Commissural alignment & TAV performance: Results from the COMALIGN-neo 2 study

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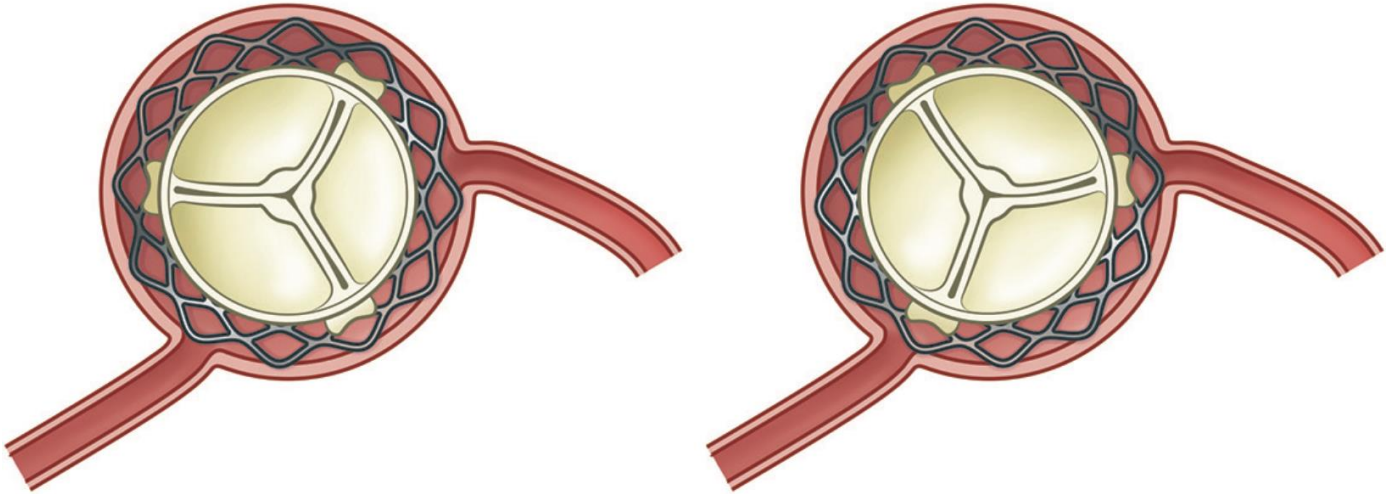
Disclosure of Relevant Financial Relationships

I, Ole De Backer received institutional research grants and consulting fees from Boston Scientific.

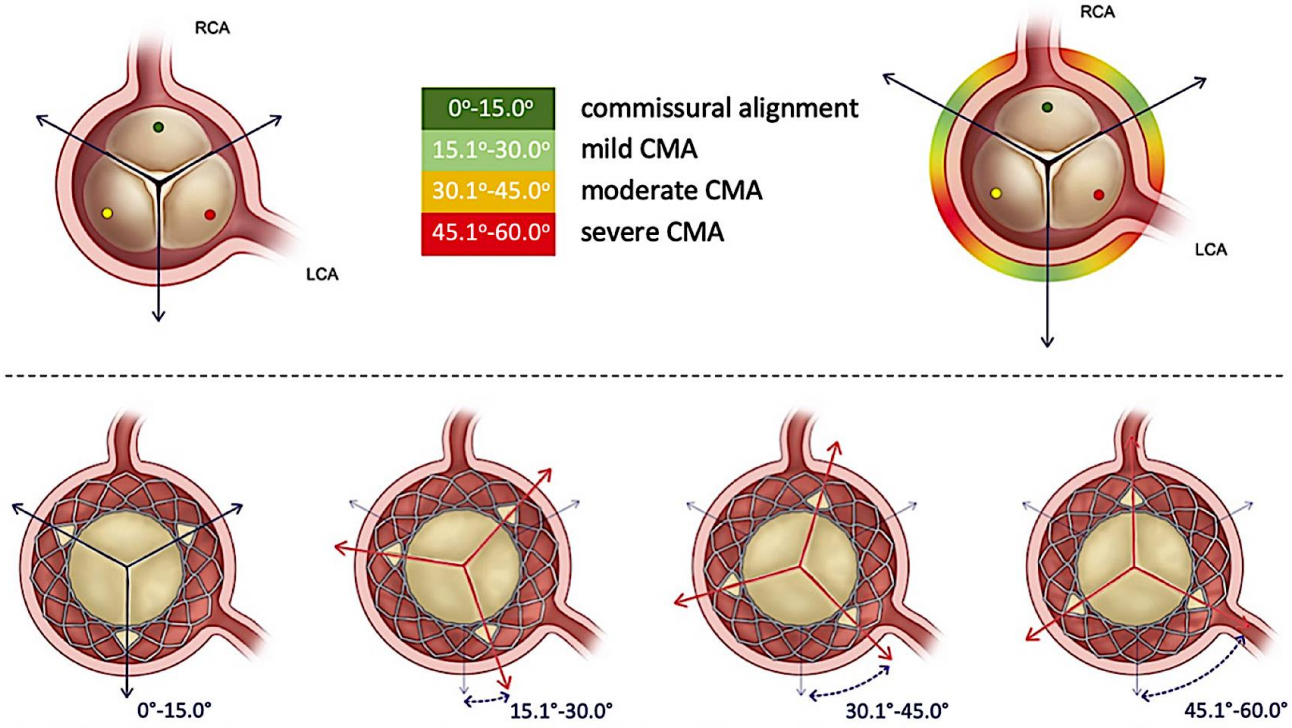
TAVR – commissural alignment



✓ **Commissural alignment**

✗ **Severe commissural misalignment**

TAVR – commissural alignment



Tang G, De Backer O. JACC Cardiovascular Interv 2021.

TAVR – commissural alignment

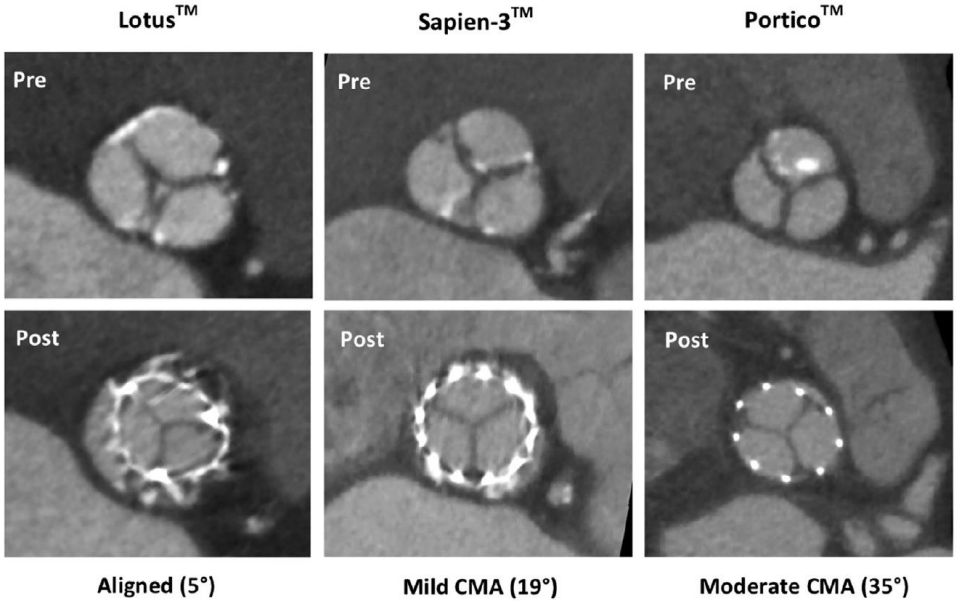
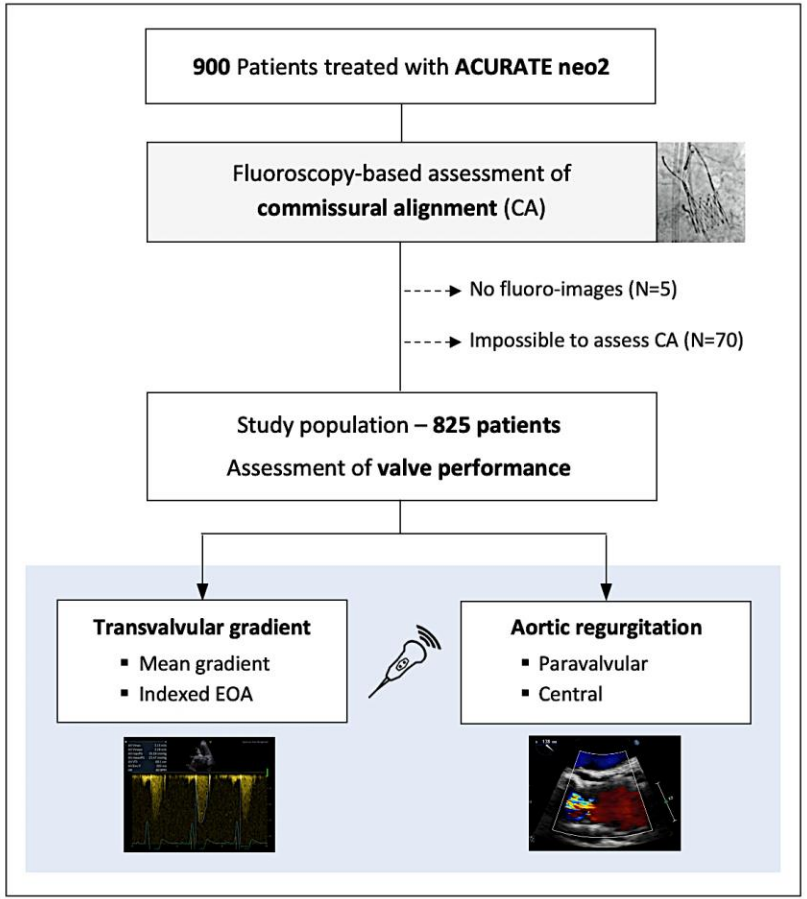


TABLE 2 Commissural Alignment in Surgical and Transcatheter Aortic Bioprostheses

	Aligned	Mild CMA	Moderate CMA	Severe CMA
SAVR				
Perimount (n = 9)	9 (100)	–	–	–
Magna (n = 9)	8 (89)	1 (11)	–	–
Epic (n = 5)	5 (100)	–	–	–
MitroFlow (n = 4)	4 (100)	–	–	–
Trifecta (n = 1)	1 (100)	–	–	–
Total (n = 28)	27 (96)	1 (4)	–	–
TAVR				
SAPIEN 3 (n = 82)	24 (29)	21 (26)	10 (12)	27 (33)
Lotus (n = 42)	5 (12)	13 (31)	12 (29)	12 (29)
Evolut R (n = 38)	8 (21)	9 (24)	8 (21)	13 (34)
Portico (n = 27)	6 (22)	2 (7)	10 (37)	9 (33)
Acurate (n = 17)	3 (18)	5 (29)	4 (24)	5 (29)
Centera (n = 6)	1 (17)	3 (50)	2 (33)	–
Total (n = 212)	47 (22)	53 (25)	46 (22)	66 (31)

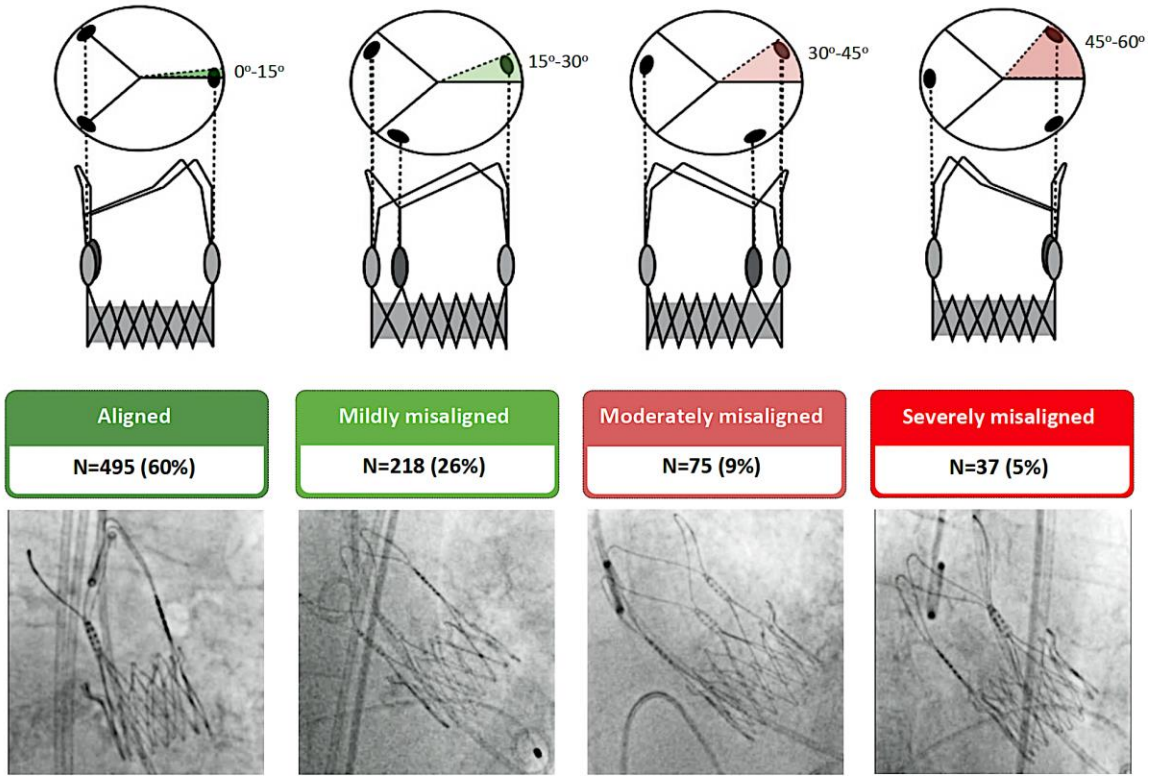
Fuchs A, De Backer O. JACC Cardiovascular Interv 2018.



COMALIGN-neo2

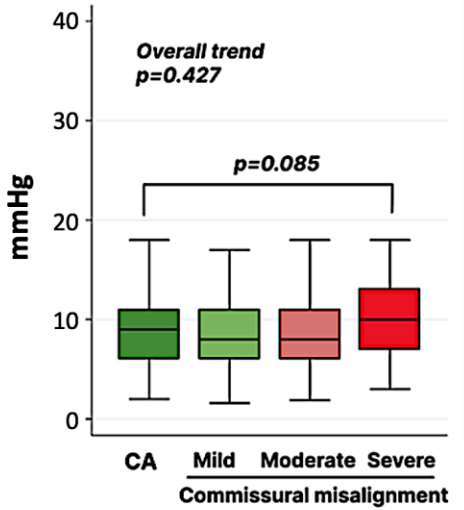
ACURATE neo2 commissural alignment & valve performance

ACURATE neo2 – commissural alignment

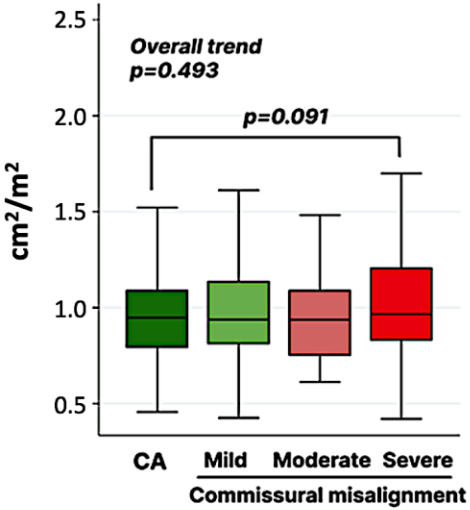


Commissural alignment & valve performance

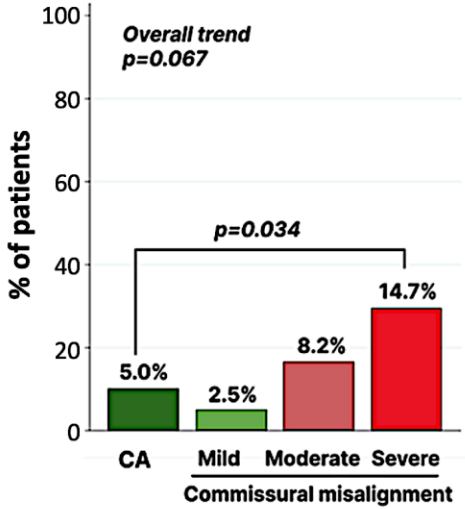
Mean gradient

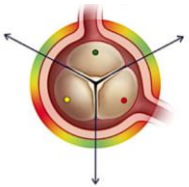


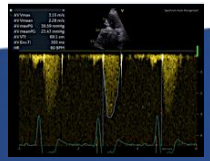
iEOA



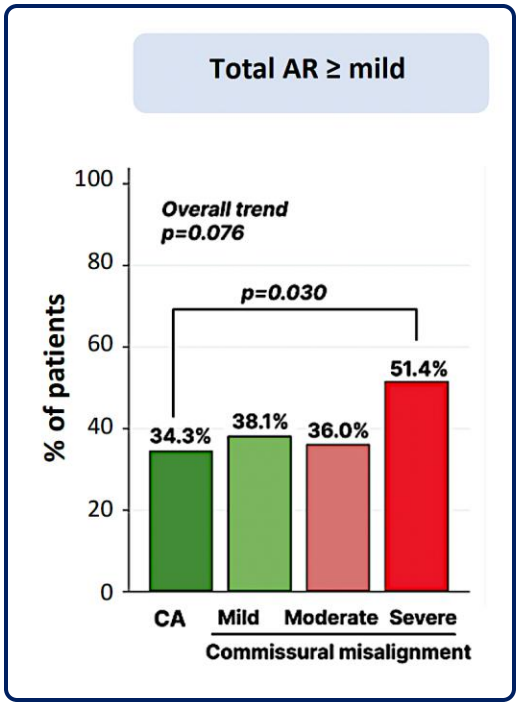
Severe PPM

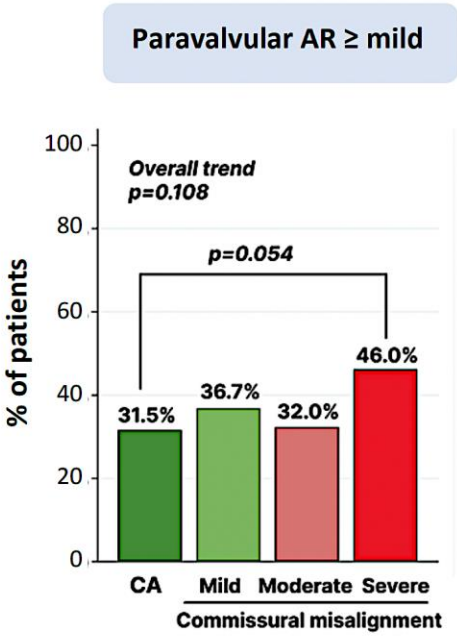


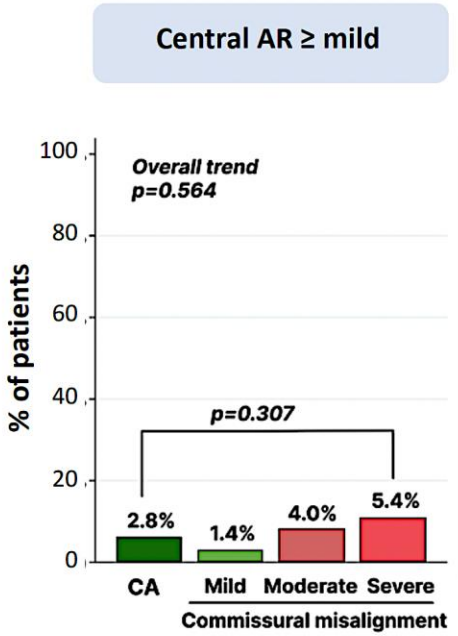


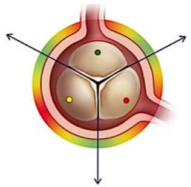


Commissural alignment & valve performance





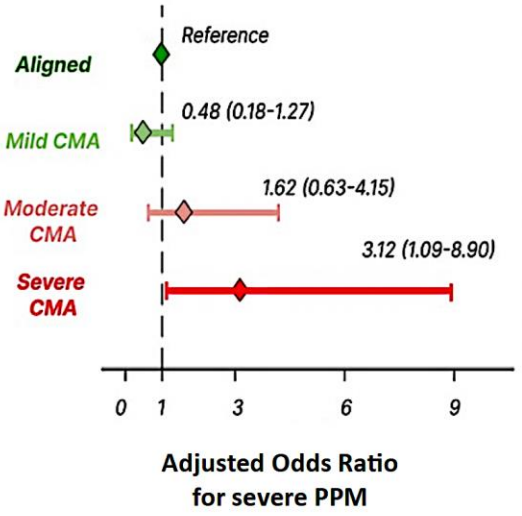




Commissural alignment & valve performance

Multivariate analysis for the risk of severe PPM

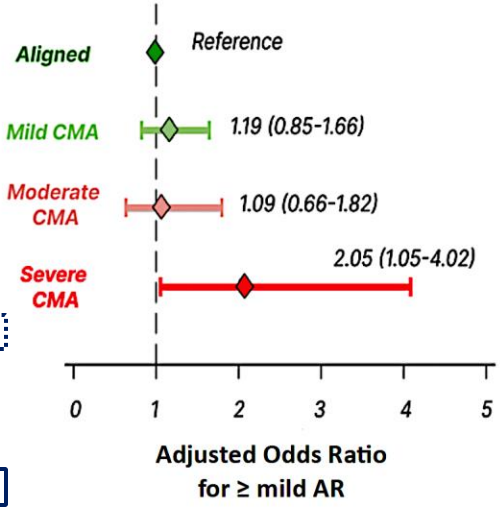
	Univariate		Multivariate	
Variable	**OR**	**P value**	**Adjusted OR**	**P value**
Aortic annulus Ø <23 mm	1.20 (0.61-2.38)	0.599		
Predilatation	1.35 (0.32-5.77)	0.685		
Postdilatation	**0.25 (0.09-0.72)**	**0.010**	**0.26 (0.09-0.75)**	**0.012**
TAV size				
23mm (reference)	-	-		
25 mm	0.57 (0.25-1.29)	0.178		
27 mm	0.72 (0.32-1.62)	0.423		
TAV implant height				
Optimal (reference)	-	-		
Deep	1.24 (0.47-3.27)	0.667		
High	n/a	0.990		
TAV commissural alignment				
Aligned (reference)	-	-		
Mild CMA	0.48 (0.18-1.29)	0.148	0.48 (0.18-1.27)	0.140
Moderate CMA	1.72 (0.67-4.37)	0.257	1.62 (0.63-4.15)	0.315
Severe CMA	**3.31 (1.17-9.34)**	**0.024**	**3.12 (1.09-8.90)**	**0.033**



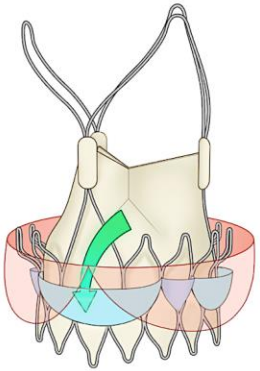
Commissural alignment & valve performance

Multivariate analysis for the risk of ≥ mild aortic regurgitation

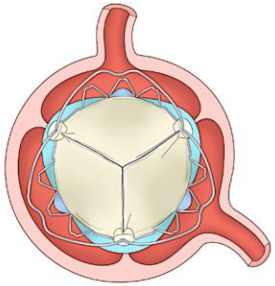
	Univariate		Multivariate	
Variable	**OR**	**P value**	**Adjusted OR**	**P value**
Aortic annulus Ø <23 mm	1.01 (0.74-1.38)	0.963		
Severe leaflet calcification	1.30 (0.93-1.80)	0.122		
Predilatation	1.60 (0.87-2.94)	0.130		
Postdilatation	1.33 (0.98-1.80)	0.067	1.28 (0.94-1.74)	0.114
TAV size				
23mm (reference)	-	-		
25 mm	1.21 (0.82-1.77)	0.339		
27 mm	1.00 (0.67-1.49)	0.999		
TAV implant height				
Optimal (reference)	-	-	-	-
Deep	0.65 (0.39-1.07)	0.091	0.69 (0.41-1.14)	0.147
High	**3.44 (1.03-11.5)**	**0.045**	3.34 (0.99-11.3)	0.052
TAV commissural alignment				
Aligned (reference)	-	-		
Mild CMA	1.18 (0.84-1.64)	0.148	1.19 (0.85-1.66)	0.303
Moderate CMA	1.08 (0.65-1.78)	0.257	1.09 (0.66-1.82)	0.728
Severe CMA	**2.02 (1.03-3.95)**	**0.040**	**2.05 (1.05-4.02)**	**0.037**



ACURATE neo2 implantation with commissural alignment

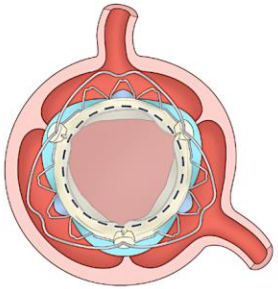


PARAVALVULAR LEAK



Optimal effect of outer sealing skirt

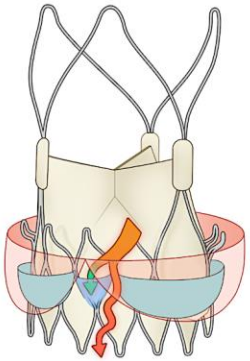
EFFECTIVE ORIFICE AREA



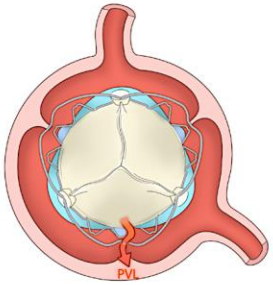
Optimal expansion of commissural posts

Aligned

ACURATE neo2 implantation with severe commissural misalignment

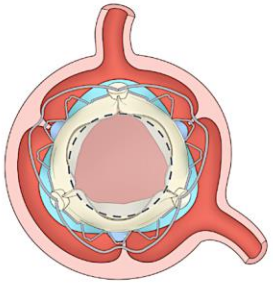


PARAVALVULAR LEAK



Suboptimal position of largest pouch of outer sealing skirt

EFFECTIVE ORIFICE AREA



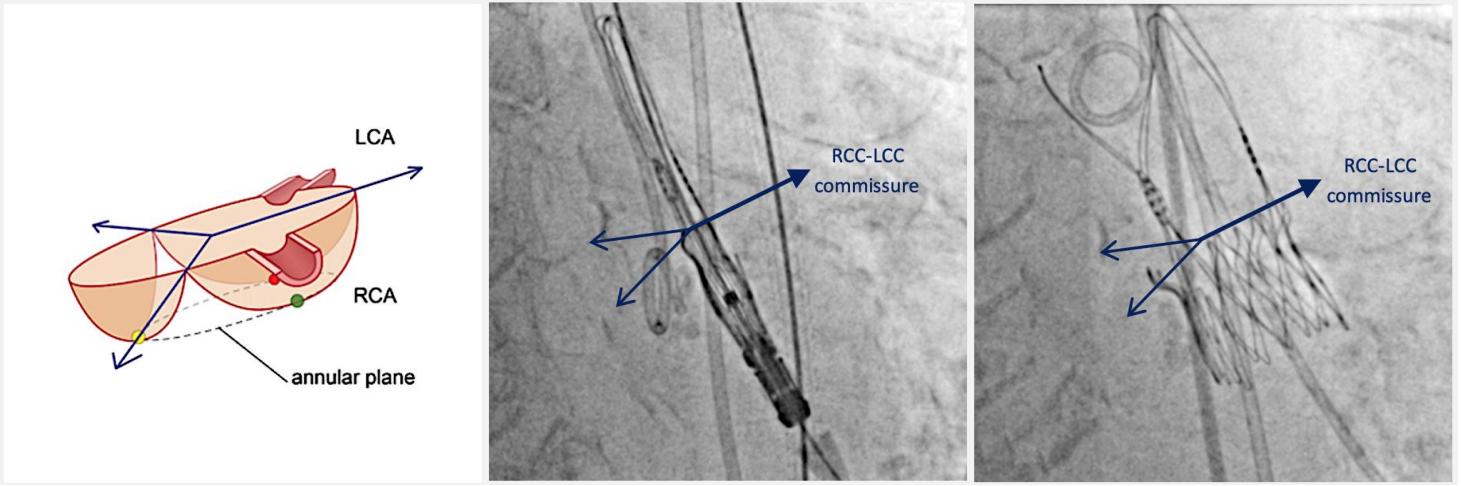
Suboptimal expansion of commissural posts

Severe CMA

ACURATE neo2

Commissural alignment implant technique

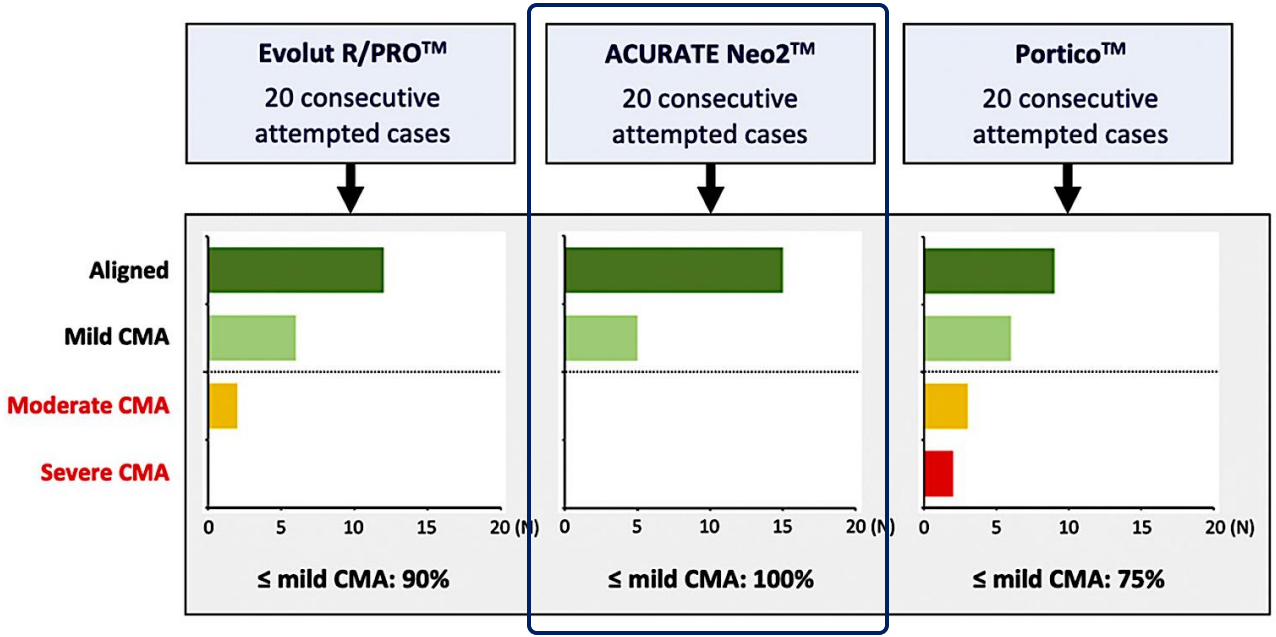
IMPLANTATION TECHNIQUE IN RCC/LCC CUSP OVERLAP VIEW – COMMISSURAL ORIENTATION

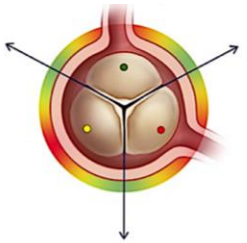


Bieliauskas G, De Backer O. JACC Cardiovascular Interv 2021.

COMALIGN study

ACURATE neo2 – best-in-class TAV





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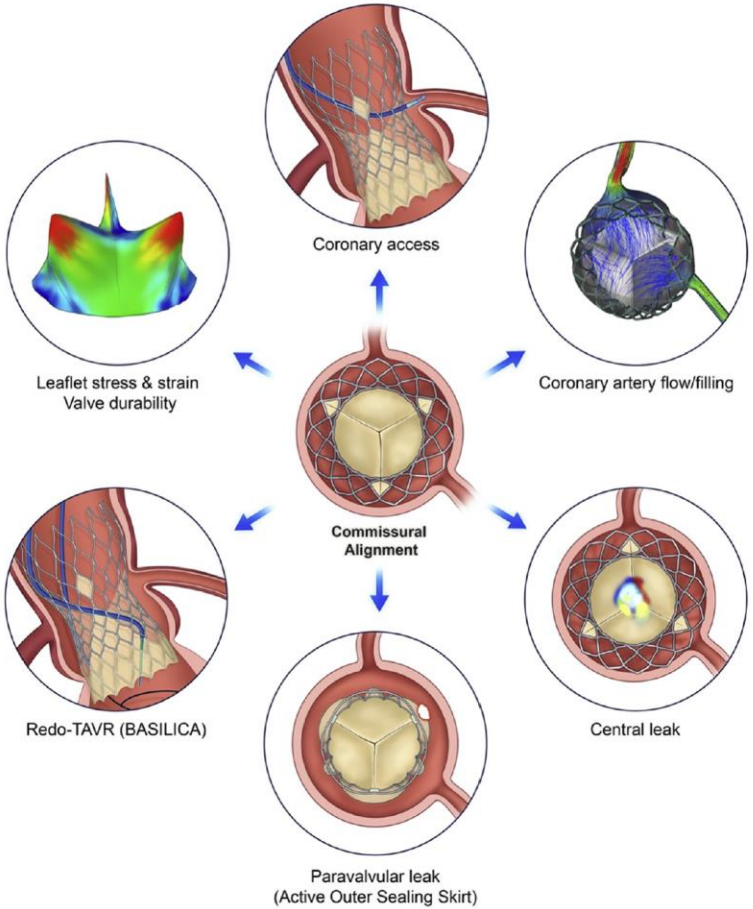

TAVR - Impact of commissural alignment

Tang G, De Backer O. JACC Cardiovascular Interv 2021.

COMALIGN-neo2 study

Take-home messages

- ✓ Commissural alignment had no statistically-significant impact on transvalvular mean gradients and EOAs. However, **severe misalignment (CMA) is associated with** increased risk of **severe patient-prosthesis mismatch (PPM)**.
- ✓ **Total aortic regurgitation** was significantly higher in **severely misaligned patients**, and this is mostly explained by a sub-optimal position of the largest pouch of the outer sealing skirt.
- ✓ **Commissural alignment is easy to obtain** when using the ACURATE neo2 platform (***best-in-class***).

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