

## Immobilization and Imaging for Stereotactic Body Radiation Therapy Motion Management

### 1. Introduction

Stereotactic body radiation therapy (SBRT) delivers a very high dose of radiation to relatively small extracranial tumors in a single or several large fractions, with a precise positioning and targeting using stereotactic equipment and methods. The total biologically effective dose (BED) for an SBRT treatment is frequently larger than that given with conventional radiation schedules and one needs to be vigilant as to the dose tolerances of normal tissues[1]. To minimize tissue toxicity in SBRT, extensive planning efforts are made to generate the dose cloud in tight conformity with the target volume, and to achieve rapid fall-off in the dose to the surrounding normal tissue.

The dose characteristics of SBRT necessitate good treatment precision to deliver the planned dose to the designated location. If it is not precise, not only may the target volume not receive a tumoricidal dose, but also the surrounding tissue will be at higher risk of radiation damage. Accurate treatment delivery requires a combination of a calibrated radiation delivery system, an immobilization device (if needed), and an imaging system [2, 3]. The radiation delivery system, either a linear accelerator or radioisotope based system, should be calibrated for both radiation output accuracy and for mechanical precision. The immobilization device immobilizes the patient and helps to reproduce the patient's simulation position. The imaging system locates, verifies, and tracks (in some systems) the position of the target.

In intracranial radiosurgery, the target maintains a rigid position relative to the skull, hence mechanical fixation using a stereotactic head frame [4] or image-based tracking of the skull without a frame [5-7] can accurately locate an intracranial target. The imaging and immobilization challenges are different with an extracranial target, which is the focus of this White Paper. The skeleton and torso are more deformable, and an extracranial tumor does not usually maintain a rigid position relative to the skeleton or torso, due to physiological processes such as organ filling and respiration. Consequently, extracranial SBRT treatment demands more sophisticated motion management. Not only are careful patient setup and appropriate body immobilization needed to reproduce and maintain the body positioning during simulation and treatment, but accurate imaging of the treatment target or its surrogate is essential in order to accurately localize the internal target. [8-10].

## 2. Motion of Extracranial Target

Interfraction motion is the day-to-day variation of the target position. For some treatment systems, careful immobilization should be applied to minimize setup variation [11, 12], and imaging should be used to fine tune the target position before each treatment session. [12, 13]

Intrafraction motion is the target position variation during treatment, which can be further defined within three categories depending on the cause of motion:

- i. Body motion is caused by a patient's voluntary or involuntary body position change during treatment. This is of greater concern in SBRT, because SBRT treatment usually takes longer than with conventional radiation therapy, and the intrafraction motion increases with increasing treatment time [14]. Commonly, patients may feel tense and be in an unnatural body position during setup and at the beginning of treatment, and gradually relax during treatment. Alternatively, a patient may become anxious and uncomfortable with the rigid immobilization device, and move throughout the treatment. Patient education, appropriate setup and immobilization with an eye toward patient comfort, and consistent monitoring are the key to address such motion. Such body movement will affect treatment at all sites, especially on or near the spine, where missing the target can be particularly detrimental. For systems that employ intrafraction motion correction, patients are often set up simply lying on a mattress with a pillow, with no immobilization device needed.
- ii. Non-respiratory motion is the target's displacement caused by volume change of nearby deformable structures (mainly GI or GU organs), during treatment. One typical example is the prostate, whose position can be affected by the bladder and rectum, or a pancreatic tumor near the stomach or bowel. Such movements can be managed, to a certain extent, by diet or medication prior to simulation and treatment. This motion can be slow and therefore dependent on the length of treatment time. After the initial setup, frequent target position verification and adjustment based on the image of the target are important.
- iii. Respiratory motion is the primary motion found in the organs or tumors of the thorax and upper abdomen. Although this motion is caused mainly by diaphragm contraction, chest wall expansion may also affect tumor position. This motion is persistent and can be restrained, but not eliminated. When the target's respiratory motion is tracked and the radiation beam is adjusted accordingly in real time, the tumor, within an appropriate PTV margin, can be safely irradiated [15, 16]. If the target respiratory motion is not tracked, tumor excursion needs to be evaluated using either fluoroscopy or dual phase CT or 4D CT [17]. When the tumor has considerable

excursion and there is no real-time tracking and correction, either gating [18] or patient respiration restriction should be applied to limit the irradiated volume [19, 20].

### 3. Immobilization

#### i. Purpose of immobilization

For SBRT systems that do not track and correct for intrafraction motion, immobilization devices serve three purposes. First, they limit patient motion during treatment (intrafraction motion). Most SBRT treatments are delivered in high dose rate mode with a faster treatment delivery. A potential consequence of the more efficient delivery is that a large fraction of dose could be delivered to a wrong location in only a few seconds if the treatment target deviates from its planned location. Second, immobilization devices avoid major positioning errors by ensuring that patients are positioned close to the intended treatment site. Patients can be positioned within several millimeters of the target by indexing immobilization devices to a treatment couch, prior to beginning the image guidance process. Third, such systems position patients close to the original simulation geometry in terms of rotation. This is typically achieved by placing registration marks on the immobilization devices.

#### ii. Current commercial systems

Current immobilization systems for SBRT applications generally include two broad types: thermoplastic masks and customized body bags. Thermoplastic masks are used in combination with head and neck supporting devices. Customized body bags generally contain polyurethane foam plastic pellets.

##### a. Alpha Cradle<sup>®</sup>

Alpha Cradle (Smithers Medical Products, Inc., North Canton, OH) devices are generated by mixing two chemical agents, producing a foam with drastically increased volume, which eventually hardens into a rigid mold around the patient [21, 22].

##### b. Vac-Lok<sup>™</sup>

Popular alternatives to polyurethane bags are vacuum devices that are reusable. Vac-Lok (CIVCO Medical Solutions, Kalona, IA) bags are filled with small polystyrene beads. It forms into a rigid, customized cradle around the patient when a vacuum is drawn through a quick-release valve [23-26].

##### c. BodyFIX<sup>®</sup> dual vacuum full body bag

BodyFIX (Elekta, Stockholm, Sweden) dual vacuum systems include a bag similar to the Vac-Lok device, where a rigid cradle is created when a vacuum is applied. In

addition, BodyFIX systems apply vacuum around patients with a clear plastic sheet over the surface of the patient to reduce respiratory motion [27-30].

d. Thermoplastic mask

Thermoplastics become soft when placed in a warm water bath. When malleable, the plastic sheet is cast over the patient's head and/or neck. As the plastic cools, it creates a rigid mask that conforms to the patient's contour. Manufacturers include CIVCO Medical Solutions (Kalona, IA) [31], Orfit Industries (Wijnegem, Belgium) [32], Qfix (Avondale, PA) [33] and BrainlabAG (Feldkirchen, Germany) [34].

iii. Common challenges to all disease sites and recommendations

a. Attenuation and build up

Immobilization devices are generally made of low density materials such as foam and thermoplastic mask. Their attenuation and dose build-up characteristics are generally small compared to other dose perturbation factors such as the treatment couch. For this reason, immobilization devices are usually not included inside the external contours of dose calculations. However, special attention should be paid when a small number of beam angles are used in treatment plans, where skin dose could be a concern. AAPM Task Group (TG) 176 addresses the dosimetric effect of immobilization devices [35].

b. Collision

Some SBRT systems utilize arc techniques or multiple gantry angles with occasionally non-coplanar beam angles. Immobilization devices increase patient body perimeters and could pose additional gantry collision risk. We recommend that each center develops a list of the combination of gantry and couch angles with potential collision risk for common immobilization devices used in the center. When in doubt, a dry run can help to identify potential collision situations prior to patient treatment. In case of robotic systems with variable SAD, simulation runs are advisable when immobilization devices exceed the safety zone around the treatment couch.

c. End-to-end test

End-to-end tests are typically performed when commissioning a SBRT program to investigate the geometric and dosimetric accuracy of the system. Such tests utilize a phantom and simulate the entire patient treatment process including CT scan, treatment planning, image verification, and dose delivery. One should be aware that such end-to-end tests on phantoms do not include uncertainties caused by immobilization devices.

d. Comfort and accuracy

Immobilization devices are intended to be as tight as possible for better accuracy, but they should not sacrifice patient comfort. SBRT is a lengthy process which includes pre-treatment imaging and delivery of a large number of monitor units. Patients typically move less if they lie inside more comfortable immobilization devices. On the contrary, patients tend to “fight” against the immobilization devices when they cannot tolerate it, which causes additional motion.

#### iv. Site specific challenges and recommendations

##### a. Lower thoracic spine lesions

The main purpose is to provide a comfortable support for immobilization of lower thoracic spine lesions. A full body bag is generally recommended [36], however there is no need for the body bag when the patient will be tracked with periodic stereoscopic imaging [61]. Diligent indexing is highly recommended because improper use of image guidance technology could align patients to a wrong vertebral body. Every effort should be made to mark the bag for initial positioning within several millimeters to the final treatment isocenter to avoid large image guidance shifts in the craniocaudal direction.

##### b. Lung, Liver and Pancreas

Immobilization devices for these disease sites share many common features with spine treatments, which use full body bags [27, 28, 30]. The unique challenges for these sites are respiratory induced motion, which may benefit from some form of abdominal compression to reduce respiratory motion.

##### c. Prostate

Immobilization devices for prostate are not different for SBRT treatments compared with traditional fractionation treatments. Body bags are utilized to support lower extremities and pelvic regions. Image guidance and tracking have more stringent criteria for SBRT applications due to the high fraction dose [22, 25, 29]. It should be noted that SBRT systems that employ real-time tracking and motion correction do not require rigid immobilization. In this case, having the patient simply lie comfortably on the treatment couch is a common approach.

##### d. Cervical and upper thoracic spine metastases

Thermoplastic masks provide better localization and immobilization than body bags for cervical and upper thoracic spines. Additional alignment marks can be drawn on the mask at the time of simulation to facilitate patient setup at treatment. The purpose of these marks is to reproduce the head rotation close to the simulation position. The marks can include superior/inferior sagittal lines, outlines of ears and eyes, left/right horizontal lines [37].

#### 4. Image Guidance

##### i. Requirements for accuracy, precision and speed

The ideal image guidance system would have very high accuracy with near-perfect precision, and would produce the result in seconds. While the commercially available systems are constantly improving, the current-generation systems have significant limitations that the user should be aware of when characterizing the clinically achievable accuracy and precision and, therefore, the recommended target margins and minimum deliverable field sizes.

##### a. Overall accuracy and precision expectations in SBRT

Commercially available image guidance systems often claim sub-millimeter accuracy, but the “real life” accuracy can be considerably different [38]. The 3-D difference between the treatment reference point and the imaging system reference point can exceed 0.5 mm, and the localization accuracy for a given patient can be very dependent on the algorithms for interpreting the complex patterns in patient images. Given all factors, an overall accuracy of 1.0 mm may be more appropriate [39, 40], and in some cases the real-life accuracy may be closer to 2.0 mm [41]. While the precision of most automated systems is quite high for the same data set, precision can be considerably different when evaluating across multiple treatment sessions or when localization approaches rely on manual user alignment.

##### b. Wide range of localization objectives in extra-cranial SBRT – bone, fiducials, soft tissue.

Depending on the treatment site and the nature of the target (whether fixed to bone or not, of different or similar density relative to the immediately surrounding tissue), the user may wish to localize on a particular set of bony landmarks, may wish to localize on implanted fiducials, or may wish to visualize soft tissue patterns in order to identify the target. Each of the aforementioned requires a different set of software tools and algorithms, and may require a different type of image data (cone-beam CT versus projection radiographs).

##### c. The challenge of achieving robust, reproducible results – automated algorithms vs. user intervention.

To achieve a high level of precision (reproducibility), minimal user intervention is desirable in order to eliminate inter-observer variability. Automated algorithms can generally achieve high precision for discrete solutions such as localizing on a handful of implanted fiducials with their high contrast and known characteristics. Automated algorithms can be challenged when interpreting more complex patterns such as bony structures shadowed by other tissue (such as lung or bowel)

which may change in shape and position with time. In the latter case, a hybrid approach is often employed, whereby the user constrains the search space and often selects an initial image alignment. Such approaches re-introduce the inter- and intra-user variability to some degree, potentially reducing overall precision.

- d. The importance of speed – the limitations of immobilization vs. patient compliance.

With the exception of a small subset of SRS/SBRT treatments, patients are not immobilized in the strict sense of the term. Sometimes, they are positioned in custom-made molds which assist with achieving a reasonably reproducible patient position and remind the patient to maintain that position during treatment. None of these molded devices are very comfortable, and many patients have limited tolerance to extended times in the treatment position due to their clinical condition. With each passing minute, the probability of patient motion increases, and long treatment sessions increase the probability of significant motion – for example, the patient shifting his/her back or extremity due to discomfort or numbness. Significant motion requires re-imaging and in some cases re-positioning of the patient in the custom mold, further extending the treatment session and increasing the probability of additional motion. Hence the importance of balancing speed with accuracy and precision. An approach with slightly lower accuracy or precision based on controlled tests in phantoms may be preferable if the overall localization process is significantly faster than a nominally more accurate and precise, but slower, method. The clinical team must weigh these factors when deciding on the localization methods to use for the scope of SRS/SBRT services provided.

- ii. Currently available technologies

The manufacturers of treatment machines offer a wide range of technological solutions, often as a suite of products rather than relying on only one technology. In addition, third-party solutions are available and can be integrated with most current-generation treatment machines. A brief description of the different technological solutions follows.

- a. X-ray based

- i. Planar images with automated algorithms

Most systems use two projections with a large hinge angle (frequently orthogonal [42-46]) and employ pattern-recognition algorithms or intensity-based matching rules. In many cases, the user can remove some of the image matrix from consideration by the automated algorithm. Some systems have few, if any, tools to assess the overall uncertainty of the calculated alignment, whereas other systems have prominent displays of metrics indicative of the overall uncertainty.

ii. Planar images with user alignment

The first-generation systems relied on user identification of features in both image sets or on simple translations of one image set relative to the reference. Many modern systems have retained this functionality as an option, and this approach continues to see widespread use, perhaps driven by the users' familiarity with such alignment methods. Assessment of the accuracy of the alignment is limited or nonexistent with such approaches.

iii. Cone-beam CT

Cone-beam CT systems have gained widespread acceptance in recent years. With a large amount of anatomical information including (to a limited extent) soft tissue visualization, cone-beam CT images enable assessment of shape distortion as well as the spatial relationship between the target and soft tissue regions of interest. Automated alignment to a reference CT image can be limited by the higher noise and more pronounced image-reconstruction artifacts in cone-beam CT images. Qualitative assessment of the calculated alignment is especially important with this technology.

b. Optical systems

Optical systems are typically used as a complementary technology to assess patient motion between image sets acquired with the primary imaging system [47, 48].

i. Surface imaging

Projection of a known pattern, coupled with detection of the distorted pattern on the patient's surface, provides a large amount of data thereby improving the integrity of the alignment calculation [48]. Such systems are susceptible to changes in the distorted pattern due to clothing, personal items such as watches and jewelry, and may be equally influenced by changes far away from the target (e.g. a slight change in chin position when treating a lower-lobe lung lesion).[49]

ii. Infrared reflector tracking

Infrared reflector tracking systems enable the user to locate the reflectors in the locations deemed most relevant to monitoring target motion. Some systems allow a variable number of reflectors, whereas other systems rely on a fixed number and separation of reflectors, with the former approach providing more flexibility to adapt to different clinical needs. A source of potential uncertainty is the variability in locating the reflectors at each

treatment session, and the possibility that a reflector could shift during the treatment session.

c. Radiofrequency beacons

Radiofrequency beacons can be implanted in or near the target and provide near-real-time information on target location [50]. The detection system must be located very close to the patient surface, potentially creating clearance concerns with the treatment machine and resulting in beam perturbation for any treatment fields traversing the detector plane. The technology has not achieved broad utilization in the United States to date.

iii. Clinical applications – advantages and limitations of each technology

a. Spine lesions

Planar images with automated alignment have gained widespread use for this application, often combined with the ability to manually adjust the alignment. Cone-beam CT is generally not deemed necessary [51-53] and could be adversely affected by the presence of any spine fixation instruments. Optical systems may be more relevant for assessing intrafraction motion, as they cannot monitor vertebral column changes..

b. Lung

Planar images are appropriate when implanted fiducials are present, or when the soft-tissue target is able to be visualized in one or both planar images [54]. Cone-beam CT is appropriate for lung target localization, with its inherent ability to visualize local tissue contrast such as seen with a well-defined lung tumor, and its ability to assess spatial relationships to nearby organs[55]. Optical systems are only relevant for assessing intrafraction motion.

c. Liver / Pancreas

Planar images are appropriate when implanted fiducials are present, as the ability to visualize the soft-tissue target is very limited in these applications [56]. Cone-beam CT is appropriate for abdominal target localization, with its inherent ability to visualize local tissue contrast and the ability to assess spatial relationships to nearby organs [57, 58]. However, non-embolized liver lesions and pancreas lesions generally do not have sufficient contrast to be identifiable on cone-beam CT. Optical systems are only relevant for assessing intrafraction motion.

d. Prostate

Planar images are appropriate when implanted fiducials are present, as the ability to visualize the soft-tissue target is very limited in these applications [59]. Cone-beam is appropriate for pelvic target localization, with its inherent ability to visualize local tissue contrast and the ability to assess spatial relationships to nearby organs. Optical systems are generally not used for this treatment site.

Radiofrequency beacons are considered a robust method for monitoring prostate target localization and intrafraction target motion [60].

iv. Recommendations

Each clinical team should evaluate the available image guidance technology relative to the planned treatment indications, with a critical and realistic assessment of each technology's limitations and the impact on overall targeting confidence. It is desirable to document the results of this assessment in an internal report, and prescribing physicians should consider these results when deciding on the appropriate target margins and dose regimens.



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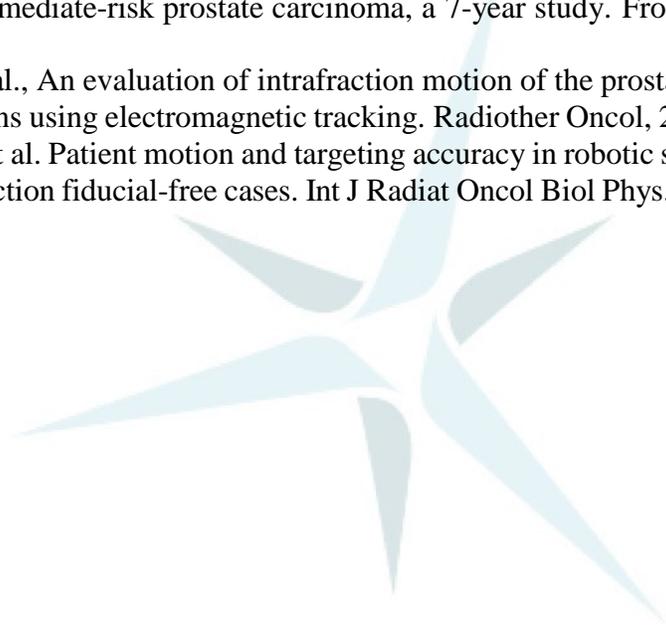
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