New Technique for Chronic Wounds Care

Pulsar II™ AWI™

Wounds, in particular chronic wounds, present a challenge to patients and healthcare providers and also represent a major health care burden worldwide. The burden is growing rapidly due to increasing health care costs, an aging population and a sharp rise in the incidence of diabetes and vascular disease worldwide. To combat the increasing number of patients with chronic wounds and wound healing problems, the need for advanced wound care technique is sharply on the raise .

Chronic Wounds

Acute wounds heal in an anticipated time range, typically 21 days or less, and repair the skin structural and functional integrity[1]. Chronic wounds, by comparison, result from an inadequate or disrupted healing process and are defined as those wounds that neither follow a normal trajectory nor restore the skin functional and structural integrity[2]. Chronic wounds or ulcers may take months or years to heal.

Chronic wounds are often classified by etiology as arterial, diabetic, venous insufficiency, pressure ulcers, or non-healing surgical wounds. However, the variability in the local chronic wound environment is largely due to one of five common actors: diminished perfusion, decreased oxygenation, increased mechanical forces, malnutrition, or systemic disease[3,4]. It is the presence of these actors that determines its chronicity. Nonetheless, the division of chronic wounds by etiologic category allows capture of the primary pathophysiologic actors and statistics by disease process common to each wound type. Regardless of the etiologic classification assigned to a non-healing wound, all chronic wounds possess similar cellular and biochemical impairments[3,5,6].

Phases of Wound Healing[7]

Normal wound healing, although intricate, proceeds in an organized fashion progressing from injury through hemostasis to inflammation, proliferation, and remodeling. During the hemostasis phase, coagulation of platelets and the formation of a clot prevent excessive bleeding and form a mechanical trap or pathogens, thus initiating the transition to a pro-inflammatory environment. A hallmark indicating transition to the inflammatory phase is the recruitment of neutrophils, leukocytes, and macrophages and the production of growth factors and pro-inflammatory cytokines.

Completion of the proliferative phase leads to the formation of well-vascularized granulation tissue and extracellular matrix. Remodeling continues the process of scar contraction by myofibroblasts, tissue replacement, and controlled collagen replacement. The resulting tissue has physical properties approximating unwounded skin.

Wound healing is not an isolated event of merely reconstructing the physical skin barrier; rather it is integrated and orchestrated with both the innate and adaptive immune system. The innate immune system and the adaptive immune system are triggered by early responder cells to protect the host from potentially harmful pathogens. Working together, these cells produce and regulate proteases, growth actors, chemokines, and cytokines to accomplish the regeneration of the skin barrier and avert infection.

In each phase of healing important events transpire, which can be described as vascular, cellular, cell signaling, or cell-tomatrix interactions. Initially, during hemostasis, vasoconstriction occurs. However, during the inflammatory and proliferative phases, angiogenesis and vasodilation predominate, to both supply the nutrients or the repair process and remove the waste and debris associated with autolytic debridement. Although the same cast of characters are largely consistent during the phases of healing, their phenotypes, cellular activities, and numbers vary greatly. Platelets are of primary importance or hemostasis and angiogenesis, macrophages or the inflammatory process, the protein laminin or proper ECM construction and storage of growth factors via ECM attachment, and fibroblasts/myofibroblasts or proliferation and remodeling. The macrophage takes on the most varied phenotypic changes during the healing process, moving from a pro-inflammatory, wound-activated macrophage (WAM) in the inflammatory phase to a repair, M2 macrophage, during proliferation and remodeling. Finally, remaining macrophages function as a component of immune surveillance after healing is complete.

Chronic Wounds and Biofilms

Chronic wounds occur as a result of either a pathophysiological progression or an acute injury that fails to heal due to infection, intrinsic processes, or extrinsic inhibiting factors. One or more of the primary pathways traversing the healing process are disrupted, for example, when wound is stalled within inflammatory stage, patients have so much difficulty to moving through and getting through it. The majority of chronic wounds are characterized by excessive or persistent

inflammation, infections, presence of biofilm, and the inability of dermal or epidermal cells to respond to reparative stimuli. Clinical observations include chronic inflammation, edema, increased levels of necrotic tissue, bioburden, a poorly developed ECM, and epithelial overgrowth.

Chronic wounds are characterized by easy secondary infection and prolonged unhealed. In recent years, increasing evidence has shown biofilm is detrimental to wound healing.

Khalid Johani et al. [8] detected the presence of biofilms in diabetic foot ulcer tissue by molecular biotechnology. These biofilms contain both that formed by a single species and by a variety of bacteria. Studies by Carla Mottola et al. [9] have shown that multi-strain biofilms are widely present in diabetic foot ulcers. The results also show that the presence of biofilms can be detected after 24 hours of culture in vitro. In addition, the presence of bacterial biofilms can be detected in pressure ulcers [10], acute wounds, and post-operative wounds [11]. When the biofilm formed, an acute wound will be converted into a chronic wound, and also a chronic wound will be prolonged or unhealed.

How can we effectively prevent biofilms in wounds before an efficient biofilm detection method is applied to clinical practice? Antibiotic treatment can achieve better results under certain conditions, but long-term antibiotic treatment is likely to cause bacterial and drug resistance [12], and once the biofilm is formed, bacteria actually are protective by shell type coding that is preventing topical treatments ,such as antibiotics and dressing. When topical treatments are limited, it is particularly important to use pressurize treatment of pulse irrigation to remove biofilm.

What is PULSAR II™AWI™ ?

Pulsar II™ AWI™, is CE marked and FDA Cleared, it is an advanced wound irrigation system , debriding many kinds of chronic non-healing wound bed of devitalized tissue without disrupting the underlying normal tissues. PULSARII™AWI™ composes a PULSAR™ irrigator and a totally contained wound irrigation bag. The irrigator delivers positive pressure through pulsation of irrigation fluid. Irrigation bag provides isolation of the wound. When a pulse of water/saline strikes a tissue, the force of the pulse causes a brief compression on that tissue. Between pulses, target tissues decompress or recoil. PULSARII™AWI™ produces multiple, rapid iterations of tissue compression-decompression cycles that mechanically dislodge bacteria, nonviable tissue, and debris from the wound bed. Adherent nonviable tissue remaining after a PULSAR II™AWI™ treatment

is hydrated and loosened, thereby assisting natural phagocytosis. Compression-decompression mechanical manipulation also assists in exudate removal. Finally, PULSAR II™AWI™ stimulates the new growth of granulation tissue and can heal the wound if the treatment modality is continued.

What dose PULSAR II™AWI™ Achieve?

PULSAR II™AWI™, delivering innovative solutions for wound care. It can be used for effective and painless chronic wound debriding, of traumatic infected wounds, pressure ulcer, vascular ulcer, diabetic foot ulcer, scald wounds, cancer wounds, etc.

PULSAR™AWI™ wound therapy does achieve:

Effective Debriding: one debridement, with 3 litres of saline which takes 3 minutes, can remove 86.9% of bacteria without frequent surgical debridement and patients are free from surgical pain usually after the third treatment, and the treatment is a NO TOUCH treatment. More frequent debridement has been shown to enhance healing for chronic non-healing wounds across a wide variety of patients.

Innovation and Safety: using 8-15 pounds per square inch of pressure provides selective hydro-mechanical debridement and removal of bacteria, necrotic tissue and biofilm with each treatment without disrupting the underlying normal tissues.

Convenient and Better Tolerated by Patients: Portable equipment, no special environmental restrictions ,wound cleaning in anytime and anywhere, such as, in an emergency or accident, nursing home, clinics, patients home and also at bedside.

Infection control: The Irrigation bag provides a closed environment to prevent splashing, eliminate cross-infection and lower the risk of cross-infection. The solidifier totally absorbs five litres of saline and converts it into gel, encapsulating the bioburden from the wound bed and neutralising it so making it safe for disposal in regular waste.

In 2004 an outbreak of multi-drug resistant Acinetobacter Baumann, traced back to open suction assisted pulse lavage treatments infected multiple patients, several of whom died from their infections[13].

In 2008 a research proved that wound irrigation bag is a useful new tool that protects the debridement facility and the personnel who operate it by significantly reducing the dissemination of infectious particles. The AWI™ bag allows for safe delivery of pulse irrigation without risk of

infection, colonization or contamination of the treatment field, patient, healthcare provider or facility[14].

How should PULSAR™AWI™ be used to debride?

PULSAR™AWI™ wound therapy system composes of an irrigator, standard tip, tunnel tip, extremity bag, or trunk bag. Before debriding please choose the suitable components according to the location of the wound bed.

For wounds located on the trunk, choose the irrigation bag for trunk, open its package, take out a standard tip and a trunk bag with granular, cut the opening into suitable size according to the size of the wound. Then apply the bag to the treatment area ,ensuring that it is fully sealed. Take out the irrigator and standard tip, attach the tip, insert the spike of the tube to the saline bag, then start to debride. After the treatment, carefully remove the irrigation bag. Finally the contaminate slain is absorbed by the granular converting it into a safe gel type material. If there is a tunnel wound, change the standard tip on the Pulsar II™ to the tunnel tip, and then debride the tunnel wound.

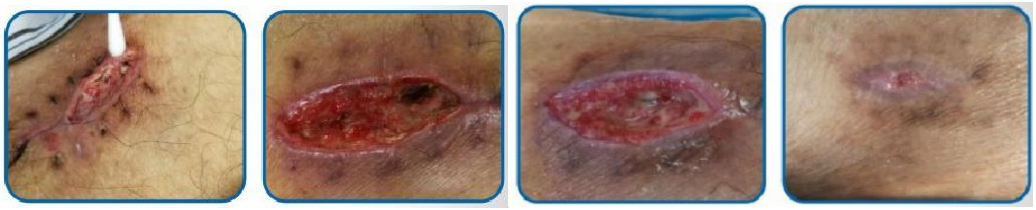
For wounds located on the extremity, choose the irrigation bag for extremity, sleeve the bag onto the patient's leg or arm to cover the treatment area and simply start to debride.

Case Studys

PULSAR II™AWI™ offers an innovative and safe pulse irrigation system to provide selective hydro-mechanical debridement of chronic non-healing wounds. It is one such innovation that is worth consideration to ensure that the wound bed is effectively debrided in a safe and painless manner, it is suitable for a variety of wounds.

Case 1:

In case 1, it was a postoperative infection wound with diabetes. Prior to treatment with PULSAR II™AWI™, the patient had received treatment for 5 months, and there was no improvement in the wound bed. After about 2 months the wound completely healed by using PULSAR II™ AWI™ and simple saline.



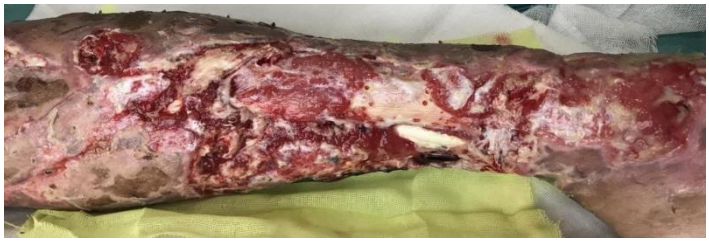
Case 2:

This case was very shocking , diabetes, postoperative infection after amputation, very serious infection ,so that his doctor told him to give up. After desperate pleas from the patient fortunately the doctor gave 2 pieces PULSAR II™ AWI™ to the patient for free and told him how to use them and also how to formulate normal saline at home. After 2 months, the patient returned to the hospital to told his doctor his wound was healed. This picture below was the amputation healed wound.

Case 3:

This woman encountered a car accident, her leg was infected and non-healing for 33 days, facing a risk of amputation .The doctor tried PULSAR II™AWI™. Only after 3 times of using the Pulsar II™ AWI™, it could be evidenced that new granulation tissue was growing. These beef red tissue was the new granulation tissue.

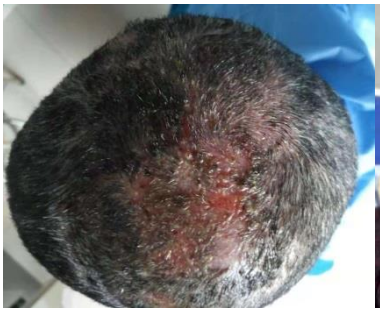
Before



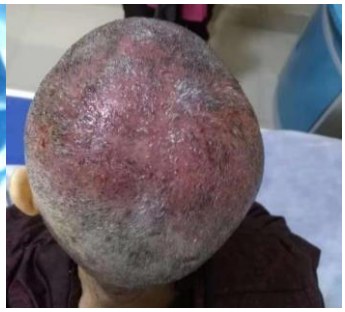
After

Case4:

Female, 70 years old, hepatic carcinomas, acute medicational ulcer. It was very difficult to clean this kind of ulcer because of the hair with tweezers, surgical blade or any other irrigation facilities. With PULSAR II™ AWI™ it was very easy to control the ulcer.



Before



After

PULSAR II™ AWI™ uses low pressure irrigation 8 to 15 pounds per square inch, generally tolerated with minimal pain or discomfort, using a **no touch, no suction** technique to remove necrotic tissue, reduce bacterial bioburden, and then enhance chronic wound healing.

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