

## Wound Care Evidence Summary

Name of Study	Number of Patients	Setting	Details	Average Weekly Mean Healing Rate Pre the geko™ device	Average Weekly Mean Healing Rate with the geko™ device	Additional Information
<b>Problematic, Hard to Heal/Non-Healing Leg Ulcers – Cumulative total 65 patients</b>						
<i>Harris, C. Duong, R., et al. (2017). Evaluation of a muscle pump-activating device for non-healing venous leg ulcers</i>	12	Home Care	<ul style="list-style-type: none"> <li>&gt;30 days on service with &lt; 30% reduction/wound size using best practice</li> <li>100% wounds deemed non-healing, 91% used compression therapy, 100% used advanced wound products</li> <li>9 VLU/ 3 veno-lymphedema</li> </ul>	0.06% weekly	<ul style="list-style-type: none"> <li>9.35% weekly (p&lt;0.01)</li> </ul>	<ul style="list-style-type: none"> <li>22% healed in 11 weeks, 44% cumulative healed in 20 weeks</li> <li>2 patients previously non-adherent to compression could now undergo high compression</li> <li>3 patients placed in optimal compression as the geko™ device decreased pain</li> </ul>
<i>Harris, C. Loney, A., et al. (2017). Refractory venous leg ulcers: bservational evaluation of innovative new technology</i>	11	Home Care	<ul style="list-style-type: none"> <li>107-year combined history recalcitrant leg ulcers</li> <li>64% using compression, 100% using advanced wound dressing</li> </ul>	N/A	<ul style="list-style-type: none"> <li>4.5% weekly -all patients</li> <li>7.0% weekly adherent to the geko™ device</li> <li>1.8% weekly non-adherent to the geko™ device</li> </ul>	<ul style="list-style-type: none"> <li>Adherent/best practice 37% healed at 12 weeks, 50% healed at 24 weeks, 69% healed at 36 weeks, 75% healed at 48 weeks</li> <li>Wounds were deemed never to heal</li> <li>Decreased nursing visits after 3-4 weeks from Q2 days to twice a week</li> </ul>
<i>Harris, C., Ramage, D., et al. (2019). Using a muscle pump activator to stimulate healing for non-healing lower leg wound in LTC residents</i>	9	Long Term Care	<ul style="list-style-type: none"> <li>3 residents (DFU), 4 (VLU) with lower leg edema, 2 (PI) on heal and foot</li> <li>All wounds deemed non-healing with a combined history 13.7 years</li> </ul>	-1.26% weekly (increase)	<ul style="list-style-type: none"> <li>11.5% weekly mean healing rate adherent to the geko™ device</li> <li>- 9.25% (decrease) non-adherent to the geko™ device</li> </ul>	<ul style="list-style-type: none"> <li>Average time to heal 10 weeks</li> <li>Of the 7 who met the inclusion criteria, those adherent to the geko™ device, 4 healed 100%, one healed 90%</li> <li>2 residents not included in data healed in 17 weeks both with unstageable PI</li> </ul>
<i>Harding, K, Jones, N., et al. (2018). Evaluating geko™ device on lower limb wounds of differing etiology</i>	25	Clinic	<ul style="list-style-type: none"> <li>(VLU), (MLU) (DFU) wounds</li> <li>&gt;3-month duration</li> <li>Standard of care plus the geko™ device for 8 weeks</li> </ul>	N/A	<ul style="list-style-type: none"> <li>Overall mean 7.6cm<sup>2</sup> decrease in wound surface area in 8 weeks</li> <li>21% increase in granulation tissue</li> </ul>	<ul style="list-style-type: none"> <li>52% reported decrease in pain</li> </ul>
<i>Adjunctive Therapy to Speed Healing (2018) Waterloo Wellington HCCSS Stream 1 – unpublished</i>	8	Home Care	<ul style="list-style-type: none"> <li>&gt;30 days on service</li> <li>Average length of stay prior to the geko™ device implementation = 42.5 weeks</li> </ul>	-3.04% weekly (increase)	6.5% weekly	<ul style="list-style-type: none"> <li>Lymphedema patient had remarkable reduction in edema at 10 days (no change to compression)</li> </ul>
<b>Early Intervention – Cumulative total 39 patients</b>						
<i>Adjunctive Therapy to Speed Healing (2018) Waterloo Wellington HCCSS Stream 2. Poster</i>	10	Home Care	<ul style="list-style-type: none"> <li>Newly admitted patients VLU</li> <li>&lt;30 days on service</li> <li>Average length of stay 22.6 days</li> </ul>	-79.29% weekly	<ul style="list-style-type: none"> <li>36.54% weekly difference in healing rate statistically significant (p=0.0003)</li> </ul>	<ul style="list-style-type: none"> <li>Average healing time 3.03 weeks/patient</li> <li>20% healed/ 1 week, 30% healed/2 weeks, 70% healed/4 weeks, 80% healed/8 weeks, 90% healed/ 9 weeks</li> <li>Estimated cost savings \$2600/patient</li> </ul>
<i>Rabley-Kach, C., Duong, R., et al. (2021). Early intervention with geko™ device for VLUs Predicted to not heal within 24 weeks. Poster</i>	11	Clinic	<ul style="list-style-type: none"> <li>Used Validated Leg Ulcer Risk Assessment Tool (VLURA) to determine risk of non-healing</li> <li>Moderate to high-risk the geko™ device applied</li> <li>Low scores re-assessed at 2 weeks, changed to moderate started on the geko™ device</li> </ul>	New wounds	10.5% weekly	<ul style="list-style-type: none"> <li>Delays due to waiting vascular studies</li> <li>10 out of 11 patients experienced increase risk scores in 2 weeks (btw initial and follow-up)</li> <li>Prior to use of VLURA tool the geko™ device initiated btw 90-100 days</li> <li>Pre-geko™ device average MH VLUs closed in 15 weeks</li> <li>With the geko™ device healing time 12 weeks</li> </ul>
<i>Murray, H. (2021). How A Change in Practice in a Nurse-led Wound Clinic: Improved Venous Leg Ulcer Healing Outcomes. Poster</i>	18	Clinic	<ul style="list-style-type: none"> <li>Patients with VLUs had the geko™ device added as soon as possible following admission</li> </ul>	15 weeks is average time to close a VLU in MH	<ul style="list-style-type: none"> <li>6.7 weeks was average time to close with the geko™ device</li> <li>55% decrease in time to wound closure</li> </ul>	<ul style="list-style-type: none"> <li>Average the geko™ device initiation time pre-evaluation was 14.3 weeks</li> <li>Average the geko™ device initiation time during evaluation was 3.8 weeks</li> <li>Faster healing times allowed patients early discharge</li> </ul>

## Microcirculatory increase in Arterial and Venous Velocity and Pulsatility to the wound bed and edge in Patients with VLU & ALU

Author	Number of Patients	Setting	Aim	Details	Results using the geko™ device	Comments
<i>Das SK et al. (2020). Neuromuscular stimulation of the common peroneal nerve increases arterial and venous velocity in pts. With venous leg ulcers</i>	14 (VLU)	Acute Care-Wound Clinic	To determine if the geko™ device increases venous and arterial flow in patients with VLUs	<ul style="list-style-type: none"> <li>Subjects who had a chronic venous leg ulcer (i.e. &gt;6 weeks, CEAP classification of C6)</li> <li>All patients were determined by Duplex ultrasound to have venous insufficiency</li> </ul>	<p><b>Peak Arterial velocity:</b></p> <ul style="list-style-type: none"> <li>increased from 57 to 78 cm/s (P = .001) - sitting</li> <li>increased from 79 to 98 cm/s (P = .001) - recumbent</li> </ul> <p><b>Peak Venous velocity:</b></p> <ul style="list-style-type: none"> <li>increased from 10 to 33 cm/s (P = .001) - sitting</li> <li>increased from 14 to 47 cm/s (P = .001) - recumbent</li> </ul>	<ul style="list-style-type: none"> <li>Exercise (toe raises) has been used with some success for treating VLUs however adherence is poor. The geko™ device therapy is equivalent to the blood flow generated by over 7 hours of continuous walking</li> </ul>
<i>Das SK et al. (2021). Microcirculatory changes in venous leg ulcers using intermittent electrostimulation of the common peroneal nerve</i>	16 (VLU)	Acute Care	To determine whether muscle pump activation increased microvascular flow in the wound bed and wound periphery of VLUs	<ul style="list-style-type: none"> <li>Presence of a hard-to-heal VLU (i.e., clinical etiological-anatomical- pathophysiological (CEAP) classification of C6 (active venous ulcer)) and &lt;10cm in max diameter</li> <li>Microcirculatory flow in both the wound bed and the periwound area were measured using laser speckle contrast imaging (LSCI) (moorFLPI-2TM, Moor Instruments Ltd., UK)</li> </ul>	<ul style="list-style-type: none"> <li><b>Microvascular flux</b> increased by a mean 27% (p=0.014) in the wound bed and by 34% (p=0.004) in the periwound area</li> <li><b>Wound bed pulsatility</b> increased by a mean 170% (p&lt;0.001) and</li> <li><b>Pulsatility increased</b> to 173% (p&lt;0.001) in periwound area</li> </ul>	<ul style="list-style-type: none"> <li>Electro activation of the muscle pump results in a considerable increase in perfusion to both the wound bed and to the periwound area</li> <li>Continuous flux and increased pulsatility are considered vital to wound healing</li> </ul>
<i>Bosanquet, Harding,K., et al. (2020). Microcirculatory Flux and pulsatility in arterial leg ulcers is increased by intermittent neuromuscular electrostimulation of the common peroneal nerve</i>	8 (ALU)	Outpatient wound clinic	To determine if microcirculatory flow to the wound bed and edge is augmented in patients with arterial ulcers had when using the geko™ device	<ul style="list-style-type: none"> <li>Standard compression is contraindicated for pts with ALUs and some are not amenable or unfit for revascularization, there is a need for alternative devise or strategies</li> </ul>	<ul style="list-style-type: none"> <li>NMES increased wound bed flux by a mean of 64% (P = 0.0005), and pulsatility by a mean of 452% (P=0.004)</li> <li>Peri-wound area flux increased with use of the device by a mean of 37% (P = 0.02), and pulsatility by a mean of 188% (P = 0.002)</li> </ul>	<ul style="list-style-type: none"> <li>Many wound treatment regimens i.e., NPWT, alternating positive pressure therapy, ultrasound therapy, and other energy-based modalities is to generate pulsatile flow</li> <li>Flux at the wound edge has proved especially predictive of healing</li> <li>Pulsatile flow keeps the peripheral circulation open and promotes extracellular fluid exchange</li> </ul>

## Randomized Control Trials - London Health Sciences

Author	Number of Patients	Setting	Aim	Details	Results using the geko™ device	Comments
Shahid, A. Sener, A., et al. (2019). <i>Use of a muscle pump activator leads to improved lower limb edema, lower limb blood flow, and urine output compared with standard ted stockings and compression devices following kidney transplant: a randomized controlled trial</i>	118	Acute Care Transplant Unit	To evaluate the effects of using TED stockings and (IPC) vs. Muscle Pump Activator (MPA) on limb edema	<ul style="list-style-type: none"> <li>Single-center randomized controlled trial</li> <li>118 patients were randomly assigned to wear TED + IPC (n = 64) or the MPA device (n = 54) from postoperative days 1 to 6</li> <li>Measured patients' weight, lower leg and thigh circumferences, urine output and patient satisfaction</li> <li>Ultrasonography of the allograft was also measured POD1-5</li> </ul>	<ul style="list-style-type: none"> <li>Ultrasonography showed higher femoral vein velocities in the MPA group vs. TED + IPC group (0.5 [SD, 0.2] cm, P &lt; .001)</li> <li>The mean total urine output in 6 days was higher in the MPA group than the TED + IPC, P = .05), which corresponded to large change in TED + IPC weight of 6.2 kg vs 2.1 kg in the MPA group (P = .04)</li> <li>Significant increase in calf and thigh circumference in the TED + IPC group but not in the MPA group (2.3 [SD, 1] cm vs 0.25 [SD, 0.8] cm, respectively, P &lt; .002)</li> </ul>	<ul style="list-style-type: none"> <li>Patients were more satisfied with use of MPA device than TED + IPC</li> <li>Leg edema significantly lower in the MAP group vs. TED + IPC group</li> </ul>
Shahid, A. Sener, A., et al. (2019). <i>The impact of a muscle pump activator on incisional wound healing compared to standard stockings and compression devices in kidney and kidney-pancreas transplant recipients: A randomized, controlled trial</i>	104	Acute Care Transplant Unit	To evaluate the impact of TED + IPC vs. muscle pump activator (MPA) on incisional wound healing in kidney and simultaneous pancreas- kidney (SPK)	<ul style="list-style-type: none"> <li>Single-center, open-label, randomized, clinical trial</li> <li>Postoperative outcomes, and incisional wound images were taken on postoperative days (POD) 3, 5, and 30, and assessed using the validated Southampton Wound Care Score</li> <li>Patient comfort between the two groups was also compared</li> </ul>	<ul style="list-style-type: none"> <li>MPA group had a significant improvement in wound healing on POD 3 (p=0.04) that persisted until POD 5 (p=0.0003)</li> <li>The rate of complex wound infections was significantly greater in the TED + IPC group compared to the MPA group (29% vs. 12%, respectively; p=0.03)</li> <li>MPA device had a cumulative positive comfort feedback of 64% vs. TED + IPC's 14%. Additionally, the discomfort percentage for the MPA device was 13% vs. 57% for TED + IPC (p&lt;0.003)</li> </ul>	<ul style="list-style-type: none"> <li>Enhancing blood flow to a surgical site is known to improve wound healing. Postoperative fluid overload is common following renal or SPK transplantation to ensure adequate vascular pre-load to the graft</li> <li>This leads to significant edema, which could compromise microcapillary blood flow to the wound</li> </ul>
Xie W, Levine MA, Sener, A., et al. (2021). <i>Daily use of a muscle pump activator device reduces duration of hospitalization and improves early graft outcomes post-kidney transplantation: A randomized controlled trial</i>	221	Acute Care Transplant Unit	To evaluate the effects of TED+IPC vs. muscle pump activator (MPA) devices on factors that could reduce postoperative complications and duration of hospitalization	<ul style="list-style-type: none"> <li>Single-center, prospective, randomized, controlled trial, 221 kidney and SPK transplant recipients were randomized to either wearing TED+IPC or MPA for six days postoperatively</li> <li>Groups were compared on postoperative urine output, lower limb edema, weight, days in hospital, mobility, serum creatinine, delayed graft function, need for dialysis, and lower extremity blood flow</li> <li>The surgical team was blinded to patient's group allocation at the time of surgery</li> </ul>	<ul style="list-style-type: none"> <li>Mean urine output in pts with MPA was greater than pts in IPC + TED group (15.99L vs. 12.6L respectively, p=0.003)</li> <li>MPA group experiences higher femoral vein velocity (18.9cm/sec vs 14.41cm/sec respectively, P =0.001)</li> <li>Calf circumference was significantly lower in the MPA group vs IPC + TED group (2.5 cm vs. 3.6 cm respectively P=0.001)</li> <li>MPA group experienced shorter hospitalization vs IPC +TED (8.15 days vs 9.36 days respectively, (p=0.038)</li> </ul>	<ul style="list-style-type: none"> <li>Improved blood flow to the renal allograft with higher peak velocity in the renal arcuate artery (p=0.001)</li> <li>Higher femoral vein velocity (P=0.001)</li> </ul>

## Randomized Control Trial - Hard to Heal Venous Leg Ulcers

Author	Number of Patients	Setting	Aim	Details	Results using the geko™ device	Comments
<i>Bull RH, Clements D, Collarte AJ, Harding KG. The impact of a new intervention for venous leg ulcers: A within-patient controlled trial. Int Wound J. 2023;1-9. doi:10.1111/iwj.14107</i>	51	Wound clinic	Comparing the rate of wound margin advance for VLU receiving 12 hours per day using intermittent stimulation of the common peroneal nerve in addition to compression, compared with compression alone.	<ul style="list-style-type: none"> <li>60 pts in wound clinic setting with VLUs were randomized. 9 pts were withdrawn post-randomization. 2 groups (51): 1 to receive SOC (n=22) multi-layer compression bandaging, the other to receive a Muscle Pump Activator (MPA) (n=29) for 12 hrs/day +SOC</li> </ul>	<ul style="list-style-type: none"> <li>The SOC cohort showed no significant difference between run-in and treatment phases</li> <li>A substantially greater proportion of MPA patients healed completely</li> <li>Reduction in VAS pain score was greater for pts who receive MPA when compared with pts who received SOC only</li> <li>VCSS shows an improvement for SOC plus MPA when compared with SOC alone</li> </ul>	<ul style="list-style-type: none"> <li>In this self-controlled study, the addition of Intermittent MPA of the common peroneal nerve over a 4-week period more than doubled the rate of wound-margin advance (WMA) towards the centre of the wound relative to a 4-week run-in period with compression alone (P = 0.016). This rate of healing was also calculated using the Percentage Area Reduction method (PAR) and the same results were seen, the rate of healing more than doubled (P = 0.011). In contrast, the SOC cohort maintained the same healing rate throughout the run-in and treatment phases of the study. This suggests that subjects' wounds were not at different stages of healing throughout the trial.</li> </ul>

## Randomized Control Trial - Hip Replacement

<i>Wainwright TW, Burgess LC, Middleton RG. (2018) A feasibility randomized controlled trial to evaluate the effectiveness of a novel neuromuscular electrostimulation device in preventing the formation of edema following total hip replacement surgery</i>	40	Acute Care Orthopedic	To investigate the role of neuromuscular electrical stimulation (NMES) in preventing edema following total hip replacement (THR)	<ul style="list-style-type: none"> <li>Single-center, randomized open label control trial, feasibility study</li> <li>Patients randomized to wear either NMES device (N=20) or compression stockings (N=20) continually from post-surgery until discharge</li> <li>The main outcome was to measure lower leg edema</li> <li>Assessed by taking measurements of the circumference of the leg on the operated leg and non-operated leg, pre-operatively, post-operatively, at two days post operatively and every day until discharge</li> <li>Secondary outcomes to measure adverse events, the presence of asymptomatic and symptomatic DVT</li> </ul>	<p>No significant differences between pre and post op swelling in the legs before application of NMES or compression</p> <p><b>Change in knee circumference operated leg</b></p> <ul style="list-style-type: none"> <li>NMES group 1.3 cm ±0.2 cm, compression stockings 2.4 cm±0.5 cm (p = 0.02)</li> </ul> <p><b>Change in thigh circumference operated leg</b></p> <ul style="list-style-type: none"> <li>NMES group 1.5 cm ±0.3cm, compression stockings group 2.9 cm±0.6 cm (p = 0.02)</li> </ul> <p><b>Change in knee circumference non-operated leg</b></p> <ul style="list-style-type: none"> <li>Difference at discharge between NMES group (0.25 cm±0.1 cm) and compression stockings group (0.43 cm±0.2 cm) was significant (p = 0.016)</li> </ul> <p><b>Change in thigh circumference non-operated leg</b></p> <ul style="list-style-type: none"> <li>Difference at discharge between NMES group (0.1 cm±0.3 cm) and compression stockings group (0.75 cm±0.3 cm) was highly significant (p = 0.006)</li> </ul>	<ul style="list-style-type: none"> <li>The NMES device performed significantly better than compression stockings in treating post-operative oedema of the nee and thigh that occurs following HR in both the operated and non-operated legs</li> <li>NMES is a safe and well tolerated lternative to compression stockings and should be considered a part of DVT prophylaxis</li> </ul>
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## Randomized Control Trial - Hip Replacement

Author	Number of Patients	Setting	Aim	Details	Results using the geko™ device	Comments
<p>Wainwright T, Burgess L, Middleton R (2020)  <i>A Single-Centre Feasibility Randomised Controlled Trial Comparing the Incidence of Asymptomatic and Symptomatic Deep Vein Thrombosis Between a Neuromuscular Electrostimulation Device and Thromboembolism Deterrent Stockings in Post-Operative Patients Recovering From Elective Total Hip Replacement Surgery</i></p>	28	Acute Care Orthopedic	To assess the feasibility the geko™ device compared to compression stockings (anti-embolism stockings), in patients recovering from hip replacement surgery	<ul style="list-style-type: none"> <li>Single-centre, randomised, open-label study; Primary outcome measure was presence of symptomatic or asymptomatic DVT at 48 hrs. post op and on same day of d/c</li> <li>Secondary objectives were to compare the levels of lower-limb edema, muscle function, hip range of motion, TUG scores and hemodynamic responses to those with compression stockings vs. the geko™ device (NMES)</li> <li>Pts. Were required to wear either NMES or compression 48 hrs post-op and then a min of 4 hours per day until d/c (POD 4)</li> </ul>	<p><b>DVT Outcome:</b></p> <ul style="list-style-type: none"> <li>In the compression stockings group, two cases of asymptomatic DVT were identified by Duplex ultrasound at 48 hours post-surgery</li> <li>No cases were found in the NMES group</li> </ul> <p><b>Edema- Mean change in ankle circumference:</b>            Postop: NMES (-0.11) vs. Compression (0.23) p= 0.22            POD 1 NMES (-0.36) vs. Compression (0.50) p=0.003            Discharge: NMES (0.21) Compression (0.45) P=0.01</p> <p><b>Change in knee circumference operated leg</b>            Postop: NMES ( -0.25) vs. Compression (0.18) P=0.15            POD 1: NMES (-0.32) vs. Compression (0.64) p=0.001            Discharge: NMES (0.29) vs. Compression (1.32) P=0.04</p> <p><b>Blood flow:</b></p> <p><b>Non-operated leg:</b></p> <ul style="list-style-type: none"> <li>Venous velocity (NMES: 0.21cm/s ± 0.77, TEDS: -1.75cm/s ± 1.73 (p=0.01))</li> <li>Peak venous velocity (NMES: 2.37cm/s ± 3.89, TEDS: -3.58 ± 7.38 (p=0.04))</li> <li>Venous volume flow (NMES: 43.38 ± 157.01, TEDS: - 101.80 ± 157.64 (p=0.04))</li> </ul> <p><b>Operated leg:</b></p> <ul style="list-style-type: none"> <li>NMES significantly increased peak venous velocity in the operated leg (p=0.006), the compression stockings did not</li> <li>NMES significantly increased mean venous velocity (p=0.02), whereas no effect was observed for the compression stockings group</li> <li>NMES significantly increased venous volume flow (P&lt;0.001), whereas as no significant effect observed in compression stockings group</li> </ul> <p><b>Functional Outcome:</b></p> <ul style="list-style-type: none"> <li>The change in TUG scores also favoured the NMES group (NMES: 150 ± 152%, compression stockings: 363 ± 257% (p=0.03)), whereas no differences in sit-to-stand scores or hip range of motion were observed</li> </ul>	<ul style="list-style-type: none"> <li>Compression stockings were chosen as the comparator as they are used as standard care for the prevention of DVT in UK hospitals</li> <li>NMES group demonstrated a general trend of a decrease in leg volume from post-surgery to discharge, vs. leg volume largely remained static or showed more prolonged swelling for the compression group</li> </ul>

## Pilot Studies - Edema & blood flow

Author	Number of Patients	Setting	Aim	Details	Results using the geko™ device	Comments
<i>Mahmood I, Chandler H, Kottam L, Eardley W, Rangan A, Baker P (2019) Neuromuscular Electrostimulation Device Reduces Preoperative Edema and Accelerates Readiness for Theater in Patients Requiring Open Reduction Internal Fixation for Acute Ankle Fracture</i>	20	Acute Care Orthopedic	To investigate the use of NMES device to reduce pre-operative edema in uni-bi and tri-malleolar fractures and to assess the safety & tolerability of the device in this patient population	<ul style="list-style-type: none"> <li>A single-centre, feasibility, open-label comparison of a prospective cohort and retrospective case control pilot study</li> </ul>	<ul style="list-style-type: none"> <li>The mean time until swelling reduced to a level permitting surgery was 1.66 days (NMES) versus 3.66 days (control) (P=0.001)</li> <li>Overall 60% of participants were ready for theater after 2 days of treatment with the NMES device compared with 27% in the control group (P&lt;0.01)</li> <li>2 pre-operative bed days saved on average per patient using the geko™ device</li> </ul>	<ul style="list-style-type: none"> <li>The geko™ device demonstrated greater preoperative edema reduction when compared with a retrospective "standard care" control group</li> <li>The geko™ device is safe and well tolerated by patients with ankle fractures</li> <li>Independent health economic modeling suggests that the savings associated with this accelerated readiness for theater is £569 per patient or \$970 USD</li> </ul>
<i>Lavi S, Camuglia A, Alemayehu M, McLellan A, Wall S, Abu-Romeh N (2015) The Impact of Peripheral Nerve Stimulation on Coronary Blood Flow and Endothelial Function</i>	10	Acute Care Cardiovascular	A pilot study assessing the effect of the geko™ device on coronary artery blood flow and endothelial function	<ul style="list-style-type: none"> <li>London Health Science Centre, UH clinical pilot study site</li> <li>Included patients with symptomatic obstructive Coronary Artery Disease (CAD) undergoing Percutaneous Coronary Intervention</li> <li>Coronary flow dynamics were assessed invasively using Doppler flow wire at baseline and with nerve stimulation 2 mins (low) and 2 mins (max)</li> <li>Measurements were taken in the stenotic coronary artery and in a control vessel without obstructive disease</li> <li>At a separate visit, peripheral blood flow at the popliteal artery (using duplex ultrasound assessment) and endothelial function assessed by peripheral artery tonometry (PAT) were measured at baseline and after one hour of nerve stimulation</li> </ul>	<ul style="list-style-type: none"> <li>Compared to baseline, there was a significant increase in coronary blood flow as measured by average peak velocity (APV) in the control vessel with nerve stimulation (20.3 ± 7.7 to 23.5 ± 10 cm/s; p = 0.03)</li> <li>Non-significant increase in the stenotic vessel (21.9 ± 12 to 23.9 ± 12.9 cm/s; p = 0.23)</li> <li>Systolic blood pressure measurements in the stenotic vessel was 116 ± 22 mmHg and 128 ± 18 mmHg, with nerve stimulation, p = 0.007. Heart rate was 64.5 ± 8 bpm at baseline and 62.6 ± 8.8 bpm with nerve stimulation, p = 0.19</li> <li>Reactive hyperemia-peripheral arterial tonometry (RH-PAT) increased from 2.28 ± 0.39 to 2.67 ± 0.6, p = 0.045</li> <li>This effect is more prominent in non-stenotic vessels. Longer stimulation improved endothelial function as measured by RH-PAT (reactive hyperemia-peripheral arterial tonometry) index p=0.045</li> </ul>	<ul style="list-style-type: none"> <li>The geko™ device was associated with an improvement in coronary blood flow in the non-stenotic vessels</li> <li>Significant increase in systolic blood pressure during nerve stimulation may have contributed to the increase in coronary flow. This may be related to an increase in venous return</li> <li>Peripheral blood flow increased in pts with peroneal nerve stimulation</li> </ul>

### Problematic, Hard to Heal/Non-Healing Leg Ulcers

1. South West/Mississauga Halton HCCSS (LHIN): IWJ Paper: Harris C, Duong R, Vanderheyden G, Byrnes B, Cattrysse R, Orr A, Keast D. Evaluation of a muscle pump-activating device for non-healing venous leg ulcers. *Int Wound J* 2017; 14:1189–1198. Patients from both SW and MH C CAC's were included. Evaluation of a muscle pump-activating device for non-healing venous leg ulcers (wiley.com)
2. Erie St. Clair/Hamilton Niagara HCCSS (LHIN): IWJ Paper: Harris, C, Loney, A, Brooke, J, Charlebois, A, Coppola, L, Mehta, S, Flett, N. Refractory venous leg ulcers: observational evaluation of innovative new technology. *International Wound Journal*. 2017. 14;6: 1100-1107. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/iwj.12766/epdf>
3. Long Term Care IWJ Paper: Harris C, Ramage D, Boloorchi A, Vaughan L, Kuilder G, Rakas S. Using a muscle pump activator device to stimulate healing for non-healing lower leg wounds in long term care residents. *IWJ* 2019;16(1):266-274. Open access available at: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/iwj.13027>
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