An analytical, mathematical annuloplasty ring curvature model for planning of valve-in-ring transcatheter mitral valve replacement

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Matthew H. Park, MS,[a,b] Mateo Marin-Cuartas, MD,[a,c] Mark Sellke, PhD,[d] Pearly K. Pandya, MS,[a,b] Yuanjia Zhu, MD, PhD,[a,e] Robert J. Wilkerson, BS,[a] David M. Holzhey, MD, PhD,[c] Michael A. Borger, MD, PhD,[c] and Y. Joseph Woo, MD[a,e]

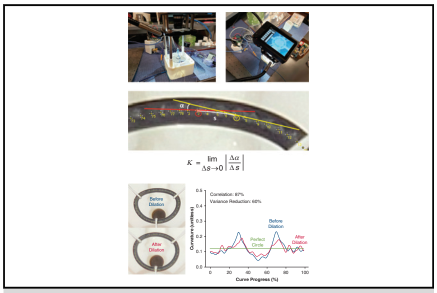
ABSTRACT

Objectives: An increasing number of high-risk patients with previous mitral valve annuloplasty require transcatheter mitral valve replacement due to recurrent regurgitation. Annulus dilation with a transcatheter balloon is often performed before valve-in-ring transcatheter mitral valve replacement, which is believed to reduce misalignment and paravalvular leakage, yet little evidence exists to support this practice. Our objective was to generate intuitive annuloplasty ring analyses for improved valve-in-ring transcatheter mitral valve replacement planning.

Methods: We generated a mathematical model that calculates image-tracked differential ring curvature to build quantifications for improved planning for valve-in-ring procedures. Carpentier-Edwards Physio M24 and M30 (n = 2 each), Physio II M24 and M26 (n = 3 each), LivaNova AnnuloFlex M26 (n = 2), and Edwards Geoform M28 (n = 2) rings were tested with a 30-mm Toray Inoue balloon inflated to maximum rated pressures.

Results: Curvature variance reduces with larger ring sizes, indicating that larger rings are initially more circular than smaller ones. Evaluated semi-rigid and rigid rings showed little to no difference between pre- and post-dilation states. Annuloflex rings (flexible band) showed a postdilation variance reduction of 32.83% ($P < .001$) followed by an increase after 10 minutes of relaxation that was still reduced by 19.62% relative to the initial state ($P < .001$).

Conclusions: We discovered that balloon dilation does not significantly deform evaluated semi-rigid or rigid rings at maximum rated balloon pressures. This may mean that dilation for these conditions before valve-in-ring transcatheter mitral valve replacement is unnecessary. Our mathematical approach creates a foundation for extended classification of this practice, providing meaningful quantification of ring geometry. (JTCVS Techniques 2023;20:45-54)



Modeling and analysis of annuloplasty ring geometry before and after balloon dilation.

CENTRAL MESSAGE

Balloon dilation does not significantly deform evaluated semi-rigid or rigid rings at maximum balloon pressures, which may mean that dilation for these conditions before ViR TMVR is unnecessary.

PERSPECTIVE

We generated a mathematical model of image-tracked differential ring curvature to build quantifications for improved planning for ViR procedures. We found that balloon dilation does not significantly deform evaluated semi-rigid or rigid rings, meaning that dilation before ViR TMVR could be unnecessary. Our approach creates a foundation for extended classification and quantification of ring geometry.

From the Departments of [a]Cardiothoracic Surgery, [b]Mechanical Engineering, [d]Mathematics, and [e]Bioengineering, Stanford University, Stanford, Calif; and [c]University Department of Cardiac Surgery, Leipzig Heart Center, Leipzig, Germany.

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Drs Park and Marin-Cuartas contributed equally to this article.

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Address for reprints: Y. Joseph Woo, MD, Department of Cardiothoracic Surgery, Stanford University, Falk Cardiovascular Research Building CV-235, 300 Pasteur Dr, Stanford, CA 94305-5407 (E-mail: joswoo@stanford.edu).

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Abbreviations and Acronyms

BVF	= bioprosthetic valve fracture
MR	= mitral valve regurgitation
MV	= mitral valve
TAVR	= transcatheter aortic valve replacement
THV	= transcatheter heart valve
TMVR	= transcatheter mitral valve replacement
ViR	= valve-in-ring

Mitral valve regurgitation (MR) is among the most prevalent forms of valvular heart disease in Western countries.[1,2] It is estimated to affect up to 19% of the general population in the United States[3] and is a major cause of global morbidity and mortality.[4] MR can be caused by various intrinsic lesions of the mitral valve (MV) apparatus,[5] and among these lesions, mitral annular dilation is among the most common. MV surgical intervention is the current gold standard for patients with severe primary MR,[6,7] and with the increase in surgical volume and expertise, as well as the excellent long-term outcomes associated with mitral repair, guidelines continue to recommend aggressive and early mitral repair when indicated.[8] Synthetic mitral annuloplasty rings are a fundamental component in mitral repair, restoring the annulus to a healthy geometry to re-establish proper leaflet coaptation and prevent further annular dilation.[9] Currently, there are dozens of mitral annuloplasty rings available with varying geometries, designs, and material properties. However, the lack of rigorous, unbiased, biomechanical comparison of the wide variety of rings makes quantifying the differences difficult, especially because the choice of ring is still largely dependent on surgeon preference.

Despite the lack of comprehensive ring comparisons, understanding ring properties is essential for thorough surgical planning, especially as an increasing number of high-risk patients with previous MV annuloplasty require further intervention due to recurrent MR particularly for those with ischemic MR and left ventricular remodeling.[10,11] For such nonoperable, high-risk patients, transcatheter mitral valve replacement (TMVR) is a common minimally invasive treatment alternative, resulting in the implantation of a mechanical prosthetic MV within an annuloplasty ring, known as a valve-in-ring (ViR) procedure. Concerningly, ViR procedures have been reported to have low levels of procedural success (as low as 57.4%[11] and 66.7%[12] in separate studies), high mortality rates (30-day, 1-year, 2-year, and 4-year mortality rates of up to 9.9%, 30.6%, 50%, and 50.3%, respectively, from different studies), and of significant paravalvular leakage rates, which remain the main predictor of mortality at follow-up.[11-17]

Because transcatheter prosthetic valves are circular whereas annuloplasty rings have a *D*-shape, annulus dilation with a transcatheter balloon is often performed in smaller rings to deform the implanted ring into a circular geometry before TMVR, which is believed to reduce the misalignment, paravalvular leakage, and patient–prosthesis mismatch.[13,18] However, the lack of characterization of the diverse rings makes planning difficult, and understanding how ring curvature reacts to balloon dilation is a critical yet not well understood component of ViR TMVR procedures. By developing the mathematical foundation to characterize and quantify ring curvature, our objective was to generate the technical methodology to build intuitive ring quantifications and to extract rigorous ring comparisons for improved planning and ring selection for ViR and annuloplasty procedures. The validation of our mathematical model and its applications for further classifying commercially available mitral annuloplasty rings, can help predict the circularity and deformation behavior of different rings following balloon dilation during ViR TMVR procedures. This model could be used as a pre-TMVR planning tool for improving patient selection and procedural planning.

MATERIALS AND METHODS

Ring Selection

Annuloplasty rings size M30 or smaller were purchased in a retail capacity and were chosen based on availability from an online surgical supply store (eSutures.com), which included a variety of flexible, semi-rigid, and rigid rings, all of which were complete rings without any of the anterior leaflet portions cut out. Only rings smaller than M30 were selected because balloon dilation is usually not performed in patients with larger annuloplasty rings. We were able to acquire and test the following rings: Carpentier-Edwards (Edwards Lifesciences) Physio M24 and M30 (n = 2 each), Physio II M24 and M26 (n = 3 each), Edwards Geoform M28 (n = 2), and LivaNova (LivaNova) Sorin Carbomedics AnnuloFlex M26 (n = 2). Each ring was tested with a 30 mm Inoue balloon (Toray Industries Inc).

Imaging Acquisition and Analysis

For annuloplasty ring testing, a custom mounting fixture was used to suspend the ring, camera, and transcatheter balloon. We then recorded the ring using a high-speed camera (Chronos 1.4; Kron Technologies Inc) and generated still images for analysis. We then performed image tracking using ImageJ software (National Institutes of Health), which translated the geometry into a planar, two-dimensional projection. This output data, which was calibrated to a millimeter scale, was a collection of approximately 70-point coordinates in sequential order around the ring. These coordinates were analyzed using a custom Python script that implemented the mathematical model calculations detailed below, as well as a Gaussian convolution smoothing filter. We were then able to perform variance analyses and quantify circularity between conditions. Curvature variance gives an approximate estimate of curvature variability throughout a shape, which is a metric that describes deviation from circularity, as a perfect circle demonstrates 0 curvature variance. Moreover, curvature variance provides a metric that can be used to compare changes in ring shape given our experimental conditions. For example, a reduction in curvature variance indicates an increase in circularity.

Mathematical Model

Using a curvature-based mathematical modeling approach, we were able to generate meaningful visualizations and quantifications comparing annuloplasty rings. This model consists of calculating the regional curvature defined by the formula

$$K = \lim_{\Delta s \to 0} \left| \frac{\Delta \alpha}{\Delta s} \right|$$

This standard curvature equation allows us to provide continuous quantification of ring circularity based on a differential approximation of the image-tracked shape analysis (Figure 1). Similar analysis has been used for native annulus classification and has additionally been used with Gaussian spline fitting.[19,20] However, using curvature as a tool for analyzing time- and stretch-dependent changes is a powerful new way to classify annuloplasty ring geometry, especially in the context of TMVR balloon dilation and requirements for ViR circularity. As such, we have plotted curvature values on an x-axis range of ring progress, including calibration geometries, to provide greater intuition and context on curvature interpretation. In general, greater circularity results in a variance reduction for plotted curvature versus curve progress, with a perfectly circular geometry resulting in a straight zero-slope line. Using this intuition, we provide additional deeper quantifications rooted in state-based variance change and correlation metrics, comparing different ring states for similarity analysis.

Experimental Procedure

To calibrate our imaging system and model, we plotted curvature for 4 custom geometries to verify the model behavior (Figure 2). A custom, 3D-printed, semi-rigid annuloplasty ring was also tested to provide calibration data for our full mounting and image acquisition setup and to illustrate our mathematical quantification (Figure 3, *A*). The 30 mm maximum diameter balloon was inflated to a pressure of approximately 2 atm and a diameter of approximately 29.5 to 30 mm within the ring for 30 seconds with 10 minutes of rest in between, while imaging data was continuously recorded (Figure 3, *B*). Finally, images were recorded in a relaxed state once the entire experiment was complete.

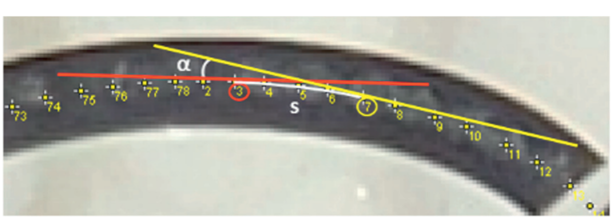
Statistical Methods

Continuous variables are reported as mean ± SE. Comparisons of all reported metrics were performed using non-parametric Friedman tests with pairwise comparisons to account for non-normally distributed statistics.

RESULTS

To generate curvature plots for each of the rings, we calculated curvature differentials around the ring, resampled the data across curve progress, and then plotted the values against curve progress denoted as a percentage (Figure 4). These graphs numerically describe annuloplasty ring shape in a plotted form, and we plotted each dilation state as overlays on the same axes to provide a visual understanding of ring shape changes throughout the dilation process. Ring types were plotted and grouped together by color and all plotted data represent curve progress-domain averages for each ring type and size.

By calculating curvature variance, we compared the curvature between rings and conditions (Figure 5, Table 1). Regarding initial ring geometry, curvature variance is reduced with larger sizes, indicating that larger rings are initially more circular than smaller sizes. Specifically, Physio II M24 rings had a curvature variance of 1.92E-3 ± 4.70E-4 and M26 rings had a lower variance of 9.92E-4 ± 6.84E-5, representing a 48.43% variance reduction ($P < .001$), whereas Physio M24 rings had a variance of 2.07E-3 ± 6.11E-4 and M30 rings had a variance of 1.21E-3 ± 4.17E-4, representing a 41.67% variance reduction ($P < .001$). We found that every ring in every size, except for the flexible Annuloflex ring, showed no significant differences between the paired initial, final, and relaxed states, indicating that dilation with our given balloon and under these conditions does not significantly influence curvature (Table 1). The Annuloflex ring was the only ring to show a significant difference between initial, final, and relaxed states, which depicted an initial state variance of 2.02E-3 ± 3.18E-4, followed by a variance reduction after dilation for the final state (1.36E-3 ± 3.62E-4, or 32.83%; $P < .001$), followed by an increase in variance after relaxation that was still reduced relative to the initial state (1.62E-03 ± 4.12E-4, or 19.62%; $P < .001$).



$$K = \lim_{\Delta s \to 0} \left| \frac{\Delta \alpha}{\Delta s} \right|$$

FIGURE 1. Curvature formula and derivation. Labeled image describing our mathematical model and parameter definition. $\Delta\alpha$ is the angle between the curve differential derivatives and Δs is the differential arc length.

DISCUSSION

The lack of characterization of the diverse rings makes planning difficult, and understanding how ring curvature reacts to balloon dilation is a critical yet not well understood component of ViR TMVR procedures. To date, there is no mathematical model to visually plot the circularity of MV annuloplasty rings. In this study, we set out to develop the mathematical foundation to characterize and quantify ring curvature, and our objective was to generate the technical methodology to build intuitive ring quantifications, and to extract ring comparisons for improved planning and ring selection for ViR and annuloplasty procedures. To accomplish these goals, we utilized an image-tracked 2-dimensional projection of ring shape and a curvature-based analysis with variance comparisons to evaluate the differences in ring circularity before and after balloon dilation. In performing our calibration experiments, we demonstrated the practical interpretation of these analyses, which depict the phenomenon that greater curvature variance across ring progress represents a greater deviation from circularity,

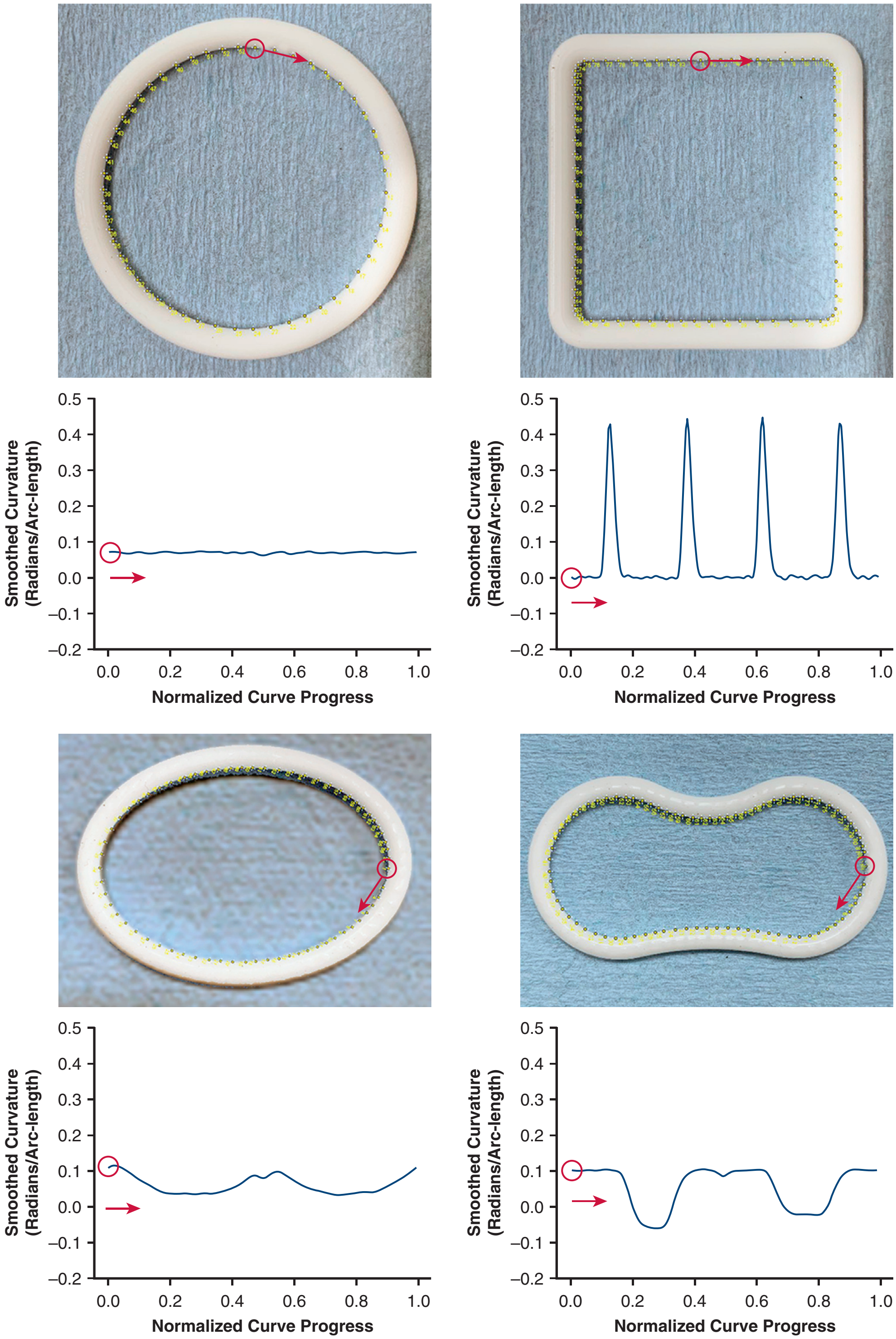


FIGURE 2. Calibration geometries with corresponding curvature plots. The *red circles* indicate from which point curvature was calculated and correspond with the *red circles* in the plots below. Note that greater circularity corresponds to reduced variance levels and corners correspond to peaks in *y*-axis curvature. A perfect *circle* would be plotted as a zero-slope line as seen in the far *left* figure.

with a perfect circle being plotted as a 0-slope line (Figures 2 and 3). Our findings show that despite balloon dilation under these specified conditions, the evaluated rigid and semi-rigid rings fail to meaningfully deform, bringing into question the practice of preimplantation dilation for ViR TMVR procedures.

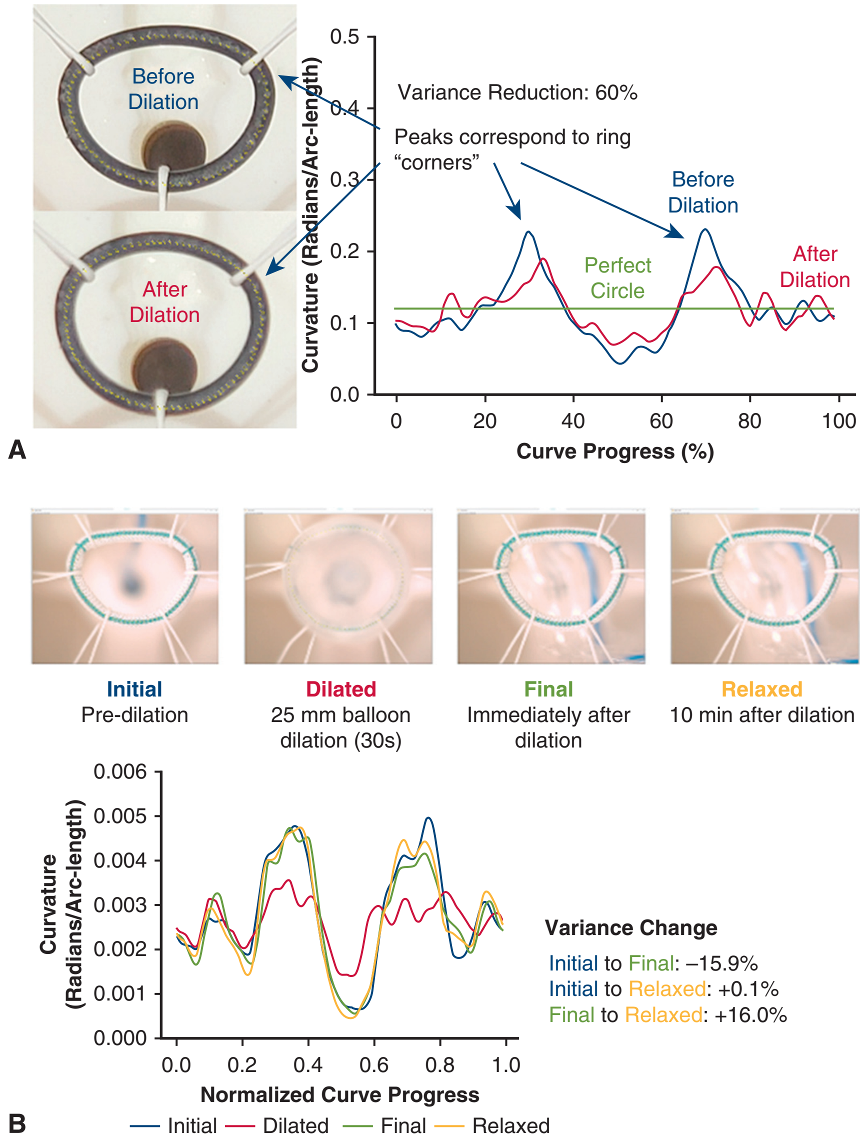


FIGURE 3. Curvature plot interpretation for annuloplasty rings. A, Data from dilation of a custom, 3-dimensional-printed, semi-rigid ring. This condition illustrates the result interpretation for a deformable, semi-rigid ring. B, Images describing the procedure of ring dilation for a Carpentier-Edwards Physio II M24 ring. Data were recorded for 3 separate conditions: the initial state, the final state (immediately postdilation), and the relaxed state (10 minutes after dilation). Curvature is plotted below with reported variance changes for this representative example.

We acknowledge that mitral annuloplasty rings can be manually deformed by using different surgical tools. However, for ViR TMVR procedures, transcatheter balloons are the only available tool to dilate annuloplasty rings. Commercially available catheter balloons have limited sizes and pressures, and the intraprocedural time to dilate the annuloplasty ring with the balloon is limited to a few seconds due to the resulting left ventricular inlet obstruction. Even in our experiments where balloon dilatation was performed under ideal conditions, not accounting for additional resistance conferred by surrounding cardiac tissues, we were not able to observe significant shape deformation of the semi-rigid and rigid rings. Our finding is therefore a crucial discovery as balloon dilation introduces additional risks such as thromboembolic events, acute cardiac decompensation during valve occlusion, annular or leaflet injury, and atrioventricular groove rupture, without having an impact on annuloplasty ring geometry changes.[21-23] Furthermore, additional postoperative calcification and scar tissue formation around the annuloplasty ring is suspected to increase annulus and annuloplasty ring stiffness, making our calculated deformation quantifications an upper bound for the pre-ViR condition, and whereas the beating heart conditions of this procedure may confer additional forces onto the annulus and annuloplasty ring, many of these forces are

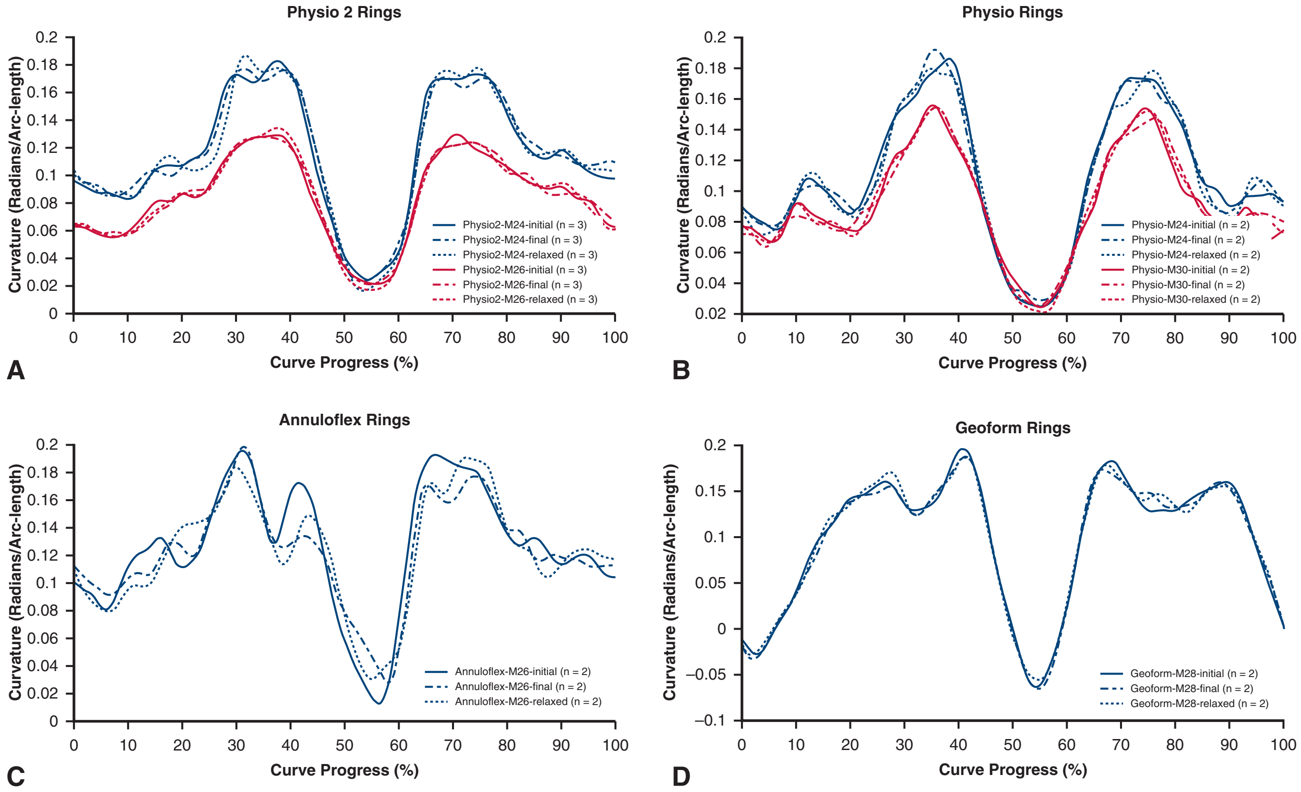


FIGURE 4. Composite averaged curvature results for (A) Carpentier-Edwards Physio II, (B) Carpentier-Edwards Physio, (C) LivaNova Annuloflex, and (D) Edwards Geoform rings plotted against curve progress. *Solid lines* indicate initial state, *dot slashed lines* indicate final dilated state (after 30-second balloon dilation) and *dotted lines* indicate relaxed state (10 minutes after final dilated state). *Blue* and *red* coloring in A and B represent unique ring sizes for the given ring type.

negligible relative to the circumferential forces applied by pressurized balloon dilation. These results point to the removal of such a practice prior to performing a ViR TMVR because balloon dilation does not seem to significantly alter ring circularity to justify the additional risks, and after observing the results in this present study, we

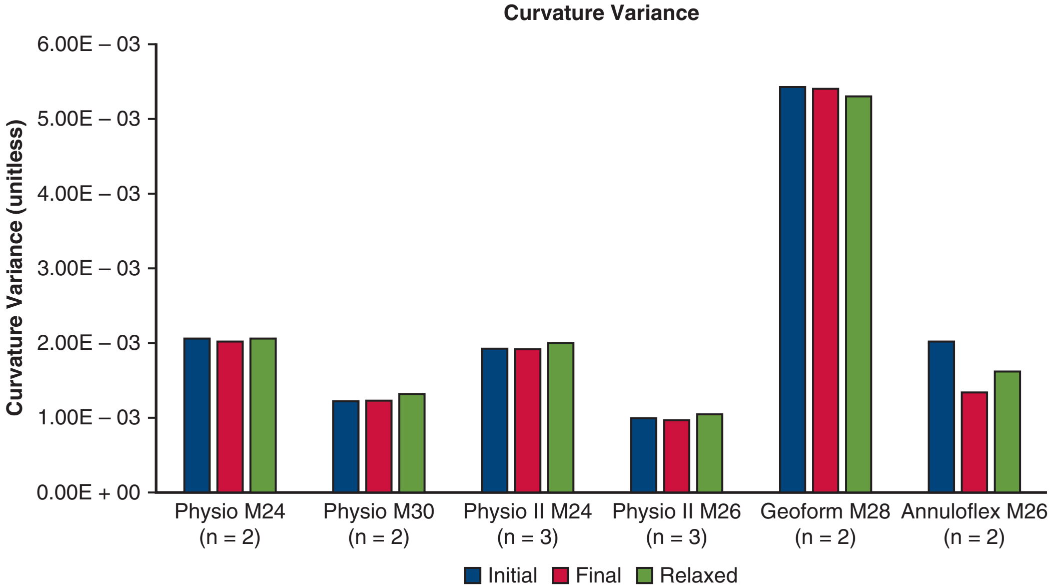


FIGURE 5. Bar plot of curvature variance for all tested annuloplasty rings before balloon dilation (initial), after 30 seconds of dilation (final), and after 10 minutes of relaxation (relaxed). Relative curvature variance reduction between conditions indicates an increase in circularity for the given ring. Rings tested were Carpentier-Edwards Physio II and Physio, Edwards Geoform, and LivaNova Annuloflex.

TABLE 1. Averaged curvature variance results for evaluated annuloplasty rings before balloon dilation (initial), after 30 seconds of dilation (final), and after 10 minutes of relaxation (relaxed)

Annuloplasty ring model	Initial	Final	Relaxed
Carpentier-Edwards Physio M24 (n = 2)	2.07E-03 ± 6.11E-04	2.02E-03 ± 5.62E-04	2.07E-03 ± 7.35E-04
Carpentier-Edwards Physio M30 (n = 2)	1.21E-03 ± 4.17E-04	1.23E-03 ± 5.62E-04	1.32E-03 ± 5.60E-04
Carpentier-Edwards Physio II M24 (n = 3)	1.92E-03 ± 4.70E-04	1.91E-03 ± 4.78E-04	2.01E-03 ± 4.46E-04
Carpentier-Edwards Physio II M26 (n = 3)	9.92E-04 ± 6.84E-05	9.70E-04 ± 9.56E-05	1.05E-03 ± 5.88E-05
Edwards Geoform M28 (n = 2)	5.43E-03 ± 2.10E-03	5.41E-03 ± 1.90E-03	5.31E-03 ± 1.92E-03
LivaNova Annuloflex M26 (n = 2)	2.02E-03 ± 3.18E-04*	1.36E-03 ± 3.62E-04*	1.62E-03 ± 4.12E-04*

Relative curvature variance reduction corresponds to an increase in circularity of ring shape. *$P < .05$ for differences between conditions using nonparametric Friedman analysis.

have since halted the practice of performing predilation before ViR TMVR implantation.

Clinically, MV annuloplasty ring shape can be classified according to shape, rigidity, and size, all of which are important characteristics for ViR TMVR consideration. Regarding shape, rings can be complete (ie, composed of a single piece with no ends) or incomplete (ie, single piece with 2 opposite ends) and regarding rigidity, rings can be rigid, semi-rigid, or flexible. The importance of these characteristics is related to the ability of these rings to conform to the shape of the transcatheter heart valve (THV). The MV, with its saddle-like shape that is dynamic throughout the cardiac cycle, can be less amenable to a circular device. As such, devices that are flexible and complete are most suited for mitral ViR because these will more easily become circular with an appropriately oversized THV. Other types of rings may lead to two main issues. The first is the presence of gaps between the THV and the rigid ring, which can lead to significant paravalvular regurgitation. The second is an inappropriately expanded THV, which can lead to leaflet pinwheeling, poor hemodynamics, and potentially shortened durability. It should be noted that MV annuli and rings can be significantly larger than valves, with some rings reaching label sizes as large as 40 mm. Rings of this size are not amenable to mitral ViR given currently available THV sizes. Moreover, rigid rings, which are commonly oval and open but rarer in the mitral position, will usually not circularize after the implantation of THVs, often resulting in paravalvular leaks and residual transvalvular obstruction, and surgery may be the first-choice therapy unless absolutely contraindicated. Patients with open rings or bands are at particular risk of paravalvular leaks if both arms of the ring are in different planes, and in patients with radiolucent surgical rings, the risk of THV malposition is much higher, which should be considered in the planning of the procedure.

Functionally in the clinic, postimplantation dilation of a THV can occur in the event of a higher transmitral pressure gradient or significant paravalvular leakage. However, based on the results of the present study, we would speculate that the postdilation condition does not considerably change the shape of the previously implanted mitral annuloplasty ring because the mitral ring and surrounding annular tissues, with the additional resistance conferred by the THV, will limit further expansion or dilation. Hence, postdilation to improve gradients does not make sense in cases where the THV is already deployed to its maximum size. Additionally, by increasing balloon dilation time intervals and by performing repeated dilation procedures, ring deformation may behave differently to accomplish the goals of reducing gradients and paravalvular leakage. However, upon increasing both of these quantities, we do not believe that the results would change significantly enough to warrant their clinical application because sustained MV occlusion carries with it significant clinical risks. As for repeat procedures, our results suggest that ring deformation is not significant under ideal, sustained dilation, strongly indicating that balloon dilation does not apply enough circumferential force to reach or surpass the yield strength of the materials to induce the onset of plasticity and permanent deformation. While repeat procedures could induce fatigue damage to the ring, which could deform the shape, the number of cycles at sub-yield strength forces would be many orders of magnitude larger than feasible within a clinical setting. As such, we have little reason to believe that longer time intervals or repeat procedures would result in different outcomes under relevant conditions.

Although our findings bring the practice of ring dilation into question, in the operating room, instances of ring deformation or fracture due to balloon dilation do occur.[22] Particularly, bioprosthetic valve fracture (BVF) is a more common practice for valve-in-valve transcatheter aortic valve replacement (TAVR) and TMVR procedures.[24-29] Valve-in-valve TAVR has shown a rapidly growing procedural volume, with an elective case volume greater than 4500 in 2019, particularly due to the increasing prevalence of bioprosthetic valves.[21] In these cases incumbent valve fracture is meant to allow for full expansion of the new valve, which is believed to reduce transvalvular gradients.[21,26] The primary discrepancies for our findings that highlight the lack of ring deformation despite the prevalence of BVF, are the differences in balloon pressures. To

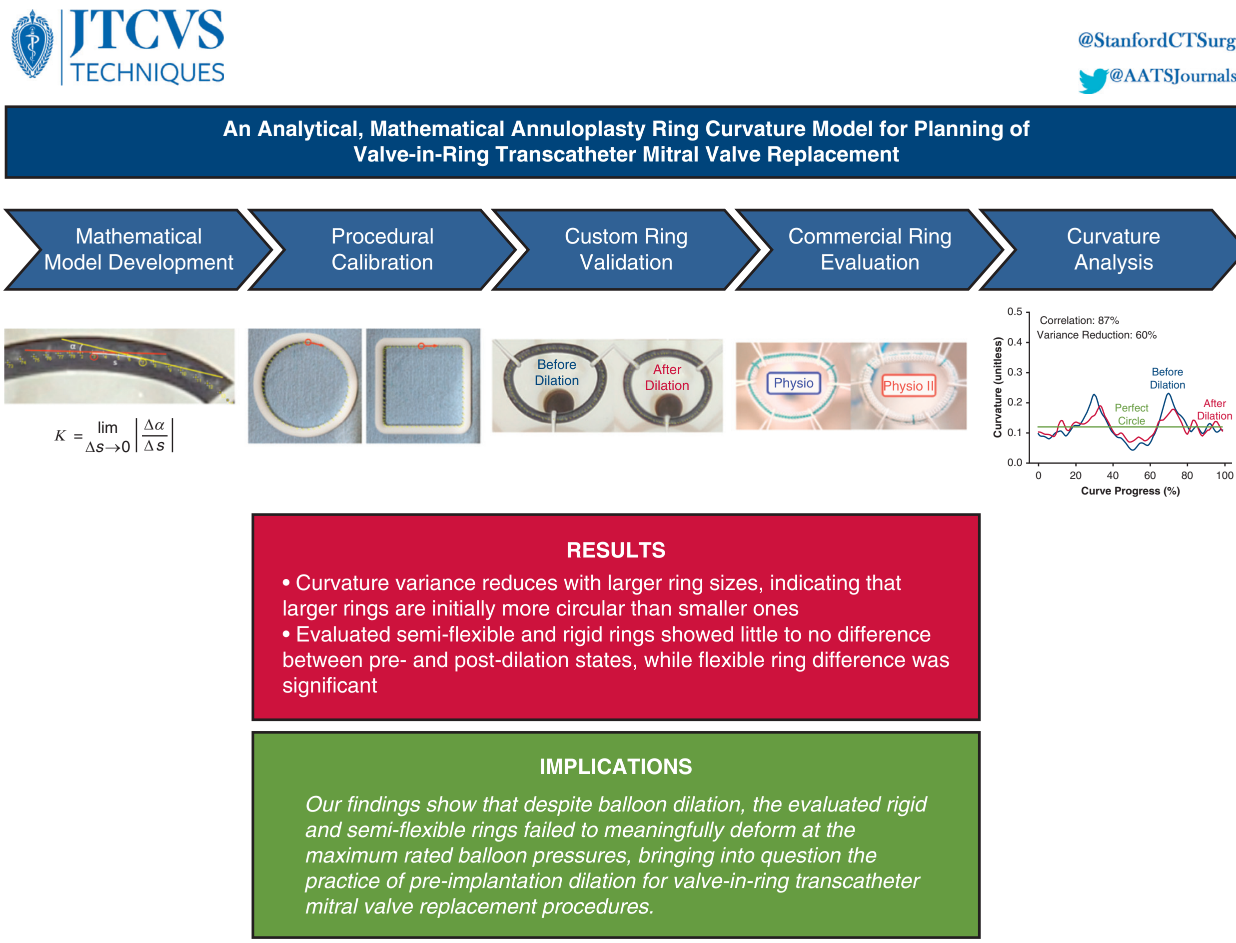


FIGURE 6. An analytical, mathematical annuloplasty ring curvature model for planning of valve-in-ring transcatheter mitral valve replacement.

achieve the pressures required for BVF, transcatheter balloons must be dilated to pressures ranging from 8 to 24 atm depending on the bioprosthetic device, which far exceed the balloon-rated burst pressures of transcatheter balloons, requiring off-label use and double syringe and/or indeflator modifications.[24] Moreover, BVF can only really occur in valves with polyester loops, as those with metal sewing rings are not capable of transcatheter balloon fracture, even in in vitro settings.[24] However, in our experiment, where we operated the Toray Inoue balloons at maximum rated capacity, balloons were inflated to pressures eclipsing 2 atm, which were not enough to meaningfully deform the rings, many of which are composed of internal metal frames. Although deforming these rings may be possible at higher pressures, off-label use of balloon dilation products adds considerable risk to this practice, highlighting the need for the development of safe and focused products dedicated to either more deformable ring materials or high-pressure transcatheter balloons, rated for deformation of specific rings.

Whereas balloon dilation does not seem to be effective in altering ring circularity at rated balloon pressures, the issues remain regarding the low success rates of ViR procedures, largely in part due to significant paravalvular leakage rates, the main predictor of mortality at follow-up. Based on Maisano and Taramasso's expert opinions, because annuloplasty devices are not carefully characterized, it is difficult to identify which prosthetics are associated with better results compared with others. Different rings have different properties, and a surgical ring that is ideal for the ViR procedure should have the ability to adapt to a circular shape, provide good anchoring and radio opacity, and have proper sizes in the range of currently available TAVR devices, which are used as the bioprosthetics for ViR TMVR implantation.[13,18] Additionally, there is little evidence, and more of a clinical belief, that a more circular annuloplasty ring shape might improve outcomes following ViR TMVR. Although this theory would need further evidence in clinical scenarios, under our experimental conditions, ring dilation with a commercially available transcatheter balloon at maximum rated pressures does not significantly alter the annuloplasty ring shape, hence hindering the actual clinical testing of this hypothesis with the currently available technology.

This feature exploration provides the basis of a much deeper question of how to design therapeutics, specifically annuloplasty rings, that are meant to accommodate for a ViR procedure in the case of further postoperative dysfunction. Our research has shown that current commonly used rings do not adequately accommodate for ViR procedures in terms of geometry, but amongst all the semi-rigid and rigid rings that were tested, the most evident increase in circularity to balloon inflation came from a custom deformable, semi-rigid ring material (Figure 3) but without a large sample size dataset, statistical significance, nor rigorous numerical analysis. Whether or not rings should be made from more deformable materials or perhaps even multimodal designs remains a deeper question that will require design constraints that simultaneously address the aims of therapeutic annulus reduction, particularly in the anteroposterior dimension, and postoperative ViR circularity accommodation, while additionally accounting for the risk of postoperative recurrent MR due to further annular dilation if the ring material is too soft. Furthermore, accommodating for ViR procedures could create a new set of design opportunities, such as the ability for annuloplasty rings to dock with ViR bioprosthetics for transcatheter implantation or even a redesign of largely circular TAVR devices to be directly suited towards the bileaflet, *D*-shaped annulus morphology of the MV. Innovative solutions, such as this modified annuloplasty ring prototype with pull-springs, provide insight on novel designs that can accommodate for future ViR procedures.[30] Regardless, greater foresight in designing MV prosthetics to accommodate for further postannuloplasty remodeling is extremely important given the increasing prevalence of recurrent MR following surgical MV annuloplasty and low success rates of ViR procedures.

Limitations

Although our results provide substantial evidence supporting our analysis, there were a few obstacles of note that provide confounding limitations. Firstly, our mathematical model provides a strong basis for performing shape analysis of annuloplasty ring circularity, yet the translation of data acquisition to computational interpretation introduces error into our quantifications. Specifically, although we took care to ensure that the orientations were consistent and that our ring fixture system was not adding any undue stresses on the rings, slight shifts in ring orientation contributed to projection mapping errors during the image tracking phase of data analysis. Although this could skew the severity of circular deformation, this was not of major concern because the ring orientations were not altered in between paired sample sets, meaning that the error would have been consistent within each ring sample. Moreover, although contributing to quantifiable ring classifications were of importance for this experiment, the primary aim for our work was to develop and verify the mathematical model for such classifications. This is not to say that we deprioritized generating specific ring quantifications and comparisons, but given the limited access and large costs of annuloplasty rings, our efforts to provide large n datasets for more conclusive quantifications were limited. This is further amplified by the fact that there are not many avenues for commercial acquisition of rings because ring consumption and infrastructure is specialized for clinical applications and distribution channels. As such, we were limited in the selection to acquire rings in a timely and cost-effective manner. Secondly, whereas care was taken to precisely track ring shape, this analysis was performed by a human operator using ImageJ software and, as such, was susceptible to operator error in image tracking. Automated systems could improve such analyses, but an individual, single operator performed image tracking for all samples and images, ensuring operator consistency throughout the experimental analyses and reducing interoperative error for paired samples. Thirdly, our experiment does not account for additional resistance conferred by surrounding cardiac tissues. Annuloplasty rings are often tied to the annulus, which secures the ring in place and adds additional resistance that would make the rings recoil even after balloon dilatation. This would mean that our results represent an upper bound for shape deformation from dilation because the clinical condition would likely deform significantly less due to these additional resistances. Lastly, our image tracking procedure only provided a 2-dimensional projection of ring shape and did not consider ring height (ie, 3-dimensionality), despite the 3-dimensional profiles of many of the tested rings. However, although ring height plays a role in deformation, implanted prosthetic valves during the ViR procedure require only 2-dimensional circularity for implantation making the tracking of the third dimension superfluous to the scope of this investigation.

CONCLUSIONS

Our mathematical approach creates a foundation for extended classification of annuloplasty rings, expanding the technical corpus of ring selection, deformation, and design. This curvature analysis provides meaningful quantification of ring geometry to interpretable and translatable insights. Our findings show that despite balloon dilation, the evaluated rigid and semi-rigid rings failed to meaningfully deform at the maximum rated balloon pressures, bringing into question the practice of preimplantation dilation for ViR TMVR procedures and bringing attention to the need to design new annuloplasty devices and/or balloons that can accommodate for future ViR TMVR intervention (Figure 6). We aim to further classify the curvature properties of many different annuloplasty rings and sizes, as well as transcatheter balloon properties, for improved transparency of surgical planning and ring and balloon selection, and we hope that our work can expand the discussion of ring and balloon design, particularly addressing postimplantation remodeling and disease progression in many patients.

Conflict of Interest Statement

Dr Borger discloses that his hospital receives speakers' honoraria and/or consulting fees on his behalf from Edwards Lifesciences, Medtronic, Abbott, and Artivion. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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