Tricuspid Annuloplasty Rings: A Quantitative Comparison of Size, Nonplanar Shape, and Stiffness

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Background. **Functional tricuspid regurgitation due to annular and ventricular dilatation is increasingly recognized as a significant source of morbidity and mortality. To repair the annulus, surgeons implant one of many annuloplasty devices that differ in size, 3-dimensional (3D) shape, and stiffness. However, there have been no quantitative comparisons between various available devices.**

Methods. **Three-dimensional scanning, micro-computed tomography imaging, analytical methods, and mechanical tests were used to compare 3 Edwards Lifesciences (Irvine, CA) and 3 Medtronic (Minneapolis, MN) annuloplasty devices of all available sizes. We measured in-plane metrics of maximum diameter, perimeter, area, height, as well as elevation and curvature profiles. Furthermore, we computed bending stiffness as well as the maximum and minimum axes of the bending stiffness.**

Results. **Most annular prostheses differed little in their in-plane geometries but varied significantly in height. In-plane properties deviated significantly from measurements of healthy human tricuspid annuli. Height of the Edwards' MC3 and Medtronic's Contour 3D resembled healthy human tricuspid valve annuli, whereas the Edwards' Physio and Classic, and Medtronic's TriAd, did not. Additionally, the elevation profiles of the MC3 and Contour 3D and curvature profiles between all devices were consistent and matched those of healthy human annuli. The tested devices also differed in their bending stiffness, both in terms of absolute values and their maximum and minimum axes.**

Conclusions. **Contoured devices, such as Edwards' MC3 and Medtronic's Contour 3D, most accurately resembled the healthy human tricuspid annulus but differed significantly in bending stiffness. To what extent prosthesis properties and shape affect tricuspid valve function remains to be determined.**

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Functional tricuspid valve regurgitation (TR) is a common comorbidity of mitral valve disease, with 30%-50% of patients with severe mitral valve regurgitation also suffering from tricuspid valve insufficiency.[1] Although functional TR was mostly ignored in the past, today's guidelines recommend treating TR concomitant to mitral valve surgery for mild-to-severe TR and for patients with annuli larger than 40 mm.[2] Currently, the majority of TR cases are treated surgically via prosthetic ring annuloplasty. Consequently, every year approximately 8000 patients in the US undergo implantation of annuloplasty devices designed to reshape and remodel the tricuspid annulus and reestablish proper valve coaptation and function.[3] In the great majority of surgical cases, TR is functional and believed to be due to valve-extrinsic causes rather than organic valve failure.[4] In functional TR, the tricuspid annulus is dilated and flattened[5] (Figure 1), thus annular devices are designed and selected to both downsize the annulus and to recreate its 3-dimensional (3D) configuration.[6,7] To this end, numerous prostheses are commercially available but potentially differ in 3 key parameters: (1) size, (2) 3D shape, (3) stiffness. Device shape may be denoted as "flat" or "remodeling/contoured" and stiffness described as "flexible", "semi-rigid", and "rigid". Although most manufacturers publish information about device size and 3D shape, these data are usually sparse and insufficient to describe the devices' complex geometries and mechanical properties. As contemporary surgical outcomes of tricuspid annuloplasty are suboptimal, with recurrent

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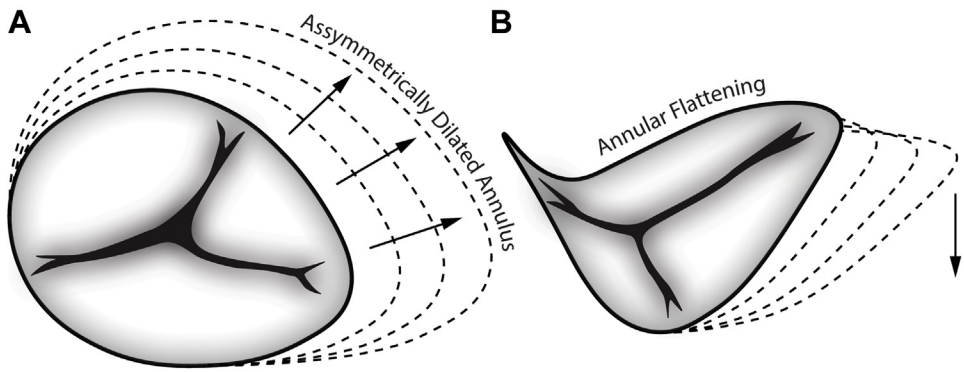

Figure 1. Illustration of disease-induced (A) in-plane and (B) out-of-plane annular changes.

significant TR in up to 18% of patients,[8,9] annuloplasty device selection, at least in part, may determine surgical success. To better inform device selection, the objective of this work was to accurately quantify and compare size, 3D shape, and stiffness of 6 commercially available annuloplasty devices.

Patients and Methods

We tested all available sizes (26-36 mm) of 6 devices (Figure 2); 3 from Edwards Lifesciences (Irvine, CA): Carpentier-Edwards Classic Ring model 4500 (Classic), Carpentier-Edwards Physio Tricuspid Ring model 6200 (Physio), and Edwards MC3 Tricuspid Ring model 4900 (MC3); and 3 from Medtronic (Minneapolis, MN): Medtronic Duran AnCore Band model 620B (Duran), TriAd Adams Band model 900SFC (TriAd), and Contour 3D Ring model 690R (Contour).

3D Scans and Geometric Modeling

All annuloplasty devices (except for the Duran band) were carefully mounted on our 3D scanner (Ultra HD, NextEngine, Santa Monica, CA). Next, 3D images were acquired and geometries were reconstructed, reduced to 3D point clouds, and point clouds skeletonized (see Figure 3). All simple geometric metrics (ie, max diameter, perimeter, height, and area) and continuous metrics (ie, elevation and curvature profiles) were based on those skeletonized centerlines.

Specifically, we computed maximum diameter as the largest distance between any 2 points along the length of those centerlines, perimeter as the arc-length integral between the 2 ends of the centerline, height as the largest orthogonal distance between any 2 points along the centerline, and area as the area of the convex hull to the projection of the centerline onto its least-squares plane. Note, we are comparing these geometric measures in the Results section against measures of the healthy and diseased annulus as published.[10,11] For the continuous elevation profiles, we computed the orthogonal distance between each point on the centerline and their least-squares plane. For the continuous curvature profiles, we computed the curvature using a standard formula based on the first and second derivatives of a best fit spline with respect to the arc-length parameter.[12,13]

Mechanical Testing

The stiffness of the Duran device and the flexible ends of the TriAd device were characterized using tensile testing. Two ends of the Duran and the TriAd devices' flexible portions were clamped and displaced while measuring the required force. Subsequently, we converted the force-displacement data to engineering stress-strain data. Material stiffness was defined as the slope of the stress-strain curves.

Micro-Computed Tomography Scans

We also performed micro-computed tomography scans (microXCT 400, Zeiss, Oberkochen, Germany) of 1 ring per ring design (size 30 mm) to characterize their metal cores at a resolution of 18.8 μm (Figure 4).

Analytical Analysis

Based on micro-computed tomography scans, the cross-sectional geometries were extracted along the centerline. Next, we analytically computed the second moments of area and multiplied them by the Young's moduli of the devices' core material to obtain the devices' bending stiffnesses. This value represents the material-dependent resistance of beams to bending with larger values indicating greater resistance to bending, which can vary with direction (anisotropy) and along its length (heterogeneity).

Results

Geometric Measures

The shape of the 6 devices in terms of standard geometric measures are summarized in Figure 5 and Table 1, where they are compared with available values of the normal and diseased annulus. All metrics for all devices increased monotonically with device size, barring height. Maximum diameter, perimeter, and area varied little among the prostheses, whereas height varied significantly between devices. Specifically, the Classic and the TriAd rings had the smallest height, of less than 1 mm, whereas the Physio ($\approx$ 3-4 mm height depending on size), MC3 ($\approx$ 4-6 mm), and

Figure 2. Second moment of area computation based on (A) micro-computed tomography images, (B) cross-sectional geometry extraction, and (C) geometry triangulation. Shown is the Edwards Classic Ring of size 30.

the Contour (≈ 7-9 mm) devices revealed progressively larger heights in their design.

3D Contour and Curvature

Furthermore, to sufficiently describe the 3D shape of these devices, we also analyzed their elevation and curvature profiles. Figure 6 representatively illustrates the profiles for all devices of size 30 mm. The elevation profiles reflect the general pattern of height with the Classic and TriAd devices being essentially flat, the Physio of medium height, and the MC3 and Contour rings revealing the most significant out-of-plane deviations. Additionally, these profiles demonstrate the spatial variations of height. Both non-flat Edwards rings, the Physio and MC3, and the Medtronic Contour showed a remarkably similar elevation profile with peaks in the anterior-septal and posterior segments of the devices. Interestingly, the curvature profiles between all devices were almost identical as well with very localized peaks in curvature in the anterior segment and a widely distributed curvature in the posterior segment. The one outlier to this pattern was the TriAd device, which showed only 1 distinct region of curvature in the posterior segment. To reduce curvature profiles to a single number in order to compare curvature between all devices and all sizes, we also computed the average curvature across the entire device length (Figure 7). We found that overall the average curvature decreased with device size and that the relative pattern between devices was consistent among all sizes. Interestingly, the Contour had the largest average curvature (ie, was the most curved) due to its extreme height profile while the TriAd band had the lowest

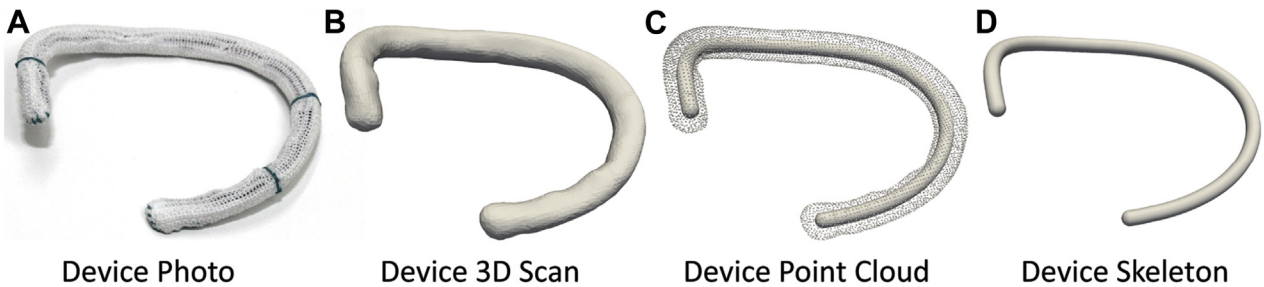

Figure 3. Simple modeling pipeline from (A) physical device to (B) 3-dimensional scan to (C) point cloud, and finally (D) skeletonized center line. Shown as an example is the size 30 mm Medtronic Contour 3D device.

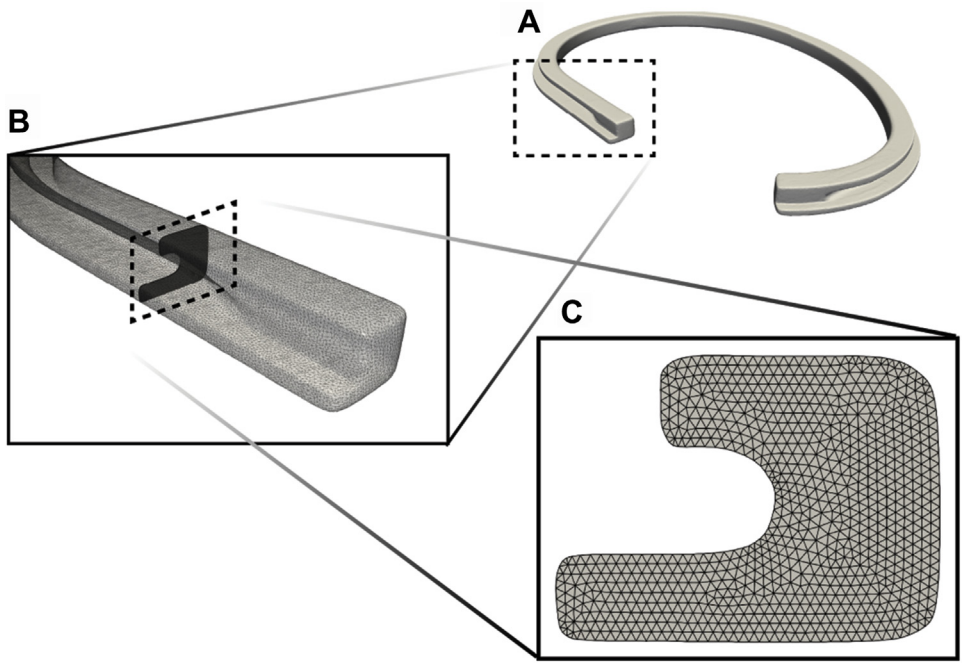

Figure 4. Second moment of inertia computation based on (A) micro-computed tomography images, (B) cross-sectional geometry extraction, and (C) geometry triangulation. Shown is the Edwards Classic Ring of size 30 mm.

average curvature due to its simpler 3D shape with only 1 curvature peak along its length.

Bending and Axial Stiffness

Figure 8 illustrates the maximum and minimum bending stiffness along the perimeter of each device of 30 mm size. Two patterns emerged: the Classic, the TriAd, and the Contour rings had homogeneous bending stiffness along their perimeters whereas the Physio and the MC3 did not. Specifically, the latter 2 prostheses had significantly reduced bending stiffness at both ends. Additionally, the contours also demonstrate that some devices had widely differing maximum and minimum bending stiffness (eg, Physio) whereas others had only small differences (eg, Contour). To compare the anisotropy (the ratio between maximum and minimum bending stiffness) in bending stiffness among devices, Figure 9A and Table 1 list the average (computed along the perimeter) maximum and minimum bending stiffness for all devices of size 30 mm. These data illustrate vastly differing bending stiffness between devices as well as vastly differing degrees of anisotropy. Specifically, the Physio device had the largest maximum bending stiffness, whereas the Classic, MC3, and Contour had similar maximum bending stiffnesses. Interestingly, the Physio also had among the lowest minimum bending stiffness of all devices. Thus, the Physio was the most difficult to bend around its maximum principle axis, but the easiest to bend around its minimum principal axis. In other words, the Physio is selectively stiff. Whereas the Classic and MC3 devices were also somewhat anisotropic, having both a stiffer direction and a softer direction, the Contour device was nearly isotropic, meaning that its stiffness only marginally depended around which axis it was bent. Figure 9B depicts the actual maximum principal and minimum principal axes. In the case of the Physio ring, it was easiest to bend the device in the out-of-annular-plan direction (ie, up and down), while it was the hardest to bend in the in-plane direction. The nearly symmetrical shape of the Contour device renders the maximum and minimum principal axes meaningless in that the difference between the maximum and minimum bending stiffness is so small that the 2 axes are essentially interchangeable. Interestingly, the maximum and minimum principal axes of all other devices did not align with the annular plane. Thus, their maximum and minimum principal axes did not specifically support or prevent out-of-plane bending. Additionally, we computed the axial stiffness of the fabric of the Duran device and the flexible ends of the TriAd device. Importantly, although both are made of similar materials, the stiffness of the fabric varied significantly. The flexible ends of the TriAd device were significantly stiffer than the Duran device (1.59 ± 0.46 and 16.26 ± 7.00 N/mm^2, $P = .005$, respectively, via Welch *t* test; Figure 9C).

Comment

The goal of surgical tricuspid annuloplasty is to remodel/reshape the diseased and deformed tricuspid annulus.[14] Specifically, in functional TR, the annulus is asymmetrically dilated and flattened[15] (Figure 1), and the goal of tricuspid annuloplasty is to reduce annular size and reestablish a normal 3D shape. However, the annulus dynamically deforms during the cardiac cycle, changing its area, shape, and height.[10] Assuming that the dynamic changes throughout the cardiac cycle are critical to the

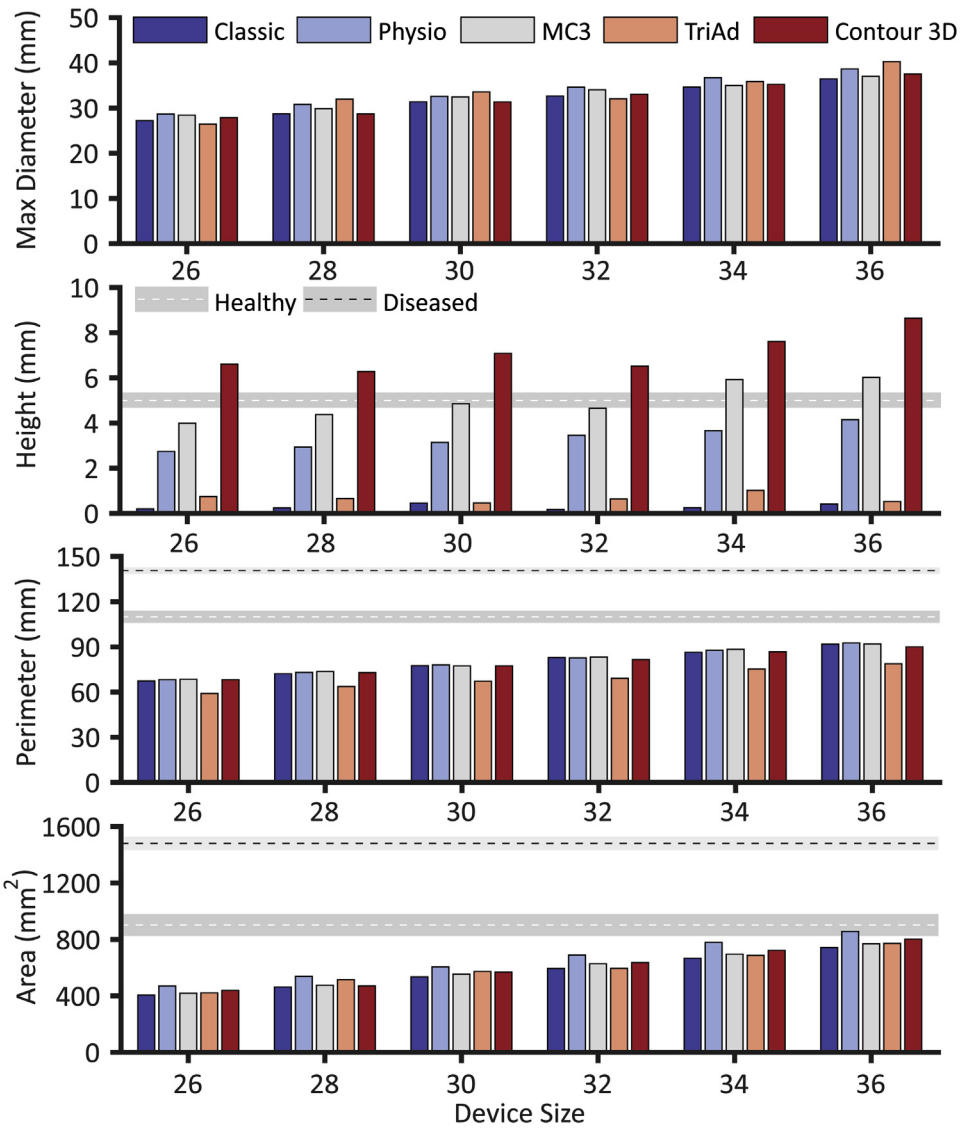

Figure 5. Measures of device geometries. Dimensions for the healthy and diseased human tricuspid annulus (as available) are reported as mean ± 1 standard error according to Malinowski and colleagues,[10] and Ring and associates,[11] respectively.

valve's optimal function, preserving annular dynamics after tricuspid annuloplasty may be a secondary goal. Additionally, restriction of these dynamics may elicit reaction forces between the periannular tissue and the device that could put undue stress on sutures and cause ring dehiscence.[16] The challenge to the practicing surgeon lies not only in optimally performing the technical steps of tricuspid annuloplasty, but also to select the most optimal device to fulfill these goals.

In the current study, we present a direct comparison of size, geometry, and mechanical properties of 6 clinically used tricuspid annuloplasty devices that may provide some guidance in prosthesis selection. Our findings highlight that there was little difference in the in-plane geometric measurements between all devices, and the prostheses scaled very similarly with increasing size. Observed values for area and perimeter were significantly below annular measurements from healthy individuals. Measurements of annular area and perimeter in healthy hearts during late systole reported by Ring and associates[11] were 1003 mm^2 and 118 mm, respectively; those of Owais and colleagues[17] were 1090 mm^2 and 122 mm, respectively; and those by Malinowski and coworkers[10] were 902 mm^2 and 110 mm, respectively. Thus, even the largest ring size essentially downsizes the average nondilated annulus by 100-200 mm^2, or approximately 20%.

In contrast to in-plane measurements, devices varied significantly in their 3D shape or height. The height of the contoured devices varied from 3-9 mm and was well aligned with the measurement of actual saddle height taken in patients. Ring and colleagues[11] reported a systolic height of 5.8 mm, and Malinowski and associates[10] reported a height of 5 mm. Maintaining anatomically correct height may be important for valve function. Salgo

Table 1. Summary of Device Geometry and Stiffness Measures

	Max Diameter (mm)					
	Size 26	Size 28	Size 30	Size 32	Size 34	Size 36
Classic	27.21	28.75	31.39	32.67	34.66	36.45
Physio	28.68	30.82	32.60	34.64	36.72	38.65
MC3	28.43	29.86	32.47	34.04	34.99	37.02
TriAd	26.43	31.96	33.58	32.06	35.89	40.30
Contour 3D	27.90	28.72	31.37	33.06	35.25	37.53
	Height (mm)					
Classic	0.20	0.25	0.46	0.17	0.25	0.42
Physio	2.74	2.93	3.15	3.46	3.66	4.15
MC3	4.00	4.37	4.86	4.66	5.92	6.02
TriAd	0.75	0.65	0.46	0.64	1.02	0.53
Contour 3D	6.61	6.28	7.08	6.51	7.61	8.64
Normal annulus[10]	5.0 ± 1.1 (mean ± 1 SD)					
Diseased annulus[11]	5.4 (mean)					
	Perimeter (mm)					
Classic	67.34	72.19	77.49	82.90	86.36	91.81
Physio	68.29	73.10	78.07	82.65	87.69	92.63
MC3	68.44	73.63	77.36	83.28	88.46	91.95
TriAd	59.12	63.64	67.18	69.16	75.28	78.76
Contour 3D	68.22	72.93	77.37	81.52	86.71	90.05
Normal annulus[10]	110 ± 14 (mean ± 1 SD)					
Diseased annulus[11]	141 (mean)					
	Area (mm^2)					
Classic	406.11	462.91	534.18	594.30	666.73	742.22
Physio	470.21	538.43	605.13	689.43	778.73	856.73
MC3	419.44	475.68	554.00	627.63	695.27	768.93
TriAd	421.71	515.28	572.84	595.48	686.69	772.26
Contour 3D	438.40	470.98	569.09	636.21	722.15	802.15
Normal annulus[10]	902 ± 257 (mean ± 1 SD)					
Diseased annulus[11]	1,482 (mean)					

	Bending Stiffness (Nm^2)				
	Classic	Physio	MC3	TriAd	Contour 3D
Maximum	26.65e-3	14.54e-3	18.60e-3	2.76e-3	22.86e-3
Minimum	46.69e-3	69.77e-3	32.73e-3	2.76e-3	25.37e-3

Dimensions for the healthy and diseased human tricuspid annulus are reported from Malinowski and coworkers[10] and Ring and colleagues,[11] respectively. Note that Ring and colleagues did not quantitatively report measures of standard deviation or error.

and coworkers[18] showed that the native saddle-shape of the mitral annulus minimized leaflet stress, thus identifying a teleological reason for the 3D configuration of the mitral annulus. Spinner and colleagues[19] investigated whether the same may be true for the tricuspid annulus but did not find significant changes in anterior or posterior leaflet stretches in their in vitro preparation when changing the annulus from flat to saddle-shaped. Significant modifications to the valve when being explanted from the animal heart to a right-heart simulator may have contributed to this negative result. In vivo studies are needed to provide evidence for or against a teleological cause for the tricuspid valve 3D annular configuration, either supporting or questioning the use of contoured annuloplasty devices.

The usefulness of comparing elevation and curvature profiles between devices lies in establishing quantitative means to identify devices that most likely reestablish normal annular shape. Our detailed geometric characterization of the investigated devices revealed little variation in elevation and curvature profiles, as the contoured devices showed peaks and valleys in the same locations that also coincide with the reported shape of the nondilated tricuspid annulus.[20] Similarly, the curvature profile of all devices was surprisingly similar as all (except for the TriAd) accurately reflected the curvature of the human tricuspid annulus.[10] Additionally, absolute curvature values were well matched with the nondilated human annulus. The TriAd was the one device defying this pattern. It showed only 1 area of peak curvature, which

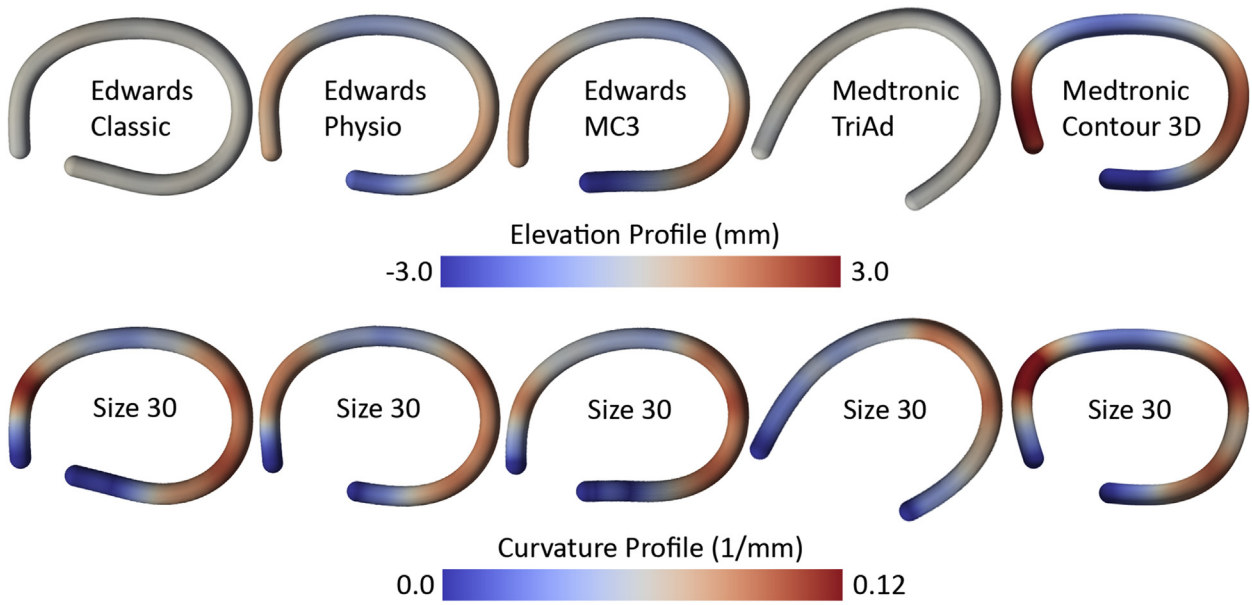

Figure 6. Elevation and curvature profiles of 5 devices representatively computed for devices of size 30 mm.

did not clearly coincide with regions of increased curvature in patients.

The current analysis of ring stiffness determined that some prostheses showed varying stiffness along their length. Specifically, the Physio and the MC3 were stiffer in the midsection of the device and softer at their ends. This design may permit the rings to conform to the natural dynamics of the annulus, which shows significant curvature and length changes in those regions.[10,13] Additionally, devices showed varying degrees of anisotropy (eg, the Physio bent more easily out of the annular plane than within the annular plane). Again, these properties may better accommodate the natural dynamics of the annulus as the tricuspid annulus has been reported to fold out of plane during systole.[21] Although the Classic and MC3 prostheses had some degree of anisotropy, it was not as prominent and the principal axes were not clearly aligned with the annular plane. Our in vivo ovine experiments,[22] however, have shown that the Duran, TriAd, and Contour rings, despite their significantly different degrees of stiffness, all essentially "froze" the natural dynamics of the tricuspid annulus. Similar findings have been reported with complete and partial mitral prostheses of varying flexibility.[23,24] Even the Duran ring, a "flexible" device, prevents the natural annular motion in sheep and human patients,[10,13] thereby calling in to question the added benefit of flexible and semirigid devices in preserving annular dynamics. However, in mitral prostheses, selective stiffness may reduce suture forces and thus reduce the risk of ring dehiscence.[25] Initial clinical reports of higher incidence of tricuspid ring dehiscence with rigid prostheses may partially corroborate these findings on the right side.[16] It is currently also unclear to what extent suture annuloplasty fits into the spectrum of device stiffness. Sutures may represent the lower limit of stiffness. Thus, clinical findings that rigid devices outperform suture annuloplasty could support rigid over flexible devices.[26,27] However, care must be taken in extrapolating these results as suture annuloplasty is a nonstandardized technique that makes direct comparison with ring annuloplasty difficult. Finally, our data also highlight that not all "flexible" devices are equally stiff. The flexible ends of the TriAd device were almost 10 times stiffer than the Duran device. Thus, care should be taken categorizing devices in overly broad terms.

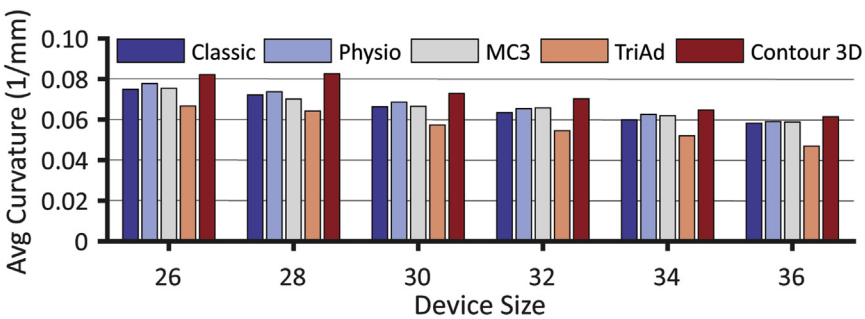

Figure 7. Average (along the device perimeter) curvature values for each of 5 devices and 6 sizes.

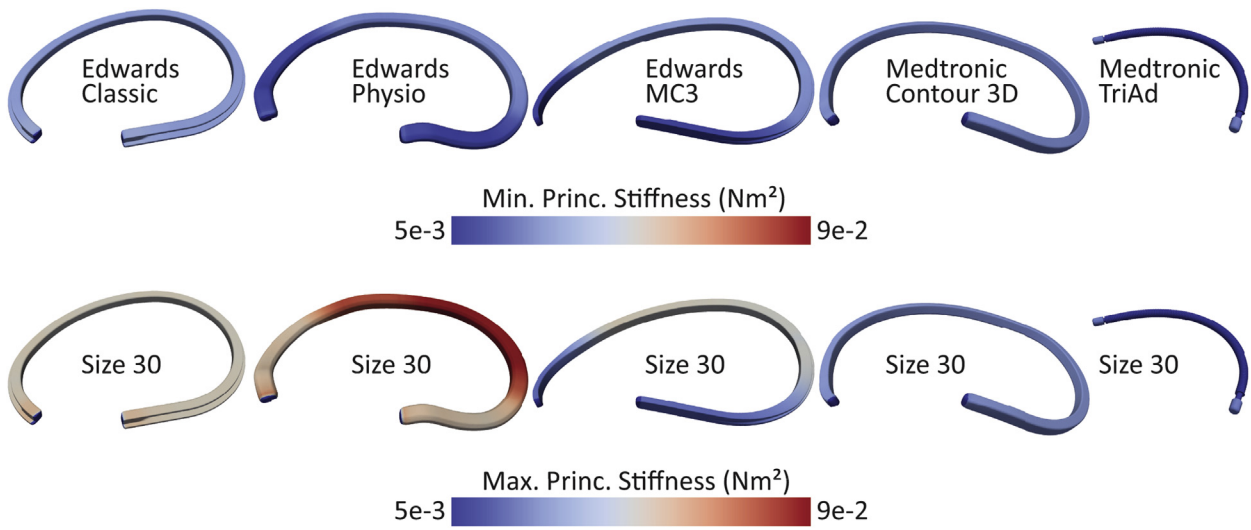

Figure 8. Maximum (Max.) and minimum (Min.) principal bending (Princ.) stiffness based on micro-computed tomography images of all devices of size 30 mm.

The results of the current study may be used to facilitate annular prothesis choice during tricuspid annuloplasty. This process should be based on clinical presentation, detailed preoperative imaging, visual intraoperative inspection, and all mechanical and geometrical properties of the device. The majority of diseased tricuspid valves present with asymmetrically dilated and flattened annulus with or without concomitant regurgitation. We hypothesize that the former scenario requires a device that is not only able to restore the physiological shape (height) but also to maximize systolic leaflet coaptation while minimizing leaflet stresses. Here, the stiff contoured device (MC3) may be preferred. Although the Contour 3D device has similar properties as the MC3 device, its curvature and shape overcorrection may unnecessarily increase stress on the native annulus. In the latter case, "preventive" annuloplasty may be adequately durable with the use of less-stiff flat devices (Physio, TriAd) or even fully flexible protheses (AnCore). We question the usefulness of rigid flat rings (such as Classic) as they do not appear to offer any advantage over more tailored newer protheses. Unfortunately, no single "annular score" exists for both the native annulus and the device that would allow for the perfect match in order to make this difficult operative decision automatic and to guarantee the long-term success.

Our long-term aim is to understand the effect of annuloplasty on tricuspid valve mechanics and to improve surgical outcomes by optimizing device design and choice. To this end, we have previously characterized tricuspid annular shape and dynamics in sheep and humans, in health[10,13] and disease,[28] after tricuspid annuloplasty,[29] and as a function of downsizing[30] and device type and size.[22] In the future, we will use the data from this work to perform virtual implantation of various annuloplasty device types and sizes in the same heart to compare their effect on the valve and the valvuloventricular complex.[31,32]

Limitations

First, we digitized and measured only 1 sample of each device type and size. It is possible, albeit unlikely, that manufacturing variations were not captured through our process. Note that we performed a verification and

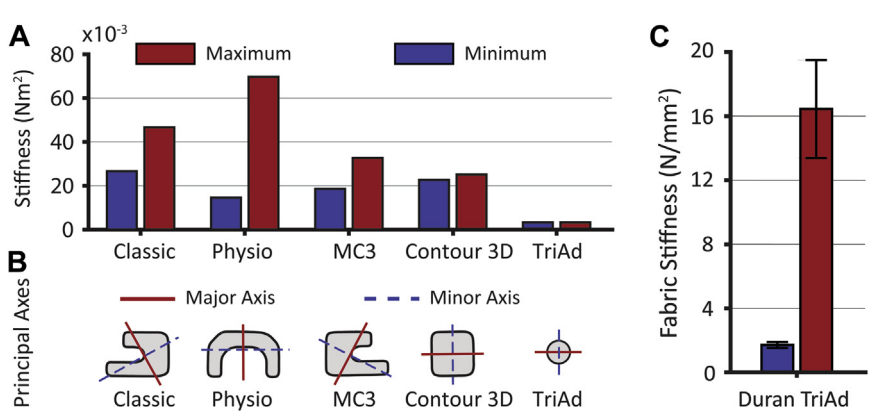

Figure 9. (A) Average (along the device perimeter) maximum and minimum principal bending stiffness based on micro-computed tomography images of all devices of size 30 mm. (B) Maximum principal and minimum principal axes of the bending stiffness. The red line depicts the major axis around which it was the hardest to bend the device, while blue line depicts the minor axis around which it was the easiest to bend the device. (C) Comparison between the axial stiffness of the Duran device and the flexible ends of the TriAd device (data shown as mean ± 1 SD, $P < .01$).

validation step to ensure that measurement-related errors were small. Specifically, for verification, we measured 1 of the devices 5 times and found maximum differences between scans being smaller than 1.1% for any of the measurements. Similarly, for validation, we 3D-printed a circular ring of similar thickness as the annuloplasty devices with a sinusoidal out-of-plane deviation. After scanning those 3D-printed rings, we compared the measured dimensions to the theoretical values and found errors smaller than 2%.

Conclusions

We comprehensively evaluated 6 tricuspid valve annuloplasty devices via 3D scanning, micro-computed tomography imaging, analytical methods, and mechanical testing and found that all devices differed little in their in-plane geometries but varied significantly in their out-of-plane geometries. The elevation and curvature profiles of most prostheses resembled those of the healthy human tricuspid annulus. The investigated devices differed most significantly in their bending stiffness, both in overall resistance to bending and in the degree of bending stiffness anisotropy. The contoured devices (ie, the Physio, MC3, and Contour) most accurately resembled the healthy human tricuspid annulus but differed significantly in bending stiffness (magnitude, heterogeneity, and anisotropy).

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Notice From the American Board of Thoracic Surgery

The 2020 Part I (written) qualifying examination will be held Monday, December 7, 2020, at multiple sites throughout the United States using an electronic format. The closing date for applications was August 28, 2020. Those wishing to be considered for examination must apply by logging in to their ABTS portal online at www.abts.org.

A candidate applying for admission to the Part I (written) qualifying examination must fulfill all the requirements of the Board in force at the time the application is received.

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