



## Supplementary material

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# Differences in Frame Geometry Between Balloon-expandable and Self-expanding Transcatheter Heart Valves and Association With Aortic Regurgitation

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**Table 1**  
**Comparison of Frame Dimensions Obtained From the Rotational Angiography at the Various Levels of the Medtronic CoreValve® System and Edwards SAPIEN® Valve Between 2 Blinded Independent Observers**

N = 30 Mean ± SD	Dimension	Correlation coefficient*	R-angio Observer 1	R-angio Observer 2	P
<b>Inflow</b>					
	D <sub>min</sub> (mm)	0.978	21 ± 3	21 ± 3	< .001
	D <sub>max</sub> (mm)	0.977	25 ± 3	25 ± 3	< .001
	Perimeter(mm)	0.997	74 ± 8	74 ± 8	< .001
	Area (mm <sup>2</sup> )	0.997	424 ± 92	425 ± 92	< .001
<b>Nadirs/Mid segment</b>					
	D <sub>min</sub> (mm)	0.965	21 ± 2	20 ± 2	< .001
	D <sub>max</sub> (mm)	0.949	24 ± 2	24 ± 2	< .001
	Perimeter(mm)	0.978	71 ± 5	70 ± 5	< .001
	Area (mm <sup>2</sup> )	0.988	385 ± 50	384 ± 51	< .001
<b>Coaptation/Outflow</b>					
	D <sub>min</sub> (mm)	0.980	22 ± 2	22 ± 2	< .001
	D <sub>max</sub> (mm)	0.942	24 ± 2	24 ± 2	< .001
	Perimeter(mm)	0.998	72 ± 6	70 ± 5	< .001
	Area (mm <sup>2</sup> )	0.999	407 ± 73	408 ± 72	< .001

D<sub>max</sub>, maximum diameter; D<sub>min</sub>, minimum diameter; R-angio, rotational angiography.

**Table 2****Baseline Characteristics. Differences Between Edwards SAPIEN® Valve XT and Edwards SAPIEN® Valve S3**

	<b>Entire cohort (50 patients)</b>	<b>ESV-xt (26 patients)</b>	<b>ESV-S3 (24 patients)</b>	<b><i>P</i></b>
Age (y)	78 ± 10	75 ± 10	80 ± 10	.084
Male, n (%)	31 (62.0)	14 (53.8)	17 (70.8)	.216
Height (cm)	170 ± 9	169 ± 6	171 ± 11	.263
Weight (kg)	80 ± 15	79 ± 17	81 ± 11	.661
Body mass index (kg/m <sup>2</sup> )	28 ± 5	28 ± 6	28 ± 5	.986
Body surface area (m <sup>2</sup> )	1.9 ± 0.2	1.9 ± 0.2	1.9 ± 0.2	.367
New York Heart Association class ≥ III, n (%)	34 (72.3)	16 (64.0)	18 (81.8)	.173
Previous cerebrovascular event, n (%)	8 (16.0)	5 (19.2)	3 (12.5)	.517
Previous myocardial infarction, n (%)	11 (22.0)	5 (19.2)	6 (25.0)	.623
Previous coronary artery bypass graft surgery, n (%)	10 (20.0)	4 (15.4)	6 (25)	.396
Previous percutaneous coronary intervention, n (%)	12 (24.0)	7 (26.9)	5 (20.8)	.614
Diabetes mellitus, n (%)	13 (26.0)	8 (30.8)	5 (20.8)	.424
Hypertension, n (%)	42 (84.0)	23 (88.5)	19 (79.2)	.370
Peripheral vascular disease, n (%)	17 (34.0)	6 (23.1)	11 (45.8)	.090
Pulmonary hypertension, n (%)	6 (12.0)	2 (7.7)	4 (16.7)	.329
Severe pulmonary hypertension, n (%)	3 (6.0)	0 (0)	3 (12.5)	.063
Chronic obstructive pulmonary disease, n (%)	10 (20.0)	6 (23.1)	4 (16.7)	.571
Atrial fibrillation, n (%)	14 (28.0)	5 (19.2)	9 (37.5)	.151
Permanent pacemaker, n (%)	5 (10.0)	1 (3.8)	4 (16.7)	.131
Logistic EuroSCORE (%)	16 ± 13	12 ± 10	19 ± 15	.063
<b>Echocardiography and cardiac catheterization</b>				
Left ventricular ejection fraction (%)	50 ± 13	53 ± 11	50 ± 14	.538
Aortic valve area (cm <sup>2</sup> )	0.74 ± 0.2	0.72 ± 0.2	0.72 ± 0.2	.539
Peak gradient (mmHg)	72 ± 21	68 ± 18	68 ± 18	.203
Mitral regurgitation ≥ II n (%)	31 (64.6)	13 (59.1)	13 (59.1)	.464

AR baseline $\geq$ II, n (%)	27 (57.4)	10 (47.6)	10 (47.6)	.221
AR index	27 $\pm$ 10	25 $\pm$ 10	29 $\pm$ 11	.218
<b>Multislice Computed Tomography</b>				
Minimal annulus diameter (mm)	22 $\pm$ 2	22 $\pm$ 2	23 $\pm$ 2	.145
Maximal annulus diameter (mm)	28 $\pm$ 3	27 $\pm$ 2	29 $\pm$ 3	.124
Mean annulus diameter (mm)	25 $\pm$ 2	25 $\pm$ 2	26 $\pm$ 2	.097
Perimeter annulus (mm)	81 $\pm$ 8	80 $\pm$ 8	82 $\pm$ 7	.257
Area annulus (mm <sup>2</sup> )	488 $\pm$ 85	463 $\pm$ 72	515 $\pm$ 90	.032
Annulus eccentricity (%)	79 $\pm$ 6	80 $\pm$ 8	82 $\pm$ 7	.953
Agatston score	4010 $\pm$ 2964	3738 $\pm$ 3438	4265 $\pm$ 2377	.537

AR, aortic regurgitation; ESV, Edwards SAPIEN® valve

**Table 3**  
**Procedural Details. Distinction Between Edwards SAPIEN® Valve XT and Edwards SAPIEN® Valve S3**

	<b>Entire cohort (50 patients)</b>	<b>ESV-xt (26 patients)</b>	<b>ESV-S3 (24 patients)</b>	<b><i>p</i></b>
<b>Access, n (%)</b>				
Transfemoral	47 (94.0)	24 (92.3)	21 (95.5)	
Transsubclavian	0 (0.0)	0 (0)	0 (0)	
Transapical	3 (6.0)	2 (7.7)	1 (4.5)	
<b>Prosthesis size (mm), n (%)</b>				
23 mm	7 (14.0)	2 (7.7)	5 (20.8)	
26 mm	26 (52.0)	16 (61.5)	10 (41.7)	
29 mm	17 (34.0)	8 (30.8)	9 (37.5)	
31 mm	0 (0.0)	0 (0)	0 (0)	
<b>Predilation</b>				
Pre- implantation balloon dilation, n (%)	41 (82.0)	25 (96.2)	16 (66.7)	.007
Balloon nominal / mean annulus diameter x 100	94 ± 5	95 ± 6	93 ± 5	.243
<b>Sizing</b>				
Valve size / minimal annulus diameter x 100 (%)	121 ± 8	124 ± 8	117 ± 6	.004
Valve size / maximal annulus diameter x 100 (%)	96 ± 6	98 ± 6	93 ± 6	.008
Valve size / mean annulus diameter x 100 (%)	107 ± 5	109 ± 5	104 ± 5	<.001
Valve perimeter / perimeter native annulus x 100	103 ± 7	105 ± 7	101 ± 6	.031
<b>Depth of Implantation</b>				
- Noncoronary sinus (mm)	8 ± 2	8 ± 2	8 ± 2	.771
- Left-coronary sinus (mm)	8 ± 2	8 ± 3	7 ± 2	.334
<b>Post-dilation</b>				
Post implantation balloon dilation, n (%)	8 (16.0)	5 (19.2)	3 (12.5)	.517
Balloon nominal diameter / mean annulus diameter x 100 (%)	107 ± 3	109 ± 3	104 ± 1	.070
Balloon nominal diameter / Valve size x 100 (%)	102 ± 6	102 ± 7	100 ± 0	.698
<b><u>AR post-TAVI</u></b>				

AR index	24 ± 6	24 ± 8	25 ± 9	.641
<b>AR post-TAVI by echocardiography, n (%)</b>				
- Mild (< 10 % circumferential extend of the leakage)	38 (86.4)	20 (87.0)	18 (85.7)	
- Moderate (10%-29% circumferential extend of the leakage)	4 (9.1)	2 (8.7)	2 (9.5)	
- Severe (> 30% circumferential extend of the leakage)	2 (4.5)	1 (4.3)	1 (4.8)	
- More-than-mild (≥ 10 % circumferential extend of the leakage)	6 (13.6)	3 (13)	3 (14.3)	.905
<b>AR post-TAVI by aortography, n (%)</b>				
- Grade 0, n (%)	13 (26.0)	4 (15.4)	9 (37.5)	
- Grade I, n (%)	35 (70.0)	20 (76.9)	15 (62.5)	
- Grade II, n (%)	2 (4.0)	2 (7.7)	0 (0)	
- Grade III, n (%)	0 (0.0)	0 (0)	0 (0)	
- Grade IV, n (%)	0 (0.0)	0 (0.0)	0 (0)	
- Grade ≥ II, n (%)	2 (4.0)	2 (7.7)	0 (0)	.166

AR, aortic regurgitation; ESV, Edwards SAPIEN® valve; TAVI, transcatheter aortic valve implantation.

**Table 4**

**Frame Analysis by Rotational Angiography. Distinction Between Edwards SAPIEN® Valve XT and Edwards SAPIEN® Valve S3**

	<b>Entire cohort (50 patients)</b>	<b>ESV-XT (26patients)</b>	<b>ESV-S3 (24 patients)</b>	<b>P</b>
<b>Degree of Expansion</b>				
Degree of valve expansion at the inflow (%)	92 ± 4	90 ± 3	94 ± 2	<.001
Degree of valve expansion at the Nadir/Mid segment (%)	88 ± 3	89 ± 3	88 ± 3	.232
Degree of valve expansion at the coaptation/Outflow (%)	92 ± 4	90 ± 4	95 ± 3	<.001
<b>Frame Eccentricity</b>				
Degree of eccentricity valve at inflow (%)	95 ± 3	95 ± 3	96 ± 3	.318
Degree of eccentricity valve at nadir/mid segment (%)	95 ± 4	95 ± 4	95 ± 3	.933
Degree of eccentricity valve at coaptation/outflow (%)	96 ± 3	94 ± 4	97 ± 2	.011
Degree of eccentricity nadir/mid adjusted to eccentricity native annulus.	21 ± 11	21 ± 13	20 ± 9	.761
Nadir/mid more eccentric than the native annulus, n (%)	1 (2.1)	1 (4)	0 (0)	.343

ESV, Edwards SAPIEN® valve.

**Table 5**  
**Relationship Between Frame Geometry and Aortic Regurgitation by Aortography and Echocardiography. Distinction Between Edwards SAPIEN® Valve XT and Edwards SAPIEN® Valve S3**

	ENTIRE POPULATION (47 patients )			ESV-XT POPULATION (24 patients)			ESV-S3 POPULATION (23patients)		
	Entire cohort ( 47 p )	< 10 % ( 41 p)	≥ 10% ( 6 p)	Entire cohort ( 23 p )	< 10 % ( 20 p)	≥ 10% ( 3 p)	Entire cohort ( 24 p )	< 10 % ( 21 p)	≥ 10% ( 3 p)
<b>Degree of Expansion</b>									
- Inflow (%)	92 ± 4	92 ± 4	93 ± 4	90 ± 3	89 ± 2	93 ± 5	94 ± 2	95 ± 2	93 ± 4
- Nadir/Mid segment (%)	88 ± 3	88 ± 3	89 ± 5	89 ± 3	83 ± 3	88 ± 6	88 ± 3	87 ± 3	90 ± 3
- Coaptation/Outflow (%)	93 ± 4	93 ± 4	93 ± 7	90 ± 4	90 ± 4	88 ± 6	95 ± 3	95 ± 2	98 ± 3
<b>Degree of Eccentricity</b>									
- Inflow (%)	95 ± 3	96 ± 3	95 ± 3	95 ± 3	95 ± 3	95 ± 5	96 ± 3	96 ± 3	95 ± 3
- Nadir/mid segment (%)	95 ± 4	95 ± 3	91 ± 6	95 ± 5	96 ± 4	90 ± 8	95 ± 3	95 ± 3	93 ± 3
- Coaptation/outflow (%),	96 ± 3	96 ± 3	93 ± 5	94 ± 4	95 ± 4	90 ± 6	97 ± 2	97 ± 2	96 ± 1
- Adjusted eccentricity	20 ± 11	21 ± 9	17 ± 20	20 ± 13	21 ± 10	11 ± 37	21 ± 9	21 ± 9	20 ± 9
- Nadir/Mid segment more elliptical than native annulus, n (%)	1 (2.2)	0 (0.0)	1 (20.0)	1 (4.5)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)

ESV, Edwards SAPIEN® valve; p, patients.