Cineangiocardiogram', Computer Programs in Medicine, 7: 219-237, 1977.
13. G.A. Slinde, 'Numerical modeling and Analysis of the Left Ventricle', Thesis, Norwegian University of Science and Technology, Trondheim, 2015.
14. W.M. Swanson and R.E. Clark, 'Dimensions and Geometric Relationships of the Human Aortic Valve as a Function of Pressure', Circulation Research,35,6, 871-872, 1974.
15. M.Nakamura, S.Wada, S. Yokosawa, H.Isoda, H.Takeda and T.Yamaguchi, 'Measurement of Blood Flow in the Left Ventricle and Aorta using Clinical 2D Cine Phase-Contrast Magnetic Resonance Imaging', Jl. Of Biomechanical Science and Engineering, Vol 2, No2, pp 46-57. 2007.
16. S.H. Alavi, E.M. Groves and A. Kheradvar,' The Effects of Transcatheter Valve Crimping on Pericardial Leaflets', The Society of Surgeons, 97,1260-1266, 2014.
17. W. de Buhr., S. Pfeifer, J.S. Huspenina,E. Wintermantel, G. Lutter, and W. Goetz,' Impairment of Pericardial Leaflet Structure From Balloon-Expanded Valved Stents', The Jl. Of Thoracic and Cardiovascular Surgery, 143, 6, 1417-1421, 2012.
18. R. Guidoin, J. Mao, R. Zegdi, J. Lin, D. How, E. Philippe, T. Ciancuilulli, L, Wang and Z. Zhabg, 'Transcatheter Heart Valve Crimping and Expansion: Commentary', Jl. of Medical & Surgical Pathology, 2,2, 144, 2017.
19. B. Amahzoune, P. Bruneval, B. Allam, A. Lafaont, J-N, Fabiani and R. Zegdi, ' Traumatic Leaflet Injury During the Use of Percutaneous Valves: a Comparative Study of Balloon- and Self-Expandable Valved Stents', European Jl. of Cardiac-Thoracic-Surgery,43, 488-493, 2013.
20. M. Toma, 'The Emergin Use of SPH in Biomedical Applications', Significance of Bioengineering and Biosciences, 1(1), SBB.0005502,2017.