Initial Clinical Experience of a Breast Specific Stereotactic Radiosurgery Device, the GammaPod™

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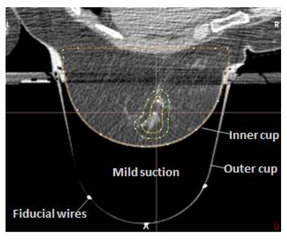
Purpose

GammaPod™ is a new stereotactic radiotherapy device dedicated to the treatment of breast cancer. It creates a focal dose with sharp dose fall-off by using 36 non-overlapping rotating cobalt-60 beams, and creates a uniform dose coverage by dynamically moving the focal spot within the breast in the prone position. A US FDA approved clinical study is being conducted at the University of Maryland to evaluate the feasibility and safety of the device to deliver a focal dose of radiation to a target in the breast. Herein reported is the initial experience with this novel device.

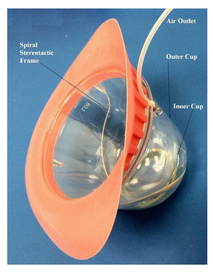
GammaPod ™ System Overview

1) ***Dynamic treatment couch, breast immobilization and localization***

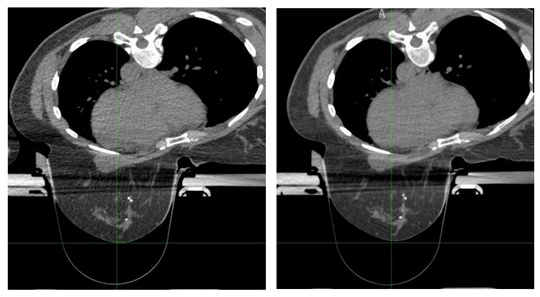


A GammaPod™ breast SBRT system commissioned at the Univeristy of Maryland School of Medicine. During treatment, patients lie prone on a dynamic couch located above the radiation unit. The couch moves the patient in a planned trajectory relative to the radiation isocenter (left); a cup system secures the breast throughout the whole procedure of imaging, planning and treatment process (middle) whereby a mild suction between inner and outer cups helps conform the breast to the inner cup (right). Fiducial wires with a spiral geometry provide stereotactic localization.

2) ***Reproducibility Study***: 24 patients with surgical clips in their breast underwent a geometric reproducibility trial in which the patients received two CT scans spaced 30 minutes (patient gets up from couch) while wearing the cup. The study showed that the vacuum-assisted breast cup allowed reproducible breast immobilization and tissue localization. The reproducibility of the 45 available clips in 11 patients was **1.13 ± 0.87 mm (0.25 – 3.47 mm)** and the patients reported good comfort.



Vacuum-assisted Breast cup and patient loader for prone imaging



2 CT scans showing clips at the same locations

3) Radiation Delivery: The GammaPod radiation unit includes 36 rotating Co-60 beams, each with circular cross-section, converging at a fixed isocenter. With dynamic couch movement, the radiation isocenter traverses throughout the breast target to paint the desired dose distribution dynamically. The GammaPod™ treatment planning system (TPS) optimizes the trajectory of the movements of the focal spots. Dose calculation is via superposition of Monte Carlo-generated kernels, each corresponding to the convergence of beams at an isocenter within the stereotactic breast cup.

Methods

Women aged 60 years or older with invasive breast cancer treated with breast conserving surgery and who required tangential radiation therapy (RT) were eligible for participation on this study. A Simon's two stage design was utilized to give >90% power of concluding that the GammaPod is capable of safely deliver an acceptable single boost dose of 8Gy. In the first stage, the GammaPod must safely delivers an acceptable boost dose in 6 out of the first 8 patients. Overall, an acceptable boost dose must be safely delivered in 13 out of a total of 17 enrolled patients. Eligibility criteria include minimum age of 60, with Stages I or II breast cancer, lumpectomy volume less than 25% of the whole breast volume, and the lumpectomy within the immobilized breast. Patients were screened for study participation at the time of CT simulation. Eligible patients had to have a clearly defined lumpectomy cavity away from the chest wall with appropriate clip placement.

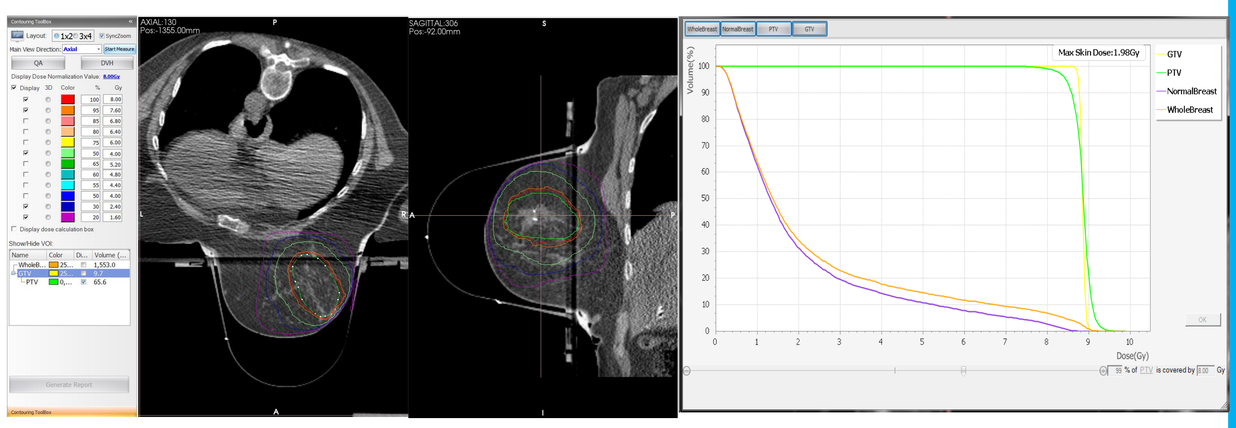
A single 'boost' dose of 8 Gy is delivered post-operatively to the tumor bed plus a 10mm margin using the GammaPod™, followed by whole breast irradiation with either hypofractionation of 40.05 Gy in 15 fractions or conventional fractionation of 50 Gy in 25 fractions. Prior to treatment, the affected breast is immobilized with a patented vacuum-assisted breast cup and imaged on a CT simulator with 1 mm slice thickness. Once the cup is placed, the negative pressure is maintained until the treatment is delivered. An inversely optimized treatment plan is generated while the patient is transported and positioned in the treatment room. Typical time between the imaging session and completion of treatment is about 60 minutes.

Results

Between 3/18/16 and 4/1/17, 13 patients have signed consent to participate the study. 12 of the 13 enrolled patients have successfully completed treatment per protocol. One patient was found ineligible for treatment after the breast cup was fitted as one of the surgical clips fell outside the treatment range, and was treated with conventional WBRT off study.

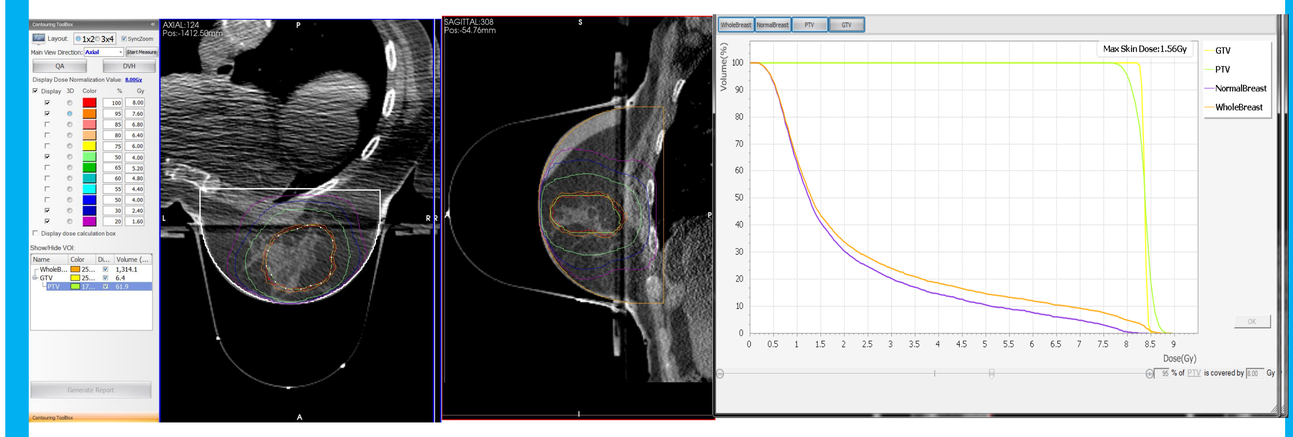
The gross target volume (GTV) is the tumor bed (TB) which is delineated by the radiation oncologist with the help of the surgical clips. TB volume ranged from 2.86 to 20.38cc, while the PTV with 10mm expansion from GTV ranged from 21.69 to 89.56cc. The median(range) $skin_{max}$, $lung_{max}$, $heart_{max}$, and PTV_{max} dose were 2.04Gy(1.13-2.87), 1.40(0.1-1.98), 1.01(0.1-2.2) and 8.71 Gy(8.35-9.26), respectively. One patient with a deep seeded TB had a minor deviation and received a dose over the prescription dose to the chest wall, while a second patient had inadequate coverage of the PTV due to its top edge being out of the reach of the treatment range of the GammaPod. With the sources near its half-life, the treatment time ranged from 17 minutes to 29 minutes.

All 12 patients completed treatment per protocol with no higher than grade 1 toxicities. Following the boost treatments, one patient developed superficial skin blistering prior to the start of whole breast RT around a silicone filler. The blisters were not painful and resolved spontaneously without intervention. Overall acute treatment toxicities (inclusive of boost and whole breast treatment) have been limited to grade 1 thus far and have been as follows: 7 patients with fatigue, 6 with dermatitis, 2 with hyperpigmentation, 2 with breast pain and 1 with limb edema.



(a) **(b)**

a) Dose distribution in one of the patients on axial and sagittal images. The isodoses shown are 100%, 95%, 50% 30% and 20% respectively. b) Dose-volume histograms for GTV, PTV, normal breast excluding PTV, and whole breast, calculated from the dose distribution of a).



(a) **(b)**

a) Dose distribution in another patients on axial and sagittal images. The isodoses shown are 100%, 95%, 50% 30% and 20% respectively. b) Dose-volume histograms for GTV, PTV, normal breast excluding PTV, and whole breast, calculated from the dose distribution of a).

Conclusions: Initial results indicate that the GammaPod system can deliver a focal dose of radiation to the breast safely. The vacuum-assisted breast cups were able to maintain the immobilization between imaging and treatment. With dynamic dose painting, the dose uniformity rivals that of external beam partial breast irradiation, but with more rapid dose fall-off outside the target, leading to substantially reduced radiation dose to the normal breast. The stereotactic boost treatment resulted in no difference in acute toxicities from that received with standard external beam RT.

The ability of delivering a focal dose of radiation opens the opportunity for single pre-operative irradiation as an alternative to intra-operative irradiation and pre-operative radioablation. Delivery of the boost treatment prior to tangential whole breast radiation was well tolerated.

Disclosure: **W. Regine, Y Niu, and C. Yu are shareholders of Xcision Medical Systems, LLC**

Acknowledgement: **This work is supported in part by NIH grant R44 CA132254**

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