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PROTON CONFORMAL FLASH RADIOTHERAPY HEAD AND NECK CLINICAL TRIAL: COMMISSIONING PROCESS AND ESTABLISHMENT OF A SAFE WORKFLOW

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ABSTRACT

Purpose: **A proton conformal FLASH radiotherapy system delivers spread-out Bragg peaks to tumor targets at ultra-high dose rate (UHDR) recently received FDA IDE approval.** The system uses multiple beam-modifying devices to deliver scanned pencil beams at ~ 500 nA nozzle current. Technical complexity of conformal FLASH technology necessitates additional considerations to ensure that the first clinical trial is carried out in a safe manner. These safety measures include validation of machine UHDR performance with proper dosimetry systems, verification of manufactured device integrity, patient-specific dose and dose-rate quality assurance (QA), and end-to-end validation of the delivery workflow.
Methods: Cross-validated dosimetry systems for UHDR, including thin-gapped ionization chambers (ICs) and IC array, multilayer Faraday cup (MLFC), and Faraday cup (FC) with ultra-fast electrometers, were used. Device QA included CT-based evaluation of 3D-printed CEMs. Patient-specific QA of dose and dose-rate distributions was performed for FLASH plans for regular-shaped targets and head-and-neck (HN) patient cases. A comprehensive TPS to image-guided FLASH treatment delivery was conducted using an anthropomorphic HN phantom.
Results: Measured depth dose R90 values in water agreed with TPS within 0.13±0.45 mm across various configurations. Reference field dose measurements agreed within 2% of TPS calculations, with FC-confirmed <1% ion recombination. All patient-specific QA plans passed 3%/3 mm gamma criteria for dose verification. Dose rate metrics, including spot-by-spot timing, were verified via machine logs and FC measurements. End-to-end UHDR delivery in the phantom met IROC gamma criteria for dose accuracy, as well as the dose rate requirement in the Conformal FLASH trial.
Conclusion: Robust UHDR dosimetry and plan-to-treatment workflows were established during commissioning of the Conformal FLASH system. Accurate and reproducible dose, dose rate, and delivery performance across all tested conditions, including clinically representative head-and-neck cases, were confirmed. **These results provide strong evidence for stable system behavior and reliable and safe conformal FLASH clinical workflow, supporting the initiation of a first head-and-neck Conformal FLASH clinical trial.**

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INTRODUCTION

A proton conformal FLASH radiotherapy system delivers spread-out Bragg peaks to tumor targets at ultra-high dose rate (UHDR) recently received FDA approval. The system uses multiple beam-modifying devices to deliver scanned pencil beams at ~ 500 nA nozzle current. Technical complexity of conformal FLASH technology necessitates additional considerations to ensure that the first clinical trial is carried out in a safe manner. These safety measures include **validation of machine UHDR performance with proper dosimetry systems, verification of manufactured device integrity, patient-specific dose and dose-rate quality assurance (QA), and end-to-end validation of the delivery workflow.**

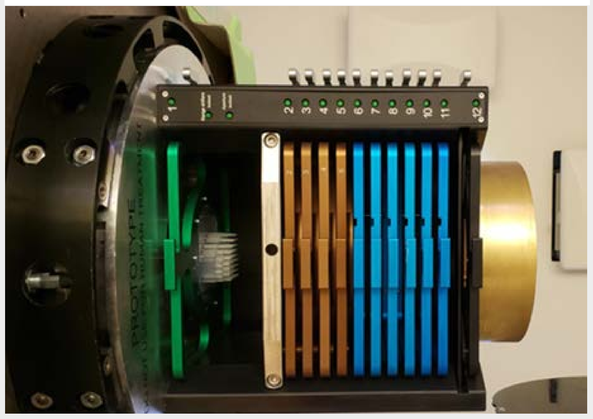

Figure 1: Dedicated FLASH snout with 3D-printed conformal energy modulator, range shifter and brass aperture.

METHODS AND MATERIALS

An isochronous cyclotron–based conformal FLASH proton therapy system (Ion Beam Applications, Belgium) has been developed to deliver conformal spread-out Bragg peaks (SOBPs) to patient tumor targets at ultra-high dose rate (UHDR). This capability is enabled by scanning a monoenergetic 228 MeV pencil beam at ~500nA nozzle current using a dedicated FLASH snout(Fig 1). The customized beam-modifying devices, including patient specific conformal energy modulator (CEM), aluminum range shifter (RS), and brass aperture (BA) are integrated within the dedicated snout. A corresponding treatment planning system (TPS) was developed to support patient-specific treatment planning and customized device design.

Commissioning the FLASH radiotherapy system and its corresponding TPS for safe clinical implementation addresses several critical challenges unique to proton FLASH radiotherapy: (i) establishing multiple cross-validated dosimetry systems capable of accurate dose measurement under UHDR conditions; (ii) enabling real-time, time-resolved dose delivery recording for dose rate derivation; (iii) implementing robust quality assurance for customized CEM and BA devices; (iv) designing specialized tests to characterize machine performance at UHDR; and (v) developing comprehensive validation strategies for the FLASH TPS.

RESULTS

Commissioning tests were designed and executed following established clinical commissioning principles and published guidelines for FLASH radiotherapy. To verify the beam model, integrated depth-dose (IDD) curves of the 228 MeV proton beam delivered through various RS slabs and CEM blocks were measured using a StingRay detector (IBA Dosimetry) in a water tank under low dose rate (LDR) delivery (Fig. 2), showing overall <1.5 mm deviations in range from the TPS calculations. Beam energy consistency between LDR and UHDR delivery modes has been confirmed using a multi-layer Faraday cup (Pyramid Technical Consultants) (Fig. 3). A scintillator-based detector (Lynx, IBA Dosimetry) with reduced iris settings was used to measure spot size, spot position and virtual source-to-axis distances (SADs).

Figure 2: Water tank measurement of IDD of a 228 MeV beam passing through multiple aluminum range shifter slabs at low dose rate.

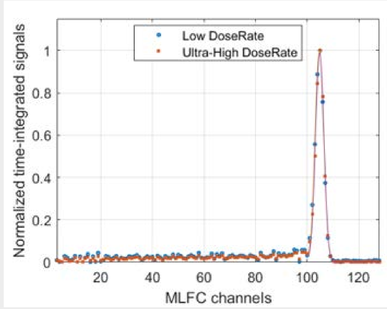

Figure 3: Overlay of time-integrated signals across MLFC channels under low dose rate (LDR) and ultra-high dose rate (UHDR) conditions, demonstrating beam range consistency independent of dose rate.

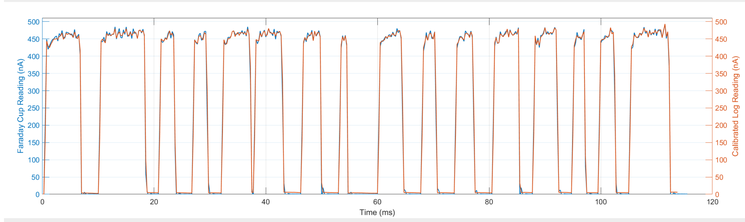

Figure 4: Calibrated machine IC log file depicting spot-by-spot UHDR beam current and timing, consistent with a Faraday cup reading with 4kHz sampling rate. The 112.25 ms delivery represents single beam from a head-and-neck patient conformal FLASH plan at 8 Gy per fraction for five fractions.

We demonstrated that a thin-gap (≤1 mm) ionization chamber with appropriate bias can accurately measure dose delivered at ~500 nA beam current with minimal ion recombination. Based on this validation, a PPC05 parallel-plate chamber (IBA Dosimetry) was used for absolute dose measurements of reference fields and resulted in <2% deviations from TPS calculations. Spot-by-spot pencil beam delivery was captured using a BC145 Faraday cup paired with a fast electrometer (Pyramid Technical Consultants), revealing intra-spot UHDR beam current and timing signatures consistent with system monitor chamber log files acquired at a 4 kHz sampling rate (Fig. 4). Machine performance metrics, including MU linearity and beam current stability, were verified.

Planar UHDR dose distributions were measured using the MatriXX AiR detector (IBA Dosimetry), which consists of a 1-mm-gap parallel-plate ion chamber array or for point dose with a PPC05. Minimal ion recombination in MatriXX AiR was confirmed through paired LDR and UHDR deliveries. Measured planar dose distributions for deliveries through customized devices achieved >97% gamma pass rates at 3%/3 mm criteria, when compared with planned doses for multiple regular-shaped target plans (Fig. 5). Device QA procedures were established and applied to manufactured CEMs and BAs. 3D printed CEMs scanned and analyzed from its CT images at 0.25 mm resolution demonstrated consistent geometric quality relative to the TPS designs. End-to-end UHDR delivery in the anthropomorphic phantom met national Imaging and Radiation Oncology Core gamma criteria for dose accuracy, as well as the dose rate requirement in the Conformal FLASH trial (Fig. 6).

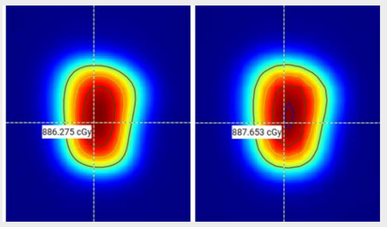

Figure 5: Comparison of one QA dose plane measured with MatriXX AiR IC array for a HN patient plan.
Left – QA plan;
Right – Measurement.

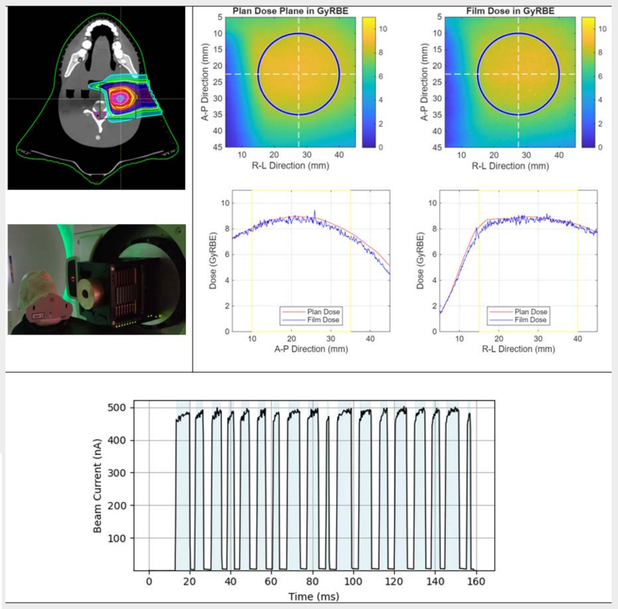

Figure 6: End-to-end test on a H&N anthropomorphic phantom – one of the two UHDR beams planned dose and EBT4 gafchromic film measured delivery dose comparison. The delivered CTV mean dose-averaged-dose rate from log file shown above was calculated to be 100.02 GyRBE/s.

CONCLUSIONS

Successful commissioning of the FDA-approved proton conformal FLASH system and its corresponding TPS is a critical step toward clinical translation of proton FLASH radiotherapy. Our work has demonstrated that robust UHDR dosimetry and plan-to-treatment workflows were established for the Conformal FLASH system commissioning. Accurate and reproducible dose, dose rate, and delivery performance across all tested conditions, including clinically representative head-and-neck cases, were confirmed through reliable and safe conformal FLASH clinical workflow. **These results support the initiation of a first head-and-neck Conformal FLASH clinical trial.**

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