Application of risk-based analysis methods to radiotherapy quality management

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Abstract
The increasing complexity of modern radiation therapy planning and delivery challenges traditional prescriptive Quality Management methods, such as many of those included in guidelines published by organizations such as the AAPM, ESTRO and IAEA. These prescriptive guidelines have traditionally focused on monitoring all aspects of the functional performance of radiotherapy equipment by comparing parameters against tolerances set at strict but achievable values. In modern radiotherapy, the number of devices, systems, and processes involved in planning and delivery lead to dramatically increasing numbers and sophistication of necessary tests and measurements to fully cover the modern radiotherapy process. There is thus a need to prioritize Quality Management (QM) activities in a way that strikes a balance between being practical in the clinical environment and optimally beneficial to patients. A systematic understanding of the likelihood and clinical impact of possible errors throughout a course of radiotherapy (RT) is needed to direct limited QM resources efficiently to produce maximum safety and quality of patient care. Task Group 100 of the AAPM has taken a broad view of these issues and has developed a framework for designing QM activities, and hence allocating resources, based on estimates of failure modes, risk assessment and clinical outcome through the RT planning and delivery process. Toward this goal, the task group has chosen the specific radiotherapy processes “intensity modulated radiation therapy (IMRT)” for analysis. The goal of this work is to apply modern risk-based analysis techniques to this complex RT processes in order to demonstrate to the RT community that these techniques may help determine more effective and safe ways to enhance the safety and quality of our treatment processes. The TG has performed a Failure Modes and Effects Analysis (FMEA) for this processes, and determined, by consensus, the most and least risky steps of these processes. This report describes the methodology and nomenclature developed, and presents the Process Maps, FMEAs, Fault Trees and QM programs developed, and finally makes suggestions on how this information can be used in the clinic.

A Priori Determination of Dose Uncertainties in IMRT Planning and Delivery

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Abstract:
The uncertainties in dose delivered to a patient arise from each step of the overall process of radiation therapy, which starts with image acquisition and ends with the dose delivery. The enhanced capabilities and functionalities of 3D RTP systems present a challenge for radiation therapy staff to maintain the quality, safety, and reliability of radiotherapy without resorting to extensive efforts in quality assurance (QA). Increased complexity of advanced technologies is inevitably associated with larger possible uncertainties, which can potentially result in unfavorable clinical consequences. This has been addressed by the development of patient specific QA; a process that is onerous, resource intensive, and not comprehensive. There are well documented clinical cases in which even a detailed QA procedure is unable to resolve large discrepancies between measured and calculated dose distributions. This observation can only be attributed to a complex interplay of uncertainties in the treatment planning and delivery process that are not accounted for in the RT process. We have developed an analytical model that incorporates all clinically significant dosimetric and spatial uncertainties in IMRT and a priori predicts overall uncertainty associated with any IMRT treatment plan. The ability to accurately predict these discrepancies at the time of the planning allows clinicians to objectively evaluate each IMRT plan and discard plans that have potentially large uncertainties. Furthermore, the minimization of overall uncertainty in treatment planning can be used as a critical element of IMRT multi-criteria optimization in the future. In summary, this analytical model has the potential to increase the safety and efficacy of IMRT, while at the same time, minimize the effort expended in time-consuming and onerous patient specific QA measurements.

Learning Objectives:
• Understand the sources of uncertainties in IMRT planning and delivery
• Learn to evaluate the impact of spatial and dosimetric uncertainties in the IMRT process.
Commissioning and clinical use of the Novalis TX for SRS and SBRT treatments

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The general outline will be as follows:

· Introduction of the Novalis technology and the HFHS experience.
· Overview of Novalis TX (NTX) and it's use in IGRT related to SRS and SBRT.
· Commissioning of NTX: measurements and experiments needed for clinical implementation.
   This will include a review of literature.
· Example studies performed at HFHS for clinical implementation.
· Clinical work flow on NTX for SRS and SBRT - example from HFHS.

Transitioning from 3D IMRT to 4D IMRT and Role of Image-Guidance

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The transition from 3D-IMRT to 4D-IMRT is mandated by clinical necessary as we are treating tumors embedded in the moving organs and/or patients with anatomic changes during the course of radiotherapy. If we do not incorporate organ motion and anatomical changes into our patient management strategy we may not be able to achieve a high tumor control probability (TCP) without introducing unacceptable normal tissue complications probabilities (NTCP). IGRT and 4DCT allows us to explicitly incorporate the time variables into 3D-IMRT, referred to as 4D-IMRT. 4D-IMRT requires efficient IGRT tools and other tools (such as fast dose calculation engines and efficient contouring tools) facilitate for adaptive radiotherapy. This refresher course will focus on how to apply currently available technologies to implement the transition from 3D-IMRT to 4D-IMRT. Using three specific clinical sites (head and neck, prostate, and lung) as examples, we will discuss challenges and technical strategies in clinical implementation of 4D-IMRT.

Optically Stimulated Luminescence (OSL) Dosimetry in Medical Physics

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Landauer, Inc.

Optically Stimulated Luminescence (OSL) is a dosimetry technique that has been used in a variety of applications for over 20 years. Landauer, Inc. has been using this technique with Al2O3:C to monitor radiation workers and their environments since 1998. This same technology is currently being used in medicine to measure the dose to patients from mammography, fluoroscopy, CT, and radiation oncology procedures.

This talk will consist of two parts: 1) a summary of the physics of OSL, and 2) an examination of its use in medical physics where it is enjoying a growing adoption at clinics throughout the US. An overview of the features and advantages of OSL as documented in peer-reviewed publications will be presented. This review will include primal dosimeter characteristics such as energy, angle, linearity, dose-rate, modality, and temperature dependence followed by a discussion of how these characteristics affect clinical use. Finally, a brief introduction to the microStar Dosimetry system and its operational advantages will be presented.
Augmenting 4D PET with deformable image registration

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Purpose/Objective:
Application of the deformation maps derived from 4D CT scans to 4D PET scans for spatio-temporal additivity of the metabolic PET signal to improve the resultant image quality. A software based solution is for combined PET/CT scanners.

Material/Methods:
Quantitative use of the positron emission tomography (PET) scans to aid in diagnosing, staging and tumor response evaluation for various cancer sites is frequently affected by a variety of factors such as tumor size and tumor motion, which may decrease the signal to noise ratio. This is apparent for gated four-dimensional PET scans. The 4DPET and 4DCT images were acquired on the hybrid PET/CT GE Discovery scanner equipped with Varian RPM system. The patient audio coaching was used during the PET and CT scans. The CT images were sorted into 6 phases corresponding to the equivalent PET bins. The CT phases were registered to phase 4 that corresponded to end of exhalation. The registration uses the Demons algorithm implemented with an image hierarchical decomposition with 3-level Gaussian pyramid. The program was written in C programming language on Linux platform. The resultant deformation fields obtained from CT scans characterized by a high anatomical resolution were resampled and interpolated with cubic B-splines to match the PET scans' dimensions. The PET images were deformed to match the bin 4 scan. Data consisted of one liver tumor case and four thoracic cancer patient.

Results:
The 4D PET images' dissimilarity due to their temporal differences is removed in the resultant deformed PET images. Their new spatial equivalence allows for their summation to create a new volumetric view. The CT phase-to-phase registration takes between 5 to 10 minutes including pre and post processing. The resultant PET images exhibit enhanced sharpness and contrast about the tumor, improve their visibility and decrease the background noise.

Conclusions:
A new synergy for combined PET/CT scanner is proposed. As 4D PET/CT gains greater acceptance in IGRT and SBRT, improved PET image quality will be highly desirable. If patient coaching and breathing reproducibility during the scan acquisition process can be maintained, this method can be applied to all cases of abdominal and thoracic 4D PET/CT scan evaluation.

Dosimetric effect of intrafraction tumor motion on gated lung SBRT

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Abstract
In intensity modulated radiation therapy(IMRT), it is well-known that the MLC leaf movement relative to the intrafraction tumor motion causes so-called interplay effect. This effect may worsen in case of lung stereotactic body radiotherapy treatment (SBRT) with high fractional dose, small target and high dose rate delivery. With extended treatment time experienced in gated lung SBRT, the motion pattern may change, adding complexity in determination of actual dose delivery.

In this study we investigated the dosimetric effect of tumor motion and baseline shift in gated lung SBRT. The tumor motion data were retrieved from 6 lung patients with various target size, each with 3 fractions of stereotactic radiotherapy treatments with Cyberknife Synchrony (Accuray, Sunnyvale CA). Phase gating through external surrogate was simulated with a gating window of 5 mm. The resulting tumor motion curves within gating phases were retrieved for interplay effect evaluation. Treatment planning and dose calculation were performed on the platform of Varian Eclipse. Planning target volume (PTV) was defined as physician-contoured clinical target volume (CTV) surrounded by an isotropic 5 mm margin. Each patient was prescribed with 60Gy/3 fractions. To calculate the interplay effect, the MLC segment leaves in observance of the present tumor motion parallel to the MLC plane were shifted. The motion shift in the depth direction, perpendicular to the MLC plane, was ignored since it represents a small source to surface distance (SSD) change of \(\leq 5\) mm with gating. The MLC leaves were shifted for each field as a function of total MU, gantry and collimator angle, and tumor motion at each segment. The newly created MLC file was imported back to the treatment planning system for dose calculation.

It was found that the deviation in PTV and CTV dose due to interplay effect is not always negligible in hypofractioned gated SBRT. Half of the patients in the study group experienced fractional dose deviation up to 20% and total dose of 10% for D95 for PTV. The maximum decrease on CTV D95 is 6% for fractional dose and 3-4% for all 3 fractions compared with static plan. Although the entire CTV volume is almost covered by prescribed dose (V100=100%) with tumor motion, qualitative comparison on the 100% isodose line distribution reveals that the CTV is on the verge of underdosing. This happens due to tumor excursion outside of the gating window, which is mostly caused by the baseline shift, i.e., the change in general trend of the motion curve during extended period of treatment time.
Acceptance and Commissioning of a Novel Ionizing Radiation Emitting Isotope Hospital Detection and Notification System Suitable for Use in Radiation Counter-Terrorism.

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Abstract

Recently UMPC Cancer Centers has installed an Emergency Department Notification System (EDNS) in one of its hospitals. This system, manufactured by ThermoFisher Scientific®, is able to identify radioactive isotopes brought in an Emergency Department by patients contaminated from exposure to radiation incidents such as a terrorist attack using a Radiological Dispersion Device (dirty bomb). Unlike other radiation monitoring systems, the hospital-based EDNS must be capable of discriminating non-medical radioactive isotopes from medical radioactive isotopes being used in nuclear medicine and radiation treatments. The EDNS consists of four NaI(Tl) scintillation detectors (10.2.5.1 40.6 cm³), a 512 channels multi-channel analyzers, a system controller, and a database-monitoring server. During testing the detection mode was set to switch from background to foreground when radiation counting level reached five standard deviations above the background level. In the foreground mode the system is capable of identifying radioactive sources in a relatively short time period. The database-monitoring server can send an alarm signal to appropriate personnel when the analysis of the results indicates such a need. The EDNS detectors were installed in the ceiling at four locations. These included two separate entrances to the emergency department, a busy location inside the emergency department and a high traffic area located on the third floor in the hospital. A series of acceptance tests were carried out to evaluate the performance of EDNS using a variety of radioactive sources of varying activities. The minimum detectable activity for a static 137Cs source was 3.5 μCi, when an unshielded source was exposed to the detectors for 5 seconds at a source-to-detector distance of 205 cm directly beneath the detectors. For a moving 137Cs source, the minimum detectable activity was 5.0 μCi. Movement of radioactive sources was simulated by placing the radioactive sources on a cart and pushing the cart along a designated path under the detectors and also having a human subject hold the source and walk under the detectors at varying speeds. The system easily detected 137Cs isotope of activity 13.4 μCi moving under the detector probe at speeds ranging from 0 to 1.5 m/s. The system accurately detected and identified all single sources tested (57Co, 60Co, 133Ba, 137Cs). However, when a combination of sources, such as 57Co+133Ba and 57Co+60Co+133Ba+137Cs was used for experiment, the system failed to detect 57Co. The reason for this is being investigated. The particular EDNS tested sent alarm signals to designated emergency personnel when it detected the radio-isotopes.

The failure mode and effects analysis for IGRT – the patient factor

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Abstract

IGRT is being released to the clinic driven by spurt of new technologies for radiation oncology applications. While it is important to ensure the proper installation and commissioning of these new imaging devices, it is important to study where the large uncertainties in the use of these devices. The mail goals of this presentation are to learn about sources of uncertainties and their failure modes. We will discuss possible residual uncertainties, various limitations and potential pitfalls related to the implementation of IGRT technologies. We will discuss suggestions of site-specific IGRT strategies.

Dosimetric evaluation of inter-fractional setup uncertainty on prostate treatment in proton therapy

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Purpose: The purpose of this work is to determine dose delivery errors that could result from inter-fractional random setup errors for prostate treatment in proton therapy.

Methods: One prostate cancer patient is selected. The plans were designed using two parallel-opposed lateral fields to deliver 79.2 CGE in 44 fractions of 1.8 CGE to the CTV. In 28 fractions, 50.4 CGE was delivered to CTV1 (prostate with 11 mm margin plus seminal vesicle with 5 mm margin), followed by a 28.8 CGE boost to CTV2 (prostate with 6 mm margin excluding the anterior rectal wall). The CTV-to-PTV margin was 2 mm. XIO CMS treatment planning system was used. The inter-fractional setup errors were simulated by shifting beam isocenter and recalculation of dose was performed without altering the beam configuration or beam shaping devices. Random setup errors of standard deviation (σ) 5 mm along AP direction were simulated by a Gaussian function. The dose distribution was recalculated for each simulated position variability of 0, ± 2 mm, ± 5
mm, ± 7 mm, ± 10 mm, and ± 15 mm. The cumulative DVH over all simulated position weighted by Gaussian probability density function, were recalculated for targets and OARs, and then compared with the original plan. Results: The dose coverage to GTV, CTV1, CTV2, PTV1, PTV2 are reduced slightly yet still fulfilling the prescribed dose coverage. The GTV V95% was reduced by 0.5%. The CTV1 and PTV1 receiving 95% of 5040 cGy was reduced by 0.2% and 0.6%, respectively. The CTV2 and PTV2 V95% were reduced by 1.8% and 2.2%, respectively. The bladder volume receiving 6000 cGy remained the same. The volume of anterior rectal wall receiving 7740 cGy was increased by 3.2%.

Conclusions: Our results suggest that a 2 mm CTV-to-PTV margin appears able to absorb random setup errors having standard deviations as large as 5 mm. Random patient setup errors (σ = 5 mm) in prostate planning didn’t confer clinically significant dose changes to the target volume or critical structures.

International calibration survey of the Leksell Gamma Knife small radiosurgery fields – project design and first results

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Introduction and purpose: An international working group on reference dosimetry of small and nonstandard fields has published a new formalism for the dosimetry of small and composite fields (Med. Phys. 35, 2008). Ionization chambers used together with existing protocols (AAPM TG21, AAPM TG51, IAEA TRS277 and IAEA TRS398), which are the backbones of radiotherapy dosimetry, are not always suitable for measurements in regions of high dose gradients or where non-uniform beam distributions are encountered. It is important to review and critically evaluate existing practice in measurement of absolute dose in small and non-standard fields. There are two main purposes of this project: 1) collect detail information about calibration procedures used for the Leksell Gamma Knife (LGK) and 2) measure output of the surveyed LGK units and compare results with treatment planning system calibration value.

Methods and Materials: Each participant of the project will receive a LGK calibration questionnaire addressing following information: LGK model (B, C1.1 or C1.2, 4C, Perfexion); protocol used for calibration (AAPM TG21, AAPM TG51, IAEA TRS277, IAEA TRS398, other); phantom used (ELEKTA ABS spherical phantom, ELEKTA solid water phantom, other); ion chamber used (manufacturer, model, volume, last date of ion chamber calibration, calibration laboratory); LGK calibration personnel (on-site physicist, ELEKTA, other); independent verification of calibration (none, RPC MD Anderson, IAEA TLD audit, national TLD or ion chamber mandatory audit, other); and, collimator relative output factors used (ELEKTA default values, values measured by on-site physicist, other). Alamine dosimeters measured with a Bruker ECS106 Electron Paramagnetic Resonance spectrometer using the protocol described in the NIST Ionizing Radiation Division Quality System Manual will be used to measure the dose rate of the each surveyed LGK unit. Three to five alanine pellets (4.8 mm in diameter and 3.0 mm in height) will be irradiated to 50.0 Gy based on each participant’s calibration data. The irradiation geometry is defined as the center of the ELEKTA ABS spherical phantom (diameter 160 mm) using 16 mm collimator on the LGK Perfexion unit and 18 mm collimator on other LGK models. It has been previously shown by the authors (Med. Phys. 36, 2009) that alanine dosimeter is an appropriate dosimeter for the LGK small radiosurgery fields with experimental uncertainty of 2.6%, 95% confidence. It is very easy to use with minimal requirements for handling and thus very useful for mail dosimetry.

Results and Conclusions: Ten LGK units participated in this project at this time (3 from the USA, 1 from Europe and 6 from Asia). The plan for this project is to survey between 50 to 100 LGK units worldwide. Calibration protocols used for ten surveyed sites were: AAPM TG21 3 times, IAEA TRS277 1 time and IAEA TRS398 6 times. ELEKTA ABS spherical phantom was used in 8 cases and ELEKTA solid water phantom in 2 cases. Following ion chambers were used for LGK calibration: PTW 31010 (0.125 cm³) 6 times, Exradin A16 (0.007 cm³) 3 times and PTW 31014 (0.015 cm³) 1 time. Calibration of the LGK unit was performed by on-site physicist in 5 cases and by ELEKTA in 5 cases. Independent verification was done only in 3 cases out of total 10 surveyed LGK units. All LGK units surveyed are currently using the ELEKTA default values for collimator relative output factors. The average ratio of planned dose to alanine dosimetry measured dose was 1.003 (range 0.975 – 1.030). This project is ongoing and more information will be provided at its conclusion.

Onset time of tumor repopulation for cervical cancer – first evidence from clinical data.

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Purpose: Accelerated tumor repopulation has a significant impact on low-dose-rate (LDR) brachytherapy. Many efforts have been made to estimate the onset time for head and neck tumors, squamous cell carcinomas and prostate cancer. However, repopulation onset time remains an unsolved issue for cervical cancer. The purpose of this study is to determine the onset time of accelerated repopulation in cervical cancer using clinical data.

Methods and Materials: The linear-quadratic (LQ) model extended for tumor repopulation was used to analyze the clinical data and MRI-based 3D tumor volumetric regression data of 80 cervical cancer patients, who received external beam radiotherapy (EBRT) and low dose rate (LDR) brachytherapy. Overall treatment times ranged from 38 to 76 days. The LDR dose was
converted to EBRT dose in 1.8 Gy fractions using the LQ formula, and the total dose ranged from 61.4 to 99.7 Gy. The patients were divided into 11 groups according to total dose and treatment time. The tumor control probability (TCP) was calculated for each group. The least $\chi^2$ method was used to fit the TCP data with two free parameters: the onset time ($T_k$) of accelerated tumor repopulation and the number of clonogens ($K$) while other LQ model parameters were adopted from the literature ($\alpha = 0.16 \text{ Gy}^{-1}$, $\alpha/\beta = 14 \text{ Gy}$ and $T_d=4.5 \text{ days}$, $T_d$-tumor effective doubling time) were fixed, due to the limited patient data. The uncertainty of the onset time $T_k$ was estimated by varying $\alpha$ in the range of (0.14, 0.18) Gy$^{-1}$ and $\alpha/\beta$ in (12, 16) Gy based on $S_2$ data derived in a separate study.

**Results:** Among the 11 patient groups, TCP varied from 33% to 100% as a function of radiation dose and overall treatment time. Higher dose and shorter treatment duration were associated higher TCP. Using the LQ model, the best fit was achieved with the onset time $T_k=19 \text{ days}$, clonogen number $K=139$, with uncertainty ranges of (11, 22) days for $T_k$, and (48, 1822) for $K$, respectively.

**Conclusion:** This is the first report of accelerated repopulation onset time in cervical cancer, derived directly from the clinical data using the LQ model. Our study verifies that accelerated repopulation does exist in cervical cancer and has a relatively short onset time. Therefore dose escalation is required to compensate for the effects of tumor repopulation if the radiation therapy course is protracted.

**Closing the loop of IMRT/IMAT QA: Dose reconstruction based on on-treatment cone-beam CT**

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In this talk, I will describe a method of reconstructing IMRT/IMAT dose delivered to a patient using the CBCT. Five HN patients were chosen, and for each patient, CBCTs were performed on three separate fractions spaced every 2 weeks starting from the first fraction. The respective MLC log-files were retrieved and converted into fluence maps. The dose was then reconstructed on the corresponding CBCT with the regenerated fluence maps. The reconstructed dose distribution, dosimetric endpoints, and DVHs were compared with that of the treatment plan. For most treatment sessions, the CBCT-based dose reconstructions yielded DVHs of the targets close (within 3%) to that of the original treatment plans. However, dosimetric changes (within 10%) due to anatomic variations caused by setup inaccuracy, organ deformation, tumour shrinkage, or weight loss (or a combination of these) were observed for the critical organs. The methodology we established affords an objective dosimetric basis for the clinical decision on whether a re-planning is necessary during the course of treatment and provides a valuable platform for adaptive therapy in future.

**AAPM New Professionals Subcommittee**

Minsong Cao, Ph.D.
Indiana University School of Medicine

Abstract: The AAPM New Professionals Subcommittee (NPSC) was developed in 2008 with the charge to support the transition of new professional into the field by providing various informational resources regarding topics of particular interest to those just beginning their Medical Physics careers. In this presentation, a brief introduction of current projects of NPSC will be given followed by questions.

**New Plan QA Solutions from SunNuclear**

Dennis Savitskij
Sun Nuclear

The introduction of rotational rotation treatment modalities such as VMAT, RapidArc, and Tomotherapy presents the clinical physicist with unique challenges in treatment quality assurance. ArcCHECK is a new product from Sun Nuclear Corporation that addresses these challenges. ArcCHECK is the first true 4D detector array designed with the rotation quality assurance in mind. In this presentation, the design advantages and the device characteristics will be discussed as well as some clinical measurement results.
Recent Developments of a linac-MR system for real-time guided radiotherapy

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Introduction
We report on our successful prototyping of a linac-MR system to allow significantly improved real-time guidance of radiation treatments. This allows for improved soft-tissue visualization not presently possible with present systems. Existing technology will always be plagued by two fundamental issues: radiographic and CT-based X-ray images cannot adequately distinguish tumours from healthy soft tissue. Guidance systems based on X-ray images cannot provide 3D imaging in real time over treatment, and thus can only correct for variability in pre-treatment set-up. To provide real-time guidance during radiation delivery i.e., to track a lung tumour as the patient breathes, most commercial systems must rely on either tracking external surrogate motion (skin surface) or a series of kilovoltage radiographs that track implanted markers, or using active markers. However, implanting active or passive markers is an invasive procedure, and questions remain about the accuracy of extrapolating the tumour shape from the marker positions compared to actual imaging of the tumour. Because of these uncertainties, radiation still needs to be applied to a layer of surrounding healthy tissue (i.e., a margin) to ensure complete coverage of the clinical tumour volume. Removing or reducing the size of these margins would preserve healthy tissue, significantly improve clinical outcomes, enable irradiation in sites where such treatments are now uncommon, and permit the safe increase of radiation dose in those sites where higher doses are needed to destroy the tumour.

Successful Prototype and Results
Our prototype successfully integrates a radiation-therapy 6 MV linear accelerator (linac) with a low-field bi-planar MR system. Both the linac waveguide and the MR system are mounted onto a single gantry that would rotate around a subject. The magnet poles are rigidly held apart with flat gradients (40 mT/m max) running under a TMX NRC console (Canada). The linac components are comprised of salvaged magnetron-based Varian 6 MV 600C decommissioned system. Magnetic and RF shielding calculations were performed by finite element analysis and confirmed with appropriate measurements. Faraday cage shielding, typical of all MR installations, was also provided. The testing phantom was an acrylic rectangular cube, with various-sized holes and immersed in a CuSO4 solution. Compared to no-radiation, MR images during linac-radiation had no geometric distortion or reduced SNR. Proof-of-concept has been shown.

Future Developments
The electrons resulting from the interaction of the linac radiation interact with tissue are scattered to deposit the therapeutic dose. We have shown that integration of a linac with an MR will perturb radiation dosimetry within the patient because of the curling of electron trajectories within magnetic fields. We will present our major design development that significantly reduces this dosimetric perturbation.