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Early Days of COVID-19 and the Experiences of Canadian Wound Care Clinicians: Preliminary Findings

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Research Background

The World Health Organization declared COVID-19 a global pandemic in March 2020. As a result, Wounds Canada, in partnership with researchers at Cape Breton University, wanted to identify strategies to support health-care professionals providing skin and wound care during the pandemic to minimize negative impacts on individuals and families.



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Goal of the Study

This research aims to understand how the delivery of skin and wound care has changed during the pandemic. The study includes feedback from nurses, dietitians, occupational therapists, physiotherapists, physicians, chiropractors, podiatrists and other types of wound clinicians.

Participants were asked if and how they adapted delivery of patient-centred wound care services, with the aim of providing practical evidence to Wounds Canada as it continues to support clinicians through educational activities and the delivery of informational resources.

Ethics: Cape Breton University Research Ethics Board approved the study.

Methods

How: Participants were asked to complete structured, semi-structured and open-ended questions using a qualitative online survey methodology.

Who: Individuals listed on the Wounds Canada database were sent a link to the survey via email. They read a Letter of Information and completed an Informed Consent form before completing the survey.

Participants were individuals who:

- deliver wound care services;
- are a regulated or unregulated health-care provider;
- were willing to complete an online survey.

When: The study has a multi-phase data collection timeline. In May 2020, the first survey was sent to participants. Approximately 275 completed it.

Follow-up surveys will be conducted in September 2020, January 2021, May 2021 and September 2021. We will compare, contrast and analyze the data for themes. The data in this poster are preliminary data from the May 2020 survey.

Data Analysis : Preliminary Findings

1. Some wound clinics were deemed non-essential and therefore temporarily shut down; this triggered the use of remote technology:

"The closing of the wound clinic triggered a series of delays, availability and access to both wound care providers and ability to maintain/secure enough PPE supplies to provide safe service."

"Our, NSWOC nurse was not considered an essential service so in-home visits could not be carried out, only virtually."

"In our program, we did not do virtual visits but there was always a photo and follow-up assessments being done by email."



2. An existing lack of professional development was exacerbated by the pandemic as stated:

"Nurses in LTC require more education and ongoing education on wound care to provide and meet the needs of their residents."

"Community care is very understaffed with high staff turnover and nurse burnout; nurses visit between 12-15 patients/day. There is decreased experience recognizing different wounds and underlying comorbidities effects on the wound, like bacterial load."

"Community nurses are under-valued. Our sector is underfunded compared to facilities. This makes it difficult to keep experienced nurses, but also increases the demands on those nurses that stay."

"During COVID, I was increasingly able to implement teaching to complete the Advanced Lower Limb assessments; I am hoping we can obtain total contact casting for supplies and education for application of the device."



3. Access to and use of virtual technology related to assessment, treatment and follow-up was not always reliable nor user friendly.

"E-technology, allowed doctors to see wound progress or challenges; yet the quality of the videos were not clear."

"A weakness was that the assessing providers were not on time, this delayed our schedule."



"As nurses our biggest challenge was to complete the dressing after the telehealth visit if the booking was 15 minutes; most clients on telehealth do not have simple dressings."

"A strength of technology is that the provider can see the wound virtually. Yet, the assessing provider needs to have a strong wound and skin knowledge base including wound etiology, signs and symptoms, present treatments, thereby making recommendations virtually. Technology is only as good as the user's capabilities."

4. Many clinicians continuously endeavored to adapt and be flexible;

"I have this deep sense that wound care services will be ever changing during the pandemic. I see that wound needs have increased and will likely continue with limited face-to-face contact, social distancing, or lockdown in communities."

"I have continued to use email with photos and phone; on one occasion I did a live video conference."

"There is a new policy, technology and toolkit for virtual health, I have not yet had education or the opportunity to use."

"I am frustrated when teams did not explore technologies other than email/phone for pictures, where poor internet connections and poor camera quality exist, this was discouraging; yet I do now get to consult with specialty staff."



5. Families and clients did not always have technology and or expertise to be assessed, treated remotely.

"It is very challenging to utilize virtual technologies with seniors, and in some community home visits as many do not have video or microphone knowledge, internet or equipment."

"Older patients are resistant to trying virtual platforms. Some virtual visit training has been done but relies on the patient being able to manage at their end, this is not consistent."



Potential Research Outcomes

The findings will:

1. Inform the practice policy for health-care professionals providing skin and wound care services
2. Provide context and support for those working in remote locations
3. Be used to develop new or modify existing professional development opportunities
4. Provide an outlet for frontline workers to share their experiences and have their voices heard



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Venous Leg Ulcer Wound Healing with geko™: "I hope that my wound will heal faster": A qualitative inquiry.

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ABSTRACT

Aim: A qualitative study focusing on exploring individual's perspectives on using the muscle-pump activator - geko™ while living with a new or recurring venous leg ulcer.

Methodology: Using qualitative interviews, seven participants discuss their experiences with leg ulcers and use of the geko™. Research ethics and client consent were obtained. Using thematic analysis, themes emerged.

Findings: 1) Participants describe use of pain medications and stress when living with leg ulcers; 2) They describe the concept of time, from the time the ulcer forms to wound healing; and 3) Participants describe feeling hopeful and were optimistic the device would help the wound become smaller and heal faster.



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Background

Chronic venous leg ulcers comprise approximately 70 to 80% of all lower limb ulcerations (Evans et al., 2019). Lower leg wound management is a burden to the health care system (CIHI, 2013). Most venous leg ulcers occur in a population where 30% already have three or more comorbidities; 85% live with leg ulcer pain, 53% have issues with mobility, 24% have problems washing or dressing, 58% had difficulty performing usual activities, of these, one-third report moderate anxiety or depression (Harrison et al., 2013).

Community nurses aim to provide person-centered care to patients living with leg ulcers (RNAO, 2015), and spend up to 50% of their time providing care to persons with venous leg ulcers (Simon et al., 2004).

Patients are the Focus

For patients living with venous leg ulcers, the emotional and socio-economic burden is significant to the individual and the health care system (O'Donnell et al., 2014; Phillips et al., 2017). Xhu and Ryan (2017) report patient pain issues and how they lead to psychosocial issues (suicide risk, relationship distress, emotional crisis). Pain is one of the leading issues community nurses attend to with community clients. VanDenKerkhof et al. (2013), report 58% of patients living with venous leg ulcers experienced moderate to severe pain and did not regularly take pain medication(s) to ease their pain.

Research Objective

This study sought to understand the perspectives of clients utilizing the geko™ device in the community. Ethical approval was granted from Homewood Health Centre Research Ethics Board & the Mississauga-Halton LIHN. **Funding:** Perfuse unrestricted educational grant.

Methodology

Method: A qualitative descriptive interview approach (Sandelowksi, 2000). The approach aims to convey the rich, thick data helping to understand individuals' experiences.

Thematic Analysis: The authors regularly met to listen to, discuss the data and field notes were kept by the authors (Braun & Clarke, 2013).

Frameworks Guiding the Study

A naturalistic inquiry approach (Lincoln & Guba, 1985); and the RNAO (2015) person-centered care, framed the qualitative questions and focused on the 'whole person' not just on their illness or disease.

Participants and Recruitment

This inquiry is part of a larger study; 7 participants consented and participated in phone conversations (Sandelowksi, 2000). Participants of diverse backgrounds, 5 females, 2 males were purposively recruited from a local LIHN, Home and Community Care Program, ON (Braun & Clarke, 2013) (Table 1).

Participants' Share: Findings

1) Participants describe use of pain medications and stress when living with leg ulcers.

Peter stated: *I took these pain and narcotic meds all the time, before using the geko™ device, and then during the time the geko™ was on my leg, I was not taking those meds, I was getting healed by the device working, and now after I stopped the device, I am great, I am feeling good"* (Research conversation, March 2020)



2) They described the concept of time, from the ulcer beginning to wound healing.

Arlene, was normally a very social person, as this was not her first leg ulcer, she stated: *"I adapted my life to the ulcer, you have to, and I stay positive over time"* (Research conversation, March 2020).



Carrie, shared the following insights: *Originally, I was in the hospital for a week. I normally work 30 plus hours a week, I went stir crazy when I got home, and*

I had to get back to work. I did not change the geko™ device, I go there to the nurses-three times a week, to the clinic, that is where they change my compression bandages. Whether I was wearing the device or not I still went three times a week... I just want the wounds to close." (Research conversation, March 2020)

3) Participants described feeling hopeful and were optimistic the muscle-pump activator - geko™ would help the wound become smaller and heal faster.

Optimism

Hope

Richard stated, well, there was, like an optimism level, ah, in me. I wanted to hope it would help the ulcer close. But then, I'm not sure if it actually did help me...because of well, at the same time the doctor put me on a water pill, maybe a couple of months back, whatever it is. It overlapped with the ulcer and the geko™, either way I wanted this "thing" closed. (Research conversation, March 2020)

Clinical Implications

Hope was described by participants as growing when offered the geko™ device to support wound healing. Participants describe feeling valued.

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The Use of a Non-invasive Pulsed Acoustic Cellular Expression (PACE®) System To Promote Angiogenesis in Chronic Wounds in Persons with Diabetes

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Introduction

- Chronic lower extremity ulcerations in patients with diabetes are a common complication with high morbidity and mortality
- Despite numerous advances in wound care and healing over the past two decades, these ulcerations continue to pose a significant clinical problem.
- Focused-extracorporeal shock wave technology (F-ESWT) is a potential modality that can assist in healing these chronic wounds by enhancing neovascularization and wound bed tissue oxygenation

Objective

- To determine the effects of (F-ESWT) administered via a pulsed acoustic cellular expression system (PACE) on tissue oxygen saturation (StO₂%) and healing in chronic diabetic ulcerations in patients with normal ABIs

Methods

- Prospective, single-site, single-arm pilot case series lasting five (5) weeks.
- Fifteen subjects— nine male/six female, all positive for diabetes and chronic lower extremity wounds that failed treatment with at least one advanced wound care therapy.
- Subjects received PACE treatment once weekly for four consecutive weeks.
- A near-infrared camera device (NIRS) was used weekly to measure and record localized wound tissue oxygenation and perfusion.
- Weekly wound measurements were also tracked.



Results

Table 1
Baseline and Final wound size and StO₂ measurements and percent change

| Patient Number | Description | Baseline | Final | Change |
|----------------|---------------------------------|----------|-------|--------|
| 1 | Wound Volume (cm ³) | 9.31 | 8.26 | -1.05 |
| | StO ₂ % | 49.0% | 60.0% | 18.0% |
| 2 | Wound Volume (cm ³) | 74.1 | 38.34 | -35.76 |
| | StO ₂ % | 57.0% | 62.0% | 8.1% |
| 3 | Wound Volume (cm ³) | 0.16 | 0 | -0.16 |
| | StO ₂ % | 58.0% | 71.0% | 18.3% |
| 4 | Wound Volume (cm ³) | 7.33 | 4.54 | -5.81 |
| | StO ₂ % | 80.0% | 83.0% | 3.6% |
| 5 | Wound Volume (cm ³) | 7.07 | 6.21 | -0.86 |
| | StO ₂ % | 57.0% | 72.0% | 20.8% |
| 6 | Wound Volume (cm ³) | 0.17 | 0 | -0.17 |
| | StO ₂ % | 69.0% | 71.0% | 2.8% |
| 7 | Wound Volume (cm ³) | 0.75 | 0 | -0.75 |
| | StO ₂ % | 69.0% | 71.0% | 2.8% |
| 8 | Wound Volume (cm ³) | 0.06 | 0 | -0.06 |
| | StO ₂ % | 82.0% | 85.0% | 3.5% |
| 9 | Wound Volume (cm ³) | 0.95 | 0.71 | -0.24 |
| | StO ₂ % | 20.0% | 52.0% | 61.5% |
| 10 | Wound Volume (cm ³) | 0.6 | 0.01 | -0.59 |
| | StO ₂ % | 82.0% | 86.0% | 4.7% |
| 11 | Wound Volume (cm ³) | 3.28 | 0.02 | -3.26 |
| | StO ₂ % | 34.0% | 81.0% | 58.0% |
| 12 | Wound Volume (cm ³) | 0.5 | 0.24 | -0.26 |
| | StO ₂ % | 48.0% | 81.0% | 40.7% |
| 13 | Wound Volume (cm ³) | 0.7 | 0 | -0.7 |
| | StO ₂ % | 47.0% | 77.0% | 39.0% |
| 14 | Wound Volume (cm ³) | 14.7 | 8.75 | -5.95 |
| | StO ₂ % | 74.0% | 86.0% | 14.0% |
| 15 | Wound Volume (cm ³) | 0.04 | 0 | -0.04 |
| | StO ₂ % | 84 | 92.0% | 8.7 |

- All 15 wounds reduced in size from baseline to end of study:**
 - Seven (46.7%) wounds healed—100% epithelialization
 - Median wound size and absolute change (excluding resolved wounds):
 - 4.54 cm³; -1.05 cm³, respectively
- All 15 patients displayed an increase in wound bed StO₂% upon study completion:**
 - Mean final StO₂: 75.7 ± 11.1% absolute change 15.07 ± 13.8%
 - 95% CI 15.1 ± 13.8 % (p=0.0008)

Disclosure Statement: This study was supported in part by SANUWAVE® through the donation of the dermaPACE® System to conduct this case series. Support was provided by Kent Imaging in the form of the Snapshot_{NIR} device. The authors have no other disclosures to report.

Case Example



Figure 1 Baseline

- 56 yo female
- PMH: IDDM, HTN, Kidney disease, calciphylaxis, DJD
- Wound duration 16 months
- Wound measurements: 9.0cmx7.1cmx0.6cm

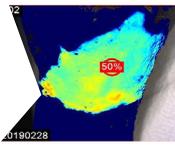


Figure 2 Baseline

- NIRS image shows blue and yellow tissue at wound base indicating low oxygenation
- Baseline O₂ saturation level 50%

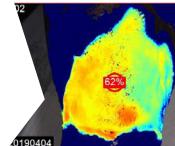


Figure 3
Post 4 dermaPACE® therapy treatments

- NIRS image shows more areas of orange and red indicating increased oxygenation
- O₂ saturation now 62%



Figure 4
Post 4 dermaPACE® therapy treatments

- Measurements after 4 PACE treatments are 8.7cmx9.5cmx0.1cm
- New evidence of epithelialization present
- Base has more granulation tissue
- Patient referred to plastics for STSG



Figure 5 Healed

- Patient fully healed with STSG
- Pre-PACE therapy Plastics refused to perform the procedure due to wound appearance and patient history

Conclusion

- Use of PACE therapy in conjunction with NIRS imaging proved to be a beneficial additional treatment for chronic lower extremity diabetic ulcerations
- Results suggest PACE therapy increases StO₂ potentially facilitating accelerated healing
- Large randomized controlled trials will assist in determining the extent to which PACE therapy can accelerate wound healing

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Abstract #6



Wound size reduction of diabetic foot ulcers over a 4-week period as a strong predictor of healing

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Background and Rationale

- About 3.4 million Canadians (9.3%) have diabetes;
- The lifetime risk of developing a diabetic foot ulcer (DFU) is reported to be 15-34% for people with diabetes;
- DFUs represent a significant economic burden for society in terms of
 - wound care
 - management of complications
 - e.g. infection, hospitalization, amputation, rehabilitation, death;
- Wound size reduction after 4 weeks has been suggested as a strong predictor of wound healing at 3 months :

Venous ulcers

→

• 30%
wound size reduction
after 4 weeks

Wound Healing at 3 months

DFUs

→

• 50%
wound size reduction
after 4 weeks

Wound Healing at 3 months

- However, no previous Canadian study examined this relationship on DFUs.
- Moreover, few data exist related to wound healing outcomes of DFUs and predictors of healing in Canada;

Objectives and Methods

Objectives:

- To determine the 1-year wound healing outcomes of patients with a DFU treated by an interdisciplinary team approach;
- To assess the validity of wound size reduction at 4 weeks to predict wound healing at 3 months;
- To identify the baseline variables associated with wound healing.

Study design: A retrospective observational cohort study

Setting: The Complex Wound Care Clinic (CWCC) of a University affiliated Regional Hospital of the Greater Québec City Area (CISSS de Chaudière-Appalaches)

Eligibility:

Inclusion criteria:

- 18 years of age and older with either type 1 or type 2 diabetes;
- With at least one DFU on the plantar aspect of the foot;
- Treated at the CWCC from 2012 to 2018.

Exclusion criteria

- Taking any drug that could inhibit wound closure

Statistical analyses:

- Predictive/explicative analyses with logistic multivariate methods
- Receiver Operating Characteristics (ROC) curve

Results

Table 1. Baseline characteristics of patients

| | n = 140 | % | Mean | SD |
|------------------------------------|----------|--------------|------|------|
| Men // Women | 91 // 49 | 65.0 // 35.0 | | |
| Age (years) | | | 67 | 12.7 |
| BMI (kg/m ²) | | | 32.1 | 8.2 |
| Type 1 // Type 2 diabetes | 5 // 135 | 3.6 // 96.4 | | |
| Peripheral neuropathy | 112 | 81.2 | | |
| Modified Charlson Index | | | 6.3 | 2.7 |
| Smoking | 29 | 20.7 | | |
| HbA1c (%) | | | 8.1 | 2.4 |
| Valid values of ABI (compressible) | 115 | | 0.9 | 0.3 |
| Monophasic Doppler waveform | 55 | 39.3 | | |
| Peripheral arterial disease (PAD) | 59 | 42.1 | | |
| Previous history of amputation | 15 | 10.7 | | |
| Baseline wound size | | | | |
| Wound area (cm ²) | | | 1.95 | 3.69 |
| Depth (cm) | | | 0.85 | 1.14 |
| Location | | | | |
| Forefoot | 118 | 84.3 | | |
| Mid foot | 6 | 4.3 | | |
| Rearfoot | 16 | 11.4 | | |
| Infection requiring antibiotics | 62 | 44.3 | | |

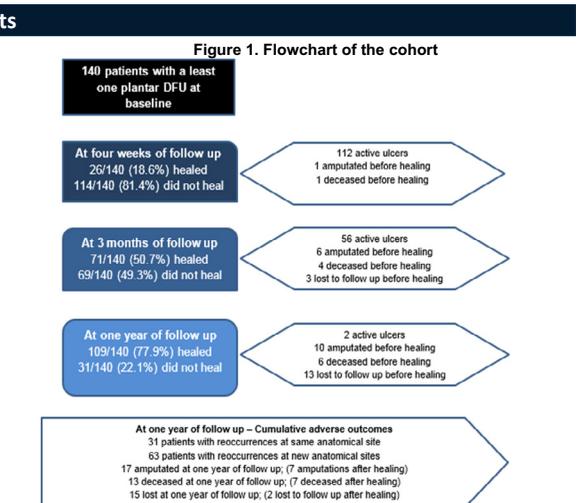
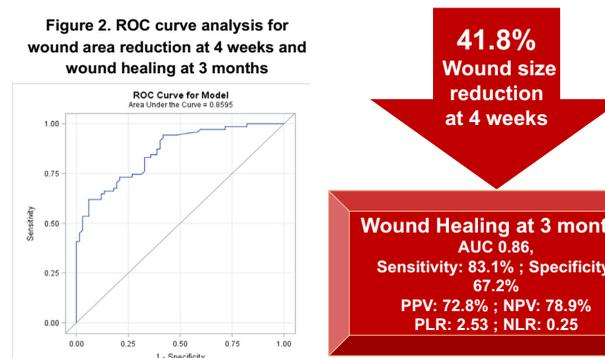


Table 2. Results of multivariate logistic regression analyses conducted to identify baseline variables with wound size reduction < 41.8% at 4 weeks

| Baseline characteristics | Adjusted multivariate analysis | | |
|---|--------------------------------|---------------|---------|
| | OR | 95% CI | P value |
| Sex (male vs female gender) | 3.58 | (1.30-9.87) | 0.01 |
| Diabetes (type 1 vs type 2) | 21.37 | (1.41-324.15) | 0.03 |
| Smoking | 4.7 | (1.44-15.29) | 0.01 |
| Monophasic Doppler | 7.52 | (2.64-21.39) | <0.01 |
| Topical antimicrobial for local infection | 6.39 | (1.96-20.81) | <0.01 |
| Antibiotics for infection | 0.36 | (0.14-0.95) | 0.04 |

Implications and Applications

- The health care provider should be cautious and intensify its management of DFUs particularly with :
 - Male patients; smoking, type 1 diabetes;
 - Having a monophasic waveform with a hand-held Doppler;
 - And not achieving a minimal 41.8% wound area reduction at 4 weeks of treatment.
- The 41.8% wound size reduction mark, as a predictor of healing, should only be used for DFUs located on the plantar aspect of the foot.

Reference

Accepted for publication on August 26th 2020 : Patry J, Tourigny A, Mercier M-P, Dionne CE. Outcomes and prognosis of diabetic foot ulcers treated by an interdisciplinary team in Canada. *International Wound Journal*. 2020. DOI: 10.1111/iwj.13505



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Adequacy Between Canadian and International Guidelines for the Prevention and Management of Diabetic Foot Ulcers

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Context

- Barriers and challenges to coordinated delivery of all necessary cares for diabetic foot ulcers (DFUs):
 - Geographical expanse
 - Variable population density across large region [1].
- Gaps and variations of DFU's care across Canada:
 - Lack of standardized tools
 - Poor coordination of care
 - Poor evidence-based implementation strategies [2].
- Differences in clinical practices guidelines have been demonstrated in a previous study from Western Pacific Regions
 - To support evidence-based practices on DFUs [3].
- International Working Group on Diabetic Foot (IWGDF) guidelines
 - Considered a gold standard of any country that would like to reduce DFU burdens [3].
 - Superior quality standard according to AGREE II tool for quality guidelines appraisal [4].

Aim

- To review and to evaluate the 3 Canadian clinical practice guidelines and recommendations (CPGRs) in comparison with the IWGDF guidance documents.
 - Objective 1 : Adequacy to IWGDF recommendations**
 - Objective 2 : Quality appraisal

Methods

Objective 1 → Objective 2 → AGREE II quality appraisal method [5]

- Rating scale from Parker and collaborators [3]

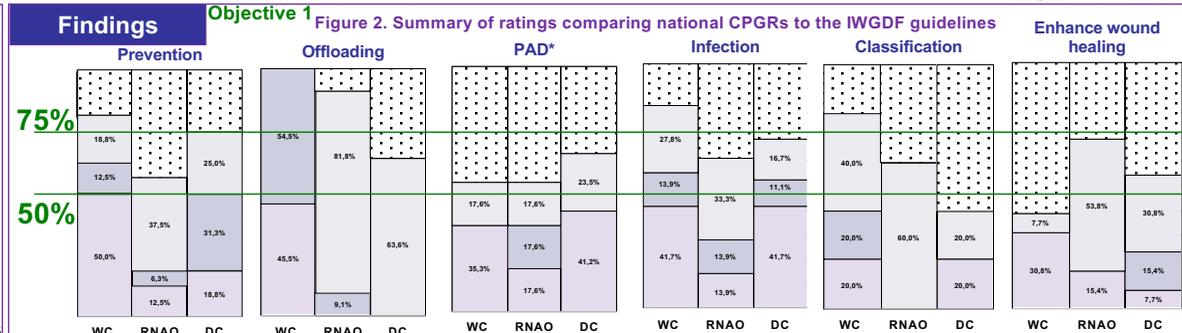
| Rating | Signification |
|-------------------|---|
| Similar | Over 80% similar to IWGDF recommendations |
| Partially similar | 20 – 80% similar to IWGDF recommendations |
| Different | Less than 20% similar to IWGDF recommendations or totally different |
| Absent | Not discussed or not presented |

- 3 blinded investigators
- Not involved in national or international DFU guidelines

Data Sources

Figure 1. Rating scale for adequacy of recommendations

- 6 chapters
- 85 recommendations
- 98 items
- Analysis**
 - Descriptive statistics
 - Narrative synthesis



- Analysis for comparing CPGRs to IWGDF recommendations**
 - WC = superior adequacy
 - Major gaps for PAD and classification chapters
 - Lack of adequacy for level of evidences
 - RNAO = inferior adequacy
 - Major gaps for all chapters
- Recommendations' items presented in the IWGDF guidance documents that were not presented in any CPGRs**
 - Prevention**
 - item #13: nerve decompression procedure to prevent DFU
 - Infection**
 - item #4: infection diagnosis with electronically measuring foot temperature or using quantitative microbial analysis
 - item #9: molecular microbiology techniques in first line identification
 - Enhance wound healing**
 - item #6: topical oxygen therapy as primary or adjunctive intervention for DFU
- Different IWGDF items in all CPGRs**
 - Infection**
 - item #17: related to infection control for people residing in a tropical/subtropical climate, that cannot be applied to Canada
 - item #24 concerning oral antibiotics to treat osteomyelitis [6]
 - Classification**
 - item #2 about classification, which can be used for DFU individual prognosis
- Not recommended items in WC**
 - Enhance wound healing**
 - item #3: dressings/applications containing surface antimicrobial agents with the sole aim of accelerating DFU healing
 - item #10: agents that are altering DFU biology such as growth factors, autologous platelet gels, bioengineered skin products and nitric oxide
 - item #12: agents that are altering DFU physical environment such as electricity, magnetism, ultrasound and shockwaves)
- Contrary items to IWGDF items in RNAO**
 - Enhance wound healing**
 - RNAO has recommended the contrary for items # 3-10-12
 - item #8: use negative pressure wound therapy for healing of a non-surgical DFU
 - Infection**
 - item #14: not using any currently available topical antimicrobial agent for treating a mild DFU infection
 - item #19: not treating clinically uninfected DFU with systemic or local antibiotic therapy with the goal of reducing the risk of infection or promoting DFU healing

Objective 2

- All CPGRs are recommended for use with modifications
- Quality appraisal: Intra-class correlation coefficients (ICCs) = Good (p < 0.0001)

• WC: Fair • RNAO: Good • DC: Good
 • Superior

Implications

Adequacy with IWGDF ≠ Quality of CPGRs

- RNAO: needs an updated document to continue its mission as a gold standard of practice
- WC : Higher adequacy with the IWGDF recommendations for evidence-based practices
 - To be read/applied along with the new WC PAD ulcers best practice recommendations [7]
- DC: needs a chapter focusing on DFU in addition to Foot care and Neuropathy chapters
- CPGRs quality appraisal**
 - Developed with an evidence-based systematic process
 - Updated regularly
 - Developed with an interdisciplinary approach by health care professionals involved in a DFU team approach;
 - Included patient-oriented research and implementation strategies.

References

No conflict of interest to declare.

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A randomized controlled pragmatic study to evaluate the use of silicone dressings for the treatment of skin tears

Kimberly LeBlanc PhD RN NSWOC WOCC (C); Kevin Y. Woo, PhD RN NSWOC WOCC (C)

Introduction

Maintaining skin integrity is espoused by several international authorities as a benchmark for patient safety and quality of care. One of the most common causes of skin breakdown is skin tears (STs) defined as "wounds caused by shear, friction, and/or blunt force resulting in separation of skin layers" (LeBlanc et al., 2011).



Several prevalence studies conducted in LTC settings indicate evidence of ST among 10-54% of their residents (Everett & Powell, 1998; McErlean, Sandison, Muir, Hutchinson, & Humphreys, 2004; Santamaria, 2009).

Careful selection of dressings with an atraumatic and non-adherent wound contact layer, such as silicone, has been documented to limit skin damage/trauma with dressing removal and to minimize pain at dressing changes (Woo & Smith, 2014). Silicone coatings consist of chains of hydrophobic polymers with alternate molecules of silicone and oxygen. Compared to other adhesives, the silicone coatings produce a lower surface tension combined with a more extensive contact interface.

In a comparative study, Matsumura et al. (2012) evaluated eight commonly used wound care products with adhesives (soft silicon, hydrocolloid, polyurethane, and acrylic adhesives) and their potential effect on the epidermis in 10 normal volunteer subjects. Dressings that incorporated soft silicone technology were less likely to cause skin stripping and removal of stratum corneum than other tested material.

Research questions

To date, this is the first study to evaluate the use of soft silicone dressings to promote healing of skin tears. The primary purpose of the proposed study is to compare the effectiveness of a soft silicone dressings for the healing of skin tears with local best practices that do not include soft silicone dressings.

Research Questions

1. Is there a difference in the proportion of complete healing between soft silicone dressings and non-soft silicone dressings for treatment of skin tears?

2. Is there a difference in healing rates between soft silicone dressings and non-soft silicone dressings for treatment of skin tears?

Research design

• **A prospective, pragmatic randomized controlled trial.**
 • Participants were randomized, using a computer based randomization program, blinded to the researcher.
 • Randomization were conducted on the unit level within the participating long-term care facilities.
 • Duration: 3-week (complete healing was anticipated with 7 to 21 day period for the majority of skin tears)

| Inclusion Criteria | Exclusion Criteria |
|--|--|
| <ul style="list-style-type: none"> Resident of participating LTC facilities Presence of a skin tear all types of skin tears All levels of exudate | <ul style="list-style-type: none"> Factors that may compromise wound healing: medical condition previous wound treatment non-compliance infection |

Intervention and comparison

Treatment group:

- Depending on the type of skin tears and potential exudate produced by the wound, an appropriate form of silicone dressing was used.
- Meptel One dressing will be used for Type 1 and Type 2 skin tears where exudate is expected to be minimal.
- Mepilex® Border Flex will be used for exudative Type 2 and Type 3.

Control group:

- Non-adherent non-silicone dressing
- Alldress



Table 1: ISTPA skin tears classification system

Measurement

Weekly measurement of wound sizes: the longest wound length and wound width dimensions that were perpendicular to each other to provide the estimation of wound surface areas.

Proportionate changes in mean surface area over the 3-week period were calculated to provide healing rates.

- All subjects were evaluated at week 0, week 1 and week 3 (i.e., at the end of the study)
- Photography of the wounds.
- Pain : NRS or Pain Assessment in Advanced Dementia (PAINAD) scale
- Adverse events



Results

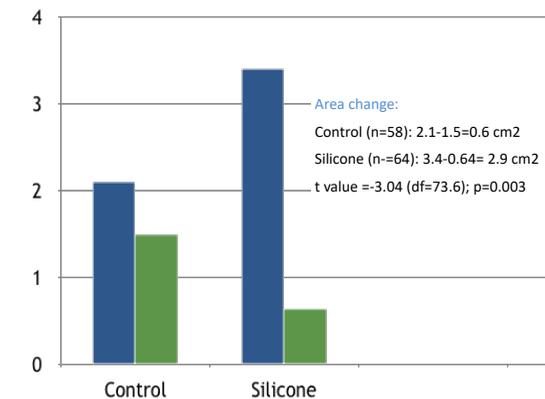
• **A nonprobability convenience sampling = 126 individuals**

- Male = 56 (44.4%)
 - Female = 70 (55.6%)
 - Mean age = 82.9 (+/- 8) years; (45-102 yo)
- Setting: long-term care facility and complex continuing care hospital in Ottawa and Toronto

| Treatment | Frequency | Percent |
|---------------------|-----------|---------|
| Alldress | 45 | 35.7 |
| Mepilex (Flex) | 55 | 43.7 |
| Meptel 1 | 17 | 13.5 |
| Nonadherent (Telfa) | 9 | 7.1 |
| Total | 126 | 100.0 |

| Skin Tear classification | Frequency | Percent |
|--------------------------|-----------|---------|
| Type 1 | 16 | 12.7 |
| Type 2 | 55 | 43.7 |
| Type 3 | 55 | 43.7 |
| Total | 126 | 100.0 |

Results and conclusion



Results of this study suggest silicone dressings are superior to nonadherent dressing for the treatment of skin tears.

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Whole vs Hole: Enabling Nurses to Apply Wholistic Wound Care

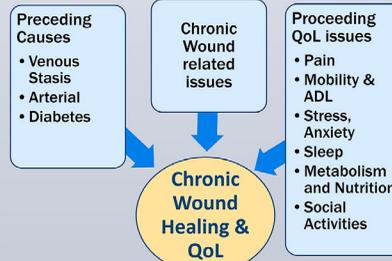
Marzieh Moattari, RN, BSc., M.Sc.N, M.Sc.ME, Ph.D.

TAHSNp Health Professions Innovation Fellowship Program,
Toronto Central Team VHA Home HealthCare



Introduction & Background

- Clients with chronic wounds in their lower limbs suffer from a variety of preceding diseases.
- They experience many Quality of Life (QoL) issues such as impaired mobility, pain, insomnia, and stress.¹
- Nurses are focused mostly on the wound itself rather than its related preceding causes and/or preceding QoL issues.²
- Inconsistency in choosing appropriate wound dressings has been documented and this can delay wound healing.³
- Integration of client-centered care in nursing practice to include the whole client rather than just the hole (wound) may enhance wound healing and thereby QoL and independence in clients suffering from chronic wounds.

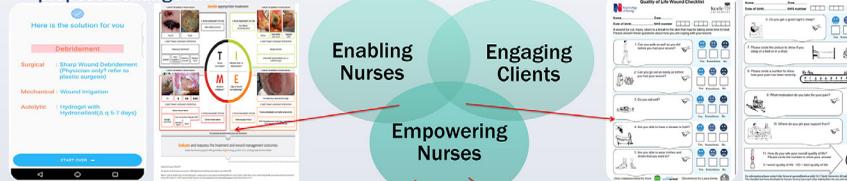


Objectives

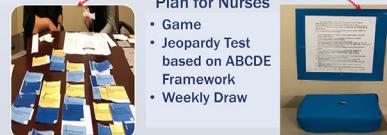
- The aims of this project are to increase:
- wound related QoL (wellbeing) by 25%,
 - wound related QoL (physical symptoms and daily living) by 25%,
 - would related overall QoL by 25%, and
 - referrals to inter-professional team members by 20%
- in clients with diabetes, arterial, and/or venous leg ulcer referring to the North Nursing Clinic by March 1st, 2020.

Methods

- Needs assessment, literature review, stakeholder engagement and the use of guidelines led to proposed change ideas



- Equipping nurses with decision making support tools to choose dressing³
- WoundS App
 - T.I.M.E. framework⁴
 - Product Picker



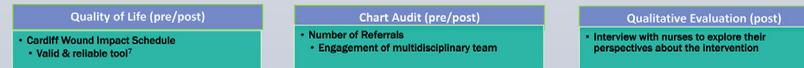
- Education & Incentive Plan for Nurses
- Game
 - Jeopardy Test based on ABCDE Framework
 - Weekly Draw

- Patient engagement in self-assessment of QoL⁵
- Clients were asked to self-assess using QoL checklist
 - Nurses to include results in their intervention plan

Kotter's Stages of Change Model was used to implement the change process⁶

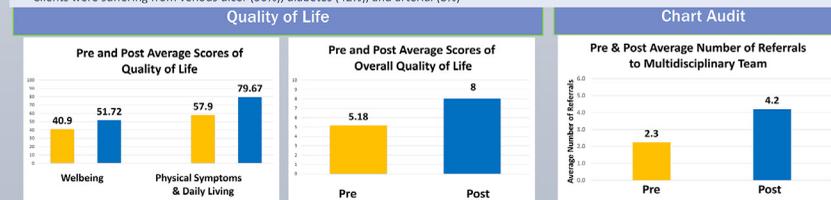


Evaluation Tools



Results

- A total of 121 charts were reviewed: 93 pre and 28 post. Of these only 12 clients were eligible (having Diabetes, Venous, or Arterial wounds) pre (January & February 2019) and 7 post (January 2020)
- Average number of visits of clients with chronic wounds and clients with other conditions were 24.5 and 9.4 respectively
- Mean age of clients with chronic wounds was 68.3 while mean age of other clients was 54.9
- Clients with chronic wounds were 58% female
- Clients were suffering from venous ulcer (50%), diabetes (42%), and arterial (8%)



- Assessment completed by 11 clients pre and 6 clients post
- A 26% and 38% increase was observed for wellbeing and physical symptoms & daily living scores
- Overall QoL score increased by 54%
- The number of referrals to multidisciplinary team increased by 83%
- The most common referrals were for ET nurse, MD, and Wound Specialist

Themes from Interviews with Nurses

The following themes were extracted from interviews with 5 nurses working in the clinic:

- **WoundS App** is a highly valuable decision making tool for new hires and new grads.
- **Quality of Life Wound Checklist** should be used on admission and every 4 weeks thereafter.
- Education program was innovative, engaging, and effective.

Sustainability Plan

- Forming a guiding coalition at organizational level to improve holistic wound care.
- Adding resources to the VHA online intranet to promote use.
- Adding Quality of Life checklist to Electronic Medical Records for nursing assessment.
- Integrating holistic wound care into nursing orientation program.

Conclusions

- Results support the increase in clients' QoL, and increase in referrals to multidisciplinary team.
- Engaging clients in QoL assessment, enabling and empowering nurses are effective strategies for implementation of holistic care to clients with chronic wounds.
- Kotter's stages of change is a valuable framework to conduct the process of change.
- Further studies with larger sample size are needed to generalize the results of this quality improvement project.

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- All nurses working at the North Nursing Clinic



Stop the Pressure! A Quality Improvement Initiative to Decrease Hospital Acquired Pressure Injury Rates.

Leslie Richards RN MScN, Colleen Wilkinson RN, MS(N)
Lakeridge Health



Aim

An Internal review identified that our pressure injury (PI) rate was higher than our comparable organizations. Our aim was to decrease the number of hospital acquired pressure injuries utilizing numerous interventions and strategies guided by RNAO's Best Practice Guidelines.

Background

Lakeridge Health is a multi-site organization consisting of 5 sites in Durham Region, Ontario. The organization is in the final year of a three year pre-designation period to become a Best Practice Spotlight Organization. The Assessment and Management of Pressure Injuries for the Interprofessional Team BPG was initiated at Lakeridge Health- Ajax Pickering site. Despite official data collection and implementation at one site, all interventions and strategies were put into effect at all sites.

Methods

Model for improvement

A Pressure Injury Interprofessional Working Group was developed to collaborate using the PDSA model for improvement to strategize, deliver, review and implement our PI initiative.

Interventions

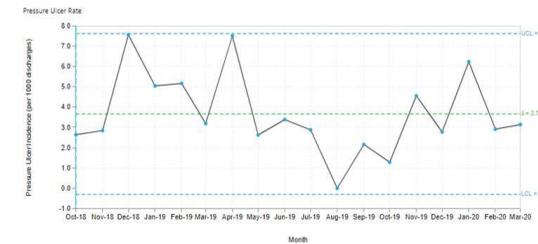


Worsening Pressure Injury Report

| Row | Location ID | Unit | Account Number | Visit ID | Name | Admit Date Time | Acquired This Admission | Site | Landmark | Stage Before | Stage | Stage Note | Documentation Date of Current Stage | Status |
|-----|-------------|------|----------------|----------|-------------|-----------------|-------------------------|--------------|-----------|--------------|---------|-----------------------|-------------------------------------|-----------|
| 5 | OPR | | 1112020 | | LH Hospital | 11/20/20 PM | | SACKAM/COOBY | COOBY | Stage 1 | Stage 2 | S14/20/20 9:50:00 AM | | Worsening |
| 19 | WKA | | 1112020 | | LH Hospital | 11/20/20 PM | | SACKAM/COOBY | 8 BUTT/CK | Stage 2 | Stage 2 | 8/25/20/20 8:40:00 AM | | No Change |



Results



Findings

Because of the corporate wide Quality Improvement initiative, the Hospital Acquired Pressure Injury rate decreased and is now in line with our peer hospitals. We believe the cumulative effect of all of our initiatives resulted in the significant rate reductions we have seen.

Implications

Utilizing the RNAO's BPG for Assessment and Management of Pressure Injuries for the Interprofessional Team provided the organization a framework for this Quality Improvement initiative and was successful in PI rate reduction.

PRESSURE INJURY (PI) REPOSITIONING CHECK

| Unit | Date | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|---------------|------|-------|----------------|----------------|---------------|------------------------|------------------------|----------------------------|----------------------------|---------|-----|--|--|--|--|--|--|--|--|--|--|--|-------|--|--|--|--|--|--|--|--|--|--|--|---------|--|--|--|--|--|--|--|--|--|--|--|--|
| <p>Step 1: Report list of patients with PI</p> <p>Step 2: Report documentation from Meditech and if not all applicable, complete the patient's assigned care plan.</p> | <p>Step 3: Round on the patient and check for support surface and circle the total position. Circle any repositioning and labels.</p> <p>Step 4: Round on the patient after 2 hours to determine final position. Record any additional repositioning, care and actions.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1"> <thead> <tr> <th>Last Name</th> <th>First Initial</th> <th>Room</th> <th>Bed</th> <th>Stage</th> <th>Wound Location</th> <th>Braden Score</th> <th>Documentation</th> <th>Support Surface/Status</th> <th>Mobility/Turn Schedule</th> <th>Comments and Interventions</th> <th>Actions</th> </tr> </thead> <tbody> <tr> <td>Mit</td> <td></td> </tr> <tr> <td>Unmet</td> <td></td> </tr> <tr> <td>Eternel</td> <td></td> </tr> </tbody> </table> | Last Name | First Initial | Room | Bed | Stage | Wound Location | Braden Score | Documentation | Support Surface/Status | Mobility/Turn Schedule | Comments and Interventions | Actions | Mit | | | | | | | | | | | | Unmet | | | | | | | | | | | | Eternel | | | | | | | | | | | | <p>1 - Wound Care Consult Needed</p> <p>2 - Registered Dietician Referral Needed</p> <p>3 - Support Service Needed</p> |
| Last Name | First Initial | Room | Bed | Stage | Wound Location | Braden Score | Documentation | Support Surface/Status | Mobility/Turn Schedule | Comments and Interventions | Actions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mit | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Unmet | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eternel | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

A - Action Descriptions

- 1 - Wound Care Consult Needed: Initiate consult through Meditech for consult stage 3 (infectious, stage 4, or stage 5) or area tissue injury. Update the unit whiteboard as needed.
- 2 - Registered Dietician Referral Needed: Registered Dietician Referral: Initiate consult through Meditech for any stage. Update the unit whiteboard as needed.
- 3 - Support Service Needed: Provide patient with support surface. Refer to prevention injury prevention order for appropriate surface. Report support surface from Unit Care and then inform the Unit Coordinator (as needed).

Contact
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1 Hospital Court, Oshawa, On L1G 2B9
lesrichards@lh.ca
905-244-3917

References
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Continuous Delivery of Oxygen is a Cost-Effective Therapy for Individuals with Chronic Diabetic Foot Ulcer

Brian Chan^{1,2}, Karen Campbell³

¹KITE-Toronto Rehabilitation Institute – University Health Network, ²Institute for Clinical Evaluative Sciences, ³School of Physical Therapy, Western University



Introduction

\$619,300

Lifetime cost of diabetic foot ulcer Ontario Public Healthcare system¹

15.7% Improvement in wounds healed using Continuous Diffusion of Oxygen (CDO) therapy²

Is CDO therapy cost-effective for individuals with advanced diabetic foot ulcer?

Objective

To evaluate the cost-effectiveness of CDO versus negative pressure wound therapy (NPWT) over a 5-year period for individuals with advanced diabetic foot ulcers for the Ontario public health care payer.

Methods

- 5-year Markov model projecting long-term health care costs and quality adjusted life years with CDO therapy and NPWT therapy
- 10,000 individuals simulated
- Model inputs based on published clinical trial results, observational studies and publicly available government documents
- Model uncertainty was evaluated using scenario and probabilistic sensitivity analyses

Results

Table 1: Initial treatment costs

| Therapy | Treatment cost per week |
|-------------|-------------------------|
| CDO therapy | \$608 |
| NPWT | \$1,125 |

Over 5-years CDO is projected to average \$4,800 less than NPWT and have a 0.025 higher quality adjusted life years.

Table 2: Scenario analysis results

| Comparison | Cost difference | QALY difference |
|--|-----------------|-----------------|
| CDO vs. HBOT | -\$14,060 | 0.025 |
| CDO vs. moist wound therapy | -\$1,860 | 0.054 |
| Debridement at all follow-up visits | -\$6,100 | 0.050 |
| Ulcer >4.9cm ² | -\$5,258 | 0.039 |
| <20% healing per week or 30% total healing 2 weeks screening | -\$6,455 | 0.085 |

In repeated simulations 79% had lower costs and higher QALYs for CDO

Discussion

- CDO results in lower costs and very slight improvements in QALYs.
- Sensitivity analyses suggest that results are robust.
- Studies were based on an indirect comparison of CDO and NPWT.
- Results are applicable to an Ontario health care setting.
- There is a need for studies evaluating the long-term impact of CDO on diabetic foot ulcers.

Acknowledgements

Funding for this project was provided by EO₂ Concepts Inc. through an unrestricted grant. The primary author had full authority over the model development, analysis and interpretation of the results. The primary author also had independent control on the results presented in this poster.

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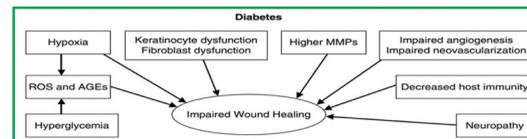
Poster No: 12

Cold Plasma Therapy Ameliorates Inflammatory Process in Diabetic Foot Ulcer

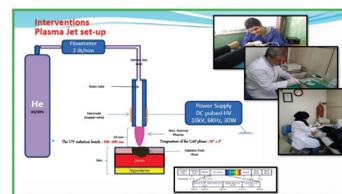
Mohammad Reza Amini¹, Motahareh Sheikh Hosseini², Sara Fatollah³, Shahriar Mirpour⁴, Farnaz Safavifar⁷, Akram Tayanloo², Mahmoud Ghoranneviss⁵, Bagher Larijani⁶, Mohammad Reza Mohajeri-Tehrani⁶, Mohammad Reza Khorramizadeh⁷

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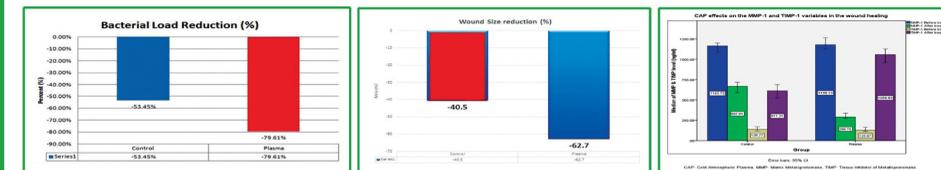
Aim: The healing process in diabetic wounds, similar to other types of chronic wounds, is impaired. Cytokines and growth factors play pivotal roles in wound vitality or duration. The aim of this study is to assess possible anti-inflammatory effects of therapeutic cold atmospheric pressure plasma on patients with diabetic foot ulcers, as part of a randomized controlled trial setting.



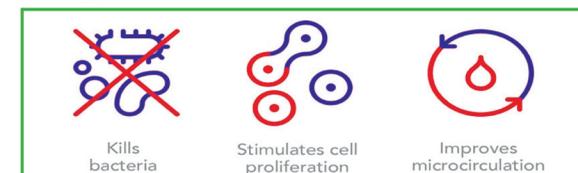
Procedure/Method: With prior informed consent, 44 patients with diabetic foot ulcers were selected and randomized. The protocol of this clinical trial was registered as (IRCT20080904001199N2), & Ethics Committee approval code of (IR.TUMS.EMRI.REC.1395.0089). 22 patients received standard care (SC) and the other 22 received SC + cold atmospheric plasma (CAP). Peripheral nerves and arteries were clinically examined in all subjects. Bacterial load was evaluated by microbiological analysis. CAP was irradiated on the wounds 5 minutes, 3 times a week for 3 consecutive weeks. Wound bed fluid samples were collected with a noninvasive procedure, adjusted quantitatively, and assayed by ELISA methodology to assess levels of inflammatory cytokines, IL-1, IL-8, INF- γ , TGF- β , VEGF, MMP-1, TIMP-1, and TNF- α .



Finding/Results: The results showed that CAP irradiation accelerates wound closure, controls infection (79.61%), and promotes overall healing process, as verified clinically over three weeks of treatment. Mean levels of cytokines IL-1 (739.44 ± 7.67), IL-8 (368.3 ± 82.4), INF- γ (17.03 ± 2.62), TGF- β (31.99 ± 5.90), VEGF (18.4 ± 3.8), MMP1 (320.9 ± 102.3), and TNF- α (22.75 ± 4.02) decreased, TIMP-1 (1057.1 ± 141.2) increased, after treatments. Significant differences before and after CAP treatments were analyzed at $P=0.001$ level.



Implications/Applications: Collectively, cold atmospheric plasma therapy helps rapid wound healing in diabetic patients, ameliorate destructive inflammatory responses, hinders spread of infection. Then, CAP could potentially prevent such catastrophic complications as lower extremities amputations in diabetic foot ulcers. However, the associated underlying molecular mechanisms are yet to be investigated.





Use of Essential Fatty Acid Oral Supplementation in the Management of Wounds of Epidermolysis Bullosa (EB): A Case Series

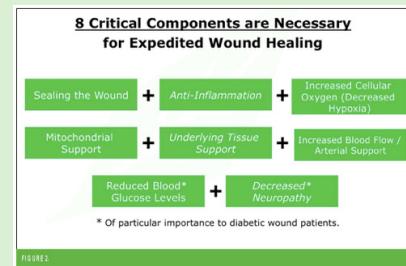
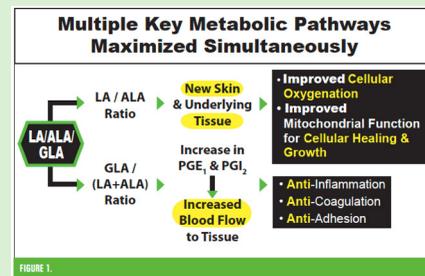
Dr. Jeffrey Matheson, MDCM

Purpose

To demonstrate the real-world effectiveness of Essential Fatty Acids (EFAs) in the role of complex wound management

Introduction

Current wound care has focused mostly on building a better dressing. Nutritional concerns are rarely considered. Skin is mainly composed of the Omega-6 fatty acid Linoleic Acid (LA) with minor amounts of Omega-3 alpha-linolenic Acid (ALA). Gamma-Linolenic Acid (GLA) enhances production of PGE1 (prostaglandin E1) that enhances blood flow and is a potent anti-inflammatory. There is no DHA/EPA in the skin. Increased blood flow and oxygen transport are essential to proper wound healing. Fatty acids work on multiple levels to improve both these issues (see Figures 1 and 2).



Methods

A plant-based supplement was given to 3 consecutive patients with Epidermolysis Bullosa at weight-based dosing of ½ teaspoon per 30 lbs body weight orally or via G-tube. The results were monitored both pictorially and in comments via survey every 2 weeks by the patients or their parents. The results presented are at 0 and 6 weeks of treatment. These are real-world results not influenced by providers outside their normal visits. Product was provided without charge.

Oral Supplementation was graciously provided by Pure Life Science Inc.

Results

CASE 1 – 27-year-old Female with Dystrophic Epidermolysis Bullosa

"I've found the oil extremely helpful. It's really been helping my wounds heal at a rate that I've never seen before. As I've been monitoring the process, I've noticed that a lot of my new sores or scrapes have healed at record time that I've never found before. The wounds are looking great although my skin still breaks down with trauma, I'm pleased to report turnaround healing has increased exponentially."



CASE 2 – 3-year-old Female with Epidermolysis Bullosa Simplex

"Huge positives. Skin seems less fragile, less blisters appearing. Wounds healing faster. Skin less dry"



Results Cont'd

CASE 3 – 18-month-old Male with Epidermolysis Bullosa Simplex

"Less blistering to the feet and ankles", "I am happy that in boldly blistered areas (an inch high or more" the skin is able to adhere back and not sluff off", "Skin reconnecting. Decrease in pain during wound care", "He has done to over 50 blisters a day ... down to 5."

Child went from not walking due to blistered feet to walking normally within 2 weeks.



Conclusion

This is the first real world study studying wound healing with oral supplementation in this very resistant population. The very positive results deserve further study as this could represent a breakthrough in wound care in general.

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A Prospective Multi-site Observational Study Incorporating BACTERIAL Fluorescence Information into the UPPER/LOWER Infection Checklists



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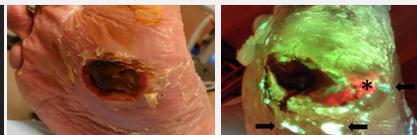
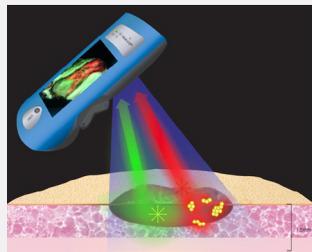


INTRODUCTION

- The UPPER/LOWER infection checklists look for signs and symptoms of local/superficial infection (UPPER) and deep infection (LOWER) to assist clinicians in identifying and distinguishing between these infection levels. This facilitates appropriate treatment with topicals vs. systemic antibiotics¹.
- All UPPER/LOWER checklist items are possible host responses to high levels of bacteria. However, host response can vary widely, and it is well known that many patients with an infected wound are asymptomatic².
- Fluorescence imaging is a novel method to visualize regions of bacteria in wounds, in real-time, without any need for contrast agents or patient contact. Clinical trials have demonstrated detection of moderate-to-heavy bacterial loads (>10⁴ CFU/g)³.
- This multi-site observational study evaluated the utility of incorporating real-time information on high bacteria loads, via real-time bacterial fluorescence imaging^{3,4}, into these checklists.

METHODS

- In this **observational study**, chronic wound patients (n=43) being seen by study clinicians for the first time:
 - Were assessed with the UPPER/LOWER checklists to look for signs or symptoms of local or deep infection
 - Underwent fluorescence imaging using the MolecuLight i:X to detect the location and load of bacteria in wounds³⁻⁵.



Standard Image **Fluorescence Image**
Fluorescence images showing cyan/white fluorescence signals (arrows) that is a hallmark of *Pseudomonas*⁵. Sampled region of red fluorescence (*) was positive for heavy growth of bacteria.

- Under the safe violet light of the MolecuLight i:X imaging device, wounds that had a red or cyan fluorescence signal were considered to have clinically significant bacterial loads. This real-time information guided immediate treatment decisions.
- 27 wounds underwent swab sampling in regions of red or cyan (when present); semi-quantitative culture analysis was completed to confirm presence of bacteria. Moderate or heavy growth was considered microbiologically positive; light growth or lower considered negative.

METHODS

UPPER Checklist

| U | P | P | E | R | + BACTERIA |
|--|--------------------------------------|---|-------------------------------------|--------------------------|--|
| Unhealthy Tissue | Pain | Poor Healing | Exudate | Reek | Fluorescence Imaging |
| | | | | | |
| Presence of >50% of debris, red friable tissue or abnormal discoloration of granulation tissue | Sudden emergence or increase in pain | Changes in wound size of less than 10% in last 7 days | Moderate to heavy amount of exudate | Presence of foul odor | Fluorescence indicative of moderate-to-heavy bacterial loads (red or cyan) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

3 or more checks indicates presence of local infection

LOWER Checklist

| L | O | W | E | R | + BACTERIA |
|--|---------------------------|--|--------------------------|-------------------------------------|--|
| Larger Size | Osseous Tissue | Warmth | Edema | Redness | Fluorescence Imaging |
| | | | | | |
| Increase in wound size or new areas of satellite breakdown | Wound that probes to bone | Increased periwound temperature of more than 3°F compared with temperature in contralateral limb | Mild to moderate edema | Redness of >2cm beyond wound margin | Fluorescence indicative of moderate-to-heavy bacterial loads (red or cyan) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

3 or more checks indicates presence of deep infection

Three symptoms present from either checklist was the threshold for infection-positive.

RESULTS

Additional of bacterial imaging to UPPER and LOWER checklists improved diagnostic accuracy

| | UPPER/LOWER | UPPER/LOWER + FL‡ | UPPER/LOWER or FL* |
|---------------------------------|-------------|-------------------|--------------------|
| Sensitivity | 82% | 95% | 100% |
| Specificity | 100% | 100% | 100% |
| Positive Predictive Value (PPV) | 100% | 100% | 100% |
| Negative Predictive Value (NPV) | 55% | 83% | 100% |
| Accuracy | 85% | 96% | 100% |

Information provided by fluorescence imaging (FL) was used:
‡ As an additional check to the UPPER and LOWER criteria or
*As an independent predictor of wound infection.

A two-tailed Fisher exact test revealed significant improvements in diagnostic accuracy (p<0.01) with the addition of FL to UPPER and LOWER checklists.

RESULTS and CONCLUSION

- Bacterial fluorescence (FL) was observed in 93% of wounds (n=37); all wounds that were positive for UPPER/LOWER were also positive for FL.
- In 18 wounds, fluorescence information added a third check to the UPPER/LOWER threshold (PPV=100%, NPV =83%).
- In 22/27 wounds swabbed, bacterial growth was observed, and this corresponded with a red or cyan (bacterial) fluorescence signal. In 17/22 wounds, heavy growth was observed.
- Using microbiology as ground truth, fluorescence information increased the sensitivity of the UPPER/LOWER checklist from 82% to 95%.

Bacterial Fluorescence Provides “Third Checkmark”, Identifies Asymptomatic *Pseudomonas*, Guides Cleaning in VLU patient with 2 LOWER checklist symptoms.

- L = Larger
- O = Osseous
- W = Warmth
- ✓ E = Edema
- ✓ R = Redness



Standard image Fluorescence image

The wound had no clinical signs and symptoms of *Pseudomonas aeruginosa*, yet fluorescence images revealed its signature cyan/white fluorescence (arrows). Images guided additional cleaning targeted to regions of cyan/white fluorescence and selection of a *Pseudomonas*-targeted dressing. A decrease in cyan/white was observed post-cleanse with modified sodium hypochlorite solution.

- Results of this multi-site study suggest that the UPPER/LOWER checklists and fluorescence images work in a complementary manner, with each providing additional, unique information not captured by the other.
- Incorporation of a bacteria-specific component into these infection checklists had high utility, identifying additional patients in need of topical or systemic antimicrobial treatment.
- Fluorescence images contributed to clinician treatment decisions regarding:
 - wound cleaning
 - location and extent of debridement
 - sampling location
- Fluorescence images provided the documentation and visual confirmation required to more rapidly activate the care team, expediting referrals, surgical procedures, and advanced therapies in this study.
- Similar findings were recently reported in a study of 350 wounds⁶. Therefore, incorporation of fluorescence image information into standard of care for wound assessment may be warranted. This would provide a bacterial-specific data point in wound assessment checklists, which currently focus on host responses to bacterial presence.

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Patient transition from hospital to home with high exuding wound(s); bridging the gap in Negative Pressure Wound Therapy (NPWT)

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INTRODUCTION

Negative Pressure Wound Therapy (NPWT) has become recognized as the gold standard of treatment for dehiscence of abdominal and sternal wounds¹. Increasingly used in the management of chronic complex wounds with higher exudate levels, its ability to reduce dressing changes to 2-3 times a week has benefits for both patients and staff. NPWT's capacity to remove exudate even in the ambulatory patient along with its conformability in complex wound geography, such as forefoot amputations² should not be underestimated. NPWT has been shown to have many localized effects on the wound bed including the reduction of oedema,^{3,4,5} angiogenesis^{4,5} and exudate drainage^{2,3,6}

METHOD

In many of Ontario's Local Health Integration Networks (LHIN), community agencies have differing criteria, assessment protocols, wait listing and dearth of canister NPWT for high exuding wounds. Patients experience step down to traditional dressing on discharge from hospital, delayed restart of NPWT once home, or NPWT system not immediately available with patient wait listed whilst receiving suboptimal wound and moisture management.

Our rehabilitation facility incurs costs associated with delayed discharges including hiring costs of traditional canister NPWT (\$60/day) plus consumables to facilitate timely discharge. Two patients had discharge delayed for 5 and 8 days respectively without guaranteed NPWT for home. A further patient required a hired system and supplies for seven days, after a 24-hour discharge delay. Resultant costs incurred were approximately \$800 (one day hospital stay, hire costs of \$420 purchase of dressing supplies and taxi costs to pick up hired system)

Aim was to assess effectiveness of a 10-day cannister NPWT system, in place of the hospital standard NPWT canister system used applied prior to discharge and changed at home before the need for alternative NPWT system provision. All patients trialled has previously used the Hospital standard canister NPWT devices.

The 10-day cannister NPWT pack (@\$250) contains three dressing kits, two canisters, illustrated professional and patient instructions, negative pressure device, and a carry case. It allows for 1-2 dressings to be applied in hospital prior to transitioning to the LHIN services, with 1-2 dressings left for home use.

RESULTS

The 10-day cannister NPWT system trialed was well reviewed by staff with application of dressings and set up of device intuitive. Staff commented on the conformability of the film drape. The one-page instructions were clear and received well by staff and patients. The three patients trialled found the device light weight, quiet, with dressing comfortable, one patient reported it "does what it says on the tin"

Case 1. Patient with stage 4 hip pressure injury with treated osteomyelitis, wheelchair dependant with mechanical hoist transfers. Transitioning home to a LHIN where hired NPWT machines are sent home with patient from acute setting. LHIN then arranges transfer of hire costs for continuation of care. Patient travelling over four hours home with high exuding wound (approximately 150mls /24 hours), 10-day canister-based (NPWT) system applied for two dressing changes in hospital to ensure effectiveness of system in managing exudate and thus reassuring patient.

Changes went without issue, canister accommodated exudate, negative pressure maintained, no periwound maceration. Second change performed on day of discharge and new cannister applied. Third dressing with additional spare canister, professional and patient instructions given to patient. Patient reported uneventful travel home with dressing patency maintained through all transfers up to scheduled time of dressing change 48 hours later.

Case 2. Patient with forefoot amputation due to diabetic neuropathic ulceration, had achieved >30% healing with NPWT in two weeks. Serous exudate @ 50mls per dressing change (48 hours). Forefoot oedema and periwound maceration (skin moist and white) without NPWT. Partial weight bearing using 2 wheeled walker with forefoot offloaded. Participating in active rehabilitation program (2 x hour sessions plus directed gym time.) Patient trialled system for weekend leave of absence. Carry case dropped on concrete, breaking canister connector. Patient clamped tubing as taught (to maintain negative pressure) and continued to hospital where, with canister replaced NPWT restarted. Second dressing applied for discharge. Visiting nurse attended twice, postponing dressing change until subsequent visit, reasoning unclear. Dressing three applied on day five post discharge. Patient noted no deterioration in dressing integrity, loss of pressure. No adverse effects (maceration, loss of granulation tissue) to wound bed reported or seen at day five in wound photographs or assessment.

RESULTS

Case 3. Patient with midline abdominal dehiscence, post emergency laparotomy, strangulated bowel with peritonitis. Comorbidities: raised BMI, diabetes, COPD, anaemia. Wound 7cm x 4cm 2.9cm deep. 80% granulation 20% subcutaneous fat and visible deep tension sutures at base. Transitioned to 10-day cannister NPWT as all hospital standard canister NPWT already in use. Applied twice, Monday, Thursday. Measurements 5.9 x 3.5cm, 2.3cm deep with no visible deep tension sutures after 4 days. Patient repatriated to acute for exacerbation of COPD and pneumonia on day 5 system in situ.

With all three patients 10-day cannister NPWT system managed exudate, maintained negative pressure and maintained an enclosed system. Unit staff found dressings and device straightforward to use. Two community staff happy with information provided to facilitate ongoing therapy. One staff unfamiliar with system, resulting in extended wear time of five days but therapy and patency still maintained.

With the onboarding of the 10-day cannister NPWT system many additional applications have been considered.

RESULTS

Previously hospital standard NPWT would be discontinued and replaced with standard wound dressing, when leaving for haemodialysis, home visit etc. The 10-day cannister system also allows consideration of patients much in need of NPWT, previously deemed unsuitable eg. high flight risk with expensive devices, those leaving against medical advice or for drug seeking. See diagram 1.

IMPLICATIONS

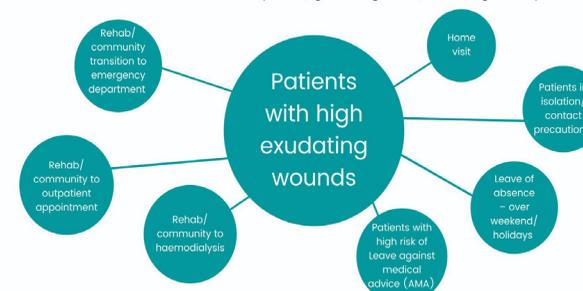
The 10-day canister-based disposable NPWT system trialed provides a cost-effective continuous therapy regimen, bridging gap from hospital to home for patients with complex high exuding wounds. It also allows for consideration of patients that we may have considered unsuitable due to their frequency off site with costly equipment. Further trials will continue for other wound types. Ongoing pre-emptive liaison with community staff about product application is essential to ensure continuity of cannister NPWT therapy for high exuding wounds.

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Consider 10-day cannister NPWT therapy for:

Patients on conventional cannister NPWT systems (high exuding wounds) transitioning from hospital to:



POSTURE DETECTION FOR PRESSURE INJURY PREVENTION WITH A NOVEL SMART SURFACE SYSTEM FOR MONITORING AT-RISK PATIENTS IN A POST-ACUTE CARE FACILITY

Kevin Woo, PhD, RN, NSWOC WOCC FAPWCA | Nicola Waters, PhD MSc RN | Jake Tran, AHL, IAWCC, PhD (student) | Umar Hasan, DO | Monica Lee, BSc

Evidence shows that healthcare-acquired pressure injuries (HAPIs) impact patient outcomes, length of stay, and hospital costs. Patient repositioning (caregiver assisted posture change) during scheduled rounds is the gold standard of care for HAPI prevention. Manual monitoring of patients' posture in a complex hospital environment is neither efficient nor practical.

Relieving interface pressure (IP) where high levels are suspected is fundamental to pressure injury prevention protocols. The accurate measurement of pressure exerted in a particular area (positioning) and how long a patient remains in one position (mobility) can be challenging. Evidence-based advice about optimal repositioning remains inconsistent.

Aim

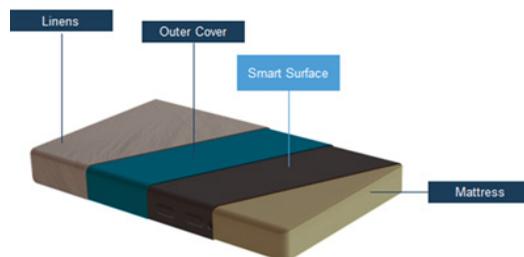
The goal of this analysis is to demonstrate the accuracy of a smart surface system (designed to monitor multiple HAPI risk factors) in detecting the postures of patients, compared to nurse observations of patient posture.

Methods

A prospective, single-site trial was conducted at an Ontario tertiary care facility. Ethics approval was granted. All staff on the study units received training in recruitment and study protocols. This poster represents one aspect of a more extensive study. Results of the microclimate analysis are published elsewhere.

The eligible population was recruited from complex continuing care and post-acute care rehabilitation settings. Inclusion criteria were adults, hospitalized for > 18 hours, at-risk of pressure injuries, as defined by the InterRAI Pressure Injury Risk Assessment Scale with or without a current pressure injury. Patients identified as being at-risk of pressure injury received standard of care while placed on the smart surface for timed intervals. Nurses' assessment data, including patients' position at the time of reposition, were collected at three-hourly time points—the smart surface recorded a range of data, including skin microclimate and IP. Comparative statistical analysis was conducted between the two datasets to determine the accuracy of the smart surface posture detection compared to the nurse assessment of posture. Results of the microclimate analysis are published elsewhere.

Figure 1. A cross-sectional view of the smart surface platform installed over a mattress. The smart surface platform comprises an array of sensors embedded in a thin, flexible surface placed underneath the bedsheet. It is not in direct contact with the patient.



Participants received standard of care, including manual repositioning as appropriate, while placed on the smart surface for timed intervals. Nurses completed a baseline assessment at the start of the 18-hour period (time point T0). Following the same protocol at three-hourly intervals (timed to coincide with manual turns where applicable), any changes from baseline (T0) or the previous assessment (T1-5) were noted.

Sensors gathered data from the subject's bedding surface in the form of IP (mmHg), temperature (Celsius) and humidity (0-100% RH) at four-second intervals. For the initial analysis, data related to mobility/activity status were extracted from the head to toe assessment forms. A comparative statistical analysis was conducted between the two datasets.

To establish accuracy of the smart surface posture detection, the smart surface system used continuous IP visualizations to determine posture, and these were compared to patient posture's recorded by nurses. Nurses recorded postures as supine, left lateral, left fetal, right lateral, right fetal, and sitting. The smart surface posture detection did the same.

Results

A total of 104-patients met the inclusion criteria; the mean age was 59 years (range 21-92, \pm 19.15). Sensor monitoring hours (1,407) generated 1,101,780 frames of surface data. Individual nurse-recorded patient postures used for this analysis totalled 600. Nurse-recorded posture observations were compared to the smart surface platform data generated at exact corresponding time points. The comparison resulted in a 92% accuracy, matching 552 out of 600 nurse postures. Using a binomial test this result was found to be statistically significant ($P < .05$) (CI 95%).

Table: Overview of trial results related to positioning. All tests of equal or given proportions of smart surface data accuracy produced p-values of less than .05.

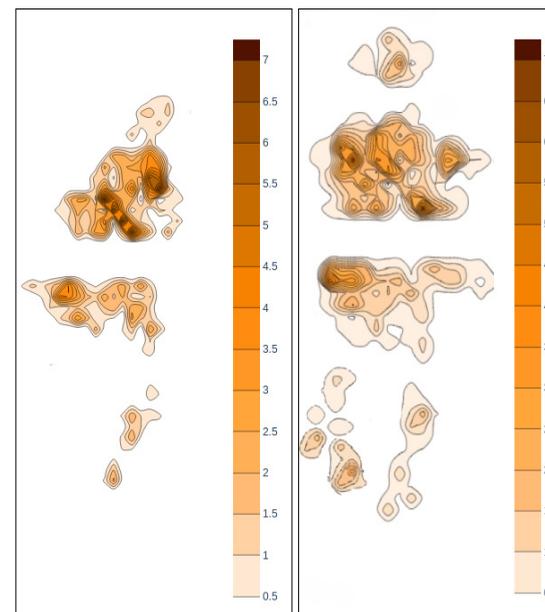
| Number of times nurses recorded patient posture | Number of times smart surface platform data postures correlated |
|---|---|
| n = 600 | n = 552, 92% (95% CI = (89%, 94%)) |

Implications

Monitoring and relieving IP from segments of the body where high levels are suspected are fundamental to pressure injury prevention protocols. However, accurately measuring how much pressure is being exerted in a particular area (positioning) and how long a patient remains in one position (mobility) can be difficult, particularly in patients with limited sensation or communication skills. Visual inspection is challenging as it is not possible to observe an at-risk area while a patient is lying on it. Additionally, visual observation is not a reliable measure of changes taking place under the skin. By the time a patient has been moved, tissue damage may already have occurred. Peterson et al., (2010) suggest that standard turning, even by experienced nurses, may not adequately unload all areas of high skin-bed IP. Further confounding this issue, frequent turning has been linked to detrimental physical and psychological impacts for patients and increased risk of musculoskeletal injury for care providers.

This study's results demonstrate high levels of accuracy in the smart surface system's ability to detect patient posture compared to observations made by nurses. This demonstrates the feasibility and potential for an intelligent system to continuously monitor patients' posture changes. Detecting and recording the patient's posture may help caregivers reposition more efficiently and reduce the risk of developing HAPIs.

Figure 2: Two examples of smart surface system-generated IP visualizations. The smart surface system recorded left fetal and supine, respectively.



Conclusions

The study shows statistically significant accuracy levels when comparing sensor-generated data of patient mobility to nurses' intermittent physical assessments. This has important implications as manual repositioning and visual inspection of skin require resources, especially time, that may be limited due to high patient acuity and competing demands.

Existing pressure injury prevention protocols that rely on intermittent physical assessment limit care providers' ability to identify risks, deliver personalized care, and measure interventions' effectiveness. The smart sensor platform's capacity to continuously and accurately measure pressure injury risk factors, including posture, offers the potential to decrease unnecessary interventions, inform targeted management strategies and improve the allocation of limited nursing resources. Having validated the smart sensor platform's ability to detect posture accurately, the next step is to teach the system to classify multiple factors related to patient positioning and other risk factors. The large volume of IP visualization data collected forms a basis for further artificial intelligence applications (e.g., machine learning algorithms to detect unobserved self-turns).

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Keywords: Pressure injury, posture detection, repositioning, sensor technology, artificial intelligence, machine learning.



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Efficacy of topical release compared to simulated systemic antibiotics in reducing polymicrobial biofilms using in-vitro modelling of diabetic foot infection.

0018

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Introduction and Aim

- Infection management in diabetic foot ulcers is complicated both by patient factors such as peripheral arterial disease and the microbial composition within the infection which tends to grow as a biofilm.
- Management of infection often includes wound dressings containing antimicrobials alone or as an adjunct to antibiotics.
- Treatment failure is common, leading to poor outcomes such as chronic ulcers and amputation (Game *et al* 2012).
- We aimed to establish whether topical release of antibiotics from calcium sulfate beads might compare favourably with systemic concentrations of antibiotics in an *in vitro* model of biofilm infection.

Methods

- Ethical approval was granted to collect debrided tissue from infected diabetic foot ulcers (DFIs) upon presentation and after a week of treatment.
- After a week of treatment blood was also collected.
- Antibiotics were assayed in tissue and blood after a week of treatment.
- Bacteria were harvested, identified and enumerated from all tissue samples.
- Collagen wound models were prepared (Price *et al* 2020).
- Bacterial species isolated from tissue from six subjects were used to inoculate wound models.
- After 72 hours antibiotic loaded calcium sulfate beads (Stimulan Rapid Cure) or simulated "systemic" antibiotics were added to models as described in Table 1.

| Subject | Antibiotic | Concentration (mg/L) added to wound model for systemic | Antibiotics loaded into beads |
|---------|------------------------------|--|---|
| DFG | Ciprofloxacin Clindamycin | 2.4* 4.2* | Vancomycin 500 mg Gentamicin 240 mg per 10 CC calcium sulfate |
| DFN | Co-amoxiclav | Amoxicillin 7.2 Clavulonic acid 2.4 | |
| DFR | Co-trimoxazole | Trimethoprim 1.1 Sulphamethoxazole 6.9 | |
| DFB | Flucloxacillin | 0.4 | |
| DFK | Flucloxacillin | 11.5 | |
| DFM | Flucloxacillin | 7.8 | |

Table 1. Antibiotics used in treatment are listed per subject. The established serum concentration of antibiotics was added to models. Where this could not be determined Cmax values were used denoted by *.

Results

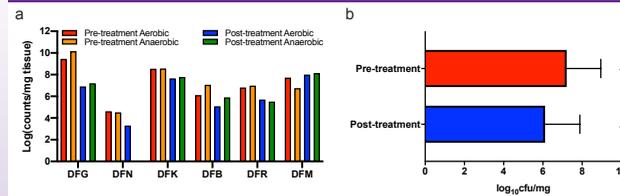


Figure 1. (a) Bacterial counts under aerobic and anaerobic growth conditions from debrided tissue collected from each patient upon presentation with a diabetic foot ulcer and after a week of treatment. (b) Overall difference of 1.1 log reduction ($p=0.03$) in bacterial counts for all subjects after a week of treatment ("post-treatment").

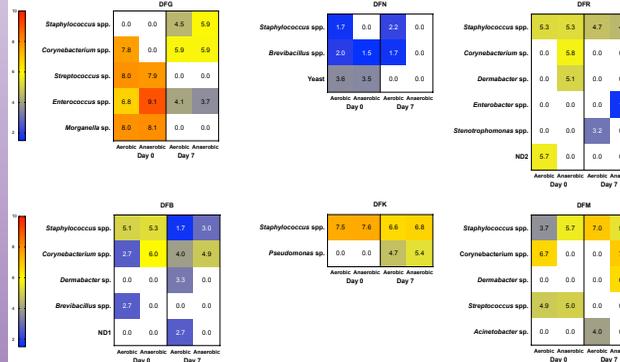


Figure 2. Identity and abundance of bacteria isolated under aerobic or anaerobic conditions from each subject's debrided tissue before treatment (day 0) and after treatment (day 7). Subject labels are at the top of each heat map, the scale is indicated on the left hand side of each row of images. Numbers on the scale and within the heat maps indicate the log of the counts per mg of tissue. From day 0 to day 7 there were few substantial changes in wound microbiota, interestingly, in DFN the yeast was not present at day 7 despite it being insensitive to antibiotics. It is possible it was removed through debridement.

Results

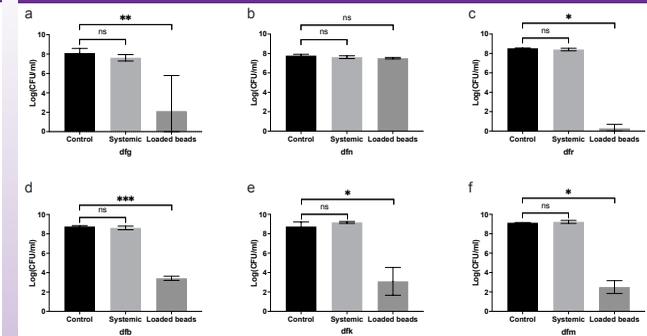


Figure 3. Bacterial species isolated from tissue before treatment were inoculated into *in vitro* models, labelled in lower case (below the y axis) to indicate the polymicrobial biofilm derived from clinical isolates corresponding to a single subject. Biofilms were exposed to no antibiotics in the controls, or simulated systemic antibiotics or calcium sulfate beads loaded with gentamicin and vancomycin as described in Table 1. In each case, simulated systemic antibiotics showed no significant reduction in biofilms. In five of six polymicrobial biofilms substantial 5-8 log reductions after exposure to antibiotic loaded beads were observed.

Implications

- Therapeutic antibiotics were often below the limit of detection in tissue samples collected from patients.
- In this model simulated systemic antibiotics did not reach sufficient concentrations to inhibit biofilm but sustained release of antibiotics at a high concentration close to the biofilm was effective in reducing or eradicating it.
- Topical release of antibiotics could be an effective means to treat DFIs, further work is required to confirm these findings *in vivo*.

Acknowledgements

The authors would like to acknowledge Biocomposites Ltd for funding this study



Improved Detection of Infection Using Bacterial Fluorescence Imaging Reveals the True Proportion of Infected Wounds in Long Term Care Facilities



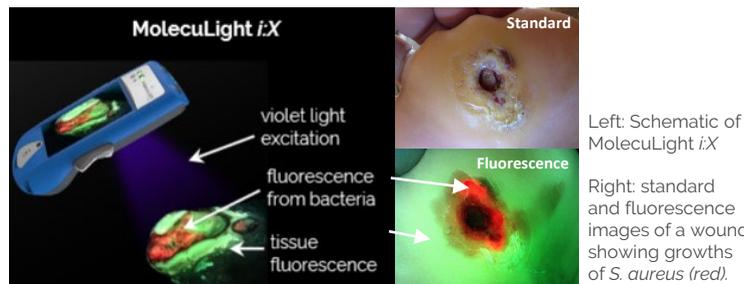
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Background

10-54% of long-term care (LTC) facility residents have chronic wounds¹. Infections often develop in wounds due to bacteria colonization, leading to complications²⁻³.

Clinical signs and symptoms of infection (CSS)⁴ is widely used in wound assessment but is a poor predictor of bacterial growths as many wounds appear asymptomatic⁵. Thus, an objective and sensitive screening method is needed.

Point-of-care MolecuLight *i:X* fluorescence imaging (FL) rapidly detects bacterial loads $>10^4$ colony-forming unit per gram (CFU/g) in/around wounds, a quantity indicative of infection^{3,6}. When excited by the 405nm violet light of FL, **bacteria fluoresce red or cyan**, while **tissues fluoresce green**, allowing bacterial burdens to be easily visualized.



Left: Schematic of MolecuLight *i:X*
Right: standard and fluorescence images of a wound showing growths of *S. aureus* (red).

Objectives

This multi-center pilot study seeks to:

- 1) Evaluate if fluorescence imaging (FL) could facilitate the detection of high bacterial loads in wounds in the long-term care setting.
- 2) Identify how FL information is used to guide wound assessments and treatment planning.

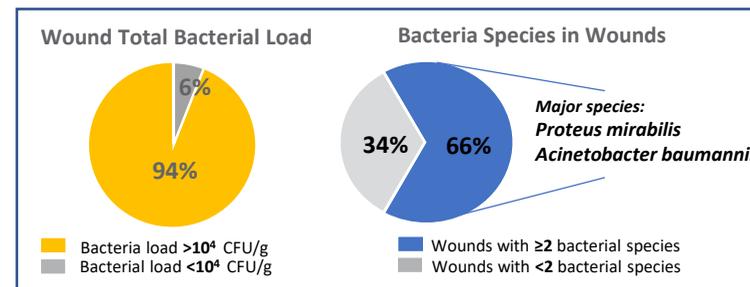
Methods

36 wounds from 26 patients in 4 long-term care centers underwent:

- 1) **CSS assessment based on IWII wound infection checklist criteria⁴.** A wound is positive for bacteria if ≥ 3 symptoms and signs are present.
- 2) **Fluorescence imaging** with MolecuLight *i:X*. High bacterial burden of $>10^4$ CFU/g is indicated by red or cyan fluorescence.
- 3) **Real-time polymerase chain reaction (qPCR) analysis** of swab samples to confirm the quantity and species of bacteria in wounds.

Results

Fluorescence-targeted sampling of wounds revealed high prevalence of bacterial-laden wounds in LTC facilities.



Swab samples were obtained from regions of red or cyan fluorescence indicated by fluorescence imaging (FL). qPCR analysis of samples revealed a high portion of wounds containing multiple bacterial species.

- **94% of wounds** (34/36) contained **bacterial load indicative of infection ($>10^4$ CFU/g)²⁻³**, and **89% of wounds** having loads $>10^6$ CFU/g. These ratios are much higher than observed previously from wounds in the outpatient setting⁶.
- Notably, **FL alerted wound care practitioners to an outbreak of *Proteus mirabilis***, detected in 86% of the wounds (31/36) at the facility. In addition, *Acinetobacter baumannii*, a pathogen identified by the W.H.O. to be highly resistant to antibiotics⁸, was detected in 33% (12/36) of the wounds.

In long-term care settings, fluorescence imaging (FL) improved detection of wounds with high bacterial loads by 70% compared to clinical signs and symptoms (CSS).

| | CSS | FL | |
|---------------------------|-----|------|---------|
| Positive Predictive Value | 91% | 94% | |
| Sensitivity | 60% | 100% | P=0.004 |
| Accuracy | 57% | 94% | P=0.004 |

FL resulted in higher sensitivity, accuracy and positive predictive value (PPV), to detect bacteria at loads $>10^4$ CFU/g compared to CSS. qPCR analysis of swab samples was used to confirm bacterial load.

Fluorescence imaging (FL) guided wound assessment, debridement and sampling.

FL pre-debridement Standard FL post-debridement



FL-guided sampling revealed:
P. mirabilis (10^7 CFU/mL)
A. baumannii (10^6 CFU/mL)
S. aureus (10^4 CFU/mL)
B. fragilis (10^4 CFU/mL)

Case 1: FL discovered high loads of bacteria at a patient's ischium that was missed by CSS. Red fluorescence indicated bacteria $>10^4$ CFU/g, which significantly reduced after targeted debridement.

FL pre-debridement Standard FL post-debridement



FL-guided sampling revealed:
P. mirabilis (10^7 CFU/mL)
B. fragilis (10^4 CFU/mL)

Case 2: FL detected bacterial burden in a non-healing lower extremity wound. Bright red fluorescence was detected in the wound bed. Debridement and sampling was done in regions of the wound with red fluorescence.

Conclusions

- **94% of wounds** sampled from long-term care residents contained clinically significant bacterial loads with multiple bacterial species.
- Fluorescence imaging improved the detection of high bacterial load in wounds by 70% compared to clinical signs and symptoms.
- Fluorescence imaging information guided wound sampling and debridement, leading to targeted pathogen identification and treatment.

Overall, our findings suggest that fluorescence imaging facilitates more timely and accurate wound assessment and treatment in the long-term care setting, mitigating risks of wound deteriorations and pathogen outbreaks.



Real-world evidence demonstrating clinical utility of bacterial fluorescence imaging to guide treatment decision making in 283 wounds

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Introduction

- Bacterial colonization (>10⁴ CFU/g) in wounds is associated with delayed healing and increased risk of infection^{1,2}.
- Evaluation of bacterial burden in wounds is currently done by visual inspection of **classic signs and symptoms (CSS)** of infection, but sensitivity of CSS to detect wounds with clinically significant bacterial load is poor³.
- More objective methods to improve detection of clinically significant bacterial loads that may hinder wound healing are needed.
- The **MolecuLight i:X** is a novel fluorescence imaging device that is used to detect clinically significant (moderate to heavy) loads of bacteria in real-time and provides information on location and load of bacteria to guide treatment decision making^{4,7}.
- Multiple clinical trials across 22 sites have repeatedly shown a **positive predictive value >95%** using the i:X to detect moderate to heavy bacterial loads, confirmed by microbiology^{4,7}.

Objectives

Here we collected real-world evidence to:

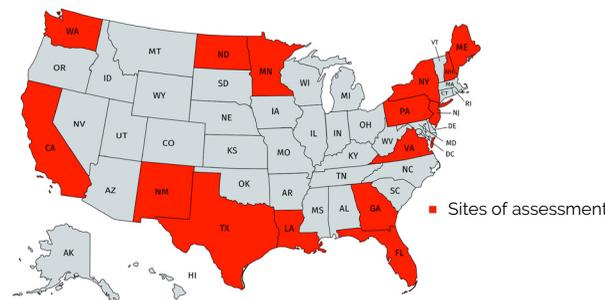
- Compare detection of wounds with clinically significant bacterial burden based on fluorescence imaging using the i:X to standard of care wound assessment (CSS).
- Evaluate how fluorescence imaging information is used to guide treatment plans.



Example of MolecuLight i:X imaging procedure performed in an outpatient clinic.

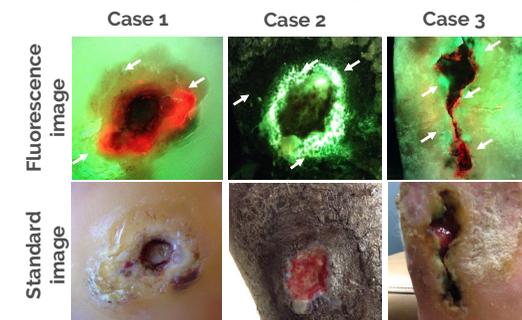
Methods

- Clinicians visually inspected wounds for CSS and created a treatment plan based on assessment.
- A fluorescence image of the wound was then captured.
- Clinicians reviewed the images and had an opportunity to revise the treatment plan.
- Real-world evidence was collected from **32 sites** across **14 states**.
- 58 clinicians** participated (44 MDs, 9 DPMs, 1 PT, 4 NP)



Safe violet light (405 nm) excites tissues and bacteria.
Red or cyan fluorescence images are indicative of bacteria at loads >10⁴ CFU/g (moderate-to-heavy)^{4,7}
Fluorescence is detected in real-time without any image processing or contrast agents.

Examples of images captured using the MolecuLight i:X (from⁹)



In all cases, CSS was negative. Biopsy was used to confirm bacterial load.

Case 1: Arrows denote red fluorescence
Bacterial load: 2.31 x 10⁸ CFU/g.

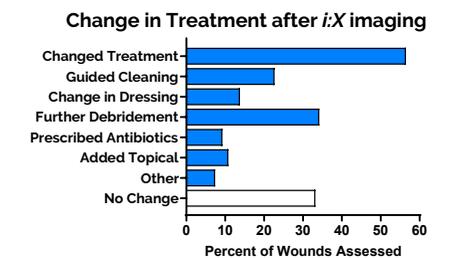
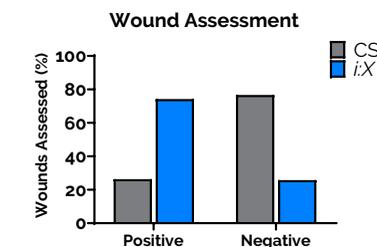
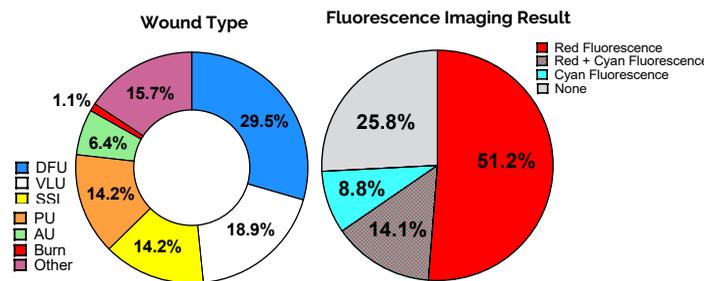
Case 2: Arrows denote cyan fluorescence
Bacterial load: 1.51 x 10⁷ CFU/g.

Case 3: Arrows denote red and cyan fluorescence
Bacterial load: 1.27 x 10⁸ CFU/g.

Results & Conclusion

283 wounds were assessed with no exclusion criteria.

The majority of wounds (n=144) had red fluorescence indicative of moderate to heavy bacteria loads^{4,5}.



Fluorescence imaging detected 48% more wounds left undetected by CSS alone.

Based on CSS, clinicians detected wounds with clinically significant bacterial loads in 26.3% of wounds. Fluorescence imaging (i:X), increased the number of wounds positive for clinically significant bacterial loads by 2.8 fold.

57% of wounds assessed underwent a change in treatment after imaging with i:X, most frequently more aggressive, targeted debridement.

Fluorescence imaging more frequently detected bacteria in wounds than CSS assessment. Using the i:X, real-time detection of bacteria can be easily incorporated into routine assessment and guides treatment decision making across multiple wound types.

1. Reddy et al. JAMA (2012)
2. Xu et al. Diabetes Care (2007)
3. Gardner et al. Biol Res Nurs. (2009)
4. Rennie et al. J Wound Care (2017)
5. Serena et al. J Wound Care (2019)
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8. Rennie et al. Diagnostics 9, 22-29 (2019)
9. Clinicaltrial.gov #NCT03540004



In vivo detection of bacteria within a biofilm using a point-of-care fluorescence imaging device



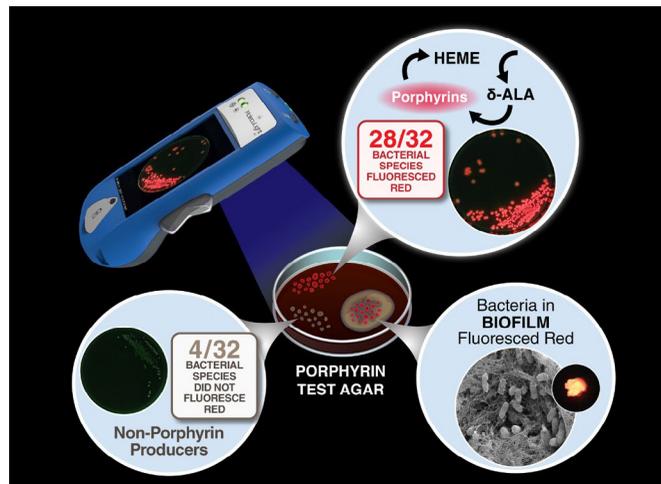
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Introduction

- Biofilm is bacteria that exists within a protective matrix, making it challenging to eradicate through antimicrobial strategies and delaying wound healing. Between 50 to 90% of chronic wounds harbor biofilms^{1,2}.
- Biofilms must be identified and mechanically disrupted to release the bacteria, yet they are challenging to detect with standard assessment.
- Prior work *in vitro* work demonstrated MolecuLight *i:X* detection of fluorescence from most common wound pathogens (e.g. *Staphylococcus*, *Pseudomonas*, *Acinetobacter*, *Enterobacter*, *Klebsiella*) and from bacteria located within a biofilm.**³
- This *in vitro* work required the addition of **aminolaevulinic acid (ALA)**, an **essential precursor of porphyrin production** which is not present in standard agar plates (e.g. blood agar, tryptic soy). Porphyrin test agar, containing ALA, was used for this work. **ALA is naturally occurring and readily available in mammalian systems without the need for supplementation.**
- In the present study, we tested the ability of the MolecuLight *i:X* to detect bacteria within a biofilm using a well-established *in vivo* polymicrobial biofilm model.

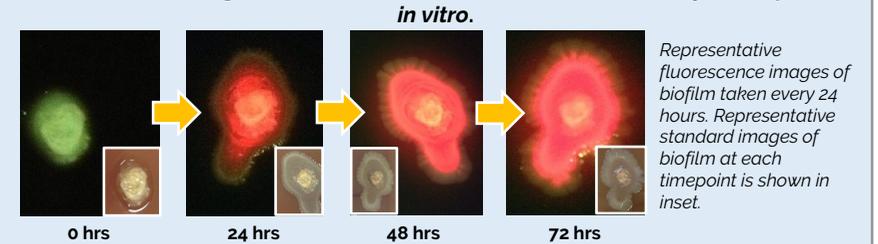


Red fluorescence was detected on MolecuLight images of 28/32 common wound pathogens, including bacteria in biofilm models³

Does bacteria in biofilm take up ALA?

- Polymicrobial biofilms (n=3) were grown without the presence of ALA and then transferred to Porphyrin Test Agar plates (containing ALA, timepoint 0 hours).
- Negative controls (n=3) were transferred onto chocolate agar lacking ALA (data not shown).
- Biofilms were imaged with the MolecuLight *i:X* every 24 hours to monitor ALA uptake capabilities through the production of red fluorescence.

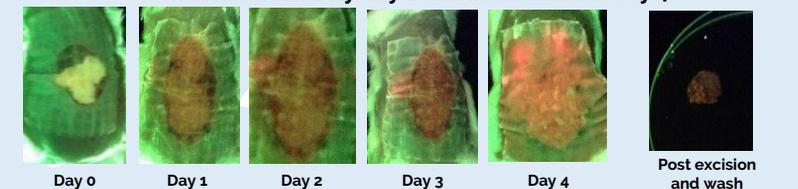
Red fluorescence was detected in polymicrobial biofilms 24 hours after transfer, indicating that bacteria encase within biofilms readily take up ALA *in vitro*.



Does bacteria in biofilm fluoresce red?

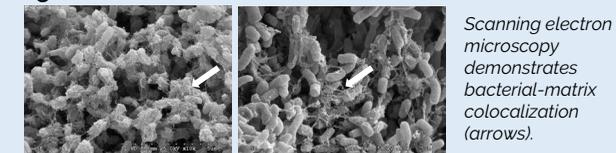
- Polymicrobial biofilms (1:1:1 parts *S. aureus*/*E. coli*/*E. cloacae*, 10⁷ CFU/biofilm) were grown *in vitro* with no exogenous ALA added.
- A mouse wound model (n=16) was inoculated (day 0) with the polymicrobial biofilms (3 biofilms per mouse). ALA uptake was solely from circulating amounts of ALA *in vivo*.
- Wounds were imaged daily for fluorescence (bacteria >10⁴ CFU/g fluoresce red) up to day 4, when wounds were excised, washed and re-imaged.
- Excised tissue was sent for microbiology (n=8), and histopathologic analysis (gram, H&E, and PAS matrix staining, n=4) and scanning electron microscopy (SEM, n=4) to confirm bacteria-matrix interaction.

Red fluorescence was readily detected from 100% of biofilm inoculated wounds *in vivo* by day 1 and intensified to day 4



Fluorescence images reveal red fluorescence in biofilm implanted in mice. Much of the biofilm biomass is removed by the bandage resulting the *ex-vivo* post excision biofilm have reduced intensity of red fluorescence.

SEM images confirmed bacteria-matrix interaction in biofilm.



Scanning electron microscopy demonstrates bacterial-matrix colocalization (arrows).

Conclusions & Clinical Implications

These findings reveal that the MolecuLight *i:X* handheld fluorescence imaging device can detect fluorescence from bacteria (at loads >10⁴ CFU/g) in biofilm.

This has implications for clinicians targeting the mechanical disruption (e.g. debridement) of biofilm and removal of bacteria in the 50-90% of chronic wounds estimated to harbor bacterial biofilms.^{1,2}



Addressing Pressure Ulcer Bacteria: Impact of Fluorescence Imaging on Assessment & Treatment



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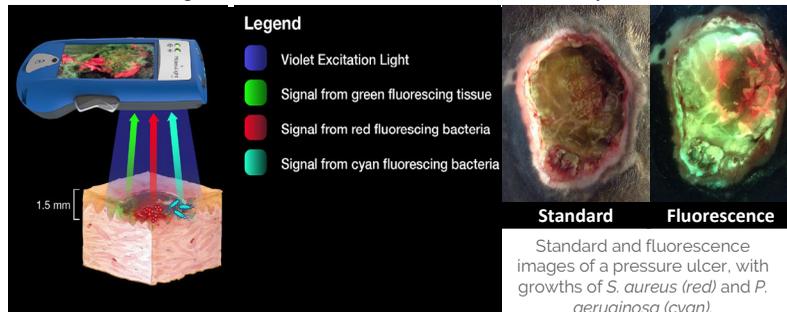
Background & Methods

Pressure ulcers (PU) result from prolonged pressure on the skin, affecting up to **15%** of inpatients¹ and **37-53%** of long-term care residents².

High bacterial loads of >10⁴ colony-forming units per gram (CFU/g) have been associated with pressure ulcer infections, complications and delayed healing^{3,4}.

High bacterial loads in PU are typically diagnosed by visual assessment of **clinical signs and symptoms (CSS)**⁵. However, patients with heavily colonized PUs (>10⁴ CFU/g) are often asymptomatic⁶, creating challenges in diagnosis and management.

Non-invasive, point-of-care **fluorescence imaging (FL)** with the MolecuLight *iX* enables rapid detection and localization of bacterial burden (>10⁴ CFU/g) within and around wounds⁷⁻⁸. Under the violet (405nm) excitation light of FL, tissues fluoresce green, whereas bacteria fluoresce red or cyan.



Standard and fluorescence images of a pressure ulcer, with growths of *S. aureus* (red) and *P. aeruginosa* (cyan).

Objective: to determine the impact of fluorescence imaging on pressure ulcer treatment selection and planning as part of a multicenter, prospective controlled clinical trial.

Methods: 22 pressure ulcers across 14 clinical sites were assessed by 20 clinicians. Each pressure ulcer underwent:

- Assessment of CSS (using IWII wound infection checklist criteria)**⁵. A wound is positive for CSS if ≥3 symptoms and signs are present.
- Fluorescence imaging (FL) with MolecuLight *iX***. Red or cyan fluorescence indicates presence of bacteria at loads >10⁴ CFU/g.
- Punch biopsy and quantitative culture analysis** to determine total bacterial load.

Clinicians then completed a survey indicating how FL information impacted patient care and treatment selection.

Results

Moderate-to-heavy bacterial burden was detected in 91% of pressure ulcers

- Wound biopsy revealed that **91% of PUs** (20/22) had bacterial loads >10⁴ CFU/g.
- Median bacterial load of PUs was **1.0 x 10⁶ CFU/g** (range: 3.1 x 10⁴ – 7.4 x 10⁸ CFU/g), loads that are indicative of infection⁶.
- The most common bacterial species detected was ***Staphylococcus aureus***.

Fluorescence imaging significantly improved detection of pressure ulcers with moderate-to-heavy bacterial burden at the point-of-care.

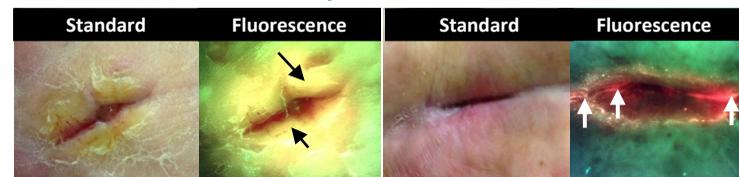


Figure 1: Representative standard and fluorescence images of pressure ulcers where fluorescence from bacteria was detected. Arrows indicate regions of red or cyan fluorescence indicative of bacteria at >10⁴ CFU/g.

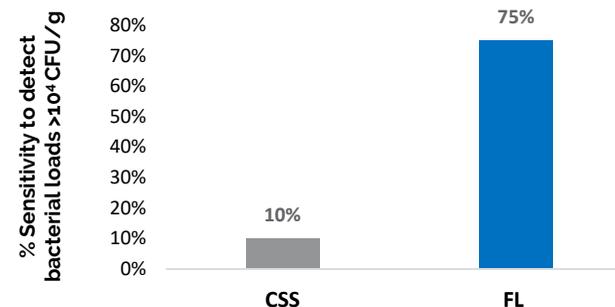


Figure 2: Clinical signs and symptoms (CSS) identified 2/22 (10%) pressure ulcers to be positive for bacteria while fluorescence imaging (FL) identified 15/22 (75%). Microbiological analysis of wound biopsy confirmed total bacterial loads.

Fluorescence imaging (FL) information impacted multiple aspects of pressure ulcer (PU) care.

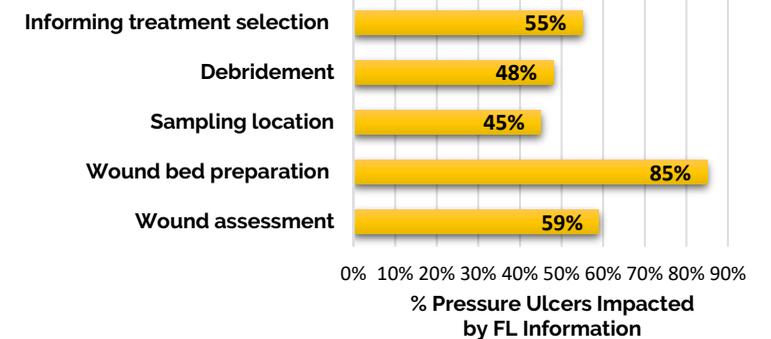


Figure 3: After completing FL imaging on pressure ulcers, clinicians completed a survey reporting how the FL information impacted their patients' care. Values represent the proportion of PUs impacted by FL information.

Conclusions

- Most (90%) of pressure ulcers assessed had bacterial loads >10⁴ CFU/g, loads associated with complications, infection and delayed healing^{3,4}.
- Point-of-care fluorescence imaging (FL) detected more pressure ulcers with bacterial loads >10⁴ CFU/g compared to CSS.
- FL information modified key aspects of wound assessment and treatment planning, with greatest impacts in wound bed preparation and assessment.

Overall, these findings suggest the use of fluorescence imaging may facilitate more accurate diagnosis of bacterial burden, enabling more targeted care planning in pressure ulcers.

References

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Development of a Skin and Wound Care Clinical Care Topic (CCT)

A Provincially Standardized Approach to Skin and Wound Care for Alberta Health Services (AHS)

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 Michele Stanley, Practice Lead – Provincial Seniors Health and Continuing Care, AHS
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Aim:

To produce a comprehensive practice support tool that equips healthcare providers with standardized, evidence-based clinical guidance for wound prevention and management.



Method:

CCTs are comprehensive practice support tools that equip healthcare providers with evidence-based clinical guidance. CCTs facilitate professional decision-making and encourage full scope of practice with access across all AHS zones and sites to one provincial resource for practice standards and competency. The CCT format offers:

- Formal development process including removal of old policy
- Existing Terms of Reference
- Provincial review by Clinical Support Services and stakeholders
- Endorsement by provincial groups
- Familiar format and vehicle
- Format enhanced by user testing through Human Factors
- Easy accessibility by clinical users
- Continual and frequent updates



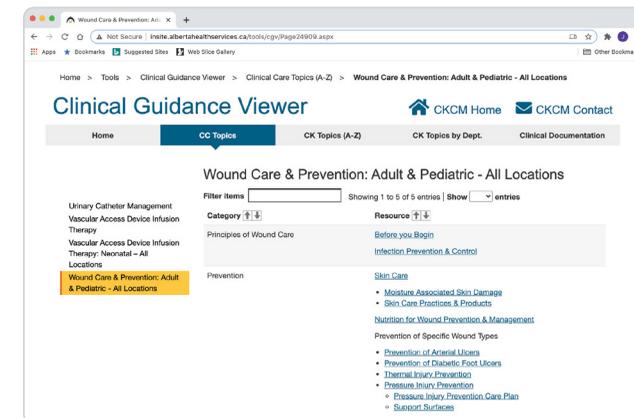
Findings and Results:

The CCT for skin and wound care offers simplified access to evidence-based information and clinical guidance. A provincial standard in skin and wound care directs content for other provincial initiatives (Connect Care – provincial Clinical information system).



Implications and Applications:

The provincial scope of the CCT project required working virtually to engage multiple stakeholders across the organization, echoing the virtual nature of this conference. The CCT will be available electronically both internally across AHS and also, eventually, externally to other organizations, provinces and jurisdictions.



SCAN QR CODE FOR MORE INFORMATION

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AHS is Canada's first and largest provincewide, fully-integrated health system

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people live in Alberta

102,700
direct AHS employees

11,700
staff in AHS wholly-owned subsidiaries

11,600
physicians



THE USE OF HYPOCHLOROUS ACID* TO PREVENT SUPRA INFECTIONS IN IMMUNOSUPPRESSED PATIENTS

Emily Greenstein APRN, CNP, CWON, FACCWS, Debashish Chakravarthy, Ph.D

INTRODUCTION

Patients may develop wounds secondary to a hypersensitivity reaction. Two examples of these types of wounds are pyoderma gangrenosum and livedoid vasculopathy. Pyoderma gangrenosum (PG) is a rare, ulcerative, cutaneous condition which is often associated with a systemic disease such as inflammatory bowel disease, rheumatologic disease, paraproteinemia, or hematologic malignancy.¹ Livedoid vasculopathy is a rare cutaneous disease that manifests as ulcers on the lower limbs. The pathology is not completely understood but there has been a link to underlying autoimmune disorders particularly lupus erythematosus, systemic sclerosis, Sjogren's syndrome and antiphospholipid syndrome.²

The mainstay treatment for these two conditions is based on immunosuppressive therapy^{1,2}. Long-term treatment with these agents is often required and can put the patient at an increased risk for the development of supra infections³, which are defined as development of a secondary infection from opportunistic microbes that are normally handled easily in patients who are not immune suppressed.

Outside of these two specific conditions (PG and livedoid vasculopathy) that are typically treated by immune suppressants, many patients presenting with wounds may also be immunocompromised. All these wounds are particularly susceptible to being infected with life and limb threatening opportunistic supra infections. Of course, this is in addition to being at risk from the usual pathogens associated with chronic wounds found in non-immunocompromised patients with wounds.

The optimum preparation of the wound bed in such patients require careful attention to the removal of debris and microbes as well as associated matter such as biofilm⁴. Without the removal of these elements that provide a nidus for supra infections, the patient will continue to be at risk with the risk being amplified with delay in eliminating these negative elements.

The use of hypochlorous acid* based wound solutions that must be delivered in a quite tight pH range (3-5.5 approximately) have been widely described in literature^{5,6}. Literature also describes these mildly acidic solutions to be pure with respect to the antimicrobial preservative that is desirable (hypochlorous acid*), and free from the much more cytotoxic and thus undesirable hypochlorite species, only in this tightly controlled pH range⁷⁻¹². The hypochlorite species, which is actually not very powerfully antimicrobial¹³, but as stated above, is cytotoxic¹⁴, is incidentally found in some traditional treatments such as Dakin's solution and other "blends" of hypochlorous acid* and sodium hypochlorite where the pH is much higher than, as stated above, the desired range of approximately 3-5.5¹⁵. Dakin's solution itself has a very high pH of approximately 10¹⁶.

It is interesting to note that the desired range of 3 -5.5 for the retention of the purity of the desired antimicrobial preservative, hypochlorous acid*, is also strongly associated with the healing of chronic wounds based on a solid body of biochemical research.^{14,15}

Pure hypochlorous acid* as a powerful antimicrobial preservative is also broad spectrum with respect to both normal wound flora as well as opportunistic pathogens, fast acting¹⁷, and its use well supported in literature in terms of being able to mechanically remove both necrotic debris and biofilm elements and to promote wound healing^{18,19,20}. In contrast, as stated previously, the hypochlorite species, which may be present as a contaminant in some products, is just not as powerful an antimicrobial preservative agent¹³ but rather, is cytotoxic^{14,15}. The safety of the hypochlorous acid* at a concentration of approximately 300 ppm seen in sensitive experiments is likely related to the fact that it is created constantly and ubiquitously in humans in phagosomes of neutrophils and macrophages^{21,22}. It is obvious that the human organism in health and homeostasis has evolved to co-exist with this powerful antimicrobial molecule when present at the normal concentration found in the body.

This poster will present a four patient case series utilizing hypochlorous acid* solution routinely to prevent supra infections in patients on systemic immunosuppressants. Patients who are treated with systemic immunosuppressants with open wounds are at a higher risk for the development of life threatening supra infections. Studies have shown a risk of 3-12% for developing a supra infections depending on the type of immunosuppressive therapy being utilized³.

METHOD

Four patient cases with these rare diseases are described. Two patients with severe cases of pyoderma gangrenosum and two cases with livedoid vasculopathy were selected. Each received 10 minute soaks of pure hypochlorous acid* solution during each dressing change. Progression of wounds and development of supra infections, if any, were tracked over time. Each patient had previously developed a supra infection prior to the implementation of the hypochlorous acid* protocol. Table 1 shows the types of supra infection that they had, and how they were treated. The protocol was followed for 3 months.

| CASE 1 | MRSA (treated with trimethoprim/sulfamethoxazole**) |
|--------|---|
| CASE 2 | One case of <i>Corynebacterium Striatum</i> and one case of MRSA (treated with vancomycin and levofloxacin) |
| CASE 3 | Streptococcus Group B (treated with amoxicillin/clavulanic acid***) |
| CASE 4 | MRSA x 2 (treated with doxycycline and then trimethoprim/sulfamethoxazole**) |

RESULTS

Each of the patients were able to remain free from infections, and more importantly, supra infections during the wound treatment period of 3 months. Each patient showed improvements in the size and tissue quality of their wounds with complete or near complete healing as shown in the case photographs.

Case 1 Livedoid Vasculopathy

History: 54 year old male with history of polymyalgia rheumatica with continuing treatment of low dose prednisone and IVG/IVM infusions. He developed a wound in an area of the left leg, reporting that that it started as a bruise that opened up. Biopsy led to a diagnosis of livedoid Vasculopathy.



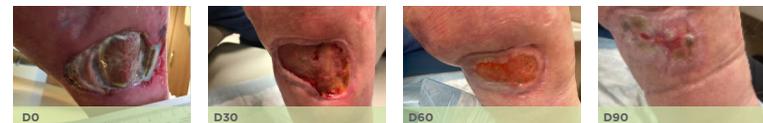
Case 2 Livedoid Vasculopathy

History: 68 year old female with history of scleroderma, osteoporosis, and Raynaud's disease with long term treatment regime of prednisone use and pentoxifylline****. She developed a wound in an area to the right of the lateral ankle. Patient reported that the wound started after she hit her ankle on her bed. A biopsy led to the diagnosis of livedoid vasculopathy.



Case 3 Pyoderma Gangrenosum

History: 71 year old male with history of diabetes, obesity, hypertension. Currently on mycophenolate mofetil***** and dapsone. He developed a wound in an area of the right posterior leg. The patient reported that the wound started as a blister that turned black. A biopsy diagnosed pyoderma gangrenosum.



Case 4 Pyoderma Gangrenosum

History: 33 year old male with history of Crohn's Disease, and anemia. The patient was on infliximab infusions*****. The patient reported that he developed a wound and black bruise area after his dog jumped on his leg. The wound was diagnosed as pyoderma gangrenosum.



CONCLUSION

Patients who are treated with immunosuppressant therapy with open wounds are at high risk for the development of supra infections in their wounds²³. PG and livedoid vasculopathy are two rare cutaneous conditions linked to underlying autoimmune diseases¹². We note from this four patient case series that no supra infection occurred during the 3 months treatment and that such absence of infection is aligned with patient experience with other types of wounds that do not require immunosuppressive therapy. The hypochlorous acid solution treatment* is thus one that holds some promise on these types of immunosuppressed patients.

The lack of cytotoxicity and the pure nature of the antimicrobial preservative, hypochlorous acid*, or HOCl, may be responsible in part for the excellent results seen in these rare and at risk for supra infection patients. We note that in addition to a higher risk of supra infections, immunosuppressed patients are at risk for a complete stalling of wound healing²⁴. That the wounds we studied proceeded to complete or near complete healing could arguably be attributed to the removal of some of the impediments to wound healing by hypochlorous acid based solution* being used. These impediments include infection, or biofilm infestation without signs of clinical infections.

Literature cited herein on the excellent clinical record of pure, pH controlled hypochlorous acid* containing wound treatment solution certainly supports this conjecture. Additionally, the pH of the HOCl solution used, which is between 3-5.5, is associated with healing of chronic wound via well researched and described pathways^{14,15} and could have contributed to the reported results. Recommendations include the development of a prospective study with a larger sample size.

*Vashe ** Bactrim (trimethoprim/ sulfamethoxazole) *** Augmentin (amoxicillin/clavulanic acid) **** Trental ***** Cellegy! ***** Remicade!

¹ Wolff K, Singsl G. Pyoderma gangrenosum. In: Freedberg IM, Eisen AZ, Wolff K et al., eds. Fitzpatrick's Dermatology in General Medicine, 5th edn. New York, NY: McGraw-Hill, 1999; 2: 2207- 2215. ² Shankar S, Vasudevan B, Deb P, Langer V, Verma R, Nair V. Livedoid vasculopathy - A vasculitic mimic. Arthritis Rheum 2015;65:791. ³ Orlicka K, Barnes E, Culver GL. Prevention of infection caused by immunosuppressive drugs in gastroenterology. Ther Adv Chronic Dis. 2015;4(4):167-165. ⁴ Sibbald RG, Williamson D, Orsted H, Campbell K, Keen D, Kissner D, Sibbald D. Preparing the wound bed: Debridement, bacterial balance and moisture balance. Ostomy/Wound Management. 2010;46(1):14-35. ⁵ Sakarya S, Gunay N, Karadokuz M, Ozturk B, Eruguz B. Hypochlorous acid: an ideal wound care agent with powerful microbicidal, antibiobiofilm, and wound healing potency. Wounds. 2016;28(2):52-59. ⁶ Armstrong DG, Sobot G, Gal P, Kevans SJ, Kirsner R, Snyder R, Sattabhai W, Armstrong DG, et al. Expert Recommendations for the Use of Hypochlorous Solutions: Science and Clinical Application. Ostomy/Wound Management. 2015; May/June:52-59. ⁷ Ostomy/Wound Management. 2015; ⁸ Robson M, Payne W, Ko F, Mentis M, Donald G, Shaffi S, et al. Hypochlorous acid as a potential wound care agent: Part II. Stabilized hypochlorous acid: its role in decreasing tissue bacterial bioburden and overcoming the inhibition of infection on wound healing. Journal of Burns and Wounds. 2007; 10(6): 8090. ⁹ Seal A, Robson M. The influence of pH on chronic wound healing and the antimicrobial activity of chlorine. Ostomy/Wound Management. 2016; 64 (10-11). ¹⁰ White GC. "Handbook of Chlorination and Alternative Disinfectants." 4th Edition, 1999. Wiley Interscience, p.215 -219. ¹¹ European Union Risk Assessment Report. Sodium Hypochlorite, 2010, p.20. ¹² Wang L, Bassini M, Najafi R et al. Hypochlorous acid as a potential wound care agent: Part I. Stabilized hypochlorous acid: A component of the inorganic armamentarium of innate immunity. J Burns Wounds. 2007 Apr 11:6:25. ¹³ Hidalgoy E, Barlowme R, Dominguez C. Cytotoxicity investigations of sodium hypochlorite in cultured human fibroblasts and its bactericidal effectiveness. Chem Biol Interact. 2002;159:265-280. ¹⁴ Klotz RA, Gillies C. Efficacy of sodium hypochlorite (Dakin's Solution) on cells of the wound module. Arch Surg. 1988;123(4):420-423. ¹⁵ Gattini, G. The significance of surface pH in chronic wounds. Wounds UK. 2007; 3 (3), 52-56. ¹⁶ Nagayoshi BS, Suryawarshi MW, Wadkar B, Seltzer S. Acidic environment and wound healing: a review. Wounds. 2015;27(1):5-11. ¹⁷ Robson MC. Treating chronic wounds with hypochlorous acid disrupts biofilm. Wound Prevention and Management. 2010; 66 (5) 9-10. ¹⁸ Day A, Alkhalil A, Carney B, Hoffman H, Moffatt L, Shupp J. Disruption of biofilms and neutralization of bacteria using hypochlorous acid solution: an in vivo and in vitro evaluation. Adv Skin Wound Care. 2017;30(5):451-551. ¹⁹ Alberto EC, Cardenas L, DO, Cipolite M, Gallagher KE. Level I trauma center experience utilizing negative pressure wound therapy with instillation: hypochlorous acid versus normal saline solution in complex or infected wounds. J Med Sci Clin Res. 2020; 8(6): 444-420. ²⁰ Hebert JM, Robson MC. The Immediate and Delayed Post-Debridement Effects on Tissue Bacterial Wound Counts of Hypochlorous Acid Versus Saline Irrigation in Chronic Wounds. Eplasty. 2016 Dec 11:6:e32. ²¹ Neugeboda J, Sottl P, Hermans M. Evaluation of vashe wound therapy in the clinical management of patients with chronic wounds. Adv Skin Wound Care. 2018; 28(3):352-357. ²² Adenier A, Phagocytes and the inflammatory response. The Journal of Infectious Diseases. Volume 187, Issue Supplement_2, June 2005, Pages S240-S. ²³ Gaini J, Dier R, Kieffer S, Dermine JF, Dardes S, Garnon E, Salsoul R, Rondard C, Desjardins M. The phagosome problem: insight into phagosome functions. Cell Biol. 2001 Jan 8; 152(1):35-50. ²⁴ Savaja P, Ranghino A, Fava PS, Savaja P, et al. Characterization and Management of Cutaneous Side Effects Related to the Immunosuppressive Therapy in Solid Organ Recipients. Curr Drug Targets. 2017;18(4):436-446. Review. ²⁵ Bostun R. Effects of immunosuppressive therapy on wound healing. Int Wound J. 2015;10(1):98-104.



What are the most important aspects revolving around wound care that are important to long term care patients?

Natalia Smith, MD, CCFP, COE



1. Introduction

Patient-centred care is informed by the patient's values and goals; however, how does one appreciate the breadth of considerations that are important to the patients? Patients in a long-term care facility have a number of risk factors for developing wounds, but little is known about the specific desires of that population group. To provide good care, decisions in health care should take into account the patient's values and preferences. There is a clear gap in the literature concerning the wound-care preferences of patients in long-term care settings, as most studies concentrate on people out in the community. Recognizing that patients in long-term care are there because of increased needs, their care should be a greater concern to caregivers, as wounds have a great impact on the patients' overall health (1). What those specific needs are, and the impact they could have on patients and health-care systems, may be different.

2. Research Question

What aspects of wound care are most important to long-term care patients?

3. Objectives

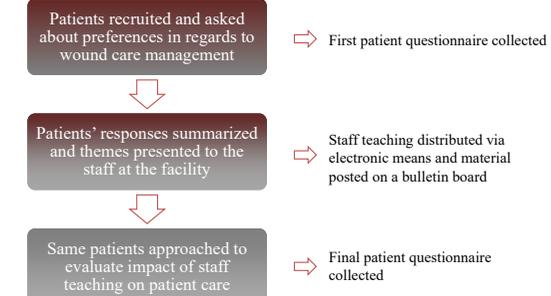
- To gain an understanding of the patient experience in wound care in a long-term care setting
- To educate those staff who are directly involved in patient care, about unmet patient needs
- The overall goal is that patient care will improve, with identified gaps, after knowledge sharing

4. Methods

Setting and Participants:

- Ethics Approval: University of Calgary (Study ID: REB20-0201), with modification of protocol during the COVID-19 Pandemic (Study ID: REB20-0201_MOD1)
- Patients were recruited from one long-term care facility in Calgary, Alberta
- Recruitment was done by physicians, an occupational therapist and nursing staff
- Patient criteria:
 - over 65 years old
 - has a wound at the time of the study
 - patient makes his/her own decisions
 - able to communicate in English
- There was an active COVID-19 outbreak at the LTC facility during recruitment and data collection

Overall Study Design:



5. Results

- Three patients were recruited for the study, and data were collected over the telephone
- In total there were 6 wounds amongst the 3 patients
- A total of 6 questionnaires were filled out

Average Age: 78
Wound Duration: 2mo-2yrs
Wounds per Patient: 1-3

Patient-Identified Concerns:

Wound-Specific Factors:

- Pain
 - Patients asked for better pain control – during interventions, as well as for ongoing unresolving wound pain
- Wound Resolution
 - Patients wished for a speedy recovery of the wound
 - Patients noted that seeing the wound and knowing about it brought up emotional responses such as being “frustrated” and “irritated”
- Social Avoidance
 - Specific wound characteristics caused some patients to avoid certain social situations
 - Patients discussed being “embarrassed” of the wound appearance
- Physical Limitations
 - Patients identified the need to modify their day-to-day activities to accommodate the wound
 - Certain body positions were avoided to minimize ongoing aggravation

Experience in Care:

- Not Feeling Informed
 - Patients felt that they were not included in their wound's journey
 - Patients expressed concerns of not knowing about wound status or treatment progress
 - Emotions of “fear” and “worry” were brought up, in relation to these uncertainties

- Lack of Preparedness
 - Patients noticed that staff were running back and forth from their rooms as they apparently forgot certain supplies
 - Patients talked about needing to remind the staff to change their dressing

3. Wound-Management Plan

- Patients were given inconsistent advice regarding their wounds and management
- Some staff members appeared to be unaware of the overall wound-care plan

4. Dignity and Respect

- Communication
 - Concerns were raised by the patients as to the language used to communicate with them
 - When patient asked about their wounds, they were met with an assortment of phrases; e.g.: “be quiet”, “don't talk”, “shhh, I'm working”
- Patients Left Exposed
 - Patients discussed being left on the beds with exposed wounds – e.g., a coccyx wound – when staff members were called away before finishing dressing the patient's wound
 - Patients felt that their dignity was lost
- Lack of Respect for Patients' Wishes
 - Patients expressed that adequate analgesia was not provided, despite asking for pain control
 - Patients' requests for analgesia before interventions was apparently denied and the patients believed it was because of time constraints

Effectiveness of Staff Teaching:

- 1-4 weeks after the initial questionnaire, patients were asked if their care had improved
- 2 of the 3 patients were reached over the telephone for the second questionnaire
- Both of these patients did not believe their care had improved

6. Conclusion and Discussion

This quality-improvement study demonstrated that patient-centred wound care is possible in a long-term care facility. By obtaining personal priorities for each of the patients, the study encouraged them to be partners in their own wound care. **The guiding principle was that people have the right to be able to participate in discussions, to be treated with dignity, and to have a voice when problems arise.** The biggest challenge to this approach is that it takes time: time to get to know the patient, to assess their wound care plan, to identify knowledge gaps and to address the patient's fears.

Most studies around these concerns are done on patients who are out in the community. Priorities may indeed be different for patients who are in a long-term care setting. The explicit concerns raised in this study about Wound Specific factors and Experiences in Care are in keeping with those identified previously in the literature, but **the concept of the Care Experience may be greater and more important than we anticipate.** The concerns raised are likely not unique to an isolated facility, but need to be addressed more broadly as our population ages and LTC facilities fill up.

7. References

- International consensus. Optimizing wellbeing in people living with a wound. An expert working group review. London: Wounds International, 2012. Available from: <http://www.woundsinternational.com>

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The efficacy of sucrose octasulfate (TLC-NOSF)* dressing in neuro-ischaemic DFU considering factors influencing wound closure rate: a post-hoc analysis of the Explorer RCT¹

Chakravarthy D; Lázaro-Martínez JL; Edmonds M; Rayman G; Jan Apelqvist, MD; Kristien Van Acker, MD; Agnès Hartemann, MD, PhD; Jacques Martini, MD; Ralf Lobmann, MD; Serge Bohbot, MD; Alberto Piaggese, MD

INTRODUCTION: Foot Ulceration is one of the most serious complications of diabetes, often leading to foot infection and amputation and which can be life-threatening¹. Until recently, no treatment had been acknowledged to enhance the healing process of these chronic wounds and no dressing had ever definitively before demonstrated improvement of their closure rate.²⁻⁴ In March 2018, a large, European, double-blind, randomized, controlled trial (the "Explorer" study), has definitively demonstrated that treating patients with neuro-ischaemic DFUs with a sucrose octasulfate (TLC-NOSF)* dressing significantly improves wound healing outcomes compared with a widely used lipido-colloid (TLC)** dressing.²

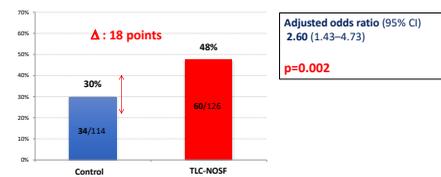
METHOD : Randomised, double blind, controlled trial, conducted in two parallel groups



The selected inclusion and exclusion criteria aimed to select patients with neuro-ischaemic DFUs covering a large variety of characteristics.

RESULTS:

Primary Endpoint : Wound Closure by Week 20. Main efficacy analysis, ITT population



• Significantly more wound closure was observed in the TLC-NOSF group

Secondary Endpoints : Time to closure (in days) by week 20 – Kaplan Meier analysis

| | Control group (n=114) | TLC-NOSF group (n=126) | Time to Closure Difference | Log rank (Mantel-Cox) |
|--------------|-------------------------|-------------------------|----------------------------|-----------------------|
| ITT analysis | 180 ± 8.7 (163.4-197.7) | 120 ± 4.7 (110.5-128.9) | 60 days | p=0.029 |

• TLC-NOSF shortened the mean time to closure by 60 days compared with a neutral dressing

Data are given as mean ± SE (95% CI). Median value are not given as the control group did not reach 50% of wound closure. Estimation is limited to the largest survival time if it is censored. Confirmed closure population.

* UrgoStart® with TLC-NOSF, Laboratoires Urigo, France; ** UrgoTul®, Laboratoires Urigo, France

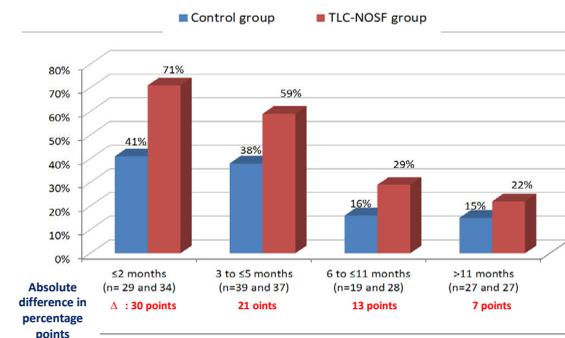
Wound duration is one of the most frequently reported risk factors affecting chronic wound closure prognosis, and recent publications highlight the importance of an early detection, assessment and management of DFUs in order to improve closure rate and reduce the wound-associated complication risks such as infection or amputation.³⁻⁵ DFU location is also known to affect healing rate.⁶ Therefore, we found it would be interesting to further document the relation between wound duration and wound closure rate within the Explorer cohort. We also propose to comment on the effect of the sucrose octasulfate dressing in subgroups of patients with different wound locations. With this purely descriptive post-hoc analysis, we aim to offer complementary and pragmatic observations from the Explorer cohort.

For these purposes, we used ITT population and reported the wound closure rates by Week 20, as defined in the original study. Receiver operating characteristic (ROC) curve analyses were used to appreciate the prognosis potential of wound duration at D0 on wound closure by Week 20. Quartile distributions of patients according to wound duration were determined. Absolute differences and Relative Risks (RR) of wound closure rates between groups were calculated with their 95% CI. In the Explorer study, all DFU locations were allowed, except from interdigital wounds (which are not suitable for accurate measurement of wound area) and wounds on the Achilles tendon on the posterior part of the heel (to avoid confusion with pressure ulcer). However, due to low numbers of patients in wound location subgroups, all DFU locations other than sole were pooled into one category for RR analysis. These analyses are merely descriptive, and no formal statistical test has been performed as we are in a post-hoc situation and alpha risk inflation was high due to multiple comparisons, thus precluding the relevance of any p value.

Impact of DFU duration on wound closure rate in the control and sucrose octasulfate groups

When cross-analysing patients' distribution according to their DFU duration by quartiles and the treatment received, the absolute difference in wound closure rates was always in favour of the therapeutic strategy with the sucrose octasulfate dressing, whatever the DFU duration was. The Relative Risks for wound closure in the DFU duration quartile categories stayed in a relatively close range (from 1.7 for the ulcers with a duration ≤2 months to 1.5 for the ulcers with a duration of more than 11 months), however the highest absolute difference was reported when the most recent DFUs were treated. The 29 percentage points difference (71% vs 41%) in wounds with a duration of 2-months-or-less tends to support the initiation of the sucrose octasulfate treatment as early as possible, for an optimal impact (Table 2).

Table 2. Closure rate and Wound duration (Control vs TLC-NOSF) (Quartiles)

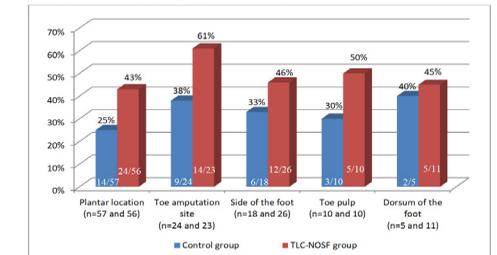


Closure rates and DFU locations

As illustrated below, a large variety of wound locations has been included in the Explorer cohort (such as on the sole of the foot, on the side, on the dorsum, etc). These locations were well balanced between the two groups at baseline, with plantar location being the most frequent location in both groups. Analysing the subgroups of patients for each location, higher closure rate by Week 20 were always reported in favour of the sucrose octasulfate dressing, whatever the sub-groups location considered. The lowest wound closure rate with the sucrose octasulfate dressing was reported in the sole location subgroup (43% vs 25% in the control group), and the highest rate was reached for toe amputation location (61% vs 38% in the control group), regrouped in the 'other subgroup'. Thus, the beneficial effect of the sucrose octasulfate dressing appeared to be coherent, whatever the location of the wounds was.



Wound closure rate according to wound location and treatment



CONCLUSION: Numerous factors are known to have an influence on DFU closure rate, the choice of the dressing is now an additional one, highlighting that in DFU management, every step really does matter. The results from this post-hoc analysis support the coherence of the outcomes reported in the original publication of the Explorer study that established the superiority of the sucrose octasulfate dressing and supporting its use in the management of diabetic foot ulcers. Higher closure wound rates were reported with sucrose octasulfate dressing, whatever the duration or location of the wound. However, the highest closure rate and closure rate difference were reported in wounds with the shortest duration, which should lead to the recommendation of initiating the treatment UrgoStart® with TLC-NOSF as soon as possible for a maximum impact in terms of wound closure outcomes, especially considering that this effective and safe treatment is simple to use and easy to implement into DFU standards of care.

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CLINICAL EVALUATION OF SUCROSE OCTASULFATE (TLC-NOSF) POLYABSORBENT DRESSINGS*: A PROSPECTIVE, OBSERVATIONAL, MULTICENTRE STUDY OF 1140 PATIENTS

Debashish Chackravarty,^{1*} Joachim Dissemond,² MD; Steffen Lützkendorf,³ MD; Michael Dietlein,⁴ MD; Ingo Neßeler,⁵ MD; Elisa Becker,⁶ Udo Möller,⁶ PhD; Laetitia Thomassin,⁷ PhD; Serge Bohbot,⁷ MD; Karl-Christian Münter,⁸ MD

OBJECTIVE

To evaluate the efficacy and safety of new sucrose octasulfate (TLC-NOSF)* dressings with polyabsorbent fibres in an unselected population of patients under real-life conditions.

METHOD

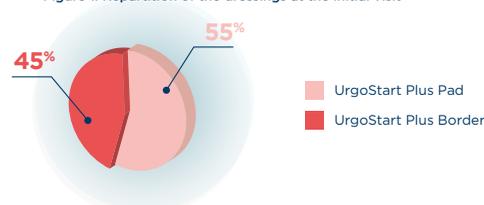
A LARGE, PROSPECTIVE, MULTICENTRE, OBSERVATIONAL STUDY WITH TWO POLYABSORBENT SUCROSE OCTASULFATE DRESSINGS**

- ▶ Conducted in Germany between July 2017 and December 2018 in 130 centres
- ▶ Patients were followed up for a maximum duration of 12 weeks, with a maximum of four documented visits
- ▶ N= 1411 patients (LU: 484 patients, DFU: 250 patients, PU: 116 patients, Other wounds: 290 patients)

▶ Primary outcomes measured:

- Clinical assessment of wound healing progression
- Wound healing rate
- Treatment duration in days
- Local tolerability and acceptance of dressings
- Changes in the exudate level and periwound skin condition

Figure 1: Repartition of the dressings at the initial visit



RESULTS

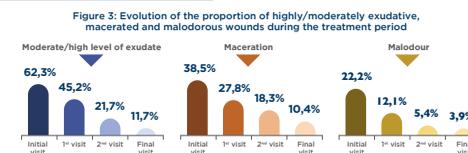
POSITIVE OUTCOMES IN TERMS OF EFFICACY, TOLERANCE AND ACCEPTABILITY

Efficacy treating the wound

- In %93,3 of the treated wounds, a wound closure or an improvement in wound healing by the final visit was reported
- Median time to achieve wound closure was 49 days for LUs, DFUs and PUs



Efficacy managing the wound bed



Tolerance and acceptability: Rated highly by healthcare professionals and patients

Patient perspective:

- ▶ No pain or minimal pain in 96,9% of the cases
- ▶ Very well accepted or well accepted by %98,1 of the patients
- ▶ Very well tolerated or well tolerated in %98,7 of the patients

Healthcare professional perspective:

- ▶ Extremely useful or useful in %94,6 of the patients
- ▶ In most of the cases, both dressings were judged as 'very easy' or 'easy' to apply since the first application, and also 'very conformable' or 'conformable'

POSITIVE & SIMILAR OUTCOMES REGARDLESS WOUND TYPE OR WOUND HEALING STAGE

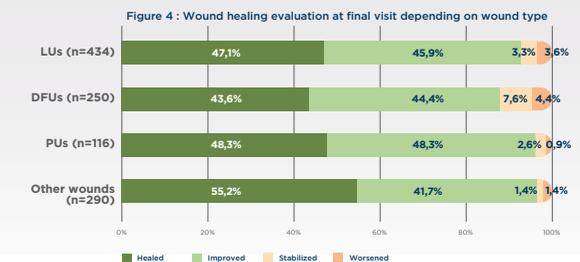
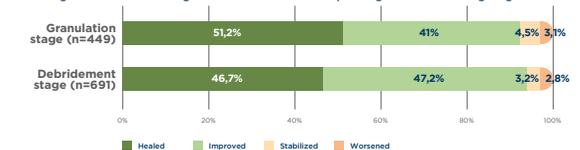


Figure 5: Wound healing evaluation at final visit depending on wound healing stage at baseline



BEST HEALING OUTCOMES ACHIEVED WHEN IMPLEMENTED 1st LINE



CONCLUSION

The positive outcomes achieved in this study are consistent with those of previous interventional studies conducted with sucrose octasulfate dressings in the local management of LUs, DFUs or PUs.

This study confirms that UrgoStart Plus:

- ▶ Is a **safe, simple and efficient** solution to treat lower limb wounds
- ▶ Can be implemented for **all LUs, DFUs and PUs** - regardless of wound healing stage - **from day 1 until complete healing**
- ▶ **The sooner** the treatment is initiated, **the better** the clinical outcomes.

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⁷Medical Affairs Department, Laboratoires URGO Medical, Paris, France.

⁸Medical Office Specialized on Phlebology, Hamburg, Germany.



REALITY: The practical management of chronic wounds with sucrose octasulfate (TLC-NOSF)* dressings: a pooled data analysis of more than 10 000 wounds¹

D. Chakravarthy, K.C. Münter, MD; S. Meaume, MD; M. Augustin, MD; P. Senet, MD; J.C. Kérihuel, MD

INTRODUCTION: While randomized controlled trials are the gold standards to demonstrate efficacy of new therapeutic strategies, the ability to extrapolate their results to the general population is often an issue.² To answer to this uncertainty, a large clinical analysis based on the conduct of various non-interventional studies has been performed with sucrose octasulfate (TLC-NOSF) dressings.

AIM: Our aim was to determine whether an analysis of the results in all the recorded clinical studies, including randomized controlled studies, and observational studies, can translate into observations and practice recommendations for routine management of wounds.

METHOD: We identified 10 studies and full study documentation and databases were obtained (for 6 studies, databases were available from one of the authors who coordinated and analyzed the study and for the other four, databases were provided by Urgo). In one of these trials conducted in early 2007 in France, only 78 patients out of 1005 received the TLC-NOSF dressing; in a second one conducted in Germany (1831 included patients), the structure of the provided database was inappropriate to allow accurate data retrieval. Overall, six French and two German studies were finally selected for data processing. Demographic data, baseline description of wounds and description of their evolution during treatment were extracted and combined. We used two main indicators of clinical outcomes to measure the impact of the TLC-NOSF dressing on this population: time to wound closure and time to 50% reduction of the Pressure Ulcer Scale for Healing (PUSH) score.³⁻⁵ Most of the studies we chose have been published.

RESULTS: Patients and wounds at inclusion: Overall, 10,220 patients (Table 1; 8102 in French and 2118 in German studies) were included (7903 with LUs, 1306 with DFUs and 1011 with PUs).

TIME TO CLOSURE: Based on the total population, mean estimates of time to closure were 111.3 days [95% CI: 105.5–117.2]. According to wound types, these estimates were 112.5 days [95% CI: 105.8–119.3] for LUs, 98.1 days [95% CI: 88.8–107.5] for DFUs and 119.5 days [95% CI: 94.6–144.3] for PUs. See Table 2.

Based on the subgroup analysis of the French cohort, time to closure appears to be substantially shorter for wounds that are treated for the first time with a TLC-NOSF dressing compared with those where this prescription has been decided after using another primary dressing (mean time: 70.2 days versus 103.7 days; log-rank test: p<0.001; Table 3). This applies to all wound aetiologies.

* UrgoStart®, Laboratoires Urgo, France

Table 1. Main characteristics of selected observational studies

| Country | Study name | Year | Investigators | No. of Investigators | Total No. included | No. included in data pooling | | | | Planned FU duration | Auto Quest | Main study efficacy outcomes | Other study objectives |
|--------------|---------------|------|---------------|----------------------|--------------------|------------------------------|-------------|-------------|----------------|---------------------|------------|--|---|
| | | | | | | LU | DFU | PU | Total selected | | | | |
| France | Confluence | 2012 | MD | 624 | 2164 | 1726 | 298 | 263 | 2287 | 8 weeks | Yes | Wound size, colorimetry, | |
| France | Speed | 2011 | MD, Nurses | 197 | 968 | 1418 | 241 | 187 | 1846 | 4 weeks | Yes | PUSH score, pain | Impact of initial colorimetric aspect on PUSH score reduction |
| France | Reponse | 2009 | MD, Nurses | 283 | 809 | 504 | 22 | 56 | 582 | 4 weeks | Yes | PUSH score, pain | |
| France | Opus | 2010 | MD, Nurses | 724 | 1505 | 532 | 75 | 111 | 718 | 20 weeks | Yes | PUSH score, pain | Time to wound closure |
| France | Start | 2008 | MD, Nurses | 457 | 2144 | 1712 | 0 | 0 | 1712 | 4 weeks | Yes | PUSH score, pain | Impact of economic status on wound response, QoL |
| France | Starter | 2009 | MD, Nurses | 372 | 1185 | 736 | 123 | 98 | 957 | 6 weeks | No | PUSH score, pain | Impact of UrgoStart dressing prescription (1st or 2nd intention) on wound evolution |
| Germany | UrgoStart | 2011 | MD | 81 | 1513 | 710 | 356 | 222 | 1288 | 4 weeks | Yes | Wound size, colorimetry, exudation, pain | QoL |
| Germany | UrgoStart Töl | 2012 | MD | 54 | 1235 | 565 | 191 | 74 | 830 | 5 weeks | No | Wound size, colorimetry, exudation, pain | |
| Total | | | | 2792 | 11,523 | 7903 | 1306 | 1011 | 10,220 | | | | |

No.—number; FU—follow-up; LU—leg ulcer; DFU—diabetic foot ulcer; PU—pressure ulcer; Auto Quest—questionnaires about wound discomfort given to patients and to be completed at home and returned directly to study coordinator; QoL—Quality of life instrument (50 EuroQoL in all cases); PUSH—pressure ulcer scale for healing v3.0; wound size—measurement of the largest and shortest wound axis

TABLE 2. Average time to closure (days)

| Wound type | Kaplan-Meier Analysis | | | |
|----------------|-----------------------|-----------|-------|-------|
| | Estimate | Std Error | Mean | |
| | | | Lower | Upper |
| DFU | 98,1 | 4,8 | 88,7 | 107,5 |
| Leg Ulcer | 112,5 | 3,4 | 105,8 | 119,3 |
| Pressure Ulcer | 119,5 | 12,7 | 94,6 | 144,3 |
| Overall | 111,3 | 3,0 | 105,5 | 117,2 |

TABLE 3: ESTIMATES OF TIME TO CLOSURE BASED ON START OF DRESSING TREATMENT AND TYPE OF WOUND

| Start dressing prescription | Wound type | n | Time to closure | |
|-----------------------------|----------------|-------------|-----------------|-------------------|
| | | | Mean estimate | 95% CI |
| 1st line intervention | Leg ulcer | 893 | 70.6 | 61.8–79.4 |
| | DFU | 99 | 57.5 | 51.4–63.6 |
| | Pressure ulcer | 102 | 67.9 | 57.0–78.8 |
| Overall | | 1094 | 70.2 | 62.3–78.0 |
| 2nd line intervention | Leg ulcer | 2604 | 103.5 | 98.1–108.9 |
| | DFU | 263 | 77.3 | 73.6–81.1 |
| | Pressure ulcer | 254 | 97.8 | 88.1–107.6 |
| Overall | | 3121 | 103.7 | 98.7–108.7 |

DFU—diabetic foot ulcer; CI—confidence interval; n—number of documented cases

- Time to closure with TLC-NOSF is similar between Leg Ulcers, DFUs and PUs at 111 days on average
- Time to closure observed in real life is consistent with the CHALLENGE RCT results which estimate time to closure at 90 days after regression analysis¹
- EXPLORER RCT found mean time to closure of 120 days on neuro-ischaemic DFUs which is consistent with these results⁶
- The earlier the TLC-NOSF treatment is initiated, the shorter the time to closure.
- The benefits of initiating the treatment sooner were also confirmed in the EXPLORER post-hoc analysis recently published⁷

CONCLUSION: These results taken together support the hypothesis that the data observed in real-life on over 10,000 patients are consistent with results from the RCTs conducted with TLC-NOSF dressings. The CHALLENGE RCT on venous leg ulcers estimated a time to closure of 90 days after regression analysis and the EXPLORER RCT showed a mean time to closure of 120 days on neuro-ischaemic DFUs.^{1,6} Therefore the conclusions derived from these RCTs in specifically selected LUs and DFUs are probably generalizable to the general population treated for chronic wounds in real-life practice. Moreover, these results suggest that the TLC-NOSF dressing may significantly reduce healing time of chronic wounds and that the earlier it is initiated, the shorter the time to closure. The benefits of initiating TLC-NOSF treatment earlier have also been confirmed recently in the EXPLORER RCT post-hoc analysis.⁷

REFERENCES: 1. K.C. Münter, MD; S. Meaume, MD; M. Augustin, MD et al. The reality of routine practice: a pooled data analysis on chronic wounds treated with TLC-NOSF wound dressings. J Wound Care 2017 Feb 2;26: 2. Flather, M., Delahunty, N., Collinson, J. Generalizing results of randomized trials to clinical practice: reliability and cautions. Clin Trials 2006; 3:6, 508-512. 3. Meaume, S., Truchetet, F., Cambazard, F. et al. A randomized, controlled, double-blind prospective trial with a Lipido-colloid Technology-Nano-Oligosaccharide Factor wound dressing in the local management of venous leg ulcers. Wound Repair Regen 2012; 20: 4, 500-511. 4. Schmutz, J.L., Meaume, S., Fays, S. et al. Evaluation of the nano-oligosaccharide factor lipido-colloid matrix in the local management of venous leg ulcers: results of a randomized controlled trial. Int Wound J 2008; 5:2, 172-182. 5. White, R., Cowan, T., Glover, D. Supporting evidence-based practice: a clinical review of TLC technology. MA Healthcare Ltd, 2011. 6. Edmonds M, et al. Sucrose octasulfate dressing versus control dressing in patients with neuroischaemic diabetic foot ulcers (Explorer): an international, multicentre, double-blind, randomised, controlled trial. Lancet Diabetes Endocrinol 2018 ; 6(3):186-196 7. Lázaro-Martínez JL, Edmonds M, Rayman G. et al. Optimal wound closure of diabetic foot ulcers with early initiation of TLC-NOSF treatment: post-hoc analysis of Explorer. J Wound Care 2019 Jun 2;28(6):358-367.



EFFECTS OF TECHNOLOGY LIPIDOCOLLOID (TLC)/SILVER* ON SKIN INFLAMMATION IN MICE

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INTRODUCTION

TLC/Silver*, a TLC-Ag dressing, combination of TLC (Technology Lipido-Colloid) and silver salts, is used to promote wound healing in wounds with risks or signs of local infection, thanks to the anti-microbial barrier properties of the silver salts. Nanocrystalline silver dressings**, also used to improve wound healing, present both anti-microbial barrier and anti-inflammatory effects.

Therefore, the goal of this study was to investigate the anti-inflammatory effects of TLC/Silver* dressings in a model of chronic skin inflammation induced by repeated skin application of 12-O-tetradecanoylphorbol-13-acetate (TPA) in hairless mice, in comparison with a lipidocolloid dressing***, TLC dressing (TLC), a nanocrystalline silver dressing (SN), desonide cream 0.05% (DC) and gauze.

MATERIAL AND METHODS

30 Hairless Skh-1 female mice (20-25 gm) purchased from Charles River France were divided in 5 groups of 6 mice each. Chronic Skin Inflammation (CSI) was induced in all mice by a daily topical application on their back of an acetonic solution of TPA during 14 consecutive days.

Daily treatments of mice began 7 days after the start of induction of inflammation and lasted for 7 days. Patches of dressings and gauze of 3x2 cm were put and were wetted with sterile water (0.25 ml/cm²) before being placed over the back of mice.

The DC was applied directly on the back of mice (0.05 g/cm²) with the same surface of treatment as for dressings and gauze, and a patch of gauze of 3x2 cm was placed over the back of mice. All the dressings and gauze were held in place with adhesive bandage. A macroscopic scoring of CSI was performed daily during the treatment period until sacrifice on Day 15. Skin samples were taken for histopathological analysis in order to determine the microscopic score of CSI. Experimental procedures were conducted in compliance with international legislation.

RESULTS

TLC/Silver* reduced significantly (Mann Whitney tests) the macroscopic score of CSI from Day 10 in comparison with gauze and lipidocolloid dressing***, similarly to nanocrystalline silver dressing**. Desonide cream, a corticosteroid cream used as positive control, presented the best anti-inflammatory effects. **No significant differences were observed between TLC and gauze.** Macroscopically, TLC/Silver* reduced to a greater extent skin inflammation and slightly faster than a nanocrystalline silver dressing** but with no statistically significant differences.

Figure 1

Effects of treatments on the evolution of global macroscopic scores of TPA-induced CSI between Day 8 and Day 15 (Mean \pm SEM of 6 mice per group)

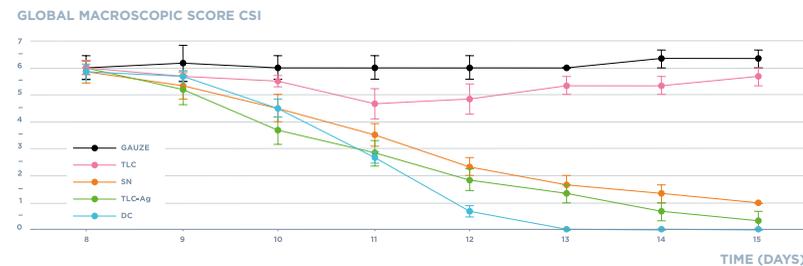


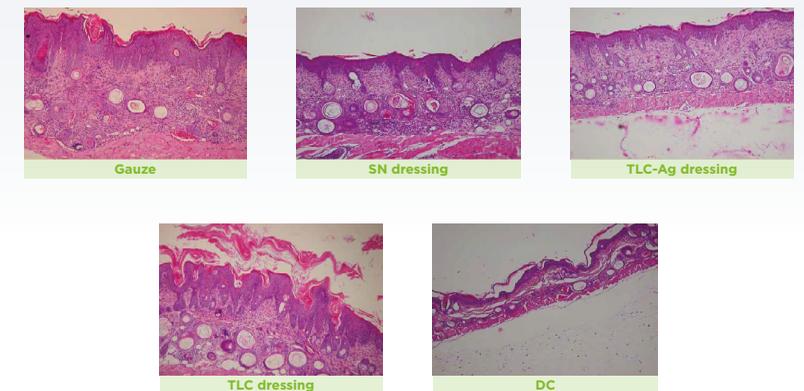
Figure 2

Photographs of back skin of TPA-induced skin mice with the different treatments taken at Day 15



Figure 3

Photomicrographs of transverse sections of TPA-induced skin samples with the different treatments taken at Day 15



CONCLUSION

These results and statistical analysis between the two silver dressings (Mann-Whitney test) demonstrate that **TLC/Silver* presents clear anti-inflammatory effects** in a non infected inflammatory skin model comparable to that of nanocrystalline silver dressings**. **TLC/Silver* can improve wound healing^{1,2}** thanks to its combination of anti-microbial barrier and anti-inflammatory effect³ and of the pro-healing properties of TLC-Ag.

* Urgotul Ag, distributed by Urgo Medical North America, Fort Worth, TX, USA

** Acticoat (R), distributed by Smith and Nephew, Canada.

*** Urgotul, distributed by Urgo Medical North America, Ft. Worth, TX, USA

¹ Lazareth I, Meunier S, Sigal-Grinberg M, Combemale P, Le Guyader T, Zagnoli A, et al. Efficacy of a silver lipidocolloid dressing on heavily colonised wounds: a republished RCT. *Journal of Wound Care* 2012;21:96-102.

² Bernard FX, Barraud C, Audoux F, Laurensou C, Apert L. Stimulation of the proliferation of human dermal fibroblasts in vitro by a lipidocolloid dressing. *Journal of Wound Care* 2005; 14:215-220.

³ Bisson JF, Hidalgo-Lucas S, Bouschbacher M, Thomassin L. Effects of TLC-Ag dressings on skin inflammation. *Journal of Dermatology* 2013; 40: 1-8



A SCIENTIFIC REVIEW OF THE CHEMISTRY OF WOUND HEALING AND THE ROLE OF HYPOCHLOROUS ACID, WHY PURITY OF THE COMPOSITION IN A WOUND CLEANSING SOLUTION MATTERS AND WHY HYPOCHLORITE IS AN INGREDIENT TO BE AVOIDED

D. Chakravarthy Ph.D, Svetlana Panicheva Ph.D, Greg Schultz Ph.D.

INTRODUCTION

The use of hypochlorous acid is wound healing is now accepted as an evidence-based method of positively affecting wound healing outcomes¹⁻⁴. The mechanism of action of hypochlorous acid on microbes at a molecular and biochemical level is well described in literature, and it is known that the hypochlorous acid molecule plays a critical and indispensable role in the normal functioning of the innate immune system⁵⁻⁸.

Hypochlorous acid (HOCl) is a weak acid with a pKa of 7.5, and therefore it does not easily or completely dissociate into the hydrogen ion (or proton) and its conjugate base, the hypochlorite ion, in neutral water. In the presence of biological matter, HOCl is a potent oxidant, reacting very fast with microbes, oxidizing various biological constituents, and killing them. The weakness of the acid is important with respect to safety to living tissue, because a strong acid when applied to tissue will release excessive quantities of hydrogen ions, bringing the pH down to very low levels (pH 1-2, for example) which will cause extensive protein denaturation, hence cell and tissue death.

Hypochlorous acid (HOCl) can dissociate to the hypochlorite anion (OCl⁻), which is the active ingredient in household bleach (NaOCl), and in Dakin's solution still used in wound care. This breakdown or dissociation begins to happen at pH values higher than approximately 6 and is almost complete at a pH of above 9, which is true of Dakin's solution.

There is much confusion in literature, and similar misperception in the understanding between the biological effects of hypochlorous acid, versus the hypochlorite species, perhaps because they are very similar in nomenclature and sound similar to the non-chemist's ears. Yet, there are significant differences between these two active chlorine species or compounds (HOCl vs. NaOCl), both of which are available commercially or pharmacy supplied to the clinician. Clinicians may not be aware of the remarkable differences between the two species of interest, pure hypochlorous acid, and hypochlorite anion which usually has a metal ion counterpart as a sodium ion (Na⁺). These differences have major biological consequences.

This review of literature aims to mitigate the confusion between hypochlorous acid and hypochlorite in chemically accurate language that is of relevance to the clinician. The review will also explain the biological consequences of choosing one over the other.

One has to note the role that hypochlorite or bleach has played in wound healing to date. It is true that during World War I, Dr. Carrel Dakin developed, at the request of the US Government, the Dakin's solution⁹⁻¹⁴. Dakin's solution is sodium hypochlorite and is typically prepared by diluting bleach with water so that the sodium hypochlorite is at a concentration of 5000 ppm⁷. Because the solution was inherently unstable¹⁵, the proper application of Dakin's as recommended by Carl Dakin's himself was required constant irrigation of the wound with rubber catheters or tubing that was perforated and that required the irrigant to be constantly channeled through to get continuous wound contact¹⁶. We will discuss later in this review that hypochlorite is actually quite a weak antimicrobial product⁸, however, it has the ability to reduce some bioburden, and, no doubt, it use saved lives in the World War I theater where mortality was extremely high due to the contamination of wounds in the extremely unsanitary conditions associated with the trench warfare associated with World War I¹⁶ pre-antibiotics era.

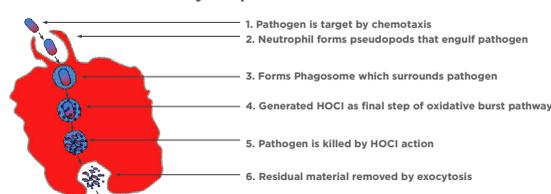
METHOD

To analyze and report the peer reviewed evidence of the relative merits of hypochlorous acid and hypochlorite, a targeted literature search that describes the conditions under which hypochlorous acid and the hypochlorite species exist as pure or nearly pure ingredients. We also looked for peer-reviewed literature on the comparative efficacies (as antimicrobial) for these two chemicals, and their side effects such as cytotoxicity, which is the most easily studied side effect to determine biological safety for use in wounds.

RESULTS OF LITERATURE SEARCH, ANALYSIS AND DISCUSSION

A search on the subject of hypochlorous acid can unearth several dozens of citations, but not all citations are relevant or specific to the subject of chemistry (specifically in the context of the inorganic chemistry of these two molecules) in way that is relevant to wound care. Many of these citations are related to the molecular synthesis (reaction), and subsequent activity of hypochlorous acid within the phagosomes in neutrophils and macrophages¹⁷⁻¹⁹. Figure 1 presents a schematic of the intracellular process.

Figure 1 The Human Inflammatory Response



From: The scientific bases for the use of hypochlorous acid to avoid pitfalls: Supplement, Wounds Volume 26, Number 12, 2014 s46-67

Hypochlorous acid, due to its inherent safety of use when used in complex or infected wounds, at concentrations of up to 300-400 ppm have many medical and non medical usage and this subject has been well reviewed in recent literature¹⁰. Our review is focused on literature related to wound care uses of hypochlorous acid and hypochlorite. The latter includes pure hypochlorite containing Dakin's or water diluted Dakin's, and mixtures of hypochlorite species and hypochlorous acids, which are referred to by us as "blends".

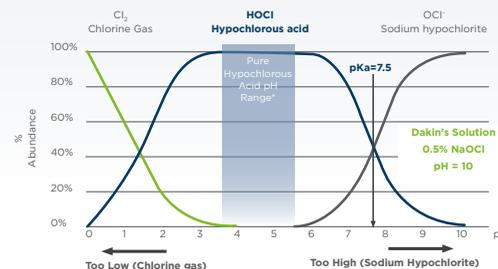
It is critical to understand the nature of equilibrium that exists between different aqueous chlorine containing agents, such as the hypochlorous species (or, Dakin's solution, a name more relevant to clinicians) and the hypochlorite anion.

The equilibrium can be expressed in terms of a chemical equation



The pKa for this conversion of the hypochlorous acid antimicrobial (it is the most potent chlorine containing oxidant/antimicrobial amongst all chlorinated chemicals^{20,21}) is 7.5. By definition, the pKa is the pH at which half of the total amount of the available hypochlorous acid (desirable) has been dissociated, or has been converted to the hypochlorite species (undesirable). This conversion is easy to see in the graph shown in Figure 2^{22,23}.

Figure 2 Chlorine-based species distribution curves as a function of pH; Hypochlorous Acid* versus the undesirable hypochlorite



The laws of physical chemistry, and a tight pH range (3.5 to 6.0) are related twin factors that ensure that hypochlorous acid is the only antimicrobial preservative present in a product formulated in the way that is shown in Figure 2^{22,23}, with close to zero level of hypochlorite.

A similar dampening of HOCl toxicity in the intracellular space by glutathione is known, however the reaction schematic is complicated with the primary reaction product reacting further with HOCl in order to rapidly dissipate it in intracellular space, reducing toxicity.

The ability of the mammalian system to be able to live in harmony with such a highly antimicrobial molecule as hypochlorous acid, has been reviewed exhaustively²⁷.

Clinical observations associated with the use of hypochlorous acid can possibly be related to the inorganic chemistry, specifically the oxidation activity of hypochlorous acid as it dissipates in the wound tissue. For example, it is now known that wound care solutions that contain hypochlorous acid as a desirable antimicrobial preservative are also indicated for mechanically removal of necrotic tissue and debris, including microbiological debris, and certainly there is some clinical evidence to support this mechanism of action^{28, 29}. In addition, recent findings show that such mechanical removal may be achieved with even greater effectiveness by combination of a forced irrigation of HOCl solution coupled with the mechanical action inherent in the Negative Pressure Wound Therapy system (NPWT)³⁰. This general process, known as instillation, is widely practiced as an improvement over standard, static NPWT³¹ and the use of hypochlorous acid solution as an irrigant has been discussed³¹ and consensus was reached on its use with the instillation system. We have examined some possible chemistry based reasons why the mechanical action of NPWT instillation is amplified with hypochlorous acid, as opposed to saline³⁰, the standard instillation medium.

There is published evidence that hypochlorous acid may indeed react with protein and amino acid substrates, and it is possible that such phenomena to further denature necrotic tissue may assist its mechanical removal. In addition, the weakly acidic pH where pure hypochlorous acid is delivered, is also known to dissociate the collagen triple helix, and such phenomenon may be particularly applicable to necrotic tissue where the collagen is already partially dissociated from its triple helix native structure. These are the four citations for the reactions of HOCl with protein side chains and peptide bonds and with chloramine transfer reactions and protein tertiary structure, which may help in the mechanical debridement of denatured proteins particularly with instillation and NPWT³²⁻³⁵. Also included are the reactions of HOCl with collagen type II and other general protein fragmentation.

The issue of relative effectiveness between the hypochlorous acid and the hypochlorite species on biofilms has also been studied and reported on. Sensitive work by Stewart et al³⁶ on the penetration of the Dakin's solution associated hypochlorite anion penetration showed rapid dissipation of the ion before it could penetrate the entirety of the exopolymeric matrix associated with mature biofilms. Work by Sauer³⁷ showed, in contrast, significant effect on quite mature biofilm of a hypochlorous/hypochlorite mixture, possibly due to the presence of the hypochlorous acid, because it was already proven³⁶ that hypochlorite does not impede established biofilm in any way. Work by Sakarya³⁸, Robson³⁸, and Shupp³⁹ have all showed pure hypochlorous acid can affect biofilm of various levels of maturity.

Finally, the issue of the lower pH associated with purity of hypochlorous acid, the mildly acidic pH range of 3.5 to 6.0 is also the pH that is associated with healing wounds^{40,41}, as opposed to wounds that are chronic and not healing. The lower pH if achieved through external means, for example, by the introduction of a pH controlled, pure hypochlorous acid solution, may be helpful to wound healing. The reasons for this has been discussed in literature⁴² and a simple reason may be that the lower pH deactivates enzymes such as matrix metalloproteinases (MMP) whose presence is deleterious to wound healing due to their ability to degrade cytokines and important growth factors. High MMP levels also negatively impact the freshly deposited molecules of the extracellular matrix that are critical for wound healing.

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Finally, the issue of the lower pH associated with purity of hypochlorous acid, the mildly acidic pH range of 3.5 to 6.0 is also the pH that is associated with healing wounds^{40,41}, as opposed to wounds that are chronic and not healing. The lower pH if achieved through external means, for example, by the introduction of a pH controlled, pure hypochlorous acid solution, may be helpful to wound healing. The reasons for this has been discussed in literature⁴² and a simple reason may be that the lower pH deactivates enzymes such as matrix metalloproteinases (MMP) whose presence is deleterious to wound healing due to their ability to degrade cytokines and important growth factors. High MMP levels also negatively impact the freshly deposited molecules of the extracellular matrix that are critical for wound healing.

CONCLUSION

A review of the literature supports the idea that in the use of an antimicrobial preservative - based cleansing solution for wound cleansing, debridement or irrigation, it is clinically beneficial to use products that do not contain the hypochlorite species. This is achieved by tight pH control of the cleansing solution at a pH range from approximately 3.5 to 6.0. Hypochlorous acid, is able to remove germs as well as necrotic debris from wounds via mechanical means, and the inherent biologically compatible chemistry of hypochlorous acid may have a role to play in explaining the documented clinical benefits associated with hypochlorous acid solution containing products as well as reducing complications associated with antibiotic resistance in wound practice.

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Leadership Accountability to Data

Critical to Wound Outcome Success

Wound Care Accountability Model



Three years after the implementation of a clinical program accountability model that was designed to improve accountability to outcomes for clients with wounds, we identified wound outcomes among teams were not consistent.

Objective

Develop a quality improvement strategy for a provincial home and community wound care program through evaluation of a clinical program accountability model.

Methods

The Plan Do Check Act framework was used to evaluate the effectiveness of the accountability model on wound clinical outcomes. We measured and compared more than 20,000 wounds over one year in defined geographic locations across Ontario. Inclusion criteria was limited to locations with >100 new wounds per month. The key performance indicators analyzed includes % of wounds measured, early confirmation of wound etiology, and % of wounds with measurement and healing goal not reaching 30% healing by week 5.

Results

Adherence and outcomes are strongly dependent on wound care **leadership, data integrity, and robust change management strategies**. Areas with superior data integrity and adherence to process consistently exhibit strong clinical leadership commitment to providing staff education on wound care standards and documentation upon hire and ongoing, as well as prioritizing wound dashboard data reviews and consistent follow-up with clinicians.

Clinical Implications

An updated accountability model was developed that emphasizes leadership, change management, and data integrity. Senior leaders will ensure all defined geographies have access to wound consultants; and remote populations will access wound experts though virtual platforms. All locations will have designated wound resource nurses to provide wound care education, mentorship, and consultation. Finally **leaders at all levels will ensure accountability** to the wound outcome data.



Negative Pressure Wound Therapy Option for Managing Complex Surgical Wounds of Critically Ill Patients Who Cannot Undergo Surgical Debridement

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Aim

- Numerous complex conditions may preclude patients with a surgical site infection (SSI) from undergoing anesthesia for surgical debridement.¹
- Negative pressure wound therapy (NPWT) with instillation of a topical solution and dwell time (NPWTi-d*),²⁻⁴ which helps efficiently cleanse and remove wound debris, may benefit patients who cannot undergo surgical debridement.
- This series describes outcomes of NPWTi-d use in large, complex post-surgical wounds of three critically ill patients for whom surgical debridement was not an option.

Procedure

- Intravenous antibiotics were administered as appropriate, and wounds were debrided at the bedside when possible.
- NPWTi-d was applied with a reticulated open-cell foam dressing with through holes (ROCF-CC)⁴ and set to instill polyhexamethylene biguanide solution or saline with a 3- to 5-minute dwell time, followed by 2 hours of NPWT.
- Negative pressure was set at -125 mmHg, and dressings were changed every 3 days.
- The goal of therapy for all wounds was to quickly remove wound debris and infectious materials.

Findings & Implications

- All wounds demonstrated a positive healing trajectory over time as evidenced by improved wound bed tissue quality at dressing changes.
- Slough and wound debris were markedly reduced in all wounds.
- NPWTi-d was an important tool in helping to prepare the wound bed environment, reduce the potential for wound regression, and progress the wound toward the next step in wound closure.
- Therapy goals were achieved quickly, benefitting the patients' health.

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Case 1. A 48-year-old female presented with chondrosarcoma to the left pelvic region, requiring an internal hemipelvectomy. Post-operative recovery was complicated with infection of the defect, and the patient developed sepsis. Antibiotics were administered and a decision was made to delay surgical debridement until the patient's condition was stable. The wound was debrided at bedside and NPWTi-d was applied with instillation of a topical solution of ½ polyhexamethylene biguanide and ½ saline for the first 3 days, followed by normal saline alone. After 14 days of NPWTi-d, the patient was stable enough to undergo surgical debridement. The wound was closed with a skin graft 6 weeks after therapy was started.



Fig 1A. At presentation, the surgical wound was covered with devitalized tissue post hemipelvectomy.



Fig 1B. After 2 days of NPWTi-d, slough was decreased with beefy red granulation tissue present.



Fig 1C. After 10 days of NPWTi-d, wound bed was granulated, and NPWTi-d was discontinued.



Fig 1D. At 6 weeks, the wound was successfully closed with a skin graft.

Case 2. A 29-year-old male sustained significant chest trauma from a fall. During resuscitation, the left antecubital fossa intravenous catheter had gone interstitial during a blood transfusion. Three weeks later, the patient presented with a full-thickness soft tissue defect covered with nonviable tissue. The patient was scheduled for an operative debridement but suffered a pulmonary embolism, thus delaying any surgical debridement as the patient required high doses of anticoagulation therapy. The wound was conservatively debrided, and NPWTi-d was applied with instillation of normal saline. NPWTi-d was discontinued after 10 days. The wound was free of slough, and wound care was switched to advanced dressings. The wound healed secondarily without skin grafting.



Fig 2A. Soft tissue defect on left arm at presentation.



Fig 2B. Wound on Day 0 after cleansing and conservative debridement.



Fig 2C. After 2 days of NPWTi-d, slough was softening.



Fig 2D. After 6 days of NPWTi-d with ROCF-CC dressings, slough was reduced, and NPWTi-d was discontinued. Wound healed secondarily.

Case 3. A 62-year-old female with history of morbid obesity and recent weight loss presented to the emergency department with a deep indurated wound. Patient comorbidities included non-insulin-dependent diabetes mellitus, hypertension, atrial fibrillation, dyslipidemia, and hypothyroidism. The patient had a panniculectomy shortly after admission; however, it dehiscence due to continued nonviable fat tissue. A decision was made to avoid further surgical debridement in this compromised patient. Antibiotics were administered, and NPWTi-d was initiated with instillation of normal saline. After 7 days, targeted sharp debridement was performed to remove necrotic subcutaneous tissue, and therapy was switched to conventional NPWT for approximately one month. Patient was then transferred to a rehabilitation facility, and wound was closed with packing.



Fig 3A. Dehiscence abdominal wound (40 cm x 12 cm x 10 cm) at presentation post panniculectomy.



Fig 3B. Wound after 3 days of NPWTi-d with ROCF-CC. Fascia was intact.



Fig 3C. After 1 week of NPWTi-d and ROCF-CC, slough was reduced. Sharp debridement was performed, and therapy was switched to NPWT.



Fig 3D. After NPWTi-d and 1 month of NPWT, wound was closed with packing.



Lower Leg Wounds and the Role of Edema: Managing Edema with the geko™ Wound Therapy Device

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Aim

Lower limb edema is caused by fluid accumulation in the interstitium. Edema can be unilateral, bilateral, acute or chronic. Patients experience limb heaviness, fatigue, throbbing, cramping, burning and itchiness as well as wound formation and/or delays in wound healing¹. Edema can be the result of calf muscle pump dysfunction. Meulendijks asserts that calf muscle pump dysfunction has been shown to be strong predictor of venous leg ulcers and healing².



Procedure/Method

A literature search was conducted using key words: edema, venous leg ulcers, calf muscle pump function, and neuromuscular electrical stimulation. Searches included the Cochrane Library, Medscape, CINAHL, PubMed, Medline, Embase, Scopus and peer reviewed journals

Findings/Results

The literature supports edema management through a variety of modalities. It is reported that using the geko™ device demonstrated improved edema reduction compared to standard of care. Changes in urine output, limb measurement or readiness for surgery were metrics used to determine outcomes.

- An RCT conducted at London Health Sciences Centre with 221 renal transplant patients, post operative day 1-6, demonstrated minimal edema to the calf by 2.5 cm with the geko™ device vs 3.6 cm in standard of care ($p=0.001$). Weight gain was 4.06 kg vs 5.18 kg ($p=0.003$) and urinary output was 15.9 litres vs 12.6 litres ($p=0.003$) using the geko™ device compared to standard of care (intermittent pneumatic compression and TED stockings)³.
- Baker *et al.* studied 20 patients using the geko™ device preoperatively for ankle fracture patients requiring surgery. The results are reported as 60% of patients were ready for surgery in 2 days, compared to 27% in control arm, a 122% improvement. Standard treatment = 3.66 days readiness for surgery vs the geko™ device + plaster cast = 1.66 days readiness for surgery ($P=0.001$)⁴
- Ingves and Power reported 2 cases of multifactorial and refractory leg edema successfully reduced by 7 and 21% with the geko™ device over 4 to 16 weeks.⁵

Implications/Applications

Edema impacts time to wound healing, patient safety, mobilization and quality of life. Clinical studies have demonstrated that the use of geko™ wound therapy device reduces edema in a range of patient groups. The geko™ wound therapy device activates the lower leg muscle pumps once per second to augment venous and arterial blood flow, reduce venous congestion, and decrease leg edema. Intervention with the geko™ wound therapy device may reduce pain and congestion in the limb thereby affording improved adherence with compression therapy. The geko™ therapy device is a simple, safe, user-friendly device that can be used as a cost-effective and efficacious adjunctive therapy or on its own to treat and manage leg edema. Innovative technology such as the geko™ wound therapy device offers the solution to the challenges of edema management and self care. As clinicians consider the provision of care, virtual Visits have become an option. Use of the geko™ wound therapy device can be taught and self managed virtually by patients and care providers, offering an alternative for clinicians to treat lower leg edema.



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Topical Management of Enterocutaneous and Enteroatmospheric Fistulas: A Systematic Review

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Background

- Enterocutaneous (ECF) and enteroatmospheric (EAF) fistulas are associated with considerable morbidity and patient care challenges, including optimal topical management.^{1,2}



Mature fistula



Non- matured fistula

Images courtesy of Tarik Alam

Purpose

- A systematic literature review was conducted to identify topical management interventions used in ECF/EAF care and to explore the role of these interventions in fistula closure and long-term fistula management.

Methods

- A search of PubMed, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and Scopus was conducted to identify English-language articles published from January 2004 to January 2019 pertaining to the topical management of adult and mixed adult/pediatric patients with ECF and EAF.
- Single person case studies, exclusively pediatric, non-English, and surgical treatment-based publications were excluded.
- Outcomes of interest included patient demographics, closure rates, fistula classification, type of topical treatment, adverse events, follow-up, long-term management, peri fistula skin protection, effluent management, dressing change frequency, and quality of life.
- Descriptive statistics were presented; no statistical analysis was performed.

Data Extraction

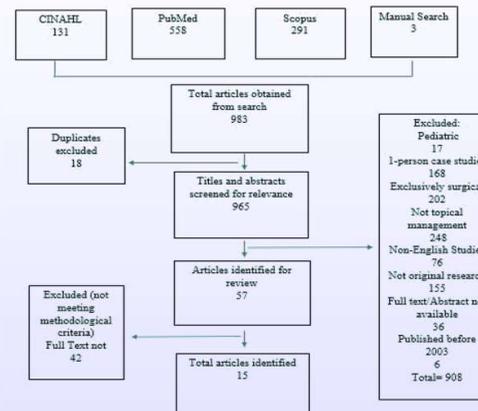


Fig. 1 Flow diagram of literature search and article selection.

Results

- Of the 983 articles identified, 57 underwent critical appraisal using the Joanna Briggs Institute checklist for case series.
- Forty-two did not meet the inclusion criteria, leaving 15, level IV, case-based publications (N = 410 patients).
- No randomized controlled trials were found.
- All studies included some form of negative pressure wound therapy (NPWT). JBI results found that each study was at high risk of bias in more than 2 domains.
- Interventions were categorized as intubation, occlusion, or isolation of the fistula.
- Of the 559 fistulas treated, spontaneous closure was reported in 164 cases, with rates ranging from 0% to 100%.
- Adverse events to treatment included pain (33 patients), new fistula formation (12), peri fistula dermatitis (2) and fistula recurrence (1). Sepsis was the leading cause of mortality (29), with reported rates ranging from 0% to 44%.

Conclusion

- Due to the high risk of bias and low quality of evidence, the exact contribution of any one intervention cannot be established. Results also suggest a high risk of publication bias.
- Although topical management might play a role in fistula closure, it is only as part of a comprehensive plan of care.



Image courtesy of Tarik Alam

Peri fistula dermatitis



Image courtesy of WOCCN

Isolation with NPWT

Implications

- Future research should focus on developing and using standardized reporting tools, classifications, and outcomes and include patient-centered outcomes such as acceptance, tolerability, pain, and quality of life relating to any one intervention.
- At this time, the evidence-base for management recommendations is limited, suggesting that interventions should mainly be based on practical considerations such as resources and clinician skill.

Keywords

enterocutaneous fistula, enteroatmospheric fistula, negative pressure wound therapy, NPWT, vacuum-assisted closure, VAC, pouch or pouching, troughing, bridging, collection device, dressing, and wound care

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Canadian East and West Coast experiences with Continuous Diffusion of Oxygen (CDO): Recalcitrant, painful and limb threatening chronic wounds

A case series

• Rosemary Hill, BSN CWOCN WOCC(C) • Michele Langille BScN, RN NSWOC, WOCC(C) • Kathryn Mutch BN, RN, NSWOC, WOCC(C)

INTRODUCTION

To investigate the influence of continuous diffusion of oxygen (CDO) on pain reduction and wound healing in a case series.

METHODS

Cases were selected as wounds that had previously deteriorated on traditional and advance modalities. Cases included: 1) A 70 year old male with painful venous leg ulcer. Previous treatment included compression therapy, pentoxifylline and doxycycline. He had increased pain and poor quality of life. CDO therapy was applied for 11 weeks. 2) A 36 year old female with a five year history of a large, painful, right lower leg ulcer and addiction history. The wound measured 58.9 cm² with eschar and a non-granulating wound bed. CDO was initiated over a three week period. A third case involved a 49 year old gentleman with type II diabetes and a limb threatening wound which had failed to respond to negative pressure wound therapy following surgical debridement. CDO was applied over an 8 week period.

The oxygen unit uses fuel cell technology to continuously generate pure (>99.9%), humidified oxygen and delivers it directly to the wound bed environment within a dressing system via tub-ing.¹

RESULTS/DISCUSSION

Specific to case 1, CDO was effective in alleviating pain, with subsequent wound closure in 12 weeks. Case 2, at 3 weeks, there was a decrease in narcotic use, epithelialized wound edges and healthy granulation tissue. A successful skin graft followed. The third case resulted in limb salvage and wound closure over a 12 week period.

CONCLUSION

Wound healing is dependent on many factors including tissue perfusion and oxygenation. Wounds may have inadequate oxygenation for many reasons - poor vascularity, pressure, edema, infection, pain etc. Providing pure humidified oxygen directly to the wound, may improve wound healing and relieve pain. Our cases include recalcitrant, limb threatening, and complex wounds, which healed with application of CDO.

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CASE PRESENTATIONS

Case 1 – A 69 year old man with a very painful venous leg ulcer, failed to respond to tradition topically antimicrobial, moisture balance and compression



March 11



April 9, CDO initiated Pain 10/10



June 26 pain 0/10



July 11, Complete closure and no pain.

Case 2 – A 36 year old with a 5 year history of lower leg ulcers, in a pain crisis with addiction. History of addictions, infections - cellulitis, sepsis



- March 18
- Wound 9.5 x 6.2cm
- Pain crisis.
- CDO initiated



March 25
Pain 8/10



April 5
Pain
4/10



April 16
Improved mood, activity,
Minor pain with dressing changes



May 9
Post skin graft

Case 3 - A 49 year old gentleman with type II Diabetes and a limb threatening wound which failed to respond to negative pressure wound therapy:



NPWT Nov 28th – Dec 13th



Jan 29th



Feb 8th



February 18th



Early Intervention with the geko™ device for Venous Leg Ulcers Predicted to Not Heal Within 24 Weeks

Authors: Rabley-Koch C. A., Duong R., Cadavez R., Attard J., Entredicho A., Oshalla H., Orr A., Ramage D., Burrows C.



Aim

Quality Improvement Initiative aimed at enhancing policies and procedures so that patients can receive the most timely and effective practice to ensure or achieve better outcomes.

Procedure/Method

Earlier use of the geko™ device was employed on patients whose venous leg ulcers (VLU) that had an elevated risk of failure to close within 24 weeks. Patients were admitted to community clinic settings at 2 Ontario nursing agencies. Eleven patients were assessed twice over two weeks using a Validated Leg Ulcer Risk Assessment tool (VLURA). Moderate to high risk scores had geko™ devices added to their standard of care for a maximum of 12 weeks. Low scores were reassessed in two weeks; those increasing to moderate were started on the geko™ device.



Validated Leg Ulcer Risk Assessment Tool

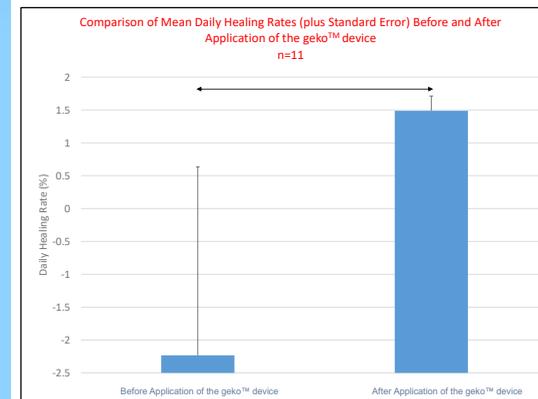
(adapted)

- Score is 11 or higher: high risk of not healing at 24
- Score is between 6-10: moderate risk of not healing at 24 weeks
- Score is 5 or less: low risk of not healing within 24 wks

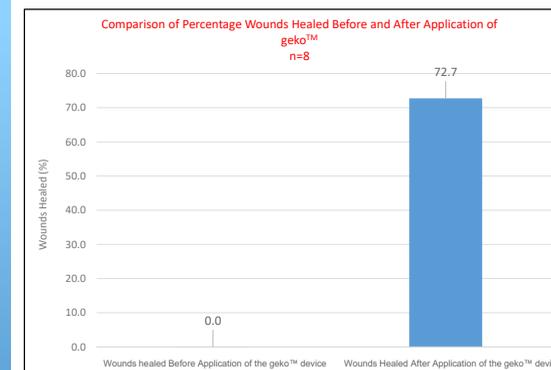
Findings/Results

- Frequent delays in the geko™ device initiation were related to a routine LHIN policy need to access vascular studies
- An average of 48.9 days elapsed between admission to device application
- Ten out of eleven patients experienced increased risk scores within the two weeks between initial and follow-up visit
- Preliminary results indicate a total of 12 wounds in 11 patients (80%) healed
- 2 wounds (13%) remained open with an average decrease in size of 88%
- One wound (6.7%) reopened
- Without use of the geko™ device the average time for VLU closure in MH LHIN is 15 weeks
- Healing time with the geko™ device is an average of 12 weeks

Healing Rates Before and After geko™ Application



Percentage Wounds Healed Before and After geko™ application



Implications/Applications

- Delays in access to timely care negatively impact wound healing
- Implementing a VLURA tool on admission identifies wounds with the greatest risk of failure to close
- Early intervention using the geko™ device improves healing outcomes and decreases nursing visits
- Delay in the geko™ device initiation was related to clinician access to vascular studies/ABPI
- More work will need to be conducted to explore this further, particularly with the geko™ device application immediately upon referral

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The effectiveness of a specialized seating program and its impact on pressure injury incidence in long term care.

Daly, O., Casey, J., Martin, S., Tierney, M., McVey, O. 2013. The effectiveness of specialist seating provision for nursing home residents. Ulster University: Northern Ireland.

Aim: While guidance is available on most aspects of pressure injury prevention and management, there has been little information on addressing these issues in seated patients. The role of specialized seating can be overlooked. This research investigates the effectiveness of a specialized seating program and its impact on pressure injury incidence in long term care.

Methods: A mixed methods design was ethically approved and employed. Participants were recruited from three long term care settings before random allocation. The control group continued to use their existing seating while the intervention group was provided with seating tailored to their individual needs following a complex assessment. Participants were observed for pressure care, posture, function, saturated oxygen levels and comfort.

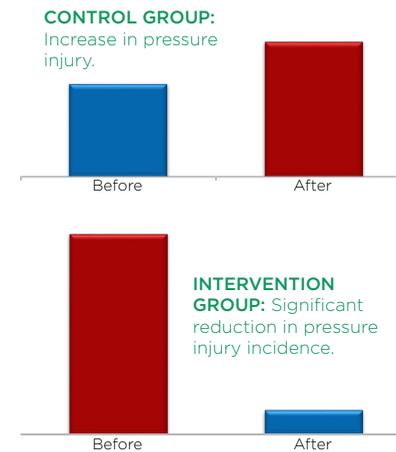
Results: The intervention participants who had red skin areas at the beginning of the trial no longer presented with these at the end of the 12 week trial period. None of the intervention participants developed skin redness.

The findings revealed;

- A significant reduction in pressure injury incidence.
- A reduction in the use of high cost cushions.
- 49% reduction in postural correction.
- 95% of patients had an increase in blood oxygen levels.
- 10% reduction in pain/discomfort levels.

Applications: Prescribed seating may contribute to a reduction in pressure injury incidence. It highlights that each patient is different, requiring individualized evaluation of seating needs before making recommendations for an appropriate seating system. This research provides evidence based pressure management through therapeutic seating.

The findings from the research are replicated by clinicians worldwide who continue to improve patient care through utilizing therapeutic seating to reduce pressure injuries, encourage early mobilization and reduce caregiver manual handling. Having conducted this ethically approved, clinical research in real life care settings, it makes it manageable for the outcomes to be replicated to improve clinical practice.





Exploring Individuals' Perspectives on Foot Care and Footwear While Living and Working with Diabetes Mellitus: A Qualitative Descriptive Approach



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Introduction

- 11 million Canadians were living with diabetes mellitus (DM) in 2016
- Diabetic foot ulceration (DFU) is a major complication; 26 million people affected worldwide
- Average cost of DFU treatment is estimated to be \$13,179 USD
- 85% of lower extremity amputations are preceded by a DFU

Background

- Individuals with DM are at considerable risk of peripheral neuropathy, decreased circulation and altered biomechanics
- Minor trauma, inappropriate footwear and improper nail care can place these individuals at significant risk for lower extremity amputation
- DFUs cause a substantial financial burden on patients and the health care system



Purpose

To explore and analyze individuals' perspectives and decision-making on the topics of foot care and footwear while living & working with DM.

Methods

Design: Qualitative descriptive approach - semi-structured 1:1 interviews with 14 questions; audio-recorded and transcribed verbatim. Written consent obtained from all participants.

Population/Setting: Eight (8) participants were purposively recruited, 18 years of age or older with Type 1 / 2 DM, with no foot ulcerations, and who work or volunteer part- or full-time.

Data Analysis: Thematic analysis and hand coding used to identify and analyze the data; 5 key themes emerged from the data.

Ethical Considerations: The study proposal was reviewed and approved by the UWO REB.



Findings

The thematic analysis identified 5 emerging themes amongst participants, including:

- 1) Inadequate foot care practices;
- 2) Limited knowledge about proper footwear;
- 3) Distancing self from the disease;
- 4) Frequent use of "Dr. Google";
- 5) Reliance on social supports.



Discussion

Findings are unique to persons' without the experience of having worn prescription footwear or orthotics, and who have no DFUs. Upon review of the literature, the following was observed:

- Social support is essential for self care and to support adherence to foot care practices.
- Online information seeking (OIS) is common however, more research is needed regarding OIS and foot care practices.
- Individuals aware of foot care practices, but frequently ignore professionals' advice.

Conclusion

A greater emphasis must be placed on preventative foot care practices and proper footwear to avoid DM related foot complications. Regular foot screening and education for patients and health care providers require improvement to address the barriers towards achieving healthy feet in individuals with DM.

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