Bolus Electron Conformal Therapy (BECT) Personalized Electron Beam Therapy Using Custom Treatment Devices

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Credited Content

Recognition to the following individuals for providing content/slides used within this presentation

- Dr. Kenneth Hogstrom (MBPCC/LSU)
- Dr. Robert Carver (MBPCC/LSU)
- Mitch Harrison, Nicole Hamm (Adaptiiv)
- Mary Snyder, Ivan Ramos (.decimal)

BECT at Siteman Cancer Center

- 12 Linear Accelerators
- 10 Radiation Oncologists who have used .decimal
- First patient treated in 2010
- Treated 100+ patients
  - Head/face/neck
  - Extremities
  - Back
  - Shoulder
  - Breast/CW scars/Nodes

Outline

I. Fundamentals of Bolus Electron Conformal Therapy

II. Clinical Workflow
  - Simulations
  - Treatment Planning/Ordering
  - Treatment Delivery

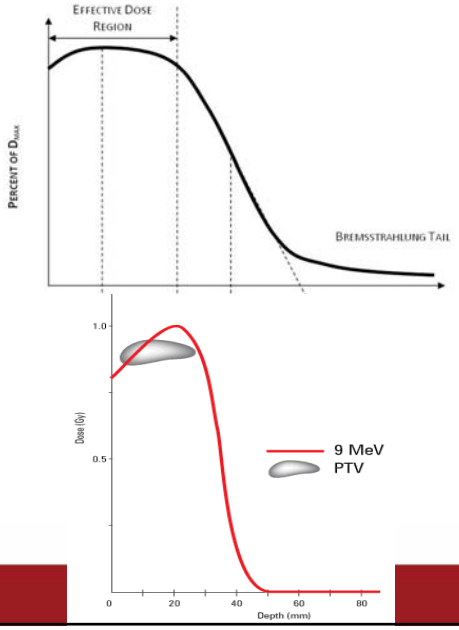
III. Clinical Cases: Nose, Back, Foot

IV. Future – Potential for Intensity Modulation

Standard Electron Therapy

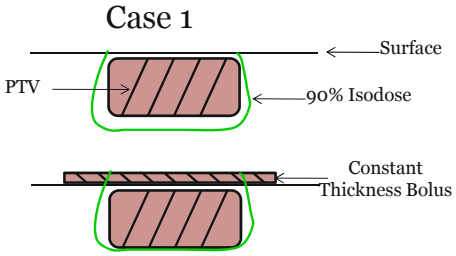
Why use electrons?

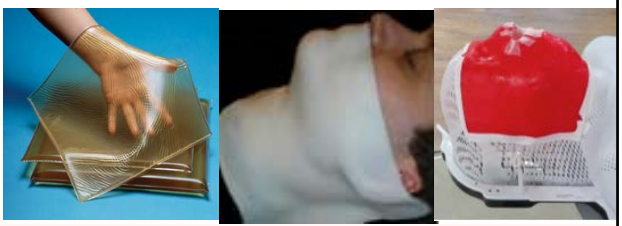
- Optimal for treating superficial tumors (d ≤ 6cm)
- Characteristics of electron dose distribution
  1. 90% - 100% dose spread (d <R_{90})
     - Uniform dose to Planning Target Volume (PTV)
  2. Sharp distal fall off (R_{90}-R_{10})
  3. Finite penetration depth (R_p)
     - Limited dose to critical structures distal to PTV



Standard Electron Therapy

- Objective:
  - Conform 90% isodose surface to distal PTV surface.
- Case 1: Uniform Thickness Bolus
  - Issue: R_{90} > d_{PTV}
  - Decreases depth of R90
  - Increases skin dose
  - SuperFlab, Aquaplast, red wax, wet gauze

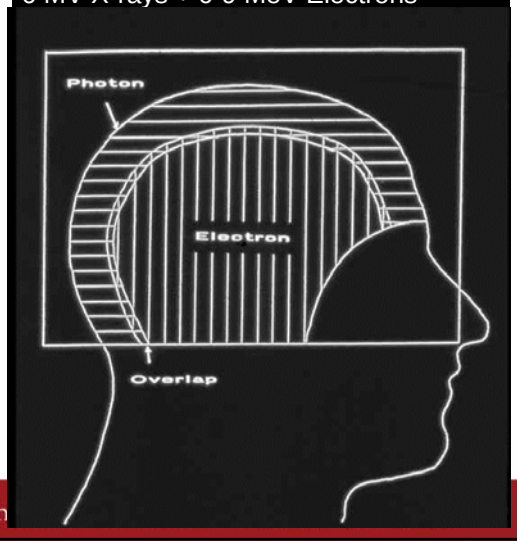




Bolus Electron Conformal Therapy

Total Scalp Irradiation
Electron+X-ray Technique (Tung et al 1995)

6 MV X-rays + 6-9 MeV Electrons

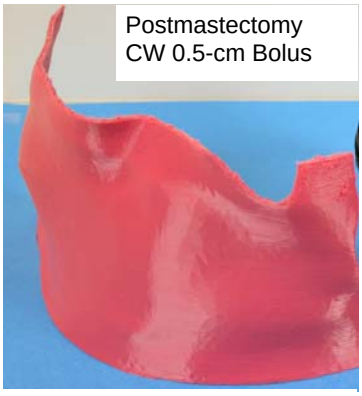


0.6-cm Bee's Wax Bolus
Manually Constructed

Constant Thickness Bolus

- Useful for MV x-ray & electron beam dose buildup

Postmastectomy
CW 0.5-cm Bolus



3D Printed PLA
Courtesy of James Robar

Reconstructed Breast
(Lee and Archer)

Partial Scalp irradiation
(Szal & Purdon)

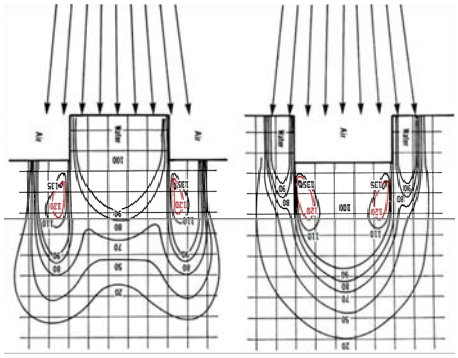
.decimal Machineable Wax
http://dotdecimal.com/products/photons/uniform-thickness-bolus/

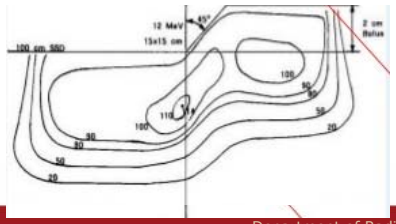
Bolus Electron Conformal Therapy

Standard Electron Therapy

Common Challenges

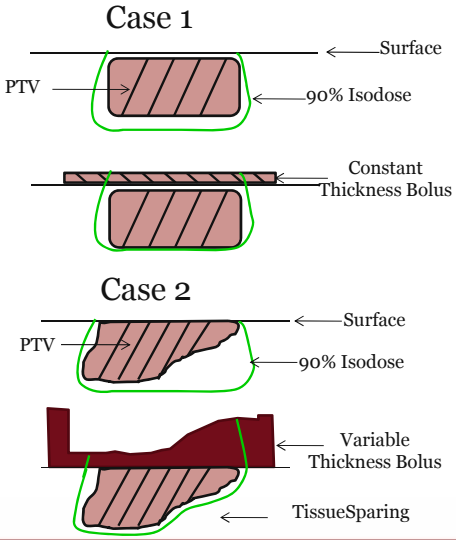
- Surface Irregularities
  - Create hot/cold spots
- Variable depth target volumes
  - Healthy tissue/OARs distal to shallow PTV treated to prescription dose
- Sloping surface creates oblique angle of incidence





Standard Electron Therapy

- Objective:
  - Conform 90% isodose surface to distal PTV surface.
- Case 1: Uniform Thickness Bolus
  - Issue: $R_{90} > d_{PTV}$
- Case 2: Variable Thickness Bolus
  - Issue: Variable d_{PTV}
  - Vary bolus thickness off-axis
  - Conform therapeutic range to distal surface of PTV

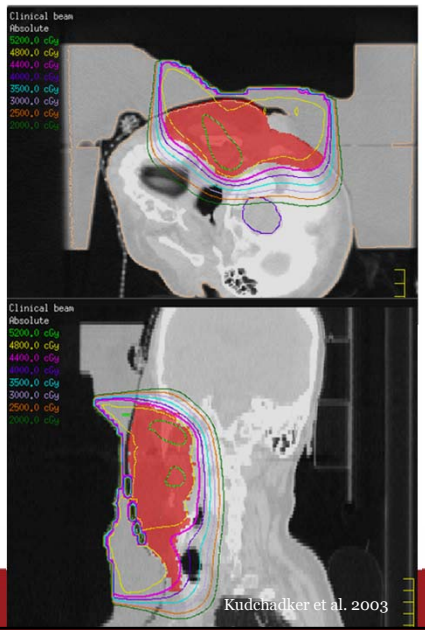


Bolus Electron Conformal Therapy

Bolus Electron Conformal Therapy (BECT)

BECT Definition: Use of a single electron beam with a variable thickness bolus designed to:

- shape the distal 90% dose surface to conform and contain the PTV,
- deliver minimal dose to adjacent (underlying) normal tissues, and
- achieve as homogeneous dose distribution as possible to the PTV.



Kudchadker et al. 2003

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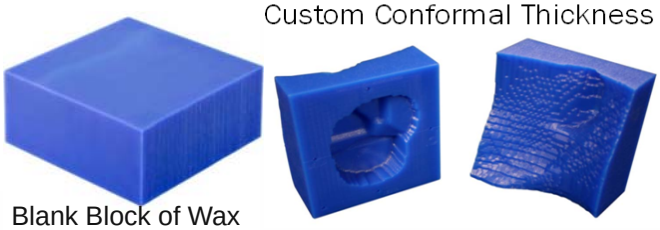
Bolus Electron Conformal Therapy (BECT)

.decimal

- Established commercial BECT product (2009)
- Creates bolus using milling techniques
- Design process utilizes work by Low et. al from MD Anderson developed in 1992
- Blue machinable wax milled to create custom bolus
  - Density = 0.92 g/cc
  - Conforms to patient surface

Custom Conformal Thickness



Blank Block of Wax

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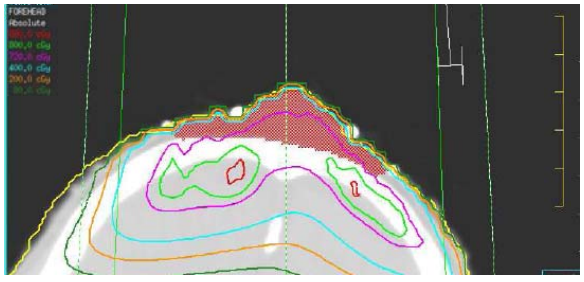
Bolus Electron Conformal Therapy (BECT)

Adaptiiv (formally 3D Bolus)

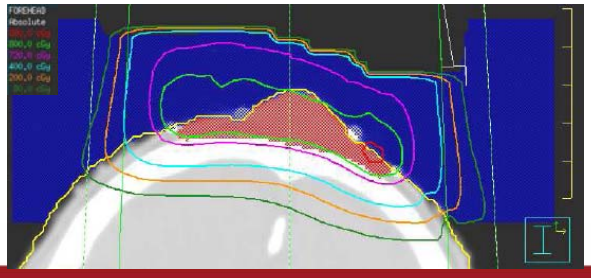
- Established commercial product (2016), 510(k) cleared July 18th
- Creates bolus via additive 3D printing techniques
- Custom software that generates a STL file to be locally printed
- Various filament materials
  - Polylactic Acid (PLA): primary recommended
  - Thermoplastic polyurethane (TPU) Under evaluation

Terminology

- Plan Characteristics
  - 9 MeV electron beam
  - Rx: 800 cGy to 90% IDL
  - Goal: Spare healthy brain tissue



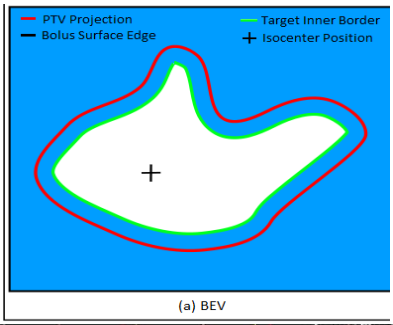
- Bolus Characteristics:
  - Distal bolus surface conforms to patient surface
  - Proximal surface shapes dose distribution.

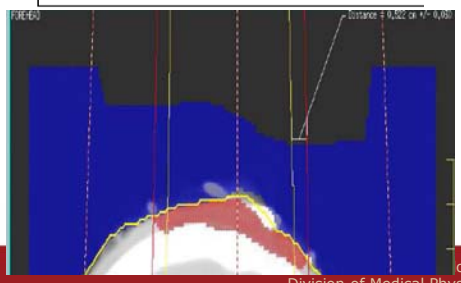


.decimal Terminology

Bolus Regions/Margins

- Modulated region
  - Bolus thickness milled to shape isodose to target
- Inner Bolus Margin
  - User specified distance in from target edge towards CAX.
  - Flat extension of modulated surface
  - Minimizes effect of rapid reduction of target thickness
  - Typically ~ 5mm

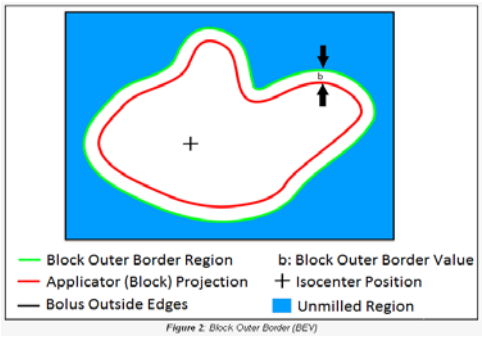


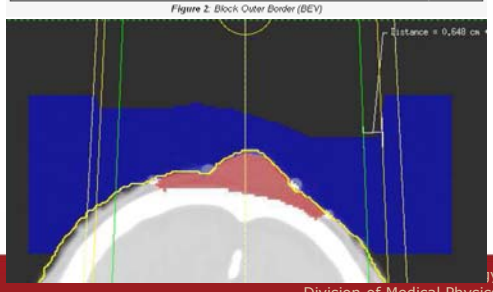


.decimal Terminology

Bolus Regions/Margins

- Outer Bolus Margin
  - User specified extension of milled surface out from block edge
  - Allows for minor modifications of block after verification simulation
  - Typically 1cm – 1.5cm
- Unmilled Margin
  - Flat outer border
  - Provides structure and aids in daily setup





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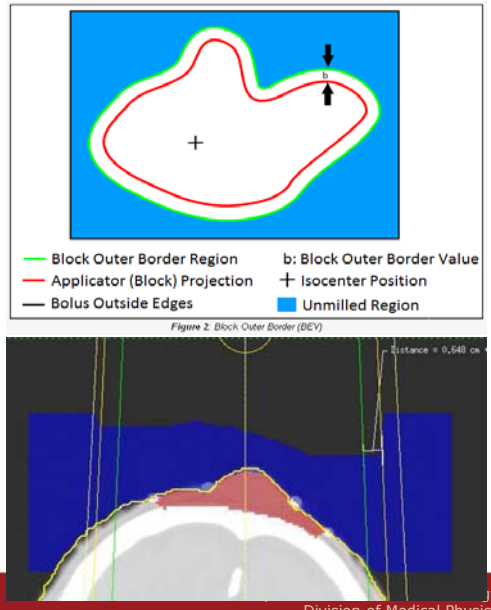
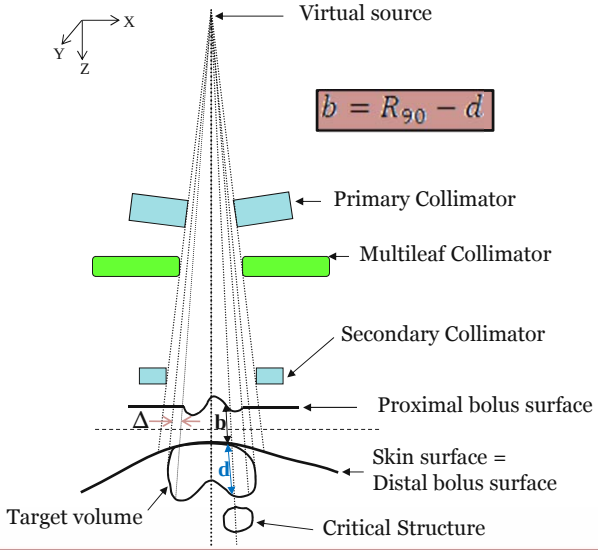


Figure 2: Block Outer Border (BEV)

Design Operators

- Uses a series of design operators (Low et al. 1992)
  1. Creation Operators
  2. Modification Operators
  3. Extension Operators

1. Creation Operator
   - Defines initial bolus thickness (b)
   - Dependent on target depth along rayline from target



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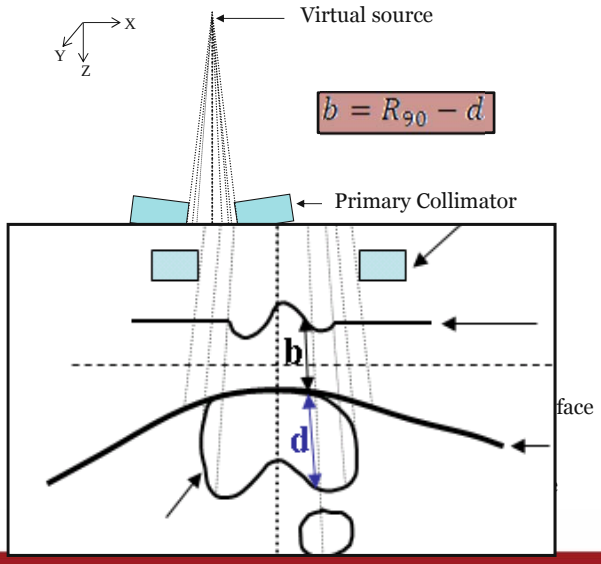

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Design Operators

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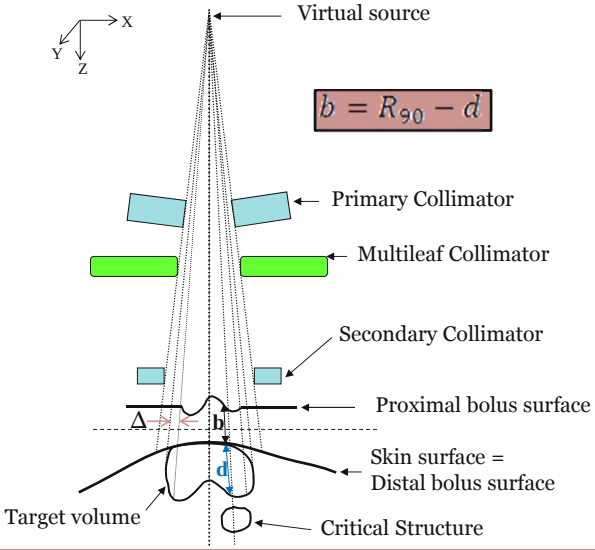
  1. Creation Operators
  2. Modification Operators
  3. Extension Operators

1. Modification Operators
   1. Smoothing bolus
   2. Adding/removing specified bolus thickness (b_i)



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Outline

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II. Bolus Electron Conformal Therapy Clinical Workflow

- Simulations
- Treatment Planning/Ordering
- Treatment Delivery

III. Clinical Cases: Nose, Back, Foot

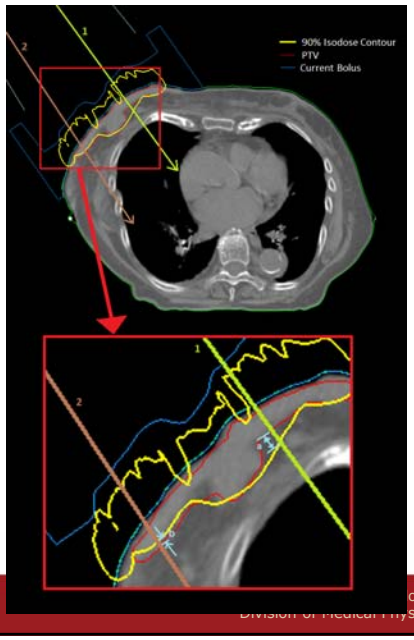
IV. Future – Potential for Intensity Modulation

General Clinical Workflow

- Patient consult (Ideally includes physicist for evaluation)
- Initial CT simulation (Day 1)
- Initial treatment planning (Day 2 – 5)
  - Multi-modality fusions
  - Contour creation
  - Beam selection
  - Virtual bolus creation
- Bolus fabrication and shipping (Day 5 – 7)
- Verification simulation (Day 8)
- Final treatment planning (Day 8 – 10)
- First treatment fraction (Day 10)

Selection Criteria

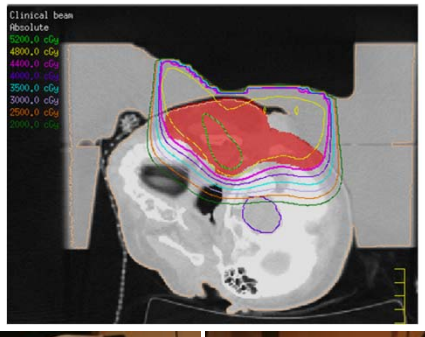
- Target volume depth less than 6cm
- Target volume depth varies throughout the field
  - Uniform thickness bolus not sufficient
- Critical structures distal to target volume
  - Modulation necessary to reduce dose to critical structure
- Patient skin surface has significant variation or defects
  - Bolus ECT can minimize hot/cold spots

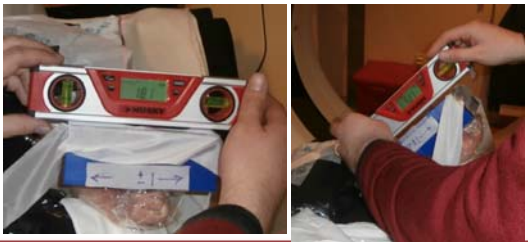


Initial Patient CT Simulation (Day 1)

Patient setup

- Physician present to delineate treatment volume
  - Typically wires skin
- Oriented to maximize bolus stability
  - Gantry angle close to AP (0° ± 20°)
- Consider and minimize possible collision of patient anatomy with applicator
  - Shoulder issues when treating neck
  - Couch table when treating extremities





Bolus Electron Conformal Therapy

Initial Patient CT Simulation (Day 1)

Immobilization devices

- Dependent upon treatment site
- Mask used for head and neck treatments
  - Cutout mask 1 cm beyond delineated treatment volume
  - If using eye shields, remove mask above eyes
- Alpha cradle/vac loc for torso and extremities
  - Important when treating areas that can flex and bend
  - Register other devices with AC if used.

Initial Patient CT Simulation (Day 1)

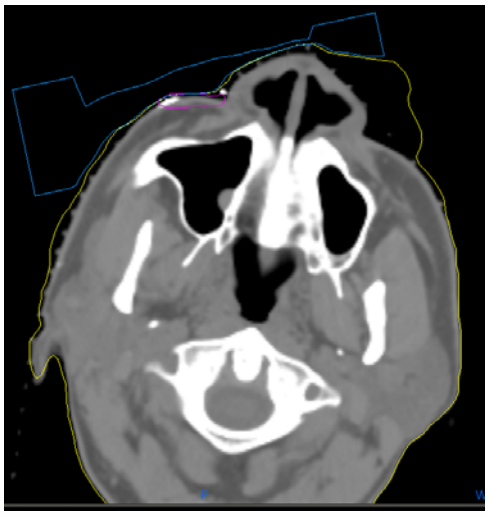
Special Considerations

- Slice thickness
  - Typically 3mm
  - Reduce to 1.5mm for small targets
- Scan length
  - Scan at least 5cm – 7cm beyond treatment volume
  - Especially important for superior or inferior extent of anatomy
- Eye shields
- Ear and nose taped/filled
- Patient marked for alignment
- Many setup images taken

Initial Treatment Planning (Days 2-5)

Contours creation in TPS

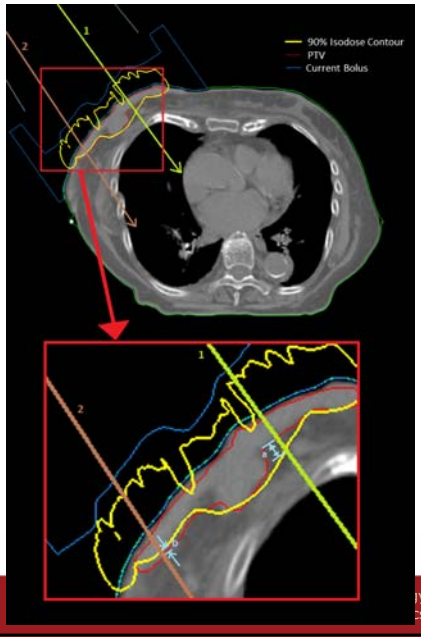
- External contour modifications
  - Includes mask/cradle
  - Extended to allow for breathing and above eyes
  - Smooth to minimize sharp edges
- Wire contour
  - Inside/Outside
  - Override densities
- PTV contour
  - Variations from transverse slice
  - Causes hotspots if not smoothed



Initial Treatment Planning (Days 2-5)

Beam selection in TPS

- Angle should be perpendicular to distal PTV surface
- Determine energy from deepest part of target volume
  - d = deepest target + 3mm
- SSD typically set to 105cm
  - Allows for bolus to clear electron applicator
  - Extended SSD for large targets/clearance
- Transfer plan, structures, and CT to bolus creation software

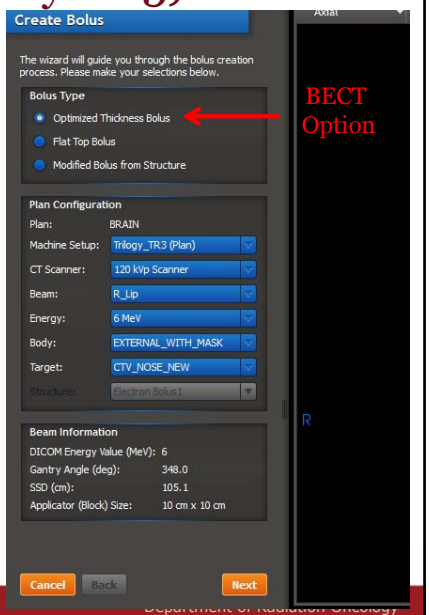


Bolus Electron Conformal Therapy

Initial Treatment Planning (Days 2-5)

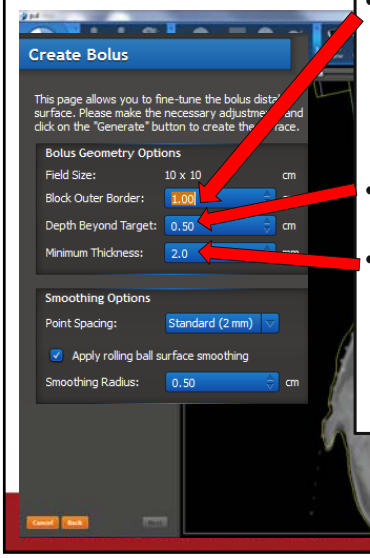
.decimal BolusECT

- Two Step Process (.decimal)
  - Distal bolus surface design
  - Proximal bolus surface design
- For BECT, select "Optimized Thickness Bolus"
- Verify plan configurations parameters and make changes as necessary

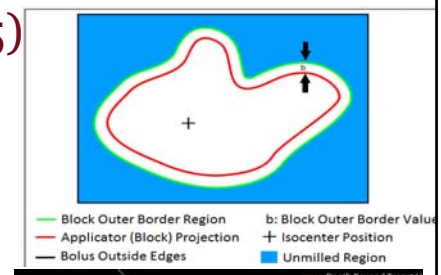


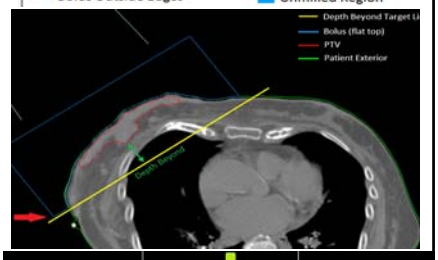
Initial Treatment Planning (Days 2-5)

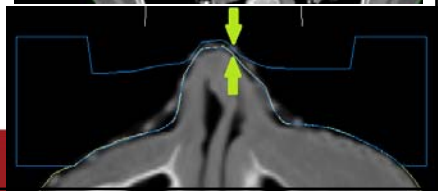
.decimal BolusECT



- Block Outer Border
  - Defaults to 1cm to allow for block modifications
  - Increase for large targets
- Depth Beyond Target
- Minimum Thickness:
  - Minimum allowable thickness of the bolus
  - Measured along a beam aligned ray-line



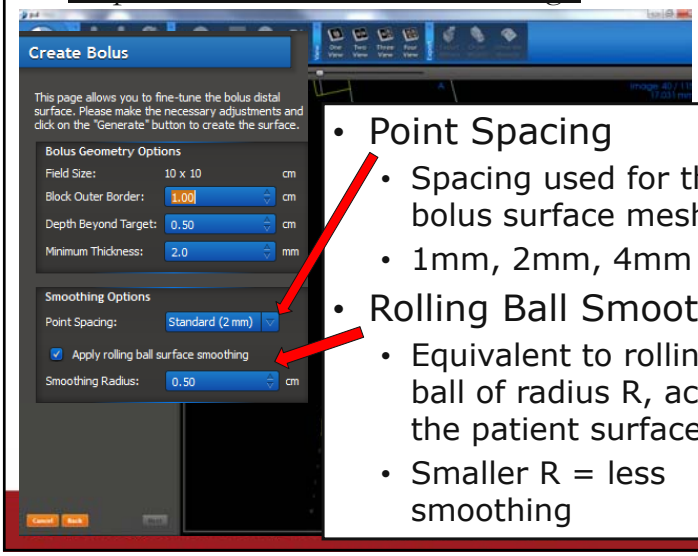




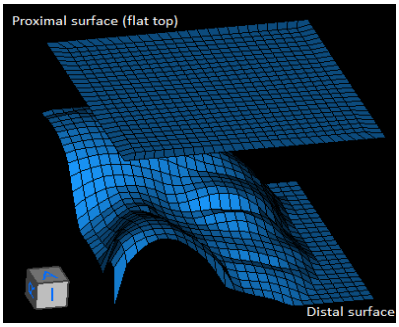
Initial Treatment Planning (Days 2-5)

.decimal BolusECT

Step 1: Distal Bolus Surface Design



- Point Spacing
  - Spacing used for the bolus surface meshes.
  - 1mm, 2mm, 4mm
- Rolling Ball Smoothing
  - Equivalent to rolling a ball of radius R, across the patient surface
  - Smaller R = less smoothing



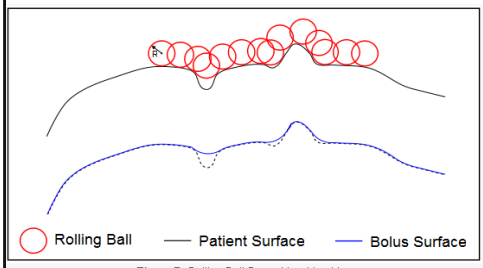
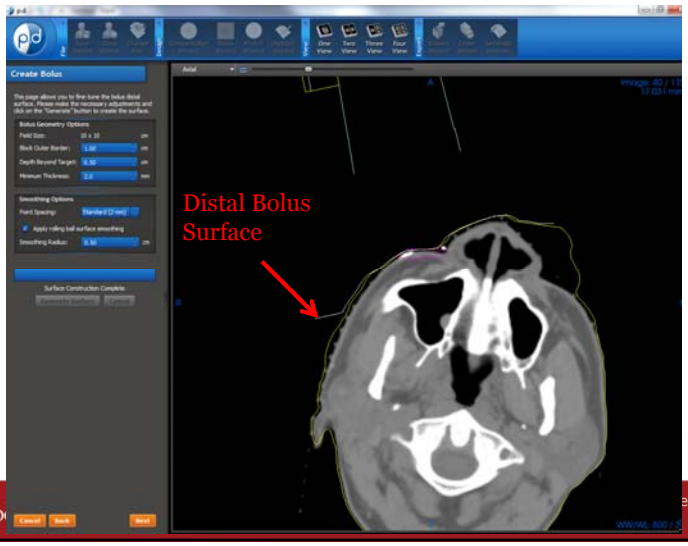


Figure 7: Rolling Ball Smoothing Algorithm

Initial Treatment Planning (Days 2-5)

.decimal BolusECT

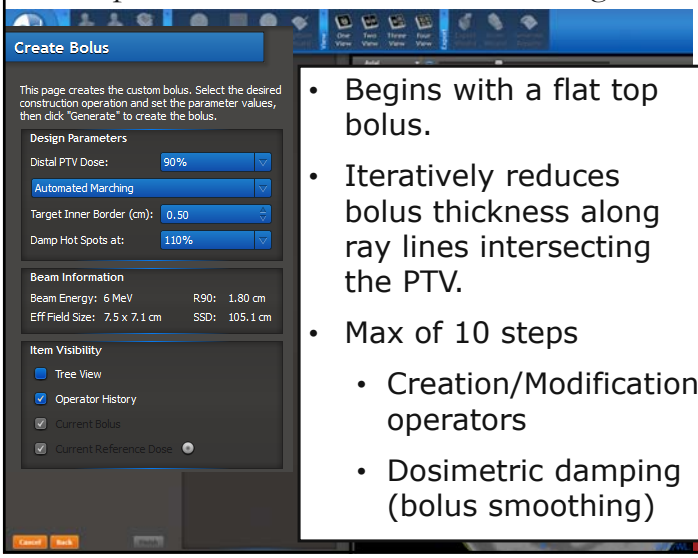
Step 1: Distal Bolus Surface Design



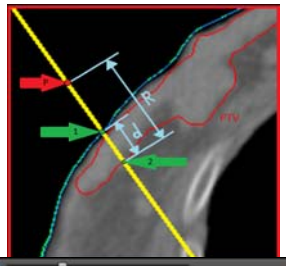
Initial Treatment Planning (Days 2-5)

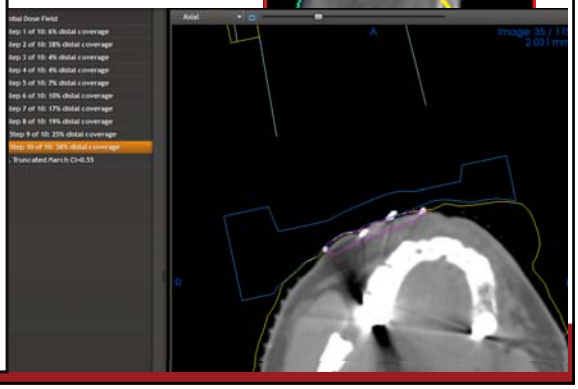
.decimal BolusECT

Step 2: Proximal Bolus Surface Design



- Begins with a flat top bolus.
- Iteratively reduces bolus thickness along ray lines intersecting the PTV.
- Max of 10 steps
  - Creation/Modification operators
  - Dosimetric damping (bolus smoothing)



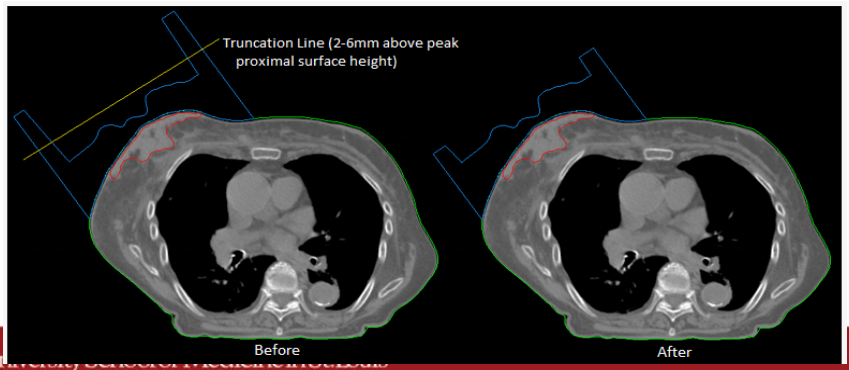


Initial Treatment Planning (Days 2-5)

.decimal BolusECT

Step 2: Proximal Bolus Surface Design

- Truncate Operator
  - Reduces the height of the bolus in the unmilled region.
  - Typically 2 – 6mm above peak proximal surface



Initial Treatment Planning (Days 2-5)

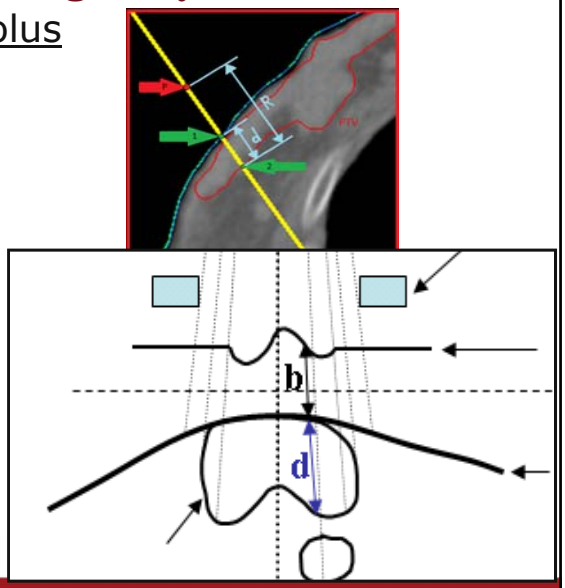
.decimal BolusECT

- P.D dose calculation uses Hogstrom Pencil Beam Redefinition Algorithm
  - Shiu and Hogstrom (1991); Boyd, Hogstrom, Rosen (1998); Boyd, Hogstrom, Starkschall (2001)
  - High degree of accuracy
  - PTV typically under covered at R_{90}
    - p.d reports 30% to 60%
    - Visually examine R_{88}
    - Plan normalization achieves coverage
- Must assess plan quality using clinically commissioned electron dose algorithm

Initial Treatment Planning (Days 2-5)

Adaptiiv 3D Bolus

- Utilizes ray-tracing to determine off-axis bolus thickness
- Incorporates smoothing to minimize localized hot/cold spots
- Smaller bolus to reduce weight, printing time
- Includes modulated surface with margin to extend outside beam



Bolus Electron Conformal Therapy

Initial Treatment Planning (Days 2-5)

Adaptiiv 3D Bolus

Planning Software | 3D Bolus Application | 3D Printer

STEP 1: Create a plan in the TPS

STEP 2: Create a bolus in 3DB software

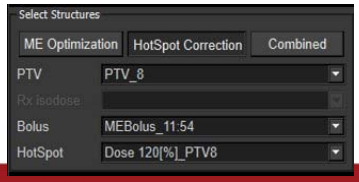
STEP 3: Bolus verification in the TPS

STEP 4: Hot Spot Correction*

STEP 5: Bolus verification in the TPS

STEP 6: Create an STL file in 3DB software

*Adaptiiv's Hotspot Correction is an automated feature and typically requires no more than 1 additional iteration back into the TPS



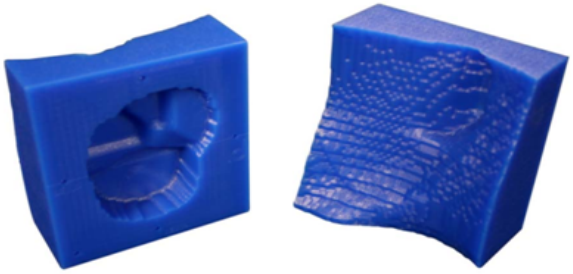
1-4 min
Average time taken to create a modulated bolus in 3D Bolus software

Fabrication and Shipping (Days 5 - 7)

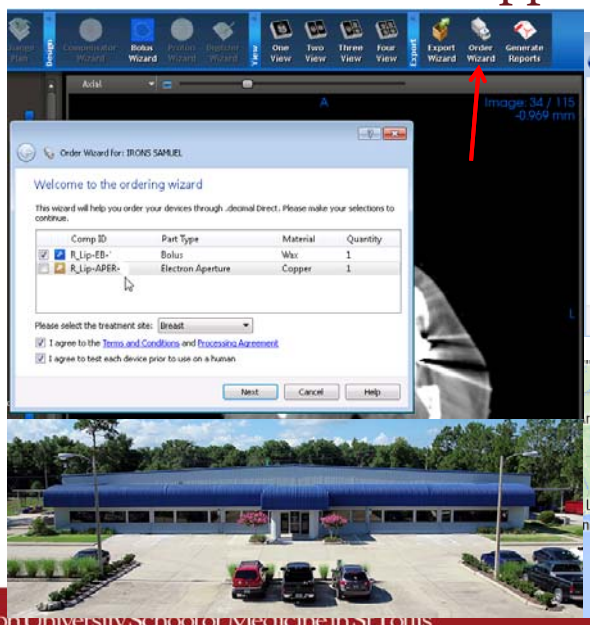
- Bolus fabrication by .decimal, LLC (Sanford, FL)
  - p.d sends bolus file to .decimal for fabrication
  - Bolus milled from machineable wax block (Low et al 1994)
  - Delivery: 1-3 days

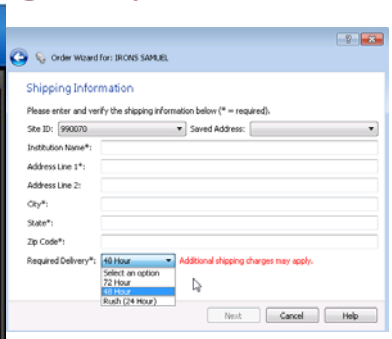
Blank Block of Wax

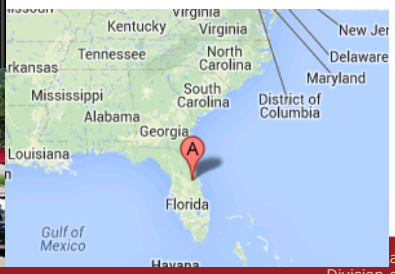
Custom Conformal Thickness



Fabrication and Shipping (Days 5 - 7)

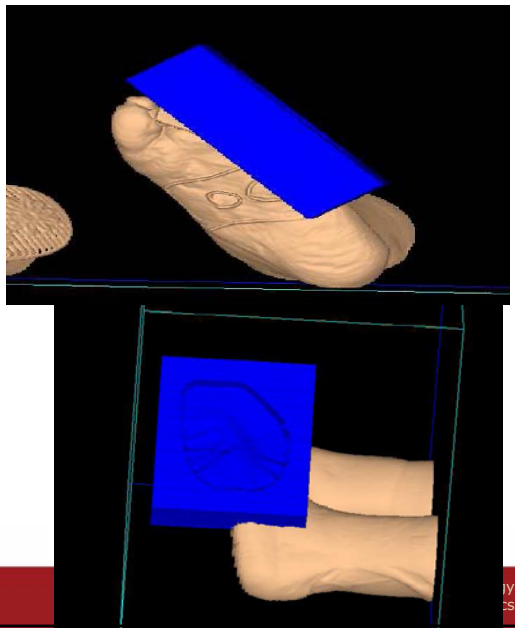






Verification Simulation (Day 8)

- QA for bolus treatment
- Examine bolus for defects
- Reduce sharp edges if needed
  - Only on patient side
  - Typically no alteration needed
- Prepare bolus for simulation
  - Add BBs on unmilled surface
- Useful printouts
  - 3D rendering of patient
  - Bolus in multiple orientations
  - Multiple axial slices with bolus

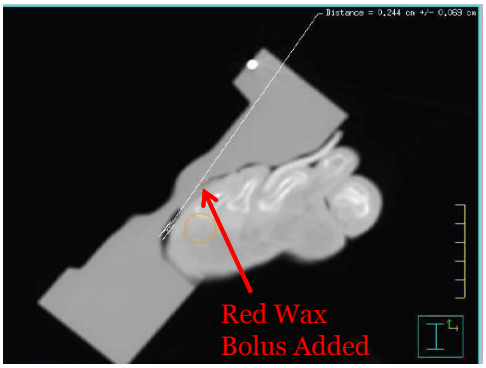


Verification Simulation (Day 8)

- Setup patient in treatment position
- Register bolus to patient
  - Align lasers to bolus X-hairs
  - Delineate lasers position on immobilization device
  - Draw bolus edge on mask/skin surface
- Measure bolus rotation
  - Transverse (within 1 degree of planned gantry angle)
  - Record sagittal angle

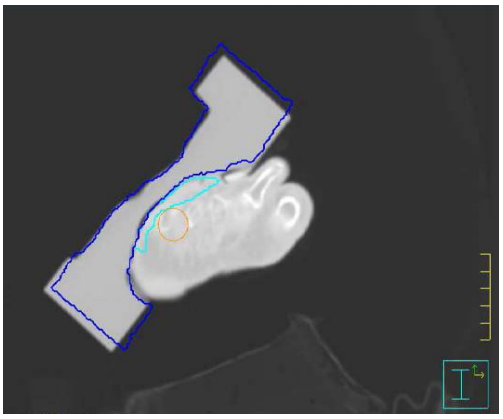
Verification Simulation (Day 8)

- Scan patient
  - Use same slice thickness as initial scan
  - Extend 5cm above and below bolus
- Examine bolus fit
  - Use lung window/level
  - Air gaps should be <3mm
  - Reposition and rescan if necessary
- Rarely alter bolus
  - Add red wax bolus to fill in large gaps
  - Bolus thickness for low energy beams



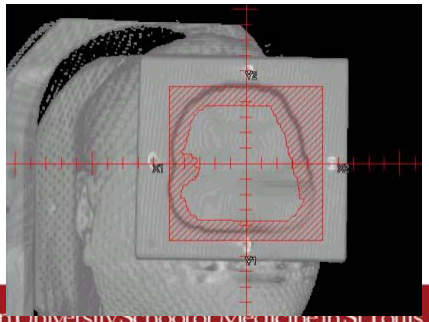
Final Treatment Planning (Day 8 – 10)

- Fuse verification and initial image sets
- Transfer structures
  - Compare bolus contour to bolus position
  - MD verifies accuracy of PTV
- Transfer initial plan
  - Adjust block and beam angle
  - Recalculate dose



Final Treatment Planning (Day 8 – 10)

- Record SSDs in R & V
  - Skin surface
  - Bolus Flattop
- Projection of light field to bolus surface



Bolus Electron Conformal Therapy

First Treatment Fraction (Day 10)

- Setup patient and bolus to marks
  - Compare to 3D printouts and setup images
- Record bolus rotation
  - Within 1 degree of verification simulation
- Align light field to bolus surface
- Verify SSDs
- Image
  - MV/KV/CBCT

ECT Costs

- .decimal (Milling)
  - Materials: $300-$995 per bolus, depending on size
  - Shipping: Costs based on location and timeframe
  - Software: Currently free for download
  - Hardware: None
- Adaptiiv (3D printing)
  - Materials: $5-$12 per bolus
  - Printing Fee: $75-$90 per print
  - Shipping: None
  - Software: Varies as company offers both upfront license and pay as you go
  - Hardware: $5000 - $10000 for 3D printer

ECT Reimbursement

- Bolus ECT requires additional medically necessary steps
  - **Re-CT** of patient with bolus in place
  - A **second plan** required for verification
  - A **second complex device** – the variable thickness bolus

CPT Codes	Description	Average APC Payment Hospital	Average commercial payments Hospital
77014	CT Guidance for placement of radiation fields	$0 (packaged)	$450 - $800
77315	Complex isodose plan	$255.69	$500 - $825
77334	Custom cutout	$188.16	$300 - $600
77300	Dose calculation	$114.70	$200 - $300
77290	Complex simulation	$255.69	$350 - $620
77334*	Compensator (Bolus)	$188.16	$300 - $600
77280*	Simple simulation (if performed on the same day as the 3-D plan this should not be charged)	$114.70	$250 - $420
77295*	3-D plan	$892.9	$2,500 - $4,500
77370	Special physics consult (if needed)	$144.70	$250 - $450
77331	Special dosimetry output factor	$114.70	$250 $450
77412-77416	Treatment delivery, electron beam	$152.05	$300 - $600

Prepared by AMAC

Outline

I. Fundamentals of Bolus Electron Conformal Therapy

II. Clinical Workflow
- Simulations
- Treatment Planning/Ordering
- Treatment Delivery

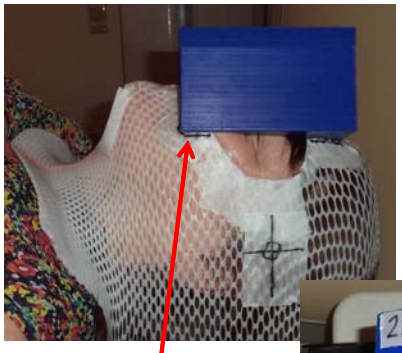
III. Clinical Cases: Nose, Back, Foot

IV. Future – Potential for Intensity Modulation

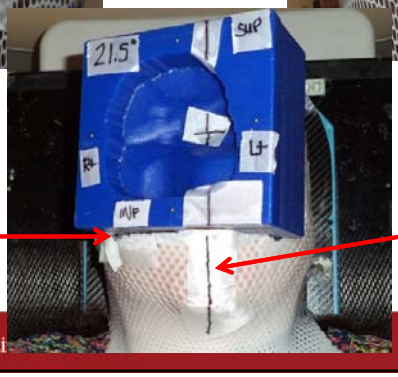
Case 1: Nose Initial Simulation

- 58 y/o F with cutaneous squamous cell carcinoma at nasion with extension towards R medial canthus.
- 12 MeV treated to 66 Gy in 2 Gy/fx

Case 1: Nose Initial Simulation



Angle L to R:
21.5 degrees



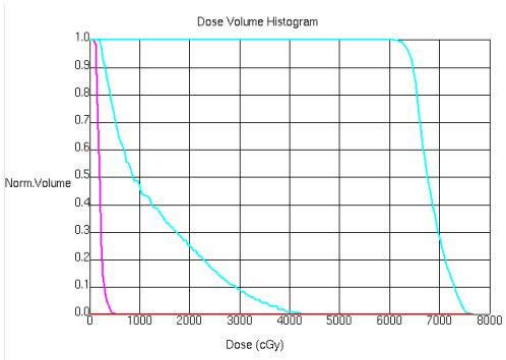
Marks align
to bolus edge

Marks align
to bolus x-hairs

Bolus Electron Conformal Therapy

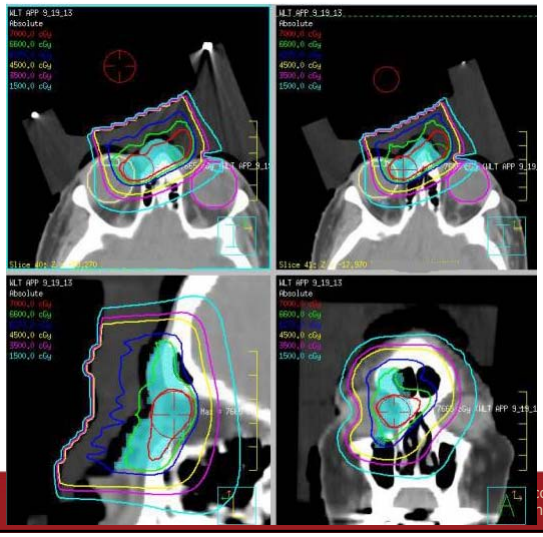
Case 1: Nose Treatment Plan

- Eye shield considered but not used due to electron energy and uncertain impact on dose distribution near PTV



ROI Statistics

Line Type	ROI	Trial	Min.	Max.	Mean	Std. Dev.
	ORIG_Lacrimal L	WLT APP 9_19_13	66.1	506.7	204.0	66.3
	ORIG_Lacrimal R	WLT APP 9_19_13	184.6	4239.3	1292.0	1020.4
	PTV-SKIN	WLT APP 9_19_13	5921.2	7642.6	6815.4	312.4



Case 1: Nose First Fraction

Response to Treatment

- Grade 2 skin reaction
- Completely cleared up at 6 week follow-up

Case 2: Back Initial Simulation

- A 34-year-old African-American male with dermatofibrosarcoma protuberans to the upper back
- Reversed prone pillow registered to Alpha Cradle

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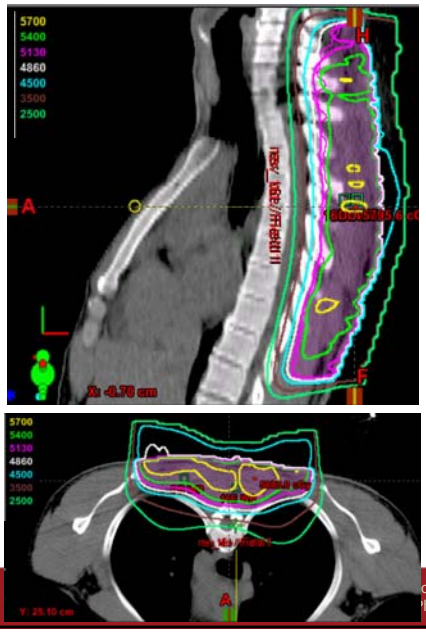
Case 2: Back Treatment Plan

- Treatment 80% using DD and 20 MeV, 20% using not bolus with 16 MeV.
  - Planning goals: 95% of PTV covered by 95% of Rx
  - RX = 54Gy @ 2 Gy fractions
  - Lung Dmean < 10Gy, V20 < 20%
  - Heart Dmean < 5 Gy, V20 < 5%
  - Mixed bolus with non-bolus to reduce dose to skin graft
  - 110cm SSD



Fields | Dose Prescription | Field Alignments | Plan Objectives | Optimization Objectives

Plan ID	Fractionation Id	Dose / Fraction [cGy]	Number of Fractions	Total Dose [cGy]
rev_16e	F1	1413.5	1	1413.5
rev_dd	F1	5201.6	1	5201.6

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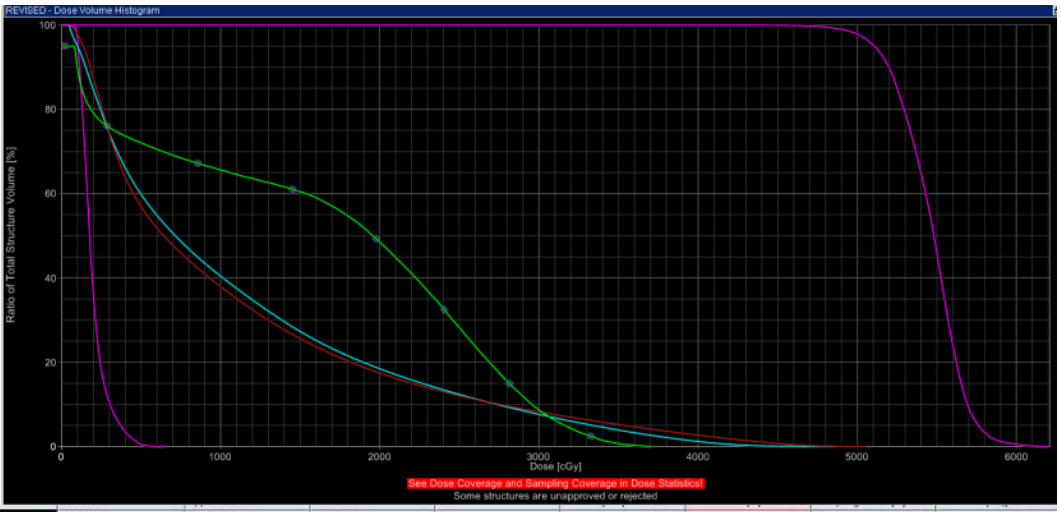
Bolus Electron Conformal Therapy

Case 2: Back Treatment Plan



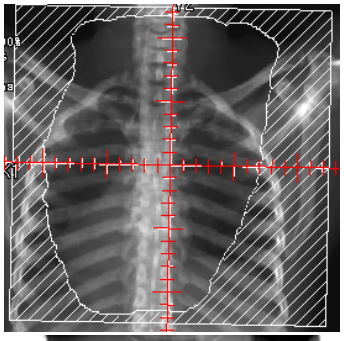
HEART	Unapproved	REVISED	C1	629.6	100.0	99.9	50.1
LUNG_L	Unapproved	REVISED	C1	1616.6	100.0	100.0	38.1
LUNG_R	Unapproved	REVISED	C1	1830.5	100.0	100.0	52.0
PTV INSIDE SKIN	Unapproved	REVISED	C1	1251.9	100.0	99.9	2577.6
SPINALCORD	Unapproved	REVISED	C1	36.8	95.0	101.1	74.2

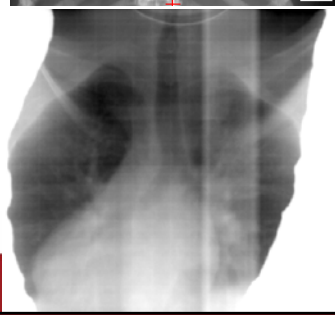
Case 2: Back Verification Simulation

Bolus Electron Conformal Therapy

Case 2: Back Treatment

- Dry desquamation along surgical incision lines.
  - Went on 4 day break between 21st and 22nd fraction.
- 6 week follow up
  - Skin recovered from treatment



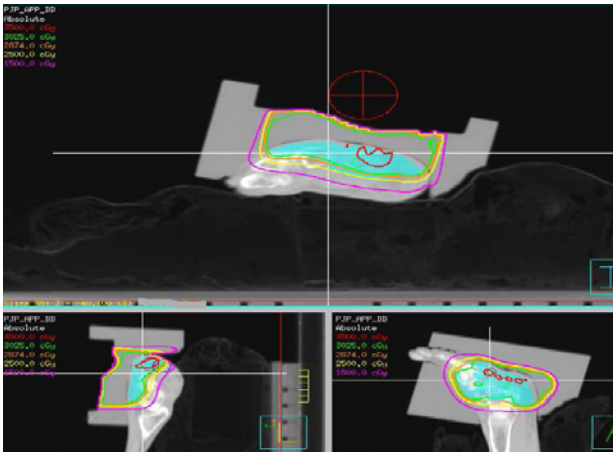


Case 3: Foot Initial Simulation

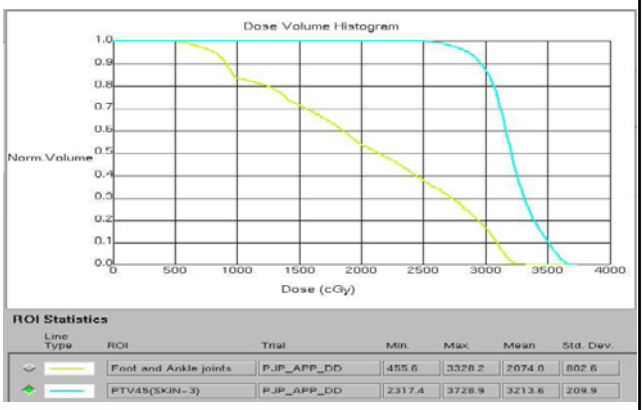
- 71 female with 2cm clear cell sarcoma of the right lateral foot
- Conservative local excision with positive margins.
- 2:1 BECT to 6X weighting
  - 95% of PTV covered by 95% Rx
  - 45Gy initial plan in 1.8 Gy fx.
  - PTV retracted 3mm from skin
  - 16 MeV (137MU) used and 6 X (61MU).
  - Mixed to reduce dose to skin, spare foot and ankle joints

Case 3: Foot Treatment Plan

BECT Isodose Distribution



BECT DVH



Case 3: Foot Verification Simulation

- 12 degree L/R
- 3.5 degree Sup/INF

Case 3: Foot First Fraction Treatment

- Results: Erythema resolved at time of 6 week follow-up.
- Patient has maintained an active life, retained ability to walk/hike.

Case 4: Face with 3D Printed Bolus

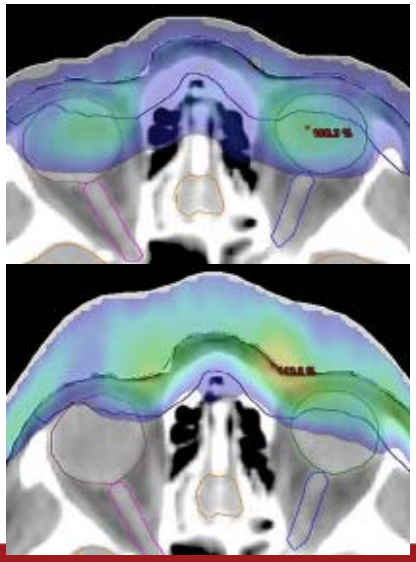
Case Details:

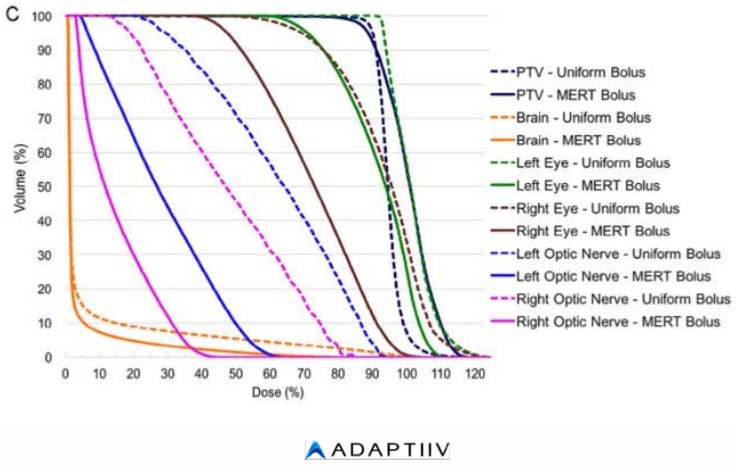
- 67-year-old female with mycosis fungoides of the forehead, eyelid and nose
- 3D modulated bolus resulted in better sparing of all the OARs while providing a similar PTV coverage compared to uniform thickness bolus

ADAPTIIV

Bolus Electron Conformal Therapy

Case 4: Face with 3D Printed Bolus

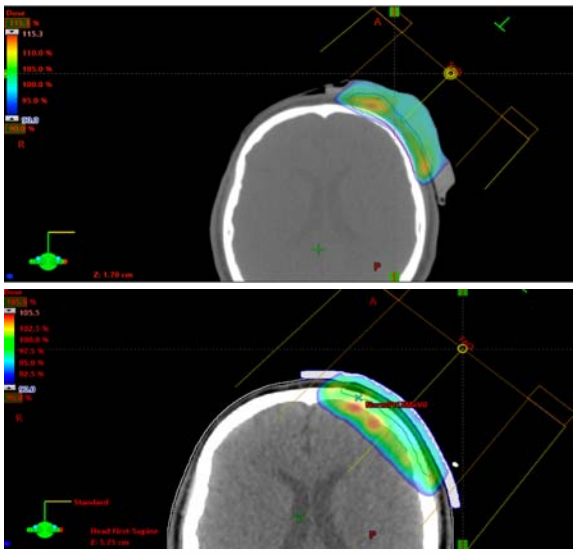




ADAPTIIV

Case 5: Partial Scalp with 3D Printed Bolus

- Adult patient with mycosis fungoides of the scalp
- Significant reduction of air gaps compared to handmade bolus
- Provided tailoring of the 90% isodose to follow the PTV contour, while limiting dose to the brain



Bolus Electron Conformal Therapy

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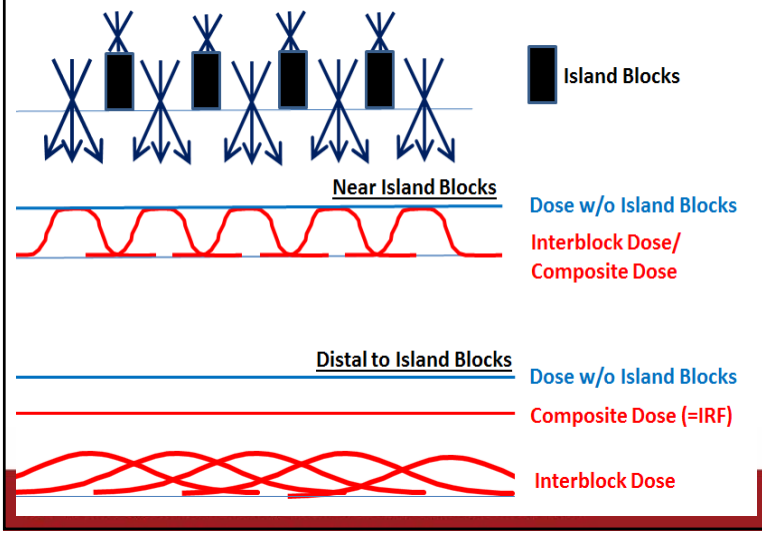
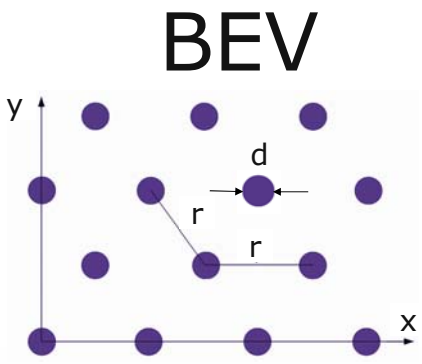
Bolus Electron Conformal Therapy with Intensity Modulation

How can electrons be intensity modulated?

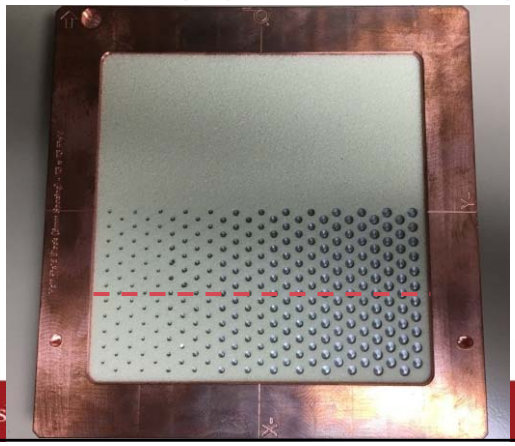


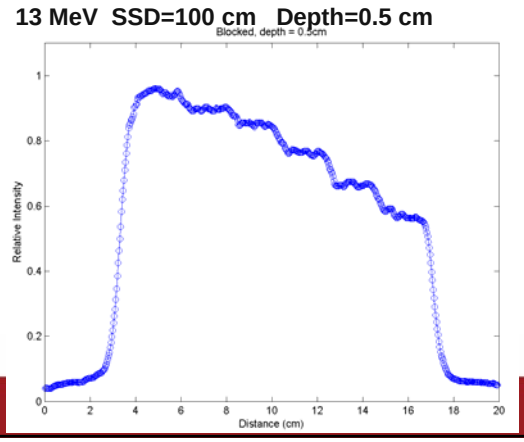


Electron Intensity Modulation Proposed Method

(Hogstrom et al 2017, accepted, JACMP)

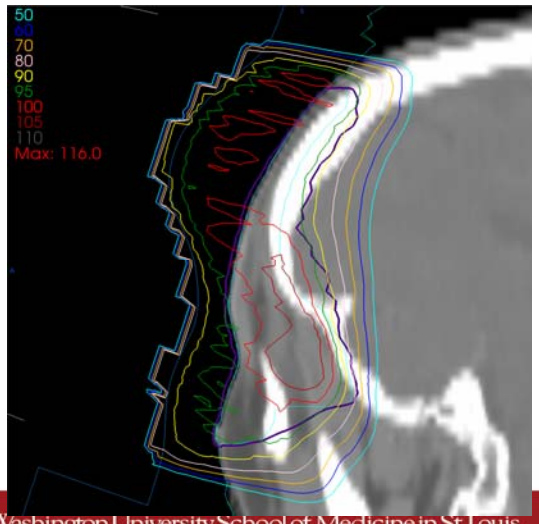
- Passive Radiotherapy Intensity Modulators for Electrons- PRIME (equivalent to compensators for x-rays)



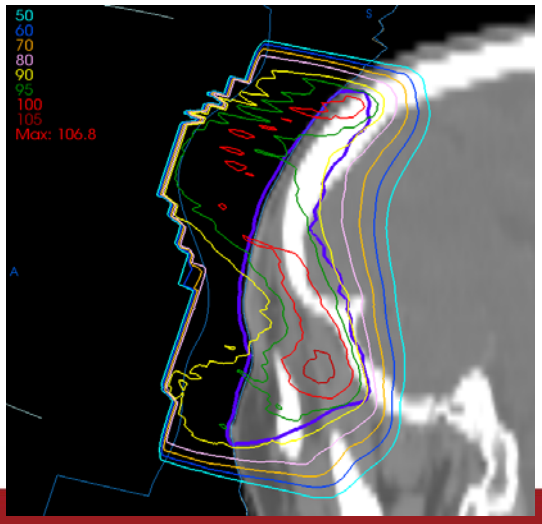


Bolus Electron Conformal Therapy with Intensity Modulation

Bolus ECT



Intensity Modulated Bolus ECT



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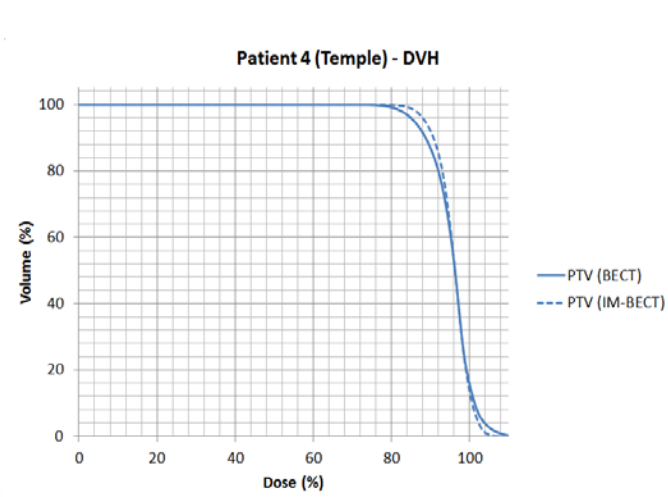
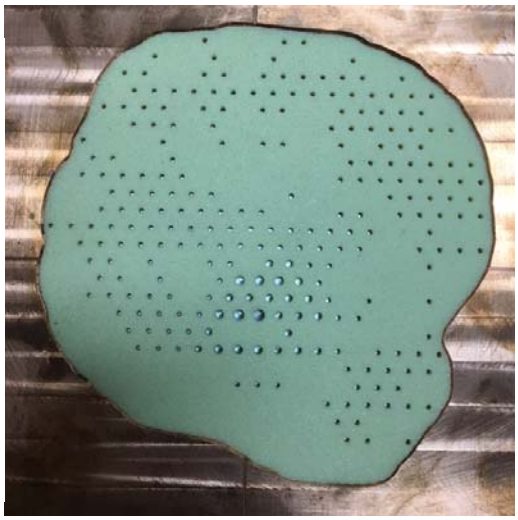
Bolus Electron Conformal Therapy

Bolus Electron Conformal Therapy with Intensity Modulation





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Passive Electron Intensity Modulators

- Under development by .decimal LLC & MBPCC
  - Planning software
  - Passive delivery device (intensity modulator)
  - Clinical QA methods
- Potential Applications
  - Bolus ECT
  - Penumbra matching of electron fields of differing energy (segmented-field ECT)
  - SSD and irregular surface effects of electrons

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Questions?

Thank you!

SITEMAN CANCER CENTER

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Bolus Electron Conformal Therapy