TEXAS CENTER for PROTON THERAPY

Benefits of Proton Therapy…

As Prevention of Radiation Toxicity and the Mechanics of New Technology

Andrew K. Lee, M.D., MPH
Medical Director

Texas Center for Proton Therapy

1

Andrew K. Lee, MD, MPH has the following financial relationship to disclose: Consultant and on speaker bureau for Tolmar Pharmaceuticals

This presentation will not discuss investigational or off-label use of therapeutics

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Clinical benefits of proton therapy

- **Higher radiation doses to tumor**
- **Minimizes dose to normal tissues**
- **Better tumor control**
- **Decreased side effects: early and late**
- **Preserve organ function**
- **Better tolerance of multi-modality therapy**
  e.g. Chemotherapy and/or surgery

"One cannot have a radiation-induced side effect in tissue that receives no radiation."

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What cases to consider for protons therapy?

Pediatric

Adults w/ projected longevity >15 years

Primary CNS
Skull-base
Mets

Para-nasal sinus
Nasopharynx
Oropharynx (especially younger HPV+)

Breast or chest wall + lymphatics (L, R, Bilateral)
Partial breast (APBI)
Recurrences (especially IMN)

Anterior/Posterior mediastinum
Lymphoma
NSCLC (stage II-III, non-operative)
SBRT

Distal esophagus (definitive, preop)
Liver

Seminoma

Prostate
RP sarcomas
Anal Ca
Recurrent rectal

Mets

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How are protons different from X-rays?

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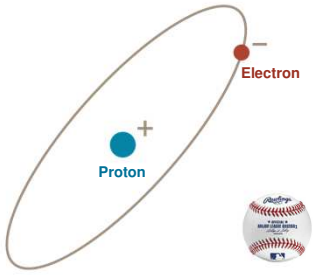
Proton is hydrogen atom without electron *(Heavy particle)*



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Protons are **accelerated** to almost light speed for treatment

Hyper-speed protons are used like "smart bullets" to kill cancer cells.

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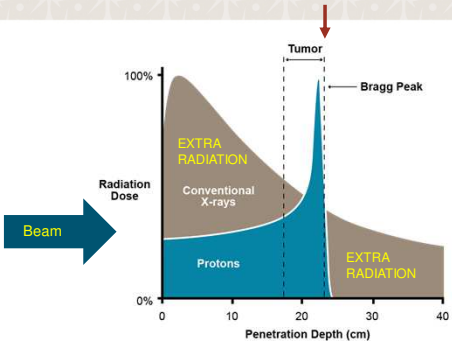
X-rays pass through tissue. **Protons STOP**



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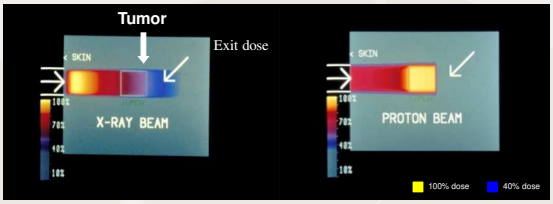
X-RAYS **PROTONS**



Exit dose NO exit dose

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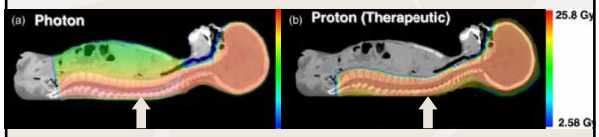
Medulloblastoma

Exit dose ~ 50% No exit dose



X-rays **Protons**

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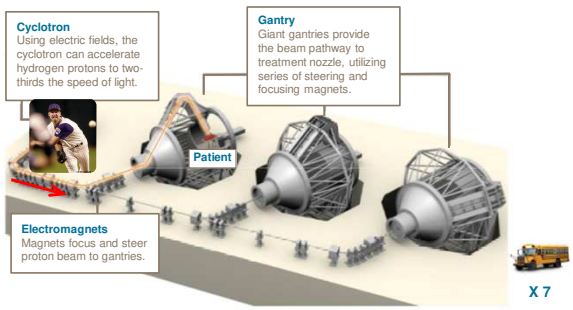
Key components



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Cyclotron accelerates protons to ~ 2/3 light speed.

Protons travel over 300,000 miles before reaching the patient (travelling around the world more than 12 times).

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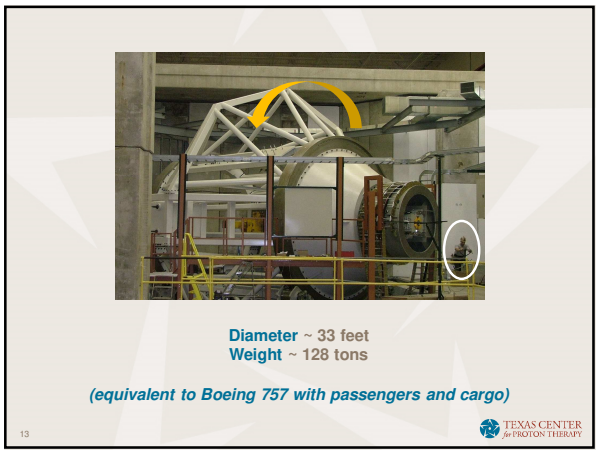

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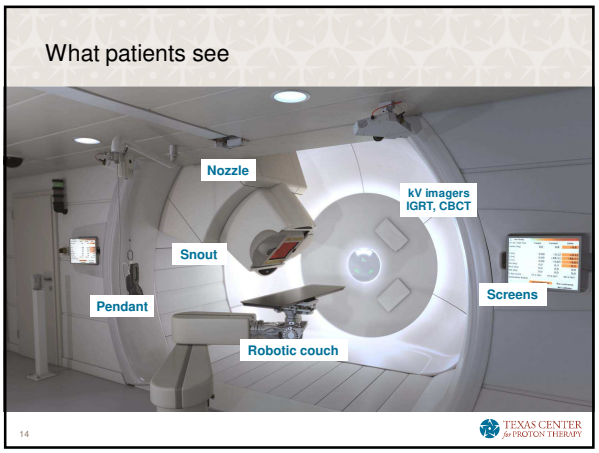

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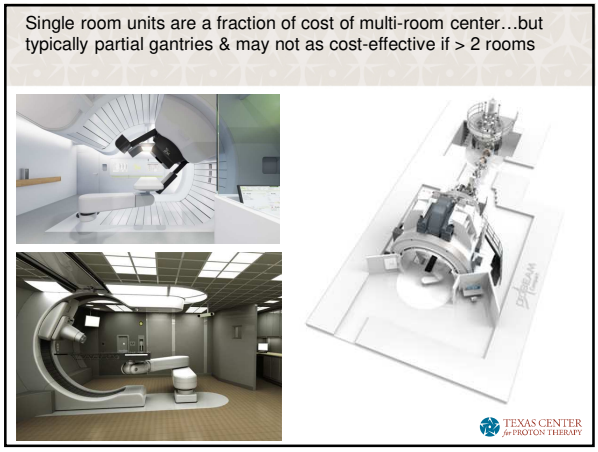

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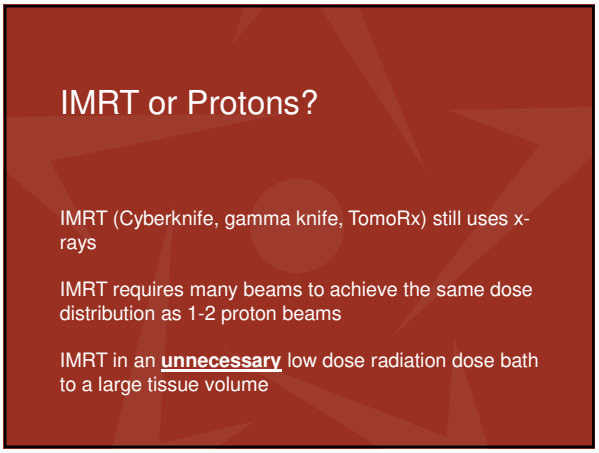

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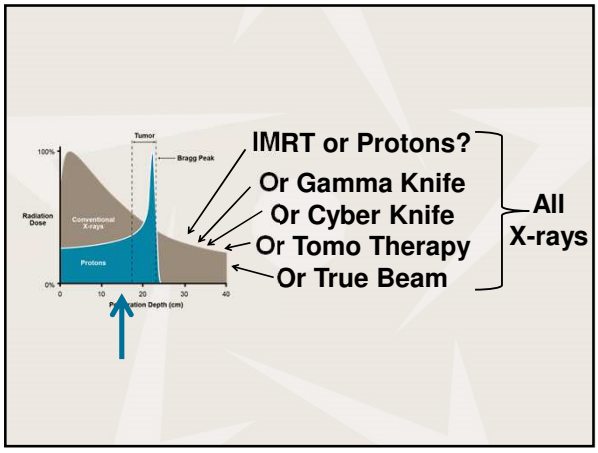

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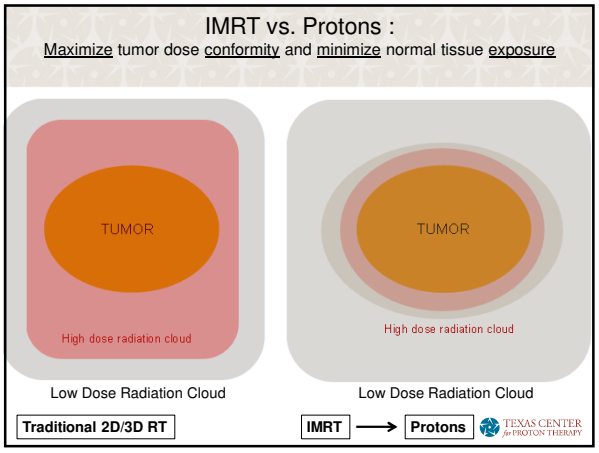

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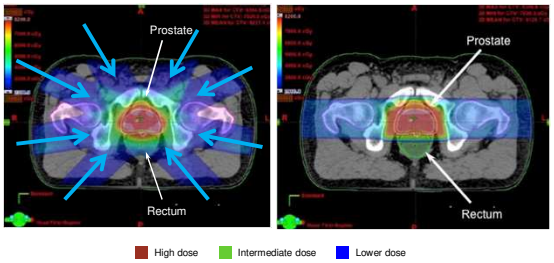
IMRT and Proton plans are both conformal
Proton plan delivers less radiation to normal tissue



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IMRT men had more **moderate-big problems**

	IMRT	Protons	P-value/ Bonferroni
Bowel urgency	15%	7%	0.001/ 0.02
Bowel frequency	10%	4%	0.003/0.05

Proton therapy decreased the incidence of "moderate to big" bowel problems reported by patients by 50%.

- Post-hoc analysis of *prospectively* collected EPIC:
  IMRT (n=204) 75.6-79.4 Gy (42-44 tx) PROSTQA
  PBT (n=1243) 76-82 GyE (38-41 tx) UFPTI

20 *Source: Hoppe et al., Cancer 2014; 120:1076-82*

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Why Proton Therapy?

Eliminate unnecessary radiation exposure

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ALARA principle:
As Low As Reasonably Achievable

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Make every reasonable effort to reduce exposure to ionizing radiation

Title 10, Section 20.1003, of the Code of Federal Regulations (10 CFR 20.1003)

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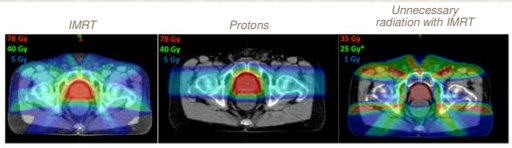
Prostate cancer



*** 25 Gy (25 Sv) of Unnecessary Radiation =**

2,500 Pelvic CTs (10 mSv)

20,833 Pelvic X-Rays (1.2 mSv)

25,000x General Public Annual Limit (1.0 mSv)

1.83x Additional Cancer Risk* (CTs, 65 yo)

Source: Matt Palmer
* http://www.xrayrisk.com/calculator/calculator-normal-studies.php

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Longer waits result in more second cancers

	Latency 5-9 years	Latency 10-14 years	Latency ≥15 years	p-trend
Oral/pharynx	1.12 (0.99 to 1.27)	1.14 (0.95 to 1.38)	0.95 (0.74 to 1.22)	0.34
Rectum*	1.13 (0.94 to 1.35)	1.33 (1.03 to 1.70)	0.91 (0.64 to 1.27)	0.54
Larynx	1.57 (1.08 to 2.36)	1.04 (0.66 to 1.70)	1.29 (0.75 to 2.30)	0.45
Lung (non-small cell)	1.12 (0.98 to 1.27)	1.37 (1.12 to 1.65)	1.62 (1.23 to 2.09)	0.0079
Female breast	1.17 (1.05 to 1.30)	1.42 (1.24 to 1.62)	1.56 (1.34 to 1.81)	0.0013
Cervix (external beam)*	1.18 (0.79 to 1.75)	1.55 (1.00 to 2.40)	2.59 (1.84 to 3.68)	0.0032
Endometrium (external beam)*	1.30 (1.08 to 1.56)	1.99 (1.60 to 2.47)	2.18 (1.78 to 2.65)	<0.0001
Prostate (external beam)*	**1.39 (1.29 to 1.50)**	**1.59 (1.41 to 1.80)**	**1.91 (1.53 to 2.38)**	**0.0031**
Thyroid*	0.89 (0.49 to 1.55)	1.03 (0.47 to 2.14)	1.21 (0.64 to 2.17)	0.47

Relative risk of second cancer at 10-14 years = 1.6, at **15 years RR = 1.9**

24 *Source: de Gonzalez et al., Lancet Oncol, Mar 2011*

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Protons reduce second cancers

- MGH report spanning 26 years (1974-2001)
- Matched 558 patients treated with protons (*20% also received some X-rays*) vs. X-ray patients from SEER registry
- CNS 32%, HN 24%, prostate 33%, sarcoma 7.8% (no ocular)
- Second cancer rates were 6.9 vs. 10.3 (per 1000 person-years) for protons vs. XRT, respectively
- Adjusted for sex, age at treatment, primary site, year of diagnosis
- Protons HR for second cancers was 0.52 (p=0.009)

25 Source: Chung et al., Int J Radiat Oncol Biol Phys 87, 2013

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Second cancer risk after primary cancer treatment with three-dimensional conformal, intensity modulated, or proton beam radiation therapy.
[M Xiang et al. Cancer May 2020, PMID 3246866]

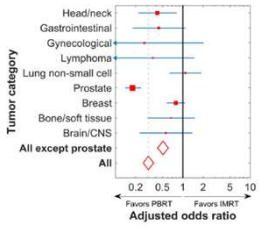

FIGURE 3. This is a forest plot of adjusted odds ratios (log axis) for the risk of second cancer for proton beam radiation therapy (PBRT) relative to intensity-modulated radiation therapy (IMRT) by tumor type. Horizontal bars indicate 95% confidence intervals. Sizes of the markers are proportional to the relative number of cases. CNS indicates central nervous system.

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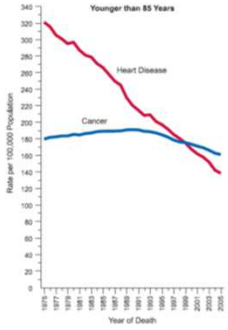
Competing risk of death



27 Source: Cancer J Clin 2009;59

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Pediatric tumors

Regular X-ray therapy may have side effects even at low doses for young children.

- Growth disturbances
- Decreased functional outcomes
  Hearing, vision, neurocognitive, etc.
- Cosmesis
- Second cancers

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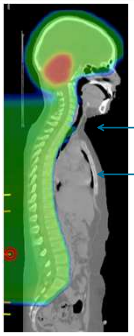
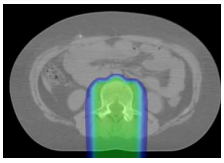
Protons reduce second cancers and have other benefits





Abdominal Organs

29 Source: MDACC

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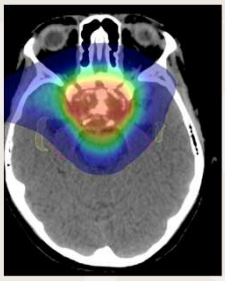
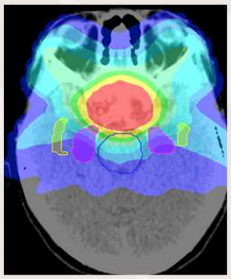
Protons vs. **IMRT** (X-rays)





30 Source: MDACC

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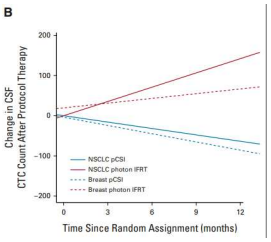
Randomized Phase II Trial of Proton Craniospinal Irradiation Versus Photon Involved-Field Radiotherapy for Patients With Solid Tumor Leptomeningeal Metastasis

Randomized phase II of Proton CSI vs. Photon IFRT with NSCLC and breast cancer with leptomeningeal spread (3 Gy x 10)

Median PFS 7.5 vs. 2.3 months, p<0.001 in favor of Protons CSI

Median OS 9.9 vs. 6.0 months, p=0.029

[Tang et al. J Clin Oncol 2022, PMID 35802849]



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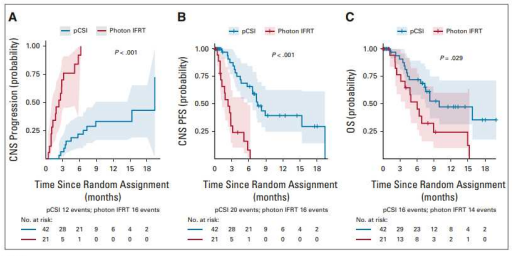

FIG 2. Patients who were randomly assigned to pCSI had significantly improved (A) CNS time to progression, (B) CNS PFS, and (C) OS. IFRT, involved-field radiotherapy; OS, overall survival; PFS, progression-free survival; pCSI, proton craniospinal irradiation.

[Tang et al. J Clin Oncol 2022, PMID 35802849]

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ASTRO TARGETING CANCER CARE

News Release

Avoiding specific region of brain during whole-brain radiotherapy prevents memory loss

Atlanta, September 23, 2013—Limiting the amount of radiation absorbed in the hippocampal portion of the brain during whole-brain radiotherapy (WBRT) for brain metastases preserves memory function in patients for up to six months after treatment, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 55th Annual Meeting.

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Lymphoma patients are often young and often cured but may suffer long-term side effects

- We are curing our patients but they are dying of late treatment-related side effects such as secondary tumors and heart disease
- Radiation for lymphoma needs to have LOW side effects

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10-15 years after treatment, other factors overcome Hodgkins disease as main cause of death

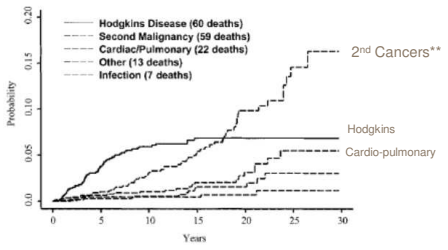

Fig 2. Competing causes of death.

** Increased solid tumor risk in XRT patients

35 Source: Ng A et al. J Clin Oncol 2002 TEXAS CENTER for PROTON THERAPY

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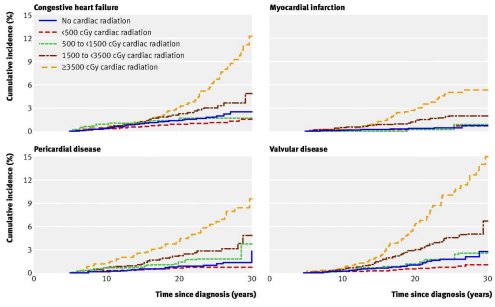
Cumulative incidence of cardiac disorders among childhood cancer survivors increases with mean cardiac radiation dose



Daniel A Mulrooney et al. BMJ 2009;339:bmj.b4606

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30-yo woman stage II Hodgkins lymphoma
Disease initially wrapped around right side of heart

Plan was chemotherapy followed by consolidative RT

37 Source: Valerie Reed, M.D.

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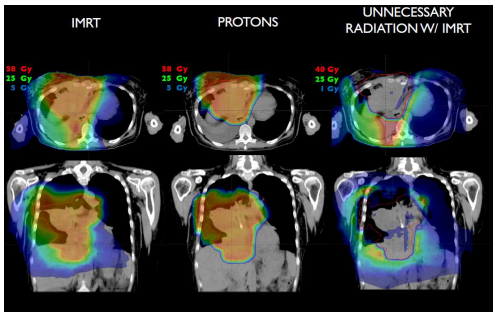
IMRT vs. PBT for Lymphoma



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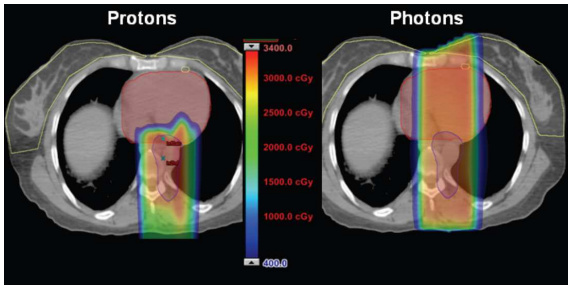
Protons better for disease in front of the heart and behind the heart (avoid heart and breast tissue)



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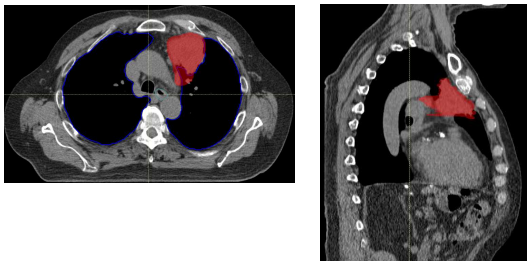
Anterior tumors (e.g. lung, thymoma, lymphoma)



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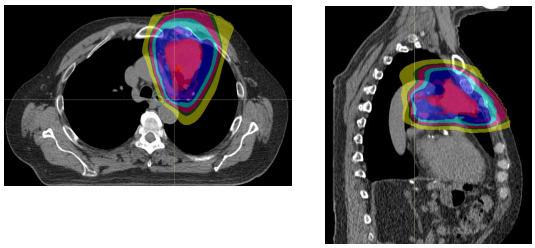
Protons can keep dose anteriorly



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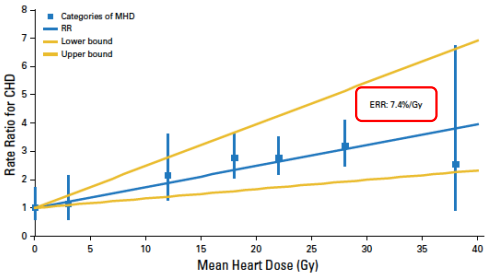
Cardiac risk for Hodgkin lymphoma survivors
ERR 7.4% per Gy (mean heart dose)



F. Van Nimwegen et al. J Clin Oncol 2015;34

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doi:10.1016/j.ijrobp.2010.05.007

CLINICAL INVESTIGATION

RATIONALE FOR AND PRELIMINARY RESULTS OF PROTON BEAM THERAPY FOR MEDIASTINAL LYMPHOMA

Jing Li, M.D., Ph.D., Bouthaina Dabaja, M.D., Valerie Reed, M.D., Pamela K. Allen, Ph.D., Haibong Cai, M.S., Mayankkumar V. Amin, John A. Garcia, B.S., and James D. Cox, M.D.

Department of Radiation Oncology, The University of Texas M. D. Anderson Cancer Center, Houston, Texas

Purpose: To evaluate the potential of three-dimensional proton beam therapy (3D-PBT) for reducing doses to normal structures in patients with mediastinal lymphomas compared with conventional photon radiation therapy (RT).

Methods and Materials: We treated 10 consecutive patients with mediastinal masses from lymphomas with 3D-PBT between July 2007 and February 2009 to 30.6–50.4 cobalt-Gray equivalents (CGE). Of those patients, 7 had primary refractory or recurrent disease, and 8 had Hodgkin lymphoma. Dosimetric endpoints were compared with those from conventional RT plans.

Results: PBT delivered lower mean doses to the lung (6.2 vs. 9.5 Gy), esophagus (9.5 vs. 22.3 Gy), and heart (8.8 vs. 17.7 Gy) but not the breasts (5.9 vs. 6.1 Gy) than did conventional RT. Percentages of lung, esophagus, heart, and coronary artery (particularly the left anterior descending artery) volumes receiving radiation were consistently lower in the 3D-PBT plans over a wide range of radiation doses. Of the 7 patients who had residual disease on positron emission tomography before PBT, 6 (86%) showed a complete metabolic response.

Conclusions: In patients with mediastinal lymphomas, 3D-PBT produced significantly lower doses to the lung, esophagus, heart, and coronary arteries than did the current conventional RT. These lower doses would be expected to reduce the risk of late toxicities in these major organs. © 2010 Elsevier Inc.

3D-PBT produced significantly lower doses to the lung, esophagus, heart and coronary arteries…these lower doses would be expected to reduce the risk of late toxicities in these major organs.

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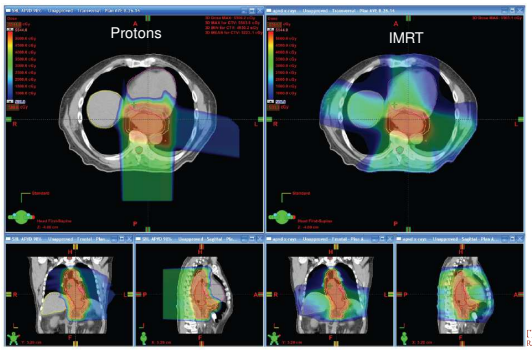
Esophageal Cancer



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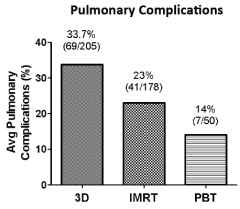
Improved perioperative pulmonary complications with proton therapy

- **444 patients who had surgery after CRT**
- **3D** (n=208, 1998-2008); **IMRT** (N=164, 2004-2011), and **PBT** (n=72, 2006-2011)
- Evaluated Pulmonary, GI, cardiac, wound healing within 30 days of surgery

- **Pulmonary complications** (ARDS, pleural effusion, RI, PNA) most predictive based on radiation type
  - **IMRT vs 3D** (OR 0.50, 95% CI 0.27-0.91)
  - **PBT vs 3D** (OR 0.32, 95%CI 0.14-0.73)
  - **IMRT vs PBT** (OR 1.56, 95%CI 0.68-3.60)



45 Source: Wang J, Lin SH, et al. Int J Radiat Oncol Biol Phys 2013 TEXAS CENTER for PROTON THERAPY

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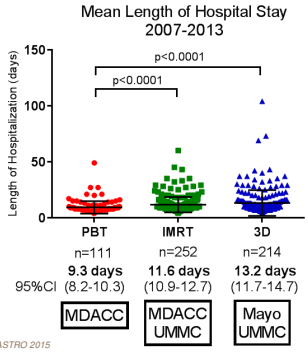
Value of proton therapy in esophageal cancer

Protons reduces ***average*** hospital stay by > 2 days and ***max*** hospital days



46 Source: Lin SH et al., ASTRO 2015 TEXAS CENTER for PROTON THERAPY

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Randomized Phase IIB Trial of Proton Beam Therapy Versus Intensity-Modulated Radiation Therapy for Locally Advanced Esophageal Cancer

Steven H. Lin, MD, PhD[1]; Brian P. Hobbs, PhD[2]; Vivek Verma, MD[3]; Rebecca S. Tidwell, PhD[4]; Grace L. Smith, MD, PhD, MPH[1,2]; Xiudong Lei, PhD[2]; Erin M. Corsini, MD[5]; Isabel Mok, RN[1]; Xiong Wei, MD[1]; Luyang Yao, MS[1]; Xin Wang, MD[2]; Ritsuko U. Komaki, MD[1]; Joe Y. Chang, MD, PhD[1]; Stephen G. Chun, MD[1]; Melenda D. Jeter, MD[1]; Stephen G. Swisher, MD[6]; Jaffer A. Ajani, MD[6]; Mariela Blum-Murphy, MD[6]; Ara A. Vaporciyan, MD[6]; Reza J. Mehran, MD[6]; Albert C. Koong, MD, PhD[1]; Saumil J. Gandhi, MD[1]; Wayne L. Hofstetter, MD[6]; Theodore S. Hong, MD[3]; Thomas F. Delaney, MD[3]; Zhongxing Liao, MD[1]; and Radhe Mohan, PhD[1]

Phase IIB randomized 145 patients to PBT or IMRT (50.4 Gy) with chemotherapy

30 went onto esophagectomy

Total Toxicity Burden (TTB) and PFS

Median FU 44.1 months

TTB was 2.3X higher for IMRT vs. PBT

3-y PFS 50.8 vs. 51.2%, 3-y OS 44.5 vs. 44.5%

J Clin Oncol 38:1569-79, 2020

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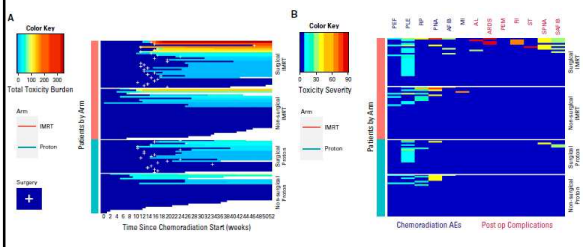
TTB: Blue is less toxic….Red is more toxic



Lin et al. J Clin Oncol 38:1569-79, 2020

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Protons may reduce unplanned hospitalizations in patients receiving ChemoRT for locally-advanced cancer

- **UPENN retrospectively reviewed 1483 adult locally-adv Ca pts treated with concurrent chemoRT with curative intent 2011-2016**
- **PBT = 391 Photon = 1092**
- **90-day adverse events CTCAEv4 grade 2 or greater gathered prospectively**
- **PBT pts were older, more comorbidities, but lower integral radiation dose outside of target volumes**
- **PBT had lower 90-day adverse events ≥ grade 3 (0.31, p=0.002) and ≥ grade 2 (0.78, p=0.006)**
- **Also less decline in ECOG PS during Rx (0.51, p<0.001)**

Baumann et al. JAMA Oncol 6: 237-46, 2020

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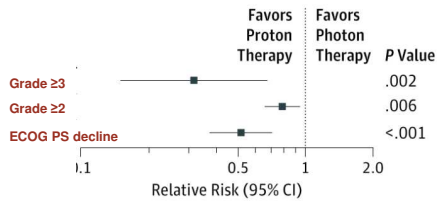
Outcome	Proton CRT Group (n = 391) No. of Events	Proton CRT Group (n = 391) Percentage (95% CI)	Photon CRT Group (n = 1092) No. of Events	Photon CRT Group (n = 1092) Percentage (95% CI)	Relative Risk (95% CI)
90-day Grade ≥3 adverse events	45	11.5% (8.3%-14.7%)	301	27.6% (24.9%-30.2%)	0.31 (0.15-0.66)
90-day Grade ≥2 adverse events	290	74.2% (69.8%-78.5%)	926	84.8% (82.7%-86.9%)	0.78 (0.65-0.93)
ECOG performance status decline	145	37.1% (32.3%-41.9%)	434	42.4% (39.4%-45.4%)	0.51 (0.37-0.71)



Baumann et al. JAMA Oncol 6: 237-46, 2020

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What is "new" in proton therapy?

- **Proton therapy has improved as technology has advanced (just like X-ray therapy)**
- **Imaging (OBI and CBCT)**
- **Treatment planning (software)**
- **Treatment delivery systems**
- **Intensity modulation**
- **Immobilization**
- **Arc therapy**
- **FLASH**

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Types of proton therapy delivery

- **Passive scattered (most common)**
- **Spot-scanning (pencil-beam scanning)**
- **Intensity modulated proton therapy (IMPT)**

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Spot scanning (pencil-beam scanning)

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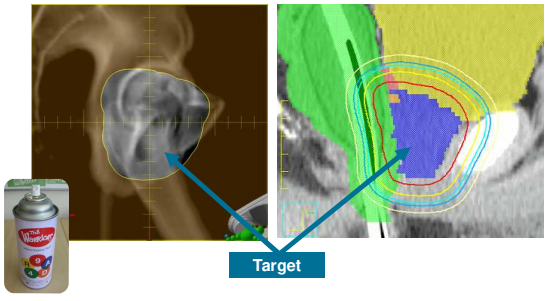
"Conventional" proton therapy (Right lateral beam's eye view)



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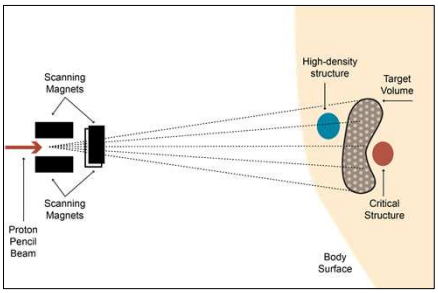
The pencil-beam scanning mode of proton beam delivery



55 Source: A Smith. Med. Phys. 2009

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Any randomized trials between IMRT vs. Protons should be done with PBS (IMPT)

	2 D X-rays	3 D X-rays	IMRT	CONVENTIONAL PROTONS (Passive-scattered)	IMPT Intensity modulated proton therapy
Conformity	+	++	++++	+++1/2	++++
Normal tissue exposure	+++	+++	++++	++	++

Highly conformal but less tissue exposure

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Pencil Beam Scanning advantages

Improved conformality…especially for concave structures

Less hardware…fewer patient specific devices

More beam angles are logistically feasible

Intensity modulated proton therapy (IMPT)

More flexibility for concomitant boost techniques
e.g. Target A treated at 1.8 GyE per fraction and Target B simultaneously treated at 2.2 GyE per fraction over same number of days

Fewer neutrons

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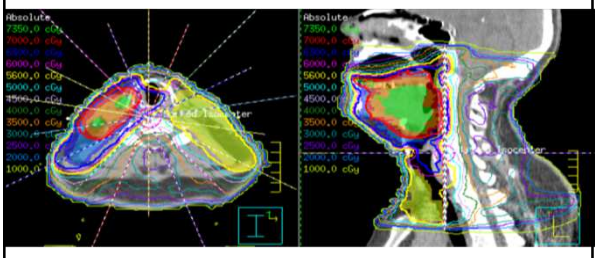
IMRT with **simultaneous integrated boost** for locally-advanced oropharyngeal cancer



Different targets receiving different dose per day simultaneously over same number of days

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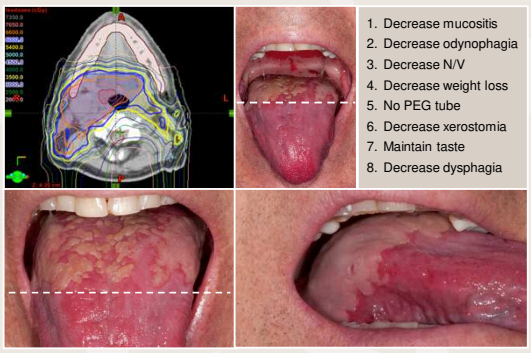
Concurrent Chemo-radiation w/ IMPT (protons)



1. Decrease mucositis
2. Decrease odynophagia
3. Decrease N/V
4. Decrease weight loss
5. No PEG tube
6. Decrease xerostomia
7. Maintain taste
8. Decrease dysphagia

60 Source: S.J. Frank

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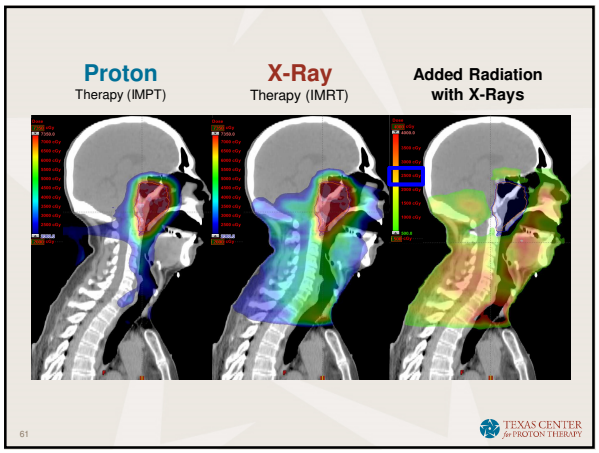

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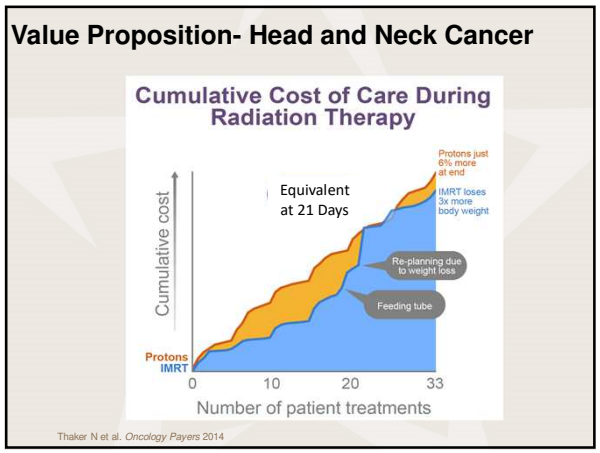

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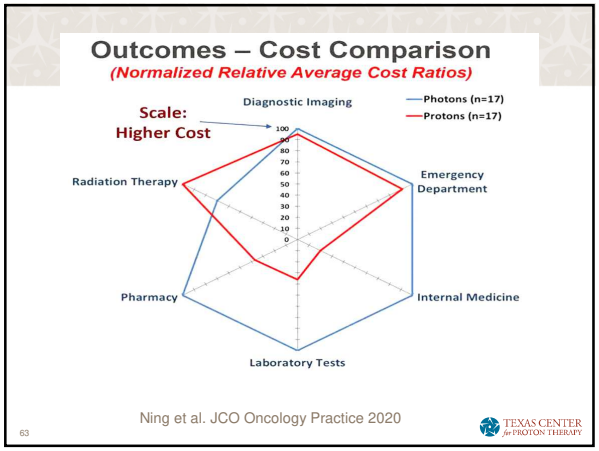

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Beyond tumor sites like CNS & HN, how can pencil beam scanning proton therapy (IMPT) expand the clinical utility of proton therapy?

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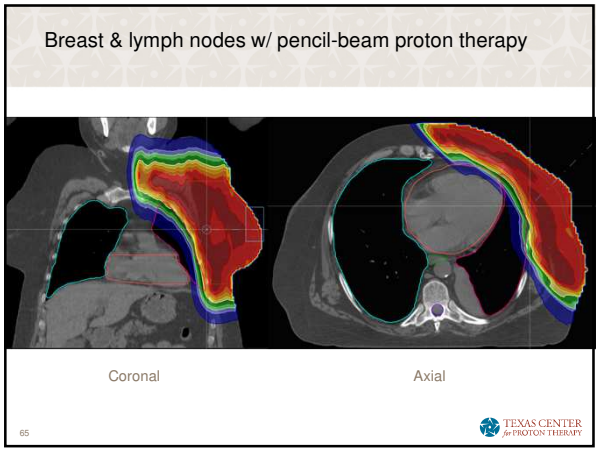

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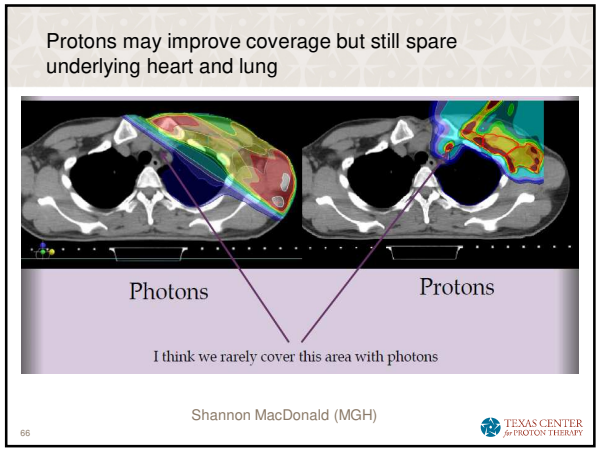

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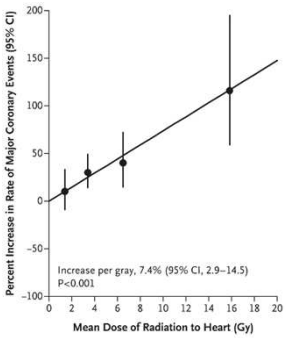
For breast cancer, linear risk of coronary events…
7.4% increase per mean dose to heart (Gy)



Darby et al. NEJM 2013;368.

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Phase II Study of Proton Beam Radiation Therapy for Patients With Breast Cancer Requiring Regional Nodal Irradiation

Rachel B. Jimenez, MD[1]; Shea Hickey, BS[1]; Nicolas DePauw, PhD[1]; Beow Y. Yeap, ScD[1]; Estelle Batin, PhD[1]; Michelle A. Gadd, MD[1]; Michelle Specht, MD[1]; Steven J. Isakoff, MD, PhD[1]; Barbara L. Smith, MD, PhD[1]; Eric C. Liao, MD, PhD[1]; Amy S. Colwell, MD[1]; Alice Ho, MD, MBA[1]; James L. Januzzi, MD[1]; Jonathan Passeri, MD[1]; Tomas G. Neilan, MD, MPH[1]; Alphonse G. Taghian, MD, PhD[1]; Hsiao-Ming Lu, PhD[1]; and Shannon M. MacDonald, MD[1]

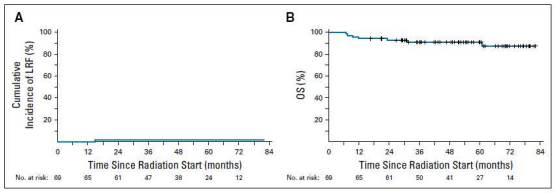

FIG 1. (A) Locoregional failure (LRF) and (B) overall survival (OS) after proton beam radiation therapy.

J Clin Oncol 37:2778-85, 2019

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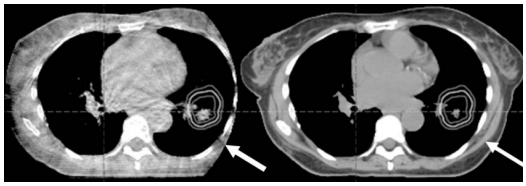
On-board CBCT helps with volumetric image guidance



CBCT Planning CT

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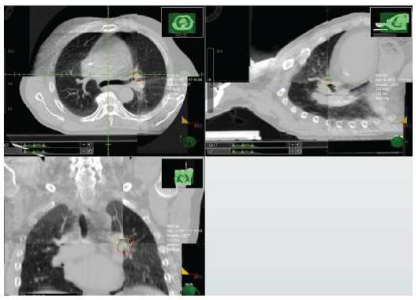
CBCT on FULL PBS gantry



CBCT reconstruction in adaPT Insight

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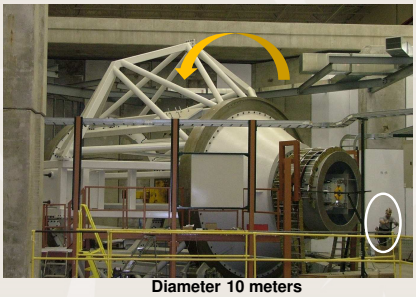

Diameter 10 meters
Weight 100 metric tons*

(*Similar to Boeing 757 with passengers and cargo)

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Why do you need CBCT with protons?

Volumetric targeting
- Lung tumor
- Liver

Improve fine 6-degree corrections
- Brain
- Skull base
- Brain stem

Image and validate PROXIMAL anatomy in beam path
- External contour (e.g. breast)
- Image changing anatomy (HN, pleural effusion)

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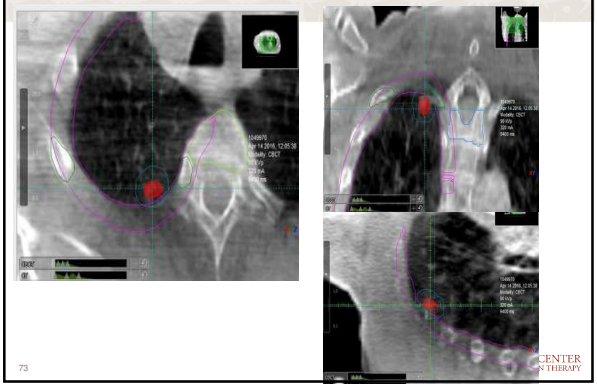
CBCT for targeting



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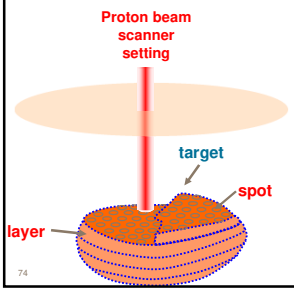
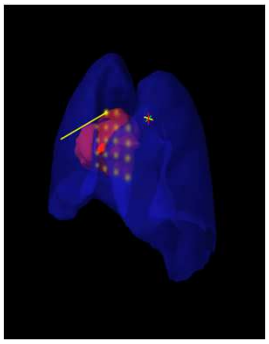
Layer and Volumetric repainting

Tumor divided in layers

Each layer, dose delivered in spots & scans over target





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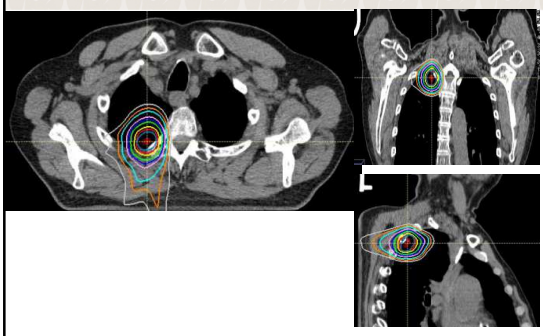
50GyE/4 fx with Layer and Volumetric repainting



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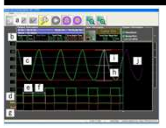
Gated proton beam during exhale phase



UBTI offers opportunity to gate beam or use breath-hold techniques

Lei Dong, PhD

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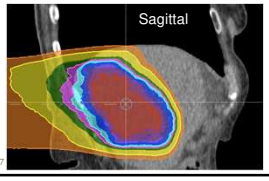
Liver Rx (4.5 CGE x 15 fx) using breath-hold PBS delivery



Requires **fast** PBS delivery

Jared Sturgeon, MD, PhD

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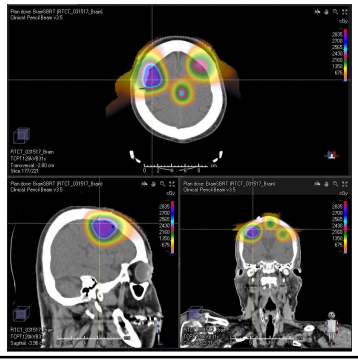
Multiple brain lesions treated in 3-5 fractions



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SBRT and Hypo-fractionation

As clinical indications* for this type of Rx increases with x-rays, proton therapy's role should also increase

***Brain, Lung, Liver, Prostate, Oligo-metastatic (better systemic Rx)**

When delivering relatively few fractions, the cost differential may be negligible compared to SBRT with x-rays

Spare normal tissue

Leaves more room for subsequent treatments

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Preparing for more cancer SURVIVORS…

In 2013, the Institute of Medicine estimated **14 MILLION** cancer survivors in U.S.

ABOUT 60% OVER AGE 65

Within the next 10 years, estimated cancer survivors are expected **to exceed** **20 MILLION**

Source: ASCO Post 2015

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Associated Press

Second Cancers Are on the Rise; 1 in 5 US Cases Is a Repeat

Aug 24, 2015By MARILYNN MARCHIONE
AP Chief Medical Writer

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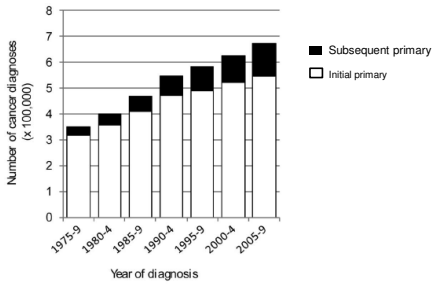
First and subsequent primary cancers in adults 1975-2009 in nine SEER registries



Morton et al. 2014 ASCO Educational Book

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Texas Center For Proton Therapy

2 full gantries and 1 fixed beam line that can deliver pencil-beam scanning proton therapy (largest pencil beam scanning proton center in region)

Only center in Texas with dedicated on-board CBCT volumetric imaging for protons

3-Tesla MRI

Advanced PET-CT imaging

Laboratory services

Anesthesia

Staff with cumulative 70+ years of dedicated proton experience

Patient-focused

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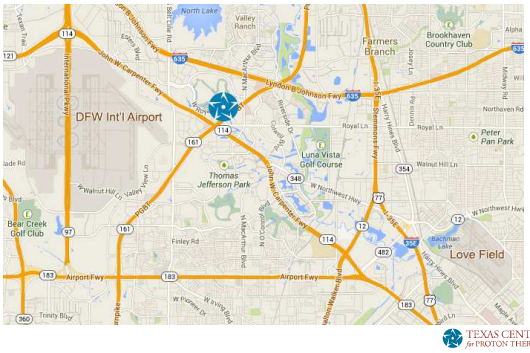
Texas Center for Proton Therapy Location



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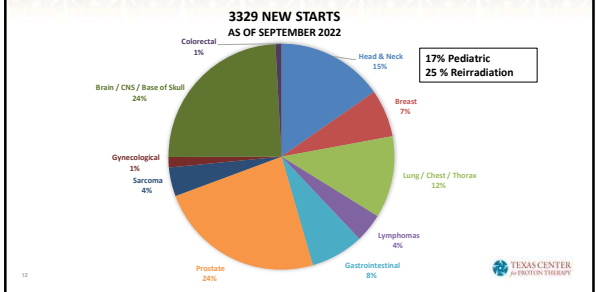
TCPT Disease Sites of New Start Patients



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NCCN Member Institutions

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Proton Landscape in the U.S.

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THANK YOU

Andrew.Lee@USOncology.com
TexasCenterForProtonTherapy.com

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