Healing is much slower with age due to aberrant cell communications leaving the body with inappropriate levels of growth factors and connexins resulting in hypo or hyper-proliferation and sustained inflammation, delaying or negating healing, or leading to hypertrophic scars and keloids. A review of laser and RF technologies in wound healing, keloids and hypertrophic scars indicates partial recovery, in the absence of longitudinal studies to control for possible reoccurrence of skin lesions. On the other hand, ultra-low energy technologies have reported complete healing of diabetic and other hard-to-heal skin lesions with no reoccurrence that is independent of the patient’s age. Studies utilizing low-energy technologies postulate that wound healing is the result of electron flow acting as a major antioxidant relieving the lesion from oxidative damage thus reducing inflammation. Persistent inflammation is the result of accumulated oxidative stress, defined as an imbalance between ROS production and their elimination by biological protective mechanisms. The negation of the age factor in wound healing by ultra-low energies is significant in light of a large body of research that postulates compromised immunity and increased low grade inflammation in aged individuals. We introduce the possibility that low-energy technologies may be mobilizing the inherent time-reversal capacities of the body’s molecular machines, one of which is oxidative stress reversal via electron donation by anti-oxidants, to repair skin damage irrespective of the patient’s age. We postulate that the reason why recent Nobel Prize research in Physiology or Medicine [1, 44 - 55] has focused on molecular mechanisms is because simple molecular mechanisms possess an unlimited capacity for time reversal, reinstating the integrity of cellular structures that existed prior to damage. This is obviously interesting beyond the evidence of reversing a hard-to-heal skin lesion back to healthy skin, and it can expand to several areas of regenerative medicine and the treatment of various diseases. Noticeably, time-reversal attributes are exclusive to the simple aspects of cellular mechanics and do not directly apply to the entangled composites of vital organs that represent Gestalts unable to reverse in time because of the inherent complexity of a Gestalt reflecting an entity that is more than the sum of its parts. Hence the effectiveness of ultra-low energy technologies that target and mimic the energy levels produced by cellular activity. We finally cite the results of a novel ultra-low energy technology on eight clinical cases with distinct lesions including acute wounds, diabetic foot ulcers, burns, a postoperative basal cell carcinoma lesion, a Herpes Zoster case and a hypertrophic scar case. The novel ultra-low energy technology used in this study is based on extensive unpublished research exploring the potential of enhancing the inherent time-reversal capacity of molecular mechanisms to mobilize the body’s natural healing responses. The technology defies the pre-existing assumption postulated by laser and RF technologies that force is necessary to reach the lower skin layers, on the basis of the mathematically proven formula [71] demonstrating that electrons can control ion channels gating, thus allowing the flow of energy inside the cells.
Technological Advances in Accelerated Wound Repair and Regeneration
Xanya Sofra, Ph.D ¹ Nuris Lampe, M.D. ²

Abstract
Healing is much slower with age due to aberrant cell communications leaving the body with inappropriate levels of growth factors and connexins resulting in hypo or hyper-proliferation and sustained inflammation, delaying or negating healing, or leading to hypertrophic scars and keloids. A review of laser and RF technologies in wound healing, keloids and hypertrophic scars indicates partial recovery, in the absence of longitudinal studies to control for possible reoccurrence of skin lesions. On the other hand, ultra-low energy technologies have reported complete healing of diabetic and other hard-to-heal skin lesions with no reoccurrence that is independent of the patient’s age. Studies utilizing low-energy technologies postulate that wound healing is the result of electron flow acting as a major antioxidant relieving the lesion from oxidative damage thus reducing inflammation. Persistent inflammation is the result of accumulated oxidative stress, defined as an imbalance between ROS production and their elimination by biological protective mechanisms. The negation of the age factor in wound healing by ultra-low energies is significant in light of a large body of research that postulates compromised immunity and increased low grade inflammation in aged individuals. We introduce the possibility that low-energy technologies may be mobilizing the inherent time-reversal capacities of the body’s molecular machines, one of which is oxidative stress reversal via electron donation by anti-oxidants, to repair skin damage irrespective of the patient’s age. We postulate that the reason why recent Nobel Prize research in Physiology or Medicine [1, 44 - 55] has focused on molecular mechanisms is because simple molecular mechanisms possess an unlimited capacity for time reversal, reinstating the integrity of cellular structures that existed prior to damage. This is obviously interesting beyond the evidence of reversing a hard-to-heal skin lesion back to healthy skin, and it can expand to several areas of regenerative medicine and the treatment of various diseases. Noticeably, time-reversal attributes are exclusive to the simple aspects of cellular mechanics and do not directly apply to the entangled composites of vital organs that represent Gestalts unable to reverse in time because of the inherent complexity of a Gestalt reflecting an entity that is more than the sum of its parts. Hence the effectiveness of ultra-low energy technologies that target and mimic the energy levels produced by cellular activity. We finally cite the results of a novel ultra-low energy technology on eight clinical cases with distinct lesions including acute wounds, diabetic foot ulcers, burns, a postoperative basal cell carcinoma lesion, a Herpes Zoster case and a hypertrophic scar case. The novel ultra-low energy technology used in this study is based on extensive unpublished research exploring the potential of enhancing the inherent time-reversal capacity of molecular mechanisms to mobilize the body’s natural healing responses. The technology defies the pre-existing assumption postulated by laser and RF technologies that force is necessary to reach the lower skin layers, on the basis of the mathematically proven formula [71] demonstrating that electrons can control ion channels gating, thus allowing the flow of energy inside the cells.
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**Keywords:**
Keloids;  
Acute wounds;  
Skin lesions;  
Hypertrophic scars;  
Inflammation;  
Necrotic wounds;  
Herpes Zoster;  
Diabetic foot ulcers;  
Cell signalling;

**Introduction**

Wound healing is the result of a complex tissue repairing process. Several technologies have been utilized to induce accelerated wound healing, wound breaking strength reflecting the restoration of the mechanical properties of tissue strength and prevention of keloids and hypertrophic scars. The skin responds to injury with a series of dynamic processes that can be summarized into three phases: a) coagulation / inflammation, b) tissue formation and c) remodeling. Technologies utilized to speed up the healing process include different forms of photo biomodulation such as ultrasound and lasers, electrical stimulation, electromagnetic fields and ultra-low microcurrent interventions.

1. **Disregulated Signaling Pathways and Persistent Inflammation underlie Abnormal Healing**

An overlook of the complex landscape of wound healing processes offers at least two therapeutic targets, reducing persistent inflammation and reinstating balance in damaged or over-excited signaling networks. Initially, hemostasis rapidly follows injury involving platelet-plug formation to reduce blood loss and prevent contamination. Inflammation first recruits, neutrophils, the phagocyte white blood cells (WBC) that kill invasive microorganisms at the wound site. Macrophages clear apoptotic neutrophils and orchestrate early wound closure events, emitting signals that lead to later scarring [2], [3]. Embryonic model studies on wound healing have indicated that prior to the onset of a wound inflammatory response, immature tissues are capable of scar-free healing [4], [5]. Additionally, entirely normal healing is observed at the genetic depletion of mast cells that release histamine and other substances during inflammatory and allergic reactions [6]. Fibrotic scarring, the pathological wound healing in which connective tissue undergoes extensive remodeling prior to replacing normal parenchymal tissue, leads to keloids when keratinocyte signals are damaged. This was evident in a wound repair study demonstrating that skin gamma delta T cells (γδ T) may be vital for recognizing keratinocyte ‘damage’ signals and releasing key growth factors for epidermal migration [7]. A more detailed account of the wound healing process maps processes that start with neutrophils and
macrophages, followed by the growth factor beta signaling pathway (TGF-b) and platelet-derived growth factor (PDGF), one of the numerous growth factors that regulate cell growth and division [8]. The earliest gene upregulations involved in wound healing include Ap1, Fos and Jun genes, [9] and the krox zinc finger transcription factors [10] that may be part of the transcriptional activation machinery for the upregulation of several hundred genes enabling cell proliferation, and the epidermal migration of keratinocytes between the scab and the healthy wound granulation tissue. Some of these genes are silenced by the polycomb group (PcG) until after wounding, when the PcG are downregulated, at which time these genes become available for transcriptional activation [11]. Re-epithelialization is driven by a number of different growth factors, including hepatocyte growth factor (HGF), the fibroblast growth factor (FGF) and epidermal growth factor (EGF). Stem cells significantly contribute in the cellular proliferation necessary to replace the lost epidermal cells, however, the extent and source of the stem cells contribution is unclear [12]. A newly discovered and clinically relevant signaling pathway is triggered by evidence that the activation of chemokine ligand 2 release by wound fibroblasts draws in a larger inflammatory response [13]. Blocking the release of chemokine ligand 2 leads to reduced inflammation and subsequently reduced scarring [14]. The transforming growth factor beta 1 (TGF-β1) is almost certainly one of the growth factors involved in the wound inflammatory response, and knockdown of the TGF-β1 signaling axis has been shown to reduce scarring [15]. All this research data supports the theory that unbalanced signaling, where certain processes are disrupted, and others are overstated, increases the wound inflammation that is the primary driver of scarring at the wound site. Chronic, persistent inflammation is a hallmark of most chronic wounds. On the other hand, resolution of the inflammatory response is the normal pathway that biological mechanisms take during acute healing.

2. Hypertrophic Scars and Keloids

Hypertrophic and keloid scars appear to be the result of a combination of inflammation and aberrant over-activity of wound fibroblasts that is not switched off but aimlessly continues after the wound repair process has been completed, i.e. a dysregulated signaling issue. Keloids are characterized by occluded blood vessels. They are non-regressive and extend beyond the margins of the original tissue damage. Interestingly, keloids tend to show a genetic predisposition, with particular association with darker-skinned populations [18]. Keloids affect between 4.5% and 16% of black and Hispanic populations, with an incidence of up to 16% in black Africans. They occur less frequently in populations with lighter skin. [20]. The prevalence of hypertrophic scars ranges from 15% to 63% in white people [21]. In terms of systemic risk factors, adolescence and pregnancy appear to be associated with a greater risk of developing pathological scars [22]. It may be that sex hormones such as estrogens and androgens have vasodilatory effects that intensify inflammation. There is unpublished clinical data of an increased incidence of keloids at the start of adolescence when there is an increase in sex steroid levels in the absence of trauma.

3. Laser Treatments for Keloids and Hypertrophic Scars

Laser devices used in the treatment of keloids and hypertrophic scars are mostly based on the principle of selective photothermolysis which involves a specific wavelength light emitted by the
laser acting on a target skin structure to either remove part or all the tissues on which the laser is applied (ablative lasers) or induce necrosis of these skin structures without, however, removing them (non-ablative lasers) [23]. However, eradicating keloids needs high level of expertise and usually has adverse effects. A lot of studies suffer from subjective evaluation of treatment outcome, limited or no follow-up, and poor study design [24]. Additionally, different skin structures respond differently to eradication. Keloid reoccurrence is more frequent in some skin structures more often than in others [22], imposing the necessity of a laser with a specific wavelength similar to that of the targeted skin structure [23] [24]. Other laser research claims statistical significance that is not convincing when the results are subjected to critical analysis. For example a recent study [25] subjected 22 Japanese patients to ND:YAG laser irradiation. They report a statistically significant improvement of p<0.01 on the subjects’ keloids and hypertrophic scars. A statistical significance of p<0.01 indicates that over 99.9% of the subjects were benefited by the treatment. However, when these results are further analyzed, it is reported that only 8 of these subjects had a clear reduction in the size of their lesions. It is not clear whether the subjects with the clear reduction in the size of their lesions were subjects with keloids or hypertrophic scars, because the sample was heterogeneous: 16 of the subjects had keloids and 6 of the subjects had hypertrophic scars. Additionally, it is reported that 10 of these subjects had a slight reduction and 4 showed no change. In terms of statistical significance 4 subjects would signify that only 82% of the subjects had some improvement, a number that is not statistically significant and only 63% of the subjects had a clear reduction in the size of their lesions. It should be noted that a percentage of 63% is only 13% higher than chance. None of the subjects had a complete recovery in their lesions. The lack of differentiation between keloids and hypertrophic scars [26] poses issues in the construct validity of these studies. The most important problem with laser treatments, however, is that both keloid and hypertrophic scars tend to recur after laser treatment [22]. Usually, laser treatments are combined with other methods such as compressive therapy, intralesional steroids, topical imiquimod, topical mitomycin C, intralesional and topical 5-fluorouracil (5-FU). 5-FU has been shown in-vitro to reduce fibroblast growth and increase fibroblast apoptosis while decreasing collagen synthesis [28]. However, 5-FU has side effects such as wound ulceration, and hyperpigmentation [29] and only 66 - 77 % of patients experience greater than 70% scar flattening, with 21-35% recurrent rate [30] None of these percentages is statistically significant.

Low-level laser therapy (LLLT) has been found to significantly decrease the time of wound healing [31]. Sixty-eight patients with foot ulcers due to Diabetes Mellitus (DM) were included in this LLLT study. They were divided into two groups, with 34 patients in the control group and 34 patients in the treatment group receiving LLLT. The initial ulcers area in square millimeters was 2747.17± 603.79 for the control group and 2608.03 ± 683.14 for the treatment group. The statistical significance was p=0.36. The final ulcer area in square millimeters was reduced in both groups, however, it was significantly more reduced in the treatment group: control group: 2424.75 ± 551.26 and treatment group 1564.79 ± 437.30 with a statistical value of p=0.218 which is not statistically significant. These investigators report a significant decrease in ulcer area in the treatment group at the statistical significance of p<0.001, however, they do not offer information on whether the ulcers wound contraction was also statistically significant in the control group that received no treatment and which also displayed an ulcers wound
contractions from 2608.03 ± 683.14 to 2424.75 ± 551.26. In any case the contraction of ulcers wounds in the treatment group did not represent complete healing. There was no follow-up to examine the possible re-occurrence of ulcers or a comparison of the severity of the re-occurring ulcers in both treated and untreated groups. Several other laser studies report significant improvement in the wounds of treated patients when compared to controls, however none of these studies report complete wound healing and no re-occurrence of the wound. [32]. Beckerman et al. [33] looked at the efficacy of laser therapy of skin and musculoskeletal disorders on the basis of 36 randomized clinical trials involving 1,704 patients. They report that no clear conclusions could be drawn on the efficacy of laser therapy on skin disorders. On the average, the efficacy of laser therapy was higher than placebo on musculoskeletal disorder such as rheumatoid arthritis, myofascial pain and post-traumatic joint disorders, however there was no complete pain alleviation or longitudinal follow up to assess the possible re-occurrence of the musculoskeletal disorder.

4. **Endogenous Electrical Fields in Wound Healing and Ultra Low Energy Devices**

Endogenous electrical fields (EF) arise instantaneously during skin injury and decline with distance from the site of injury. Naturally occurring endogenous EF also orient division and direct cell migration [34][35]. The disruption of endogenous EFs causes specific abnormalities of CNS development [34]. Wound-generated endogenous EFs controlled the polarization index of cell division concentrated at the wound site. Chemically enhancing endogenous EFs increased the polarization index, while chemically reducing the wound-generated EF reduced the polarization index almost to zero [34]. The possibility that cell proliferation will increase by enhancing wound-generated endogenous EF has also been investigated [34]. Chemically enhancing the endogenous EF increased cellular proliferation in the first 200 - 600 μm from the wound site, and chemically reducing the endogenous EF decreased cell division especially in the first 200 μm from the wound site. During wound healing, angiogenic capillary sprouts invade the fibrin/fibronectin-rich wound clot developing a microvascular network throughout the granulation tissue. As collagen accumulates in the granulation tissue to produce a scar, the density of blood vessels diminishes. A number of research articles report that electrical stimulation enhances angiogenesis [36][38]. Angiogenesis is directly related to wound generated endogenous EFs. There is evidence that injured tissue becomes electrically polarized by endogenous EFs relative to surrounding normal tissue. This appears to be the result of cellular depolarization along with an increase of extracellular K ions in the damaged areas. [37]. When physiological EFs with the above parameters are applied in vitro to cells in culture, they appear to determine the orientation, the migration and the axis of division of epithelial cells. EFs are associated with other cell behaviours crucial to tissue growth and repair in wound healing [39]. Bok Lee et al. [40] conducted a series of studies with an electrical device that delivers a direct current that ranges from 3mA (1mA = 0.001 Amp) down to 100 nanoamperes (1 nanoampere = 10⁻⁹ amperes). The device was designed to switch the direction of current flow halfway through the cycle, which is around 23 min, delivering a square wave bipolar current with a voltage ranging from 5V up to a maximum of 40V. These investigators report that ultra-low microcurrent has notable therapeutic effects on diabetes, hypertension and wound healing. They differentiate their device from other TENS devices because their device emits ultra-low microcurrents that reach the nanoampere range, thus
being more compatible with endogenous EFs. They also postulated that the steady stream of electrons emitted by their device into the skin acts as a super antioxidant because this steady stream electron delivery amounts to more electrons entering the skin when compared to the interrupted mode of delivery adopted by other TENS devices. Antioxidants donate electrons to free radicals, turning them back into stable molecules, an interesting time-reversal process observed only with simple molecular mechanisms that is impossible in complex entities. Complex entities like vital organs, for example, are composed by stable intertwined cellular structures determined by specialized stem cell differentiation and as such they are transformed into Gestalt entities that are more than the sum of their parts. The reason why damaged organs cannot spontaneously go back in time and transform into the healthy state of their previous existence, unlike free radicals that can turn back into stable molecules by electrons addition, is because Gestalt entities are more than the sum of their parts; they are not just cells, they have evolved into specific organs, a liver, a heart, a kidney, etc. and therefore, they cannot be reduced back into their parts, the cells that originally composed them during human development or into the embryonic stem cells prior to their differentiation process, without losing their most important component, the Gestalt that defines them with the specificity of a liver, heart or kidney and distinguishes them from other organs. The large literature of microcurrent studies reporting effectiveness on wound healing via low energies that target and mimic the energy levels produced by cellular activity supports this premise that time reversal is only inherent in molecular mechanisms. Several microcurrent studies have reported enhancing soft tissue healing [41], increased secretion of growth factors [35] and adenosine triphosphate (ATP) production [42]. Microcurrent has been also found to stimulate fibroblasts and U037 cells’ secretion of transforming growth factor-β1 which is a major regulator of cell-mediated and therefore controlled inflammation, and tissue regeneration [43]. In the current study we used a new technology originally invented in London University and repeatedly modified over the last 20 years on the basis of unpublished in vitro and clinical research as well as extensive electronic research.

Methodology

The ultra-low energy technology IELLIOS was used in the study. It was originally invented in London University in 1992 and was subsequently modified over a period of 20 years on the basis of unpublished in vitro, clinical and electronic research. The technology has been used for over 10 years in clinical practice by over 800 physicians around the world with no reported adverse reactions or sides effects. It is subjectively experienced as relaxing despite the fact that it is imperceptible. Contraindications, warnings and cautions are according to the list provided under TENS devices by the FDA, although the IELLIOS nanoamp output (nanoamp = 10⁻⁹ Amperes) is substantially lower than any other TENS devices which are usually in the milliamp range (milliamp = 10⁻³ Amperes). The technology stores 9,600 sine and square waveforms synthesized on the basis of an original mathematical formula with resultant frequencies ranging from 0.25 – 10,000 Hz. The 9,600 signals are emitted in a sequence determined by a second prototypical mathematical formula at time intervals determined by a third prototypical mathematical formula. The technology is designed to emit four different complex waveforms simultaneously in a variety
of discrete specific times that range from 4 secs to 24 secs. The four different waveforms are emitted simultaneously from the four virtual channels designed by prototypical software via the technology’s single channel and through a pair of tour grade ultra-silver-plated microphone cables with stainless surgical steel leads attached to their ends. The leads must make contract with the patient’s skin. Leads are sanitized prior to each usage. During treatment, the device’s voltage output ranges from 0.003\( \mu \)V to 0.5\( \mu \)V \((\mu \text{V}=10^{-6} \text{Volts})\) depending on the resultant frequency. The device’s current output reaching the skin ranges from 10 nanoamps to 60 nanoamps.

**Procedure**

This research project was conducted over a period of four years, giving the opportunity to follow up all patients involved in the study. The studies were conducted by independent clinics at different parts of the world including the USA, Netherlands, Aruba, Hong Kong and Singapore, and were supervised by different licensed physicians who had just started using the IELLIOS technology. None of the doctors had any bias or conflicts of interest that could affect the direction of the results. All clinical studies were self-financed by the doctors themselves. The procedure was conducted by nurses who had no bias or conflict of interest. The nurses had basic knowledge on how to operate the device. All patients were screened by a licensed clinician or licensed clinical dermatologist who assessed the patient’s history and symptomatology to determine diagnosis. All patients filled a medical questionnaire and a consent form. None of the subjects had a cardiac pacemaker, implanted defibrillator or other implanted metallic or electronic devices. None of the women who participated in the study was pregnant, was trying to get pregnant or had knowledge of the possibility of being pregnant (e.g. missed a menstruation cycle). None of the subjects was familiar with the IELLIOS or its indications for use prior to the first treatment. The before and after photos of these patients were reviewed and scored by three independent judges who received the photos by e-mail and who were in completely different parts of the world from each other. The three judges were independent physicians who did not know each other and who were blind to the methodology and technology used in this research project. The judges were given information about the number of treatments that each patient received because that was necessary to determine the score on the speed of healing. However they were not informed as to which of the pictures they received for each patient were the before treatment pictures and which were the after treatment pictures. Additionally, the judges did not know the patients’ history and did not personally know any of the patients. Scoring was based on a scale from 1 to 10 with 1 signifying no healing and 10 signifying maximum healing and / or highest healing speed. The judges e-mailed back the pictures with their scores and 3 scores were assigned to each of the subjects. The score given to all the before treatment pictures, which was the same for degree of healing and speed of healing, and two scores given to the after pictures for degree of healing and speed of healing because the judges had rated some of the after pictures as having a higher degree of healing but a slower rate of healing, depending on the number of treatments offered, and visa-versa.

**Results:**

**Case 1. Traffic Accident**
Male 39-years-old patient who had a car accident scraping off the skin and flesh on his right-hand knuckles and losing the fingernails of his middle, ring and little finger. His hand’s knuckles evidenced wound enlargement through contraction of the surrounding musculature and an increase in resting tissue tension. The knuckle wounds of his index and middle fingers were 4mm long, 3.5mm wide and 3.75mm deep respectively, exposing the bone under the phalanx of his index and middle finger. Following the accident, he was admitted to the emergency room from where he was referred to a plastic surgeon who recommended surgery but warned the patient that he may never grow new nails or regain mobility on his hand. The patient was devastated because he was in construction and primarily worked with his hands. He was recommended for an IELLIOS treatment twenty days after his accident and upon arrival he reported constant pain, increased inflammation, edema, and fever. Despite the oral antibiotics and antibiotic cream given to him by the plastic surgeon, his injury appeared to be getting worse. He expressed little hope as to the effectiveness of the IELLIOS treatment, since nothing else had worked and as a result of his previous consultation with the well-known plastic surgeon who had warned him that the injury may cause permanent damage to his hand. After the initial consultation and upon completion of the necessary paperwork he received twelve 60-min IELLIOS treatments once or twice a week for a period of six weeks. He reported pain alleviation and an improvement on his injuries the morning after the first treatment. The subsequent treatments appeared to speed up healthy skin growth and tissue remodelling. Although no surgical debridement was performed, two weeks after the 12th treatment his hand had completely healed. All damaged tissue was replaced by healthy skin without leaving a scar and his nails had fully grown (Figure 1). The three judges scores were as follows: before treatment healing: 1.3; after treatment speed healing 7.6; after treatment degree of healing: 9.6.

Case 2. Knife Cut Accident.
Female 53-years-old with a knife cut wound on her finger. She experienced excessive bleeding and went to the emergency room where the wound was stitched. Four days later she visited her

Figure 1. Traffic accident wound. Before treatment and two weeks after the 12th treatment
doctor who recommended the IELLIOS treatment. She received four 20-min treatments twice weekly for two weeks. Immediately after the first treatment the inflammation around the stitches was diminished as seen in the second picture of Figure 2. After the second treatment, the patient reported that she was able to move her finger without experiencing pain. After the fourth treatment ten days later, the wound had completely closed leaving a minor scar (Figure 2). The three judges scores were as follows: before treatment healing: 4.6; after treatment speed healing 7.6; after treatment degree of healing: 6.3.

**Case 3. Diabetic Foot Ulcers.**

Female 84-year-old patient. Diabetic foot ulcers do not adhere to cellular and molecular events involved in the healing of an acute wound. The ulcer wound fibroblasts appear senescent, have diminished migratory capacity [16], and appear unresponsive to growth factor signals [17], which is reflected in dramatically reduced levels of TGF-β receptors. Immune cells signalling appears to be disrupted in chronic wounds like diabetic foot ulcers as demonstrated by their significantly reduced phagocytic and bactericidal activities [18]. There is generally necrotic debris and a heavy inflammatory infiltrate, particularly of neutrophils, and these cells may be phenotypically different from their equivalents in healing acute wounds [16]. Peripheral limb edema is a feature of diabetes that has been identified as a significant risk factor for amputation in patients with diabetic foot ulcers[72]. This patient suffered from diabetic ulcers, neuropathy, and lower limb lymphedema. The diabetic ulcers was 4.5 mm deep, 2 cm wide and 2 cm long. She had been unresponsive to antibiotic medication and other traditional wound treatments that she had received in the past. She received six 30-min IELLIOS treatments once weekly for six weeks. During the six weeks of treatment the wound appeared to go through the proliferative and
maturation phases normally without signs of infection. Epithelial cells at the edge of a wound appeared to proliferate after the third treatment and the edema was significantly reduced. Epithelialization appeared to occur from within the wound and after the fourth treatment the wound appeared to close through the formation of granulation tissue. The wound continued to heal after the IELLIOS treatment with more extensive reepithelialisation and a wound contraction that had reduced the wound by 93% leaving some pinkish redness around it. The third photo was taken a year after the first IELLIOS treatment (Figure 3). There was no reoccurrence of the foot ulcers during the two years follow up. The patient also reported permanent neuropathic pain relief on that leg as a result of the six IELLIOS treatments that she had received. The three judges scores were as follows: before treatment healing 1.3; after treatment speed healing 7.6; after treatment degree of healing: 8.6.

Case 4. Necrotic Tissue Wound nine days after Liposuction Procedure:
This 39-year-old female patient was a non-smoker, with no reported previous medical conditions, complications or surgical procedures other than undergoing liposuction nine days prior to the IELLIOS treatments. As a result of the liposuction, she developed a necrotic wound of the Eschar type composed by an accumulation of cellular debris, dead cells and tissue. The wound was the result of a liposuction procedure. Eschar necrotic wound presented as dry, thick, leathery tissue that was black in colour. Necrosis is the death of cells in living tissue caused by trauma. Necrotic tissue is defined as dead or devitalized tissue. Normally, this type of tissue adheres to the wound.
and cannot be removed, significantly delaying wound healing unless the necrotic tissue is surgically removed. The necrotic wound that was 4mm deep, 16 cm long and 8.5 cm wide. Prior to each IELLIOS treatment the wound was cleaned with iodine solution and then the IELLIOS treatment was performed twice a week for 30 minutes, for eight consecutive weeks for a total of sixteen sessions. After the fourth treatment, the wound appeared to change into a slough wound composed by a deeper area characterized by a combination of deep red and yellow-white tissue that was moist and stringy in appearance, and surrounded by a more shallow thin pink outline of granulated tissue shown in picture 2 in Figure 4. Epithelialization appeared to progress from within the wound outwards, with new granulation tissue filling in the wound and connecting its edges as well as microscopic blood vessels forming on the surfaces of the granulated skin as in picture 3 of Figure 4. After the fourteenth treatment the skin had the appearance of full thickness and was light pink in colour as in picture 4 of Figure 4. The patient reported full skin recovery after a month following the sixteenth treatment with a flat faded scar. The three judges scores were as follows: before treatment healing 1.3; after treatment speed healing 6.3; after treatment degree of healing: 7.6. The before and after photos were taken by the technician who operated the IELLIOS procedures. Only the scores of the before and the after pictures were included, however, all pictures sent to the judges are depicted in Figure 4 to show the progress of the wound healing process.

Case 5. Hypertrophic Scar after a 3-year old Liposuction Wound:
This patient developed a hypertrophic scars from a liposuction procedure similar to the procedure that had left the necrotic wound in case 4. The patient underwent the liposuction procedure three years prior to her first IELLIOS treatment. This was a female patient 39-year-old, non-smoker, with no reported previous medical conditions, complications or surgical procedures other than the liposuction wound which had subsequently left the hypertrophic scar. She reported that following liposuction the wound had developed debris, inflammation and erythema as well as post-

Figure 5. Hypertrophic scar surrounded by post-inflammatory pigmentation before and after 10 IELLIOS treatments.
inflammatory hyperpigmentation that covered a large part of her waist, part of her abdomen and her backside. The resulting hypertrophic scar was 3.5 mm raised, erythematous and brownish-red in colour, 20 cm long and 4 cm wide. It was reportedly hard to the touch and felt tender, painful or itchy according to the patient’s reports. After the completion of the necessary paperwork including the medical questionnaire and consent form, she received 6 treatments with the IELLIOS over a period of 6 weeks. After the sixth treatment the hypertrophic scar had been almost completely reabsorbed, being replaced by new tissue, leaving a faded flat scar of around 12 cm long and 1.5 mm wide. The pigmentation that previously covered her waist, part of the abdomen and backside was also significantly reduced. The patient reported no reoccurrence of the hypertrophic scar. The scores of the three judges were as follows: before treatment healing : 2.3; after treatment speed healing 6.3; after treatment degree of healing: 7.6. The photos provided were taken by the treating technician.

Case 6. Postoperative Wound after removal of Basal Cell Carcinoma:
Female patient 84-year-old with severe sun damage, chronic venous insufficiency and a history of basal cell carcinomas, a type of cancer developed in various area of her body exposed to the sun, including face and legs. Patient was diagnosed with diabetes mellitus and had neuropathy on both legs. The basal cell carcinomas on the side of her face were first surgically removed by her dermatologist leaving a large wound of 8 cm long and 3 cm wide. As the wound dried it formed a hard layer of a scab. There were another seven smaller wounds around ranging from 1 x 2 mm to 2 x 3 mm each. The patient was given six 30-min treatments with the IELLIOS once weekly for six consecutive weeks. The patient reported healing immediately after the first

![Postoperative wound prior to treatment and after six treatments.](image)
treatment that became progressively more evident as both the inflammation and post-inflammatory pigmentation were reduced. The wound healed normally creating a layer of granulation tissue that covered the base of the wound closed and appeared to have regenerated into new skin changing colour from red and brown to light pink. This appeared to be the maturation or strengthening phase, where the wound looks closed and repaired, yet it is still healing. The scores of the three judges were as follows: before treatment healing: 2.3; after treatment speed healing 7.6; after treatment degree of healing: 8.3.

Case 7. Herpes Zoster:
Female 86-year-old patient with no reported medical history. She developed a fully blown

Figure 7. 86-year-old-female with Herpes Zoster. Before the 1st treat and after the 2nd treatment
condition of Herpes Zoster, a viral infection caused by the varicella-zoster virus. On the first week after experiencing pain, hyperesthesia, facial lesions and fever she went to the hospital where she was treated with antiviral medications including Amciclovir and Valacyclovir, anti-inflammatory corticosteroids and cool compressions to soothe the rash. After the initial consultation and upon completion of the necessary paperwork she was treated with the IELLIOS ultra-low-energy technology which she had never tried before. Prior to treatment she presented weakness of the right-side muscles of her face and her right eye was dropping and half-closed. Her right cheek and mouth were covered with extensive lesions. She was treated for 40 minutes and then she was offered a second 40-minute treatment a week later. Both the cheek and mouth lesions completely cleared after the second treatment and her left and right side of her face were balanced. The before photos were taken by the operator and the after photos were taken by the patient’s daughter. The patient reported that immediately after her second treatment she observed major improvement on the Herpes Zoster lesions when the after pictures were taken. A week after the second treatment the skin lesions had completely disappeared in the absence of scar formation. There was no erythema or hyperpigmentation and the skin appeared normal. To date, 2 years and 4 months following the two treatments, there have been no reoccurrences of Herpes Zoster in this patient. (Figure 1). The scores of the three judges were as follows: before treatment skin healing: 2.3; after treatment speed healing 9.3; after treatment degree of healing: 8.3.

Case 8. Second Degree Burn:
Female 28-year-old patient and spilled hot boiling soup on her thighs. She went to the hospital

Figure 8. Second degree burn; healing progress from the 1st to the 4th treatment.
where she was diagnosed with a second-degree burn. She came for a consultation three days after her injury. It was confirmed that this was a second-degree burn affecting the epidermis and dermis can causing blistering and inflammation and areas of moist exposed tissue. Upon completion of the necessary paperwork she received 4 IELLIOS treatments twice a week for two weeks. She had never heard of IELLIOS prior to her treatment and expressed both surprise and doubt as to the effects of the treatment, since she experienced no sensation other than the cool touch of the probes. The four treatments were performed by two different operators who were not informed that the procedure was part of a study and had basic training on how to perform the procedure. The day after the first treatment the patient reported extensive healing that became more visible two days after the first treatment. The wounds were closed after the third treatment and new skin had resurfaced. The post inflammatory pigmentation observed after the third treatment was reduced after the fourth treatment. The patient reported that two weeks after her four treatments the pigmentation was significantly reduced, and the skin of her thighs appeared to be normal (Figure 3). The scores of the three judges were as follows: before treatment healing: 2.3; after treatment speed healing 8.3; after treatment degree of healing: 7.6.

Results Analysis

We performed an one-way ANOVA for repeated measures on the degree and speed of healing given by the three independent judges to the prior to treatment pictures and the after treatment pictures. The mean average of the three judges’ scores for the 3 categories are given on table 1.

<table>
<thead>
<tr>
<th>Before Treatment Degree / Speed of Healing</th>
<th>After Treatment Speed of Healing</th>
<th>After Treatment Degree of Healing</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1.3</td>
<td>7.6</td>
<td>9.6</td>
</tr>
</tbody>
</table>

*Table 1. The mean average scores of the 3 judges for before and after treatment degree and speed of healing*

The repeated measures ANOVA compares means across one or more variables that are based on repeated observations. The summary of data is given on Table 2. The $F$-ratio value was 70.82343. The $p$-value is < .00001. The results were significant at $p < .01$. Statistical significance at $p<0.01$ level indicates that a treatment will be effective in over 99.9% of subjects while only less 1% of the subjects will not be benefit from the treatment. The statistical analysis data is given below. The $p$-value was < .00001 suggesting that treatment results were substantially more significant. Our sample was heterogeneous, including a large variety that included acute and chronic wounds each with a different aetiology. Additionally, the subjects age ranged from late 30s to early 80s and the number of treatment varied from subject to subject. The reason for including such a heterogeneous sample that varied both in wound
 severity and degree of skin damage was the only significant factor on how many treatments each case required as well as the speed and extent to which a wound healed.

![Figure 9. The substantial difference between degree of healing prior and after treatment as well as the speed with which such healing occurred is depicted in the chart above](chart)

We also included a hypertrophic scar in this group to see how an old closed wound would respond and if there was a possibility for healing a hypertrophic scar at a similar speed as an acute wound. However, additional research on specific wounds and a larger sample is required.
before we can conclusively assess the validity and reliability of the treatment modality used in this study.

**Conclusion:**

The results of our clinical case studies suggest that the main determining factor in how fast and how well a wound will heal depends on the severity of the wound rather than the age of the patient. Bok Lee et al. (2007, 2010) [40] came to similar conclusion that ultra-low microcurrents accelerated healing while negating the effect of a person’s age on wound healing. The number of treatments required for complete healing depended on the chronicity and severity of the lesion, with more chronic severe lesions requiring more treatments in both our study and Bok Lee’s studies. Bok Lee et al. interpreted the effect of ultra-low microcurrents on tissue regeneration as the result of a highly potent antioxidant effect on local tissues and indicated that the antioxidant effects of this type of therapy may “change the concept of management of chronic diseases” on the basis of the premise that oxidative stress and oxidative damage are common causes of persistent inflammation and the pathology of chronic lesions. These results on wound healing where age is not a factor directly contradicts a large body of literature postulating that healing is much slower with age due to immune insufficiency, oxidative stress and disrupted cell communications predisposing the body with inappropriate levels of growth factors, connexins and sustained inflammation [77]. We reviewed a number of other methods available for the treatment of wounds, keloid and hypertrophic scars that included a number of different lasers. All laser studies we reviewed reported keloids and hypertrophic scar improvement and partial wound healing. However, there was little or no follow up to control for reoccurrence of keloids, hypertrophic scars or skin lesions. The ultra-low microcurrent studies we reviewed appeared to demonstrate complete healing where age was not a factor with no reoccurrence of the skin lesions. As previously stated, the most important problem with laser treatments is that both keloid and hypertrophic scars tend to recur after laser treatments [22].

The concept that ultra-low energies act as a major anti-oxidant healing via alleviation of oxidative stress is interesting in light of the correlation between oxidative damage and chronic inflammation. Mitochondrial oxidative metabolism necessary for energy production produces reactive oxygen species (ROS) and organic peroxides. Energy production is necessary for cell homeostasis, signal transduction, gene expression, receptor activation, e.t.c. [74] [75]. Infections and injuries trigger an immune activity that needs to be powered by extra energy leading to an overproduction of ROS in the cells and tissues causing oxidative stress and the expression of genes involved in inflammatory pathways, the synthesis and secretion of proinflammatory cytokines and subsequently, chronic inflammation [76].

The case studies we presented were collected over a period of four years and each case was monitored for at least one year after treatment was completed, confirming that there was no reoccurrence in the wound lesions or an incidence of hypertrophic scars. The novel ultra-low energy technology used in this study is validated by recent research suggesting that at certain very low energies the electrons control the gates of potassium, sodium and calcium ion channels thus allowing the flow of signalling inside the cell [71]. We define signalling as the composition of a sequence of specific sine and square waveforms that range from
0.250 Hz to 10,000 Hz developed on the basis of a prototypical formula. Four of these complex waveforms are delivered simultaneously in a sequence that is also determined by a prototypical mathematical formula, at varying time intervals ranging from 3 to 24 secs that is also based on a third proprietary formula. The formulas have been synthesized on the basis of a 20 year clinical and laboratory unpublished research. Our explanation for the speed and degree of healing observed in the clinical cases included in this study is based on the possibility that this ultra-low energy technology configuration is mobilizing the inherent time-reversal capacities of the body’s molecular machines to repair skin damage irrespective of the patient’s age. The antioxidant effect on tissues postulated by Bok Lee et al. (2007, 2010) is also an aspect of the inherent time reversal capacity of free radicals turning back into stable molecules, simply by filling in their missing electron by the electron donating antioxidants. Obviously, if this assumption is validated by future research it will have a great impact in several areal of regenerative medicine. The overall concept of the healing capacity of ultra-low energies is not new or unsupported by other research. Poltawski and Watson 2013 [73] examined a large number of all peer-reviewed studies on the effects of ultra-low microcurrent in tissue healing at intensities similar to those produced by the body and concluded that microcurrent therapy can promote healing in a variety of bone and skin lesions. Wirsing et al. (2013) [78] studied 47 patients with hard-to-heal venous, arterial and mixed leg ulcers treated with 1.5 μA current intensity and found a mean reduction of the wound surface in 95% of the cases with complete healing achieved within three months for the majority of the cases with no clinical side effects. The patients included in our group showed relatively fast complete healing, however, our sample was small and heterogeneous, including a large variety of skin lesions and aetiologies. Additionally, we did not have a placebo group and did not directly compare the treatment used with other methodologies, rendering our research as merely a collection of case studies rather than a well-controlled experiment. Our main goal, however, was not to perform a controlled experiment but rather to draw attention to the unrealised potential of ultra-low energy technologies in treating dysfunctional tissue, so they can be more widely used and researched by experimental teams or clinicians treating hard-to heal skin lesions.

Acknowledgments

The Authors would like to thank Dr Gerald Pollock for his electronic research and the formulas he developed in London University, and Dr Xanya Sofra for the development of the formulas implemented in the novel ultra-low energy technology used in this study.

References


34. Bing Song, Min Zhao, John V. Forrester, and Colin D. McCaig. Electrical cues regulate the orientation and frequency of cell division and the rate of wound healing in vivo. PNAS October 15, 2002 99 (21) 13577 13582; https://doi.org/10.1073/pnas.202235299 https://www.pnas.org/content/99/21/13577?ijkey=f7e9f9da1e409d807f14d23f03d0453c00533b9&keytype2=tf_ipsecsha


**Author biography**

1. **Xanya Sofra** Dr Sofra is an international speaker in several Medical and Anti-aging societies. She is the Director of Research and Development of new technology originally invented in London University. Her current research is on signaling pathways, wound healing and novel interventions resulting in visceral fat decrease and hormonal balance increase.

2. **Nuris Lampe** Dr Lampe is the Director of Lampevita Dermatology Clinic and medical staff in the Clinical Dermatology Department of Horatio Oduber Hospital. Dr Lampe is also a consultant in the Drug Registration Government section in Aruba’s Heath System.
Your image file "Hand before and after.jpg" cannot be opened and processed. Please see the common list of problems, and suggested resolutions below.

Reason: The image file is corrupt or invalid. Please check and resubmit.

Other Common Problems When Creating a PDF from an image file

You will need to convert your image file to another format or fix the current image, then re-submit it.
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Table 1. The mean average scores of the 3 judges for before and after treatment degree and speed of healing

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Table 2. Summary of Data

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Figure 9. The substantial difference between degree of healing prior and after treatment as well as the speed with which such healing occurred is depicted in the chart above.