Update on Graftworx implantable piezoelectric sensors for remote monitoring: when will they be available

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Remote, real-time monitoring
Wireless data transmission

- MicroSensor (Piezoelectric polymer)
  - Convert mechanical flow forces to electrical transduction
  - Proprietary machine learning parameters based on sensor data
- Microchip blue-tooth technology
  - Wireless transmission of data
  - Micro-battery
- External data processor for analysis and reporting

In vitro experiments
Bench top flow model

Degree of stenosis
Location of stenosis

In vivo proof of concept
Ovine carotid bypass

Ability of the sensor to transmit thru tissue under physiologic conditions

Neville RF, Gupta SK, Kuraguntla DJ. J Vasc Surg 2017;65:1793-1801

Disclosures

- Graftworx Scientific Advisory Board

In vivo: graft stenosis/occlusion
Ovine AVG model

Ability of the sensor to detect stenosis and occlusion thru tissue

Neville RF, Gupta SK, Kuraguntla DJ. J Vasc Surg 2017;65:1793-1801
**Human proof of concept trial**

**AV fistula patients**

- External sensor patch
- Patients scheduled for fistulogram +/- angioplasty
- N = 76
- Measurements performed pre- and post-angioplasty

![Image of AV fistula patient with sensor patch](Courtesy of Dr. Murat Sor)

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**Human proof of concept trial**

**Detection of Stenosis**

- 100% successful data acquisition and automatic data storage
- Findings corroborated by fistulogram
  - 11 without significant stenosis
  - 65 with stenosis or occlusion

![Graph showing data acquisition and automatic storage](Image 1)

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**Additional sensors and data metrics**

- Microphone
- Accelerometer
- PPG+
- Thermal
- Phonoangiography
- Spectral Analysis
- Volumetric Flow Rate
- Heart Rate
- Blood Pressure
- Pulse Wave Velocity
- Potassium Concentration
- Near/Far IR
- IR/Red
- Signal Analysis
- Peak detection allows for volume detection

![Graph showing additional sensors and data metrics](Image 2)

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**Detection of blood volume**

- Peak detection allows for volume detection

![Graph showing detection of blood volume](Image 3)

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**Detection of hematocrit**

- Sensor vs Coulter counter Hct values from human blood samples
- Strong correlation between sensor and measured Hct value

![Graph showing sensor vs Coulter counter Hct values](Image 4)

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**Detection of flow rate**

- High correlation to Transonic flow probe under pulsatile flow
  - Sensitivity: 100%
  - Specificity: 75%

![Graph showing detection of flow rate](Image 5)
**Data processed through algorithm**

**Raw Data:**
- Optical, acoustic, thermal, mechanical

**Signal Processing:**
- Feature detection, spectral analysis

**Analysis:**
- Trend, machine learning

**Clinical Metrics:**
- Flow rate, hematocrit/Hgb

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**Clinical Trial Beginning in Europe**

- Real-time data remotely monitored from patient to database automatically
- Clinician alerted when select criteria met
- Multimodal sensing from a single patch
  - Monitoring of dialysis access
  - Fluid status

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**Generate physiological data**

**Form Factor**
- 7-day sweat- and water-proof device
- Easy to apply, comfortable to wear

**Telemetry and Microprocessor platform**
- Multi-modal data capture platform: 10 sensors
- Optical, acoustic, thermal, mechanical
- Automatically detects patient’s AV access

**Low power, reliable transmission**
- Ultra low power to increase device lifespan
- Battery life: 2-3 months
- Automatic measurement 8x per day
- Bluetooth data transmission to hub

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**Real-time fluid management**

**Form Factor**
- Forearm or upper arm

**Target Vessel**
- AV access
- Radial artery

**Machine Learning**
- Fluid imbalance cycles every 48 hours.
- Success with Hct/Hgb, O2 sat, flow rate translates into CHF application
  - CHF patients go through sporadic periods of fluid imbalance

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**When will they be available?**

<table>
<thead>
<tr>
<th>Clinical metric</th>
<th>Bench/Proof of Concept</th>
<th>FPA/Pilot</th>
<th>Clinical Registry</th>
<th>Required Regulatory Clearance</th>
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</thead>
<tbody>
<tr>
<td>Hematocrit (%)</td>
<td>Q1 2018 (30 pts)</td>
<td>Q3 2019</td>
<td>Q1 2019</td>
<td>Q1 2020</td>
</tr>
<tr>
<td>Blood Flow</td>
<td>Q1 2018 (100 pts)</td>
<td>Q3 2019</td>
<td>Q1 2019</td>
<td>Q1 2020</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Target</th>
<th>Base/Proof of Concept</th>
<th>FPA/Pilot</th>
<th>Clinical Registry</th>
<th>Required Regulatory Clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stenosis %</td>
<td>Q1 2019</td>
<td>Q1 2019</td>
<td>Q1 2019</td>
<td>Q1 2020</td>
</tr>
<tr>
<td>Cardiac output</td>
<td>Q1 2018</td>
<td>Q1 2018</td>
<td>Q1 2018</td>
<td>Q1 2018</td>
</tr>
</tbody>
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**Thank you**