

**REVIEW ARTICLE**

# The muscle pump activator device: From evidence to lived experiences

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**Abstract**

A chronic wound is one that fails to progress through a normal timely sequence of repair, or in which the repair process fails to restore anatomic and functional integrity after 3 months. The most common chronic wounds include venous, ischaemic and mixed leg ulcers, diabetic foot ulcers and pressure injuries. Chronic wounds place immense physical and psychosocial burden on patients and exact heavy costs for healthcare systems, with many patients continuing to live with chronic wounds even after all management options have been exhausted. The muscle pump activator (MPA) device can be used to bridge this therapeutic gap. By stimulating the common peroneal nerve to activate venous muscle pump of the leg and foot, the MPA device increases blood flow to the lower leg and foot to improve conditions for healing. Currently, evidence in the literature exist to show that the MPA device improves wound outcomes over standard compression therapy, decreases edema and increases wound healing rates. In this review, we also present a series of chronic wound patients treated with the MPA device in multicentre clinics to demonstrate the ability of the MPA device to improve wound outcomes, reduce pain and edema and improve patient quality of life.

**KEYWORDS**

chronic wound, medical device, muscle pump activator, ulcer, wound healing

**Key Messages**

- The muscle pump activator (MPA) device has demonstrated efficacy improving the outcomes of patients living with chronic wounds, even in those recalcitrant to standard compression therapy
- Evidence in the literature has shown the MPA device to be efficacious in increasing blood flow to common chronic wound sites (lower leg and foot) and can be used alongside compression therapy to improve wound outcomes
- We report on 127 chronic wound patients in multicentre clinics demonstrating the effectiveness of the MPA device to improve wound healing outcomes, reduce pain and edema and enhance patient quality of life

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## 1 | INTRODUCTION

A chronic wound is one that fails to progress through a normal, orderly and timely sequence of repair, or in which the repair process fails to restore anatomic and functional integrity after 3 months.<sup>1</sup> The most common acute wounds are post-incision and trauma-induced, while the most common chronic wounds include:

- Venous, ischaemic and mixed leg ulcers (VLUs)
- Foot ulcers especially in persons with diabetes but also including neuropathy, ischaemia and neuroischaemic lesions with other associations
- Pressure injuries (PIs)

VLUs are most commonly caused by venous valve dysfunction that leads to elevated venous pressure, lower leg edema and subsequent deterioration of overlying skin. VLUs are typically localized in the gaiter region (lower third of calf) and are characterized as having ser-piginous margins and granulation tissue base that are often associated with pain.<sup>2</sup> VLUs are described according to the CEAP classification for venous disorders<sup>3</sup>:

- Clinical—telangiectasia, varicosities, anatomical, pathophysiology
- Aetiology—congenital, primary, etc.
- Anatomical—superficial veins, deep veins, etc.
- Pathophysiology—reflux, obstruction, etc.

Assessment of VLUs involves measuring the ankle-brachial pressure index (ABPI) or pulses assessed with an audible handheld doppler (AHHD).<sup>4</sup> The current standard of care for VLUs involves the use of compression therapy. If ABPI  $\geq 0.9$  or if multiphasic pulses (biphasic or triphasic) are heard on AHHD, then there is adequate blood supply for healing and full compression can be applied. However, if pulses are monophasic or absent, patients should be referred for sequential lower leg duplex doppler studies to rule out arterial disease. Deep clots often require ultrasound identification and possible anticoagulation. Mixed venous and arterial disease (ABPI  $\geq 0.5$ – $0.9$ ) requires modified compression, but with great caution if values are between 0.5–0.65.<sup>2</sup>

Ischaemic ulcers are caused by lack of arterial perfusion resulting in tissue necrosis. They are typically localized on the lower limb as this region is the furthest from the heart and especially vulnerable to poor circulation. Ischaemic ulcers are characterized as having well-defined borders with surrounding skin having a shiny appearance, cold temperature and dependent rubor/blanching on elevation. They are often associated with pain, especially at night. The most common sites include the toes,

heel and sides of the feet, and can arise because of microvasculature or macrovasculature dysfunction. This is often associated with intermittent claudication. Atherosclerosis and peripheral arterial disease are examples of diseases affecting the macrovasculature. Care for ischaemic ulcers involves addressing underlying cardiovascular risk factors (e.g., type 2 diabetes, smoking, hypercholesterolemia and hypertension), optimizing the wound environment through antimicrobial dressings and maintaining a clean dry environment in areas with ischaemic necrosis and eschar often with povidone-iodine until revascularization with dilation or bypass.<sup>5,6</sup>

Livedoid vasculopathy is the result of clotting in the very small peripheral vessels. This can lead to localized painful infarctions, a porcelain white atrophy of the skin and even small necrotic crust over new or active lesions. This is most common over the malleoli, but when also noted at the proximal dorsum of toes, it can indicate systemic involvement. This disorder responds to low-dose oral anticoagulation or pentoxifylline.<sup>7</sup>

Diabetic foot ulcers (DFUs) arise from neuropathy that is often present with a combination of poor glycemic control and type 1 or type 2 diabetes, and often suboptimal footcare. This ulcers are most commonly localized to the plantar weight-bearing aspect of the foot including the metatarsal heads (~80%), hammer toes and the heels. Evaluation of DFU involves three components<sup>8–11</sup>:

- Vascular: presence of micro-angiopathy and peripheral vascular disease, which can limit wound perfusion
- Infection: signs of covert infection (localized/superficial and any three of five NERDS criteria): Nonhealing,  $\uparrow$ Exudate, Red friable granulation, Debris, Smell; and signs of overt infection (surrounding/deep and any three of seven STONEES criteria):  $\uparrow$ Size,  $\uparrow$ Temperature, Os (probes to bone), New areas of breakdown, Edema/erythema,  $\uparrow$ Exudate, Smell.
- Pressure: this can be direct pressure—deep forces applied to the foot causing skin breakdown, with muscle and subcutaneous fat being most susceptible. Shear pressure is a deep force caused when the skin and bony skeleton move in opposite directions. With coexisting shear, the direct pressure required to cause injury is reduced. Superficially, friction can cause callus or blister formation.

One test frequently used in the diagnosis and management of diabetes is the HbA1c, that measures an individual's average blood glucose over a 90-day period. As per the Diabetes Canada guidelines, diabetes can be diagnosed at a HbA1c  $\geq 6.5\%$ , the target range for those living with diabetes is a HbA1c  $\leq 7.0\%$ , and individuals with diabetes are advised to maintain a blood pressure  $\leq 130/80$  mmHg.<sup>12</sup> In contrast, the World Health

Organization's (WHO) target for 2030, HbA1c for those living with diabetes is  $\leq 8\%$ , and in developing countries, the World Bank advises diabetic patients to maintain a target HbA1c  $\leq 9\%$  with blood pressure  $\leq 160/95$ .<sup>13,14</sup> The International Working Group on the Diabetic Foot has outlined the core principles for management of DFUs that include treatment of any infection, restoration of tissue perfusion, pressure offloading and ulcer protection including the preferred total contact cast, or a removable walker made irremovable. All other offloading options may be used based on system availability and patient preference.<sup>15</sup>

Pressure injuries (PI) arise from prolonged applied pressure on an area that interrupts blood flow. PIs are usually oval shaped and typically localized over bony prominences of the body, including the heel and ankle bones. Elderly, non-ambulatory patients are at highest risk of developing PIs.<sup>16</sup> However, postoperative bedridden patients wearing thromboembolic deterrent (TED) stockings are also at an increased risk for developing PIs, especially on the heels or dorsum of toes and these regions should be checked daily.<sup>17</sup> Care for PIs involves alleviating the pressure, managing necrotic tissue and optimizing the wound environment through reducing moisture and applying antiseptics proximal to the necrosis and in the toe webs to prevent bacterial or fungal infection.<sup>16</sup> Other sources of chronic wounds may be a result of trauma (e.g., falls and skin tears). The purpose of this review and case series is to synthesize available evidence on the use of the MPA device from the literature and present chronic wound patients treated with the MPA device in interprofessional wound care clinics.

## 2 | TREATMENT WHEN MANAGEMENT OPTIONS HAVE BEEN EXHAUSTED

Chronic wounds place immense physical and psychosocial burden on patients and exact heavy costs for health-care systems. While management strategies are in place for chronic wounds, many patients continue to live with chronic wounds even after all management options have been exhausted or may have contraindications to optimal standard of care. An example includes some patients with VLU may not be able to tolerate optimal compression therapy due to pain, local edema or ischaemia. This therapeutic gap may be filled by the use of a muscle pump activator (MPA) device. The MPA geko™ device is used in wound care and is applied over the fibular head without disturbing compression therapy. The device functions by stimulating the common peroneal nerve to activate venous muscle pumps of the leg and foot, augmenting

blood flow. The MPA device results in a twitch response at the ankle and a contraction of the muscles of the anterior compartment of the lower leg, stretching of the calf muscle and activation of the calf muscle pump.<sup>18,19</sup> This is responsible for the increased blood flow to the lower leg and foot. If the twitch response was absent, as seen in late-stage diabetic neuropathy where motor function is lost, there may be decreased therapeutic benefit. However, a Speckle spectroscopy study showed an increase in microcirculatory flux in absence of a twitch response, and an even greater increase in microcirculatory flux in the presence of a twitch response.<sup>20</sup> In a study by Das and colleagues, microcirculatory flux in the wound bed increased by 27% and in the periwound area by 34%, while pulsatility increased by 170% in the wound bed and 173% in the periwound area.<sup>21</sup>

MPA is in contrast to electrostimulation, where electrodes supplying low-level current are applied to wound margins to aid in wound healing by potentially reducing inflammation, possibly increasing blood flow and controlling localized edema.<sup>22</sup> This article reviews literature evidence regarding the efficacy of the MPA device in managing chronic wounds and reflecting on clinical use of the MPA device.

## 3 | MUSCLE PUMP ACTIVATOR DEVICE: EVIDENCE FROM THE LITERATURE

The MPA device has been studied for applications in wound healing, edema prevention and management, pain management, venous thromboembolism (VTE)/deep venous thrombosis (DVT) prophylaxis, adherence to therapy and increasing blood flow to the lower extremities. Main outcomes from published articles are summarized in Table 1.

### 3.1 | Venous leg ulcers

In the RCT conducted by Bull and colleagues,<sup>24</sup> all patients with VLUs received standard of care (SOC) compression therapy for 4 weeks. Patients were then randomized to receive SOC with continued compression therapy with or without the MPA device for another 4 weeks. Wound size was documented weekly. Patients were followed for an additional 4 weeks while on SOC therapy. The patients that were treated with the MPA device exhibited a >2-fold increase healing rate, with 42% of patients achieving wound closure compared to 27% for patients who only received SOC therapy. The increased healing rate observed in the RCT can be at least partially

TABLE 1 Outcomes of muscle pump activator device usage in published articles.

Article	N patients	Mean age	% female	Type of wound	Outcomes
<b>RCT</b>					
Aquil et al. <sup>23</sup>	54	52	38.9	Lower limb edema	<ul style="list-style-type: none"> <li>Improved wound healing, decreased infections, decreased edema</li> </ul>
Bull et al. <sup>24</sup>	60	67.5	N/A	VLU	<ul style="list-style-type: none"> <li>Patients treated with MPA + standard compression showed twofold increase in healing rate compared to patients treated with standard compression alone</li> </ul>
<b>Interventional crossover trial</b>					
<sup>a</sup> Williams et al. <sup>25</sup>	10	27.1 ± 3.8	60	Healthy volunteers, no wounds	<ul style="list-style-type: none"> <li>Improved venous flow and peak velocity in the legs</li> <li>Superior to intermittent pneumatic compression</li> </ul>
<b>Open label study</b>					
Das et al. <sup>26</sup>	14	68	N/A	VLU	<ul style="list-style-type: none"> <li>MPA device usage increased peak arterial and venous blood flow in sitting and recumbent positions</li> </ul>
<b>Observational study</b>					
Bosanquet et al. <sup>18</sup>	8	72	50	Ischaemic	<ul style="list-style-type: none"> <li>Increase in perfusion to both the wound bed and to the periwound area.</li> </ul>
Das et al. <sup>21</sup>	16	68	37.5	VLU	<ul style="list-style-type: none"> <li>MPA device increased microcirculatory flux in the wound bed by 27% and in the periwound area by 34%.</li> <li>Pulsatility increased by 170% in the wound bed and 173% in the periwound area with MPA device usage</li> </ul>
Harris et al. <sup>27</sup>	11	69.9	45.5	VLU	<ul style="list-style-type: none"> <li>Pain reduction, wound size reduction, edema reduction</li> <li>Average weekly reduction of 4.5% in wound SA</li> </ul>
Harris et al. <sup>28</sup>	7	N/A	N/A	DFU, VLU, mixed, pressure, surgical	<ul style="list-style-type: none"> <li>9.75% weekly reduction in wound SA</li> </ul>
<sup>a</sup> Jawad et al. <sup>29</sup>	10	40.5	20	Healthy volunteers, no wounds	<ul style="list-style-type: none"> <li>Improved venous return and reduced venous stasis</li> </ul>
<sup>a</sup> Tucker et al. <sup>30</sup>	30	N/A	N/A	Healthy volunteers, no wounds	<ul style="list-style-type: none"> <li>Promising tool for VTE/DVT prevention</li> </ul>
<b>Pilot study</b>					
Yilmaz et al. <sup>31</sup>	11	62.9	9.1	Critical limb ischaemia	<ul style="list-style-type: none"> <li>Increased blood velocity in anterior tibialis artery</li> <li>No significant difference in pulse oximetry oxygen saturation levels</li> </ul>
<b>Case series</b>					
Jones et al. <sup>32</sup>	30	N/A	12	VLU, DFU, mixed	<ul style="list-style-type: none"> <li>Improved pain and edema</li> <li>Mean wound SA decreased 7.6 cm</li> </ul>
Ingves and Power <sup>33</sup>	2	65	50	Mixed, DFU	<ul style="list-style-type: none"> <li>Improved edema</li> <li>–68.5% reduction in wound SA and 21% reduction in edema</li> </ul>
<b>Open label physiological study</b>					
<sup>a</sup> Warwick et al. <sup>34</sup>	10	N/A	N/A	Healthy volunteers, no wounds	<ul style="list-style-type: none"> <li>Significant increase in venous blood flow in the lower limb both with and without a plaster cast</li> </ul>
<b>Health economics analysis</b>					
Summers et al. <sup>35</sup>	N/A	N/A	N/A	N/A	<ul style="list-style-type: none"> <li>Good method for VTE prevention in those contraindicated for mechanical and pharmacological methods of prophylaxis</li> </ul>

<sup>a</sup>Studies that had healthy volunteer participants instead of wound patients are intended to demonstrate the mechanism of action of the MPA device.

explained by a study conducted by Warwick and colleagues,<sup>36</sup> which found the use of the MPA device increased microcirculation on the dorsum of the foot by 141% in healthy volunteers. Blood flow increased by two- to three-fold when the MPA device was used in combination with compression.

Patients with VLUs in several case series only received treatment with the MPA device after they had failed to demonstrate satisfactory healing for more than 4 weeks on SOC therapy. The results of the RCT conducted by Bull and colleagues support the use of the MPA device early in VLU therapy.<sup>24</sup> Early use of the MPA device is also supported by the results of an evaluation study conducted in an Ontario nurse-led community wound clinic, which found that incorporation of the MPA device as soon as possible without waiting for completion of 30 days of SOC therapy decreased average wound closure time by 55%.<sup>37</sup> The results of the physiological response study conducted by Warwick and colleagues demonstrate the importance of optimizing compression even with MPA device usage.<sup>36</sup>

### 3.2 | Diabetic foot ulcers (DFU: neuropathic, ischaemic, mixed)

Patients with diabetes presenting with foot ulcers should be assessed to determine if the DFU is of ischaemic, neuropathic or mixed aetiology. The MPA device causes a twitch response at the ankle and activation of the calf muscle pump that is partially responsible for increased blood flow to the foot. Loss of the twitch response, as seen in late-stage diabetic neuropathy, may result in decreased therapeutic benefit. However, increased blood flow is still observed in absence of a twitch response.<sup>20</sup> Achieving optimal diabetic control (HbA1c <8, WHO standards) is crucial in the management of patients with DFUs.

### 3.3 | Ischaemic and mixed arterial/venous ulcers

Complete vascular assessment and consultation with vascular surgeon for potential angioplasty, endarterectomy or bypass to improve blood flow should be considered in the management of patients with ischaemic or mixed arterial/venous ulcers.

### 3.4 | Edema control

In an RCT conducted by Aquil and colleagues, in kidney and kidney-pancreas transplant patients, 31% patients

treated with TED and intermittent pneumatic compression perceived an improvement in incisional wound swelling versus 48% treated with the MPA device ( $p < 0.001$ ).<sup>23</sup>

Patients with lymphedema may exhibit improvement in woody fibrosis after treatment with the MPA device.<sup>38</sup> If pitting edema is present, the MPA device may provide therapeutic benefit for the secondary edema control. However, larger controlled studies are required to evaluate the efficacy of the MPA device in treating woody fibrosis.

## 4 | CLINICAL EXPERIENCE WITH THE MPA DEVICE: SKIN ULCER TREATMENT AND EDEMA CONTROL

In our clinic and collaborator clinics (Canada, United Kingdom, Australia), the MPA device has been used to improve clinical outcomes for many patients, of which we will be reporting on 127 with wounds of various aetiologies (Table 2). In general, patients expressed satisfaction with the use of the MPA device for: pain reduction, comfort of use, improved quality of life, increased mobility and were more engaged due to the twitching sensations elicited by the MPA device.<sup>39</sup> Healthcare providers have also expressed positive feedback in regard to the ease of use of the device and a reduction in nursing visits.

According to current manufacturer instructions, two versions of the MPA device exist, with a 24 h continuous use version being used primarily for edema reduction and DVT prophylaxis and a 12 h/day 7 days/week version for wound care applications including edema

TABLE 2 Patient demographics of documented case series and case reports.

Patient demographics (Number of patients documented)	
Total number of patients	127
Average age	73 (21)
Type of ulcers and edema control	
Venous leg ulcer	70
DFU (neuropathic, ischaemic, mixed)	4
Ischaemic and mixed ulcers	8
Traumatic and surgical ulcers	3
Lymphedema	1
Multiple aetiologies <sup>a</sup>	41

<sup>a</sup>Includes a varied number of VLU, DFU, ischaemic, mixed, trauma, pressure injuries and surgical ulcers.



management.<sup>40</sup> However, we have also been successful with the device using various treatment regimens according to clinician experience, patient preference and tolerance.

#### 4.1 | Venous leg ulcers

The MPA device has been used to treat many patients with VLUs, with 70 patients being reported in this case series. Patients experienced wound size reduction, edema improvement, pain control, increased mobility and enhanced wound margin advance rate (measure to standardizing change between large and small wounds).<sup>41</sup> Of the 70 patients, 30 individuals achieved complete wound closure after a mean treatment duration of 9 weeks with the MPA device. There were no adverse complications with the MPA device. However, some patients experienced a contact dermatitis that was alleviated using alternate device placement sites.

#### 4.2 | Diabetic foot ulcers (DFU: neuropathic, ischaemic, mixed)

Individuals with diabetes are more prone to developing foot ulcers associated with neuropathy and are often trauma-induced. Patients with peripheral vascular disease often display areas of necrosis or gangrene of the toes and heel, and some are of mixed aetiology. Many patients with DFUs have been treated with the MPA device, four patients with DFUs are reported in this case series. These patients experienced wound size reduction, edema reduction, pain control and enhanced state of mind. Accelerated weekly healing rates were also exhibited. All four patients had a mean wound duration of 21 months and achieved wound closure after an average 7-week treatment duration with the MPA device. The MPA device was generally well-tolerated. One patient experienced an itchy skin rash due to the adhesive at the application site and a second patient demonstrated peri-wound callous and wound base hypergranulation that was surgically debrided without further complications.

#### 4.3 | Ischaemic and mixed arterial/venous ulcers

Ischaemic ulcers often present with dependent rubor (disappear or blanches on elevation), decreased circulation time, decreased foot temperature and capillary refill >3 s (toe compressed, and after release, watch for capillary refill in seconds). Loss of hair and nail changes

(thickened and lack of lustre) are less reliable clinical signs.

Two patients with ischaemic ulcers in this case series were treated with the MPA device. A 74-year-old patient was treated with the MPA device 24 h each day for 3 weeks and noted reduced wound size, pain and edema. In terms of wound characteristics, there was increased granulation and reduced slough. On assessment, there was an improved QOL score and she also reported greater ankle range of motion. The second patient was the 87-year-old with the MPA device utilized daily for 12 h/day, 7 days/week over 6 weeks. Prior to starting the MPA device her wound decreased 63%. Following 6 weeks of MPA therapy her wound reduced in size by 97% and her pain numeric rating scale improved from 8/10 to 2/10. In particular, she stated the twitching motions gave her hope that the therapy was working. No complications were experienced by either patient.

Mixed arterial and venous disease often presents with some symptoms of claudication when walking a variable distance and may be associated with ulcers that may have features of both arterial and venous disease with delayed healing.<sup>30</sup> A total of six patients with known mixed arterial/venous ulcers were treated with the MPA device in this summary. Post-device application, improvements in wound size, healing rate, pain, edema and some reduction of woody fibrosis were documented. Of the six patients treated, four patients with a mean wound duration of 5 months (only reported for 1/4 patients) achieved complete closure after an average of 8.75 weeks. Only one patient experienced a reported local contact dermatitis from the adhesive hydrogel under the applied MPA device.

#### 4.4 | Post-surgical or trauma associated leg ulcers

Three MPA device treated patients had ulcers secondary to surgery (2) or trauma (1) for an average of 14 months. Two patients (one trauma, one surgery) experienced complete wound closure after an average of 5.25 months of treatment. The remaining post-surgical patient experienced a 59% wound size reduction after 2 months. Decreases in pain and edema were also noted.

#### 4.5 | Edema control

Excessive edema may interfere with reparative mechanisms and adequate edema control has previously been shown to accelerate the healing rate of foot wounds in patients with diabetes.<sup>42</sup> The activation of the calf muscle

pump with stimulation of the ankle reflex often results in the reduction of leg and foot edema.<sup>43</sup> Many of the patients in the categories mentioned above did have an improvement in local foot edema even when they were using compression therapy. Compression therapy when associated with elastic systems can often have a high pressure at the level of the ankle, resulting in redistribution of edema above the compression and into the foot. This edema may clear with the twitch response at the ankle even without compression, as edema control can be achieved with MPA device usage.<sup>43,44</sup>

In a 60-year-old female patient confined to bed due to severe lymphedema for 4 years, treatment with the MPA device for 4 weeks resulted in a fivefold increase in urinary output, a loss of 60 lbs and reduction in papilloma. The patient experienced improved quality of life and was able to sit in a chair again.

#### 4.6 | Multiple aetiology ulcers

In 41 patients with ulcers of varying aetiologies including VLU, DFU, ischaemic, mixed, trauma, pressure and surgical ulcers, the use of the MPA device resulted in accelerated weekly healing rates and reduction in wound size. Wound closure was achieved in 15 patients.

### 5 | DISCUSSION

Chronic wounds result from a failure of wounds to progress through the normal wound healing phases of inflammation, proliferation and remodelling. Several factors are contributory, including persistent inflammation, failure to re-epithelialize, defective extracellular matrix remodelling and insufficient perfusion.<sup>45</sup> Chronic wounds can persist for years with significant negative impact on patient baseline functioning due to alterations to their body image, mobility impairments and pain.<sup>46</sup> This may force changes in lifestyle, create difficulties in performing activities of daily living, lead to social withdrawal and reduce mental well-being.<sup>39</sup>

Aside from the physical and psychosocial burdens that chronic wounds place on patients, chronic wounds also exact heavy costs on healthcare systems. Studies have estimated the cost of PI management in the United States to be approximately USD 43 000 per PI, and foot ulcers collectively cost USD \$2.8b in 2019.<sup>47</sup> In the United Kingdom, management of VLUs cost an estimated GBP 2b annually, with nursing visits and dressing changes being the primary cost drivers.<sup>48</sup> Community leg and foot ulcers cost the province of Ontario, Canada approximately CDN 511 m annually.<sup>49</sup> Chronic

wounds are more likely observed in older adults, with foot ulcers being especially more prevalent in diabetic patients with poor glycemic control, ischaemia and/or neuropathy. With an ageing population and increasing prevalence of diabetes, the cost of chronic wounds for healthcare systems is expected to rise.<sup>50</sup>

The MPA device works by stimulating the common peroneal nerve to activate the calf and foot muscle pumps, with applications in venous thromboembolism prevention, edema control and wound healing (VLUs, DFUs, ischaemic ulcers, mixed arterial/venous ulcers, PIs and trauma/post-surgical wounds).<sup>18,19</sup> In an RCT of patients with venous ulcers that were not healing at the expected rate, the MPA device was shown to be superior to SOC therapy in both wound size reduction rate and complete wound closure rate.<sup>24</sup> In case series (Table 1) and clinical experience (Table 2) with the MPA device, wounds treated with the MPA device exhibited increased healing rate, reduced wound dressings resulting in a decreased need for nursing visits, improved patient quality of life and provided pain and edema control. Importantly, the MPA device is worn just below the knee, allowing it to be compatible with optimal compression therapy increasing the effectiveness of compression therapy. This was demonstrated by a two- to three-fold increase in blood flow when the MPA device was used in combination with compression.<sup>36</sup>

For patients with peripheral artery disease (PAD), an audible doppler is often monophasic and ABPI less than 0.4–0.6. However, in persons with diabetes or over 65 years of age, the ABPI can be falsely elevated.<sup>51</sup> In patients with PAD and ischaemic rest pain associated with their ulceration, revascularization by arterial bypass or angioplasty will be required. In patients with PAD and impaired healing without rest pain in their ulceration, different wound management options may be considered, but if healing is not initiated, revascularization is also indicated. However, vascular reconstruction may not be feasible in some patients with PAD, especially with distal disease. These patients may benefit from the addition of MPA device therapy to prevent amputation.

Currently, many patients with chronic lower extremity wounds managed with SOC compression therapy fail to achieve adequate healing.<sup>24</sup> The large number of dressing changes, nursing visits and specialist services are the leading drivers of the high cost of care.<sup>48</sup> Given the ability of the MPA device to improve outcomes for long-standing nonhealing wounds, the MPA device offers a potentially large cost-saving opportunity for healthcare systems. This cost-saving impact could be particularly pronounced if therapy with the MPA device is initiated early ( $\leq 4$  weeks) in wound management as demonstrated by the increased

wound healing efficacy of an MPA device + SOC compression therapy regimen in a recent RCT.<sup>24,37</sup>

## 6 | CONCLUSION

Chronic wounds fail to progress through an orderly set of stages or do not heal within an expected time frame. VLU, DFU (neuropathic, ischaemic, mixed), PI, venous ulcers and diabetic neuropathy ulcers are the most common. Severe ischaemic peripheral vascular disease more often will present with ischaemic and gangrenous changes in toes, heels and may be more proximal as well due to infection and trauma.

Chronic wounds may persist for weeks to several years, placing an increased burden on the healthcare system and reducing patient physical and mental well-being. There is evidence supporting the use of the MPA device in wound care with therapeutic benefits including increased blood flow, resulting in potential increase in healing rates, edema control, pain control and improved patient quality of life. These in turn would typically lead to decreased cost of wound dressings and reduced nursing visits.

The incorporation of the MPA device in wound therapy guidelines may provide large cost savings for healthcare systems. The MPA device may improve wound outcomes and reduce amputation rates, especially in some patients with PAD who are not eligible for vascular reconstruction. While the evidence continues to build for the use of the MPA in wound care, the risk/reward ratio needs to be considered in areas where the evidence levels are low. The MPA has proven safe, with the risks often amounting to the the device use cost. Over time, these questions will need to be addressed.

### AUTHOR CONTRIBUTIONS

**R. Gary Sibbald:** Conceptualization; data curation; project administration; supervision; writing – original draft; writing – review and editing. **Ryan S. Q. Geng:** Data curation; formal analysis; investigation; methodology; writing – original draft; writing – review and editing. **Jacqueline Slomovic:** Data curation; formal analysis; investigation; writing – original draft. **Michael Stacey:** Conceptualization; data curation; supervision; writing – review and editing.

### CONFLICT OF INTEREST STATEMENT

RGS has received honoraria from Perfuse/FirstKind, Quart Medical, Novartis, Medexus Pharmaceuticals Canada along with Ontario Government (Project ECHO Ontario Skin & Wound—Ministry of Health and Micro-credentials—through Ministry of Colleges and

Universities and Sault College all unrelated to this work). MS is a consultant for Perfuse/FirstKind and Sterasure. RSQG and JS have no conflicts to disclose.

### DATA AVAILABILITY STATEMENT

The data that supports the findings of this study are available in manuscript.

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