Facility Selection

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June 11, 2014
1. SMC introduction
2. SMC proton therapy project
   : Decision Making Process
      ✓ Facility and Specification
      ✓ Vendor Selection
3. Summary
SAMSUNG MEDICAL CENTER: History

- Founded Nov 9, 1994 by the Samsung Life Public Welfare Foundation.
- A non-profit hospital: 7,400 employees including ~1,200 doctors.
- Since March 1997 an affiliated education hospital of Sungkyunkwan Univ.
- Opened Samsung Cancer Center (2008)
- Will open Proton Therapy Center (2015)
SAMSUNG MEDICAL CENTER: Statistics

Total Number of Annual Patients

Statistics, Share of Cancer Incidence in Korea

- 9.0% of share of Korea’s cancer patients in 2011 (19,726 patients)

Incidence of cancer patients in Korea & SCCC’s share (’00~’11)
SAMSUNG MEDICAL CENTER: Radiation Oncology: Statistics

**Machine**
(May, 2014)
- Linac 5, Tomotherapy 2, HDR 1
- CT simulator 2, Simulator 1
- RTPs (Pinnacle 14, iPlan 2, Nucletron 1)
- Aria, ROChart

**People**
(May, 2014)
- Physician: 19 (12/7)
- Nurse & Administration: 13
- RTTs/Dosimetrist: 33/8
- Medical Physicists: 13

**Patients**
(2013)
- Daily: 350~ 400
- Total RT Patients: 5,118

**Treatments**
(2013)
- 2D, 3DCRT, IMRT, Gated RT, SBRT, SRS, TBI, TSET, BrachyTherapy (HDR)
- 2 Shifts: 8:00 AM ~ 12:00 PM
Proton Therapy Center Project
SMC Proton Center Project: **Aim**

- Introduce the most advanced radiation therapy system.
  - Improved treatment outcomes with minimal toxicity.
  - Improved quality of life of patients.

- Total cost donated by the Samsung Life Public Welfare Foundation.
SMC Proton Center Project: $C$-ion vs $P$roton

Review: benefits of Carbon ion therapy system

<table>
<thead>
<tr>
<th></th>
<th>Proton</th>
<th>Carbon ion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosimetric Conformity</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Biological Superiority</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Biological Uncertainty</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Research Capability</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Optimization of Plan</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>( Beam angle selection)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IGRT Option</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>(CBCT/in-room CT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Experience</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Cost benefit</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Facility Site Limitation</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
Remote site considered, BUT convenience factor for patients and physicians main reason for decision to build in the SMC compound.
SMC Proton Center Project: Patient Number Projection

- Estimation made in 2007 and 2008
- Projection of proton patients number was based on past SMC’ statistics.
- Assumed all patients are internally referred. i.e No referral from other hospitals.
- Conservative estimation.
SMC Proton Center Project: Patient Number Projection

Number of Patients

1,800,000 in 2015

RT ratio for Cancer Patients

25% in 2015

1995 1997 1999 2001 2003 2005 2007

Ratio for Cancer/Total Patients

1.2% in 2015

1995 1997 1999 2001 2003 2005 2007

RT patients in 2015

\[1,800,000 \times 1.2\% \times 25\% = 5,400\]

: RT patients in 2013: 5,118

Proton TX eligible patient ratio:

\[10\%: \sim 14\%: \sim 756/\text{year}\]

\[540/\text{year}\]
Expected proton therapy candidates

1. One radiation oncologist reviewed the annual RT patients at SMC and estimated proton RT eligible patients to be 14.76%.*

2. Conducted a survey regarding the daily amount of total proton candidates among the total number of patients for 5 physicians.

<table>
<thead>
<tr>
<th>Physician</th>
<th>Highly recommendable(^{(a)})</th>
<th>Recommendable(^{(b)})</th>
<th>Expected Annual Accrual ({(a)+(b)\times0.6} \times 10^{(c)})</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>8</td>
<td>23</td>
<td>218</td>
</tr>
<tr>
<td>B</td>
<td>13</td>
<td>25</td>
<td>280</td>
</tr>
<tr>
<td>C</td>
<td>5</td>
<td>66</td>
<td>446</td>
</tr>
<tr>
<td>D</td>
<td>16</td>
<td>42</td>
<td>412</td>
</tr>
<tr>
<td>E</td>
<td>21</td>
<td>28</td>
<td>378</td>
</tr>
<tr>
<td>Avg.</td>
<td>12.6</td>
<td>36.8</td>
<td>346.8</td>
</tr>
</tbody>
</table>

Total number of new patients in 2007:~ 3,000 → ~11%

* (Australian MedAustron Method) Radiotherapy and Oncology 2004;73(Suppl2)
SMC Proton Center Project: Treatment Rooms

<table>
<thead>
<tr>
<th>operation hours</th>
<th>Room 1G</th>
<th>Room 2G</th>
<th>Room 3G</th>
<th>Room 1G</th>
<th>Room 2G</th>
<th>Room 3G</th>
<th>Room 1G</th>
<th>Room 2G</th>
<th>Room 3G</th>
<th>Room 1G</th>
<th>Room 2G</th>
<th>Room 3G</th>
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</thead>
<tbody>
<tr>
<td>20 min</td>
<td>240</td>
<td>480</td>
<td>720</td>
<td>300</td>
<td>600</td>
<td>800</td>
<td>360</td>
<td>720</td>
<td></td>
<td>450</td>
<td>900</td>
<td></td>
</tr>
<tr>
<td>25 min</td>
<td>192</td>
<td>384</td>
<td>582</td>
<td>240</td>
<td>480</td>
<td>720</td>
<td>288</td>
<td>576</td>
<td>864</td>
<td>360</td>
<td>720</td>
<td></td>
</tr>
<tr>
<td>30 min</td>
<td>160</td>
<td>320</td>
<td>480</td>
<td>200</td>
<td>400</td>
<td>600</td>
<td>240</td>
<td>480</td>
<td>720</td>
<td>300</td>
<td>600</td>
<td>900</td>
</tr>
</tbody>
</table>

* Calculation Assumed 25 fractions for each patient on Average

Initial plan of 3 treatment rooms changed to 2 treatment rooms.
Estimated proton therapy candidates profile

- CNS: 5%
- Thorax: 19%
- GI: 19%
- GU: 9%
- H&N
- Thorax
- GI
- GU
- Breast
- GY
- Sarcoma
- Lymphoma
- Pediatric
- Mets
- Benign
Analysis on the Treatment Technique of Disease Site

For candidate disease sites, data gathered for:
- Proton RT techniques (Static/Scanning/IMPT)
- Port numbers
- Beam Angles
- Field size
- Gating /Non-gating

Necessity of large fields size was one of discussion points
Review the X-ray plans to estimate the % of patients for large field size.

<table>
<thead>
<tr>
<th>Disease site</th>
<th>Field Size</th>
<th>case 1</th>
<th>case 2</th>
<th>case 3</th>
<th>case 4</th>
<th>case 5</th>
<th>Max FS (cm)</th>
<th>Tumor Size (SOBP: cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>brain</td>
<td>X</td>
<td>(5.6~7)</td>
<td>(6.9~9)</td>
<td>(6.4~8)</td>
<td>(9.8~11.9)</td>
<td>(4.3~4.9)</td>
<td>12x11</td>
<td>1.9~9</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>(5~7.4)</td>
<td>(7.7~8.3)</td>
<td>(6.8~7.2)</td>
<td>(10~10.5)</td>
<td>(4.6~4.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>head &amp; neck</td>
<td>X</td>
<td>(9.4~13.8)</td>
<td>(7.8~13.2)</td>
<td>(9.4~14.3)</td>
<td>(7~7.7)</td>
<td>(7.6~15.6)</td>
<td>16x17</td>
<td>3~8.9</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>(7.4~14.2)</td>
<td>(9.4~14.5)</td>
<td>(5.7~16.4)</td>
<td>(9.7~9.8)</td>
<td>(7.2~16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>esophagus</td>
<td>X</td>
<td>(10.2~12.1)</td>
<td>(9.8~11.1)</td>
<td>(7.9~12.2)</td>
<td>(7.6~8.4)</td>
<td>(6.8~8.8)</td>
<td>13x17</td>
<td>4.4~7.3</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>(9.8~11)</td>
<td>(15.7~16.3)</td>
<td>(11.5~12.7)</td>
<td>(8.2~8.7)</td>
<td>7.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>lung</td>
<td>X</td>
<td>(9.7~12.3)</td>
<td>(6.1~7.4)</td>
<td>(9.9~12.3)</td>
<td>(10.7~13.7)</td>
<td>(13~16)</td>
<td>16x19</td>
<td>3.5~13.3</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>8.5</td>
<td>(8.2~8.8)</td>
<td>(13.8~14.3)</td>
<td>(11.3~12.2)</td>
<td>(17.5~18.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>liver</td>
<td>X</td>
<td>(16~18.5)</td>
<td>(7.3~8.2)</td>
<td>(6.5~6.8)</td>
<td>(7.7~15.2)</td>
<td>(8.2~9.9)</td>
<td>19x20</td>
<td>3~16.4</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>(19.3~19.8)</td>
<td>(7.3~8)</td>
<td>(6.5~7.3)</td>
<td>(7.8~13.8)</td>
<td>(11.9~12.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pancreas</td>
<td>X</td>
<td>(9~9.7)</td>
<td>(8.9~9.8)</td>
<td>(11.4~12.5)</td>
<td>(9.8~10)</td>
<td>(9.7~11.4)</td>
<td>12x13</td>
<td>5.2~7.3</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>(8.1~9.5)</td>
<td>(7.5~10)</td>
<td>(10~12.5)</td>
<td>(7.5~9)</td>
<td>(7~10.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rectum</td>
<td>X</td>
<td>(13~17)</td>
<td>(12~16)</td>
<td>(12.5~14)</td>
<td>(16.5~12)</td>
<td>(12.5~16)</td>
<td>17x18</td>
<td>&gt;20</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>15.5</td>
<td>9.5</td>
<td>15</td>
<td>17.5</td>
<td>12.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>prostate</td>
<td>X</td>
<td>5.6</td>
<td>7.7</td>
<td>7.2</td>
<td>(8.1~8.2)</td>
<td>7.4</td>
<td>9x8</td>
<td>3.8~5.4</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>(5.5~6)</td>
<td>(6.3~7.3)</td>
<td>(6.2~7.3)</td>
<td>(6.7~7.4)</td>
<td>(6~7.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cx/pelvic</td>
<td>X</td>
<td>(9~10)</td>
<td>(11.5~12)</td>
<td>(6~8)</td>
<td>(6.2~8)</td>
<td>(12~14.5)</td>
<td>15x14</td>
<td>4.6~7.2</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>7.7</td>
<td>(11~12)</td>
<td>(7~8.4)</td>
<td>(5.5~5.6)</td>
<td>13.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. High Throughput

- Auto beam scheduling
- Fast beam switching between rooms
- Fast energy changing in scanning delivery
- MLCs
- Low down time with good engineering Supports

2. Two Treatment Rooms WITH rotating Gantries

- Space is reserved for possible future expansion and for incorporating updated technology in the future
3. State-of-the-art proton therapy

- **IGRT/Gating/Fluoroscopy/Gated X-ray imaging**
  - CT verification: CBCT vs In-room CT
  - Fluoroscopy: Necessary
  - Gated X-ray, 4DCBCT
  - Gating: External marker gating
  - Internal marker gating

- **Scanning/ IMPT**
  - PBS and Continuous Scanning (line scanning)
  - Fast Scanning Speed:
    - To reduce Treatment time
    - For motion mitigation
Position Verification for Particle Therapy

Symposium on the Promises and Perils of Proton Radiotherapy, 2009: Lei Dong
Preliminary Images of CBCT

Axial and DRR images of a head phantom scanned by CBCT integrated into Sumitomo PTS.

Courtesy of Aizawa Hospital
4. Future development through research collaboration with PTS supplier.

5. Project to incorporate current technology through continual updates


A Maintenance plan, for the post-warranty period must be decided upon and planned in advance. This decision requires accurate information and consideration of cost, and the merits and demerits of each plan.
## SMC Proton Center Project: Equipment

<table>
<thead>
<tr>
<th></th>
<th>Room 1</th>
<th>Room 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gantry</strong></td>
<td>Rotating Gantry: Conventional Type (w rolling floor)</td>
<td>Rotating Gantry Conventional Type (w rolling floor)</td>
</tr>
<tr>
<td><strong>Patient Positioning System</strong></td>
<td>Robotic Couch</td>
<td>Robotic Couch</td>
</tr>
<tr>
<td></td>
<td>* couch top needs to be designed to maximize the beam accessibility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Max Weight: 200 Kg</td>
<td></td>
</tr>
<tr>
<td><strong>Nozzle</strong></td>
<td>Conventional + Scanning (25 x 25 cm) (24 x 24 cm)</td>
<td>Scanning Dedicated 30 x 40 cm (patient aperture can be used)</td>
</tr>
<tr>
<td><strong>MLC</strong></td>
<td>Yes (20 x 20 cm) Pitch: 3.1 mm, 5.1 mm * MLC can be extracted.</td>
<td>No</td>
</tr>
<tr>
<td><strong>Setup Verification System</strong></td>
<td>- Two Orthogonal X-rays/Fluoroscopy (images can be taken during RT)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- CBCT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* In room CT space is reserved</td>
<td></td>
</tr>
<tr>
<td><strong>Gating</strong></td>
<td>Yes (Anzai system)</td>
<td>Yes (Anzai system)</td>
</tr>
</tbody>
</table>
SMC Proton Center Project: **RTPs**

**Issues regarding final decision on RTPS**

1. Support for SHI’s Delivery Technique: Wobbling, Uniform Scanning, PBS (Spot Scanning, Line Scanning, IMPT), MLC, Aperture with PBS, Ridge filter
2. Pencil Beam with GPU
3. MC development
4. Dose summation with other RTP’s plan (X-ray)
5. Scripting support
6. Robust plan
7. Remote planning

**RayStation** by RaySearch Lab with X-rays options was chosen. Test version of candidate RTPS were evaluated for a couple of months.
R&V: requisite support criteria
1. SHI’s Beam Delivery information
2. RaySearch Planning Information
3. HIS and Oncology Chat (Korean )
4. Remote Access (Open network): ~500m
5. Integrate IGRT for proton in R&V.
6. Integrated plan comparison: X-ray vs. Proton
SMC Proton Therapy Center Project: Research Collaboration

- **Respiratory-correlated CBCT (4D CBCT)**

- **Virtual Simulator for collision prevention**

References:

- J. Kim et al., Medical Physics, vol. 38, 1028, (2011)
SMC Proton Therapy Center Project: Research Collaboration

Monte Carlo Code

Profile Monitor

Ridge Filter

Vacuum Pipe

Scanning Magnet

Scatterer

Dose and Flatness Monitor

MLC

DH Kim et al

Specifications of Sumitomo nozzle system
SMC Proton Center Project: Time Line

- **2007, 04**: Project Launch
- **2010, 10**: Forward L.O.I to Sumitomo Heavy Industry
- **2011, 04**: Purchasing Contract with Sumitomo signed
- **2011, 10**: Ground Breaking
- **2011, 10**: Radiation Safety Approval Process
- **2013, 05**: Start of Machine Installation
- **2014, 11**: Takeover by SMC
- **2015, Q3**: beginning of Treatment.
SMC Proton Center Project: Selection Process

- **Presentation**: Product presentations by invited vendors

- **Review**: Machine specification of vendors
  - Hospital management surveyed various PTC centers

- **Send 1\(^{st}\) RFP (Common)**
  - Analysis of pros and cons of each suppliers products made through
    - Consult Korean Food and Drug Administration
    - User site visits for each vendor
    - Communication with vendor engineers
    - Attended education program for particle therapy

- **Send 2\(^{nd}\) RFP (Vendor specific)**
Contact made with KFDA to understand Medical device registration regulation in Korea.

Consulted with KINS (Korea Institute of Nuclear Safety) for project schedule and information/data requirements.

✓ Some data/documents/information need to be provided by the PTS supplier.
SMC Proton Center Project: Current Stage

2013.05.15: beginning of Installation
2014.01.15: Cyclotron Beam test
2014.02.28: 1st Gantry Beam test
2014.03.17: 2nd Gantry Beam test
2014.07.30: G1 ATP
2014.09.30: G2 ATP
2014.11.15

2014.4.30: G1 KFDA appl.
2014.5.30: G2 KFDA appl.
2014.5.30: KINS Inspection
Decisions were primarily based on SMC’s patient data.
The Project needs to incorporate current technology through continual updates.
Maintenance plan, for the post-warranty period must be decided upon and planned in advance.
Consulting Regulation Institute is necessary.