Healing of chronic wound by Wireless Micro Current Stimulation

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Keywords: Chronic and acute wound; pain and wound healing; savings.

Key points

1. The capacity of nitrogen and oxygen to donate electrons, has significant positive impact on wound healing.
2. Faster healing of deep dermal injuries compared with that achieved with conventional therapy strategies
3. None or less dressing changes for burns victims will reduce the psychological problems, such as symptoms of posttraumatic stress disorder, anxiety, and depression.
4. The implementation of the method should facilitate huge pain relief for many patients and huge cost savings in ongoing dressings and nursing care.

ABSTRACT

A new method of using electrical stimulation for wound healing is presented. Charged air gases are used instead of electrodes to supply the current to the wound. In a model calculation it is shown that the new method compared to the usual does not give qualitatively different physiological effects in tissues. We have tested the method in clinical treatments in different chronic wound and burns, where we have found that this method has procedural and patient advantages, it can replace the traditional way of transferring the current between electrodes, it has a faster wound healing and pain reduction, it is able to cover bigger wounds, it is easy to administrate, it minimizes the risk of infection and it offers significant savings in ongoing nursing and dressing.

INTRODUCTION

Electrical stimulation (ES) to encourage wound healing involves the transfer of energy to a wound via an electric current. The usual practice of ES is to transfer the current through surface electrode pads that are in wet, electrolytic contact with both the external skin surface and the wound bed. Two electrodes are required to complete the electrical circuit.[1,2]

When a wound occurs, there is a weak but measurable current between the skin and inner tissues called the “current of injury”. It is thought that the current continues until the skin defect is repaired and that the healing process is interrupted if the current ceases.[1, 2] ES may mimic the current of injury, restarting or accelerating the wound-healing process.[1, 2]

ES and its effects in healing chronic wounds are well documented.[a,b] Until now, the current has been introduced into the body with electrodes, but despite the very positive effects on the healing rate of chronic wounds, this method is not often used because of the disadvantages entailed when electrodes are used to transfer the current.[3, 4]

In this paper, we demonstrate a new method that utilizes the current-carrying capacity of charged air gas, based on the ability of nitrogen and oxygen to accept or donate electrons. We call this method W*ireless Micro Current Stimulation* (WMCS).

By calculating the currents and voltages in tissues with a simple geometry, we show that there are no qualitative differences between the electrical variables when the current is supplied with the usual method and with WMCS.

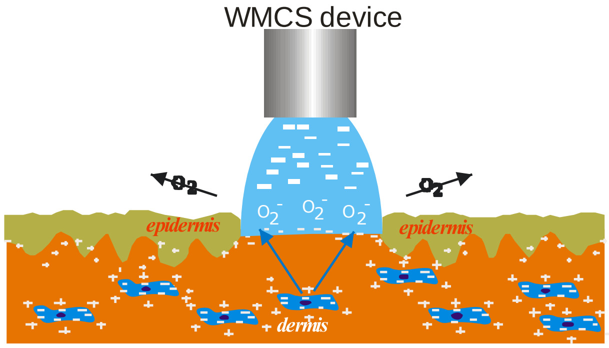
We also report the results of treatments of different types of wounds with ES using the WMCS method, and demonstrate the versatility of the WMCS method when the size of the lesions is greater than the maximum size usually considered treatable with ES.

METHODS

In the lower atmosphere, the production of N_2^+, O_2^- and a few free electrons, is primarily caused by radiation from alpha-activities. These so-called primary ions will within a few microseconds gather around themselves a cover of mostly water molecules held together by polarization forces. These processes typically give rise to a concentration of air-borne electrically charged particles in the order of some hundreds per milliliter.[5]

If a weak direct current electric field is applied to the atmosphere, the naturally produced N_2^+ and O_2^- will move, the former in the direction of the field and the latter in the opposite direction. For a field strength of 10^4 V m^{-1}, the velocity of N_2^+ will be in the order of 1.4 m s^{-1} and that of O_2^- about 2 m s^{-1}.[5]
If the field strength exceeds a certain value, which at atmospheric pressure is about 3 10^6 V m^{-1} (3 megavolts per meter; the breakdown field strength), a few free electrons can be accelerated to high velocities and energies, so that they can knock electrons from the oxygen and nitrogen molecules, creating more positive and negative molecules.[5]
If an O_2^- ion lands on a conductive surface (like the skin), it gives up its negative charge, ceases to exist as an O_2^- ion, and turns into an oxygen molecule and a few water molecules. This process is called "plate out". In other words, the O_2^- never enters the body. However, the charge on the plated-out O_2^- will induce a current in the body cells and fluids.[5]

The unit used to produce the O_2^--induced current in the body is a WMCS device, shown diagrammatically in the figure in a typical exposure situation. The flow of O_2^- ions from the unit is directed towards the target (the patient), which is isolated from the ground. The target is connected back to the WMCS device through a control box that records the exposure rate and the total exposure, or the charge passing through the body.
The return path, established by wrist or ankle straps, has a dual purpose. It makes the measurement of exposure possible and it maintains the target at virtually zero potential with respect to the ground.



Tissue electrical potentials and currents supplied with electrodes or WMCS
Questions have been raised regarding whether the WMCS method and the usual ES method can be expected to produce the same physiological effects. Whatever mechanism underlies the beneficial effects of ES these effects are related to the distribution of currents and voltages in the tissue. Therefore, we calculated these quantities in a simple model to compare the two methodologies.

The electrical potential (φ) and the current density (j) inside the tissue depend on the shape and position of the electrodes, the conductivity (σ) of the tissue, and the geometry of the body. In each area of tissue where σ is constant, Laplace's equation ($\Delta\varphi = 0$) must be met with the appropriate boundary conditions. In general, this can only be calculated with numerical methods, e.g., finite element calculations, etc. However, for simple geometries and constant conductivity over the whole area, analytical solutions can be given.
Because we want to *compare* the situation when the current is supplied by two small plate electrodes with the WMCS method, where the current is "sprayed" onto a given area at a virtually constant current density, we believe more insight into the problem can be gained by studying these analytical solutions than with a lot of numbers obtained from numerical calculations. Therefore, we will consider a case in which the semi-infinite area of $z > 0$, bounded by the plane $z = 0$, is filled by a tissue of constant conductivity, σ. For $z \to \infty$, the potential is taken to be 0. The current is supplied through a small disk of radius a, around (0, 0, 0), with the other electrode far away, i.e., at infinity, where $\varphi = 0$. In case A, the disk is given a fixed voltage, V_0,

whereas in case B, a current with constant current density, j_0, is supplied over the disk. Case A models the usual method and case B the WMCS method. Both methods have cylindrical symmetry around the z-axis, and the solution for φ can therefore be given in cylindrical coordinates (r, θ, z), where r is the distance to the z-axis, θ is the polar angle, and z is the distance from the surface. In both cases A and B, the solution for z ≥ 0 has the form:

$$\varphi = \int_0^\infty f(s) J_0(sr) e^{-sz} ds \tag{1}$$

where J_0 is a Bessel function of order zero, and f(s) is a function that must be chosen such that φ satisfies the boundary conditions for z = 0.

In case A, the boundary conditions for z = 0 are: φ = V_0 for 0 ≤ r ≤ a, and the current density, $j_z = -\left(\sigma \frac{\partial \varphi}{\partial z}\right)_{z=0} = 0$, through the plane z = 0 for r > a. This will be fulfilled when f(s) is given by:

$$f_A(s) = \frac{2V_0}{\pi s} \sin(sa) \tag{2}$$

For this value of f(s), the integral (1) can be expressed by the elementary function:

$$\varphi_A = \frac{2V_0}{\pi} Arc\sin\left(\frac{2a}{\sqrt{(r-a)^2 + z^2} + \sqrt{(r+a)^2 + z^2}}\right) \tag{3}$$

The total current, I_A, in case A can now be found by integrating the current density, j_z, over the disk-shaped electrode with voltage V_0:

$$I_A = 2\sigma V_0 \int_0^a \left(\int_0^\infty \sin(sa) J_0(sr) ds \right) r^2 dr = 4\sigma a V_0 \tag{4}$$

In case B, f(s) must be: $f_B(s) = \frac{j_0 a}{\sigma} \frac{J_1(sa)}{s}$, ($J_1$ is the Bessel function of order 1) which gives:

$$\varphi_B = \frac{j_0 a}{\sigma} \int_0^\infty e^{-sz} J_0(sr) J_1(sa) \frac{ds}{s} \tag{5}$$

The integral in eqn 5 cannot be given in an elementary form when z > 0, but can be expressed as an infinite sum of hypergeometric functions. For z = 0, φ_B is given by single hypergeometric functions. We will not give the explicit forms here, but the average value of φ_B over the disk r < a, for z = 0, is found to be $V_{av} = \frac{8 j_0 a}{3\pi\sigma}$, and the maximal value $\varphi_{B,max} = \frac{j_0 a}{\sigma}$. Because the total current is $I_B = \pi a^2 j_0$, the ratio of the current to the average voltage is: $I_B/V_{av} = \frac{3\pi^2 \sigma a}{8}$, whereas in case A we get: $I_A/V_0 = 4\sigma a$.

Figs 1–2 show the values for the electrical potential at different values of r and z in cases A and B.

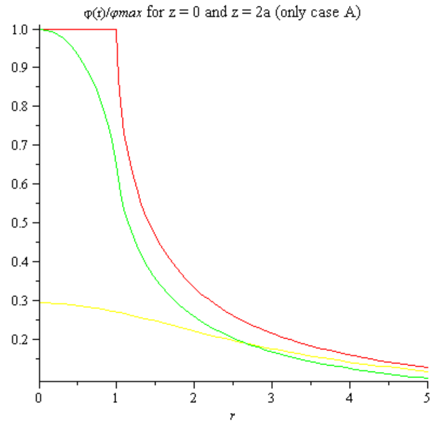


Fig. 1: φ/φ_{max} as a function of r/a for z = 0 (case A, red; case B, green) and z = 2a (case A, yellow).

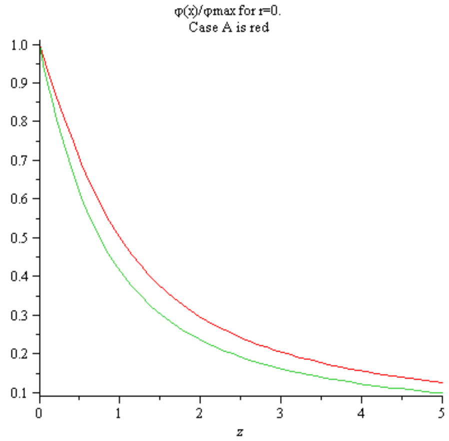


Fig. 2: φ/φ_{max} as a function of z/a for r = 0 (case A, red; case B, green).

When we compare the figures for cases A and B, no significant differences can be seen. However, it must be noted that an electrode is usually much smaller than the wound, whereas the current in the WMCS method is supplied over a larger area. This means that a ≈ 1 mm in case A, whereas it can easily be 10 mm or more in case B. From the expressions for the total currents, we see that for the same current in cases A and B, the ratio between V_0 and $\varphi_{B,max}$ is $V_0/\varphi_{B,max} = \pi a_A/(4a_B) \approx 10$.

RESULTS

It has been demonstrated in many tests that ES is very effective in accelerating wound healing.[1,2] Therefore, it is not the intention of this article to report any further investigation of ES, but to present clinical studies of different wound healing situations in which the WMCS technology has proved to be effective, low-risk, pain-free noninvasive alternative to the usual method.

The following pictures show two similar situations in which ES was used to heal bed sores.

The picture above shows a situation in which electrodes are used. The picture is presented with the permission of Professor Luther Kloth, Department of Physical Therapy, Marquette University, Milwaukee, WI (USA). Two electrodes are used: one in contact with the intact skin and the other in contact with the wound bed.

The picture above shows a similar situation, only in this case, WMCS is used. There is no physical contact between the injured skin and the treatment unit (the anode) from which the charged particles will be sprayed, under control, over the total area of the wound. The cathode is connected noninvasively to the intact skin of the patient at a distance, by wrist straps.

WMCS therapy in patients with leg ulcers or diabetic foot ulcers
P. Wirsing

We have used the WMCS technology for some months and conclude that the method can be used successfully in the treatment of leg ulcers of any origin and in patients with ulcers arising from diabetic foot syndrome.

All stages of wound healing can be treated with WMCS. Necrosis must be removed completely, and fibrin or other coverings must also be removed as far as possible. The kind of dressing applied previously to the wound is not important, but all residue of silver dressings must be removed completely from the wound before WMCS therapy is commenced.

The WMCS device must be directed (adjusted) to a distance of about 10–15 cm straight onto the wound. Before WMCS therapy is commenced, the patient must be connected to the cathode via a wrist strap. The duration of treatment per session is 60 min, once a day if possible. However, treatments ranging from once a day to twice a week are recommended. At the end of the treatment the WMCS device switches off automatically.

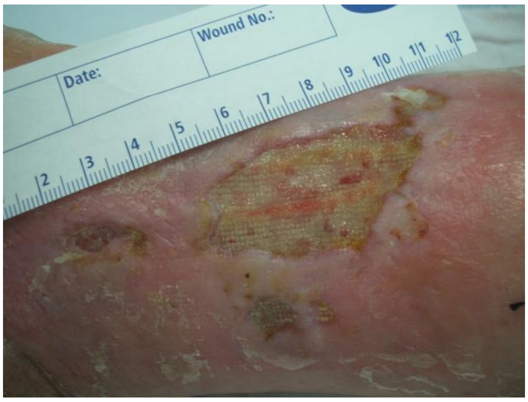
No severe complications have been reported by the patients after treatment. Very rarely, a very smooth burning sensation was reported, but no analgesics or other medications have ever been required. A slight redness surrounding the wound was sometimes observed, which disappeared in a few hours.

A dramatic improvement in the arterial blood flow was seen in all patients, independent of the cause of the ulcer. This was also observed in patients with a severe arterial occlusive disease or diabetic micro- and/or macroangiopathy. A clear reduction in the bacterial burden was also observed, even a few days after treatment. After only one session of treatment, better perfusion of the wound and contraction of the wound edge were seen. After each session, a fine protective film (not a biofilm!) was observed over the wound.

In sessions performed at a rate of one every 1–2 days, no special wound dressing was required, whereas at frequencies of one session every three or more days, a dressing should be applied, depending on the stage of wound healing. With higher rates of treatment, faster improvement in the wound and earlier success were achieved.

Case 1
Report of WMCS treatment for arterial leg ulcers
P. Wirsing

An 84-year-old male patient with severe arterial occlusive disease had four leg ulcers on the right lower limb for one year, a large one (45 mm × 22 mm, 3 mm deep) and three smaller superficial leg ulcers (a = 8–5 mm, b = 16–4 mm, c = 9–8 mm). Neither an arterial reconstruction nor an interventional procedure to improve his arterial blood flow was possible. Accompanying diseases, including anemia, hyperuricemia, stage III renal failure, chronic venous insufficiency, etc., were treated optimally. Modern wound dressings adapted to the stage of wound healing were used without altering the wound status and no further improvement was considered possible.
The patient was then treated with WMCS as an outpatient, at intervals of 2–3 days. After 10 sessions, the fibrin and other covering disappeared. After 15 sessions, very good granulation tissue was visible in the wound bed and at the wound edge. A clear reduction in exudate, with fewer dressing changes, was achieved. After 15 sessions, there was a significant reduction in the wound area.



Case 1, Photo 1

Ulcers before WMCS therapy
Size of the wound is 1166 mm^2

Case 1, Photo 2

After 15 sessions of WMCS therapy (three weeks) Size of the wound is 768 mm^2

The patient suffered no pain or other disorder during or after any WMCS session. We have now (OCT 2011) been treating several wounds cases and we are all convinced of the success of the WMCS therapy and our patients wishes to continue the treatment until the total closure of their wounds.

Cases 2–3
Report of WMCS treatments of burns
Frank Siemers, Karl L. Mauss, Peter Mailander

We report two patients who suffered thermal injuries. Following their accidents, the patients were treated according to standard procedures. After surgical debridement (blister removal and wound surface cleansing) was completed, the wound area was covered with an antiseptic dressing. The facial region was treated with a semiocclusive dressing 24 h after the injury. Thermal injuries to the limbs were covered with a hydrocolloid dressing.

Case 2:
A male patient aged 55 years scalded himself with boiling water on the left side of his face and his left arm (7% total body surface area [TBSA]). The degree of scalding was deep in some areas (2b°). Some parts of the wound area showed prolonged recapillarization. On day 4, there was no recapillarization or healing in the central wound areas, a sign of deep dermal injury.

WMCS treatment was commenced at day 4. During the first treatments, the patient complained of a pain sensation in the treatment area after 10 min. On subsequent days, the treatment was painless, and the treatment sessions lasted 30 min.

On day 7, the areas that formerly showed deep partial-thickness lesions were reepithelialized. The patient reported less-intense pain sensations (according to a visual analogue scale [VAS]) in the WMCS-treated areas during and following the therapy compared with those in the untreated areas (VAS: 2 vs 6, respectively).

Case 2 Photo 1

Burn before WMCS therapy was commenced

Case 2 Photo 2

Burn after four sessions of WMCS therapy

Case 3:

A 34-year-old male patient suffered a partial- to deep-thickness facial burn injury from a flame (3% TBSA). His forehead region, both cheeks, and both ears were affected by the injury. WMCS treatment was commenced on the day of injury. Following four courses of treatment (treatment duration 60 min/d), all areas were completely reepithelialized.

Case 3, Photo 1

Burn before WMCS therapy was commenced

Case 3, Photo 2

Burn after four sessions of WMCS therapy

Summary

In our first experience of using the WMCS technology to treat thermal injuries, we observed faster healing of deep dermal injuries compared with that achieved with conventional therapy strategies. The patients reported a reduction in pain during and after treatment.

Our first results of linking conventional therapy and WMCS are promising, and we would like to continue to extend our knowledge. Therefore, we would like to establish a series of studies designed to expand the scientific understanding of this interesting method.

Case 4:
Report on WMCS treatment for burns
Mongkol Vanitchpakdeedecha, Vachara Chuapaknam

The pain experienced after burns is one of the most intense and lasting pains. It is difficult to control, and further pain is experienced during dressing changes and wound cleaning. In a recent wound-care survey of the pain and trauma experienced at dressing changes, dressing removal was considered the time of greatest perceived pain. Psychological problems, such as symptoms of posttraumatic stress disorder, anxiety, and depression, are also known to occur, are well documented, and can last for some time after the injury. Furthermore, it might be necessary to wait for a week or more to determine whether the tissues have healed by themselves or require further treatment.

Case 4, Photo 1

Burn during first WMCS therapy

Case 4, Photo 2

Burn after two sessions of WMCS therapy

Case 4, photo 1 shows a flame-burned female, aged 50 years, brought into a hospital unit late on the evening of 27 October 2010 after flame damaged 30% of her skin, with second degree burns to the front of her body, leaving her in excruciating pain. After cleaning and preparation, the patient was brought into the room in which the WMCS treatment was to be performed. The room was a normal hospital bedroom.
Photo 1 shows the first WMCS treatment on 28 October. The patient was in excruciating pain and required aggressive analgesic treatment. At the end of the first treatment, the patient was relaxed and able to sit up in the bed without severe pain and she slept relatively quietly the following night.

The present WMCS technology can cover an area of up to approximately 700 cm^2. Because of the huge area of this wound, we chose to use two pieces of equipment. After the wound had been divided into appropriate areas, each part was treated by transferring 1.5 μA of current in sessions of 1 h, to a total at 5,400 μC.

On the first day of treatment, we decided to let the dressing fabric remain on the wound, because from previous burns cases, we knew that it does not affect the healing process but even protects the very fine film that is created during the WMCS treatment. The fabric can be removed after a few days of treatment without damaging the skin or patient.

Case 4, photo 2 was taken on day 2, and shows part of the patient's upper leg. The almost dried fabric can be seen on top of the fine protecting film created under it.

Case 4, Photo 3

Burn after 3 sessions of WMCS therapy

Case 4, Photo 4

Burn 49 days after injury

Case 4, photo 3 was taken on day 3, shortly after the fabric had been removed without any pain to the patient. The protective film now covering the total area of the burns can be seen. No further dressing was required. On day 3, after the third WMCS treatment, the patient was able to step out of bed by herself without severe pain, go to toilet, and walk around the room.

After 10 days of treatment, the patient went home, visiting the hospital unit as an outpatient for observation, with little further treatment.

Case 4, photo 4 was taken 49 days after the accident, during regular follow-up at the hospital. The patient's skin was totally healed, with no scar tissue, and the skin pigmentation was even returning.

Case 5

Report on WMCS treatment for Wound Hypergranulation

Aditya Wardhana

A five-year-old girl had superficial and deep dermal burns, covering 27% TBSA. After wound treatment with ointment and a foam dressing, granulation tissue was apparent after the eschar was removed by the foam dressing. We should have performed a skin graft to close the wound but decided instead to apply the WMCS technology, which we had used in more than 40 patients since March 2011, with very encouraging results.

Treatment with WMCS showed us quite rapidly that this might be the optimal treatment for her wounds, and we decided to continue the treatment using only this new method.

We found that WMCS promoted the migration of epithelial cells to the center of a wound, to close the granulation tissue, and in some areas in the middle of the granulation tissue, there were islands of epithelial cells.

WMCS may also accelerate the second phase of wound healing, to the maturation phase. However, to test this proposition, we wish to set up a series of experiments designed to investigate this phenomenon.

Case 5, Photo 1

Day 1 before WMCS therapy

Case 5, Photo 2

Day 6 after the 6th WMCS therapy

Case 6
Report on WMCS treatment of a breast cancer wound
Finn S. Andersen

It is well known that managing wounds in patients with cancer is complicated by the physiological changes that occur in the patients after surgery, radiation therapy, and chemotherapy, which are often part of the usual treatment.

The following case, in which a fungating wound was healed, is unique because the disease technologies used included metronomic chemotherapy, regular injections with Helixor P, and ES with WMCS.

The patient was a 65-year-old female who found a small wound just on top of her right breast nipple in late 2008, with no idea that it could be cancer. In the period after late 2008, the wound grew. In August 2009, she was hospitalized with breathing problems, and her pleural cavity was emptied of almost 3 L of fluid.

The hospital also found a 86×111 mm^2 ulcerated necrotizing wound just over the right breast nipple, involving the thorax wall. A biopsy showed that this wound was the result of cancer. The patient was offered treatment for her cancer using conventional methods, but refused all options.

She was then told about WMCS and agreed to try this method to cure the unpleasant-smelling and infected wound.

The following pictures were taken just before the WMCS treatments. The patient received 86 treatments, each of 1 h.

Case 6, Photo 1

Day 1 during the 1st WMCS treatment

Case 6, Photo 2

Day 7 after the 7st WMCS treatment

Case 6, Photo 3

Day 86 during the 86st WMCS treatment
End of treatment

Case 6, Photo 4

Follow-up at the hospital seven months after the first treatment

During the WMCS treatment period, the patient also received metronomic chemotherapy and regular injections of Helixor P. This kind of treatment has no wound-healing effect, so we attributed the excellent wound healing to WMCS. The patient also reported that her overall well-being improved during the period of treatment.

DISCUSSION

By using the capacity of nitrogen and oxygen to donate electrons, a charge can be transferred through the air to the wound bed without any physical connection to the wound or the surrounding skin, allowing a noninvasive technology to accelerate the healing of acute and chronic wounds.

In all cases mentioned in this paper, a current of 1.5 μA was the basis of treatment, and all treatments were performed in sessions of 30 or 60 min.

The cathode was a normal electrostatic discharge wrist strap, connected to either the wrist or ankle, at some distance from the wound. The connection between the wrist straps and the equipment was made with a standard wire, with no further resistance than that presented by the cable itself.
In all the cases described, the patient was lying on a hospital bed that had been electrically insulated from the ground by rubber placed between the bed poles and the floor. This insulation is necessary to prevent any ground connection that might interfere with the measurement of the total effect (coulombs) passing into the patient. During each treatment, we also ensured that neither the bed nor the patient was in contact with the wall, to prevent any misreading of the coulomb counts.

The cases described in this paper are examples of the many patients treated by each author in 2009, 2010 and 2011. In a few cases, the patients complained of pain, which they described as “burning pain”, during the very first session. To explain why this pain occurs, it will be necessary to establish an appropriate study, but at the time of writing this paper, we have no model with which to undertake this research.

Healing the wound caused by an underlying breast tumor differed from all our other cases of wounds treated with the WMCS technology. Many questions can be asked, including whether the results of WMCS would have been just as good if the underlying cause had been a more aggressive tumor. To answer this and many other questions, a series of studies must be undertaken, and at the time of writing, we do not have a model for such studies.

CONCLUSION

Electrical stimulation in which electrodes is in use for transferring the current to the wound is a well-known technology for accelerating wound healing, and has been described and investigated in a large number of clinical trials. Electrical stimulation and its effect on chronic wounds are well documented.
Different biological effects can be described, depending on the application:

- Chemotaxis of macrophages[6,7] and neutrophilic granulocytes[8-10] to initiate wound cleaning;
- Increased blood flow;[10-14]
- Increased oxygen concentration around the wound;[10,12]
- Stimulation of granulation tissue formation;[8]
- Increased synthesis of collagen and other components of the extracellular matrix;[8,15-18]
- Reorganization of the extracellular matrix;[19-22]
- Facilitation of angioneogenesis and the activation of growth factor production (demonstrated for vascular endothelial growth factor);[8,10,23,24]
- Activation of reepithelialization using the targeted migration of keratinocytes;[8,25-29]
- Antimicrobial effects, e.g., on Gram-positive (*Staphylococcus aureus*, *S. epidermidis*, *Enterococcus faecium*) and Gram-negative bacteria (*Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*), but not with the strength of typical antiseptics;[10,30-34]
- Reduction of edema;[35-37]
- Reduction of pain around wounds.[23]

It has been demonstrated in the present paper that electrical stimulation during which a charge is delivered by electrically charged gas molecules with the WMCS technology provides the same advantages as traditional ES, but has the added advantages as:

– its “shower” effect allows the method to create the “current of injury” in one session;
– it is easy to administer;
– there is no direct contact with the wound;
– it minimizes the risk of infection;
– it has a fast pain reduce effect;
– if has huge cost-saving potential during wound dressing and ongoing nursing care;
– it is portable, for home nursing care.

It is difficult to predict whether a wound will be a traumatic nonhealing wound, but all at-risk candidates, such as diabetic patients, cancer patients, and weak patients, should be treated with WMCS as soon as a wound appears. By treating these patients from the very start, the total number of sessions required to heal these wounds can be minimized.

From an overall perspective, this should facilitate huge pain relief for many patients and huge cost savings in ongoing dressings and nursing care.

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