Impact of Oversizing on Stent Frame Fatigue Strains in Self-Expanding Aortic Valve Replacement

Rajesh Kandula

ABSTRACT

This paper delves into the impact of oversizing on fatigue strains in nitinol stent frames used in aortic heart valve replacements. While oversizing, the practice of using a prosthetic valve larger in diameter than the native aortic annulus, offers benefits like reduced valve migration risk and increased effective orifice area (EOA), it also poses challenges. Oversizing can lead to annular rupture and conductive abnormalities, potentially inducing mechanical fatigue. As nitinol stents become more prevalent in medical applications, comprehending their mechanical responses under real-life loading conditions becomes essential. This understanding is pivotal for ensuring the long-term reliability of these devices and safeguarding patient health. In this paper, Finite Element Analysis has been used to study the impact of oversizing the heart valve on anatomic geometry.

Keywords: Aortic valve oversizing, Finite Element Analysis, Nitinol Fatigue, Nitinol heart valve.

1. INTRODUCTION

The development of bioprosthetic heart valves has significantly advanced cardiovascular medicine, providing viable solutions for patients suffering from valvular heart diseases. Among these, the aortic heart valve is critical in maintaining blood flow from the left ventricle to the aorta.

The aortic valve is the most common disease in the older population. Aortic regurgitation (AR) and aortic stenosis (AS) are the two common disease conditions affecting the aortic root, the beginning portion of the aorta. If not treated, these conditions can cause severe illness and even death. Aortic regurgitation (AR) occurs when the aortic valve does not close properly and allows blood to leak back into the left ventricle from the aorta during diastole (ventricle relaxation phase). This regurgitation of blood reduces the efficiency of the heart’s pumping action and can lead to volume overload in the left ventricle [1]. The compliance of the aortic valve annulus in AR is typically increased due to the dilation and expansion of the annular diameter. Aortic stenosis (AS) is a condition characterized by the narrowing (stenosis) of the aortic valve. This narrowing obstructs the flow of blood from the heart into the aorta and the rest of the body [2]. The primary cause of aortic stenosis is typically the build-up of calcium deposits on the valve leaflets, leading to their thickening and reduced mobility [3].

Ensuring the reliability and durability of bioprosthetic heart valves remains a complex challenge due to the demanding physiological conditions they must withstand within the human body. Oversizing is one of the critical parameters that play a major role in the durability of the heart valve. To address this challenge, an essential aspect of the design process involves rigorous verification and evaluation of the valve’s performance under realistic in-vivo loading conditions. Finite Element Analysis
(FEA) has emerged as a powerful computational tool that enables comprehensive and detailed investigations into the mechanical behavior of complex structures, such as bioprosthetic heart valves.

Oversizing is nothing but a difference in the diameter between the stent frame and the aortic annulus diameter. Oversizing helps the valve to sit in the aortic root and overcome migration and paravalvular leaks [4]. At the same time, having a larger oversize can lead to rupture of the anatomy [5] and can increase pressure on the adjacent anatomy, causing conduction abnormalities [6]. Valve migration study is not part of the scope. A published study [7] where Edwards SAPIEN XT and Medtronic CoreValve analyzed moderate oversizing (5%–20% by area) and large oversizing (20.1%–35% by area). It was observed that more annular rupture was observed in the large oversize subgroup.

This paper presents the impact of oversizing the aortic heart valve in patient-specific anatomy using Finite Element Analysis (FEA). The aim is to evaluate the valve’s structural integrity and stent frame fatigue strains under in-vivo loading conditions under various oversized (5%, 10%, 15%, and 20%) conditions.

---

**TABLE I: Aortic Annular Diameter and Corresponding Oversize Condition**

<table>
<thead>
<tr>
<th>Oversize %</th>
<th>Aortic annulus diameter</th>
<th>Stent frame outer diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>5% oversize</td>
<td>31.50</td>
<td>33.00</td>
</tr>
<tr>
<td>10% oversize</td>
<td>30.00</td>
<td>33.00</td>
</tr>
<tr>
<td>15% oversize</td>
<td>28.75</td>
<td>33.00</td>
</tr>
<tr>
<td>20% oversize</td>
<td>27.50</td>
<td>33.00</td>
</tr>
</tbody>
</table>

---

Fig. 2. Leaflet geometric profile.

Fig. 3. THV assembly (Stent frame with leaflet and skirt).

Fig. 4. Aortic valve assembly in aortic root.

Fig. 5. Strain limit diagram [10].
2. Materials and Methods

2.1. Stent Frame

Nitinol, a nickel-titanium alloy, is widely used in the manufacturing of cardiovascular stents due to its unique super elastic and shape memory material properties. The stent frame designs used for the analysis presented in this paper is based on the design discussed in detail in this article [8]. The stent frame design (Fig. 1) is unchanged from the previous article. The referenced article [8] has further details on the geometrical parameters of the stent frame and the uniaxial properties of the Nitinol (Ni50.8 Ti49.2) material used.

2.2. Leaflets

The geometry of the leaflet (Fig. 2) used is the same as the one reported in the referenced article [8]. THV assembly of stent frame with leaflet and skirt is shown in Fig. 3. The mechanical properties used for the porcine pericardium used for the leaflets and the inner skirt are detailed in the referenced article [8].

2.3. Aortic root model

In this analysis, it was reported that the aorta is aneurysmal and has root dilatation Morganti et al. article [9]. The chosen size of the ventricular-aortic junction diameter (Annulus diameter) was 30 mm. Further details on the anatomical parameters utilized for the CAD model of the aortic root are discussed extensively in the referenced article [8]. The stent frame utilized in this model was designed to be 10% oversized. Aortic root parameters are scaled to create 5%, 15%, and 20% of the oversizing anatomic geometry. The dimensions of the aortic annulus, stent frame, and the percentage of oversize are detailed in Table I. Transcatheter heart valve (THV) deployed in aortic annulus geometry is shown in Fig. 4. Compliance with the aortic root was not taken into consideration in this simulation. Aortic root geometry is used to represent the contact with the stent frame at the basal plane. Analysis of the aortic root is not part of the scope.

\[
\text{Oversize percentage} = \frac{(\text{Annulus diameter} - \text{Stent frame diameter})}{\text{Annulus diameter}} \times 100
\]

2.4. Finite Element Model and Loading

The element types used for meshing each of the components and the boundary conditions are identical to those of the referenced article [8]. Also, for the loading conditions, 5%, 10%, 15%, and 20% oversizing for annular deployment, pressure gradients experienced by the valve during systolic/diastolic phases of the cardiac cycle, and 2.8% of distention radial displacement to represent the reduction in annual diameter between systolic to diastolic phases of the heart were used identical to those detailed in the reference article [8].

3. Results and Discussion

Traditional fatigue analysis methods like the Goodman and Soderberg approaches may not be directly applicable to Nitinol material due to its unique properties and behavior. Nitinol's fatigue life prediction is assessed using cyclic strain amplitude and mean strains. The paper cited as [10] created a constant-life diagram based on diamond testing that covered $10^7$ cycles. This constant strain life diagram (Fig. 5) is used as a starting point to design a stent frame. All the samples survived lower strain amplitudes under 0.4% strain amplitudes. Few diamond fractures were observed between 0.4% to 0.6% strain amplitudes under lower mean strains. Stent frame was assessed for mean

Fig. 6. Mean strain; (A) 5% Oversize, (B) 10% Oversize, (C) 15% Oversize, (D) 20% Oversize.
strains and strain amplitudes using principal strain tensors from systolic and diastolic loading conditions. Figs. 6 and 7 indicate the mean strains and strain amplitudes on the stent frame for different oversize conditions. Dot plots for all four different oversized conditions of the stent frame mean strains and strain amplitudes are plotted with a Gen-1 Nitinol constant life diagram shown in Fig. 8.

While the data presented in the constant-life diagram in the literature is based on stent diamonds and uniaxial load data of micro-dog bone structures, more evaluations are necessary for the suitability of such data in assessing the fatigue life of the whole stent structure. Also, the durability of the nitinol stent frame is influenced by both the austenite finish temperature and the mechanical properties that arises from the particular manufacturing process employed, which can differ between manufacturers. Consequently, it is crucial to create a customized fatigue life diagram for the specific material being used.

4. Conclusion

This article introduces a novel stent design tested in various oversized anatomical configurations. By subjecting the stent to systolic and diastolic loading, we aimed to comprehend the fatigue strains resulting from oversizing. The findings indicate that a lower oversized stent frame yields lower mean strains but a higher strain amplitude, while the opposite is true for higher oversized stent frames. Notably, a 10% oversized condition offers the optimal balance with both lower strain amplitude and mean strains. Personalizing stent frames to fit individual patient anatomy could further enhance these outcomes.
CONFLICT OF INTEREST

Author declares that there is no conflict of interest.

REFERENCES