

Inside Out: Next Generation Technology that Transmits Physical Intelligence Wirelessly, and Applies AI in real time: How can it Help in Vascular Treatment?

Barry T Katzen MD
 Chief Medical Innovation Officer
 Founder and Chief Medical Executive Emeritus
 Miami Cardiac and Vascular Institute

Professor of Interventional Radiology and Surgery
 FIU Herbert Wertheim College of Medicine
 Founding Chairman, Department of Miami Cardiac & Vascular Institute
 Interventional Radiology




Inside Out: Next Generation Technology that Transmits Physical Intelligence Wirelessly, and Applies AI in real time: How can it Help in Vascular Treatment?


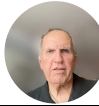
Barry T Katzen MD
 Chief Medical Innovation Officer
 Founder and Chief Medical Executive Emeritus
 Miami Cardiac and Vascular Institute

Professor of Interventional Radiology and Surgery
 FIU Herbert Wertheim College of Medicine
 Founding Chairman, Department of Miami Cardiac & Vascular Institute
 Interventional Radiology




Disclosures

- Advisory Board
 - Boston Scientific
 - Philips Healthcare
 - WL Gore
 - Alio
 - Xenter


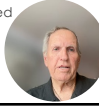



Key Technology Microsensor: micro chip



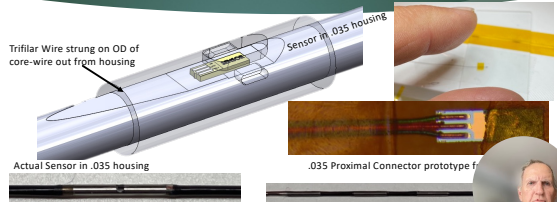

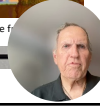

Microsensors

- Captures physiologic data: physical intelligence to be used by artificial intelligence
- Broad potential applications resulting from what can be measured: pressure, flow, biologic information oxygen, sugar others?
- Being able to obtain information not currently measured in real time
- Potential to be incorporated into devices, with data transmitted wirelessly from the patient to a hub and then to the EMR and potential APPs

Key Technological Innovation

- The .035" wire configuration significantly reduces the criticality of placement, underfill, encapsulation, masking, etc.

Endovascular Application: sensors 5cm apart

for pressure sensor placement (5cm apart)

Flex-to-ribbon transition

Conductive traces in polymer jacket along length of wire

Control Hub

Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

Xenter Wireless Devices at a System Level

1 Xenter's Wireless Devices - SmartWire & SmartVUS

2 XenFi Hub (in-lab)

3 XenterView on boom screen

XMD Cloud Data Collection and AI Engine

Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

Initial Results in Pressure Measurement

- Fidelity of the pressure wave form, much greater than traditional transducer based traditional wave forms
- AI being applied to the curves and area under the curves, anticipated to have much greater sensitivity to differences if they exist
- First application to TAVR
- Endovascular Wire developed at the same time, characteristics of 'Torque wire' and exchange wire
- Imagine: workhorse wire with hemodynamic sensor information AI applied to wave forms and differences

Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

First Clinical Application

Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

First Application: Wireless Physiology Guidewire for Transcatheter Aortic Valve Replacement (TAVR)

Real-time Waveform: Post-TAVR Aortic Valve Mean Pressure Gradient (Yellow Area)

5 Second "Snapshot": Pre-TAVR Aortic Valve Mean Pressure Gradient (Yellow Area)

Sensor Locations

Wireless Clip: Enables sensor conditioning, power, and wireless communications to Wireless Network and proprietary cloud



Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

Role of AI in Assessing Physical Intelligence Data

- Pressure sensors have much higher fidelity, therefore information, than traditional transducer methods
- Changes in pressure waves include amplitude, shape, and area under the curve
- In TAVR applications AI will be used to predict paravalvular leak (PVL) in real time of deployment
- For Endovascular Wire significant potential and applications exist

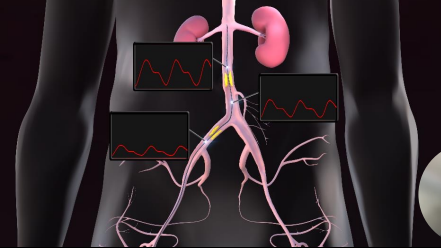
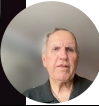
Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

Endovascular Workhorse wire with 3 pressure sensors: Data sent wirelessly, no box or cables


Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

Imagine Realtime Information with AI Analysis

Potential EndoVascular Applications


- Multiple sensors can be placed on a wire, allowing real time data to be transmitted from multiple locations simultaneously **wirelessly**
- First vascular applications: 3-5 sensors along a 20 cm segment
- Potential applications: Aortic and Aorto-iliac occlusive disease where real time pressures can facilitate procedural decision making and endpoint determination
- AI and development of physiologic ratios offer potential to create **new endpoints** in peripheral intervention
- Currently 0.035, but 0.014 and 0.018 in the pipeline
- Deploy sensors for measurement of other parameters and purposes combining IVUS and Physiology
- Apply AI to create new indices



Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

Potential for Endovascular Applications

- Deliver real-time physiologic information with workhorse wire: impact on workflow?
- Pressure Measurements have had significant endpoint value during aortic and iliac interventions
- Potential for developing new endpoints for therapeutic procedures and fusion of data with imaging modalities, IVUS, Angio
- AI analysis of high fidelity data may predict need for further intervention, or not.
- All data and analysis saved to the cloud with image fusion capabilities, all wireless
- Altering workflow by providing this information to operator in realtime, without catheter or wire exchanges, no boxes or cables, wireless transmission



Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA

Thank you