METHOD OF WOUND TREATMENT USING CONDENSATION WARMING

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ABSTRACT

A method of treating a wound using condensation warming is disclosed. A wound dressing is applied over the wound in which the wound dressing has an inlet and an outlet and furthermore forms a substantially airtight cover over the wound. A vapor is supplied to the wound dressing via the inlet. The wound is warmed by condensing the vapor into a condensate on a surface of the wound, thereby releasing a latent heat of vaporization. The condensate is removed from the wound dressing via the outlet.
METHOD OF WOUND TREATMENT USING CONDENSATION WARMING

CROSS-REFERENCE TO RELATED APPLICATIONS


BACKGROUND OF THE INVENTION

[0002] Some wounds, such as chronic wounds or complex wounds, are difficult to treat and may take months or years to heal. A chronic wound is a wound that fails to heal in an orderly set of stages and in a reasonable amount of time. Complex wounds would include surgical wounds with complications as well as severe burns. Wounds that do not heal properly can lead to amputation and even loss of life. Common types of chronic wounds are leg ulcers, pressure ulcers (bedsores), and diabetic foot ulcers.

[0003] Leg ulcers occur due to impairment of circulation in the lower leg. When blood vessels are not functioning properly, the tissue surrounding those vessels no longer receives an adequate supply of fresh blood. Oxygen cannot reach those tissues, leading to an open wound.

[0004] Pressure ulcers can occur in people of any age and are typically caused by staying in the same position for a prolonged period of time. Lying in bed or sitting in a wheelchair can put sustained pressure on the skin over a bony prominence. This pressure can cut off the blood supply and lead to a pressure ulcer or bed sore.

[0005] Diabetic foot ulcers are a common complication of diabetes. A diabetic can be unaware of a minor foot injury due to the loss of pain sensation associated with neuropathy. Continued walking on an unnoticed injury causes increased trauma and can lead to more serious injury that can become chronic.

[0006] Several million people are afflicted with chronic wounds and other serious wounds every year. Elderly people have thinner skin which is more easily damaged and bedridden elderly people are at a particularly high risk. Chronic wounds that take months to heal or those that never heal, cause severe pain and hardship with much diminished quality of life, and are a drain on healthcare resources.

[0007] A chronic wound may become hypothermic due to a poor blood supply and/or the loss of the insulating quality of a healthy layer of skin. Gentle warming dilates blood vessels, stimulating local circulation and increasing oxygen perfusion to encourage healing. What is needed is a safe method of transferring sufficient heat to warm a wound to normal body temperature (37 degrees C.) without the danger of potentially harmful higher temperatures.

SUMMARY OF THE INVENTION

[0008] Sensible heat is heat that changes the temperature of a substance. In comparison, latent heat (sometimes called hidden heat) is heat that is absorbed or released upon a change of state (gas, liquid, solid) of a substance without a change in temperature. The heat content difference between the two can be very significant. For example, the amount of sensible heat released when one pound of water is cooled by one degree Fahrenheit is one B.T.U. However, the amount of latent heat released when one pound of water is condensed is nine hundred seventy B.T.U.s.

[0009] This invention primarily uses latent heat of vaporization in lieu of sensible heat. This is done because of the comparatively larger quantities of heat that can be transferred at normal body temperature. The use of a dew point temperature which coincides with normal body temperature allows the latent heat to be released to the wound tissues at this optimal temperature. Lower temperatures may not sufficiently warm the wound and higher temperatures may cause harm.

[0010] Latent heat is absorbed outside a wound dressing so it may be released inside the dressing. The change of state from a liquid to a vapor (evaporation) occurs above 37 degrees C. outside the dressing. The change of state from a vapor to a liquid (condensation) occurs at 37 degrees C. inside the wound dressing. A large amount of heat is being transferred from the outside to the inside of the dressing without the use of potentially harmful elevated temperatures. The heat is distributed within the dressing based on demand with the coldest wound tissues receiving the greatest amount of heat. This process may also be described as self-regulating as the condensation may occur at the cool, but not the warm portions of the wound.

[0011] In one form, a gas source and a liquid water source both may enter a heated humidifier. The heater of the humidifier uses heat energy to both heat the gas and to vaporize the water into the gas. The gas, which is flowing, transports the water vapor. Upon evaporating, the water vapor absorbs latent heat of vaporization. The combination of gas and water vapor leaves the heated humidifier at a dew point temperature of 37 degrees C., and enters the inlet of a substantially airtight negative pressure type wound dressing. Inside this wound dressing, because this gas was previously saturated at 37 degrees C., the water vapor may condense forming dew directly on wound surfaces cooler than 37 degrees C. The dew releases latent heat which gently warms these cool wound tissues. Condensation does not necessarily occur evenly throughout the wound. Cooler areas of the wound may condense more water and receive more latent heat. Without needing to use a complex array of temperature sensors within the dressing, this latent heat transfer process is able to continuously deliver heat to where it is needed. It is able to regulate itself automatically based on wound tissue temperatures. As the wound warms, condensation and release of heat will lessen and stop when all areas of the wound and dressing begin to exceed 37 degrees C.

[0012] The outlet of the wound dressing may be connected to a vacuum source. In some forms, this vacuum source can be used to remove the condensate from the wound dressing. In some forms, this vacuum source can also remove the gas, non-condensed water vapor and any wound exudates. The vacuum source may also be the power source that creates flow or wound ventilation. This can eliminate the need for fan or the necessity for pressure induced flow.

[0013] Between dressing changes, when the wound is exposed, it is common practice to cleanse a wound. Wounds are cleansed to aid the removal of exudates, debris, slough, and contaminants, and to prevent infection. The condensate created within the dressing of this invention can also perform a cleansing function which is continuous and not relegated to just between dressing changes. First, the condensate dilutes the wound exudate, allowing the vacuum source to remove
more exudate. Secondly, the condensate aids the gentle removal of debris, slough, and infectious material by the vacuum source.

Inherent in this invention is the use of a moist wound therapy. When wounds dry out, they form a scab which slows down the healing process. The condensing water vapor in the dressing assuages this moist wound environment. The aspiration of liquids by the vacuum source prevents any condensate build-up.

In some forms, the gas source can be oxygen or a mixture of gases containing oxygen, such as oxygen and air. An oxygen gas source would enable the use of topical oxygen therapy under a negative pressure. Oxygen is both a nutrient and an antibiotic, and an adequate supply assists each of the steps in wound healing. Oxygen facilitates healing by suppressing the proliferation of bacteria, promoting tissue granulation, and accelerating epithelialization.

Also, in some forms, the vacuum source can perform negative pressure wound therapy (N.P.W.T.). Typically, in this case, a dressing is selected to be a dressing that is commonly used for this purpose. Healing is promoted by suctioning excess exudates from the wound. Excess fluids are detrimental to the healing process and can cause maceration of the skin.

Ventilation provided by the flow of conditioned gas through the dressing can also be beneficial to the healing process. This fresh flow removes stagnant gasses, vapors, and odors which otherwise would accumulate inside the dressing.

Some forms of the device and related method are not only capable of safely warming a wound, they can: cleanse the wound; minimize dressing adherence; apply moist wound therapy; apply topical oxygen therapy; apply negative pressure wound therapy; and remove stagnant vapors and odors. Moreover, these modalities can all be performed simultaneously.

The device and related method may increase the efficacy of standard negative pressure wound therapy. Alone, N.P.W.T. effectively treats a wound using only one controlled variable, that of negative pressure. This apparatus can treat the wound with up to five different controlled variables simultaneously. The variables can include oxygen content, relative humidity, temperature, total ventilation flow rate, and negative pressure. Each variable can be adjusted individually for maximum benefit.

While individual successful therapies can each be effective, simultaneous application of multiple successful therapies allows the individual benefits to build upon each other and become cumulative. The hope is that the individual efficacies will also build upon each other and become cumulative.

These and still other advantages of the invention will be apparent from the detailed description and drawings. What follows is merely a description of some preferred embodiments of the present invention. To assess the full scope of the invention, the claims should be looked to as these preferred embodiments are not intended to be the only embodiments within the scope of the claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

**FIG. 1** is a schematic flow diagram of the one embodiment of this wound warming system showing how it connects to other wound healing components. The relative size of the wound warming system may be much smaller than shown.

**FIG. 2** is the wound warming system of **FIG. 1** installed in an enclosure and comprising a wound warming device.

**DETAILED DESCRIPTION OF THE INVENTION**

Hereinafter, I will refer to the apparatus as a “wound incubator”, and define that as an apparatus used to maintain environmental conditions suitable for the healing of wounds. Incubators are used in tissue culture rooms to grow stem cells, skin fibroblasts and other types of cells. Incubators are used in microbiology for growing bacteria and other microorganisms. This “wound incubator” is meant to mimic the fetal environment and encourage a rapid proliferation of new cells to replace those lost or damaged. A protective environment of controlled temperature, humidity, and oxygen concentration is maintained inside the dressing. The result is an ideal wound environment for cellular growth much as a greenhouse provides the best environment for the growth of healthy plants.

**FIG. 1** is a schematic flow diagram showing the relationship between the wound incubator 1, the wound dressing 18, and the wound vacuum unit 22. This drawing also shows how these components are connected with each other as well as being connected with an oxygen source 4. The flow of gasses through the wound incubator 1 and the wound dressing 18 is powered by the suction force created by the wound vacuum unit 22 or other vacuum source.

Referring again to **FIG. 1**, air is always available to be freely drawn in through the air intake 2 after passing through a bacterial filter 3. Oxygen is supplied by either wall outlet oxygen, an oxygen concentrator, or bottled oxygen 4. An adjustable pediatric (lower available flows) flow meter or other adjustable flow limiting means is used as the oxygen flow rate controller 5. Flow rates are measured in liters/min. The sum of the air and oxygen flow rates is the total flow rate and is governed by a flow limiting device called the total flow rate controller 8. With both the oxygen and total flow rates set, a free flow of air makes up the difference. Oxygen flow 6 through tubing or other conduit, mixes with a free flow of air in a space called the mixture plenum 7 under atmospheric pressure. This guards against an over-pressurization malfunction as a positive pressure would flow freely out of the air intake 2 while maintaining atmospheric pressure. From this mixture plenum 7 the air/oxygen mixture flows freely as the suction force draws it into the total flow rate controller 8. This device may be adjustable, but once a desired total flow rate is known, a constant flow rate makes component design and control simpler. A good constant flow rate device is a filtered orifice flow restrictor. A filter protects the tiny orifice from plugging up. The total flow rate is intended to be very low, at perhaps 0.5 to 1.0 liters/min. This flow rate is preferably high enough to sufficiently warm most wounds and aspirate the dressing liquids; and low enough to be well below the capacity of the vacuum source. The total flow rate controller 8 creates the pressure differential that sets a boundary between
atmospheric pressure and the negative pressure determined by the wound vacuum unit 22. The gas is then drawn into the humidifier inlet 10.

[0028] The purpose of the humidifier 11, its water source 16, its heater 9, and secondary heater 14 is to deliver gas saturated with water vapor at 37 degrees C to the wound dressing inlet 19 while also minimizing condensation along the way. There are many ways to do this. For ease of explanation, FIG. 1 shows the humidifier 11, the humidifier heater 9 and the secondary heater 14 as being separate components. Most modern heated humidifiers combine such components into a package. Heated humidifiers are also used when supplying respiratory gases to a patient. They are available in many different designs, including: heated passover humidifier, by-pass humidifier,wick humidifier, vapor transfer cartridge, and capillary force vaporizers. Most would be appropriate for this application, providing they could be downsized for the lower flow rates. The humidifier could be controlled by using sensor 13 and maintaining a 37 degree C dew point at this location. Preferably, the humidifier produces water vapor only. Unlike mist or droplets, molecules of water vapor are too small to transport bacteria. For the humidifier's water source, distilled water would typically be used and it could be supplied from a re-fillable container. A sterile IV type bag of water could also be used.

[0029] Between the humidifier outlet 12 and the wound dressing inlet 19 is the dressing delivery conduit or tubing 15. This delivery tube can be short to reduce heat loss. In any event, there can be some heat loss in this delivery tube. If the temperature drops below 37 degrees C at any location before the dressing inlet 19, there would be unwanted condensation. One way to minimize delivery tube condensation is to add heat with a secondary heater 14. This secondary heat source adds sensible heat to offset the loss of sensible heat in the delivery conduits. This added heat would slightly exceed the heat loss and could be controlled by using sensor 17 located as close as possible or within the dressing inlet 19. In some forms, the secondary heater 14 can be a heating element or sleeve around some or all of the tube 15 to try to maintain the temperature of the vapor at just above 37 degrees C prior to the inlet 19. In lieu of secondary heater 14, condensation could also be minimized by using a by-pass humidifier, a heated delivery tube, an insulated delivery tube, or a heated wire breathing circuit.

[0030] There are many methods of controlling the chosen humidifier and associated heat sources so that heated gasses enter the dressing slightly warmer than their 37 degrees C dew point temperature. The wound dressing 18 may be chosen from among the many available existing negative pressure dressings. Most likely an inlet tube connection 19 can be added to the typical dressing. This connection should be added in a location non-adjacent to the existing outlet tube connection 20.

[0031] Condensation will form on the inside of the outer surface of the dressing when its temperature is below 37 degrees C. To minimize this condensation, the dressing may be covered with an insulated pad or blanket. This will reduce the heat loss and keep the dressing warmer.

[0032] Dressing exit tubing 21 extends to the remotely located wound vacuum unit 22. This unit may be chosen from the many types available. The operation of this unit is to be as per the manufacturer's instructions. This added "wound incubator" is not meant to change any of the operational or safety requirements of the typical negative pressure wound therapy as recommended by the vacuum unit manufacturers. A wound vacuum unit is not necessary. Another vacuum source, such as a wall outlet vacuum, may also be used instead along with a suction unit, regulating the vacuum and collecting the liquids.

[0033] While FIG. 1 is used to show basic components and principles of operation, FIG. 2 is used to show these same components enclosed in a wound incubation device 23. This wound incubation device 23 contains a filtered air intake 2, a gas supply inlet connection 24, and an outlet connection 25 to the wound dressing 18. The face of this device may be used to mount operational controls and display desired information.

[0034] Because of the fear of possible contamination, all components touched by the water are typically designed for single patient use. The wound incubator may be configured to be mounted on an IV pole or on a bed rail, placed on a bedside table or designed to be portable. It should be located close to the wound site. It uses an electrical power source from a battery or a 120V power cord. Temperature sensor 17 communicates with the wound incubation device 23. The wound vacuum unit 22 may also be configured to communicate with the wound incubator.

[0035] Another embodiment would have the components of the wound incubator and the components of the vacuum source contained in a single enclosure. Both of these devices would not only share a single enclosure, they also would share a power supply, electronics, displays and communications. A single enclosure would save space, costs, and be simpler to hook up and operate. Dressing inlet and outlet tubes would go to the same device. A small oxygen source could also be contained in this single enclosure, and could be designed for stationary or portable applications.

[0036] Diabetic foot ulcer patients who wish to remain ambulatory sometimes use a boot or cast over their dressed wound. The boot lessens wound trauma by transferring weight bearing from the wound area to other parts of the leg. If a negative pressure dressing were adapted for use within a boot or cast, a wound incubator could be connected to this boot at times when the patient is non-ambulatory. The wound incubator, vacuum source, and small oxygen source could be fitted into a briefcase and carried by the patient from home to work and back.

[0037] This wound warming method could be suitable for chronic wounds, complex wounds and other difficult to heal wounds. These wounds would include those on humans as well as warm-blooded animals. With animals, the dew point temperature used would correspond to that particular animal's normal body temperature.

[0038] It will be appreciated by those skilled in the art that while the invention has been described above in connection with particular embodiments and examples, the invention is not necessarily so limited, and that numerous other embodiments, examples, uses, modifications and departures from the embodiments, examples and uses are intended to be encompassed by the claims attached hereto.

1. A method of treating a wound using condensation warming, the method comprising:

   applying a wound dressing over the wound, the wound dressing having an inlet and an outlet and forming a substantially airtight cover over the wound;

   supplying a vapor to the wound dressing via the inlet;

   warming the wound by condensing the vapor into a condensate on a surface of the wound thereby releasing a latent heat of vaporization; and
removing the condensate and any uncondensed vapor from the wound dressing via the outlet.

2. The method of claim 1 wherein the vapor supplied via the inlet is maintained at a temperature just above a temperature at which the vapor condenses, thereby promoting condensation of the vapor when the vapor comes into contact with a comparably cooler surface of the wound.

3. The method of claim 2 wherein the condensing the vapor to warm the wound occurs in a self-regulating manner with condensation of the vapor and release of the latent heat of vaporization on the surface of the wound lessening as the wound warms.

4. The method of claim 2 wherein the temperature of condensation is 37 degrees Celsius.

5. The method of claim 1 wherein the condensate forms directly on the surface of the wound and directly warms the wound.

6. The method of claim 1 further comprising the step of evaporating a liquid from a liquid source to form the vapor prior to supplying the vapor to the wound dressing via the inlet, in which the step of evaporating absorbs the latent heat of vaporization into the vapor.

7. The method of claim 6 wherein the step of evaporating the liquid from the liquid source is performed by a humidifier that heats and humidifies the liquid to form the vapor.

8. The method of claim 6 wherein the temperature at which absorption and release of the latent heat of vaporization occurs is essentially same temperature.

9. The method of claim 1 wherein a vacuum source in fluid communication with the outlet performs the step of removing the condensate and any uncondensed vapor from the wound dressing via the outlet.

10. The method of claim 9 further comprising the step of drawing the vapor through the wound dressing using the vacuum source exclusively, thereby eliminating a need for a positive pressure source.

11. The method of claim 9 wherein the vacuum source also creates a negative pressure in the wound dressing and simultaneously performs negative pressure wound therapy on the wound.

12. The method of claim 1 wherein a gas source is mixed with the vapor and wherein the gas source is an oxygen-rich gas in comparison to atmospheric air and simultaneously provides topical oxygen therapy to the wound.

13. The method of claim 1 further comprising the step of diluting wound exudates using the condensate thereby facilitating removal of the wound exudates by the vacuum source.

14. The method of claim 1 further comprising the step of removing at least one of wound debris, slough, and infectious material whereby transport of the at least one of wound debris, slough, and infectious material is facilitated by the condensate.

15. The method of claim 1 wherein the condensate is water.

16. The method of claim 1 further comprising controlling a flow of a gas source to the inlet using a gas flow controller.

17. The method of claim 1 further comprising the step of mixing a controlled flow of oxygen and a free flow of filtered air under atmospheric pressure in at least one of a mixture space or plenum to provide a particular composition for a gas source.

18. The method of claim 1 further comprising heating a dressing delivery tube to minimize condensation therein.

19. The method of claim 1 wherein the wound dressing is used on a foot wound and both the wound dressing and the foot wound are enclosed inside a boot or cast with the boot or cast providing off-weighting of the foot.

20. The method of claim 1 wherein the condensate also provides moist wound therapy for the wound.

21. The method of claim 1 wherein the method of treatment includes simultaneously:

   - cleansing the wound;
   - minimizing dressing adherence;
   - applying moist wound therapy;
   - applying topical oxygen therapy;
   - applying negative pressure wound therapy; and
   - removing stagnant vapors and odors.

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