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Research article

## Evidence-based region of interest matching guidelines for sarcoma volumetric image-guided radiation therapy <sup>☆</sup>



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### ABSTRACT

**Purpose:** Region-of-interest (ROI) guidelines for online cone-beam computed tomography (CBCT) radiotherapy may improve matching reproducibility and reduce inter-user variability of soft tissue sarcoma (STS) image guidance. The purpose of this work is to standardize ROI STS CBCT image registration guidelines using the plan-do-study-act (PDSA) cycle for the lower extremity, retroperitoneal, pelvis, and thorax.

**Methods:** Based on anatomic bony surrogates, initial ROI matching guidelines for STS were developed by a team of radiation therapists, physicists and oncologists (Plan). Retrospective, qualitative evaluation of the guidelines was completed by the designated sarcoma lead therapist to determine clinical feasibility (Do). Validation of the ROI guidelines was performed through independent evaluation by radiation therapy CBCT imaging experts on a cohort of 10 patients per anatomic region (Study).

**Results:** Draft ROI guidelines were evaluated by 2 independent observers who registered weekly CBCT images to test their validity. Each observer assessed 5 patients per anatomic site, testing ROI options for accuracy of image registration and feasibility, while some ROI borders were adjusted based on algorithm matching performance. Validated ROI guidelines were presented to the sarcoma multidisciplinary site group, and an inter-professional committee of imaging experts for approval prior to clinical implementation (Act).

**Conclusion:** ROI matching guidelines for STS IGRT were standardized for 4 anatomic sites using the PDSA cycle for change testing and implementation. IGRT guidelines are intended to improve STS image registration reproducibility, and in turn, are expected to improve the confidence of IGRT decision making and workflow efficiencies for a rare disease with diverse presentation.

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### Introduction

Soft tissue sarcomas (STS) are rare and present many challenges for the standardization of patient positioning, image guidance, and accurate radiotherapy delivery [1,2]. Approximately 200 STS patients are treated with radiation therapy annually in our institution. Confounding factors include variability in anatomic presenta-

tion, and changes in tumor size and shape during the treatment course [3].

Image Guided Radiation Therapy (IGRT) assures the accuracy of patient positioning prior to treatment delivery by reducing geometric uncertainties [4,5]. Cone-beam computed tomography (CBCT) guidance systems allow for online volumetric visualization of patient anatomy, enabling daily setup variations to be quantified and corrected prior to treatment delivery, while monitoring daily patient changes and deformations [5,6]. Efficient incorporation of daily CBCT application and decision making into the clinical workflow is influenced by the confidence in image assessment by end users, and their experience and comfort with volumetric image visualization and literacy [7,8].

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IGRT has had a significant impact on the clinical role of the Radiation Therapist and in some institutions, IGRT decisions rely on front-line therapists [9]. An institutional training program was designed to familiarize therapists with CBCT technology and consolidate image guidance concepts/knowledge at the onset of clinical implementation [10]. This previous work highlighted training, education and continuous clinical support are required for successful CBCT implementation [10,11]. Specifically for sarcoma IG training, a specialized sarcoma radiation oncologist and lead sarcoma experts in radiation therapy and medical physics were involved in developing the curriculum and highlighting anatomical cross sectional anatomy considerations.

Safety considerations, education and consensus guidelines for IGRT have been identified as key issues to complement an expanding image guidance culture [12]. In particular, many have emphasized the importance of the quality paradigm in the era of IGRT to ensure that practice keeps pace with technology, and considerations are made for how to handle clinical information previously unavailable [4,8]. Specifically, a lack of literature exists on optimal regions of interest (ROI) for CBCT image registration to facilitate consistent practice for radiation therapists, ensuring reliable registration results and subsequent treatment targeting. As such, the validation of standardized ROIs for image registration is required to ensure safe and efficient clinical practice. At the time of this analysis, IGRT guidelines for the STS sites were not optimized through standardized reference procedures.

The aim of this study was to develop standardized STS IGRT guidelines for four anatomic sites including lower extremity, retroperitoneal, pelvis and thorax using the plan-do-study-act (PDSA) cycle to facilitate change [13]. The PDSA cycle is a widely used framework for systematic improvement of a process. These guidelines are intended to improve matching reproducibility and reduce inter-user variability for a rare disease.

## Methods

This work was performed under institutional ethics approval.

### Plan

Based on anatomic bony surrogates, initial ROI matching guidelines for STS were developed by a team of radiation therapists, physicists and oncologists. The defined imaging region of interest (ROI) affects the reproducibility of image registration between the daily CBCT and reference planning computed tomography (CT) scan, as this area is used by the volumetric software for automatic image registration. ROI definition often involves a tumor surrogate as visualization of the actual tumor may be suboptimal, and in the case of large STSs, may not be fully encompassed by the imaging field-of-view. Bone was identified as a surrogate for STS CBCT-IGRT, as it remains stable in situations where the tumor volume may change in size and shape significantly. In addition, bone has also been identified in previous work as an organ-at-risk (OAR) that if protected may result in reduced bone fracture risk for patients [14]. Choosing bone as a priority in image guidance and matching ensures its protection despite soft tissue changes which may occur throughout the course of radiotherapy. Appropriate bony surrogates were considered in the development and initial drafted ROI guidelines for the four STS anatomic locations by an imaging working group formed for this purpose.

### Do

Retrospective, qualitative evaluation of drafted ROI guidelines was completed by the radiation therapist sarcoma lead (S.A.) to

determine their clinical feasibility. Patients (5 per anatomic site;  $n = 20$ ) who received CBCT-guided intensity modulated radiation therapy were randomly selected between January 2013 and April 2014. The image registration process began with an automatic bone match based on the recommended ROI, with subsequent evaluation of registration accuracy and assessment of STS target coverage within the planning target volume (PTV) contour. Draft ROI guidelines were adjusted accordingly.

### Study

The objectives of the study phase were: to ensure optimal algorithm matching performance using the drafted guidelines throughout a treatment course; to assess quantitative translational and rotational offsets within institutional thresholds to identify a mismatch or failed attempt (see Fig. 1); to evaluate draft ROI options; and to adjust, revise and document changes to ROI borders if required to improve matching consistency.

The draft ROI guidelines were independently evaluated by two institutional radiation therapy imaging experts (C.H., W.L.). Data validation was performed through retrospective image registration of 10 identified STS patients (different from those evaluated in the “Do” phase) for each sub-site that had clinically stable set ups and positioning to allow for assessment of the image registration without a significant set up variation bias ( $n = 40$ ). There was no overlap in data validation patients between the two imaging experts.

Each imaging expert independently performed registrations by delineating ROI borders on the reference CT images outlined in draft guidelines. For each patient validation, 4–6 weekly CBCT images were reviewed depending on patient dose-fractionation to evaluate ROI consistency and reliability throughout a course of RT. Automatic image registration was performed to assess the matching success of proposed borders. Registration results were qualitatively evaluated by the validators to ensure a successful match, indicated by a visual spatial assessment that the correct bony anatomy was registered. Quantitatively, the translational and rotational offsets provided by the rigid registration were reviewed to see if they met current institutional guidelines and thresholds of 1.0 cm and 5°, realizing that this was a patient cohort that received radiotherapy with stable standardized positioning. Specifically, a custom extremity immobilization device (T-Form Extremity Immobilizer System, Bionix RT, Toledo, OH) was utilized for the lower limb, a polystyrene bead vacuum cradle (VacLok®, Civo Medical Solutions, Kalona, IA) was used for retroperitoneal patients, thorax patients were immobilized on a chestboard (MedTech, Orange City, IA) while pelvis patients were positioned supine with pillows under their head, and a standard immobilizer (Contour Fabricators Inc. Medical Solutions, Denton, Michigan) under their legs.

### Act

Analysis from the ‘study’ phase contributed to amendment of the ROI borders. Finalized guidelines were approved by the multidisciplinary sarcoma site group consisting of therapy, oncology and physics with STS expertise. The final ROI guidelines were presented to an inter-professional image-guidance institutional committee for review and approval before clinical implementation.

## Results

### Plan

Based on anatomic bony surrogates in the 4 STS locations, ROI matching guidelines were drafted by the inter-professional team of STS experts.

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