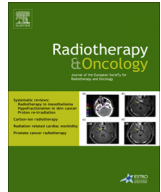




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Original article

Review of the patient positioning reproducibility in head-and-neck radiotherapy using Statistical Process Control

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ABSTRACT

Background and purpose: A remarkable improvement in patient positioning was observed after the implementation of various process changes aiming to increase the consistency of patient positioning throughout the radiotherapy treatment chain. However, no tool was available to describe these changes over time in a standardised way. This study reports on the feasibility of Statistical Process Control (SPC) to highlight changes in patient positioning accuracy and facilitate correlation of these changes with the underlying process changes.

Materials and methods: Metrics were designed to quantify the systematic and random patient deformation as input for the SPC charts. These metrics were based on data obtained from multiple local ROI matches for 191 patients who were treated for head-and-neck cancer during the period 2011–2016.

Results: SPC highlighted a significant improvement in patient positioning that coincided with multiple intentional process changes. The observed improvements could be described as a combination of a reduction in outliers and a systematic improvement in the patient positioning accuracy of all patients.

Conclusion: SPC is able to track changes in the reproducibility of patient positioning in head-and-neck radiation oncology, and distinguish between systematic and random process changes. Identification of process changes underlying these trends requires additional statistical analysis and seems only possible when the changes do not overlap in time.

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Accurate patient positioning is extremely important in head-and-neck radiotherapy (HNRT) considering the close proximity of target volumes to organs at risk. Rigid patient positioning variation can be partially corrected by treatment couch corrections prior to treatment and most geometric positioning uncertainties are accounted for by planning target volume (PTV) margins [1–3]. However, non-rigid patient deformation is commonly observed in HNRT in spite of individualised patient immobilisation due to changes in posture, weight loss or tumour shrinkage [4–9]. Non-rigid variations in patient positioning are commonly managed by adapting the treatment plans when target coverage or sparing of critical structures is at risk [10]. Plan adaptation often requires re-scanning the patient, re-contouring and re-planning, which can take several days. During this time the patient has to be treated with the original treatment plan. This approach is sub-optimal and impacts on staff resources. It is therefore important to improve patient positioning reproducibility as much as possible as part of a quality management programme and minimise the number of

plan adaptations. However, tools to monitor patient positioning reproducibility are not readily available. Statistical Process Control (SPC) is a suitable candidate for this task and has been a widely used tool in aviation and automotive industries to monitor processes for many decades [11,12]. In radiation oncology, SPC has increasingly been used during the last decade to monitor the results of quality control (QC) of treatment machines and of individual patient treatment plans [13–21]. The current feasibility study investigates the suitability of SPC to monitor the reproducibility of patient positioning over a large cohort of patients. The study aims to determine whether or not (1) SPC can track changes in patient positioning reproducibility; (2) SPC can distinguish between systematic and random process changes; and (3) it is possible to uniquely identify the process changes underlying the trends observed with SPC?

Materials and methods

Patient cohorts

This study is based on the retrospective analysis of CBCT image data of 191 patients who were treated with radiotherapy to the head-and-neck region between May 2011 and January 2016. New

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treatment plans that were created after manufacturing a new head rest and mask, and acquiring a new planning-CT scan to counteract anatomical changes or patient re-positioning problems were treated as independent study cases. Daily setup corrections were based on daily planar 2D kV imaging for the majority of patients while weekly CBCT imaging was applied to verify the patient anatomy. For selected cases, for instance when the PTV was in close proximity of critical organs at risk, daily CBCT imaging was used for patient position verification. Patients were included in this study based on the availability of CBCT data of at least 3 weekly CBCTs, or at least 10 daily CBCTs to obtain data representative for the whole treatment period. In addition, inclusion criteria required that C1–C3 and at least 3 other match structures as defined below were visible. This resulted in 196 study cases in total.

Patient immobilisation

A 2.4 mm Reloadable Head and Shoulder S-Frame Kevlar Mask (Q-Fix, Avondale PA, U.S.A.) in combination with a vacuum bag as individual head rest was used for all patients. Overall, four different types of individualised head supports were used for patient immobilisation as detailed in [Supplementary Data A](#). Bite blocks ($n = 5$) and tongue depressors ($n = 18$) were used at the indication of the treating Radiation Oncologist.

Multiple rigid registration protocol

Multiple rigid image registrations were retrospectively performed using Varian Offline Review software (Varian Medical Systems Inc., Palo Alto, CA). On average 8 CBCT scans per patient were sequentially registered to the planning CT (pCT) using each of the following match structures: C1–C3, C3–C5, C5–C7, C7–C9, mandible, occipital bone and the larynx [4]. Region of interests (ROIs) were based on the pCT to ensure consistent registration approach across all patient treatment fractions, with automatic registrations performed using translations only in the anterior-posterior (AP), superior-inferior (SI), and left-right (LR) direction.

Quantification of setup reproducibility

Deformation D was calculated for each ROI, translational axis $k = x, y, z$ and fraction f , as the difference between the match results M of the reference ROI, C1–C3, and the individual ROI [5]:

$$D_{f,k}^{ROI} = M_{f,k}^{ROI} - M_{f,k}^{C1-C3} \quad (1)$$

The systematic 3D deformation for each ROI was determined by calculating the average vector length of the resultant 3D deformation vectors over all fractions for each patient:

$$D_f^{ROI} = \sqrt{(D_{f,x}^{ROI})^2 + (D_{f,y}^{ROI})^2 + (D_{f,z}^{ROI})^2} \quad (2a)$$

$$D_{syst}^{ROI} = \sum_{f=1}^F \frac{D_f^{ROI}}{F} \quad (2b)$$

To assess the random deformation for each ROI without averaging out the random variation of the different directions, the standard deviation (SD) of the deformation over all treatment fractions was determined for each direction first, followed by calculating the vector sum of the SDs of all directions:

$$SD_k^{ROI} = \sqrt{\frac{1}{F-1} \sum_{f=1}^F (D_{f,k}^{ROI} - m_{f,k}^{ROI})^2} \quad (3a)$$

with

$$m_{f,k}^{ROI} = \sum_{f=1}^F \frac{D_{f,k}^{ROI}}{F} \quad (3b)$$

$$D_{rand}^{ROI} = \sqrt{(SD_x^{ROI})^2 + (SD_y^{ROI})^2 + (SD_z^{ROI})^2} \quad (3c)$$

Subsequently, the overall average systematic and random deformation per patient was estimated by averaging the 3D deformation over all ROIs to obtain two key quality measures for further analysis using SPC.

$$D_{syst} = \sum_{ROI} \frac{D_{syst}^{ROI}}{N_{ROI}} \quad (4a)$$

$$D_{rand} = \sum_{ROI} \frac{D_{rand}^{ROI}}{N_{ROI}} \quad (4b)$$

Statistical Process Control charts

The construction of various SPC charts has been described in many papers and text books [11–21]. For the current study, individual value charts were constructed as described by Wheeler [11]. In summary, a small dataset acquired during a period where the process is deemed to be stable functions as the reference dataset. Subsequently, the centreline \bar{D} and the lower and upper process limits, LPL and UPL for the observation period, were calculated from these m reference data points D_i as follows:

$$\bar{D} = \sum_{i=1}^m \frac{D_i}{m} \quad (5a)$$

$$LPL, UPL = \bar{D} \pm 3/d_n \cdot \frac{\sum_{i=2}^m |D_i - D_{i-1}|}{m-1} \quad (5b)$$

These process limits were subsequently applied to determine whether the process was in or out-of-control during the observation period. For an individual value chart, the constant d_n equals 1.128 [20]. Exponentially weighted moving average (EWMA) charts [12] were constructed to analyse trends and detect small changes over time of the systematic and random 3D deformation for each ROI. The values E_i of the test statistic in the EWMA charts were calculated using:

$$E_i = \lambda D_i + (1 - \lambda) E_{i-1} \quad (6)$$

λ is a constant between $0 < \lambda \leq 1$ that determines the depth of memory (smoothing) of the EWMA, D_i is the calculated deformation of fraction i , and E_0 is the average deformation during the reference period. The lower and upper process limits LPL and UPL were calculated using:

$$LPL, UPL = \mu_0 \pm L\sigma \sqrt{\left(\frac{\lambda}{2-\lambda}\right) [1 - (1-\lambda)^{2i}]} \quad (7)$$

μ_0 and σ are the mean and SD for the reference data set, and L is a factor determining the width of the process limits. Normal probability tests showed that the systematic and random deformations in this study were generally not normally distributed ([Supplementary Data B](#)). Therefore, $\lambda = 0.05$ and $L = 2.492$ were used to obtain similar type I and type II error probabilities as for normally distributed data [22].

For both individual charts and EWMA charts, a reference period including 15 patient treatments was chosen as the period of time representing a stable process. The appropriateness of this was assessed by verifying that the EWMA values over the next 15 patients were well within the calculated process limits.

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