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CLARITY PSO
A Patient Safety Organization

RO-ILS THEMED REPORT:

SURFACE GUIDED RADIATION THERAPY

PATIENT SAFETY WORK PRODUCT

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INTRODUCTION

In the quest to improve clinical practice, and make it safer, the tendency is to think that more is better. More technology, more complexity, more checklists. More steps. More double checks! Radiation oncology professionals aren't alone in the mindset; social science research confirms that the central tendency is to ignore subtractive changes when evaluating solutions to problems.[1]

Before taking on the additional expense and complexity of a surface guided radiation therapy (SGRT) system, radiation oncology practices need to conduct a prospective risk analysis of the proposed changes and think thoroughly about the risks and benefits. This report examines the technology of surface imaging, and how this can impact the safety of radiation delivery, both positively and negatively, as well as the limitations of the technology.

SGRT: POSITIVE IMPACT ON SAFETY

Case 1: Intrafractional Movement.
A patient received a single fraction stereotactic body radiation therapy (SBRT) treatment to the spine. The practice's protocol is to take a cone-beam computed tomography (CBCT) image before and after treatment. The after-treatment CBCT image showed a 2.5 mm shift from the initial approved for treatment CBCT, which represented some degree of intra-fraction patient motion.

A 2.5 mm shift could be significant for spinal SBRT, where the steep gradient between target and spinal cord must be delivered with high accuracy. Even with currently available high dose rate linear accelerators, treatment times can last several minutes. Patients have been shown to move during this timeframe, either through systematic drifts (muscle relaxation) or random motions, especially if the patient is uncomfortable or in pain.

State-of-the-art SGRT technology provides sub-millimeter accuracy in intra-fraction surface motion monitoring. This technology could be used as an adjunct to standard IGRT, to detect intrafraction motion as it happens, allowing for exclusionary gating if motion exceeds a clinic-defined threshold. SGRT has the potential to take normal respiration into account, preventing inappropriate triggers. A systematic drift, or one-time random motion, could have been detected by an SGRT system, allowing for treatment cessation to re-establish position.

Case 2: Incorrect Set-up of Immobilization Accessory.
Two patients with breast cancer were treated sequentially using the same breast board, but different breast board settings. One day the therapists did not adjust the settings between the first and second patient. This led to a 5 cm difference in planned vs. actual table height setting for this patient.

There are several safety measures which might have caught the error, including table tolerance interlocks in the oncology information system (OIS), verification of lasers to patient marks, photo documentation of the breast board settings, etc. Using an SGRT system would be an additional safety measure, as it can detect differences in breast board angle and other setup device settings that affect the patient surface shape. This is depicted in Figure 2.3 from *Surface Guided Radiation Therapy*.[2] However, clinical workflow can impact how effective this is. For instance, for the reference surface image, practices can use the DICOM generated surface, or the surface image captured at simulation. The practice might also re-capture the surface image in the room on the virtual simulation (v-sim) day. Re-capture of the image on the v-sim day may be done if the surface imaging from the simulator is captured by only one camera and is deemed inferior in quality. If the workflow is to re-capture the surface image on the v-sim day, and this error occurs at the v-sim, surface imaging will not act as a safety barrier.

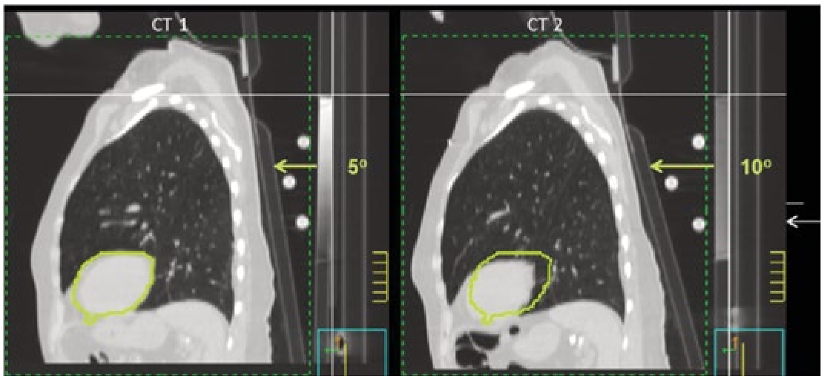

FIGURE 2.3 The CT scan used for treatment planning was acquired at a 5° breast board angle (CT1) while the CT scan of the pretreatment filming position was acquired at the documented 10° breast board angle (CT2).

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Case 3: Wrong Shift (Resulting in a Laterality Error).

A patient was scheduled for v-sim and treatment on the same day. The patient was supposed to be shifted 5 cm to the right from setup marks according to the treatment plan. However, the documentation for the therapists incorrectly stated that the patient was to be shifted to the left. The error was discovered during pre-treatment imaging.

As in Case 2, there are multiple ways this error could have been prevented. The first thing to consider is the decoupling of v-sim from treatment. This removes some of the time pressure element from the therapy team, and also removes patient expectations for treatment that day. With no patient expectations for treatment, there is less of a barrier to making a plan adjustment. Also, there may be more time for assessment of the treatment set up and images if treatment does not immediately follow. A 5 cm shift from midline set up marks would have been clearly left or right on the patient, which would make a pre-treatment time out confirming laterality particularly important for this case. Table interlocks are able to catch this error after day 1 reference table parameters are captured. Pre-treatment imaging did catch this particular error and is a valuable tool. SGRT could have assisted the error detection by flagging the error before the pre-treatment imaging was taken. This also would have saved the patient some imaging dose. However, this is only a barrier if the practice fully integrated their SGRT system by defining the reference surface at simulation, with shifts automatically transferred from the treatment planning system (TPS) to the SGRT database.

Case 4: Shift Transcription Error.

When preparing a complicated 3 site/3 isocenter treatment plan for delivery, the dosimetrist made a transcription error, switching anterior/posterior shifts with superior/inferior shifts. This resulted in a 7.5 cm offset, for one of the isocenters. The error was discovered after delivery of some treatment to the wrong location. The error was noted when a subsequent therapist aligned to the patient skin markings and noticed that the light field did not look correct in relation to the surface anatomy. In retrospect, therapists from the initial portion of treatment acknowledged that it did look high, but they trusted they made the shifts correctly.

This incident would have been a reportable event in some states. The most important thing to take away from this incident is the need for the whole treatment team to trust their instincts. The therapists know surface anatomy exceptionally well, and any sense that a field seems incorrect based on surface anatomy should be heeded. As in the previous cases, SGRT could have been an additional error detection tool if it was closely integrated with the TPS and/or the OIS. The same caveats about workflow and degree of implementation apply to this scenario.

SGRT: NEGATIVE IMPACT ON SAFETY

SGRT is often used as primary setup or a respiratory motion management tool to implement breath-hold or gating. The increased complexity of adding an SGRT system into the treatment workflow also provides new workflows which may be susceptible to error.

Case 5: Inadequate Plan Import

A patient with breast cancer was to be treated with 4-fields and was set up using SGRT. Instead of sending both of the isocenters to the SGRT database, the dosimetrist only sent the tangent plan. This was not caught at SGRT setup field import. The error was discovered during patient setup. Identifying and correcting the error took significant time, delaying the treatment start by a day, and added to the patient's discomfort since they were kept on the table for longer than necessary.

Implementing breath hold treatment introduces complexity, regardless of the system used to achieve it. The RO-ILS national database contains numerous examples of related events, including:

- patients who were treated in free breathing (FB) rather than breath-hold (BH),
- a patient who should have been treated with gating but was instead treated without gating,
- a patient who was nearly treated (i.e., a near miss) with a gating file from a previous patient, and
- a patient with treatment planned on a BH scan rather than the intended FB plan.

These examples illustrate the value of having prospective risk analysis and developing systematic solutions for implementation of new technologies. For instance, the physician can label the beam names and plans as FB or BH to communicate their intent and empower dosimetry staff to catch fields or contours placed on the wrong scan. Upon import, designating the scans as FB or BH aids in selection of the correct image set for planning. Many practices do beam time outs, to confirm the beam parameters before delivery, and SGRT information can be included in this to ensure the proper patient is loaded.

An additional consideration is the impact of new technology in general on safety. Marks et al showed that initially with new technology, incident numbers can rise, but they decline over time.[3] Another notable aspect from this data is that after a high technology solution is added, the workflows on low technology can be adversely affected. The example cited is with the introduction of dynamic wedges, more physical wedges could be forgotten on the linac without dynamic wedge. Therefore, caution and planning must be used whenever implementing new technology throughout the practice.

LIMITATIONS OF SGRT

Case 6: Wrong Target Contour (Laterality).

A patient with metastatic prostate cancer had disease in both hips and presented with right hip pain. After simulation, the physician erroneously contoured the left hip, which also had disease on CT. The laterality error propagated through the complete 2nd chart check. Having done a time out with the patient indicating the right hip was to be targeted, the therapists noted that the wrong (e.g. left) hip was in the field when the shifts were applied for this 800 cGy x 1 plan.

SGRT can catch errors related to shifts, but it is not a panacea. In this example, the error originated from a wrong laterality contour. The two major error prevention techniques in this case are peer review (e.g., chart rounds) and timeout (i.e., asking the patient what is being treated). It is important to note the patient's role in preventing this safety event. Practices should be clear that although a fully implemented SGRT system has the potential to decrease shift errors, there are many such errors which can still propagate, and current safety barriers remain critical.

MITIGATION STRATEGIES AND SOLUTIONS

Strategy #1: Process Development and Update

Standard operating procedures are the cornerstone of safe practice but especially when utilizing new technology. Prior to the actual implementation of hardware and/or software, staff need to establish protocols that will be followed consistently, especially regarding staff communication. Simple and clear documentation is the best method of communicating intent. For example, it may be helpful to include FB or BH in the plan name or beam labels. Additionally, these processes need to be reassessed and revised regularly with increased experience.

Strategy #2. Speed of Deployment

As is the case with all new technologies, practices should not try incorporating SGRT for every patient right from the start, as it deserves a slow ramp up. It is important to be selective initially so that staff can develop experience with the technology before rolling it out to more inclusive patient groups. Practices may want to consider initially setting up as normal, with SGRT as an additional item for verification purposes, to get accustomed to the system. Once comfortable with how the system works, application would then begin with specific disease sites, such as breast or extremities before expanding to other areas. It is always prudent with new technology to start with simple plans (i.e., tangent breast, 3D conformal extremity) before utilizing with more complicated treatments (i.e., VMAT breath hold, matching fields).

Strategy #3. Staff Training and Comfort

With new advancements, practices should consider initially training a smaller, specialized group of staff before expanding to a broader cohort of staff. These dedicated individuals can attend external trainings and lead the effort within the practice, including educating other staff as appropriate. Additionally, from safety culture to technology, it can take time for mindsets to change. Staff may have some initial hesitation when trusting that technology is working. Therefore, it is important to demonstrate the value of the technology, by highlighting the errors that can be caught, while still managing the appropriate expectations (see Strategy #4).

Strategy #4. Safety Fundamentals

Technology-based tools are located at the top of the hierarchy of effectiveness and can help identify and mitigate human errors. Nevertheless, staff need to trust their instinct if something doesn't feel right. Staff need to be empowered to "stop the line" whether to question a colleague or equipment. It is important to not be over reliant on just one tool. The bedrock of other fundamental safety processes, such as timeouts and peer review, must not be diminished with advancements, as technology is not a substitute for safety fundamentals.

Strategy #5. Additive and Subtractive

Radiation oncology professionals must consider that simply adding more tools and processes to an already complex system may not always be the best method of making practice safer. There are certainly benefits of technology, including SGRT, but the added risk must not be ignored and may not happen where you expect it.[3] There must be a critical eye on whether the addition of complexity to your practice justifies the gained functionality.

CONCLUSION

Surface imaging is a tool that has the potential to be value additive and act as a safety barrier. However, its value is dependent on the way in which it is implemented, and care must be taken when implementing any new technology to prevent the introduction of new error pathways.

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