BrachyNext
Working Together to Shape the Future of Brachytherapy

High-Dose-Rate Intraoperative Radiation Therapy: The Nuts and Bolts of Starting a Program, and New Directions

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Disclosures

None

Outline

- Background
- JHH HDR-IORT Program
- Tips and Challenges
- New Directions

IORT Defined

- Intraoperative radiotherapy: a technique where a high, single fraction of radiation is delivered during a surgical procedure to a surgically exposed tumor or tumor bed while the normal tissues are protected from the radiation

Rationale for IORT

- Radiation therapy controls locoregional disease
- With improved systemic agents, local control becomes more important
- Higher radiation doses result in improved local control
- In many cases, total dose is limited by tolerance of adjacent normal structures

History of IORT

- Modern era began in 1960s after electron beam from linear accelerators became widely available, thus allowing for:
  - Excellent dose homogeneity
  - Rapid dose falloff
  - Control of depth of penetration
  - Rapid dose delivery

History of IORT (Cont'd)

- IORT given alone in large doses of 25-40 Gy to intact tumors → excessive morbidity, minimal improvement in survival
- Revival of interest in IORT driven by change in prescription paradigm
  - Now, routinely given as boost to moderate doses of EBRT and after surgical debulking → minimal morbidity and improved outcomes

Common Uses for IORT

- Malignancies with high risk for local recurrence in close proximity to radiosensitive structures:
  - Colorectal
  - Pancreatic
  - Gastric
  - Gynecologic
  - Retroperitoneal sarcomas
  - Head and Neck
  - Recurrent tumors

Advantages of HDR-IORT

- Direct visualization and thus greater accuracy in determining areas at risk
- Allows for movement and shielding of sensitive adjacent normal tissues
- Allows for re-treatment of previously irradiated recurrent tumors
- Eliminates delay between surgery and EBRT

JHH HDR-IORT Program

- November 2006
- Prior to program initiation, spent several weeks at existing IORT programs
- Patients selected based on established criteria during multidisciplinary consultations

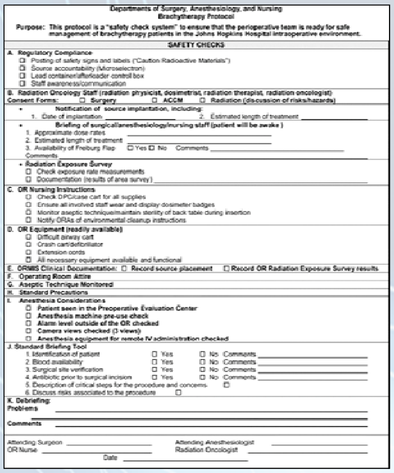
Team

- Radiation oncology
  - Physicians, mid-level providers, residents
- Surgical oncology
  - Physicians, mid-level providers, residents
- Physics
- Anesthesia
- Nursing staff
- Coordinator

JHH HDR-IORT Safety Initiative

- Armstrong Institute for Patient Safety and Quality (AIPSQ) & Dr. Peter Pronovost
- Checklists
- Safety simulations
- Risk-assessment workshops

Safety Checklist & Flowchart



Departments of Surgery, Anesthesiology, and Nursing
Brachytherapy Protocol

Purpose: This protocol is a "safety check system" to ensure that the perioperative team is ready for safe management of brachytherapy patients in the Johns Hopkins Hospital intraoperative environment.

SAFETY CHECKS

A. Regulatory Compliance
- ☐ Posting of safety signs and labels ("Caution Radioactive Materials")
- ☐ Source accountability (Microselectron)
- ☐ Lead container/afterloader control box
- ☐ Staff awareness/communication

B. Radiation Oncology Staff (radiation physicist, dosimetrist, radiation therapist, radiation oncologist)
Consent Forms: ☐ Surgery ☐ ACCM ☐ Radiation (discussion of risks/hazards)
- Notification of source implantation, including:
  1. Date of implantation ______ 2. Estimated length of treatment ______
- Briefing of surgical/anesthesiology/nursing staff (patient will be awake)
  1. Approximate dose rates ______
  2. Estimated length of treatment ______
  3. Availability of Freiburg Flap ☐ Yes ☐ No Comments ______
  Comments ______
- Radiation Exposure Survey
  - ☐ Check exposure rate measurements
  - ☐ Documentation (results of area survey) ______

C. OR Nursing Instructions
- ☐ Check DPC/case cart for all supplies
- ☐ Ensure all involved staff wear and display dosimeter badges
- ☐ Monitor aseptic technique/maintain sterility of back table during insertion
- ☐ Notify ORAs of environmental cleanup instructions

D. OR Equipment (readily available)
- ☐ Difficult airway cart
- ☐ Crash cart/defibrillator
- ☐ Extension cords
- ☐ All necessary equipment available and functional

E. ORMIS Clinical Documentation: ☐ Record source placement ☐ Record OR Radiation Exposure Survey results.

F. Operating Room Attire

G. Aseptic Technique Monitored

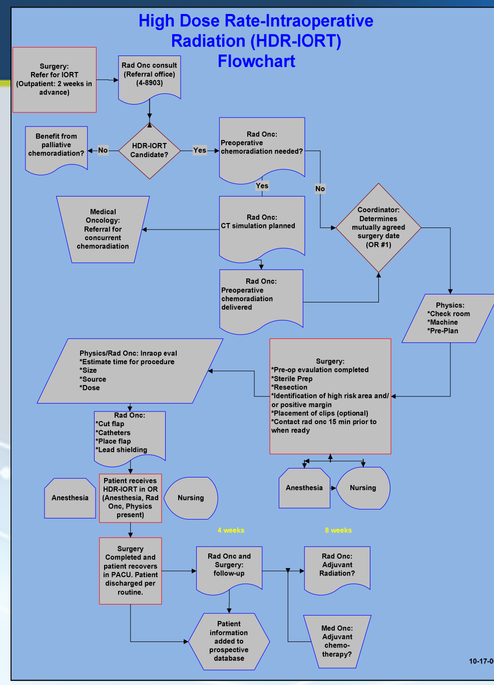
H. Standard Precautions

I. Anesthesia Considerations
- ☐ Patient seen in the Preoperative Evaluation Center
- ☐ Anesthesia machine pre-use check
- ☐ Alarm level outside of the OR checked
- ☐ Camera views checked (3 views)
- ☐ Anesthesia equipment for remote IV administration checked

J. Standard Briefing Tool
1. Identification of patient ☐ Yes ☐ No Comments ______
2. Blood availability ☐ Yes ☐ No Comments ______
3. Surgical site verification ☐ Yes ☐ No Comments ______
4. Antibiotic prior to surgical incision ☐ Yes ☐ No Comments ______
5. Description of critical steps for the procedure and concerns ☐
6. Discuss risks associated to the procedure ☐

K. Debriefing:
Problems ______
Comments ______

Attending Surgeon ______ Attending Anesthesiologist ______
OR Nurse ______ Radiation Oncologist ______
Date ______



Moningi et al. J. Contemp. Brachy. 2014

Scheduling of IORT

- The decision to perform IORT will need to be determined **PRIOR** to the surgery
- If IORT is needed during surgery, patient will need to be scheduled for a **second surgery/IORT**
- Intake form is completed (confirm what equipment is needed)
- Confirm billing codes needed for procedure

Scheduling of IORT

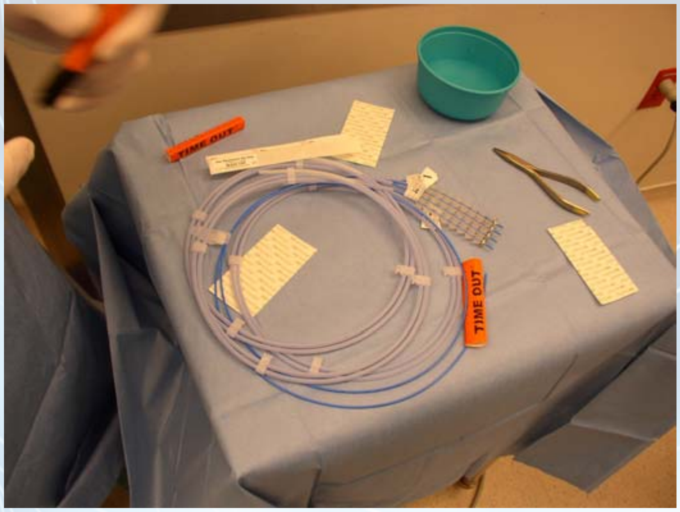
- Patient is seen in consultation by all disciplines
  - Is pre- or postoperative radiation needed?
  - Consent
  - Pre-operative clearance
- IORT coordinator determines **optimal** OR date with surgery, radiation oncology, anesthesia, and nursing
- OR date is scheduled, **estimated** time of HDR procedure determined (30 min-several hours)

Equipment

- OR - shielded and wired for HDR
- Afterloader - Nucletron microSelectron
- Planning system – Plato (now Oncentra Masterplan)
- Freiburg Flap*
- Catheters – 150 cm 6F Lumencaths*
- Stainless steel buttons*
- Lead sheets for organ shielding*

*Sterilized prior to procedure

Flap Prep Table



Timeline

Arrive in OR ---- Radiation Oncologist consults with Surgeon and Physicist
---Determines Rx “Parameters”

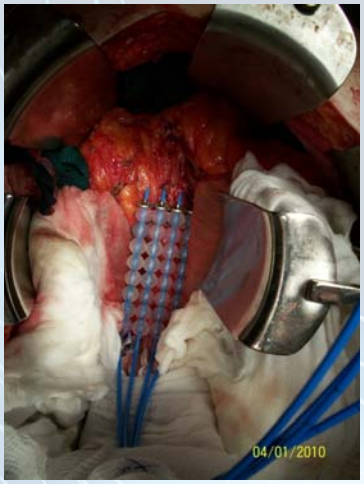
Rad Onc
-- Assembles catheters, buttons, flap
--- Places Flap and Lead Shielding in patient

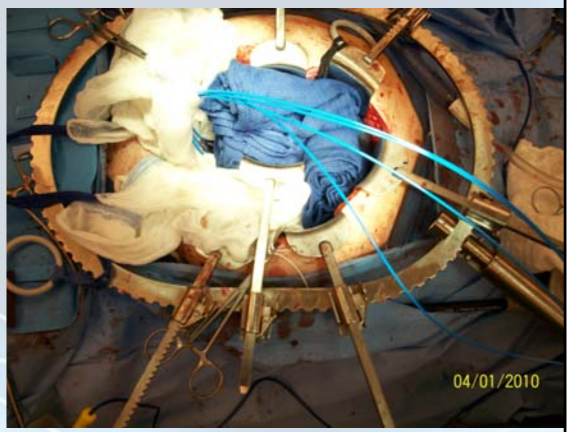
Physicist
Oncentra planning

Rad Onc and Physicist
-- Review Oncentra planning
--- Check cable run
---- Treatment delivered

Physicist -- surveys patient
Rad Onc --- removes flap and lead, etc

Flap in Position and Packed





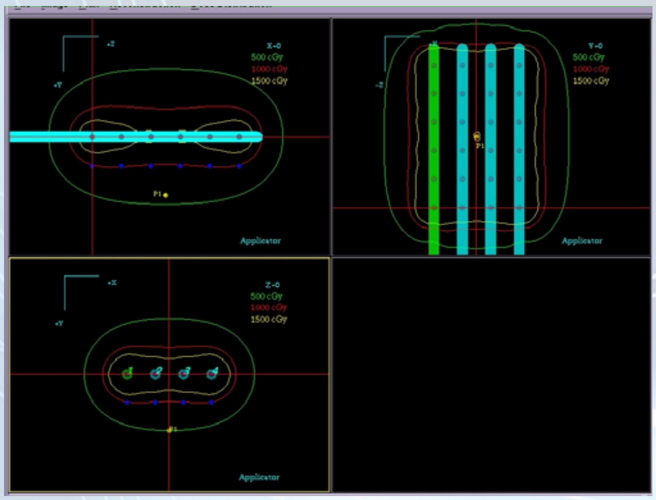
Two-sided Treatment

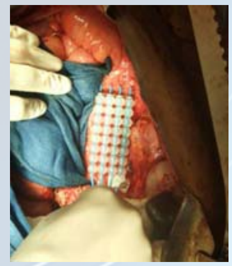
Two-sided Treatment

Brachy Planning Process

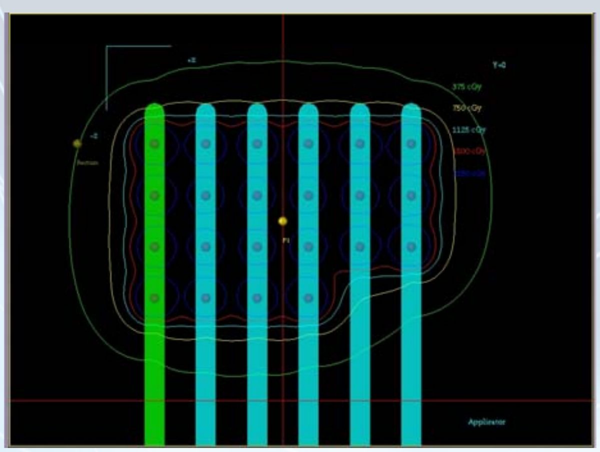
- PLATO planning system (more recently Oncentra Masterplan)
  - Library plans of square flaps are recalled
  - Dwell positions are selectively added or deleted to match required shape and size
  - In small number of cases, catheter end positions are adjusted

Example Flap Geometry
Typical

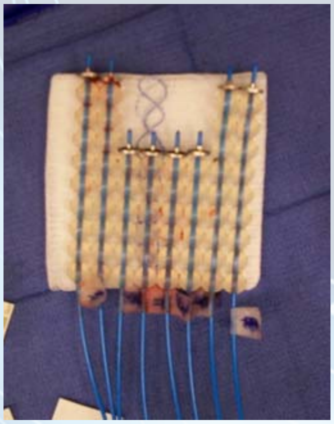


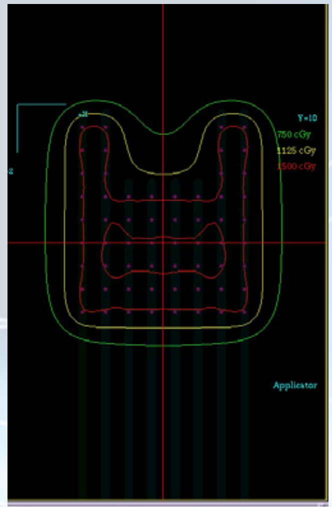


Example Flap Geometry
Custom



Example Flap Geometry
Custom

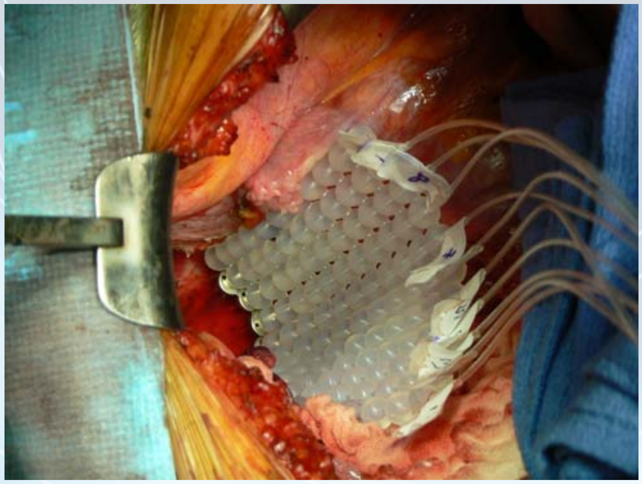




Brachy Planning Process

- All plans are planar
  - Calculations demonstrate that dose varies less than 5% for flaps with radius of curvature greater than 3.7 cm
    - For Rx depth of 10 mm (5 mm into tissue)
  - "Only applies to Convex side of flap"
- Dose points are created at Rx depth for each dwell position
- Plan is Optimized and Prescribed to Dose Points
- Double check total time*activity/dose for area

Acceptable Flap Curvature



Un-acceptable Flap Curvature

Customized non-planar plans were created for select treatments

Conditions for Freiburg Flap

- Radius of curvature greater than 3.7 cm
- Backscatter material (i.e., wet towel) on flap minimum of 1 cm
  – (max effect no backscatter = –4%)
- Buttons are placed 10 mm from catheter tip
- Catheter off-set is 1494 mm for all catheters

Conditions for Lead Shielding

- Lead thickness of 3 mm produces about 50% attenuation
- Water equivalent material (~4 mm) between lead and tissue is needed to absorb excess electrons immediately below lead surface
- Lead sheets are wrapped in several layers of wet towels

Conditions for Lead Shielding

Lead	Relative Dose at Depth in Tissue 0 mm	4 mm	8 mm	12 mm
None	100%	100%	100%	100%
0.9mm x1	147%	84%	81%	79%
0.9mm x2	121%	67%	65%	63%
0.9mm x3	96%	53%	53%	53%

JHH HDR-IORT Program – Results

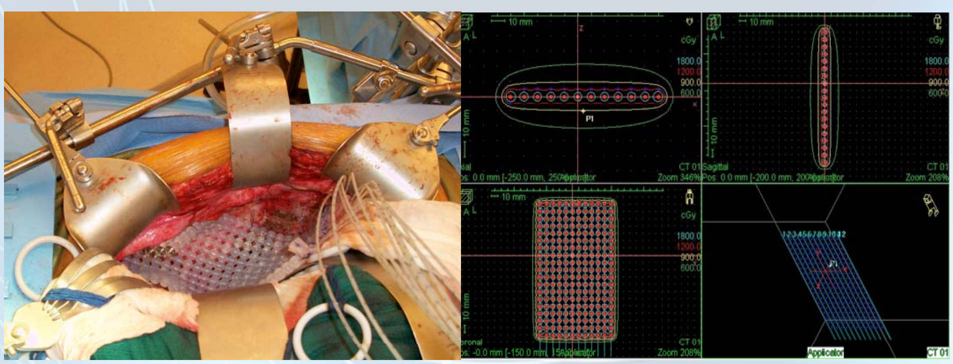
- November 2006- May 2014
- 205 patients scheduled
- 122 (60%) patients treated & analyzed*
  - 48% sarcomas
  - 34% colorectal
  - 10% other GI
  - 8% GU
- Median OS = 35.7 months

**Includes primary and recurrent tumors*

Case #1

- 35-year-old male undergoes resection of *well-differentiated retroperitoneal sarcoma* with negative margins and lymph nodes
- 7 months later: biopsy-confirmed liposarcoma → surgery + **12 Gy HDR-IORT** → 45 Gy EBRT in 25 fx
- 3 years later: biopsy-confirmed liposarcoma outside of previous tx field → surgery + **12 Gy HDR-IORT** → 39.6 Gy IG-IMRT in 22 fx
- 25-month f/u: doing well with no new recurrences

Case #1

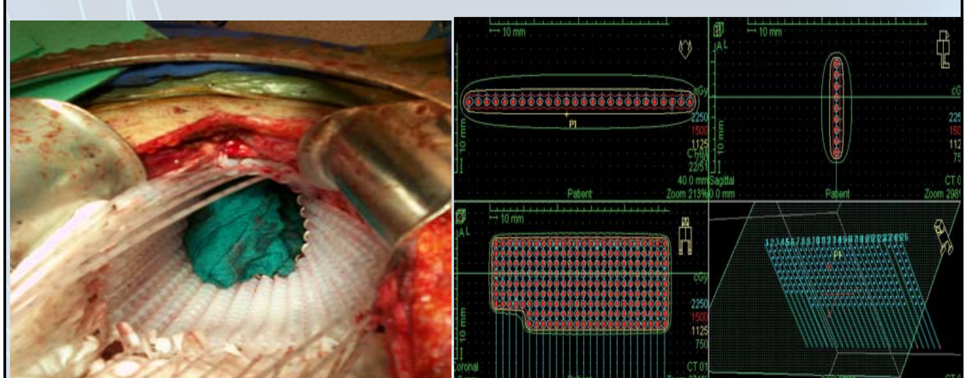


A) Freiburg flap is placed on the right lateral abdominal wall intraoperatively. Normal tissues were immobilized out of the radiation field. **B)** A HDR-IORT dosimetric plan showing 12 Gy prescribed to the to surface. Notice the sharp fall-off of dose with increased distance from the source.

Case #2

- 38-year-old diagnosed with *moderately differentiated locally advanced rectal adenocarcinoma*
- Received neoadjuvant 5-FU + 54 Gy EBRT
- 3 months later: local progression → FOLFIRINOX
- 3 months later: further progression + bowel obstruction → colonic diversion
- 3 months later: 5-FU + 36 Gy EBRT + total pelvic exenteration + **12 Gy HDR-IORT**
- 3 months later: determined to be MSI-H → gemcitabine + docetaxel RCT →MK-3475 RCT
- 5 months later: doing well

Case #2



A) Freiburg flap placed to cover the pelvis circumferentially following a pelvic exenteration. A 1-cm separation was used to limit overlap of the flap and prevent hotspots anteriorly. **B)** An HDR-IORT dosimetric plan showing 12 Gy prescribed to the surface.

Challenges to Consider

1. Good communication
2. IORT coordinator
3. Obtain relevant outside medical records and previous treatment summaries
4. Proper access and sterilization of all required equipment
5. All involved physicians and physicists present during the actual “beam on” time
6. Compliance with established safety protocols
7. Billing compliance using appropriate reimbursement codes

Mid-Level Providers in Radiation Oncology and Their Role in Brachytherapy

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Materials and Methods

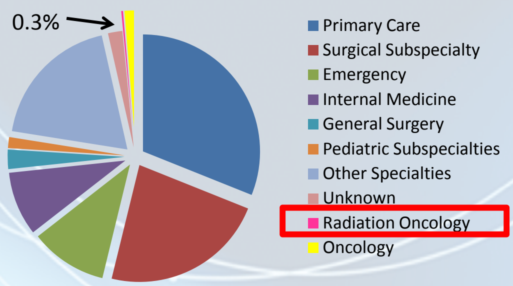
- Literature review
- Medicare reimbursement guidelines
- AAPA/MD Board of Physicians credentialing
- AAPA census review
- Personal experience at JHU Dept. of Radiation Oncology

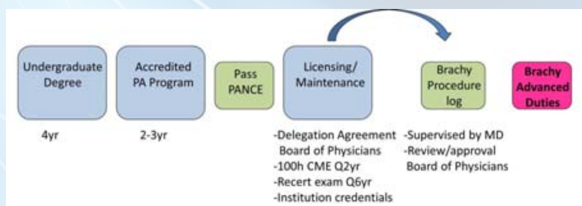
Need for Mid-Level Providers

- Increasing patient population in oncology and advancing technologies in radiation oncology
- Increased demand of assistance with procedural-based aspects of HDR-IORT
- Need improved workflow
  - Physician assistants (PAs) can perform procedures (IORT) under a licensed agreement
  - PAs can charge for brachytherapy services

Results

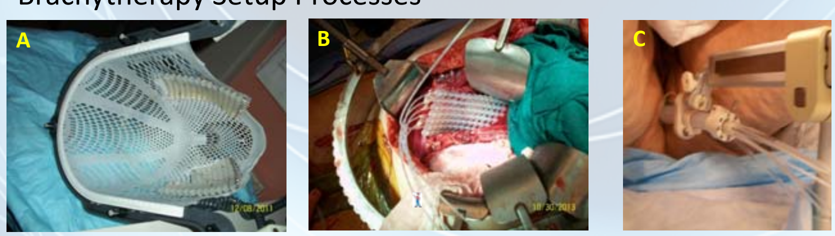
- 2010 AAPA census: Only 0.3% of PAs practice in Radiation Oncology and salaries are less than average





Results

- Practices can be reimbursed for 85-100% of physician fees for multiple brachytherapy CPT codes billed by PAs
- Applicator/Catheter Insertion/Implantation CPT codes
  - Multiple site codes: 20555, 22999, 47999, 49999, 49421, 45999, C9725
  - Daily insertion fee if multiple fractions
- Brachytherapy Setup Processes



Equipment assessment and setup which can be performed by a credentialed PA. (A) Brachytherapy skin treatment setup, estimated simulation time: 3-4hr; (B) Typical IORT case, estimated equipment setup: 30-45mins; (C) Endorectal brachytherapy setup, estimated simulation time: 2.5hr, treatment day: 30-45mins.

Conclusions: Roles of PAs

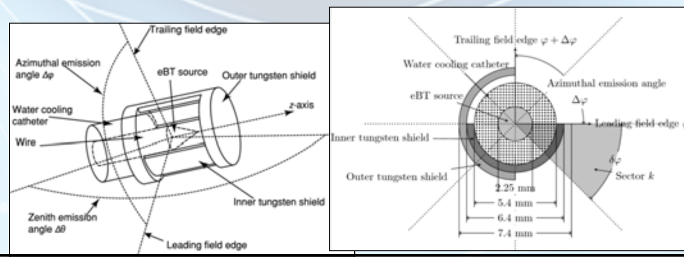
- Emergent role of mid-level providers has been increasing in awareness and utilization in specialty clinics
- PAs can assist in improving patient treatment flow, provider workflow, and overall patient care and patient experience
- PAs can be cost effective and time efficient for Radiation Oncology departments
- PAs can help fill the deficit of increasing demand for experienced providers for brachytherapy procedures
- PAs can be an integral part of implementing clinical trials
- In an academic setting, establishing the role of PAs in brachytherapy technology can assist with resident training

Conclusions: HDR-IORT

- Proper planning, resources, and multidisciplinary collaboration needed
- Infrequent utilization of IORT is likely due to lack of awareness, physician experience, and access
- Additional programs will likely increase the likelihood of durable local control for patients with advanced or recurrent tumors

New Directions

- Novel chemotherapy or targeted agents
- Combination of SBRT/SABR and HDR-IORT
- Amifostine and HDR *Small et al. Int J Gynecol Cancer 2011*
  - RTOG 0116: cisplatin, amifostine, EBRT, IORT in cervical cancer
- Dynamic rotating shield HDR-IORT *Liu et al. Med Phys 2013*
  - Can boost tumor while minimizing toxicity
  - Less invasive plans with better dose distribution



Collaboration: Thank You

- During implementation:
  - H. Malhotra, PhD, M. Podgorsak, PhD and W. Jaggernauth, MD
  - Roswell Park Cancer Institute
  - Mayo Scottsdale/Len Gunderson, MD
- Johns Hopkins Radiation Oncologists/Physics
  - Drs. Herman, Frassica, Zellars, Asrari, Wharam
  - Woody Armour, Yi Le
- Johns Hopkins Surgeons
  - Drs. Ahuja, Gearhart, Terezakis, Pawlik, Efron, Weber, Eckhauser, etc. (22 total)
- Johns Hopkins Anesthesia
  - Drs. L. Mark, Rodriguez-Paz, Pronovost

Thank You!