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Open-Source Medical Devices (OSMD) Design of a Small Animal Radiotherapy System

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Abstract. Open-Source Medical Devices (OSMD) was initiated with the goal of facilitating medical research by developing medical technologies including both hardware and software on an open-source platform. Our first project was to develop an integrated imaging and radiotherapy device for small animals that includes computed tomography (CT), positron emission tomography (PET) and radiation therapy (RT) modalities for which technical specifications were defined in the first OSMD conference held in Madison, Wisconsin, USA in December 2011. This paper specifically focuses on the development of a small animal RT (micro-RT) system by designing a binary micro multileaf collimator (bmMLC) and a small animal treatment planning system (SATPS) to enable intensity modulated RT (IMRT). Both hardware and software projects are currently under development and their current progresses are described. After the development, both bmMLC and TPS will be validated and commissioned for a micro-RT system. Both hardware design and software development will be open-sourced after completion.

1. Introduction

Open-source has emerged as a popular concept in the world of technology, especially in software development. However, interest is also growing in hardware open-source initiatives. There is a need to design and build medical instruments that are inexpensive and affordable to research groups. The open-source model is also a playground for innovation. This leading principle directed to the initiation of the Open-Source Medical Devices (OSMD) concept at the Morgridge Institute for Research in cooperation with the University of Wisconsin. The main goal of OSMD is to collaborate globally to promote medical research by making medical instruments and technology available as an open-source resource to research groups around the world. Furthermore, the concept of OSMD is ideally suited to facilitate accelerated introduction of medical technology to developing countries and places with limited research resources. OSMD initiative aims to create a forum for free sharing and development of ideas and existing resources. Importance of the open-source model in the medical field has been discussed in Technology Quarterly of the Economist in June of 2012, where our work with the OSMD initiative was also featured along with other open-source medical device software projects [1].

It should also be noted that the open-source initiatives do not preclude protecting intellectual property with patents or copyrights as they can coexist. Valuable and novel ideas generated from the use of the open-source platform do not have to be themselves put into open-source but can be formally protected with a patent or copyright. Furthermore, the open-source model can be a way of ensuring

that good ideas are preserved at the expiration of a patent. The open-source platform also becomes a test-bed for proving feasibility of intellectual property and making them ready for demonstration and licensing. Some novel ideas will not pass the hurdle of cost and effort of applying for a patent but may be still excellent and useful ideas worth memorializing in an open-source code or hardware design. Such a symbiotic relationship is demonstrated in figure 1.
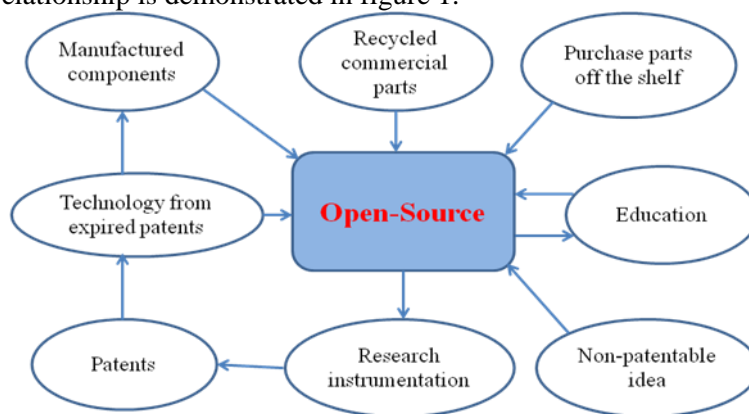

Figure 1. Significance of open source platform and its relation with patents and education.

While initiating OSMD, we have realized the importance of preclinical research in the field of medical research. For this reason, we chose to initiate OSMD with the development of a small animal imaging and therapy system (SAITS) that includes micro-CT, micro-PET and micro-RT modalities. This is a first of a kind integrated system that facilitates RT with both anatomical (CT) and functional (PET) imaging. The SAITS should be readily scalable to enable transition from preclinical/research medical device to clinical devices.

The design specifications of the SAITS were determined during the first OSMD Conference in December, 2011, which was held in Madison, Wisconsin, USA [2]. As the project is big and multifaceted, we started focussing on the micro-RT part of the SAITS. The first part of this project is to design a binary micro multileaf collimator (bmMLC) with the potential for use in IMRT applications. The second part of this project is to develop a small animal treatment planning system (SATPS) using kV x-rays to supplement the existing in-house MV TPS called WiscPlan [3,4]. Hence, the WiscPlan TPS will extend from the MV to kV energy range and will be available as open-source software.

2. Methods
The OSMD design should be simple and easily reproducible. Modular designs are encouraged. For each OSMD project, the technical specifications and preliminary design are discussed with interested collaborative groups before finalizing the design and building it. Several iterations of design might be necessary to address any potential problems. The final design needs to be validated before it can be available as open-source technology. Progress of these projects can be monitored on the OMSD website [2].

For this specific project, the small animal imaging and RT field was surveyed and customer requirements were discussed with potential system users. This helped to create an engineering requirements document with technical specifications for the system. The specifications were updated after the brainstorming discussion at the first OSMD Conference [2]. Solidworks[TM] software was used to design the 3D model of the system. To develop the SATPS, WiscPlan was used as a starting point. The convolution/superposition based TPS, WiscPlan, was developed throughout the last 10 years [3,4]. For the kV extension, kV energy deposition kernels (EDK) and kV x-ray fluence spectra need to be added to the current MV WiscPlan. The EDKs at kV energies will be created using the EGSnrc user-code, EDKnrc [5].

3. Results

The schematic of SAITS system was designed in Solidworks™ drawing software that is shown in figure 2. The body of the system was designed as a slip ring gantry system for continuous rotation, facilitating micro-CT and micro-RT. With a slip ring gantry, both CT imaging and RT treatment have more freedom as well as better efficiency. The custom built gantry is 100 cm in diameter with 12 cm diameter bore which facilitates imaging and treating small animals up to the size of rats. A 250 kVp x-ray tube with a dual focal spot has been considered so that both RT treatment and CT imaging is possible with the same x-ray tube. The source to isocenter distance will be 30-40 cm, with the maximum imaging and

Figure 2. Schematic of the integrated micro-CT, micro-PET and micro-RT system.

treatment field size at the isocenter being 10 cm x 10 cm. For beam collimation, the bmMLC is designed to provide IMRT treatments with the treatment resolution of 1 mm x 1 mm at isocenter. Two separate designs of the bmMLC have been pursued.
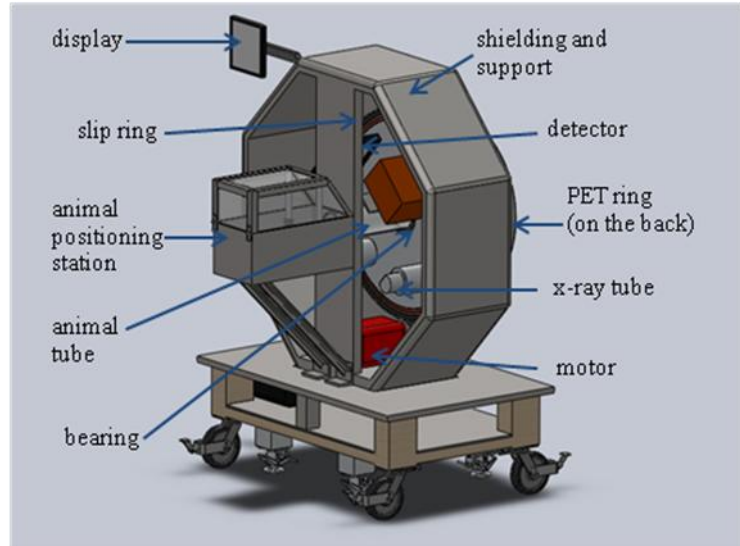
3.1 The bmMLC Design 1

The bmMLC system was designed using Flexinol™ actuator wire that features muscle-like contraction when electrically driven. The design consisted of 0.5 mm thick brass collimator leaves, a customized collimator support structure, Flexinol™ and an open-source Arduino microcontroller. When electricity was passed through the Flexinol™, it contracted, pulling the assembly against the spring on the supporting tube to open the leaves. The bmMLC leaves come to a

Figure 3. bmMLC prototype using Flexinol™ wire.

default closed position when power is turned off. The opposing collimator leaves were stacked in an interleaved position. Figure 3 illustrates the physical set up of the 20 (10+10) leaf binary collimation systems. The actuation system in the prototype worked, however, we moved on with a different design due to slow response of Flexinol™ wire and lack of sufficient force to overcome interleaf friction between the collimator leaves for full actuation.
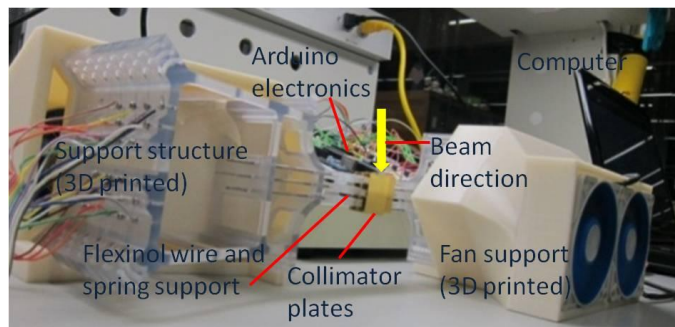
3.2 The bmMLC Design 2

This design implements servomotors for actuation. The rotation of a servomotor horizontally pulls and rotates the collimator plates via a pivot point that leads to opening and closing of the beam path. This design is more robust and has better reproducibility than the previous design. A similar actuation mechanism was proposed by Cadman et al. in 2006 for TomoTherapy™ beam delivery [6]. The 0.5 mm thick, custom-designed brass collimator-plate is connected to the motor via wire cable, which

spools around the servomotor to open the collimator (physically 0.75 cm wide). The tension spring brings the plate to a closed position as the motor releases. The spring will also act as a fail-safe mechanism closing the beam when not powered. The collimator-plates are interleaved so that consecutive plates move in opposite directions. The schematic of the design was completed in Solidworks^{TM} and it is shown in figure 4(a).
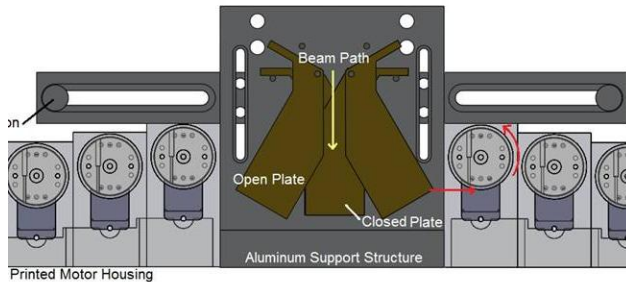

Figure 4(a). Solidworks^{TM} model of the bmMLC design. The red arrows demonstrate the movement of the collimator plate and the motor. The yellow arrow points in the beam direction.
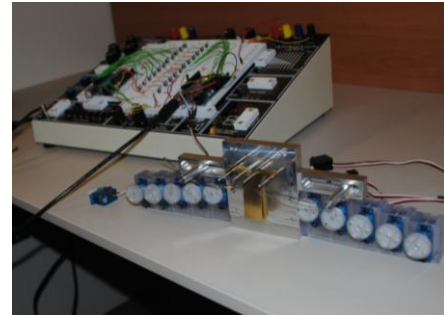

Figure 4(b). Setup for mechanical testing, actuation controlled by Arduino microcontroller.

As shown in figure 4(b) the new bmMLC prototype has been built and tested using ten interleaved collimator-plates which create a maximum field size of 1.5 x 2cm^2 at isocenter (with magnification = 2). Each micro servomotor has 1.5 kg·cm torque and rotates 170° in less than 0.5 seconds. The motor force was enough to overcome the leaf-to-leaf friction. The materials are easily available and cost less than $300 (USD). Both bmMLC designs were created and assembled at the Morgridge Institute for Research utilizing the machine shop and 3D printing technologies for custom parts.
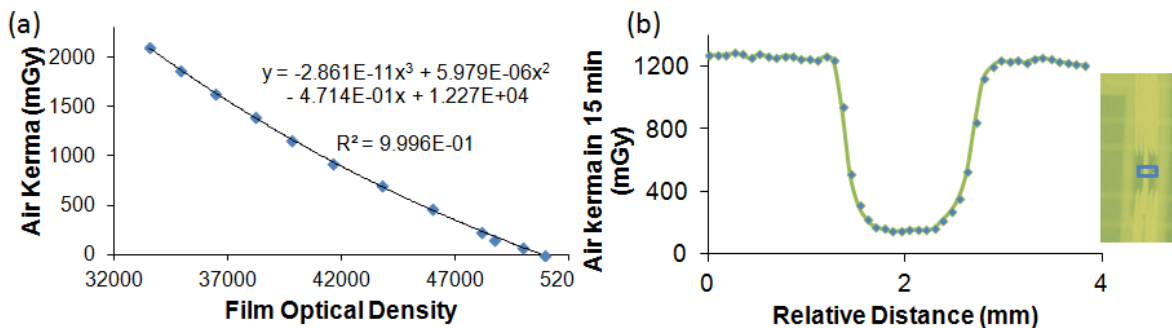

Figure 5. (a) Gafchromic^{TM} EBT2 film calibration for 250 kVp x-ray (b) Horizontal air kerma profile (through blue box in the film picture) in the bmMLC via the film measurement for one leaf closed.

The dosimetric characteristics of the bmMLC (Design 2) were evaluated using a fully-characterized 250 kVp x-ray beam (HVL: 18.5 mm Al or 3.15 mm Cu) from UW-Accredited Dosimetry Calibration Lab (ADCL) with reference to the AAPM Report No. 72 [7]. The air kerma rate for the 250 kVp beam (with added filtration: 0.99 mm Al + 3.22 mm Cu) was 1.30 mGy/sec at 1 m. The bmMLC was set up directly in front of a Gafchromic^{TM} EBT2 film for measurement. The film was placed 100 cm from the x-ray source where the field size was 10 x 10 cm^2. Primary collimators were not used in this set up. The Gafchromic^{TM} EBT2 film calibration curve associates the optical density and air kerma to the film, which is shown in figure 5a. The films were scanned after 48 hours post-irradiation with the same orientation and face, and saved as 'TIFF' images at 300 dpi resolution (0.072 mm/pixel) using a professional grade flatbed scanner (Epson Expression 10000 XL). A third degree polynomial was a good fit for the calibration curve.

The calibration curve was used to measure the dosimetric parameters as follows: transmission: < 0.1%; leakage: 6.5 ± 0.1%; horizontal (80%-20%) penumbra: 2.6 ± 0.2 mm; vertical penumbra: 0.4 ± 0.1 mm. Figure 5b shows the horizontal profile through a single, closed collimator leaf, which depicts the blue box on the image of the EBT2 film. It shows that the dose at the closed collimator leaf is reduced to about 7% of the non-collimated area. The minimal amount of measured dose in the closed leaf is due to scatter through other leaves and the support structures. The dosimetric performance can be improved by further optimizing the design and set-up as shown in figure 6.

The bmMLC design has been updated to make the system more robust and reproducible. The motion mechanism is the same, but new custom-leaves (similar shape but bigger size to improve rotation) have been fabricated and placed in interleaved position with 1 cm physical beam opening. And, 20 interleaved collimator plates will provide 2 cm x 2 cm beam opening at isocenter. Custom-
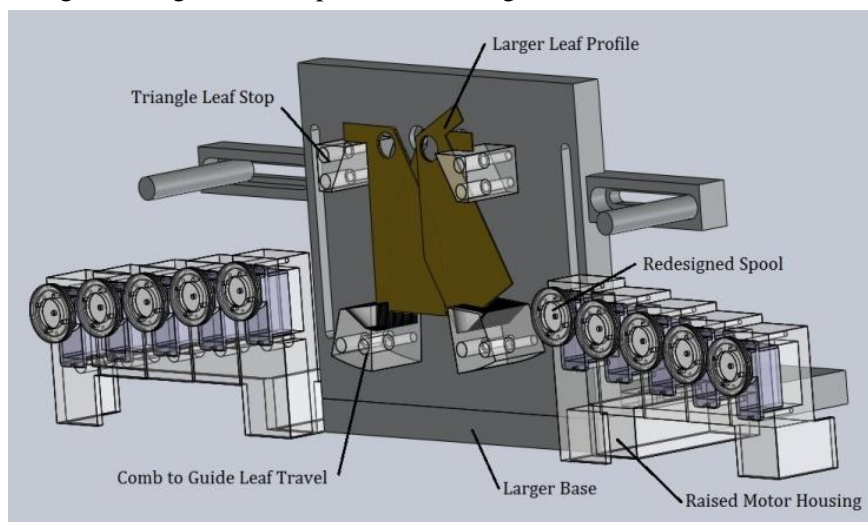

Figure 6. Solidworks^{TM} design of revised mechanical design of bmMLC

designed and 3D printed comb (to guide the leaves precisely) and brass-spacers (to space the leaves exactly 0.5 mm to avoid swaying away from the leaf path) have also been printed and machined. The revised design is illustrated in figure 6. When the design and assembly is complete, full mechanical and dosimetric tests will be performed on this updated collimator version.

3.3. SATPS software development

To date, the in-house TPS, WiscPlan can be used only for megavoltage external photon beams. The WiscPlan TPS workflow consists of four main steps. After running the WiscPlan TPS code, a MATLAB user interface opens up. The first step is to load the DICOM-RT geometry with the CT images and contours, and then select the target region of interest (ROI) and patient directory. Contouring on the CT image can be done in Pinnacle, Eclipse or other contouring software packages that are compatible with DICOM-RT images, where the structures are saved. The loaded geometry is updated and displayed in the MATLAB interface. The second
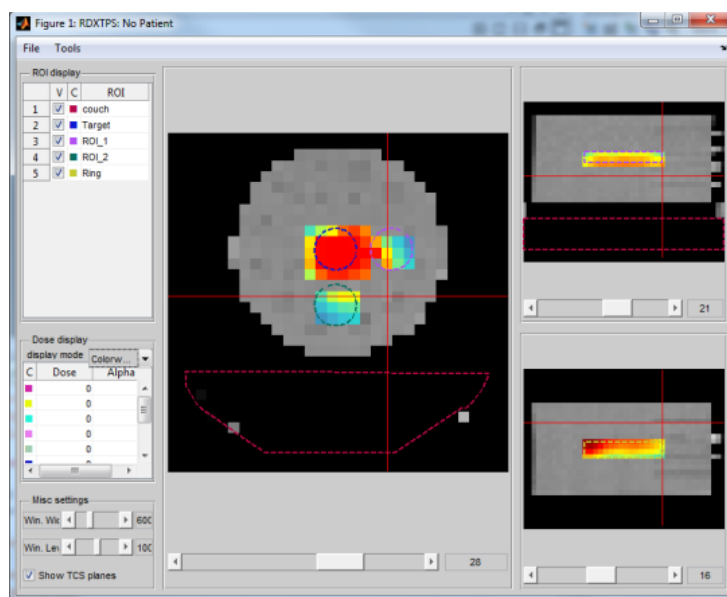

Figure 7. MATLAB interface in WiscPlan showing calculated dose distribution in a phantom

step is to perform beamlet dose calculation using an in-house MATLAB code that prompts a command window to run the dose calculation. After the beamlets are calculated, the WiscPlan optimization code is run in a command window that prompts the user to select the target and all ROIs. After the optimization window opens, dose parameters are adjusted if necessary. The optimization cycle can be paused and resumed until the user is satisfied with the optimization. The last step is to save the optimization results. In the MATLAB interface, the dose distribution can be displayed for the selected regions. This workflow is currently implemented for a 6 MV Tomotherapy[TM] beam. A screenshot of WiscPlan's MATLAB interface showing the dose calculation distributions for a cylindrical test phantom using a 6 MV beam is shown in figure 7.

4. Discussion

The WiscPlan TPS needs to be updated so that it generates the planning files that will communicate with the bmMLC controller and the x-ray source. In addition, software to connect WiscPlan with the bmMLC and x-ray tube also needs to be developed. In order to expand WiscPlan for low energies, EDKs for 300 keV and lower energy are needed. Some work has been done to create EDKs at low energies in the past [5,8,9]. Those projects used EGS4 Monte Carlo Codes to obtain the EDKs where incident photons of a given energy are forced to interact at the centre of a 60 cm radius water sphere and the secondary particles are followed within that geometry. The sphere is divided into 24 radii shells and 48 cones [10]. We have received the EGS4 user-code EDKnrc from NRC-Canada [5]. We intend to follow their code to create additional low energy kernels from 10 keV to 300 keV. Once the EDKs are obtained, the kernel file in WiscPlan will be updated along with other necessary changes like fluence spectra. We received fluence spectra for the well-characterized x-ray tube at the UW-ADCL for 250 kVp energy. This 250 kVp beam will be utilized to initially check and validate the WiscPlan TPS at low energies.

In addition to dose calculation and planning for small animals, the WiscPlan extension at low energies can also be applicable to calculate dose for imaging applications in the clinic, such as radiography, fluoroscopy, mammography and CT imaging.

5. Conclusion

The OSMD concept has been initiated with the design of a small animal imaging and therapy system. Currently, the micro-RT system is designed on a slip-ring gantry. Work on both hardware and software part of this project has started. A bmMLC has been designed and tested. In addition, a MV to kV treatment planning system is also being developed within the WiscPlan TPS. After completion, both hardware and software aspects of the project will be validated, and will be available as open-source resources at the OSMD website.

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