EXTERNAL TISSUE DISTRACTION WITH EXPANDING FRAMES

Related Application

This application is a continuation-in-part application of U.S. Application No. 09/203,832 filed December 1, 1998.

Background and Summary of the Invention

It is well accepted by scientific authorities that living tissue can be made to grow in response to a gentle, sustained tensile force which, in the prior art, has generally been induced through a mechanical arrangement. This phenomenon has been demonstrated in many kinds of living tissues including skin, bone, muscle, nerves, blood vessels, lungs and even in isolated tissue cultures. (See references attached in Exhibit A.) The physiological mechanisms which contribute to this universal property of living tissue have recently been reviewed. (See references attached in Exhibit A.) Furthermore, many useful medical devices have been developed which rely on this universal property of tensile force induced tissue growth. (See references attached in Exhibit A.) However, as mentioned, these prior art devices typically operate through a mechanically induced tensile force occasioned by hooks, pins, or other more invasive, complication prone surgical procedures for establishing mechanical procedures for establishing mechanical connections between which the tensile forces are created.

The inventor herein has himself previously invented a non-invasive, mechanical device for applying a sustained tensile force to a soft tissue or skin surface to thereby enlarge a patient's soft tissue. The inventor has received patents on these various non-invasive devices and methods including U.S. Patents number 5,695,445 and 5,662,583, the disclosures of which are incorporated herein by reference. While the inventor's work is continuing, he has engaged in rigorous clinical testing as a necessary predicate to receiving FDA approval which has confirmed the clinical effectiveness of his devices and methods in enlarging soft tissue including female breasts. More particularly, the device used in his clinical studies utilizes a low level vacuum to apply a tensile force on the skin surface of a breast, with an adhesive surface being used to seal the vacuum against the patient's skin. This device takes the form of a bra-like appliance which is portable and aesthetically acceptable in that its presence is virtually undetectable as it is worn by the patient during her daily activities. These prototype devices being used are fully operational and have confirmed the effectiveness of a sustained tensile force in achieving soft tissue growth and enlargement.

As the inventor has continued his further work and development in this area, he has continued to seek ways to improve his devices with respect to their effectiveness, aesthetics, and comfort to a potential patient. One of the more difficult problems to solve with the inventor's vacuum based devices has been the need to maintain the vacuum as the device is worn throughout daily activities and yet be so unobtrusive as to be undetectable to those around the patient and who may be in close proximity to her. The inventor has developed one such device in which a vacuum may be established as the patient

begins her day, and then supplemented or even reestablished with a hand operated pump and valve mechanism should the vacuum become reduced to an unacceptable level or otherwise escape as the patient twists and bends her torso in her normal daily activities. However, even with this particular arrangement, the inventor has sought to further improve his device by developing an alternative means for delivering a distracting force and yet permitting the patient to twist and turn her torso as needed without the inconvenience of reestablishing or supplementing the vacuum needed to achieve the soft tissue enlargement. While the inventor had previously conceived of various mechanical arrangements for establishing and maintaining a tensile force in this application, and indeed received U.S. Patent number 5,662,583 issued September 2, 1997 for several of them, these arrangements were subject to their own difficulties. For example, several of them required a somewhat elaborate arrangement of mechanical springs, wires, interleaved shell members, or other such mechanical and moving parts as to be fairly intricate and perhaps difficult to reliably implement. Another embodiment disclosed and claimed in the '583 patent included utilizing an intermediate material which could be caused to shrink upon curing. While such a curably shrinking material could effectively create the desired tensile force, it may possibly require replacement of the once shrunk intermediate material at least on a daily basis as the patient would remove the bra and then reapply it, depending upon the material chosen and its capability for cycling, on demand. For these reasons, among others, the inventor has previously focused his activities on vacuum based devices.

In order to solve the potential difficulties with maintaining a vacuum in the vacuum based devices and the intricacies of the

mechanical devices, the inventor herein has previously succeeded in conceiving and developing a further mechanical embodiment for creating the required tensile force in a soft tissue expander. More particularly, the inventor has conceived of utilizing a "memory material" which may be moved into a first physical arrangement for being adhered to the surface of the soft tissue desired to be enlarged, and then causing the memory material to transform into its second physical arrangement to thereby create the required tensile force. The first physical arrangement may be a non-memory arrangement and the second physical arrangement may be the memory arrangement. More particularly, the memory material may comprise one of the shape memory alloys, an example of which is Nitinol as disclosed in U.S. Patent number 3,174,851, the disclosure of which is incorporated herein by reference. Nitinol and some other related nickel-titanium or copper-zinc-aluminum methyl alloys have a "shape memory affect" that has been previously utilized in a number of useful medical devices. These include as an orthodontic arch where the arch is cooled and then placed in the patient's mouth which warms it and moves it into a stressed shape to exert pressure on the patient's teeth. Still other medical applications known to the inventor are as an expandable filter which is used in the blood vessels and as a bony anchor. These shape memory alloys or "SMA" have two crystalline phase forms with a transition temperature that can be set at approximately normal body surface temperature (approximately 30 degrees centigrade). At temperatures greater than this transition temperature, these alloys prefer the Austenite phase while at lower temperatures they prefer the Martensite phase. The Martensite phase crystal structure consists of a series of planes that may be readily displaced allowing the alloy to be easily

deformed in nearly any direction. When the alloys are heated to a temperature at or above the transition temperature, the Austenite crystal phase is preferred which forces the planes to revert back into their original configuration. In effect, this hardens the alloys and forces them to spring back and restore their original or "set" shape. These alloys may also be activated by passing an electrical current through them. Thus, these metal alloys give the appearance of "remembering" their originally set shape. Cooling and heating these alloys below and above the transition temperature can be repeated thousands of times, each time changing the property of the alloy from being soft for fashioning into a second physical arrangement to rigid which causes them to spring back into their set shape or original physical arrangement. The set shape or "shape memory" may be set by imprinting the desired form or shape into the alloy and then heating it to temperatures approximating 500 degrees centigrade.

In addition to shape memory alloys, certain plastics may also be engineered to move between a first physical arrangement and a second physical arrangement as a function of temperature, as known to those of ordinary skill in the art. These plastics may also be utilized as a "memory material" suitable for implementing the present invention.

In implementing these memory materials, the cups or domes described in one or more of the inventor's previous patents could include some form of memory material in their fabric. Below body temperature, these domes would be soft and conformable to the shape and contour of the underlying breast or soft tissue surface to be enlarged. As the patient's body temperature heats the domes and memory material, they will tend to revert and spring back to their

previously imprinted "memory" of a deeper/wider dome. If appropriately adhered to the underlying soft tissue surface or skin, this reversion or "springing back" of the memory material will then impart a tensile force to the underlying skin or tissue surface as would be effective for creating soft tissue enlargement in a suitable therapeutic regimen. Additionally, a small battery operated electronic circuit may be provided to activate and increase the tension of some of the fibers that would be set for a higher transition temperature. This would allow the bra to operate in an intermittent duty cycle in addition to maintaining a constant tension.

In order to appropriately distribute the tensile force while at the same time adhering the memory material to the underlying tissue, a layer of gel, or an air or other fluid filled bladder, may be an appropriate interface between the skin and layer of memory material, and an appropriate adhesive substance placed between the layer of gel and the underlying skin. As the inventor has disclosed in one or more of his prior patents, this adhesion could be effected with any one of a well known group of surgical adhesives which are known to bond appropriately to a skin surface without damage for extended periods of time. This may preferably be a layer of sticky silicone gel. Alternatively, the inventor has further conceived of implementing the principles of surface tension as a non-abrasive way of achieving this necessary adhesion. More particularly, a fluid may be placed on the gel layer, or on the patient's soft tissue just prior to application of the bra, and the inventor has found that the forces attributable to surface tension are sufficient to maintain an appropriate adherence between the soft tissue and the gel as the memory material transitions physical arrangement to thereby impart

the desired tensile force. Thus, the inventor has conceived of utilizing a memory material for mechanically inducing a tensile force in an appropriately chosen soft tissue site, as well as the concept of utilizing a thin layer of fluid as an interface for creating a surface tension to maintain adherence between a layer of gel or other intermediary layer to insure a distribution of the tensile force across the skin surface to thereby avoid undesired shear forces or other concentrating effects which might cause undesired abrasion or damage to the skin surface.

As a continuation of the inventor's efforts, he has conceived of a further embodiment for applying a distractive force to an underlying soft tissue. This newest embodiment incorporates many of the advantages of the inventor's prior embodiments while providing even greater control over the application of the force and dramatically improving its user friendliness including its physical size and contours. As can be appreciated, this aspect of the invention is important as its appearance as it is worn can be in an area of a person's physique ordinarily considered to be private, i.e. such as a bra over a woman's breasts.

In the inventor's newest embodiment, a thin expandable rubber-like membrane that can espouse the contours of the small relatively flat tissue at rest and can stretch and expand to the contour of the enlarged distracted tissue. (Breast in the most common application but face might be an emerging one) is provided as well as an expansion mechanism or frame that is mechanically linked to the membrane and can stretch it to form a dome-like structure. In one version of this newest embodiment, a membrane is provided both above and below the frame, and may encapsulate it.

These newest embodiments provide a quantum leap in the practicality of the external tissue enlargement device. By eliminating the vacuum components, some of the constraints of the bladder rim (forces, pressures and areas in some combination and fashion still need to be equilibrated), and the need for multiple cup sizes, patient compliance, public acceptance and cost will be greatly improved. For the breast enlargement application, this new embodiment will be as simple to use and not bulkier than a padded bra.

Another related application of tension induced soft tissue generation is the rejuvenation of the aged face. Modern plastic surgery has realized that in facial rejuvenation, a face fill is just as important as a face lift. In other words, plumping up the face and restoring the subcutaneous fat atrophy associated with aging is nearly as effective as a face lift. Cosmetic surgeons currently fill up the wrinkle lines with fat grafts or collagen injections and significantly improve the facial stigma of old age. A wrinkle patch that induces tissue growth under the wrinkles or a rejuvenating face mask that fills up the lost fat are potentially very useful applications of this technology of tension induced tissue growth.

This newest embodiment aims to further refine the design of the mechanical expansion frames found in the inventor's prior patents and to disclose the use of positive fluid pressure (gas or liquid) as the transducing force that can be used to expand these frames and create the necessary distractive force. As these tissue expansion frames expand, they are capable of rising from relatively flat surfaces to progressively deeper dome-like shells. When these novel types of frames are mechanically connected to the surface of the tissues (either through adhesives, through surface tension effect, or

otherwise), their expansion pulls up the tissues, inducing a distractive force which causes them to grow.

Fluid pressure, however, is isotropic and will cause a simple inflatable structure to expand in all three dimensions, opening up like a balloon. The desired effect, on the other hand, is that of inducing a flat frame to rise as a three-dimensional dome-like shell. In other words the leaflets of the frame should not open up; rather, the desired expansion should induce the frame to keep a relatively even thickness forcing it to spread out only in two dimensions. By circumferentially constraining the frame either at its edges or though its inherent tailored design, the induced surface spread should cause it to rise as a dome-like shell. The three-dimensional surface contour of the dome, its excursion, and the force of deformation depend upon the fluid pressure applied and the mechanical design of the inflatable structure. Under the effect of positive fluid pressure, the rising and progressively deeper dome-like shell pulls up and distracts the tissues that are mechanically connected to its concave surface, inducing them to grow.

The main subject of this newest embodiment is the concept of a frame, which, in its resting state, can espouse the surface contour of the body part to be enlarged. This frame is connected to the underlying tissues either through a glue or layer of adhesive or through surface tension effect. A compliant expandable membrane may be additionally used to serve as the interface and the mechanical link between the frame and the surface of the tissue to be distracted. Although, other means for securing the underlying soft tissue to the frame may be used. For example, surgical attachment may be used. The frame is designed such that it can be inflated and under the effect of internally applied positive fluid pressure it can

rise into progressively deeper domes. The range of excursion could stretch from flat to a nearly spherical surface in order to maximize the amount of induced distractive force. Furthermore, the surface contour of the expanded frame may be designed such that it can deviate from the perfect sphere as it expands into a dome. This is needed to evenly expand a complex surface, or to differentially expand certain areas relative to others. (i.e. from flat to tear drop in the case of a breast or more complex surface contour in the case of a full face). The force and extent of elevation of this frame can be gauged by the amount of fluid pressure applied. This frame will need to distribute the counterforce of distraction through its rim pressing against the tissues at the periphery. Therefore, as in the previous inventions, there is a need to equilibrate the pressures, forces, and/or the surface areas of the frame in relation to the contact surface area of the non-expanding surrounding rim.

Fluids under positive pressure have many useful applications. The inventor is, however, interested in those that result in rigid dome-like shell structures as compared to the simple inflatable balloon or ring-like tire. Applications more relevant to the present invention are the inflatable self supporting dome-like structures such as the ones used to cover stadiums or the umbrella-like and shield-like antennae deployed in aerospace applications.

While fluids under positive pressure are used in medicine to inflate tissue expanders (inflatable silicone shells), these devices are internal. They are surgically inserted under the skin and they stretch it from the inside out instead of the external device described herein which can raise the surface of the tissue by pulling it up from the outside. Furthermore these common tissue expander

devices inflate like simple balloons instead of converting a flat frame into a dome-like shell.

In the present invention, the required effects of positive pressure inflation are mostly linear (one-dimensional), or preferably mostly sheet like (two-dimensional) expansion of the frame instead of the inherent three-dimensional ballooning effect of unrestrained inflation. To achieve this dimensional restriction, the basic building block may include one or more of the following several alternative design options.

In its simplest form, the expanding frame consists of an airtight flat bladder made out of an inner and an outer expandable membrane interconnected by a network of non-expandable links. The mechanical properties, the thickness, and the tailoring of these membranes are adjusted such that with inflation, this bladder which cannot blow up like a balloon, will distort into a dome-like shell (see figure 1 and its description below). This might be a mechanically inefficient means of using pressure to pull up the tissues, but it is contemplated by the inventor that it would be effective in this application. Other more efficient designs might be used, at least some of which are described below and others of which would be apparent to those of ordinary skill in the art having once gained the benefit of the inventor's disclosure herein.

The simplest building block for the mechanically more efficient design is the piston-in-cylinder or some sort of corrugated accordion bellows that can expand in only one dimension under the effect of applied fluid pressure. A two-dimensional expansion will result from linking these one-dimensional blocks at various angles. The simplest geometrical design could be considered to be that of repeating triangles. When each side of the triangle expands one-dimensionally,

the result is a two dimensional stretch of the construct. If, in addition, the edges of the repeating triangular pattern are constrained and prevented from stretching, the frame is forced to rise as a dome. This is the structural basis for the geodesic dome design (see figure 7a&b and the discussion below). A person of ordinary skill in the art of computer aided design knows that any complex three-dimensional surface can be reduced to a series of adjacent triangles. Expanding the sides of these judiciously designed array of triangles can induce a controlled and preferential distraction of any complex body surface that needs to be enlarged. Other geometric shapes and arrangements for the frame itself may be used, as is described in greater detail below. Additionally, the details of the structure used for the "legs" or struts which form the frame can be varied to provide other ways for restraining the frame movement as it is expanded in order to achieve the desired application of a distractive force.

While some of the principal advantages and features of the invention have been discussed above, a fuller understanding of the invention may be attained by referring to the drawings and description of the preferred embodiment which follow.

Brief Description of the Drawings

Figure 1 depicts in cross section the successive positions of a memory material as it transitions from a first physical arrangement to a second physical arrangement.

Figure 2 is an enlargement of a weave formed from a plurality of complex fibers woven into a weave of memory material.

Figures 3 a & b are cross sectional views of a bra incorporating the present invention with Fig. 3a depicting the bra configured as the memory material is in a first physical arrangement and Fig. 3b depicting the bra configuration as the memory material has transitioned into a second physical arrangement.

Figure 4 depicts a frontal view of a patient wearing the bra embodiment of the invention.

Figure 5 is a cross sectional view detailing the bra embodiment of the invention as adhered to a breast.

Figure 6a&b are cross-sectional views of a frame member shown in both a relaxed and an inflated state.

Figure 7a-c depict a frame constructed in a geodesic configuration, and a detail view of a frame member.

Figure 8 depicts a front view of a florentine dome frame construction.

Figure 9 depicts a frame constructed to apply a differential force to various underlying tissue areas, as would be desired for use with a complex surface area.

Figure 10 depicts a cross-sectional view of a segment or strut which could be used to form any one or more of the frames.

Figure 11 is a front view of a frame formed of triangular members.

Figure 12a&b are cross-sectional views of a cellular construction, in both a relaxed and inflated configuration, for a frame member.

Figure 13a&b are top views of the cellular construction frame member of figure 12.

Figure 14a&b are cross-sectional views of an inflatable cell construction having a network of non-expandable interconnecting links sandwiched between two expandable membranes in both a relaxed and inflated view.

Figure 15a&b are side views of a frame member which is sealed and filled with a fluid to enhance its inflatability.

Detailed Description of the Preferred Embodiment

As shown in Fig. 1, a dome 20 of memory material 22 may be treated to "set" its shape in a memory as depicted in position 24. As used in the invention first disclosed in the parent to the present patent, the memory material 20 may be chosen to be a shape memory alloy having a transition temperature at approximately body surface temperature which is approximately 30 degrees centigrade. As the shape memory alloy is taken to a lower temperature, it may then be fashioned into a shape such as that shown at position 26. Then, as the temperature of the memory material approaches its transition temperature, it may successively taken on the shape shown at positions 28, 30, 32, and then reaching its memory position at position 24. Thus, a memory material may be used in the parent invention to provide a bra or other dome like structure which may be fashioned into a relatively shallow shape but which upon reaching its transition temperature deflects to a significant degree in order to provide the mechanism for creating a mechanical tensile force in an underlying soft tissue.

Referring now to Figure 2, the memory material 20 as used in the bra embodiment of the parent invention, may be fashioned from a weave 34 comprised of a mesh or cross pattern of a plurality of individual complex fibers 36. Each complex fiber 36 may be a coil, spring, or serpentine arrangement of one or more strands of a shape memory alloy or, alternately, thin strips of shape memory alloy may be interweaved together and, by being able to glide past each other

provide the necessary allowance for expansion and contraction of the material as it transitions between a first physical arrangement and a second physical arrangement. Although these constructions of the memory material are considered as preferable by the inventor in implementing his parent invention, as known to those of ordinary skill in the art still other constructions may be used in implementing the memory material, it only being required that its construction be amenable to allow for the desired excursion between the two physical arrangements as desired to effect a tensile force in an underlying soft tissue.

As shown in Figs. 3a and b, a bra 38 constructed in accordance with the teachings of the parent invention provides a good application for enlarging a patient's soft tissue such as a pair of female breasts 40. As shown therein, the bra 38 comprises a multi-layer construction. An outer layer 42 may be a supportive bra having an ornamental, aesthetic, or decorative covering as may be pleasing to the feminine eye. Beneath is preferably an outer layer of expandable or extensible material 44 which, with a corresponding similar layer 46, surrounds therebetween a layer 48 of memory material for imposing a tensile force as it is caused to move from the first physical arrangement as shown in Figure 3a to the second physical arrangement as shown as Figure 3b. The memory material 48 may be bathed by a lubricating fluid or gel 50 to facilitate the multiple cycling of the memory material between its two physical arrangements. A fluid layer, which may comprise a layer of gel 52 or an air or fluid filled bladder or other such spacer, may preferably then be provided to help conform the bra 38 to the body contour and to prevent pressure points and shear forces between the bra 38 and the underlying soft tissue 40. The fluid layer 52 may be confined

itself inside an extensible envelope similar to the layers of extensible material 44, 46. Lastly, on the inside surface of the fluid layer 52, a layer of adhesive 54 may be applied to adhere the fluid layer 52 to the skin of the soft tissue 40 and to avoid any separation therebetween as the bra 38 is cycled between the positions shown in Figs. 3a and b. Alternatively, a fluid may be provided instead of an adhesive layer with the adhesive forces thus being provided by surface tension. Indeed, the inventor contemplates that it may be preferable for a thin film of fluid to be provided as it is thought to be less susceptible to shear forces and therefore less likely to abrade the skin surface upon repeated use of the bra 38 over any extended period of time as might be recommended in a typical therapeutic regimen. As contemplated by the inventor, the bra 38 of the embodiment of the parent invention, as worn by a patient, is shown in Figure 4.

As is taught in several of his prior patents, the inventor contemplates that a ring, periphery, or lip 56, as best shown in Figure 5, may be integrally formed as part of the dome 20, and surround it at its periphery, to support it against the patient's chest as the offsetting surface for the compressive force which balances the tensile force created by the bra 20. With this supporting ring 56, the domes 20 may be supported from the patient and thereby have their forces balanced to achieve an effective tensile force in the soft tissue as is required to achieve the purposes of the invention. For a more detailed explanation, reference is made to any one or more of the inventor's prior patents mentioned above. However, it should be noted that with the parent invention, the ring or periphery 56 may be either integrally formed with the dome 20 or constructed from material which does not exhibit

the "memory" feature as is used to form the arcuate portion of the dome 20. Instead, any suitable structural material may be used with the memory material spanning the interior of the ring 56. With either embodiment, the inventor contemplates that a dome 20 could readily be constructed which would expand between two to three times its periphery which would correlate to a five times to ten times increase in surface area of the dome 20. With this degree of excursion, a substantial tensile force could be created although, as is known to those of ordinary skill in the art, lesser forces and smaller excursions could readily be provided for using the teachings herein as well as the known information relating to shape memory alloys and other types of memory materials.

For implementation as a breast enlargement device, such as with the bra embodiment of the invention as is explained in some detail herein, a bra could readily be constructed of a soft forming material at temperatures below body surface temperature, with the cup areas of the bra containing shape memory alloy fibers, weave, mesh, or sheets in its fabric. The bra would first have its memory material "set" in an appropriate shape, as predetermined to direct the growth in the chosen locations of the patient's breast by properly applying the desired tensile force. In other words, with the bra of the parent invention, the breast may be contoured and sculpted by encouraging growth in preselected areas to thereby fill in where needed. The bra is then placed on a patient, with appropriate attention being given to properly adhere the bra interior lining or gel to the skin of the breast by applying either a layer of fluid or adhesive. The bra cups are heated by the natural heat of the patient's breasts to approach the body surface temperature which is approximately thirty degrees centigrade. As the temperature of the bra rises, the shape memory

alloy acts as a spring and as it returns to its "memory" configuration it exerts a tensile force on the patient's breasts, pulling the breasts along with them as they reconfigure into a deeper dome shape. With appropriate engineering design as would be known to those of ordinary skill in the art, the tensile force of the alloy spring weave/sheet can be appropriately adjusted to exert an evenly applied, or shaped uneven force to provide for sculpting of the breast, distending or distracting force substantially equal to the approximately 15 to 30 mmHg of pressure as taught with the inventor's prior vacuum type bra devices. Alternately, a greater or lesser tensile force could be engineered as desired depending upon the appropriate therapeutic regimen recommended, or as learned to be more physiologically effective through greater clinical experience with the bra of the parent invention. Additionally, several of the fibers may be set at a higher transition temperature and then activated by a battery powered electronic circuit 58 to cycle intermittently to thereby provide a supplemental tensile force, as desired. The battery powered electronic circuit 58 may be appropriately concealed at any convenient point on the bra, and connected to those fibers selected to be in the region of interest to apply the force in the manner and location desired. Further refinement of the construction and design using finite element analysis, as would be well known to those of ordinary skill in the art, can maintain this tensile force constant as the spring like reversion pulls from a flat sheet to a spherical structure having a depth even greater than a hemisphere.

While the embodiment best explained herein relates to the use of a bra to expand the female breast, it would be apparent to those of ordinary skill in the art that the parent invention may also be used in other applications without undue experimentation. Examples

of these include as a simple soft tissue expander as might be useful for replacing collagen and fat injections and other aloplastic implants typically used in the prior art to improve contour defects caused by aging, involution or scarring. With an appropriately designed mask to be worn at night, for example, wrinkles, dimples, lips and even sunken or hollowed features of the face may be filled by expanded soft tissue whose growth would be induced by the present invention. For such applications, the dome and surrounding lip or periphery would be used.

It should also be apparent to those of ordinary skill in the art that the particular fluid utilized to create the surface tension for achieving adherence between the fluid layer or other liner surface may be chosen from amongst many suitable fluids including mineral oil, baby oil, water, physiologic saline, various kinds of water or oil based gels, glycerine, creams, and ointments, all of which have been found to adhere to the skin surface and withstand tensile forces in excess of the approximate 15 to 30 mmHg required in various therapeutic regimens with the vacuum based device. In several of those embodiments, a thin membrane is bonded to the skin and the vacuum is generated in the enclosed space between the inner surface of the membrane and the dome. In this embodiment, surface tension has been successfully implemented by the inventor. Furthermore, it is believed that the thin membrane embodiment may also be successfully implemented in the memory material embodiment as disclosed and claimed herein.

As shown in fig. 6&7, the inventor has further advanced his invention to include the construction of a frame 100 comprised of a plurality of arranged struts or legs 102 which may be individually inflated to cause them to lengthen, and to constrain that lengthening

by a peripheral restraint 104 in order to force a two dimensional lengthening. This is shown in fig. 7 as a matrix of triangles formed in an overall shape of a hexagon. However, any other polygonal shape of convenience could be used as well, so long as the desired distractive force may be induced in the underlying tissue. With the use of struts that exhibit the necessary resiliency to achieve the desired excursion, nodes or junctures 106 may be used that are rigid to provide an overall strength to the frame. Also, support rods 108 may be provided conveniently within the central core of one or more struts 102 and serve to limit their excursion and help distribute the loading so as to achieve the desired distribution of distractive forces across the underlying soft tisue.

The basic polygon need not be a triangle like in the classical geodesic dome but could be an assemblage of squares, pentagons, rings, circles, or other shapes. There are a number of alternate related options to this geodesic structure version. The Florentine dome version 108, (figure 8) for example, consists of radially and circumferentially connected linearly expanding struts 102. In this scenario, the original grid is that of concentric circles 110 interconnected by a number of radial rays 112 originating from the center 114. Again, as in the geodesic version the peripheral edges 116 at the rim of the expanding frame 102 should be prevented from stretching. To accommodate the increased surface, the frame 102 is forced to rise into a dome upon inflation. In yet a more general form of this version, the pattern need not be concentric circles but can be a series of complex closed curves similar to the altitude lines in the map of a mountain, as shown in fig. 9. These expanding curves are preferably held together by a series of interconnecting radially expanding rays 118. Pressure inside such a construct will

cause it to stretch and depending upon the peripheral constraint 116, to rise like a dome with a shape dictated by the geometrical arrangement of the curves and the linear rays. To prevent serpentine-like elongation instead of the desired rigid linear expansion of the individual segments or struts, an internal reinforcement in the form of semi-rigid telescopic mechanical backbone 120 may be included as needed, as shown in fig. 10. This mechanical backbone 120 is preferably formed from a pair of opposed rods 122, with a sliding joinder 124 overlying their inner ends 126 and providing a limited and defined (and otherwise controlled) excursion within each strut. Indeed, different backbones 120 may be provided in different struts within the same frame so as to more exactly design and tailor the desired excursion at different locations within the frame. This would be especially desirable to match complex surface contours intended to be "grown".

This corrugated / expanding cylinder version does not need to consist of individual well-defined segments or struts separated by connectors. The entire construct can be judiciously molded into a semi-continuous sheet of corrugations running and expanding in various directions. For example, see figure 11 which shows a continuous pattern of triangles. However, these could also rings, disks or any closed polygon. The extent of expansion with inflation is determined by the physical/mechanical characteristics of the material used and by the depth of the in-foldings of the corrugations; with deeper corrugations allowing more excursion with inflation. Of course, this construction provides even greater design opportunity for creating a frame to match any desired surface.

A more generalized version of the corrugated frame design would consist of a sheet-like array of inflatable fusiform 128 or elongated

football shaped cells interconnected at the waist, as shown in fig. 12,13. Positive pressure inside these elongated fusiform cells 128 will cause them to widen and assume a spherical shape. In doing so, they push each other out in all directions causing the desired two-dimensional spread of the frame (see figure 12,13). This may be conveniently referred to as the egg crate version.

An alternative means of achieving this restricted two-dimensional expansion is to have an array of inflatable cells 130 sandwiched between two expandable membranes 132 that are prevented from separating through a network of non-expandable interconnecting links 134 as depicted in fig. 14. It is noted that this is similar to the design initially depicted above in figure 6. With inflation, the individual cells, originally fusiform 128 (as in the egg crate version) cannot get taller because of the restraining ligament in their central core; they can only get fat. With increasing pressure of inflation progressively fatter cells push each other out to induce a widening and a two-dimensional spread of the frame, instead of a simple inflation or ballooning out of the sandwich. This is conveniently referred to as the enrobed restrained version of the egg crate. Instead of fusiform or cellular construction, the frame could be comprised also of a continuous membrane which could be wrinkled or otherwise mechanically collapsed and which would then unfold upon inflation. With this construction, a pair of sheet-like members could be joined at various locations across the surface of the sheets and multiple members joined to form the frame. Still another embodiment is comprised of a plurality of polygon-shaped members which are individually inflatable and which are themselves joined together to form the entirety of the frame. For example, each individual polygon could be formed in the shape of a triangle and

multiple triangles could be joined at their corners to form the frame, or circles or other curvilinear, regular or irregularly shaped individual cells could be interconnected into an array.

In all of the newest embodiments, an internal backbone mechanical framework of telescopic studs might be added to control the movement and rigidity to the construct or strut, as shown in fig. 10.

Another detail of the newest embodiment of the present invention may be commented on. This is the mechanical coupling of the expandable frame to the expandable membrane, which in turn is in contact with the tissues to be expanded. By virtue of its design, the expanding frame pushes outward while pulling behind it a smooth concave surface for even contact with the tissues. The moving segments of the frame are not necessarily smooth (they will have inherent dimples and ridges) and there could be some difficulty in gluing them to a concave smooth surface, i.e. the underlying soft tissue. To overcome this, the expanding frame may be conveniently sandwiched between two expandable membranes and the space between these two membranes sealed and filled with a fluid as depicted in fig. 15. Induced negative pressure in the fluid caused by the elevation of the dome and pull of the outer membrane will provide the mechanical link between them, and force the inner membrane at the concave surface to rise in unison.

Depending upon its mechanical characteristics, the stretching or distracting force can be adjusted to provide a constant distraction force equal in magnitude to the force generated by the vacuum used in the inventions previously disclosed in the inventor's prior patents. This force of distraction can be engineered to remain constant over the normal range of excursion, or to be altered, through use of the various mechanisms mentioned herein. In the case

of the use of the present invention to expand the breast, an excursion may preferably range from the relatively small breast shape to a large D cup size. (From flat to ~ 5/8 sphere).

The technology used to "grow" the breast can similarly be applied to expand any body part and in particular can be used to fill up the face. These devices, including the newest embodiments would be applied over the wrinkle lines and/or the entire face. Under the effect of sustained distraction and over a period of time, the atrophic subcutaneous tissues of the aged face can be filled up with newly generated stretch induced tissue. The rejuvenating face mask and the wrinkle patch preferably uses the same kind of expandable rubber membrane and expansion frame used in the breast device. Surface tension supplied by a hydrating gel (a widely used cosmetic product) preferably provides the mechanical link between the device and the facial skin.

Various changes and modifications to the invention would be apparent to those of ordinary skill in the art. Those changes, variations, and modifications are fairly included in the scope of the present invention which should be considered as limited by only by the scope of the claims appended hereto and their legal equivalents.

What is claimed is:

1. A device for expanding a patient's soft tissue, said device comprising a dome adapted for placement in a sealing condition over a soft tissue site desired to be enlarged, said dome comprising a layer of memory material.

2. The device of claim 1 further comprising a sticky layer extending across the interior of said dome for providing the sealing condition of said dome to said soft tissue site.

3. The device of claim 2 further comprising a liner, said liner being secured inside of said layer of memory material, said liner being adapted to provide a surface for said sticky layer, said sticky layer being provided by surface tension.

4. The device of claim 2 wherein said sticky layer comprises a layer of adhesive material.

5. The device of claim 2 further comprising a fluid layer located between the layer of memory material and said sticky layer, said fluid layer minimizing any lateral stress force between the layer of memory material and said soft tissue.

6. The device of claim 2 wherein said memory material comprises a shape memory alloy having its transition temperature set at about normal human body surface temperature.

7. The device of claim 2 wherein said layer of memory material comprises a weave of memory material.

8. The device of claim 7 wherein said weave of memory material is formed of a plurality of individual fibers of said memory material, each of said fibers comprising a complex fiber.



9. The device of claim 7 wherein said weave of memory material is formed of a plurality of relatively thin strips of said memory material.

10. The device of claim 7 further comprising a ring positioned generally about the periphery of said dome, said weave of memory material extending across said ring and said ring defining the soft tissue site to be enlarged when sealed to said patient's soft tissue.

11. The device of claim 8 further comprising an electronic circuit, and wherein a selected number of said fibers are electrically connected to said electronic circuit to permit their separate transition from one physical arrangement to another.

12. The device of claim 10 wherein said ring is integrally formed as part of said dome.

13. The device of claim 12 wherein said ring is made of material other than memory material.

14. A bra for enlarging a patient's breast size, said bra comprising at least one dome for adhering to one of said patient's breasts, said dome comprising a layer of memory material.

15. The device of claim 14 further comprising a sticky layer extending across the interior of said at least one dome providing the sealing condition of said at least one dome to said patient's breast.

16. The bra of claim 15 further comprising a liner, said liner being secured inside of said layer of memory material, said liner being adapted to provide a surface for said sticky layer.

17. The bra of claim 15 further comprising a fluid layer located between the layer of memory material and said sticky layer, said fluid layer minimizing any lateral stress force between the layer of memory material and said breast.



18. The bra of claim 15 wherein said layer of memory material comprises a weave of memory material.

19. The bra of claim 18 wherein said memory material comprises a shape memory alloy having its transition temperature set at about normal human body surface temperature.

20. The bra of claim 18 further comprising an electronic circuit, and wherein a selected portion of said weave is electrically connected to said electronic circuit to permit its separate transition from one physical arrangement to another.

21. The bra of claim 18 further comprising a ring positioned generally about the periphery of said dome, said weave of memory material extending across said ring and said ring defining the portion of said patient's breast to be enlarged when adhered to said patient's breast.

22. The bra of claim 21 wherein said ring is integrally formed as part of said dome.

23. The bra of claim 22 further comprising a fluid layer located between the layer of memory material and said sticky layer, said fluid layer minimizing any lateral stress force between the layer of memory material and said breast.

24. The bra of claim 23 wherein said bra includes a pair of said domes.

25. The bra of claim 24 wherein said bra further comprises a surface for counterbalancing any stress forces created by said memory material.

26. The bra of claim 25 wherein said memory material is secured to said fluid layer.

27. The bra of claim 26 wherein said memory material is sandwiched between a pair of layers of expandable material.

28. The bra of claim 27 wherein said memory material comprises a shape memory alloy having its transition temperature set at about normal human body surface temperature.

29. A method of enlarging a patient's soft tissue comprising the steps of adhering a layer of memory material to a surface of the soft tissue desired to be enlarged, said layer of memory material being biased into a first physical arrangement, causing said memory material to move into a second physical arrangement to thereby create a tensile force in said soft tissue, and maintaining said tensile force throughout a sufficient treatment regimen to thereby enlarge said soft tissue.

30. The method of claim 29 further comprising the step of biasing the memory material by lowering its temperature below normal human body surface temperature, and wherein the step of causing the movement of said memory material into the second physical arrangement comprises permitting the patient's body to elevate the temperature of said memory material to approximately body surface temperature, said memory material having its transition temperature set within a range of between about 10 degrees below to about normal human body surface temperature.

31. The method of claim 30 wherein the step of adhering said memory material includes the step of adhering with a layer of fluid sufficient to create an adequate surface tension between said soft tissue surface and said layer of memory material to maintain them in contact as said memory material transitions between said first and second physical arrangements and for at least a portion of said treatment regimen.

32. The method of claim 31 further comprising a fluid layer adhered to the layer of memory material, and wherein said fluid is applied

between said fluid layer and said soft tissue surface to thereby adhere said layer of memory material to said soft tissue surface.

33. A method of adhering a soft tissue expander to a surface of soft tissue comprising applying a fluid between said expander and said soft tissue surface to thereby create a surface tension therebetween.

34. In a soft tissue expander having a surface adapted to be adhered to a soft tissue site throughout a treatment regimen, the improvement comprising a fluid placed between said surface and said soft tissue site to thereby create a surface tension therebetween.

35. The device of claim 34 wherein said soft tissue expander comprises a fluid layer, the fluid thereby being placed on said fluid layer to thereby adhere said fluid layer to said soft tissue site.

36. The device of claim 35 wherein said soft tissue expander further comprises a layer of memory material for inducing a tensile stress in said soft tissue site, said fluid layer being adhered to said memory material layer.

37. A bra for enlarging the breast size of a patient, said bra including a pair of domes for fitting to the pair of said patient's breasts, each of said domes being made of a shape memory alloy weave woven of complex fibers, a fluid layer adhered to the inside surface of each of said domes, and an adhesive layer applied to the inside layer of each of said fluid layers so that each of said domes may be adhered to one of said breasts as said shape memory alloy is in a first physical configuration and which will exert a tensional force on each of said breasts as said shape memory alloy returns to an original configuration.

38. The bra of claim 37 wherein said adhesive layer comprises a layer of an adhesive.

39. The bra of claim 37 wherein said adhesive layer comprises a layer of moisture sufficient to create an adhesive force with surface tension.

40. A device for expanding a patient's soft tissue, said device comprising a frame adapted for attachment to a soft tissue site desired to be expanded, said frame comprising at least one frame member which is inflatable to expand the frame and induce a distractive force in the underlying soft tissue site.

41. The device of claim 40 wherein said frame is comprised of a plurality of inflatable frame members, and further comprising a peripheral restraint surrounding said frame to restrict lateral movement of said frame as the frame members are inflated.

42. The device of claim 41 wherein said frame members are arranged in a plurality of polygons.

43. The device of claim 41 further comprising a stabilizer rod contained within at least one of said frame members and positioned to control the movement of said frame member as it is inflated.

44. The device of claim 41 wherein said frame members are arranged in an asymmetric shape.

45. The device of claim 41 wherein said frame members are formed from a bellows material to allow for their expansion and contraction in response to their inflation and deflation, respectively.

46. The device of claim 40 wherein said frame is comprised of a plurality of interconnected generally spherically shaped cells.

47. The device of claim 46 further comprising at least one membrane attached to said frame and extending over a substantial portion thereof.



48. The device of claim 47 further comprising a second membrane, said frame being sandwiched between said membranes, and one of said membranes being adhered to the underlying soft tissue.

49. The device of claim 48 further comprising at least one reinforcing rod contained within said frame.

50. The device of claim 49 further comprising a plurality of reinforcing rods contained within said frame, one of said rods being contained within substantially each of the cells comprising the frame.

51. The device of claim 40 further comprising at least one membrane attached to said frame and extending over a substantial portion thereof.

52. The device of claim 51 further comprising a second membrane, said frame being sandwiched between said membranes, and one of said membranes being adhered to the underlying soft tissue.

53. The device of claim 52 further comprising a fluid substantially filling said space between said membranes.

54. A device for expanding soft tissue, said device comprising an inflatable frame contained within two membranes, one of said membranes being adapted for attachment to the underlying tissue.

55. The device of claim 54 further comprising a peripheral restrictor surrounding said frame.

56. The device of claim 55 wherein said frame is comprised of a plurality of frame members, at least one of which is inflatable.

57. The device of claim 55 wherein said frame is comprised of a plurality of cells, said cells being interconnected and inflatable.



58. The device of claim 57 further comprising a plurality of mechanical supports contained within said frame cells to restrict their movement as the frame is inflated.

59. The device of claim 56 wherein said frame members are arranged in a plurality of polygons.

