May 16th, 11:35 AM

Collaborative Research in Medical Sensing: Wearable Wireless Sensor for Pressure Ulcer Prevention

John McNeill
Worcester Polytechnic Institute

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Collaborative Research in Medical Sensing: Wearable Wireless Sensor for Pressure Ulcer Prevention

John McNeill, Ph.D.
WPI ECE Department

May 16, 2017
Disclosures

• Grant/Research Support:
  – In-kind support, Boston Scientific

• Graphic content warning: Images of
  – Pressure ulcer wound
  – Porcine model animal experiment
### Development of Biomedical Collaboration

<table>
<thead>
<tr>
<th>Greatest Engineering Achievements of the 20th Century</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Electrification</td>
</tr>
<tr>
<td>2. Automobile</td>
</tr>
<tr>
<td>3. Airplane</td>
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<tr>
<td>4. Water supply &amp; distribution</td>
</tr>
<tr>
<td>5. Electronics</td>
</tr>
<tr>
<td>6. Radio &amp; television</td>
</tr>
<tr>
<td>7. Agricultural mechanization</td>
</tr>
<tr>
<td>8. Computers</td>
</tr>
<tr>
<td>9. Telephone</td>
</tr>
<tr>
<td>10. Air-conditioning &amp; refrigeration</td>
</tr>
<tr>
<td>11. Highways</td>
</tr>
<tr>
<td>12. Spacecraft</td>
</tr>
<tr>
<td>13. Internet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Engineering's Grand Challenges</th>
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<tbody>
<tr>
<td>Make solar energy economical.</td>
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<tr>
<td>Provide energy from fusion.</td>
</tr>
<tr>
<td>Develop carbon sequestration methods.</td>
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<tr>
<td>Manage the nitrogen cycle.</td>
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<tr>
<td>Provide access to clean water.</td>
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<tr>
<td>Restore &amp; improve urban infrastructure.</td>
</tr>
<tr>
<td>Advance health informatics.</td>
</tr>
<tr>
<td>Engineer better medicines.</td>
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<tr>
<td>Reverse engineer the brain.</td>
</tr>
<tr>
<td>Prevent nuclear terror.</td>
</tr>
<tr>
<td>Secure cyberspace.</td>
</tr>
<tr>
<td>Enhance virtual reality.</td>
</tr>
</tbody>
</table>

- General direction: NAE Grand Challenges
  - Health; Sustainability; Security

**Collaboration History**

**2011-12**
- MQPs: Wired / Wireless pressure ulcer prevention device
  Morianos, Jones, Gutierrez; Williams, Truhanovitch, Hause
  Advisors: Mendelson (BME), Bitar (WPI ECE), Dunn (UMMS)

**2015**
- McNeill, Dunn meet at UMMS/WPI Research Collaboration event
- $20K + $5K WPI/UMMS Seed Grant funding
  Partial support for MS student Matthew Crivello

**2016-17**
- McNeill ½ sabbatical at UMMS
- TA support for PhD student Devdip Sen
- 2 MQPs (ECE, BME)
  Agdeppa, Hussain, Kim, Loehle; Ooyama-Searls, Pachucki, Parent
  Advisors: McNeill, Mazumder, Mendelson

**2017-18**
- $25K UMass Technology Commercialization (OTCV) funding
- $10K Massachusetts Technology Transfer Center (MTTC)
Motivation: Pressure Ulcer Prevention

• Painful
• Increases risk for secondary infection
• Wound healing takes up to several months
  – May not heal at all in compromised patients
• Adds $11B annually to US health care costs
• Demographics: Increasing cost, incidence, prevalence

→ Need compact, low-cost prevention for patients:
  • In hospital setting
  • Confined to bed at home
  • With limited mobility in wheelchairs

Healing of pressure ulcer over several months

Cause: Localized Pressure

- External pressure over ~30mmHg restricts blood flow
- Ischemia; tissue deprived of oxygen
- Can lead to tissue necrosis
Opportunity for Prevention

- Well-known locations on body at risk for pressure ulcer formation
- Location depends on patient environment:
  - Hospital setting
  - Confined to bed at home
  - With limited mobility in wheelchair

**System Approach: Pressure Ulcer Prevention**

- **Device**: Low-cost, disposable, wearable sensor patch
- **System**: Wireless data collection from multiple at-risk sites
- **Algorithm**: Assess risk from pressure vs. time profile
- Low-cost, disposable, wearable sensor patch
- Measure local pressure, temperature
- Small size, comfortable to wear for long duration
Benefits of Our Approach

- Low cost: $10 / sensor
- 7-day wearable; disposable
- Meet needs for multiple populations:
  - Caregiver: Reduces workload
  - Doctor: Detailed pressure-time information
  - Patient: Improved independence

Drawbacks of Existing Techniques:
- 2-hour turn protocol
  - Workload, injury risk for caregivers
  - Not supported by controlled trials
- Offloading beds
  - Expensive (> $10K), fixed location
- Pressure mapping pad
  - Expensive (> $1K), caregiver interpretation
$11B annual cost in US for pressure ulcer treatment

- Potential annual market population:
  - Hospitals 35.1 million
  - (2014: No Medicare reimbursement)
  - Nursing homes 1.4
  - Long term / residential care 1.0
  - In-home care 5.3

Potential Population (5% at risk) 2.1 million
Estimated Gross Annual Market > $120 million

- Demographic demand accelerating
  - Aging, longer lived population

Flexible Wired Prototype

- Implement sensors, measurement circuitry on flexible substrate
Animal Experiment Data Acquisition

- **Surgical protocol**: Anesthetized pig immobile on back for ~ 7 hours
- **Identified at-risk sites** for placement of wired sensors
- **Acquire data** from multiple sites
Experimental Results

- Pressure, temperature vs. time over 7 hour duration
- Surgical protocol: Animal repositioned every 90 minutes
Experimental Results

- Pressure, temperature vs. time over 7 hour duration
- Verified ability to resolve threshold, pressure relief events
- Importance of multiple sensors for each at-risk point
Current Status

• Wireless prototype verified
  MS: Matt Crivello
  PhD student: Devdip Sen
  WPI Undergraduate project:
  ECE MQP: Amanda Agdeppa
  Ali Hussain
  David Kim
  Victoria Loehle
## Development Plan Status

<table>
<thead>
<tr>
<th>Activity / Milestone</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure contact pressure, temperature, moisture</td>
<td>Verified</td>
</tr>
<tr>
<td>Wireless self-powered measurement</td>
<td></td>
</tr>
<tr>
<td><strong>Human wearable, biocompatible sensor</strong></td>
<td>IN PROGRESS (OTCV, MTTC, M2D2)</td>
</tr>
<tr>
<td>Animal model trials</td>
<td></td>
</tr>
<tr>
<td>Evidence based algorithm</td>
<td></td>
</tr>
<tr>
<td>Human trials (Class 2)</td>
<td>FUTURE FUNDING (NIH, NSF, SBIR, STTR, PARTNERS)</td>
</tr>
<tr>
<td>Clinical use</td>
<td></td>
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</tbody>
</table>

- Licensing most likely path to commercialization
- IP Status: Provisional patent application filed June 2016

### Potential Partners
- Boston Scientific: Wearable sensors
- Johnson & Johnson: Managing diabetes, surgery recovery
- Convatec, Acelity, Smith & Nephew, Medtronic, GE, …

➡️ **M2D2 support**: Preliminary results for future funding

**Technology**: Disruptive shift in pressure ulcer prevention
# Interdisciplinary Development Team

## UMMS Division of Plastic Surgery

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raymond Dunn, M.D.</td>
<td>Chief; P.I.</td>
<td>Head, Wound Care</td>
</tr>
<tr>
<td>Kelli Hickle, M.D.</td>
<td>Resident</td>
<td>Surgical resource</td>
</tr>
<tr>
<td>Heather Tessier</td>
<td>Lab Director</td>
<td>Animal model resource</td>
</tr>
</tbody>
</table>

## WPI Electrical & Computer Engineering

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Position</th>
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</thead>
<tbody>
<tr>
<td>John McNeill, Ph.D</td>
<td>Professor</td>
<td>Sensor electronics</td>
</tr>
<tr>
<td>Xinming Huang, Ph.D</td>
<td>Professor</td>
<td>Internet of Things</td>
</tr>
<tr>
<td>Devdip Sen</td>
<td>Student</td>
<td>Prototype fab / test</td>
</tr>
</tbody>
</table>

## WPI Biomedical Engineering

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Yitzhak Mendelson, Ph.D.</td>
<td>Professor</td>
<td>Skin-friendly materials</td>
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</table>
Acknowledgments

• Supported by a grant from the UMMS/WPI Collaborative Seed Funding Initiative.

• William Appleyard [WPI]
  – Assistance with sensor fabrication

• Heather Tessier [UMMS]
  – Access to experimental resources
  – Compliance with the IACUC-approved protocol
Summary: Lessons Learned

- Find an important problem: Listen to practitioners
  - Reduce cost, improve quality of care
  - Meets needs for majority of patient populations
  - Reduce workload on caregivers
- Clinical partner a must
- Engineers:
  - Interdisciplinary team
  - Different experimental constraints
  - Rapid prototyping
- Need credible plan for entire development cycle
  - Bring in partner resources (business, IP, …)
- Multiple funding sources
  - Get out of your comfort zone