Open Source Medical Devices: Lessons Learned From a Complex Collaborative Research Project

Surendra Prajapati
Department of Radiation Physics
M D Anderson Cancer Center, Houston, TX

Acknowledgments

- Advisors
  - Thomas Rock
  - Mackenzie
  - Michael Jeraj
- Committee
  - John Bajpai
  - Larry DeWerd
  - Michael Kissick
  - Bryan Bednarz
- Kevin Eliceiri & Medical Engineering Team @ Morgridge Institute for Research
  - Ben Cox
  - Michael Petry
  - Ben Lee
  - Ben Cox
  - Robert Swader
  - Xiaohu Mo
  - Abraham Weingart
  - John Bajpai
  - Anand Waru
  - John Bajpai
- Medical Physics Colleagues
  - Pittsburgh
  - Madison
  - Baltimore
  - Chicago
  - San Francisco
  - Austin

Robert Jeraj IG Research Group
- Tyler Brehm
- Jennifer McNeil
- Tim Perk
- Matthew
- Matt Harmon
- Christie Lin
- Matt Scarpelli
- Alison Roth
- Enrique Cuna
- Damian Valentinuzzi
- Enrico

- Alumni
- Benny T.
- Nade C.
- Kendra M.
- David M.
- David S.
- Nikita S.
- Jennifer S.
- Corey S.
- Mark S.
- Emily S.
- Alex S.
- Katherine S.

- Larry DaVinci and UWMRR
- John Bajpai
- Michael Kissick
- John Bajpai
- Bryan Bednarz
- Michael Kissick
- BME Design Groups
- Kristy Wendt
- Jan Patrick

Open-Source Medical Devices (OSMD)
**Motivation for OSMD**

- Forum for free sharing and development of ideas and resources
  - To complete medical devices design that have been left out
  - Involve good ideas from small labs with less resources
  - Networking to provide matching expertise

- Make affordable medical devices for research
  - Goal within 1/3rd, 1/4th cost of commercial systems
  - Only cost is for the physical parts

**Significance of OSMD**

- Manufactured components
- Recycled commercial parts
- Purchase parts off the shelf
- Technology from expired patents
- Patents
- Research instrumentation
- Non-patentable idea
- Education

**First OSMD Project**

![Image of medical device]
OSMD Conference

- Identify interested researchers and collaborate
- Determine design specifications for integrated micro-CT/PET/RT system
- Collective scientific fun brainstorming

https://morgridge.org/open-source-medical-devices/video-archive

Sub-Systems

Support systems
- Gantry design/assembly
- Gantry motor
- Slip-rail system
- Animal support and positioning system
- Measure animal vital
- Radiation shielding
- Gas build support structure
- Power supply
- Laser alignment system
- Live-view camera system
- Computing hardware and electronics

mRT
- X-ray tube and generator
- Detector system
- Beam collimation

mCT
- CT detector system
- X-ray source, same or separate from RT
- CT electronics
- Design support and geometry

mPET
- PET detector
- PMT electronics

Software
- Dose verification and monitoring
- Treatment planning system
- PET and CT image reconstruction
- Image analysis
- Image co-registration

Management
- QA
- Database management
- Electronic recording
- Scheduling
- Fail-safety
- Record and verify PACS

mRT to Initiate OSMD

- Need to kick-off OSMD by giving out our ideas and technology first
- This project is big and multi-faceted
- Chose to develop a portion of mRT system that can deliver IMRT in preclinical settings
- Make it available via OSMD
Innovation: mRT with IMRT

- Critical component 1: mechanical design of binary micro-MLC (bmMLC) for mRT and its dosimetry
- Critical component 2: kV treatment planning system for mRT (WiscPlankV) to enable IMRT dose delivery
  - Validation of WiscPlankV dose calculation using the bmMLC assembly
  - AAPM 2016 Poster: SU-F-T-667

Design of bmMLC

- Simple and concise design
- Smallest dynamic collimator designed for any RT system
- Using 3D printing to fabricate custom-build parts
- Using open-source micro-controller (Arduino)
- Designed to provide 1 mm resolution at isocenter using 0.5 mm thick interleaved brass plates, with leaf motion < 1 sec

bmMLC Design 1: Iterations
**bmMLC Design 2: Iterations**

- Fishing line
- Steel spring
- Music wire comb
- Closed leaf
- Open leaf

**Current bmMLC Design**

**Current Design Prototype: One Side And Leaf Fabrication**

- Bottom support
- Top support
- Main support
- Spool on motor
- Leaf stop
- Curved leaf end
- Leaf comb
- Arduino microcontroller
- Brass leaves with stainless steel wires glued at 2 positions around the rotating pivot

(a) Front view

(b) Open view

(c) Closed view
Current Design Prototype Assembling

Current Design Prototype: Full Assembly (Material Cost < $500)

Phantom Design and Fabrication

- Homogeneous stack phantom
- Heterogeneous stack phantom
WiscPlankV: Dose Distribution

Difference between measurement, simulation and WiscPlankV dose calculation < 5%

OSMD Impact

- Several medical device engineers contacted us with questions on how to open-source their ideas
- There has been a lot of interest shown by medical physics community
- We have openly shared our idea
- WiscPlan TPS has been used by several researchers as we have shared with it freely

Our OSMD Challenges

- We started a very ambitious project
- Interest by several outside researchers but their interest would come into play in later part in the project
  - I had no experience to manage interests for future project
  - We received no outside interest for hardware project
- Hardware design collaboration is still challenging
- Proposal for inter-university collaboration turned into mostly a inter-department collaborations
  - Got help from different research groups at UW-Madison
  - A lot of colleagues (who are not in the project) shared ideas for mRT project
**General OSMD Challenges**

- A lot of work, not easy to begin
- Driven by passion not interest from institute, need a critical mass
- Not transparent information from vendors
- Funding
- Potential regulatory obstacle for clinical developments

**Conclusions**

- OSMD initiative was a good start and a great learning experience
- A part of an OSMD project on mRT was completed
  - bmMLC Design was demonstrated
  - Both bmMLC and WiscPlankV are available via the OSMD website: https://morgridge.org/open-source-medical-devices/
- We hope that our effort to open-source our ideas and technology will kick-off the OSMD and involve many research groups in the future
- We need a consortium organization or AAPM tasks group (critical mass) with a web platform to share ideas and collaborate

---

**Thank you!**

Email: prajapatisurendra@gmail.com