REDUCED PRESSURE WOUND DRESSING HAVING A WOUND CONTACT SURFACE WITH COLUMNAR PROTRUSIONS

BACKGROUND

1. Field of the Invention

The present invention relates generally to tissue treatment systems and in particular to distribution manifolds for wound treatment.

2. Description of Related Art

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," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, including faster healing and increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a porous pad or other manifolding device. The porous pad contains cells or pores that are capable of distributing reduced pressure to the tissue and channeling fluids that are drawn from the tissue. The porous pad often is incorporated into a dressing having other components that facilitate treatment.

Distribution manifolds for delivering reduced pressure treatment are also commonly referred to as reduced pressure dressings, or in the case of treatment of a wound, wound dressings. Such dressings are characterized by structural features that allow fluid flow through the material. For example, one material that is often used as a wound dressing is reticulated, open-cell polyurethane foam. The foam includes a plurality of interconnected pores that allow fluid flow throughout the foam. When a reduced pressure is applied to one area of the foam, this reduced pressure is quickly distributed to other areas of the foam and is easily transmitted to tissues adjacent the foam. One problem with open-cell foams and similar materials is tissue in-growth, which prevents easy removal of the foam following treatment. For open cells foams with pore sizes on the order of 100-1000 microns, in-growth of tissue may occur relatively

quickly. As the new tissue enters the pores or cells of the foam, the foam acts as a lattice, and tissue grows within the pores and around the walls that form the perimeter of the pores. This effectively attaches the foam to the tissue site, and the foam must be forcibly removed by tearing the new tissue and breaking any bonds that have formed between the tissue and the foam. Not only is this detrimental to the healing process, but the tearing of this tissue may cause discomfort to the patient.

One way to circumvent the problem of tissue in-growth is to increase the frequency of dressing changes. If new dressings are applied with increased frequency, there is less tissue in-growth, and thus less disruption of new tissue upon removing the old dressing. One downside to increased dressing changes is the increased costs associated with materials (i.e. new dressings) and labor. Changing a dressing is labor intensive and diverts the attention of medical personnel from other important tasks. Increased dressing changes also result in more aggravation to patients and their wounds.

SUMMARY

The problems presented by existing reduced pressure treatment systems are solved by the systems and methods of the illustrative embodiments described herein. In one embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of protrusions positioned on a first side of the backing substrate with each of the protrusions having substantially circular cross-sectional shape and having a diameter of between about 0.1 and 2.0 millimeters. The backing substrate has a plurality of apertures formed therein to allow fluid communication between the first side and a second side opposite the first side. A reduced pressure source fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to a tissue site.

In another embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of protrusions positioned on a first side of the backing substrate, each of the protrusions having a substantially polygonal cross-sectional shape and having a width of between about 0.1 and 2.0 millimeters. The backing substrate has a plurality of apertures formed therein to allow fluid communication between the first side and a second side opposite the first side. A reduced pressure source

fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to a tissue site.

In another embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of columnar voids positioned on a first side of the backing substrate, each of the columnar voids having substantially polygonal cross-sectional shape and having a width of between about 0.1 and 2.0 millimeters.

In another embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of protrusions positioned on a first side of the backing substrate, each of the protrusions having substantially circular cross-sectional shape and tapering inward from the base at which the protrusions meet the backing substrate. The backing substrate has a plurality of apertures formed therein to allow fluid communication between the first side and a second side opposite the first side. A reduced pressure source is fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to a tissue site.

Other objects, 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

FIG. 1 illustrates a reduced pressure treatment system 11 according to an embodiment of the present invention.

FIG. 2 illustrates the distribution manifold according to an embodiment of the present invention.

FIG. 3 illustrates the shape of the protrusions of the distribution manifold according to an embodiment of the present invention.

FIG. 4 illustrates a plurality of columnar voids of a distribution manifold according to an embodiment of the present invention.

FIG. 5 illustrates a plurality of columnar voids of a distribution manifold according to an embodiment of the present invention.

FIG. 6 illustrates a backing substrate with circular protrusions according to an embodiment of the present invention.

FIG. 7 represents an illustrated reproduction of a photograph of a distribution manifold taken through a microscope according to an embodiment of the present invention.

FIG. 8 represents an illustrated reproduction of a photograph of an exemplar distribution manifold having a plurality of columnar voids disposed in a backing substrate according to an embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

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.

The several embodiments of the present invention described herein are provided to assist in the healing of wounds and generation of new tissue. Reduced pressure therapy is administered to patients with a reduced pressure delivery system. This form of advanced wound healing therapy can be readily integrated into a clinician's wound healing procedures. The therapy optimizes patient care and decreases costs associated with treatment of patients having traumatic and chronic wounds. With the innovative embodiments of the reduced pressure delivery system described herein, reduced pressure therapy can be administered either in the hospital, in community settings such as assisted living complexes and convalescence homes, or in the home.

Reduced pressure delivery to a wound or tissue site promotes wound healing and/or tissue growth by removing infectious materials and other fluids from the wound or tissue site. Reduced pressure treatment further promotes tissue growth by imposing forces on the tissue, thereby causing micro-deformation of the tissue, which is believed to contribute to the development of granulation tissue at the tissue site. The forces imposed on the tissue site by the delivery of reduced pressure further encourage improved blood flow to the tissue site, which further assists in the growth of new tissue.

Referring to FIG. 1, a reduced pressure treatment system 11 according to an embodiment of the present invention includes a reduced pressure dressing, or distribution manifold 15 fluidly connected to a reduced pressure conduit 19. The reduced pressure conduit 19 is fluidly connected to a reduced pressure source 23 such as a vacuum pump or another source of suction. The distribution manifold 15 is placed against a tissue site 31 of a patient

and is used to distribute a reduced pressure provided by the reduced pressure source 23. Typically, reduced pressure is maintained at the tissue site by placing an impermeable or semi-permeable cover 25 over the distribution manifold 15 and the tissue site 31. The reduced pressure also serves to draw wound exudates and other fluids from the tissue site 31. A canister 27 may be fluidly connected to the reduced pressure conduit 19 and disposed between the wound dressing 15 and the reduced pressure source 23 to collect the fluids drawn from the tissue site 31. A distribution adapter 35 may be connected to the reduced pressure conduit 19 and positioned on the distribution manifold 15 to aid in distributing the reduced pressure to the distribution manifold 15.

Referring to FIGS. 2 and 3, the distribution manifold 15 is particularly well suited to promote tissue growth at the tissue site 31 yet prevent in-growth of new tissue into the distribution manifold 15. The distribution manifold 15 includes a backing substrate 41 with a tissue contact surface 43. The tissue contact surface 43 preferably includes a plurality of projections, or protrusions 51 that extend from the backing substrate 41. As more specifically shown in FIG. 3, the shape of the protrusions 51 may be substantially cylindrical in shape. Alternatively, the cross-sectional shape of the protrusions 51 may be square, rectangular, triangular, polygonal, elliptical, or any other shape. The protrusions 51 may be tapered or of uniform cross-sectional area throughout.

Referring more specifically to FIG. 3, the height, H, of the protrusions 51 is preferably between about 0.1 and 5.0 millimeters, and more preferably about 2 millimeters. The width, W, of each protrusion is between about 0.1 and 2.0 millimeters, and more preferably about 0.25 to 0.5 millimeters. The width of the protrusions 51 illustrated in FIG. 3 equals that of the diameter since the cross-sectional shape of each protrusion 51 is circular. If the protrusions 51 are square in cross-sectional shape, the width of the protrusions 51 are an edge length of the square. For other cross-sectional shapes, the width is the average of the longest lateral distance through the centroid, C, of the cross section and the shortest lateral distance through the centroid of the cross section. The lateral, center-to-center spacing, E, between each protrusion 51 is preferably between about 0.1 and 1.0 millimeters, and more preferably about 0.5 millimeters. The spacing of the protrusions 51 create distribution channels 61 through which reduced pressure may be delivered to the tissue site 31 and exudates withdrawn from the tissue site 31. It is generally preferred that the height of the protrusions 51 be greater than the width

of the protrusions 51. More specifically, the ratio of height to width, H:W, should be greater than about 1:1, and more preferably greater than about 2:1

The shape, sizing, and spacing of the protrusions 51 may vary depending upon the particular tissue site 31 being treated, the type of material from which the protrusions 51 and backing substrate 41 are made, and the amount of reduced pressure being applied to the tissue site 15. For example, for tissue sites that are highly exudating, it may be advantageous to position the protrusions farther apart to maintain adequate distribution channels 61 between the protrusions 51. In one embodiment of the present invention, the shape, sizing and spacing of the protrusions 51 is uniform for a particular distribution manifold 15. In other embodiments, the shape, sizing, and spacing of the protrusions 51 may vary. For example, protrusions 51 having different cross-sectional shapes may be disposed on the backing substrate 41. Similarly, the sizing and spacing of the protrusions 51 may vary to supply selected portions of the tissue site 31 with more or less reduced pressure.

The presence and sizing of the protrusions 51 allow the protrusions 51 to distribute reduced pressure to the tissue site 31, but prevent new tissue that grows at the tissue site 31 from attaching to the protrusions 51 of the distribution manifold 15. By eliminating the pores or cells that are typically used to deliver reduced pressure to a tissue site, new tissue is not able to wrap around the walls that form the pores or cells. While new tissue growth will grow into the field of protrusions 51 and may even wrap around some of the protrusions 51, the new tissue is not capable of securing itself to the protrusions 51 since the base of each protrusion is anchored to the backing substrate 41.

In addition to distributing reduced pressure to the tissue site 31, the distribution manifold 15 also serves to impart stresses and strains to the tissue site 31 similar to those seen with cellular foam that traditionally has been used in reduced pressure systems. Other materials sometimes used in reduced pressure systems as distribution manifolds, such as gauze, do not have this effect on tissue. The stresses and strains created by the distribution manifold 15 are believed to cause micro-deformation of existing tissue and plays a significant role in the generation of new tissue at the tissue site. The amount of stress and strain impaired to a tissue site is determined by the amount of reduced pressure supplied to the tissue site and the surface morphology of the manifold that contacts the tissue site. As reduced pressure is applied, portions of the tissue site are pulled against the distribution manifold 15, and more particularly against the protrusions 51, which results in the development of stresses and strains

within the tissue. The sizing of the protrusions 51 on a scale similar to that of the pores of the cellular foam is believed to be one reason for the development of stresses and strains that are similar to those seen with use of the foam.

In one embodiment, the backing substrate 41 is formed from the same material as the protrusions 51. Preferably, that material is silicone or another medical grade material that is relatively impermeable to fluid flow. Alternatively, the material may be a semi-permeable material that allows select fluids or amounts of fluids to pass. The backing substrate 41 may include a plurality of apertures 71 that allow distribution from a surface of backing substrate 41 opposite the protrusions 51 to the tissue contact surface 43 from which the protrusions 51 extend. Since the presence of the apertures 71 could have the same effect on tissue in-growth as that of pores, it is important that the backing substrate 41 and protrusions 51 be removed from the tissue site 31 prior to any new tissue advancing into the apertures 71. In practice, this may be accomplished by knowing the approximate rate of tissue growth, the height of the protrusions 51, and determining the amount of time likely required for new tissue growth to reach the apertures 71.

While the distribution manifold 15 has primarily been described as including backing substrate 41 and plurality of protrusions 51, the distribution manifold 15 may further include cellular foam or another material that is positioned adjacent to or attached to the surface of the backing substrate 41 opposite the protrusions 51. The use of a cellular foam or other material increases the ability of the reduced pressure conduit 19 or the distribution adapter 35 to deliver and distribute reduced pressure to the backing substrate 41. The protrusions 51 and backing substrate 41 serve as a barrier to new tissue growth entering pores of the cellular foam or other material.

Referring to FIGS. 4 and 5, a distribution manifold 115 according to another embodiment of the present invention is illustrated. Instead of a plurality of protrusions such as those of distribution manifold 15, distribution manifold 115 includes a plurality of columnar voids 151 formed or otherwise positioned within a backing substrate 141. The term columnar is not meant to imply any particular cross-sectional shape, since the shape of the voids may be any shape as described previously with reference to protrusions 51. Rather, the term columnar refers to the voids generally being greater in length than in width. The voids 151 themselves create a plurality of distribution channels 161 that may be joined by a main channel at an end

of the distribution channels 161 opposite that of a tissue site. Alternatively, the distribution channels 161 may simply be apertures that pass completely through the backing substrate 141.

The shape and size of the voids 151 may be similar to that of the protrusions 51 of manifold 15. As previously described, a cellular foam, distribution adapter, or other manifolding device may be placed in fluid communication with the distribution channels 161 to deliver reduced pressure to the tissue site.

EXEMPLARY DISTRIBUTION MANIFOLD HAVING PROTRUSIONS

Referring to FIGS. 6 and 7, one particular distribution manifold 215 that has been tested and that has demonstrated growth induction rates similar to those of cellular foam utilizes a two inch diameter backing substrate 241. The backing substrate includes a plurality of protrusions 251 that are generally circular in cross-sectional shape and tapered inward from the base at which the protrusions meet the backing substrate 241. A plurality of apertures 271 are provided in the backing substrate 241 to allow fluid communication with distribution channels 261 between the protrusions 251. The apertures 271 are disposed in rows and columns that are positioned between the rows and columns of the protrusions 251. The positioning of the apertures 271 in this pattern results in one aperture 271 being centered between every four adjacent protrusions 251 that are arranged in a square pattern (see FIG. 6).

The sizing of the protrusions 215 is such that on the two inch diameter backing substrate 241, approximately 7500 protrusions are present. The width of each protrusion at the base is about 0.5 mm, the height of each protrusion is about 1.5 mm, and the lateral center-to center spacing between the protrusions is about 0.75 mm. The ratio of height to width of the protrusions is about 3:1, and the ratio of the spacing to width is about 1.5:1. The tapering of each protrusion 51 is about a five degree draft angle from the longitudinal axis of the protrusions 51 to aid in molding the distribution manifold 215.

Distribution manifold 215 was sized based on an expected rate of tissue growth and the desired period of use between changes of the distribution manifold 215. For reduced pressures of about 125 mm Hg, one to two millimeters of tissue growth may be expected over a 48 hour period. Since it is desired to change the distribution manifold 215 every 48 hours, a protrusion height of about 1.5 mm allows the majority of the spacing between the protrusions 251 to fill with new tissue growth between dressing changes, but prevents the tissue from attaching to the distribution manifold 251.

Referring more specifically to FIG. 7, an illustrated reproduction of a photograph of the distribution manifold 215 taken through a microscope is provided. The photograph illustrates a top view of the distribution manifold 215 showing the protrusions 251 extending from the backing substrate 241. Also illustrated are apertures 271 disposed between the protrusions 251.

EXEMPLARY DISTRIBUTION MANIFOLD HAVING VOIDS

Referring to FIG. 8, an illustrated reproduction of a photograph of an exemplar distribution manifold 315 having a plurality of columnar voids 351 disposed in a backing substrate 341 is provided. The backing substrate 341 is about 1.5 mm thick, and the width (diameter) of each void 351 is about 0.35 mm. Since the voids 351 extend through the backing substrate 341, the height of each void 351 is about 1.5 mm. The lateral center-to-center spacing between the voids 351 is about 0.75 mm. The ratio of height to width of the voids is about 4.3:1, and the ratio of the spacing to width is about 2.1: 1.

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

We claim:

1. A reduced pressure treatment system for delivering a reduced pressure to a tissue site comprising:

a distribution manifold including a backing substrate with a first side and a second side and a plurality of protrusions positioned on the first side of the backing substrate, each of the protrusions having a substantially circular cross-sectional shape and having a diameter of between about 0.1 and 2.0 millimeters, the backing substrate having a plurality of apertures formed therein to allow fluid communication between the first side and the second side opposite the first side; and

a reduced pressure source fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to the tissue site.

2. The reduced pressure treatment system of claim 1, wherein a lateral center-to-center spacing of the protrusions is between about 0.1 and 0.5 millimeters.

3. The reduced pressure treatment system of claim 1, wherein a height of the protrusions is greater than the diameter of the protrusions.

4. The reduced pressure treatment system of claim 3, wherein a ratio of the height to diameter of the protrusions is 2:1.

5. The reduced pressure treatment system of claim 1, wherein the protrusions are made from medical grade silicone.

6. A reduced pressure treatment system for delivering a reduced pressure to a tissue site comprising:

a distribution manifold including a backing substrate with a first side and a second side and a plurality of protrusions positioned on the first side of the backing substrate, each of the protrusions having substantially polygonal cross-sectional shape and having a width of between about 0.1 and 2.0 millimeters, the backing substrate having a plurality of apertures formed in rows and columns between the protrusions to allow fluid communication between the first side and the second side opposite the first side; and

a reduced pressure source fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to the tissue site.

7. The reduced pressure treatment system of claim 6, wherein a lateral center-to-center spacing of the protrusions is between about 0.1 and 0.5 millimeters.

8. The reduced pressure treatment system of claim 7, wherein a ratio of a height of the protrusions to a width of the protrusions is 2:1.

9. The reduced pressure treatment system of claim 6, wherein the protrusions are made from medical grade silicone.

10. A reduced pressure treatment system for delivering a reduced pressure to a tissue site comprising:

a distribution manifold including a backing substrate and a plurality of columnar voids positioned on one side of the backing substrate, each of the columnar voids having a substantially polygonal cross-sectional shape and having a width of between about 0.1 and 2.0 millimeters.

11. The reduced pressure treatment system of claim 10, wherein a length of the columnar voids is greater than a width of the columnar voids.

12. The reduced pressure treatment system of claim 10 wherein:

the columnar voids create a plurality of distribution channels that are joined to a main channel at an end of the distribution channels; and

a reduced pressure source is fluidly connected to the distribution channels of the backing substrate to deliver the reduced pressure to the tissue site.

13. The reduced pressure treatment system of claim 12, further comprising a plurality of apertures disposed in the backing substrate.

14. A reduced pressure treatment system for delivering a reduced pressure to a tissue site comprising:

a distribution manifold including a backing substrate with a first and second side and a plurality of protrusions positioned on the first side of the backing substrate, each protrusion having a base end nearest the backing substrate and a second end opposite the base end, at least one of the protrusions having a substantially circular cross-sectional shape and tapering inward such that a width of the at least one protrusion at the base end is greater than a width at the second end, the backing substrate having a plurality of apertures formed therein to allow fluid communication between the first side and the second side; and

a reduced pressure source fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to the tissue site.

15. The reduced pressure treatment system of claim 14, wherein:

the apertures are disposed in rows and columns that are positioned between the protrusions;

the apertures are positioned such that one aperture is centered between about every four adjacent protrusions arranged in a substantially square pattern.

16. The reduced pressure treatment system of claim 14, wherein:

the width of the at least one protrusion at the base end is about 0.5 mm,

a height of the at least one protrusion is about 1.5 mm, and

a lateral center-to center spacing between the protrusions is about 0.75 mm.

17. The reduced pressure treatment system of claim 14, wherein:

a ratio of a height to a width of the protrusions is about 3:1, and

a ratio of a spacing to a width of the protrusions is about 1.5:1.

18. The reduced pressure treatment system of claim 14, wherein the tapering of the at least one protrusion is at about a five degree angle from a longitudinal axis of the at least one protrusion.

19. The reduced pressure treatment system of claim 14, wherein the protrusions are sized such that about 7500 protrusions fit onto a circular backing substrate having about a two inch diameter.

20. The reduced pressure treatment system of claim 14, wherein the protrusions are made from medical grade silicone.