A Validation Study of the OpSens Left Ventricle Pressure Guidewire

Philippe Généreux, MD, FRCPC, FACC

Interventional Cardiologist

Director, Structural Heart Program, Gagnon Cardiovascular Institute, Morristown Medical Center, NJ

Disclosure Statement of Financial Interest

Abbott Vascular: Consultant, advisor, speaker Fees; Abiomed: Consultant, advisor, speaker fees; BioTrace Medical: Consultant, advisor, speaker Fees; Boston Scientific: Consultant; CARANX Medical: Consultant; Cardiovascular System Inc.: Consultant, PI Eclipse Trial; Edwards LifeSciences: Consultant, advisor, speaker fees, proctor, research grant, PI EARLY-TAVR trial, PI PROGRESS trial; GE Healthcare: Consultant; iRythm Technologies: Consultant; Medtronic: Consultant, advisor, speaker fees; Opsens: Consultant; Pi-Cardia: Equity, consultant; Puzzle Medical: Equity, consultant; Saranas: Equity, consultant; Shockwave: Consultant, speaker fees; Siemens: Consultant; Soundbite Medical Inc.: Equity, consultant; Teleflex: Consultant; 4C Medical: Consultant, PI Feasibility study

Background

- The hemodynamic evaluation of AS before and after TAVR have relied mainly on echocardiography measurements or hemodynamic assessment derived by catheterization
- While the use cardiac catheterization (double pigtails) represents the gold standard, its use is cumbersome and time consuming, and has decreased with the use of TTE
- However, echocardiographic measurements are highly dependent on acquisition technique, patient anatomy, and vary based on type of aortic valve prosthesis used.
- Discordance and discrepancies exist between echocardiographic and invasive measurements, especially post-TAVR implant, most likely due to inherent limitations of echocardiographic data acquisition in transvalvular gradient and velocity, and other phenomena such as flow recovery

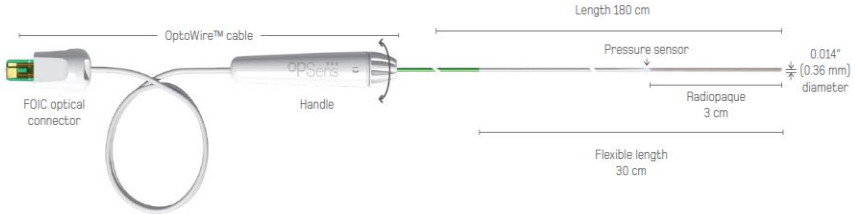
Objectives

- **To establish the degree of agreement related to gradient measurement during TAVR between the OpSens OptoWire III and its new proprietary TAVR algorithm and hemodynamic value derived by catheterization and echocardiogram (TTE and TEE)**

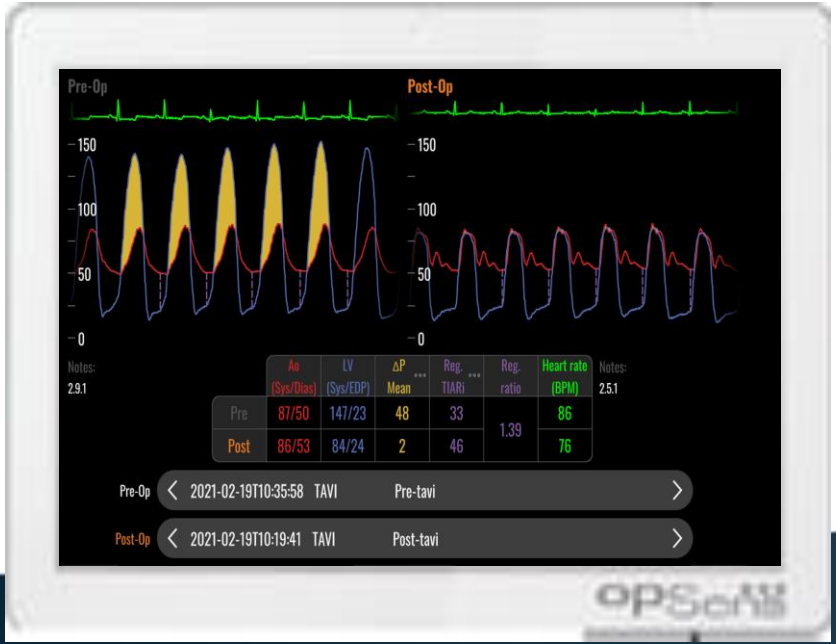
Methods: Study Design

- Prospective, single-arm, single-center study
- Subjects underwent hemodynamic assessment before and after TAVR using standard hemodynamic assessment using 2 pigtails (1 aortic and 1 ventricular) and hemodynamic assessment using the OpSens OptoWire III
- Each subjects also underwent transthoracic and transesophageal echocardiogram before and after TAVR
- Independent echocardiographic core laboratory will analyze all TTE and TEE data
- Investigator initiated study sponsored by Edwards Lifesciences and OpSens Medical (institutional research grant)

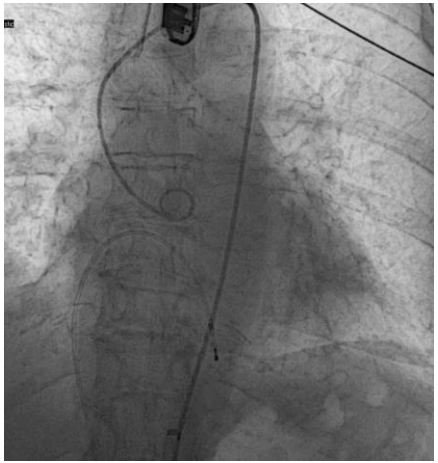
Study Device: OpSens OTW III and its New TAVR Algorithm



Live Gradient and Aortic Insufficiency Assessment

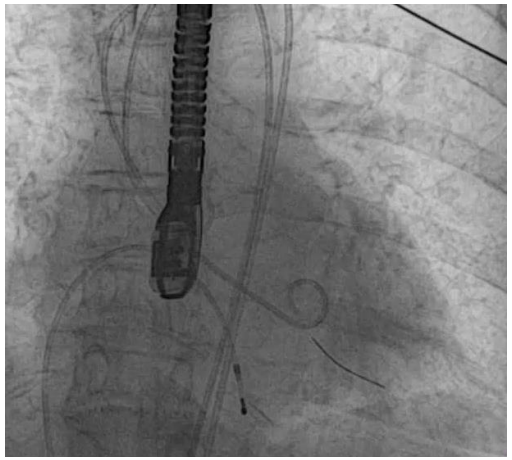


Root angiogram Baseline

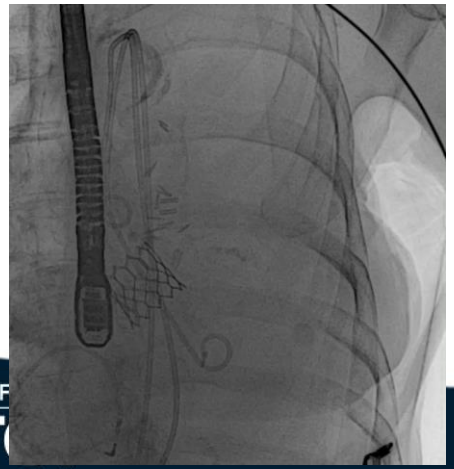


2-pigtail gradient Baseline

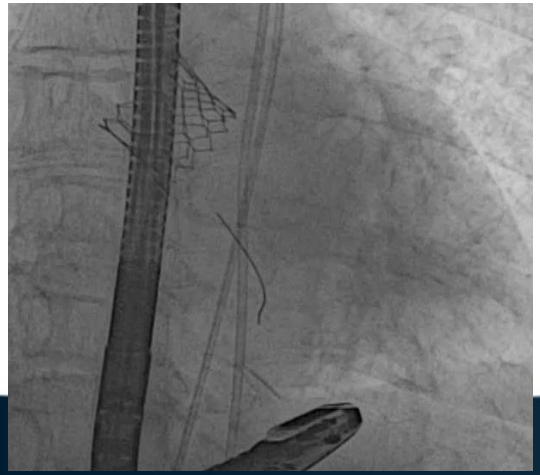
OpSens Wire Gradient Baseline



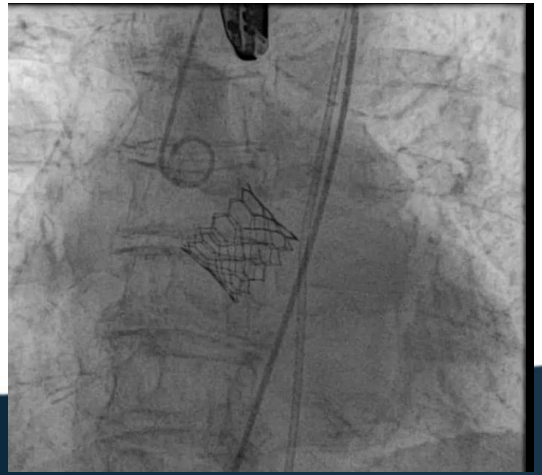
2-pigtail gradient Post-TAVR



OpSens Wire Gradient Post-TAVR



Root angiogram Post-TAVR



Method: Study Population and Primary Endpoint

- Subjects with severe aortic stenosis (AS) undergoing TAVR using the Edwards SAPIEN 3/SAPIEN 3 Ultra system
- 20 consecutive subjects
- **Primary Endpoint:** Final post-TAVR mean gradient correlation between OpSens OptoWire III and hemodynamic value derived by catheterization

Results

- Between July 2021 and September 2021, 20 patients were consented and enrolled in the current study

Baseline Characteristics; n=20

Age	79 (IQR 6.5)
Female	45% (9)
BMI	27.5 (IQR 5.3)
Hypertension	77% (17)
Dyslipidemia	70% (14)
Diabetes	20% (5)
Current Smoker	20% (4)
Atrial Fibrillation	35% (7)

Previous PCI	20% (4)
Previous CABG	10% (2)
Previous PPM	15% (3)
Previous Stroke/TIA	10% (2)
PVD	30% (6)
Severe COPD or O2-dependant	5% (1)
Kidney Disease on dialysis	10% (2)
STS	2.8% (IQR 7.3)

Baseline Characteristics

Transfemoral Approach	100% (20)
Sapien Ultra 23mm	20% (4)
Sapien Ultra 26mm	70% (14)
Sapien 3 29mm	10% (2)
Pre-dilation	0% (0)
Post-dilation	0% (0)
General anesthesia	100% (20)
Rhythm at time of TAVR	
Sinus	85% (17)
Atrial Fibrillation	15% (3)

Pre-TAVR Measurements

Transthoracic Echocardiogram	
AVA (cm^2)	0.76 ± 0.14
Peak Velocity (cm/s)	362 ± 72
Peak gradient (mmhg)	54 ± 21
Mean gradient (mmhg)	33 ± 14
LVEF (%)	53% ± 11
Transesophageal Echocardiogram	
Peak Velocity (cm/s)	376 ± 71
Peak gradient (mmhg)	58 ± 22
Mean gradient (mmhg)	34 ± 13

Pre-TAVR Measurements

Cath 2-Pigtail	
Peak gradient (mmhg)	44±22
Mean gradient (mmhg)	35±14
OpSens OTW III Wire	
Peak gradient (mmhg)	40±18
Mean gradient (mmhg)	35±14

Post-TAVR Measurements

Transthoracic Echocardiogram	
AVA (cm^2)	1.84 ± 0.35
Peak Velocity (cm/s)	165 ± 47
Peak gradient (mmhg)	11.7 ± 6.9
Mean gradient (mmhg)	5.8 ± 3.1
LVEF (%)	55% ± 11
Transesophageal Echocardiogram	
Peak Velocity (cm/s)	166 ± 40
Peak gradient (mmhg)	12.2 ± 5.6
Mean gradient (mmhg)	5.6 ± 2.7

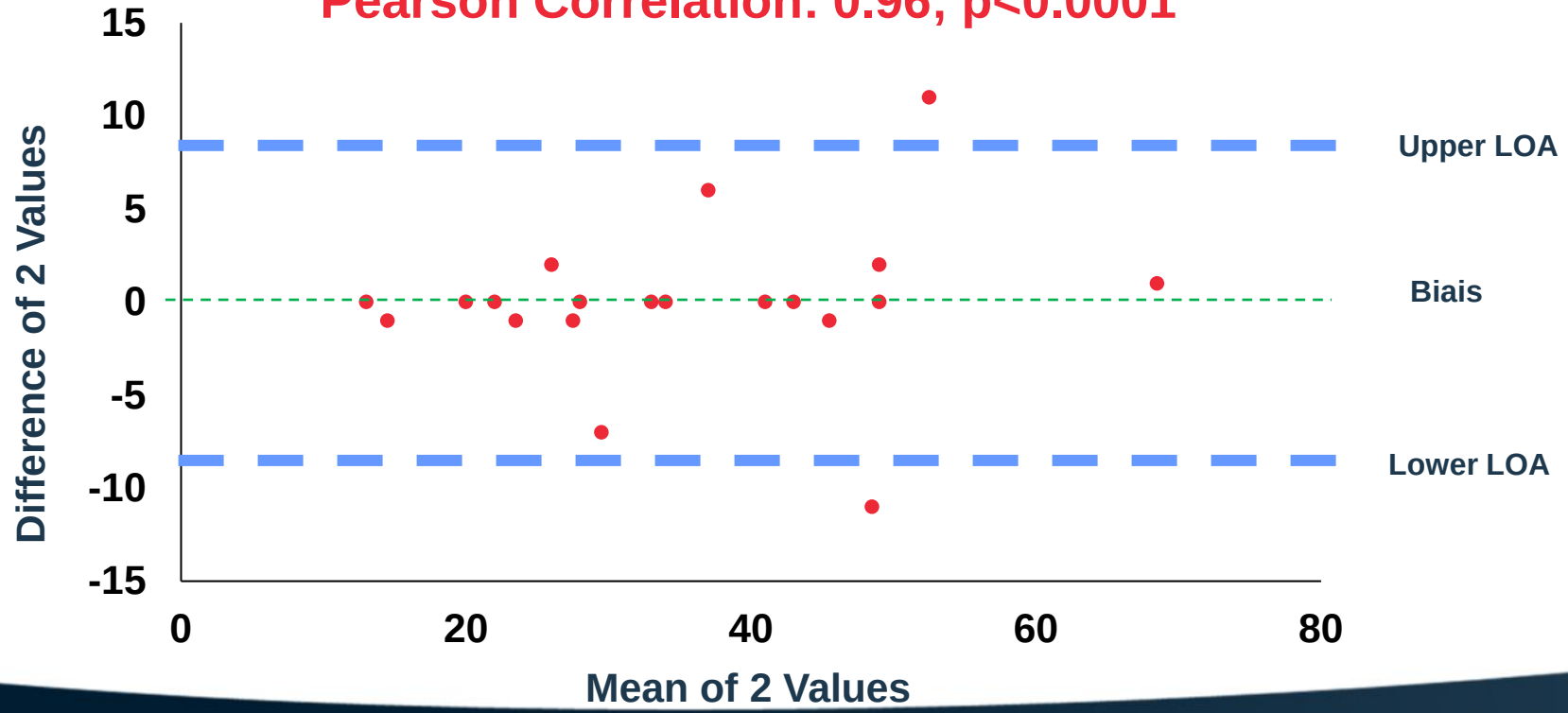
Post-TAVR Measurements

Cath 2-Pigtail	
Peak gradient (mmhg)	3.0±4.1
Mean gradient (mmhg)	2.2±3.5
OpSens OTW III Wire	
Peak gradient (mmhg)	1.1±2.4
Mean gradient (mmhg)	2.8±2.7

Pre-TAVR Mean Gradient

2-Pigtail vs. OpSens Wire; n=20

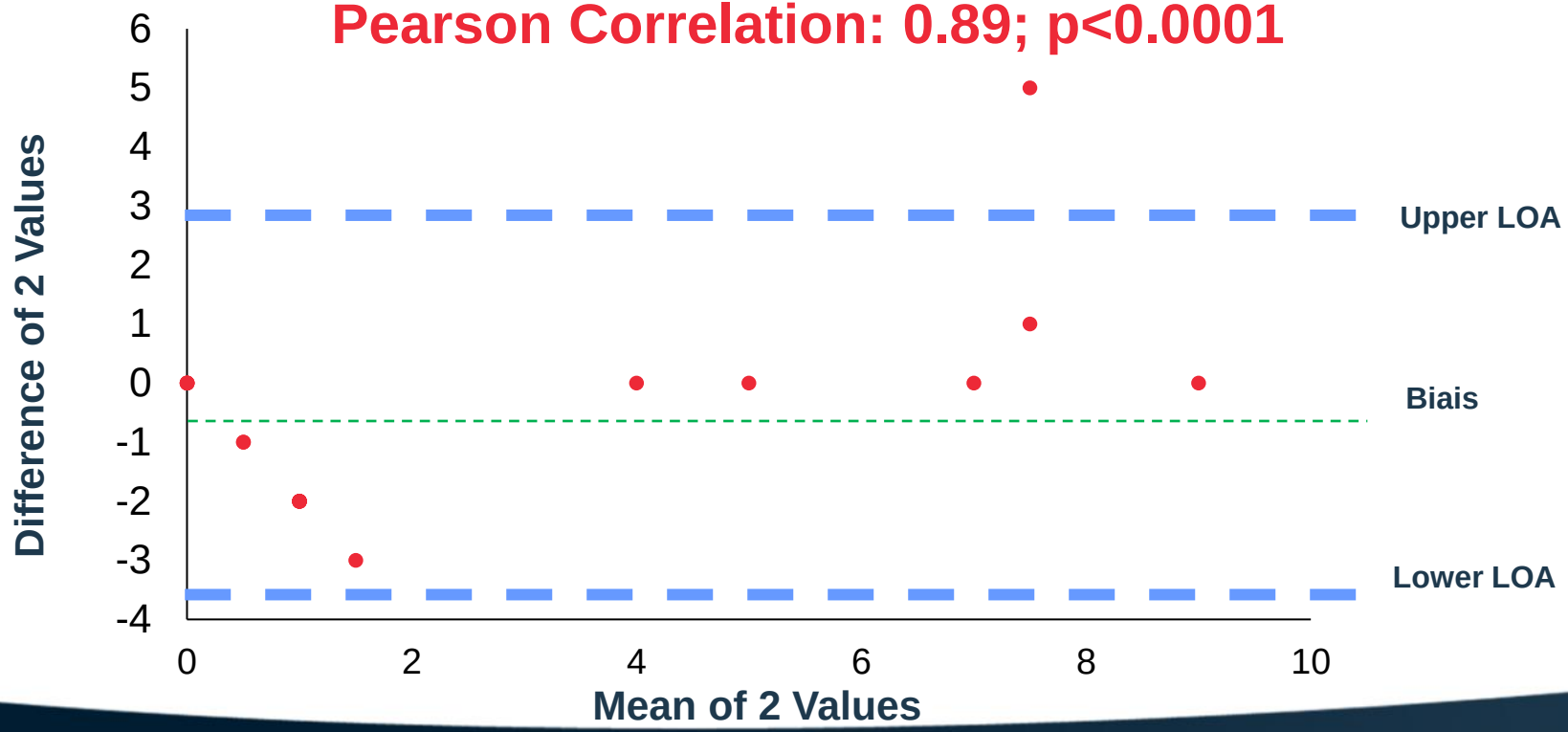
Pearson Correlation: 0.96; p<0.0001



Post-TAVR Mean Gradient

2-Pigtail vs. OpSens Wire; n=20

Pearson Correlation: 0.89; p<0.0001



Correlation Between Different Modalities of Measurement of Mean Gradient Before and After TAVR

Pre-TAVR Mean Gradient		Post-TAVR Mean Gradient	
Modality	*Pearson Correlation*	**Modality**	*Pearson Correlation*
OpSens vs. Cath	***0.96***	***OpSens vs. Cath***	***0.89***
OpSens vs. TEE	0.96	OpSens vs. TEE	0.61
OpSens vs. TTE	0.70	OpSens vs. TTE	0.71
Cath vs. TEE	0.96	Cath vs. TEE	0.55
TEE vs. TTE	0.81	TEE vs. TTE	0.63
Cath vs. TTE	0.84	Cath vs. TTE	0.75

Clinical Endpoints 24hours; n=20

Death	0%
Stroke/TIA	0%
Transfusion	0%
VARC-3 Bleeding complications	0%
VARC-3 Vascular complications	0%
Need for PPM	0%
Conversion to surgery	0%
Adverse event related to OpSens Wire	0%

Discussion

- The OpSens OTW III wire and its new TAVR algorithm demonstrated excellent correlation with measurement derived by 2 pigtails
- Compared to TTE and TEE, The OpSens OTW III wire and its new TAVR algorithm demonstrated the strongest correlation with catheterization measurement, both before and after TAVR

Limitations

- Small number of patients from a single center
- General anesthesia was used for all patients
- Results with different TAVR prosthesis will be interesting
- Timing of measurements were close in time but not simultaneous, especially for TTE
- Atrial fibrillation and arrhythmia during TAVR procedure may explain some of the discordant results observed

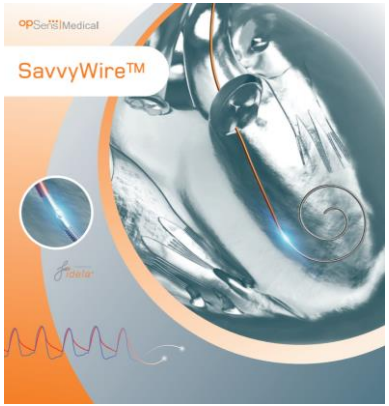
Conclusions

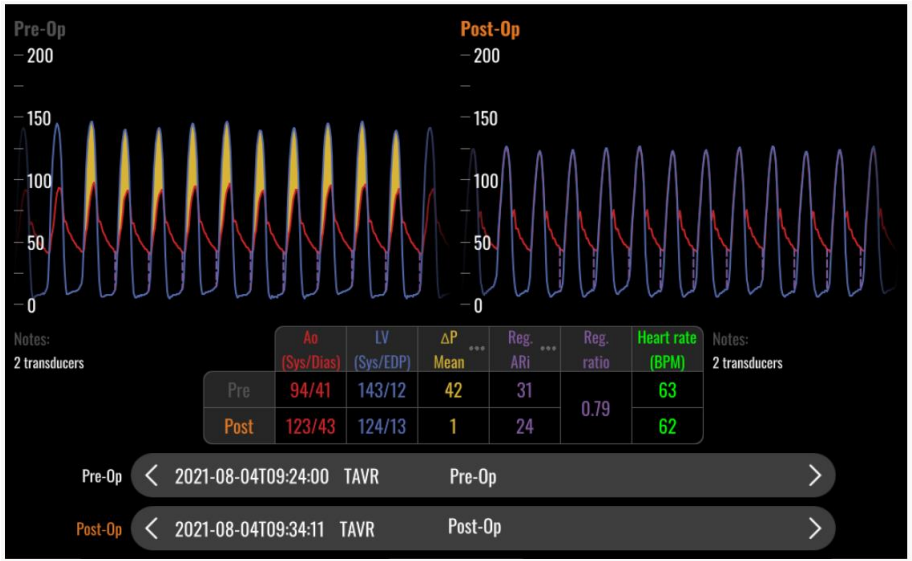
- Hemodynamic assessment derived from the OpSens OTW III wire and its new TAVR algorithm demonstrated excellent correlation with measurement derived by 2 pigtails, both before and after TAVR
- Integration of this new technology within a dedicated TAVR wire with live hemodynamic assessment could bring meaningful value to TAVR operators

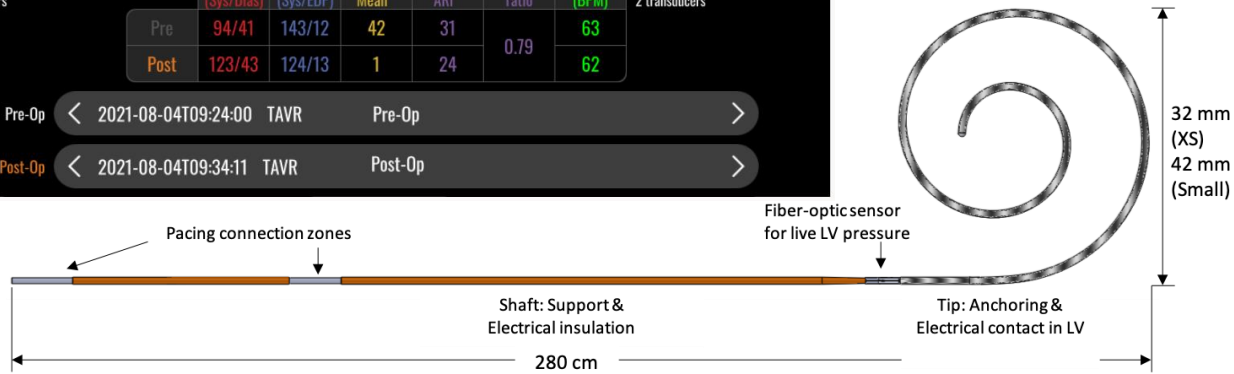
FIH Study SavvyWire™ OpSens

Ongoing in Canada 20 patients

-Workhorse TAVR wire
-Pacing
-Live gradient
-AI assessment







Thank You!

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