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(54) Title: APPARATUS AND METHOD FOR CONCURRENT TENSIVE AND COMPRESSIVE IMMOBILIZATION OF THE BREAST IN IMAGING AND INTERVENTION

(57) Abstract: An apparatus and method for treating a tumor mass location in a breast of a patient. The breast is stabilized in space, preferably by creating a reduced pressure environment around the breast in combination with a compression force being applied to the chest wall around the breast. Particle beams are applied to a tumor mass location positioned at the center of a substantially spherical (or cylindrical) portion of a chamber filled with a fluid having an electron density substantially similar to the breast. The patient treatment platform is translated to aim the particle beam at the tumor mass location while traversing and beams perpendicular to the portion of the chamber.

Fig. 9
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APPARATUS AND METHOD FOR CONCURRENT TENSIVE AND COMpressive immobilization of the breast in imaging and intervention

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/201,933 entitled “APPARATUS AND METHOD FOR CONCURRENT TENSIVE AND COMpressive immobilization of the breast in imaging and intervention” filed on December 17, 2008, incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] Breast cancer remains a scourge on humanity. For early-stage breast cancers progress has been made toward improved local control and better cosmetic outcomes. However, present-day approaches require multiple radiographic techniques and interventions just to establish a diagnosis of breast cancer. In addition, an estimate must be made of the extent of, and possible metastatic spread of the cancer, even before proceeding with treatment. This may take many weeks to coordinate and accomplish.

[0003] The treatment phase for breast cancer again requires multiple procedures, high cost and delays. The entire process can extend over many weeks. It typically requires anesthesia, surgery, lymphatic tracing and sampling, along with post operative radiation therapy of part, or all, of the breast. Cosmetic results vary widely and the cost is great.

SUMMARY OF THE INVENTION

[0004] One embodiment of the present invention is a method of treating a tumor mass location in a breast of a patient, including directing an isocenter of a particle beam at a center of a spherical portion of an outer chamber that overlaps the tumor mass location after passing the particle beam through a first fluid at least partially filling the outer chamber. Next it passes the beam through a second fluid at least partially filling an inner chamber having a reduced pressure environment that encompasses at least a portion of the breast. While beaming the patient's breast compressive force is maintained. The compressive force is against at least a portion of the patient's chest and is created using a plate that is fixed to the inner chamber with an airtight seal.

[0005] In one refinement of the embodiment the particle beam is a proton particle beam, and the first fluid and the second fluid are the same and have an electron density substantially similar to the breast.

[0006] Another refinement of the embodiment includes rotating the particle beam and the breast relative to one another while continuing to direct the isocenter of the particle beam at the center of the spherical portion of the outer chamber. Another refinement of the embodiment includes creating the relative rotation by moving a robotic arm connected to a treatment platform upon which the patient lays.
Another refinement of the embodiment includes deactivating the particle beam at various times while rotating the particle beam and the breast relative to one another. In another refinement of the embodiment the particle beaming occurs after a surgical intervention on the breast, and further comprising deactivating the particle beam when the particle beam would otherwise pass through an existing incision site on the breast.

Another refinement of the embodiment includes deactivating the particle beam when the beam would otherwise pass through a planned future incision site on the breast.

Another refinement of the embodiment includes directing the particle beam so that it only passes through an underside of the breast of the patient.

Another refinement of the embodiment includes first imaging the breast and obtaining data regarding the tumor mass location within the breast and providing the data to a computer directing the particle beams at the breast.

In another refinement of the embodiment the imaging is done using a combination of 3-D ultrasound and CT.

Another embodiment of the present invention is a method of treating a tumor mass location of a breast, including directing an isocenter of a particle beam toward a center of a spherical portion of a chamber enclosing the breast and through a fluid having an electron density substantially similar to the breast. The center of the spherical portion of the chamber overlaps the tumor mass location, and the particle beam is substantially normal to the spherical portion of the chamber. The method further includes applying a compressive force while beaming against at least a portion of a chest wall around the breast. The compressive force is created using a plate that is fixed to the chamber with an airtight seal.

One refinement of the embodiment includes rotating the breast and spherical portion of the chamber relative to the particle beam to scan through a plurality of particle beam entry angles into the breast while continuing to direct the particle beam substantially normal to the spherical portion of the chamber.

Another refinement of the embodiment includes directing the particle beam only through an underside of the breast.

Another refinement of the embodiment includes deactivating the particle beam except when scanning an underside of the breast.

Another refinement of the embodiment includes rotating the breast and spherical portion of the chamber relative to the particle beam by moving a robotic arm connected to a treatment platform upon which the patient lays.

Another refinement of the embodiment includes deactivating the particle beam at various times while rotating the particle beam and the breast relative to one another.

Another refinement of the embodiment includes first imaging the breast and obtaining data regarding the tumor mass location within the breast and providing the data to a computer directing the particle beam at the breast.
In another refinement of the embodiment the imaging is done using a combination of 3-D ultrasound and CT.

Another embodiment of the present invention is a method of treating a tumor mass location of a breast of a patient. The method includes applying a compressive force against at least a portion of a chest wall around the breast using a plate that is fixed to an inner chamber with an airtight seal. The method further includes reducing pressure within the inner chamber that encloses at least a portion of the breast after creating a fluid tight seal between the inner chamber and the patient. The inner chamber is at least partially filled with a fluid having an electron density substantially similar to the breast, and positions an outer chamber at least partially filled with the fluid so that a center of a spherically shaped portion of the outer chamber overlaps the tumor mass location. A particle beam is scanned across an arc of a portion of the outer chamber while directing an isocenter of a particle beam at the center of the portion.

One refinement of the embodiment includes scanning the particle beam only across an underside of the breast.

Another embodiment of the present invention is a method of treating a breast cancer tumor mass location. The method includes stabilizing the breast by simultaneously applying a compressive force to a portion of a chest wall using a plate and providing a reduced pressure environment via a chamber in a fixed spatial relationship with respect to the plate. The method further includes applying an isocenter of a particle beam to a center of spherical portion of an at least partially fluid filled chamber that encloses at least a portion of the breast. The fluid has an electron density substantially similar to the breast, and the center overlaps the tumor mass location.

In one refinement of the embodiment the breast is stabilized by providing a reduced pressure environment around the breast.

Another refinement of the embodiment includes providing the reduced pressure environment using a fluid tight seal between a wall defining an inner chamber and a patient's body, and positioning the hemispherical portion of the chamber around at least a portion of the breast.

Another refinement of the embodiment includes first imaging the breast to determine data regarding the tumor mass location within the breast, and providing the data to a computer controlling the application of the particle beam.

Another embodiment of the present invention is a method of treating a tumor mass location in a breast of a patient, including stabilizing the breast within a reduced pressure environment enclosed by a chamber having a wall at least a portion of which is spherically shaped; imaging the breast to determine the location of the tumor; beaming the tumor with particles through the spherically shaped portion of the chamber; and rotating the beam relative to the tumor mass location around a center of the spherically shaped portion of the chamber, wherein the center overlaps the tumor mass location. In another refinement of the embodiment the patient is prone on a treatment platform, and the patient is rotated with respect to at least one stationary particle beam.
Another refinement of the embodiment includes directing the particle beam only through an underside of the breast.

Another refinement of the embodiment includes deactivating the particle beam except when scanning an underside of the breast.

Another refinement of the embodiment includes using fiducial markers positioned within or on the breast to identify the tumor mass location.

In another refinement of the embodiment, during stabilization of the breast and during beaming the tumor with particles, the chamber is filled with a fluid having an electron density substantially similar to the breast.

In another refinement of the embodiment the beaming is controlled to overlap a biopsy track along which prior surgical intervention of the breast has occurred.

Another embodiment of the present invention is an apparatus for treating a tumor location in a breast, including a first wall having an interior surface defining a first chamber sized to encompass at least a portion of the breast. The apparatus includes tensive and compressive means for stabilizing the breast within the first chamber. This apparatus also includes a second wall having an internal surface defining a second chamber, the second wall including a spherical (or cylindrical) portion around a center. The first chamber is smaller than and positioned substantially within the second chamber, and the second chamber is movable with respect to the first chamber to position the center of the spherical portion to overlap the tumor location.

In one refinement of the embodiment an edge of the first wall includes an adhesive for attaching the first wall to the breast in a substantially fluid tight fashion.

In another refinement of the embodiment the adhesive is a replaceable tape.

In another refinement of the embodiment the spherical portion of the second wall is substantially hemispherically shaped.

In another refinement of the embodiment at least a portion of the first wall is substantially hemispherically shaped.

In another refinement of the embodiment the spherical portion of the second wall is substantially hemispherically shaped.

In another refinement of the embodiment at least a portion of the first wall is visually transparent.

Another refinement of the embodiment includes a fat equivalent fluid at least partially filling the first chamber and the second chamber.

In another refinement of the embodiment the means for stabilizing the breast within the first chamber is a reduced pressure environment generated by a pump fluidly connected to the first chamber by a conduit connected to a first port in the first wall, and wherein the conduit passes through a second port in the second wall.
In another refinement of the embodiment the first wall defines a first port and further includes a valve within the first port.

In another refinement of the embodiment the first and/or second wall is manufactured from a material that may be sterilized for reuse.

In another refinement of the embodiment the first and/or second wall is a plastic.

In another refinement of the embodiment the first and/or second wall is a composite.

Another embodiment of the present invention is an apparatus for treating a tumor location in a breast including a first shell having an interior surface defining a first chamber sized to encompass at least a portion of the breast. At least a portion of the shell defines a spherical portion having a center. At least a portion of the first chamber is filled with a fluid having an electron density substantially similar to breast tissue. The apparatus further includes tension and compressive means for stabilizing the breast within the first shell.

In another refinement of the embodiment the portion of the first shell is substantially hemispherically shaped.

In another refinement of the embodiment an edge of the shell includes an adhesive for attaching the shell to the breast in a substantially fluid tight fashion.

In another refinement of the embodiment the adhesive is a replaceable tape.

In another refinement of the embodiment an edge of the shell includes molding shaped to overlay an area around the breast.

Another refinement of the embodiment includes a second shell having an internal surface defining a second chamber. The second shell includes a spherical portion around a second center, and the first chamber is smaller than and positioned substantially within the second chamber. The second chamber is movable with respect to the first chamber to position the second center to overlap the tumor location.

Another refinement of the embodiment includes the fluid at least partially filling the second chamber.

In another refinement of the embodiment the means for stabilizing the breast within the first chamber is a reduced pressure environment generated by a pump fluidly connected to the first chamber by a conduit connected to a first port in the first shell. The conduit passes through a second port in the second shell.

In another refinement of the embodiment the shell defines a port.

Another refinement of the embodiment includes a valve in the port of the shell.

In another refinement of the embodiment the first and/or second wall is manufactured from a material that may be sterilized for reuse.

In another refinement of the embodiment the first and/or second wall is a plastic.

In another refinement of the embodiment the first and/or second wall is a composite.
Another embodiment of the present invention is an apparatus for stabilizing a breast during an imaging or interventional procedure. The apparatus includes a chest plate and an adjustable arm having a first portion attached to the chest plate, and a second portion attached to a patient platform. The arm is movable from a first position to a second position in which the chest plate exerts pressure on a patient. In another refinement of the embodiment the chest plate is shaped to contour to at least a portion of the human female anterolateral chest. The chest plate defines an opening through which the breast may protrude.

In another refinement the embodiment further includes a chamber for providing a reduced pressure environment. An air tight seal is present between a first side of the chest plate and the chamber.

In another refinement of the embodiment the arm is attached to the patient platform by at least one hinge. In another refinement the embodiment further includes at least one inflatable bladder attached to a second side of the chest plate.

In another refinement the embodiment further includes a plurality of inflatable bladders attached to a second side of the chest plate. In another refinement the embodiment further includes instrumentation for measuring the pressure in at least one of the inflatable bladders. In another refinement the embodiment further includes instrumentation for monitoring the compressive force exerted by the chest plate against the patient. The instrumentation may be in communication with any of the patient, the chest plate, one or more inflatable bladders, the arm, and/or the coupling between the arm and the patient support or robotic couch.

In another refinement of the embodiment the chest plate includes a plurality of attached segments. In one aspect, at least some of the segments are adjustable with respect to adjacent segments.

In another refinement of the embodiment a first side of each segment is attached to a chamber for providing a reduced pressure environment. An air tight seal is present between the first side of the chest plate and the chamber.

In another refinement of the embodiment a second side of each segment includes a damper attached thereto.

In another refinement of the embodiment the damper is an inflatable bladder. In another refinement the embodiment further includes padding. In one aspect, the padding is located between the patient and the chest plate. In another aspect, the padding is between the patient and the patient support or robotic couch. The padding and/or bladders may be custom fitted to a patient.

Alternatively, the padding and/or bladders may be designed or configured for a specific patient configuration or combination of an arm, a chest plate and a robotic couch.
Another embodiment of the present invention is an apparatus for fixation of a patient's breast. The apparatus includes a chest plate shaped to at least partially conform to the anterolateral chest of a human mammal, a chamber affixed with an airtight seal to the chest plate, and a rigid member connecting the chest plate to a platform upon which a patient may lay. The member may translate from a first relaxed position to a second compressive position. In one aspect, the member translates from a first or no contact patient position into a second or patient contacting position. In the second position, the arm and chest plate are positioned to provide compressive forces to at least a portion of the chest of the patient receiving treatment using a device secured to the patient using the arm and chest plate.

Another embodiment of the present invention is a method for stabilizing the breast for an imaging or interventional procedure. The method includes positioning a chest plate with an opening so that the breast protrudes through the opening into a chamber attached to the chest plate by an airtight seal. The method further includes reducing the pressure in the chamber while pressing the chest plate against the patient.

In one aspect, the tension/compression breast stabilization apparatus or treatment support includes a chest plate contoured to conform at least partially to the shape of a female human chest; an opening in the chest plate sized to allow passage of a female human breast; a chamber coupled to the chest plate so that the interior of the chamber is over the opening in the chest plate; a treatment platform; and an arm connected to the chest plate and moveably coupled to the patient support. In one alternative, the chamber interior is has a generally hemispherical shape. In another alternative, the chamber interior is sized to envelop a breast within the opening. In one aspect, there is a shaped padding on the surface of the treatment platform that at least partially conforms to a body portion of a patient fitted to the chest plate. In another aspect, there is a fluid tight seal between the chamber and the chest plate. In other aspects, the arm at least partially encircles the chest plate or at least partially encircles the chamber. In still other aspects, there is a second arm connected to the chest plate and moveably coupled to the patient support.

In still other variations, there is a damper attached to the chest plate. In one aspect, the damper is a bladder, or a bladder is filled with a fluid. There may also be provided a pump connected to the interior of the bladder configured to adjust the amount of fluid inside the bladder. In addition, there may be a gauge connected to measure the pressure within the bladder.

In one embodiment, moveably coupled includes rotation about a hinge that joins the arm to the patient support. In another embodiment, moveably coupled includes sliding the arm relative to the patient support to adjust the spacing between the chamber and the patient support. In still another aspect, the arm is coupled to the treatment table or robotic couch using a sliding or lift arrangement. In an embodiment using a sliding or lifting arrangement, a pneumatic cylinder, a pulley, a rack and pinion or other suitable mechanical or electromechanical linkage or system may be provided to adjust the position and orientation of the arm relative to the treatment table or robotic couch.
In still another aspect, the patient support is a robotic couch having a robotic
coupling configured to mate securely to a computer controller robotic patient positioning system. In this
embodiment, the tension/compression breast stabilization apparatus would be coupled to a patient table
using any suitable means, including a dual coupler system. The patient table is part of a computer
controlled patient positioning system that uses a robot to maneuver the patient table to allow a patient on
the patient table to be measured, diagnosed or treated with therapy.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 illustrates a side cross-sectional view of one embodiment of a breast fixation apparatus
encompassing at least a portion of a breast having a tumor.

FIG. 2 illustrates a side cross-sectional view of the embodiment of a breast fixation apparatus of
FIG. 1 in which the spherical portion of the fixation apparatus is centered on a tumor mass location in a
different location within the breast.

FIG. 3 illustrates a top view of a fixation apparatus of the present invention
enclosing a breast with a tumor.

FIG. 4 illustrates a side view of a treatment apparatus of the present invention.

FIG. 5 illustrates a side cross-sectional view of an inner chamber of a multi-
chamber fixation and treatment apparatus of the present invention.

FIG. 6 illustrates a side cross-sectional view of the inner chamber and outer chamber of a multi-
chamber fixation and treatment apparatus of the present invention.

FIG. 7 illustrates a top view of a compressive/tensive fixation apparatus of the present invention
enclosing a breast.

FIG. 8 is an end view of a compressive/tensive fixation apparatus of the present invention
enclosing a breast.

FIG. 9 is a top perspective view of a patient laying on a beam treatment platform with the breast
stabilized by an embodiment of the present invention.

FIG. 10 is an end view of a compressive/tensive fixation apparatus of the present invention
enclosing a breast.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be
used to describe the same. It will nevertheless be understood that no limitation of the scope of the
invention is thereby intended, such alterations and further modifications in the illustrated device, and such
further applications of the principles of the invention as illustrated herein being contemplated as would
normally occur to one skilled in the art to which the invention relates.

As previously noted, the current standard of care for treatment of breast cancer
includes anesthesia, surgery, lymphatic tracing and sampling, along with post operative radiation therapy
of part, or all, of the breast. Thus, at present, a patient who develops breast cancer has no choice but to
accept scarring and deformity of the breast - or to have the breast removed entirely. The present invention
is a novel method and apparatus to treat breast cancers (particularly early-stage breast cancers) using
protons, or other heavy ion particle beams. As used herein, the term "particle beam" includes those
particle beams that have undergone testing and/or clinical evaluation such as protons, carbon, pions or pi
mesons, helium (alpha particles), neon, iron and even anti-matter in the form of anti-protons.

[00075] Particle beam radiotherapy has shown superior dose distribution in tissues, and
provides new opportunities for the treatment of breast cancer. Partial breast radiation has shown
increasing promise in the treatment of early stage cancer, thus particle therapy appears to be a feasible
approach. Many variations in technique along with different fractionation schedules are possible. The
approach of the present invention could provide for shorter treatment times and better cosmetic results,
and could prove to be more cost effective as well. One challenge for radiation of the breast has been
reproducibly immobilizing the breast for treatment planning and proper targeting. In addition, high skin
dosage represents another challenge. Various embodiments of the present invention provide for improved
treatment options.

[00076] The methods and apparatus of the present application are preferably used in
conjunction with a proton or carbon particle beam. While other particle beams might at present hint at
better clinical results (such as anti-protons), cost constraints in the production or use of other particle
beams might preclude their widespread usage. Results from proton and carbon beam treatments for
cancers, such as ophthalmic melanomas, head and neck tumors, chordomas, and, recently, prostate and
lung cancers are very encouraging. Particle beam treatments have the ability to provide tumoricidal
dosage within tissues with millimeter geometric accuracy along with precision dosage accuracy while
sparing surrounding normal tissues. Given existing economic tradeoffs, proton beams are presently
preferred. However, the usage of other particle beams is contemplated as within the scope of the invention
unless specifically claimed otherwise herein.

[00077] Recent developments in breast conserving therapies have validated a number of
principles. By removing the tumor mass along with a rim of normal tissue, and including the tumor bed
and all or part of the breast in the radiation field local control similar to that with mastectomy is often
achieved. Conserving the breast has many physical and psychological advantages. However, present
multi-modality approaches often take a long time to accomplish and are very expensive. Other ablative
techniques (examples include RF ablation, and hypothermia or hyperthermia probes) have proven
inadequate for local control.

[00078] Image acquisition and/or treatment planning preferably include stabilization of
the breast. In one embodiment of the present invention, such stabilization of the breast is accomplished
using a means for stabilizing the breast, such as a breast fixation apparatus. Examples of such a breast
fixation apparatus are described in U.S. Patent No. 6,254,614, entitled "DEVICE AND METHOD FOR
IMPROVED DIAGNOSIS AND TREATMENT OF CANCER," that issued on 3 July 2001, and U.S.
with particle beams" filed on December 16, 2009, the contents of each of these is incorporated herein by reference. While other apparatus and methods for stabilizing the breast are contemplated as within the scope of the invention (as further discussed below), the various embodiments of the present invention described and illustrated herein will focus on this preferred mechanism. Namely, the preferred breast fixation apparatus stabilizes the breast in space by providing a reduced pressure environment around the breast. Stabilizing the breast in space allows reproducible positioning, and permits determination and recordation of various data sets concerning, for example, tumor mass location, using imaging techniques. In one embodiment, imaging is preferably done using a combination of CT and 3-D ultrasound. This allows for precise fusion of data with options for better clarification of tissue characteristics.

[00079] The current standard of care involves surgical intervention (with associated anesthesia, incision site(s), etc.) with post-operative radiation therapy. As discussed below, in view of the current standard of care it is assumed that early applications will be those in which the radiation therapy is either supplemented or replaced by particle beam therapy according to the methods and apparatus of the present invention. That is to say, a tumor is at least partially, but preferably entirely, surgically excised from the breast followed by particle beam therapy. Additionally, the methods and apparatus of the present invention might find use as a pre-operative form of therapy.

[00080] Unlike photon treatment (such as x-rays and gamma rays) some particle beams penetrate a known distance into tissue. Therefore, they are often used to treat cancers located on the surface of or below the skin. As an example, in proton particle beam therapy, protons deposit their energy over a very small area, which is called the Bragg peak. The Bragg peak can be used to target high doses of proton beam therapy to a tumor while doing less damage to normal tissues in front of and behind the tumor. Thus, it is contemplated as within the scope of the invention that clinical results might eventually result in evolution of the standard of care to permit omission of surgical intervention, and treatment of breast cancers, particularly early stage breast cancers, solely by particle beaming. That is to say, clinical success might be achieved with particle beam therapy alone, and obviate the need for surgery. Consequently, it is contemplated as within the scope of the invention that applications of one or more embodiments of the present invention will preferably eventually be used without the need for anesthesia, surgery and/or post-operative (internal or external) radiation treatments. It should be understood, however, that it is also contemplated as within the scope of the invention that the methods and apparatus of the present invention might be used in conjunction with anesthesia, surgery or post-operative radiation. However, various applications of at least some embodiments of the present invention present the possibility of treating early-stage breast cancer more cheaply possibly in a single session leaving minimal scarring (or no scar at all) on the exterior of the breast.

[00081] Various embodiments of the present invention are contemplated for use with or without surgical intervention. Thus, as used herein, the term "tumor mass location" is intended to be construed broadly. It should be understood that the term tumor mass location might refer to the location of an existing tumor mass within the body. However, it should further be understood that as used herein a tumor mass location is present even in those instances in which particle beam therapy is preceded by
surgical intervention in which the tumor mass is partially and/or entirely excised. Even after, for example, a lumpectomy removal of cells, the location of the resultant cavity (that fills with fluid and shrinks and closes after the surgery) is considered the tumor mass location. Similarly, when referring to or claiming herein treatment of a breast cancer tumor, it is contemplated as within the scope of the invention that such refers to treatment of the location of an existing tumor or to the location at which a tumor was thought present prior to surgical intervention.

[00082] With reference to Figure 1, there are illustrated aspects of one embodiment of the present invention. The exterior surface 110 of a breast 100 of a patient having a tumor mass location 105 requiring treatment is placed at least partially (and, as illustrated in FIG. 1, preferably entirely) within a fixation apparatus 120. The breast fixation apparatus 120 preferably includes at least one port 125 connected to a pump 130 by a conduit 123. The conduit 123 or the breast fixation apparatus 120 preferably includes a valve at port 125. The presence of such a valve in conjunction with use of a conduit 123 that is detachable from the port 125 permits the pump 125 to reduce the pressure within, and then the valve is closed and conduit 123 can be removed. Thus, the apparatus still attached to the patient during imaging and/or interventional procedures is minimized. Aspects such as a closable valve and removable conduit (and pump) are preferable, but not necessary, in this embodiment (as well as embodiments discussed below that further include a second outer chamber that encompasses at least a portion of the inner chamber). As will be discussed below, only the inner chamber need include a reduced pressure environment. Additionally, fixation apparatus 120 might be pressed against the body by a strap or band (not illustrated) that extends around the patient to be tied, or tightened similar to a belt. Alternatively, the fixation apparatus might be constructed as part of a bra-like apparatus for retention on the patient's chest and breast(s).

[00083] In one embodiment, the cup-like fixation apparatus 120 is preferably at least partially spherical (the portion of apparatus 120 in FIG. 1 that lies below the imaginary line 119 that passes through the center 135 of the spherical portion). In one refinement of such an embodiment, the fixation apparatus 120 preferably includes a substantially rigid plastic spherical portion with an outer surface 121 and an inner surface 122. The plastic (or composite) is preferably substantially transparent to the particular imaging modality (or modalities) used. An internal cavity 124 exists between the inner surface 122 of fixation device and the exterior surface 110 of the breast 100. The cavity 124 is preferably filled with fluid 150. Aspects of fluid 150 are discussed further below.

[00084] As illustrated in Figure 1, the center 135 of the spherical portion of fixation apparatus 120 is preferably at the center, or substantially overlaps the center, of the tumor mass location 105. It should be understood that a tumor mass location is not necessarily a symmetrical volume, and thus the concept of a center for the tumor mass location is broader than the typical geometrical concept of a center of a circular area or spherical volume. The center of the tumor mass location will be selected to maximize the energy dose delivered by the incident particle beam to potentially cancerous cells while minimizing the dose received by healthy surrounding tissue. The energy dose resulting from the particle beam, however, is typically modeled as a spherical volume with smaller dosages received the further the
distance from the isocenter of the particle beam. It should further be understood that an oddly shaped
tumor mass location might be treated as having more than one center to subject to treatment by particle
beam therapy. In other words, multiple overlapping spheres of smaller radius resulting from the particle
beam energy dose might be preferred to a single sphere of a larger radius.

[00085] With reference to FIG. 2, wherein like elements are labeled as previously
described, a particle beam 140 is directed at the tumor mass location 105 along a single trajectory
designated by the lines making up rectangle 155. Particle beam 140 is aimed at the center 135 (see FIG.
1) of the spherical portion of fixation apparatus 120, and the particles are intended to have a penetration
depth that extends to that center with a maximum energy dose release in a substantially spherical volume
157 within breast 100. Particles that travel a trajectory normal to the surface of the spherical portion of the
fixation apparatus 120 have an equal path of electron density to the center of the hemisphere. This is
because the spherical volume traversed by the particle beam preferably includes either breast tissue or
fluid 150. The fluid 150 acts as a compensator to allow delivery of spread-out Bragg peak energies
precisely to the tumor mass location 105 and to a precise margin (volume 157 of FIG. 2) of the
surrounding tissues. In one refinement of this embodiment, this is accomplished by placing the tumor
center (preferably tagged with a fiducial marker during surgery) at the center of the sphere created by the
fixation device. The fixation, apparatus retains within it the electron-isodense fluid medium and the breast
tissue itself. By creating an "anatomy of advantage," it is possible to deliver uniform dosage - due to
substantially identical path radii to the center of the spherical portion. Fluid 150 is preferably a fat
equivalent fluid (such as water) that has an electron density substantially similar to that of the breast. As
used herein, fluid is intended to encompass both liquids and gels, it being understood that a gel is
contemplated as within the scope of the invention for filling the interior volume of the chamber (or
chambers as in below described embodiments) surrounding the breast.

[00086] The fluid 150 within volume 124 of fixation apparatus 120 is preferably held at a
slightly reduced pressure to expand the breast 100 to its structural envelope. It should be understood that
fluid 150 only needs to be present in the portion of volume 124 that is below the imaginary line 119 that
partially delineates the spherical portion of fixation apparatus. However, fluid 150 might fill the entire
cavity between the exterior surface 110 of breast 100 (and the chest wall) and internal surface 122 of
fixation apparatus 120. Air is pumped out of the internal cavity 124 through port 125 by pump 130. The
fluid 150 preferably replaces the air as it is pumped out, but might be pumped in before or after pumping
out the air. For patient comfort, the fluid 150 is preferably first heated to approximately body temperature.

[00087] Creating the reduced pressure environment requires a substantially fluid tight seal
between the rim of the fixation apparatus 120 and the patient's body. As illustrated in FIG. 1, the rim
might include patient specific molding 128 that is shaped to conform to the chest of the patient's body,
and to provide a fluid tight seal. It should be understood, however, that it is contemplated as within the
scope of the invention that the rim of the fixation apparatus may be attached entirely to the chest, entirely
to the breast, or to some combination of the chest and breast.
Once a tissue diagnosis is established, fiducial markers are positioned to identify a location relative to, and preferably substantially at or near to the center of the tumor mass location. An example includes, but is not limited to, clips left in place during surgical excision of the tumor mass. The fiducial markers might be positioned within the breast at the tumor mass location. Alternatively, the fiducial markers for identifying the tumor mass location might be positioned on the skin of the breast. Treatment planning with a particle beam also includes determination of the isocenter of treatment and the dose. As used herein, the term isocenter is the position at which there is a maximum of the energy dose delivered by the particle beam.

With reference to FIG. 3, wherein like reference numerals are used as in FIG. 1, the isocenter of the treatment preferably is at the center of the tumor mass location 105. The breast 100 is placed in a reduced pressure environment within fixation apparatus 120. The reduced pressure environment is preferably filled with a fat equivalent fluid 150. In one application a first particle beam 185 is applied with an isocenter that overlaps the tumor mass location 105. The patient is then rotated (as indicated by the arrows 186), with the beam off, and a second particle beam 195 is applied having an isocenter that overlaps the tumor mass location 105, preferably at the same position as the first particle beam. Both the particle beam 185 and the particle beam 195 travel substantially identical path radii (labeled as distance X in FIG. 3) to the center of the spherical. Alternatively, the particle beam could be on the entire time during patient rotation and scan across the surface of the breast while being aimed or directed (having an isocenter) at the tumor mass location 105. The dose will preferably include a tumoricidal sphere 200 around the tumor 105, and a larger sphere 220 of lesser dosage.

As illustrated in FIG. 4, in one embodiment treatment is provided to the breast using the breast fixation apparatus. The patient is preferably in a prone position, so that the isocenter 305 overlaps the center of a spherical portion 300 projecting below the movable treatment platform 400. The cavity 324 within the spherical portion will be filled with a fluid 350 whose electron density is similar or identical to that of the breast tissue. The same reduced pressure environment preferably exists within cavity 324 as used for imaging and/or treatment planning. This provides a compensator for the path of the particle beam, which, in fact, converts any size and shape of breast into a substantially spherical shape along a range of potential trajectories. Such a compensator allows more straightforward beam energy calculations and equidistance to the tumor mass location from any point on the outer surface 321 of the breast fixation apparatus 320.

With the treatment plan determined, and the tumor securely placed at the center of the spherical portion of the breast fixation apparatus, treatment preferably proceeds with a low-angle gantry trajectory aimed at the isocenter. At this position, using a robotic arm 450 controlling the treatment platform 400, the patient will be rotated (as indicated by arrow 460) around the isocenter with the beam on. This will smears the skin dosage around the breast and allow for simple changes of gantry angle to allow multiple arcs of treatment. Due to the forced symmetry with the fluid compensator, the patient may be spun about the isocenter (that overlaps the tumor mass location) preferably with a beam of constant energy. The gantry angle may be changed and the same patient motion from before may be used.
However, it should be understood that tumors of irregular shape might preferably be subject to beam energies of greater energy along select entry angles into the breast. Also, tumors of irregular shape might instead, or in addition, require beaming more than one center of a tumor mass location.

[00092] One embodiment of the apparatus allows for improved placement of the tumor at the center of a "sphere" using two chambers as illustrated in FIGS. 5-6. The inner chamber of the device is filled with electron isodense fluid and provides negative pressure to stabilize the breast. The larger outer chamber is preferably filled with the same isodense fluid. The outer chamber can be moved around the smaller inner chamber so the tumor can be centered within the larger (outer) chamber, without making adjustments in the position of the tumor - without moving the breast (or the patient). Thus, FIGS. 5-6 illustrate aspects of a dual chamber apparatus for fixation and treatment of a breast. FIG. 5 illustrates an inner chamber 520 of an embodiment that could allow for improved placement of the tumor at the center of the outer chamber 620. Briefly, the breast 500 is enclosed within an inner chamber 520. Inner chamber 520 may be hemispherical or other shape. As illustrated in FIG. 5, inner chamber 520 is a cylindrical chamber. Outer chamber 620 (see FIG. 6) is positioned so that the tumor 505 is at the center of the larger outer chamber 620 around the inner chamber 520, the latter being fixed to the patient.

[00093] With reference to Figure 5, the exterior surface 510 of a breast 500 of a patient having a tumor mass location 505 requiring treatment is placed at least partially (and, as illustrated in FIG. 5, preferably entirely) within a fixation apparatus 520. The breast fixation apparatus 520 preferably includes at least one port 525 connected to a pump 530 by a conduit 523. The conduit 523 or the breast fixation apparatus 520 preferably includes a valve at port 525. Only the inner chamber need include a reduced pressure environment (or other means for stabilizing the breast).

[00094] The fixation apparatus 520 as illustrated is cylindrical, but other shapes (including an at least partially spherical shape) are contemplated as within the scope of the invention. The fixation apparatus 520 preferably includes a substantially rigid plastic portion with an outer surface 521 and an inner surface 522. The plastic (or composite) is preferably substantially transparent to the particular imaging modality (or modalities) used. An internal cavity 524 exists between the inner surface 522 of fixation device and the exterior surface 510 of the breast 500. The cavity 524 is preferably filled with fluid 550. The properties of fluid 550 are identical to previously described fluid 150. The centerline axis of the cylindrical fixation apparatus 520 includes a point 535 that is preferably, but not necessarily, at the center, or substantially overlaps the center, of the tumor mass location 505. However, it should be understood that while such is preferred in a single chamber embodiment, in the dual chamber embodiment the positioning of the inner chamber 520 with respect to the tumor mass location is not of particular importance. The inner chamber 520 should be positioned to provide a reduced pressure environment around the breast 500 (or to otherwise accommodate some other form of means for stabilizing the position of the breast).

[00095] With reference to FIG. 6, wherein like elements are labeled as previously described, particle beam 685 is directed at the tumor mass location 505 along a first trajectory. Particle beam 685 is aimed at the center 505 of the spherical portion of outer chamber 620, and the particles are
intended to have a penetration depth that extends to that center with a maximum energy dose release in a spherical volume within breast 500. Particles that travel a trajectory normal to the surface of the spherical portion of the outer chamber 620 have an equal path of electron density to the center of the spherical portion. This is because the spherical volume traversed by the particle beam preferably includes either breast tissue or fluid 550. The fluid 550 also at least partially fills the volume between the interior surface 622 of outer chamber 620 and exterior surface 521 of inner chamber 520. The fluid 550 acts as a compensator to allow delivery of spread-out Bragg peak energies precisely to the tumor mass location 505 and to a precise margin of the surrounding tissues. The dual chamber apparatus retains within it the electron-isodense fluid medium and the breast tissue itself. Again, by creating an "anatomy of advantage," it is possible to deliver uniform dosage due to substantially identical path radii to the center of the spherical portion.

The fluid 550 within volume 524 of fixation apparatus 520 is preferably held at a slightly reduced pressure to expand the breast 500 to its structural envelope. Air is pumped out of the internal cavity 524 through port 525 fluidly connected by conduit 523 to pump 620. Conduit 523 also passes through a similar port 625 in the wall defining outer chamber 620. Creating the reduced pressure environment requires a substantially fluid tight seal between the rim of the fixation apparatus 520 and the patient's body. As illustrated in FIGs. 5-6, the rim might include patient specific molding 528 that is shaped to conform to the chest of the patient's body, and to provide a fluid tight seal. It should be understood, however, that it is contemplated as within the scope of the invention that the rim of the fixation apparatus may be attached entirely to the chest, entirely to the breast, or to some combination of the chest and breast.

FIG. 6 illustrates how the double chamber embodiment can be rotated around the center of the outer chamber 620 for application of particle beam(s). The center of the at least partially spherical outer chamber 620 at least partially overlaps the center 505 of the tumor mass location. The reduced pressure environment is provided by the inner chamber 520. Adjustments to the outer chamber 620, however, can be made in a more straightforward manner by moving only the outer chamber 620, leaving the patient, and the inner chamber apparatus in contact with the patient, stationary.

With reference to FIG. 6, wherein like reference numerals are used as in FIG. 5, the isocenter of the treatment preferably is at the center of the tumor mass location 505. The breast 500 is placed in a reduced pressure environment within inner chamber 520. The inner chamber 520 and outer chamber 620 are both at least partially filled with a fat equivalent fluid 550. In one application a first particle beam 685 is applied with an isocenter that overlaps the tumor mass location 505. The patient is then rotated (with the beam off), and a second particle beam 695 is applied having an isocenter that overlaps the tumor mass location 505, preferably at the same position as the first particle beam 785. Both the particle beam 685 and the particle beam 695 travel substantially identical path radii (labeled as distance Y in FIG. 6) to the center of the spherical portion of the outer chamber 600. Alternatively, the particle beam could be on the entire time during patient rotation and scan across the surface of the breast.
while being aimed or directed (having an isocenter) at the tumor mass location 505. The dose will preferably include a tumoricidal sphere around the tumor 505, and a larger sphere of lesser dosage.

It should be understood that relative movement (primarily rotation) between the tumor mass location of the patient laying prone on a treatment platform and the beam preferably occurs by rotation of the patient via translation of the treatment platform. It is contemplated as within the scope of the invention, however, that the patient/breast remains stationary and the breast is beamed from different angles by moving the beam source. Regardless of the mechanism by which the beam's trajectory into the breast and toward the tumor mass location is altered, a preferred implementation of the present invention is a skin-sparing treatment in which the dose to the skin of the breast is spread out. Minimizing of external scarring and skin damage to the breast is considered an important psychological facet to patient treatment. Leaving aside the physiological preference for spreading the dose around the breast to minimize the damage to any given portion of the skin (and underlying tissue between the skin and the tumor mass location), such psychological factors are often of critical importance to patients.

One potential treatment aspect of the present invention entails moving the patient (spinning around the center) during beam-on treatment so that the dose to skin (and other surrounding tissue) is spread out. This geometric dispersion allows for skin-sparing while concentrating the energy via a beam isocenter that overlaps the tumor mass location. Additionally, other treatment aspects of the present invention can be implemented to achieve similar ends. It should be understood that the angles selected for beaming do not require rotation around the full circumference of a circle on the exterior surface of the substantially spherical shape surrounding the breast. Such angles might be selected based on cosmetic effect (i.e. minimize the dosage on the more readily visible top half of the breast when the patient is standing). Thus, in another aspect of the present invention, the patient is not rotated around a circumference, but only around an arc. In a variation of this aspect, even if rotation occurs around an entire circumference, the beam may be turned off during portions of that rotation. For example, the beam might be off when it would otherwise be scanning across the top side of the breast.

In another potential treatment aspect of the present invention, beaming of the breast occurs only along select trajectories, or the beam is only on at select time intervals during scanning of the same around one or more circumferences or arcs on the spherical (including, but not limited to, hemispherical) portion of the chamber enclosing the breast. This is considered desirable as part of an integrated approach to treatment. Namely, some physicians might consider it preferable to avoid beaming that intersects existing wound sites in the form of incisions from past surgical intervention. Thus, in lieu of a more extended period of time in which the patient recovers from such surgical intervention, particle beam therapy might be implemented sooner after surgical intervention. Additionally, more integrated patient therapy might involve planning particle beam therapy to avoid beaming planned future incisions expected to be made in upcoming surgical intervention. Similarly, depending on physician preference, particle beam therapy might be planned in order to beam along or overlap, for example, a biopsy track, on the assumption that cancerous cells might have drifted from the tumor mass location along that track, so that beaming along or overlapping the biopsy track is preferred.
In another embodiment of the present invention the apparatus for treating the breast includes an inner chamber encompassing at least a portion of the breast as illustrated in FIG. 5. The breast is positioned at least partially, and preferably entirely, within an internal volume of the inner chamber. The inner chamber is positioned within an internal volume of an outer chamber. Both the inner chamber and the outer chamber (as illustrated in FIG. 6) are preferably at least partially filled with a fluid having an electron density substantially similar to that of the breast.

Both the inner and outer chambers are preferably, but not necessarily, at least partially spherically shaped. For example, FIG. 1 illustrates a first chamber at least a portion of which has a hemispherical shape. Similarly, FIG. 6 illustrates an outer chamber at least a portion of which has a spherical shape. However, it should be understood that it is contemplated as within the scope of the invention that portions of either or both of the inner and outer chambers might have other shapes. For example, if only radial particle beaming were desired, then either or both of the inner and/or outer chambers might be cylindrically shaped. Those of ordinary skill in the art will understand that it is of greater importance that the shape of the outer chamber be controlled. The shape of the inner chamber is of lesser importance, except as might pertain to shaping the same to insure that it is better secured to the patient. That is to say, insuring equivalent particle path lengths for the particle beam can be controlled by having a substantially spherical (or cylindrical) outer chamber in combination with an inner chamber whose shape need only be determined based on other considerations. Such other considerations include enclosing the breast, being at least partially filled with a fat equivalent fluid, being secured to the patient, and fitting within the outer chamber. In other words, the outer chamber should be positioned so that the tumor mass location is at the center of the spherical portion of the outer chamber. The shape of the inner chamber in a multi-chamber embodiment is not as important to the issue of substantially identical path length of the particle beam (as the beam and breast are shifted relative to one another). Additionally, only portions of the outer chamber need be spherically shaped, those portions preferably comprising the appropriate trajectories for particle beaming. In other words, it is contemplated as within the scope of the invention that only some portion (whether it be an arc, or a circumference of a circle on the outer surface of a sphere) of the outer chamber need include a spherical shape (circular or other shape that has circumferential arcs in a cylindrical embodiment). Additionally, the outer chamber might include more than one spherical portion, and such spherical portions need not be contiguous, though each preferably will have the same center. In yet another embodiment in which multiple tumor mass location “centers” are beamed, the non-contiguous spherical portions of the outer chamber might have different centers.

Furthermore, it should be understood that in the embodiments including multiple chambers, preferably only the inner chamber includes a reduced pressure environment (or other means for stabilizing the breast in space). Thus, the only fluid tight seal that needs to be present (in reduced pressure embodiments) is between the inner chamber and the patient's body (whether to the chest wall, the breast, or some combination of both). Since the patient is preferably lying prone no fluid tight seal is necessary for the outer chamber, the inner chamber with the breast positioned therein simply being dipped into the at least partially fluid filled outer chamber.
Various applications of the present invention were discussed above in conjunction with embodiments of the breast fixation apparatus disclosed in U.S. 6,254,614. However, those of ordinary skill in the art will recognize that the present invention will also find use with other breast fixation apparatus. Various embodiments herein have been described in which stabilization of the breast is accomplished by creating a reduced pressure environment around the breast. Those of ordinary skill in the art will understand that other embodiments of stabilizing the breast are contemplated as within the scope of the invention.

It should further be understood that other forms of stabilizing the breast using tension are contemplated as within the scope of the invention. For example, the inner chamber might be attached (via adhesive, for example) to the breast at a plurality of contact points that might be pulled substantially radially outward to draw the breast outward, that tension fixing the breast in space. Such tension based stabilization of the breast is preferred to fixation through, for example, two or more plates that apply pressure to the breast.

In another example, a self-sucking kind of device could pull the breast into a cup mold of a hemisphere. Such might be accomplished by fixing the breast using a liquid or gel that solidified into the desired at least partially spherical shape. Various other embodiments along these lines might omit the reduced pressure environment and/or breast fixation apparatus as disclosed in U.S. 6,254,614. Some examples of such embodiments might include plates or other grasping mechanisms for fixing the breast in space. However, the presently preferred embodiment uses a medium surrounding the breast that is fluid and adjustable. As discussed in U.S. Patent No. 6,254,614 increased pressure might cause cancer cells to pass through the lymph system more rapidly, thus increasing the possibility that the cancer might spread to other portions of the body. Despite such potential issues, it should be understood that pressure based systems for fixation of the breast in space are contemplated as within the scope of the invention. However, such a method for fixation of the breast is less preferred than the reduced pressure environment previously described. As an example, fixation apparatus that involve actual contact with the breast will interpose objects along at least some beam paths to the tumor mass location. The presence of such objects alters the particle path length for those trajectories that intersect such objects. This makes it more difficult to continuously scan along all possible arcs or circumferences of circles of the substantially spherical portion of the chamber that retains therein the fluid having a electron density substantially the same as the breast.

As previously noted, in one embodiment, imaging is preferably done using a combination of CT and 3-D ultrasound. It should be understood that other imaging techniques are also contemplated as within the scope of the invention. Examples of imaging techniques include Magnetic Resonance Imaging (MRI), Computerized Axial Tomography (CT) [including, but not limited to, cone beam CT], 3-D radial and standard ultrasound, Positron Emission Tomography (PET) scanning, radial and other x-rays, RF targeting with fiducial markers, radio guided imaging (for example, in conjunction with a radioactive seed for localizing the tumor), and other techniques (or combinations thereof) known to those of ordinary skill in the art. Imaging might also be accomplished in conjunction with more invasive
procedures, such as via a catheter inserted into the breast with a target for an infra-red imaging system. Such imaging modalities can be registered, integrated and presented for optimal treatment planning.

[000109] At least some of the embodiments discussed herein preferably include breast fixation, positioning, verification, and targeting allowing for rotational accuracy in time, speed and duration. Beam energies can be applied in a number of configurations and trajectories, and, as previously mentioned, might be applied to more than one tumor mass location center within the breast as an isocenter. Complete adjustment capability during the entirety of beam transfer is preferred, with multiple safety stops to minimize or prevent patient harm.

[000110] The methods and apparatus of the present application are preferably used on patients in a prone position. However, use in a supine or other position is also contemplated as within the scope of the invention. The prone position, however, is more preferred.

[000111] Various embodiments of the methods and apparatus of the present invention should allow for low numbers of treatment fractions and, therefore, lower cost and potentially improved cosmetic effect. As one non-limiting example that was previously discussed, the apparatus and method stabilizes the breast and provides equal radial beam distances to the tumor. In essence, the anatomy of the breast is transformed to a near perfect sphere using an electron isodense fluid around the breast with the tumor centrally placed at the center of the spherical portion of the chamber. This arrangement makes treatment planning and execution much simpler. In addition, this device and technique allows for "arc treatment" of the tumor caused by rotating the patient around the isocenter with the beam on - allowing for a spreading of the entrance dose to the skin over a larger area and allowing for higher dosages to be used in a shorter time.

[000112] As should be apparent from the discussion above, accurate, reproducible positioning and immobilization of the breast is an increasingly important issue as methods for diagnosis and treatment of breast cancer becomes more sophisticated. The above described embodiments relate to novel methods for stabilization of the breast by equal negative pressure applied within a negative pressure chamber positioned around the breast. The description that follows pertains to additional embodiments for improved immobilization of the breast.

[000113] Three aspects of breast deformability and motion limit the accuracy in breast immobilization. First, there is deformability of the breast. This is due to the elastic and non-rigid nature of the breast that changes the general morphology of the organ due to position and gravitational forces. Second, there is breathing. Breathing causes expansion of the chest outward, displacing the entire breast. Third, there are general body movements which can cause movement of the torso, chest wall and breast.

[000114] The previously described apparatus for providing a reduced pressure environment assists in maintaining the breast in a maximally distended position and to resist deformation due to gravity. However, unless the chamber is firmly affixed to a stable structure, the chest wall and torso can generate considerable motion of the breast as well. We now describe another embodiment of the present invention to assist in addressing the latter two of three motion concerns. Such embodiment preferably includes a firm, yet pliable chest plate. The chest plate preferably functions to provide an
airtight seal around the breast and chamber, and to spread the compressive forces smoothly across the chest wall and to allow protrusion of the breast outward into a reduced pressure environment chamber. In one preferred implementation, the chest plate is held adjacent to the body by an adjustable lever or attachment arm or arms connected to the imaging table or treatment couch. Thus, the plate can be compressed against the chest wall and thereby restrict the outward expansion of the chest from breathing while allowing air exchange by way of movements of the diaphragm and abdominal wall. Additionally, this compression restricts any movement of the torso in general, but allows free movement of one or more other body parts.

[000115] The adjustable attachment arm is adjustable is several different aspects. In one aspect, the arm is itself adjustable by, for example, the movements of several segments that together form the arm. Each of the segments may be adjusted relative to one another or in groups. In another aspect, adjustable refers to the movement of arm position relative to the treatment table or robotic couch. In this regard, the arm is movable between positions that change the relationship between the arm and the treatment table. For example, the arm may swing relative to the treatment table such as when the arm is hinged alongside or to the treatment table or robotic couch (see FIG. 7 for example). In another example, the arm may raise and lower relative to the treatment table. This type of adjustment may be provided when the arm is coupled to the treatment table or robotic couch using a sliding or lift arrangement. In an embodiment using a sliding or lifting arrangement, a pneumatic cylinder, a pulley, a rack and pinion or other suitable mechanical or electromechanical linkage or system may be provided to adjust the position and orientation of the arm relative to the treatment table or robotic couch. Here adjustable may refer to changes in the horizontal and/or vertical arrangement of the arm and robotic couch. These various aspects of the adjustable attachment arm may be used alone or in any combination in order to provide patient support and stability to address the aforementioned motion concerns. In one regard, adjustable refers to the horizontal separation of the arm second portion from the patient or the patient platform (i.e., less separation in order to provide stability and engage with the patient and more separation to disengage from the patient).

[000116] Additional variations in the implementation of a chest plate are contemplated as within the scope of the invention. For example, additional components might be included to permit further compression of the chest plate against the chest wall and to accurately calibrate and adjust the compressive force against the chest. In addition, the pressure measured can be recorded and used in subsequent treatments or measurements to ensure that the prior treatment conditions including patient placement, bladder/padding configuration as well as compressive force and negative pressure are accurately replicated through a patient's course of treatment.

[000117] As one example, there can be an air bladder or multiple interconnected bladders that are attached to a pressure gauge and to a simple hand pump, such as that used with a sphygmomanometer. These bladders might also be used as part of the sealing mechanism, as cushions to evenly apply pressure and to adjust the measured pressure of the device against the chest wall. Regardless of the particular implementation (attached to treatment couch or elsewhere, presence of bladders, etc.), as
the chest plate is compressed against the chest wall, the resulting compressive force can be measured and recorded as a treatment parameter for the patient. In addition, the compressive force applied to the subcutaneous fat of the chest wall acts to push the breast tissue further outward toward the chamber by way of extrusion. This should limit or reduce the amount of negative pressure applied to the chamber to stabilize the breast itself.

[000118] In one embodiment motion is minimized via a combination of the use of tensive (negative pressure) and compressive (from the chest plate) (positive pressure) applied differentially. The chest plate is preferably a rigid plate having the contour of the anterolateral chest. The chest plate has a hole to allow protrusion of the breast outward and into the negative pressure chamber. A lever arm connects the chest plate to the couch or treatment platform or an extension beneath the patient. Thus, the plate is compressed against the chest wall by a vice-like compression. Pneumatic bladders in and around the chest plate can be used to seal the chamber, adjust for variations in chest contour and allow for fine adjustment, (see FIGs. 8 and 10)

[000119] The chest compression will transmit no breathing motion to the breast and allow for diaphragmatic breathing primarily. The chest compression will also allow for locally restricted motion of the thorax. In addition, with increasing amounts of fat in the subcutaneous region of the chest wall, one would expect a great propulsive protrusion of the breast tissue out into the chamber (the "tooth paste" effect).

[000120] We will now generally describe aspects of an apparatus combining the use of tensive (negative pressure) and compressive (from the chest plate) (positive pressure) applied differentially. This general description will then be supplemented with further details as described with reference to Figures 7-10.

[000121] In the most basic form the tension/compression breast stabilization apparatus or treatment support will include a reduced pressure chamber attached to a chest plate. The reduced pressure chamber is preferably affixed with an airtight seal to a chest plate. The reduced pressure chamber may take the form of the illustrated embodiments, those shown or described above in FIGs. 1, 5 or 6, or any of the embodiments described in U.S. Patent No. 6,254,614, entitled "DEVICE AND METHOD FOR IMPROVED DIAGNOSIS AND TREATMENT OF CANCER," that issued on 3 July 2001, and/or U.S. Patent Application Ser. No. 12/644,970 entitled "Apparatus and Method for the Treatment of Breast Cancer with Particle Beams" filed on December 16, 2009.

[000122] At least a portion of the chest plate conforms to the shape of the anterolateral chest. The chest plate is preferably centered on the breast, with an opening allowing protrusion of the breast into the reduced pressure chamber. The chest plate is preferably composed of a single layer or multiple layers of material. The plate attaches to an adjustable positioning arm or arms. The arm or arms attach the chest plate to the treatment platform (robotic couch, imaging or interventional table, etc.) or any other adjacent or self-contained portion of the imaging or treatment assembly that serves to stabilize the arm and hence the chest plate. With simple registration marks placed on the skin of the chest and oriented with the chest plate, reproducible and accurate placement of the apparatus is assured.
In a preferred variation of the basic form of the tension/compression apparatus it further includes a plurality of dampers are positioned between the chest plate and the patient. In the embodiment of FIG. 8, the dampers are fluid filled bladders. In another example, compression air bladders might be used to cushion and conform the chest plate to the chest wall. Additionally or alternatively, the bladder may also provide an airtight seal against the skin of the chest. Additionally or alternatively, the pressure within the bladders may be adjustable so that the inflatable bladders might be used to adjust the actual, measurable pressure of the chest plate 710 against the chest wall. In addition, the size, configuration and pressure of the bladders may be documented for each patient in order to permit reproduction of the patient specific treatment environment used during imaging and/or treatment. In still another variation, padding is provided for positioning and patient comfort at locations on the torso, arms, head and neck. Padding may also be form fitted to the patient and used to aid in patient immobilization during imaging or treatment.

Referring now to Figures 7-10, further details of the present invention are illustrated therein. These figures illustrate various views of a patient 722 on a treatment platform 730 with a breast 700 positioned and immobilized by an embodiment of the tension/compression breast stabilization apparatus. There is illustrated a patient 722 has a shoulder 702, arm 704 and breast 700. Breast 700 protrudes through an opening 711 defined by chest plate 710 into a reduced pressure environment. The top end of the chest plate 710 is attached to the reduced pressure chamber 740 by a fluid tight seal. FIG. 7 illustrates an embodiment of a single arm 715 that is connected at ends 714 to a hinge 716 that is in turn connected to treatment platform or robotic couch 730. The arm 715 is shaped to at least partially encircle the chamber 740 and engage with the top surface of the chest plate 710. The arm 715 may be sized and shaped to remain within the perimeter defined by the chest plate 710. In an alternative embodiment, the arm is sized and/or shaped to extend at least partially beyond the perimeter of the chest plate 710.

FIG. 8 illustrates an embodiment of the tension/compression breast stabilization apparatus that includes a plurality of dampers are positioned between the bottom end of the chest plate 710 and the anterolateral chest of the patient 722 adjacent to the breast 700. Such dampers might be, for example, one or more fluid filled inflatable bladders 720. At least one compression arm 715 is used to press the chest plate 710 against the patient. Compression arm 715 has a first portion 712 attached to the chest plate 710 and a second portion 714 attached to the treatment platform 730. In one embodiment the lever arm 715 pivots using hinge 716. However, other mechanisms for attaching a second portion 714 (preferably an end) of the lever arm 715 are contemplated as within the scope of the invention, as are translation mechanisms other than pivoting.

As illustrated in FIG. 10, a contoured padding 780 is incorporated into or placed on the treatment platform 730. The padding 780 may provide patient comfort and/or provide immobilization or stability. It is contemplated as within the scope of the invention that similar padding positioned between the patient's arm and/or shoulder and, for example, the compression arm 715 might be
present. Additionally or alternatively, the padding 780 may only be on one side or only adjacent a portion of the patient 722 as shown in FIG. 8.

[000127] With reference to FIG. 9, there is illustrated embodiment of the tension/compression breast stabilization apparatus. The patient 722 rests upon treatment platform 930 coupled to a pole 902. The patient 722 is illustrated as undergoing beam therapy from particle beam source (not shown) delivered through a nozzle 910. The nozzle 910 is precisely aimed at the immobilized breast 700 of the patient 722. The chest plate 710 is preferably attached to the treatment platform 930 by two lever arms 911,913 that are affixed via, for example, hinges 916, 918 to the platform 930.

[000128] In still another embodiment, the treatment platform 930 is a robotic couch having a coupling mechanism configured to mate securely to a computer controller robotic patient positioning system. Additional details of this embodiment are described in U.S. Patent Application Publication No. US 2009/0070936 entitled "Patient Positioner System" filed on September 11, 2008, the entirety of which is incorporated herein by reference. In this embodiment, the tension/compression breast stabilization apparatus would be coupled to the patient table 50 using any suitable means, including the dual coupler system 52. The patient table 50 is part of the patient positioning system 20 that uses robot 22 to maneuver the patient table 50 as described in paragraphs [0040-0047] and shown in FIGs. 1, 2 and 3 of U.S. Patent Application Publication No. US 2009/0070936 which are specifically incorporated herein by reference.

[000129] As previously discussed, a number of existing imaging technologies can be used with one or more of the embodiments discussed herein for stabilization for imaging, biopsies and interventions. The images thus obtained can be used for further surgical interventions and treatment planning and targeting for treatments with ionizing radiation and particle beams. Examples include whole breast irradiation, partial breast irradiation, brachytherapy and other invasive and non-invasive ablative technologies. Reliable and reproducible immobilization of the breast opens many other opportunities for targeted diagnostics and treatments. The morbidities of inaccurate breast position and stabilization are well known, especially in dosages of radiation given to the heart and lungs in standard therapies. Thus, further precision in limiting breast motion will allow for great advances in registration and analysis of data sets from the differing imaging modes of ultrasound, X-ray and MRI.

[000130] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the inventions are desired to be protected. It should be understood that while the use of words such as preferable, preferably, preferred or more preferred utilized in the description above indicate that the feature so described may be more desirable, it nonetheless may not be necessary and embodiments lacking the same may be contemplated as within the scope of the invention, the scope being defined by the claims that follow. In reading the claims, it is intended that when words such as "a," "an," "at least one," or "at least one portion" are used there is no intention to limit the claim to only one item unless specifically stated to the contrary in the claim. When
the language "at least a portion" and/or "a portion" is used the item can include a portion and/or the entire item unless specifically stated to the contrary.
IN THE CLAIMS

1. A treatment support, comprising:

   a chest plate contoured to conform at least partially to the shape of a female human chest;
   an opening in the chest plate sized to allow passage of a female human breast;
   a chamber coupled to the chest plate so that the interior of the chamber is over the opening in the chest plate;
   a treatment platform; and
   an arm connected to the chest plate and moveably coupled to the patient support.

2. The treatment support of claim 1 wherein the chamber interior is has a generally hemispherical shape.

3. The treatment support of claim 1 wherein the chamber interior is sized to envelop a breast within the opening.

4. The treatment support of claim 1 further comprising a damper attached to the chest plate.

5. The treatment support of claim 4 wherein the damper is a bladder.

6. The treatment support of claim 5 wherein the bladder is filled with a fluid.

7. The treatment support of claim 5 further comprising a pump connected to the interior of the bladder configured to adjust the amount of fluid inside the bladder.

8. The treatment support of claim 5 further comprising a gauge connected to measure the pressure within the bladder.

9. The treatment support of claim 4 further comprising a shaped padding on the surface of the treatment platform that at least partially conforms to a body portion of a patient fitted to the chest plate.

10. The treatment support of claim 1 further comprising a fluid tight seal between the chamber and the chest plate.

11. The treatment support of claim 1 wherein the arm at least partially encircles the chest plate.

12. The treatment support of claim 1 wherein the arm at least partially encircles the chamber.
13. The treatment support of claim 1 further comprising a second arm connected to the chest plate and moveably coupled to the patient support.

14. The treatment support of claim 1 wherein moveably coupled includes rotation about a hinge that joins the arm to the patient support.

15. The treatment support of claim 1 wherein moveably coupled includes sliding the arm relative to the patient support to adjust the spacing between the chamber and the patient support.

16. The treatment support of claim 1 wherein the patient support further comprises a robotic coupling.

17. An apparatus for treating a tumor location in a breast, comprising:

10 a first wall having an interior surface defining a first chamber sized to encompass at least a portion of the breast;

tensive and compressive means for stabilizing the breast within the first chamber;

15 a second wall having an internal surface defining a second chamber, the second wall including a spherical portion around a center;

wherein the first chamber is smaller than and positioned substantially within the second chamber, and wherein the second chamber is movable with respect to the first chamber to position the center of the spherical portion to overlap the tumor location.

18. The apparatus of claim 17, wherein an edge of the first wall includes an adhesive for attaching the first wall to the breast in a substantially fluid tight fashion.

19. The apparatus of claim 18, wherein the adhesive is a replaceable tape.

20. The apparatus of claim 17, wherein the spherical portion of the second wall is substantially hemispherically shaped.

21. The apparatus of claim 17, wherein at least a portion of the first wall is substantially hemispherically shaped.

22. The apparatus of claim 21, wherein the spherical portion of the second wall is substantially hemispherically shaped.

23. The apparatus of claim 17, wherein at least a portion of the first wall is visually transparent.

24. The apparatus of claim 17, further comprising a fat equivalent fluid at least partially filling the first chamber and the second chamber.
25. The apparatus of claim 24, wherein the means for stabilizing the breast within the first chamber is a reduced pressure environment generated by a pump fluidly connected to the first chamber by a conduit connected to a first port in the first wall, and wherein the conduit passes through a second port in the second wall.

26. The apparatus of claim 24, wherein the first wall defines a first port and further includes a valve within the first port.

27. An apparatus for treating a tumor location in a breast, comprising:
   a first shell having an interior surface defining a first chamber sized to encompass at least a portion of the breast, wherein at least a portion of the shell defines a spherical portion having a center, and wherein at least a portion of the first chamber is filled with a fluid having an electron density substantially similar to breast tissue; and,
   tensile and compressive means for stabilizing the breast within the first shell.

28. The apparatus of claim 27, wherein the portion of the first shell is substantially hemispherically shaped.

29. The apparatus of claim 28, wherein an edge of the shell includes an adhesive for attaching the shell to the breast in a substantially fluid tight fashion.

30. The apparatus of claim 29, wherein the adhesive is a replaceable tape.

31. The apparatus of claim 27, where an edge of the shell includes molding shaped to overlay an area around the breast.

32. The apparatus of claim 27, farther comprising a second shell having an internal surface defining a second chamber, the second shell including a spherical portion around a second center, wherein the first chamber is smaller than and positioned substantially within the second chamber, and wherein the second chamber is movable with respect to the first chamber to position the second center to overlap the tumor location.

33. The apparatus of claim 32, further comprising the fluid at least partially filling the second chamber.

34. The apparatus of claim 33, wherein the means for stabilizing the breast within the first chamber is a reduced pressure environment generated by a pump fluidly connected to the first chamber by a conduit
connected to a first port in the first shell, and wherein the conduit passes through a second port in the second shell.

35. The apparatus of claim 33, wherein the first shell defines a port.

36. The apparatus of claim 35, further comprising a valve in the port of the first shell.

37. An apparatus for stabilizing a breast during an imaging or interventional procedure, comprising:

   a chest plate;
   an adjustable arm having a first portion attached to the chest plate and a second portion attached to a patient platform, wherein the arm is movable from a first position to a second position in which the chest plate exerts pressure on a patient.

38. The breast stabilization apparatus of claim 37, wherein the chest plate is shaped to contour to at least a portion of the human female anterolateral chest, the chest plate defining an opening through which the breast may protrude.

39. The breast stabilization apparatus of claim 38, further comprising a chamber for providing a reduced pressure environment, an air tight seal being present between a first side of the chest plate and the chamber.

40. The breast stabilization apparatus of claim 39, wherein the arm is attached to the patient platform by at least one hinge.

41. The breast stabilization apparatus of claim 39, further comprising at least one inflatable bladder attached to a second side of the chest plate.

42. The breast stabilization apparatus of claim 39, further comprising a plurality of inflatable bladders attached to a second side of the chest plate.

43. The breast stabilization apparatus of claim 42, further comprising instrumentation for measuring the pressure in at least one of the inflatable bladders.

44. The breast stabilization apparatus of claim 43, further comprising instrumentation for monitoring the compressive force exerted by the chest plate against the patient.

45. The breast stabilization apparatus of claim 37, wherein the chest plate includes a plurality of attached segments, at least some of the segments being adjustable with respect to adjacent segments.
46. The breast stabilization apparatus of claim 45, wherein a first side of each segment is attached to a chamber for providing a reduced pressure environment, an air tight seal being present between the first side of the chest plate and the chamber.

47. The breast stabilization apparatus of claim 46, wherein a second side of each segment includes a damper attached thereto.

48. The breast stabilization apparatus of claim 47, wherein the damper is an inflatable bladder.

49. The breast stabilization apparatus of claim 39, further comprising padding.

50. An apparatus for fixation of a patient's breast, comprising:
a chest plate shaped to at least partially conform to the anterolateral chest of a human mammal;
a chamber affixed with an airtight seal to the chest plate; a rigid member connecting the chest plate to a platform upon which a patient may lay, wherein the member may translate from a first relaxed position to a second compressive position.

51. A method of treating a tumor mass location in a breast of a patient, comprising:
directing an isocenter of a particle beam at a center of a spherical portion of an outer chamber that overlaps the tumor mass location after passing the particle beam through a first fluid at least partially filling the outer chamber and next passing the beam through a second fluid at least partially filling an inner chamber having a reduced pressure environment that encompasses at least a portion of the breast;
maintaining a compressive force while beaming, the compressive force being against at least a portion of the patient's chest using a plate that is fixed to the inner chamber with an airtight seal.

52. The method of claim 51, wherein the particle beam is a proton particle beam, and wherein the first fluid and the second fluid are the same and have an electron density substantially similar to the breast.

53. The method of claim 52, further comprising rotating the particle beam and the breast relative to one another while continuing to direct the isocenter of the particle beam at the center of the spherical portion of the outer chamber.

54. The method of claim 53, further comprising creating the relative rotation by moving a robotic arm connected to a treatment platform upon which the patient lays.
55. The method of claim 53, further comprising deactivating the particle beam at various times while rotating the particle beam and the breast relative to one another.

56. The method of claim 55, wherein particle beaming occurs after a surgical intervention on the breast, and further comprising deactivating the particle beam when the particle beam would otherwise pass through an existing incision site on the breast.

57. The method of claim 55, further comprising deactivating the particle beam when the beam would otherwise pass through a planned future incision site on the breast.

58. The method of claim 53, further comprising directing the particle beam so that it only passes through an underside of the breast of the patient.

59. The method of claim 52, further comprising first imaging the breast and obtaining data regarding the tumor mass location within the breast and providing the data to a computer directing the particle beams at the breast.

60. The method of claim 59, wherein the imaging is done using a combination of 3-D ultrasound and CT.

61. A method of treating a tumor mass location of a breast, comprising:
   directing an isocenter of a particle beam toward a center of a spherical portion of a chamber enclosing the breast and through a fluid having an electron density substantially similar to the breast, wherein the center of the spherical portion of the chamber overlaps the tumor mass location, and wherein the particle beam is substantially normal to the spherical portion of the chamber; and
   applying a compressive force while beaming against at least a portion of a chest wail around the breast using a plate that is fixed to the chamber with an airtight seal.

62. The method of claim 61, further comprising rotating the breast and spherical portion of the chamber relative to the particle beam to scan through a plurality of particle beam entry angles into the breast while continuing to direct the particle beam substantially normal to the spherical portion of the chamber.

63. The method of claim 62, further comprising directing the particle beam only through an underside of the breast.

64. The method of claim 62, further comprising deactivating the particle beam except when scanning an underside of the breast.
65. The method of claim 62, further comprising rotating the breast and spherical portion of the chamber relative to the particle beam by moving a robotic arm connected to a treatment platform upon which the patient lays.

66. The method of claim 65, further comprising deactivating the particle beam at various times while rotating the particle beam and the breast relative to one another.

67. The method of claim 66, further comprising first imaging the breast and obtaining data regarding the tumor mass location within the breast and providing the data to a computer directing the particle beam at the breast.

68. The method of claim 67, wherein the imaging is done using a combination of 3-D ultrasound and CT.

69. A method of treating a tumor mass location of a breast of a patient, comprising:
   applying a compressive force against at least a portion of a chest wall around the breast using a plate that is fixed to an inner chamber with an airtight seal;
   reducing pressure within the inner chamber that encloses at least a portion of the breast after creating a fluid tight seal between the inner chamber and the patient;
   at least partially filling the inner chamber with a fluid having an electron density substantially similar to the breast;
   positioning an outer chamber at least partially filled with the fluid so that a center of a portion of the outer chamber overlaps the tumor mass location; and
   scanning a particle beam across an arc of the portion of the outer chamber while directing an isocenter of a particle beam at the center of the portion

70. The method of claim 69, further comprising scanning the particle beam only across an underside of the breast.

71. A method of treating a breast cancer tumor mass location, comprising:
   stabilizing the breast by simultaneously applying a compressive force to a portion of a chest wall using a plate and providing a reduced pressure environment via a chamber in a fixed spatial relationship with respect to the plate;
   applying an isocenter of a particle beam to a center of spherical portion of an at least partially fluid filled chamber that encloses at least a portion of the breast, wherein the fluid has an electron density substantially similar to the breast, and wherein the center overlaps the tumor mass location.
The method of claim 71, wherein the breast is stabilized by providing a reduced pressure environment around the breast.

The method of claim 72, further comprising first imaging the breast to determine data regarding the tumor mass location within the breast, and providing the data to a computer controlling the application of the particle beam.

A method of treating a tumor mass location in a breast of a patient, comprising:
- stabilizing the breast within a reduced pressure environment enclosed by a chamber having a wall at least a portion of which is spherically shaped;
- imaging the breast to determine the location of the tumor;
- beaming the tumor with particles through the spherically shaped portion of the chamber; and rotating the beam relative to the tumor mass location around a center of the spherically shaped portion of the chamber, wherein the center overlaps the tumor mass location.

The method of claim 74, wherein the patient is prone on a treatment platform, and the patient is rotated with respect to at least one stationary particle beam.

The method of claim 74, further comprising directing the particle beam only through an underside of the breast.

The method of claim 74, further comprising deactivating the particle beam except when scanning an underside of the breast.

The method of claim 74, further comprising using fiducial markers positioned within or on the breast to identify the tumor mass location.

The method of claim 74, wherein during stabilization of the breast and during beaming the tumor with particles the chamber is filled with a fluid having an electron density substantially similar to the breast.

The method of claim 74, wherein the beaming is controlled to overlap a biopsy track along which prior surgical intervention of the breast has occurred.

A method for stabilizing the breast for an imaging or interventional procedure, comprising:
- positioning a chest plate with an opening so that the breast protrudes through the opening into a chamber attached to the chest plate by an airtight seal;
- reducing the pressure in the chamber while pressing the chest plate against the patient.
Fig. 1