

Impact of Neo-Commissural Alignment on Frame Morphology in the SAPIEN 3/3 Ultra Valve

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

Grant/Research Support

Grant/Research Support

Grant/Research Support

Consultant Fees/Honoraria

Ineligible Company

Abbott

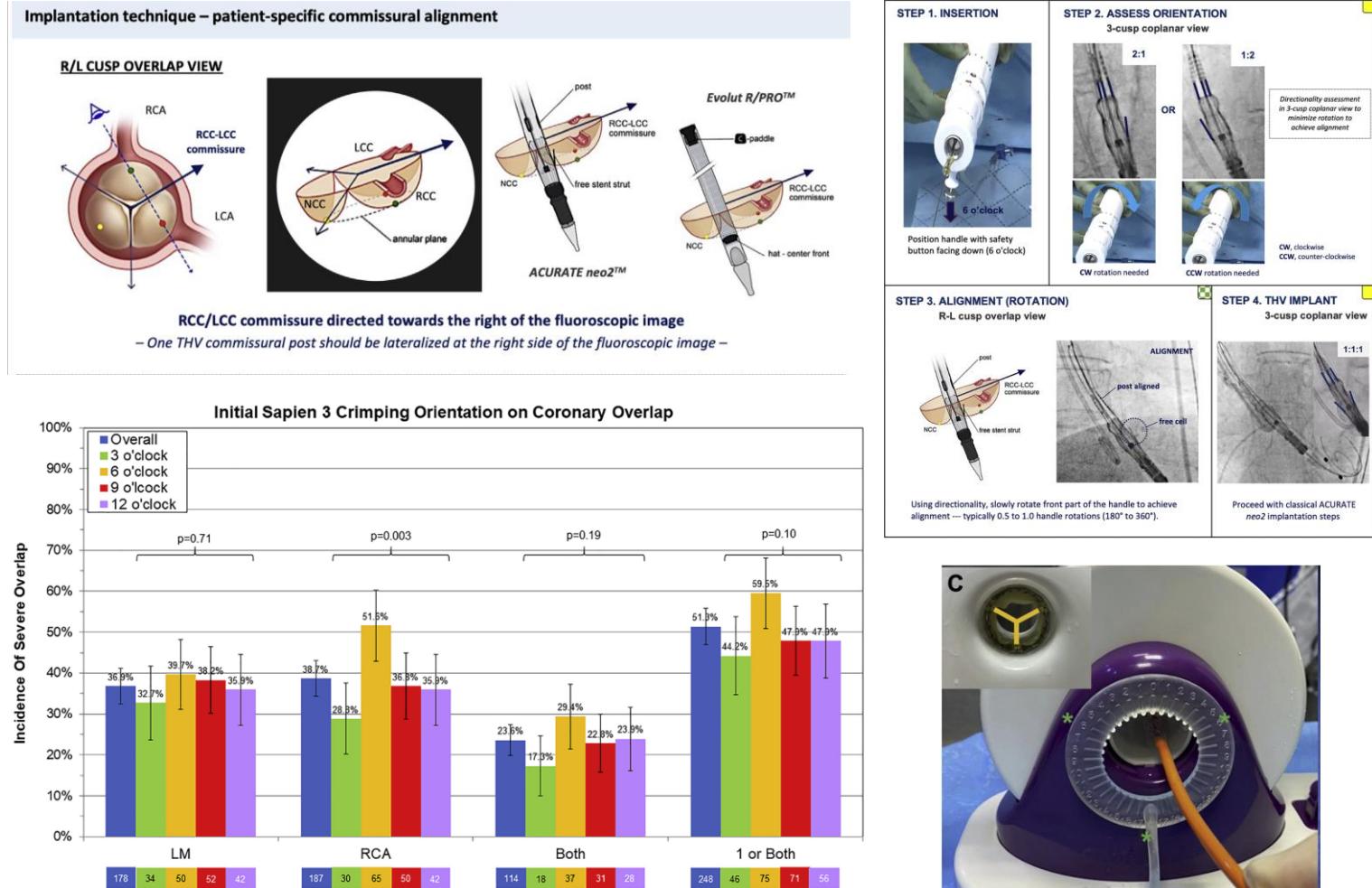
Edwards Lifesciences

Boston Scientific

Jenscare Scientific

Why this study?

- For Self-Expanding Valves (SEV), patient-specific commissural alignment technique can achieve 88% patients.
- For BEVs, crimping orientation showed no impact on commissural alignment.
- No large cohort showed patient-specific commissural alignment in BEVs.



Tang GHL et al. JACC Cardiovasc Interv 2020; 13(9):1030-1042.

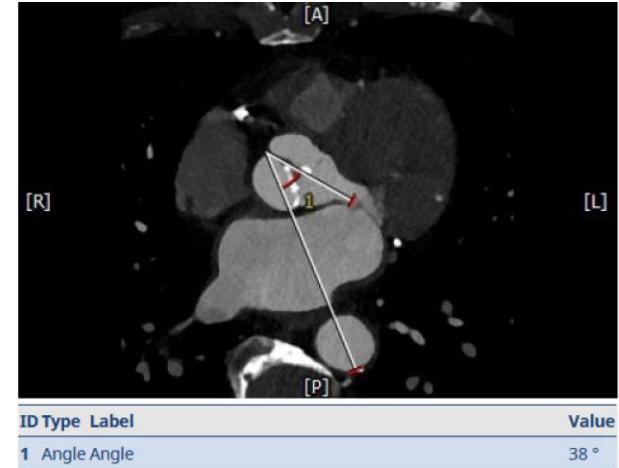
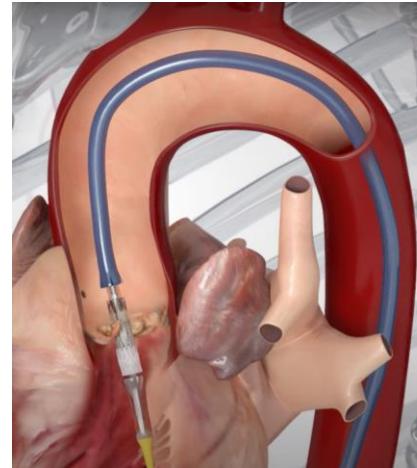
Tang GHL et al. JACC Cardiovasc Interv 2022; 15(15):1497-1518.

PART I

Crimping Method



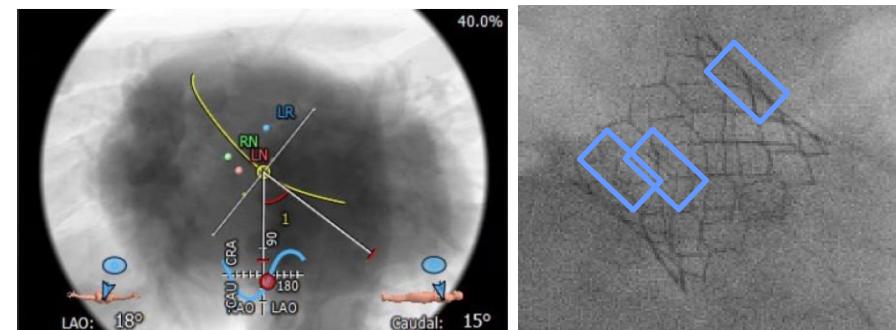
- Flush port at 12 o'clock
- Flex direction at 6 o'clock



Step 1: measure the angle of RN commissure-descending aorta **38°**



Step 2: crimping the valve at patient-specific clock
Clockwise $38^\circ \approx 1:30$

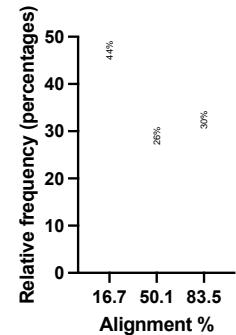


Step 3: check commissural alignment
at commissural overlap view

PART II

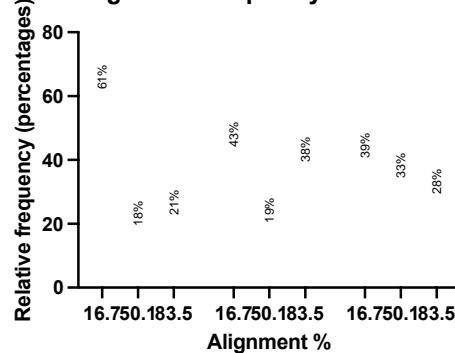
Frame Morphology Evaluation

Alignment Frequency Distribution



all patients

Alignment Frequency Distribution



random
AAO
anti-AAO

2020 July-
2021 Jan.

Random

28 patients

2021 Jan.-
2022 May

Aortic arch orientation

42 patients

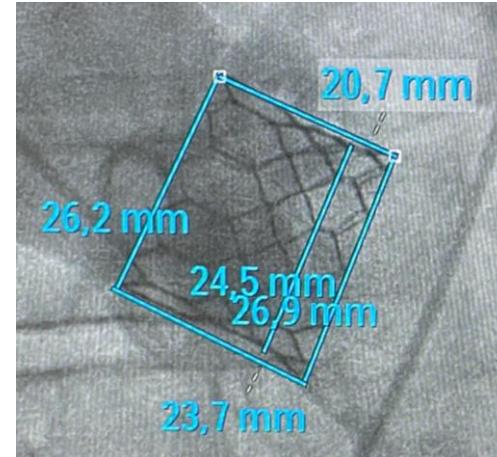
2022 May-
2024 May

Anti aortic
arch orientation

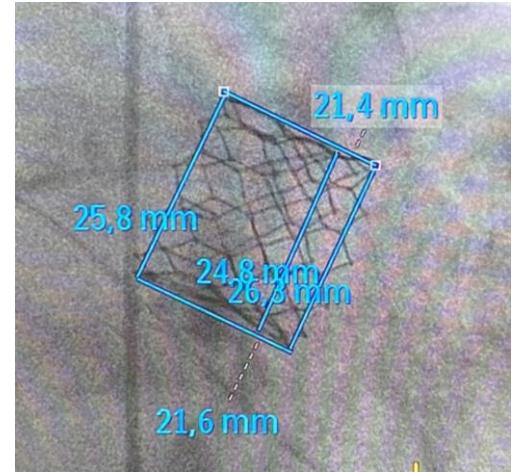
2023 Jan-
2024 May

BEV frame
morphology
evaluation

131patients



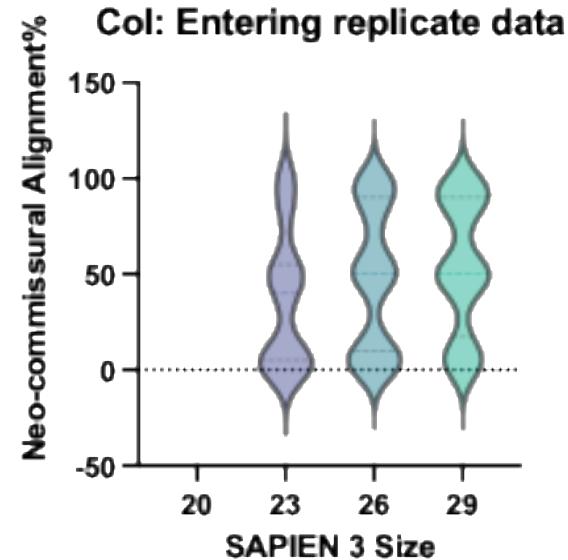
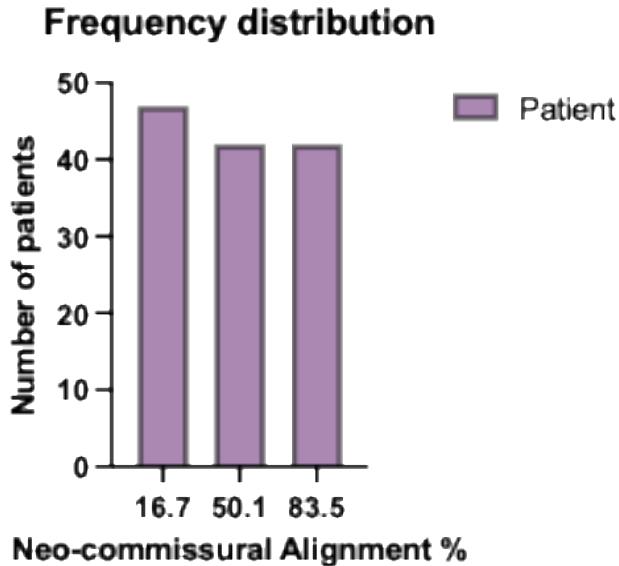
Standard 3-cusp View
LAO 7° CRAN 12°



Cusp-Overlap View
RAO 15° CAU 15°

Using Philips C-arm automatic calibration

Results: Commissural Alignment



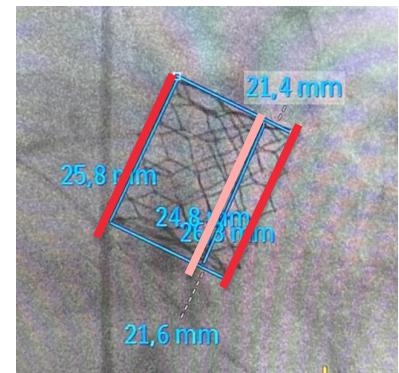
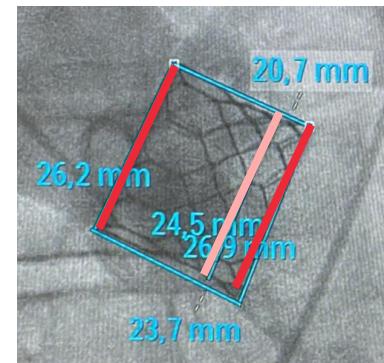
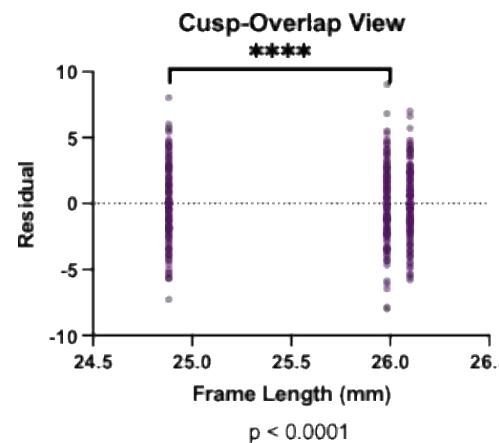
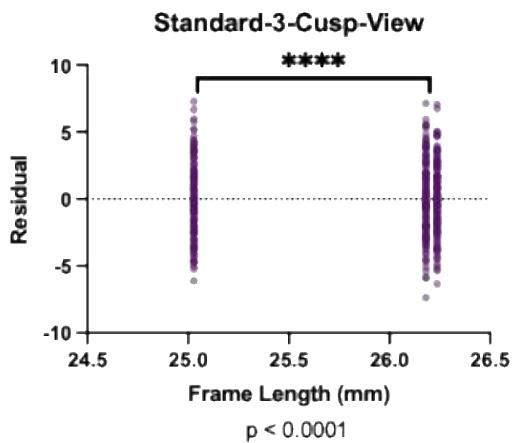
A total of **131 patients** were included, with 42 (32%) showing alignment, 42 (32%) neutral CA, and 47 (36%) misalignment.

Results: Frame Evaluation

	3-Up	3-Mid	3-Low	3-Left	3-Right	2-Up	2-Mid	2-Low	2-Left	2-Right
Number of values	131	131	131	131	131	128	128	128	128	128
Minimum	19.90	18.90	18.80	16.10	15.00	20.30	17.60	18.00	16.30	15.70
Maximum	33.30	32.30	33.30	27.90	28.90	33.10	32.90	35.00	29.90	27.30
Range	13.40	13.40	14.50	11.80	13.90	12.80	15.30	17.00	13.60	11.60
Mean	26.24	25.03	26.18	21.91	21.07	26.10	24.88	25.98	21.49	20.81
Std. Deviation	2.709	2.845	2.902	2.360	2.530	2.724	2.944	2.981	2.555	2.441
Std. Error of Mean	0.2366	0.2486	0.2536	0.2062	0.2211	0.2407	0.2602	0.2635	0.2258	0.2157

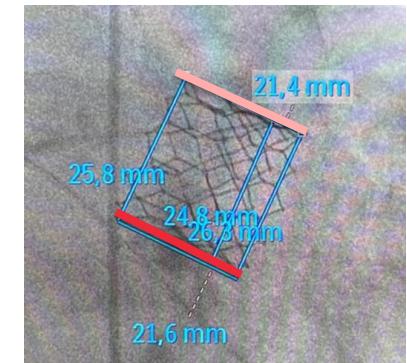
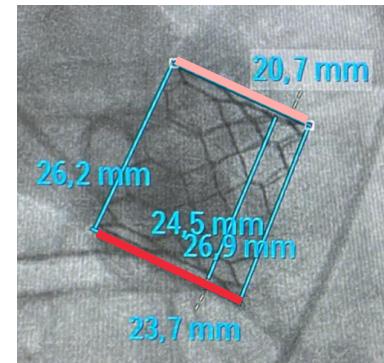
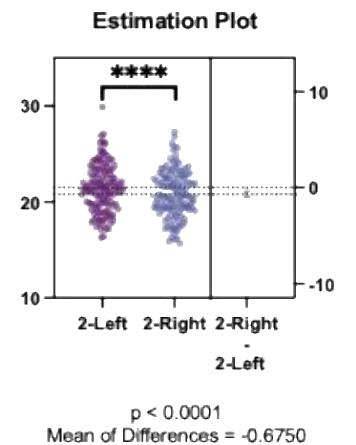
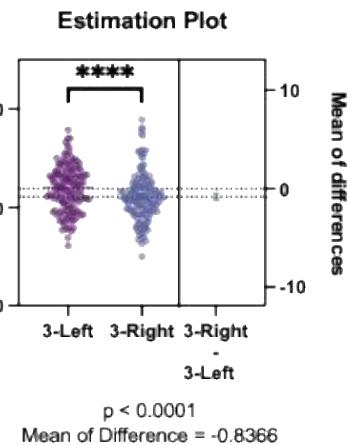
1. Frame height at the **annulus level was significantly shorter** (25 ± 3 mm) than at the inflow (26 ± 3 mm) and outflow (26 ± 3 mm) levels in both the 3-cusp view ($p < 0.0001$) and the 2-cusp view ($p < 0.0001$).
2. The frame height on the **outer curve was significantly longer** than on the inner curve in both views (3-cusp: $p < 0.0001$, mean difference = -0.8 mm; 2-cusp: $p < 0.0001$, mean difference = -0.7 mm).

Frame Evaluation



Standard 3-cusp View

Cusp-Overlap View

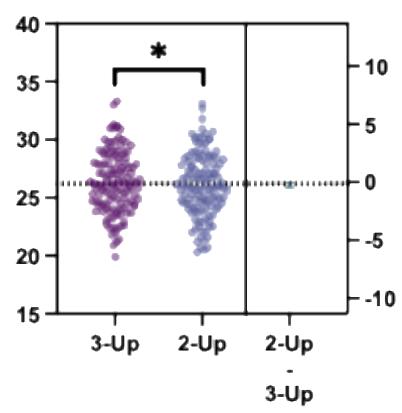


Standard 3-cusp View

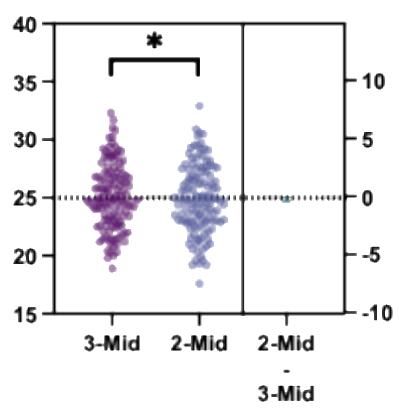
Cusp-Overlap View

Frame Evaluation: 3-Cusp View vs. 2-Cusp View

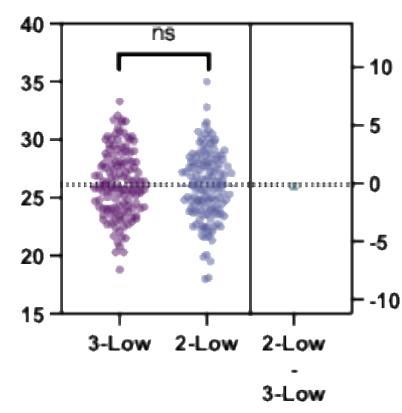
Estimation Plot



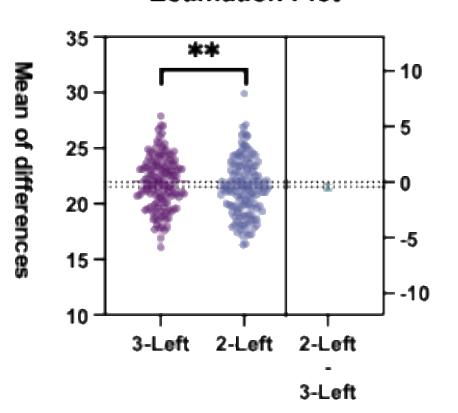
Estimation Plot



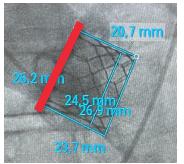
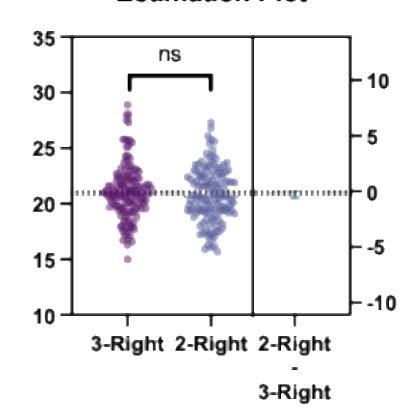
Estimation Plot



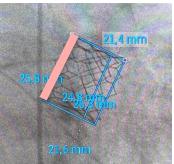
Estimation Plot



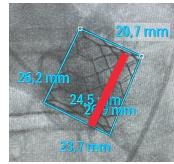
Estimation Plot



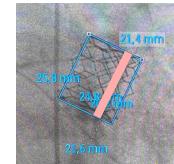
Standard 3-cusp View



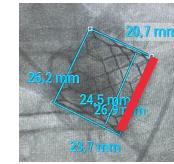
Cusp-Overlap View



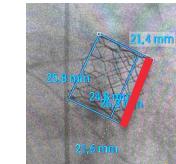
Standard 3-cusp View



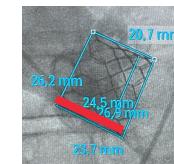
Cusp-Overlap View



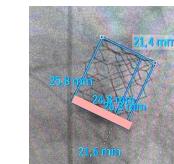
Standard 3-cusp View



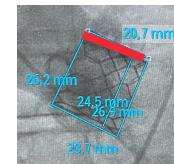
Cusp-Overlap View



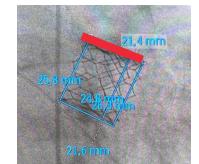
Standard 3-cusp View



Cusp-Overlap View



Standard 3-cusp View

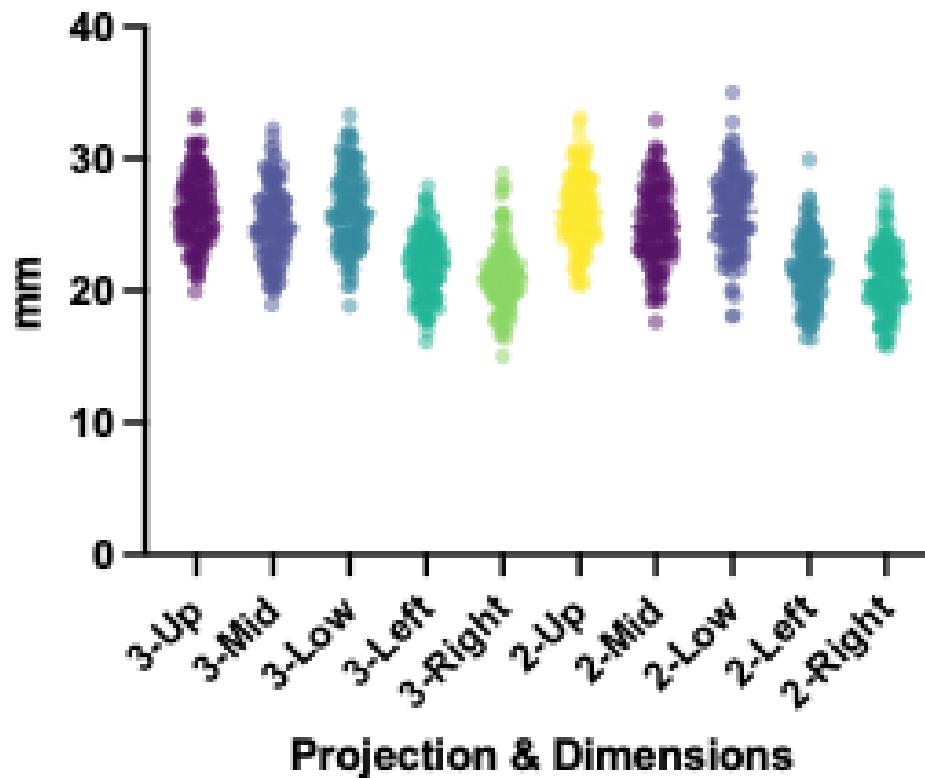


Cusp-Overlap View

1. Compared with the 3-cusp view, the outflow, annular, and outer curve measurements were significantly shorter in the 2-cusp view
2. No significant differences were observed for the inflow and inner curve dimensions.

Frame Evaluation among CA groups

Valve Frame Dimensions



When comparing across the three CA groups, no significant differences were found in any of the valve dimensions, in the difference between outflow and annular height, or in the dimensional differences between the 3-cusp and 2-cusp views.

Conclusion

- The SAPIEN 3 and SAPIEN 3 Ultra frames exhibit **asymmetric expansion** in both the vertical and horizontal dimensions.
- Frame morphology **varies depending on the projection view**, which may correspond to the characteristic geometry of the native annulus.
- **Commissural alignment** appears to have **minimal influence** on overall valve frame geometry.
- The long-term impact on transvalvular gradient and valve function related to both frame morphology and commissural alignment is currently being evaluated in Part III of this study.