TITLE OF THE INVENTION

DYNAMIC, REDUCED-PRESSURE TREATMENT SYSTEMS AND METHODS

RELATED APPLICATION

[0001] The present invention claims the benefit, under 35 U.S.C. § 119(e), of the filing of U.S. Provisional Patent Application serial number 61/116,121, entitled "Dynamic, Reduced-Pressure Treatment System and Method," filed 19 November 2008, which is incorporated herein by reference for all purposes.

BACKGROUND

[0002] present invention relates generally to medical treatment systems and, more particularly, to dynamic, reduced-pressure systems and methods.

[0003] Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "NPWT," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, which may include faster healing and increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a porous pad or other manifold device. The porous pad contains cells or pores that are capable of distributing reduced pressure to the tissue site and channeling fluids that are drawn from the tissue site. The possible benefits of treating a tissue site with reduced pressure include reduction in edema, enhanced blood flow, promotion of granulation of tissue, decreasing of bacterial colonization, removing of inhibiting agents, promotion of a moist healing environment, and enhanced epithelial migration.

SUMMARY

[0004] Problems with existing reduced-pressure treatment systems and methods are addressed by the systems and methods of the illustrative, non-limiting embodiments described herein. According to an illustrative, non-limiting embodiment, a dynamic, reduced-pressure treatment system for treating a tissue site on a patient includes a manifold for placing adjacent to the tissue site, a sealing member for coupling to the patient's epidermis to form a fluid seal over the tissue site, a reduced-pressure source for producing reduced pressure, a reduced-pressure delivery member for delivering reduced pressure from the reduced-pressure source to the manifold, and a wave generator associated with the reduced-pressure delivery member. The wave generator imparts a wave to the reduced pressure developed by the reduced-pressure source.

[0005] According to another illustrative, non-limiting embodiment, a method for manufacturing a dynamic, reduced-pressure treatment system for treating a tissue site on a patient includes the steps of: providing a manifold for placing adjacent to the tissue site, providing a sealing member for coupling to the patient's epidermis and operable to form a fluid seal over the tissue site, providing a reduced-pressure source for developing a reduced pressure, and providing a reduced-pressure delivery member for delivering reduced pressure from the reduced-pressure source to the manifold. The method further includes the steps of providing a wave generator and associating the wave generator with the reduced-pressure delivery member. The wave generator imparts a wave to the reduced pressure developed by the reduced-pressure source.

[0006] According to another illustrative, non-limiting embodiment, a method for treating a tissue site on a patient includes the steps of: disposing a manifold adjacent to the tissue site, placing a sealing member on the patient's epidermis to form a fluid seal over the tissue site, fluidly coupling a reduced-pressure delivery member to the manifold, and fluidly coupling the reduced-pressure delivery member to a reduced-pressure source for providing reduced pressure to the manifold. The method further includes associating a wave generator with the reduced-pressure delivery member. The wave generator imparts a wave to the reduced pressure developed by the reduced-pressure source.

[0007] According to another illustrative, non-limiting embodiment, a reduced-pressure delivery member includes a first lumen for transmitting a liquid and a a second lumen for transmitting a gas. The first lumen has a first interior space and the second lumen has a

second interior space. A first liquid-impermeable-and-gas-permeable member is coupled to the second lumen in at least a portion of the second interior space.

[0008] According to another illustrative, non-limiting embodiment, a reduced-pressure delivery member includes a first lumen for transmitting a gas and a second lumen for transmitting a liquid. The first lumen has a first interior space and the second lumen has a second interior space. The first lumen is formed at least in part from a fluid impermeable material. The second lumen is formed from a gas-permeable-and-liquid-impermeable material and is disposed within the first interior space.

[0009] Other features and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIGURE 1 is a schematic diagram with a portion shown in cross section of an illustrative, non-limiting embodiment of a dynamic, reduced-pressure treatment system;

[0011] FIGURE 2 is a schematic diagram with a portion shown in cross section of an illustrative, non-limiting embodiment of a wave generator for use with an embodiment of a dynamic, reduced-pressure treatment system;

[0012] FIGURE 3 is a schematic diagram with a portion shown in cross section of another illustrative, non-limiting embodiment of a wave generator for use with an embodiment of a dynamic, reduced-pressure treatment system;

[0013] FIGURE 4 is a schematic diagram of another illustrative embodiment of a wave generator for use with an embodiment of a dynamic, reduced-pressure treatment system;

[0014] FIGURE 5 is a schematic, perspective view of an illustrative embodiment of a reduced-pressure delivery member for use with an embodiment of a reduced-pressure treatment system;

[0015] FIGURE 6 is a schematic, perspective view of an illustrative, non-limiting embodiment of a reduced-pressure delivery member for use with an embodiment of a reduced-pressure treatment system;

[0016] FIGURE 7 is a schematic, perspective view of an illustrative, non-limiting embodiment of a reduced-pressure delivery member for use with an embodiment of a reduced-pressure treatment system; and

[0017] FIGURE 8 is a schematic cross section of the reduced-pressure delivery member of FIGURE 7 taken along line 8-8.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0018] In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part hereof. 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 invention. To avoid detail not necessary to enable those skilled in the art to practice the embodiments described herein, 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 illustrative embodiments are defined only by the appended claims.

[0019] Referring now primarily to FIGURE 1, an illustrative embodiment of a dynamic, reduced-pressure treatment system 100 for treating a tissue site 104, e.g., a wound 102, a damaged area of tissue, is presented. The wound 102 may involve epidermis 103, dermis 105, and subcutaneous tissue 107. The dynamic, reduced-pressure treatment system 100 may also be used at other tissue sites. The tissue site 104 may be the bodily tissue of any human, animal, or other organism, including bone tissue, adipose tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, ligaments, or any other tissue. The dynamic, reduced-pressure treatment system 100 may include a manifold 112, an sealing member 111, a reduced-pressure delivery member 144, a reduced-pressure subsystem 113, and a wave generator 110.

[0020] The manifold 112 distributes reduced pressure and may be formed from any manifold material suitable for distributing reduced pressure. In one illustrative embodiment, the manifold 112 is made from a porous and permeable foam material and, more particularly, a reticulated, open-cell polyurethane or polyether foam that allows good permeability of wound fluids while under a reduced pressure. One such foam material that has been used is the VAC® GranuFoam® Dressing available from Kinetic Concepts, Inc. (KCI) of San Antonio, Texas. Any material or combination of materials may be used for the manifold material provided that the manifold material is operable to distribute the reduced pressure. Unless otherwise indicated, as used herein, "or" does not require mutual exclusivity.

[0021] The term "manifold" as used herein generally refers to a substance or structure that is provided to assist in applying reduced pressure to, delivering fluids to, or removing fluids from a tissue site. A manifold typically includes a plurality of flow channels or pathways. The plurality of flow channels may be interconnected to improve distribution of

fluids provided to and removed from the area of tissue around the manifold. Examples of manifolds may include, without limitation, devices that have structural elements arranged to form flow channels, cellular foam, such as open-cell foam, porous tissue collections, and liquids, gels, and foams that include, or cure to include, flow channels. The manifold material may also be a combination or layering of materials. For example, a first manifold layer of hydrophilic foam may be disposed adjacent to a second manifold layer of hydrophobic foam to form the manifold 112.

[0022] The reticulated pores of the GranuFoam® material are helpful in carrying out the manifold function, but again other materials may be used. A material with a higher or lower density (smaller pore size) than GranuFoam® material may be desirable in some situations. Among the many possible materials, the following may be used: GranuFoam® material or a Foamex® technical foam (www.foamex.com). In some instances it may be desirable to add ionic silver to the foam in a microbonding process or to add other substances to the material, such as antimicrobial agents. The manifold 112 may be a bio-absorbable material or an anisotropic material.

[0023] The sealing member 111 covers the manifold 112 and extends past a peripheral edge 114 of the manifold 112 to form an extension 116 on an intact portion of the epidermis 103. The extension 116 has a first side 118 and a second, patient-facing side 120. The extension 116 may form a fluid seal against the epidermis 103 or against a gasket (e.g., another drape portion near wound edge 109) by a sealing apparatus 124, and any references to forming a seal with the epidermis 103 should be regarded as also including a seal formed against such a gasket. The sealing apparatus 124 may take numerous forms, such as an adhesive sealing tape, or drape tape or strip; a double-side drape tape; an adhesive 126; a paste; a hydrocolloid; a hydrogel; or other sealing device. If a tape is used, the tape may be formed of the same material as the sealing member 111 with a pre-applied, pressure-sensitive adhesive. The adhesive 126 may be applied on a second, patient-facing side 120 of the extension 116. The adhesive 126 provides a fluid seal between the sealing member 111 and the epidermis 103. "Fluid seal," or "seal," means a seal adequate to maintain reduced pressure at a desired site given the particular reduced-pressure source or subsystem involved.

[0024] The sealing member 111 may be an elastomeric material. "Elastomeric" means having the properties of an elastomer and generally refers to a polymeric material that has rubber-like properties. More specifically, most elastomers have elongation rates greater than 100% and a significant amount of resilience. The resilience of a material refers to the material's ability to recover from an elastic deformation. Examples of elastomers may

include, but are not limited to, natural rubbers, polyisoprene, styrene butadiene rubber, chloroprene rubber, polybutadiene, nitrile rubber, butyl rubber, ethylene propylene rubber, ethylene propylene diene monomer, chlorosulfonated polyethylene, polysulfide rubber, polyurethane, EVA film, co-polyester, and silicones. Further still, other non-limiting examples of sealing member materials may include a silicone drape material, such as a 3M Tegaderm® drape material, an acrylic drape material, such as one available from Avery Dennison, or an incise drape material.

[0025] The reduced-pressure subsystem 113 includes a reduced-pressure source 140, which can take many different forms, and may include the reduced-pressure interface 150 or other components to provide reduced pressure to the manifold 112. The reduced-pressure source 140 provides reduced pressure as a part of the dynamic, reduced-pressure treatment system 100. As used herein, "reduced pressure" generally refers to a pressure less than the ambient pressure at a tissue site that is being subjected to treatment. In most cases, this reduced pressure will be less than the atmospheric pressure at which the patient is located. Alternatively, the reduced pressure may be less than a hydrostatic pressure at the tissue site 104. Unless otherwise indicated, values of pressure stated herein are gauge pressures.

[0026] The reduced pressure delivered may be constant or varied (patterned or random) and may be delivered continuously or intermittently. Although the terms "vacuum" and "negative pressure" may be used to describe the pressure applied to the tissue site, the actual pressure applied to the tissue site may be more than the pressure normally associated with a complete vacuum. Consistent with the use herein, an increase in reduced pressure or vacuum pressure typically refers to a relative reduction in absolute pressure.

[0027] The reduced-pressure source 140 provides reduced pressure. The reduced-pressure source 140 may be any device for supplying a reduced pressure, such as a vacuum pump, wall suction, or other source. While the amount and nature of reduced pressure applied to a tissue site will typically vary according to the application, the reduced pressure will typically be between -5 mm Hg and -500 mm Hg and more typically between -100 mm Hg and -300 mm Hg.

[0028] In the illustrative embodiment of FIGURE 1, the reduced-pressure source 140 is shown having a reservoir region 142, or canister region. An interposed membrane filter, such as a hydrophobic or an oleophobic filter, may be interspersed between reduced-pressure delivery member 144 and the reduced-pressure source 140. A first portion 146 of reduced-pressure delivery member 144 may have one or more devices, such as device 148. For example, the device 148 may be another fluid reservoir, or collection member to hold exudates

and other fluids removed. Other examples of the device 148 that may be included on the portion 146 of reduced-pressure delivery member 144 or otherwise fluidly coupled to the reduced-pressure delivery member 148 include the following non-limiting examples: a pressure-feedback device, a volume detection system, a blood detection system, an infection detection system, a flow monitoring system, a temperature monitoring system, etc. Some of these devices may be formed integrally with the reduced-pressure source 140. For example, a reduced-pressure port 141 on reduced-pressure source 140 may include a filter member that includes one or more filters, e.g., an odor filter.

[0029] The reduced pressure developed by reduce-pressured subsystem 113 is delivered through the reduced-pressure delivery member 144 to a reduced-pressure interface 150, which may be an elbow port 152. In one illustrative embodiment, the elbow port 152 is a TRAC® pad available from Kinetic Concepts, Inc. of San Antonio, Texas. The reduced-pressure interface 150 allows the reduced pressure to be delivered through the sealing member 111 to the manifold 112, as well as to a sealed space 154 in which the manifold 112 is located. The sealed space 154 is formed by the sealing member 111 over the tissue site 104. In this illustrative embodiment, the reduced-pressure interface 150 extends through the sealing member 111 and into the manifold 112. Reduced pressure is supplied by the reduced-pressure delivery member 144 to the manifold 112. The supply of reduced pressure may be direct or in conjunction with reduced-pressure interface 150.

[0030] The wave generator 110 is typically associated with the reduced-pressure delivery member 144. For example, the wave generator 110 may be fluidly coupled to the reduced-pressure delivery member 144 on a second portion 138 or with a tributary conduit (see, e.g., tributary conduit 302 in FIG. 3). The wave generator 110 imposes a wave form on the reduced pressure supplied by the reduced-pressure subsystem 113; that is, the wave generator 110 develops a wave. The wave typically causes the pressure to vary at the tissue site 104. Preferably, the wave generator 110 allows for a wide frequency range with respect to the absolute value of the pressure experienced at the tissue site 104. The frequency range of the wave may be about 0.5 Hz to about 20 Hz and greater. The wave generator 110 may also control the amplitude of the wave. The wave generator 110 may take many forms, such a piezoelectric transducer, a diaphragm member, a valve arrangement, etc.

[0031] The wave generator 110 creates a wave, or change in the pressure or energy in the reduced pressure in the reduced-pressure delivery member 144. The change could be accomplished with a sonic wave or a pressure wave, and so the term "wave generator" has been used. The wave generator 110 may function to develop a sonic wave or a pressure wave

by electrical means or mechanical means. The wave generator 110 may utilize a reduced-pressure source, gear set using kinetic motion, piezoelectric transducer, a diaphragm member, a valve arrangement, etc. With respect to mechanical options, anything that produces a mechanical variation may be used, such as a displacement device. The wave generator 110 may also be an electrically-powered membrane. Other non-limiting examples of devices and arrangements that may be used as the wave generator 110 will be presented further below in connection with FIGURES 2-4.

[0032] In operation, according to one illustrative embodiment, of the dynamic, reduced-pressure treatment system 100, the manifold 112 is placed adjacent to the tissue site 104, and the sealing member 111 is placed over the tissue site 104, manifold 112, and a portion of the epidermis 103 to form a fluid seal seal. The fluid seal creates the sealed space 154. If not already installed, the reduced-pressure interface 150 is fluidly coupled to the sealed space 154. The reduced-pressure delivery member 144 is fluidly coupled to the reduced-pressure source 140 and the reduced-pressure interface 150. In this embodiment, the wave generator 110 is associated with the reduced-pressure delivery member 144. When the reduced-pressure source 140 is activated, reduced pressure may be provided to the manifold 112 and ultimately to tissue site 104, and when the wave generator 110 is activated, the wave generator 110 imparts a wave and provides dynamic pressure or energy variation at the wound site 104.

[0033] As previously noted, the wave generator 110 may take many forms, such as a piezoelectric transducer, a diaphragm member, or an arrangement of valves, such as solenoid-operated valves. A number of different, non-limiting, illustrative embodiments of wave generators will now be presented.

[0034] Referring now primarily to FIGURE 2, an illustrative embodiment of a wave generator 200 for use as part of a dynamic, reduced-pressure treatment system is presented. For example, the wave generator 200 may be used as the wave generator 110 in the dynamic, reduced-pressure treatment system of FIGURE 1. In forming the wave generator 200, a piezoelectric transducer 202 is fluidly coupled, i.e., is placed in fluid communication with, a reduced-pressure delivery member 204. The reduced-pressure delivery member 204 receives reduced pressure from a reduced pressure subsystem 206, which includes a reduced-pressure source 208. The reduced-pressure subsystem 206 introduces reduced pressure into the reduced-pressure delivery member 204. The reduced-pressure subsystem 206 also receives fluids through the reduced-pressure delivery member 204 as suggested by arrows 210. In this

illustrative embodiment, the wave generator 200 has been fluidly coupled to the reduced-pressure delivery member 204.

[0035] The wave generator 200 has a movable face member 212 that extends into an interior portion of the reduced-pressure delivery member 204 or is otherwise fluidly coupled to fluid within the reduced-pressure delivery member 204. The movable face member 212 moves relative to the reduced-pressure delivery member 204 at a frequency that may be controlled by a power-and-control connection 214. The power-and-control connection 214 may be a separate power cord and a device for setting and controlling the frequency of the movable face member 212 or the amplitude of the movement of the movable face member 212 . The movable face member 212 imparts a wave onto the fluid already present in reduced-pressure delivery member 204. The wave causes the absolute pressure or energy delivered to vary with a frequency in the range of 0.5 Hz to 20 Hz or greater.

[0036] In still a more particular illustrative, non-limiting embodiment, the wave generator 200 may be a piezoelectric transducer with a piezoelectric member comprising the movable face member 212. In this embodiment, the movable face member 212 is electrically driven. In response to receiving a desired wave form or frequency information, the wave generator 200 may develop a wave form in the fluid of the reduced-pressure delivery member 204 with the desired frequency or wave form using physical displacement of the movable face member 212. The possible frequency range, or spectrum, for the wave developed within the reduced-pressure delivery member 204 with this approach is large from 0.5 Hertz to 20 Hertz and higher. The frequency may include any subset of the previously stated range, e.g., 5-20 Hz, 10-20 Hz, 5-15 Hz, etc.

[0037] Again, the wave generator may take numerous other forms. The wave generator may be a mechanically or electrically activated wave generator or the wave generator may utilize a diaphragm or may utilize a system of valves that turn on and off to achieve the desired effect. A device could be added to the reduced-pressure delivery conduit to press and close, i.e., pinch, the conduit or delivery member, e.g., the reduced-pressure delivery member 144 in FIGURE 1, in a pattern that causes a pressure wave. Another illustrative, non-limiting embodiment follows.

[0038] Referring now primarily to FIGURE 3, another illustrative embodiment of a wave generator 300 is presented. The wave generator 300 includes a tributary conduit (or lumen) 302 that is fluidly coupled to a reduced-pressure delivery member 304. The reduced-pressure delivery member 304 is fluidly coupled to a reduced-pressure subsystem 306. The reduced-pressure subsystem 306 includes a reduced-pressure source 308. The reduced-

pressure subsystem 306 delivers reduced pressure to the reduced-pressure delivery member 304. At the same time, the reduced-pressure subsystem 306 pulls and receives fluid as suggested by arrow 310.

[0039] The wave generator 300 includes a wave-imparting member 312, which may be a diaphragm pump, a piston, a piezoelectric member, or any device that is operable to produce a pressure or energy wave on the fluid within the reduced-pressure delivery member 304. One or more power-and-control connection members 314 may be coupled to the wave generator 300 to provide electrical power and to control the amplitude or frequency of the energy or pressure wave imparted.

[0040] Referring now primarily to FIGURE 4, another illustrative embodiment of a wave generator 400 is presented. The wave generator 400 is fluidly coupled to a reduced-pressure delivery member 404. The wave generator 400 includes a plurality of valves, e.g., a first valve 416, a second valve 418, and a third valve 420. The wave generator 400 may further include a plurality of chambers, e.g., a first chamber 422, second chamber 424, and third chamber 426. A plurality of regulators, e.g., a first regulator 428, a second regulator 430, and a third regulator 432, is associated with the plurality of chambers. The first pressure regulator 428 is fluidly coupled to the first chamber 422. The second pressure regulator 430 is fluidly coupled to the second chamber 424. Similarly, the third pressure regulator 432 is fluidly coupled to the third chamber 426. Each pressure regulator 428, 430, 432 is operable to regulate pressure, e.g., operable to step down the pressure to a desired level.

[0041] A manifold chamber 434 is fluidly coupled to the pressure regulators 428, 430, 432 and provides reduced pressure thereto. The reduced pressure is supplied by a reduced-pressure subsystem 406 through a reduced-pressure supply conduit 405 to the manifold chamber 434. The reduced-pressure subsystem 406 may include a reduced-pressure source 408. The pressure can be controlled in each of the chambers 422, 424, and 426 to establish the desired pressure level. In this regard, the pressure regulators 428, 430, and 432 may reduce or increase the pressure as needed. Typically, the pressure regulators, e.g., regulators 428, 430, and 432, increase the absolute value of the pressure in the chambers, e.g., chambers 422, 424, and 426 .

[0042] As a non-limiting example, the pressure in the first chamber 422 may be P_1, the pressure in the second chamber 424 may be P_2, the pressure in the third chamber 426 may be P_3, and $P_1 > P_2 > P_3$. Thus, opening and closing of the valves 416, 418, 420 may be sequenced to expose the fluid in reduced-pressure delivery member 404 to different pressures (P_1, P_2, and P_3), and thereby creates a wave. A controller may be associated with the valves 416, 418, 420,

which may be solenoid valves, to coordinate the opening and closing of the valves 416, 418, 420. The opening and closing of the valves 416, 418, and 420 may allow for a wave to be generated with a frequency in the range of 0.5 Hz to 20 Hz and greater. The frequency range may be any subset of the previously stated range.

[0043] The dynamic variation of pressure or energy by the wave generator, e.g., 110, 200, 300, 400 at the tissue site, e.g., tissue site 104, may help with the healing process. The wave generator may help to debride or clean the wound in a continuous fashion. The wave generator may generally help keep the wound cleaner by removing dead tissue. In addition, the wave generator may de-sensitize nerves and thereby help reduce the patient's pain. The wave generator may also help provide a dynamic motion to the tissue that causes tissue to form with a certain orientation.

[0044] The wave generator, e.g., wave generator 110, 200, 300, 400, may be located at various locations. Depending on how rigid aspects of the dynamic, reduced-pressure treatment system are, the wave generator may need to be close to the tissue site or may be positioned further from the tissue site. Thus, if the maximum amplitude of the wave generator is not adequate for a given location, the wave generator may need to be moved closer, and if the maximum amplitude of the wave generator is more than adequate, the wave generator could be positioned further away from the tissue site. The compressibility of the fluid in the reduced-pressure delivery member will also be a factor in determining the position of the wave generator with respect to the tissue site.

[0045] It should be appreciated that the more incompressible the fluid in the reduced-pressure delivery member, e.g., the delivery member 144 in FIGURE 1, is, the less energy that is required to deliver a certain amplitude for a wave or alternatively the further the wave generator 110 may be located from the tissue site 104 without expending any additional energy. To help make the fluid more incompressible for purposes of transmitting amplitude or for other reasons, the reduced-pressure delivery member 144 may be formed in such a way as to provide a segregated portion for the liquid and another portion for any gases. By segregating the fluid from any gases, a substantially incompressible fluid or more incompressible fluid than would otherwise exist may result and be utilized with the wave generator 110. Moreover, segregating the more incompressible fluid portion may facilitate flow of fluids from the wound site 104 toward the reduced-pressure subsystem 113 with a minimal risk of blockage. The reduced-pressure delivery conduit 144 may be formed in a number of ways to achieve this desired performance, and illustrative, non-limiting embodiments are described below in connection with FIGURES 5-8.

[0046] Referring now primarily to FIGURE 5, a reduced-pressure delivery member 500 may be formed as a conduit 502 that includes at least one lumen, e.g., first lumen 504, for transmitting a liquid (a substantially incompressible fluid), and at least one lumen, e.g., second lumen 506, for transmitting a gas. The first lumen 504 has a first interior space 508. The second lumen 506 has a second interior space 510 that is covered proximate a distal end 512 by a first liquid-impermeable-and-gas-permeable member 514. The liquid-impermeable-and-gas-permeable member 514 is operable to substantially restrict liquid while substantially allowing gas to enter. In addition to the first liquid-impermeable-and-gas-permeable member 514, which is located proximate the distal end 512, one or more additional liquid-impermeable-and-gas-permeable members 514 may be located at discrete locations on the interior of the second lumen 506 or disposed continuously throughout the second interior space 510 of the second lumen 506.

[0047] The first liquid-impermeable-and-gas-permeable member 514 may be made from any material that is liquid impermeable but gas permeable. The first liquid-impermeable-and-gas-permeable member 514 may be formed, as one non-limiting example, from a synthetic fluoropolymer such as a poly-tetrafluoroethylene material (PTFE). For the illustrative embodiment of FIGURE 5, a third lumen 516 and a fourth lumen 518, which are both analogous to first lumen 504, are provided and are available to transmit a fluid. The lumens 504, 506, 516, 518 may be made of any fluid impermeable, flexible material, such as high-density polyethylene (HDPE), high impact polystyrene (HIPS), low-density polyethylene (LDPE), nylon, polycarbonate, polypropylene, polyethylene, polyvinyl chloride (PVC), urethanes, etc.

[0048] The first liquid-impermeable-and-gas-permeable member 514 substantially restricts entry into the second lumen 506 to gas while liquids may enter the first lumen 504 (and lumens 516 and 518). The liquid in the first lumen 504 (or lumens 516 and 518) may be used with a wave generator to transmit a wave or may be used to efficiently remove fluids. The wave generator, e.g., wave generator 110 in FIGURE 1, may be fluidly coupled to the first interior space 508 of the first lumen 504 and may also be fluidly coupled to the third lumen 516 and the fourth lumen 518. Thus, the wave generated by the wave generator is delivered through the liquid, or incompressible fluid, in the first lumen 504 or other lumens.

[0049] Referring now primarily to FIGURE 6, another illustrative embodiment of a reduced-pressure delivery member 600 is presented. The reduced-pressure delivery member 600 may be formed as a conduit 602 that includes at a first lumen 604 for transmitting a liquid and a second lumen 606 for transmitting gases. The first lumen 604 has a first interior space

608. The second lumen 606 has a second interior space 610 that is covered proximate a distal end 612 by a first liquid-impermeable-and-gas-permeable member 614, which is operable to substantially restrict liquid while substantially allowing gas to enter. In addition to the first liquid-impermeable-and-gas-permeable member 614, additional liquid-impermeable-and-gas-permeable members may be distributed at discrete locations or continuously throughout the second interior space 610 of the second lumen 606. The first liquid-impermeable-and-gas-permeable member 614 may be made from the same material as the first liquid-impermeable-and-gas-permeable member 514 in FIGURE 5. The lumens 604 and 606 may be made of any fluid impermeable, flexible material. A wave generator, e.g., wave generator 110 in FIG. 1, may be fluidly coupled to the first lumen 604 for imparting a wave.

[0050] Referring now primarily to FIGURE 7, another illustrative embodiment of a reduced-pressure delivery member 700 is presented. The reduced-pressure delivery member 700 may be formed as a conduit 702 that includes a first lumen 704 for transmitting gases (substantially compressible fluid), e.g., air, and a second lumen 706 for transmitting a liquid (substantially incompressible fluid). The first lumen 704 has a first interior space 708. In this illustrative embodiment, a third lumen 710 and a fourth lumen 712 are provided for transmitting a gas.

[0051] The first lumen 704, third lumen 710, and fourth lumen 712 are spaced and concentrically disposed about the second lumen 706. The second lumen 706 is disposed within an interior space of the other lumens 704, 710, 712 and defines an interior conduit therein. An exterior wall 714 of the conduit 702, which makes up the exterior walls of the first lumen 704, third lumen 710, and fourth lumen 712, is made from a fluid impermeable, flexible material, such as the materials previously mentioned. The exterior wall 716 of the second lumen 706 is made from a liquid-impermeable-gas-permeable material, such as a synthetic fluoropolymer, e.g., a poly-tetrafluoroethylene material (PTFE). The exterior wall 716 of the second lumen 706 is also an interior wall of the first lumen 704, third lumen 710, and fourth lumen 712. In one alternative, illustrative embodiment, the first lumen 704 may be a 360 degree conduit with a first interior space into which the second lumen 706 is inserted.

[0052] As fluid is pulled through the second lumen 706 of the reduced-pressure delivery member 700, gases are free to pass through the exterior wall 716 of the second lumen 706 as suggested by arrows 717 and into the first lumen 704, third lumen 710, or fourth lumen 712. As such, the fluid remaining within the second lumen 706 contains less gas and is therefore more incompressible. As previously noted, a wave generator may more easily or efficiently impart a wave on the fluid when the fluid is more incompressible, and a wave

generator, e.g., wave generator 110 in FIGURE 1, may be fluidly coupled to the first lumen 704 or lumens 710 and 712 for imparting a wave thereto.

[0053] The systems and methods herein may allow reduced-pressure treatment of a wound site with dynamic pressure or energy that preferably allows high frequency variation and controls the pressure or energy wave amplitude. Moreover, it does so with reliability and with minimal energy requirements.

[0054] Although the present invention and its advantages have been disclosed in the context of certain illustrative, non-limiting embodiments, it should be understood that various changes, substitutions, permutations, and alterations can be made without departing from the scope of the invention as defined by the appended claims. It will be appreciated that any feature that is described in a connection to any one embodiment may also be applicable to any other embodiment.

CLAIMS

What is claimed is:

Claim 1. A dynamic, reduced-pressure treatment system for treating a tissue site on a patient, the system comprising:

a manifold adjacent the tissue site for distributing reduced pressure to the tissue site;

a sealing member coupled to the patient's epidermis to form a fluid seal over the tissue site;

a reduced-pressure source for producing reduced pressure;

a reduced-pressure delivery member for delivering reduced pressure from the reduced-pressure source to the manifold; and

a wave generator associated with the reduced-pressure delivery member, wherein the wave generator imparts a wave to the reduced pressure developed by the reduced-pressure source.

Claim 2. The dynamic, reduced-pressure treatment system of claim 1 wherein the wave generator is associated with the reduced-pressure delivery member between the reduced-pressure source and the sealing member.

Claim 3. The dynamic, reduced-pressure treatment system of claim 1 wherein the wave generator is operable to impart a wave to the reduced pressure with a frequency greater than about one Hertz.

Claim 4. The dynamic, reduced-pressure treatment system of claim 1 wherein the wave generator imparts a wave to the reduced pressure with a frequency in the range of about 0.5 Hz to about 20 Hz.

Claim 5. The dynamic, reduced-pressure treatment system of claim 1 wherein the wave generator imparts a wave to the reduced pressure with a frequency greater than about 20 Hertz.

Claim 6. The dynamic, reduced-pressure treatment system of claim 1 wherein the wave generator comprises a piezoelectric transducer in fluid communication with the reduced-pressure delivery member.

Claim 7. The dynamic, reduced-pressure treatment system of claim 1 wherein the wave generator comprises a diaphragm member in fluid communication with the reduced-pressure delivery member.

Claim 8. The dynamic, reduced-pressure treatment system of claim 1 wherein the wave generator comprises a plurality of chambers with valves and wherein each of the chambers is selectively in fluid communication with the reduced-pressure delivery member.

Claim 9. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises a conduit and wherein the conduit comprises:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space; and

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space.

Claim 10. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises a conduit and wherein the conduit comprises:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space;

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space; and

wherein the wave generator is in fluid communication with the first lumen.

Claim 11. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises a conduit and wherein the conduit comprises:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space;

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space; and

wherein the first liquid-impermeable-and-gas-permeable member comprises a synthetic fluoropolymer.

Claim 12. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises a conduit and wherein the conduit comprises:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space;

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space;

wherein the first liquid-impermeable-and-gas-permeable member comprises a synthetic fluoropolymer; and

wherein the synthetic fluoropolymer comprises a poly-tetrafluoroethylene material (PTFE).

Claim 13. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises:

a first lumen for transmitting a gas, the first lumen having a first interior space;

a second lumen for transmitting a liquid, the second lumen having a second interior space;

the first lumen comprising a fluid impermeable material; and

the second lumen formed from a gas-permeable-and-liquid-impermeable material and disposed within the first interior space.

Claim 14. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises:

an outer lumen having a first interior space and formed from a fluid impermeable material and wherein the first interior space comprises a liquid flow path;

an inner flow member comprising a lumen formed from a gas-permeable-and-liquid-impermeable material and disposed within the first interior space; and

wherein the wave generator is in fluid communication with the liquid flow path.

Claim 15. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises:

an outer lumen having a first interior space and formed from a fluid impermeable material and wherein the first interior space comprises a liquid flow path;

an inner flow member comprising a lumen formed from a gas-permeable-and-liquid-impermeable material and disposed within the first interior space;

wherein the wave generator is in fluid communication with the liquid flow path; and

wherein the gas-permeable-and-liquid-impermeable material comprises a synthetic fluoropolymer.

Claim 16. The dynamic, reduced-pressure treatment system of claim 1 wherein the reduced-pressure delivery member comprises:

an outer lumen having a first interior space and formed from a fluid impermeable material and wherein the first interior space comprises a liquid flow path;

an inner flow member comprising a lumen formed from a gas-permeable-and-liquid-impermeable material and disposed within the first interior space;

wherein the wave generator is in fluid communication with the liquid flow path;

wherein the gas-permeable-and-liquid-impermeable material comprises a synthetic fluoropolymer; and

wherein the synthetic fluoropolymer comprises a poly-tetrafluoroethylene material (PTFE).

Claim 17. A method of manufacturing a dynamic, reduced-pressure treatment system for treating a tissue site on a patient, the method comprising the steps of:

providing a manifold for placing adjacent to the tissue site and operable to distribute reduced pressure to the tissue site;

providing a sealing member for coupling to the patient's epidermis and operable to form a fluid seal over the tissue site;

providing a reduced-pressure source for developing a reduced pressure;

providing a reduced-pressure delivery member for delivering reduced pressure from the reduced-pressure source to the manifold;

providing a wave generator for imparting a wave to the reduced pressure developed by the reduced-pressure source; and

associating the wave generator with the reduced-pressure delivery member.

Claim 18. The method of manufacturing of claim 17 wherein the step of associating the wave generator with the reduced-pressure delivery member comprises associating the wave generator with the reduced-pressure delivery member between the reduced-pressure source and the sealing member.

Claim 19. The method of manufacturing of claim 17 wherein step of associating the wave generator with the reduced-pressure delivery member comprises coupling the wave generator to the reduced-pressure delivery member between the reduced-pressure source and the sealing member.

Claim 20. The method of manufacturing of claim 17 wherein the wave generator imparts a wave to the reduced pressure with a frequency greater than about one Hertz.

Claim 21. The method of manufacturing of claim 17 wherein the wave generator imparts a wave to the reduced pressure with a frequency in the range of about 0.5 to about 20 Hertz.

Claim 22. The method of manufacturing of claim 17 wherein the wave generator imparts a wave to the reduced pressure with a frequency greater than about 20 Hertz.

Claim 23. The method of manufacturing of claim 17 wherein the wave generator comprises a piezoelectric transducer fluidly coupled to the reduced-pressure delivery member.

Claim 24. The method of manufacturing of claim 17 wherein the wave generator comprises a diaphragm member fluidly coupled to the reduced-pressure delivery member.

Claim 25. The method of manufacturing of claim 17 wherein the wave generator comprises:

a plurality of valves in fluid communication with the reduced-pressure delivery member;

a plurality of chambers associated with the plurality of valves; and

wherein the plurality of valves are operable to selectively open and close to generate a wave in the reduced-pressure delivery member.

Claim 26. The method of manufacturing of claim 17 wherein the reduced-pressure delivery member comprises a conduit and wherein the conduit comprises:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space; and

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space.

Claim 27. The method of manufacturing of claim 17 wherein the reduced-pressure delivery member comprises a conduit and wherein the conduit comprises:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space;

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space; and

wherein the first liquid-impermeable-and-gas-permeable member comprises a synthetic fluoropolymer.

Claim 28. The method of manufacturing of claim 17 wherein the reduced-pressure delivery member comprises a conduit and wherein the conduit comprises:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space;

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space;

wherein the first liquid-impermeable-and-gas-permeable member comprises a synthetic fluoropolymer; and

wherein the synthetic fluoropolymer comprises a poly-tetrafluoroethylene material (PTFE).

Claim 29. The method of manufacturing of claim 18 wherein the reduced-pressure delivery member comprises:

a first lumen for transmitting a gas, the first lumen having a first interior space;

a second lumen for transmitting a liquid, the second lumen having a second interior space;

the first lumen comprising a gas-and-liquid-impermeable material; and

the second lumen comprising a gas-permeable-and-liquid-impermeable material disposed within the first interior space.

Claim 30. The method of manufacturing of claim 18 wherein the reduced-pressure delivery member comprises:

a first lumen for transmitting a gas, the first lumen having a first interior space;

a second lumen for transmitting a liquid, the second lumen having a second interior space;

the first lumen comprising a gas-and-liquid-impermeable material;

the second lumen comprising a gas-permeable-and-liquid-impermeable material disposed within the first interior space; and

wherein the gas-permeable-and-liquid-impermeable material comprises a synthetic fluoropolymer.

Claim 31. The method of manufacturing of claim 18 wherein the reduced-pressure delivery member comprises:

a first lumen for transmitting a gas, the first lumen having a first interior space;

a second lumen for transmitting a liquid, the second lumen having a second interior space;

the first lumen comprising a gas-and-liquid-impermeable material;

the second lumen comprising a gas-permeable-and-liquid-impermeable material disposed within the first interior space;

wherein the gas-permeable-and-liquid-impermeable material comprises a synthetic fluoropolymer; and

wherein the synthetic fluoropolymer comprises a poly-tetrafluoroethylene material (PTFE).

Claim 32. A method for treating a tissue site on a patient, the method comprising the steps of:

disposing a manifold adjacent to the tissue site, wherein the manifold is operable to distribute reduced pressure to the tissue site;

placing a sealing member on the patient's epidermis to form a fluid seal over the tissue site;

fluidly coupling a reduced-pressure delivery member to the manifold;

fluidly coupling the reduced-pressure delivery member to a reduced-pressure source for providing reduced pressure to the manifold; and

associating a wave generator with the reduced-pressure delivery member for imparting a wave to the reduced pressure developed by the reduced-pressure source.

Claim 33. The method of claim 32 wherein the step of associating a wave generator comprises the step of associating the wave generator with the reduced-pressure delivery member between the reduced-pressure source and the sealing member.

Claim 34. The method of claim 32 wherein the wave generator imparts a wave to the reduced pressure with a frequency greater than about one Hertz.

Claim 35. The method of claim 32 wherein the wave generator imparts a wave to the reduced pressure with a frequency in the range of about 0.5 to about 20 Hertz

Claim 36. The method of claim 32 wherein the wave generator imparts a wave to the reduced pressure with a frequency greater than about 20 Hertz.

Claim 37. The method of claim 32 wherein the wave generator comprises a piezoelectric transducer in fluid communication with the reduced-pressure delivery member.

Claim 38. The method of claim 32 wherein the wave generator comprises a diaphragm member in fluid communication with the reduced-pressure delivery member.

Claim 39. The method of claim 32 wherein the wave generator comprises a plurality of chambers with valves and wherein each of the chambers selectively in fluid communication with the reduced-pressure delivery member.

Claim 40. A reduced-pressure delivery member comprising:

a first lumen for transmitting a liquid, the first lumen having a first interior space;

a second lumen for transmitting a gas, the second lumen having a second interior space; and

a first liquid-impermeable-and-gas-permeable member coupled to the second lumen in at least a portion of the second interior space.

Claim 41. The reduced-pressure delivery member of claim 40, wherein the first liquid-impermeable-and-gas-permeable member comprises a synthetic fluoropolymer.

Claim 42. The reduced-pressure delivery member of claim 40, wherein the first liquid-impermeable-and-gas-permeable member comprises a synthetic fluoropolymer; and wherein the synthetic fluoropolymer comprises a poly-tetrafluoroethylene material (PTFE).

Claim 43. A reduced-pressure delivery member comprising:

a first lumen for transmitting a gas, the first lumen having a first interior space;

a second lumen for transmitting a liquid, the second lumen having a second interior space;

the first lumen comprising a fluid impermeable material; and

the second lumen formed from a gas-permeable-and-liquid-impermeable material and disposed within the first interior space.

Claim 44. The reduced-pressure delivery member of claim 43, wherein the gas-permeable-and-liquid-impermeable material comprises a synthetic fluoropolymer.

Claim 45. The reduced-pressure delivery member of claim 43, wherein the gas-permeable-and-liquid-impermeable material comprises a synthetic fluoropolymer and wherein the synthetic fluoropolymer comprises a poly-tetrafluoroethylene material (PTFE).