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Original Research Article

Statistical process control: machine performance check output variation

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ABSTRACT

Background: The aim of this study was to illustrate and evaluate the use of different statistical process control (SPC) aspects to examine linear accelerator daily output variation through machine performance check (MPC) over a month.
Methods: MPC daily output data were obtained over a month after AAPM TG-51 were performed. Baseline data were set, and subsequent data were conducted through SPC. The Shewhart chart was used to determine the upper and lower control limits, whereas CUSUM for subtle changes.
Results: The upper and lower control limits obtained via SPC analysis of the MPC data were found to fall within AAPM Task Group 142 guidelines. MPC output variation data were within ±3% of their action limits values and were within 1% over thirty days of data. The process capability ratio and process acceptability ratio, C_p and C_{pk} values were ≥2 for all energies. Potential undetected deviations were captured by the CUSUM chart for photons and electrons beam energy.
Conclusions: Control charts were found to be useful in terms of detecting changes in MPC output.

Keywords: CUSUM, Machine performance check, Statistical process control

INTRODUCTION

In radiation therapy, the goal is to deliver a prescribed dose to a tumor volume while minimizing its effect on the surrounding normal tissues. To ensure accuracy and proper dose delivery, linear accelerator (linac) quality assurance (QA) testing is undertaken daily, weekly, monthly, and annually, to a clinically acceptable commissioned data tolerance[1-3]

MPC (Varian Medical Systems, Palo Alto, CA, USA) output QA tests are carried out daily before any patient treatment. It is an application that relies on a fully integrated and automated imaging system, comprised of an electronic portal imaging device (EPID), kilovoltage (kV) or megavoltage (MV), and an on-board imager (OBI).

In this study, the variation in daily output in terms of photon and electron energies was monitored using MPC over a month. The observed uncertainties in the results were analyzed using SPC, primarily the Shewhart control chart. SPC is a graphical tool for process performance monitoring and is used to identify systematic and random errors, thereby preventing the occurrence of faults. Several reports have used SPC to assess certain aspects of the linac retrospectively to investigate trends, constancy, and variability in the QA process.[4-6] Binny et al used SPC to explore the variation in output across six machines, while others have examined the feasibility of a linac EPID system as a control mechanism for real-time patient dose and beam monitoring.[7-9] The complexity associated with linac QA tests required a precise process to verify the linac performance and recommend preventive actions and remedies as needed. MPC tracks a wide range of geometric, mechanical, and imaging parameters

automatically. Any of these factors have shown to function as predictors and warnings for subsequent failures. Hence, the purpose of this work is to use SPC tools to assess one these factors over thirty days: MPC output.

METHODS

Radiation output measurements from an Edge TrueBeam (Varian Medical Systems, Palo Alto) linac were carried out based on clinically available photons (6 and 10 MV, 6 and 10 FFF) and electrons (6, 9, 12, 15 MeV). The linac was calibrated annually using the AAPM TG-51 and subsequent MPC baseline data set.[10] Finally, daily output constancy checks using MPC were performed over thirty days at GenesisCare clinic from May to June 2022.

Statistical analysis

Shewhart control chart

The Shewhart control chart, a SPC model, monitors that a process variable remains on target and within given upper and lower limits. It assumes that the variations (fluctuations) that lie within the control are random, and that those found outside (interruptions) are systematic. The output variation from MPC was recorded daily and was plotted against time for individual energies. The central, upper, and lower limit were then calculated:

$CL = \mu$ (1)
$UCL = \mu + 3\sigma$ (2)
$LCL = \mu - 3\sigma$ (3)

where, the center limit (CL) corresponds to the average for the process. CL is used as a reference for the data point spread. The upper (UCL) and lower (LCL) control limits indicate the process width. Data falling within the UCL–LCL range signifies a process that is in control and affected only by random errors. However, data falling outside the UCL–LCL range indicates a process that is out of control and related to systematic errors in data acquisition. As a requirement, most control charts that monitor data from a region of interest are normally distributed.

The normality of the MPC data for all energies was assessed through the Anderson-Darling (AD) statistic to check for the data distribution behavior via the following hypotheses: [11]

H_0: Data are sampled from a population that is normally distributed. H_1: Data are sampled from a population that is not normally distributed.

The decision to reject the null hypothesis (H_0) is dependent on the p-value with a specified significance level of 5%. For a p-value greater than 0.05, the test is considered normally distributed. The equation for AD is as follows:

$$AD^* = AD\left(1 + \frac{0.75}{N} + \frac{2.25}{N^2}\right) \text{ (4)}$$

Process analysis

The process capability for short-term performance compared the output of an in-control process to the action limits (ALs). It is characterized by indices C_p and C_{pk}. C_p is used to find trend in systematic and non-systematic errors and is expressed as:

$$C_p = \frac{(UAL-LAL)}{6\sigma} \text{ (5)}$$

Similarly, the process acceptability C_{pk} represents how close the process center is to the action limit and is calculated as follows:

$$C_{pkl} = \frac{(\mu-LAL)}{3\sigma} \text{ (6)}$$
$$C_{pu} = \frac{(UAL-\mu)}{3\sigma} \text{ (7)}$$
$$C_{pk=\min\left(\frac{UAL-\mu}{3\sigma}, \frac{\mu-LAL}{3\sigma}\right)} \text{ (8)}$$

where UAL is the upper AL, and LAL is the lower AL. The AL is set to ± 3% for MPC and is based on AAPM TG-142.[2] The parameters μ and σ are the mean and standard deviation of the process respectively, for the individual measurements of the output variation. The process performance criteria are set as follows 1) C_{pk} <1.33 means that the process is not capable, 2) 1.33 <C_{pk} <1.66 means that the process has limited capability and 3) C_{pk} > 1.66 means that the process is capable.

Cumulative sum control chart

A cumulative sum (CUSUM) chart is used to monitor subtle shifts in the process mean based on the cumulative deviation from the target.[12] The chart will indicate an out-of-control process by an upward or downward drift of the CUSUM until it crosses a specific limit. In tabular form, CUSUM is given by:

$Ci+ = \max [0, -\mu - k + C+i-1]$ (9)
$Ci- = \max [0, \mu - xi - k + C-i-1]$ (10)

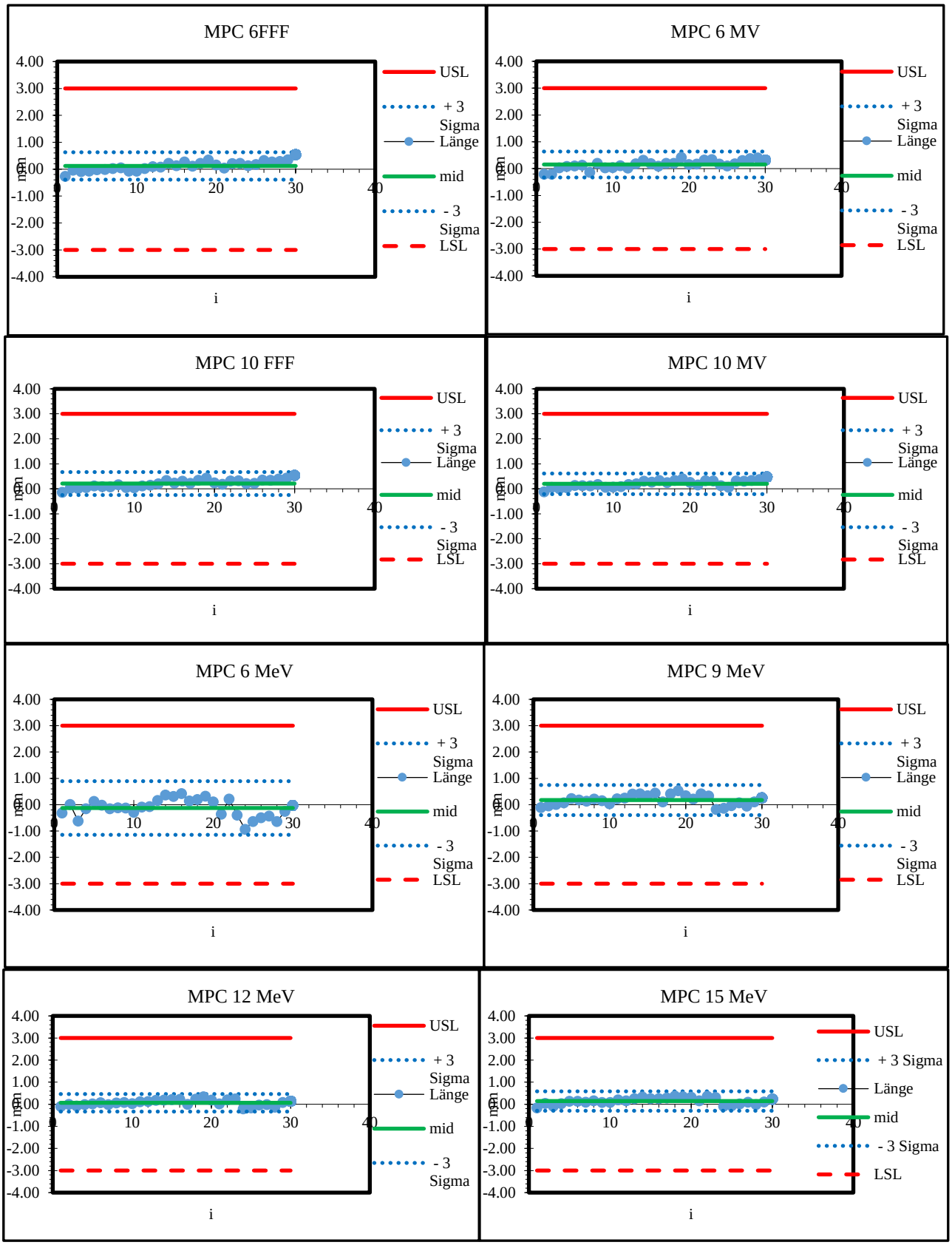
When $i = 0$, $Ci-$ and $Ci+ = 0$.

k is the reference value set to 0.5 to detect one-sigma (1σ) shifts in the mean. h is typically set to five and the tolerance to ±3%, based on AAPM TG-142. The CUSUM was performed for all energies.

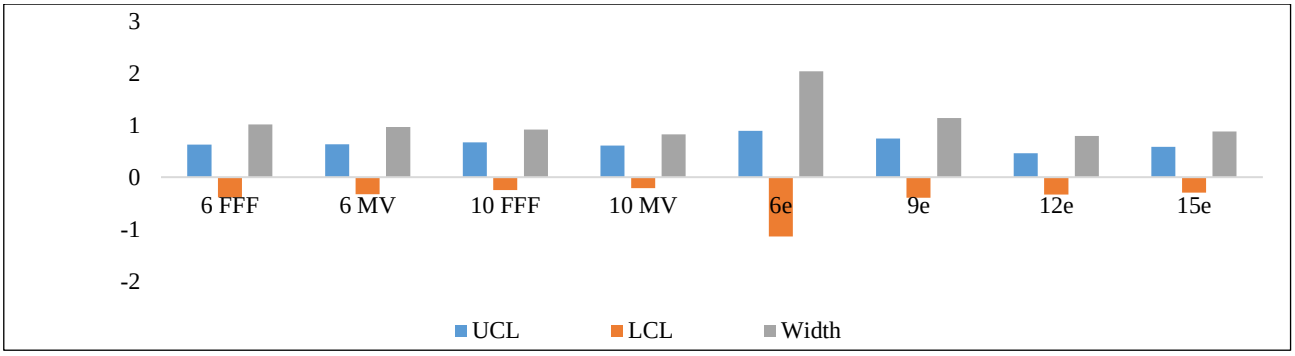
RESULTS

SPC methods were applied to all MPC derived output for different energies. During the acquisition period, MPC output variation data were within ±3% of their AL values and were within 1% over thirty days of data. Individual X-charts for different energy data points are illustrated in Figure 1. They are characterized by the upper, central,

and lower lines. The ensuing calculated width is well below the action limit and the warning level (UCL). The width is more pronounced at 6 MeV for the MPC output variation (Figure 2).



Figures 1: Individual value X-chart for MPC output variation for different energies over thirty days.



Figures 2: Individual value X-chart width for MPC output variation for different energies over thirty days.

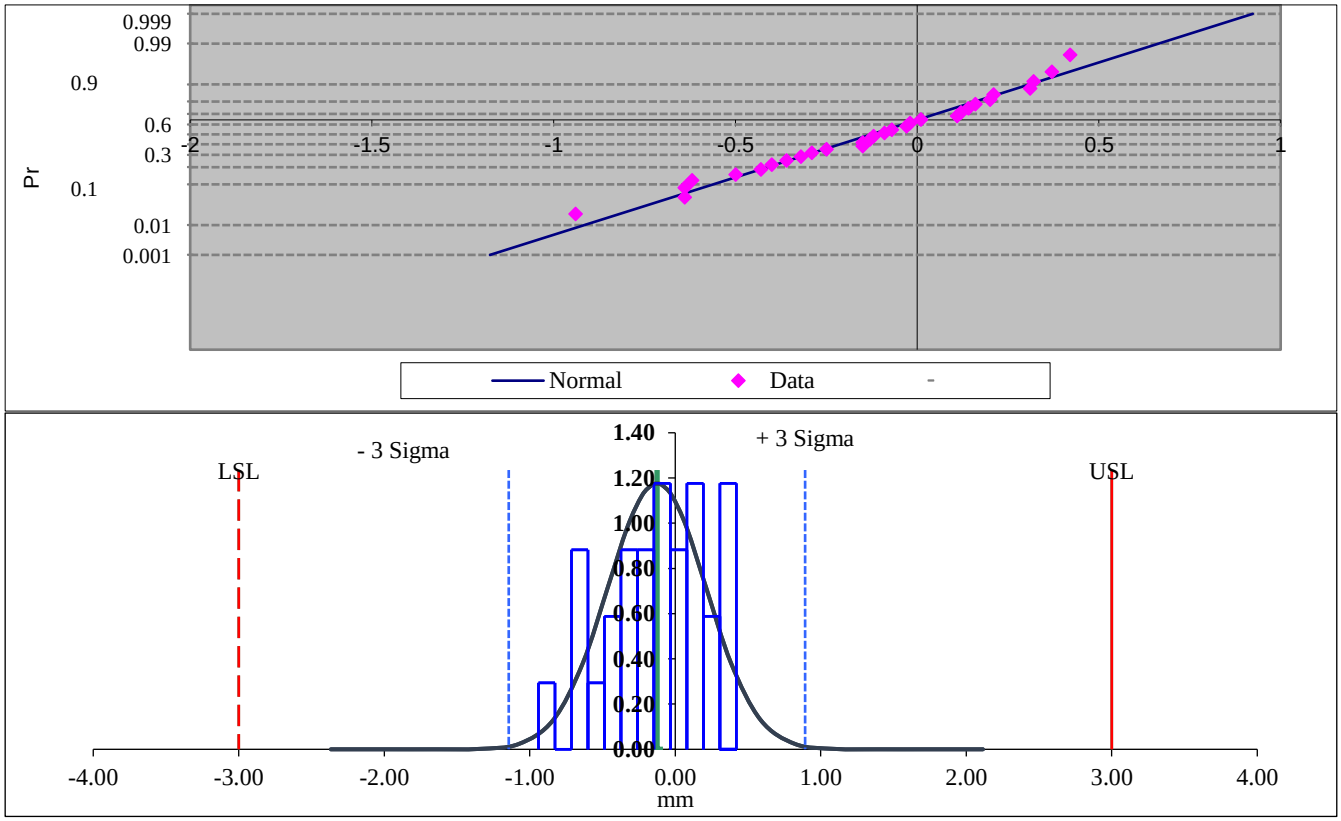


Figure 3: Probability and histogram plots based on Anderson-Darling test for 6 MeV MPC.

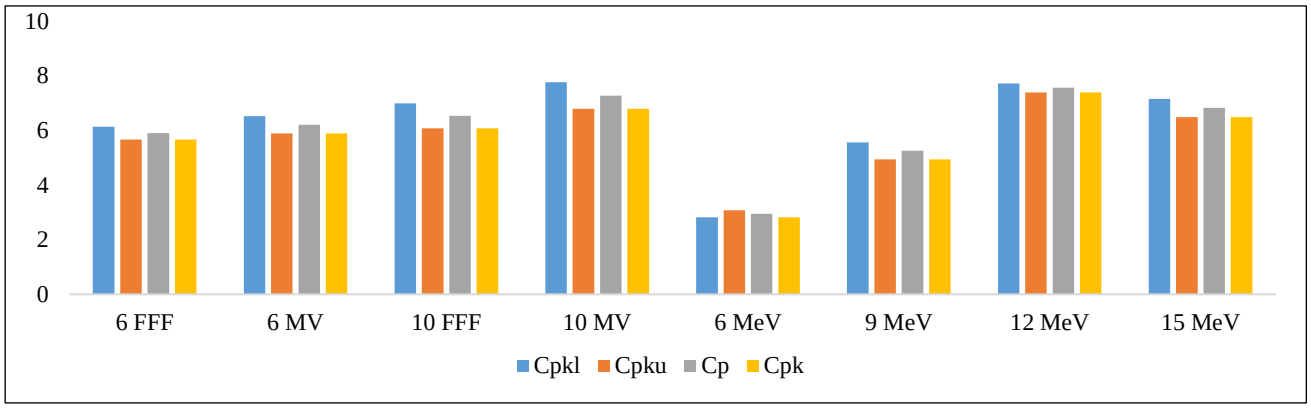


Figure 4: Capability ratio (Cp) and acceptability indices (Cpk, Cpku, Cpkl) for MPC output variation for all energies over 30 days.

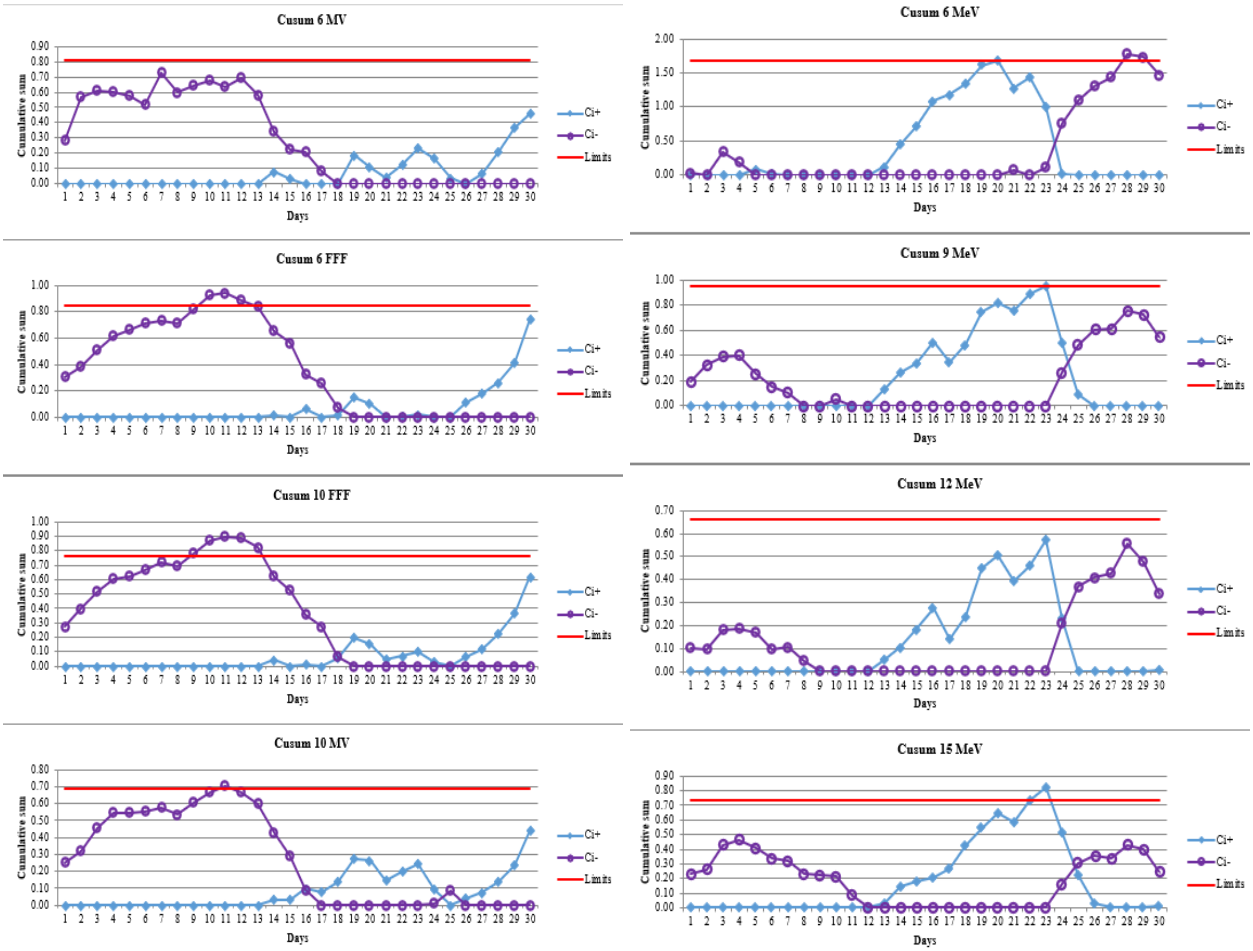


Figure 5: The two-sided CUSUM control chart plots the values of Ci+ and Ci- for each energy derived MPC. If either statics lies beyond the stated decision-value Hi (threshold), the process is considered to be out of control.

Table 1: AD normality test results for all energies.

Tests	6 FFF	6 MV	10 FFF	10 MV	6e	9e	12e	15e
AD test statistic	0.2007	0.5063	0.2086	0.4898	0.2362	0.2459	0.2406	0.2841
AD* test statistic	0.2063	0.52019	0.21436	0.50332	0.24268	0.25267	0.24719	0.29192
p-value	0.8702	0.1861	0.8502	0.2048	0.7683	0.7359	0.7538	0.6065

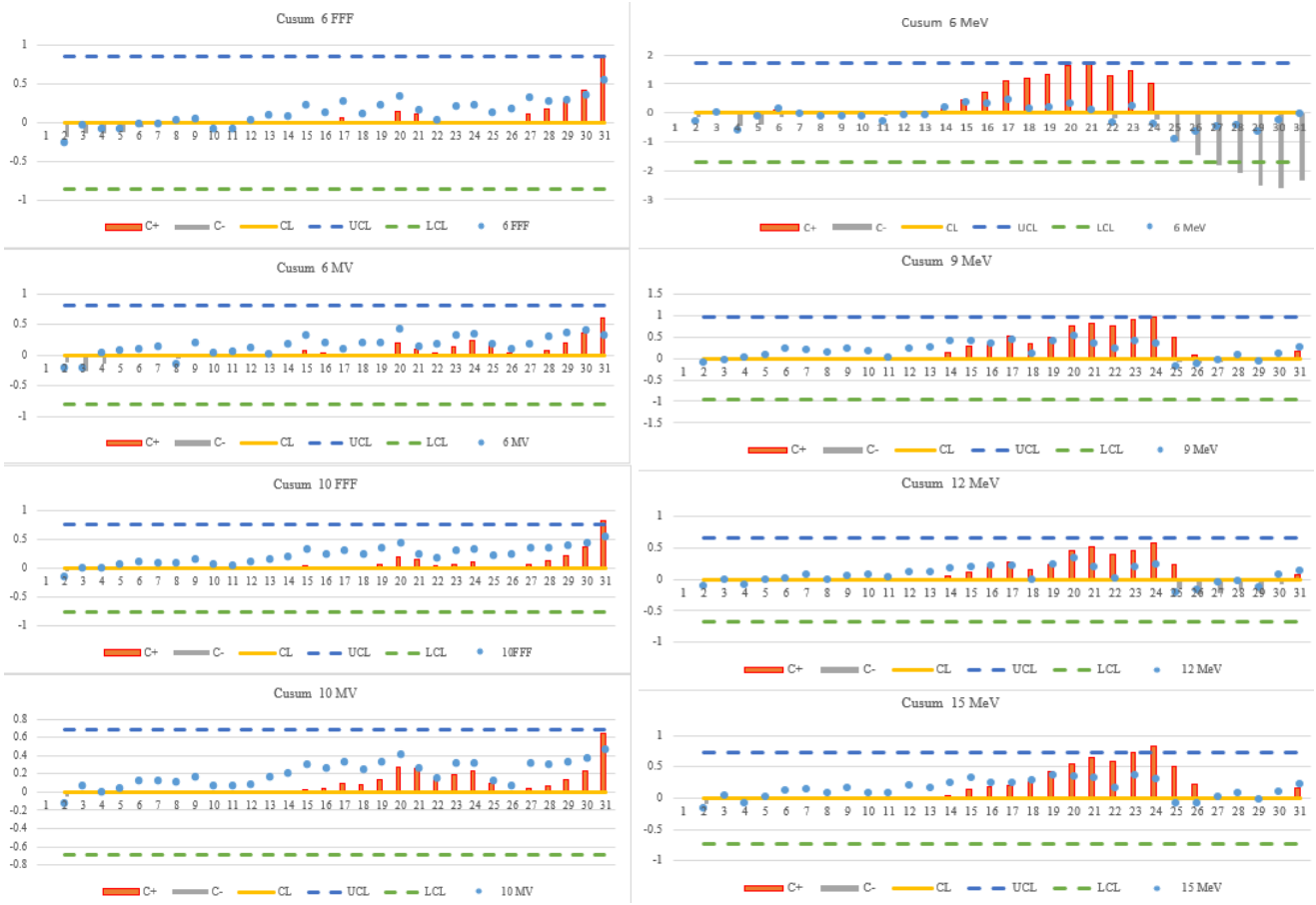
Normality test using Anderson-Darling for MPC data

The results of the normality via the AD test are listed in Table 1. The p-value is greater than 0.05; hence, H_0 is not rejected because there is insufficient evidence to conclude that the data do not follow a normal distribution. Figures 3 show an example of the normal probability plot and a histogram for 6 MeV electron energy. For readability purposes, not all MPC energies are illustrated.

Process capability and acceptability

The process capability ratio and process acceptability ratio, C_p and C_{pk}, were used to indicate the process performance of MPC output variation. They are displayed in Figure 4, where the acceptability indices C_{pku} and C_{pkl} are used to calculate C_{pk}. The results show that the C_{pk} and C_p values were ≥ 2 for all energies, implying that the process is very capable. A larger value of C_p is indicative of good process capability and acceptability.

Figure 5 displays the CUSUM for all the positive and negative changes in the data to monitor small shifts in the process mean for all energy output variations. There is no significant shift in the process mean from the target value, as illustrated by the CUSUM chart for most cases. It does not appear to show any obvious trends (Figure 6) that require intervention. It is within the control limits and has a well below tolerance threshold of 3%.



Figures 6: CUSUM Chart for MPC output variation for all energies. Time series of cumulative sums of positive and negative changes.

DISCUSSION

In this study, SPC control charts were generated to determine the upper and lower limits of the MPC output variation. This approach offers better insight into how to track and when to act on varying data points, in- or out-of-control limits, in contrast to the fixed limits based on the standard deviation. It is characterized by process variability, where points outside the control limit are out of control and require attention. However, the main drawback lies in the subjectivity with which points are classified as being inside or outside the control limits. A point that is close to the mean is better than one that is within the control limits. As a result, a CUSUM chart, which is mostly intended for quality control processes in industry, was used to distinguish any abnormalities that may arise and undetected by the Shewhart process. In this study, all MPC output variation was found to be in control, based on the corresponding Shewhart chart. However, the CUSUM charts showed a drift in the beam owing to the atypical make-up of the chart, which is prone to 1σ sensitivity, as shown in Figure 5. The maximum ULC of 0.89% was observed for 6 MeV with the Shewhart chart, well below the TG-142 recommendation for the daily output (3%). However, the CUSUM shows that the process is out of control for 6 FFF, 10 FFF, 6 MeV, and 15 MeV, for CUSUM target (0%). This analysis of MPC output variation would benefit from a joint approach based on Shewhart charts and CUSUM to identify changes in the process. In this case, the CUSUM would focus on subtle changes in the region of interest concealed by the Shewhart charts. Our data also revealed that the control limits were smaller than the action limits for the daily output variation. Caution should be used when analyzing the process, as the linac may be affected by system noise, as pointed out by Hossain et al [13].

The evaluation of the process capability C_p and acceptability C_{pk} indices for the MPC output variations is equally important, as it can provide insight and an overview of the process. C_p and C_{pk} are derived from a normal distribution (Figures 3) and are greater than two for all MPC energies (Figure 4), suggesting that the process is capable and meets the specifications in this study. Note that the data was acquired over thirty days.

Further work will include the use of fishbone chart to provide a set of probable root causes of machine errors, useful while troubleshooting.[14] In addition, comparative studies could be performed to include exponentially weighted moving average (EWMA) chart suitable for detecting slow drifts of a process, and CUSUM.[15]

CONCLUSION

The current study sought to elucidate facets of a new tool added to the linac machine. MPC is an automated process that works independently of the linac parameters without any setup and is apt to perform daily output measurements. However, the absence of a linearity check and hesitancy to accept MPC as a QA tool constitute some of its disadvantages. In this study, we presented SPC as a dependable analytical tool to identify long and short-term systematic and non-random errors undetected during routine quality checks.

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Ethical approval: Not required

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