Safety Considerations for Proton Therapy

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Promises of proton therapy

Sensitive to WET variation
Potential reasons for WET variation

- Potential range perturbations caused by the immobilization device
- Setup error
- Inter and intra-fractional motion
- Patient anatomy change
  - Tumor regression
  - Patient weight loss
  - Development of edema
  - Bladder and bowel filling variation

Range perturbations caused by the table top

Setup error example
Range uncertainty due to physiological change such as small bowel filling change

Change of seroma example
Recommendations

- Include immobilization devices or patient support devices into the calculation if a proton beam goes through these devices.
- Robust treatment plan
  - Beam angle selection – minimize the potential WET variations.
  - If the proton beam angle cannot avoid potential WET variations, such as going through air cavities, larger range uncertainties should be allowed.
  - Appropriate treatment planning parameters and margins
  - Appropriate robust optimization settings
- Well defined IGRT protocols and residual setup error tolerance
- Closely monitoring the anatomy change and setup variations using CBCT
- Verification CT to assess the dosimetry stability
- Adaptive planning
Immobilization device
- Uniform low density
- Homogeneous construction
  - For example, “tennis racket” type table is not compatible with proton therapy
- Hardware clearance
- Range pullback accuracy

Evaluate the homogeneity and internal structures
- Check inhomogeneities such as voids or regions of higher than nominal density.

HU to RSP calibration curve
- Using artificial tissue phantoms, the CT numbers are converted to relative proton stopping powers and then to WET for dose calculations.
- The materials used for immobilization device are usually different from the tissue materials used in the CT number calibration process, therefore, a measurement is required to check the accuracy of the stopping power calculation.
Range pullback measurement on immobilization devices

<table>
<thead>
<tr>
<th>Measured range pullback [mm]</th>
<th>TPS simulated range pullback [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.9</td>
<td>2.3</td>
</tr>
<tr>
<td>4.8</td>
<td>3.7</td>
</tr>
<tr>
<td>5.1</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Characterize the immobilization device in TPS

- The change of proton distal range due to the immobilization device must be taken into account in the TPS. For proton radiotherapy, the couch top and immobilization devices in the beam path act as range shifters.
- If the measured range pullback matched the calculated one in TPS
  - Include the immobilization device in the external contour, incorporate it into the calculation.
- If the measured value does not match the calculated one in TPS
  - Contour the immobilization device, override the CT number/physical density for the correct proton relative stopping power.

HU override for non-biological tissue

- For example, breast implant
  - Saline-filled: 0.9% salt concentration distilled water
  - Silicone – polydimethylsiloxane (PDMS)

Table 2: Characteristics of test sample materials, linearity value range at 1 mrad diaphragm level

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mass (g)</th>
<th>Density (g/cm^3)</th>
<th>Relative Stopping Power (RSP)</th>
<th>Measured pH</th>
<th>Calculated pH</th>
<th>Measured density (g/cm^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distilled water</td>
<td>0.51</td>
<td>0.999 ± 0.001</td>
<td>0.000 ± 0.002</td>
<td>0.998</td>
<td>0.998</td>
<td>0.999 ± 0.002</td>
</tr>
<tr>
<td>Saline</td>
<td>0.51</td>
<td>0.999 ± 0.001</td>
<td>0.000 ± 0.002</td>
<td>0.998</td>
<td>0.998</td>
<td>0.999 ± 0.002</td>
</tr>
<tr>
<td>Saline (20% NaCl)</td>
<td>0.51</td>
<td>0.999 ± 0.001</td>
<td>0.000 ± 0.002</td>
<td>0.998</td>
<td>0.998</td>
<td>0.999 ± 0.002</td>
</tr>
<tr>
<td>Saline (30% NaCl)</td>
<td>0.51</td>
<td>0.999 ± 0.001</td>
<td>0.000 ± 0.002</td>
<td>0.998</td>
<td>0.998</td>
<td>0.999 ± 0.002</td>
</tr>
</tbody>
</table>

Ref Medical Dosimetry 39 (2014) R8-09
Motion evaluation

- The purpose of assessment of the target motion:
  - Not only for margin,
  - Also for choosing the beam angle to minimize the effect of respiratory motion and interplay effect.
- For proton therapy, the dosimetric impact of tumor motion is a complex function of:
  - Inter- and intra-fractional motion
  - Treatment plan: beam angle selection, robust planning parameters
  - Delivery system: the scanning time and spot size
  - Fractionation etc.
- A well defined procedure flow chart is recommended.

Range uncertainty

- Proton treatment planning needs to be done by experienced planners who understand the impact of range uncertainties.
- Understand the sources that impact range uncertainties. Therefore, mitigate those can be mitigated.
- Robust planning with appropriate range uncertainty margins.
RO-ILS Case Study: Incorrect Density Factor

https://www.astro.org/Patient-Care-and-Research/Patient-Safety/RO-ILS/RO-ILS-Education

Case Example:
- **Overview:** A typo error by a dosimetrist resulted in the PTV being assigned a density of 0. There was about 80% coverage on the PTV. This error was not appreciated by anyone as the dosimetrist finalized the plan.
- **Details:** The evening before the scheduled start, the dosimetrist worked on transferring the approved IMRT plan into the oncology information system (OIS). The dosimetrist notified the medical physicist that the plan was ready for IMRT QA. Standard IMRT measurement-based QA was completed and did not identify the error. Physics was not aware the patient would be starting the next day and therefore did not perform the required second check of the treatment plan that evening. The following morning the physicist was aware the plan was ready for QA and performed a second check; the physicist noticed the incorrect density of 0. The physicist notified the dosimetrist and physician and the remaining 43 fractions were re-planned with the correct density, accounting for the dose already delivered during the first fraction. While there was only 80% coverage of the PTV for the first fraction, the subsequent re-planned fractions corrected for this deficiency and the patient continued treatment to completion.

**Contributing Factors/Root Causes:**
- **Human error** related to data entry (i.e., dosimetrist assigning the wrong density value to a treatment volume).
- **Rushed work and compressed timeline** (e.g., dosimetrist working on plan the evening before the patient started treatment).
- **Numerous special procedures scheduled** on the same morning preventing the physicist from performing the second check as part of normal work duties (e.g., as they would have done even in a non-rushed situation).
- **Ineffective communication** of scheduled treatment start date.
- **Lack of awareness** of the ineffective communication of scheduled treatment start date.
- **Failure of staff to perform established process** (e.g., failure of busy therapist staff to perform comprehensive initial chart check of all pertinent information that needs to be completed prior to patient start treatment, such as, approval of the prescription, signed consent form and verifying physics QA was completed).
- **Lack of a forcing function** (e.g., hard stop) to prevent treatment of patient in the absence of a completed second check.

Thank you!