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# Elastic Recoil and Deployment Asymmetry of the Transcatheter Heart Valve in Bicuspid Versus Tricuspid Anatomy

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## ABSTRACT

**Background:** Data supporting the use of transcatheter aortic valve replacement (TAVR) for bicuspid aortic valve (BAV) is limited compared to tricuspid aortic valve (TAV) anatomy, as the BAV anatomy poses unique challenges to prosthesis expansion and symmetric deployment.

**Aims:** We aim to compare the acute recoil and asymmetry of the SAPIEN-3 valve between BAV and TAV anatomies and their impact on procedural outcomes.

**Methods:** We conducted a single-center study of patients who underwent TAVR with the SAPIEN-3 valve. We measured acute recoil, deployment asymmetry, and length asymmetry from intraprocedural angiogram before and after postdilation, as well as before and after predilation. Hemodynamic and procedural outcomes were studied.

**Results:** Among 946 patients, 9% had BAV. In the RAO view, BAV patients had significantly higher absolute and relative acute recoil across all diameters, while in the LAO view, only central diameter relative recoil was significantly higher ($p < 0.001$). Deployment asymmetry was more common in BAV patients with an OR of 1.88 (CI 1.19, 2.96; $p = 0.01$). Predilation reduced both length and deployment asymmetry in RAO and LAO views for TAV and BAV patients ($p < 0.001$). Postdilation significantly reduced acute valve recoil in both groups ($p = 0.002$ and $p = 0.032$). Hemodynamic outcomes were comparable between TAV and BAV patients, and there were no significant associations between deployment or length asymmetry and procedural outcomes.

**Conclusions:** Acute recoil, deployment asymmetry, and length asymmetry are common in BAV patients but do not affect short-term clinical outcomes or hemodynamics.

## 1 | Introduction

Transcatheter aortic valve replacement (TAVR) has emerged as the preferred therapeutic option for older adults with severe aortic stenosis (AS). Nevertheless, patients with bicuspid aortic valves (BAV) have been excluded from randomized studies. Case series and observational data have demonstrated the feasibility of successful TAVR in BAV AS. Wijesinghe et al. initially

**Abbreviations:** BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; THV, transcatheter heart valve.

showed success with first-generation balloon-expandable valves in 11 patients, achieving successful transcatheter heart valve (THV) deployment in 10 patients [1]. Subsequently, Makkar et al. compared propensity score-matched tricuspid AV (TAV) patients from the STS-ACC TVT Registry with 2691 BAV patients treated with SAPIEN-3 (S3) and found no significant differences in 30-day or 1-year mortality rates [2]. These results were further fortified when Makkar et al. reached the same conclusion after analyzing STS-ACC TVT data that included 3168 propensity-matched pairs of patients with BAV and TAV AS and deduced no significant differences between the two groups in procedural complications, valve hemodynamics, and moderate or severe paravalvular leak [3]. However, patients with BAV AS present a challenge to the structural heart team due to multiple unique anatomical factors, irregular morphology, and asymmetrically calcified leaflets that impact the success rate of the TAVR procedure. THV selection, valve sizing, preprocedural imaging, candidate assessment, and procedural deployment in TAVR all require an awareness of the special characteristics of BAV. Moreover, successful deployment in TAVR is immensely reliant on the tissue-stent interaction; and significant recoil or valve asymmetry could theoretically have a bearing on valve gradients and regurgitation. The purpose of this study, therefore, was to evaluate the relationship between acute recoil, deployment asymmetry, and length asymmetry with native valve anatomy and the acute, short-term, and midterm hemodynamic consequences these mechanical variations have on the S3 THV.

## 2 | Methods

### 2.1 | Study Population

All consecutive patients who underwent TAVR between July 2018 and July 2020 at the Cleveland Clinic using the S3 valve and underwent a preprocedural gated cardiac computed tomography (CT) scan were included. Patients who underwent TAVR using other valves or did not undergo a preprocedural cardiac CT were excluded from the current analysis. The study protocol was approved by the Institutional Review Board at Cleveland Clinic Foundation and patient consent was waived.

### 2.2 | Study Parameters

Baseline patient characteristics including demographics, comorbidities, echocardiographic, and procedural data were obtained from the electronic medical records. Echocardiographic measurements were obtained by an experienced sonographer and adjudicated by an expert, board-certified echocardiogram reader according to established guidelines [4].

### 2.3 | Cardiac CT and Assessment of Anatomic Valve Type and Calcium Scoring

Preprocedural gated cardiac CT was analyzed using iNtuition software (TeraRecon Inc., San Mateo, CA, USA). First, the aortic valve was visualized in short-axis view. BAV group was defined as partial or completely fused cusps or sinus BAV [4]. Using the Agatston score, aortic valve calcification was calculated by selecting the aortic valve leaflets only excluding calcified nonaortic valve structures. To control for contrast, a region of interest (ROI) was selected in the ascending aorta at the level between left and right coronary arteries, and the mean and standard deviation (SD) Hounsfield units in the ROI were collected. The threshold for calcium detection was calculated as mean + 4 SD. Hypoattenuating leaflet thickening (HALT) was identified on post-TAVR-gated cardiac-CT scans.

### 2.4 | Fluoroscopy and Assessment of Deployment Asymmetry, Length Asymmetry, and Recoil

Intraprocedural biplane right anterior oblique (RAO) and left anterior oblique (LAO) fluoroscopy images were recorded and analyzed using Syngo Dynamics (Siemens, Herlanger, Erlangen, Germany). First, horizontal diameters of the S3 valve at the upper, middle, and lower sites were measured at time of maximum valve inflation and immediately after deflation. Absolute recoil was calculated as absolute difference between maximum inflation and postdeflation diameters, and relative recoil was calculated as absolute recoil divided by diameter at maximum inflation. Second, distance from the border of the prosthetic valve stent to the aortic sinuses was measured on both left and right sides en face. Deployment asymmetry ratio was then calculated as the ratio between both diameters, the mean and SD of the ratio was calculated, and asymmetric deployment was defined as a ratio superior to mean + SD or inferior to mean − SD. Finally, length of the S3 valve stent was measured as the vertical diameter at the right and left sides of the stent en face. Length asymmetry ratio was calculated as the ratio between both diameters and ratio mean and SD was calculated. Length asymmetry was then defined as a length ratio superior to mean + SD or inferior to mean − SD (Figure 1). To quantify the effect of postdilation on the THV acute recoil and asymmetry the above measurements were repeated after postdilation.

### 2.5 | Outcomes

Postprocedural trans-thoracic echocardiography (TTE) was performed at discharge, after 30 days and between 6 and 18 months. Aortic valve mean gradient and the presence of moderate or more para-valvular leak were included in the study outcomes, in addition to the need for postprocedural implantation of a permanent pacemaker (PPM) (Central illustration 1).

### 2.6 | Statistical Analysis

Baseline characteristics were compared using a two-sided Student *t* test or Mann–Whitney U test for continuous variables and $\chi^2$ test for categorical variables. Continuous variables were reported as mean ± SD or median (interquartile range), and categorical variables as proportions. A matched comparison was performed to assess the effect of balloon aortic valvuloplasty, matching patients 1:1 based on pre-TAVR transvalvular aortic mean gradient using SPSS (Fuzzy matching algorithm). The

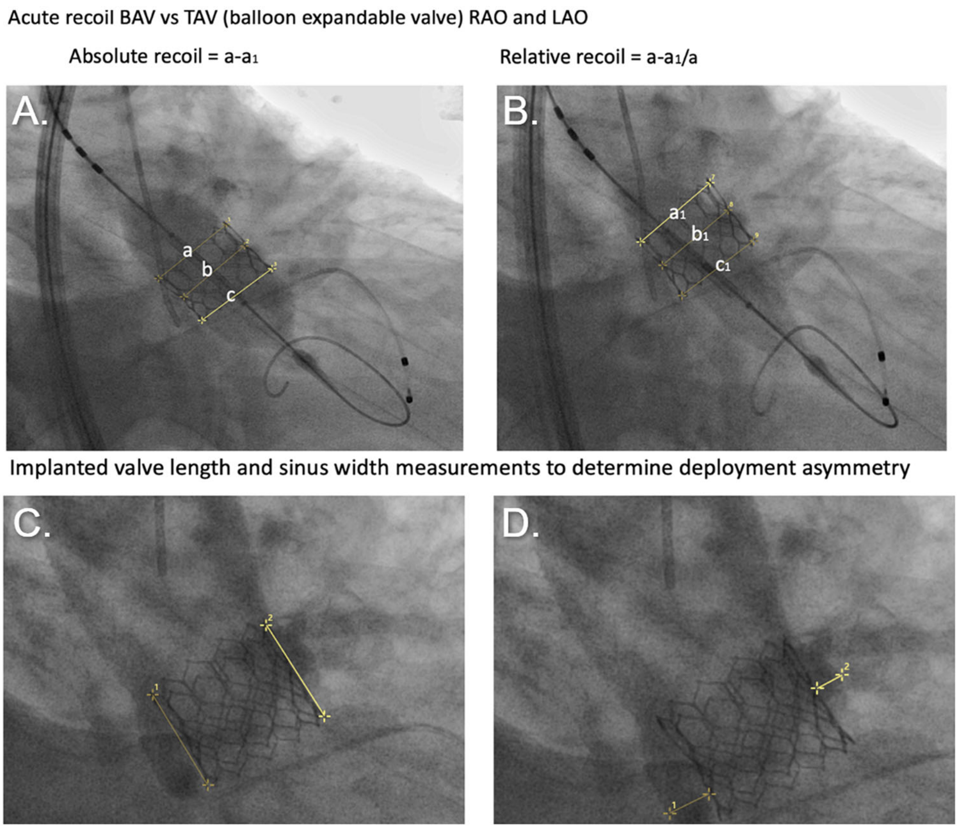



**FIGURE 1** | Measurements taken in angiograms depicting how the measurements are made. Stent diameter measurements (upper level—a, mid-level—b, lower level—c) of SAPIEN 3 on angiography at full balloon expansion (A) and immediately after balloon deflation (B). (a − a1) = Absolute Recoil of THV at Outflow; (b − b1) = Absolute Recoil of THV at Waist; (c − c1) = Absolute Recoil of THV at Inflow; ((a − a1)/a) × 100 = Relative Recoil of THV at Outflow; ((b − b1)/b) × 100 = Relative Recoil of THV at Waist; ((c − c1)/c) × 100 = Relative Recoil of THV at Inflow. (C) Length of the SAPIEN-3 valve on either side measured en face. (D) Horizontal distance between the outer border of the stent on either side to the outer border of the sinus that is filled during contrast injection is measured to give the deployment asymmetry. LAO = Left anterior oblique, RAO = Right anterior oblique, THV = Transcatheter heart valve. [Color figure can be viewed at wileyonlinelibrary.com]

coefficient of variation (CoV) of asymmetry ratios, expressed as (SD/Mean) × 100, was compared between groups. Higher CoV indicates greater asymmetry. Linear regression tested associations between native valve type and recoil, and binary logistic regression tested associations with deployment and length asymmetry. Associations of asymmetry with post-TAVR outcomes were tested using linear regression for mean gradient and binary logistic regression for PPM placement and paravalvular leak, adjusting for native valve type, calcium score, and valve size.

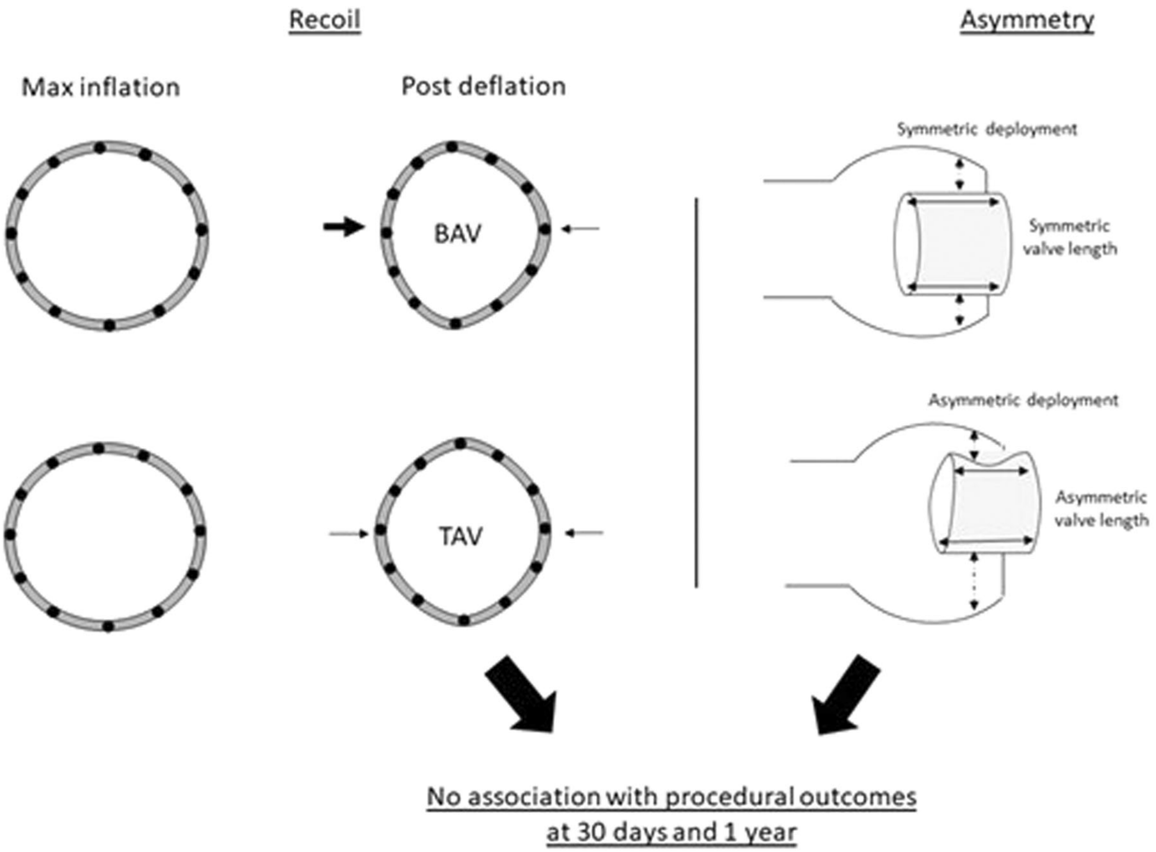
## 3 | Results

Out of 1220 patients who underwent TAVR during the study period, 946 patients had a pre-TAVR CT scan, out of which 85 patients (9%) had BAV. The most common BAV type in our cohort was Sievers type 1 R-L (61%) followed by followed by type 1 R-N and type 1 L-N (16% and 0.06%, respectively). TAV patients were older compared to BAV patients (79.9 ± 9.1 years vs. 74.8 ± 10.4, $p < 0.001$), 58.6% of the patients were males, 86.6% had hypertension, and 32.9% had diabetes mellitus. Pre-TAVR mean AV gradient was significantly lower in TAV patients than in BAV patients (37.5 ± 15.0 mmHg vs. 41.0 ± 14.5, $p = 0.05$). Mean calcium score was lower in TAV patients than in BAV patients, but it did not reach statistical significance (1022.0 ± 851 vs. 1205.3 ± 1026, $p = 0.06$). Balloon-expandable valves were used in all patients, transfemoral access was used in 96.4% of patients, 38.6% received a 26 mm prosthesis, 32% received a 23 mm, 24.4% received a 29 mm, and 5% received a 20 mm valve. Baseline and procedural characteristics are described in Table 1.

### 3.1 | Acute Recoil

In the RAO view, absolute and relative recoil after TAVR were significantly greater in BAV patients in the upper, central, and lower diameters than in TAV patients ($p < 0.001$) despite the absence of a significant difference in maximum inflation diameter between the two groups (Table 2).

In the LAO view, there was no significant difference in absolute recoil between TAV and BAV on any of the three diameter levels, and relative recoil was significantly higher only in the central diameter (4.0% ± 2.3%) of the stent frame in BAV patients than in TAV patients ($p < 0.001$) (Table 2). When adjusting for calcium score and implanted valve size, relative recoil in the central diameter in the RAO view was significantly higher in BAV than in TAV; however, it was significantly lower




**CENTRAL ILLUSTRATION 1** | Acute valve recoil, deployment asymmetry and length asymmetry of the TAVR valve in bicuspid aortic valve (BAV) and tricuspid aortic valve (TAV).

**TABLE 1** | Clinical and procedural characteristics of patients grouped by native valve type.

| Characteristic | TAV (*n* = 861) | BAV (*n* = 85) | *p* value |
|---|---|---|---|
| Age, years | 79.9 ± 9.1 | 74.8 ± 10.4 | **< 0.001** |
| Male gender, *n* (%) | 508 (59) | 46 (54) | 0.40 |
| Hypertension, *n* (%) | 753 (87.4) | 66 (77) | **0.03** |
| Diabetes mellitus, *n* (%) | 289 (33.6) | 22 (25.8) | 0.25 |
| Atrial fibrillation, *n* (%) | 329 (38.2) | 28 (33.3) | 0.52 |
| NYHA class 3 or 4, *n* (%) | 580 (67.4) | 44 (51.6) | **0.02** |
| STS Risk score for mortality | 5.8 ± 4.7 | 3.8 ± 2.3 | **< 0.001** |
| Femoral access route, *n* (%) | 827 (96.1) | 85 (98.8) | 0.32 |
| Pre-TAVR mean AV gradient, mmHg | 37.5 ± 15.0 | 41.0 ± 14.5 | **0.05** |
| Total calcium score, HU | 1022.0 ± 851 | 1205.3 ± 1026 | 0.06 |
| Implanted valve size, *n* (%) (mm) | | | |
| 20 | 42 (4.9) | 5 (6.0) | 0.51 |
| 23 | 282 (32.7) | 21 (25) | |
| 26 | 331 (38.4) | 34 (40.5) | |
| 29 | 206 (24.0) | 25 (28.6) | |

*Note:* Values are either mean ± standard deviation or frequencies with proportion. Bold values are statistically significant at $p < 0.05$.
Abbreviations: AV = Aortic valve, BAV = Bicuspid aortic valve;, HU = Hounsfield units, NYHA = New York Heart Association, STS = Society of Thoracic Surgeons, TAV = Tricuspid aortic valve, TAVR = Transcatheter aortic valve replacement.

**TABLE 2** | Absolute and relative recoil with maximum inflation diameter and deployment and valve asymmetry grouped by native valve type.

| | RAO view | | | LAO view | | |
|---|---|---|---|---|---|---|
| **Recoil parameter** | **TAV ($n = 861$)** | **BAV ($n = 85$)** | ***p* value** | **TAV ($n = 861$)** | **BAV ($n = 85$)** | ***p* value** |
| Absolute upper recoil, mm | 0.7 ± 0.5 | 1.0 (0.6) | **< 0.001** | 0.6 ± 0.7 | 0.7 ± 0.4 | 0.42 |
| Absolute central recoil, mm | 0.9 ± 0.5 | 1.2 ± 0.7 | **< 0.001** | 0.8 ± 1.3 | 0.1 ± 1.1 | 0.08 |
| Absolute lower recoil, mm | 0.8 (0.5) | 1.1 (0.6) | **< 0.001** | 0.6 ± 0.9 | 0.8 ± 0.5 | 0.13 |
| Relative upper recoil, % | 2.9 ± 2.1 | 4.1 ± 2.5 | **< 0.001** | 2.6 ± 3.6 | 2.8 ± 1.6 | 0.60 |
| Relative central recoil, % | 4.0 ± 2.4 | 5.3 ± 2.9 | **< 0.001** | 3.1 ± 2.1 | 4.0 ± 2.3 | **0.001** |
| Relative lower recoil, % | 3.5 ± 2.3 | 4.8 ± 2.9 | **< 0.001** | 2.8 ± 5.2 | 3.2 ± 2.3 | 0.41 |
| Maximum inflation upper, mm | 2.3 ± 0.24 | 2.33 ± 0.23 | 0.31 | 2.4 ± 0.3 | 2.4 ± 0.3 | 0.24 |
| Maximum inflation central, mm | 2.21 ± 0.24 | 2.21 ± 0.23 | 0.87 | 2.3 ± 0.3 | 2.3 ± 0.3 | 0.52 |
| Maximum inflation lower, mm | 2.28 ± 0.24 | 2.3 ± 0.26 | 0.34 | 2.4 ± 0.3 | 2.4 ± 0.3 | 0.08 |

*Note:* Values are either mean ± standard deviation or frequencies with proportion. Bold values are statistically significant at $p < 0.05$.
Abbreviations: BAV = Bicuspid aortic valve, LAO = Left anterior oblique, RAO = Right anterior oblique, TAV = Tricuspid aortic valve.

in BAV in the LAO view ($p < 0.001$) (Supporting Information S1: Table 1). In patients who underwent postdilation ($n = 255$), TAV and BAV patients had significantly less recoil ($p = 0.002$ and $p = 0.03$, respectively).

### 3.2 | Deployment and Length Asymmetry

After TAVR, deployment asymmetry was found in 37.8% of patients. The incidence of valve deployment asymmetry was significantly higher in BAV patients compared to TAV patients (53% vs. 36%, $p = 0.004$), even after adjusting for calcium score and implanted valve size (OR 1.88, CI 1.19, 2.96; $p = 0.01$) (Supporting Information S1: Table 1). Forty-seven percent of patients experienced length asymmetry. The incidence of length asymmetry was not different between the groups (48% vs. 47%, $p = 0.91$). There was no significant difference in the calcium score of implanted valve size between patients who had post-TAVR stent deployment asymmetry or length asymmetry, and those who did not (Table 3). Eighty-three percent of patients who had deployment asymmetry had concomitant length asymmetry ($p < 0.001$) but there was no significant relationship between deployment asymmetry with absolute or relative central recoil in RAO nor LAO (Supporting Information S1: Table 2). Deployment and length asymmetry were also comparable before and after postdilation.

### 3.3 | Effect of Predilation on Deployment and Length Asymmetry

In patients with TAV, the balloon aortic valvuloplasty group exhibited substantial reductions in asymmetry (measured as CoV) across all parameters. The RAO right/left (R/L) ratio decreased from 8.67% to 4.82%, the LAO R/L ratio from 8.10% to 6.30%, and the RAO LAO R/L ratio from 6.83% to 4.64% (all $p < 0.001$). Deployment asymmetry followed the same pattern, with the RAO R/L ratio decreasing from 42.88% to 34.07%, the LAO R/L ratio from 41.54% to 36.71%, and the RAO LAO R/L ratio from 31.14% to 28.27% (all $p < 0.001$). Conversely, in BAV patients, the RAO R/L ratio showed a modest decrease from 8.70% to 8.36%, while the LAO R/L ratio and RAO LAO R/L ratio saw reductions from 8.72% to 7.71% and from 7.88% to 6.84%, respectively (all $p < 0.001$). Notably, the RAO R/L ratio deployment increased from 43.99% to 48.61%, whereas both the LAO R/L ratio deployment and the RAO LAO R/L ratio deployment declined, from 74.17% to 60.55% and from 46.37% to 44.05%, respectively (all $p < 0.001$) (Table 4).

### 3.4 | Procedural Outcomes

There were no significant associations between native valve anatomy and post-TAVR gradient at discharge, PPM placement, or para-valvular leak after TAVR ($p = 0.69$, $p = 0.07$, and $p = 0.9$, respectively). Additionally, there was no association between BAV and higher post-TAVR gradients at 30 days or 1 year ($p = 0.78$ and $p = 0.18$). However, linear regression adjusted for native valve type, calcium score, and implanted valve size, revealed a significant association between central relative recoil in the RAO view with higher post-TAVR mean AV gradient at discharge (Coef. 1.14, CI 1.02–1.28, $p = 0.03$), nevertheless, there was no significant correlation between recoil in either biplane views with higher post-TAVR AV mean gradients at 30 days and 1 year (Table 5). Moreover, there was no relationship between central relative recoil in either view with paravalvular leak, nor there was an association between deployment asymmetry or length asymmetry with procedural outcomes (Table 5).

Among the subset of patients who required a post-TAVR cardiac-CT ($n = 144$), 17 patients had HALT, out of which, nine patients (53%) had asymmetric valve deployment, and eight patients (47%) had asymmetric valve length (Table 3).

## 4 | Discussion

This study demonstrated a higher degree of acute recoil in BAV patients compared to TAV patients. Second, greater deployment

**TABLE 3** | Clinical, anatomic, and procedural characteristics and outcomes in patients grouped by deployment and length asymmetry status.

| | Deployment asymmetry (difference in distance of THV frame from sinus wall) | | | Length asymmetry (difference in distance of THV frame from sinus wall) | | |
|---|---|---|---|---|---|---|
| | **Present ($n = 358$)** | **Absent ($n = 588$)** | ***p* value** | **Present ($n = 445$)** | **Absent ($n = 501$)** | ***p* value** |
| Valve type (BAV vs. TAV) | | | **0.004** | | | 0.91 |
| BAV ($n = 85$) | 45/85 (53%) | 40/85 (47%) | | 41/85 (48%) | 44/85 (52%) | |
| TAV ($n = 861$) | 313/861 (36%) | 548/861 (64%) | | 404/861 (47%) | 457/861 (53%) | |
| Total calcium score, HU | 1090.7 ± 904.6 | 1006.7 ± 846 | 0.15 | 1083.5 ± 908 | 998.5 ± 832 | 0.13 |
| Valve size, *n* (%) (mm) | | | 0.27 | | | 0.12 |
| 20 | 16 (4.6) | 30 (5.3) | | 18 (4.2) | 28 (5.7) | |
| 23 | 103 (29.4) | 191 (33.5) | | 137 (31.7) | 157 (32.2) | |
| 26 | 149 (42.6) | 206 (36.1) | | 182 (42.1) | 173 (35.5) | |
| 29 | 82 (23.4) | 143 (25.1) | | 95 (22.0) | 130 (26.6) | |
| PVL, *n* (%) | 28 (8.0) | 47 (8.3) | 0.99 | 35 (8.1) | 40 (8.2) | 1.00 |
| Post-TAVR Gradient at discharge, mmHg | 10.5 ± 4.4 | 10.3 ± 4.2 | 0.52 | 10.3 ± 4.4 | 10.4 ± 4.4 | 0.64 |
| Post-TAVR Gradient at 30 days, mmHg | 12.3 ± 5.2 | 12.2 ± 4.5 | 0.78 | 13.5 ± 5.9 | 14.0 ± 6.4 | 0.73 |
| Post-TAVR Gradient at 1 year, mmHg | 13.4 ± 5.4 | 14.2 ± 7.6 | 0.32 | 12.2 ± 5.1 | 14.1 ± 7.0 | 0.06 |
| Pacemaker, *n* (%) | 16 (4.5) | 26 (4.4) | 1.00 | 21 (4.7) | 21 (4.7) | 0.81 |
| HALT, *n* (%) | 9 (53) | 8 (47) | 0.44 | 8 (47) | 9 (53) | 0.61 |

*Note:* Values are expressed as either means with SD or proportions. Bold values are statistically significant at $p < 0.05$.
Abbreviations: BAV = bicuspid aortic valve, HALT = Hypoattenuated leaflet thickening, HU = Hounsfield units, PVL = paravalvular leak, TAV = tricuspid aortic valve, TAVR = transcatheter aortic valve replacement, THV = Transcatheter heart valve.

TABLE 4 | Comparison of coefficient of variation (CoV) between matched patients who underwent predilation and no predilation in each view.

| TAV | No predilation ($n = 45$) (%) | Predilation ($n = 45$) (%) | $p$ value |
|---|---|---|---|
| RAO R/L valve length | 8.67 | 4.82 | **< 0.001** |
| LAO R/L valve length | 8.10 | 6.30 | **< 0.001** |
| RAO LAO R/L valve length | 6.83 | 4.64 | **< 0.001** |
| RAO R/L deployment asymmetry | 42.88 | 34.07 | **< 0.001** |
| LAO R/L deployment asymmetry | 41.54 | 36.71 | **< 0.001** |
| RAO LAO R/L deployment asymmetry | 31.14 | 28.27 | **< 0.001** |
| **BAV** | **No predilation ($n = 21$) (%)** | **Predilation ($n = 21$) (%)** | **$p$ value** |
| RAO R/L valve length | 8.70 | 8.36 | **< 0.001** |
| LAO R/L valve length | 8.72 | 7.71 | **< 0.001** |
| RAO LAO R/L valve length | 7.88 | 6.84 | **< 0.001** |
| RAO R/L deployment asymmetry | 43.99 | 48.61 | **< 0.001** |
| LAO R/L deployment asymmetry | 74.17 | 60.55 | **< 0.001** |
| RAO LAO R/L deployment asymmetry | 46.37 | 44.05 | **< 0.001** |

*Note:* Values are mean of coefficients of variation (CoV). The groups are matched for pre-TAVR transvalvular aortic mean gradient. Bold values are statistically significant at $p < 0.05$.
Abbreviations: BAV = Bicuspid aortic valve, LAO = Left anterior oblique, RAO = Right anterior oblique, R/L ratio = Right/left ratio, TAV = Tricuspid aortic valve.

asymmetry was observed in BAV than in TAV. Third, the BAV anatomy was not associated with adverse procedural outcomes; however, a higher degree of recoil was associated with higher post-TAVR mean AV gradients at discharge. Fourth, neither deployment asymmetry nor length asymmetry were associated with adverse procedural outcomes. Fifth, acute elastic recoil, deployment asymmetry, and length asymmetry were not associated with adverse hemodynamic outcomes at 30 days or 1 year.

Historically, it was unknown whether TAVR is an appropriate option for treatment of severe AS in BAV patients due to clinical concerns including unknown valve durability, anatomic challenges, and potential procedural risks that can arise from asymmetrical anatomy and calcifications, asymmetrical cusps' size and associated aortic disease [5, 6]. Later, TAVR was described as a potential alternative to surgery in patients who are at high surgical risk [2]. Approximately 10% of patients currently treated with TAVR have BAV disease [7]. Although TAVR is currently widely utilized, its effectiveness and safety in BAV patients are not fully established because only few studies have investigated the mechanics of the BE THV in BAV patients.

### 4.1 | Acute Elastic Recoil

This is a common phenomenon in BE THVs because of the rigid and uncompromising reinforcement of the metal stent [8]. Previous studies have found that recoil was more common in SAPIEN XT than S3 and others confirmed the presence of recoil at deployment of an S3 stent [9, 10]. Our study revealed consistent results noting recoil of 4% after deployment of an S3 valve in TAVs and 5.3% in BAVs. We found that acute elastic recoil was greater in BAV patients, and this can be explained by many anatomical variations. First, all the AV complex's dimensions are typically greater in BAV than in TAV, which raises the possibility of having an annulus size outside of the range that is currently covered by THV. In the BAVARD (Bicuspid Aortic Valve Anatomy and Relationship With Devices) multicenter registry data, prostheses were, on average, 11% smaller than the mean annulus diameter at baseline in BAV patients causing obvious under-expansion or annulus injury if sized according to the annulus dimensions and encouraging leaflet thrombosis [11]. This highlights the necessity for enhanced sizing policies, the selection of the proper prosthesis size, and procedural method modification [11]. Second, the irregular anatomy of a BAV valve predisposes the stent to unequal recoil and asymmetry as in two-thirds of BAV patients, the AV complex form is nontubular. In the flared or tapered configuration, the AV complex's point of greatest resistance and narrowest dimensions may be above the annulus at the commissural level, leading to a less circular deployment [11, 12]. Third, due to their geometry, BAV undergo excessive strain, stretch, and wall shear stress on their free leaflet edge during opening, causing an increase in their calcification load causing further irregularities in the anatomical structures the prosthetic stent is placed into [13]. This also explains the absence of uniformity in the degree of recoil across the length of the THV in our study which showed increased recoil in the central diameter, rather than the upper and lower diameters. In our cohort, 61% of BAV patients had a Sievers type 1 R-L fusion which explains why the RAO biplane view revealed significantly higher absolute and relative elastic recoil across all three diameters of the prosthetic stent frame in contrast to the LAO biplane view which would typically show decreased expansion in a Sievers type 1 R-N fusion. Similar to our study, Sammour et al. found acute recoil to be more prominent when measured in the RAO projection as opposed to the LAO projection [9]. In another study, Spaziano et al. reported that the annulus minimal diameter is viewed in an extreme RAO caudal position [14]. Compared to the RCS in LAO view, contact between the prosthesis' frame and the annulus would be noticeable sooner in the RAO view [14]. The results of our study show lower relative recoil after postdilation than after initial deployment which may be due to less overall expansion of the stent frame during postdilation in comparison to its stretch during initial deployment leading to a

**TABLE 5** | Association of asymmetric deployment and valve length and relative recoil in mid-valve position on with procedural outcomes.

| Post-TAVR mean AV gradient at discharge | | |
|---|---|---|
| | **Coefficient (95% CI)** | ***p* value** |
| Relative recoil mid, RAO | 1.14 (1.02, 1.28) | **0.03** |
| Relative recoil mid, LAO | 0.97 (0.85, 1.12) | 0.71 |
| Deployment asymmetry | 0.50 (−0.17, 1.17) | 0.15 |
| Length asymmetry | −0.42 (−1.08, 0.23) | 0.20 |
| **Post-TAVR mean AV gradient 30 days** | | |
| | **Coefficient (95% CI)** | ***p* value** |
| Relative recoil mid, RAO | 0.09 (−0.13, 0.31) | 0.41 |
| Relative recoil mid, LAO | 0.18 (−0.002, 0.36) | 0.053 |
| Deployment asymmetry | 0.86 (−0.18, 1.89) | 0.1 |
| Length asymmetry | −0.26 (−1.26, 0.74) | 0.6 |
| **Post-TAVR mean AV gradient at 1 year** | | |
| | **Coefficient (95% CI)** | ***p* value** |
| Relative recoil mid, RAO | 0.07 (−0.19, 0.32) | 0.59 |
| Relative recoil mid, LAO | −0.1 (−0.44, 0.22) | 0.52 |
| Deployment asymmetry | 1.29 (−0.16, 2.74) | 0.08 |
| Length asymmetry | 0.15 (−1.27, 1.57) | 0.84 |
| **Permanent pacemaker implantation** | | |
| | **Odds ratio (95% CI)** | ***p* value** |
| Relative recoil mid, RAO | 0.99 (0.98, 0.99) | **0.03** |
| Relative recoil mid, LAO | 1.00 (0.99, 1.01) | 0.98 |
| Deployment asymmetry | 1.00 (0.97, 1.03) | 0.95 |
| Length asymmetry | 1.01 (0.97, 1.04) | 0.93 |
| **Para-valvular leak** | | |
| | **Odds ratio (95% CI)** | ***p* value** |
| Relative recoil mid, RAO | 1.00 (0.95, 1.17) | 0.89 |
| Relative recoil mid, LAO | 1.00 (0.99, 1.01) | 0.48 |
| Deployment asymmetry | 0.99 (0.95, 1.04) | 0.78 |
| Length asymmetry | 1.00 (0.95, 1.04) | 0.88 |

*Note:* Coefficients adjusted for native valve type, calcium score, and implanted valve size. Values are expressed as coefficients or odds ratios with 95% confidence intervals. Bold values are statistically significant at $p < 0.05$.
Abbreviations: AV = Aortic valve, LAO = Left anterior oblique, RAO = Right anterior oblique, TAVR = Transcatheter aortic valve replacement.

lesser degree of recoil. Although postdilation is usually attempted in cases of paravalvular leak, the benefit of resolving to it in cases of under-expansion of the THV stent frame is debatable, especially because of its association with higher rate of subacute strokes in the PARTNER I trial and the lack of association between higher recoil and worse procedural outcomes [15].

## 4.2 | Deployment and Length Asymmetry

The deployment of a prosthetic valve in the aortic annulus is a meticulous procedure, and variations in deployment position and length can lead to distinct hemodynamic consequences [16, 17]. THV eccentricity, which has been demonstrated to cause leaflet maladaptation, is one factor that may contribute to structural valve deterioration [18]. Abbasi et al. showed that eccentric valves had a > 100% higher maximal main stress at the commissure regions than noneccentric valves when there was valve under sizing [19]. Thirty- Eight percent of our entire cohort had deployment asymmetry and this phenomenon was seen more common in native BAV than TAV, which is a result of the asymmetrical morphology of BAVs often leading to heavy calcification of the valves, asymmetric stent geometries causing an increase in the risk of thrombosis and leading to a less durable prosthetic valve [6, 20].

We found that pre-TAVR balloon aortic valvuloplasty increases valve symmetry considerably except that few asymmetry parameters modestly increase due to the selection bias in patients with native BAV. The procedure likely breaks calcium fragments, allowing better valve expansion. Though device success rates have been shown to be similar between both direct TAVR and predilated group in the DIRECT and DIRECTAVI trial, balloon predilation has been shown to have its own benefits like uniform prosthesis expansion, reduced paravalvular leak and reduced need for balloon postdilation [21–23]. Though we have not assessed the effect of predilation on under/over-expansion across the diameter of balloon-expandable valves, we assessed asymmetrical expansion and found predilation to be beneficial both TAV and BAV.

### 4.3 | Procedural Outcomes

The outcomes we focused on in this study were post-TAVR AV mean gradient at hospital discharge, 30 days and 1 year, in addition to paravalvular leak, overall PPM implantation, and overall HALT.

There is a higher chance of PPM implantation after self-expanding valve implantation in patients with coronary cusp fusion due to the horizontal orientation of the valve orifice and anterior-posterior expansion toward the AV node [4]. Compared to functional (tricommissural) BAV, congenital (bicommissural) BAV is associated with greater eccentricity in THV deployment, though without a significant difference in expansion ratio [24]. However, a large study found no difference in post-TAVR AV mean gradients, PVL, or PPM placement between BAV and TAV patients with new-generation devices, which aligns with our findings [25]. Additionally, a multicenter study showed acceptable TAVR outcomes in BAV patients [26]. This contrasts with a meta-analysis that found higher rates of moderate to severe PVL in BAV patients, a difference mitigated by BE valves [27]. Our study reported PVL the day after TAVR, unlike the meta-analysis, which also noted increased periprocedural complications in BAV patients in the main analysis but not in the matched population [27].

### 4.4 | Impact of Recoil on Procedural Outcomes

We found a significant association between relative recoil and higher post-TAVR AV mean gradients only at discharge and not at 30 days or 1 year post-TAVR TTEs which is consistent with a previous study that showed no relationship between the degree of acute recoil and post-TAVR AV mean gradients [10]. In regard to PVL, our study showed no association with acute recoil sharing similar findings to previous studies [9, 10]. They showed no relationship between the degree of acute recoil and post-TAVR aortic regurgitation. In our study, we found an association between acute recoil in the RAO view and PPM implantation; however, RR was 0.99. No previous studies focused on the effect of acute recoil on PPM implantation. In addition, not many studies were conducted on the relationship between acute recoil and hemodynamic and procedural outcomes, especially the S3 valve.

Another main finding in the present study is that deployment asymmetry and length asymmetry were not associated with any of our procedural outcomes: post-TAVR AV mean gradient, PVL, and PPM implantation. One study found contrasting results, showing that valves with deployment asymmetry had increasing post-TAVR AV mean gradients at 1 and 2 years, while symmetric valves had decreasing gradients. However, that study also found, like ours, that deployment asymmetry had no impact on PVL or post-TAVR aortic regurgitation [17]. No studies on the impact of length asymmetry on procedural outcomes were found, thus the need for more studies. Although some studies have focused on increased leaflet stress and unequal strain distribution caused by eccentric valve deployment and increased acute recoil, only 17 patients in our cohort had HALT on post-TAVR CTs and there was no association between increased recoil nor asymmetry with an increase in post-TAVR AV mean gradients [28, 29]. This discrepancy, however, highlights the need for longer-term and muticenter studies. To the best of our knowledge, this is the first time where the asymmetrical expansion of valves and their variation with predilation were assessed in both LAO and RAO views using biplane images.

## 5 | Limitations

Our study has some limitations. First, it is a single-center retrospective study. Second, we included patients who received a S3 valve only, while other commercially available valve types can provide different mechanical insights, and hence cause varying degrees of acute recoil and deployment asymmetry. Third, observational data with longer follow-up are needed to establish whether these mechanical differences will cause long-term clinical outcomes and if higher postprocedure gradients will result in reduced prosthesis longevity.

## 6 | Conclusion

Although the eccentricity of the anatomy of BAV causes increased acute recoil and valve deployment asymmetry, TAVR remains a feasible and overall safe treatment choice for BAV AS. We have found that acute recoil has led to higher post-TAVR gradient only at hospital discharge and not at 30 days or 1 year, and that deployment asymmetry and length asymmetry had caused no effect on immediate procedural outcomes. Long-term data are needed to understand the impact of valve recoil and deployment asymmetry on valve durability.

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#### Conflicts of Interest

The authors declare no conflicts of interest.

#### References

1. N. Wijesinghe, J. Ye, J. Rodés-Cabau, et al., "Transcatheter Aortic Valve Implantation in Patients With Bicuspid Aortic Valve Stenosis," *JACC: Cardiovascular Interventions* 3 (2010): 1122–1125.

2. R. R. Makkar, S. H. Yoon, M. B. Leon, et al., "Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid

Aortic Stenosis and Mortality or Stroke," *Journal of the American Medical Association* 321 (2019): 2193.

3. R. R. Makkar, S. H. Yoon, T. Chakravarty, et al., "Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke Among Patients at Low Surgical Risk," *Journal of the American Medical Association* 326 (2021): 1034–1044.

4. H. Jilaihawi, M. Chen, J. Webb, et al., "A Bicuspid Aortic Valve Imaging Classification for the TAVR Era," *JACC: Cardiovascular Imaging* 9 (2016): 1145–1158.

5. C. M. Otto and D. E. Newby, "Transcatheter Valve Replacement for Bicuspid Aortic Stenosis," *Journal of the American Medical Association* 326 (2021): 1009.

6. G. Tarantini and T. Fabris, "Transcatheter Aortic Valve Replacement for Bicuspid Aortic Valve Stenosis: A Practical Operative Overview," *Circulation: Cardiovascular Interventions* 14 (2021): e009827.

7. Y. Ahmad, M. V. Madhavan, S. J. Baron, et al., "Clinical Research on Transcatheter Aortic Valve Replacement for Bicuspid Aortic Valve Disease: Principles, Challenges, and an Agenda for the Future," *Structural Heart* 7 (2023): 100102.

8. T. W. Duerig, D. E. Tolomeo, and M. Wholey, "An Overview of Superelastic Stent Design," *Minimally Invasive Therapy & Allied Technologies: MITAT: Official Journal of the Society for Minimally Invasive Therapy* 9 (2000): 235–246.

9. Y. Sammour, A. N. Kadri, R. D. Gajulapalli, et al., "Comparison of Acute Recoil After Valve Deployment and After Post-Dilation in Patients Undergoing Transfemoral-Transcatheter Aortic Valve Replacement With SAPIEN-3 Valve," *Catheterization and Cardiovascular Interventions* 96 (2020): 1522–1530.

10. L. Nombela-Franco, H. B. Ribeiro, M. Urena, et al., "Incidence, Predictive Factors and Haemodynamic Consequences of Acute Stent Recoil Following Transcatheter Aortic Valve Implantation With a Balloon-Expandable Valve," *EuroIntervention* 9 (2014): 1398–1406.

11. D. Tchetche, C. de Biase, L. van Gils, et al., "Bicuspid Aortic Valve Anatomy and Relationship With Devices: The BAVARD Multicenter Registry," *Circulation: Cardiovascular Interventions* 12 (2019): e007107.

12. T. Y. Xiong, Y. Feng, Y. J. Li, et al., "Supra-Annular Sizing for Transcatheter Aortic Valve Replacement Candidates With Bicuspid Aortic Valve," *JACC: Cardiovascular Interventions* 11 (2018): 1789–1790.

13. C. Gollmann-Tepeköylü, F. Nägele, C. Engler, et al., "Different Calcification Patterns of Tricuspid and Bicuspid Aortic Valves and Their Clinical Impact," *Interactive Cardiovascular and Thoracic Surgery* 35 (2022): ivac274.

14. M. Spaziano, P. Thériault-Lauzier, N. Meti, et al., "Optimal Fluoroscopic Viewing Angles of Left-Sided Heart Structures in Patients With Aortic Stenosis and Mitral Regurgitation Based on Multislice Computed Tomography," *Journal of Cardiovascular Computed Tomography* 10 (2016): 162–172.

15. R. T. Hahn, P. Pibarot, J. Webb, et al., "Outcomes With Post-Dilation Following Transcatheter Aortic Valve Replacement: The PARTNER I Trial (Placement of Aortic Transcatheter Valve," *JACC: Cardiovascular Interventions* 7 (2014): 781–789.

16. H. Takagi and T. Umemoto, "Impact of Paravalvular Aortic Regurgitation After Transcatheter Aortic Valve Implantation on Survival," *International Journal of Cardiology* 221 (2016): 46–51.

17. D. R. Mangels, M. Siki, R. Menon, et al., "Hemodynamic Effects of Valve Asymmetry in Sapien 3 Transcatheter Aortic Valves," *Journal of Invasive Cardiology* 30 (2018): 138–143.

18. R. Gurvitch, D. A. Wood, E. L. Tay, et al., "Transcatheter Aortic Valve Implantation," *Circulation* 122 (2010): 1319–1327.

19. M. Abbasi and A. N. Azadani, "TCT-621 The Synergistic Impact of Eccentric and Incomplete Stent Deployment on Transcatheter Aortic Valve Leaflet Stress Distribution," *Journal of the American College of Cardiology* 66 (2015): B253–B254.

20. B. B. Yeats, P. K. Yadav, L. P. Dasi, and V. H. Thourani, "Treatment of Bicuspid Aortic Valve Stenosis With TAVR: Filling Knowledge Gaps Towards Reducing Complications," *Current Cardiology Reports* 24 (2022): 33–41.

21. A. McInerney, R. Vera-Urquiza, G. Tirado-Conte, et al., "Pre-Dilation and Post-Dilation in Transcatheter Aortic Valve Replacement: Indications, Benefits and Risks," *Interventional Cardiology (London, England)* 16 (2021): 28.

22. K. Toutouzas, G. Benetos, V. Voudris, et al., "Pre-Dilatation Versus No Pre-Dilatation for Implantation of a Self-Expanding Valve in All Comers Undergoing TAVR," *JACC: Cardiovascular Interventions* 12 (2019): 767–777.

23. F. Leclercq, P. Robert, M. Akodad, et al., "Prior Balloon Valvuloplasty Versus Direct Transcatheter Aortic Valve Replacement," *JACC: Cardiovascular Interventions* 13 (2020): 594–602.

24. H. Kawamori, S. H. Yoon, T. Chakravarty, et al., "Computed Tomography Characteristics of the Aortic Valve and the Geometry of SAPIEN 3 Transcatheter Heart Valve in Patients With Bicuspid Aortic Valve Disease," *European Heart Journal—Cardiovascular Imaging* 19 (2018): 1408–1418.

25. S. H. Yoon, S. Bleiziffer, O. De Backer, et al., "Outcomes in Transcatheter Aortic Valve Replacement for Bicuspid Versus Tricuspid Aortic Valve Stenosis," *Journal of the American College of Cardiology* 69 (2017): 2579–2589.

26. S. H. Yoon, T. Lefèvre, J. M. Ahn, et al., "Transcatheter Aortic Valve Replacement With Early- and New-Generation Devices in Bicuspid Aortic Valve Stenosis," *Journal of the American College of Cardiology* 68 (2016): 1195–1205.

27. C. Montalto, A. Sticchi, G. Crimi, et al., "Outcomes After Transcatheter Aortic Valve Replacement in Bicuspid Versus Tricuspid Anatomy," *JACC: Cardiovascular Interventions* 14 (2021): 2144–2155.

28. A. Fuchs, O. De Backer, M. Brooks, et al., "Subclinical Leaflet Thickening and Stent Frame Geometry in Self-Expanding Transcatheter Heart Valves," *EuroIntervention* 13 (2017): e1067–e1075.

29. W. Sun, K. Li, and E. Sirois, "Simulated Elliptical Bioprosthetic Valve Deformation: Implications for Asymmetric Transcatheter Valve Deployment," *Journal of Biomechanics* 43, no. 16 (2010;1): 3085–3090.

**Supporting Information**

Additional supporting information can be found online in the Supporting Information section.