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Table of Contents

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A Feasibility and Safety Study of a Novel Human Decellularized Dermal Matrix Used in the Treatment of Chronic Diabetic Foot Ulcers

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Introduction

- The number of diabetics is projected to reach 439 million by 2030 or approximately 10% of the world's adult population.[1]
- Up to 25% of diabetics are expected to have chronic foot ulcers, with 85% of these leading to lower extremity amputations.[1,2]
- This equates to a limb being amputated somewhere in the world every 20 seconds due to diabetes.[3,4]
- The most common treatment for chronic diabetic foot ulcers (DFU's) is weekly debridement.
- The success rate for complete wound closure with standard of care is variable and takes on average 8 - 9.5 weeks.[5,6]
- Advanced wound care products are available but they are costly, many require repeated applications, and they have low efficacy (see Figure 1).

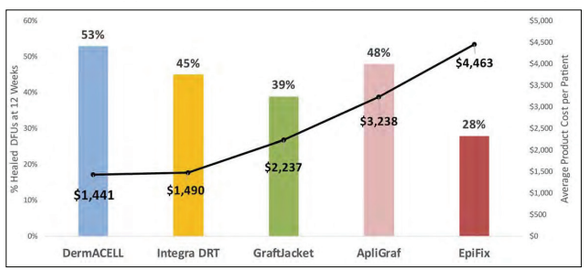


Figure 1. A comparison of recently published 12 week healing rates along with the average cost of product per patient foradvanced treatments. Expense per patient based on our cost to purchase. From Cazzell et al., Wound Repair Regen. 25(3):483-497 (2017)

Objectives

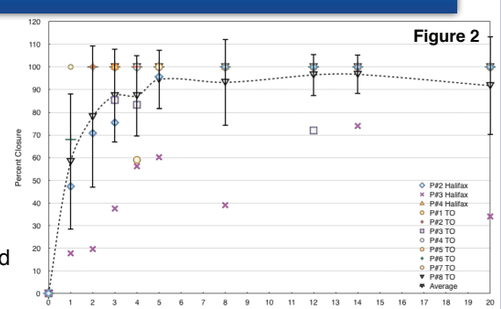
- In order to address the unmet need for a safe, consistent, and effective treatment for DFU's we have developed a sterile, highly-purified, decellularized regeneration scaffold derived from donated human skin.
- The purpose of this study was to conduct a clinical trail to perform a limited pilot study to determine the safety and effectiveness of our scaffold in the treatment of non-healing DFU's.

Methods

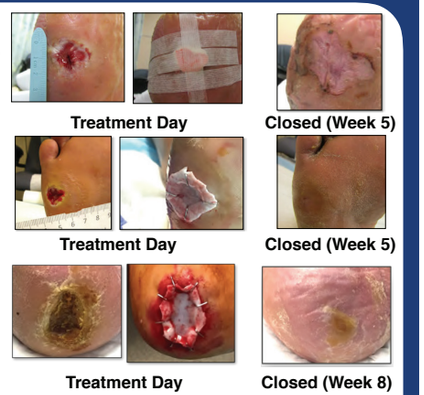
- 11 patients were treated with 8 located at St. Michael's Hospital in Toronto and 3 located at the QEII hospital in Halifax.
- Following standard of care procedures, each wound was debrided to provide a bleeding wound bed. A piece of decellularized human dermis was applied by sizing to approximately 2-3 mm past the margins of the ulcer with the dermal side in contact with the wound bed.
- Grafts were secured with staples for the first 6 patients, thereafter grafts were applied with only a bolstered dressing for the first week.
- A non-adherent dressing (e.g. Mepilex) was used to cover the graft, followed by dry gauze or retentive dressing.
- All patients received off-loading using a device appropriate to ulcer location.
- Follow-ups were at weeks 1,2,3,4,12, and 20 and the Leg Ulcer Management Tool (LUMT) was administered. Digital photography was utilized to capture the appearance and size of the ulcer at each visit.

Results

- Patients treated were predominantly male (10 male, 1 female), with a range of ages (32-77 years), and evenly split between Type I and Type II diabetics.
- Ulcer location, size, and time present before treatment covered a range of values as did co-morbidities and general health.



- Average wound size was 142 mm^2 (Range = 25-563 mm^2). Ulcer presence prior to treatment averaged 16 weeks (range = 2 - 96 weeks)
- A total of 9 patients (82%) had achieved 100% closure between 2-8 weeks (Figure 2).
- Mean and median times to closure were 3.3 and 2.5 weeks, respectively and time to 50% closure was less than 1 week.
- One patient was non-compliant with offloading and was lost to follow-up, another completed 20 weeks without achieving 100% closure. This patient was the most severely ill of our subjects with many significant co-morbidities (coronary artery disease, myocardial infarction, moderate kidney disease, disc degeneration disease)



- All patients received only 1 application. No cases of infection or severe adverse reactions were reported. No cases of recurrence have been reported 1 year post treatment.

Conclusions

- Our decellularized scaffold has shown promising results in DFU healing occurring on average in 3.3 weeks with only one application.
- Although very encouraging, no statistically based conclusions can be drawn due to the small size of the study. Further studies are warranted.

Clinical Significance

- Our decellularized scaffold has promoted increased DFU healing.
- Clinicians noted advantages such as ease of use and one time application.

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(4) Armstrong, et al, Diabetes Care 2013,
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Acknowledgements

We wish to thank Karl Conlan for preparing all of the decellularized tissue used in the clinical study.

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Individual's perspectives on foot care and footwear while living and working with diabetes mellitus: A qualitative descriptive approach.

Janet L Kuhnke BScN, MS, NSWOC, DrPsychology, Audrey Walsh PhD, & Ashley Devoe BScN Student
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Background

Daily foot care and professionally fitted footwear is essential to prevent foot complications (IWGDF, 2012; WHO, 2005). Persons with diabetes should take an active and empowered role in their foot care and footwear (Diabetes Canada, 2013). Only two in five Canadians with DM check their feet daily (Webster et al., 2011).

Foot care education may be effective in the short-term, yet, there is insufficient robust research evidence to support that education alone is effective in reduction of ulcerations and amputation (Dorresteijn et al., 2013).

Cues from family, friends, or health care professionals support some individuals to conduct a daily foot examination, yet when clients have to rely on family less foot checks are done (Bell et al., 2005; Chin et al., 2013).

Persons who had a family member with an amputation and who conducted foot self-care, were less fearful than those who conducted less foot care behaviours (Scollan-Kollopoulos et al., 2010).

Statement of Purpose

Explore individual's perspectives on foot care and footwear choices while living and working with diabetes; using qualitative descriptive approach (Sandelowski, 2000).

Data Collection

Fourteen participants with diabetes and no foot ulcers were interviewed, data were recorded, typed verbatim and data was themed using Nvivo (Braun & Clarke, 2006).

CBU ethics/consent in place.

Researchers kept reflexivity notes, field notes, and journals.

Data saturation and data verified by 2 persons with diabetes.

Who did we meet?

- 11 persons: 21 - 65 years
- 3 persons: 66, 77 & 85 years
- Lived with DM for 13 months to 43 years.

Participants Stories

When did you first learn about diabetic foot care?

Participants described learning about foot care when they were diagnosed, and for some years after their diagnosis. They learned about foot care from various people including: nurses, staff at a diabetes clinic, while studying at college, after having a surgical foot complication, a family physician's secretary, and from family. Some learned about foot care from listening to stories about "others" in the community undergoing an amputation or living with a foot ulcerations and some where not sure.

Length of Time with Dx (years)	When did you first learn about foot care?
13 months	Nurses neighbours – 30 days ago
2	DM Clinic
3	When diagnosed
3	Today - at this study
5	DM Clinic
7	College education
11	DM Clinic
15	2.5 years ago after foot complication
15	GP's secretary
18	DM Clinic
29	DM Clinic
34	Dad lived with DM and amputations
37	Not sure
43	Not sure

From whom did you first learn about foot care?

2 - not sure
1 - physician secretaries
5 - diabetic clinic
1 - "Listening to stories of others in the community"
1 - Nurse neighbours
1 - "from my Dad - DM"
1 - formal college education
1 - after surgery
1 - at this study

When did you first learn about footwear?

Participants is this study did not consistently learn about having professionally fitted footwear. Due to employment types, participants wore a variety of running shoes, work boots, dress shoes, and sandals. Participants searched the internet, listened to stories from friends and family to gain knowledge of comfortable footwear. Few had financial coverage / benefits for fitted shoe liners or prescribed footwear.

Length of Time with Dx (years)	When did you first learn about footwear?	From whom did you first learn about footwear?
13 months	Community Nurses	Community Nurses
2		DM Clinic
3	When diagnosed	Not sure
3	At this study	At this study
5		DM Clinic
7	College education	College education
11		DM Clinic
15	2.5 years > foot complication	2.5 years > foot complication
15	GP's secretary	Surgeon and Foot Specialist
18		DM Clinic
29		DM Clinic
34	Dad - DM amputations	Dad / self-reading
37	Not sure	Stories / Reading / DM Clinic
43	Not sure	Self reading

Themes

1. **Participants describe an 'external locus of control':**
   - Describe their foot care and footwear as "out there" or as a separate entity from self.
   - Describe the responsibility of their foot care and footwear as belonging to someone else, and not necessarily self.
2. **Fear and worry about complications:**
   - Fear of a foot complication or amputation, or worry about having a foot ulcer, is major part of their narratives.
   - Fear is real and worsened as most participants were aware of a community or family member that was undergoing active foot ulcer or amputation. Yet, amputation is cognitively normalized; accepted as part of their future narratives.
3. **Participants did not describe consistent or regular access to diabetes foot care:**
   - They use wide-ranging educative sources.
   - The internet is searched at random and no specific sites are accessed.
4. **Participants do not fully engage or link their blood glucose results to increased risk for a diabetic foot ulcer:**
   - High blood glucose levels affect ability of nerves to function – diabetic neuropathy; and affects the blood vessels (Vanik et al., 2013). They participate in reactive care activities, and few are actively engaged in prevention.

Discussion

Thank you to the participants for sharing their stories.

Internal versus external control refers to "the degree to which persons expect that a reinforcement or an outcome of their behavior is contingent on their own behaviour or personal characteristics, **versus**, the degree to which persons expect that reinforcement of outcome is a function of chance, luck or fate, is under the control of powerful others, or is simply unpredictable" (Rotter, 1990, p. 489).

Participants described an external locus of control – as if something outside of their control was managing their risk of foot complications (Prsybiski, 2010).

Fear of ulcers and amputation was normalized by the participants. "My father had amputations, so I will probably have them as well".

Self-efficacy, or the personal belief that one can control risk in their lives was lower and needs further research (Mudge & Price, 2004).

Participants described a disconnect between their blood glucose levels and the increased risk of foot complications (Hummer et al., 2011; O'Hea et al., 2009).

Limitations

- This was a small community based study with 14 participants.
- Included participants with no foot ulcers.
- Participants were from small villages and rural areas of the Eastern Health Zone in Nova Scotia.
- We started with small focus groups and due to the intense warm weather changed our recruiting method after participants were worried about their health and did not want to come to a community building for the group.
- Privacy was of concern for participants as they were from small communities.
- Persons with foot ulcers wanted to be part of the study.
- We have applied for funding to expand this study.

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nova scotia health authority | Diabetes Care Program of Nova Scotia

Putting Feet First: Focussing on Foot Care for People with Diabetes

P TALBOT, J PAYNE, M DUNBAR

Diabetes Care Program of Nova Scotia (DCPNS), Halifax, NS, Canada

Background

- Foot problems are a devastating complication of diabetes adding to the burden for patients and their caregivers as well as the healthcare system
- DCPNS continues to lead intensive efforts to profile the diabetic foot and foot risk ratings while promoting prevention messages to the broader diabetes population

1992	Guidelines highlighted the need for routine foot care assessments for the diabetes population
1997	Released ***Surveying and Preventing Diabetes Complications in Nova Scotia***, which included a chapter on Foot Problems
2004	Hosted a ***Diabetes Foot Care Roundtable*** to identify issues, needs, and strategies regarding prevention, screening, and management of diabetic foot complications
2007	Released ***The Diabetic Foot in Nova Scotia: Challenges and Opportunities***
2010	Updated standardised provider and patient resources for use across multiple care settings
2017	Released ***Diabetes and Lower Extremity Amputations***

Purpose

- We examined the burden of the most serious foot problem – lower extremity amputation (LEAs) – between 1996/97 and 2012/13 among Nova Scotian adults (≥ 20 years) with type 1 and type 2 diabetes

Methods

- Individual-level data linkages:

Hospital records
Canadian Institute for Health Information Discharge Abstract Database, 1996/97-2012/13 (LEAs)

Provincial insurance records
Nova Scotia Insured Persons Database, 1996/97-2013/14
(date of birth, date of death, sex)

Diabetes Centre visit records
DCPNS Registry, 1996/97-2013/14
(diabetes type and duration)

Diabetes surveillance records
Canadian Chronic Disease Surveillance System, 1996/97-2012/13 (diabetes type)

- Cohort defined as all diabetes cases with LEAs in the period
  - Inference testing inappropriate (no p-values)

- Key Measures:

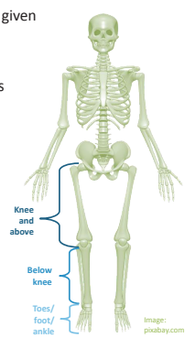
LEA admission
Any acute hospital admission with ≥ 1 procedure code denoting an amputation of the lower limb (pelvis to toe)

LEA admission rate
Number of individuals with ≥ 1 LEA admission in a given year divided by the population for that year

LEA admission rate ratio
Rate of LEA admissions among those with diabetes divided by the rate among those without diabetes

Survival Post-LEA
Number of years from the first LEA admission in the period to death or end of the period

Level of LEA procedure
LEA procedure performed closest to the pelvis for a given admission:
  - Toes/foot/ankle
  - Below knee
  - Knee and above



Results

The LEA rate reflects the number of people who had an LEA divided by the total population

Between 1996/97 and 2012/13, the LEA rate **decreased more** among people with **diabetes**

55% among people with Diabetes vs **50%** among people without Diabetes

During the same period, the prevalence of diabetes **doubled**

from **5** out of **100** to **11** out of **100**

Which means the same number of LEAs were performed annually among people with diabetes

281 LEAs per year in Nova Scotia

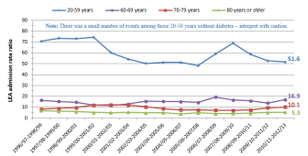
Diabetes **194** vs No diabetes **87**

Annual number was **stable** over time for people with **diabetes** while it **decreased** over time for people **without diabetes** – by 2012/13, **78%** of LEAs were performed on people with **diabetes**

People with **diabetes** who had an LEA were in hospital **1-4 days longer** than people without diabetes

The LEA rate ratio reflects the excess burden of LEAs associated with diabetes

For **working age adults (20-59 years)** with **diabetes**, the LEA rate was **52x higher** than for people **without diabetes**



Survival reflects the time elapsed from the first LEA to death

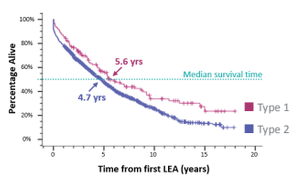
At first LEA, people with **type 1** diabetes were **13 years younger** than people with **type 2**

Type 1 Type 1

... 50 52 54 56 58 60 62 64 66 68 70 ... age in years

People with **type 1** diabetes lived **1 year longer** after their first LEA than those with **type 2** diabetes, regardless of the level of LEA

No matter the diabetes type, prognosis post-LEA was poor – **half** of the people **died within 5-6 years** of their first LEA



Conclusions

- Despite a doubling of diabetes prevalence from 1996/97 to 2012/13 among NS adults, the number of LEA admissions for people with diabetes remained stable
  - As a result, the LEA admission rate among those with diabetes decreased dramatically over time – by 55%
- Although the rate of LEA admissions declined, LEAs remain a significant concern
  - People with diabetes accounted for 3 out of 4 LEA admissions
    - ~ Those of working age were disproportionately affected
  - Prognosis was poor once an LEA occurred
    - ~ Only about half survived 5-6 years post-LEA
- LEAs are associated with poor survival rates, reinforcing the need for continued focus on prevention strategies

Recommendations

- Delaying the onset of the disease in at-risk individuals as well as slowing the progression in those with established disease will result in significant benefit to individuals, families, and the healthcare system
- Recommendations targeting the following priority areas are key:
  - Health promotion and disease prevention messages and policies
  - Population-based initiatives focussed on wellness and risk factor reduction to delay or prevent diabetes and progression to complications
  - Education of healthcare providers about the value of routine foot assessments, standard assessment tools, etc.
  - Education of persons with diabetes about preventive practices and signs and symptoms of pending foot problems
  - Improved access to foot care and footwear (e.g., improved insurance and publicly-funded coverage)
  - Early identification of a high-risk foot
  - Multidisciplinary treatment of foot ulcers

Diabetes Care Program of Nova Scotia (DCPNS)
Website: diabetescare.nshealth.ca

The DCPNS, nested within the Nova Scotia Health Authority, Primary Health Care, has a mission *to improve, through leadership and partnerships, the health of Nova Scotians living with, affected by, or at risk of developing diabetes,* remains the same.

Presented at Wounds Canada Spring Conference, Halifax, Nova Scotia, April 12-13, 2019

Dartmouth General Hospital (DGH) Inpatient Pressure Injury Consult Team

N.Cheng (MD), G.Davis (MD), S.Thomas (RN), P.Traves (PDt), Cecilia Murphy (RN)

Introduction

The **DGH Inpatient Pressure Injury Consult Team** was a multidisciplinary initiative started in Jan of 2015 to improve the identification, prevention, and treatment of pressure injuries.

Background

- Pressure ulcers/injuries are a cause of significant morbidity and mortality.
- Accreditation Canada has identified the incidence of hospital-acquired pressure injuries as a key indicator of quality of care.
- 2014 audits at Dartmouth General Hospital (DGH) demonstrated
  - •A high prevalence of pressure ulcers (18%) compared to surrounding hospitals in the Capital Health district.
  - •Minimal/incomplete/inaccurate wound care documentation.
  - •Lack of care plans initiated for high risk patients, as identified via Braden Scores.
  - •Delayed or lack of involvement of OT/Dietitians to optimize care on high risk patients.
- Many physicians expressed lack of knowledge regarding appropriate treatment of pressure ulcers.
- It was recognized that pressure injury prevention and treatment is a multidisciplinary issue requiring a coordinated team effort and continuity of care.

Methods

- A working group was formed to develop a consult team that would utilize a standardized, multi-disciplinary approach to diagnose and stage pressure injuries, and develop patient-centered treatment plans which conform to best practice guidelines.
- The consult team included a hospitalist, plastic surgeon, dietitians, occupational therapists, and registered nurses
- We engaged the family of a patient who died from a severe hospital-acquired pressure injury, to provide teaching materials to educate hospital staff about the enormous negative impact that pressure injury can have, and the important role each care provider plays in the prevention, early identification and appropriate management of these injuries.
- Data was gathered from our consults, as well as annual pressure ulcer prevalence studies, Patient Safety Incident Reports, and CMG data on metrics such as percentage of patients with a completed Braden scale and percentage of patients with a completed care plan.

Purpose of the Team

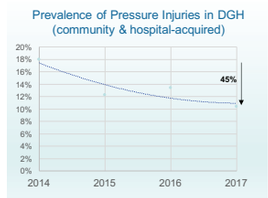
- To assess patients with pressure injuries (Stage II and above) via a multidisciplinary, evidence-based approach focused on: nutrition, pressure offloading, and local wound care, using a patient-centered approach.
- To educate front-line staff re: diagnosis and management of pressure ulcers, and educate re: the use of appropriate care plans, offloading & nutrition strategies, and to provide regular follow-up to guide and adjust treatment as required.
- To provide debridement and guidance re: advanced wound therapies as appropriate.
- To assist with transitions to the community with respect to nutrition, offloading equipment, and local wound care, with education and engagement of care providers in the home or subsequent care facility.

Evolution of the Consult Team Role

- As we had a multidisciplinary team involving key stakeholders in the care and prevention of pressure injuries, we were able to identify multiple contributing factors and optimization strategies in the management of pressure injuries, individualized to each patient scenario and situation
- Our data was used to identify care and knowledge gaps, which informed the development of several educational/QI initiatives
- As DGH front-line staff's comfort with pressure injury management improved via education and guidance, they were able to manage many cases independently, and our team focused on more severe/complicated cases.

Results

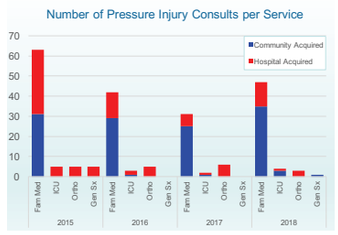
•A multidisciplinary survey conducted in 2017 demonstrated high rates of satisfaction with the care provided by the Pressure Injury Team, including appreciation for the continuity of care and multi-disciplinary approach, improved transitions of care to the community, and overall greater awareness of the importance of pressure injuries and their prevention & management.

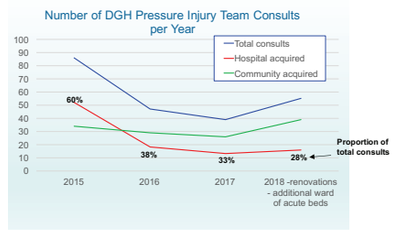


Prevalence Results
Hospital Acquired Pressure Ulcers

	NSHA	Central Zone	DGH
2015	14.2%	9.2%	6.1%
2016	12.5%	8.8%	8.0%
2017	11.9%	9.0%	5.6%

*Note: 2018 Prevalence Data not yet available





Discussion

• 2015-2017 data showed an improvement in the prevalence of hospital acquired pressure injuries, as well as a decrease in the overall number of consults. 2018 saw a rise in both community and hospital acquired pressure injury consults, corresponding to the hospital bed expansion, however the proportion of hospital-acquired injuries continued to fall. These improvements were attributable to improved knowledge and processes re: prevention and management by front-line staff via multiple hospital-wide educational efforts.

•This is the first inpatient multidisciplinary pressure injury consult team in the Nova Scotia region, and it received NSHA Innovative Leading Practice Award in 2018. It operates with no additional funding, using existing hospital resources. We are not aware of any similar inpatient teams across the Atlantic Provinces.

Conclusion

• The development of the DGH Inpatient Pressure Injury Consult Team meets numerous Strategic Priorities of the Nova Scotia Health Authority. Improved delivery of quality health services is enhanced through an increase in inter-professional education and research opportunities. It meets the overall goal of providing person-centered, high-quality, evidence-informed, and sustainable health care for Nova Scotians, focusing on the individual needs of each patient and family using a well-rounded multidisciplinary approach.

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Multi-Center Evaluation of an Advanced Extracellular Matrix Technology for the Management of Chronic Wounds – A Canadian Experience

[1]Rose Raizman, RN-EC, PHCNP, NSWOC, WOCC (C), MSc, MScN; [2]Rosemary Hill, RN, BSN, CWOCN and [3]Kevin Woo, PhD, RN, NSWOC, WOCC(C), FAPWCA
[1]Lawrence S. Bloomberg Faculty of Nursing, University of Toronto Scarborough Health Network|Centenary Hospital, Toronto; [2]Vancouver Coastal Health – Lions Gate Hospital; [3]Queen's University, West Park Health Center, Toronto Western Hospital

Introduction

ECM$^{\phi}$ technology works as a scaffold to help rebuild missing or damaged tissue. Unlike traditional collagen dressings, ECM$^{\phi}$ is entirely natural, and is an accurate mimic of the scaffold found in healthy tissue. ECM$^{\phi}$ contains collagen, but also a range of other secondary molecules that are important for healing[1]. Additionally, ECM$^{\phi}$ has been shown to modulate wound proteases[2]. The aim of this case series was to clinically evaluate an advanced extracellular matrix (ECM$^{\phi}$) technology across different Canadian care settings for the management of chronic wounds.

Methods

Thirty patients were recruited from three sites (see also population summary below). Wound types included DFU's, PU's, skin tears, pilonidal sinus, necrotizing fasciitis, venous leg ulcers, dehisced abdominal and traumatic wound. Wound management was undertaken across various care settings, including in-patient, out-patient and home health. All wounds were managed with best practice, including debridement, maintenance of a moist wound environment and appropriate compression and off-loading. All wounds were managed with an ECM$^{\phi}$, applied every 2-7 days to the wound bed. Wounds were visually inspected, imaged and measured over the course of management with ECM$^{\phi}$.

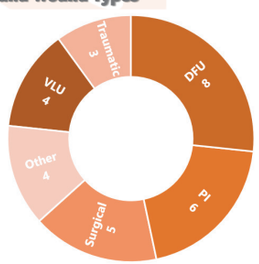
Population

Demographics and Wound Types

30
Wounds

♂**19**
(63%)

♀**11**
(37%)



Average wound age:
23 weeks
Range 0 to 104 weeks

Baseline average wound size:
23 cm²
Range 0.1 to 165 cm²

Results

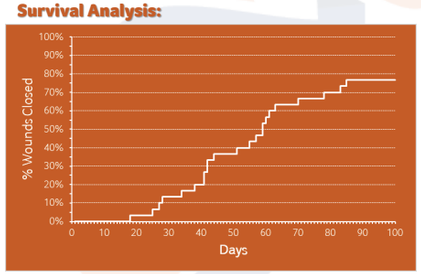
Outcomes

Wounds closed:
77%
(By week 12; n=23/30)

Average % wound size at 4 weeks:
36%
(SD=33%; range, 0% to 96%)

'Respondents' at 4 weeks:
70%
(>50% reduction in area at 4 weeks; n=21/30)

Survival Analysis:



'Respondents' sub-analysis:

VLU: **50%** (n=2/4)	Surgical: **100%** (n=5/5)
DFU: **75%** (n=6/8)	Traumatic: **67%** (n=2/3)
PI: **67%** (n=4/6)	Other: **50%** (n=2/4)

Conclusions

This represents the first Canadian evaluation of ECM$^{\phi}$ for the management of wounds. Improvements to the granulation tissue were observed, and otherwise stalled chronic wounds began to resolve[3,4]. Results to date are encouraging, and the availability of this advanced technology to Canadian wound specialists provides another tool for the management of these complex pathologies.

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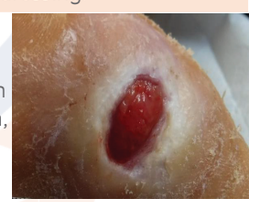
Financial support was provided by Aroa Biosurgery Limited (New Zealand). The authors would like to acknowledge the assistance of Drs. Vonne Heeswijk and Sandi Dempsey in data analysis and preparation of this poster.

ϕEndoform Natural Dermal Template; ^Hydrofera Blue Classic; www.appulsemed.com

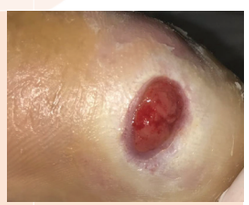
Case Study 1

Patient: 60 year old male.
Medical History: Non-insulin-dependent diabetic (Hgb A1c 7.2%), original transmetatarsal amputation in 2016.
Wound Description: Diabetic foot ulcer, painful when infected otherwise has neuropathy to plantar aspect of his foot.
Previous Treatments: Two courses of antibiotics, gauze dressing.

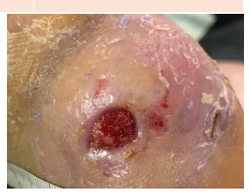
Week 0:
2.0 x 1.2 cm.
100 % granulation tissue, maceration, neuropathy.
ECM$^{\phi}$, GV/MB* foam.



Week 1:
1.0 x 0.9 cm.
100% pink granulation tissue, moisture.
ECM$^{\phi}$, GV/MB* foam, TCC.



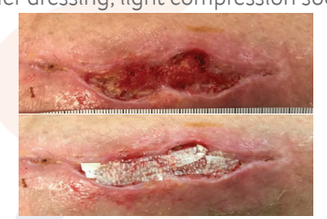
Week 5:
0.8 x 0.5 cm.
83% wound closure.



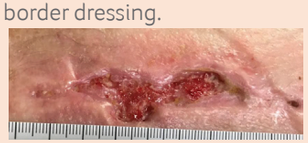
Case Study 2

Patient: 54 year old female.
Medical History: Celiac disease, hypertension, idiopathic neutropenia.
Wound Description: Post surgical wound.
Previous Treatments: Dressings, topical antibiotic, debridement, cadexomer iodine.

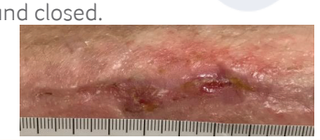
Week 0:
5.8 x 2.0 cm. 10% slough, 90% granulation tissue. ECM$^{\phi}$, GV/MB* foam border dressing, light compression sock.



Week 2:
3.8 x 1.7 cm. Epithelialization, 100% granulation tissue. ECM$^{\phi}$, GV/MB* foam border dressing.



Week 5:
Wound closed.



Self-Applied Photobiomodulation Device Therapy as an Adjuvant Treatment for Acceleration of Hard-to-Heal Wounds with Various Etiologies

Rose Raizman[1,2], Lilach Gavish[3]

[1]Scarborough Health Network , Toronto, Canada. [2]UfT, Toronto, Canada. [3]The Hebrew University of Jerusalem, Jerusalem, Israel

Background: **Photobiomodulation (PBM)** is a non-invasive optical irradiation in the visible to near infrared range of the spectrum that is absorbed in the cells and produces non-thermal photochemical increase in ATP synthesis .

Objective: Evaluation of **home-use self-applied (PBM) device***, for acceleration wound healing

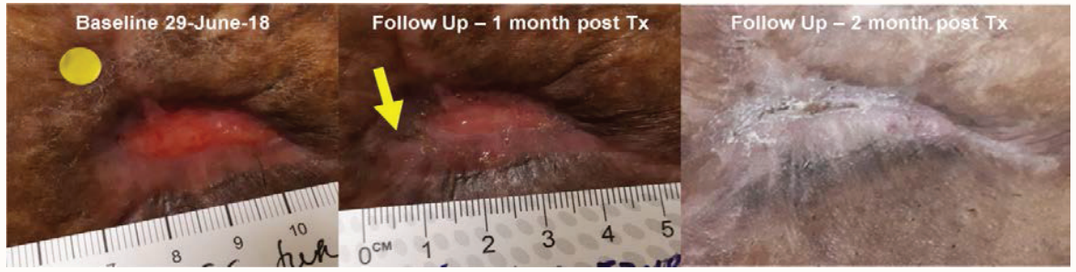
Methods: 16 patients (11:5 male:female, 43-84 years old) from outpatient wound clinic. Including 3 abdominal wounds, 5 diabetic foot ulcers (DFU), 2 dehisced limb incisions, 3 Venous leg ulcers, and 3 complicated wounds. PBM treatment (808nm, 250mW peak power, 15KHz, 5J/min, ray size 4.5×1.0cm2) was self applied over the wound bed, wound margins, and over nearby lymph nodes.

Results: Abdominal wounds - complete epithelialization in 5-6 Tx by 9-21 days. DFUs: Three closed within 2 weeks after 4-6 Tx. Two achieved 50% decrease in 1 week. Complicated wounds: improved / completely resolved + significant pain alleviation in 1-3 days. Venous ulcers - extremely painful venous ulcers, not responding to combination pain medication, - pain resolved within a week.

Conclusion: Based on our previous experience and the cases presented here, self-applied PBM, led to accelerated healing and rapid pain alleviation over standard care alone. Moreover, the treatment encouraged patient's involvement in own care.

*B-Cure laser, Good Energies, Israel

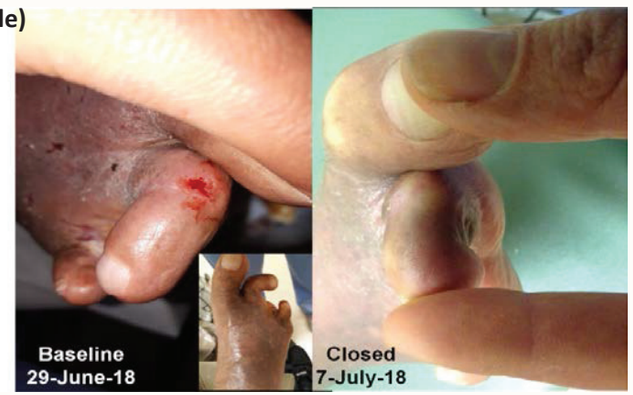
Example 1: Abdominal Wound with Lupus (43, female)



Medical Background: Lupus, diabetes type 2, chronic anemia. Surgical wound , non-healing for 2 years. After sepsis, was on NPWT with instillation but the wound did not improve. **Treatment Protocol: PBM self applied at the clinic (6Tx):** 0.5 min over wound bed + 2X2.5' on wound margin. **Results**: After 9 days, complete epithelialization. Patient went on active vacation, wound remained closed

Example 2: DFU with chronic PAD (67, Male)

Medical Background: 3 years with chronic DFU, PAD amputation July 2017, attempted repeated angioplasties and different therapies including HBOT. Comorbidities include GARD,CAD, PAD, on cortisone cream for generalized rash. Since amputation had chronic ulcerations of various severity. The little ulcer presented here did not close with 2 montsh of hyaluronic acid. Additional ulcers and scabs not shown here are also present in other regions of the foot



Treatment Protocol: PBM self applied at home since June 29: daily 0.5' wound bed, 2' on scab (other wound not shown), twice daily on lymph nodes - 1' on groin, 1' on popliteal**.** **Results**: One week after first Tx wound showed here closed. Skin texture improved. Less pain when he is wearing shoes.

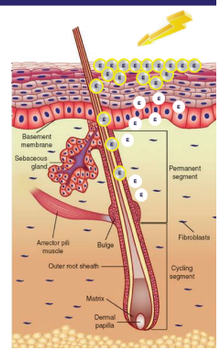
Topical application of nanoparticles containing vitamin E for radiodermatitis prevention in women with breast cancer: a randomized pilot study

Fernanda Mateus Queiroz Schmidt[1], Carol Viviana Serna González[1]*, Rodrigo Calixto Mattar[2], Luciana Biaguini Lopes[3], Marinilce Fagundes dos Santos[3], Vera Lúcia Conceição de Gouveia Santos[4]

[1] Graduate Program in Adult Health Nursing, School of Nursing, University of São Paulo; [2] Regional Cancer Hospital of Passos City in Minas Gerais province, Brazil; [3] Biomedical Sciences Institute, University of São Paulo; [4] Medical Surgical Department, School of Nursing, University of São Paulo; Brazil. *Correspondence Author: cvsernag@usp.br

BACKGROUND

- Approximately 90-95% of women with breast cancer receiving radiotherapy, suffer from radiodermatitis (RD). (Leventhal, Young, 2017) which is a cutaneous reaction to ionizing radiation, consisting of painful injuries with erythema, dry desquamation and moist desquamation. (Singh et al., 2016)
- Topical treatment with antioxidants, such as Vitamin E, could possibly be a strategy to prevent RD due to the fact that they can counteract oxidation. (Singh, Beattie, Seed, 2013). However studies are still poorly consistent. To facilitate Vitamin E penetration in intact skin, nanotechnology is being explored as a plausible option (Kavoosi et al., 2018).



GENERAL OBJECTIVE

To evaluate the prevention of acute radiodermatitis using a cream consisting of lipid nanoparticles containing vitamin E (2%) in women with breast cancer submitted to radiotherapy, and to calculate the sample size for a clinical trial.

METHODS

Design: Randomized, controlled, double-blind pilot study. Approved by the ethics committee in the clinical setting and the University of São Paulo School of Nursing.

Treatments	Same Tube For each group
Intervention Lipid nanoparticles* containing vitamin E	
Control 1 Solely the cream (no lipid nanoparticles, no vitamin E)	
Control 2 Lipid nanoparticles (no vitamin E)	

* Nanostructured lipid carriers type, Inventiva® Brazil

Inclusion Criteria: ≥ 18 years, breast skin without alteration

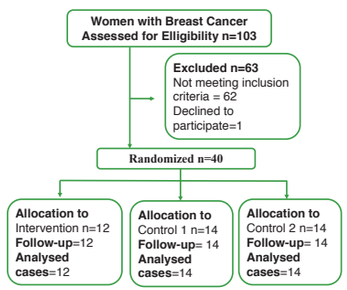
Exclusion Criteria: Previous radiotherapy, radical mastectomy, malignant wounds, allergies to cream components, concurrent chemotherapy, use of anti-inflammatory therapy, use of another intervention to prevent radiotherapy.

Study Protocol:
- Cream application 3 times a day
- Standard recommendations for RD prevention
- Assessments 3 times per week and 2 times after the end of the treatment

Data collection instruments:
- A socio-demographic and clinical data tool
- Periodical assessments: RD classification tools: Radiation Therapy Oncology Group (RTOG) and common toxicity criteria - NCI (CTCAE) version 5.0; RD related symptoms and thermography.
- Quality of Life Questionnaire (EORTC-QLQ-30)
- Quality of Life Questionnaire – Breast Cancer (EORTC-QLQ-BR23)

RESULTS

1. Pilot Study Flow CONSORT (Eldridge et al. 2016)



2. Sample socio-demographic and clinical characterization table

Socio-demographic Variables	Total n=40	p-value
Age (mean ± SD)	60.1 ± 14.3	0,14**
Skin Color White / Mulatto / Black	33/40 (82.5%) / 5/40 (12.5%) / 2/40 (5%)	0,83***
Educational Level Elementary School*	20/40 (50%)	0.19***
Marital Status Married*	24/40 (60%)	0.4***
Current Occupation Retired*	21/40 (52.5%)	0.14***
Number of children (mean ± SD)	2.2 ± 1.6 (n=40)	0.04**
Family income $BRL (mean ± SD)	3671.9 ± 4069	0.6**

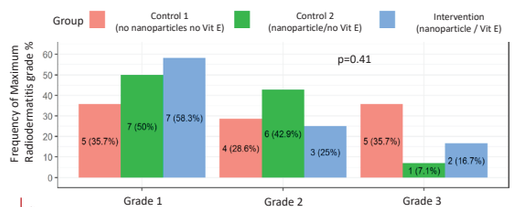
Clinical Variables	Total n=40	p-Value
BMI (mean ± SD)	28.8 ±5.6	0.91**
Solar Exposition (yes)*	26/40 (65%)	0.24***
Cancer Type Invasive ductal carcinoma*	25/40 (62.5%)	0.68***
Cancer Staging 1A (T1N0M0)*	20/40 (50%)	0.48***
Cancer treatment Conservative Surgery* / Chemotherapy / Hormone-therapy	37/40 (92.5%) / 12/40 (30%) / 21/40 (52.5%)	0.28*** / 1 / 0.54
Comorbidities Hypertension* / Diabetes Mellitus	25/40 (62.5%) / 6/40 (15%)	0.77*** / 0.24
Smoking Current Smokers / Ex-smoker	3/40 (7.5%) / 14/40 (35%)	0.95***

Variables Related to radiotherapy	Total n=40	p-value
Radiotherapy type Boost 30 sessions (60 Gy)* / No Boost 25 sessions (50 Gy)	26 (65%) / 14 (35%)	1***
Irradiated place Breast* / Surgical area (Boost doses) / Sub Clavicular Fossa	40/40 (100%) / 26/40 (65%) / 13/40 (32.5%)	1***
Breast height (mean ± SD)	8.4±1.6	0.87**
Breast Lateral-lateral distance cm (mean ± SD)	15.9 ± 3.6	0.38**
Breast radiotherapy Dose Maximum (Median Gy [range])	64 [56 - 64,9]	0.77**
Sub Clavicular Fossa Dose Maximum (Median Gy [range])	53.4 [53.3 – 54.5]	0.29**

*Most common category. The study groups were statistically compared for all the variables **ANOVA or Kruskall-Wallis Test ***Exact-Fisher test

No statistical differences were observed between the groups corresponding to most of the socio-demographic variables, indicating a successful randomization.

3. Radiodermatitis incidence by grades



100 % of the patients had radiodermatitis to some degree. No statistical differences were observed between the groups corresponding to radiodermatitis incidence and its classification. There were no patients with grade 4 radiodermatitis.

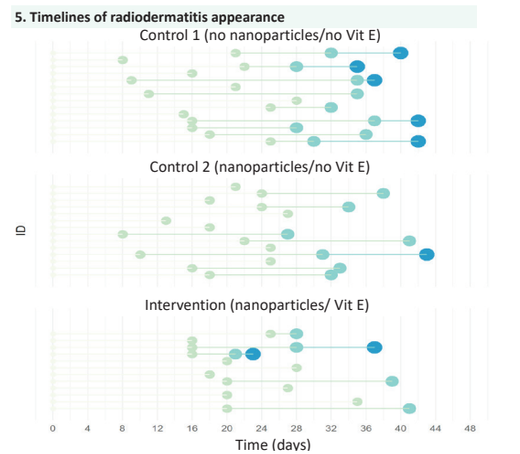
4. Radiotherapy interruption by radiodermatitis apperearance

Variables	A. Intervention n=12	B. Control 1 n=14	C. Control 2 n=14	Total n=40	p-value
Radiotherapy interruption Moist desquamation	1/12(8.3%)	**4/14(28.6%)**	0/14(0%)	5/40 (12.5%)	0.06*
Radiotherapy interruption duration Days (mean ± SD)	9 ± NA (n=1)	**12,5 ± 5,2 (n=4)**	n=0	11,8 ± 4,8 (n=5)	0.59**

* t-student Test **ANOVA Test

No statistical differences were observed between the groups corresponding to the radiotherapy interruption; however control 1 group had the highest incidence and duration.

5. Timelines of radiodermatitis appearance



The time needed to get radiodermatitis grade 1 was longer in the intervention group for patients submitted to 25 sessions (without boosting) p=0,03 (ANOVA)

6. Grade 1 Radiodermatitis Symptoms

Faint Erythema localization	A. Intervention n=12	B. Control 1 n=14	C. Control 2 n=14	Total n=40	p-value
Breast Right Upper Quadrant	6/12 (50%)	12/14 (85.7%)	12/14 (85.7%)	30/40 (75%)	0.06*
Breast Inframammary	7/12 (58.3%)	13/14 (92.9%)	13/14 (92.9%)	33/40 (82.5%)	0.04**

* Exact Fisher Test **ANOVA Test

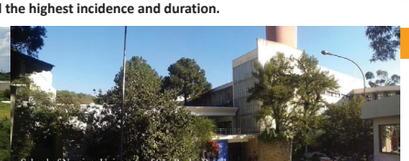
Radiodermatitis Symptoms	A. Intervention n=12	B. Control 1 n=14	C. Control 2 n=14	Total n=40	p-value
Itching incidence	12/12 (100%)	13/14(92.9%)	11/14(78.6%)	36/40(90%)	0.30*
Itching duration Median [range]	21.5 [15.2-29.5]	11 [7.2-15.5]	10.5[1.2-17.5]	13 [6.8-21]	0.04**

* Exact Fisher Test **Kruskal Wallis

Statistical differences were observed between the groups corresponding to faint erythema localization, being less incident in the intervention group. The itching incidence was higher in the intervention group as well.

CONCLUSIONS AND IMPLICATIONS

- The final sample size calculation for the full clinical trial is 103 women, 36 for each branch, with 80% of power test and 5% of statistical significance.
- There was no statistically significant difference in the radiodermatitis incidence and its grading between the treatment groups.
- Vitamin E application was identified as a potentially protective compound with regards to the radiodermatitis appearance time (longer) and faint inframammary erythema (less incident).
- Vitamin E application was related to longer a itching duration as a radiodermatitis associated symptom
- No statistically significant differences were observed between the health-related quality of life between treatments, either as between pre and post radiotherapy results.
- Breasts with tumors had higher temperatures compared to healthy breasts. Cancer breast temperature increased with radiotherapy. There were no differences in temperature between radiodermatitis grades or treatment groups.
- In the future, bigger samples will clarify the effect of this intervention, and sequentially, health care providers could consider the use of antioxidants with nanotechnology for the prevention of radiodermatitis.



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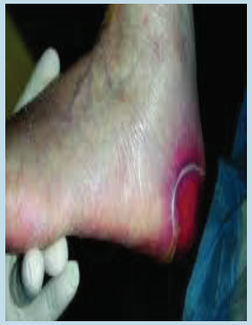
Heel Pressure Injury Prevention in the ED—Quality Improvement Initiative

Cherie Clarke PT, Professional Practice Leader & Theresa MacNeil RN IIWCC, Clinical Nurse Educator

nova scotia health authority
Eastern Zone

AIM

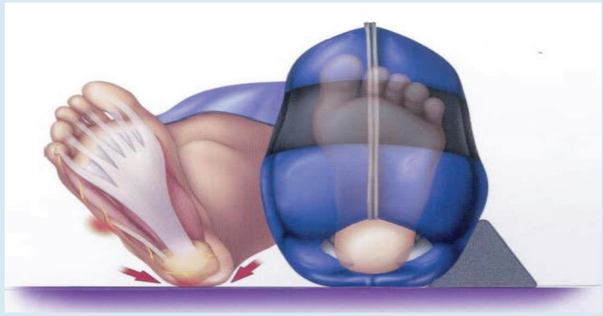
The Nova Scotia Health Authority Pressure Injury Prevalence: A Quality Initiative (QI) **2016** data uncovered that within the Eastern Zone (EZ) the **heel** was the anatomical location most likely to sustain a hospital acquired pressure injury at **29.2%**. This QI was designed to establish a process to address pressure redistribution needs of patients who present to the Cape Breton Regional Hospital (CBRH) Emergency Department (ED) with a fractured hip &/or lower limb long bone injury.



Prevention Matters

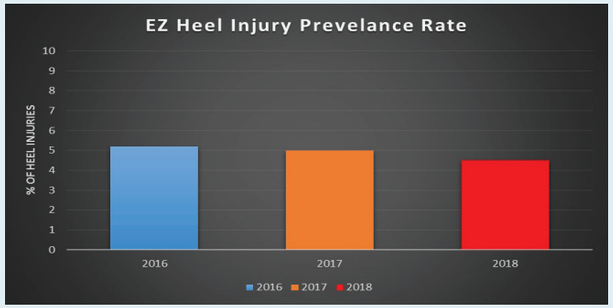
PROCEDURE

In July 2017, leadership from ED, Orthopedics, Occupational Therapy (OT) & Interprofessional Practice & Learning met to discuss process development, education needs & support. Education was provided by a professional practice leader, product rep & clinical educators on the QI initiative & pressure relief product. The ED was stocked with various sizes of offloading boots, daily safety huddles provided a venue to identify patients awaiting orthopedic consult & those who required the expertise of OT preoperatively.



FINDINGS

NSHA Pressure Injury Prevalence studies from 2017 & 2018 revealed prevalence of hospital acquired heel injuries was **reduced by 13.5%.** The pilot at the CBRH ED proved to be valuable, as a result implementation occurred in the remainder of the EZ ED's & education expanded to include peri-operative services. Ongoing evaluation, learning & adapting continues to guide this work.



GOING FORWARD

Engagement with Emergency Health Services (EHS) to establish a process addressing pressure redistribution needs during interfacility transport has occurred. A chart audit will be conducted to capture data on hospital acquired pressure injuries specific to patients with hip fractures who underwent surgical intervention. Further engagement is planned with EHS to examine opportunities where education & interprofessional partnership can reduce pressure injuries.

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Pressure Injury Prevalence: A Quality Initiative, Nova Scotia Health Authority, Eastern Zone 2017
https://www.google.ca/search?ei=1ImSXNaDMYSU-gSq-ofgAg&q=prevention+matters+pictures&oq

Virtual Care

nova scotia health authority

Virtual Wound Care Clinic in Cape Breton, Nova Scotia

2018 STATS Jan 1 - Dec 31

169 new referrals **245** patients scheduled for virtual visits

New Waterford
Sydney Mines
Glace Bay
North Sydney
Cheticamp
Inverness
Neil's Harbour
Baddeck

Aim
The Nova Scotia Health Authority (NSHA) Cape Breton Virtual Wound Care clinic provides wound assessment/follow-up and prescribes treatment in an efficient and timely manner via telehealth technology. The objectives of the virtual clinic are to:

- Improve the patient experience
- Decrease stress of travel
- Reduce congestion at the Cape Breton Regional Hospital (CBRH)

Method
Specialists at CBRH use telehealth to connect to patients located at various smaller rural facilities throughout Cape Breton. These patients are assisted by a nurse who uses a hand held examination camera connected to telehealth device to provide a close up view of the wound.

Quantitative data was collected to measure: number of patients per clinic, number of referrals, and time savings for patients. Qualitative data was collected on overall health care provider and patient experience.

Utilizes physician time more **efficiently** and **effectively**

Findings
Results from the virtual clinic showed that patient appointments, on average, tripled from 4 in-person appointments, to 12 virtual appointments, per week. In 2018, 245 patients were scheduled to be seen virtually. Data showed the virtual clinic saves patients, on average, a total of 3.6 hours (2 hours travel via ambulance, in addition to 90 minutes wait time for the ambulance to return).

eliminates **3.6 hours** an average of 2 hours travel via ambulance plus up to 1hr30mins wait time for the ambulance to return to CBRH for pick up to return home

Improved patient experience

"Virtual appointments allow for frequent re-assessment".
-Provider

12 Virtual Visits per clinic

4 In Person per clinic

300% More patients seen per clinic

"This is great! Patients are seen quicker".
-Staff Member

"[This] will be great in winter time, terrible to travel those roads and is so unpredictable".
-Patient

Implications
The integration of virtual wound care appointments into existing ambulatory care wound clinics, has the potential to increase clinic efficiency, reduce patient/provider travel, improve clinical outcomes and increase patient satisfaction. The success of the Cape Breton virtual wound care clinic suggests there is potential to provide home-based wound care in partnership with community nursing agencies.

Gillis, A., Lake, S., Heckman, K., March 2019

Improving the odds: Free and accessible podiatry service for low income residents with diabetes.

Daniel Marsh, Ph.D. and Caroline Leverett, M.Sc.
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Introduction

Nova Scotia is one of the Canadian Provinces that does not provide health care coverage for podiatry services. Private health plans often supplement this coverage and the cost of allied health services including podiatry. However, low-income and/or self-employed individuals often do not have private health insurance and cannot afford the cost of appropriate foot care.

Aim

To partner with a local Health Foundation and provide free and accessible podiatry service to low-income rural Nova Scotia residents with diabetes.

Procedure

- In 2014, an operating budget of $5000 was provided by the Annapolis West Health Foundation to develop and implement a pilot project to treat low income diabetic patients.
- The pilot project goals were to:
  a) identify and refer appropriate patients based on diabetes, foot assessment and lack of private insurance
  b) book patient treatments for podiatrist
  c) discharge or book follow up appointments with treatment plan.
- Based on positive results and patient demand, a diabetic foot care program with an annual budget of $20,000 has been adopted by Annapolis West Health Foundation and fully supported by the Health Centre administration.

Program History

Year	Treatments	Patients	New Patients
2014*	27	23	23
2015	196	70	57
2016	281	67	31
2017	329	68	30
2018	366	70	24

*** 3 month pilot only**

Summary of Findings

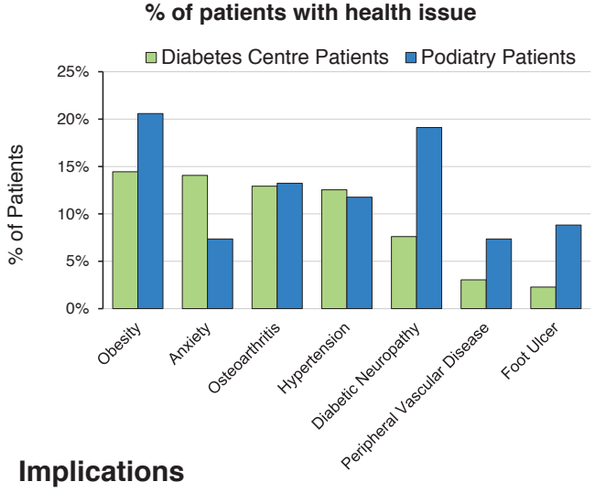
- **51% of patients are treated 1-2 times per year**
- **91% of patients are "moderate risk" and treated 7 times per year or less**
- **6% of patients are "high risk" and are treated weekly to manage foot ulcers**

Patient Population

ANNAPOLIS COMMUNITY HEALTH CENTRE

	Diabetes Centre		Podiatry Service	
	COUNT	AGE	COUNT	AGE
MALE	139	67.0 ± 0.8	45	69.4 ± 1.5
FEMALE	124	68.2 ± 1.1	23	76.1 ± 3.3

Figure 1. Diabetic Patient Health Profile.

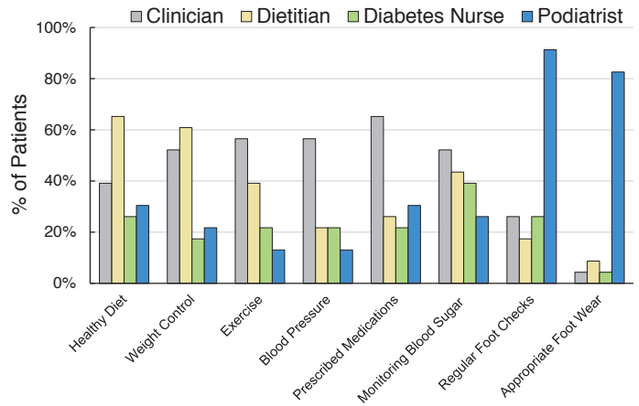


Implications

- **Podiatrist a valuable team member for management of diabetes-related health issues: especially of unique high risk patient population**
- **Community partnerships can bridge the gap and assist in providing necessary health services that are insufficiently resourced by the health authority**
- **Timely intervention and appropriate management of diabetic foot issues can avoid high costs associated with lower limb amputation or hospitalization for foot ulcers.**

Figure 2. Podiatrist is Integrated into Health Centre Collaborative Team

Patients were surveyed to determine which Health Centre care provider assisted them with information to better manage diabetes-related health issues.
- Podiatrist is identified as a resource across the spectrum of issues



Diabetes Self-Care Activities Measure

(Toobert et al., *Diabetes Care* 23:943-950, 2000)

Patients were surveyed to assess their diabetes self-management practices .
- Minimal participation in exercise is lower than previously reported in other studies: reflects mobility issues of this patient group (Figure 1).

How Many of the Past 7 Days Did You:	Average
Follow a healthy eating plan	3.8
Eat fruits and vegetables; meat, dairy	4.4
Participate in an exercise program	0.8
Monitor blood sugar and take recommended medications	4.2
Wash and inspect feet	4.2