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

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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
• 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

• 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
Commercial Impact

$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>
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<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>Human wearable, biocompatible sensor</td>
<td>IN PROGRESS (OTCV, MTTC, M2D2)</td>
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<tr>
<td>Animal model trials</td>
<td></td>
</tr>
<tr>
<td>Evidence based algorithm</td>
<td>FUTURE FUNDING (NIH, NSF, SBIR, STTR, PARTNERS)</td>
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<tr>
<td>Human trials (Class 2)</td>
<td></td>
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<tr>
<td>Clinical use</td>
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- 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>
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</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>
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### WPI Electrical & Computer Engineering

<table>
<thead>
<tr>
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<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>
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### WPI Biomedical Engineering

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