



Agenda Item 1

Featured Start-Up – Xcision Medical Systems, LLC



BOARD OF REGENTS

SUMMARY OF ITEM FOR ACTION
INFORMATION OR DISCUSSION

TOPIC: Featured Start-Up – Xcision Medical Systems, LLC (information item)

COMMITTEE: Economic Development and Technology Commercialization

DATE OF COMMITTEE MEETING: March 31, 2016

SUMMARY: Xcision Medical Systems, LLC was founded by Dr. Cedric Yu, Professor in the Department of Radiation Oncology at the University of Maryland’s School of Medicine. The company is developing solutions that will enable an expanded role of radiation, based on a patent from the University of Maryland, Baltimore.

Xcision’s initial funding was via an NIH Small Business Innovation Research (SBIR) grant. The company has received additional federal, state, and private investments since that time.

ALTERNATIVE(S): This item is for information purposes.

FISCAL IMPACT: This item is for information purposes.

CHANCELLOR’S RECOMMENDATION: This item is for information purposes.

COMMITTEE RECOMMENDATION:

DATE:

BOARD ACTION:

DATE:

SUBMITTED BY: Joseph F. Vivona (301) 445-2783

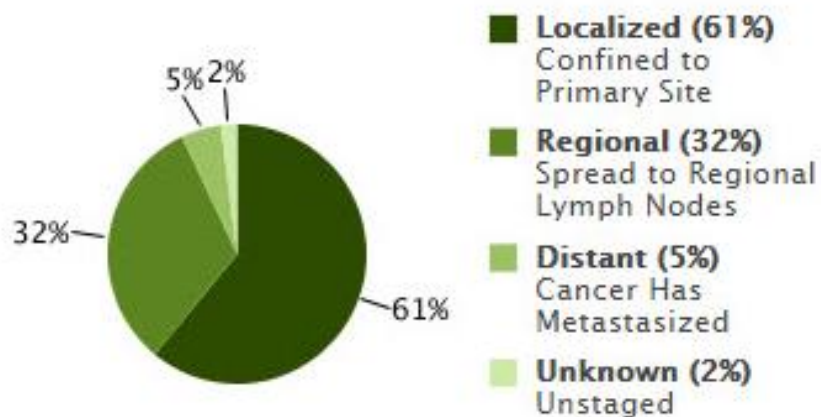


Cedric Yu, D.Sc.

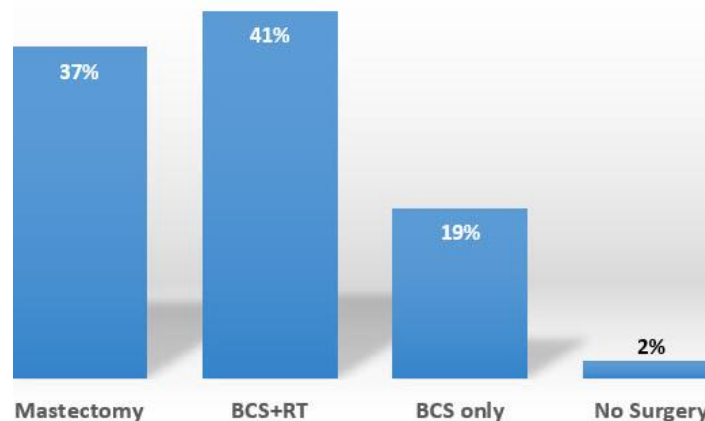
Carl M. Mansfield, M.D. Professor
University of Maryland School of Medicine
CEO, Xcision Medical Systems, LLC

230,000+ NEW BREAST CANCER

Stage at Diagnosis



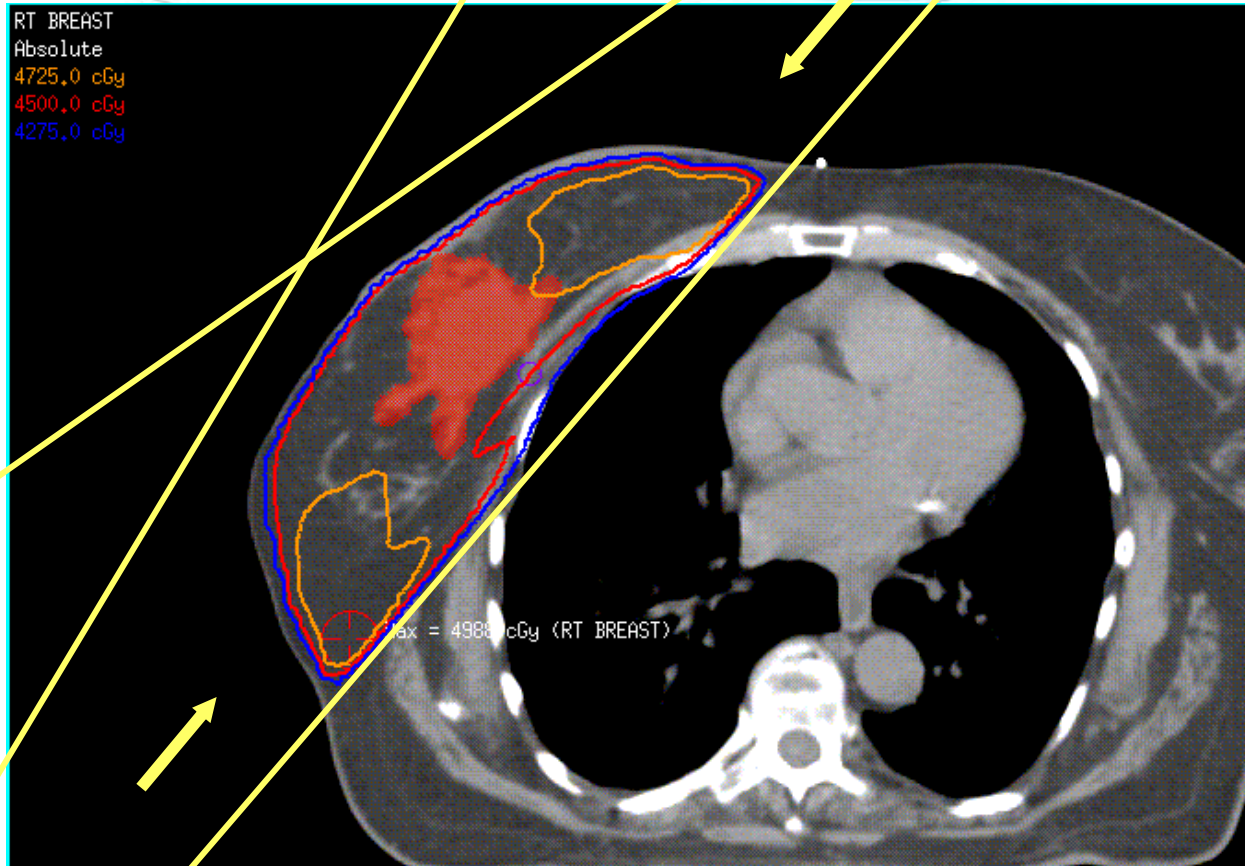
Treatment Approach



Standard of Care

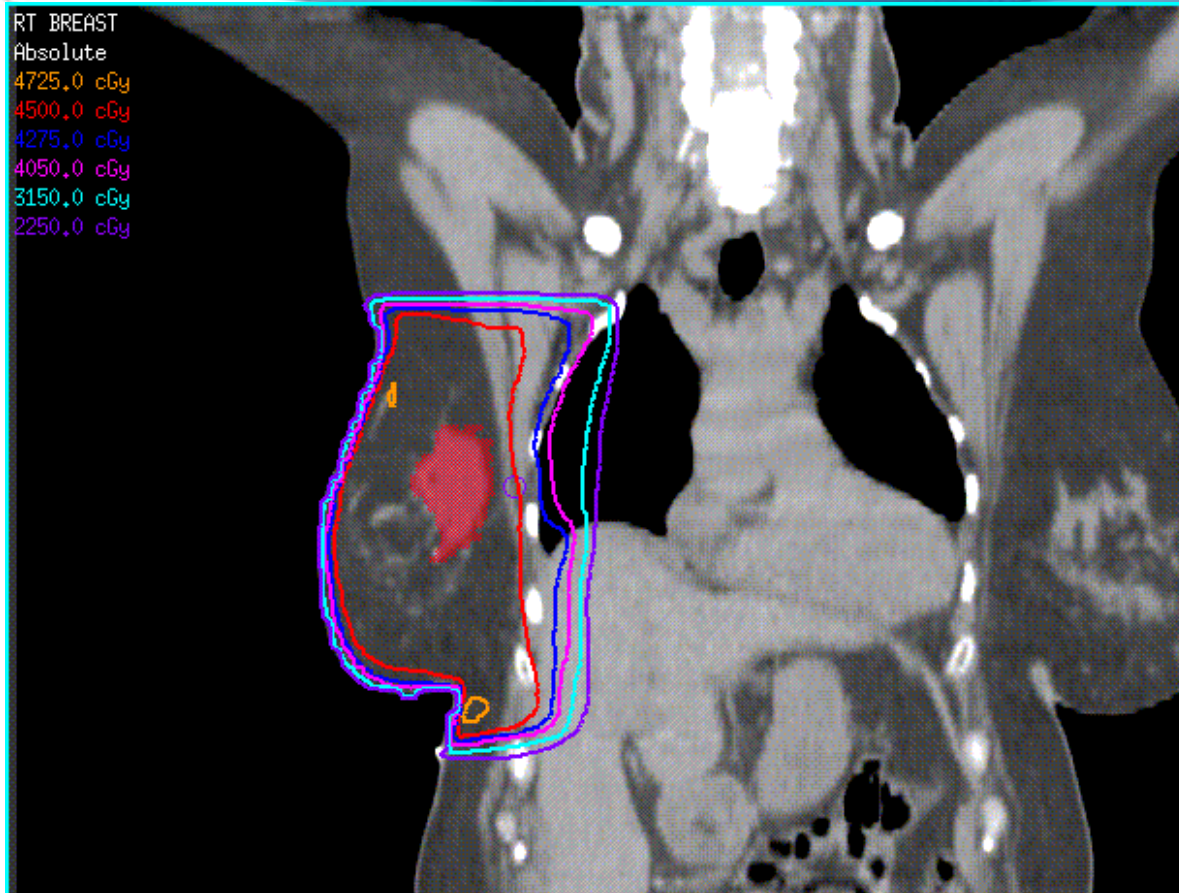
NCI Cancer Trends Progress Report - 2012

CURRENT BREAST IRRADIATION



Two tangential beams, giving the breast a 'radiation bath'

CURRENT BREAST IRRADIATION



To save the breast:

surgery, 6-8 weeks healing, then 5-7 weeks of radiation

GRADE 3 TOXICITY

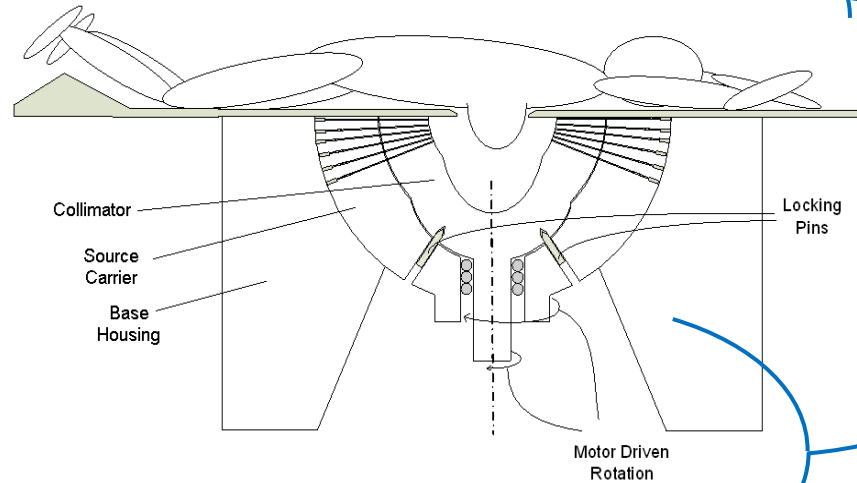
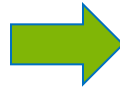
Toxicity OF Three-Dimensional Conformal Radiotherapy for Accelerated Partial Breast Irradiation. Jaroslaw T. Hepel et al. Int, J. Rad. Biol. Phys. Vol 75 No. pp 1290-1296, 2009

25% Grade 2-3 at median follow-up of 15 months after Accelerated Partial Breast Irradiation (APBI) using External Beam

Canadian Phase III trial, showed 29% unfavorable cosmesis with EXRT APBI – T. Whelan

IS THERE A CONVENIENT, NONINVASIVE, LESS TOXIC WAY?

Toxicity



HUGE SUPPORT FROM UMB

- Development Office: Patent application and exclusive licensing
- Dean's Office: Allow me to go part-time in order for me to get an SBIR grant ~\$4M from NIH (unfortunately, I have to forgo tenure)
- Department and UMMC: Facility for radiation testing, serve as leader of a clinical consortium to conduct clinical study
- My gratitude: donation of Xcision shares to UMBF

THE GAMMAPOD

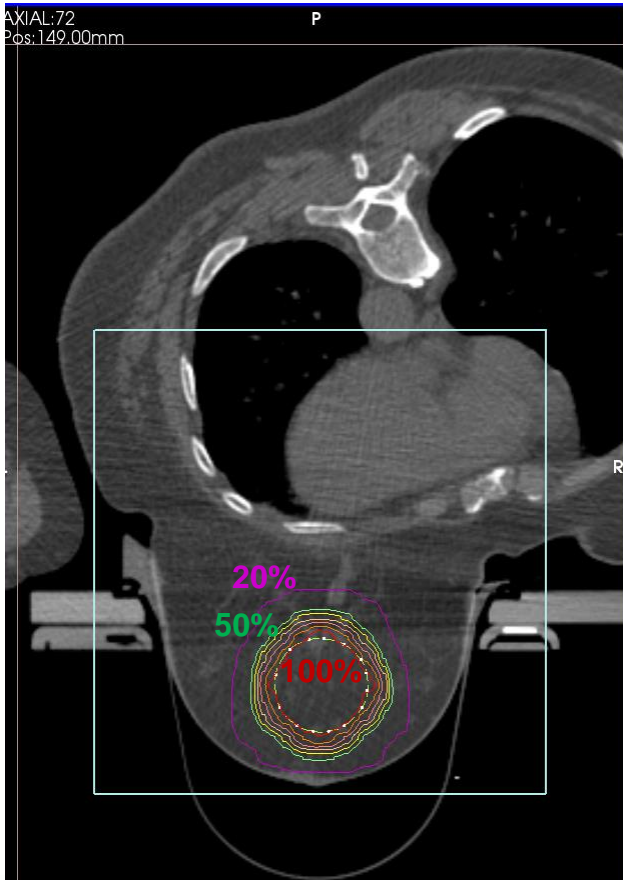


www.xcision.com

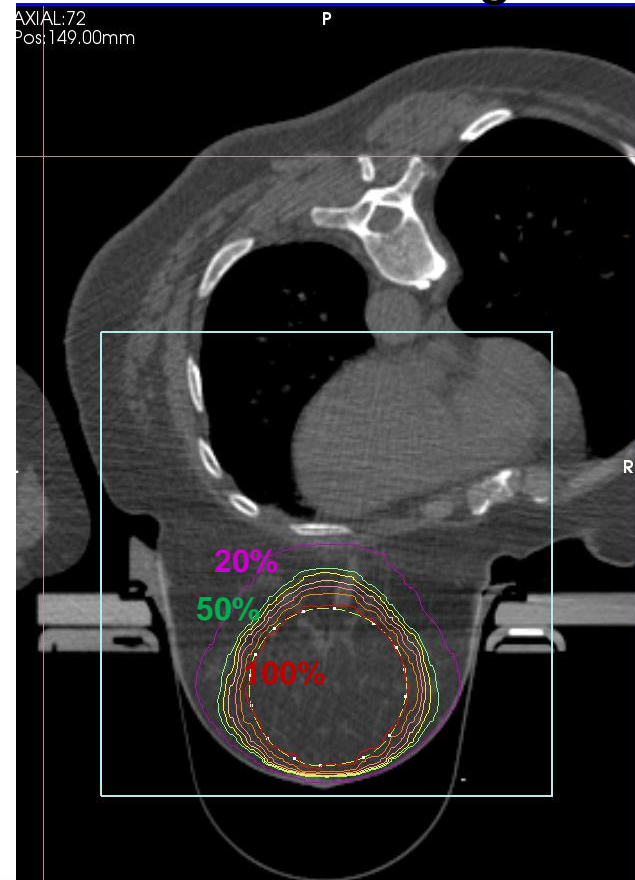
xcision

EXAMPLE DOSE DISTRIBUTIONS

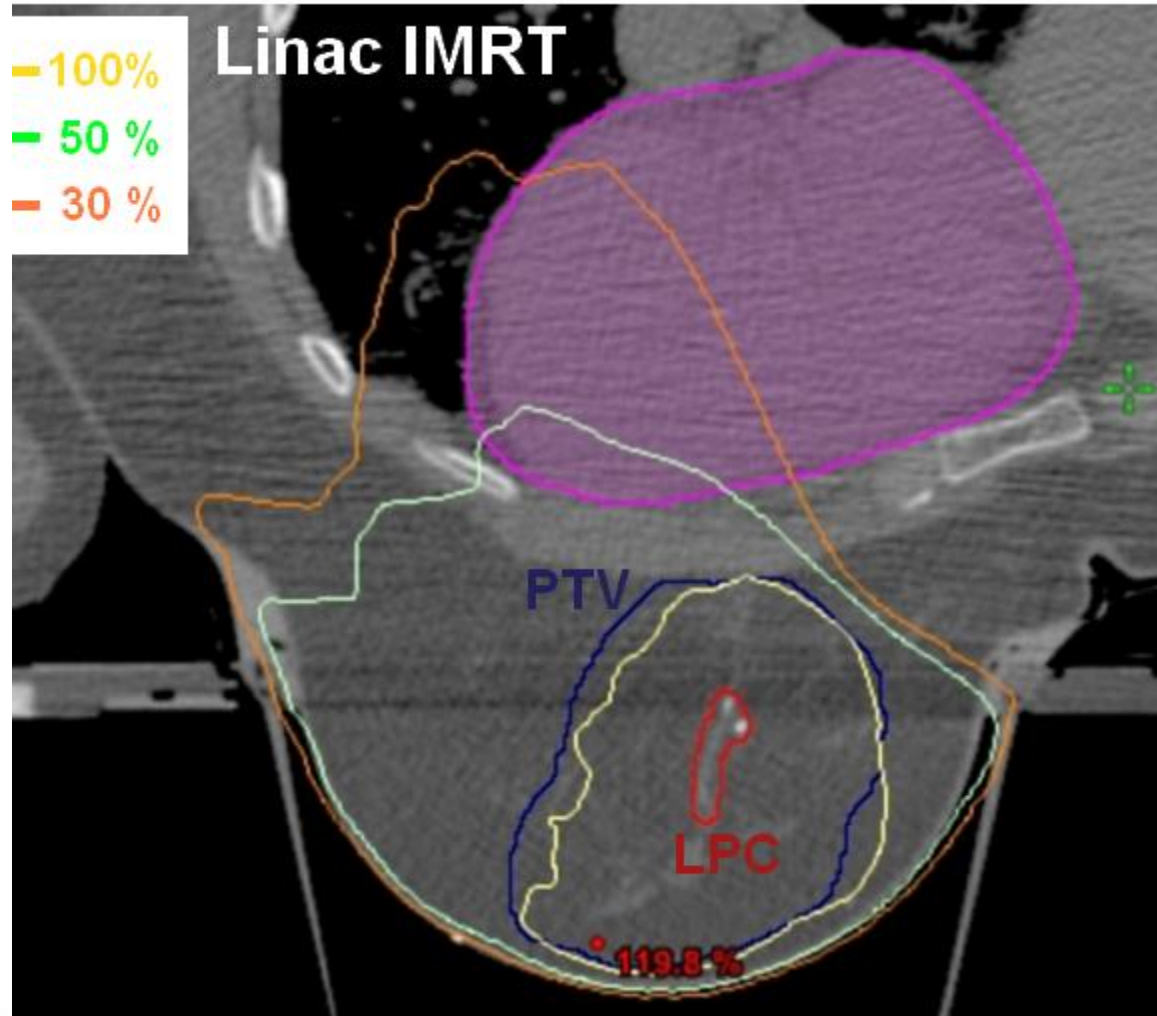
45 cc target



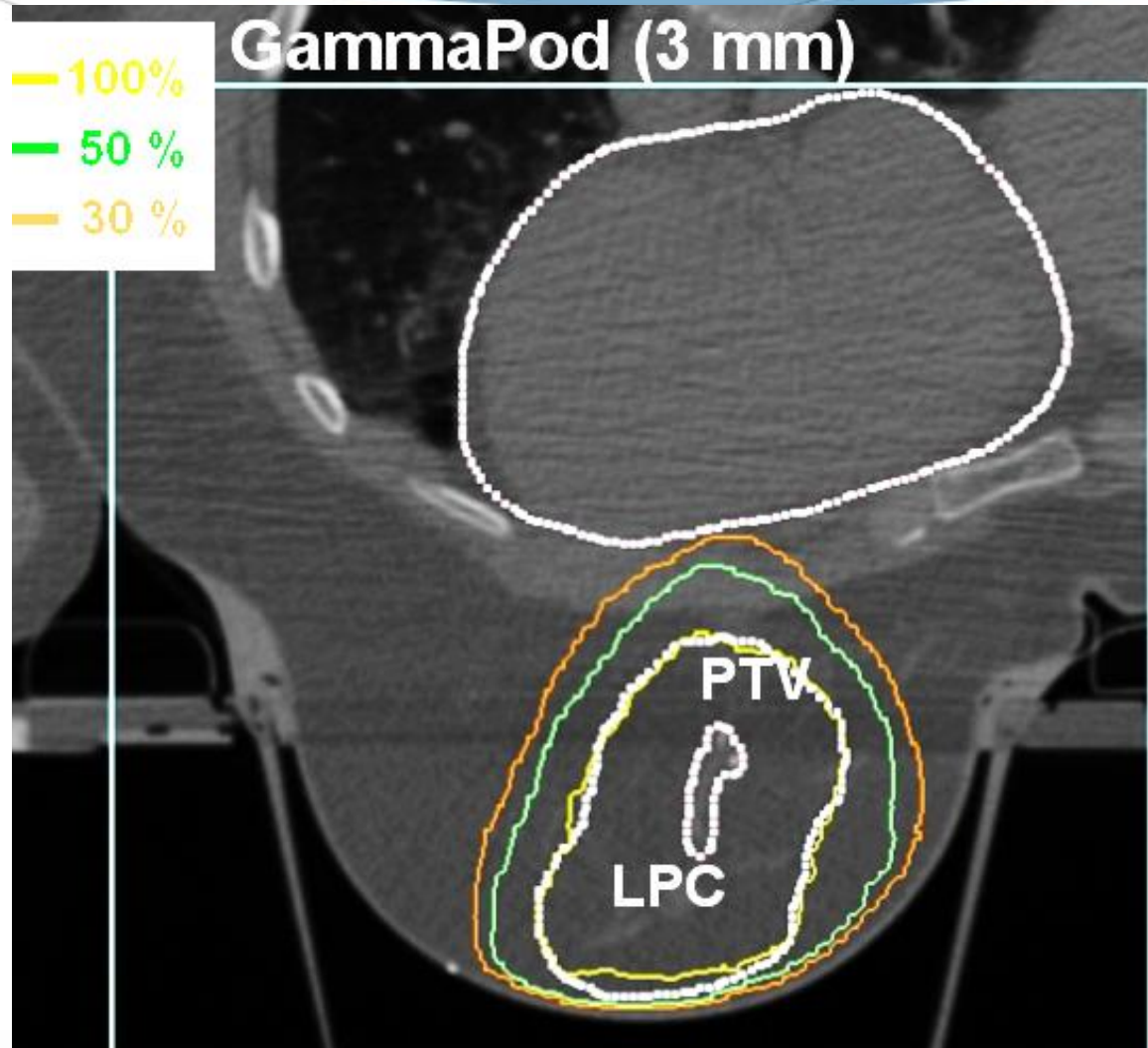
215 cc target



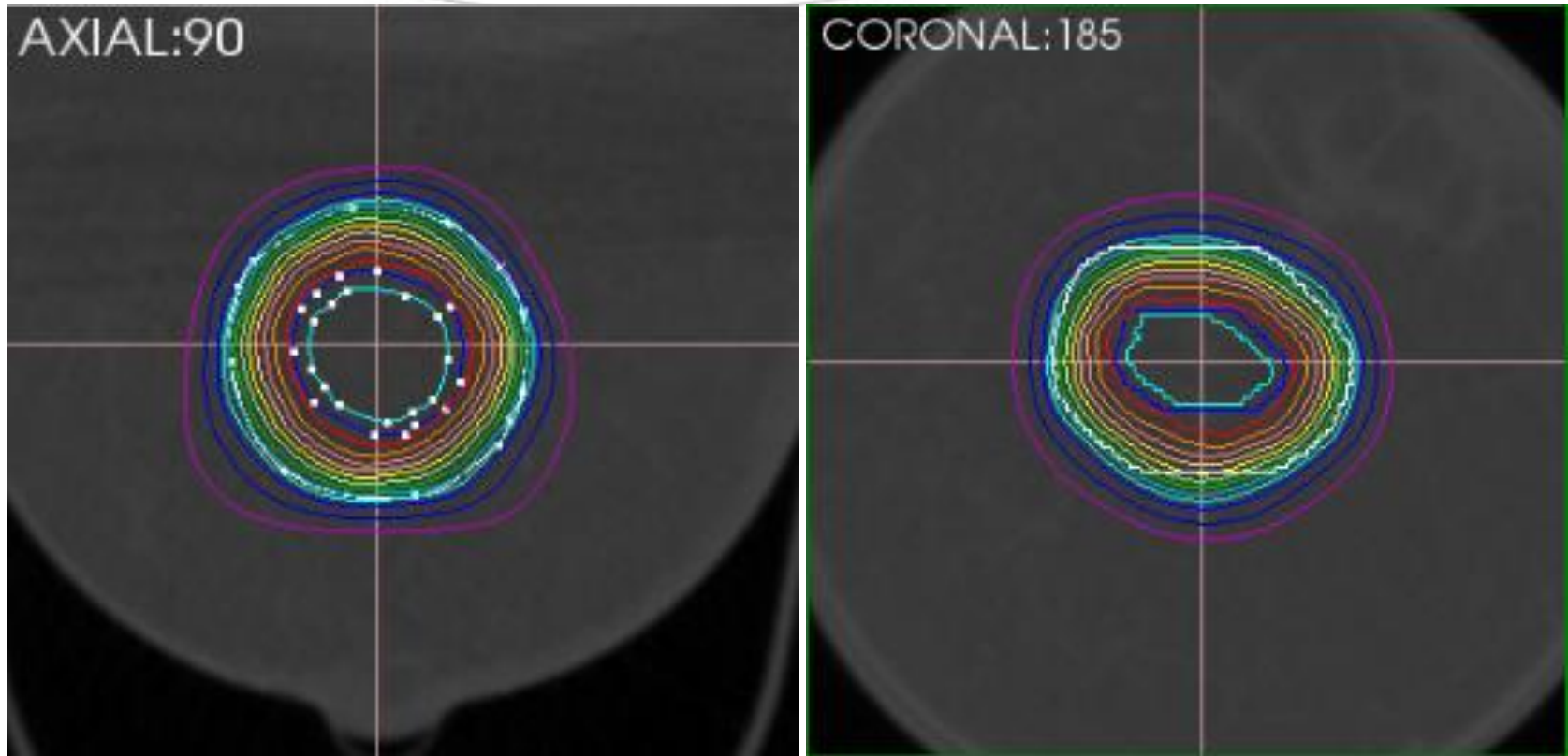
Linear Accelerator



GAMMAPOD



DOSE PATTERN



3.5cm Tumor+3mm gets 18Gy
6.1 cm Tumor bed gets 10Gy



No need for surgery
No need for 5-7 weeks of radiation
1-3 irradiation is enough

focus on: radiotherapy | 9

GammaPod offers breast-specific SBRT

Accelerated partial breast irradiation (APBI), used to treat patients following breast-conserving surgery, is commonly performed using multicatheter interstitial brachytherapy or balloon-based brachytherapy devices. But now there's another option: GammaPod, a breast-specific stereotactic body radiation therapy (SBRT) device that delivers radiation using rotating Co-60 sources.

Developed by the University of Maryland School of Medicine and Xcision Medical Systems, GammaPod also includes tungsten collimators, a dynamically controlled patient support table, and a breast immobilization cup that additionally functions as the stereotactic frame. In collaboration with the University of Maryland researchers,

said Karolinska medical physicist Jakob Ödén.

GammaPod comprises a hemispherical source carrier containing 36 Co-60 sources. The source assembly rotates in synchrony with the collimator structure (which offers apertures of 1.5 or 2.5 cm), giving rise to 36 non-coplanar, concentric arcs focused at the isocentre. The patient is treated in prone position with the breast positioned inside the hemispherical assembly and immobilized using negative pressure.

Ödén and colleagues modelled spherical targets with diameters of 2, 4, 5.6 and 6.5 cm for GammaPod. They evaluated the 2 cm target in a central position close to the chest wall, while the other targets were also evaluated in four peripheral



not necessarily for breast cancer because the planning target volume definition of 1 cm expansion from the surgical cavity is rather arbitrary. The probability of finding residual tumour foci in the breast post-surgery does not drop abruptly at 1 cm from the cavity wall," Ödén explained. "At larger distances, however, we do want the dose to be as low as possible to minimize dose to the lung and heart. Doses at these larger distances are much smaller with GammaPod, giving it a potential clinical advantage."

The team also calculated skin doses for the four scenarios with targets close to the skin. For all target sizes, relative skin doses were considerably lower for GammaPod than for any of the brachytherapy

Oncology Scan—The Vision of Medical Physics

By Eric E. Klein, PhD, *Senior Editor*, Nesrin Dogan, PhD, *Associate Editor*, Zhe Chen, PhD, *Associate Editor*,
Claudio Fiorino, PhD, *Associate Editor*

Ödén et al. Dosimetric comparison between intra-cavitary breast brachytherapy techniques for accelerated partial breast irradiation and a novel stereotactic radiotherapy device for breast cancer: GammaPod. *Phys Med Biol* 2013. (4)

Summary: This article describes the results of a dosimetric study aimed at comparing the performance of a dedicated stereotactic radiation therapy device known as GammaPod, with a more extensively well-developed intracavitary accelerated partial breast irradiation afterloader (5). The GammaPod is a spherical source carrier that provides a complete patient support system with distributions achievable by volumes with diameters of up to 10 cm.

therapy (3DCRT) has become an established modality for selected women with early-stage breast cancer. Over the past decade, technical improvements for APBI dose delivery have involved mainly the development of multilumen balloon and multicatheter applicators, whereas the techniques using 3DCRT and intensity modulated radiation therapy (IMRT) have remained relatively unchanged. The introduction of the GammaPod as a dedicated stereotactic radiation

The authors conclude that GammaPod allows adequate and more uniform dose coverage to centrally and peripherally located targets, with acceptable dose falloff and lower relative skin dose than the brachytherapy techniques considered.

CONSORTIUM MEMBERS



First Patient Treated on 3/18/16

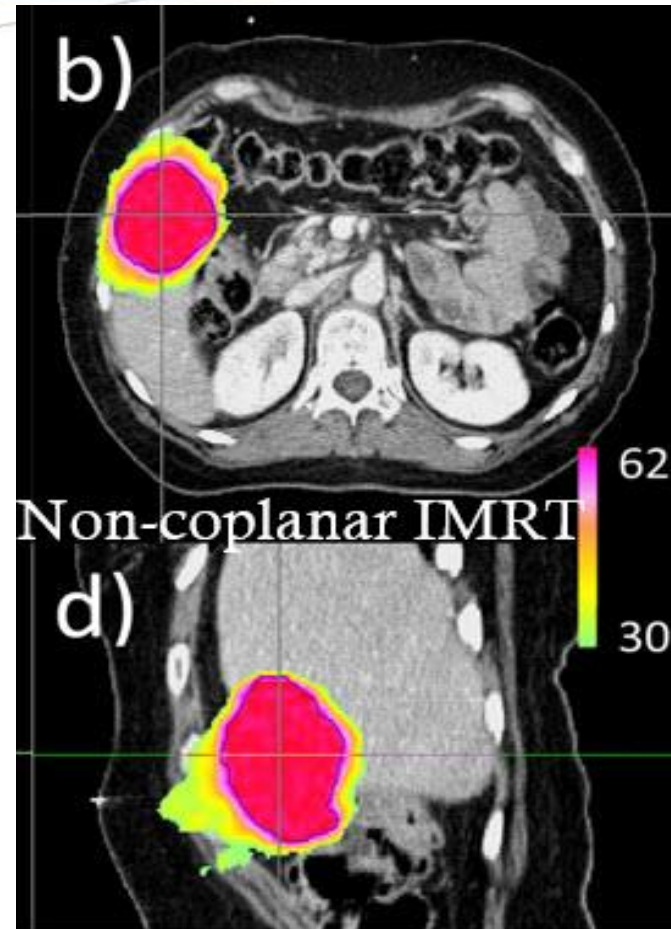
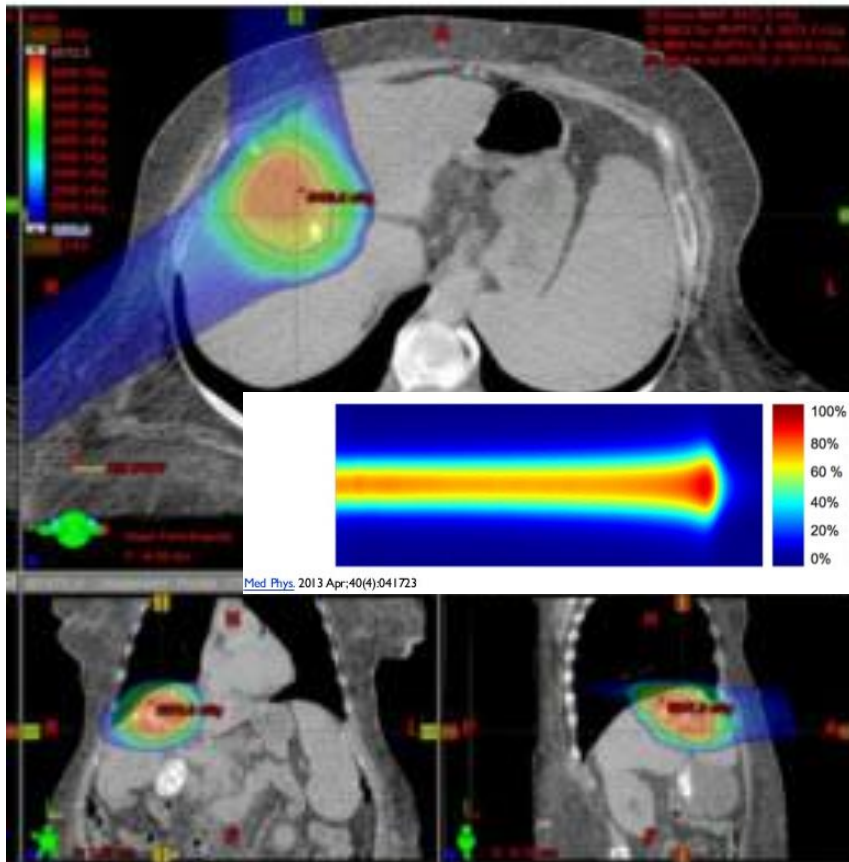


ON-TRACK FOR MARKET LAUNCH

- 2015:
 - FDA IDE approval
 - State Radioactive material license.
 - NRC registry
- 2016
 - Install 3 more sites
 - FDA Clearance by end of 2016
- In 3 years, reach 50 systems/year at ~\$3.0M/system

COMPARE WITH PROTONS

Protons



S.J. Gandhi et al: Practical Rad Oncol. 2015 1-10.

12 ISSUED PATENTS

- US # 8,031,835 2009, breast tomosynthesis imaging
- US # 7,597,104B2 2009, Breast immobilization
- US # 8,146,186B2 2009, Breast Positioning
- US # 8,042,209 2011, patient couch
- **US # 8,788,017 2014 GammaPod**
Also issued in Aus, EU, JP, CN
- US # 8,280,001 2010 Dynamic Dose painting
- US #8,641,592B2 Prostate.
- US #8,819,877 Patient Loader
- US #9,155,912B2 xPod
- Volumetric ultrasound
- 4D delivery

MY RECORD

- **20 issued patents and 1 pending**

Most licensed by Market leaders: Elekta, Varian, Siemens, Xcision

- **1995 – invented IMAT (Varian’s RapidArc + Elekta’s VMAT, they made \$billions)**

>50% of radiation treatments in the world using this technology

- One of 25 most important works published in PMB’s 60 yr history

- **1998 – invented Direct Aperture Optimization**

Sublicensing and infringement awards > \$10M

- **2008 – dose rate regulated tracking**

Licensed to a company for \$3M

MANAGEMENT

Board – Currently four members (all are shareholders)

- Chris Amies, Ph.D., Senior VP, Siemens Medical
- Mohan Suntha, MD., MBA., CEO of St Joseph Hospital, Baltimore
- Cedric Yu, D.Sc., Carl Mansfield Professor of Radiation Oncology
- Nan Malin, General Manager, Penguin Fund
- Jerome Zhang, M.D., Founder of Sihuan Pharmaceutical, Inc.

Executives

- Cedric Yu, D.Sc., Founder and CEO
- Will Wells -VP Business Dev. >30 yrs of experience in RT industry
Peter Maton -VP Engineering, >20yrs of R&D management
- Michelle Crawley –VP Operations, >20yrs of operating manager
- Marrine Sheng – Financial Controller

SUMMARY

- Using ~\$17M (~50% from investments), with the strong SUPPORT from UMB, we turned an idea into a major medical device, the GammaPod™
- In the process, it
 - Built a strong leadership team, and
 - Created a strong IP portfolio, with a new potential game-changer in the pipeline
- Secured initial funds for developing new IP
- **Additional \$15M is needed to finish the job.**