

System and Method for Treating a Wound Using Ultrasonic Debridement

Technical Field

The invention relates generally to wound treatment systems and methods,
5 and more specifically to a system and method of treating a wound by combining ultrasonic debridement and reduced pressure therapy.

Background Art

Wounds to the skin typically fall into two categories: chronic and acute. The
10 natural healing mechanism in animals repairs acute wounds quickly by closing the wound, filling in lost tissue, and covering the wound with a new layer of skin. Those having observed wound healing in children often observe the healing of small acute wounds in a few days. Chronic wounds are often wounds in which the natural healing mechanisms have been impaired. Chronic wounds typically linger for
15 extended periods of time and may never heal. Such wounds are often observed among the elderly or people suffering from diabetes. Another problem associated with wounds is infection. Infection is the invasion of a wound by pathogenic microorganisms or bacteria that grow within the wound, produce toxins, and subsequently injure the tissue surrounding the wound. To reduce the chance for
20 infection of a wound, the wound is first cleaned to remove those microorganisms or bacteria that may have invaded the wound when it was created. Next, the wound typically is debrided or sterilized to remove nonviable or necrotic tissue and any microorganisms or bacteria resident within the wound. The third step in the treatment of a wound is to apply a dressing to cover the wound and promote its
25 healing with the application of medication.

The debriding of a wound is often accomplished with mechanical surgical methods, referred to as sharps debridement. Specifically, the non-viable or necrotic tissue is cut from the wound and removed. Sometimes, surgical treatment of a wound will trigger the body's response to an acute wound and the wound will heal.

30 While the debridement process often involves cutting away tissue within the wound, recent efforts have involved the use of ultrasonic energy. A description of the use of ultrasonic energy and its use on skin appears in the following U.S. patents: Suroff, 4,040,414 (Ultrasonic Personal Care Instrument and Method);

Beaty, et al., 5,312,329 (Piezo Ultrasonic and Electrosurgical Handpiece); Sakurai, et al., 5,391,144 (Ultrasonic Treatment Apparatus) ; Novak, et al., 6,171,265 (Handpiece for Use With a Multifunctional Operating Endoscopic Instrument); and in the following published PCT application: Babaev, WO 97/17933 (Method of
5 Spraying A Surface Using Ultrasonic Radiation). Further descriptions are found in the following articles: King, et al., Burns, Vol. 22, No. 4, Pg. 307, (Debridement of Burn Wounds with a Surgical Ultrasonic Aspirator); Vanderburgh, et al., Gynecologic Oncology, Vol. 39, Pg. 103 (1990); (Debridement of Vaginal Radiation Ulcers Using the Surgical Ultrasonic Aspirator); and Herte, et al., Am. Society of
10 Plastic and Reproductive Surgeons Prelim. Rpt. (Nov. 1978); (Comparative Wound Healing in Animal Subjects Using the Cavitron Ultrasonic Surgical Aspirator vs. Conventional Surgical Instrument).

Further, in recently issued U.S. Patent No. 6,916,296 to Soring, et al., entitled
15 System for Antiseptic Surgery, a system using ultrasound was proposed for wound healing. Specifically, a device called a sonotrode is placed in a liquid within the wound. The sonotrode generates ultrasonic vibrations and cavitations in the liquid that leads to destruction of the bacteria cells. Specifically, the high level of energy released in the fluid kills the bacteria cells by rupturing their cell walls. While U.S. Patent No. 6,916,296 reports a significant reduction in germ count in a wound, it is
20 also taught that high levels of energy can be used for very short periods of time, or that lower levels of energy can be used for longer periods of time — up to several minutes.

In practice, the use of ultrasound to debride wounds involves relatively high amounts of ultrasonic energy typically applied in a focused manner to energize a
25 relatively small area of a wound for a short period of time. The area over which ultrasonic energy is broadcast at any given time is typically less than about 5 cm². Since the treatment is focused, the ultrasonic energy is typically only applied for less than about 60 seconds to any specific area.

Following debridement, wounds are dressed to cover the wound and promote
30 healing. In recent years, it has been found that the application of reduced pressure to a wound promotes healing in many cases. This is particularly evident in chronic wounds, such as those that develop in elderly patients, but may also occur in any type of wound. Studies have also revealed that frequent irrigation of a wound helps promote healing by aiding in the removal of wound exudate, unwanted bioburden,

and optionally, serving as an effective vehicle for the application & delivery of medication. Examples of wound treatment systems employing some of these techniques are found in the following U.S. patents: Zamierowski, 4,969,880 (Wound Dressing and Treatment Method); Zamierowski, 5,100,396 (Fluidic Connection
5 System and Method); Zamierowski, 5,261,893 (Fastening System and Method); Zamierowski, 5,527,293 (Fastening System and Method); Argenta, et al., 5,636,643 (Wound Treatment Employing Reduced Pressure); Argenta, et al., 5,645,081 (Method of treating tissue damage and apparatus for same); Zamierowski, 6,071,267 (Medical Patient Fluid Management Interface System and Method); Vogel,
10 et al., 6,135,116 (Method for Treating Ulcers); and Hunt, et al., 6,142,982 (Portable wound treatment apparatus).

While ultrasonic debridement has been taught as a way of initially clearing a wound of nonviable or necrotic tissue, the procedure has not gained acceptance as part of broad-based system for accelerating healing of a wound, in part due to the
15 labor-intensive process involved with traditional ultrasonic debridement. A need currently exists for a system that utilizes ultrasonic energy at low energy levels over a prolonged period of time to debride a wound. For ease of use and improvement in performance, the application area over which the ultrasonic energy is applied should be relative large compared to existing procedures, which call for a more focused
20 beam. Also needed is a system that employs a non-focused, low energy debridement procedure such as ultrasound, with reduced pressure therapy, and optionally, with a system providing fluid irrigation and removal of debrided tissue.

All of the patents, patent applications, and other publications referenced herein are incorporated by reference to the maximum extent allowable by law.

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Disclosure of Invention

The problems presented by wound treatment systems tissue dressings are solved by the systems and methods of the present invention. In accordance with one embodiment of the present invention, a wound treatment system is provided that
30 includes a distribution manifold, a reduced pressure source, and an ultrasonic energy transducer. The reduced pressure source is fluidly connected to the distribution manifold to deliver reduced pressure to a tissue site, and the ultrasonic energy transducer is positioned adjacent to the distribution manifold.

In accordance with another embodiment of the present invention, a wound treatment system for debriding and healing a wound site includes a distribution manifold, a reduced pressure source fluidly connected to the distribution manifold, an acoustically-conducting membrane, and an ultrasonic energy transducer. The
5 acoustically-conducting membrane is positioned between the distribution manifold and the wound site, and the ultrasonic energy transducer is coupled to the membrane.

In still another embodiment of the present invention, a wound treatment system includes means for dressing a wound, means for reducing pressure at the
10 wound, and means for debriding the wound.

In accordance with yet another embodiment of the present invention, an ultrasonic wound treatment system for treating a wound site includes an ultrasonic energy transducer configured to deliver ultrasonic energy to substantially all of the wound site at a power level less than about 1 W/cm^2 . The ultrasonic energy is
15 delivered during a selected duration such that substantially all of the wound site is exposed to ultrasonic energy for at least ten minutes per day (10 min/day).

In yet another embodiment of the present invention, a wound treatment system includes a distribution manifold configured to be placed in fluid communication with a wound. A fluid source is fluidly connected to the distribution manifold and configured to deliver a fluid to the wound during a first selected
20 duration. An ultrasonic energy transducer is configured to be placed in ultrasonic communication with and deliver ultrasonic energy to the wound during a second selected duration. A reduced pressure source is fluidly connected to the distribution manifold and configured to deliver a reduced pressure to the wound during a third
25 selected duration.

In accordance with another embodiment of the present invention, a method for treating a wound includes simultaneously applying reduced pressure and ultrasonic energy to the wound to debride and heal the wound.

In still another embodiment of the present invention, a method for treating a
30 wound includes delivering a fluid to the wound and allowing the fluid to dwell at the wound for a selected duration. Ultrasonic energy is applied to the wound during the selected duration, and a reduced pressure is applied to the wound following the selected duration to remove the fluid and any debrided tissue.

In another embodiment of the present invention, a multipurpose wound dressing includes a distribution manifold that is configured to distribute a reduced pressure to a wound site. An ultrasonic energy transducer is positioned adjacent to the distribution manifold to provide ultrasonic debridement to the wound site.

5 In yet another embodiment of the present invention, a multipurpose wound dressing includes a distribution manifold configured to distribute a reduced pressure to a wound site. An acoustically-conducting membrane is positioned on a tissue contact side of the distribution manifold and is configured to contact the wound site. An ultrasonic energy transducer is operatively coupled to the acoustically-conducting
10 membrane.

Other objects, features, and advantages of the present invention will become apparent with reference to the drawings and detailed description that follow.

Brief Description of Drawings

15 Figure 1 illustrates a front cross-sectional view of a system for applying reduced pressure and ultrasonic energy to a wound or tissue site according to an embodiment of the present invention; and

Figure 2 depicts a front cross-sectional view of a system for applying reduced pressure and ultrasonic energy to a wound or tissue site according to an
20 embodiment of the present invention.

Best Mode for Carrying Out the Invention

In the following detailed description of the preferred embodiments, reference is made to the accompanying drawings that form a part hereof, and in which is
25 shown by way of illustration specific preferred embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is understood that other embodiments may be utilized and that logical structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the
30 invention. To avoid detail not necessary to enable those skilled in the art to practice the invention, the description may omit certain information known to those skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims.

Referring to FIGS. 1 and 2 a wound treatment system 10 according to an embodiment of the present invention includes a multipurpose wound dressing 11 having the capability of providing ultrasonic debridement to the wound, a reduced pressure source 12 to deliver reduced or subatmospheric pressure to the wound, and optionally, a fluid delivery source 14 to irrigate the wound with a fluid. A computer system 16 including a processor 17 and a user interface 18 may be provided to control all of the system functions of the reduced pressure therapy, debridement, and fluid delivery.

Referring more specifically to FIG. 1, the wound treatment system 10 is preferably used to debride and promote the healing of a wound site 100. Wound site 100 is surrounded by tissue 102. At least a portion of the wound site 100 includes a compromised layer of tissue 104, which may include a mixture of healthy, and non-viable live cells, dead cells, and varying amounts of contaminants such as micro-organisms and bacteria. Experimentation has revealed that this compromised layer of tissue may be as thick as 5mm. While conventional treatment of the surface of the wound may remove dead tissue and bacteria on the surface of the wound, the bacteria beneath the surface are not removed and may continue to harbor infections. Debridement of the wound assists in the removal of this hidden bacteria.

The multipurpose wound dressing 11 includes a distribution manifold 20, an ultrasonic energy transducer 50, a tube 42 for fluidly communicating with the distribution manifold, and, optionally, a drape 30. The distribution manifold 20 is configured to be placed adjacent to the wound site 100. The distribution manifold 20 includes a plurality of flow channels or pathways to facilitate the distribution of reduced pressure or fluids to or from the wound site. In one embodiment the distribution manifold 20 is a porous foam and includes a plurality of interconnected cells or pores that act as flow channels. The porous foam may be a polyurethane, open-cell, reticulated foam such as GranuFoam manufactured by Kinetic Concepts, Inc. of San Antonio, Texas. If an open-cell foam is used, the porosity may vary, but is preferably about 400 to 600 microns.

The drape 30 is positioned over the distribution manifold 20 when an open wound site is treated to seal and isolate the wound site. If the wound site being treated is a subcutaneous or deep tissue wound site, drape 30 may not be necessary to maintain reduced pressure at the wound site. Drape 30 may be any biocompatible, flexible material. Drape 30 may be impermeable or semi-permeable

to liquid, gas, or both depending upon a given application. A reduced pressure applicator 40 is placed under the drape 30 and over the distribution manifold 20. The tube 42 is fluidly connected at a distal end to the applicator 40 and is fluidly connected at a proximal end to the reduced pressure source 12, which may be a pump or a wall suction outlet. Near the reduced pressure source 12, the tube 42 is schematically represented as reduced pressure delivery tube 42a. The reduced pressure source is capable of supplying reduced pressure to the wound through the reduced pressure delivery tube 42a and distribution manifold 20. While the applicator 40 provides one means of transferring reduced pressure from the reduced pressure delivery tube 42a to distribution manifold 20, applicator 40 may be omitted if the reduced pressure delivery tube 42a is placed in direct fluid communication with distribution manifold 20.

A fluid delivery tube 42b may be provided to deliver a fluid to the wound and may similarly be fluidly connected to the distribution manifold by the applicator 40. The representation of tubes 42, 42a, and 42b in FIGS. 1 and 2 illustrate that a common applicator may be used for delivering reduced pressure and fluids to the distribution manifold 20. This may be accomplished by using the tube 42 for only one purpose at any time. More specifically, the tube 42 may be used to alternately deliver reduced pressure and fluids. In another embodiment, the tube 42 may be a dual lumen tube having a lumen for reduced pressure delivery and a lumen for fluid delivery. In still another embodiment (not illustrated), separate tubes may be used to fluidly communicate with the distribution manifold 20. If separate tubes are used, the use of an applicator 40 is optional.

The ultrasonic energy transducer 50 may include a frequency generator and an amplifier and is used to transmit ultrasonic energy to the wound site 100. The ultrasonic energy transducer may be a piezoelectric transducer or a surface wave acoustic device. In FIG. 1, the ultrasonic energy transducer 50 is placed between the applicator 40 and distribution manifold 20 to emit a low level of ultrasonic energy. The ultrasonic energy transducer 50 may be connected to one or both of the applicator 40 and the distribution manifold 20, or alternatively may be placed between the applicator 40 and distribution manifold 20 without physical connection to either. In one embodiment, the ultrasonic energy transducer 50 may be embedded within the distribution manifold 20.

The distribution manifold 20 acts as a transmission medium to relay ultrasonic energy to the wound site 100. When a reticulated foam is used, the transmission efficiency of the foam may be enhanced by using the fluid delivery source to infuse the foam with water, aqueous and sub-aqueous solutions, or gels. The presence of fluid within the foam improves the ability of the foam to transfer the ultrasonic energy. In this regard, the distribution manifold performs both the functions of a manifold and a transmission medium for ultrasonic energy. It should further be noted that gels or other transmission enhancing substances may be placed within or on the distribution manifold 20. For example, a gel may be placed between the distribution manifold 20 and the wound site 100 prior to the transmission of ultrasonic energy through the distribution manifold 20 to enhance energy transmission.

The amount of ultrasonic energy being applied to the wound by the ultrasonic energy transducer 50 is less than that of traditional ultrasonic debridement transducers. Preferably, if a high frequency (about 800 to 4000 kHz to) transducer is used, the power applied to the transducer is about 1.0 W/cm^2 , and more preferably about 0.5 W/cm^2 . If a low frequency (about 20 to 120 kHz to) transducer is used, the power applied to the transducer preferably is about 0.5 W/cm^2 , and more preferably about 0.1 W/cm^2 .

Referring to FIG. 2, the ultrasonic energy transducer 50 may be positioned remotely from the wound site 100 and may be operatively connected to an acoustically-conducting membrane 70 positioned between the distribution manifold 20 and the wound site 100. The membrane 70 may be connected to the distribution manifold 20, or alternatively may be placed without connection between the distribution manifold 20 and wound site 100 prior to administration of reduced pressure and ultrasonic therapies. In this embodiment, the low level of ultrasonic energy produced by the ultrasonic energy transducer 50 is transmitted across the membrane 70 and radiates into the compromised tissue layer 104. The proximity of the membrane 70 to the wound site 100 in some circumstances may improve the debridement performance of the wound treatment system 10. Since the ultrasonic energy is typically produced at low power, the ultrasonic energy transducer 50 may be positioned at or near the periphery of the wound site 100. Positioning of the membrane 70 between the distribution manifold 20 and the wound site 100 should not interfere with the capability of the distribution manifold to deliver reduced pressure or fluids to the wound site 100. In this regard, the membrane 70 is

preferably formed from a naturally porous material, or alternatively is manufactured to include holes, pores, projections or other structural features that promote flow within, around, or through the membrane. The membrane may be made from a metallic foil, thin sheets of Lexan®, or any other material that is capable of
5 conducting an ultrasonic wave.

In operation, the multipurpose dressing described herein combines reduced pressure therapy, ultrasonic debridement, and optional fluid delivery for debriding, cleaning, and healing the wound site. All of these functions may be integrated into a combined system that provides for the intermittent or continuous operation of each
10 function individually or simultaneously, without changing the dressing between functions. Since the dressing is intended to remain in place for several days between changes, the ultrasonic energy transducer is optimized to provide debridement over long time periods at low power.

In one exemplary operational example, an irrigation or medicinal fluid is
15 delivered by the fluid delivery source 14 to the distribution manifold during a first selected duration. Preferably, the first selected duration is about five (5) minutes. During this duration, the fluid is allowed to permeate the distribution manifold 20 and irrigate the wound site 100. During a second selected duration following the first selected duration, the fluid is allowed to dwell at the wound site and ultrasonic
20 energy is transmitted to the wound site 100 by the ultrasonic energy transducer. The ultrasonic energy debrides the wound of nonviable and necrotic tissue. Preferably, the second selected duration is about fifteen minutes (15), or about three times the first selected duration. Following the second selected duration, transmission of ultrasonic energy is ceased, and reduced pressure is applied through the distribution
25 manifold by the reduced pressure source. The reduced pressure removes the delivered fluid from the wound and distribution manifold, as well as wound exudate and debrided tissue. The application of reduced pressure continues for a third selected duration, which is preferably about forty (40) minutes, or about three times the second selected duration. The exemplary time durations described above may
30 vary, and each of the procedures (i.e. fluid delivery, ultrasonic debridement, and reduced pressure therapy) may be performed independently of one another, or simultaneously with one or both of the other procedures.

It should be apparent from the foregoing that an invention having significant advantages has been provided. While the invention is shown in only a few of its

forms, it is not just limited but is susceptible to various changes and modifications without departing from the spirit thereof.

Claims

1. A wound treatment system comprising:
a distribution manifold positioned adjacent to a wound and having a plurality
of flow channels for distributing reduced pressure as an aspect of reduced
5 pressure therapy;
a reduced pressure source fluidly connected to the distribution manifold to
deliver reduced pressure to a tissue site; and
an ultrasonic energy transducer positioned adjacent to the distribution
manifold for ultrasonic debridement over an area corresponding to the
10 distribution manifold.
2. The system of claim 1, wherein the ultrasonic energy transducer is a
piezoelectric transducer.
- 15 3. The system of claim 1, wherein the ultrasonic energy transducer is a surface
acoustic wave device.
4. The system of claim 1, wherein the distribution manifold is a porous foam.
- 20 5. The system of claim 1, further comprising a drape placed adjacent to the
distribution manifold to cover the distribution manifold and the ultrasonic
energy transducer.
6. The system of claim 1, further comprising:
25 a reduced pressure applicator fluidly coupled between the reduced pressure
source and the distribution manifold;
a drape positioned over the reduced pressure applicator and the distribution
manifold; and
wherein the ultrasonic energy transducer is positioned between the reduced
30 pressure applicator and the distribution manifold.
7. The system of claim 1 further comprising a fluid delivery tube fluidly
connected to the distribution manifold.
- 35 8. The system of claim 7, wherein the fluid delivery tube is configured to deliver
a fluid and reduced pressure to the distribution manifold.

9. The system of claim 1, further comprising:

a reduced pressure applicator fluidly coupled between the reduced pressure source and the distribution manifold;

a tube fluidly coupled between the reduced pressure applicator and the reduced pressure source;

a drape positioned over the reduced pressure applicator and the distribution manifold;

wherein the ultrasonic energy transducer is positioned between the reduced pressure applicator and the distribution manifold; and

wherein the tube is configured to selectively deliver one of reduced pressure and a fluid to the wound site.

10. A wound treatment system for debriding and healing a wound site comprising:

a distribution manifold having a plurality of flow channels for distributing reduced pressure;

a reduced pressure source fluidly connected to the distribution manifold;

an acoustically-conducting membrane positioned between the distribution manifold and the wound site; and

an ultrasonic energy transducer coupled to the membrane.

11. The system of claim 10, wherein the ultrasonic energy transducer is a piezoelectric transducer.

12. The system of claim 10, wherein the ultrasonic energy transducer is a surface acoustic wave device.

13. The system of claim 10, wherein the membrane is between and in contact with the distribution manifold and the wound site when reduced pressure is applied through the distribution manifold.

14. The system of claim 10, wherein the membrane allows fluid communication between the distribution manifold and the wound site.

15. The system of claim 14, wherein the membrane is porous.

16. The system of claim 10, wherein the ultrasonic energy transducer is located remotely from the wound site.

17. The system of claim 10, wherein the distribution manifold is porous foam.

18. The system of claim 10 further comprising a drape positioned over the distribution manifold and the acoustically conducting membrane.

19. A wound treatment system comprising:

means for dressing a wound that includes a drape;

means for reducing pressure at the wound that includes a distribution manifold positioned adjacent to the wound; and

means for debriding a wound that includes an ultrasonic energy transducer associated with the distribution manifold.

20. An ultrasonic wound treatment system for treating a wound site comprising:
an ultrasonic energy transducer configured to deliver ultrasonic energy to substantially all of the wound site at a power level less than about 1 W/cm^2 and during a selected duration such that substantially all of the wound site is exposed to ultrasonic energy for at least ten minutes per day (10 min/day).

21. The system of claim 20, wherein the selected duration is characterized by periods when the ultrasonic energy transducer is turned off and periods when the ultrasonic energy transducer is turned on.

22. The system of claim 20, further comprising a fluid delivery line configured to irrigate the wound with a fluid during the selected duration.

23. The system of claim 22, further comprising a reduced pressure delivery line configured to apply a reduced pressure to the wound following the selected duration.

24. The system of claim 23, wherein the fluid delivery line and the reduced pressure delivery line are the same.

25. A wound treatment system comprising:

a distribution manifold having a plurality of flow channels for distributing reduced pressure and configured to be placed in fluid communication with a wound;

a fluid source fluidly connected to the distribution manifold and configured to deliver a fluid to the wound during a first selected duration;

an ultrasonic energy transducer configured to be placed in ultrasonic communication with and deliver ultrasonic energy to the wound during a second selected duration; and

a reduced pressure source fluidly connected to the distribution manifold and configured to deliver a reduced pressure to the wound during a third selected duration.

26. The system of claim 25, wherein the first, second, and third selected durations occur during distinct time periods.

27. The system of claim 25, wherein the fluid delivered during the first selected duration is allowed to dwell at the wound during the second selected duration.

28. The system of claim 27, wherein the reduced pressure removes the fluid and any tissue debrided during the application of ultrasonic energy.

29. A multipurpose wound dressing comprising:

a distribution manifold having a plurality of flow channels for distributing reduced pressure to a wound site; and

an ultrasonic energy transducer positioned adjacent to the distribution manifold to provide ultrasonic debridement to the wound site.

- 5 30. A multipurpose wound dressing comprising:
- a distribution manifold having a plurality of flow channels for distributing
 reduced pressure to a wound site;
- an acoustically-conducting membrane positioned on a tissue contact side of
 the distribution manifold and configured to contact the wound site; and
- 10 an ultrasonic energy transducer operatively coupled to the acoustically-
 conducting membrane.