Title: BREAST IMMOBILIZATION DEVICE FOR RADIOThERApY

Abstract: The present document describes a human breast immobilization device for use during a radiotherapy treatment, which is shaped to enclose a human upper body and comprises a first breast holding cup, shaped for positioning a first breast of a patient for a radiotherapy beam, while minimizing unwanted radiotherapy to healthy tissue; and a second breast holding cup, shaped for displacing a second breast of a patient out of a radiotherapy treatment field, for avoiding said radiotherapy beam on healthy tissue of said second breast.
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CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35USC § 119(e) of US provisional patent application 61/860,351, filed on July 31, 2013, the specification of which is hereby incorporated by reference.

INTRODUCTION

[0002] Breast cancer is the most common malignancy diagnosed in women in the western world. Breast conserving therapy, consisting of lumpectomy followed by radiotherapy (RT), is the preferred treatment for patients in which negative margins can be obtained, and for whom acceptable cosmetic results can be obtained. However, whole breast RT is associated with rates of acute toxicity >2 between 20-48%.

[0003] Irradiation of the breast is a technically complex procedure. In order to ensure accurate delivery of the RT dose, patients must be treated in a position that can be reproduced at each treatment fraction. Patient immobilization is of great importance during RT administration and heavily relies on the patient's positioning during the planning CT scan, which is used in the treatment planning process that defines treatment beam geometry with respect to the patient. Patient positioning is most effective when it renders the patient and breast stable during treatment and is easy to reproduce. The position must also be comfortable in order to avoid voluntary or involuntary movement during treatment. Traditionally, patients who undergo radiotherapy of the breast are positioned lying supine on an inclined breast immobilization device (Fig. 1A). The arms are placed above the head and supported by armrests. In the supine position, gravity causes large breasts to drop either laterally or caudally, as seen in Fig. 1B, creating an infra-mammary fold. In older patients, who often have flaccid breasts, the breast also tends to drop laterally (Fig. 1B). The fold causes a bolus effect, increasing severe acute and long term skin toxicity. This position is more difficult to reproduce daily for treatment, and the resulting setup uncertainty can in turn
affect the accuracy of the delivered dose. In addition to reproducibility issues, this position of the breast can have dosimetric consequences in that larger volumes of lung and heart (in left-sided breast cancer) end up in the tangential RT fields, as shown in (Fig. 1C). The increased radiation dose to normal organs can lead to short and long term side effect such as radiation pneumonitis lung fibrosis, brachial plexopathy.

[0004] Patients with large breasts experience more severe acute and long-term skin and subcutaneous toxicity that may last long after the end of the treatment. In this group of patients, rates of acute dermatitis grade >2 are as high as 68-90%. It is thought that the increased separation of a large breast dropping laterally and/or caudally in a patient lying supine increases RT dose heterogeneity. Furthermore, the position of a large breast on the supine patient's chest leads to a large area, at the level of the infra-mammary fold, where the breast and the patient's chest wall are in contact. This causes a bolus effect on the skin of that area, increasing its dose (e.g. exponentially), and thus the occurrence of acute dermatitis during RT.

[0005] To address these issues, different positioning techniques that aim to change patient geometry in order to optimize dosimetry have been tested. Some techniques include positioning the patient in the prone or lateral decubitus positions. Both aforementioned positioning techniques have been shown to decrease lung and heart doses, as well as improve homogeneity and decrease hotspots.

[0006] However, these alternate positioning techniques have major drawbacks: treatment in the prone and lateral decubitus positions necessitates a specific commercial treatment board, and most importantly, technologists well-trained in positioning patients using these techniques. Patient set-up in the prone position is also more difficult, as the light field is not visualized on the patient's skin. The prone position is often uncomfortable and difficult to maintain for the patient who may have significant arthritis, back pain, or difficulty lying on the stomach for a prolonged period of time. Furthermore, coverage of the most
lateral and medial portions of the breast, as well as the chest wall, can be reduced, raising concern of decreased doses to target tissues. Another disadvantage of radiotherapy in these alternate positions is that they do not allow for irradiation of the regional lymph nodes. Finally, some studies have shown that prone positioning may lead to an increased rate of Grade 1-2 skin toxicity.

[0007] Other devices have also been used to improve treatment of patients with large pendulous breasts in the supine position: thermoplastic shells can be placed over the chest and secured onto the breast board, to hold the breast in place. However, the disadvantages of using these devices often include undesired skin dose, and difficulty placing the breast into the shells, especially as acute toxicity progresses and the woman's breast becomes increasingly erythematous, edematous and tender.

[0008] Therefore, there is a need for new devices or device having the potential to reduce undesirable side effects of radiation on healthy tissues. By decreasing acute skin toxicity, the device will reduce cost for dressing, prescription, and nursing care during treatment and care service after completion of the treatment.

[0009] Furthermore, the present tendency in radiation oncology is to reduce the number of treatments. This is not possible for patients with large and/or pendulous breasts due to the severity of the side effects. Therefore, there is a need for devices or device that could allow a reduction of fractions as with patients with small breast (e.g. 25 treatments compared to 20 or 16 treatments). The reduction of fractions is more cost effective for radiation oncology departments as it decreases the number of visits the patient make to the department. It also allows other patients to start treatment more rapidly since more places are available on treatment units.

[0010] Furthermore, there is a need for devices or device that may result in a better dose homogeneity within the treated breast, and help daily
reproducibility of positioning. This, in turn, could increase the quality of life for these patients.

SUMMARY

[0011] According to an embodiment, there is provided a human breast immobilization device for use during a radiotherapy treatment, shaped to enclose a human upper body, comprising:

- a first breast holding cup, shaped for positioning a first breast of a patient for a radiotherapy beam, while minimizing unwanted radiotherapy to non-targeted tissue; and
- a second breast holding cup, shaped for displacing a second breast of a patient out of a radiotherapy treatment field, for avoiding the radiotherapy beam on non-targeted tissue of said second breast.

[0012] The device may be fabricated in an elastic fabric.

[0013] The fabric may be inert to radiation.

[0014] The first breast holding cup may be shaped to mold said breast in a fixed shape.

[0015] The first breast holding cup may be shaped for positioning the first breast on top of a chest wall.

[0016] The first and second breast holding cups are thermoformed in the device.

[0017] The human breast immobilization device may further comprise a first seam under the first breast holding cup, to restrict elasticity of the fabric under the first breast holding cup and stabilize positioning of the breast during use of the device.

[0018] The human breast immobilization device may further comprise a second seam, near an external side of the second breast holding cup, under an opening for inserting an arm in the device, for increasing restraint on, and hold on the second breast.
The human breast immobilization device may further comprise a first opening between the first and second breast holding cup, to provide access to the first or second breast during treatment.

The opening may be sealable.

The opening may be running from a top to a bottom of a frontal portion of said device.

The human breast immobilization device may be further comprising a second opening between the first and second breast holding cup, to provide access to a skin of a patient.

The human breast immobilization device may further comprise on a dorsal portion a first fastener, to adjust a circumference of the device under the first and second breast holding cup.

The human breast immobilization device may further comprise on a frontal portion a second fastener, to adjust a circumference of the device and help close the device on a patient.

The human breast immobilization device may further comprise on a dorsal portion a third opening, running the length of the dorsal portion from top to bottom, to put on and take off the device.

The human breast immobilization device may further comprise an extension inserted in the third opening, to increase the size of the device.

The human breast immobilization device may further comprise at least a third fastener on the dorsal portion, to help close the device on said patient.

The human breast immobilization device may further comprise sleeves for inserting a pair of arms.

The sleeves comprise at least one strap to restrain the arm away from the radiotherapy beam.
In the human breast immobilization device the present invention, no seams are present on the first breast holding cup in a radiotherapy treatment field.

The fabric may be translucent.

The device may exert a pressure from about 5 mm Hg to about 20 mm Hg, or from about 10 mm Hg to about 20 mm Hg, or from about 5 mm Hg to about 10 mm Hg to the human upper body.

The device may exert a pressure from about 5 mm Hg to about 10 mm Hg to a breast area.

The device may be reversible.

The human breast immobilization may comprise:

- a frontal portion having:
  - a first breast holding cup, shaped for positioning a first breast of a patient for a radiotherapy beam, while minimizing unwanted radiotherapy to non-targeted tissue; and
  - a second breast holding cup, shaped for displacing a second breast of a patient out of a radiotherapy treatment field, for avoiding said radiotherapy beam on non-targeted tissue of the second breast;
  - a seam, under the first breast holding cup, for restricting elasticity of a fabric under the first breast holding cup;
  - a sealable first opening, between the first and second breast holding cup, to provide access to the first or second breast;

- a dorsal portion having:
  - a fastener, to adjust a circumference of said garment under the first and second breast holding cup,

wherein the garment is made from an elastic fabric, wherein the fabric is contributing minimally to a radiation surface dose buildup during the radiotherapy treatment.
According to another embodiment, there is provided a human breast immobilization garment for use during a radiotherapy treatment and comprising:

- a first breast holding cup, shaped for positioning a first breast of a patient to receive a radiotherapy beam while minimizing exposure of non-targeted tissue to radiation from the beam; and
- a second breast holding cup, shaped for displacing a second breast of the patient away from the radiotherapy beam to thereby avoid exposure of the second breast to radiation from said beam.

The garment may be shaped to enclose an upper part of a human body.

According to another embodiment, there is provided a use of a human breast immobilization device or garment of the present invention to position a breast of a patient for a radiotherapy treatment.

The use of the device or garment of the present invention may be to reduce the exposure of a volume of patient tissue to a radiotherapy beam.

According to another embodiment, there is provided a method of treating a breast cancer comprising the step of positioning a breast of a patient with a human breast immobilization device or garment of the present invention for a radiotherapy treatment.

The following terms are defined below.

The terms "restriction", "restrain", "constrain" are intended to mean limiting or controlling or holding the portion of the upper body or the breast in order to restrict movement during treatment.

The term "radiotherapy beam" is intended to mean a beam of radiation, usually X-rays, to treat an illness, more specific to the present application is the treatment of breast cancer.
The term "radiotherapy treatment field" is intended to mean the specific target region of the radiotherapy beam, and the general region surrounding it. Exposure to the radiotherapy beam includes any exposure to the radiation from the beam, including wanted exposure to the tumor/cancerous tissue, as well as the unintentional exposure to the non-targeted tissue.

The term "elastic" is intended to mean the reversible deformation of a material, and more particularly of the material of the device of the present invention.

The term "translucent" is intended to mean the property of a material to allow light, but not detailed images, to pass through; semitransparent.

The term "expandable" is intended to mean the property of a material to increase in extent, size, volume, etc.

The term "target area" or "target locus" is intended to mean the part or portion of the breast that is intended to receive the radiotherapy beam while minimizing exposure of non-targeted tissue. The target area includes the targeted cancerous tissue, and may also include non-targeted tissue which may also be unintentionally targeted by the radiotherapy beam despite best efforts to avoid it during treatment.

The term "non-targeted tissue" is intended to mean tissue that is substantially outside of the target area, such as the tissue of the non-treated second breast, as well as the tissue of the other organs near the treatment area, as well as some of the tissue inside the target area that is not the direct target of the treatment, but is unintentionally irradiated during the treatment. The non-targeted tissue may be healthy tissue; but it may also be non-healthy tissue having a disease or condition that is normally not the subject of the cancer treatment by radiotherapy.

The term "upper body" or "upper part of a human body" is intended to mean the torso or trunk of the patient, and may also include the limbs (arms),...
but will usually exclude the head, inasmuch as it will have openings or sleeves to accommodate the arms, and an opening for the head.

[0051] Features and advantages of the subject matter hereof will become more apparent in light of the following detailed description of selected embodiments, as illustrated in the accompanying figures. As will be realized, the subject matter disclosed and claimed is capable of modifications in various respects, all without departing from the scope of the claims. Accordingly, the drawings and the description are to be regarded as illustrative in nature, and not as restrictive and the full scope of the subject matter is set forth in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0052] Further features and advantages of the present disclosure will become apparent from the following detailed description, taken in combination with the appended drawings, in which:

[0053] Fig. 1A illustrates an inclined breast immobilization device used in a radiotherapy treatment in the supine position;

[0054] Fig. 1B illustrates that gravity causes large breasts to drop either laterally or caudally creating an infra-mammary fold;

[0055] Fig. 1C illustrates that larger volumes of lung and heart (in left-sided breast cancer) end up in the tangential RT fields;

[0056] Fig. 1D illustrates that the breast is raised on the chest wall and does not drop when a device according to the present invention is used;

[0057] Fig. 2A illustrates the front of an embodiment of the device of the present invention;

[0058] Fig. 2B illustrates the back of an embodiment of the device of the present invention;

[0059] Fig. 2C illustrates the front of an embodiment of the device of the present invention;
Fig. 2D illustrates the back of an embodiment of the device of the present invention;

Fig. 3A illustrates the front of an embodiment of the device of the present invention;

Fig. 3B illustrates the back of an embodiment of the device of the present invention;

Fig. 3C illustrates the front of an embodiment of the device of the present invention;

Fig. 3D illustrates the back of an embodiment of the device of the present invention;

Fig. 4A illustrates the front of an embodiment of the device of the present invention;

Fig. 4B illustrates the back of an embodiment of the device of the present invention;

Fig. 4C illustrates the front of an embodiment of the device of the present invention;

Fig. 4D illustrates the back of an embodiment of the device of the present invention;

Fig. 5 illustrates a close view of the breast holding cup 12, seam 16 and second opening 40, in an embodiment of the device of the present invention;

Fig. 6 illustrates a close view of the breast holding cup 14, and seam 30, in an embodiment of the device of the present invention;

Figs. 7A-D illustrates the shape of extensions according to embodiments of the present invention.

It will be noted that throughout the appended drawings, like features are identified by like reference numerals.

DETAILED DESCRIPTION
In embodiments there is disclosed a human breast immobilization device 10 for use during a radiotherapy treatment, shaped to enclose a human upper body, which comprises

- a first breast holding cup 12, shaped for positioning a first breast of a patient for a radiotherapy beam, while minimizing unwanted radiotherapy to non-targeted tissue (which is often healthy tissue); and
- a second breast holding cup, shaped for displacing a second breast of a patient out of a radiotherapy treatment field, for avoiding said radiotherapy beam on the non-targeted tissue of said breast.

In order to resolve challenges in positioning breasts of breast cancer patients, a new device, as seen in Figs. 2-7.

According to an embodiment, the device 10 of the present invention covers the shoulders, including the arms if desired, to the pubis. It is designed to conform itself in the treatment position of the patient, where the arms are raised above the head at different angles between 90 and 45 degrees depending on the planning needs and patients comfort. The device 10 raises the treated breast on the chest wall, changing the shape as well as the geometry of the breast with respect to the tangential treatment fields of the radiotherapy beam, such that the breast is held to position the target locus or area optimally for the radiotherapy beam, while minimizing exposure of the non-targeted tissue to radiotherapy. The device 10 decreases the infra-mammary fold and the breast separation between the medial and lateral limits of the breast which causes radiation dermatitis, and reduces irradiation to non-targeted (and often or normally healthy) organs such as the lung and heart tissues when the left breast is treated. The device 10 is also designed to mold the breast in a given fixed shape or configuration to increase the reproducibility of daily positioning, thus ensuring a better dose homogeneity and more efficient accuracy of the daily dose delivery. Also, the device 10 makes patients feel more comfortable and less vulnerable by being covered during radiotherapy sessions.
[0076] Referring now to the drawings, and more particularly to Figs. 2-7, the device 10 includes a first breast holding cup 12, shaped for positioning the first breast needing irradiation for a radiotherapy beam while minimizing unwanted radiotherapy to non-targeted (often or normally healthy) tissue, such as underlying organs like the lungs and heart. The device 10 also includes a second breast holding cup 14, shaped for displacing the second breast of a patient out of a radiotherapy treatment field, for avoiding said radiotherapy beam on non-targeted (often or normally healthy) tissue of said second breast. According to an embodiment, the first breast holding cup 12, is shaped for positioning a first breast needing irradiation on top of the chest wall for a radiotherapy beam, while minimizing irradiation to non-targeted (often or normally healthy) tissues surrounding or underlying the first breast, such as underlying organs like the lungs and heart. The first breast holding cup starts about 3/4 of an inch (about 1.9 cm) from the center of the device (which corresponds to about the center of the torax of the patient). According to another embodiment, the second breast holding cup 14 starts about 2 inches (5.08 cm) from the center of the device (which corresponds to about the center of the torax of the patient), such that the cup is decentered, such that a breast held therein will be displaced and held safely outside the radiotherapy treatment field, toward, for example, the armpit on the side of the body of the patient that is not receiving treatment.

[0077] According to an embodiment, the breast holding cups 12, 14 may be thermoformed in the device according to standardized breast sizes using appropriate molds, ranging from A to F cups. According to an embodiment, during the thermoforming process, the fabric of the device may lose some of its elastic properties, without significant degradation of the performance and properties of the device 10.

[0078] According to another embodiment, the device 10 may also have a seam 16 under the first breast holding cup 12, for restricting elasticity of the fabric under the first breast holding cup 12, and help with the stabilization of the position of the breast during use of the device 10. According to another
embodiment, the device 10 may also have a seam 30 (Fig. 6), near the external side of the second breast holding cup, under the opening for inserting the arm. Seam 30 helps increase the restriction on the side of the untreated breast, permitting more restraint to hold the untreated second breast out of the treatment field.

[0079] According to another embodiment, a sealable first opening 18 may be found between the first and second breast holding cups 12, 14, to provide access to the first or second breast of the patient during treatment. According to an embodiment, the sealable opening may be an opening sufficiently large to let a hand inside the device 10, which is positioned in between the first and second breast holding cups 12, 14. According to another embodiment, the sealable opening may be running from the top (e.g. near the neck region) to the bottom (e.g. near the lower abdominal region) of the frontal portion of the device 10. According to an embodiment, the first opening may be sealed with any suitable means, such as buttons, snaps, hooks, hook and loop fastener, and zippers.

[0080] According to another embodiment, the front portion of the device 10 may also comprise a second opening 40 between the breasts, which gives access to the skin of the patient. This opening may be used for example, to read the radiotherapy source to skin distance during treatment.

[0081] Now referring to Figs. 2-6, according to another embodiment the device 10 may also include on a dorsal portion, a fastener 20 to adjust a circumference of the device 10 under the first and second breast holding cups 12, 14. The fastener 20 may be any suitable means of adjusting the circumference of the device 10, such as straps that can be tied together, straps of hook and loop fastener, etc. The fastener 20 is positioned on the dorsal portion of the device 10, in line with the lower part of the breast holding cups 12, 14. Pulling and fastening the fastener 20 adjusts the circumference of the device 10 and increases the tension in the fabric under the breast holding cups 12, 14, but not on the fabric covering the breasts themselves. According to another embodiment, the device
10 may also include on the frontal portion, a fastener 32 to adjust the circumference of the device 10 to help close the device on the patient.

[0082] According to another embodiment, the dorsal portion of the device 10 may also comprise a sealable third opening 50, running the length of the dorsal portion of the device 10 from top to bottom. The sealable third opening 50 allows the patient to put on and take off the device 10. According to an embodiment, the third opening 50 may be sealed with any suitable means, such as buttons, snaps, hooks, hook and loop fastener, and zippers. According to an embodiment, the device 10 may be made in a few standard sizes fitting a majority of patients.

[0083] Now referring to Figs. 7A-D, according to another embodiment, the device 10 may also be enlarged using extensions 70 which are added to the back of the device 10, with appropriate fasteners (e.g. compatible zippers), in the third opening 50. This permits the device 10 of the present invention to cover sizes ranging from 8 to 24. According to an embodiment, the extension 70 may be V shaped, to accommodate patients having wide shoulders and small legs (Fig. 7A). According to another embodiment, the extension 70 may be rectangular or square, to provide an equal extension at all positions (Fig. 7B). According to another embodiment, the extension 70 may be X shaped, for patients having a strong waist (Fig. 7C). According to another embodiment, the extension 70 may be Y or inverted Y shaped, for patients having wide shoulders or narrow shoulders, respectively (Figs. 7D).

[0084] Now referring to Figs. 2-4, according to another embodiment, the dorsal portion may also have further fasteners, such as second and third fasteners 22, 24. Second and third fasteners 22, 24 help close the device 10 on the patient.

[0085] Now referring to Figs. 2, 3 and 4, according to another embodiment, the device 10 may be fabricated with our without sleeves. According to an embodiment the sleeves 60 are positioned to accommodate the
position of the arms during treatment. According to an embodiment, they may be adjustable with straps 62, 64, 66 (such as hook and loop fastener straps) to restrain flaccid under arm away from the treatment field.

[0086] According to an embodiment, the seams on the device 10 are of the open and elongated type, in order to minimize their thickness. Furthermore, no seams are present in the radiotherapy treatment field, and specifically not in the first breast holding cup.

[0087] According to another embodiment, the device 10 is reversible. This allows only one type of device 10 to be manufactured and be used in radiotherapy treatment of any one of the right or left breast. This also allows reducing inventory of the device 10, as only one type may be used for both breasts.

[0088] According to an embodiment, the device 10 can be made of a translucent expandable, elastic material. According to an embodiment, the material can be primarily of spandex and nylon that molds and retains the shape of the breast. According to an embodiment, the device 10 may be fabricated from an elastic fabric that is as inert to radiation in order to contribute minimally to the radiation surface dose buildup on the patient's skin during a radiotherapy treatment. Also, according to an embodiment, it is important that the fabric contributes minimally to a radiation surface dose buildup during said radiotherapy treatment, in order to only minimally increase skin dose due to increased electron contamination.

[0089] According to another embodiment, the device 10 is made from a fabric that is translucent. The use of a translucent fabric permits the visibility of skin references done on the patient (e.g. tattoos). Preferably, the device is made from a fabric that is translucent, and expandable (elastic). Most preferably, the device is made from a fabric that is translucent, expandable, malleable and that can withstand thermoforming without losing any one of these properties. Most preferably, the fabric is chosen from nylon, spandex, or a combination of nylon
and spandex. The pattern is created taking into account the compression in mm Hg. The compression exerted by the device may be from about 5 mm Hg to about 20 mm Hg, or from about 10 mm Hg to about 20 mm Hg. Preferably, the device exerts from about 5 mm Hg to about 10 mm Hg on the breast area, and about 20 mm Hg for the rest of the device. This retains and maintains the shape of the breasts for each radiotherapy treatment.

[0090] In use, the human breast immobilization device or garment of the present invention is used for positioning a first breast of a patient for a radiotherapy beam, such that the target area (or target locus) of the breast is optimally positioned to receive the radiotherapy beam, while minimizing unwanted radiotherapy to non-targeted tissue, inasmuch as unintentional irradiation of the non-targeted tissue near the target tissue (that is, tissue distal from the treated target tissue as well as tissue adjacent or nearby the treated target tissue) is avoided.

[0091] The present invention will be more readily understood by referring to the following examples which are given to illustrate the invention rather than to limit its scope.

**EXAMPLE 1**

**STYLE SPECIFICATION SHEET OF THE DEVICE FABRIC**

- STYLE NO : 4296 from CDRM Compressive Therapy Specialists.
- CONSTRUCTION : 420 DENIER SPANDEX 25% and 70 DENIER NYLON 75%
- GAUGE : 56
- WIDTH : 92"
- COURSES : 29 ± 2
- WALES : 34 ± 2
- WEIGHT : 6.10
- WARP STRETCH: 110% ± 10%
- FILL STRETCH: 60% ± 10%
EXAMPLE 2

FABRIC CHARACTERIZATION REPORT

[0092] According to an embodiment, the fabric is intended to be used for organ immobilization when treating breast cancer patients with external beam Linac based radiation therapy. The aim of the investigation is to determine the water-equivalent thickness in the buildup region of the fabric for 6 and 18 MV photon beams.

[0093] All measurements are conducted on a Varian Novalis iX Linear Accelerator (sn 4674). Two fabric orientations are used: i) naturally loose, and ii) stretched. Only normal incidence is investigated whereby the photon beam is always normal to the fabric: no oblique incidence is investigated. The setup is at source to skin distance (SSD) 100 cm using a parallel-plate Attix chamber imbedded in solid water. A high quality electrometer (Keithly 35617 or Victoreen 150) is used with a low noise triax cable. The chamber is at +300 V and signal is collected in the charge mode.

[0094] The Linac is run at a rate of 400 Monitor Unit (ML) - a measure of the dose delivered by the linear accelerator) per minute and 200 MU is delivered at each run. Photon energies of 6 and 18 MV are used. Solid water sheets are used to measure the Percent-depth Dose.

[0095] The Linac configuration was as follows:

- Gantry: 0 degrees
- Collimator: 0 degrees
- Table: 0 degrees
- Field size 10 x 10 cm²
• No MLC or shielding

Results

[0096] All data is normalized to their respective dmax (1.5 cm for 6 MV and 3.0 cm for 18 MV).

Data set #1:

<table>
<thead>
<tr>
<th>Depth (mm) in SW</th>
<th>6 MV PDD</th>
<th>18 MV PDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>O(surface)</td>
<td>15.6</td>
<td>14.0</td>
</tr>
<tr>
<td>loose fabric</td>
<td>28.2</td>
<td>19.4</td>
</tr>
<tr>
<td>stretched fabric</td>
<td>24.9</td>
<td>17.7</td>
</tr>
<tr>
<td>5.0 mm SW</td>
<td>85.9</td>
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<tr>
<td>10.0 mm SW</td>
<td>98.4</td>
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</tr>
<tr>
<td>15.0 mm SW</td>
<td>100.0</td>
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</tr>
<tr>
<td>30.0 mm SW</td>
<td>94.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Data set #2:

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<th>Depth (mm) in SW</th>
<th>6 MV PDD</th>
<th>18 MV PDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>O(surface)</td>
<td>16.3</td>
<td>14.6</td>
</tr>
<tr>
<td>loose fabric</td>
<td>25.3</td>
<td>18.1</td>
</tr>
<tr>
<td>stretched fabric</td>
<td>23.7</td>
<td>17.4</td>
</tr>
<tr>
<td>15.0 mm SW</td>
<td>100.0</td>
<td>91.3</td>
</tr>
<tr>
<td>30.0 mm SW</td>
<td>94.4</td>
<td>100.0</td>
</tr>
</tbody>
</table>

[0097] Conclusions

[0098] The solid water data is reproducible between measurements, and agrees well with expected values measured previously. The stretched fabric provides slightly less buildup than the loose fabric, as expected. For the 6 MV photon beam, the style 4296 stretched fabric increases the surface dose from
16.3% for the open beam to 23.7%. Based on a linear interpolation (keeping in mind that a parabolic representation is more common) between the surface and 5.0 mm this is equivalent to less than 1 mm of extra buildup, and could be estimated to be equal to about 0.66 mm of extra buildup. For the 18 MV photon beam, the style 4296 stretched fabric increases the surface dose from 14.6% for the open beam to 17.4%. Based on a linear interpolation (keeping in mind that a parabolic representation is more common) between the surface and 5.0 mm this is equivalent to less than 1 mm of extra buildup, and could be estimated to be equal to about 0.40 mm of extra buildup.

**EXAMPLE 3**

**TESTIMONIES**

[0099] With the approval of the radiation oncology department of the McGill University Health Center, two patients are treated using a device according to an embodiment of the present invention. The two patients needed whole breast irradiation for the treatment of their breast cancer. In preparation for radiation planning, the first patient is scanned as usual on the breast board, without additional support for the treated breast. She had a pendulous D-cup size breast which rested laterally, almost touching the scan table. The breast fold created extended all along the lateral border of the breast and interiorly. Her radiation fields was planned, but the amount of the ipsilateral lung included was unacceptably wide. To reduce the lung exposure, the breast coverage had to compromise reduced. The problem of target coverage, the amount of lung within the treatment fields, the anticipated suboptimal dosimetry and significant acute and potentially long term skin toxicity with the large breast fold, led to use of the device of the present invention. With this device, the mammary fold is eliminated by raising the breast on the chest wall, which decreased substantially the separation between the medial and lateral limits of the breast. With a more
suitable geometry, optimal target coverage is achieved with acceptable amount of lung within the radiation fields and adequate dosimetry.

[00100] The second patient presented similar issues, which are somewhat more severe because she had a larger breast. Further complicating the treatment plan, this patient received radiotherapy to the contra lateral breast for cancer a decade earlier. During her treatment at that time, she developed grade 3 skin toxicity which required daily dressing for several weeks. The treatment left her with permanent cutaneous changes with scarring of the skin, extensive telangiectasia (dilated red vessels) and with significant fibrosis of the breast. As for the first patient, the device solved the problem of the mammary fold and optimized the position of the breast on the chest wall. The breast coverage and the lung exposure are compared and the dosimetry from the planning scans with and without the device. The advantages with the use of the device are unequivocal.

[00101] Both patients tolerated their treatment well with only grade 1 skin toxicity (erythema), and no other cutaneous reactions. The second patient, who had experienced from of previous radiation treatment 10 years ago and anticipated a difficult journey with radiotherapy, was extremely pleased with the outcome at the end therapy.

[00102] While preferred embodiments have been described above and illustrated in the accompanying drawings, it will be evident to those skilled in the art that modifications may be made without departing from this disclosure. Such modifications are considered as possible variants comprised in the scope of the disclosure.
CLAIMS:

1. A human breast immobilization device for use during a radiotherapy treatment, shaped to enclose a human upper body, comprising:
   - a first breast holding cup, shaped for positioning a first breast of a patient for a radiotherapy beam, while minimizing unwanted radiotherapy to non-targeted tissue; and
   - a second breast holding cup, shaped for displacing a second breast of a patient out of a radiotherapy treatment field, for avoiding said radiotherapy beam on non-targeted tissue of said second breast.

2. The human breast immobilization device of claim 1, wherein said device is fabricated in an elastic fabric.

3. The human breast immobilization device of claim 2, wherein said fabric is inert to radiation.

4. The human breast immobilization device of claim 1, wherein said first breast holding cup is shaped to mold said breast in a fixed shape.

5. The human breast immobilization device of any one of claim 1, wherein said first breast holding cup is shaped for positioning said first breast on top of a chest wall.

6. The human breast immobilization device of any one of claims 1-5, wherein said first and second breast holding cups are thermoformed in said device.

7. The human breast immobilization device of any one of claims 2-6, further comprising a first seam under said first breast holding cup, to restrict elasticity of said fabric under said first breast holding cup and stabilize positioning of the breast during use of said device.
8. The human breast immobilization device of any one of claims 2-7, further comprising a second seam, near an external side of said second breast holding cup, under an opening for inserting an arm in said device, for increasing restraint on, and hold on said second breast.

9. The human breast immobilization device of any one of claims 1-8, further comprising a first opening between said first and second breast holding cup, to provide access to said first or second breast during treatment.

10. The human breast immobilization device of claim 9, wherein said opening is sealable.

11. The human breast immobilization device of claim 9 or 10, wherein said opening is running from a top to a bottom of a frontal portion of said device.

12. The human breast immobilization device of any one of claims 1-11, further comprising a second opening between said first and second breast holding cup, to provide access to a skin of a patient.

13. The human breast immobilization device of any one of claims 1-12, further comprising on a dorsal portion a first fastener, to adjust a circumference of said device under said first and second breast holding cup.

14. The human breast immobilization device of any one of claims 1-13, further comprising on a frontal portion a second fastener, to adjust a circumference of said device and help close said device on a patient.
15. The human breast immobilization device of any one of claims 1-14, further comprising on a dorsal portion a third opening, running the length of said dorsal portion from top to bottom, to put on and take off the device.

16. The human breast immobilization device of claim 15, further comprising an extension inserted in said third opening, to increase the size of said device.

17. The human breast immobilization device of any one of claims 13 to 16, further comprising at least a third fastener on said dorsal portion, to help close said device on said patient.

18. The human breast immobilization device of any one of claims 1 to 17, further comprising sleeves for inserting a pair of arms.

19. The human breast immobilization device of claim 18, wherein said sleeves comprise at least one strap to restrain said arm away from said radiotherapy beam.

20. The human breast immobilization device of any one of claims 1 to 19, wherein no seams are present on said first breast holding cup in a radiotherapy treatment field.

21. The human breast immobilization device of any one of claims 2 to 20, wherein said fabric is translucent.

22. The human breast immobilization device of any one of claims 2 to 21, wherein said device exerts a pressure from about 5 mm Hg to about 20 mm Hg, or from about 10 mm Hg to about 20 mm Hg, or from about 5 mm Hg to about 10 mm Hg to said human upper body.
23. The human breast immobilization device of any one of claims 2 to 22, wherein said device exerts a pressure from about 5 mm Hg to about 10 mm Hg to a breast area.

24. The human breast immobilization device of any one of claims 2 to 23, wherein said device is reversible.

25. The human breast immobilization device of any one of claims 2 to 24, comprising:
   • a frontal portion having:
     - a first breast holding cup, shaped for positioning a first breast of a patient for a radiotherapy beam, while minimizing unwanted radiotherapy to non-targeted tissue; and
     - a second breast holding cup, shaped for displacing a second breast of a patient out of a radiotherapy treatment field, for avoiding said radiotherapy beam on non-targeted tissue of said second breast;
     - a seam, under said first breast holding cup, for restricting elasticity of a fabric under said first breast holding cup;
     - a sealable first opening, between said first and second breast holding cup, to provide access to the first or second breast;
   • a dorsal portion having:
     - a fastener, to adjust a circumference of said garment under said first and second breast holding cup,

   wherein said garment is made from an elastic fabric, wherein said fabric is contributing minimally to a radiation surface dose buildup during said radiotherapy treatment.

26. A human breast immobilization garment for use during a radiotherapy treatment and comprising:
- a first breast holding cup, shaped for positioning a first breast of a patient to receive a radiotherapy beam while minimizing exposure of non-targeted tissue to radiation from said beam; and
- a second breast holding cup, shaped for displacing a second breast of the patient away from said radiotherapy beam to thereby avoid exposure of said second breast to radiation from said beam.

27. The garment according to claim 26 wherein said garment is shaped to enclose an upper part of a human body.

28. Use of a human breast immobilization device or garment of any one of claims 1 to 27 to positioning a breast of a patient for a radiotherapy treatment.

29. The use of the device or garment according to any one of claims 1 to 27 to reduce the exposure of a volume of patient tissue to a radiotherapy beam.

30. A method of treating a breast cancer comprising the step of positioning a breast of a patient with a human breast immobilization device or garment of any one of claims 1 to 27, for a radiotherapy treatment.
### A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61B 6/04 (2006.01), A61N 5/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C.

See patent family annex.

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**Date of the actual completion of the international search**
2 October 2014 (02-10-2014)

**Date of mailing of the international search report**
08 October 2014 (08-10-2014)

**Name and mailing address of the ISA/CA**

Canadian Intellectual Property Office

Place du Portage 1, C1 14 - 1st Floor, Box PCT

50 Victoria Street

Gatineau, Quebec K1A 0C9

Facsimile No.: 001-819-953-2476

**Authorized officer**

Saadia Khan (819) 934-6752

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Form PCT/ISA/210 (second sheet) (July 2009)
### INTERNATIONAL SEARCH REPORT

**PCT/CA2014/000596**

#### Box No. II

**Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☑ Claim Nos.: 30  
   because they relate to subject matter not required to be searched by this Authority, namely:

   Claim 30 is directed to a method for treatment of the human or animal body by therapy, which the International Searching Authority is not required to search under Rule 39.1(iv) of the PCT. However, this Authority has carried out a search based on the alleged effect or purpose/use of the product as claimed in claims 28 and 29.

2. ✗ Claim Nos.: 
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ✗ Claim Nos.: 
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

#### Box No. II

**Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ✗ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ✗ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ✗ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos.:

4. ✗ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos.:

### Remark on Protest

- ✗ The additional search fees were accompanied by the applicant=s protest and, where applicable, the payment of a protest fee.

- ✗ The additional search fees were accompanied by the applicant=s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

- ✗ No protest accompanied the payment of additional search fees.
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