Accountable Procurement: A Collaborative Partnership Approach to New Product Evaluation

CHCA Halifax Tuesday Nov 14, 2017 1330 -1500



Rochelle Duong

Manager, Home and Community
Care - Wound Care Program

Mississauga Halton Local Health
Integration Network



Connie Harris

RN, ET, IIWCC, MSc

Wound Healing & Tissue Repair

Consultant Perfuse Medtec Inc.



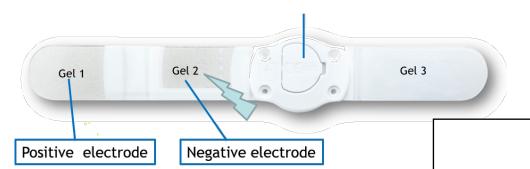


A Muscle Pump Activator Medical Device

The geko[™] Wound Therapy device is:

- a wrist-watch sized
- easy to use (6 hours per day/6 days/week)
- self-contained
- self-retentive (hydrogel)
- battery operated
- 10 gm medical device, worn at the fibular head to stimulate the common peroneal nerve.
- Stimulates once per second
- 10 settings
- The higher the setting, the larger the pulse width and the larger the charge

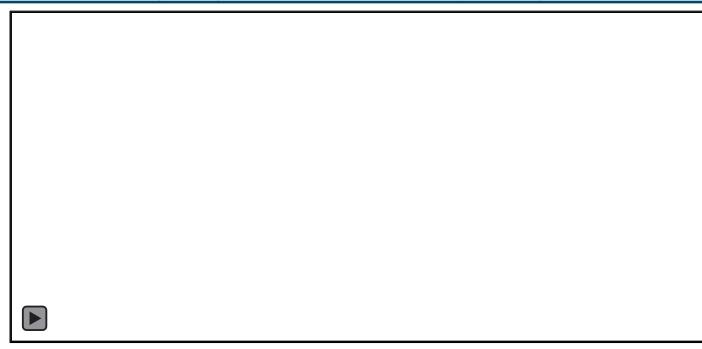
Housing containing battery power source and "brains", no gel







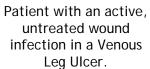




- 1. 0-15 seconds baseline measurement. The geko™ device is not activated.
- 2. 15-30 seconds the geko[™] device is active, before a foot twitch is achieved; resulting in a 100% 200% increase in microcirculatory flux
- 3. 30-45 seconds the geko[™] device is activated at a <u>higher setting</u>, causing the foot to twitch, resulting in a 1,000% increase in microcirculatory flux

An Adjunctive Therapy for Wound Care





K. Harding CAWC Conference 2016.

(*Using Speckle contrast optical spectroscopy to measure microcirculatory tissue perfusion)



Microcirculatory flux* with normal cardiac systole in same Venous Leg Ulcer.



Microcirculatory flux *with the geko™ device activated:

- 225% increase in flux to the wound bed (p<0.001)
- 67% increase in flux to peri-wound skin (p<0.001).
- The geko[™] device increases venous, arterial and microcirculatory blood flow in the lower limb in residents with chronic venous insufficiency and intermittent claudication.
- It reduces edema, compresses the lower leg venous valves, augments the calf muscle pump and reduces the symptoms of chronic venous insufficiency, promoting conditions suitable for wound healing.

geko™ Impact on Blood Volume Flow/ Velocity

In residents with PVD with intermittent claudication:

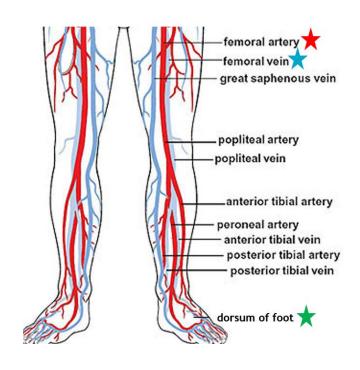
- ★ 29% increase in arterial volume flow
- 23% increase in venous volume flow
- microcirculatory flux increased by 22.55 flux units Barnes et al. 2015

In residents with lower limb vascular disease (CVI or PVD):

★ 31.5% increase in arterial flow Barnes et al. 2016

In residents with Chronic Venous Insufficiency:

Regular use over 6 weeks caused 51% increase in Venous Volume Flow and 60% increase in Peak Velocity. Williams et al. VEINS Conference 2014.







Important Information

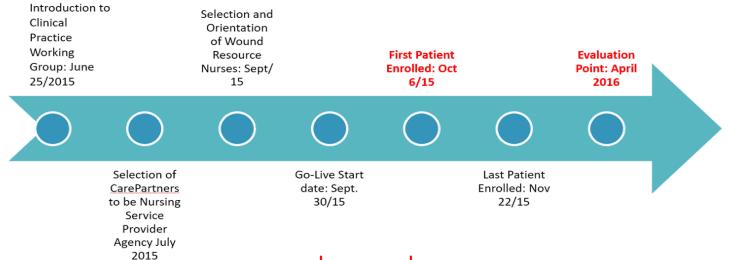
Please also see the Instructions for Use (IFU) provided with the device for important safety information.





Background - How we came together

- The Mississauga Halton LHIN (MH LHIN) is committed to working with partners on the delivery of wound care that supports excellent patient outcomes, enhances the patient experience and balances clinical efficacy and innovation.
- Local data indicated that lower leg wounds were a challenge in the region.
 A novel technology, the geko™ device that was recently trialed by other
 LHIN partners with optimal success was selected to evaluate







Background - How we came together

• In the fall of 2015 MH LHIN worked collaboratively with CarePartners and Perfuse Medtec Inc. (the Canadian Distributor of the geko™ device) to evaluate the geko™ device and its effects on patients with venous leg and diabetic foot ulcers.

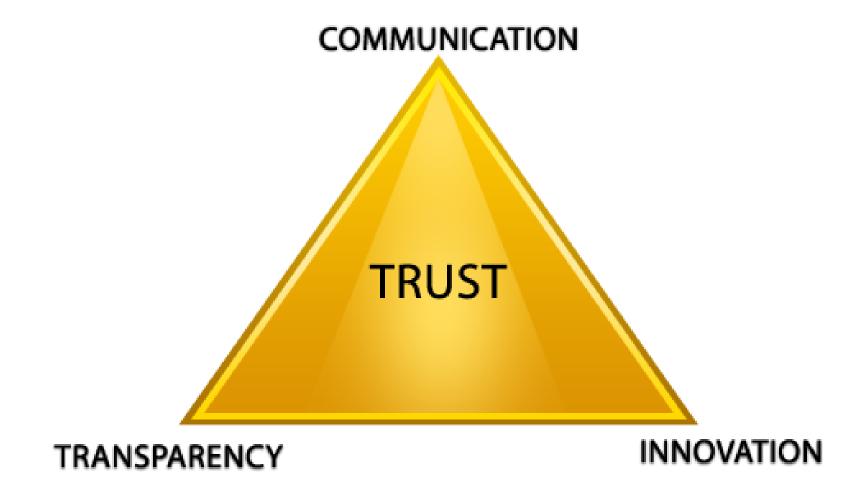








Common Expectations





Mississauga Halton





Evaluation Objectives - MH LHIN (formerly CCAC)

- Primary: To evaluate the efficacy and suitability of using the geko[™] device to close venous leg ulcers (VLUs), diabetic foot ulcers (DFUs) and mixed venous/arterial leg ulcers (VLU/ALUs), by measuring the size of wounds bi-weekly through photography and hands on measurement.
- Secondary Objective: To collaboratively developed a reproducible process for measuring/evaluating product innovation within home care including its impact on patient outcomes and experience.



The geko™ Device Evaluation with MHCCAC - Updated Oct 23, 2015

Product Evaluation-geko™ device-Portable Electrical Stimulation Device involving Mississauga Halton CCAC, CarePartners and Perfuse Medtec Inc.

Participants

Mississauga Halton CCAC:

- Rochelle Duong, RN, BScN, IIWCC Manager, Patient Care Programs

 Wound Care Perfuse Medtec Inc.
- Dorace Ramage RN (support from Shannon McKie), Geoff Fournie

arePartners:

- Connie L. Harris RN, ET, IIWCC, MSc, CNS Wound & Ostomy / Clinical Lead Wound OBP Quality and Professional Practice Team
- · Jeff Deenen, RN Regional Manager, Operations Mississauga Halton
- Ava Orr, RN Diana Ghimbasan, RN, Nurse Managers
- · Annabelle Entredicho, RN, ET
- Front-line nurses: YdaMay Escober-Cruz; Carolyn McKnight; Nicole Fritz; Volodymyr Revchuk; Jennifer Brown

Purpose

The purpose of this proposed assessment is to determine the efficacy and suitability of using Portable Electrical Stimulation for venous leg ulcer, diabetic foot ulcer and mixed venous/arterial leg ulcer healing, for community patients in Mississauga/Halton delivered through the geko[™] device. Case studies may be published individually. Ethics approval may be sought to publish a collective case series should the group desire.

Perfuse Meditec Inc. will also work to assist with a cost benefit analysis in the use of geko™ as an adjunctive therapy for MHCCAC as it relates to DFU, VLU & mixed VLU/ALU patients by increasing closure rates and decreasing LOS

Objectives

- To assess the degree of wound healing for DFU, VLU & mixed VLU/ALU by measuring the size
 of wounds bi-weekly through photography and hands on measurement. Edema, where
 routinely tracked will be measured using standard techniques.
- To assess the degree of patient comfort, including pain reduction and satisfaction through the Client/Patient Satisfaction survey at prior to starting geko[™], at 6 weeks and at the end of treatment.
- To assess the uptake of patient education and independence with treatment through provider observation and patient demonstration within the first two weeks of application.

Pg. 1





Service Provider Organization (SPO) Experience & Expectations

- Time commitment- 9 month evaluation:
 - Training of nurses
 - Ensuring that patients met the criteria
 - Arranging joint visits with Perfuse Medtec staff to start device
 - Conference calls bi-weekly to monthly
 - Ensuring that reports were completed and submitted

BRN	Wound etiology	Start date	CP Team	Baseline	week 2	week 4	week 6	week 8	week 12	week 16	Wee
	251		- 0		20-	3-	16-	Nov	Due Dec 28 (Yda May will resen	Due	Due Feb
	DFU	5-Oct 7-Oct	Tm 8 Team 2	6-Oct	Oct 19- Oct	Mov misse	Nov 18- Nov	30 Nov 30	Dec 28	Jan 25 Due Jan 27 (will be late)	Due Feb 24
	VLU	21- Oct	Team 14	21-Oct	6- Nov	in hospi tal					
	DFU	21- Oct	Team	21-Oct	5- Nov	Due Nov 19- done Nov 27	Dec 15- labelled as week 4	Due Dec 17	Due Jan 14	Due Feb	Due Mar 11
	VLU	21- Oct	Team 8	21-Oct	3- Nov	Email re: derm atitis Nov 10 +		send er	nd of trea	atment v	week o
1				-Nov	18- Nov	Dec 15 (really week 6)	Dec 26 (really week 8)	Due Dec 30	Due Jan 27	Due Feb 24	Due Mar 24 Due
	Car	'nР	ar	tners :	Nov 26 Nov 25	Dec 11 Due Dec 9	Dec 24 Due Dec 23	Due Jan 7	Due Feb 4 Due Feb 3	Due Mar 4 Due Mar 3	April 3 Due April 2

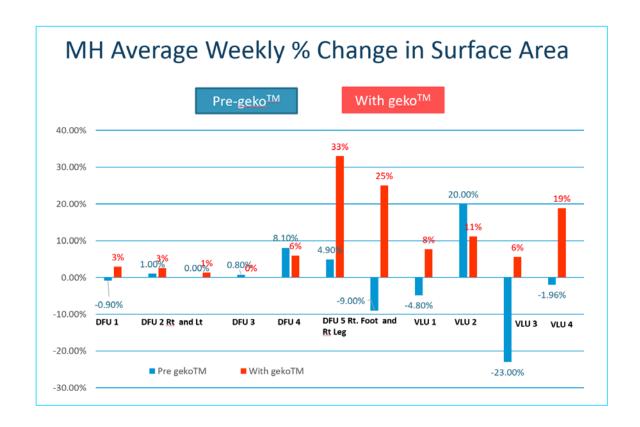
Perfuse Medtec Inc. (Canadian Distributor of the geko[™] device) Experience and Expectations

- Training of nurses
- Support to nurses and patients if required
- Provided geko[™] products at no cost to the CCAC/LHIN during the evaluation
- Clear communications and collaboration with nurses and CCAC/ LHIN; Secure email systems to share de-identified data with patient consent
- Clear roles, processes, sharing of data and reporting
- Organization and Efficiency: will this evaluation result in addition to the formulary?
- Deliverables: disseminate results, posters for conferences, publish in peer-reviewed journal



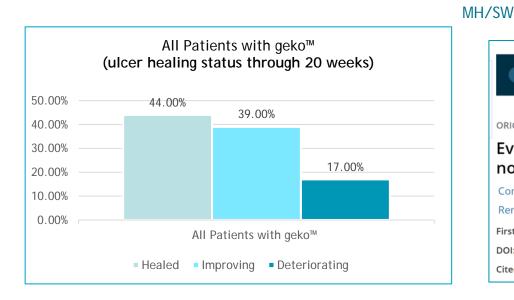


Preliminary and Final Analysis

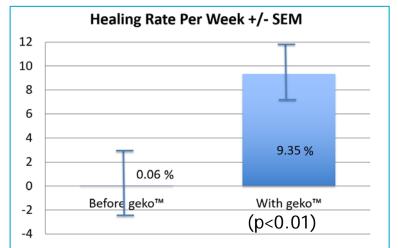




Results with Chronic Non-Healing Venous Leg Ulcers (combined with SW results)







This rate of healing would support the percentage of healing expected from wounds deemed as "healable" wounds despite the chronicity.





Patient Experience

Patients report a feeling of hope: "I can feel it working"



- Venous Leg ulcer patients showed better rates of healing; 3/5
 DFU patients were not adequately offloaded
- Overall patients expressed satisfaction with the geko™ treatment
- 78% of patients experienced accelerated weekly percentage healing rates in spite of multiple comorbidities and the complexity of their wounds.¹





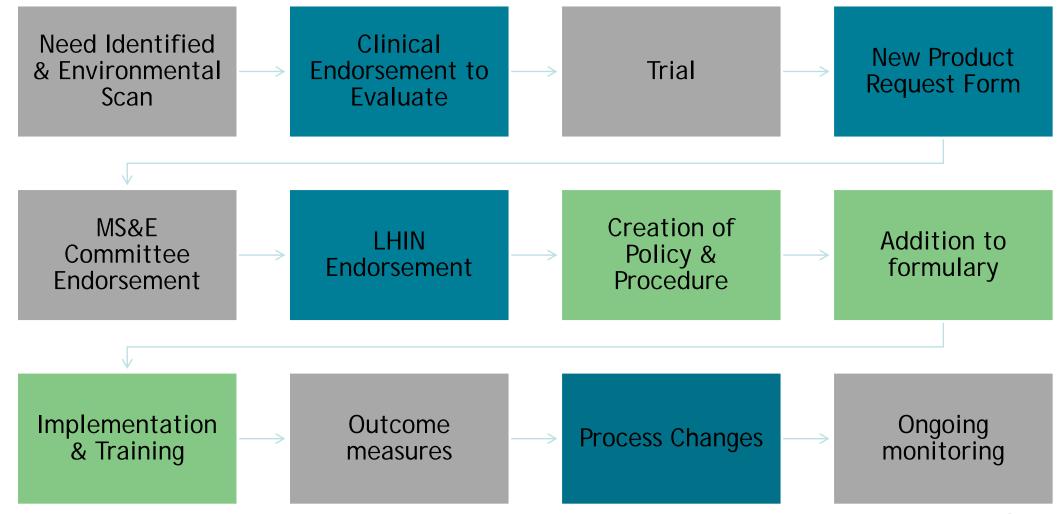
Long-term Results

 The steps followed to evaluate the device was integral in formulating the current MH LHIN, Home and Community Care New Product Innovation Evaluation Process.





MH LHIN New Product Process



Mississauga Halton

Implementation & Training Plan

MH LHIN Leadership financial, implementation & ordering process planning

geko™ Policy, Procedure & Order forms completion & Approval

SPO frontline training sessions hosted by MH LHIN

Voluntary SPO team meeting training sessions

ET/ WCA /CPL training sessions

Vascular Surgeon & Physician training LHIN Hospitals (THP & HH)

Community wound clinic training (e.g. Applewood clinic - Dr. Sibbald)

Central ordering team training & Job Aids

Short Stay Acute Wound & Access (Hospital) team training session & Job Aids

Formal geko[™] launch communication announcing the availability of geko[™] within MH LHIN- Home & Community care geko[™] Launch and availability on formulary





Education...... 7 events, 111 nurses and Webinars for self-learning



Ontario

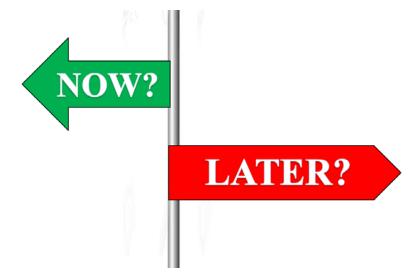
Mississauga Halton Local
Health Integration Network
Réseau local d'intégration
des services de santé de

Mississauga Halton

Perfuse

What's Been Learned So Far?

When is the right time to use the geko™ Wound Therapy device?





Venous Leg Ulcer, Arterial Leg Ulcer or Diabetic Foot Ulcer wound that has shown <30% reduction in size following best practice for 30 days best practice







The geko™ Device Ordering & Monitoring

ET/ MD/ WCA

- -Must be familiar with the geko[™] device and assesses patient for eligibility
- -Orders device on Initial geko[™] order forms

Care Coordinator

- -Reviews that eligibility is met and authorizes equipment
- -Adds authorization codes for tracking purposes

SPO Clinician

- -Reorders geko[™] devices every two weeks
- -Reassesses for continued appropriateness with each reorder

Patient Care Manager/ Wound Care Clinical Practice Lead

- -Approves geko[™] use beyond initial 6 weeks or planned therapy to a max of 8 weeks
- -Reviews and monitors geko[™] utilization reports & patient outcomes

Events & Happenings at the Mississauga Halton LHIN (Continued)

Celebrating our first Mississauga Halton LHIN Employee Recognition Event

Our organization is on an exciting journey of transformation towards a better connected system that creates more seamless care for patients. As we learn and grow on our journey together, recognition is a corner stone of our culture.

On Nov. 6, 2017, we celebrated 98 employees who had milestone anniversaries ranging from five to 35 years. Employees received a certificate of recognition and an anniversary pin. We also bid farewell to nine colleagues who retired in 2017.

We also recognized four initiatives that were nominated for the 2017 Quality Award, which represents our best in the relentless pursuit of quality:

- Ed Castro and Heather Kundapur for one-Link
- Rochelle Duong for Geko Moving into Sustainable Spread Phase1
- Louise Murray for Central Ordering Process and Procedure Improvements
- Heather Reid for Process Standardization: Transition & Patient Flow, Central Ordering & Downtime Planning

Congratulations to our 2017 Quality Award Winner Rochelle Duong!

Geko is a device used to close venous leg and foot ulcers. Results from a trial revealed that 78% of patients experienced accelerated weekly percentage healing rates. Rochelle introduced, initiated and implemented the new product to the LHIN and continues to monitor for success.



Our journey to transform health care continues and each of us plays a critical role in the relentless pursuit of quality. Thank you to all of you for the work you do!

Comprehensive Spread

The geko™ Wound Therapy Device: Resources for Implementation



Wound Clinic Posters

On-Line Learning

Mailers

Primary Care



Request for Orders



Website: www.gekowound.ca



Brochure



Draft Eligibility Screens



Primary Care Offices















HCP Instructions





Sharing

LHIN Interactive workshop:

- Reviewed the Mississauga Halton LHIN Home and Community Care experience
- Shared policies, procedures, inclusion/ exclusion criteria, strategies for success and lessons learned.
- Showcased the geko[™] Learning Management System for Education and Training.
- Provided a collaborative environment, giving participants an opportunity to share and commence process-building.





Summary of Progress: Innovation Adoption

Adopted from: https://www.canada.ca/en/health-canada/services/publications/health-system-services/report-advisory-panel-healthcare-innovation.html

- Leadership to drive Innovation
- Papers, Posters, Speaking
- Physician Conferences
- Consumer Uptake

Implementation & Early Adoption

Proof of Value and Reimbursement

- **Publish**
- Integration into Service Delivery
- Metrics and Performance Analysis: Cost Effectiveness & Financial Model

Health System Needs & Priorities

Journey

Innovation

Partnership Capacity Bullding

Paradigm shift

Clinical Guideline Integration

- CHCA, Wounds Canada, CAET
- Workshops

Diffusion, Scaling up &

Widespread Adoption

Research & Development

Proof of Relevance

Pliot Testing Commercialization

- Clinician Interest
- Patient Evaluations what is the best fit?
 - Randomized Control Trials

Proof of Concept

- **New Therapy**
- **RCTs**



Mississauga Halton

Thank-you!

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