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Novel Implant Techniques.
What is different?

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Financial Disclosure

I, Eberhard Grube have the following financial interest/arrangement that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

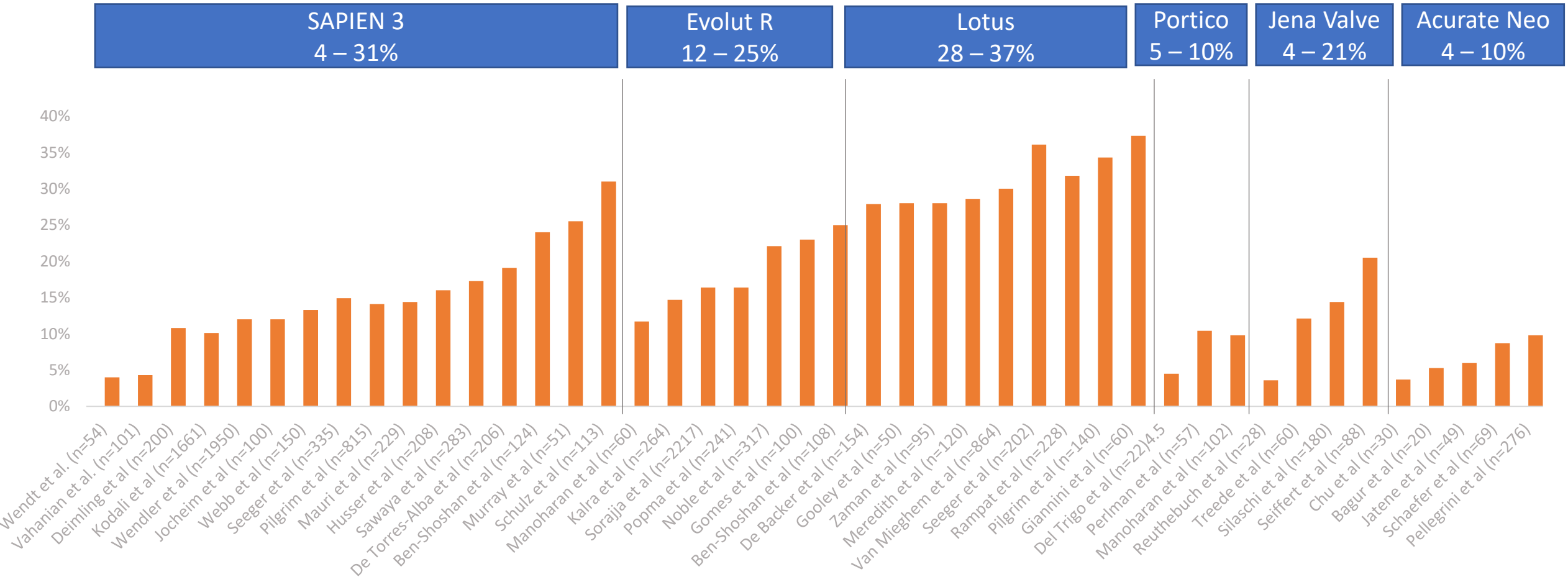
Speaker Bureau/ SAB: Medtronic, Boston Scientific, HighLife, Jena Valve, Protembis

Equity Interest: Cardiovalve, Claret, Shockwave, Valve medical, CardioMech, Millipede, Imperative Care, Pi-Cardia, Ancora, Laminar, ReNiva Medical

Reducing Conduction Disturbance

Need for Refined Procedural Technique

Conduction disturbances and new pacemaker implantation are one of the most frequent complications after TAVI.



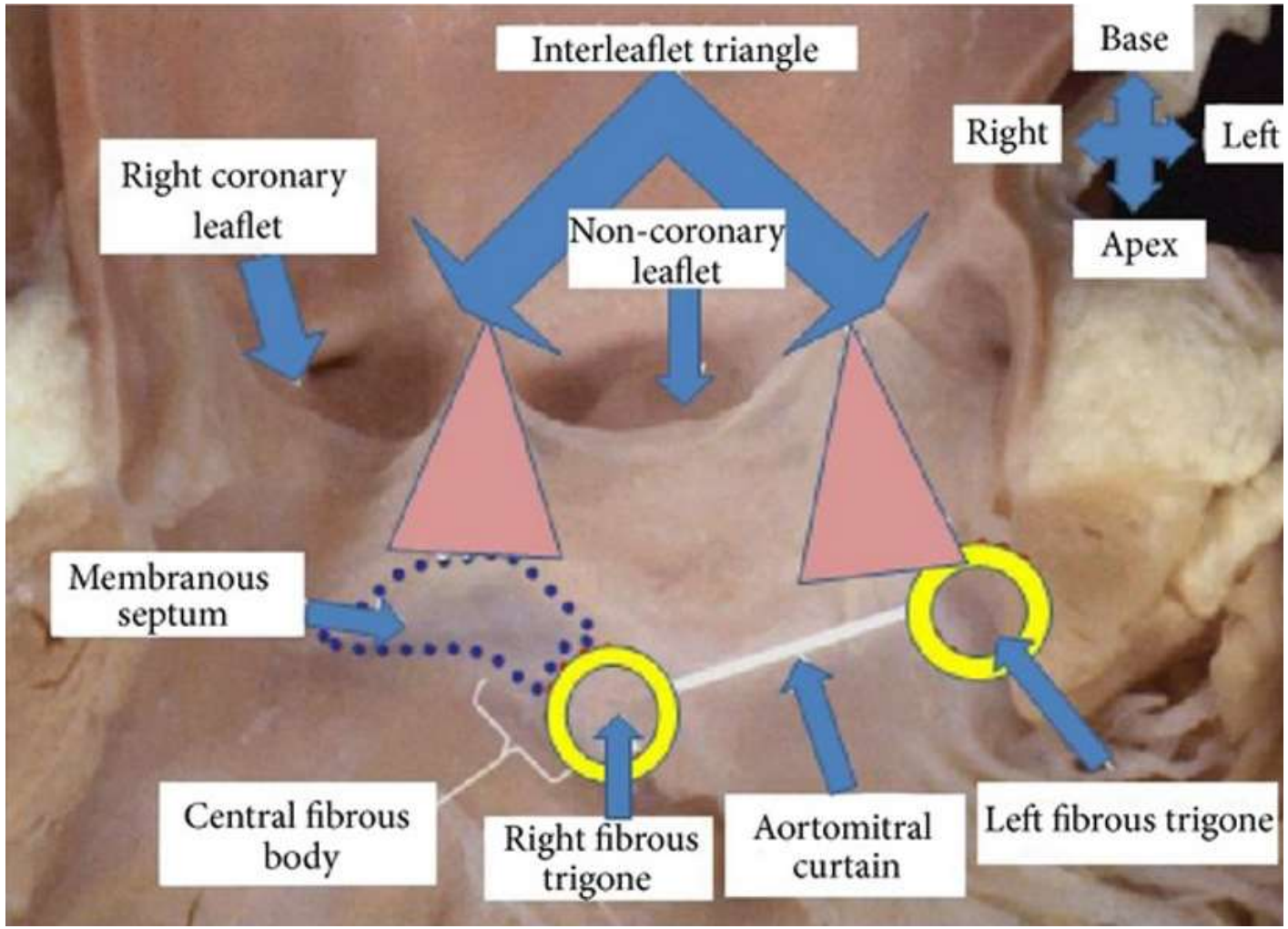
Auffret et al., Circulation 2017;136:1049-69

Reducing Conduction Disturbance

Need for Refined Procedural Technique

Conduction disturbances can arise when there is compression or inflammation of conductive tissue located near the noncoronary cusp.

Implantation depth has been the most common procedural factors (both modifiable) associated with conduction disturbances post-TAVR



[1]Mangieri, et al. Front Cardiovasc Med. 2018;5:85. Figure reused by CCBY license from Neragi-Miandoab S, Michler RE. A review of most relevant complications of transcatheter aortic valve implantation. ISRN Cardiol. 2013;2013:956252. Published 2013 May 12. doi:10.1155/2013/956252

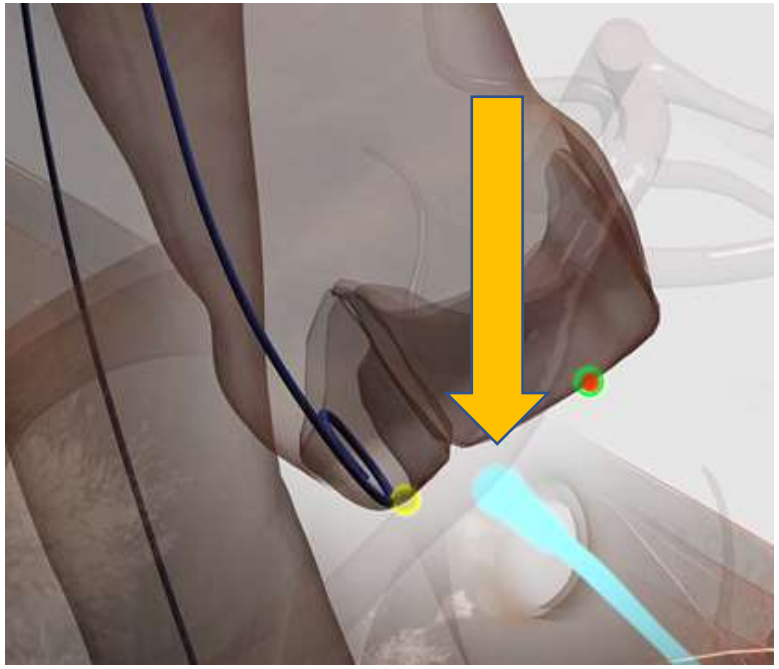
Conventional Implant View

Three-cusp Co-planar Projection

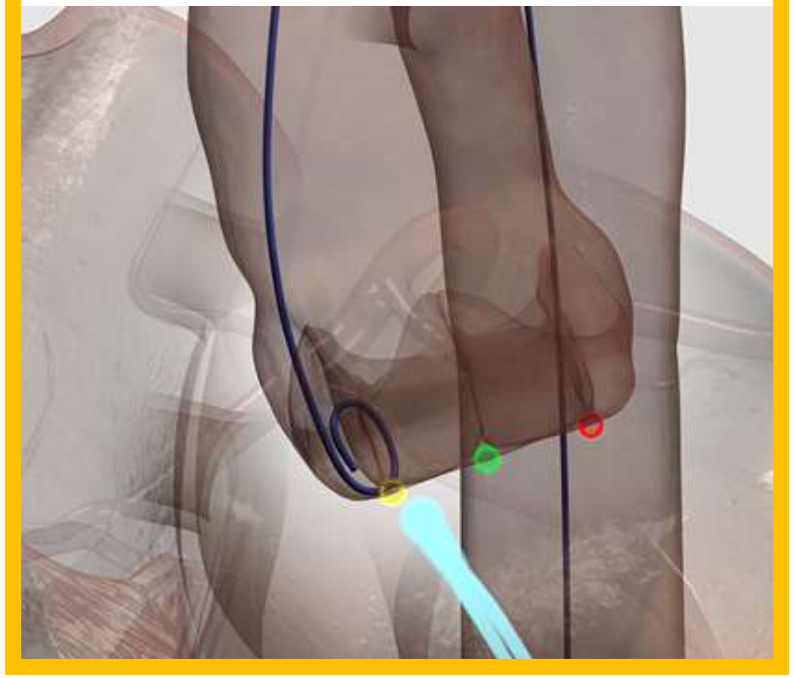
Historically, the standard position of deployment is at an alignment of the right cusp between the left and the noncoronary cusps in a coplanar view.

Anatomical modeling below, with **the AV node shown in light blue**, demonstrates the greater visual separation between the basal annular plane and the conduction system when using the cusp overlap view.

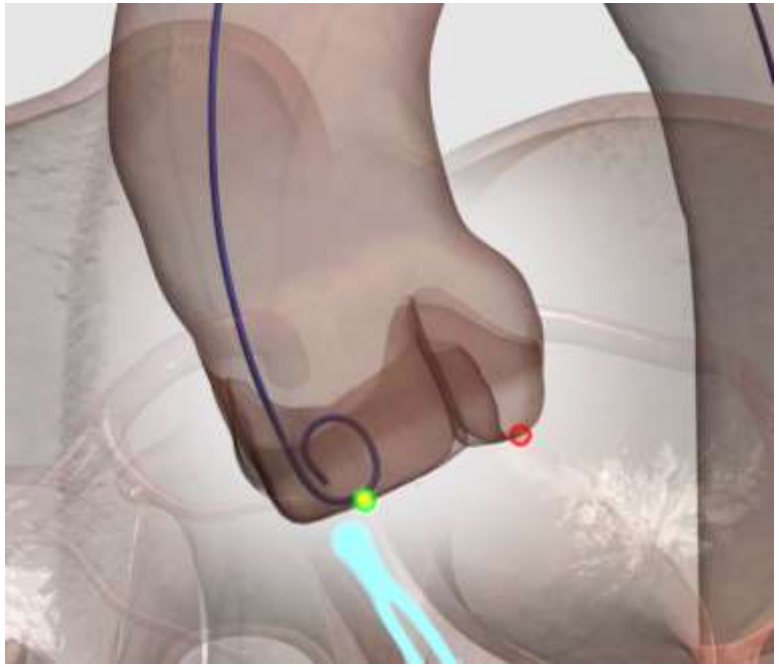
Cusp Overlap View



3 Cusp Co-planar View



LAO View

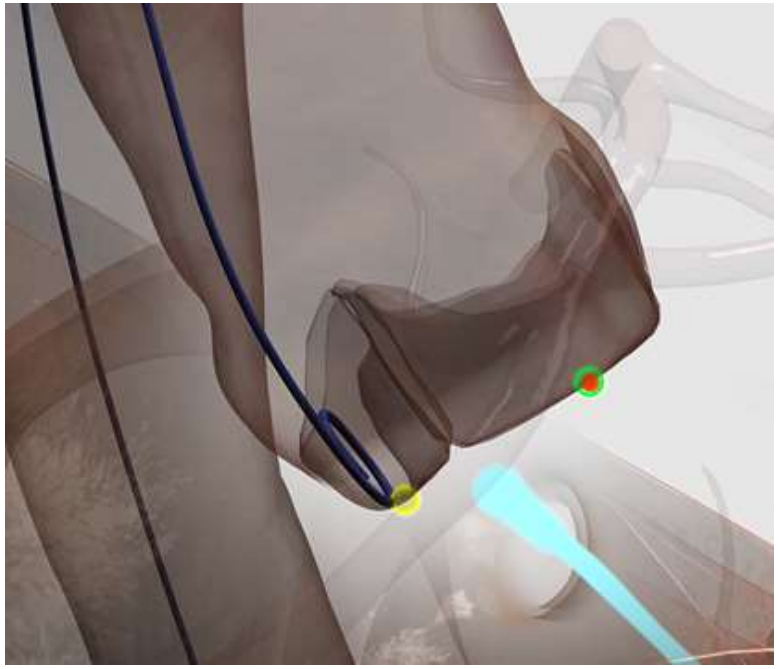


Conventional Implant View

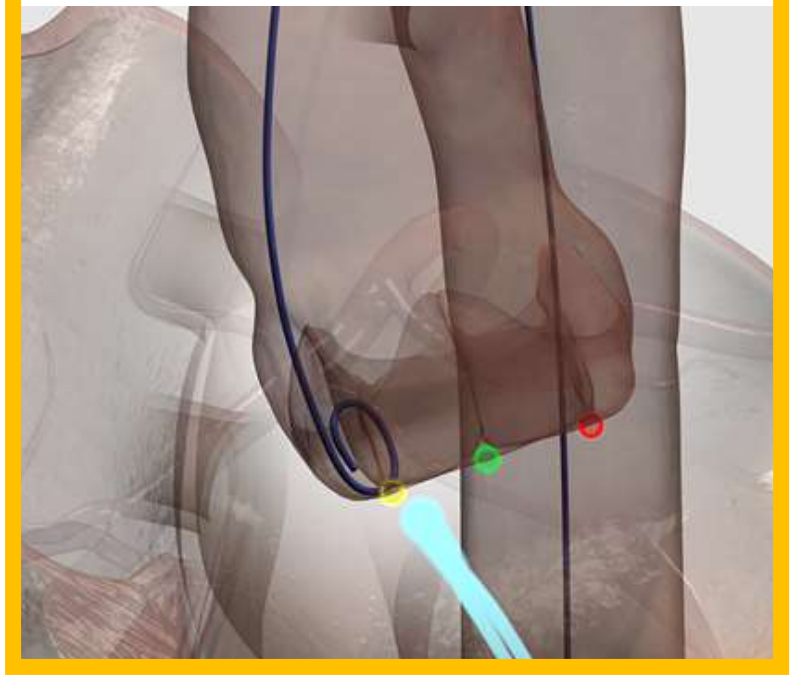
Three-cusp Co-planar Projection

- Valve positioning using the conventional 3-cusp coplanar projection typically involves an LAO view in order to align the three cusps on one plane.
- Using the three-cusp technique, the operator often deployed the valve without a clear representation of **how the native annulus is located relative to the conduction system because the location of the conduction system is obscured by the radiographic foreshortening of the LVOT**

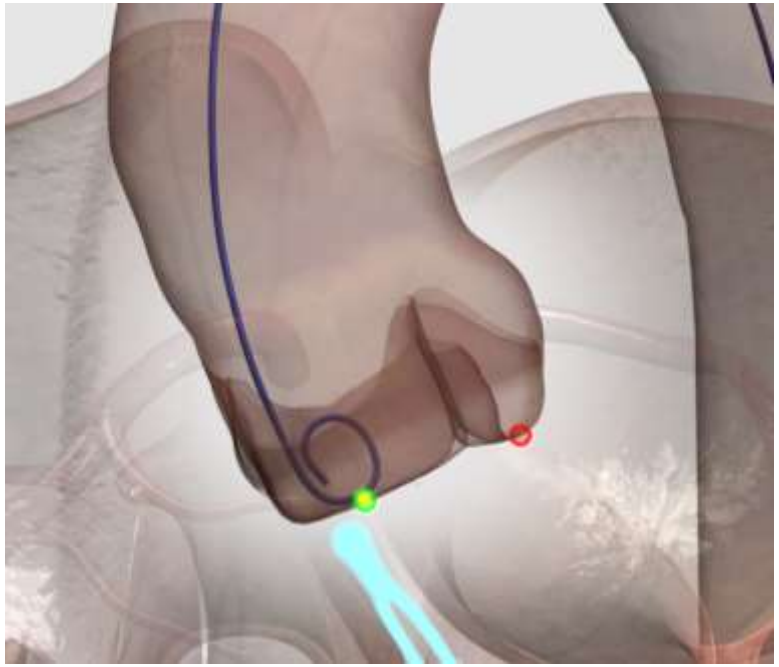
Cusp Overlap View



3 Cusp Co-planar View



LAO View



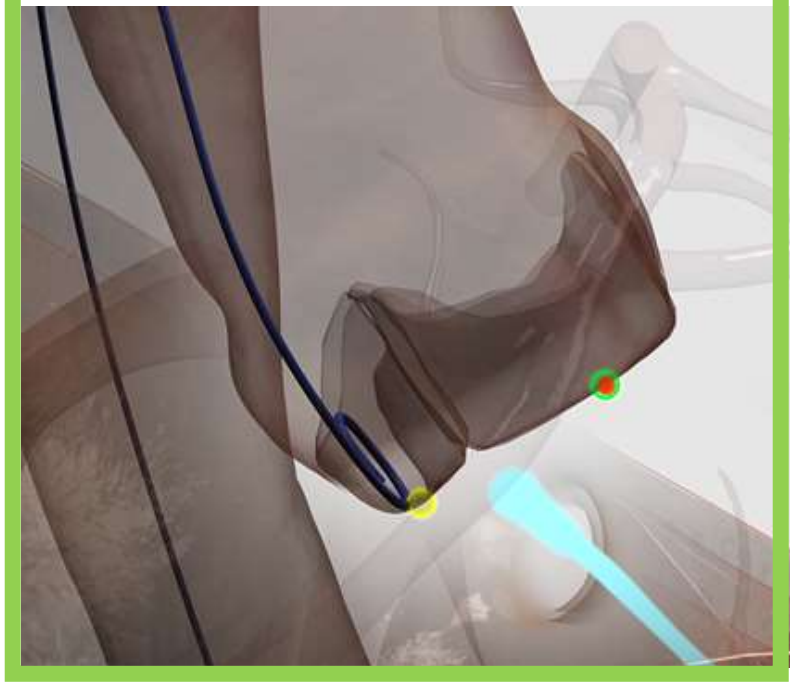
Cusp Overlap Technique

New Technique for Controlled and Precise Implantation

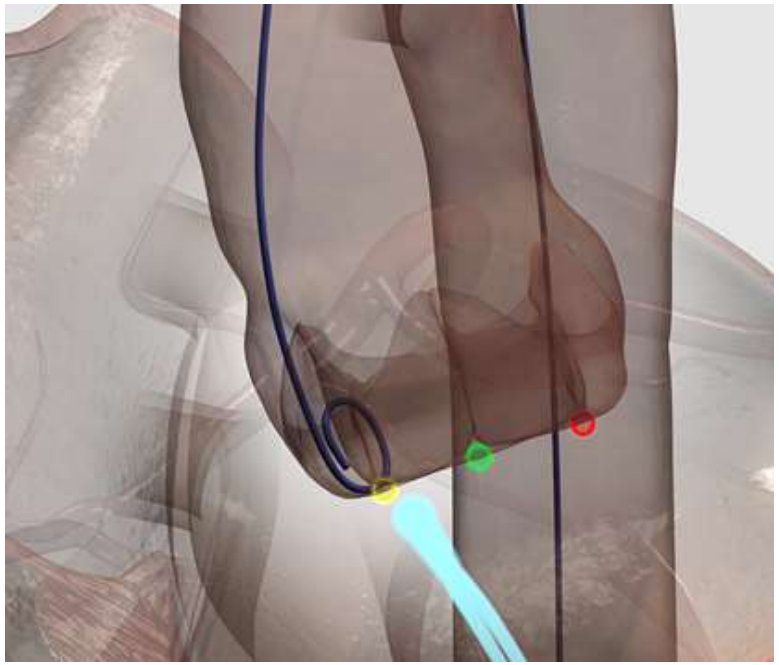
- In contrast to the conventional view, the Cusp Overlap projection isolates the noncoronary cusp while overlapping the right and left commissures along the basal annular plane

- The **Cusp Overlap view elongates the LVOT** and accentuates the NCC/RCC commissure, creating a better reference of the conduction system and promoting a more precise implant depth control relative to the AV node and membranous septum.

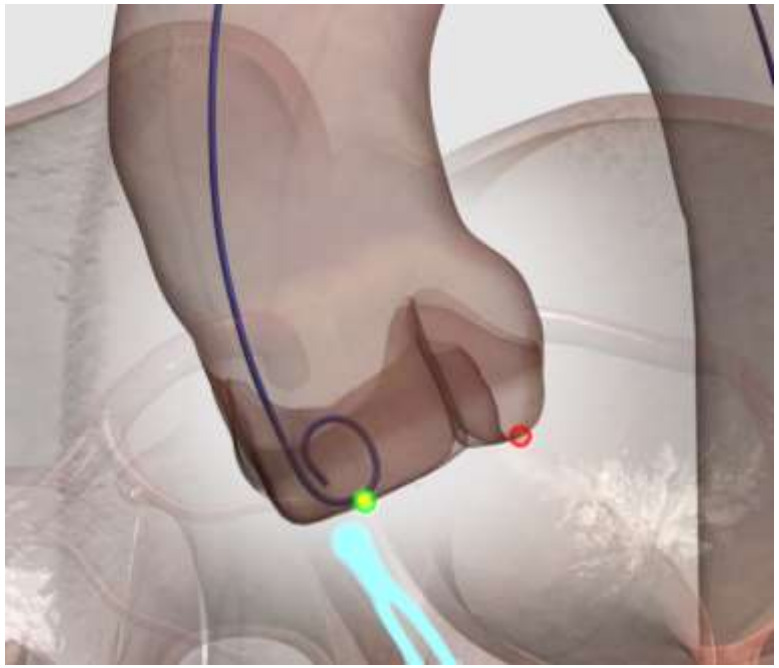
Cusp Overlap View



3 Cusp Coplanar View



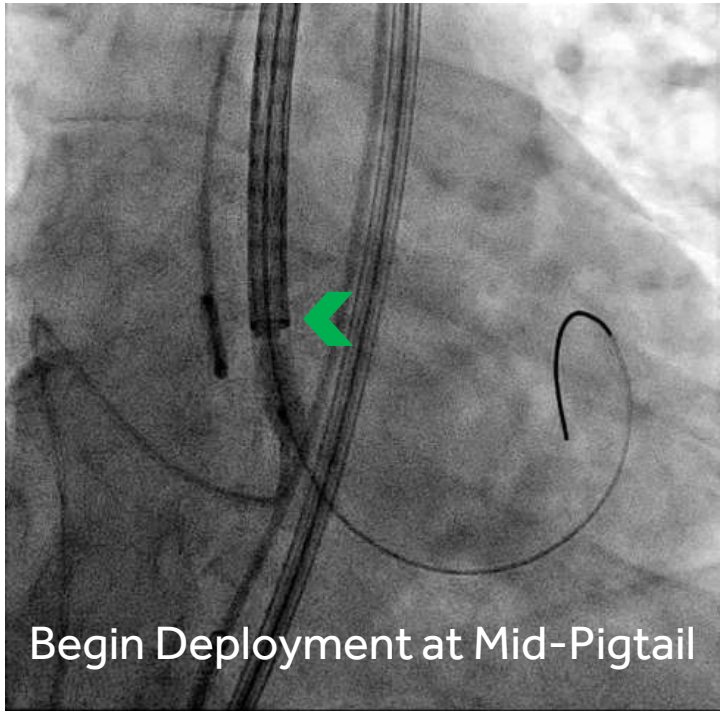
LAO View

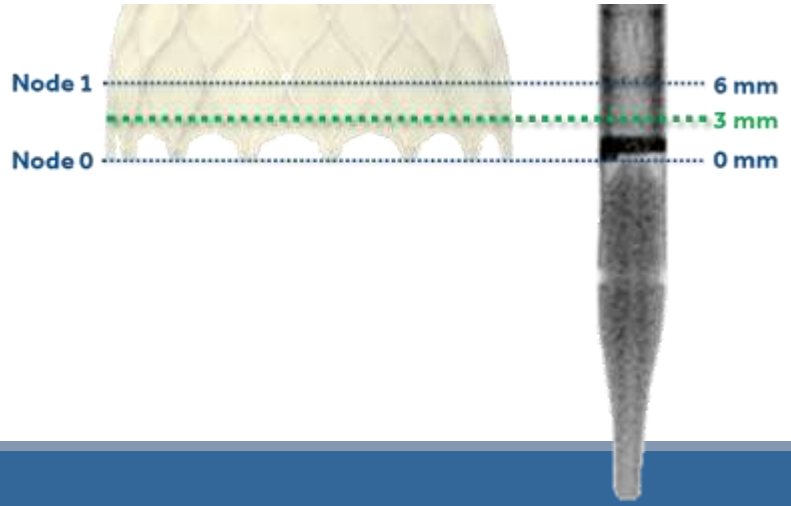


Cusp Overlap Technique

New Technique for Controlled and Precise Implantation

- General steps for the Cusp Overlap Technique with Evolut valves:
  - Cross arch according to best practices
  - Change image projection to predetermined Cusp Overlap view (based on preprocedural CT planning but **usually an LAO view**)
  - Position system with the catheter marker band at the **midpoint of pigtail catheter**
  - Begin slow deployment targeting a 3mm implant depth



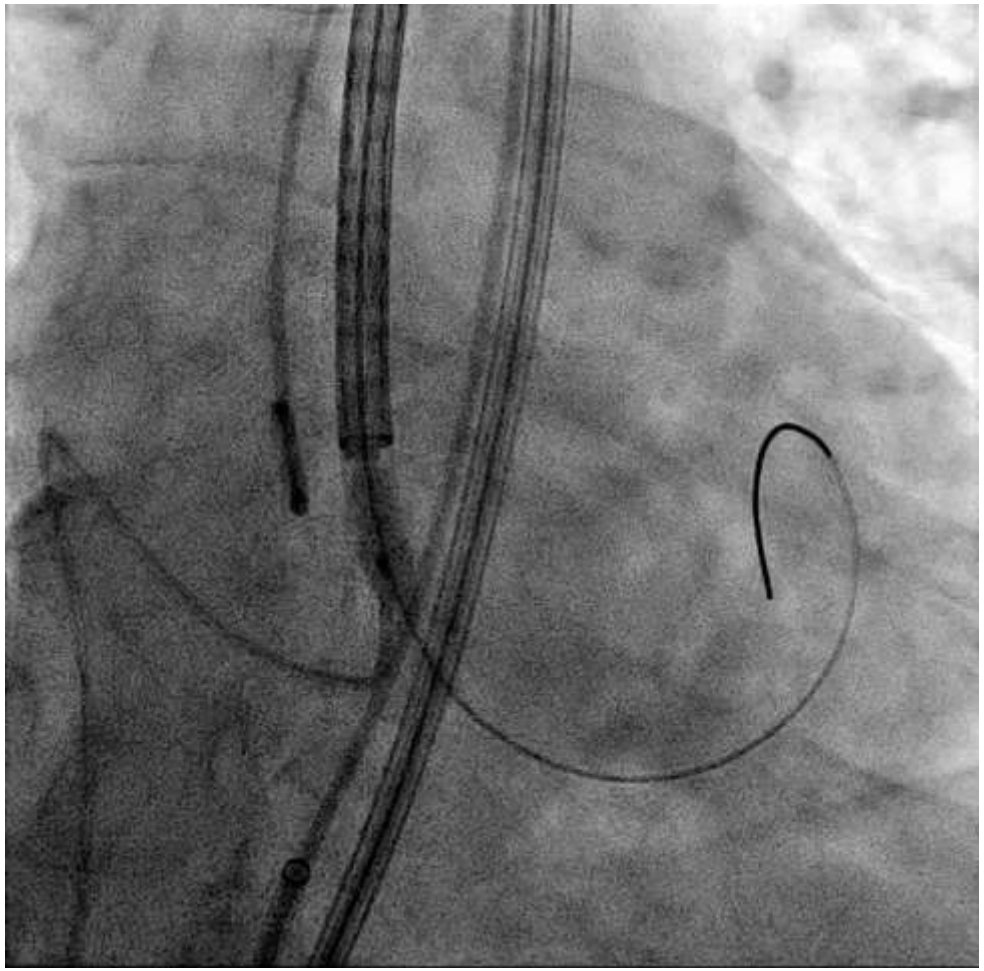


3 mm Target Implant Depth

Cusp Overlap Technique

New Technique for Controlled and Precise Implantation

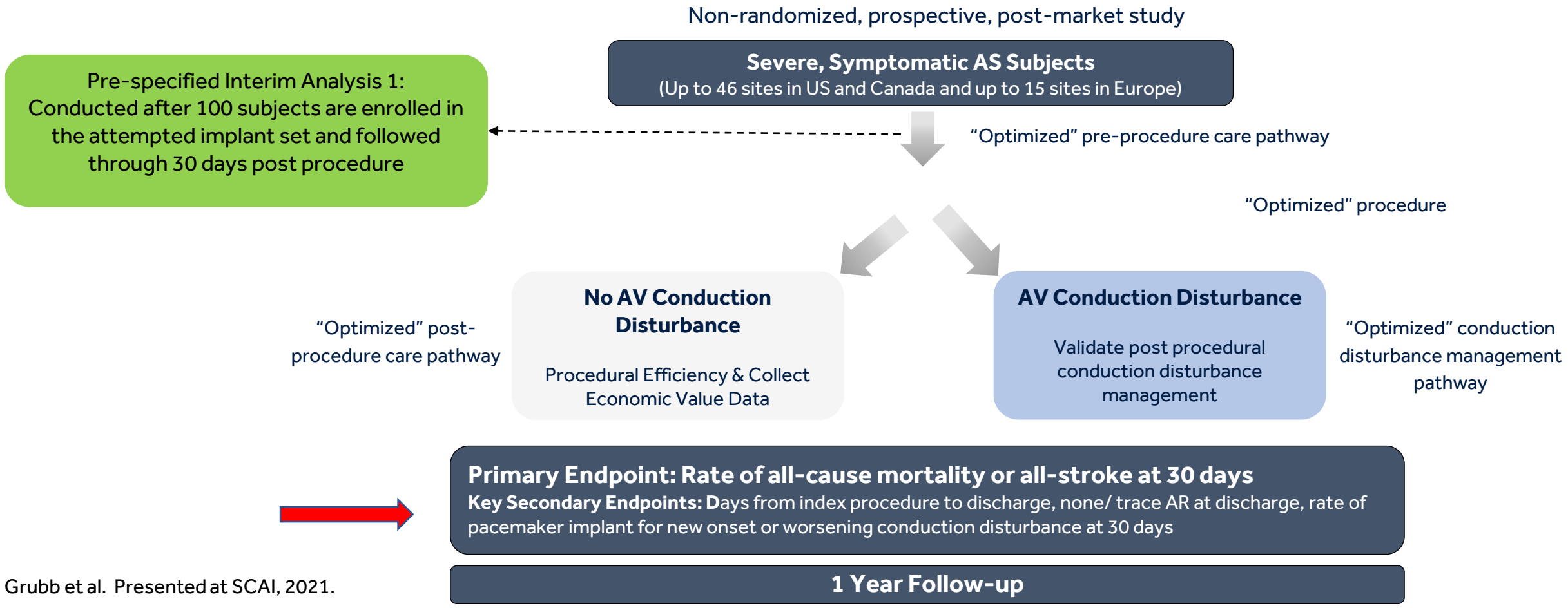
- Procedural changes in addition to the new projection view:
    - Starting with the marker band at the midpoint of the pigtail **to help avoid advancing the bioprosthesis into the ventricle where the inflow portion of the valve may flare and interact with the membranous septum and conduction tissues.**
    - Using a stiffer, double-curved **Lunderquist** wire



Clinical Data with Cusp Overlap

OPTIMIZE PRO Study

The primary objective of the Optimize PRO study is to investigate outcomes associated with utilizing the cusp overlap technique during valve deployment as well as a pre- and post-procedural TAVR care pathway centered on safe early discharge.



Grubb et al. Presented at SCAI, 2021.

Clinical Data with Cusp Overlap

OPTIMIZE PRO Patient Characteristics

Mean ± SD or %	Roll-In (N=71)	Main Cohort (N=100)	Combined (N=171)
Age (years)	77.4 ± 8.1	79.3 ± 6.5	78.5 ± 7.3
Body mass index (kg/m^2)	29.7 ± 5.9	29.5 ± 5.6	29.6 ± 5.7
Male (%)	56.3	54.0	55.0
NYHA III/IV	40.8	33.0	36.3
STS-PROM (%)	2.9 ± 1.9	2.9 ± 2.1	2.9 ± 2.0
Diabetes mellitus	23.9	34.0	29.8
Hypertension	90.1	82.0	85.4
Peripheral arterial disease	8.6	9.0	8.8
Previous percutaneous coronary intervention	23.9	26.0	25.1
Arrhythmia history	22.5	30.0	26.9
Pre-existing RBBB (baseline ECG core lab)	5.7	6.1	6.0
Pre-existing PPI/ICD	0	0	0

Grubb et al. Presented at SCAI, 2021.

Clinical Data with Cusp Overlap

OPTIMIZE PRO Procedural Outcomes

Median [1st,3rd quartile], Mean ± SD or %	Roll-In (N=71)	Main Cohort (N=100)	Combined (N=171)
Total time in procedure room (minutes)	114 [91, 144]	117 [93, 143]	115 [92, 144]
Femoral access site	100	100	100
Lunderquist extra-stiff guide wire	54.9	72.7	65.3
Anesthesia type			
Conscious sedation/monitored anesthesia care	84.5	83.0	83.6
General anesthesia	15.5	17.0	16.4
Bioprosthesis used			
Evolut PRO	9.9	15.0	12.9
Evolut PRO+	90.1	85.0	87.1
Pre-balloon valvuloplasty	46.5	46.0	46.2
Post-dilatation	12.7	17.0	15.2
Embolic protection device used	38.0	42.0	40.4
Implant depth, NCC (mm), core lab	3.3 ± 3.0	3.3 ± 2.9	3.3 ± 2.9

Grubb et al. Presented at SCAI, 2021.

Clinical Data with Cusp Overlap

OPTIMIZE PRO Procedural Outcomes

%	Roll-In (N=71)	Main Cohort (N=100)	Combined (N=171)
Conduction Disturbance Group			
No ECG changes	50.7	61.0	56.7
Pre-existing RBBB and no ECG changes	5.6	3.0	4.1
New onset LBBB	28.2	25.0	26.3
ECG changes & pre-existing RBBB, LBBB, IVCD, or 1st degree AV block	12.7	8.0	9.9
Peri-procedural HAVB	2.8	3.0	2.9
Post procedure recovery location			
ICU	29.6	22.0	25.1
PACU / Procedure recovery room	63.4	73.0	69.0
Stepdown floor or telemetry unit	74.6	80.0	77.8
Number of valves implanted			
1	100	100	100
Discharged with external Holter monitor	25.4	25.0	25.1

Grubb et al. Presented at SCAI, 2021.

Clinical Data with Cusp Overlap

OPTIMIZE PRO 30-day Outcomes

The interim analysis of Optimize PRO Study demonstrates excellent safety outcomes at 30-days:

- No deaths
- No disabling strokes
- Single-digit pacemaker implantation rates (8.8% for combined cohort).

Kaplan-Meier rates as n (%)	Roll-In (N=71)	Main Cohort (N=100)	Combined (N=171)
All-cause mortality or all stroke	0 (0)	5 (5.0)	5 (2.9)
All-cause mortality	0 (0)	0 (0)	0 (0)
All stroke	0 (0)	5 (5.0)	5 (2.9)
Disabling stroke	0 (0)	0 (0)	0 (0)
Non-disabling stroke	0 (0)	5 (5.0)	5 (2.9)
Life threatening or disabling bleed	1 (1.4)	1 (1.0)	2 (1.2)
Major vascular complications	1 (1.4)	0 (0)	1 (0.6)
Reintervention	0 (0)	0 (0)	0 (0)
Permanent pacemaker implant	5 (7.0)	10 (10.0)	15 (8.8)
Myocardial infarction	0 (0)	2 (2.0)	2 (1.2)
New-onset LBBB (site reported)	17 (23.9)	27 (27.0)	44 (25.7)
Hospital readmission (site reported)	3 (4.2)	8 (8.1)	11 (6.5)

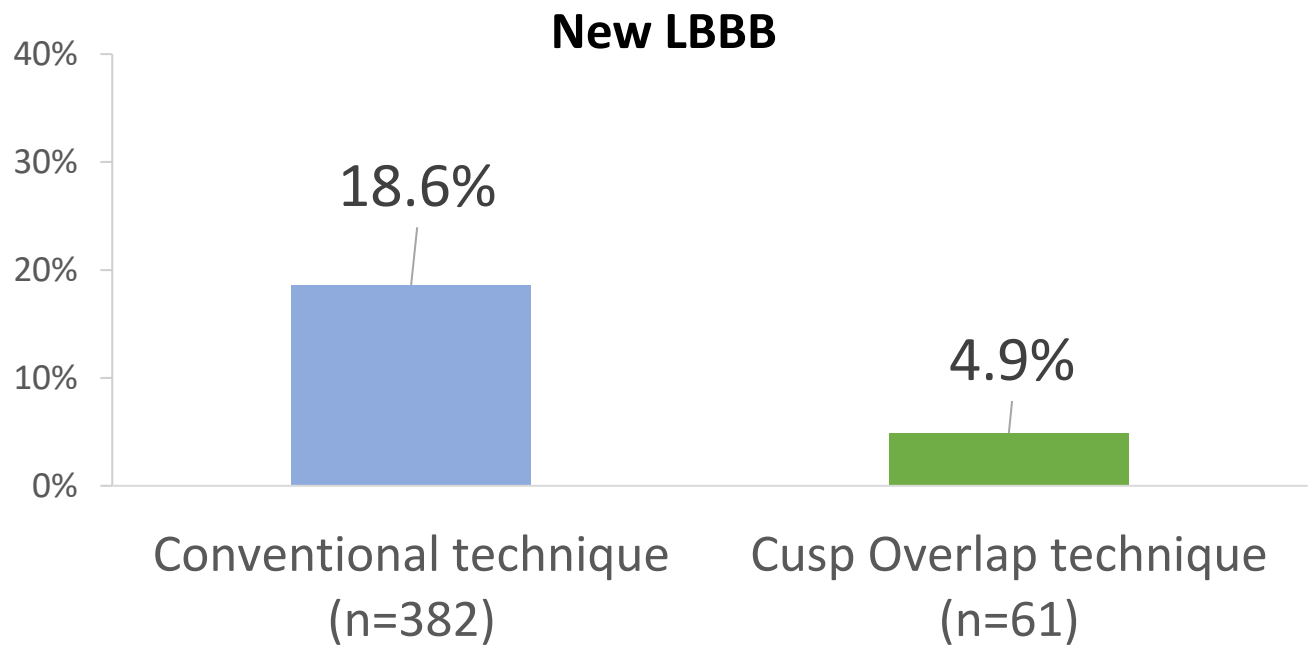
Grubb et al. Presented at SCAI, 2021.

Real World Experience

Cusp Overlap in Latin American and Europe

Recent evidence from centers in Latin America and Europe on use of the cusp overlap technique show single-digit rates of pacemaker implantation and new-onset left bundle branch block.

Country	Patients	New PPI
Argentina	36	2
Brazil	13	1
Chile	6	0
Colombia	10	0
Costa Rica	31	2
Mexico	15	1
Uruguay	3	0
TOTAL	114	6
TOTAL w/o previous PPI	105	
Effective PPI rate	**5.7%**	

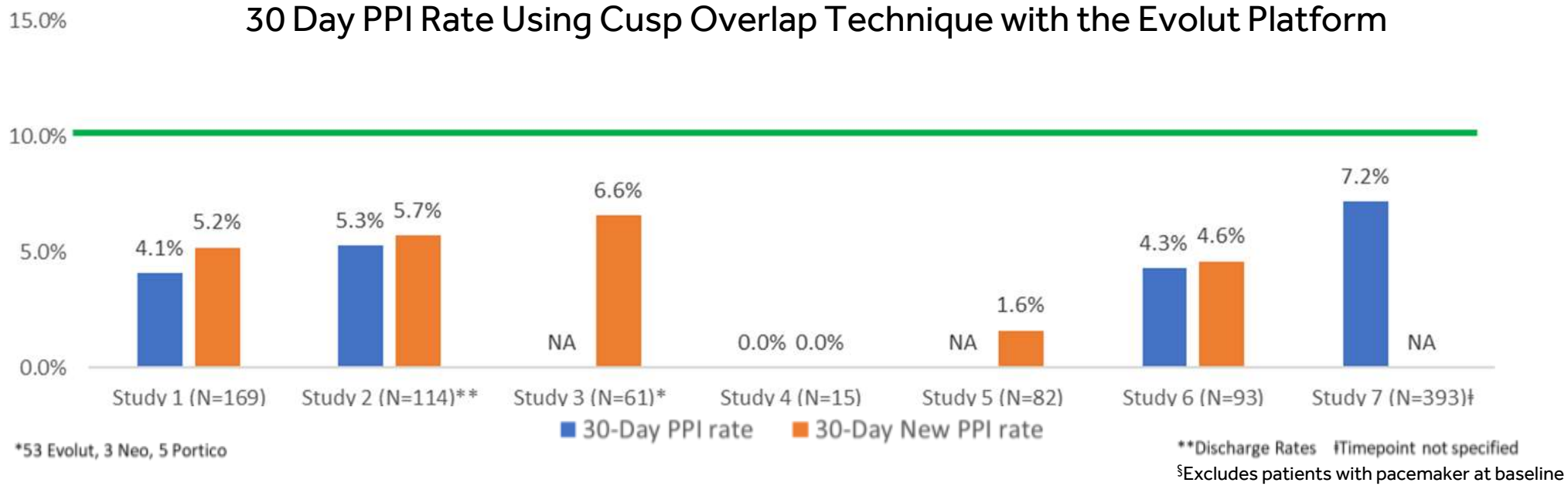


Mendiz et al. J Invas Cardiol 2021.

Real World Experience

Cusp Overlap Technique and Low Pacemaker Rates

Cusp overlap technique has been associated with single-digit pacemaker rates in several other single center and multicenter clinical studies.



Study 1- Gada et al., presented at TCT 2020. *Reduction of rates of permanent pacemaker implantation with 34 mm Evolut R using cusp overlap technique;* **Study 2** - Gada et al., presented at TCT 2020. *Reproducibility of cusp overlap technique to reduce permanent pacemaker implantation with Evolut – the Latin American Experience;* **Study 3**- Mendiz et al., Presented at TCT 2020. *Cusp Overlapping Technique for TAVR Procedures with Self-Expandable Valves;* **Study 4**- Giuliani et al., presented at TCT 2020. *Impact of Cusp-Overlap technique on pacemaker requierement among transcatheter aortic valve replacement;* **Study 5**- Gada et al., presented at TCT 2019. *Site-level variation and predictors of post-TAVR permanent pacemaker implantation in the Evolut low Risk Trial;* **Study 6**- Pisaneillo et al., ACC 2020. *Implantation of self-expanding transcatheter heart valves in the annular plane is associated with low implant depths and pacemaker rates;* **Study 7**- Aljabbary et al., presented at CCC 2020. *Cusp Overlap Method for Self-Expanding Transcatheter Aortic Valve Replacement.*

New Implant Technique: What's Different?

Summary

What's different with the Cusp Overlap view and technique?

- Overlap the right and left cusps with **isolation of the noncoronary cusp**
- With Evolut platform valves, **new procedural approaches include starting a slow valve deployment with the marker band at midpoint of the pigtail catheter, as well as use of a stiff Lunderquist wire**

What's different with outcomes?

- **Low rate of new-onset conduction disturbances and pacemaker implantation rate**
  - OPTIMIZE PRO trial showed a new pacemaker implantation rate of 8.8%
  - Real world use of cusp overlap in lower volume Latin American centers yielded a 4.9% rate of new-onset LBBB

As TAVI continues to expand to younger, lower risk patients, there is a great need to adopt best practices when it comes to avoiding persistent conduction disturbances.

The cusp overlap technique is safe and effective at providing a controlled, precise implant with a reduced risk of interfering with the native conduction system.