Wound care: Novel programs for clinical care and early intervention

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Continuum of research

- Bench to bedside.

Basic science: Bench research

Pre-clinical studies (Development)

Phase I clinical trial
Safety (Pilot)

Phase II clinical trial
Efficacy (Medium size)

Phase III clinical trial
Large scale/ multi-center/ pivotal
Improving clinical care

Multidisciplinary teams are key to research and development.

Include the end user: Clinicians
Nursing personnel
Non-professionals
e.g. carers/patients
Pressure Ulcer Research Program

Examples to be discussed: Research studies enhanced by this approach

1. Clinical care delivery
2. Pressure ulcer prevention
Clinical care delivery

Challenges

Clinical:
Patient need is complex and on-going

Pragmatic:
Transportation
Education of end users
Telehealth/Telemedicine

Addresses many challenges in clinical care delivery

Additional motivation:
- Clinical outcomes
- Cost benefit to health care system
VA Telehealth Initiative

VHA populations often rural and/or large geographical area

Centers of expertise serve large areas

Health Buddy

Audio/Videophone
VA Telehealth Initiative

Office of Care Coordination

- Home-based Telehealth
  - Care of veterans in the home

- Clinic Telehealth
  - Inter-facility videoconferencing

Real-time or Store-and-Forward
San Juan PR VAMC: Home Telehealth for Wound Care

Home Telehealth Serves veterans living in Puerto Rico, Vieques and U.S. Virgin Islands

Team members
Clinicians
Nurse
Dietician
Administrative support
Cleveland VAMC: Telehealth programs/research projects

- **Home Telehealth**
  - Reliability of Digital Photography for Wound Evaluation
  - Store-and-forward

- **Clinic Telehealth**
  - Inter-facility videoconferencing
  - Real-time
Reliability of Digital Photography for Wound Evaluation – feasibility study

Two raters of similar experience & training assessed pressure ulcers using:

a) Digital photos
b) In-person assessment
Reliability of Digital Photography for Wound Evaluation

In-person assessments completed within 24hrs of digital imaging

Wound Descriptors

- Wound length
- Wound width
- Wound bed description
- Exudate type and color
- Peri-wound tissue description
- Peri-wound tissue color
Intra-method agreement of wound descriptors

Substantial agreement
• Wound bed description
• Peri-wound tissue color

Fair agreement
• Exudate type and color
• Peri-wound tissue description

Significant difference (p<0.01)
• Wound length
• Wound width
Reliability of Digital Photography for Wound Evaluation

Conclusion

• Persistent variation in intra-method agreement persists, despite involvement of two similarly trained and experienced raters.

• Intra-method variation observed highlights a need for improved wound measurement techniques

Caveat:
Likelihood of a different process or outcome of care occurring as a result of the observed differences has not been assessed.
VISN10 SCI Telehealth Clinics- (pilot clinical studies)

Cleveland SCI/D Service

Columbus VAMC

Chillicothe VAMC

Cincinnati VAMC

Dayton VAMC
VISN10 SCI Telehealth Clinics

Cleveland SCI/D Service

**Team members**
- SCI specialist physician
- Nurse
- Therapist
- Biomedical engineer
- Epidemiologist/statistician
- Administrative support

Remote sites

**Team members**
- Clinician
- Nurse
- Therapist
Pressure ulcer care: Tele-consultation

• Live viewing of pressure ulcers during videoconference

• Viewing of stored images from digital cameras during videoconference

• Recommendations for future prevention & treatment
Outcomes measured

- Clinical variables
- Utilization of health care system
- End user satisfaction evaluations
  Patient and provider
Pressure ulcer prevention: Wheelchair Tele-Consultation

Real-time static and dynamic evaluation of seating interface pressures

Pressure mapping provides visual feedback to veteran for pressure relief method
Pressure ulcer prevention: Wheelchair Tele-Consultation

Direct viewing of wheelchair and seating posture

Recommendations for wheelchair prescription, pressure relief method and posture
Pressure ulcer prevention: Neuromuscular electrical stimulation (NMES)

- NMES provides at-risk individuals with a method for achieving an independent pressure relief regime.
- Dynamic alternating bilateral stimulation (left/right) provides weight-shifting.
- Used daily for a long period (over 6 months).
Pressure ulcer prevention using NMES: hypothesis driven research

Primary hypotheses

- Long term exercise of paralyzed gluteal muscles will improve the intrinsic health of the tissue at the seating interface.

- Dynamic weight shifting produced by the gluteal stimulation system will augment the efficacy of conventional pressure relief maneuvers.
Pressure ulcer prevention using NMES

Subject inclusion criteria
• Individuals with SCI over 18 years of age
• Contractile response to electrical stimulation of gluteus maximus

Outcomes measured
• Interface pressures
• Transcutaneous blood flow
• Muscle bulk (gluteal muscle thickness)
Interface pressure measurement

Repeated assessments over several months and years

Tekscan Advanced Cliniseat System
Interface pressure measurement

Desired outcomes: static pressure distributions

![Graph showing mean contact pressure (mmHg) with two peaks, one labeled Baseline (pre-stimulation) and the other labeled Following stimulation.]
Long term effects on interface pressures: static pressure maps

Baseline

Following treatment
Motivation for development of novel analytical method

Spatial alignment

Temporal alignment

Simultaneous evaluation of multiple data points

Determination of truly significant differences within huge data sets
Longitudinal Analysis with Self-Registration (LASR)

- **Spatial alignment**
- **Temporal alignment**

Simultaneous evaluation of multiple data points

Determination of truly significant differences within huge data sets
Long term effects on interface pressures: LASR analysis static mode

Baseline vs post-treatment
Interface pressure measurement

Desired outcomes: dynamic pressure distributions
Long term effects on interface pressures: LASR analysis dynamic mode

No stimulation: T=0

Baseline vs post-treatment

Left side on: T=5.5
Pressure ulcer prevention using NMES

Conclusion

Clinical implications
Regular use of an implanted gluteal stimulation system can:

• Decrease sitting pressures
• Provide an extra means of weight-shifting
• Improve local blood flow
• Increase muscle size

Continued usage of stimulation is necessary to sustain improvements in tissue health.
Multidisciplinary teams in wound care and research

Multidisciplinary Clinical Research is one of the major NIH Roadmap initiatives*

….move beyond the confines of their own discipline and explore new organizational models for clinical care and research

* http://nihroadmap.nih.gov/overview.asp
• Wound care is a multi-factorial problem with no single ‘right’ answer

• Different approaches should complement not compete
Cleveland VAMC Pressure Ulcer Research Program

- Overall focus: clinical research on pressure ulcer management in spinal cord injury (SCI), in order to:
  - Validate current treatment methods
  - Explore novel prevention and treatment methods

- Clinical studies crossing the boundary between research and clinical care
Cleveland VAMC Pressure Ulcer Research Program

Bridging the gap between research and clinical practice

- Establishment of Skin Care Team consisting of research and clinical personnel
- Closer partnership between the SCI Unit and FES Center
- Introduction of rigorous methodological standards and measurements into clinical care, e.g. standardization of the measurement of wounds
Ultimate Goal

To improve the care and quality of life of individuals with spinal cord injury
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