

Spreading and Scaling an Innovation in Wound Care: The geko™ Wound Therapy Device



CHCA Conference
Tuesday Oct 17, 2017
1530-1630
Sutton Place, Edmonton

Connie Harris RN, ET, IIWCC, MSc
(Wound Healing & Tissue Repair)
Connie.harris@perfusemedtec.com
226-749-2720



Road from Concept to Adoption is Challenging

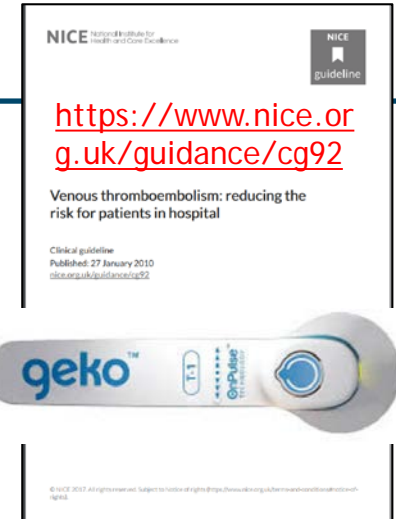
Disruptive technology lacks a predicate model:

- Is the product right?
- What patient is right?
- What price is right?
- Where will the funding for purchase come from?
- How long will it take?
- Will a big company copy our idea?
- What amount of corporate funding is right to see this through?
- What level of evidence is right?
- What study design(s) is right?
- What researchers are right?
- What country is right?

.....ask 100 people and you will receive 100 answers.

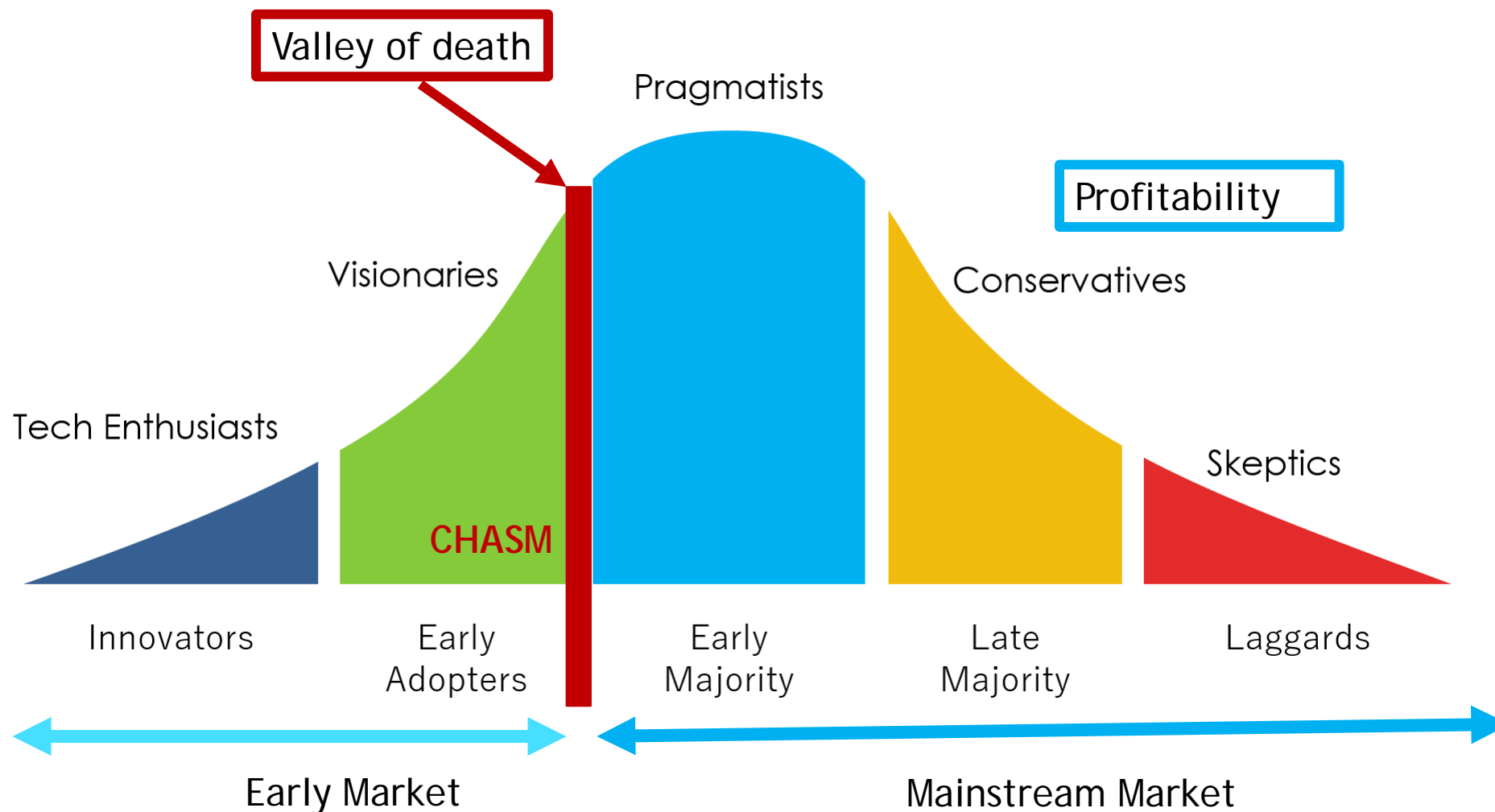
Some Truisms in Innovation

- The first product is almost never right.
- Resistance to change places huge barriers
- Disruptive innovation is often viewed initially with skepticism
- WIFM plays a big role (What's in it for me?)
- It is very difficult for a start-up to have the staying power to weather the time and demands placed on innovation adoption



Innovation Adoption Curve

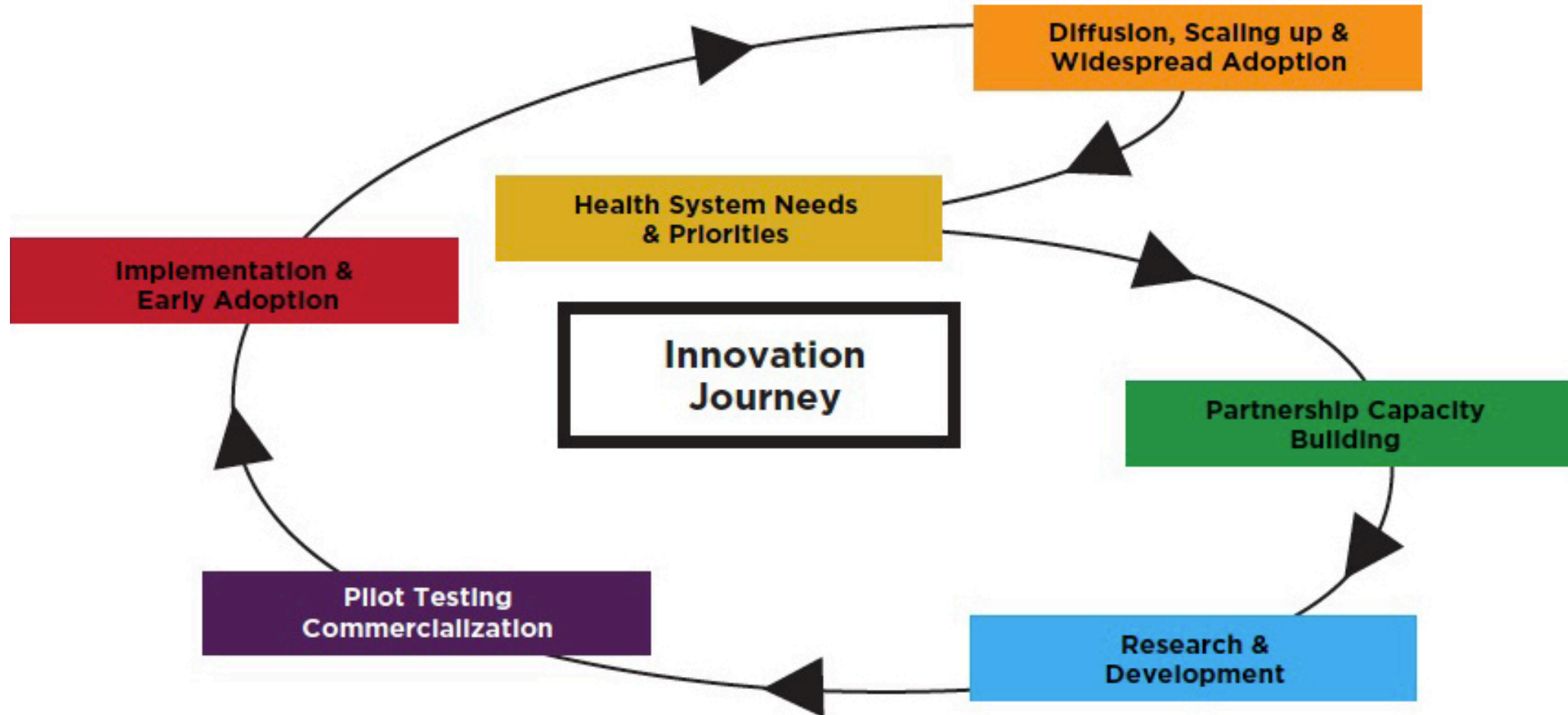
Adapted from Rogers 1983 <http://www.free-power-point-templates.com>



www.gekowound.ca

Build the Evidence for Innovation Adoption

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



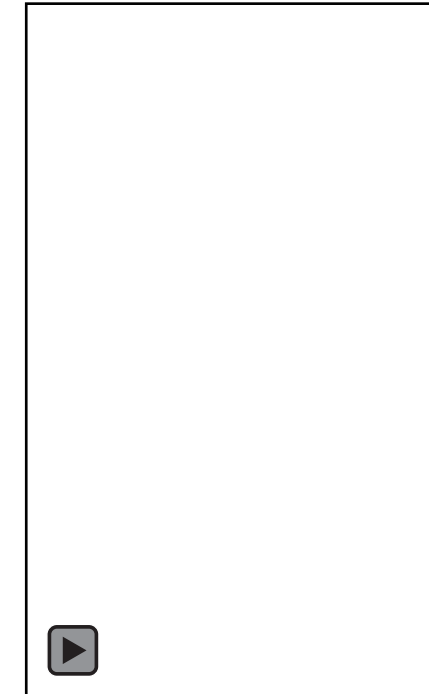
A Muscle Pump Activator Medical Device

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.

With:

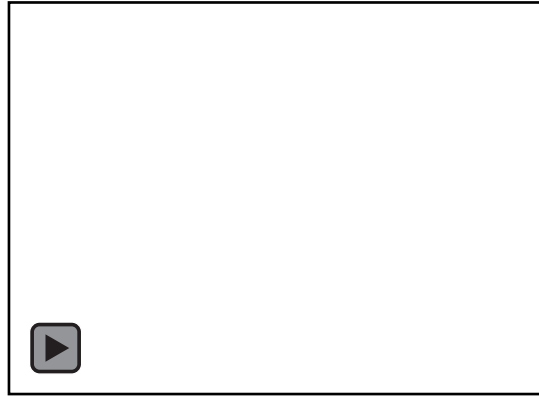
- Stimulates once per second
- 10 settings
- The higher the setting, the larger the pulse width and the larger the charge



Initial Idea: A perfect fit as an Adjunctive Therapy for Wound Care?



Patient with an active, untreated wound infection in a Venous Leg Ulcer.



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 ($p < 0.001$).

(*Using Speckle contrast optical spectroscopy to measure microcirculatory tissue perfusion)
K. Harding CAWC Conference 2016.

- The geko™ device increases venous, arterial and microcirculatory blood flow in the lower limb in patients 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.

Challenges to getting in the door.....



Barriers to entry:

- Where's the evidence?
 - Lack of Randomized Controlled Trials in Wound Care
 - "I won't look at White papers"
 - Health Technology Assessments are biased against Innovation: require many years of research trials
 - Lack of unified processes for new product evaluation

How do you break down the barriers?

What do you do with a low-risk, Health Canada Registered, medical device that may have significant upside potential for the system and the patient?

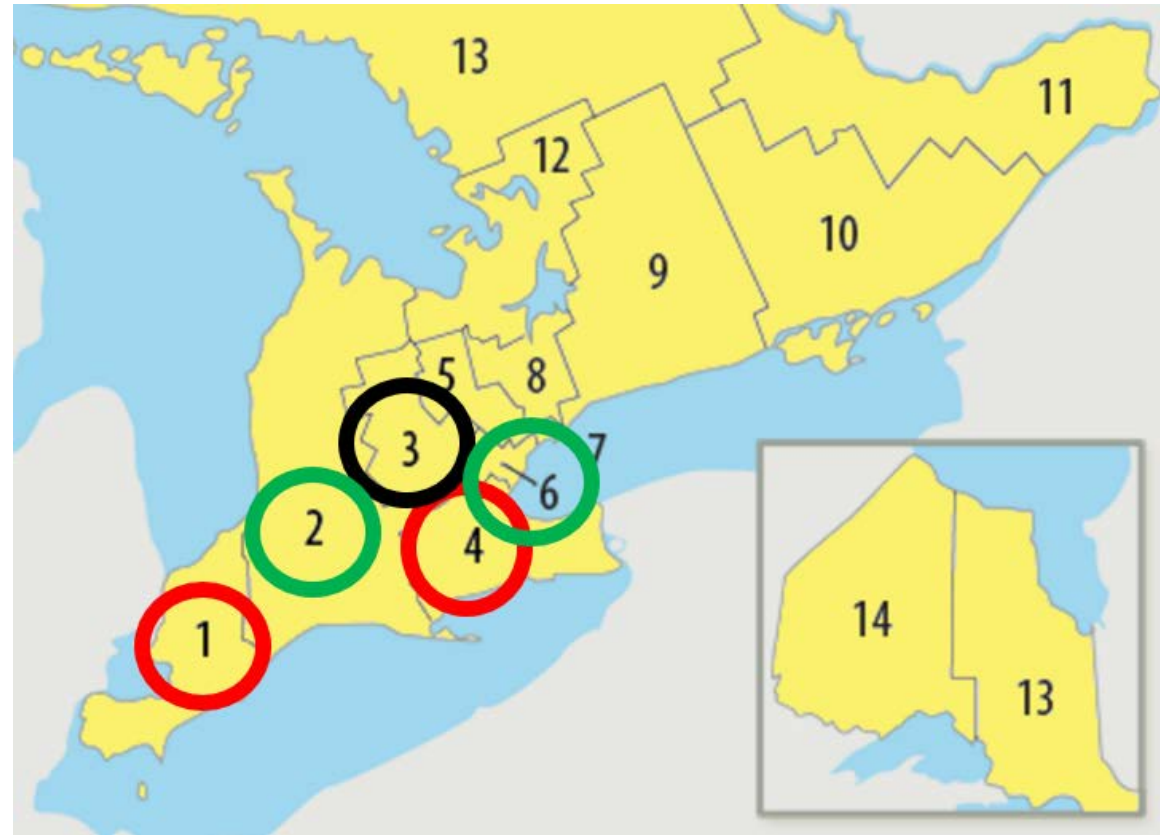
Initial Strategy: Plastics; Cardiovascular, Vascular Surgeons

Patient Selection:

“No hope of healing without a miracle”



A Paradigm Shift - Technology Evaluations in the Community Sector



Results

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



www.gekowound.ca

SPOTLIGHT ON INNOVATION

Modernizing Home Care

A Process to Evaluate and Adopt Innovation

Facilitating consistent access to, and use of, innovative wound care products can have a tremendous positive impact on the efficiency and effectiveness of home care service delivery and patient quality of life. The Mississauga-Halton Community Care Access Centre (MH CCAC) has successfully achieved this goal by using a structured collaborative approach to testing, measuring and adopting the geko™ device for rapid wound healing.

Embracing Innovation

The Ontario Health Innovation Council, established in November 2013 by the ministries of Research and Innovation, Health and Long-Term Care, and Government and Consumer Services, identified the need to expand the adoption of innovative new technologies in all health care settings, including home care. In their 2013 report, *The Catalyst Towards an Ontario Health Innovation Strategy*, the council recommended the following:

- actions to support strategic, value-based procurement;
- evidence-based review of emerging health technology innovations; and
- coordinated pathways for the adoption and diffusion of innovative health technologies.

Innovative health technologies offer many opportunities to improve patient experience, achieve better outcomes and reduce health care costs. One application is wound care. Annually Canada spends \$3.9 million (3 percent of total public health care expenditures) on wounds. In home care, 50 percent of nursing visits involve wound care and approximately 35 percent of home care patients have a chronic wound (CIBL 2012).

Chronic wounds impact patients and their families, who may experience pain, disability, depression, anxiety, hospitalization, financial burden and death (Graham et al., 2003). For the MH CCAC, the cost of managing wounds in the home is significant. In 2014/15, the MH CCAC spent at least \$260,000 managing the most challenging wounds: arterial leg ulcers (ALUs), venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs). This amount does not include medical supplies, rehabilitation and personal support worker services.

To address this challenge, in 2015, the MH CCAC identified an opportunity to develop a strategic, value-based approach for the systematic adoption and use of an innovation for wound care. The project would become the nucleus for strategic procurement and adopting a new way to manage the medical supply and equipment formulary. This presented a chance to address the current unstructured approach that had resulted in an extensive formulary supply listing, confusion among frontline staff, inconsistent practice and potential waste. Development of a strategic, value-based approach would reinforce the adoption and diffusion of new health technologies the MH CCAC, in addition to addressing current operational challenges.

Testing Innovation

The following actions were fundamental to this work:

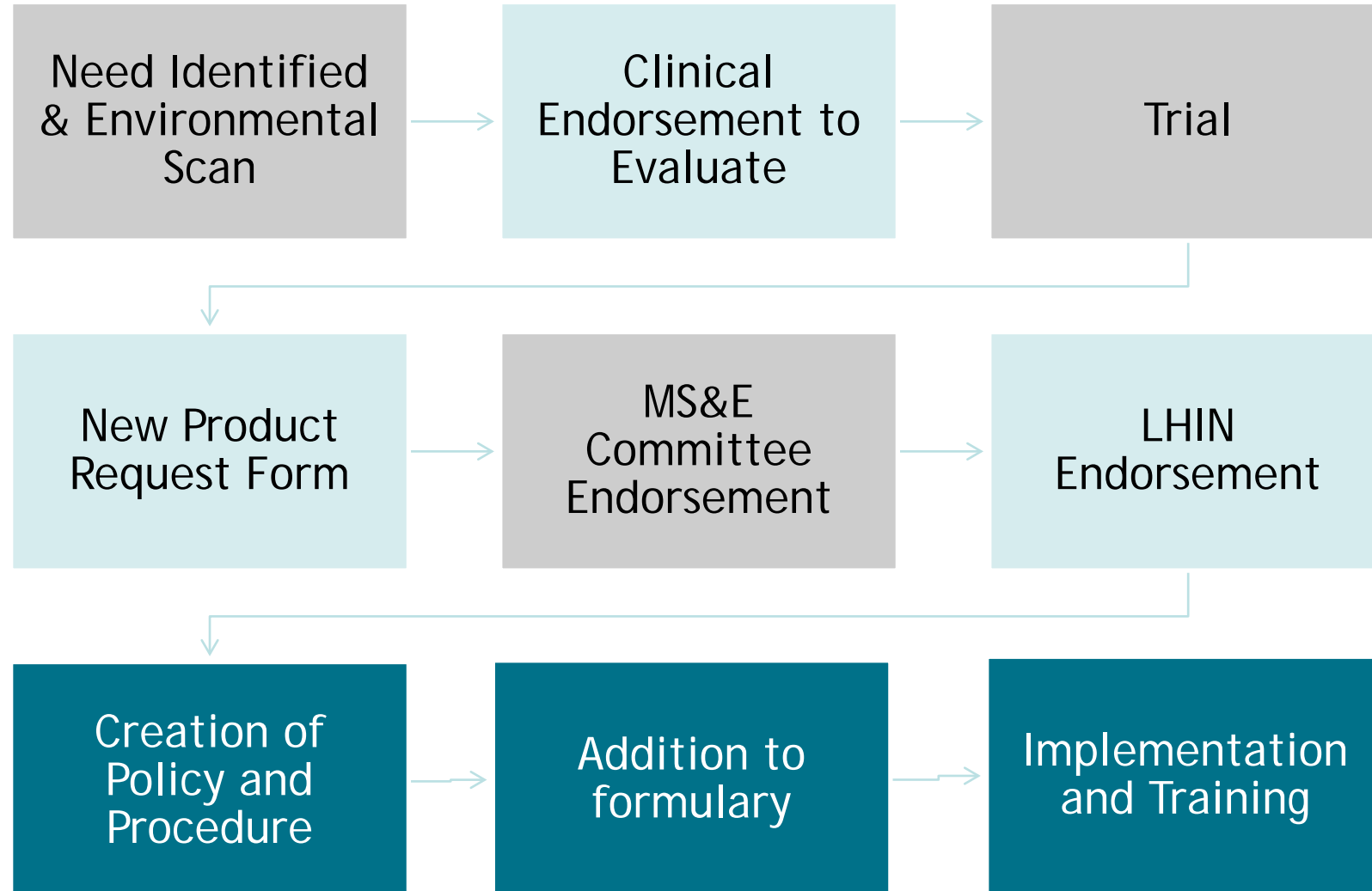
1. **Alignment of technology and priorities.** Ensure the innovative technology addressed a strategic priority for the Mississauga-Halton population.
2. **Structured collaboration.** Facilitate a collaborative and shared approach with a frontline service provider organization.
3. **Comprehensive measurement.** Evaluate based not only on price, but include clinical efficacy and measures of value such as reduced service use and patient satisfaction.
4. **Strategic procurement and process improvement.** Engage a broad range of key stakeholders in defining and refining the MH CCAC procurement approach and creating an evidence-informed algorithm to guide future additions to the medical supply and equipment formulary.

Thank you to our SPOTLIGHT ON INNOVATION sponsor Perfuse Medtec Inc., the distributor of geko™. A true wound care innovation, these self-contained devices increase venous return by over 100 percent, arterial flow by over 75 percent and microcirculatory flow by one percent. The geko™ device activates nature's mechanism (effort muscle pump) once per second to heat wounds and modulate edema. It replicates the blood pumping action (the peristalsis) of continuous walking.

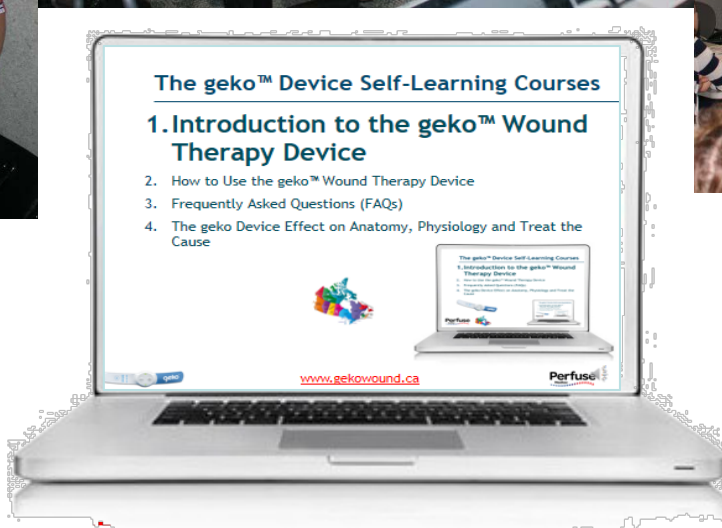
For more information on the geko™ device and its application, visit www.gekowound.ca

Perfuse Medtec

New Product Process



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



The geko™ Wound Therapy Device: Resources for Implementation

Perfuse **geko™**

DO YOU HAVE A WOUND ON YOUR LEG OR FOOT?

Ask your nurse about the geko™ device to:

- Increase blood circulation
- Promote wound healing.

You may be eligible to use the geko™ device, along with your compression bandages and/or off-loading shoe, to help heal your wound.

Visit www.gekowiedes.com for more information



geko™ Wound Therapy
Provides an increased blood circulation to promote wound healing naturally from the inside

Perfuse **geko™**

A Paradigm Shift for Wound Care

Dear Doctor,

If you have patients with a venous, mixed arterial/leg ulcer or diabetic foot ulcer, you may be able to receive the geko™ wound therapy device as part of their care through the Perfuse Medical device and community Care program. If this is already existing, please contact your local Perfuse Medical representative for more information. If not, you can make a new referral.

Here is a brief overview of the geko™ device benefits for wound healing of leg/foot ulcers:

- The geko™ device increases blood circulation to the skin and wound bed.
- The geko™ device increases blood circulation to the skin and wound bed.
- The geko™ device increases blood circulation to the skin and wound bed.

Attached to this letter are the geko™ wound therapy device which provides additional information about the geko™ device and how to use it. Please contact your office for patients. Use the website www.gekowiedes.com as well as an extended delivery kit to support the device. Please refer to the geko™ device to learn more about the geko™ device and how to use it.

It would be happy to meet you and demonstrate the geko™ device and answer any questions you may have.


Perfuse **geko™**

Primary Care Mailers

Perfuse **geko™**

Wound Therapy

Providing increased blood circulation to promote wound healing naturally from the inside



Perfuse **geko™**

Brochure

Perfuse **geko™**

DO YOU HAVE A WOUND ON YOUR LEG OR FOOT?

Ask about the geko™ device to increase circulation and promote wound healing.

Contact Us:
Information / Demonstrations:
email: info@perfusemedtec.com
Ordering: email: order@perfusemedtec.com
Supported by several peer reviewed papers; please visit our website: www.gekowiedes.com

Distributed in Canada by:
Perfuse **geko™**

Flyers for Primary Care Offices

Wound Clinic Posters

The geko™ Device Self-Learning Courses

1. Introduction to the geko™ Wound Therapy Device
2. How to Use the geko™ Wound Therapy Device
3. Frequently Asked Questions (FAQs)
4. The geko™ Device Effect on Anatomy, Physiology and "Treat the Cause"



www.gekowiedes.com

On-Line Learning Management System

geko™

Wound Healing

Perfuse Medical

Website: www.gekowiedes.com

Request for Orders

geko™ 2 Device Evaluation Eligibility Checklist

Patient Name: _____ Date: _____

Signature: _____

1. Has the patient been treated with the geko™ device in the past? ☐ Yes ☐ No

2. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

3. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

4. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

5. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

6. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

7. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

8. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

9. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

10. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

11. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

12. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

13. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

14. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

15. Is the patient currently being treated with the geko™ device as an adjunctive therapy? ☐ Yes ☐ No

Signature of Physician/ Nurse/ Designation: _____ Print Name: _____ Date (mm/yyyy): _____


Draft Eligibility Screens

geko™

Patient Information Leaflet

Wear the device 6 hours a day for 6 days a week. Follow any additional instructions from your healthcare provider.

1. Prepare the skin and apply the device.
 - Clean: pat dry skin on the inside of the leg, below and behind the knee.
 - The long white and green behind your knee: the blue and goes to the front of your knee, as shown in the above illustration.
 - Find the location mark that the nurse has drawn on your leg to position the geko™. The dashed line goes over the CENTRE of the round hole (blue head).
2. Turn the device on and choose the best setting:
 - Press the "1" button. Each press of the "1" increases the power setting.
 - Your foot should move slightly upwards and outwards when your knee is bent.
 - Press the negative "-" button to reduce the setting. There are 10 simulation settings indicated by the number of flashes of the green light.
3. Sanitizing the device:
 - The device stops automatically after 6 hours. Press and hold either button down until the light stops flashing to turn the device off before then. Peel the strip or adhesive back slowly at a 30 degree to the leg. Use one finger of the other hand to "touch" the skin down as you remove it, rather than pulling the adhesive away from the skin. This will prevent damage to the skin.



Patient Instructions

geko™ **geko™**

geko™ Wound Therapy

Provides an increased blood circulation to promote wound healing naturally from the inside.

If you have patients with venous, mixed or diabetic foot ulcers whose WOUNDS ARE NOT REDUCED IN SURFICIAL AREA BY 50% AT 4 WEEKS OF TREATMENT... THEN WE HAVE A NEW PRODUCT THAT COULD HELP!


More information on using the geko™ Wound Therapy device is available at www.gekowiedes.com click on wound healing action.

Postcards

geko™

User Information Guide

For Health Care Professionals



Supported by several peer reviewed papers and the receipt of multiple awards including Best New Product or Service in Long Term Care, by the Ontario Long Term Care Association.

Perfuse **geko™**
For Canadian Use Only

HCP Instructions

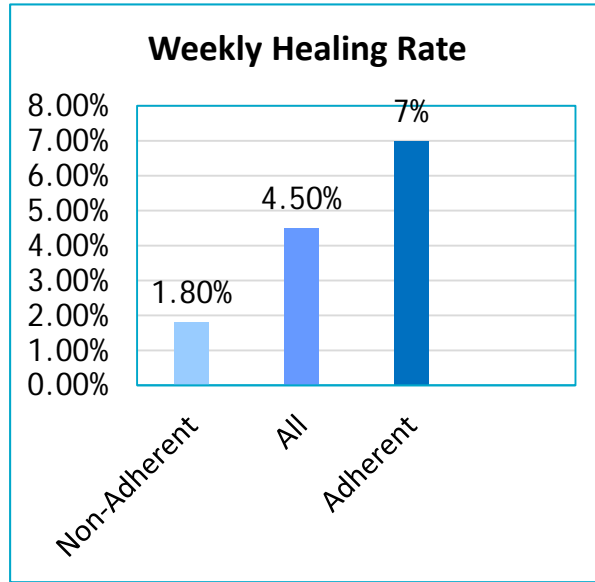
Contact us:
info@perfusemedtec.com
Orders: 1-888-244-5579

Spread

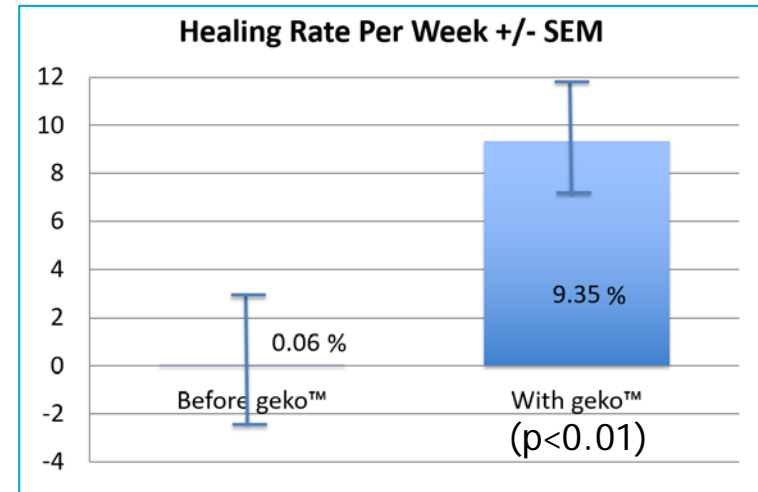
- **LHIN Interactive workshop:**
 - Reviewed the Mississauga Halton LHIN Home and Community Care experience resulting in the Canadian Home Care Association Spotlight on Innovation Award in 2016, and adding the device to their formulary.
 - Shared policies, procedures, inclusion/ exclusion criteria, strategies 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.



Experience with Chronic Non-Healing Venous Leg Ulcers in Ontario LHINs:



ESC/HNHB



MH/SW

IWJ International Wound Journal
Explore this journal >

ORIGINAL ARTICLE

Refractory venous leg ulcers: observational evaluation of innovative new technology

Connie Harris, Amanda Loney, Jillian Brooke, Amanda Charlebois, Lucy Coppola, Sowmil Mehta, Norman Flett

First published: 30 June 2017 Full publication history

DOI: 10.1111/iwj.12766 View/save citation

Cited by (CrossRef): 0 articles Check for updates Citation tools

Am score

Early View

Browse Early View Articles Online Version of Record published before inclusion in an issue

IWJ International Wound Journal
Explore this journal >

ORIGINAL ARTICLE

Evaluation of a muscle pump-activating device for non-healing venous leg ulcers

Connie Harris, Rochelle Duong, Gwen Vanderheyden, Beth Byrnes, Renee Cattryse, Ava Orr, David Keast

First published: 2 August 2017 Full publication history

DOI: 10.1111/iwj.12784 View/save citation

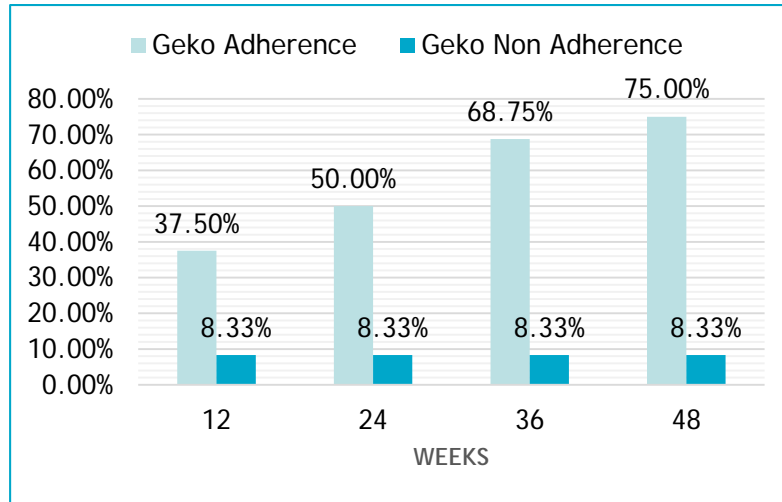
Cited by (CrossRef): 0 articles Check for updates Citation tools

Early View

Browse Early View Articles Online Version of Record published before inclusion in an issue

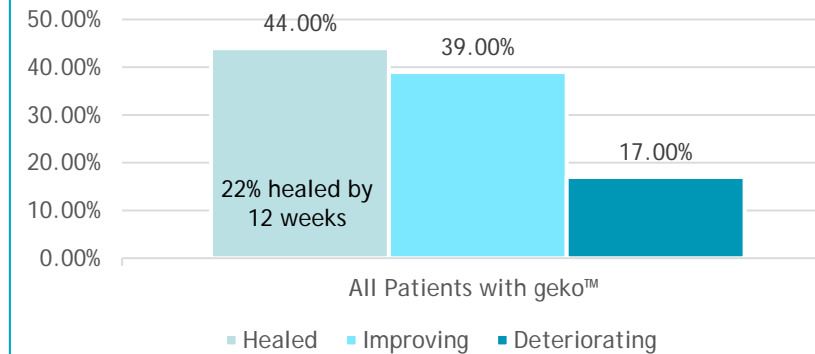
Experience with Chronic Non-Healing Venous Leg Ulcers in Ontario LHINs:

Cumulative Proportion Healed with geko™ and Best Practices



ESC/HNHB

All Patients with geko™
(ulcer healing status through 20 weeks)



MH/SW

IWJ International Wound Journal
[Explore this journal >](#)

ORIGINAL ARTICLE

Refractory venous leg ulcers: observational evaluation of innovative new technology

Connie Harris ✉, Amanda Loney, Jillian Brooke, Amanda Charlebois, Lucy Coppola, Sowmil Mehta, Norman Flett

First published: 30 June 2017 [Full publication history](#)

DOI: 10.1111/iwj.12766 [View/save citation](#)

Cited by (CrossRef): 0 articles [Check for updates](#) [Citation tools](#)

[Browse Early View Articles Online Version of Record published before inclusion in an issue](#)

IWJ International Wound Journal
[Explore this journal >](#)

ORIGINAL ARTICLE

Evaluation of a muscle pump-activating device for non-healing venous leg ulcers

Connie Harris ✉, Rochelle Duong, Gwen Vanderheyden, Beth Byrnes, Renee Cattryse, Ava Orr, David Keast

First published: 2 August 2017 [Full publication history](#)

DOI: 10.1111/iwj.12784 [View/save citation](#)

Cited by (CrossRef): 0 articles [Check for updates](#) [Citation tools](#)

[Browse Early View Articles Online Version of Record published before inclusion in an issue](#)

Case Study: Non-healing Venous Leg Ulcer

Community Care Patient History:

- Female patient with 20 year history of VLU, unable to tolerate compression, pain 10/10 during dressing change, 8/10 other times, refused ABPI measurements.
- Many advanced dressings utilized with no benefits
- Multiple wounds covered in fibrin/ slough with copious exudate over an area 85 cm²; daily dressing changes



Results with geko™ device:

At 12 weeks:

- 85% reduction in SA 12.1cm²
- Patient stopped geko™ at family request;
- Pain reduced to 3/10
- Nursing visits q 3 days
- Wearing high compression bandages.



Experience with the geko™ Device for Other Types of Lower Leg Wounds:

Based on data from Canadian/UK case studies, patients who may benefit from the geko™ device could include:

- Foot and ankle surgeries
- Total hip and knee replacements
- Surgical incisions
- Arterial Leg Ulcers
- Diabetic Foot Ulcers (with effective pressure offloading devices)
- Pressure Injuries (with effective pressure redistribution)
- Traumatic Wounds (pre-tibial injuries and skin tears)
- Veno-Lymphedema.

What's Next?



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



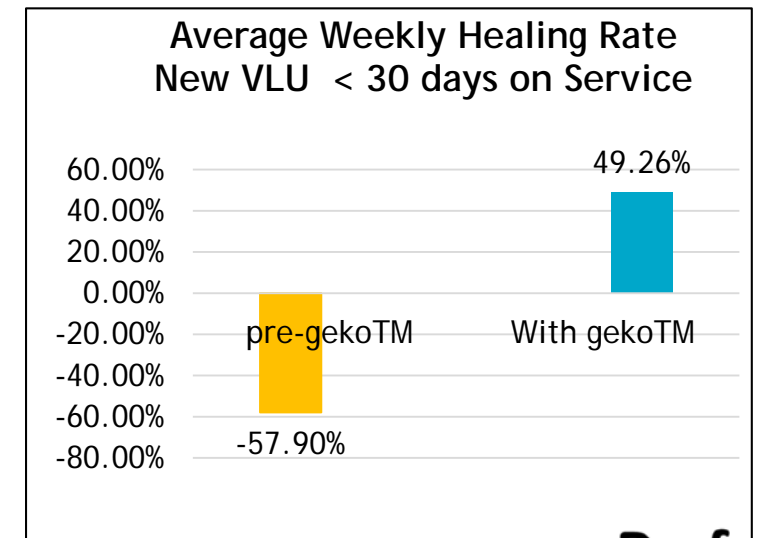
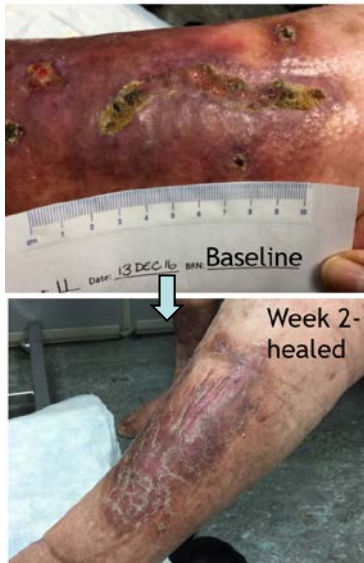
Experience with New VLUs <30 days on service: Preliminary Results

Community Care Patient History (WW CCAC/LHIN):

- 8 patients: Initial wound count: 7 patients with 1 wound each. 1 with multiple areas (3 measured)
- Largest wound 6.75cm² (SA=L x W) at baseline
- Average length of stay prior to geko™ implementation = 25.75 days
- Average weekly change in wound size pre-geko™ = -57.9% (increase) in Surface Area (range of -618% to 27.7%). 5 additional wounds documented at baseline in 3 patients.

Results with the geko™ device:

15 wounds closed - average of 2.6 weeks/wound OR 2.97 weeks per patient (range of= 5 days to 5.7 weeks)
Average weekly change in wound size = 49.26% reduction SA per wound OR 47.7% per patient (range of 17.5% to 100%).



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

Diffusion, Scaling up & Widespread Adoption

- Paradigm shift
- Clinical Guideline Integration

Health System Needs & Priorities

Implementation & Early Adoption

Proof of Value and Reimbursement

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

Innovation Journey

Partnership Capacity Building

- CHCA, Wounds Canada, CAET
- Workshops

Pilot Testing Commercialization

Proof of Relevance

- Clinician Interest
- Patient Evaluations - what is the best fit?

Research & Development

Proof of Concept

- New Therapy