HDR Brachytherapy: Interstitial Treatments for GYN Panel Discussion*

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*This session qualifies for SAM credits.

Disclosures

H. Al-Hallaq: None

J. Prisciandaro:

- Non-clinical evaluation agreement (Varian Brachytherapy)

J. Zoberi:

- Advisory Board (Varian Brachytherapy)
- Stock in publicly traded entities (Varian, Viewray)

Learning Objectives

- Describe the treatment and planning workflow for interstitial HDR brachytherapy for gynecologic (GYN) malignancies
- Discuss the role of 3D imaging including CT and MRI for interstitial HDR planning
- Describe the selection/optimization of applicator geometry
- Compare/contrast the use of standard loading to dosimetric optimization for plan development
- Understand the impact of increasing complexity on QA and safety

Outline

- Introduction
- Panel discussion
- Conclusions

Reminder: To obtain SAM credit, please answer questions online.

Introduction

Clinical Motivation

- "Statement of consensus of the authors….[but] the suggested dose and fractionation schemes have not been thoroughly tested."
- "Variations in approaches to interstitial brachytherapy, as with most medical procedures, are commonplace and may readily fall within accepted and appropriate management of these patients with vaginal cancers."
- Panel discussion is intended to share the experience and practices of three institutions

S. Beriwel *et al.*, Brachytherapy 2012, 11:68-75

Question 1 (HA)

Describe your institution's workflow and timeline on day of HDR implant and subsequent treatment days.

HDR Brachy for GYN Workflow

Redesign of process map to increase efficiency: Reducing procedure time in cervical cancer brachytherapy

Antonio L. Damato*, Larissa J. Lee, Mandar S. Bhagwat, Ivan Buzurovic, Robert A. Cormack, Susan Finucane, Jorgen L. Hansen, Desmond A. O'Farrell, Alecia Offiong, Una Randall, Scott Friesen, Akila N. Viswanathan

Department of Radiation Oncology, Dana-Farber Cancer Institute, Brigham and Women's Hospital, Boston, MA

Table 1
List of tasks in a cervical cancer brachytherapy treatment

Task no.	Task	Personnel	Resources	Prerequisite task no.
1	Preprocedure evaluation	AU, RN, anesthesia	Laboratory work, patient chart	None
2	Preinsertion preparations	AU, RN, RT, TA	Brachy suite	1
3	Applicator insertion	AU, RN, RT, TA	Brachy suite, applicator, ultrasound	2
4	Imaging	AU, RT, AMP	Brachy suite, CT scanner	3
5	Contouring	AU	TPS	3, 4
6	Standard plan	AMP	TPS	3
7	Prior radiation EQD2	AMP, AU	EQD2 spreadsheet, prior dose information	None
8	Plan optimization	AU, AMP	TPS, EQD2 spreadsheet	5, 6, 7
9	QA preparation	AMP	TPS, R&V	8
10	Independent check	AMP (not same as for Tasks 6–9)	Secondary calculation software, TPS, R&V	9
11	Treatment	AU, AMP, RT	Brachy suite, TCS, plan printout	10
12	Post-treatment	AU, RN, TA	Brachy suite	11

AU = authorized user; RN = registered nurse; RT = radiation therapist; TA = technical assistant; Brachy = brachytherapy; AMP = authorized medical physicist; TPS = treatment planning system; EQD2 = equivalent dose in 2 Gy fractions; R&V = record & verify; TCS = treatment console system.

For each task, the personnel, resources, and prerequisite tasks needed to perform that task are listed. Anesthesia personnel remain with the patient throughout all the tasks.

HDR Brachy for GYN Workflow

- Contouring & planning in *parallel*
- Complete EQD2 worksheets prior to day of implant
- "Independent check… separated into subtasks to be performed/documented at different phases of the process"
- Planning time = 88±19 min (pre-optimization)
- Planning time = 63±16 min (post-optimization)
- *Reduction in planning time = 25 min* (29%) ($p<0.01$)

A.L. Damato *et al.*, Brachytherapy 2015, 14:471-480

HDR Brachy for GYN Workflow

Implant time and process efficiency for CT-guided high-dose-rate brachytherapy for cervical cancer

Jyoti Mayadev[1,*], Lihong Qi[2], Susan Lentz[1], Stanley Benedict[1], Jean Courquin[1], Sonja Dieterich[1], Mathew Mathai[1], Robin Stern[1], Richard Valicenti[1]
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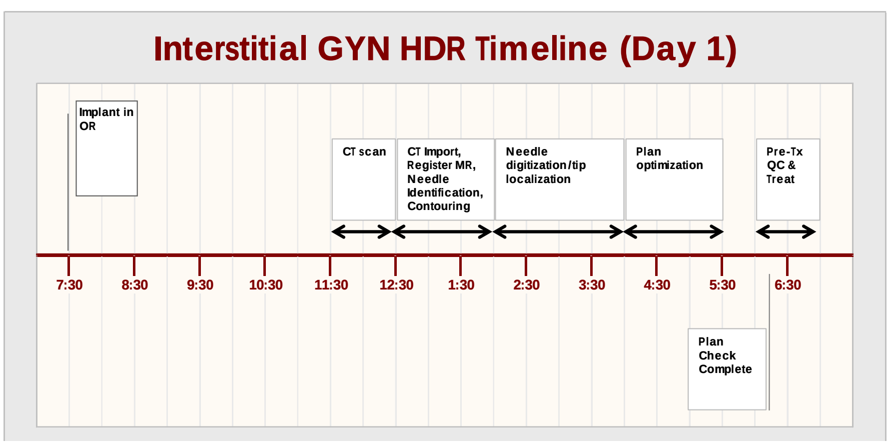
[2]Division of Biostatistics, Department of Public Health Sciences, School of Medicine, University of California Davis, Davis, CA

- "Patient preoperative evaluation, the use of an anesthetic, applicator placement, image acquisition, dosimetric planning time, patient transfers, treatment delivery, applicator removal, and patient recovery… must be skillfully coordinated to ensure that the patient is treated in a safe and efficient manner."

Workflow at U of C

Workflow Overview	University of Chicago
Location of implant	Operating room (OR)
3D imaging modality for simulation	CT scan (pre-implant MRI is registered)
Number of applicators implanted	> 20 titanium needles + tandem
Number of applicators loaded	~ 16 titanium needles + tandem
Number of fractions/implants	5 fractions in 1 implant (75%) 6 fractions in 2 implants (25%)
Location of HDR afterloader	LINAC vault
Planning strategy	3D with volume optimization
Do you parallelize any tasks?	Yes (contouring, needle digitization & check, EQD2 worksheet, MRI import)
Physics FTE allotment	2 FTE on initial day; 1 FTE on subsequent days
EQD2 worksheet use during planning?	Yes
Use of virtual plans or “pre-plans”?	Yes CT-based to plan needle loading & retraction
Re-planning/re-imaging?	No, needles adjusted to match plan prior to treatment

Timeline at U of C



Currently: implant and treat fraction 1 on day 1
Treat BID day 2 and 3
Removed immediately following fraction 5 in hospital room

Workflow at U of M

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Workflow Overview	University of Michigan
Location of implant	Operating room (OR)
3D imaging modality for simulation	CT and MR scans
Number of applicators implanted	~ 13 plastic needles (range 6 – 24)
Number of applicators loaded	~ 11 plastic needles
Number of fractions/implants	3 - 4 fractions in 1 implant
Location of HDR afterloader	HDR suite
Planning strategy	3D with volume optimization
Do you parallelize any tasks?	No, with exception of EQD2 worksheet
Physics FTE allotment	2 FTE on initial & subsequent days (1 MP, 1 dosimetrist)
EQD2 worksheet use during planning?	Yes
Use of virtual plans or "pre-plans"?	No
Re-planning/re-imaging?	Yes if needles deviate by > 3 mm

Timeline at U of M

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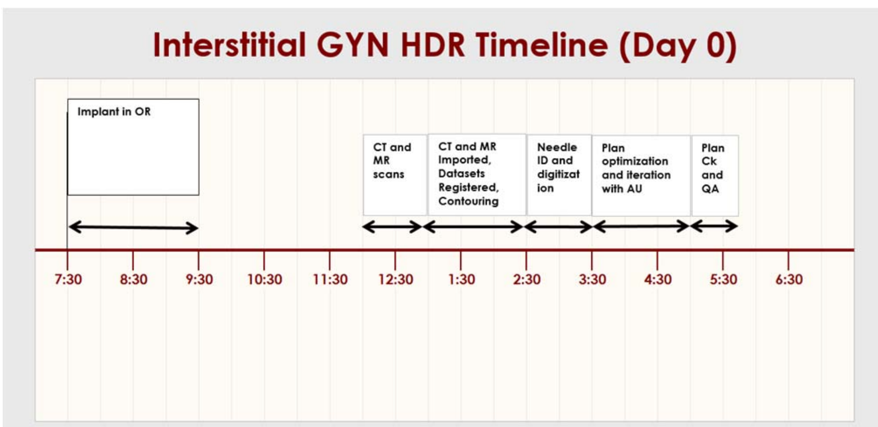


Currently: implant and plan day 0
Treat BID day 1 and 2
Removed immediately following fraction 3 or 4 in HDR suite

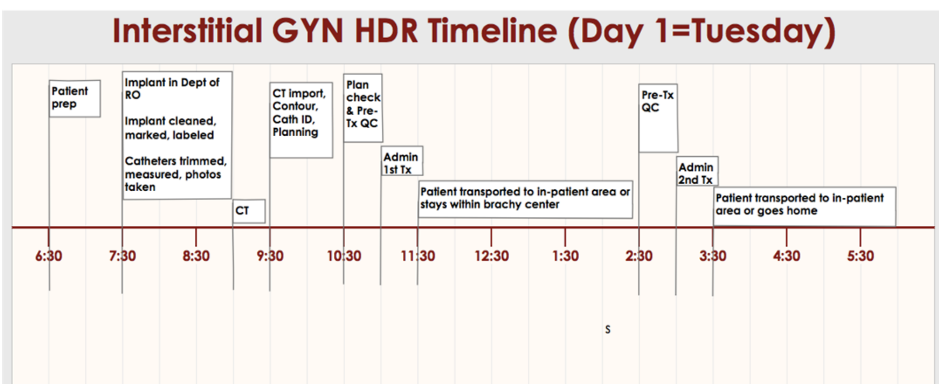
Workflow at WUSM

Washington University in St. Louis
School of Medicine

Workflow Overview	Washington University
Location of implant	Dept. of RO (HDR suite or procedure room)
3D imaging modality for simulation	CT scan (may occasionally acquire MRI, too)
Number of applicators implanted	8-18 6-French plastic needles in VC/grid templates
Number of applicators loaded	All implanted needles
Number of fractions/implants	8 fractions in 1 implant (start T, finish F)
Location of HDR afterloader	HDR brachytherapy vault (2 RAUs with 1 per vault)
Planning strategy	Uniform dwell times to mimic LDR experience
Do you parallelize any tasks?	Occasionally (MRI sim while planning on CT)
Physics FTE allotment	1 AMP (+ 1 CMD) on initial day; 1 AMP on subsequent days for BID treatments
EQD2 worksheet use during planning?	No, not yet
Use of virtual plans or "pre-plans"?	No
Re-planning/re-imaging?	No, needles adjusted to match plan prior to treatment

Timeline at WUSM

Washington University in St. Louis
School of Medicine

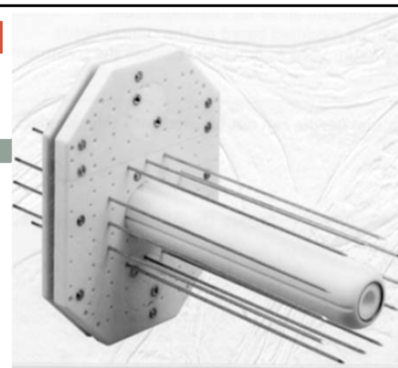


Currently: Treat twice daily T-F (4-6 hours apart)
Implant removed after last treatment on Fridays
Implant 1-2 patients on Tuesdays

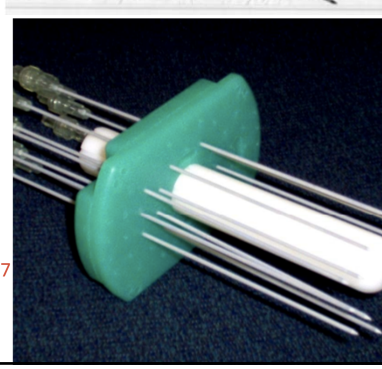
Question 2 (JZ)

What applicators and implant geometry do you use for HDR GYN interstitial brachytherapy?

Background:GYN Interstitial Applicators



- Needles
  - Metal
  - Plastic
- 2 main perineal template types
  - Martinez Universal Perineal Interstitial Template (MUPIT)
  - Syed-Neblett template

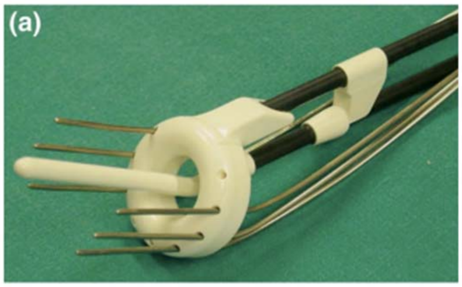


R. Zwicker *et al.*, GEC-ESTRO Handbook of Brachytherapy, Ch 17 (2002)
A. Martinez *et al.*, IJROBP 1984, 10:297-205
A.M.N. Syed *et al.*, Endocurie Hyp Onc 1986; 2:1-13

Background: Hybrid IC + ISI Applicators

Vienna

Venezia



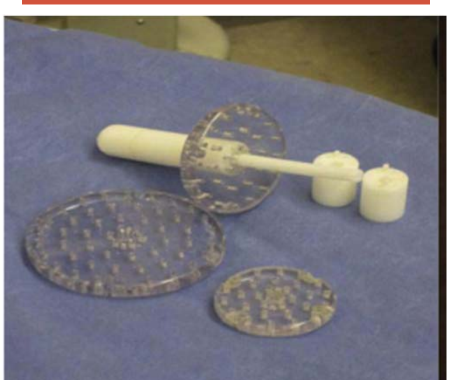
C. Kirisits *et al.*, IJROBP 2006; 65(2):624-630
Wavelength.elekta.com

Background: Custom ISI Applicators

Washington University in St. Louis School of Medicine

"2.5 cm ISI Cylinder": segments with holes drilled in periphery joined to a circular plexiglass template

4x3 vaginal recurrence at mid and distal vaginal wall. 2.5cm ISI Cyl, 13 caths insertion depth 10 cm

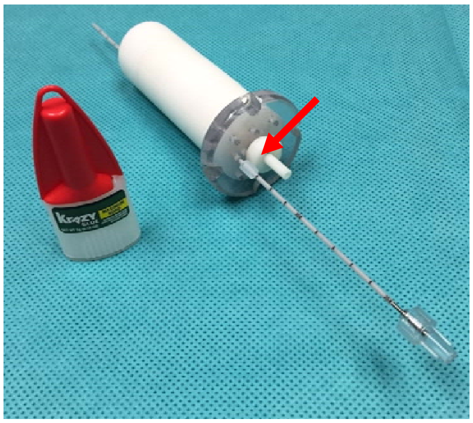


P.T. Dyk *et al.*, Brachytherapy 2015; 14:231-237

Background: Custom ISI Applicators

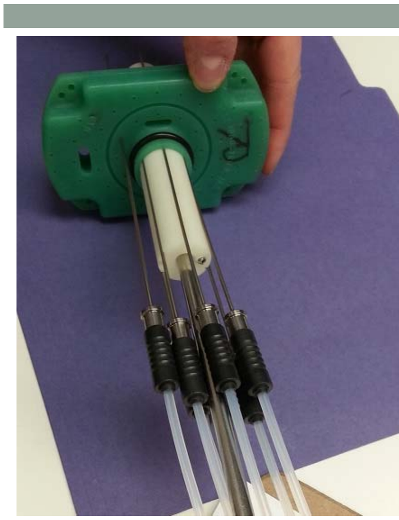
Washington University in St.Louis School of Medicine

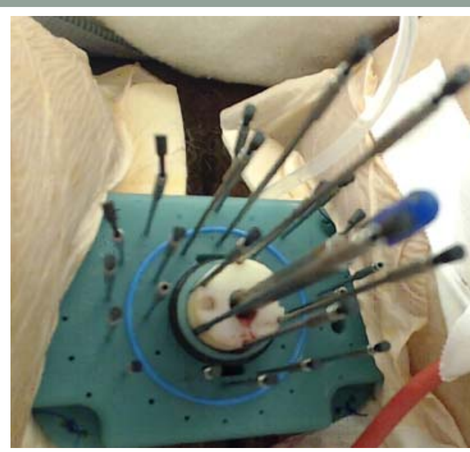
"3x3 square ISI Cylinder": segments with holes drilled in a 3x3 grid, 6-Fr plastic needle w/1 cm markings, and a friction collar



2 cm recurrence at vaginal apex. 3x3 sq ISI cyl, 9 caths, depth of 4 cm sup to cylinder

U of C: Syed-Neblett with Ti Needles & Central Tandem





Patient population: >67% with cervical cancers

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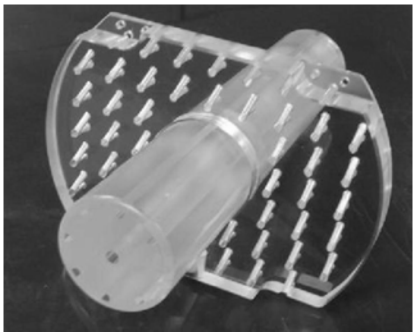
Currently – Custom (template needles can be inserted straight or at an angle of 15°)



Near future (for limited lateral parametrial invasion)

Varian Medical Systems

Patient population: ~ 80% with endometrial cancer

S.B. Johnson *et al.*, JACMP 2014, 15(1):202-212

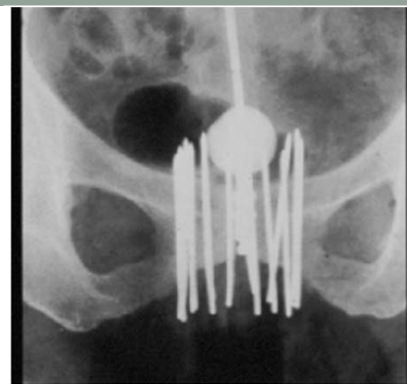
Question 3 (JZ)

How do you optimize the applicator geometry for a particular implant?

Background: Placement Methods and Guidance

Aim: tailor the radiation dose to the patient's anatomy with better target volume coverage

- Free-hand (Ra-226, Co-60)
- Perineal and/or vaginal templates
- Fluoroscopy (Nag et al.)
- CT (Erickson et al.)
- U/S (Stock et al.)
- MRI (Erickson et al.)
- Laparotomy/Laparoscopy (Fokdal et al.)
- → Improved needle placement accuracy



GEC-ESTRO Handbook of Brachytherapy, Ch 17, 2002.

WUSM: Placement of Applicators

Washington University in St.Louis School of Medicine

RO performs implant in Brachytherapy Suite:

- Assisted by OR-trained nurses and RTTs dedicated to Brachy
- Pelvic EUA to evaluate disease extent
- Fiducial markers placed at the superior and inferior extents of the visible or palpable tumor for reference on CT imaging
- No **real-time** imaging guidance, but may display **pre-implant images** (e.g., MRI) in room to help reconstruct tumor geometry
- Determine applicator type, needle length, and number of needles
- Needles placed, can use **digital rectal exam guidance**
- **Post-implant CT** reviewed by MD in TPS, determines activation length

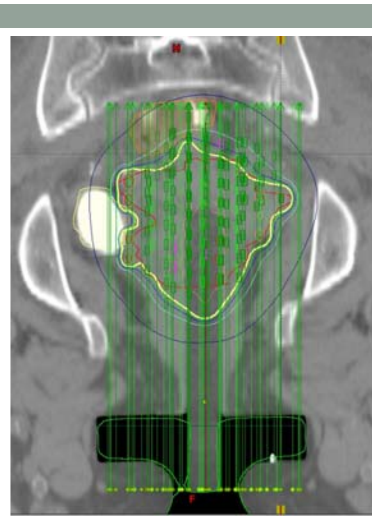
U of M: Placement of Applicators

RO and Gyn Onc performs implant in OR:

- Pelvic exam to evaluate disease extent
- Pre-implant MRI reviewed/displayed in room
- Needles placed, guided manually by DRE and/or US imaging
- On occasion mini-lap is utilized
  - E.g., if lesion is in close proximity or adheres to bowel, patient unable to get MR and unsure of patient's response to EBRT, for intact uterus – uterus extremely retro- or anteverted
- Determine number of needles and length

U of C: Placement of Applicators

- In OR:
  - Pelvic EUA
  - Fiducial markers into tumor (lateral, sup, inf borders)
  - Real-time transabdominal US guidance
  - Digital rectal exam to assess needle positions
  - Use of virtual pre-plan
- Needles adjusted during post-implant CT simulation



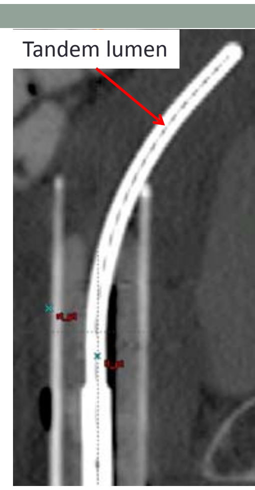
Virtual Plan with Simulated Needles

Question 4 (HA)*

How do you digitize needles/catheters?

Needle Digitization on CT

- “The lumen of the [needle] is well visualised and a markerstring is not always necessary.” -Hellebust
- “Image-based catheter [and needle] digitization suffers from low efficiency and is prone to human errors.” –Wang

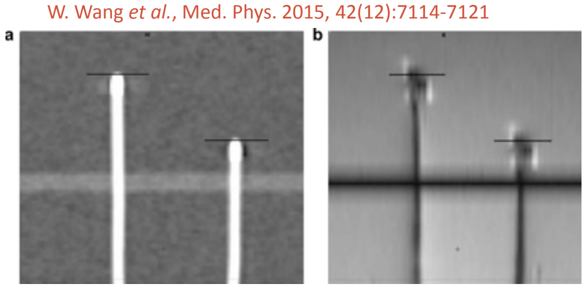


T.P. Hellebust *et al.*, Radiotherapy and Oncology 2010, 96:153–160
W. Wang *et al.*, Med. Phys. 2015, 42(12):7114-7121

Needle Digitization on MRI

- “In MRI-based reconstruction, using conventional clinical MR sequences, the catheter/stylet and metal applicator can only be visualized by susceptibility artifacts.
- The size and shape of the artifacts are not real representations of the catheter/stylet and applicator, and greatly depend on the MR sequence parameter”

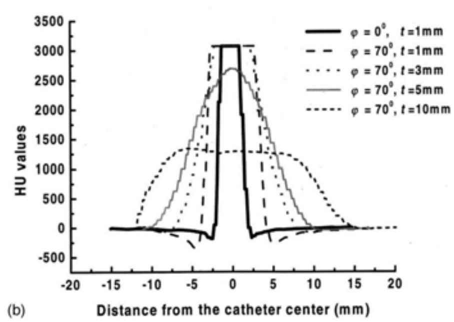
W. Wang *et al.*, Med. Phys. 2015, 42(12):7114-7121



T.P. Hellebust *et al.*, Radiotherapy and Oncology 2010, 96:153–160

Digitization accuracy in CT vs MRI

- “Imaging slice thickness limits digitization accuracy.” #
  - Typically, CT slices thickness < MRI slice thickness
  - CT: Accuracy to < 1mm if slice thickness < 2mm
  - MRI: Accuracy 1-2 mm*

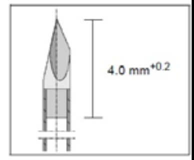


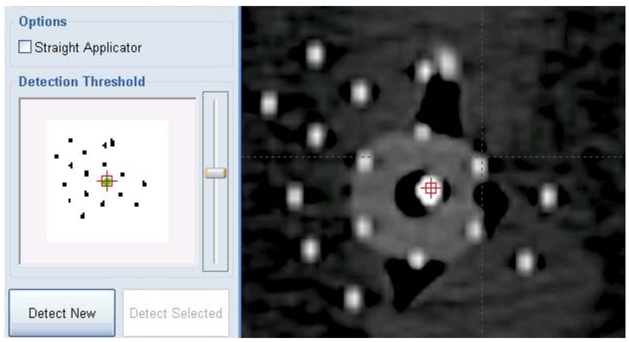
N. Milickovic *et al.*, Med. Phys. 2000, 27(5):1047-1057

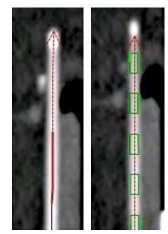
#W. Wang *et al.*, Med. Phys. 2015, 42(12):7114-7121
*A.A.C. de Leeuw *et al.*, Radiotherapy and Oncology 2009, 93:341–346.

Needle Digitization at U of C

- Thresholding-based applicator detection with manual tweaking (~1.5-2 hours for 20-30 needles):
  - Cannot account for the dead space in needle tip
  - Has reduced accuracy when needles cross

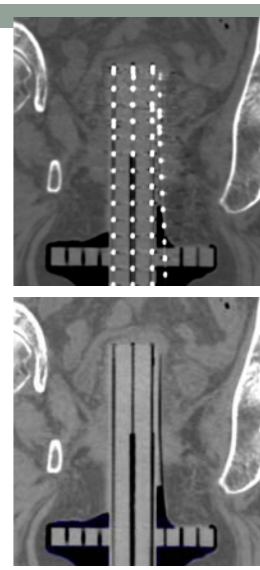






Needle Digitization at U of M

- Two datasets acquired, one with coded x-ray markers and one without
  - Current technique – Needles reconstructed on the dataset with the x-ray marker and needles verified on dataset without markers (~1.5 min/needle)
  - Near future – Transitioning to thresholding-based applicator detection using dataset without markers (~1 min/needle)



Needle Digitization at WUSM

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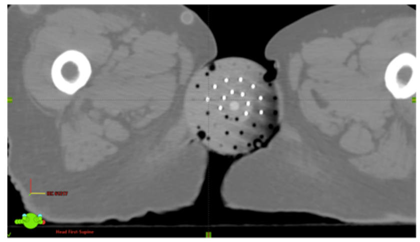
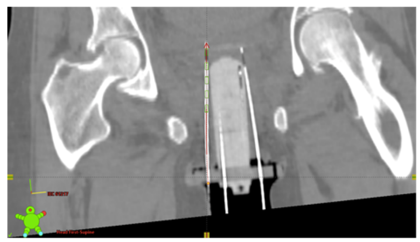
- CT, 2 mm slice thickness
- Al markers (not coded)
- May take another CT w/out some markers
- May use metal artifact reduction
- Markers digitized on CT by CMD (numbering diagrams used for reference) ~ 30 min
- Checked by AMP ~ 15 min





Question 5 (JZ)

With the added capability of customizing isodose distributions via source-stepping technology, what isodose planning strategies do you use for HDR GYN interstitial brachytherapy?

Background: Isodose Planning Strategy per ABS

- ABS 2012 recommends optimizing dose to CTV
  - Defined on CT using fiducials, pre-implant imaging, clinical findings (or on MRI)
- Optimization goals:
  - D90 >= 100% of Rx dose
  - Minimize dose to OARs, track 0.1 cc, 1cc, 2cc of B, R, S, & SB
  - Use GEC-ESTRO WG II recommendations for EQD2 dose limits
  - Review the dwell times – look for really high times
  - Evaluate location of hot spots, e.g., keep 150% isodose around needles
- Can use quality indices, e.g.,
  - conformity index -- between 0.6 and 0.8 (Major et al)
  - HI or dose homogeneity index -- fraction of target receiving between 100% and 150% of Rx dose -- 0.6-0.7

S. Beriwal *et al.*, Brachytherapy 2012, 11(1):68-75.
Potter et al, *Radiotherapy & Oncology.* 2006;78:67-77.

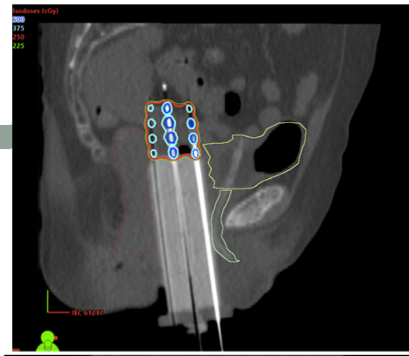
Background: HDR Optimization Techniques

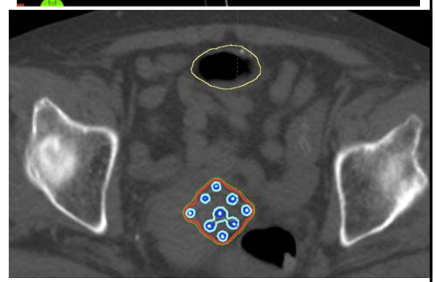
What optimization technique should we use? We have choices:

- Point-based Optimization:
  - Geometric Opt (GO): Source dwell positions used for optimization of dwell weights
  - Dose Point Opt (DPO): Dose points placed at some distance along catheters
- Volume-based Optimization, e.g. IPSA & VO
  - Contour structures, e.g. target, rectum, bladder
  - Input dose-volume constraints into an optimizer
- Manual Optimization, e.g., Graphic Opt & Dose shaper
  - Real-time isodose shaping tools to fine-tune doses, e.g., after GO or VO
  - Can also be applied after use of conventional ISI systems, e.g., Paris system
- ABS: No specific strategy recommended other than **manual isodose shaping**

S.V. Jamema *et al.*, J Med Phys 2014, 39 (3): 197-202

WUSM – Isodose Planning





- No HDR optimization
- Plan mimics LDR implant-based isodose
- Activate dwells: 1 cm spacing, AL based on MD (fiducials)
- Initially set time ~ 1 sec/dwell
- Based on Paterson-Parker system to derive "activity loading" needed to deliver a minimum dose to implant = Rx
- Distribute activity uniformly: Quimby-like, equal linear intensity
- Evaluate coverage of implant = surrogate for target (rarely contour a target)
- Evaluate dose in contact with OARs, size of 150-200% isodoses, track urethra dose.

E.H. Quimby, Am J Roentgenol Rad Ther 1935,33:306-316.
R. Paterson and H.M. Parker HM, Br J Radiol 1938,11:313-339

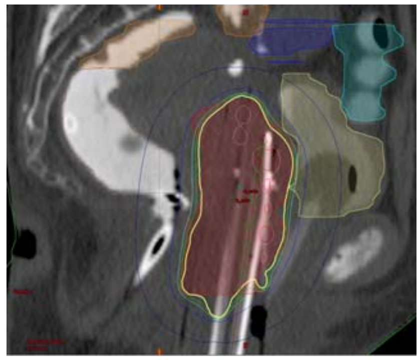
U of M: Volume Optimization with Manual Tweaking

- Post-implant CT and MR simulations acquired and registered
- OAR contoured on CT
- HR-CTV contoured on MR, copied to CT and reviewed/edited on CT
- Initially run volume-based optimization
  - HR-CTV, bladder, rectum, sigmoid, and bowel contoured
  - Dose-volume constraints entered into optimizer
    - CTV 70-85 Gy (EQD2)
    - B D2cc < 80 Gy*
    - R/S/B D2cc < 65 Gy*
- Manually tweak to minimize hot/cold spots in dose distribution & re-evaluate EQD2

* Recently updated based on EMBRACE II: www.embracestudy.dk

U of C: Volume Optimization with Manual Tweaking

- Pare needles to ≤ 20:
  - Eliminate needles (< 1cm or converging)
  - Prioritize peripheral loading to cover target
  - Volume optimization can be used to indicate importance of needle
  - Manual tweaking to reduce hotspots & meet D2cc criteria for OAR



Question 6 (JIP)*

How do you use MRI in the treatment of interstitial GYN cases?

Possible scenarios for integration of MR

- Pre-implant
  - Without the applicator
  - With the applicator
  - Can be used for pre-planning, rough estimation of location of disease during implant/planning, planning with registration to post implant CT
- Planning simulation
  - With CT
  - MR alone

U of M Technique

- Diagnostic MR is acquired in the absence of the applicator.
- Images provide a ball park of estimate of where to target the implant
- Additionally, at time of planning simulation, an MR is acquired along with CT.
  - MR used to define the HR-CTV
  - CT used for applicator reconstruction and delineation of OARs
  - MR and CT are rigidly registered, HR-CTV copied to CT

U of M: Use of MRI

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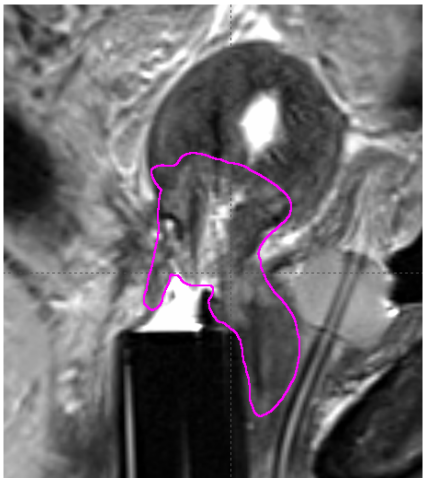

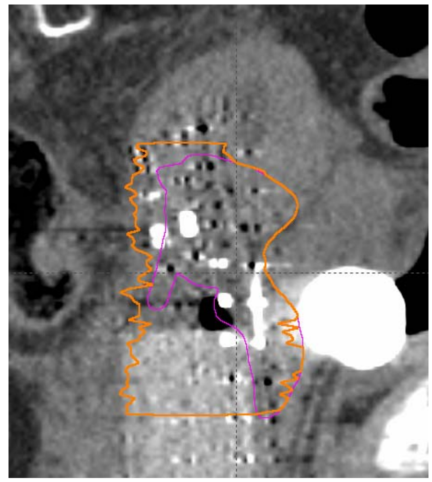

WUSM: Attempts with MRI

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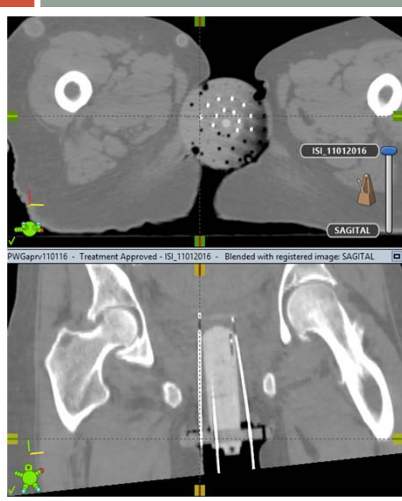
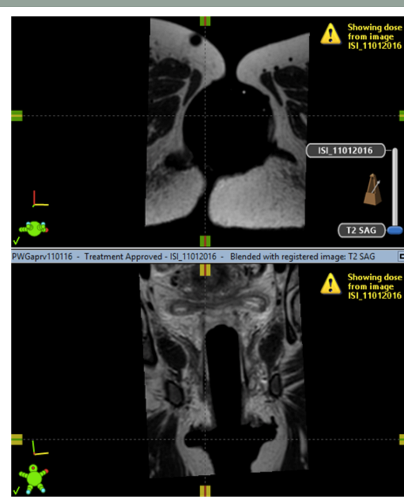
School of Medicine



CT with Al markers



T2W 3D with no markers

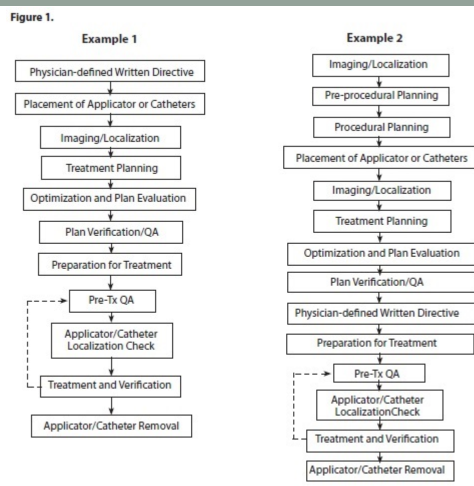
U of C: Use of MRI

- Diagnostic MRI acquired without applicator (within 1 week of implant)
- Rigidly registered to CT scan
- Used to guide delineation of HR-CTV

Question 7 (HA)*

At which points of the workflow do you implement safety checks?

"Checklists and forms can be useful tools in maintaining quality and prevention of errors."



"A generic checklist for HDR brachytherapy is unlikely to prove useful."

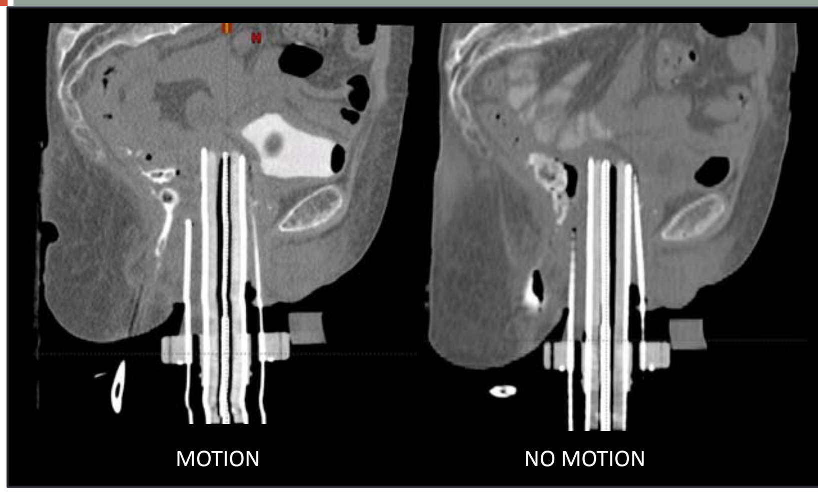
B. Thomadsen *et al*., ASTRO White Paper, PRO Suppl 2014, 4.

Check Timepoints at U of C

Timepoint	**Univ. of Chicago Checks**
Applicator insertion	N/A
Simulation	Use of oral/IV contrast, needle placement, scan parameters, CT image accuracy (*patient motion*)
*Planning**	*Needle identification & tip localization, dose/dwell accuracy*
Physics Plan Check	EQD2 summary, accuracy of dwell positions, dose calculation, documentation
Pre-treatment	Needle retractions, radiation survey
Applicator connection	Applicator + TGT length (n=2), accuracy of connection
Treatment	Delivery accuracy, equipment functionality
Post-Treatment	Rad survey, accuracy/documentation of dose delivery in charts

*Note: no formal checklists but AMP performs dry-run of physics plan check.

Check for Patient Motion During CT sim



Check Timepoints at U of M

Timepoint	Univ. of Michigan Checks
Applicator insertion	Review needle placement, length of needle extending from applicators, stylets in place, and connector end clear of fluid
Simulation	Review needle numbers, lengths, positions (subsequent scans), and integrity, presence of markers, and scan parameters
*Planning**	Needle identification & tip localization, review contours and OAR constraints, perform EQD2 calc
Physics Plan Check	EQD2 summary, accuracy of dwell positions, dose calculation, documentation
Pre-treatment	Needle length, cleanliness, and numbering, patient comfort (AU); plan transfer, rad survey
Treatment	Delivery accuracy, equipment functionality
Post-Treatment	Rad survey, accuracy/documentation of dose delivery in charts

Check Timepoints at WUSM

Washington University in St. Louis School of Medicine

Timepoint	Washington Univ. Checks
Applicator insertion	Post-insertion measurements of catheter lengths (2 sets: CMD/AMP)
CT sim	AMP/RTT: Markers fully inserted, catheters identifiable, scan parameters
Planning	CMD: CT scan ID, MD: implant geometry (needles near OARs, AL)
Physics Plan Check	Correct CT, Rx, contours, catheter digitization, catheter properties, activation length, dwell time entry, isodoses, independent check of total dwell time
Pre-treatment	2 RTTs/AMP: Needle retractions, cleanliness, integrity; patient position; patient ID & site; rad survey. AMP: console plan vs tx plan, accuracy of decay by console
Applicator connection	2 RTTs/AMP: Accuracy & clearance of connection
Treatment	RTT/AMP/AU: T/O, delivery accuracy, equipment functionality
Post-Treatment	RTT/AMP: Rad survey, documentation of treatment record in chart

BJH/WUSM/SCC ISI Medical Physics Consultation

Patient: Patient ID:
Radiation Oncologist: Site: Implant Date: Sim Date:

Drawing of implant here (with patient orientation):

Implant preparation prior to CT-sim:

- ☐ Label catheters
- ☐ Cut catheters (leave about 8-9 cm of catheter exiting from skin)
- ☐ Measure catheters and identify colors of catheters on measurement form
- ☐ Generate drawings of implant (distal ends vs. proximal ends), acquire photos, indicate patient orientation & catheter numbering on photos
- ☐ Attend CT sim
- ☐ Emergency removal considered? If non-standard, discuss with MD

In CT-sim, prior to image acquisition:

- ☐ Decide on patient position (should mimic position for treatment).
- ☐ Verify buttons flush with skin surface
- ☐ Verify markers fully inserted
- ☐ Contact MD for wiring of surface anatomy, if any
- ☐ Acquire CT with "GYN ISI" protocol
- ☐ Set appropriate scan length
- ☐ Verify scan time -- **Have scan acquired using breath-hold, if necessary**

Check of CT images:

- ☐ Check breath-hold on images, if necessary
- ☐ Check markers are visible at distal end of catheters, i.e., inside buttons – sharp bends, obstructions, markers slipped out
- ☐ Check catheters are identifiable on images (metal artifacts obscuring catheters, catheters crossing)
- ☐ Need for repeat scan with certain markers removed?
- ☐ Need for O-MAR?
- ☐ Acquire photographs of implant.
- ☐ Correct CT scan exported for planning? CT study no./no. of images __________ / _______

Description of Medical Physics Consult: **(1) CT Sim**: Assists the MD by preparing implant for imaging, and then evaluating adequacy of images for planning. **(2) Performs catheter length measurements** (see measurement sheets). **(3) Treatment Planning:** Assists MD and Dosimetry in plan generation and optimization; performs plan QA checks. **(4) Performs an independent calculation check of planned treatment time** (see Paterson-Parker Implant Calc). **(7) Pre-treatment QA**: Assists RTT by verifying treatment connections and treatment setup.

Notes:____

Medical Physicist: ______________________ Date: ______________

Radiation Oncologist: ______________________ Date: ______________

jz edited 09.09.16

Washington University in St. Louis School of Medicine

Use Checklists:

- Ensures all physicists do the "bare minimum" tasks & checks
- Common to many institutions
- Tailor/update these lists based on our individual practice & experience

Question 8 (JIP)*

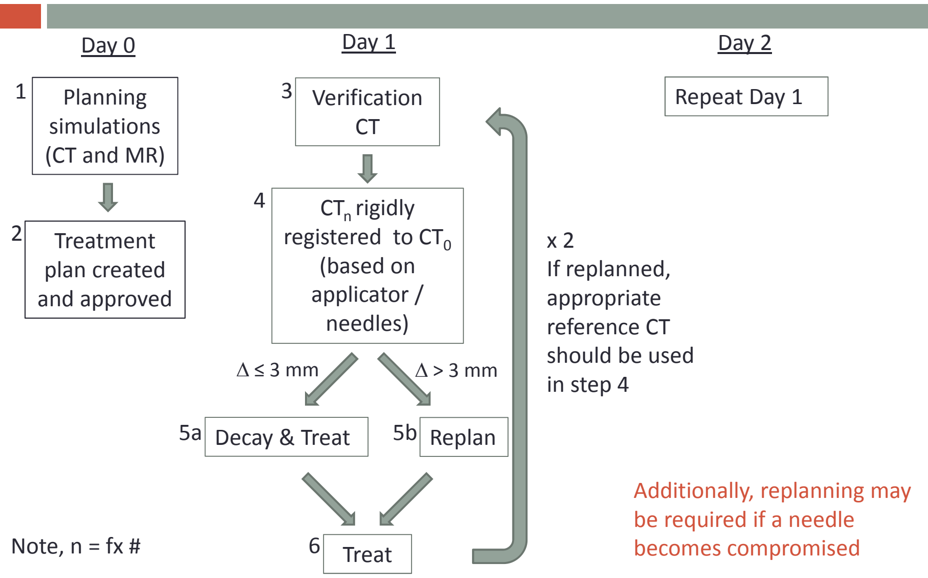
How do you assess reproducibility of implant over multiple fractions?

U of M Technique

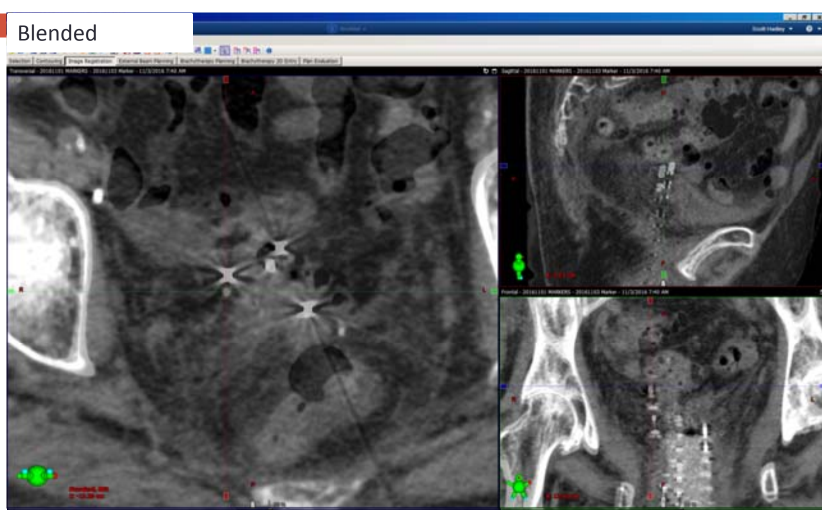
MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

- Typical workflow is for the patient to receive their planning scans on the same day as their implant, but their first fraction is delivered the following day.
- Prior to fraction 1 and each subsequent scan, a verification CT simulation is acquired and rigidly registered to the planning CT based on the cylinder applicator.

U of M Post Implant Workflow

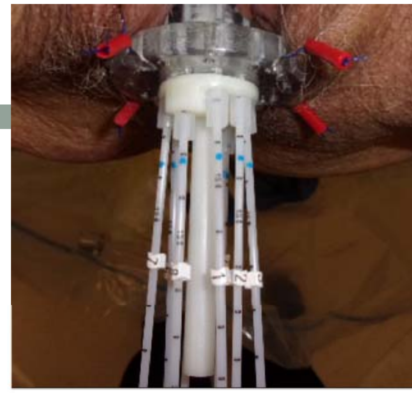


Replanning scenario



It is imperative to communicate with outside staff/departments that are caring for our patients. Signage may not be sufficient!

WUSM: Reproducibility



- Goal: Use same plan with decay correction for all 8 fx
- Fixation at time of implant:
  - Templates sutured in place
  - Plastic needles glued with friction cups against templates by RTTs.
  - Paint pen marks placed by RTTs
- Pre-tx:
  - Check "marks" on catheters
  - Check integrity of implant
  - Have MD adjust, if needed
  - May re-plan, if needed
- Care instructions, U-shaped cushion if out-patient

U of C: Reproducibility

- AU measures needle retraction & verifies marks on needles
- Adjusts if necessary prior to each fraction (~ 1-3mm) to match planned retractions
- Initially, repeat CT was used to assess needle reproducibility over 3 days

Question 9 (JIP)

How can the safety of applicators for use in MRI be assessed?

Concerns Presented by Implanted Applicator

- Tissue damage due to:
  - Movement of the device due to displacement force due to the Bo
  - Torque of the device due to the Bo
  - Vibrations of the device due to gradient fields
  - Heating produced by gradient and RF fields
- Image artifacts

J.G. Delfino and T.O. Woods, Curr Radiol Rep 2016, 4:28

Classification of Passive Implants

- MR unsafe
  - An item that is known to pose hazards in all MRI environments (e.g., magnetic items)
- MR safe
  - An item that poses no known hazards in all MRI environments (e.g., nonconducting, nonmagnetic items) such as a plastic
- MR conditional
  - An item that has demonstrated no known hazards in an MR under specific conditions

T.O. Woods, J Magn Reson Imaging 2007, 26:1186-1189.

Classification of Passive Implants

- Caution - A medical device that is deemed MR Conditional under one environment may not be safe to scan in another. This includes changes in:
  - Field strength
  - Spatial gradient
  - dB/dt (time rate of change of the magnetic field)
  - RF fields
  - Specific absorption rate (SAR)

T.O. Woods, J Magn Reson Imaging 2007, 26:1186-1189.

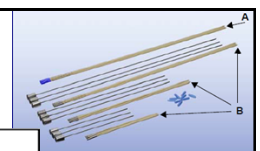
Device Tests to Address Potential Hazards

Hazard	Related Tests	Test Method
Force	Magnetically induced displacement force	ASTM F2052
Torque	Magnetically induced torque	ASTM F2213
Heating	RF field-induced heating	ASTM F2182; ISO TS 10974
	Gradient field-induced heating	ISO TS 10974
Vibration	Gradient field-induced vibration	ISO TS 10974

ASTM International – Founded as the American Society for Testing and Materials
ISO TS - International Organization for Standardization/Technical Specification

J.G. Delfino and T.O. Woods, Curr Radiol Rep 2016, 4:28

Example IFU



Comp... Description	Manual Cleaning	Machine Cleaning	Autoclave	CT	MRI
Plastic needle, ø 2.0 mr	25	25	✓	✓	MR
with mandrin for 113 mr				-	MR
Plastic needle, ø 2.0 mr	25	25	✓	✓	MR
with mandrin for 200 mr				-	MR
Plastic needle, ø 2.0 mr	25	25	✓	✓	MR
with mandrin for 320 mr				-	MR
Plastic needle, ø 2.0 mr blunt tip	25	25	✓	✓	MR
with mandrin for 320 mr				-	MR

MRI Safety Information

MR

Non-clinical testing and MRI simulations were performed to evaluate the Plastic Interstitial Needles. Non-clinical testing demonstrated that the Plastic Interstitial Needles are MR conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla only.
- Maximum spatial gradient magnetic field of 10,000 Gauss/cm (100T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operation Mode of the MR system.
- All stainless steel parts (such as obturators/mandrins, marker wires, length gauges, etc.) must be removed prior to entering the MR environment.

MRI Related Heating

Under the scan conditions defined above, the Plastic Interstitial Needles are expected to produce a maximum temperature rise of less than 1.4° C after 15 minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the Plastic Interstitial Needles extends approximately 5 mm from this device when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.

Varian Medical Systems, IFU – Plastic Interstitial needles, GM11007560-7580, GM11010750

Alternatively…

- If you have a custom applicator or applicator not tested by the vendor:
  - Review and perform ASTM and ISO/TS test specifications
  - Contract with a MR testing lab (e.g., MR:comp, Magnetic Resonance Safety Testing Services)
  - Perform simple tests in-house

U of C In-House Testing

- Titanium needles not rated as MR conditional although vendor is performing tests
- MRI performed in Radiology so discussions with MR physicist and IFU provided to Radiology

Conclusions

Increasing Complexity for Interstitial GYN HDR Procedures

- 3D imaging (CT vs MRI)
  - Placement, planning, verification
  - Use of MRI may require commissioning
- Coordination among team → safety & efficiency
- Safety checks & communication essential during time-constrained procedures
- No one-size-fits-all

Thank you for your attention!