Streamlining TAVI: Pacing, Pressure, and Procedural Efficiency

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SavvyWire® Guidewire

The SavvyWire® guidewire is the first and only Sensor-Guided TAVI solution designed to optimize TAVI through efficient, predictable wire performance, hemodynamic measurement and LV pacing capabilities.

PERFORMANCE

High performance TAVI wire.

SavvyWire is engineered for workhorse guidewire performance to support stable valve delivery and positioning.

PRESSURE

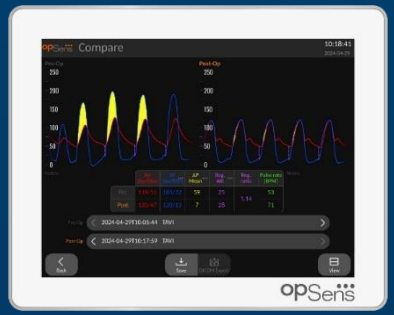
Continuous, invasive hemodynamic feedback.

Powered by Fidela® technology, SavvyWire delivers continuous, accurate hemodynamic measurement and display.

PACING

Rapid LV pacing.

SavvyWire is designed for efficient LV pacing, without the need for adjunct devices or venous access.



SavvyWire® Guidewire

Product Overview

- 0.035" guidewire
- Exchange length for valve catheters, 280cm
- Pre-shaped tip, 2 sizes available: extra small & small
- On-label LV pacing indication
    - PTFE insulative sleeve
- Proprietary technology with Fidela® optical pressure sensor and optical connector

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SavvyWire® Guidewire Portfolio of Studies

First in Human[1]

- 20 patients, 2 sites, 2 physicians
- Safety and Efficacy end-points
- ***Published in*** EuroIntervention
- ***Conclusions: The results of this study showed the safety and efficacy of the SavvyWire for TAVI. The use of this wire would simplify the TAVI procedure (no right ventricular pacing, no catheter-wire exchanges for hemodynamic measurements) and facilitate the clinical decision-making process.***

Post Market Registry[2]

- 60 patients, 3 sites
- All-comers registry
- Prospective collection of data on safety and performance of the SavvyWire
- Presented at TVT2023
- **Conclusions: SavvyWire was safe, effective, and functional for live transvalvular hemodynamic evaluation and rapid pacing during TAVR procedures.**

Accuracy Validation[3]

- 20 patient Accuracy study
- OptoWire III and TAVI algorithm compared to 2-pigtail measurements
- Published in JSCAI
- **Conclusions: Hemodynamic assessment derived by the OpSens wire and its TAVR algorithm demonstrated excellent correlation with measurements 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.**

SAFE-TAVI[4]

- 119 patients, 8 sites
- Prospective, non-randomized, single-arm, multi-center
- Effective rapid pacing end-point
- Published in JACC-CI
- **Conclusions: Use of the guidewire during TAVR procedures appeared to be efficacious and safe. This device could help minimize interventions during the procedure and improve the clinical decision making after transcatheter heart valve deployment.**

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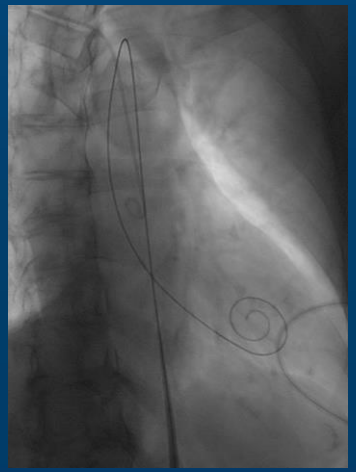
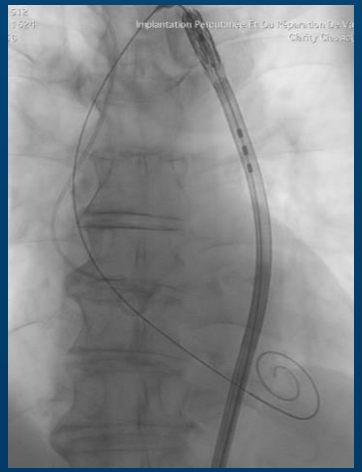
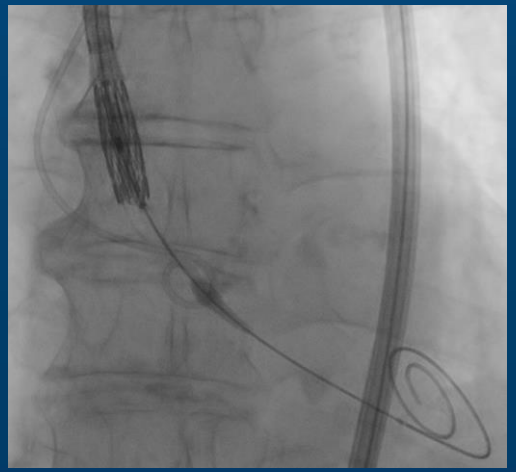
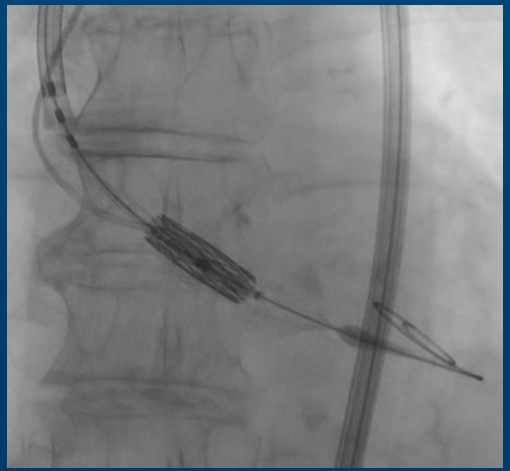
1. ***Rodes-Cabau et al. EuroIntervention 2022;18: e345- e348.*** DOI: 10.4244/EIJ-D-22-00190
2. ***Farjat-Pasos et al.*** J INVASIVE CARDIOL 2024;36(2). doi:10.25270/jic/23.00242
3. P. Généreux et al. JSCAI, VOLUME 1, ISSUE 4, 100309, JULY 2022
4. Regueiro***, et al.*** J Am Coll Cardiol Intv. 2023 Dec, 16 (24) 3016–3023

SavvyWire® Guidewire: Performance

The SavvyWire® guidewire is engineered for workhorse guidewire performance to facilitate stable valve delivery and positioning

Valve Delivery and Positioning

SavvyWire® Guidewire: Performance

First in Human[1] (N=20)

Results	n (%)
Guidewire kink	0 (0%)
Valve malposition/embolization	0 (0%)
Need for a second valve	0 (0%)
Successful valve implantation	20 (100%)

Post-Market SavvyWire Registry[2] (N=60)

Results	n (%)
Guidewire deformation or damages	0 (0%)
LV perforation	0 (0%)

SAFE-TAVI[3] (N=119)

Results	n (%)
Successful valve advancement and positioning into the intended position	117 (99.2%)
Freedom from major complications related to the SavvyWire guidewire	117 (99.2%)

ORIGINAL RESEARCH

FOCUS ON TRANSCATHETER AORTIC VALVE REPLACEMENT

Safety and Efficacy of TAVR With a Pressure Sensor and Pacing Guidewire

SAFE-TAVI Trial

Ander Regueiro, MD, PhD,[a] Alberto Alperi, MD, PhD,[b] Victoria Villalta, MD, PhD,[c] Luis Asmarats, MD, PhD,[d] Jose Antonio Baz, MD,[e] Luis Nombela-Franco, MD, PhD,[f] Alvaro Calabuig, MD, PhD,[g] Antonio Muñoz-García, MD,[h] Manel Sabaté, MD, PhD,[a] Cesar Moris, MD, PhD,[b] Maxime Picard-Deland, MSc,[i] Emilie Pelletier-Beaumont, MSc,[i] Josep Rodés-Cabau, MD, PhD[i]

ABSTRACT

BACKGROUND The SavvyWire (OpSens Inc) is a 0.035-inch preshaped guidewire with dedicated pacing properties and a distal pressure sensor allowing for continuous hemodynamic pressure monitoring.

OBJECTIVES This study sought to determine the efficacy and safety of the guidewire during transcatheter aortic valve replacement (TAVR) procedures.

METHODS This prospective, multicenter clinical study included patients with severe aortic stenosis undergoing TAVR in 8 European centers. The primary efficacy endpoint was defined as effective left ventricular rapid pacing runs with the guidewire translating into a significant systemic pressure drop (below 60 mm Hg). The safety outcome included the absence of major procedural complications related to the guidewire.

RESULTS A total of 121 patients (mean age: 82.2 ± 5.9 years, 50% women) were included in the study, and 119 (98.3%) patients were finally treated with the study device. A balloon-expandable valve was implanted in 45 (37.8%) patients. Predilatation and postdilatation were performed in 89 (74.8%) and 14 (11.8%) patients, respectively. The primary efficacy endpoint was achieved in 116 (98.3%) patients, and the mean aortic systolic arterial pressure achieved during rapid pacing was 46.6 ± 11.3 mm Hg. Hemodynamic assessment with the use of the OptoMonitor 3 (OpSens Inc) without additional catheter exchange was achieved in 117 (99.2%) patients. The safety endpoint was achieved in 117 (99.2%) patients. No procedural mortality, stroke, or ventricular perforation was reported.

CONCLUSIONS The use of the guidewire during TAVR procedures appeared to be efficacious and safe. This device could help minimize interventions during the procedure and improve the clinical decision making after transcatheter heart valve deployment. (SavvyWire Efficacy and Safety in Transcatheter Aortic Valve Implantation Procedures [SAFE-TAVI]; NCT05492383) (J Am Coll Cardiol Intv 2023;16:3016–3023) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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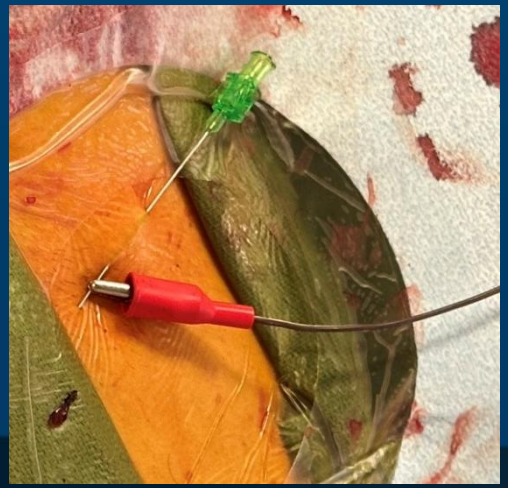
3. Regueiro***, et al.*** J Am Coll Cardiol Intv. 2023 Dec, 16 (24) 3016–3023

SavvyWire® Guidewire: LV Pacing

The SavvyWire® guidewire's combination of an insulated shaft, uncoated tip, and welded core construction is designed to enable direct and reliable electrical current delivery to the heart

- On-label, unipolar left ventricular pacing
- Built-in shaft insulation – left ventricular pacing
- Eliminates RV access for eligible patients



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SavvyWire® Guidewire: LV Pacing

First in Human[1] (N=20)

Results	n (%)
Rapid pacing capture failure	0 (0%)

Post-Market SavvyWire Registry[2] (N=60)

Results	n (%)
Significant loss of capture	0 (0%)

SAFE TAVI[3] (N=119)

Results	n (%)
Adequate LV pacing capture leading to a reduction of systolic aortic pressure <60mmHg	116 (98.3%)

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE
RESEARCH CORRESPONDENCE

A pressure wire for rapid pacing, valve implantation and continuous haemodynamic monitoring during transcatheter aortic valve implantation procedures

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Introduction

The SavvyWire (Opsens Medical) is a new 0.035" preshaped guidewire with dedicated pacing properties and a distal pressure sensor allowing for continuous haemodynamic pressure monitoring. This study aimed to determine the safety and efficacy of the SavvyWire during transcatheter aortic valve implantation (TAVI).

Methods

This was a prospective, observational study including patients with severe symptomatic aortic stenosis undergoing TAVI. The study was approved by Health Canada and the local Ethics Committee of each participating centre. All patients provided signed informed consent for participating in the trial (ClinicalTrials.gov: NCT05082337).

SAVVYWIRE

The SavvyWire is a 280 cm long, stiff 0.035" pressure wire (**Figure 1A**), which is connected to the OptoMonitor (Opsens Medical), a system which displays pressure signals and TAVI-specific metrics (**Figure 1B**). The guidewire is designed for unipolar pacing with unique conductive and insulation properties. Pacing is achieved by connecting the cathode of an external pacemaker to a pacing connection zone on the shaft, while the anode is connected to a subcutaneous needle in the patient's groin (**Figure 1C, Figure 1D**).

The study procedures and procedural steps are summarised in **Supplementary Figure 1**.

STUDY OUTCOMES

The safety primary outcome included the absence of major procedural complications related to the SavvyWire.

The efficacy primary outcomes consisted of (i) effective rapid pacing runs, defined as an adequate ventricular pacing capture, with no capture loss and leading to a reduction of aortic pressure of ≥50% and/or a systolic blood pressure (SBP) of <60 mmHg, and (ii) accurate pressure recordings, defined as pressure wire measurements similar to those obtained simultaneously with a pigtail catheter (difference <5 mmHg).

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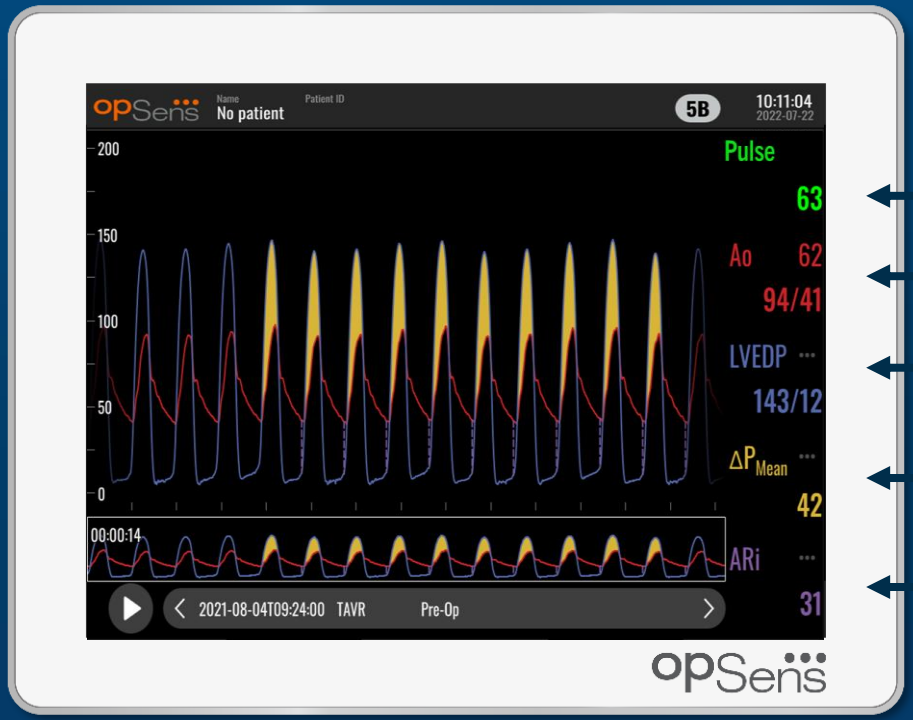
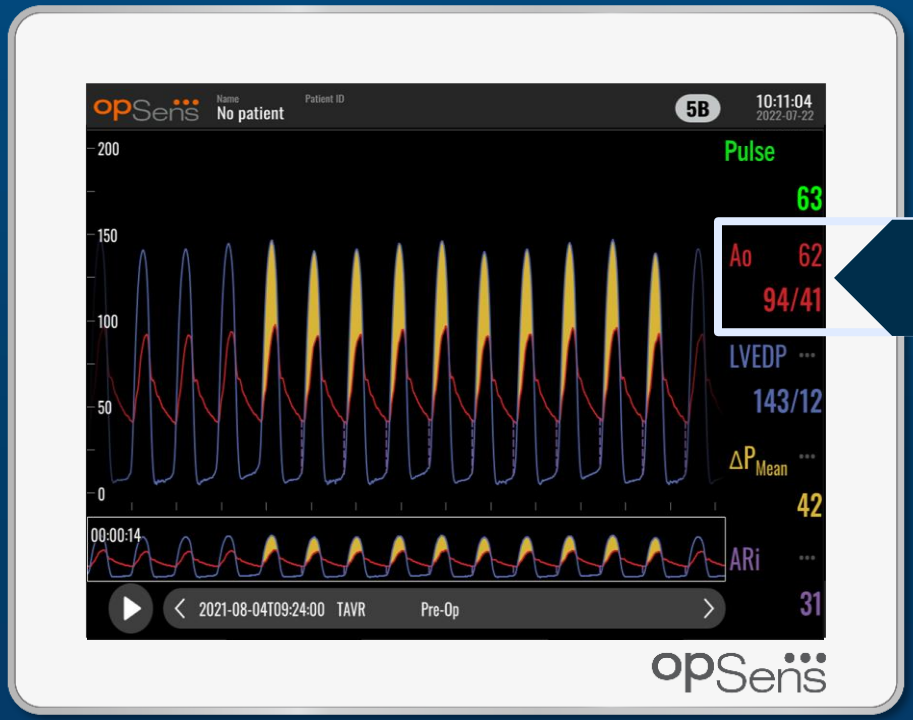
SavvyWire® Guidewire: Hemodynamics



Continuous measurement and display

- Pulse rate
- Aortic pressures (from aortic pigtail/transducer)
  - ✓ Systolic, diastolic
- Left ventricular pressures
  - ✓ Systolic, diastolic, LVEDP
- Transvalvular gradients
  - ✓ Mean, peak-to-peak, instantaneous
- ***Aortic Regurgitation indices***
  - ✓ ***ARi, ARi ratio, TIARi***

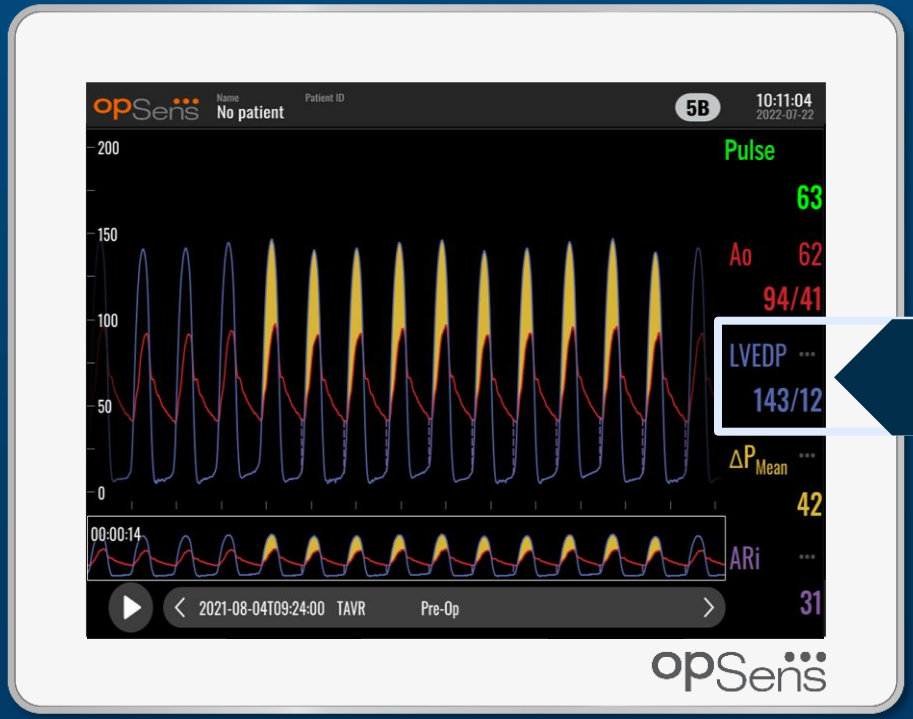
SavvyWire® Guidewire: Hemodynamics



Display of aortic pressure measurements may support

- Assessment of effectiveness of LV pacing

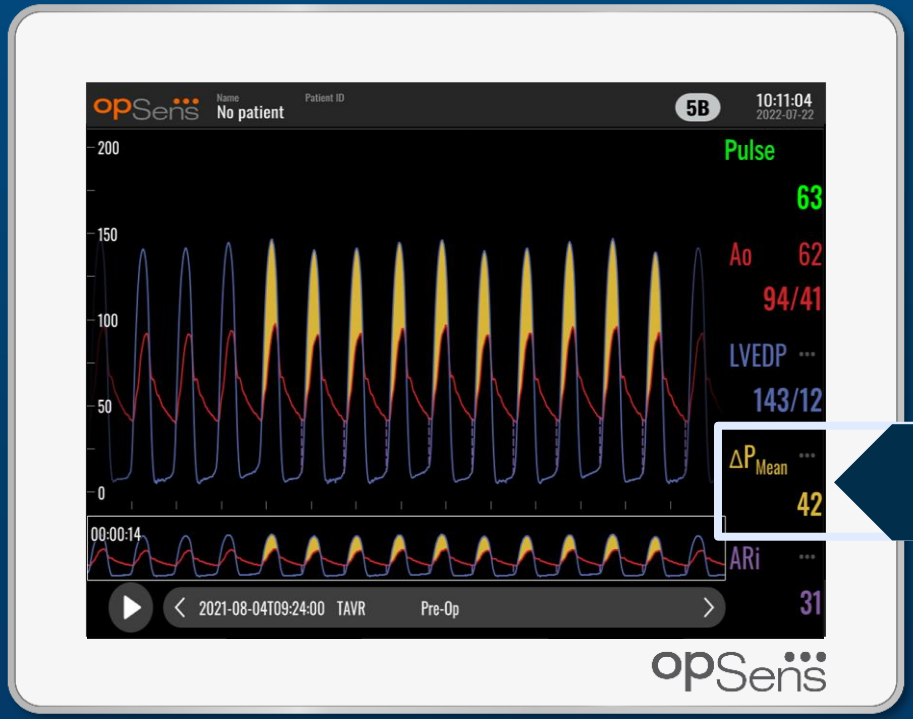
SavvyWire® Guidewire: Hemodynamics



Display of left-ventricular pressures including LVEDP may support

- Assessment of patient's hemodynamic and cardiac functional status throughout the procedure
- Assessment of PVL and need for post-dilatation
- Assessment of effectiveness of post-dilatation
- Assessment of procedural success

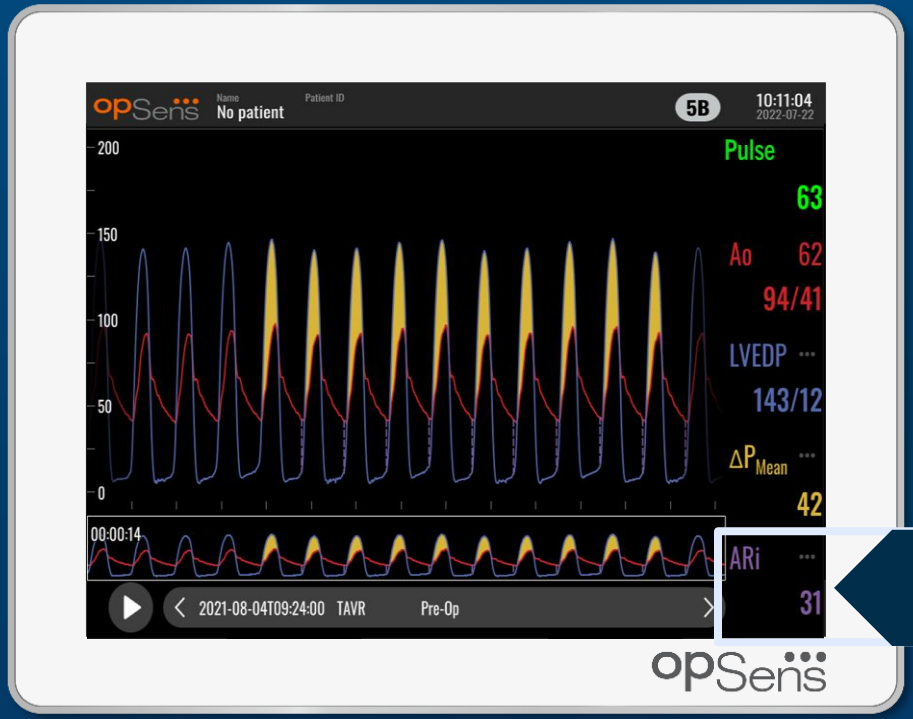
SavvyWire® Guidewire: Hemodynamics



Calculation of transvalvular gradients may support

- Assessment of effectiveness of pre-dilatation
- Decision-making for need of post-dilatation
- Assessment of effectiveness of post-dilatation
- Assessment of procedural success

SavvyWire® Guidewire: Hemodynamics



Calculation of indices for aortic regurgitation may support

- ***Decision-making for need of post-dilatation***
- ***Assessment of effectiveness of post-dilatation***
- ***Assessment of procedural success***

SavvyWire® Guidewire: Hemodynamics

Complementary Accuracy Study[1] (N=20)

Pre-TAVI Mean Gradient		Post-TAVI 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

SAFE TAVI[2] (N=119)

Results	**n (%)**
Adequate LV pacing capture leading to a reduction of systolic aortic pressure <60mmHg	116 (98.3%)

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Editorial

Real-time Hemodynamic Monitoring During TAVR, Stepping Toward the Ideal TAVR Wire

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Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of aortic stenosis and is now the main treatment of choice for patients older than 80 years or with a life expectancy <10 years.[1] With its widespread use, TAVR continues to evolve, with many centers now adopting a streamlined and protocolized approach. Minimalist TAVR is associated with favorable patient outcomes, shorter lengths of stay, lower costs, and improved patient satisfaction.[2] Smaller caliber delivery systems and safe access management techniques have facilitated the so-called minimalist approach. However, the ideal TAVR delivery guidewire remains to be developed. Newer TAVR guidewires with the ability to pace the left ventricle have been developed but have not been widely adopted.[3] Pacing via the delivery left ventricular guidewire can theoretically decrease the risk of complications associated with temporary pacemaker placement and can lead to shorter procedure times. The ideal TAVR wire would (1) facilitate easy valve crossability, (2) allow ventricular pacing, (3) provide adequate support for valve delivery and deployment, and (4) monitor intraprocedure valve hemodynamics in real time.

In this study, Généreux et al bring us one step closer to finding the ideal TAVR wire.[4]

This study was designed to assess the feasibility and accuracy of the OpSens OptoWire III, a 0.014″ pressure wire (FDA approved for coronary use). A novel TAVR hemodynamic software algorithm was used during TAVR to assess pre- and post-TAVR hemodynamics. Hemodynamic measurements were compared with standard echocardiographic and catheterization measurements of aortic stenosis with the double-pigtail technique. In keeping with prior studies, pre-TAVR measurements between all modalities had good correlation, with some discrepancies between echocardiographic and invasive catheterization measurements after valve deployment. The OpSens OptoWire III demonstrated excellent correlation and the strongest correlation with catheterization measurements before and after TAVR compared with transthoracic echocardiogram and transesophageal echocardiogram.

As mentioned in the current study, the interest in the OpSens OptoWire III stems from the fact that it carries the same fiber optic sensor that is also embedded in a recently developed TAVR guidewire by the same manufacturer. Currently under investigation, the "Savvy" wire is a 0.035″ guidewire used for TAVR device delivery with the capability of ventricular pacing and potentially real-time hemodynamics (NCT05082337). The excellent correlation between the 0.014″ OptoWire III with standard catheterization measurements validates the TAVR algorithm—which, if embedded within a larger caliber TAVR delivery wire, would allow for real-time hemodynamic measurements during TAVR.

The ability to measure intraprocedure hemodynamics during TAVR may be important for many reasons. First, aortic regurgitation after TAVR deployment may be estimated with the aortic regurgitation index (diastolic blood pressure − left ventricular end-diastolic blood pressure/systolic blood pressure × 100). Sinning et al[5] showed improved outcomes in patients with an aortic regurgitation index >25. Such an index can be particularly important in patients in whom transthoracic echocardiogram windows are limited. Second, as shown in this study, discrepancies exist between invasive catheterization and echocardiographic measurements after TAVR. After TAVR, initial invasive hemodynamic measurements are performed routinely in many centers, but not all. Incorporating hemodynamic assessment into the TAVR guidewire would simplify the procedure and improve efficiency, making it more acceptable by TAVR operators.

The application of a hemodynamic wire has potential benefits not only in TAVR but also in evaluating the diagnosis of aortic stenosis severity. In patients with aortic stenosis of uncertain severity, a hemodynamic assessment would be beneficial. Pressure wire evaluation of aortic stenosis severity has been described and is useful as well in certain disease states such as atrial fibrillation and low flow states.[6,7]

To summarize, in this validation study, the authors have demonstrated the feasibility and validation of a 0.014″ pressure wire for measuring and evaluating valve hemodynamics during TAVR.[4] The incorporation of this technology within a 0.035″ guidewire would improve TAVR procedure efficiency. This study brings us one step closer to the development of an "ideal TAVR wire" with support, pressure

Keywords: Transcatheter aortic valve replacement; pressure wire; hemodynamics.
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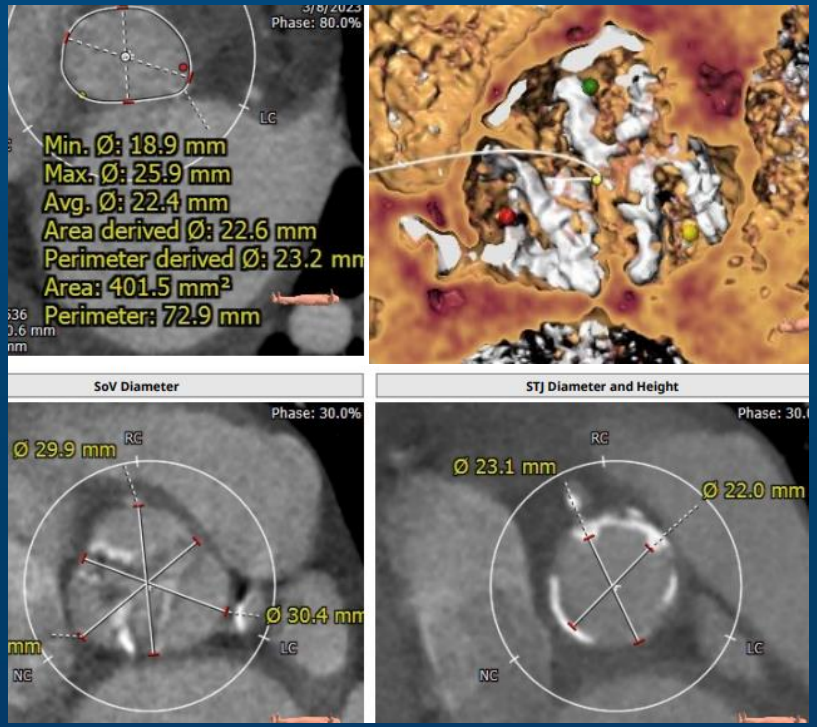
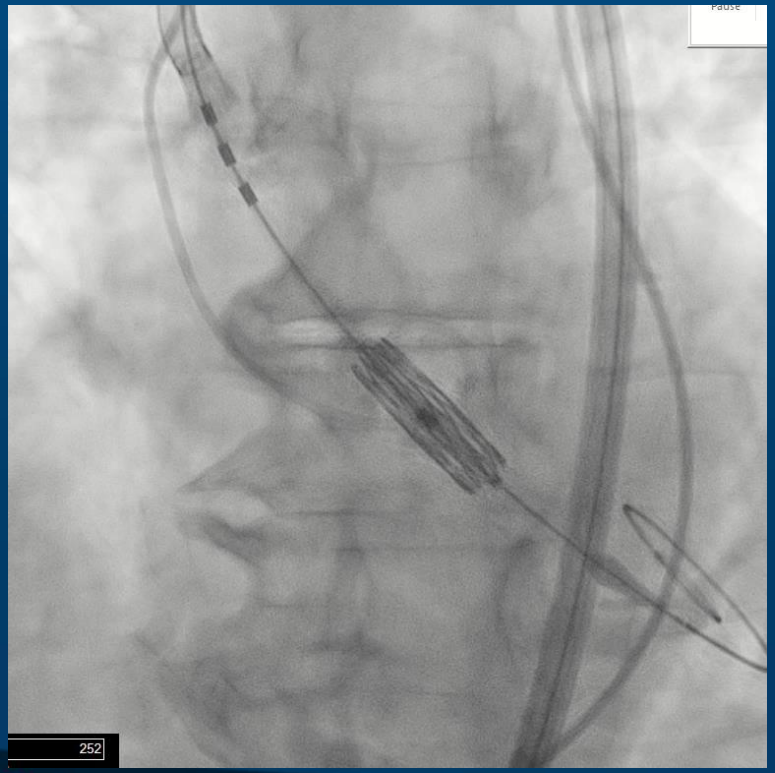
1. P. Généreux et al. JSCAI, VOLUME 1, ISSUE 4, 100309, JULY 2022
2. Regueiro, ***et al.*** J Am Coll Cardiol Intv. 2023 Dec, 16 (24) 3016–3023

Case Presentation



Case Presentation



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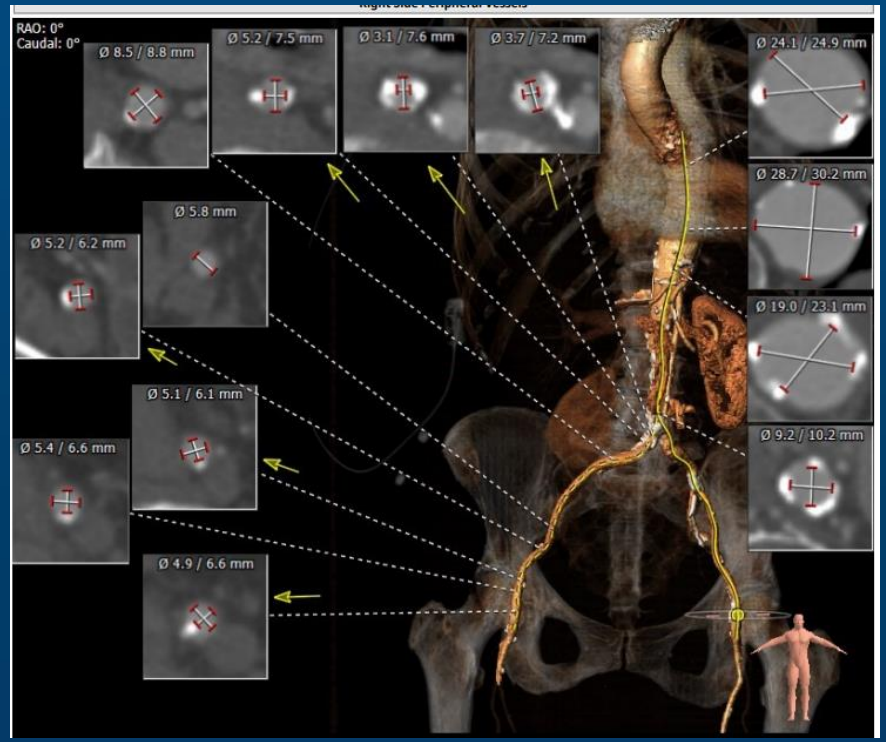
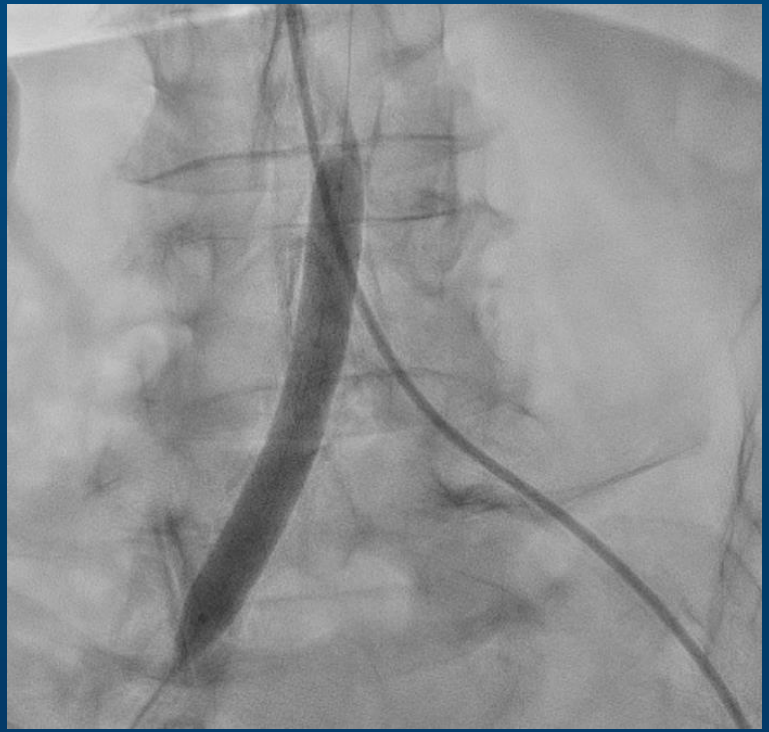
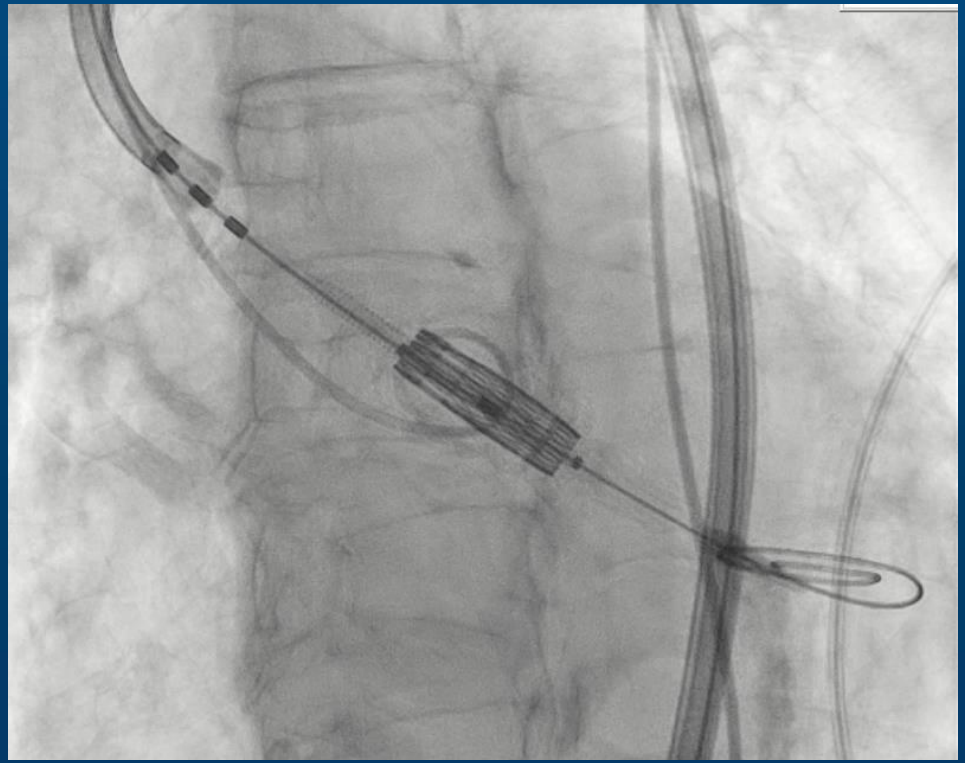




Case Presentation



SavvyWire® Guidewire

The SavvyWire® guidewire can improve the flow of the procedure and is designed to optimize TAVI through efficient, predictable wire performance, hemodynamic measurement and LV pacing capabilities

- Can improve lab efficiency and throughput
- Standardized invasive hemodynamics support lifetime patient management
- Eliminates need for venous access, reducing the number of access sites
- Improves TAVI workflow efficiency by minimizing device exchanges
- Replaces existing TAVI guidewire, one transducer, one pigtail, access kit, pacing lead, and closure device
- Avoids transducer setup and calibration time