AN ABSTRACT OF THE THESIS OF

Chelsea M. Page for the degree of Master of Science in Medical Physics presented on June 2, 2017

Title: Process quality improvement analysis for the acquisition of reproducible real time motion data in a clinical environment

Abstract Approved:

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James A. Tanyi

**Background:** In a preliminary study that compared two immobilization devices in their ability to minimize prepositioning deviation during stereotactic body radiation therapy (SBRT) of the lung, liver or spine, it was found that patients in the BodyFIX system required shifts up to four times greater than those in a Vac-Lok system. A follow on study was designed to compare the BodyFIX and Vac-Lok systems with regard to patient stability during each SBRT treatment session. In order to conduct the latter study, irrespective of the immobilization device or the motion tracking methodology utilized, realistic guidelines on study implementation are highly desirable. The purpose of this study is to derive a protocol that will facilitate reproducible data acquisition.

**Methods:** In lung, liver or spine SBRT, the variability of intra-fractional target motion can negate the potential benefits of four-dimensional treatment planning that serves to account for the dosimetric impacts of organ/target motion. Immobilization systems, specifically BodyFIX and Vac-Lok, play a crucial role in patient motion management. On the day of treatment, each patient undergoes routine setup/alignment to define an approved treatment position. Subsequently, each patient is monitored continuously in real time with a surface imaging system (VisionRT) to acquire data on patient motion that would be lost by a simply performing a pre- and a post- treatment interrogation of the patient's position with volumetric imaging. The clinical and analytical workflow of the suggested study has been analyzed with the aim of outlining a consistent framework that encompasses the entire data collection process.

**Results:** Criteria for identification of potential study candidates and their subsequent recruitment were formalized. Checklists were designed such that each key member in the research group had clearly defined set(s) of instructions regarding his/her role. Furthermore, procedures for proper training of each key study member were designed and to

be implemented by the study coordinator. Deviations from protocol framework will be carefully documented.

**Conclusions:** The protocol and suggested process will serve as a platform to ensure consistent and comprehensive execution of a patient motion monitoring study irrespective of the motion management system or the motion tracking tool.

# PROCESS QUALITY IMPROVEMENT ANALYSIS FOR THE ACQUISITION OF REPRODUCIBLE REAL TIME MOTION DATA IN A CLINICAL ENVIRONMENT

by
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in partial fulfillment of
the requirements for the
degree of

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School of Medicine

Oregon Health & Science University

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CERTIFICATE OF APPROVAL

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This is to certify that the Master's Thesis of

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has been approved

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Member

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Member

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ABBREVIATIONS

**3D** Three-Dimensional

**4D** Four-Dimensional

**AP** Anterior-Posterior

**CTV** Clinical Target Volume

**CT** Computed Tomography

**DICOM** Digital Imaging and Communication in Medicine

**FPS** Frames per Second

**GTV** Gross Tumor Volume

**IGRT** Image-Guided Radiation Therapy

**OAR** Organs at Risk

**PTV** Planning Target Volume

**ROI** Region of Interest

**RPM** Real-time Position Management

**RT** Radiotherapy

**SBRT** Stereotactic Body Radiation Therapy

# 1. Introduction

This thesis outlines a process quality improvement study performed at the Oregon Health and Science University in which a protocol has been derived that will help facilitate reproducible data acquisition. Originally, the study aimed to compare and focus on the disparity produced between two systems used to immobilize lung, liver, and spine patients during stereotactic body radiation therapy (SBRT). The two technologies of evaluation interest being CIVCO Radiotherapy Vac-Lok, where the patient is cradled around the torso, and Elekta BodyFIX, where the patient's entire body is fully nestled and additionally sealed with a unique cover sheet [1]. It should be noted, there is no clinical gold standard for immobilization devices and are always decided upon by physician preference. A series of unforeseen circumstances, workflow disconnections, and time restrictions redirected the focus to creating a protocol and suggested process outline as well as an analytic platform in a way that could easily be taken on by another student in the future. The present study is progressively relevant since medicine is a continuously growing field and clinical protocol requires adequate immobilization for all stereotactic treatments [2].

Cancer is one of the leading causes of death worldwide. In 2017, between both males and females, 1,688,780 new cases of cancer have been predicted. 17% of those are lung, liver, or spine related. Out of the projected deaths, lung cancers make up 27% of male deaths and 25% of female deaths which is more than any other cancer. Liver cancers make up 3% of both male and female projected deaths. Central nervous system cancers make up a combined 6% of both male and female projected deaths. Developing effective lung, liver, and spine cancer treatment techniques are becoming increasingly more important since a significant number of people in the United States are dying from these every year [3]. Stereotactic body radiation therapy has been proven effective for the treatment of lung, liver, and spine tumors with the ability to deliver a high dose per fraction over a small number of fractions. It involves tight planning margins and steep dose gradients to protect the surrounding organs at risk (OAR) [4]. However, the intra-fractional motion of lung, liver, and spine tumors during SBRT treatment is highly affected by respiration. Immobilization devices are used in an effort minimize and even eliminate target motion to ensure that the prescribed dose is hitting the target. The following content has been designed to ensure a comprehensive execution of a patient motion tracking study,

irrespective of the motion management tool or the motion tracking tool.

## 1.1. Description and History of SBRT

Stereotactic body radiation therapy refers to a procedure for treating tumors in the kidney, lung, liver, pancreas, prostate, and spine. This type of therapy uses a hypofractionation technique with ultrahigh fraction doses anywhere from 6 to 30 Gy [5]. The goal of any kind of radiotherapy is to deliver a high dose to the target volume while sparing as much normal tissue as possible but this is especially important in SBRT treatments. Generally, a tumor is a good candidate for SBRT if it is well-circumscribed with a average cross-section of 5-cm or less. It should be accordingly obvious that the accuracy of dose delivery and conformity of dose distribution are absolutely critical. In addition to good tumor coverage, patient immobilization and respiratory motion management are large factors in developing an effective plan.

Radiobiologically, high dose in fewer fractions will have a much more potent biological effect than that of a conformal 3D/IMRT plan with the same total dose over a more standard fractionation scheme. The requirements for positional and numerical accuracy in dose delivery are $\pm$5mm and $\pm$5%, respectively. There are several errors introduced along the way to patient treatment that could contribute to the uncertainty in dose delivery. Contouring, beam models, setup and alignment, movement, and delivery are just a few larger contributors.

## 1.2. Motion Management Systems

Immobilization systems reproducibly position patients and help keep them still during treatment. There are several variations of immobilization devices available depending on the site being treated. An ideal system secures the patient and constrains motion in a relatively comfortable position. It is crucial that the system does not interfere with simulation for planning or treatment. More specifically, no high Z material should be utilized and there may be size constraints for the simulation bore. The motion management system should maintain its integrity throughout the course of a patient's treatment. Lastly, it should be easy to use with regards to setup and treatment times in a busy clinic [6].

In our department, there are two systems commonly used in the treatment of lung, liver, or spine. The two technologies being evaluated are CIVCO Radiotherapy Vac-Lok, where the patient is cradled around the torso, and Elekta BodyFIX, where the patient's entire body is fully nestled and additionally sealed with a unique cover sheet.

Which poses the question, is one more advantageous to use in terms of immobilizing the patient through the entirety of the treatment, for each treatment session? There are

two arguments to made here. On one hand, the BodyFIX dual-vacuum system has more contact with the patient and should theoretically stabilize the patient for the entirety of the treatment. On the other hand, the Vac-Lok system may provide more comfort to the patient, reducing the urge to move. Both are valid outlooks, but the next question is, how can we make a statement about this? The type of monitoring or image capture will affect how sure we can be.

## 1.3. Motion Tracking Techniques

Developing an accurate dosage plan for radiation therapy is crucial to the success of the treatment, yet many obstacles still exist in spite of the application of modern technology. Current treatment planning is static and based on the initial computed tomography (CT) simulation scan. At this moment in time there are significant uncertainties in understanding motion and deformation of the internal anatomy. It helps to accurately reconstruct the delivered dose distribution and to generate more accurate image basis for adaptive planning and delivery. However, direct monitoring of internal motion remains a very difficult task, due to limitations in spatiotemporal resolutions in imaging development such as 4DCT and other factors such as concomitant dose considerations. Very often, an indirect approach is taken where a partial measurement is used in combination with a model that relates the internal anatomy to the measurement. Indirect monitoring can include electronic portal imaging (EPI), optical marker tracking, and fluoroscopic/cone-beam computed tomography (CBCT)-based monitoring.

Optical monitoring has the benefit of being radiation-free at high frame rates. As an advancement from optical marker tracking, the development of photogrammetry techniques provides a data-intensive yet noninvasive way for monitoring patient external surface motion in real time. Such systems, exemplified by VisionRT, determine 3D coordinate of points on the patient surface based on reference measurements made from two images taken from different angles. Real time imaging is usually considered to be 30 frames per second (FPS) but variably run from 3-30 FPS in modern, general-purpose imaging. To monitor motion and thoracic/abdominal setup, skin surface is monitored at 10 Hz and reconstructed. Potentially, such surface data can be aligned to a reference data volume or longitudinally to the measurement acquired at a preceding time to facilitate setup and real time monitoring [7], [8]. Previously, several studies have used CBCT pre-, intra-, and post- treatment to perform an interrogation of the patient's change in position. The advantage to a volumetric imaging method is that tumor location can be seen. The disadvantage is that it only accounts for the tumor location at three predetermined times. Real time tumor motion during radiation therapy can be quantified using x-ray

fluoroscopy. This gives a continuous log of data that can be used to truly "track" tumor motion.

There are other ways other than fluoroscopy to monitor not tumor motion but body motion. The VisionRT system is a monitoring product that can track surface motion with better than 1 mm accuracy and as a result is used for the treatment of SBRT lung patients [9]. On the day of treatment, each patient undergoes routine setup/alignment to define an approved treatment position. Subsequently, each patient is monitored continuously in real time with a surface imaging system (VisionRT) to acquire data on patient motion that would be lost by a simply performing a pre- and a post- treatment interrogation of the patient's position with volumetric imaging. The non-invasive nature of the VisionRT system utilizes a harmless 3D stereo camera technique to track the patient in real time and making it preferred method over the longer CBCT method.

## 1.4. Specific Aims of Study

In a preliminary study that compared two immobilization devices in their ability to minimize prepositioning deviation during stereotactic body radiation therapy of the lung, liver or spine, it was found that patients in the BodyFIX system required shifts up to four times greater than those in a Vac-Lok system. A follow on study was designed to compare the BodyFIX and Vac-Lok systems with regards to patient stability during each SBRT treatment session. In order to conduct the latter study, irrespective of the immobilization device or the motion tracking methodology utilized, realistic guidelines on study implementation are highly desirable. The purpose of this study is to derive a protocol that will facilitate reproducible data acquisition.

**Aim 01:** Formalize criteria for identification of potential study candidates and their subsequent recruitment.

**Aim 02:** Design checklists such that each key member in the research group has clearly defined set(s) of instructions regarding his/her role. Design procedures for proper training of each key study members.

### 1.4.1. Timeline

Below is a basic schematic of an estimation of time allocation per our study recommendations. It should be noted that this study was originally designed to answer a very specific question. During the collection process, we ran into several unforeseen errors

in the project design and documented them accordingly. When the initial data analysis process began, we recognized that the crucial monitoring data was not being stored as an exportable file. While this was a set back leading to a smaller cohort of patients used in the analysis, it was a valuable learning experience.

It was not until the second data analysis attempt that we realized that we had not collected enough patients to draw a statistically significant conclusion. So often in research we want (and in this case planned for) positive results but that is clearly not always going to be the case. We outlined all the successes and failures of the original project design and were able to establish the a comprehensive protocol and analysis platform. The next attempt at this project will undoubtedly provide sufficient data if this documented is followed intensively.

| | Months | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Activities** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Application for IRB approval (see Section 1.4.2) | | | | | | | | | | | | |
| Development of research tools | | | | | | | | | | | | |
| Determination of sample size and candidate criteria | | | | | | | | | | | | |
| Training of key study members | | | | | | | | | | | | |
| End-to-end test on a single patients | | | | | | | | | | | | |
| Validation of monitoring systems | | | | | | | | | | | | |
| Data collection | | | | | | | | | | | | |
| Data entry and analysis | | | | | | | | | | | | |
| Report writing and submission | | | | | | | | | | | | |

Figure 1.1: Estimation of time allocation. This timeline serves as a recommendation and should be used as a guide.

### 1.4.2. IRB Approval

Approval by an institutional review board (IRB) is required in order to publish the type of data that will be collected in this study. The study coordinator and principle investigator should apply for "Expedited Review" and allow four to six weeks for approval. This category of research is eligible for "Expedited" review since it poses no risks to the subjects. The submission process begins with the study coordinator requesting an IRB account. The study coordinator will complete the application and list themselves as the Primary Contact before sending to a faculty PI for certification. Once the PI certifies submission, it is transferred to IRB staff for processing and review. Next, the study coordinator will make changes to the application based on review comments and recommendations and resubmit once all issues have been resolved. Upon final review by the IRB Chair, a final approval and receipt of approval letter.

# 2. Materials and Methods

This section outlines the materials and methods currently being implemented for clinical protocol development in our department. Figure 2.1 is an overview of the methods that are of interest and where they lie in the treatment/data acquisition process.

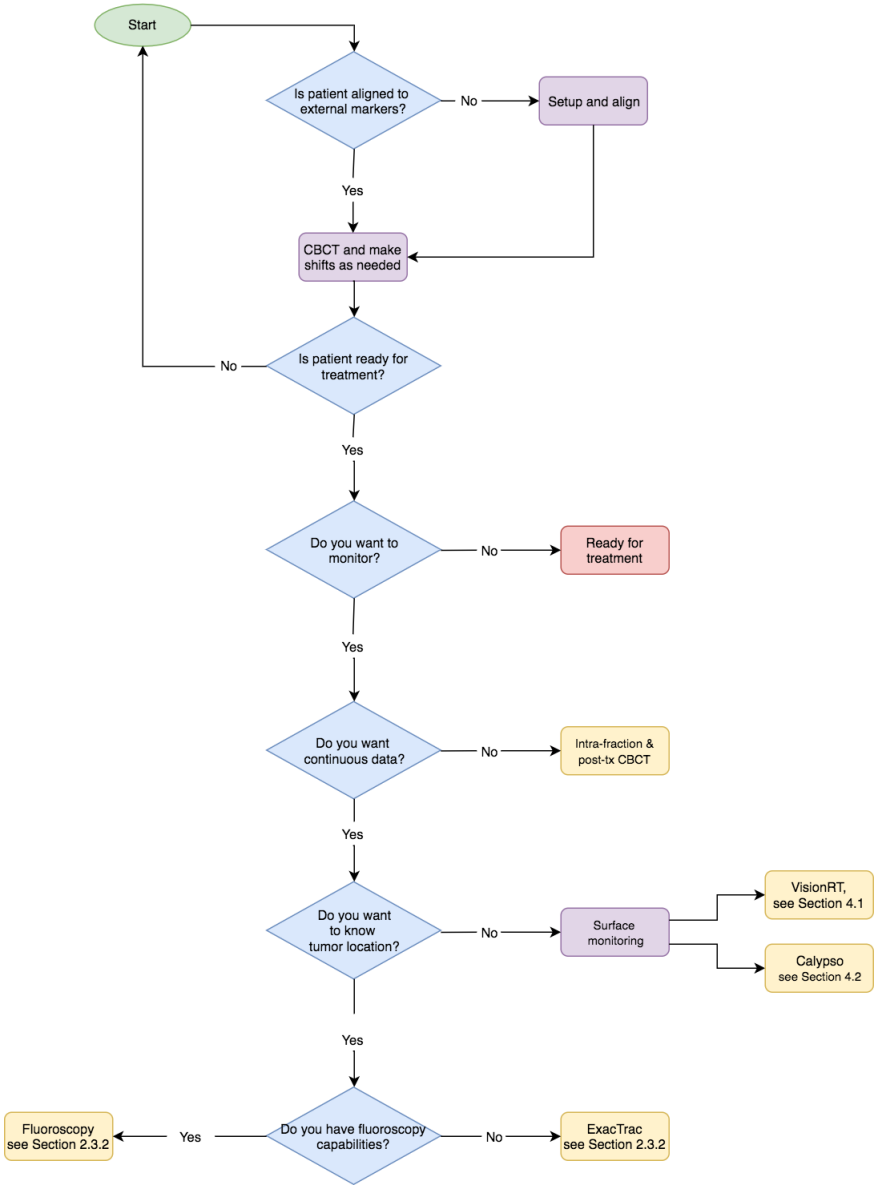


Figure 2.1: A flowchart illustrating the patient treatment process as well as the advantages of different treatment monitoring modalities.

## 2.1. Immobilization Devices

The following details the two immobilization devices of comparison interest. In our department, there are two systems preferentially used for treatment of the lung, liver, or spine - CIVCO Radiotherapy Vac-Lok, where the patient is only stabilized around the area of interest (generally thoracic or abdominal), and Elekta BodyFIX, where the patient's entire body is fully secured and additionally sealed with a top cover sheet.

### 2.1.1. Vac-Lok

The Vac-Lok system aims to focus on patient comfort and come in various materials, sizes, and shapes providing a custom solution to each patient. The cushions are filled with tiny polystyrene beads to create a rigid, comfortable cradle around the patient when the vacuum is drawn through a self-sealing quick-releasing valve [10].

Figure 2.2: This is an example of a Vac-Lok immobilization bag similar to the ones used in our department. This bag only holds the patient from the torso, up and can be paired with other positioning wedges and support cushions. Image accessed April 2017, available at `http://civcort.com/ro/products/Vac- Lok-Positioning-Cushions.htm`.

A CBCT study (see Section 2.3.1) conducted at Princess Margaret Hospital in Toronto found that when using Vac-Lok on SBRT lung cases, 67% of the patients were within 3-mm tolerance at the end of treatment but that by using image guidance a 5-mm treatment margin is sufficient to account for the motion [11]. Vac-Lok may be preferential to patients as it is less restricting than other immobilization devices.

### 2.1.2. BodyFIX

The BodyFIX system uses a dual-vacuum technology that aims to maximize intra-fraction patient stability by attempting to reduce voluntary and involuntary patient movement.

The BodyFIX BlueBAG is manufactured entirely from radio-translucent materials, styropore nylon, to provide artifact-free image clarity and minimal beam attenuation. The unique cover sheet acts as the second vacuum and produces uniform pressure around the patient on the day of treatment.


(a) (b)

Figure 2.3: Components of the BodyFIX immobilization system as seen in the clinic. (a) A BodyFIX bag with cover sheet molded and on the treatment table. (b) BodyFIX portable vacuum used for to create a dual vacuum system.

A CBCT study (see Section 2.3.1) of intra-fraction motion of SBRT lung patients in BodyFIX systems conducted at Sunnybrook Health Sciences Center found that the mean (and range of) intra-fraction tumor motion for patients immobilized with the Bodyfix was 0.8 mm (0-2.5 mm) in the ML direction, 0.9 mm (0-2.7 mm) in the AP direction, 1.5 mm (0-5.7 mm) in the SI direction, and 2.3 mm (0-6.3 mm) overall [12]. There is some controversy over whether or not the BodyFIX system is a true dual-vacuum system. If the plastic is not placed correctly, it may compromise the integrity of the system. For our study, we asked that the wrap only come up to the patients waist, leaving the chest exposed for monitoring.

## 2.2. Pre−Treatment Methods

Setup, alignment, and target localization are required processes to treat a patient both accurately and precisely over multiple days of treatment. External marker localization (see Section 2.2.1) coupled with CBCT (see section 2.2.2) is the widely accepted pre-treatment method used in radiotherapy. There is individual value in each step.

### 2.2.1. External Marker Localization

One of the most reliable and common methods for patient geometrical setup and predicting target location is use of external markers [13]. External markers are often defined at CT simulation and are either placed on the cast/immobilization device or on the patient via tattoo mechanism in reference to isocenter. The value of this method lies in the ease of setup and guidance for initial treatment setup. The disadvantage is that while some structures may follow the bony anatomy nicely, other organs may undergo significant motion with respect to that bony anatomy, such as the prostate [14]. Image guidance provides a visual aid to negate the uncertainty as a result of setup and positioning. CBCT of target location on the day of treatment can confidently be fused to the CT from simulation that was used for planning.

### 2.2.2. Localization CBCT

A preliminary study in our department analyzed which of the two immobilization devices produced the largest alignment deviation using on board volumetric cone beam CT (CBCT) scan. A cohort of 63 lung, liver, and spine patients were analyzed, 18 of those being Vac-Lok and 45 BodyFIX. It was found that patients in a BodyFIX system required shifts up to four times greater than that of patients in a Vac-Lok system. This is not an incredibly shocking conclusion and agrees with what we would expect. BodyFIX patients are setup using lasers to align to external markers on the vacuum bag and then shifted into position while Vac-Lok patients take advantage of tattoos on the skin to align to lasers and then shifted accordingly. The BodyFIX systems has the additional uncertainty of the patient's position in the bag itself. The Vac-Lok system use of tattoos eliminates this uncertainty entirely.

| | Vac-Lok ($n = 18$) | | | | BodyFIX ($n = 45$) | | | |
|---|---|---|---|---|---|---|---|---|
| | VRT | LNG | LAT | ANG | VRT | LNG | LAT | ANG |
| min $\sigma$ | 0.05 | 0.10 | 0.05 | 0.00 | 0.00 | 0.13 | 0.05 | 0.00 |
| max $\sigma$ | 0.76 | 0.54 | 2.51 | 1.77 | 1.37 | 1.79 | 3.79 | 1.39 |
| range | 0.71 | 0.44 | 2.46 | 1.77 | 1.37 | 1.66 | 3.74 | 1.39 |

Table 2.1: Localization CBCT Deviation Results (cm)

Our follow on study was designed as a result of these conclusions. We are interested in the comparison of the BodyFIX and Vac-Lok systems with regards to patient stability during each SBRT treatment session. In order to conduct this type of study, we need to explore the options for image guidance and monitoring methods accessible during the patient's treatment.

## 2.3. During Treatment Methods

The five types of modalities used for tracking body motion during the treatment session are CBCT, VisionRT, Calypso, ExacTrac, and fluoroscopy. In our department we are capable of monitoring using any of these methods with the exception of fluoroscopy. A discussion on fluoroscopy is still given as it offers excellent real-time data of exact tumor location.

### 2.3.1. CBCT

Unlike optical monitoring methods, CBCT uses ionizing radiation. Ionizing radiation has the power to increase the potential for secondary cancers. While CBCT is still considered non-invasive, there is theoretically more risk anytime a patient is exposed to ionizing radiation. The acquisition of a CBCT takes several minutes. This is additional time where the patient is on the table not being treated and may lead to patient discomfort. Many studies have investigated target movement by taking a CBCT midway through and after a given treatment to compare to the one taken pre-treatment for setup. Voxels can be tracked individually and compared to the pre-treatment CBCT to draw conclusions of tumor location. The disadvantage is that this is not considered real time and only provides information at two or three predetermined times.

### 2.3.2. Real Time Monitoring

#### VisionRT

VisionRT is a system which tracks patient's position before and during radiation therapy, to aid in setup and treatment accuracy. The system utilizes proprietary 3D stereo camera unit to track the skin surface and compare it to the ideal position with submillimeter accuracy. The VisionRT system uses the body contour created from the CT simulation scan in planning to select regions of interest (ROI). The the skin-rending, shown in the actual monitoring of a patient, uses a reference image that is captured on the day of treatment, post-setup, using the 3D stereo camera technology, Figure 2.4. The deviation values are calculated from the baseline of the reference image. The non-invasive nature of the camera system makes it desirable for monitoring patients for real time data acquisition.

A study analyzed the validity of the VisionRT system real time 3D surface imaging for respiratory motion during radiotherapy. They were able to record 3D sequences of surface data of the thoracic region over 8-15 second periods at 3 frames/second. 3D surface data was acquired from 14 patients in the intended treatment position during

CT simulation. In order to analyze the data, software tools were developed to extract transverse contours through the thorax, abdomen and pelvis, for all recorded frames for each patient. For each contour, 3 points were monitored. The AP coordinates of these points were measured. These values were plotted against time along both transverse and sagittal contours. Amplitudes, periods and phase shifts were compared across the contours and from patient to patient [15]. The results of this study validate demonstrate that respiratory motion can effectively be monitored using the VisionRT system and thus makes it a useful tool for our study for thoracic patient motion .

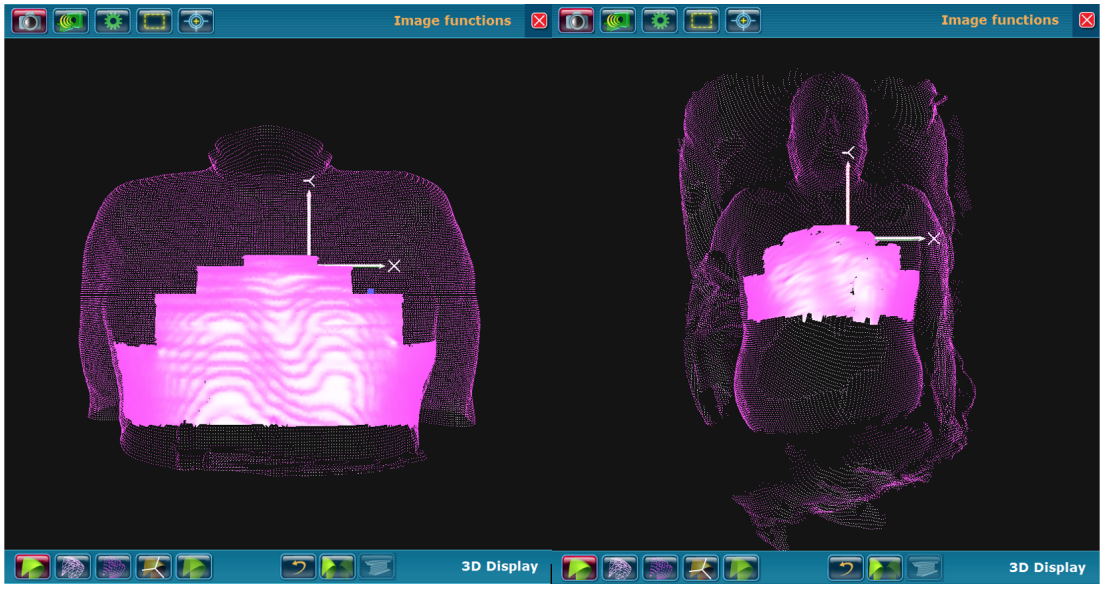


Figure 2.4: The image on the left represents a predetermined region of interest selection. The image on the right shows that image in monitoring mode, superimposed on of the reference image.

### Calypso Beacon System

The Calypso Surface Beacon transponder has only recently become available clinical application. It is designed to be used for real time motion tracking during external beam radiotherapy and can be used anywhere on the body where intra-fraction motion may be a concern. The two beacons are configured in an 'L' shape and able to detect slight movements and continuously transmit accurate target location.

A recent phantom study (quasar respiratory phantom), aimed to validate the transponder in terms of stability, reproducibility, orientation sensitivity, cycle rate dependence, and respiratory waveform tracking accuracy. Submillimeter resolution was achieved throughout breathing (sinusoidal) waveforms. No positional drift was observed within runs and the standard deviation within a run was shown to be independent of displacement, ve-

locity, and acceleration. Angular measurement was observed to deviate nonlinearly from true Beacon angle. Beacon angles varied from $0^o$ to $15^o$ with regard to Beacon orientation [16].

Figure 2.5: Calypso surface beacon transponder. Image accessed May 2017, available at `https://www.varian.com/sites/default/files/resourceattachments CalypsoSurfaceBeaconTransponderRAD10289Mar2013.pdf`.

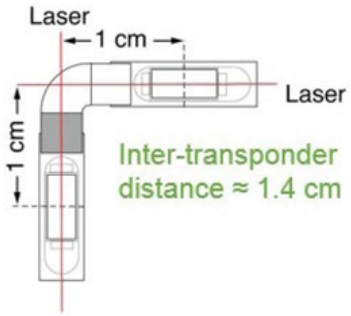


Figure 2.6: Schematic diagram showing the design of Calypso Surface Beacon. Image downloaded May 2017, `http:// onlinelibrary.wiley.com/doi/10.1120/ 10.1120/jacmp.v17i4.6152` .

### ExacTrac X-Ray Monitoring

ExacTrac is an in-room x-ray based monitoring system that is able to detect intra-fractional tumor motion. The room is equipped with two kV x-ray units. ExacTrac can be used with existing IGRT solutions to provide internal verification of the patients positions regardless of couch and gantry angle.

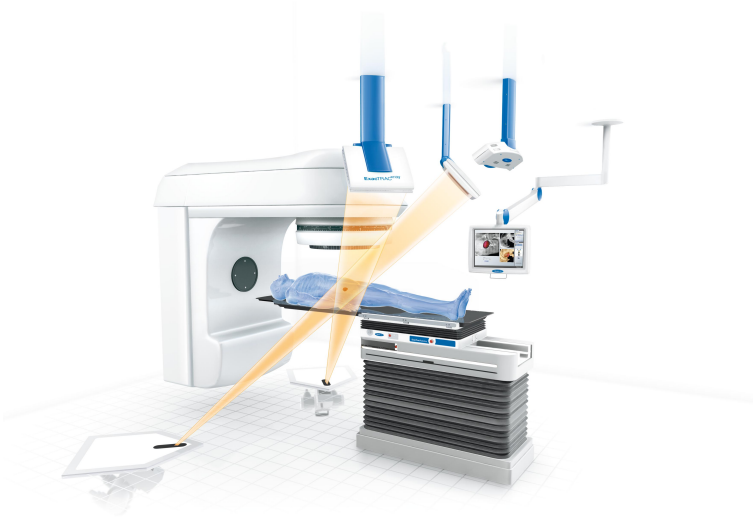

Figure 2.7: ExacTrac in room x-ray setup. Image downloaded from clinic's ExacTrac brochure, `2008 BrainLAB AG, Printed in Germany ONC-BR-E-IGRT-09/08 Q:450`.

ExacTrac Snap Verification uses x-ray images acquired during treatment delivery or between fields to instantly detect and visualize internal tumor displacement. A threshold-based margin analysis algorithm indicates whether patient setup correction is recommended or not. ExacTrac automatic couch control can then be used to realign the patient remotely [17].

### Fluoroscopy

While our department is not currently equipped with fluoroscopic technology for external beam therapy, the option should certainly not be ruled out. Fluoroscopy systems produce projection x-ray images and allow real-time x-ray insight of the patient with very high temporal resolution. General systems usually use a pulsed x-ray beam in conjunction with digital image acquisition. The lower the frame rate, the lower the radiation dose. Low frames can be especially beneficial in radiation therapy when high temporal resolution is not necessary [8].

Mobile fluoroscopy systems are C-arm devices and are frequently used in operating rooms and intensive care units. Technically, a C-arm could be used in external beam radiotherapy. From a realistic standpoint, it is not exactly feasible. There is increased risk in gantry/C-arm collisions and possibly C-arm blocking part of the beam. In typical SBRT cases, the gantry makes use of a full range of angles. In order for fluoroscopy to truly be beneficial, the system must be integrated into the linear accelerator used for treatment.

## 2.4. Methods

In lung, liver or spine SBRT, the variability of intra-fractional target motion can negate the potential benefits of four-dimensional treatment planning that serves to account for the dosimetric impacts of organ/target motion. Immobilization systems, specifically BodyFIX and Vac-Lok, play a crucial role in patient motion management and aim to limit intra-fractional motion. In order to test the stability capabilities of the two systems, each patient was monitored continuously in real time with a surface imaging system (VisionRT) to acquire data on patient motion.

For this prospective study, lung, liver, and spine SBRT patients were selected and tagged as a potential study candidate. On the day of CT simulation, the patients were immobilized in either a Vac-Lok or BodyFIX bag. In order to monitor these patients, the VisionRT system requires manual ROI selection. The ROI field size selected was relatively standard for all patients regardless of tumor site or motion management system to ensure consistent data.

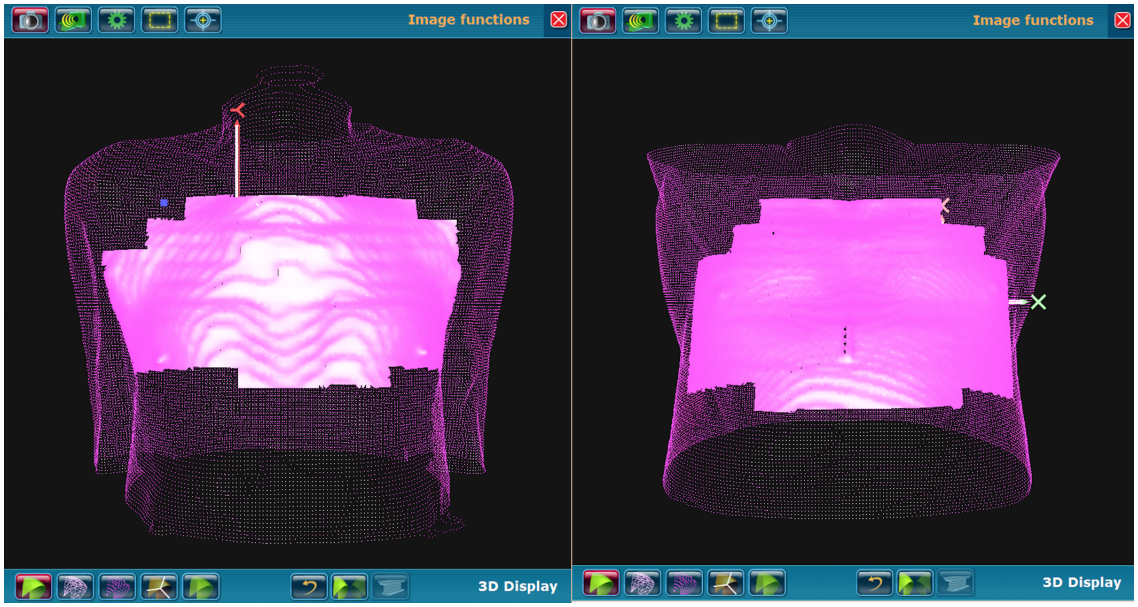


Figure 2.8: The images illustrate what an ROI selection may look like for a patient positioned arms up and a patient positioned arms down. Notice that the highlighted area does not extend into the armpit nor up into the collar bone. It was essential to be mindful of immobilization device/camera interference.

On day of treatment, a reference image from the VisionRT was captured post-approved setup. The previously selected ROI was superimposed onto the reference image and monitored during treatment. The data collected is continuous over time and provides deviations in each direction. The monitoring process was done for each day that the patients were treated.

# 3. Results

The purpose of this study is to derive a protocol that will facilitate reproducible data acquisition. Each of the specific aims were reached and have been presented. Deviations from protocol framework will be carefully documented.

**Aim 01:** Criteria for identification of potential study candidates and their subsequent recruitment were formalized.

- See Appendix A for optimal patient selection criteria
- See Appendix B for physician request email template

**Aim 02:** Checklists were designed such that each key member in the research group had clearly defined set(s) of instructions regarding his/her role. Procedures for proper training of each key study member were designed and will be implemented by the study coordinator.

- See Section 4.1.2 for VisionRT methodology checklist
- See Section 4.2.2 for Calypso methodology checklist
- See Appendix C for CT simulation checklist
- See Appendix D for VisionRT checklist
- See Appendix E for Calypso checklist

# 4. Discussion

There are clear advantages and disadvantages for each motion tracking technique. Some system characteristics seem positive in theory (which we have now explored in detail), but are unfortunately unforable from a workflow standpoint. We can now outline the processes involved in collecting and analyzing useful real time data to compare two different immobilization techniques.

| Treatment Session Monitoring Components | | | | | | |
|---|---|---|---|---|---|---|
| Technique | Real-Time Monitoring | Patient Positioning | Target Localization | Non-Invasive | Radiation | Currently Implemented |
| CBCT | | ✓ | ✓ | ✓ | ✓ | ✓ |
| VisionRT | ✓ | ✓ | ✓† | ✓ | | |
| Calypso | ✓ | ✓ | ✓* | ✓* | | |
| ExacTrac | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Fluoro | ✓ | ✓ | ✓ | ✓ | ✓ | |

Table 4.1: Treatment Session Monitoring Components

† The VisionRT system has setup and alignment capabilities which is why is falls into the target localization category. However, the surface monitoring system does not has internal images capabilities.

* Calypso does not provide internal imaging of target location. However, surface beacons can be place relative to target so that only a specific part of the surface is being recorded. Calypso is listed as non-invasive for the interest of surface monitoring but it should be noted that traditionally, Calypso seeds are implanted in the patient (commonly prostate).

In our department, we have one vault equipped with VisionRT and a separate vault equipped with Calypso. A patient is not a candidate for the study if the chosen immobilization device is coupled with another motion management system. For example, a patient's body motion data would not be valuable if they were immobilized with a Vac-Lok and a wingboard. This excludes the active breathing coordinator (ABC) found in the Calypso vault as it does not contribute additionally to patient stability or interfere with monitoring. For ease of organization and to avoid confusion, the next two sections will outline the prospective VisionRT and Calypso process separately.

## 4.1. VisionRT Surface Monitoring Option

**Preliminary Data Analysis**

Of the data we were able to collect, we can still make statements of the maximum deviations observed but no logical conclusions can be drawn from the data as a whole. There were 12 viable Vac-lok data points (treatment days) and 32 BodyFIX.

| | Vac-Lok ($n = 12$) | | | BodyFIX ($n = 32$) | | |
|---|---|---|---|---|---|---|
| | VRT | LNG | LAT | VRT | LNG | LAT |
| mean | 0.1105 | 0.1189 | 0.0685 | 0.1205 | 0.1243 | 0.0673 |
| $\sigma$ | 0.0887 | 0.1158 | 0.0623 | 0.1040 | 0.1074 | 0.0649 |
| max | 1.0717 | 1.9881 | 0.5457 | 1.3414 | 1.3162 | 0.9229 |

Table 4.2: Data from run-through trial. (cm)

It becomes difficult to compare these numbers to that of the preliminary, alignment deviation study where data points were defined as individual patients and not treatment days (see Table 2.1). There was significantly more data with 18 Vac-Lok patients and 45 BodyFIX patients which explains the statistically significant differences of standard deviations in each direction. Table 4.2 clearly outlines the lack of statistically relevant data. The results of Vac-Lok are nearly identical to that of BodyFIX. We suspect that an increase in data points will cause an increased difference between means and standard deviations of the two systems.

In the CBCT study, BodyFIX had identifiably more sources of uncertainty and therefore logically described it's results, as previously discussed. For the suggested study, the two systems were introduced to the same errors and uncertainties. Inter- and intra-patient variability became much more prominent when we looked at real-time time data as opposed to a CBCT. The data collected can be heavily affected by individual habits of the patient. Further analysis of the suggested study will need to be much more sophisticated than the preliminary study to account for the large amount of uncertainties.

### 4.1.1. Recommended Methodology to Obtain Useful Clinical Data within a Clinical Environment: VisionRT

In this section, we recommend a list of methodological details and guidelines on performing the described or similar study. Bullet points represent questions or ideas to be considered and should be unique to the study of interest. Checkboxes indicate requirements that must be performed.

1. *Patient pool selection* (see Appendix A)

☐ Choose a specific treatment, type of patient, or combination of the two

- Take notes of patients' plan for treatment as it develops.
- Recognize that documented plans may be given different names for billing purposes. For example, a plan documented as an eight fraction VMAT may be considered an SBRT from a physics standpoint. It is important to look at each plan as they printed.
- Being a physics assistant is highly recommended. Responsibilities of this job include running nightly, patient QA and becoming familiar with those plans. Potential candidates are less likely to go unnoticed.
- Patients with more than one isocenter are not recommended. Elderly (85+) are also not recommended, and are the most likely to refuse to participate.

☐ Determine the required sample size

- A power calculation should be done to determine the required number of measurements needed to make certain the mean value is accurate within a margin of error, $\pm\epsilon$.
- For this study, $\epsilon = \pm 5$mm because this is the positional accuracy necessary for SBRT treatments. The margin or error could be made even tighter by using 3mm. The $Z$ value for a 5% confidence level is equal to 1.960. The variation in the mean is the standard deviation $\sigma$. The average $\sigma$ from the run-through trial can be used as an estimation and is equal 0.09. The following expression determines a required sample size.

$$n = \left[\frac{(Z)(\sigma)}{\epsilon}\right]^2 \tag{4.1}$$

  For this study, $Z = 1.960$, $\sigma = 0.09$, and $\epsilon = \pm 5$mm, the required number of measurements would be 13 for each category (Vac-Lok, BodyFIX). If the smaller $\epsilon = \pm 3$mm is used, the required number of measurements increases to 35 for each category.
- Note that these power calculation results give the number of patients needed, not the number of treatment days.

☐ Become familiar with how the type of patient selected is currently treated

2. *Training and educational engagement*

☐ Develop strong communication relationship with CT simulation therapists

- CT simulation therapists should also be informed of the study intentions so they can set up patients accordingly (i.e. expose patient skin for mon-

itoring). They can provide insight on physician preferences, scheduling, and even suggest potential candidates.

- The CT simulation control room is small and can get crowded quickly. Ask therapists how they prefer to be informed of which patients are of interest. Entering a comment into Mosaiq such as 'VRT PT. *your initials*' is an effective suggestion.
- Sim documents in Mosaiq is the best way to get information on immobilization devices used.
- In Mosaiq, select location in the top bar. In the dropdown that says 'Queued Location' select CT Sim. This is the most current schedule and should be checked daily for new patients.

☐ Train therapists to use VisionRT for thoracic monitoring (see Appendix D)

- Therapist will appreciate communication or reminders for patients that will be monitoring *before* their first day of treatment. It is highly recommended to be present for that first day of treatment.

**OR**

☐ Medical physicist or researcher oversight daily

- This is a tedious and unrealistic method for a master's student and/or physics assistant. There are several factors that play into the tentative nature of a clinical treatment schedule so a flexible schedule of the study coordinator is required.
- Taking notes daily would explain illogical data trends. Did the patient go to the bathroom mid-treatment? Did the therapist move the couch to avoid gantry collision? Did a BodyFIX bag pop?

3. *Preparing for monitoring*

☐ Request physician VisionRT orders (see Appendix B)

- Requesting physician orders sends a VisionRT import request to the physics QCL

☐ Export plan from treatment planning system to monitoring system (VisionRT):

- **In Aria Eclipse**
  (a) Quicklinks > Treatment Planning > External Beam Planning
  (b) Open patient using search bar
  (c) Select correct plan, do this by drag and drop into workspace
  (d) File > Export > Wizard
    – Select Plan and then Next

- Uncheck *Include setup fields*
- Check *Include structure set*
- Select *DICOM export to VisionRT* and *Finish*

☐ Import plan and structures to monitoring system:

- **In VisionRT**

(a) At VisionRT home screen select *New Patient Entry*

(b) Enter MRN, patient name, patient date of birth, and select *Create Entry*

(c) Click *SITE* icon
- In label dropdown, select *SBRT* and save

(d) At the top of the workspace there are *Mode* icons and *Image function* icons; under *Image function* select the CT scanner to the right of the camera

(e) Select *IMPORT RTPLAN*
- Select file with patient name and open DICOM file that begins with *RTPLAN...*
- It will ask if you want to import *DICOM RTBEAMS*, select no
- It will then ask if you want to import *DICOM STRUCT*, select yes
- Open DICOM file that begins with *RTSTRUCT...* and check *BODY*, *Import*
- Confirm patient position

(f) Change label to plan name and save

(g) Under *Image functions* select the dashed, rectangle
- CTRL + click and drag will select regions of interest
- CTRL + right click and drag will de-select
- click and drag will rotate the patient
- *FILTER* will erase unwanted pixels

(h) Select *STORE SELECTION* at the bottom of the workspace once satisfied with ROI selection

(i) Highlight plan name and select *FIELD*
- Label as 'Monitoring' and save

(j) Select the CT scanner icon as in step 4, and select *IMPORT RT-STRUCT*
- Open DICOM file that begins with *RTSTRUCT...* and check *BODY*, *Import*
- Confirm patient position

(k) Change label to 'Monitoring' and save

(l) Under *Image functions* select the dashed, rectangle and then *IMPORT*
  - Select desired timestamp and ROI
  - Select *IMPORT* and *ACCEPT*

(m) *STORE SELECTION* and close patient

☐ Complete QCL request

- **In Mosaiq:**
  - In the *View* dropdown, select *Location*
  - In the *Location* dropdown, select *Physics*
  - Look for *VRT upload*, right-click and select *Complete*

4. *Data collection process*

- Depending on what method of therapist involvement is chosen, it may be considered useful for the study coordinator to follow patients throughout their treatment process. Make notes of start and end dates, cancellations, patients that refuse to participate, how many BodyFIX, how many Vac-Lok, etc.
- Check VisionRT periodically to make sure monitoring data is being stored to an exportable file correctly. Real-time data is organized by MRN and stored on the VisionRT desktop under a file named 'P Data'.
- Documentation, communication, and flexibility are things to keep in mind when collecting data in a clinical setting. It is important to understand that the priority lies with the patient, not the project.

5. *Analyzing data*

☐ Convert .txt to .csv for analysis ease

- The .txt file holds a lot of information. Depending on what specifically will be analyzed, it may be useful to delete certain columns. This will limit confusion during matrix computation and ultimately make the code run more quickly.

☐ Run a statistical test on the groups of data to see if their is statistically significance

☐ Calculate average deviations, standard deviations, maximum deviations, etc.

- It may be advantageous to create a table similar to Table 4.2

☐ Perform a regression analysis

- Figures 4.1 and 4.2 illustrate the inter- and intra-patient variability that occurs during a study of this nature.

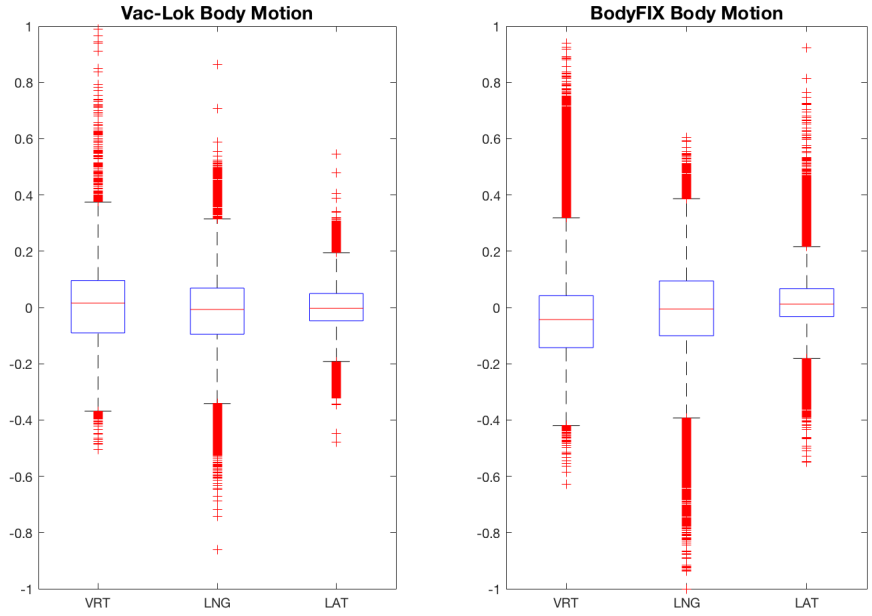


Figure 4.1: Example of a boxplot comparison of each direction between the two systems. The high number outliers illustrates the intra-patient variability that occurs.

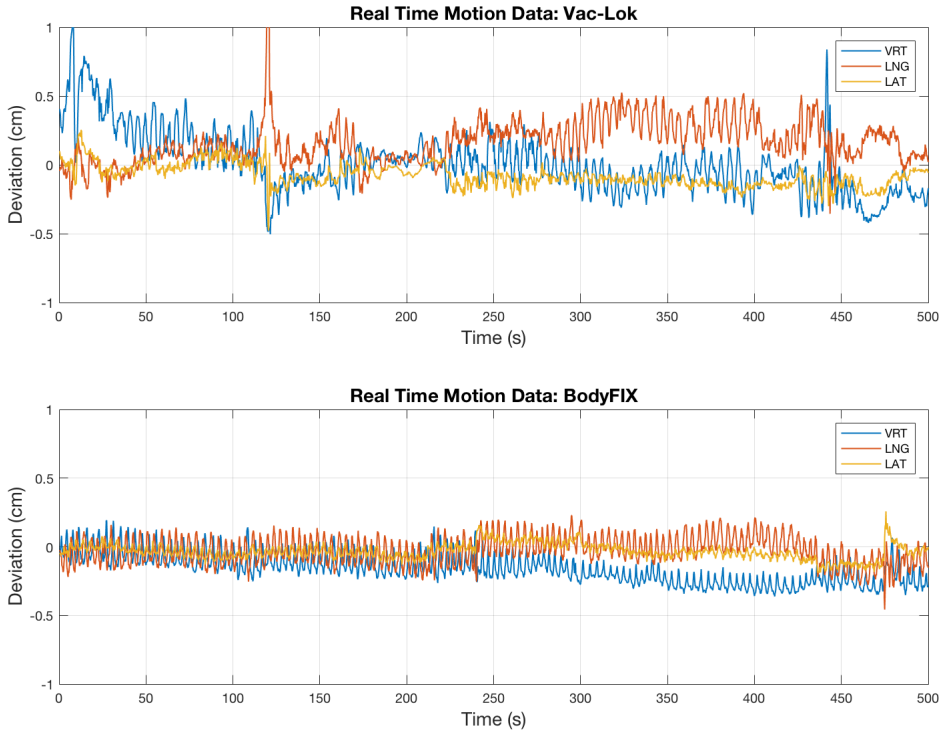


Figure 4.2: An example of real time motion data over treatment time in each direction for two patients.

- A traditional analysis approach, such as ANOVA, may give limited insight to the data and more sophisticated regression analysis is preferred. Mixed effect models deal with missing values in settings where repeated measures are made on the same statistical units or where measurements are made on clusters of related statistical data.
- A mixed effects model applies to clustered data. Clustered data suggests that a response is measured for each subject and each subject belongs to a group of subjects (cluster). For example, body motion data grouped by motion management device. The motion management device forms the the cluster. The linear model can be extended to allow for dependent data structures. A fixed factor is a qualitative covariate while a fixed effect is a quantitative covariate. A random factor is a qualitative variable whose levels are randomly sampled from a population of levels being studied. A random effect is a quantitative variable [18]. The model takes all of these into account.

$$Y_{ij} = x_{ij}^t \beta + u_{ij}^t \gamma_i + \epsilon_{ij}; \qquad i = 1, ..., m; j = 1, ..., n_i \tag{4.2}$$

Where $m$ is the number of clusters, $n_i$ is the size of cluster i, $x_{ij}$ is the covariate vector of the j-th member of cluster i for fixed effects, $\beta$ is the fixed effects parameters, $u_{ij}$ is the covariate vector of the j-th member of cluster i for random effects, and $\gamma_i$ is the random effect parameter.

☐ Create plots of motion deviation over time, box plots, and histograms to illustrate data patterns and variability

☐ Discard unfavorable data

- It is easy to understand the importance of outliers in this study. They may lead to higher maximum deviations that do not accurately represent what is physically occurring. The study coordinator may have preconceived ideas about what results they expect to obtain. If unexpected data was obtained during they data collection process, the coordinator may want to discard the data assuming that a mistake was made. However, to discard data, there must be strong statistical grounds otherwise all data should be utilized in the analysis.
- Box plot diagrams are a excellent graphical method depicted by quartiles and interquartiles that assist in defining upper and lower limits. Any data found beyond these limits can be considered outliers and can be discarded.
- Outliers can also be identified mathematically. Let $n$ be the number of

data values in the data set. The second quartile is the median and the middle of the data set.

$$Q2 = \frac{1}{2}(n+1) \tag{4.3}$$

The first (lower) quartile is the median of the lower half of the data set.

$$Q1 = \frac{1}{4}(n+1) \tag{4.4}$$

The third (upper) quartile is the median of the upper half of the data set.

$$Q3 = \frac{3}{4}(n+1) \tag{4.5}$$

The interquartile range (IQR) is the spread of the middle half of the values and is found by subtracting Q1 from Q3. There for the lower and upper limits can be found:

$$LL = Q1 - 1.5 * IQR \tag{4.6}$$

$$UL = Q3 + 1.5 * IQR \tag{4.7}$$

☐ Fourier analysis

- During CT simulation, patients often are scanned with a device that tracks their breathing patterns over time. If the frequency of the breathing waves can be determined, then a Fourier transform of the motion data will provide the option to only include certain frequencies. Potentially, the breathing motion can be eliminated from continuous tracking motion so only other sources of movement are included in analysis. This method has the power to provide a better comparison of immobilization device stabilization, independent of patient breathing habits.
- The equation below is the Fourier series equation. It says that any periodic signal, $x(t)$, can be reconstructed from sine and cosine waves with frequencies that are multiples of the fundamental, $f$. The amplitudes are represented by the $a_n$ and $b_n$ coefficients.

$$x(t) = a_0 + \Sigma a_n cos(2\pi ftn) - \Sigma b_n sin(2\pi ftn) \tag{4.8}$$

The Fourier series analysis equations decompose the time domain so that amplitude as a function of frequency can be determined. $T$ is the period of the signal.

$$a_0 = \frac{1}{T}\int_{-T/2}^{T/2} x(t)dt \tag{4.9}$$

$$a_n = \frac{2}{T} \int_{-T/2}^{T/2} cos\big[\frac{2\pi tn}{T}\big] dt \tag{4.10}$$

$$b_n = \frac{-2}{T} \int_{-T/2}^{T/2} sin\big[\frac{2\pi tn}{T}\big] dt \tag{4.11}$$

☐ Draw conclusions; refer to preliminary study on setup deviation

## 4.2. Calypso Surface Beacon Option

### 4.2.1. Calypso Liver Patient Project Design

The original design of our project included using Calypso surface beacons to monitor SBRT and hypofraction patients. A delay in equipment delivery suspended this portion of the study. However, we can confidently adapt what we have learned from the VisionRT system to create a similarly styled protocol checklist and analysis framework. Similarly to the VisionRT process, the study coordinator will want to prepare the system and inform therapist of a new patient before their first day of treatment. The steps for Calypso are listed below:

**In Calypso:**

1. Make sure to be in *Data Entry Mode*
    - Username: 4Dadmin
    - Password: System1
2. Select *Patient* on the left-hand side of the screen
3. Section *New* and enter patient name and MRN, then *Next*
4. In the *Input CRF* dropdown, select *Varian Eclipse*
    - The name *Varian Eclipse* is not specific to the Eclipse treatment planning system and should be selected for Monaco or Pinnacle plans as well
5. Select *Apply Changes*

### 4.2.2. Recommended Methodology to Obtain Useful Clinical Data within a Clinical Environment: Calypso Surface Beacons

In this section, we recommend a list of methodological details and guidelines on performing the described or similar study. Bullet points represent questions or ideas to be considered and should be unique to the study of interest. Checkboxes indicate requirements that must be performed.

1. *Patient pool selection* (see Appendix A)

    ☐ see Section 4.1.2, point 1.

2. *Training and education engagement*

☐ see Section 4.1.2, point 2.

☐ Train therapists to use Calypso surface beacon system for thoracic and abdominal monitoring (see Appendix E)

3. *Preparing for monitoring*

☐ Request physician Calypso order (see Appendix B)

- see Section 4.1.2, point 3, for Mosaiq QCL instructions

☐ Select a surface point respective of target location

- The point can be decided upon close inspection of the contoured CT scan.
- The study coordinator must place the beacon according to that point each day of treatment. It may be beneficial to mark the location with BBS.
- Target location is crucial for this method of tracking.
- If the patient is in a BodyFIX system, the beacon must be placed directly onto skin prior to the secondary vacuum. If the patient is in a Vac-Lok system, the beacon can simply be placed directly onto the patient's skin.

4. *Data collection process*

- Depending on what method of therapist involvement is chosen, it may be considered useful to follow patients throughout their treatment process.
- The Calypso system has an 'Association' tool that works similarly to VisionRT's reference image capture technique. A baseline recording of the beacons configuration will be performed post-approved treatment setup each day of treatment.
- Real-time data is stored on the Calypso system.
  - In *Data Entry Mode* select *Export* on the left-hand side of the screen
  - Find the patient's name under *Patient Session*
  - Select a specific treatment session or *Select all* for each treatment recorded and *Okay*
- The data is exported as a .csv file to the Network drive under the *varian2.db* database and *Calypso* folder.
- Documentation, communication, and flexibility are things to keep in mind when collecting data in a clinical setting. It is important to understand that the priority lies with the patient, not the project.

5. *Analyzing data*

☐ see Section 4.1.5, point 5.

# 5. Future Studies

Medicine is a practice that is continuously growing. There are and always will be ways to improve treatment and immobilization techniques of lung, liver, and spine stereotactic radiotherapy. Listed below are a few areas to investigate in the future.

## 5.1. The Suggested Lung, Liver, and Spine Study

This thesis thoroughly details the steps needed to acquire reproducible real time motion data within a clinical environment in order to compare two immobilization devices. The entirety of the project focused on a very specific future study. If the provided protocols, checklists, and analytics are followed closely, then an evaluation of the effectiveness of the Vac-Lok immobilization device compared to BodyFIX with regards to body motion control in the thoracic/abdominal region will be achieved. The study aims to compare and quantify body motion in individual directions.

## 5.2. Location Specific Body Monitoring

An interesting analysis continuation of the suggested study would be to link movement to target location while still comparing Vac-Lok to BodyFIX. The same data acquired with VisionRT and Calypso surface would be sufficient but a much larger cohort of patients would be necessary. The only additional task would be to separate patients into to designated groups based off the specific treatment site. For example, patients could be divided into groups, Vac-Lok right upper lung, Vac-Lok right lower lung, BodyFIX right upper lung, BodyFIX right lower lung, etc. An analysis of this nature would actually provide information that has been lost, or rather, not consider in the previously mentioned analysis.

Unfortunately, there are several landmark challenges that may arise. Suppose a patient has a very posterior lesion near the chest wall and spine. Surface monitoring directly above this location will not provide data that describes a direct correlation between body motion and tumor site. It will only provide information on the movement of the surface. In order to confidently associate surface monitoring motion with treatment site, an extended study using some form of internal imaging, like ExacTrac is needed.

## 5.3. ExacTrac Verification/Fluoroscopic Monitoring

Currently, our department has ExacTrac Snap Verification capabilities and could certainly be integrated into the suggested study. The process of implementing of this type of monitoring could be adapted from the provided protocols. A method (algorithm) of voxel/pixel tracking would need to be created in order to successfully follow tumor movement during treatment but this is not any different than a CBCT pre- ands post- scan study. The spine could be used as a stable landmark for all lung, liver, and spine patients.

If the department was ever to be equipped with a integrated external beam/fluoroscopic system, it would undoubtedly serve as the best method to acquire real time monitoring data. With the right x-ray tracking algorithm, target deviation could be calculated quickly for every day of treatment, in every direction. This type of data could also be used to determine a probability function coupled with a biomechanical modeling technique to optimize treatment planning and dose distributions. Fluoroscopy could provide significantly more image data than that on a CT scan.

# 6. Conclusions

In summary, a study was originally designed to compare the BodyFIX and Vac-Lok systems with regards to patient stability during each SBRT treatment session. In order to conduct the study, irrespective of the immobilization device or the motion tracking methodology utilized, realistic guidelines on study implementation are needed. The purpose of this study is to derive a protocol that will facilitate reproducible data acquisition.

The clinical and analytical workflow of the suggested study has been analyzed with the aim of outlining a consistent framework that encompasses the entire data collection process.

The present report provides detailed framework and a checklist style protocol, based on preliminary study of the real-time data recording process, including clinical as well as physical aspects. We believe that designed analysis platform and protocol checklist should be applicable for acquiring clinical data within a clinical environment, and have provide several methods of doing so. The protocol and suggested process will serve as a platform to ensure consistent and comprehensive execution of a patient motion monitoring study, irrespective of the motion management system or the motion tracking tool.

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# A Appendix

**Optimal Patient Selection**

1. Treatment *(select one)*
   - ☐ SBRT
   - ☐ Hypofractionated treatment
2. Site *(select one)*
   - ☐ Lung
     - ☐ Right upper lobe
     - ☐ Right middle lobe
     - ☐ Right lower lobe
     - ☐ Left upper lobe
     - ☐ Left lower lobe
   - ☐ Liver
     - ☐ I segment
     - ☐ II segment
     - ☐ III segment
     - ☐ IVa-IVb segment
     - ☐ V segment
     - ☐ VI segment
     - ☐ VII segment
     - ☐ VIII segment
   - ☐ Spine
     - ☐ Cervical spine
     - ☐ Thoracic spine
     - ☐ Lumbar spine
     - ☐ Sacral spine
3. Motion-Management *(select one)*
   - ☐ Vac-Lok (only)
   - ☐ BodyFIX
4. Patient
   - ☐ You have used your clinical judgment
   - ☐ Fits protocol eligibility criteria (1, 2, 3)
5. Notes

   _____
   _____
   _____
   _____
   _____

☐ By checking this box I have informed the CT simulation team, either in-person or through Mosaiq, that the patient listed below will be considered in the execution of the study.

_____

Patient MRN

# B Appendix

**Physician Request Email Template**

This email should be sent after the patient has been through CT simulation and a start date has been chosen. Once the physician makes the request, it will put a note into the patient's file and add a request to the Physics QCL in Mosaiq.

Hello Dr.[*insert Physician name*],

Please kindly order [*insert VisionRT or Calypso*] in addition to CBCT for the following patient for motion tracking only.

[*insert patient(s) name*]

Thank you,
[*insert your name*]

# C Appendix

### CT Simulation Process for Selected Candidates

Below is an example of the CT Simulation Note that is currently used for approval in our department. Rather than creating an entirely new checklist, we suggest that:

- ☐ Under *Set-up Instructions*, verify that patient's thorax/abdomen has not been covered
- ☐ Under *Comment*, simply note that this patient is being considered for the VisionRT or Calypso study

**Patient Position:**

- ☒ Supine
- ☐ Prone
- ☐ Decubitus
- ☒ Head First
- ☐ Feet First
- ☐ Other

**Extremity Positioning**

- ☐ Arms Up
- ☐ Arms Across Chest
- ☒ Arms by Sides
- ☐ Arms Akimbo
- ☐ Legs Frogged
- ☐ Other

**CT/SIM orders:**

- ☐ IV contrast
- ☐ Oral contrast
- ☐ Rectal contrast
- ☐ MRI/PET fusion
- ☐ Electron cutout
- ☐ Sim and Treat
- ☐ Wire scar
- ☒ 4DCT
- ☐ Other

**Devices:**

- ☐ Full Pad
- ☐ Knee Sponge
- ☐ Vacloc
- ☐ Wingboard
- ☒ Bodyfix
- ☐ Compression Arc
- ☐ Breast Board
- ☐ Mask Select.
- ☐ SRS Halo
- ☐ Exactrac
- ☐ Shoulder retractors
- ☐ Belly Board
- ☐ Other:
- ☐ Marker Select
- ☐ ABC Device

**Contrast:** ☐ IV: Contrast Type: Amount:

☐ Oral Amount:

Contrast Notes:

**Scan Parameters: Top of lungs to Diaphragm**

**Set-up Instructions: Body Fix, arms on the side, knee sponge bilat levelers. Vac 70 Shift from bbs on bag:**

**Comment:**

# D Appendix

**Real-Time Data Acquisition with VisionRT**

*Monitoring Thoracic/Abdominal Sites*

1. **Before patient arrives:**

   ☐ Pull up the patient in VisionRT in **'TREATMENT'** mode

   ☐ Verify 'MONITORING' field is available and selected

   ☐ Ensure DICOM reference surface and correct ROI are displayed

2. **When patient arrives:**

   ☐ Align the patient using technique requested (lasers)

3. **The patient is now ready for INTERNAL IMAGING**

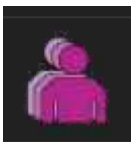
   ☐ Perform CBCT per MD orders

   ☐ Make approved CBCT post imaging shifts

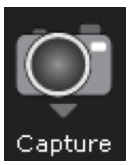
4. **Capture VisionRT reference image for intra-fraction motion monitoring:**

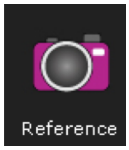
   ☐ Capture reference image *immediately after* the patient is aligned based on internal imaging

   ☐ Change from DICOM to 'MONITORING' field



   ☐ Select **'CAPTURE'** and then **'REFERENCE'**



5. **Monitor the patient for intra-fraction motion management:**

   ☐ Select the play button in the VisionRT software


   ☐ Define couch angles

   ☐ Begin patient treatment

   ☐ During treatment, select appropriate couch angle in VisionRT for non-coplanar beams

6. **When treatment is complete, select pause before patient moves and then exit 'TREATMENT' mode**

# E Appendix

**Real-Time Data Acquisition with Calypso Surface Beacons**

*Monitoring Thoracic/Abdominal Sites*

1. **Before patient arrives:**

   ☐ Pull up the patient in Calypso in **'TREATMENT'** mode

2. **When patient arrives:**

   ☐ Allow study coordinator to place surface beacon

   ☐ Align the patient using technique requested

3. **The patient is now ready for INTERNAL IMAGING**

   ☐ Perform CBCT per MD orders

   ☐ Make approved CBCT post imaging shift

4. **Capture baseline record of beacon configuration for intra-fraction motion monitoring:**

   ☐ Go into treatment vault and position Calypso magnetic monitoring board over beacons, out of the way of the gantry

   ☐ Capture beacon configuration post-approved treatment setup

5. **Monitor the patient for intra-fraction motion management:**

   ☐ Select the record button in the Calypso software

6. **When treatment is complete, select pause before patient moves and then exit 'TREATMENT' mode**

# F Appendix

**Notes to Next Study Coordinator**

- The study of interest requires IRB approval. The application should be submitted before data collection process begins.
- The study process began by acquiring patients that present themselves as good candidates. The easiest way to do this is to constantly scan the CT simulation schedule. Any patient tagged as a lung, liver, or spine was of interest.
- It is important for the study coordinator to be present at the day of simulation not only because that is when the immobilization device is chosen and molded, but to assure patient's skin be exposed to monitor them using the VisionRT system. It is not a common practice to leave the skin exposed; many times patients may ask for blankets or in the case of BodyFIX, the plastic seal will normally be covering the patients entire torso. This exposure is essential and we lost several potential candidates by not being present on this day.
- The second essential step in this process is to request VisionRT orders from the attending physician while simultaneously importing the patient plan and body structure set into the VisionRT system to prepare for the first day of treatment. The VisionRT system needs this information in order to successfully monitor a patient and the therapists need physician orders to be able to monitor during treatment.
- Therapists need to be informed on which patients would need monitoring at least before the first day of treatment. It was feasible to be present at each new start, but not every treatment day for each patient which leads to our second main error. Without a researcher present for each treatment, there may be some oversight or failure to collect data at all since monitoring lung, liver, and spine patients is not used universally and is currently being implemented for clinical protocol development in our department. Being absent can lead to inconsistent data, unrecorded days, and monitoring in the wrong patient record. Additionally, many older patients refused to participate and were bothered by the bright red light. A suggestive solution would be to have deviation from protocol framework documented and built into therapist training/education session.
- The patient data is stored as a .txt file on the VisionRT system under a file, 'P

Data'. The folders are organized by MRN. The .txt file needs to be converted to a .csv. A Matlab code as been created that will import the .csv file and analyze the data by each patient, each day, each direction (vertical, longitudinal, lateral). The code also provides the largest deviations recorded and how many instances the patient was in that position.

- Our third and probably largest problem was that we were not able to collect a sufficient number of patients to conduct a useful statistical analysis. As a result of our second error coupled with the third, there were some cases of strange patterns, or patients going ten times out of tolerance for over one minute. These patients had to be discarded and as a result lowered our already small pool of candidates.
- An overall problem may be that only one physician uses the Vac-Lok system regularly, so those patients were hard to come by.