Debilitating chronic veno-lymphoedema: using a muscle pump activator medical device to heal wounds and improve skin integrity

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Key words

Exudate, geko™ device, muscle pump activator, veno-lymphoedema

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Abstract

This case study describes the experience of adding a muscle pump activator medical device (geko™, Firstkind) to the care of a 66-year-old male with veno-lymphoedema and chronic renal failure, causing lower leg blistering resulting in wounds. He had received daily or twice daily dressing changes with frequent infections for 5 years, with bilateral amputation and hemodialysis predicted as eventual outcomes. Instead, his episodes of blistering with open wounds reduced, along with accelerated healing, a reduction in fibrotic oedema and a return to more normal skin integrity. His mobility and ankle range of motion rapidly increased. Additionally, his renal function improved during the treatment, with a reduction in serum creatinine to the point that hemodialysis was no longer being considered. The improvements in his skin integrity and level of pain, reduction in the incidence and severity of infections, increase in mobility, and activity and general quality of life were remarkable and unprecedented in our experience caring for patients with veno-lymphoedema.

Secondary lymphoedema is a progressive disease, causing accumulation of protein-rich lymphatic fluid in the interstitial spaces often in the arms or legs, due to failure of the lymphatic drainage system, caused by disease or iatrogenic processes, such as radiation/chemotherapy, trauma or complications of chronic venous insufficiency (veno-lymphoedema) (Raju et al, 2012). Its progress is marked by chronic swelling, localised pain, atrophic skin changes and secondary infections (Basta et al, 2014) which cause subsequent inflammation.

Over time, adipose tissue hypertrophy, fibrosis, disfigurement, and loss of function negatively impacting quality of life. There is no cure and it requires lifelong treatment (International Lymphoedema Framework [ILF], 2012). In addition to exercise and limb elevation, adjunctive therapies include complete decongestive therapy (CDT), simple lymph drainage (SLD), manual lymph drainage (MLD), or intermittent pneumatic compression (IPC) and compression bandaging or garments (Kayiran et al, 2017). However, many patients cannot access, afford or tolerate adjunctive therapies (ILF, 2012; Kayiran et al, 2017).

MPA evaluation

In the autumn of 2015, a new battery-operated, disposable muscle pump activator (MPA) medical device (geko™, Firstkind) was being evaluated for patients with recalcitrant venous leg ulcers. Applied to the fibular head and stimulating the common peroneal nerve once per second, it activates the leg and foot muscle pumps, resulting in increased venous, arterial and microcirculation to the legs and reduction of oedema (Ingves and Power, 2014; Ravikumar, 2015; Williams et al, 2015). The devices were provided at no cost by the Canadian distributor, Perfuse Medtec Inc. The methodology and results of the full evaluation have been published (Harris et al, 2017). This paper provides the details of one man's case study.

The patient

This 66-year-old man had significant bilateral skin breakdown on his lower legs and feet requiring daily to twice daily nursing visits for 5 years. Due to the frequent large blisters that formed, deroofed and created open wounds, bullous pemphigoid had been ruled out. He had brawny oedema to the knees bilaterally related to longstanding end-stage veno-lymphoedema, chronic renal disease and morbid obesity. His comorbidities included chronic obstructive lung disease and smoking; uncontrolled type 2 diabetes (HgA_{1c} 7.6% to 10.9%, FBG >12-18); with eventual dialysis predicted. He could

not elevate his legs to the level of his heart 50% of the day as advised by his physician, presumably based on Simon et al (2004), who recommended total leg elevation in hospital or lift them independently.

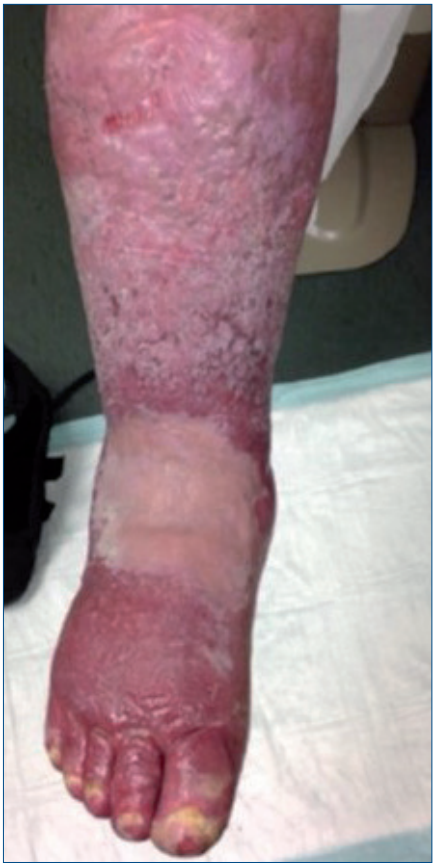
In the 12 months prior to the evaluation, he had three hospitalisations for cellulitis of the legs and sepsis with acute-on-chronic renal failure, including once with multiple maggots in the dressings and wound. The consulting surgeon anticipated eventual bilateral leg amputation. The patient was on 16 medications, of which only one (Atorvastin) lists peripheral oedema as a side effect, lacked sensation to touch to the legs, with chronic low back pain and leg pain varying in location, but 8–10/10 on a scale of 0–10 (10 being the worst). He described "stabbers of pain", which caused his legs to twitch and jump, waking him up in the night. He frequently over-medicated his analgesics (oxycodone/acetaminophen and gabapentin), leaving him with no analgesia until the scripts could be refilled at the appropriate time.

At the start of the evaluation, his Ankle Brachial Pressure Indices (ABPI) were 1.0 bilaterally, with biphasic wave forms. Compression was a single layer of tubular bandaging and liner providing less than 5–10 mm Hg and was often removed within hours due to pain. The skin on both feet was denuded with copious greenish serous exudate from multiple open areas on the toes, heels and both legs (*Figures 1 and 2*). Three de-roofed blisters on the lateral left leg were chosen as the primary wound. Unfortunately, no specific photographs or measurements of these blisters were recorded. He was started on a 30-day course of antibiotics. His pain was described as 8–10/10, despite his oral analgesia.

The plan was to cleanse the legs and wounds, apply a wound contact layer, hypertonic gauze and bulky dressing daily. The R-2 gekoTM devices were applied to both legs at the fibular heads at the maximum intensity setting (8), with no visible leg twitch. The devices were to be worn 6 hours per day, 5 days per week. Instruction was provided to him and his wife regarding correct placement, application and removal, and skin care.

Results

Although the initial open areas had closed by week 12, new blisters, such as those seen in *Figure 3* caused copious exudate, resulting in



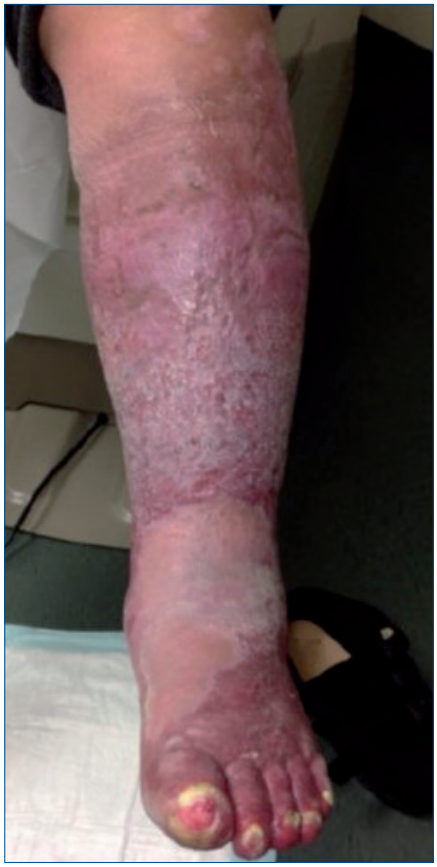
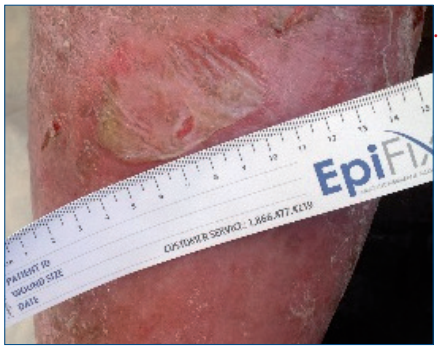


Figure 1 (above left). Right Leg and foot at baseline. Figure 2 (above right). Left leg and foot at baseline.



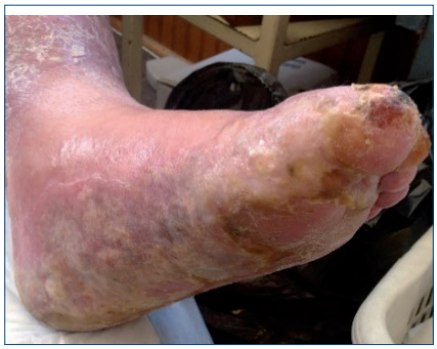
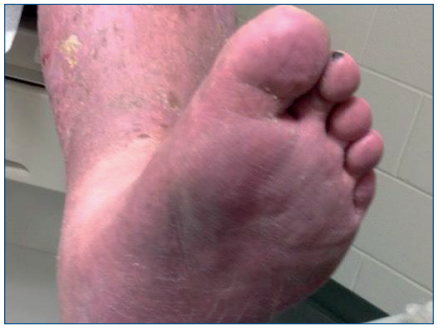


Figure 3 (above left). New blisters. Figure 4 (above right). Build up of devitalised skin on foot.

Table 2. Parameters of comparison.

Parameter	60 weeks pre-geko	60 weeks with geko 5 days per week/10–12 hours/day on average	52 weeks post-evaluation (geko used 24 hours/day ≈ twice weekly)
Infection in legs	Almost constant; 3 episodes cellulitis with sepsis; frequent IV Rx	2 infections requiring oral antibiotics	1 infection requiring oral antibiotics
Hospitalisations for leg infections	3	0	0
Nursing and Wound Care Specialist (WCS) Visits	400 nursing 11 WCS	319 nursing 16 WCS	137 nursing 5 WCS



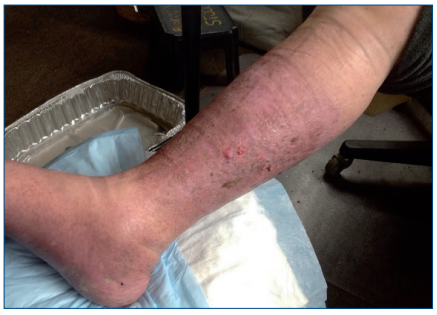


Figure 5 (top). Normal appearance of feet at 42 weeks. Figure 6 (below). Right leg at 55 weeks.

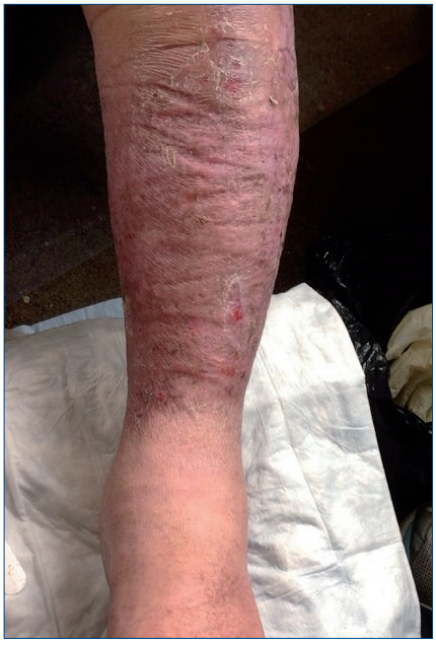


Figure 7. Left leg at 55 weeks.

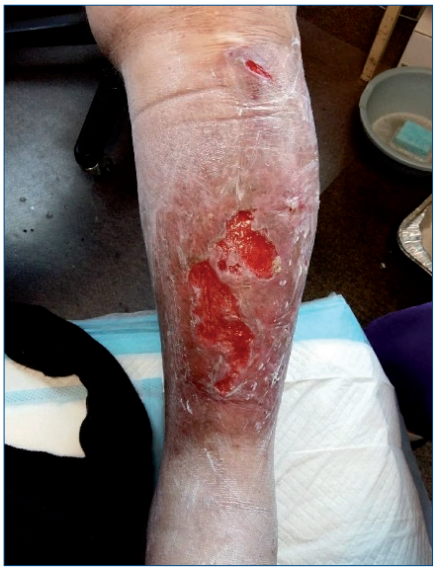


Figure 8. Left leg, 13 weeks post-evaluation.

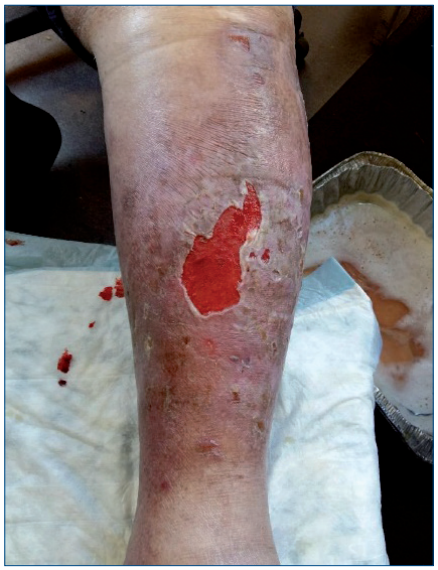


Figure 9. Left leg, 17 weeks post-evaluation.

such a buildup of dry skin on the feet by week 12 that he required a 2-hour debridement (*Figure 4*). He had difficulty discontinuing the devices independently after 6 hours of treatment, so by week 14, his wife applied them in the morning and removed when she returned home at night, thus increasing the treatment time. Although the formal evaluation concluded in April 2016, he wished to continue to further his beneficial response. The type of antimicrobial topical dressing changed several times, based on signs of superficial infection, exudate amounts and patient preference. By week 29, the left leg required dressings every 2 days, the right leg daily. Fewer dressing supplies were required. By 42 weeks, his feet and legs had a more normal appearance (*Figure 5*) and were almost unrecognisable as the same limbs by week 55 (*Figures 6 and 7*).

Nursing visits were eventually decreased to twice weekly and stopped the evaluation at 60 weeks. Although he understood that the devices could not be provided in perpetuity under the terms of the evaluation, he worried that his legs would deteriorate to the previous state. The wound care specialist nurse provided new devices to use if blisters recurred, which they did, but never to the degree they had before. In the next 12 months he used the devices on the affected (usually left) leg infrequently when large blisters opened. Wearing the device for 24 hours 2–3 days per week, the deroofed blisters would close quickly, as evidenced in *Figures 8* and *9*. The skin integrity did not return to the thickened state of before.

He continued to use the ReadyWrap® (L&R) compression wraps daily. The neuropathic pain was managed by Cymbalta 30 mg (2 x per day) and Lyrica 75 mg (2 x per day), and never returned to the previous level. Dressing changes were pain-free versus excruciating. Other comparisons of note were the decreased number of nursing visits, antibiotics and hospitalisation for his legs (*Table 2*). Dressing supplies were not tracked so economic analysis not possible.

The patient experience with the MPA device

The patient initially expressed uncertainty in his ability to heal and described his quality of life (QoL) as being 'terrible' (10/10), using a numeric 'Delighted to Terrible' scale. The wound prevented him from doing things that he liked to do. By week 6, he described satisfaction with his overall QoL as a 6/10 (with 0 being 'delighted'). He felt that there was improvement in his wounds and that they were in fact healable. At week 37, he was 'delighted' with the MPA devices, forgot that they were on, and offered to talk to anyone interested in his positive experience.

At 55 weeks, he described a 100% change to the condition of his legs. He said: "I can see and feel the difference, I couldn't even lift my legs onto the stool before. Now I can. My legs were 'alien skin', now they are softer. I didn't even have ankles before." He was pleased by the reduction in oedema in the legs and feet bilaterally, and his ability to wear compression wraps. He asserted: "I think that it was great, (it's) the only thing that really worked," noting improvements in his ability to perform daily activities and to join in activities he enjoyed prior to developing a venous leg ulcer, in the physical characteristics of the wound, and consequences of the wound, and his feeling of wellbeing. He was no longer upset by the look of his legs.

Discussion

The change to the appearance of his legs and feet, his mobility and his pain was surprising to all. The subtle changes from firm, fibrotic brawny oedema to softer, more pliable tissue with increased flexion

of the ankles and toes had started by week 2, long before his compression therapy was optimized at 46 weeks. A highly significant fibrinolytic effect has been demonstrated with the early geko device with a reduction in the Tissue Plasminogen Antigen (tPA) levels in the MPA-stimulated leg and arm ($P<0.001$) (Jawad, 2012), and a reduction in the level of Plasminogen Activator Inhibitor 1 (PAI-1) ($P<0.001$) in the treated limb in vascular patients (Barnes et al, 2016).

Theoretically, reducing plasma levels of PAI-1 is thought to slow the progression of chronic kidney disease (Eddy and Fogo, 2006) and may even result in a degree of disease regression. His tPA and PAI-1 levels were not being tracked, but his serum creatinine was. Normal serum creatinine levels for males are 70–120 µmol/L (The Kidney Foundation of Canada, 2019). His level was 222, 10 days prior to starting the evaluation, 199 at 6 weeks, 181 at 18 weeks (his lowest in 70 weeks) and 186 at week 45.

His wife stated that there was no further mention of dialysis during the years that he used the MPA device 5 days per week, although his blood sugars remained high and his cigarette smoking continued. The only medication changes during that time, other than one course of antibiotics, were for analgesia and anxiety. It is unclear what role the geko device played in his feeling of wellbeing and the lower serum creatinine levels; these are observations only and many other factors can affect renal function. A possible hypothesis suggested by his nephrologist is that patients with a lot of venous pooling in their legs could have improved renal perfusion through reducing the third spacing effects of pooling peripherally. After completing the evaluation, when he used the MPA devices sparingly for blisters, his serum creatinine levels gradually increased to 211 µmol/L at 4 months and 206 at 10 months. In late December 2017, he became septic from an undiagnosed bladder infection, suffered a stroke and sadly passed away.

Conclusion

The improvements in his skin integrity, level of pain, mobility and activity, and general quality of life were remarkable and unprecedented in our experience caring for patients with veno-lymphoedema. To the best of our knowledge, this is the first time that the MPA devices have been documented as a 'maintenance therapy' for wound care. Throughout his treatment, he expressed his wish to share his story with others so that they might also benefit. The care of patients with severe veno- lymphoedema may well be improved with the addition of this device.

Please note: visit *https://www.gekodevices.com/wp-content/uploads/2019/06/1145-Chronic-veno-lymph-PDF_V2.pdf* to view the study's evaluation results.

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