(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 199521882 B2
(10) Patent No. 705754

(54) Title
Method and apparatus for promoting soft tissue enlargement and wound healing

(51)[6] International Patent Classification(s)
A61B 017/03 A61H 001/00
A61F 005/41

(21) Application No: 199521882 (22) Application Date: 1995 .03 .27

(87) WIPO No: WO95/26690

(30) Priority Data

(31) Number	(32) Date	(33) Country
08/220186	1994 .03 .30	US
08/408423	1995 .03 .22	US

(43) Publication Date : 1995 .10 .23
(43) Publication Journal Date : 1995 .12 .07
(44) Accepted Journal Date : 1999 .06 .03

(71) Applicant(s)
Khouri Biomedical Research, Inc.

(72) Inventor(s)
Roger K Khouri

(74) Agent/Attorney
SPRUSON and FERGUSON,GPO Box 3898,SYDNEY NSW 2001

(56) Related Art
WO 93/69727
US 3382867
US 3874387

OPI DATE 23/10/95 APPLN. ID 21882/95
AOJP DATE 07/12/95 PCT NUMBER PCT/US95/03480
AU9521882
IN

(51) International Patent Classification 6 : A61B 19/00

A1

(11) International Publication Number: WO 95/26690

(43) International Publication Date: 12 October 1995 (12.10.95)

(21) International Application Number: PCT/US95/03480

(22) International Filing Date: 27 March 1995 (27.03.95)

(30) Priority Data:

08/220,186	30 March 1994 (30.03.94)	US
08/408,423	22 March 1995 (22.03.95)	US

(81) Designated States: AM, AU, BB, BG, BR, BY, CA, CN, CZ, EE, FI, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LV, MD, MG, MN, MW, MX, NO, NZ, PL, RO, RU, SD, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
With international search report.
With amended claims and statement.

(71) Applicant: KHOURI BIOMEDICAL RESEARCH, INC. [US/US]; 2 Kingsbury Place, St. Louis, MO 63112 (US).

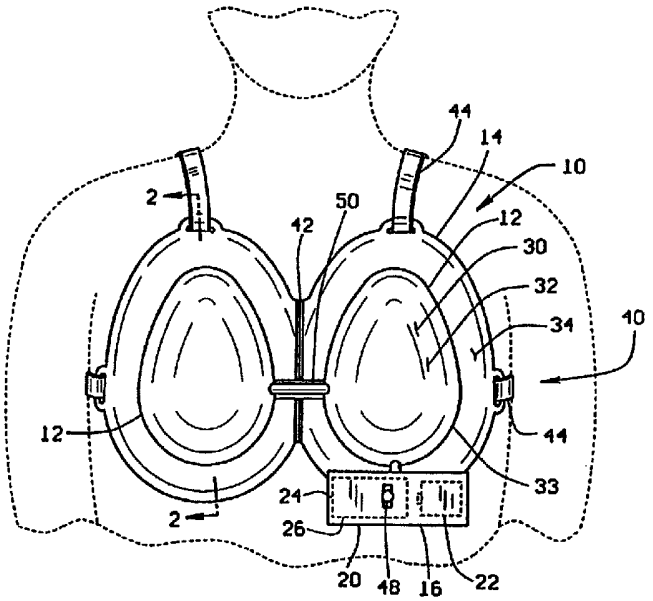
(72) Inventor: KHOURI, Roger, K.; 2 Kingsbury Place, St. Louis, MO 63112 (US).

(74) Agents: HAFERKAMP, Richard, E. et al.; Rogers, Howell & Haferkamp, Suite 1400, 7733 Forsyth Boulevard, St. Louis, MO 63105 (US).

(54) Title: METHOD AND APPARATUS FOR PROMOTING SOFT TISSUE ENLARGEMENT AND WOUND HEALING

(57) Abstract

An apparatus and method for healing open wounds through enlargement of soft tissue surrounding said wound is comprised of a dome (12) configured to fit over the wound and at least a portion of the surrounding soft tissue. The dome (12) has a rim (14) with a surface area equal to or greater than the normal area of the dome opening to prevent medical complications caused by excessive pressure to the skin. A gasket (46) or other cushioning material may be provided about the periphery of the dome (12) for patient comfort and improved seal. The dome (12) also includes a vacuum pump (20) with a power source (22), pressure sensor (24), and servomechanism (26) for regulating the pressure within the dome (12) to any one of several protocols using pressures which might temporarily exceed non-damaging levels.



METHOD AND APPARATUS FOR PROMOTING SOFT TISSUE ENLARGEMENT AND WOUND HEALING

Cross Reference To Related Application

This application is a continuation-in-part of Serial No. 08/220,186 filed March 30, 1994.

Background and Summary of the Invention

There are numerous instances where persons desire enlargement of the soft tissues in their bodies. One such instance is for the replacement of one or both breasts amputated during a mastectomy in order to restore physiological symmetry and psychological well-being. Other instances are for correction of natural abnormalities such as dimpling. Still other instances are for augmentation of physical attributes to improve cosmetics and self-esteem. These latter soft tissue enlargements are principally directed to breast enlargement in females and penis enlargement in males.

Prosthetic implants have been developed for insertion below the skin. However, the severity of the potential complications including scarring, implant rupture, capsular contracture, necrosis and implant migration as well as the recent adverse publicity thereof

have significantly reduced the desirability of these implants. Thus, there is a societal need for other means to obtain soft tissue enlargement.

Some soft tissue enlargements occur naturally. For instance, during pregnancy the skin over a woman's abdominal region enlarges approximately nine times its previous area to accommodate the fetus without a proportional decrease in skin thickness. In other words, the abdominal skin tissue actually enlarges and does not merely stretch during pregnancy. Similarly, the skin will expand to accommodate any growth under the skin.

In the past, plastic surgeons have used this phenomena to their advantage to expand skin in order to accommodate prosthetic implants or provide tissue to close wound defects. To conduct this procedure, the surgeon inserts a balloon beneath the skin in the area where additional skin is desired. By progressively expanding the balloon, the skin first stretches and eventually actually grows to accommodate the increased volume underneath it. When the desired amount of skin is formed, the balloon is deflated and removed, and the implant is inserted into the cavity left by the balloon. Also, the excess skin can be used to cover a wound defect, an ulcer or a depressed scar. Similar methods have been used by African native tribes to enlarge lips, nostrils, and earlobes.

Other surgical techniques have used tissue expansion to achieve other types of soft tissue growth. For instance, balloons have been successfully situated underneath nerves, veins, tendons, and the like to expand and thereby elongate these tissues to repair damage and alleviate various abnormalities.

A more advanced surgical method is known as callotasis distraction osteogenesis or limb lengthening. This method comprises cutting the bone about its periphery at the location where lengthening is desired,

leaving the tissues inside and around the bone intact. Brackets are attached to the bone on each side of the separation, and the bone segments are slowly pulled away from one another while remaining integral over a period of several months. Not only does this cause the mended bone to be longer, but also the soft tissue surrounding the bone actually grows to accommodate the increased limb length. Similar methods have been used by African native tribes to lengthen necks for cosmetic purposes.

Each of these above-mentioned apparatuses and methods requires an invasive surgical technique to accomplish the soft tissue expansion. Invasive techniques increase the likelihood of the complications associated with the procedure including those mentioned above with respect to implant surgery. In addition, the expense of surgery precludes many persons having their abnormalities corrected or physical attributes enhanced.

Other soft tissue enlargement techniques have been developed which use other mechanisms to cause the enlargement. For instance, an instrument and technique have been developed for the non-surgical correction of inverted nipples due to short lactiferous ducts. The instrument is comprised of a cup having an internal volume shaped like that of the final desired nipple. The user places the cup over the inverted nipple, pumps the air out of the cup with a syringe and adjusts the vacuum within the cup using a check valve to just below the threshold of discomfort. Thus attached, the device puts the lactiferous ducts in tension and extends them sufficiently after two to three months of wear at 8-12 hours per day.

Although this device is sufficient for its intended purpose, it is not suitable for general soft tissue enlargement. Laceration and contusion can occur if too strong of a suction is applied to soft tissue. As the pressure within the inverted nipple instrument is not

regulated, contusion or laceration can occur. When a vacuum is developed within the cup of the instrument, an equal and opposite force is applied to the patient about the rim of the cup. Excessive contact forces against the patient can cause ulceration, laceration, and contusions. As the contact forces are not regulated in the nipple instrument, these further complications also can occur. In addition, general soft tissue enlargement is not feasible with the instrument due to the size and shape of the cup.

Another prior art device is disclosed in U.S. Patent No. 936,434 as a device for enlarging a woman's breasts. This device included a pair of cups for placement on the breasts and a pump for exhausting the air. However, this patent provides no teaching as to the pressures to be used, the potential danger to the skin tissues, or any suggestions as to how the device is to be retained in place during use. Apparently, the device is used in a clinical setting and is not suitable for long term ambulatory wear such as for 8-10 hours. As the patent suggests that the vacuum acts to cause the veins and arteries to engorge, thereby nourishing the breasts, it is clear that the patentee is suggesting that the breast tissue actually expands through this expansion of blood vessels alone. This patent has been the subject of ridicule by at least one medical authority. See "An Anthology Of Plastic Surgery" edited by Harry Hayes, Jr., M.D., Section 6, "Quackery and Nostrums" pub. 1986 by Aspen Publishers, Rockville, Maryland.

Finally, another prior art device although notorious is worthy of note. This device is commonly referred to as a penis pump and is sold primarily as a novelty as its long-term enlargement efficacy has never been proven and is in fact universally disclaimed by its distributors. The device is comprised of a cylinder having one open end into which the penis is inserted and

a pump attached to it such that a vacuum can be created within the cylinder. Not only does this device have the same drawbacks as the nipple instrument with respect to potential complications, but also it is unlikely that sufficient vacuum can be maintained by the device to cause any notable long-term soft tissue enlargement. Further, this device is apparently designed to accomplish two tasks unrelated to enlargement. First, the device is used for stimulation and sexual gratification. Second, the device is used to promote erection by drawing blood into the penis.

There is also another condition routinely experienced by many patients in which the generation of soft tissue is important. That condition evolves from injuries or diseases which produce wound infections or ulcers which have a tendency to exude bodily fluids and resist healing. At least one effort has been made in the prior art, as known by the inventor herein, to address this problem. This prior art solution involves the use of an occlusive, or airtight, dressing covering the wound coupled with a suctioning of fluid from the wound either once or repeatedly in order to dry it out and create an environment more conducive to wound healing. It is not believed that this prior art considers the problems of excessive contact forces against the patient's skin which can cause ulceration, laceration, and contusions. Also, this prior art teaching is not focused on soft tissue enlargement through the use of a vacuum alone and instead relies at least in part on the use of suction for removing wound fluid and creating an environment that promotes healing. The importance of enlarging the surrounding soft tissue to close the wound is not a clear focus of this prior art method.

Most of these prior art devices and methods have failed to achieve long term soft tissue enlargement while preventing damage to the soft tissue being enlarged, as

well as surrounding tissue. The inventor herein has succeeded in designing and developing a new generalized method and apparatus for soft tissue enlargement which prevents damage to soft tissue. The apparatus used for this enlargement is comprised of a rigid fluid-impervious dome having a rim about its periphery and a vacuum pump for reducing pressure to thereby apply a distracting force to the soft tissue isolated by and within the dome. The rim has sufficient surface area such that the pressure applied to the patient by the rim is less than or equal to the negative pressure applied to the soft tissue under the dome. Thus, as long as pressure within the dome is regulated to a limit below which medical complications cannot occur, the opposing contact pressure against the patient is below this threshold as well. With this approach, damage is avoided not only to the soft tissue being enlarged, but the surrounding tissue as well. In the preferred embodiment of the apparatus, the vacuum pump has a self-contained power source. In addition, a pressure sensor and servomechanism control the pump such that the vacuum within the dome is maintained at a magnitude less than 35 mm Hg. Variant embodiments may be configured to fit over and enlarge a human breast, a human penis, an infected wound, open sore, ulcer, or any other desired area.

The method of use is comprised of the steps of attaching the dome to the location of desired enlargement, and creating a vacuum within the dome. The vacuum should be maintained for a minimum of eight hours per day and results should be sufficient after several months.

While the practical advantages and features of the present invention and method have been briefly described above, a greater understanding of the novel and unique features of the invention may be obtained by referring to

the drawings and Detailed Description of the Preferred Embodiment which follow.

Brief Description of the Drawings

Figure 1 is a front elevation view of the soft tissue enlargement apparatus of the present invention, showing the breast augmentation embodiment;

Figure 2 is a cross-sectional view of the breast enlargement embodiment taken in the plane of line 2-2 of Figure 1;

Figure 3 is a cross-sectional schematic of a dome and soft tissue in the early stages of enlargement;

Figure 4 is a cross-sectional schematic of a dome and soft tissue in the latter stages of enlargement;

Figure 5 is an orthographic projection of the penile augmentation embodiment of the present invention; and

Figure 6 is a partial cross-sectional view of a dome in place over an open wound.

Detailed Description of the Preferred Embodiment

The soft tissue enlargement apparatus 10 is generally comprised of a dome 12 having a rim 14 and vacuum pump assembly 16 for creating a vacuum within the dome. Although the vacuum pump assembly 16 may be a separate hand-held pump in one variant embodiment, in the preferred embodiment the vacuum pump assembly 16 is a self-contained vacuum pump 20 with an independent power source 22, pressure sensor 24, and servomechanism 26 for driving, regulating and controlling the vacuum pump 20.

Regulation of the pressure within the dome is essential to prevent contusions caused by rupturing capillaries adjacent the surface of the skin, separating epidermis from dermis and causing blisters. Medical data suggest that these contusions and blisters will not occur if pressure within the dome is maintained at less than 25-35 mm Hg for extended periods of time. Thus, the vacuum pump 20 must be regulated to control the pressure

within the dome to within this limit. In addition, skin ulceration can occur if excessive contact pressures are applied thereto. Medical data suggest that a contact pressure less than 15-20 mm Hg may be applied indefinitely without such ulceration. However, contusions may occur due to positive contact pressures upon the skin at pressures for appreciable time periods above this ulceration limit. The preferred embodiment of the present invention was developed with these limits in mind and will not apply a continuous vacuum or a continuous contact pressure greater than 25-35 mm Hg.

Several forces are developed within the dome and about the rim as a result of evacuating air from the dome. A suction force is developed within the dome 12 equal to the vacuum pressure multiplied by the enclosed tissue surface area 30. The vacuum or vacuum pressure may also be thought of as a negative pressure. The vector sum of the suction force upon the tissue surface area 30 may be called the normal force and is equal to the vacuum pressure multiplied by the normal area 32 of the dome opening, i.e., the area bounded by the periphery 33. An opposing force is imposed on the user by the rim 14 to balance the normal force and is equal but opposite to the normal force. The contact pressure of the rim 14 against the user is equal to this opposing force divided by the annular rim surface area 34, i.e., the surface area between the rim and patient which supports the dome's pressure. Therefore, if the rim surface area 34 is configured to be greater than or equal to the normal area 32 at the dome opening, then the contact pressure against the patient's skin will not exceed the magnitude of the vacuum pressure within the dome 12. Another physical phenomenon further aids in the enlargement forces upon the soft tissue under the dome 12. If the tissue only slightly protrudes into the dome as shown in Figure 3 and as is typically the initial condition, then

the surface area 30 under the dome is only slightly larger than the normal area 32 at the dome opening. Therefore, as the suction force is directly proportional to the surface area of the tissue under the dome, the suction force is only slightly larger than the normal force. As enlargement occurs, more tissue protrudes into the dome 12 as shown in Figure 4 thereby providing more surface area 30 under the dome. Because the surface area 30 under the dome is larger, the suction force generated is increased. Thus, the rate of enlargement increases as treatment continues.

One specific embodiment includes a dome 12 configured to fit over a human breast as shown in Figures 1 and 2. This embodiment includes a rim 14 having a surface area 34 greater than the normal area 32 of the dome opening thereby preventing medical complications to the soft tissue as long as the pressure is properly regulated within the dome 12. The pressure reducing means 16 is located underneath the patient's breast, so that the apparatus 10 may be hidden under loose-fitting clothes. As with the general embodiment, the vacuum pump assembly 16 of this embodiment is preferably comprised of a vacuum pump 20 with a power source 22, a pressure sensor 24 and servomechanism 26 to drive and control the vacuum pump and to regulate the pressure within the dome 12.

As shown in Figure 1, this specific embodiment may take the form of a bra 40 having two domes 12 spaced by a hinge 42. Straps 44 may be attached to the bra 40 to retain the bra 40 in place. A gasket 46 may also be included about the rim 14 to improve the patient's comfort and enhance the seal about the rim. In the preferred embodiment, this gasket 46 may be a silicone gel cushion or other soft, conforming type material. Petroleum jelly or other sealant gel may also be used to supplement or supplant the gasket. A manual override 48

is included on the vacuum pump assembly 16 so that the patient or doctor may vary the pressure below the optimal level so as to be more comfortable. Although two vacuum pump assemblies 16 may be used, one depending from each dome 12 so as to provide different pressures in the domes, the preferred embodiment places the domes in fluid communication with a conduit 50.

A second specific embodiment is shown in Figure 5 wherein the dome 12 is configured to fit over a human penis. As can be seen from the figure, this embodiment comprises essentially the same features as the bra embodiment described above. The principal differences between these embodiments are the configurations of the dome 12' and rim 14' as well as the positioning of the straps 44'.

As shown in Figure 6, a dome 52 may be conveniently located over an open wound 54. A pump 56 (including an appropriate control) draws a vacuum through a connecting tube 58 in substantially the same manner as has been explained above.

In order to use the invention, the patient places the dome over the area of desired enlargement and adjusts the straps for comfort. Then the patient simply turns the vacuum pump on and the device goes to work. These apparatuses are intended to be worn 8-12 hours per day and can be worn during sleep. After several months, notable and long-term enlargement should occur. When the desired enlargement is achieved, the use of the device may be suspended. If additional enlargement is desired, then use may be continued. Occasional use or use at a reduced pressure may also be desired to maintain the desired enlargement.

For alternate applications, such as in a hospital, clinic or other professional setting, the invention may be applied to the area of desired enlargement, or over an open wound or ulcer, and the vacuum pump and control

turned on in order to automatically apply an appropriate regimen of vacuum and rest. As noted above, a vacuum may be developed with the invention and maintained at a continuous negative pressure sufficient to provide tissue enlargement and yet not cause damage to surrounding soft tissue for extended time periods. Alternatively, a "cycling" regimen may be provided by the invention which may promote more rapid tissue enlargement. For example, the vacuum pump may be controlled to develop a pressure as high as 100 mm Hg for several minutes and then return to a much lower level considered to be safe for extended periods, such as between 15-20 or even 35 mm Hg. Upon further testing, other protocols for treatment or use may be found to produce an accelerated enlargement of soft tissue. The present invention should not be considered as limited to any particular protocol as the inventor contemplates that different protocols may be readily learned and utilized with the present invention.

There are various changes and modifications which may be made to the invention as would be apparent to those skilled in the art. However, these changes or modifications are included in the teaching of the disclosure and it is intended that the invention be limited only by the scope of the claims appended hereto.

The claims defining the invention are as follows:

1. A method for growing a patient's soft tissue, said method comprising the steps of:

subjecting a portion of the patient's soft tissue desired to be grown to a vacuum with a dome; and

supporting said dome from said patient by a contact surface area sufficiently large to provide a contact pressure less than a pressure which will cause damage to the patient's tissue in contact with said contact surface area.

2. The method of claim 1 wherein the step of subjecting a portion of the patient's soft tissue desired to be grown to a vacuum includes subjecting an open wound and at least a portion of the soft tissue surrounding said open wound to a vacuum with said dome for accelerating the closing of the open wound through enlargement of the patient's soft tissue surrounding the open wound.

3. The method of claim 2 wherein the step of subjecting a vacuum includes the step of:

regulating the vacuum within the dome.

4. The method of claim 3 wherein the step of regulating the vacuum includes the step of:

regulating the vacuum to different pressures over time.

5. The method of claim 3 wherein the step of regulating the vacuum includes the step of:

regulating the vacuum to be maintained at or below about 35 mm Hg.

6. The method of claim 1 wherein the step of subjecting a portion of the patient's soft tissue desired to be grown to a vacuum includes:

placing the dome over said soft tissue portion, and

creating a vacuum within said dome, and wherein the step of supporting the dome includes the step of supporting the dome with a rim having a contact surface area substantially equal to or greater than a normal area of said dome defined by a periphery surrounding an opening in said dome.

7. The method of claim 6 further comprising the step of regulating the vacuum within the dome.

8. The method of claim 7 wherein the step of regulation includes the step of regulating the vacuum to 35 mm Hg or less.

9. The method of claim 1 wherein the step of subjecting a portion of the patient's soft tissue desired to be grown to a vacuum includes:

selecting a dome with a support surface circumscribing the dome, the support surface defining an opening therein generally aligned with the dome, the opening having an area A;

placing the device on the patient so that the dome is positioned over the soft tissue portion and so that a contact surface area of the support surface engages tissue of the patient all around the soft tissue portion, said dome having an opening surrounded by a periphery defining a normal area; and

evacuating the dome to a pressure P sufficient to promote growth enlargement of the soft tissue portion, such evacuation causing the contact surface area to press against the tissue engaged thereby at a contact pressure;

the contact surface area being sufficiently large so that when the dome is evacuated to the pressure P, the contact pressure induced by the pressure P is insufficient to cause damage to the tissue engaged by the contact surface area.

10. The method of claim 9 wherein the contact pressure has a magnitude less than or equal to the pressure P.

11. The method of claim 1 wherein the step of subjecting a portion of the patient's soft tissue desired to be grown to a vacuum includes:

placing the device on the patient so that the dome is positioned over an open wound and the soft tissue surrounding the open wound and so that the contact surface area of the support surface engages other tissue of the patient all around the soft tissue for accelerating the closing of the open wound through enlargement of the patient's soft tissue surrounding the open wound,

said device being selected to have a contact surface area sufficiently large so that when the dome is evacuated to the pressure P, the contact pressure induced by the pressure P is insufficient to cause damage to the tissue engaged by the contact surface area.

12. The method of claim 11 wherein the contact pressure has a magnitude less than or equal to the pressure P.

13. An apparatus for growing a patient's soft tissue, said apparatus comprising a dome adapted to enclose a portion of the patient's soft tissue desired to be grown, said dome being sufficiently rigid to withstand a vacuum therein, said dome having a periphery with a contact surface area, said dome being supported from said patient by the contact surface area, the contact surface area being sufficiently large to provide a contact pressure less than a pressure which will cause damage to the patient's tissue in contact with said contact surface area.

14. The apparatus of claim 13 wherein said dome is adapted for enclosing an open wound and at least a portion of the soft tissue surrounding said wound, the periphery of said dome defining a normal area, and further having a rim for surrounding said open wound and soft tissue portion, said contact surface area being

defined by the rim and being configured for engaging the soft tissue, said contact surface area being substantially equal to or greater than said normal area, the apparatus further comprising:

a vacuum pump configured for evacuating the dome to a pressure sufficient to promote growth enlargement of the soft tissue surrounding the open wound,

said dome being configured to withstand a vacuum sufficient to promote growth enlargement of the soft tissue surrounding the open wound.

15. The apparatus of claim 13 wherein said dome is sufficiently rigid to withstand 35 mm Hg of negative pressure therewithin.

16. The apparatus of claim 15 wherein said dome is sufficiently rigid to withstand temporary peak negative pressures of 100 mm Hg therewithin.

17. The apparatus of claim 13 further comprising:

a regulator connected to said vacuum pump for maintaining a desired vacuum within said dome.

18. The apparatus of claim 17 wherein said rim comprises a gasket.

19. The apparatus of claim 13 wherein said dome is adapted for enclosing an open wound and at least a portion of said patient's soft tissue surrounding said wound,

the periphery of said dome defining a normal area,

said dome having a gasket about the periphery, the contact surface area being defined by the gasket, said gasket being configured so that evacuation of the dome causes a contact pressure between the contact surface area of the gasket and the tissue engaged thereby, the contact surface area of the gasket being sufficiently large so that when the dome is evacuated to a pressure sufficient to promote growth enlargement of the soft tissue, then the contact pressure is insufficient to cause damage to the tissue.

20. The apparatus of claim 19 wherein said contact surface area is substantially equal to or greater than said normal area.

21. The apparatus of claim 20 further comprising a vacuum pump connected to said dome for generating the vacuum within said dome.

22. The apparatus of claim 21 further comprising a regulator connected to said vacuum pump for use in varying the pressure in said dome to thereby permit different protocols of vacuum to be applied to said wound.

23. The apparatus of claim 13 wherein the periphery defines a normal area, the periphery including:

a rim adapted to surround said enclosed soft tissue for supporting said dome said contact surface area being substantially equal to or greater than said normal area.

24. The apparatus of claim 23 wherein said dome is sufficiently rigid to withstand 35 mm Hg of negative pressure therewithin.

25. The apparatus of claim 24 further comprising a vacuum pump connected to said dome for reducing the pressure therewithin.

26. The apparatus of claim 25 further comprising a regulator connected to said vacuum pump for maintaining a desired vacuum within said dome.

27. The apparatus of claim 26 further comprising a gasket positioned between said rim and said patient for improved comfort and sealing of said dome.

28. The apparatus of claim 27 further comprising a manual control for said vacuum pump to permit patient adjustment of the vacuum within the dome.

29. The apparatus of claim 26 further comprising:

a second one of said dome and rim combinations;

a hinge joining said rims; and

a fluid communication means connected between said domes to thereby equalize the vacuum therein.

30. The apparatus of claim 29 wherein each dome is configured to surround a human breast.

31. The apparatus of claim 26 further comprising:

a second one of said dome and rim combinations;

a hinge joining said rims; and

a second vacuum pump and regulator connected to said second dome to thereby permit a different vacuum to be induced in each dome.

32. The apparatus of claim 26 wherein said dome is configured to surround a human penis.

33. The apparatus of claim 1 wherein said dome is a first dome, the apparatus further comprising a second dome similar in structure to said first dome, said second dome being sufficiently rigid to withstand a vacuum therein, said second dome having a periphery with a contact surface area, said second dome being supported from said patient by the contact surface area, the contact surface area being sufficiently large to provide a contact pressure less than a pressure which will cause damage to the patient's tissue in contact with said contact surface area, said first and second domes being adapted for enlarging the soft tissue within the patient's breast, each of said first and second domes being configured to surround one of the patient's breasts, each of said first and second domes having an opening surrounded by the periphery thereof defining a normal area; and

the peripheries of said first and second domes each having a rim, each rim being adapted to surround one of the patient's breasts, each of said rims being adapted for supporting one of said first and second domes, said contact surface areas being defined by said rims and being sufficiently large to provide a contact pressure less than a pressure which will cause damage to the tissue beneath said rims wherein each of said contact surface areas is substantially equal to or greater than each of said normal areas.

34. The apparatus of claim 33 wherein each of said first and second domes is sufficiently rigid to withstand 35 mm Hg of pressure therewithin.

35. The apparatus of claim 34 further comprising a vacuum pump connected to each of said first and second domes for reducing the pressure therewithin.

36. Apparatus as defined in claim 1, said apparatus being portable;

said dome being supported from said patient by a contact surface area sufficiently large to provide a contact pressure less than a pressure which will cause damage to the patient's tissue in contact with said contact surface area.

37. The apparatus of claim 36 further comprising a second dome, each of said domes being adapted to surround one of a woman's breasts.

38. The apparatus of claim 37 wherein said contact surface area substantially surrounds each of said domes.

39. The apparatus of claim 38 further comprising a portable vacuum pump connected to said domes for maintaining a vacuum in said domes.

40. The apparatus of claim 39 further comprising a regulator connected to said portable vacuum pump for regulating the vacuum in said domes.

41. The apparatus of claim 40 wherein said contact surface area includes a gasket substantially surrounding each of said domes.

42. The apparatus of claim 41 wherein said gaskets are made of a soft, conforming material.

43. The apparatus of claim 42 wherein said gaskets are made of silicone gel.

44. The apparatus of claim 42 wherein said vacuum pump includes a pressure sensor for sensing the vacuum in the domes, and a servomechanism for regulating the pressure in said domes.

45. The apparatus of claim 13 adapted for accelerating the closing of an open wound, substantially as hereinbefore described with reference to the accompanying drawings.

46. The apparatus for accelerating the healing of an open wound, substantially as hereinbefore described with reference to the accompanying drawings.

47. The apparatus for enlarging a patient's soft tissue, substantially as hereinbefore described with reference to the accompanying drawings.

DATED this Eleventh Day of January 1999

Khouri Biomedical Research, Inc.

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

STATEMENT UNDER ARTICLE 19

The amendments set forth herein amend the claims of the subject application into conformance with the claims of U.S. Patent Application Serial No. 08/220,186, on which priority of the subject international application is based. These claims reflect the subject matter as set forth in the specification and drawings of the international application and contain no new subject matter.

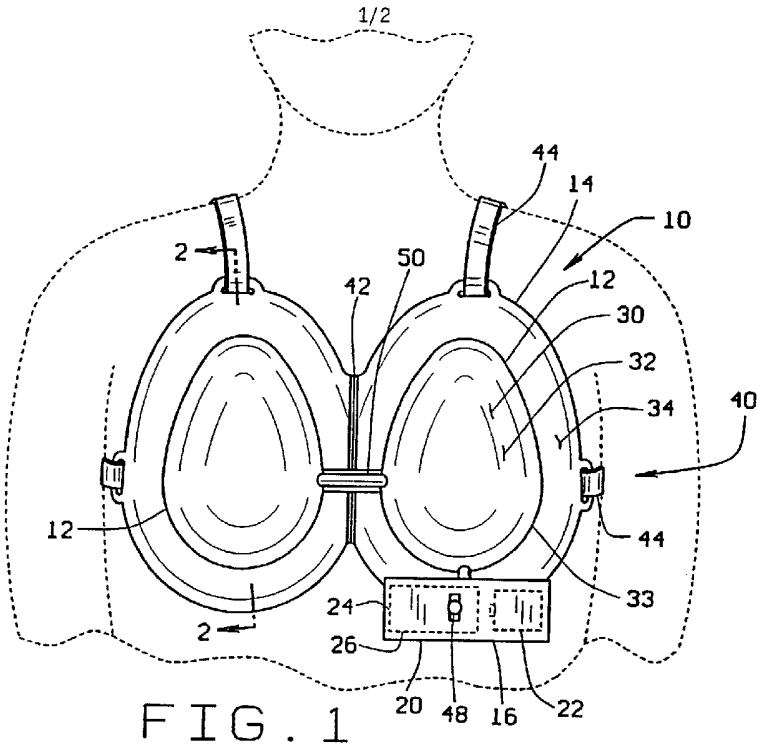


FIG. 1

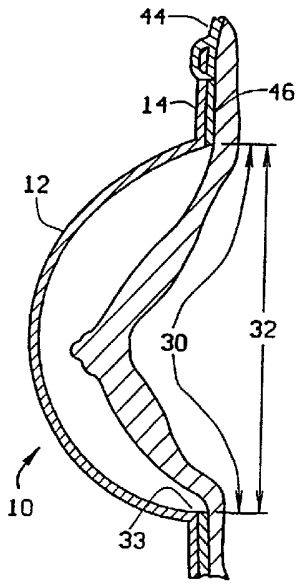


FIG. 2

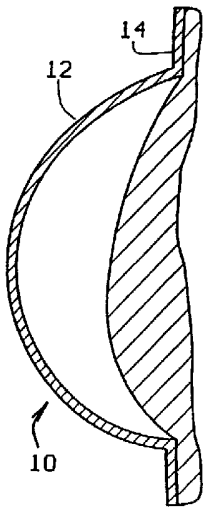


FIG. 3

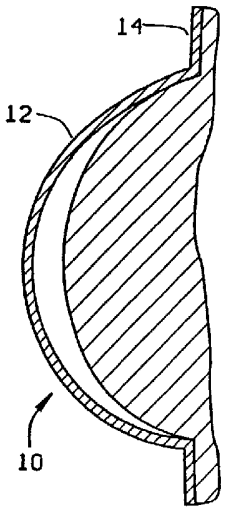


FIG. 4

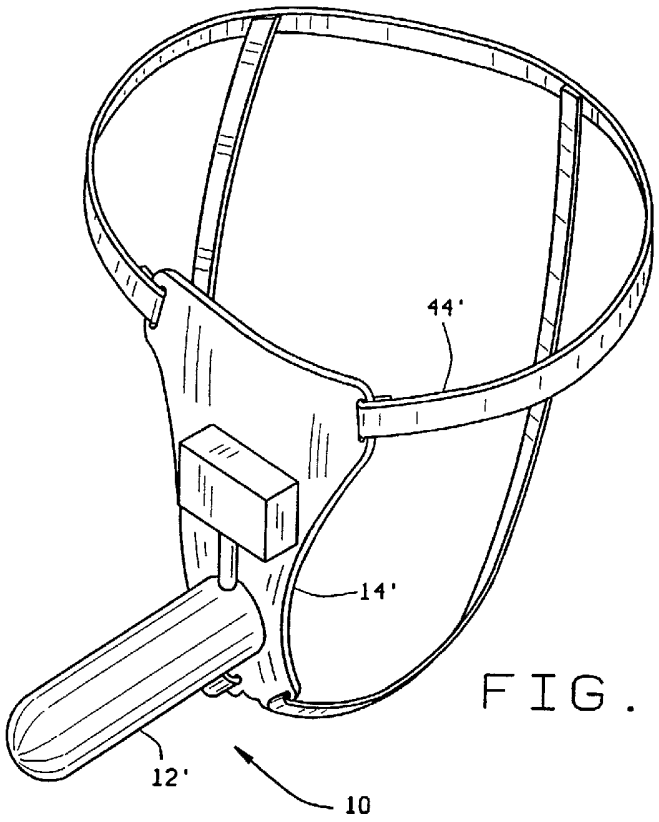


FIG. 5

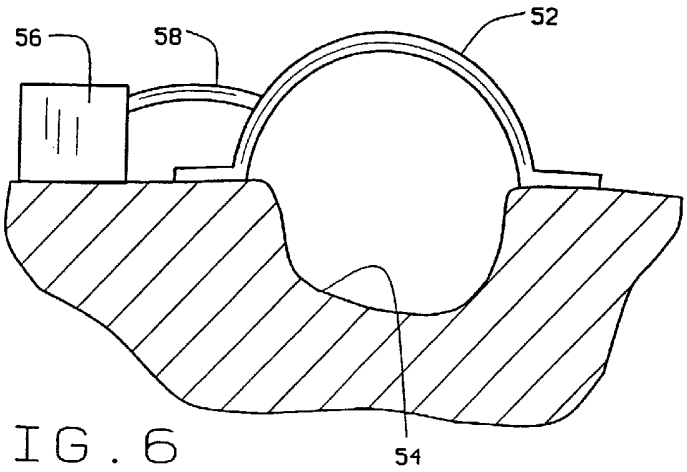


FIG. 6