Remote Measurement Of Blood Flow In Any Artery Or Graft Using An Implantable Ultrasonic Sensor With Transmission To The Internet (From IntelVasc): How Does It Work, And Experimental Data

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Disclosures

WL Gore - speaker
Cook Medical - speaker
IntelVasc - CMO and co-founder

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INTELVASC™

VASCULAR INSIGHTS

MONITORING VASCULAR OCCLUSION REMOTELY

THE PROBLEM

PERIPHERAL ARTERIAL DISEASE to USD...

33M suffer from PAD in US

$20B healthcare expenditure

TIME TO DIAGNOSIS / COST

LATE $45,000

MODERATE $15,000

EARLY $7,000

1,3M Surgeries a year

Time Matters!

30% PAD patients will have STROKE, HEART ATTACK, AMPUTATION

90% PAD patients are ASYMPTOMATIC

65% PAD patients miss MEDICAL CHECK-UP

IDENTIFYING CLINICAL COMPLICATIONS EARLY

MEDICAL VISIT → BIOSENSOR INSERTION → AT-HOME MONITORING → MOBILE BASED CLINICAL UPLOAD → REMOTE CLINICAL EVALUATION

Patient attends an outpatient medical visit

The specialist inserts the sensor subcutaneously

Biosensor sends data to mobile app comfortably from home

Assessment data is uploaded to the cloud

If vascular problems are detected, clinical visit is scheduled

HIGHER PATIENT COMPLIANCE

Higher attendance in-person or remote FU visits

IMMEDIATE VASCULAR DETECTION

- Patient only attends a clinical visit if a problem is detected
- Efficient video-consultancy
- Simpler surgical interventions
- Shorter ICU stays

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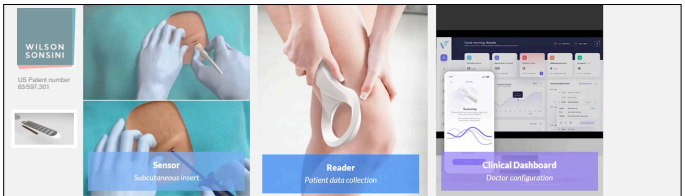
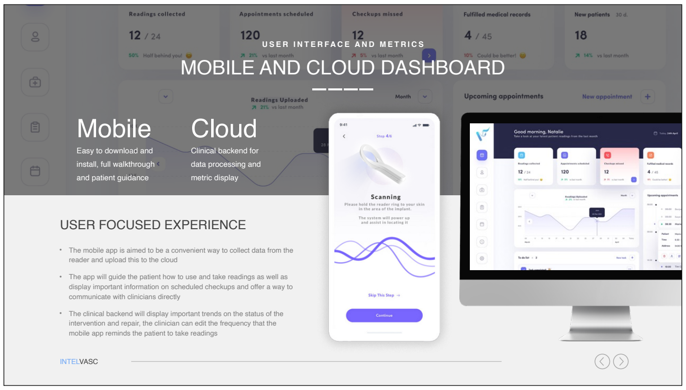


STEP 1 **Insertable Sensor** — The subcutaneous sensor is inserted by the clinician in an outpatient setting and the patient is discharged

STEP 2 **At-Home Scanning** — The patient scans the implant as indicated by the clinician

STEP 3 **Clinical Review** — The physician can access and review the clinical data and will receive an alert if a problem is detected


USER INTERFACE AND METRICS
MOBILE AND CLOUD DASHBOARD
Mobile
Easy to download and install, full walkthrough and patient guidance
Cloud
Clinical backend for data processing and metric display
Readings collected
12 / 24
Appointments scheduled
120
Checkups missed
12
Fulfilled medical records
4 / 45
New patients
18
Readings Uploaded
Upcoming appointments
New appointment
Scanning
Please hold the reader ring to your skin in the area of the implant.
The system will power up and assist in locating it
Skip This Step
Continue
Good morning, Natalie
USER FOCUSED EXPERIENCE
The mobile app is aimed to be a convenient way to collect data from the reader and upload this to the cloud
The app will guide the patient how to use and take readings as well as display important information on scheduled checkups and offer a way to communicate with clinicians directly
The clinical backend will display important trends on the status of the intervention and repair, the clinician can edit the frequency that the mobile app reminds the patient to take readings
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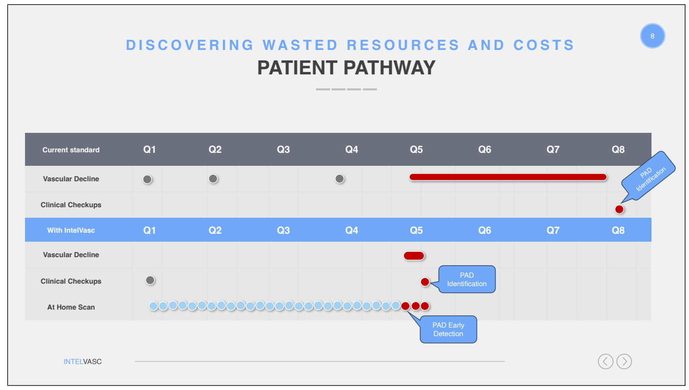
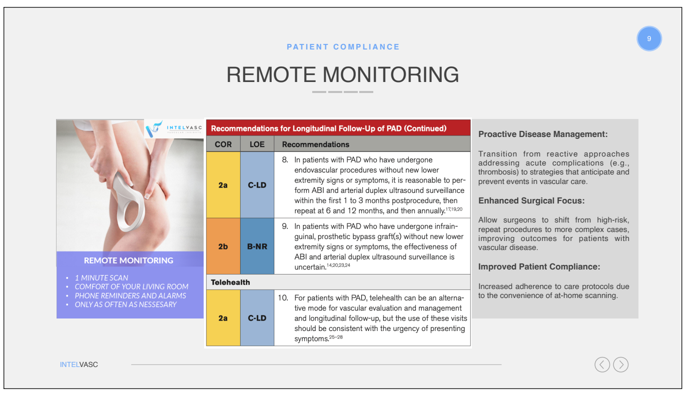

DISCOVERING WASTED RESOURCES AND COSTS
PATIENT PATHWAY
8
Current standard
Q1
Q2
Q3
Q4
Q5
Q6
Q7
Q8
Vascular Decline
Clinical Checkups
PAD Identification
With IntelVasc
Vascular Decline
Clinical Checkups
PAD Identification
At Home Scan
PAD Early Detection
INTELVASC


PATIENT COMPLIANCE
REMOTE MONITORING
9
INTELVASC
REMOTE MONITORING
1 MINUTE SCAN
COMFORT OF YOUR LIVING ROOM
PHONE REMINDERS AND ALARMS
ONLY AS OFTEN AS NESSESARY
Recommendations for Longitudinal Follow-Up of PAD (Continued)
COR
LOE
Recommendations
2a
C-LD
8. In patients with PAD who have undergone endovascular procedures without new lower extremity signs or symptoms, it is reasonable to perform ABI and arterial duplex ultrasound surveillance within the first 1 to 3 months postprocedure, then repeat at 6 and 12 months, and then annually.17,19,20
2b
B-NR
9. In patients with PAD who have undergone infrainguinal, prosthetic bypass graft(s) without new lower extremity signs or symptoms, the effectiveness of ABI and arterial duplex ultrasound surveillance is uncertain.14,20,23,24
Telehealth
2a
C-LD
10. For patients with PAD, telehealth can be an alternative mode for vascular evaluation and management and longitudinal follow-up, but the use of these visits should be consistent with the urgency of presenting symptoms.25–28
Proactive Disease Management:
Transition from reactive approaches addressing acute complications (e.g., thrombosis) to strategies that anticipate and prevent events in vascular care.
Enhanced Surgical Focus:
Allow surgeons to shift from high-risk, repeat procedures to more complex cases, improving outcomes for patients with vascular disease.
Improved Patient Compliance:
Increased adherence to care protocols due to the convenience of at-home scanning.
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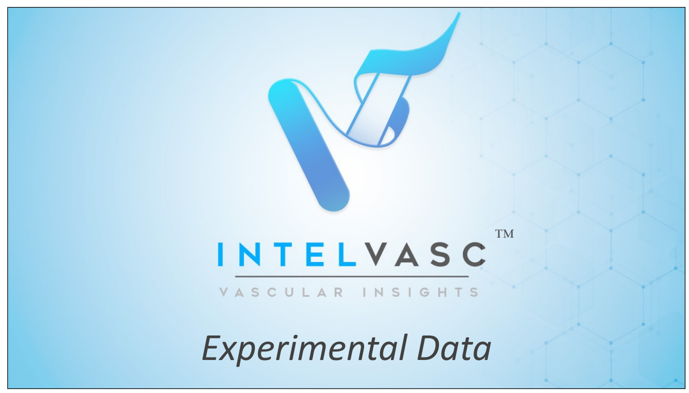
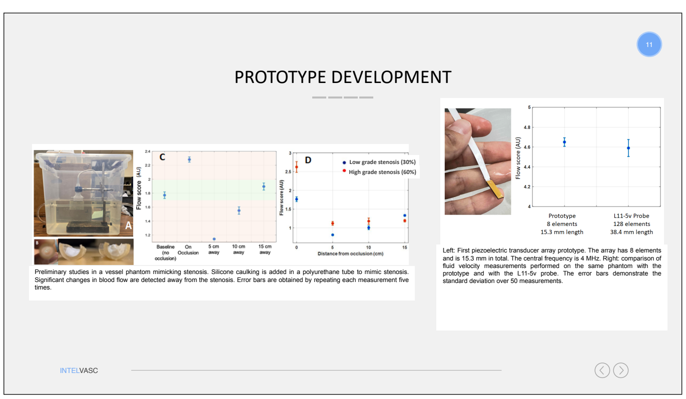

INTELVASC™
VASCULAR INSIGHTS
Experimental Data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PROTOTYPE DEVELOPMENT
A
B
C
Flow score (AU)
Baseline (no occlusion)
On Occlusion
5 cm away
10 cm away
15 cm away
D
Low grade stenosis (30%)
High grade stenosis (60%)
Flow score (AU)
Distance from occlusion (cm)
Preliminary studies in a vessel phantom mimicking stenosis. Silicone caulking is added in a polyurethane tube to mimic stenosis. Significant changes in blood flow are detected away from the stenosis. Error bars are obtained by repeating each measurement five times.
Flow score (AU)
Prototype
8 elements
15.3 mm length
L11-5v Probe
128 elements
38.4 mm length
Left: First piezoelectric transducer array prototype. The array has 8 elements and is 15.3 mm in total. The central frequency is 4 MHz. Right: comparison of fluid velocity measurements performed on the same phantom with the prototype and with the L11-5v probe. The error bars demonstrate the standard deviation over 50 measurements.
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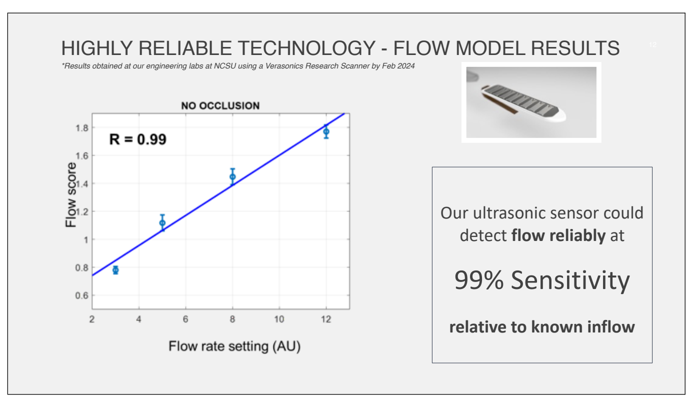
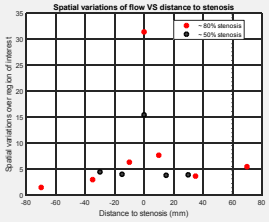
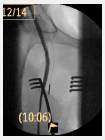

HIGHLY RELIABLE TECHNOLOGY - FLOW MODEL RESULTS
*Results obtained at our engineering labs at NCSU using a Verasonics Research Scanner by Feb 2024
NO OCCLUSION
R = 0.99
Flow score
Flow rate setting (AU)
Our ultrasonic sensor could detect flow reliably at
99% Sensitivity
relative to known inflow

First cadaver study

Insertion of the sensor prototype over the perfused artery in a cadaveric leg, The sensor was connected and controlled by the Verasonics scanner

Spatial variations of flow can be attributed to
- Turbulence or Very high flow velocity (both due to stenosis)





Sensor with respect to vessel (with contrast)

Sensor with respect to guide wire in vessel

PATHWAYS OF EXPLORATION

DEVELOPMENT PATHS

AT HOME FLOW ASSESSMENTS FOR STENOSIS MONITORING

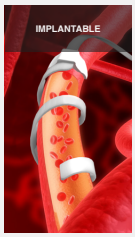
- NON-INVASIVE WEARABLE
- INVASIVE IMPLANTABLE

NON-INVASIVE PASSIVE ASSESSMENTS

- USER FRIENDLY
- CONVENIENT + NO MAINTENANCE
- CHARGEABLE

ON DEMAND, DIRECT FLOW ASSESSMENT

- REPEATABLE AND RELIABLE MEASUREMENTS
- VERSATILITY ON MANY OTHER VESSELS
- ONE TIME IMPLANT DURING INITIAL SURGERY



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Medical Institutions

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Scientific Societies

VEINS, ESC European Society of Cardiology, esvs, VEITH

US Patent number 63/597,301
Submitted by

WILSON SONSINI

Monitoring Vascular Stenosis, Anytime, Anywhere.

Early Diagnosis Remotely From Home

Vascular Sensor
Monitoring vessel stenosis to anticipate vascular events

Wirelessly Powered
An idle biosensor. Powered only when needed

Easy To Implant, Easy To Use
Surgeon focused design, patient focused experience

AI Powered – Reliable Metrics
A powerful data backend assisting informed medical decisions