3D Printed Respiratory Motion Phantom for Next Generation Cancer Radiotherapy

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Biomedical Engineering 200/300

Section 304

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Function

During Lung Cancer radiotherapy treatment, movement of lung tumors caused by breathing makes it difficult to accurately target the tumor while minimizing radiation to surrounding healthy tissue. To improve treatment, the QUASAR system uses a dynamic phantom to simulate respiratory motion while imaging and motion-tracking approaches are used in tandem with a phantom containing anatomically realistic tumor inserts [1]. These inserts are used within the system to help validate tumor-tracking and radiotherapy technologies before they are used to treat patients because tumors are difficult to track while moving. Phantom effectiveness will be tested by checking if the system can accurately identify and track tumors under programmed respiratory motion [1]. By testing and validating tumor detection, the accuracy of lung cancer radiotherapy can be improved while unnecessary exposure of healthy tissue to radiation can be reduced.

Client Requirements

Dr. Shepard outlined the following requirements for the respiratory motion phantom:

- The phantom should be compatible with the existing QUASAR respiratory motion phantom system.
- The phantom should simulate lung tissue and lung tumors and lesions with realistic physical and imaging characteristics.
- The phantom should be capable of containing two lung tumor inserts.
- The tumor inserts should be reusable to perform experimental validation procedures.
- The tumor inserts should be replaceable to allow different tumors and patient-specific geometries to be evaluated.
- The phantom should allow realistic tumor geometries derived from CT scans and 3D Slicer rather than solely spherical tumor models.
- The phantom should allow the radiation delivery and tumor-tracking systems to be evaluated for how accurately they track moving lung lesions.
- The phantom should have imaging and material characteristics that allow the tumors and surrounding lung tissue to be distinguished using CT imaging.

Design requirements

1. **Physical and Operational Characteristics**

a. **Performance requirements**

   i. The lung phantom should be compatible with the QUASAR system to simulate lung tissue, and two tumors or lesions with realistic physical and imaging characteristics. The phantom will be used multiple times to perform multiple experiments, so the tumor inserts should be reusable. The tumor inserts should be replaceable to allow a variety of different geometries to be studied. These geometries should be derived from CT scans and 3D Slicer. The inserts themselves do not need to support any physical load, however they must be able to be supported and moved easily by the QUASAR motion phantom.

b. **Safety**

   i. The QUASAR phantom body should never be lifted while it is full of liquid or connected to the drive unit to avoid mechanical failure. Hands, loose clothing, and cables must be clear of the moving insert, chest wall platform, and translation stage while the motor is powered or active. The unit should always be positioned on a flat, level surface. The product must comply with global medical device engineering benchmarks outlined in IEC 60601-1 which dictates that electrical parts should be properly insulated, and ISO 13485 [2] which requires clear labeling.

c. **Accuracy and Reliability**

   i. The inserts must be capable of being reused multiple times to perform experimental validation procedures. The inserts must be physically realistic, taking their geometries from CT scans and 3D slicers, rather than generic spheres. The inserts must accurately represent multiple different tumors to allow patient-specific geometries to be evaluated. The phantom must provide a realistic image of the tumors and accurately track their movement to a high degree of certainty.

d. **Life in Service**

   i. Respiratory motion phantom inserts do not typically have a defined replacement interval and should remain in service as long as they continue to meet dimensional, mechanical,

imaging, and dosimetric requirements. Custom inserts should remain in service as long as they accurately represent the patient's anatomy and clinical conditions and continue to perform as intended. Replacement should be based on loss of accuracy, damage, or failed QA verification rather than age alone. [3]

ii. The phantom should withstand a rotation of around 15 cycles per minute, which is standard to mimic breathing frequency. [4]

e. **Shelf Life**

i. A common shelf life for medical equipment such as a respiratory motion phantom insert is around 5-10 years, but that is likely much longer than the project will require. The phantom should maintain its structural integrity for at least a year when stored at room temperature, in an indoor, dry environment. [5]

f. **Operating Environment**

i. The phantom should be compatible with CT imaging and able to withstand any rotation or other forces from the QUASAR machine. The phantom should remain securely positioned throughout operation in the machine. [6]

ii. The phantom must operate properly in the clinical environment, within room temperature of 18-25°C and a relative humidity of 20-70%. [7]

g. Ergonomics

i. The phantom should be user-friendly and able to be inserted into the QUASAR machine intuitively or as per usual procedure. It should only require one person to set up and have clear markers to indicate insertion orientation. There should be enough space for the radiochromic film to be placed into without difficulty.

ii. The phantom should be lightweight enough to transport and able to be placed stably on a surface.

h. **Size**

i. The lung phantom insert should be sized to fit within the existing QUASAR respiratory motion phantom and meet its dimensional constraints without interfering with the system's programmed motion. The two simulated tumors should be positioned and sized so that they fit correctly within the lung phantom insert while maintaining the intended spacing and placement from the CT-based design.

i. **Weight**

i. The phantom insert should be lightweight enough to be easily installed, removed, and handled, while still being strong enough to maintain its shape during repeated motion on the QUASAR system. The weight should also be low enough that it does not interfere with the programmed respiratory motion of the QUASAR phantom. The two simulated tumors should also be kept relatively lightweight since they are part of the moving insert, while still having enough material to accurately reproduce their intended size and shape.

j. **Materials**

i. The lung portion will be fabricated using a material that can produce CT characteristics similar to human lung tissue. A candidate material is PLA-LW (lightweight) because its microscopic bubbles make it lower density, which is useful for representing the low-density characteristics of lung tissue. Its density and radiological properties can also be adjusted by changing the infill percentage. [1]

ii. The tumor regions will be fabricated using a material with a higher CT density than the surrounding lung tissue so that the tumors can be distinguished on CT images. A candidate material is PLA+ because it can produce higher-density regions than PLA-LW and its CT characteristics can be adjusted using different

infill percentages. Different infill patterns, such as gyroid and grid, can also be used to adjust the density of the printed tumors. [1]

iii. The phantom will also need materials and components that allow it to integrate with the QUASAR respiratory motion phantom. A magnet or other magnetic attachment component may be used to securely connect the insert to the QUASAR system while still allowing it to be removed when needed. The attachment should be durable enough to withstand repeated respiratory motion and should not interfere with CT imaging or the movement of the phantom.

k. **Aesthetics, Appearance, and Finish**

i. The phantom should have a clean and organized appearance with smooth surfaces and no sharp edges that could make the insert difficult to handle or install into the QUASAR phantom. The different components should fit together securely and maintain a consistent overall shape, while the lung and simulated tumor regions should be distinguishable for easy identification during setup and testing. The printed surfaces should be consistent and free of major printing defects that could affect the geometry or CT imaging characteristics. Color is not a major design requirement, since functionality and accurate reproduction of the lung and tumor structures are more important, but using different colors for the lung and tumor regions could make the components easier to identify. Overall, the phantom should have a professional appearance suitable for repeated laboratory testing.

2. Product Characteristics:

a. Quantity:

i. The client needs one completed phantom compatible with the QUASAR system. The phantom reusable and replaceable tumor inserts with varying geometries. The phantom will be modular so many iterations of tumors can be studied.

b. Target Product Cost

i. Because the phantom will be fabricated using 3D printing, manufacturing costs are expected to be low at around $5-10 per prototype. With this in mind it will be significantly cheaper than existing comparable lung phantoms.

3. Miscellaneous

a. Standards and Specifications

i. For custom inserts designed for the QUASAR Respiratory Motion Phantom, the design should follow relevant ASTM standards for imaging and radiotherapy phantoms, include appropriate verification and validation testing, and use materials that accurately reproduce the desired imaging and mechanical properties [8], [9]. If the inserts are intended for future clinical or commercial use, development should align with ISO 13485:2016 quality management requirements for medical devices [8]. FDA clearance is generally not required for research-use-only (RUO) phantom inserts, but commercialization may require compliance with FDA medical device regulations and quality system requirements [9].

b. Customer

i. The customers are Dr. Shepard and Dr.Slagowski who will use the phantom to test tumor tracking radiotherapy technologies for lung cancer treatment. They prioritize the accuracy of the tumor density. They prefer the phantom to fit organic and realistic tumor shapes as opposed to the spherical tumor models that don't replicate what tumors resemble.

c. **Patient-related concerns**

i. The device will not be coming in direct contact with any patients as it is a model of the patient's lungs. For this reason, there are limited patient concerns. However, if the project moves into making custom phantoms for different patients, then it will be important to keep patients' medical images such as CT scans confidential as per HIPPA regulations. [10]

d. **Competition**

i. Custom respiratory-motion phantoms incorporating multiple lung lesions have been reported in the literature. D. Lustermans et al. developed a 3D-printed dynamic anthropomorphic thorax phantom containing three tumors with realistic respiratory motion for 4DCT evaluation [11], while D. Hong et al. created a patient-specific lung phantom containing six nodules of varying size and morphology using 3D printing and silicone casting [12]. These studies demonstrate that custom multi-lesion phantom designs are feasible and support the development of advanced quality assurance workflows beyond the single-target configurations commonly supplied with commercial respiratory-motion phantoms such as QUASAR and Dynamic Thorax.

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