Impact of Tricuspid Annuloplasty Device Shape and Size on Valve Mechanics - A Virtual Case Study

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Abstract

Tricuspid valve disease significantly affects 1.6 million Americans. The gold-standard treatment for tricuspid disease is the implantation of annuloplasty devices. These ring-like devices come in various shapes and sizes. Choices for both shape and size are most often made by surgical intuition rather than scientific rationale. To understand the impact of shape and size on valve mechanics and to provide a rational basis for their selection, we used a subject-specific finite element model to conduct a virtual case study. That is, we implanted four different annuloplasty devices of six different sizes in our virtual patient. After each virtual surgery, we computed the coaptation area, leaflet end-systolic angles, leaflet stress, and chordal forces. We found that contoured devices are better at normalizing end-systolic angles, while the one flat device, the Edwards Classic, maximized coaptation area, and minimized leaflet stress and chordal forces. We further found that reducing device size led to increased coaptation area but also negatively impacted end-systolic angles, stress, and chordal forces. Our case study demonstrates the potential impact of device shape and size on measures of valve mechanics. Expanding our study to many more valves may, in the future, allow for universal recommendations.

Keywords: Annulus, Functional tricuspid regurgitation, Repair, Leaflet coaptation, Leaflet kinematics, Predictive simulation

1 Introduction

The tricuspid valve ensures unidirectional blood flow from the right atrium to the right ventricle. It normally does so through the well-orchestrated interactions between its leaflets, its annulus, and its subvalvular apparatus. When this interaction is
disrupted, the valve fails and leaks. In fact, an estimated 1.6 million Americans suffer significantly from so-called tricuspid valve regurgitation. Failure is most often secondary to other conditions and thus due to valve-extrinsic factors. That is, outward remodeling and dilation of the right ventricle – in pulmonary hypertension for example – increase the tricuspid valve circumference and pull on the valve’s chordal structure. Together, these mechanisms alter valve mechanics and thus disrupt its leaflets’ ability to coapt.

When leakage is severe valve repair is required, for which surgical annuloplasty remains the gold standard. While a seemingly simple procedure, 30 years of innovation have yielded numerous device strategies. Today, surgeons can choose from a range of devices that come in different shapes and sizes. Although manufacturers provide guidelines for choosing device type (i.e., shape) and size, device selection is often driven by surgeon experience and preference. For example, one documented strategy is to choose the device size identically to the device size chosen for the concomitant mitral valve repair. Others choose to always pick the smallest available size. The variability in device selection strategies and the clear lack of objective guidelines may explain, at least in part, why regurgitation recurs in 10-30% of patients within a few years of surgery.

Thus, objective guidelines may improve surgical outcomes. Toward such guidelines, we first must understand the impact of device shape and size on tricuspid valve mechanics.

The impact of device selection on valve mechanics is mostly unknown, which stems from i) our inability to directly compare different devices within a single patient, and ii) direct comparison of the repaired valve to the original, healthy valve being obviously impossible in a clinical setting. Computational models can overcome these clinical limitations by providing access to both the healthy and the diseased valve and by allowing for a direct comparison between different devices. Thus, to study the impact of annuloplasty device shape and size on tricuspid valve function, our goal is to use our previously developed and validated Texas TriValve as a case study in which we virtually implant four different devices in six sizes. For each surgical scenario, we quantify five measures: (1) regurgitant orifice area and (2) coaptation area as primary measures of valve function, (3) end-systolic angle as a measure of leaflet kinematics, (4) leaflet stress, and (5) chordal forces as a measures of device-induced mechanobiological stimulation and possible predictors for long-term failure. Please note, this being a case study, we are not aiming to provide general recommendations but rather to demonstrate the impact of shape and size selection by means of one virtual patient.

2 Methods

2.1 Texas TriValve

For this work, we used the Texas TriValve 1.0. A complete account of all model details, including the geometry, material properties, and boundary conditions, can be found in our recent work. In short, we built this model of the human tricuspid valve from a donated healthy heart that was rejected from implantation. First, we used an organ preservation system that perfused and paced the beating heart and recreated a realistic hemodynamic environment for the tricuspid valve. In this system, we measured transvalvular pressure, annular dynamics, and leaflet kinematics. After collecting these data, we excised the tricuspid valve and conducted in-vivo and in-vitro geometric and material characterizations of the valve leaflets and chordae tendineae. That is, we first took images of the flattened valve leaflets to quantify their shape, which we then non-rigidly transformed onto the shape of the in-vivo annulus. Next, we quantified chordal insertion sites from those same images and marked them in our geometric valve model. Then, we mechanically interrogated each valve leaflet and each leaflet’s chordae tendineae using biaxial and uniaxial extension, respectively. We cast these data into the form of a Fung-type constitutive model and the Ogden material model, again, respectively. We assumed both materials to behave quasi-incompressibly. Additionally, we measured the thickness of valve leaflets and chordae, which we assigned to the geometric representation of the valve. Finally, we discretized leaflets using linear quadrilateral shell finite elements (Abaqus element S4R), while we discretized the chordae...
using three-dimensional linear multi-segmented truss elements (Abaqus element T3D2)\textsuperscript{13}. We validated our model against echo-based measurements taken in the organ preservation system.

### 2.2 Disease Model

To investigate the impact of device shape and size on the mechanics of the diseased – i.e., regurgitant – tricuspid valve, we altered our healthy valve model to mirror the pathology of pulmonary arterial hypertension-induced functional tricuspid regurgitation. As such, we asymmetrically dilated the tricuspid annulus in the lateral direction until achieving an end-diastolic annular area increase of 62% and an annular circularity of one\textsuperscript{27}. The free edges of the leaflets were passively dilated by the same amount, thus retaining their original leaflet height but increasing their surface area by approximately 30%, similar to values seen in\textsuperscript{19}. We also held the thickness of the leaflets constant while we displaced the papillary muscle heads to induce tethering of the chordae tendineae\textsuperscript{33}. Additionally, we increased the transvalvular pressure load to 42.5 mmHg to account for our virtual patient’s hypertensive state\textsuperscript{23}. Figure 1 shows the healthy and diseased Texas TriValve at both end-diastole and end-systole.

### 2.3 Virtual Device Implantation

In total, we virtually implanted 24 annuloplasty devices, four different shapes of six different sizes (26 to 36). Three devices were chosen from Edwards Lifesciences’ (Irvine, CA) offering, the Cosgrove-Edwards Classic Ring model 4500 (Classic), the Carpentier-Edwards Physio Tricuspid Ring model 6200 (Physio), and the Edwards MC3 Tricuspid Ring model 4900 (MC3); and one device was from Medtronic’s (Minneapolis, MN) offering, the Contour 3D Ring model 690R (Contour). Figure 2 shows all four annuloplasty devices used in this study. Note, all devices are considered “rigid” or “stiff”\textsuperscript{7}. The exact geometries of the devices were determined via 3D-scanning, the detailed results of which we reported previously\textsuperscript{15}; device areas and heights are provided in Table 1. The virtual repairs themselves were conducted as follows: First, we identified for each device an orientation that best fit the diseased shape of the annulus under the constraint that the anterior portion of the septal annulus remained free. Next, we displaced all finite element nodes along the tricuspid annulus toward the closest point along the device, which we modeled as a rigid body owing to the devices’ high stiffness. Additionally, we displaced the free nodes of the anterior portion of the septal annulus along a smooth line connecting the two ends of the annuloplasty devices. Finally, after the annuloplasty devices were virtually implanted in the diseased valve, we applied the transvalvular pressure gradient to the ventricular surface of each leaflet to quasi-statically simulate valve closure. All simulations were conducted in Abaqus/Explicit 2020 (Dassault Systèmes, Vélizy-Villacoublay, France) on one Intel Xeon Platinum 8160 “Skylake” node at the Texas Advanced Computing Center. We discretized the leaflets with 8,819 elements and the chordae with 3,002 elements. Additionally, we used uniform mass scaling to ensure a minimum stable time increment of $1 \times 10^{-6}$ seconds. Moreover, we used Abaqus’ general contact scheme
with the frictional penalty set to 0.1 to enforce contact between the leaflets.

3 Results

3.1 Leaflet coaptation

Figure 3 shows the outcomes of all 24 virtual repairs in which we implanted the four annuloplasty devices of six different sizes. We first found that not all device shape and size combinations restored full leaflet coaptation. For those shape and size combinations that failed to eliminate all regurgitant gaps, we quantified the percent difference of the gap size relative to the annular orifice area. From those numbers, it appears the Classic device was most effective in reestablishing leaflet coaptation, while the Contour device was least effective. That is, the Classic device required the least annular reduction (size 34) to establish full coaptation, while the Contour device required the most annular reduction (size 28).

To deepen our coaptation analyses, we next depict how device shape and size impact the ratio between coaptation area and leaflet area. In other words, we quantify how much of the leaflet is being effectively used toward closure. Figure 4 shows these ratios for each device shape and size relative to the healthy baseline and the unrepaired disease case. We found that, for a given device size, the Classic produced the most coaptation area while the Physio produced the least. We also found that sizes 30 and smaller, regardless of shape, restored healthy levels of coaptation area.

3.2 Leaflet kinematics

We also investigated post-repair leaflet kinematics. Here, we define end-systolic angle as the angle between the annular plane and each leaflet at end-systole, see Figure 5a. Thus, an angle of zero degrees reflects a leaflet that coapts within the annular plane. Figure 5b shows the end-systolic angle for each leaflet and each repair case. Interestingly, device shape had a leaflet-dependent effect on leaflet kinematics. That is, for the anterior and posterior leaflets, we found that all devices lead to a decrease in end-systolic angles relative to baseline conditions, implying that these leaflets were allowed to billow to a final location closer to the annular plane than under healthy conditions. In contrast, for the septal leaflet, most devices increased the end-systolic angle relative to the healthy baseline. Similarly, device size also had a leaflet-dependent impact. For the anterior leaflet, we found that decreasing device size led to decreasing end-systolic angle, while in the posterior leaflet, the end-systolic angle appeared independent of device size. Finally, for the septal leaflet, decreasing device size appeared to increase the end-systolic angle. To rank all devices, we summed the difference between the end-systolic angles between the healthy baseline and the repaired cases across all leaflets and sizes. Thereby, we found that the Contour device led to the smallest total differences in end-systolic angle while the Classic device led to the largest total differences in end-systolic angle, see Table 2.

We conducted a similar analysis for device size, see Table 3. Here we found that – across leaflets and device shapes – increasing device size led to decreasing differences in end-systolic angle.

3.3 Leaflet kinetics

Additionally, we investigated post-repair leaflet kinetics. That is, we computed the device-induced stress in each leaflet. Figure 5c shows the average maximum principal Cauchy stress across each leaflet center while Figure 5d shows regions where those stresses were averaged. Here, again, we found that the impact of device shape and size was leaflet dependent. For the anterior leaflet, we found that all devices lead to an increase in leaflet stress relative to the unrepaired case and could not restore healthy baseline stress. In contrast, in both the posterior and septal leaflets, all devices lead to a decrease in leaflet stress relative to the unrepaired case and trended toward restoring healthy baseline stress. As for the impact of device size, we found that, for the anterior leaflet, stress was independent of device size. On the other hand, in both the posterior and septal leaflets, stress decreased with decreasing device size toward healthy baseline conditions. Again, to rank devices, we summed the difference between stress in the healthy and the repaired valves across all leaflets and sizes. Thereby, we found that the Classic device led to the smallest total differences in stress while the Physio device led to the largest total differences in stress, see Table 2. We conducted a similar analysis for device size, see Table 4.
Fig. 2  The four different annuloplasty devices used in this study. Three devices were from Edwards Lifesciences (Irvine, CA), the Cosgrove-Edwards Classic Ring (Classic), the Carpentier-Edwards Physio Tricuspid Ring (Physio), and the Edwards MC3 Tricuspid Ring (MC3); and one device was from Medtronic (Minneapolis, MN), the Contour 3D Ring (Contour). All devices are considered “rigid.”

Fig. 3  Atrial view of all repair cases overlaid with maximum principal Cauchy stress. Closure percentage, i.e., regurgitant gap size relative to total orifice area, is reported below any repair simulation with a value less than 100%.
Table 1  Annuloplasty device specifications. Note that the area of the healthy tricuspid annulus of the Texas TriValve is 564.57 mm$^2$ at end-diastole and 396.87 mm$^2$ at end-systole, while the area of the unrepaired diseased valve is 917.6 mm$^2$ at both end-diastole and end-systole. The height of the healthy tricuspid annulus is 7.14 mm at end-systole while the height of the unrepaired diseased valve is 6.29 mm at end-systole.

<table>
<thead>
<tr>
<th>Device Area (mm$^2$)$^1$</th>
<th>Size 26</th>
<th>Size 28</th>
<th>Size 30</th>
<th>Size 32</th>
<th>Size 34</th>
<th>Size 36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic</td>
<td>409.40</td>
<td>464.46</td>
<td>536.54</td>
<td>594.72</td>
<td>666.28</td>
<td>743.13</td>
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<tr>
<td>Physio</td>
<td>486.45</td>
<td>557.78</td>
<td>624.17</td>
<td>715.02</td>
<td>806.15</td>
<td>882.55</td>
</tr>
<tr>
<td>MC3</td>
<td>426.30</td>
<td>480.25</td>
<td>570.66</td>
<td>638.75</td>
<td>969.04</td>
<td>777.43</td>
</tr>
<tr>
<td>Contour</td>
<td>453.43</td>
<td>476.00</td>
<td>578.34</td>
<td>652.91</td>
<td>726.01</td>
<td>827.05</td>
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</table>

<table>
<thead>
<tr>
<th>Device Height (mm)$^2$</th>
<th>Size 26</th>
<th>Size 28</th>
<th>Size 30</th>
<th>Size 32</th>
<th>Size 34</th>
<th>Size 36</th>
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<tbody>
<tr>
<td>Classic</td>
<td>1.06</td>
<td>2.14</td>
<td>2.53</td>
<td>2.50</td>
<td>2.48</td>
<td>2.52</td>
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<tr>
<td>Physio</td>
<td>3.53</td>
<td>3.72</td>
<td>4.19</td>
<td>4.60</td>
<td>4.99</td>
<td>5.86</td>
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<tr>
<td>MC3</td>
<td>4.86</td>
<td>4.85</td>
<td>5.45</td>
<td>5.48</td>
<td>6.70</td>
<td>6.96</td>
</tr>
<tr>
<td>Contour</td>
<td>7.60</td>
<td>7.08</td>
<td>8.31</td>
<td>8.11</td>
<td>8.93</td>
<td>10.07</td>
</tr>
</tbody>
</table>

1 “Area” was calculated as the inscribed area after projecting the device circumference onto a 2D plane.
2 “Height” was calculated as the largest orthogonal distance between any two points along the device circumference.

Table 2  Total device-induced change in end-systolic angle and stress for each device shape. That is, for end-systolic angle and stress we summed the differences between the healthy baseline and each repair case across all leaflets and device sizes. Note, we report stress as the average maximum principal Cauchy stress across each leaflet center.

<table>
<thead>
<tr>
<th>Σ Angle (deg)</th>
<th>Σ Stress (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic</td>
<td>324.04 759.5</td>
</tr>
<tr>
<td>Physio</td>
<td>189.07 918.5</td>
</tr>
<tr>
<td>MC3</td>
<td>187.65 773.5</td>
</tr>
<tr>
<td>Contour</td>
<td>97.61   841.6</td>
</tr>
</tbody>
</table>

3 Here we found that – across leaflets and device shapes – increasing device size led to increasing differences in leaflet stress.

3.4 Chordal forces
In our final analysis, we investigated the impact of device shape and size on chordal forces. Figure 6 shows the total sum of all chordal forces in the apical direction, i.e., normal to the annular plane. Here we found that chordal forces depended on both device shape and size. Of the four devices, the Contour induced the largest forces. Conversely, the Classic induced the smallest chordal forces, approximating those forces of the healthy baseline. We also found that chordal forces increased with increasing device size, much faster so for the Contour and the Physio device than for the other two devices.

Table 3  Total device-induced change in end-systolic angle and stress for each device size. That is, for end-systolic angle and stress we summed the differences between the healthy baseline and each repair case across all leaflets and device shapes. Note, we report stress as the average maximum principal Cauchy stress across each leaflet center.

<table>
<thead>
<tr>
<th>Σ Angle (deg)</th>
<th>Σ Stress (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size 26</td>
<td>152.14 414.6</td>
</tr>
<tr>
<td>Size 28</td>
<td>148.13 436.2</td>
</tr>
<tr>
<td>Size 30</td>
<td>143.04 507.9</td>
</tr>
<tr>
<td>Size 32</td>
<td>126.30 584.5</td>
</tr>
<tr>
<td>Size 34</td>
<td>118.83 659.8</td>
</tr>
<tr>
<td>Size 36</td>
<td>109.92 690.2</td>
</tr>
</tbody>
</table>

4 Discussion
In this study, we used our previously developed subject-specific finite element model of the human
tricuspid valve to investigate the impact of annuloplasty device shape and size on valve mechanics. By implanting four different devices (i.e., shapes) of six different sizes in our virtual patient, we showed that the choice of device shape and size significantly impacts valve mechanics.

4.1 Impact of Device Shape

Specifically, we found that device shape impacts all measures of valve mechanics, including its coaptation area, leaflet kinematics, leaflet stress, and chordal forces. For example, the Classic produced the most coaptation area for a given size and the Physio the least. This trend correlates with these devices’ “true” size. That is, the Classic device has the smallest “true” inscribed area, while the Physio has the largest. The impact of device shape on leaflet kinematics and leaflet stress was more complex in that it was leaflet dependent. However, overall, we found that the Contour device led to the smallest overall deviations from healthy end-systolic angles, while the Classic device led to the largest deviations. Interestingly, this trend correlates with these devices’ degree of “contour” or height. Specifically, the Classic is the flattest of the devices with a near-zero height, while the Physio and MC3 are mid-high, and the Contour has the most height. Thus, it appears that the 3D profile of the devices allows for more physiological leaflet motion. We also found that the Classic device led to the smallest overall deviations of stress from the healthy case, while the Physio device led to the largest deviation in stress. Thus, device height appears negatively correlated with achieving healthy leaflet stress. Increased stress also induced larger chordal forces so that the Classic led to the most physiological subannular mechanics, while the Contour led to the largest chordal forces. This is somewhat contradictory with findings on the mitral side where it was suggested that increased “saddle” or profile height leads to lower stress. Overall, it appears that there is no perfect device solution. While the low-profile Classic device most effectively re-established coaptation area, healthy leaflet stress, and chordal forces, it disrupted leaflet kinematics most. Especially on the septal leaflet, it led to early coaptation well below the annular plane. In contrast, the Contour device was most effective in re-establishing healthy leaflet kinematics but appeared to be suboptimal in creating coaptation area, healthy leaflet stress, and normal chordal forces.

4.2 Shape Recommendation for our Virtual Patient

For our one virtual patient, we recommend the Classic device. It outperformed the other three devices in three critical measures of valve mechanics: coaptation area, leaflet stress, and chordal forces. It was beat out only in its ability to restore healthy leaflet kinematics. However, since the impact of changes to leaflet kinematics is currently unknown, we weigh its importance for the time being as low. This comes somewhat as a surprise given that the Classic device, as the name suggests, is the oldest and presumably least evolved of the four. It appears that here the adage “oldie but goodie” applies.

4.3 Impact of Device Size

We also found that device size impacts all measures of valve mechanics. For example, we found
Tricuspid annuloplasty devices impact leaflet kinematics and kinetics. (a) Here, we define the end-systolic angle for each leaflet as the angle made by a virtual fiducial marker and the annular plane at end-systole. (b) Tricuspid annuloplasty devices fail to restore healthy leaflet kinematics. (c) Tricuspid valve annuloplasty devices have a leaflet-dependent impact on stress. (d) Please note, we average maximum principal Cauchy stresses in the belly region of each valve leaflet, indicated by the shaded regions on a 2D representation of the leaflet surface.

that coaptation area increased with decreasing device size. The impact of device size on leaflet kinematics was more complex. Here we found that size had a leaflet-dependent impact. Increasing size led to larger end-systolic angles in the anterior leaflet relative to the healthy baseline while being the opposite in the septal leaflet and having no effect in the posterior leaflet. Across leaflets and device shapes, we found that increasing device size led to overall smaller deviations in end-systolic angle from the healthy baseline. The impact of device size on leaflet stress was similarly complex, yet with different trends. Here increasing device size led to increasing leaflet stress in both the posterior and the septal leaflets relative to the healthy baseline, but had minimal impact on stress in the anterior leaflet. This finding was somewhat surprising as others have argued that, in the spirit of Laplace’s law, increasing annular size, i.e., radius, would globally lead to larger stress. However, it appears that the kinematic constraints due to chordal attachment and contact negate the simplifying assumptions of Laplace’s law, at least in the anterior leaflet. Across leaflets and device shapes,
we found that increasing device size increased overall leaflet stress. This trend coincided with the impact of device size on chordal forces. That is, increasing device size also increased the chordal forces. Overall, as for device shape, there is no perfect device size. While smaller devices maximize coaptation area and minimize leaflet stress and chordal forces, they led to abnormal leaflet kinematics. Vice versa, larger devices, while normalizing leaflet kinematics, limit coaptation area and induced larger leaflet stress and chordal forces.

4.4 Size Recommendation for our Virtual Patient

Annuloplasty device sizing, both on the tricuspid and the mitral valve, may not always be grounded in science. Here we found that a device of size 30 for the Classic device was sufficiently small to restore normal coaptation area while providing a good trade-off against the disruption of leaflet end-systolic angle and leaflet stress. Without knowledge about the relative importance of coaptation area, end-systolic angle, leaflet stress, and chordal forces, we recommend a size 30 to our patient. Thus, we don’t choose an excessive undersizing strategy as others have done. This choice is also supported by our prior work in sheep that found that excessive undersizing (i.e., choosing devices smaller than 30) may negatively impact right ventricular function. Future studies may find that increased leaflet stress may be an important factor in leaflet remodeling and may contribute to long-term repair failure, in which case we would re-evaluate our recommendation. That is, we would recommend a smaller size that reduces remodeling-inducing leaflet stress. Please note that we found the impact of device size to be shape-dependent. Thus, our size recommendation should be understood to depend on our device choice.

4.5 Limitations

Our study is subject to several limitations. Most importantly, this is not a population study but a case study on a single virtual patient. Thus, our findings cannot be extrapolated to other patients and should be interpreted carefully. Also, importantly, we have ignored hemodynamics. For example, we have ignored that decreasing device size increases the pressure gradient across the valve. We want to note, however, that we have previously shown in sheep that even dramatic annular cinching leads to minor gradients that are not clinically significant. We have also limited our analysis to a single time-point at end-systole and ignored the dynamics of the valve throughout the cardiac cycle. We do so, arguing that the valve’s mechanics at that one time-point primarily determine its function. Overall, we encourage readers to keep these limitations in mind and appreciate our work as a virtual case study and our recommendation not as a general recommendation.

5 Conclusion

Based on analyses of coaptation area, leaflet kinematics, leaflet stress, and chordal forces, we found that device shape and size have significant impact on valve mechanics. Further, we recommend that our virtual patient be treated with a Classic device of size 30. Importantly, this is a case study, and our recommendation cannot and should not be extrapolated to other patients or patient populations. More models like ours may allow in the future to understand subject-specific factors that render one device or size more optimal than others.
Acknowledgments

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Conflicts of Interest

Manuel K.Rausch has a speaking agreement with Edwards Lifesciences. None of the other authors have conflicts of interest to disclose.

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