

¿Qué es lo siguiente en el cierre de orejuela?

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Left Atrial Appendage Closure Through the Years



Challenges of Older Generation Left Atrial Appendage Closure Devices

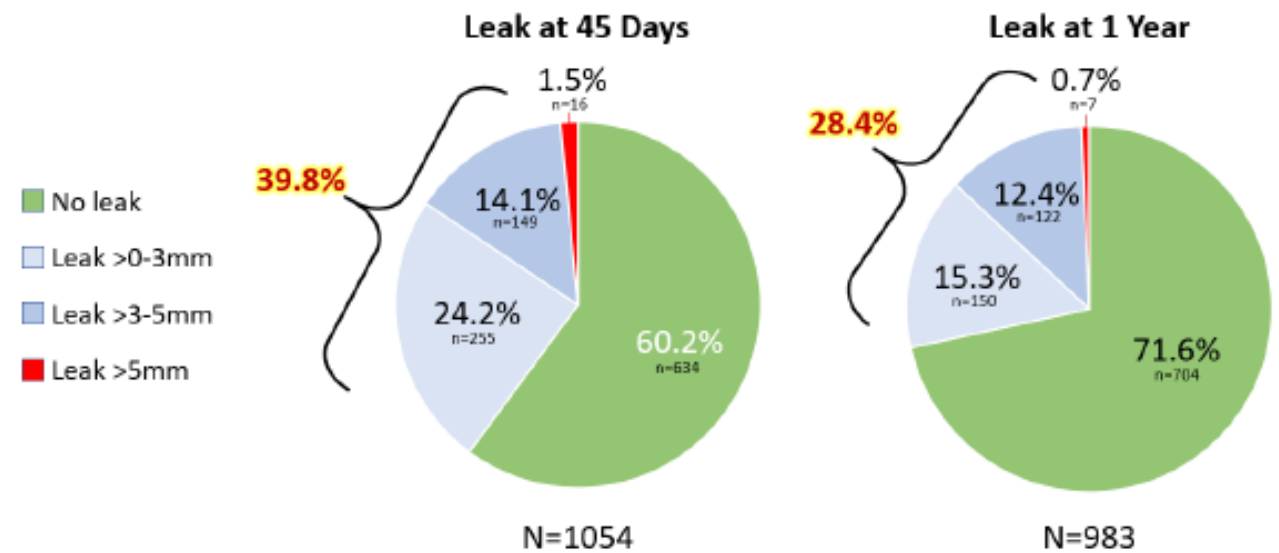
Presence of Peri-Device Leak

NCDR LAAO Data¹ Legacy WATCHMAN Patients

Leak Prevalence at 45 Days	
Leak Size	N = 51,333
No Leak	37,696 (73.4%)
Leak >0-5mm	13,258 (25.8%)
Leak >5mm	370 (0.7%)

} 26.5%

Clinical Trial Data² Composite of Legacy WATCHMAN Patients in PROTECT AF, PREVAIL, and CAP2

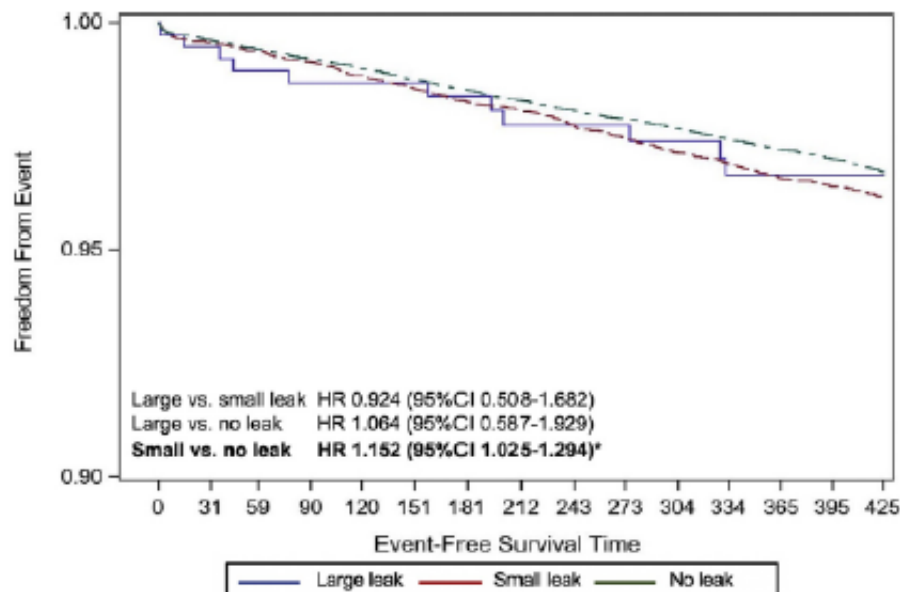


Challenges of Older Generation Left Atrial Appendage Closure Devices

Impact of Peri-Device Leak on Thromboembolic Events

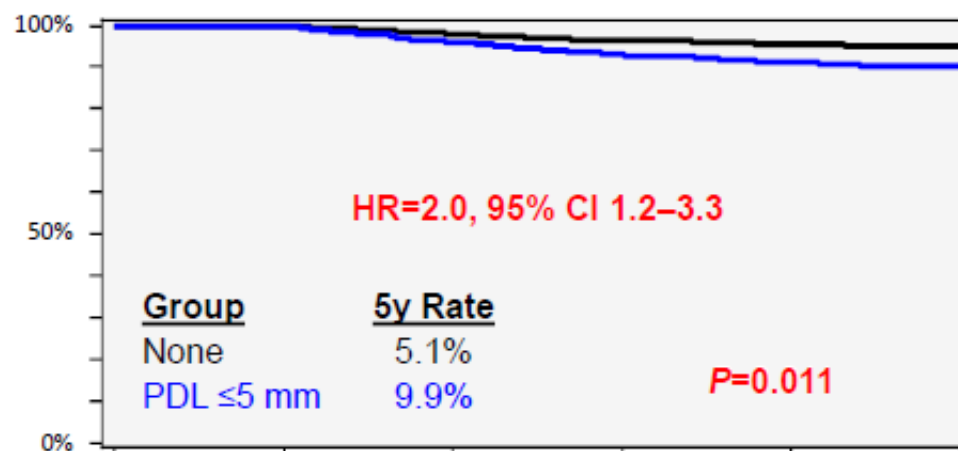
Leak presence at 45 days or one year has an impact on long-term thromboembolic events

Any Stroke, TIA, Systemic Embolism by Leak at 45 Days¹
 No (0 mm) leak vs small (>0-5mm) leak vs large (>5mm) leak
 (N = 51,333 Legacy WATCHMAN subjects)



* Statistically significant

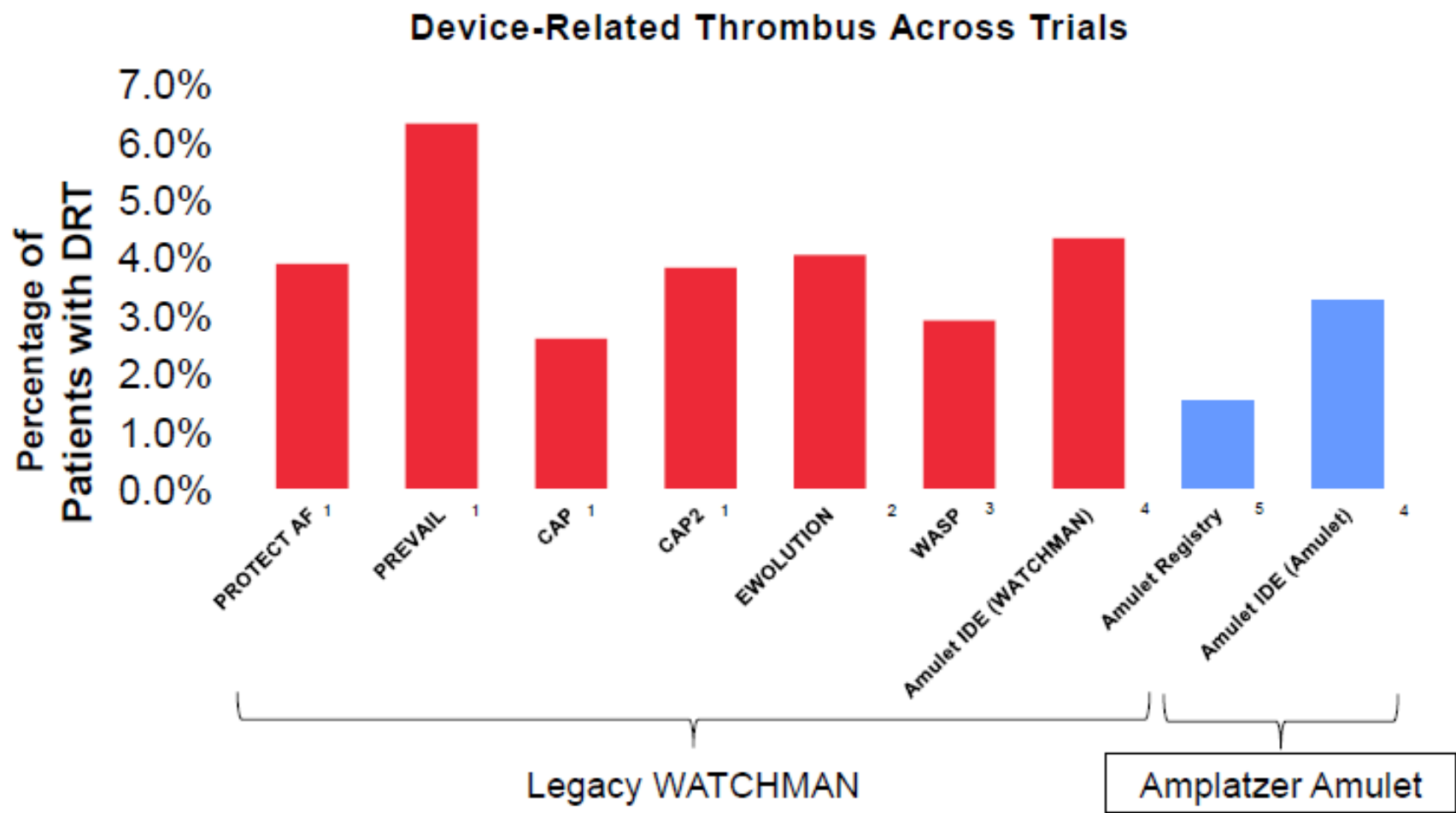
Adjusted 5-Year Rates of Ischemic Stroke/SE by Leak at 1 Year²
 None vs PDL ≤5 mm[§]
 (N=976 Legacy WATCHMAN subjects; excludes leaks >5mm)



§ Landmark analysis from the time of leak assessment (1 year). Between-group differences in baseline patient demographics, medical history, bleeding/stroke risk factors, and LAA size/complexity were assessed. Outcomes were adjusted for mortality using stepwise procedure in a Cox proportional hazards regression model for univariate variables with P ≤ 0.2.

Challenges of Older Generation Left Atrial Appendage Closure Devices

Device-Related Thrombus Prevalence



Across nine trials, DRT was observed in 3.4% of patients

Addressing Leak and Device-Related Thrombus

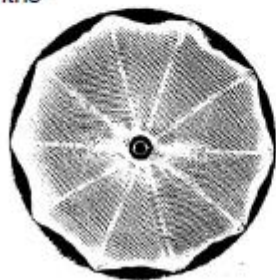
Device structural changes

Legacy WATCHMAN



10 strut frame

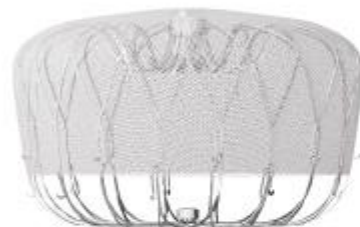
71.6% of subjects had complete closure at 12 months¹



3.74% of subjects had device-related thrombus reported through 60 months of follow-up²

WATCHMAN FLX

18 strut frame
Designed for conformability to appendage and improved sealing



Less exposed metal on the threaded insert
Designed to reduce device-related thrombus

PINNACLE FLX Results

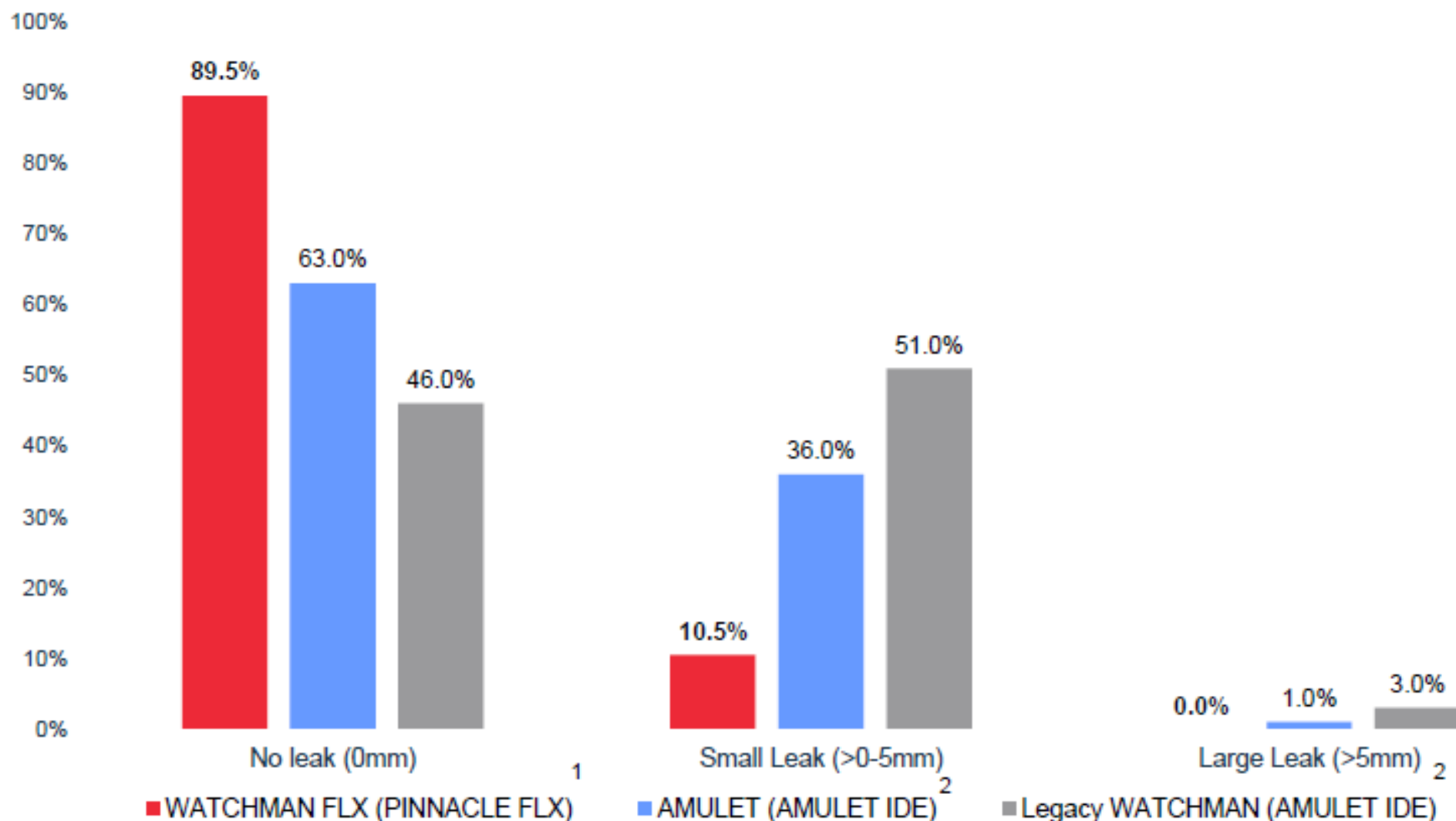
89.5% Of subjects had complete closure at 12 months³

1.8% Of subjects had a device-related thrombus reported through 24 months of follow-up⁴

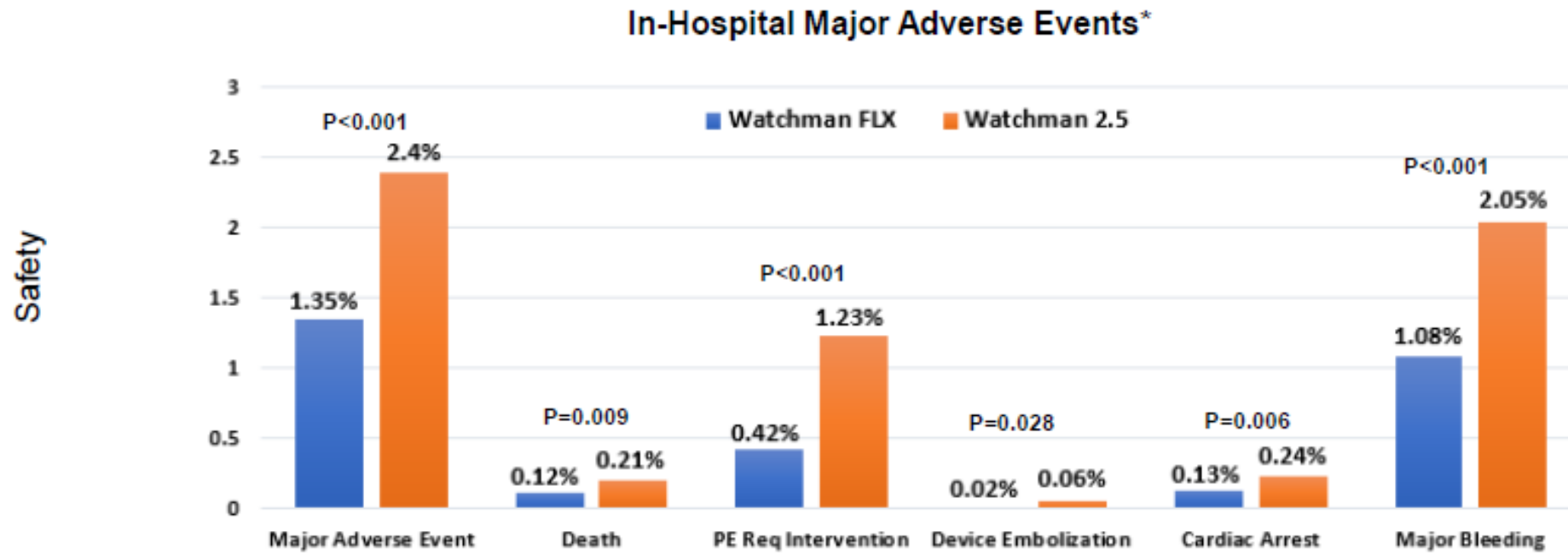
Improvements in Leak Across Device Iterations

Newer devices have less leak than previous generations

Corelab Adjudicated 1-year Residual Jet



Newer devices are associated with fewer in-hospital major adverse events and shorter procedure times



*Composite of death, cardiac arrest, stroke, TIA, ICH, SE, major bleeding, major vascular complication, MI, pericardial effusion requiring intervention, and device embolization

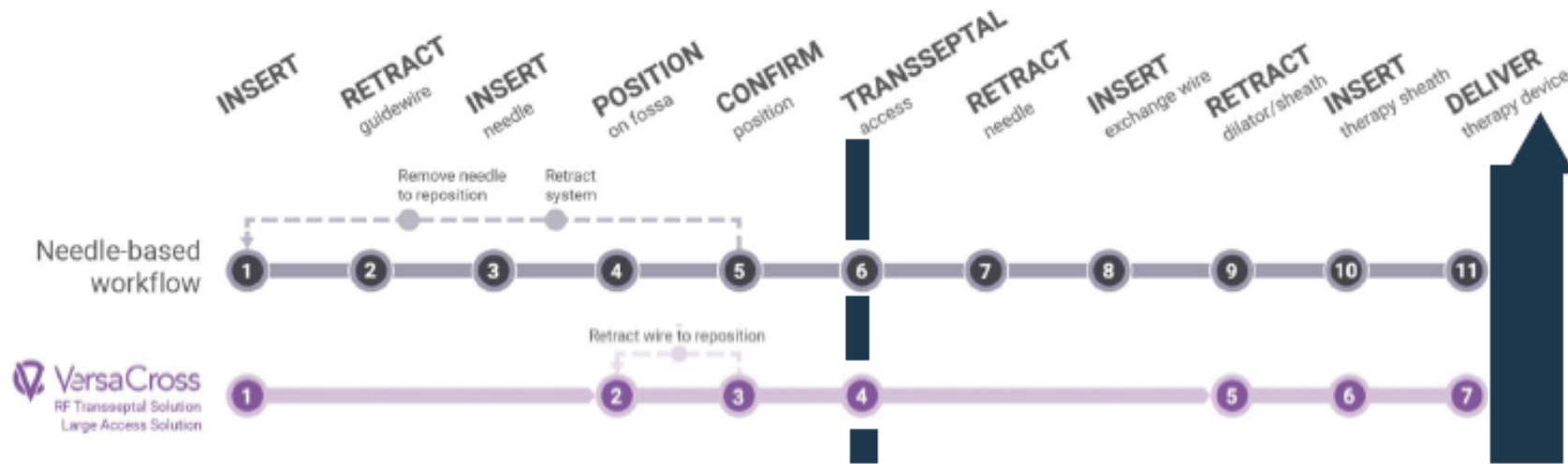
Procedure Duration

WATCHMAN 2.5: 87 minutes

WATCHMAN FLX: 83 minutes

- The procedure start time is the time that the patient entered the location in which the procedure is intended to be performed
- The procedure stop time is the time when the operator breaks scrub at the end of the procedure (NCDR data dictionary)

Advancements in transseptal technology have also lead to reduced complications and greater efficiency



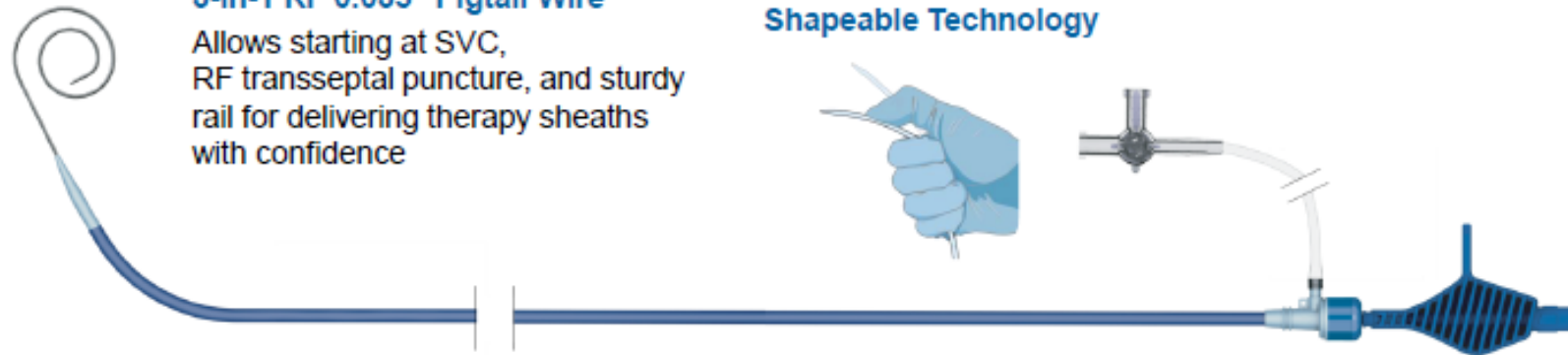
NRG® RF needle reduced incidence of tamponade vs. mechanical needle (p=0.031)³

Compared with needle-based workflow, the VersaCross® RF System results in:

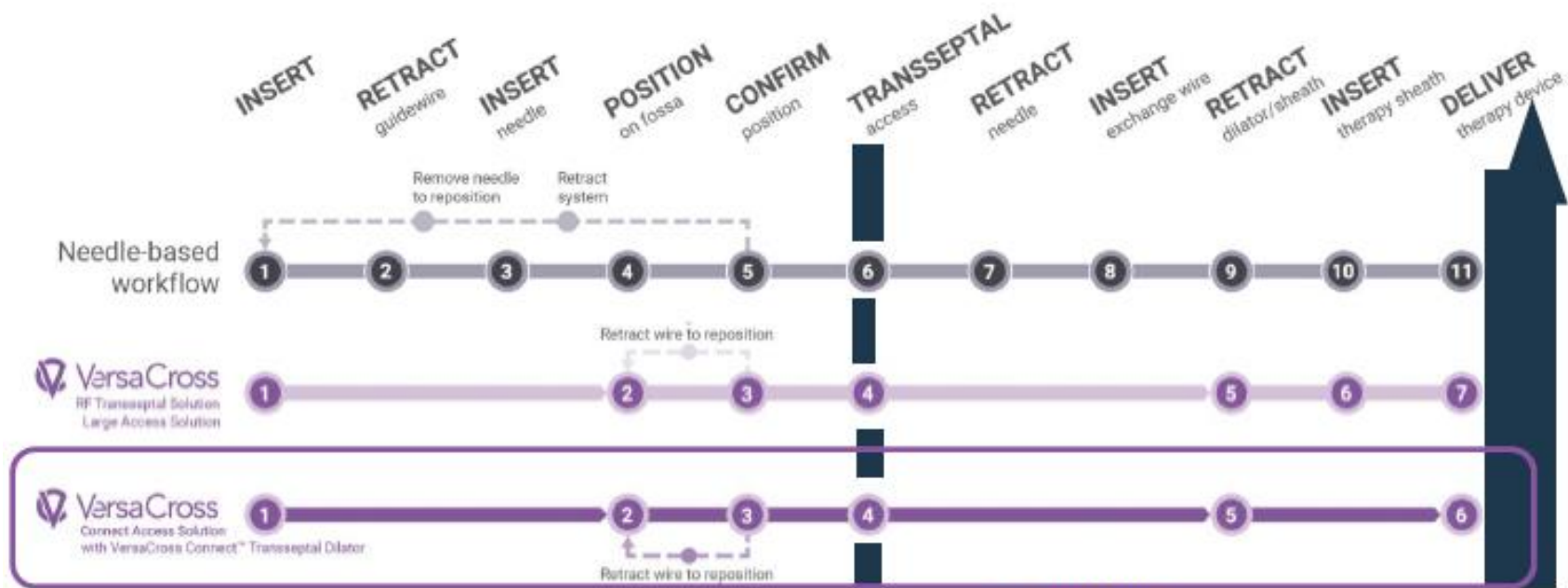
- **2X faster** WATCHMAN sheath delivery (6.7 ± 2.4 min vs. 13.4 ± 5.4 min (p=0.002))¹
- **13% faster** time to final implant release (p=0.03)²
- **67% lower** fluoroscopy dose (p=0.006)²

3-in-1 RF 0.035" Pigtail Wire
Allows starting at SVC,
RF transseptal puncture, and sturdy
rail for delivering therapy sheaths
with confidence

**Dilator with TRUform™
Shapeable Technology**



VersaCross® Connect Transseptal Dilator: Zero-Exchange WATCHMAN Sheath Delivery



Streamlined LAAC workflow eliminates unnecessary device exchanges

Reduced exchanges, device manipulation and procedure time may lead to reduced risk of embolic events^{4,5}



OMNIVIZ™ Technology



Seamless Transition



Dilator with TRUform™ Shapeable Technology



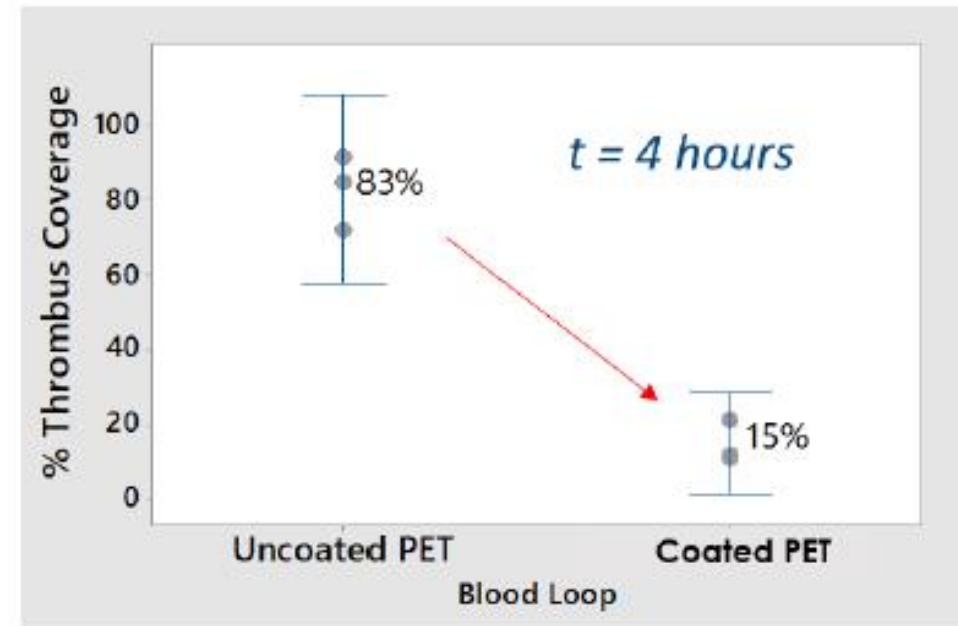
Snap Lock



Next Steps in Device Design:

Hemocompatible device coatings may further reduce thrombogenicity and improve endothelialization

Blood Tests	Bovine Blood	Human Blood Loop
Materials	Fabric	Full Device
Time	10 minutes	4 hours



Results: Increased hemocompatibility of the coated fabric resulted in less acute thrombus

Next Steps: Coatings tested in challenging canine studies

Utilization of a challenging canine pre-clinical model for thrombogenicity to evaluate the hemocompatibility of different candidate designs

Study Design

- N = 12 canines
- 6 in the uncoated device arm
 - 6 in the coated device arm

Canines were given no OAC or APT for the duration of the study

Study Results

Control (Uncoated)
[Same animal, different time points]

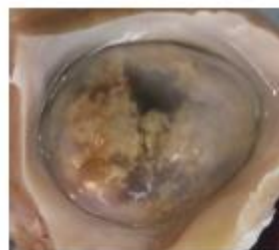
Coated
[Same animal, different time points]

14 Days

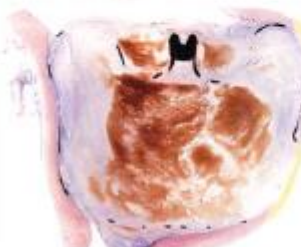
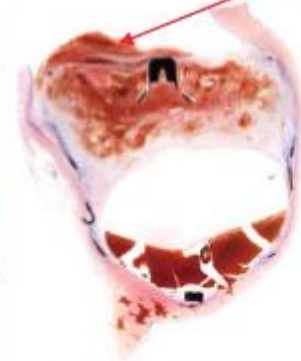


*Surface thrombus highlighted in red

45 Day Explants



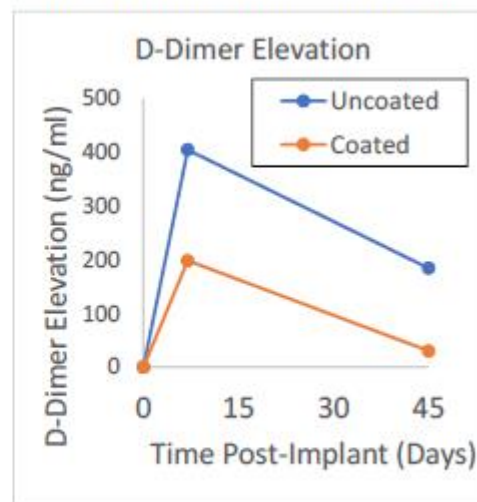
Histology



Complete endothelialization

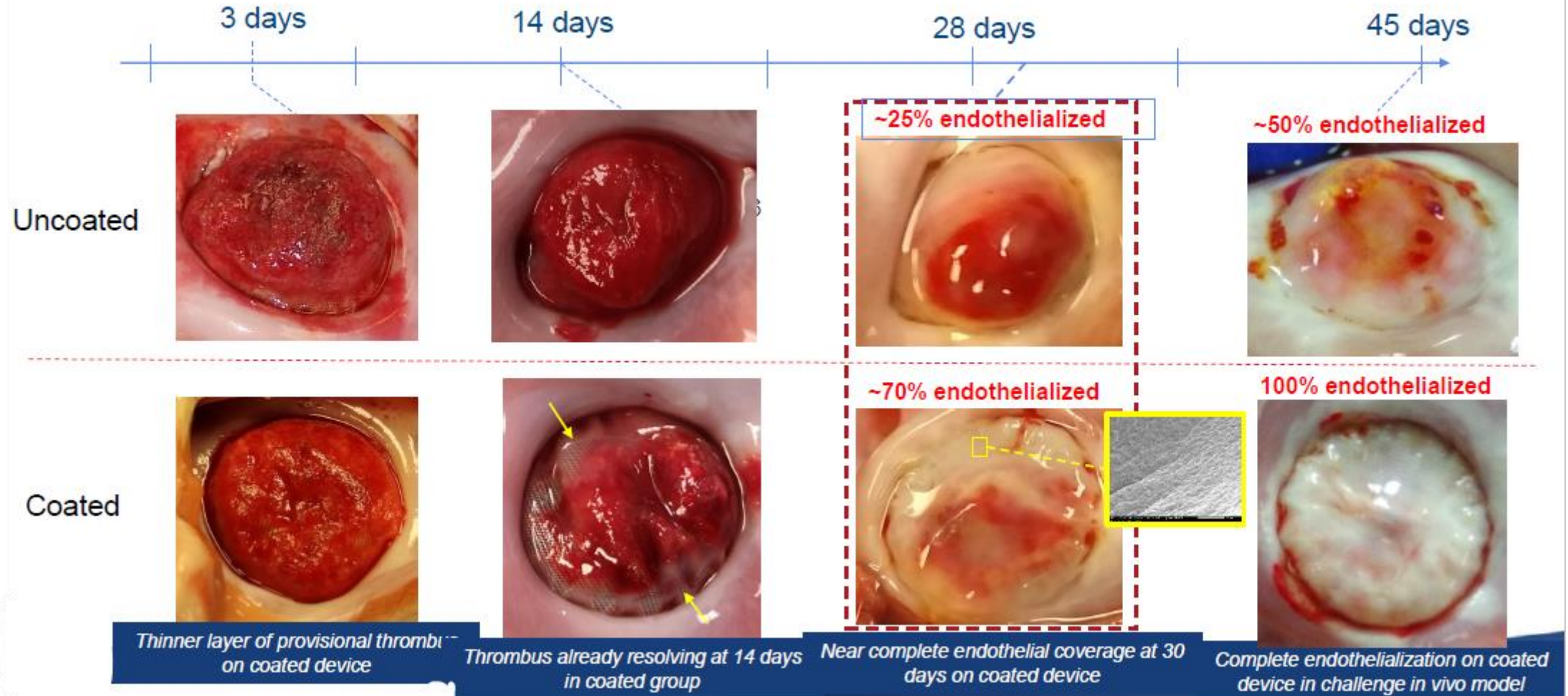
Unresolved thrombus

Less activation of coagulation system (D-Dimer) in coated group



Stages of Healing: A timeline

Coated devices showed faster healing in a challenging canine model (no OAC or APT)



Summary of Results

- Blood Loop Results: Increased hemocompatibility led to less acute thrombus in the coated fabric group
- Canine Results: Better performance in the coated group across multiple measures of healing including d-dimer, surface thrombus, and endothelialization

Is a conscious sedation 4D ICE guided procedure the future?

- Current ICE allows non-GA single operator procedure, but imaging is sub-optimal potential compromising procedural quality / safety
- Next generation ICE has TEE like resolution, X-plane with color, 3D recon, and MPR reconstruction which may allow an ICE guided procedure without imaging compromises



Conclusions

- LAAC technology continues to advance to optimize procedural and long-term outcomes
 - Innovations in device design and TS technology have improved safety and efficiency
 - Innovations in device design have reduced leaks and improved efficacy
 - Hemocompatibility technology is promising to reduce DRT

