PROCEDURE FOR INCLUDING IGRT IN RTOG PROTOCOLS

Introduction

Image Guidance is defined here as the complete process that extends from the step of imaging a patient at the time of simulation through the step of imaging the patient again at the treatment unit. This process includes the procedures for manually or automatically comparing these two datasets to determine a series of mechanical movements of the patient support system to correct for detected positioning errors. The possible variations in the way each step can be handled results in a large number of different overall IGRT approaches. The guidelines described here are designed to apply to all Image Guided Radiation Therapy (IGRT) methodologies (2D-2D, 3D-3D, and 2D-3D) that use ionizing radiation for the imaging that occurs in the treatment room. Techniques like the use of ultrasound or fiducial markers placed on the patient's skin are not currently included in these guidelines. At this point in time the majority of commercial systems are rigid body based. Some academic centers have deformable registration available, but this approach will not be allowed in RTOG protocols at this time. It is anticipated that these centers will assist the RTOG in implementing this technology in the near future.

Protocol IGRT Description and Specifications

All protocols that use IGRT for patient setup must include a clear statement of the procedure to be employed for registering image datasets. For example, head and neck treatments that include the supraclavicular region as part of the target volume should have a discussion of how day-to-day variations in the patient's anatomy due to difficulties with upper body immobilization are to be handled when fusing images. This discussion might include issues like the extent of the patient's anatomy to include in the registration process (e. g., the clip box size should be set to contain the high dose PTV from base of skull to C6 inclusive) and a statement about where the clip box should be centered on the patient. The centroid where the translational and rotational offsets are to be measured from can also be defined. The type of IGRT (e.g. implanted fiducials, 2D, 3D) permitted and the correction strategy (offline, daily online corrections, adaptive), and tolerances for corrections need to be clearly defined. Statements should be included to specify exactly how the corrections are to be carried out (translation ignoring rotation, translation correction for translation and rotational offsets, translation and rotation correction). The anatomy to be used to drive the registration (fiducial, bone anatomy, soft tissue) and the type of fusion (manual or automated (cross correlation/mutual information)) to be used should also be stated. Deformable registration techniques are not allowed in RTOG protocols at this time, and the protocol should have a statement about this exclusion. The protocol IGRT specifications should also give recommendations on estimating or correcting (e.g., adding the IGRT dose to the IMRT dose) patient dose due to the IGRT component of the study.

Depending on the exact use of IGRT in a particular protocol, a credentialing procedure may be required. The need for credentialing will be determined by the protocol PIs with the approval of the RTOG IGRT Committee. The credentialing procedure will include a single "dry run" using patient data. This dry run can be the same patient used as a test patient for protocols that include IMRT or other advanced technology procedures. For some protocols this could be a retrospective analysis of a patient treated with a technique that was similar to the one used in the new protocol. It might also be the first patient accrued to the protocol. The region of interest or clipbox used for image registration

needs to be documented on this case.

IGRT Questionnaire

IGRT questionnaires will need to be completed by each institution entering patients on an IGRT protocol. This Questionnaire should list all IGRT technologies available at that institution. Also daily QA procedures for each device should be described in detail. The QA procedure must ensure alignment of imaging and treatment beam isocenters. The process for dealing with set-up errors should be described. Estimated doses from imaging and procedures for dealing with it should also be included in the questionnaire.

Image Registration Software Tests

The design and implementation of the image registration software used for different IGRT systems can vary considerable from one manufacturer to the next. For example, some systems are based on the registration of 2D radiographic images, while others use full 3D volumetric information. Additionally, as a method of improving the performance of the registration software, some systems allow the user to erase parts of one image dataset that might be problematic in that the same information is not present in the other dataset. For example, contrast materials present in the CT-Sim study might not be present for the in-room study, and these regions can be removed from consideration during the fusion process. Other systems take a different approach that relies on establishing a "clip-box" to restrict the information that is used during registration.

Another difference between systems is their use of bone and soft tissue registration techniques. These two approaches can give different results, but the differences will not be evident until complex objects are analyzed. It is for these reasons that an additional test that uses actual patient data is included in the overall procedure described here.

This test is modeled after the approach used for credentialing for RTOG #0236 (A Phase II Trial of Stereotactic Body Radiation Therapy (SBRT) in the Treatment of Patients with Medically Inoperable Stage I/II Non-Small Cell Lung Cancer) and #0438 (A Phase I Trial of Highly Conformal Radiation Therapy for Patients With Liver Metastases). A major difference compared to what was or is being done for these two protocols is that the number of patients will be reduced to one for future IGRT protocols. This is possible because the phantom tests described above will provide information guaranteeing that each treatment unit can hit points in space as the treatment unit is moved around the test object and the couch is rotated.

The test performed here for a single patient will require the institution to send CT-Sim information plus two in-room imaging datasets (gathered on two different days). The institutions must fuse the datasets according to protocol instructions, and they must record the setup error shift information. The clipbox for fusion will be specified. The datasets will be submitted via Secure FTP to the ITC and forwarded to the RTOG so that the registration process can be repeated at RTOG Headquarters. This part will be accomplished by using recently installed equipment that is now available at RTOG Headquarters. These systems can handle registration for Elekta Synergy, Varian OBI and Tomotherapy DICOM datasets. These systems will also allow remote handling of the datasets so that the Physicist PI named on a particular protocol can help with this credentialing review process. The radiation oncology PI of the protocol will be informed of the IGRT credentialing status of participating sites.