Varian's Linac Radiotherapy Systems

Sasa Mutic, PhD, FAAPM, SVP Radiation Treatment Solutions
Andy Whitman, SVP Government Affairs

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General Linac Fair Balance Safety Statement

Intended Use Summary

Varian Medical Systems' linear accelerators are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Important Safety Information

Radiation treatments may cause side effects that can vary depending on the part of the body being treated. The most frequent ones are typically temporary and may include, but are not limited to, irritation to the respiratory, digestive, urinary or reproductive systems, fatigue, nausea, skin irritation, and hair loss. In some patients, they can be severe. Treatment sessions may vary in complexity and time. Radiation treatment is not appropriate for all cancers.

Medical Advice Disclaimer

Varian as a medical device manufacturer cannot and does not recommend specific treatment approaches. Individual treatment results may vary.

Not all products or features available for sale in all markets

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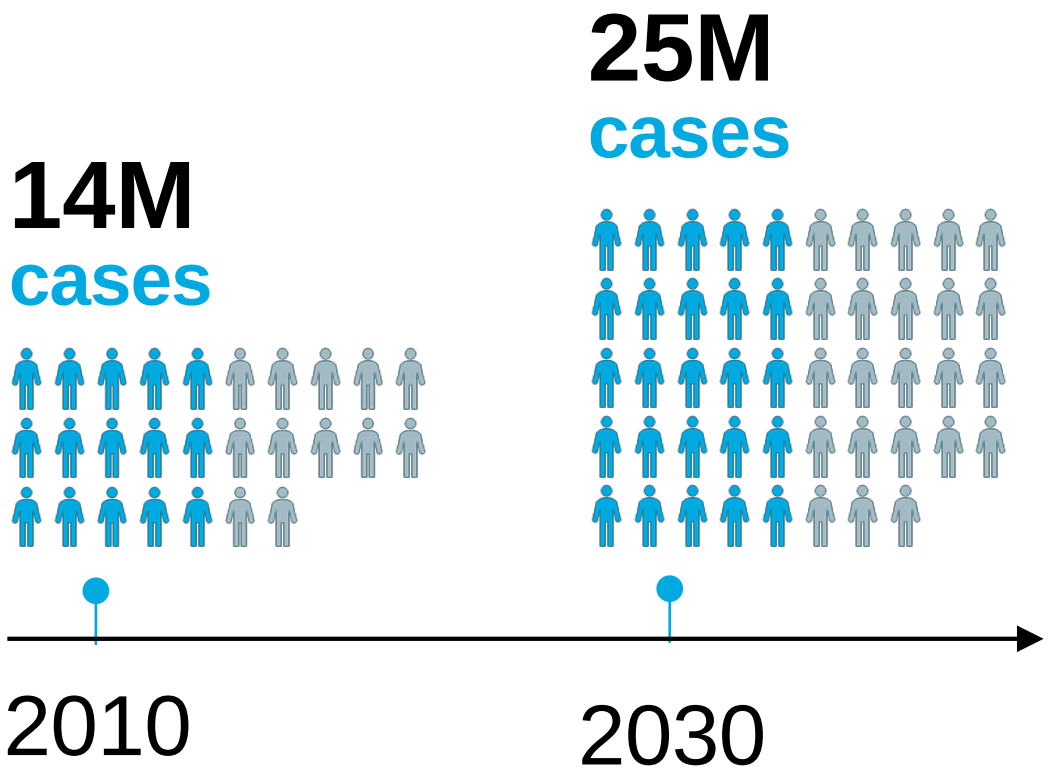
Global cancer burden is rising



Cancer survivorship is increasing

5-year
cancer survival rate is increasing due to earlier diagnosis and enhanced treatments

By 2035 **an additional 150,000** skilled clinicians will be needed

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The gap between access and need…

By 2035 we will need an additional 150,000 skilled clinicians

What is Needed	2015	GAP	2035
Radiation Oncology Centers	7,700	3,200	10,900
Linear Accelerators	13,100	21,800*	21,800
Radiation Oncologists	23,200	22,300	45,500
Medical Physicists	10,000	29,300	39,300
Radiation Technologists	33,300	96,900	130,200

Source: Expanding global access to radiotherapy. Lancet Oncol. Vol 16, Sept. 2015
* 8,700 new machines + 13,100 replacements = 21,800 machines needed

Innovation is key to closing the gap

- ✓ Automate
- ✓ Simplify
- ✓ Efficiency
- ✓ Quality

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Investing in innovation

~$1.5B

Total organic and inorganic investment over 4 years

>50%
Headcount dedicated to software

>1,000
R&D engineers

>1,000
Active patents

>120
Active clinical collaborations

13
Global R&D sites

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Why is Innovation in RT Important?

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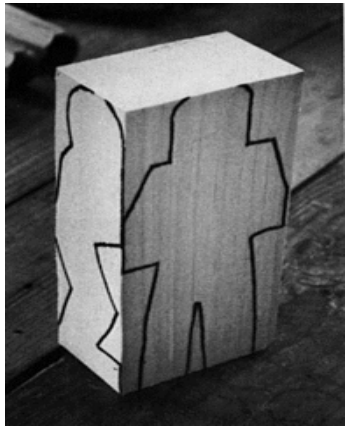
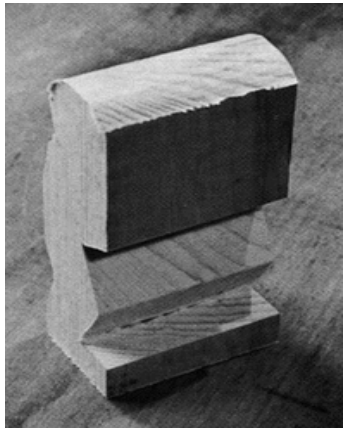
Radiation Dose Sculpting

Cobalt-60

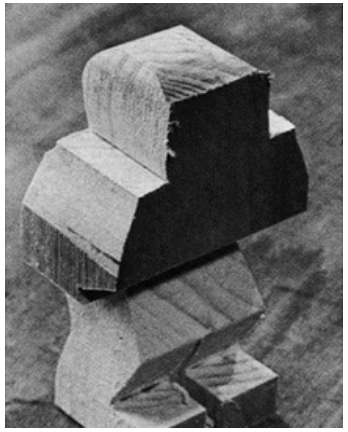
No Sculpting



2-D Radiotherapy

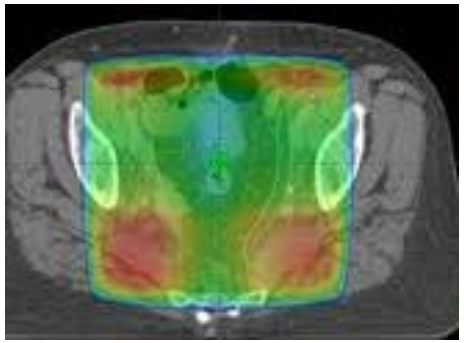


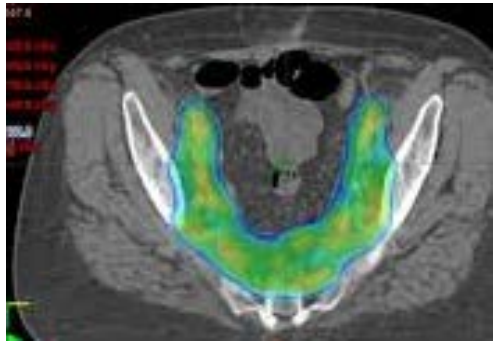
3-D Radiotherapy



IMRT

Linac





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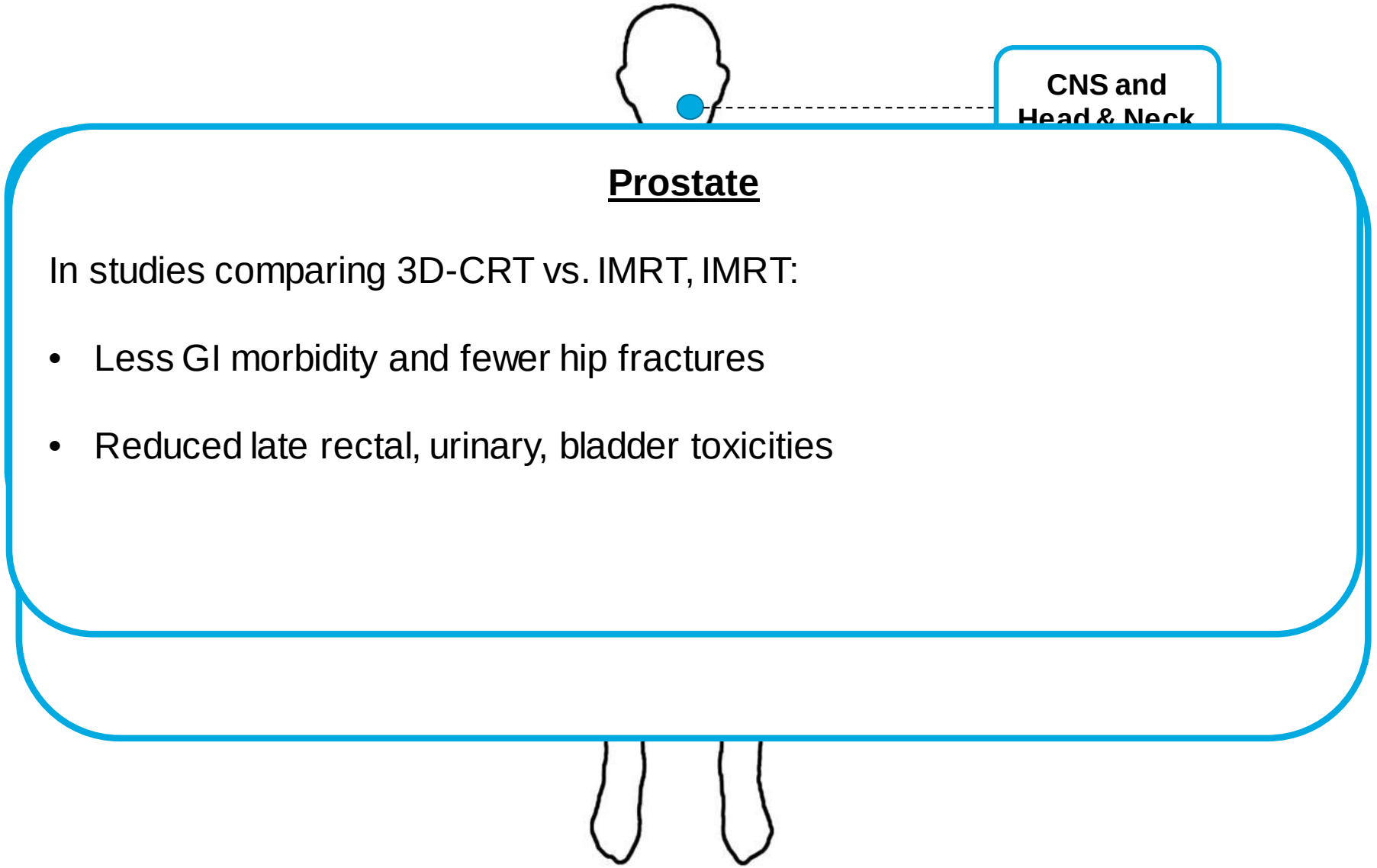
IMRT Medically Necessary Indications



Prostate

In studies comparing 3D-CRT vs. IMRT, IMRT:

- Less GI morbidity and fewer hip fractures
- Reduced late rectal, urinary, bladder toxicities

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Studies available on “References” slide

Halcyon™ Radiotherapy System

Bridging the Radiotherapy Quality Gap in LMICs

Cobalt-60 RT

- Lower upfront investment
- Limited clinical outcomes

Bridging the Gap?

- Higher quality care
- Less:
  - Shielding
  - Staffing
  - Electricity
  - Cost

Traditional Linacs

- Higher upfront cost
- Clinical outcome improvements

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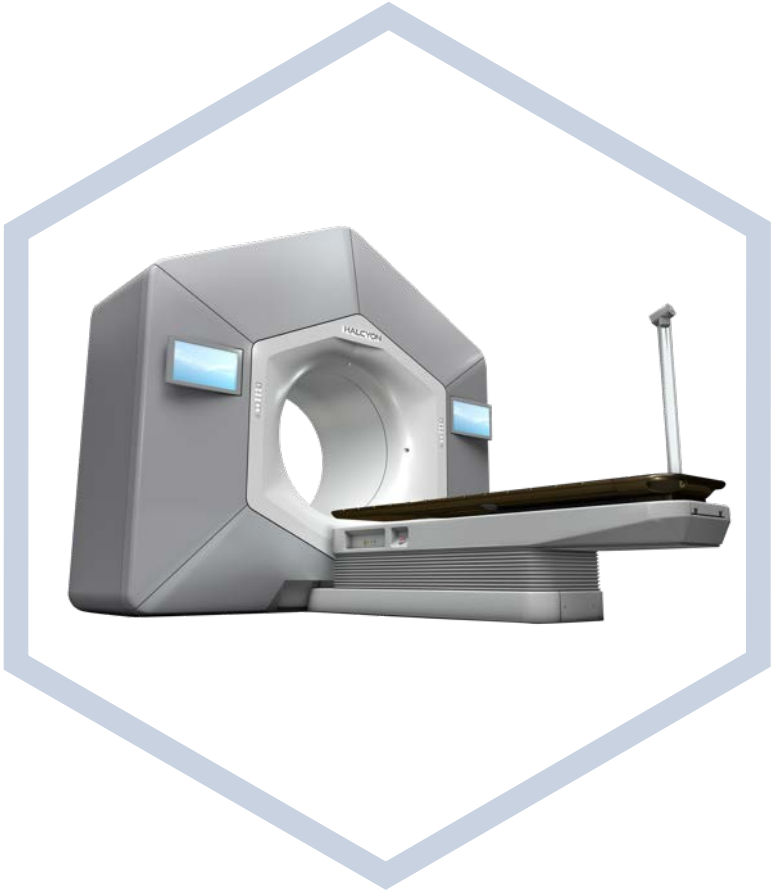
An Innovative Platform for Leveling the Playing Field

High quality of care and increased access to RT around the globe

High Quality Care

Increased Safety

High Patient Volumes



Lower Cost Installations

Improved Patient Experience

Lower Staffing

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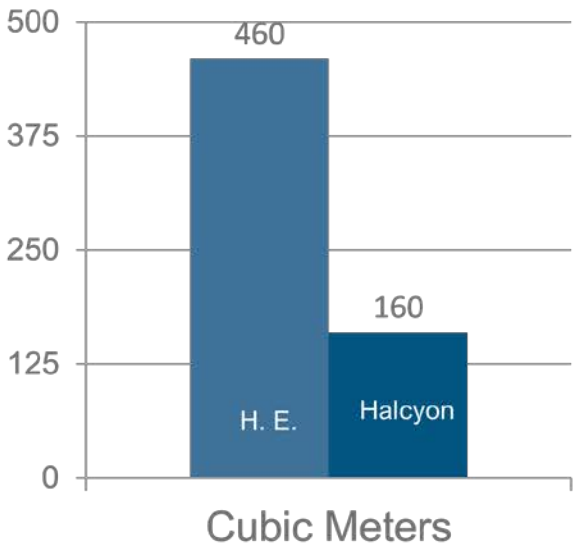
Halcyon Environmental Footprint

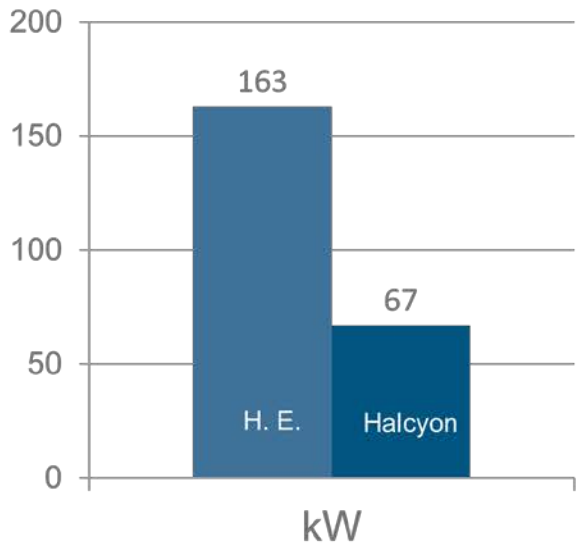
vs. Conventional High Energy (H.E.) Linac

Concrete Usage



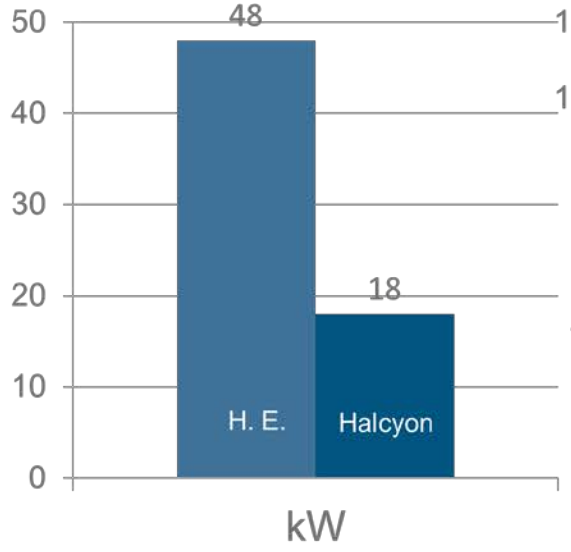
- Bunker size requirements
- Shielded requirements

Cooling Needs



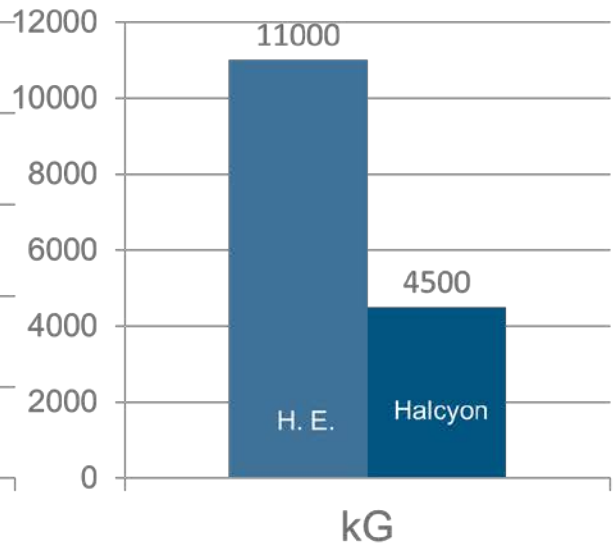
- Chiller water capacity
- Air-conditioning capacity

Energy Usage



- Ready mode energy
- Beam-on energy

Weight



- Shipping containers
- Product materials

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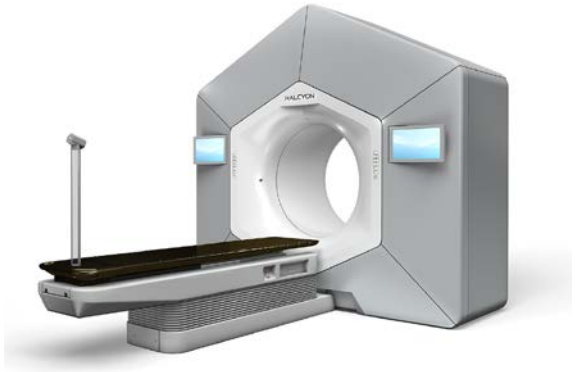
Halcyon

Lower cost of ownership

- Small footprint
- Internal primary beam shielding
- Less electricity consumption
- Internal service diagnostics
- More compact parts
- Lower need for ancillary equipment
- Lower staffing requirements

Safety features

- Safety by design
- Ring design – no collisions
- Human centric design
- Internal machine performance tests



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Halcyon In Practice

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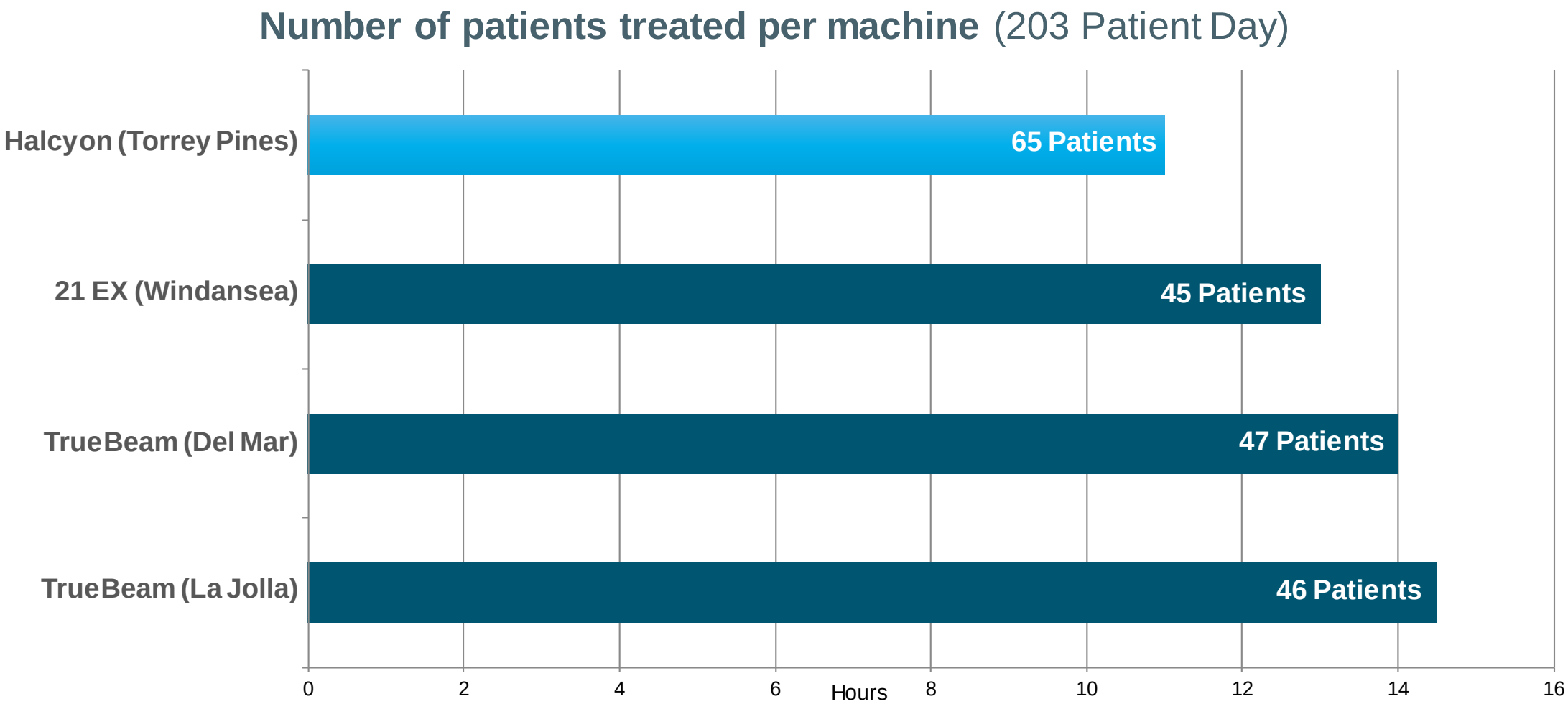
Halcyon Experience at University of California, San Diego

High Throughput Compared to Other Varian Linacs



Data courtesy of University of California, San Diego

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La LIGA Nacional Contra el Cáncer/Instituto de Cancerología

Cobalt Replacement in Guatemala

- USAID grant funded project in partnership with WashU
- Replace cobalt with Halcyon at LIGA/INCAN and benchmark with US standards
- Cobalt removal/disposal support from NNSA
- Training provided by WashU and Varian

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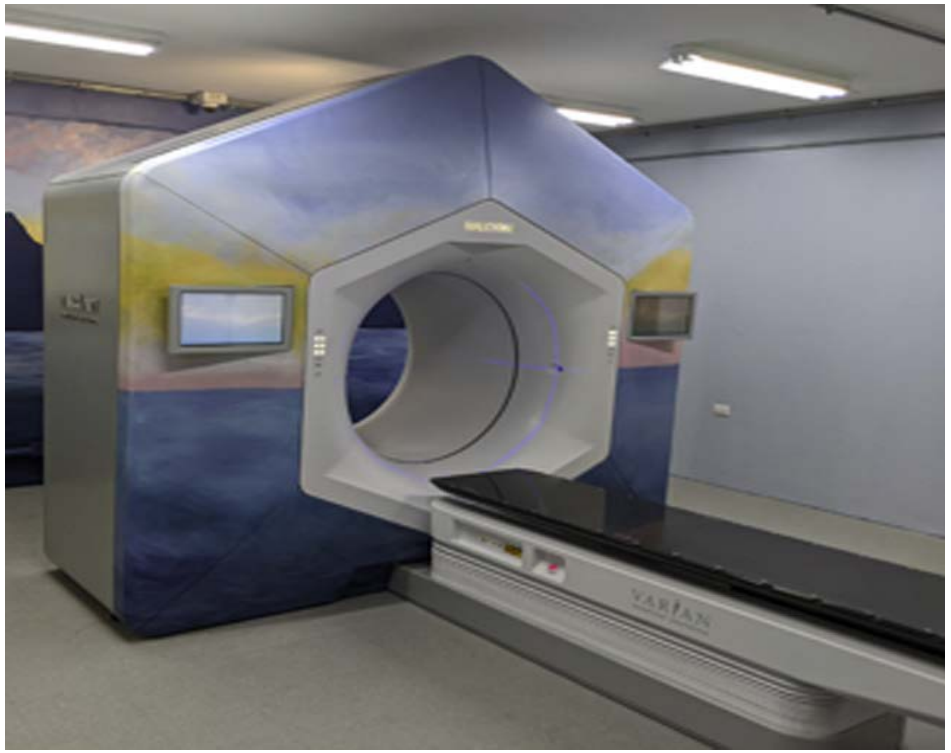
Cobalt and Halcyon™ System

Technology Comparison

Cobalt-60 unit	Halcyon System
	

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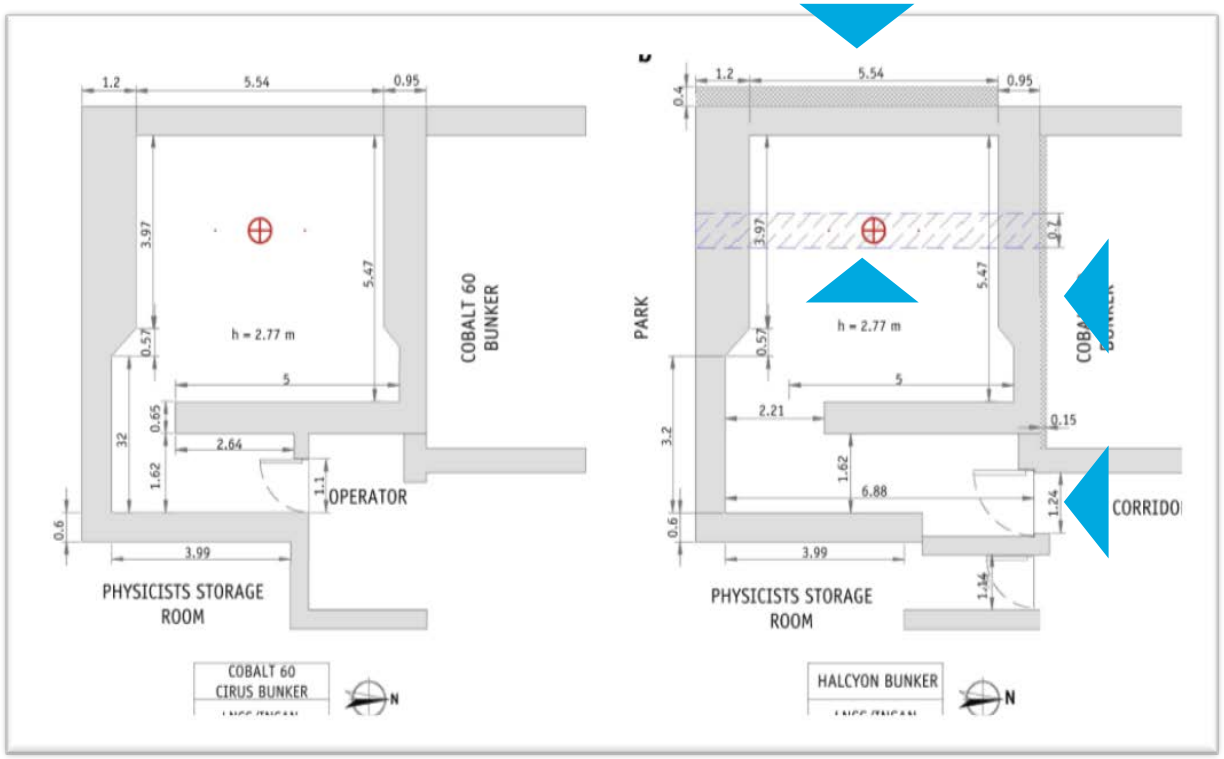
LIGA/INCAN Treatment Room Modification

Minimal Modifications – Fast Installation

- Existing cobalt vault required minimal modifications
- Concrete shielding added to walls near parking lot, adjoining treatment room, and ceiling
- Modifications to the maze were required for a new door to accommodate Halcyon's cooling system
- Bunker modifications cost $300,000 and were completed in 3 months
- Halcyon installed in 7 days



Velarde A, Najera KD, Gay H, Powderly WG, Mutic S, Green J, Michalski JM, Henke L, de Falla V, Laugeman, E, Catu M, Hugo GD, Cai B, van Rheenen J. Taking Guatemala From Cobalt to IMRT: A Tale of US Agency Collaboration With Academic Institutions and Industry. *Int J Radiat Oncol Biol Phys*. 2020 Aug 1;107(5):867-872.

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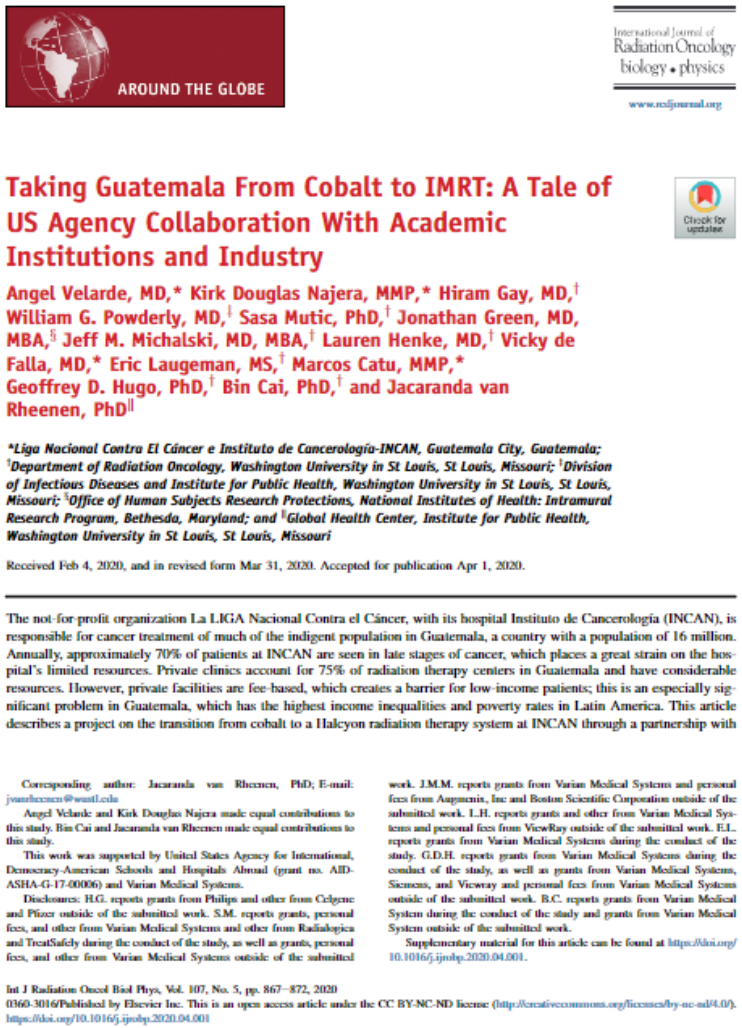
LIGA/INCAN Clinical Implementation

High Throughput – High Quality

- Halcyon treatments began in November 2019
- Increased treatment capacity, reducing waiting list from 3-9 months to 2 weeks
- Treated maximum of 94 patients in one day
- Treatments are 100% IMRT



AROUND THE GLOBE

International Journal of Radiation Oncology biology • physics

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Taking Guatemala From Cobalt to IMRT: A Tale of US Agency Collaboration With Academic Institutions and Industry

Angel Velarde, MD,* Kirk Douglas Najera, MMP,* Hiram Gay, MD,† William G. Powderly, MD,‡ Sasa Mutic, PhD,† Jonathan Green, MD, MBA,§ Jeff M. Michalski, MD, MBA,† Lauren Henke, MD,† Vicky de Falla, MD,* Eric Laugeman, MS,† Marcos Catu, MMP,* Geoffrey D. Hugo, PhD,† Bin Cai, PhD,† and Jacaranda van Rheenen, PhD‖

*Liga Nacional Contra El Cáncer e Instituto de Cancerología-INCAN, Guatemala City, Guatemala; †Department of Radiation Oncology, Washington University in St Louis, St Louis, Missouri; ‡Division of Infectious Diseases and Institute for Public Health, Washington University in St Louis, St Louis, Missouri; §Office of Human Subjects Research Protections, National Institutes of Health: Intramural Research Program, Bethesda, Maryland; and ‖Global Health Center, Institute for Public Health, Washington University in St Louis, St Louis, Missouri

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The not-for-profit organization La LIGA Nacional Contra el Cáncer, with its hospital Instituto de Cancerología (INCAN), is responsible for cancer treatment of much of the indigent population in Guatemala, a country with a population of 16 million. Annually, approximately 70% of patients at INCAN are seen in late stages of cancer, which places a great strain on the hospital's limited resources. Private clinics account for 75% of radiation therapy centers in Guatemala and have considerable resources. However, private facilities are fee-based, which creates a barrier for low-income patients; this is an especially significant problem in Guatemala, which has the highest income inequalities and poverty rates in Latin America. This article describes a project on the transition from cobalt to a Halcyon radiation therapy system at INCAN through a partnership with

Corresponding author: Jacaranda van Rheenen, PhD; E-mail: jvanrheenen@wustl.edu

Angel Velarde and Kirk Douglas Najera made equal contributions to this study. Bin Cai and Jacaranda van Rheenen made equal contributions to this study.

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Supplementary material for this article can be found at https://doi.org/10.1016/j.ijrobp.2020.04.001.

Int J Radiation Oncol Biol Phys, Vol. 107, No. 5, pp. 867–872, 2020

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https://doi.org/10.1016/j.ijrobp.2020.04.001

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HyperArc™ High-Definition Radiotherapy: A Clinical Alternative to Cobalt-based Radiosurgery

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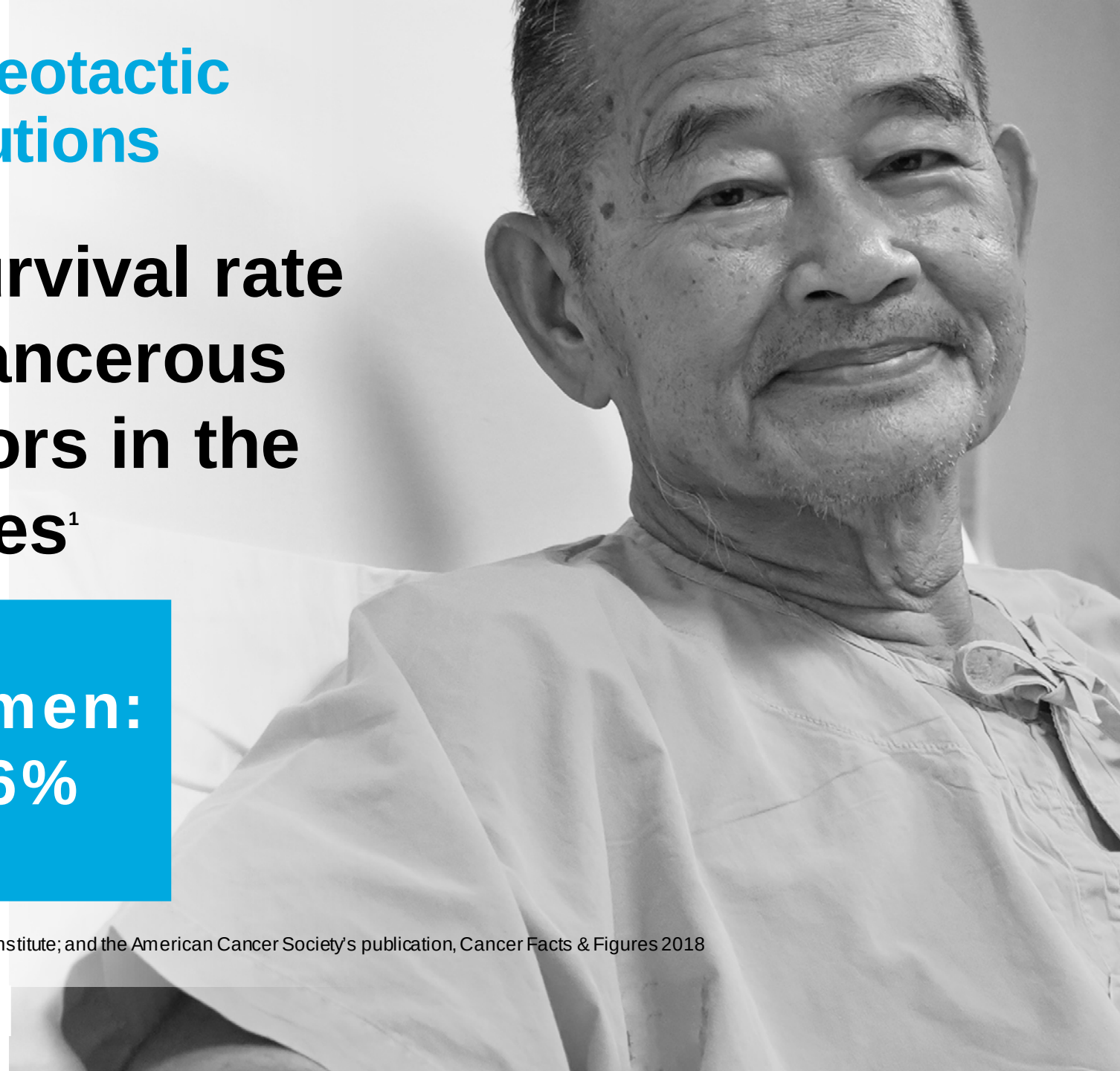
Increasing need for Stereotactic Radiosurgery (SRS) solutions



Projected 5-year survival rate for people with cancerous brain or CNS tumors in the United States[1]

Men:	Women:
34%	36%

[1] Central Brain Tumor Registry of the United States; the National Cancer Institute; and the American Cancer Society's publication, Cancer Facts & Figures 2018

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The Landscape of Cancer Incidence

The Relation to Metastatic Disease

18.1M

New incidences of cancer globally

Top 3

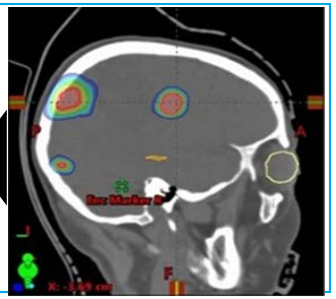
Disease sites with incidences of cancer are linked directly to brain mets

6M

Incidence from top 3 disease sites

~20%

Of all cancer incidences develop metastatic brain lesions



>50%

Of all brain tumors

5%

SRS utilization today

World Health Organization. (2018). *Global Cancer Observatory*. Retrieved from International Agency for Research on Cancer: https://gco.iarc.fr

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HyperArc High-Definition Radiotherapy

Increase access to high-quality, safe cranial radiotherapy

Defined

- Immobilization, patient setup, imaging

Streamlined

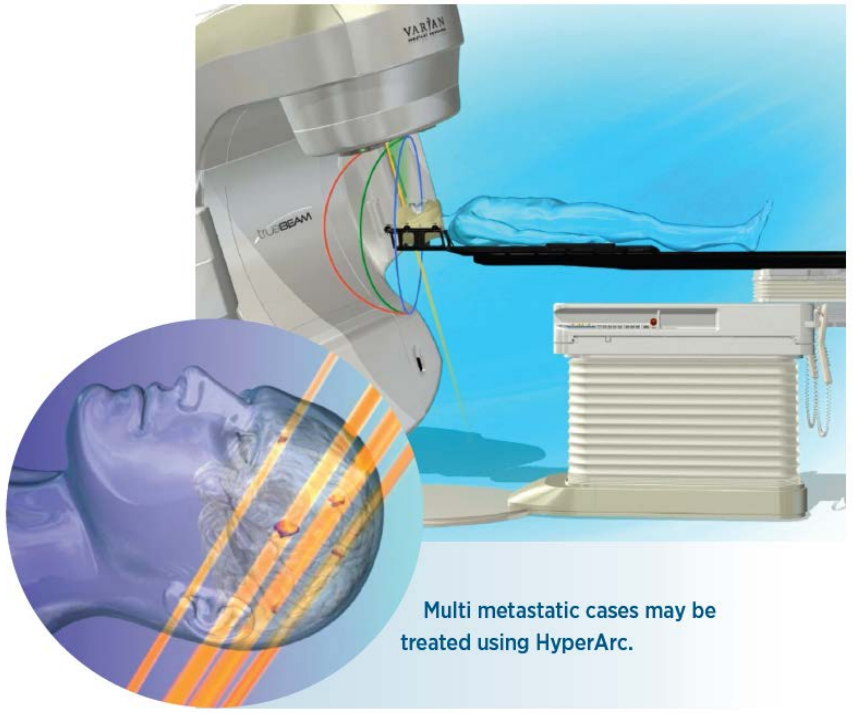
- Consistent planning workflow and collision pre-check

Optimized

- Beam trajectory, collimator angle, dose distribution

Automated

- One-click delivery, imaging even at non-coplanar couch angles



Changes clinical landscape to allow more clinicians to delivery cranial radiotherapy safely and confidently.

NOT AVAILABLE FOR SALE IN ALL MARKETS

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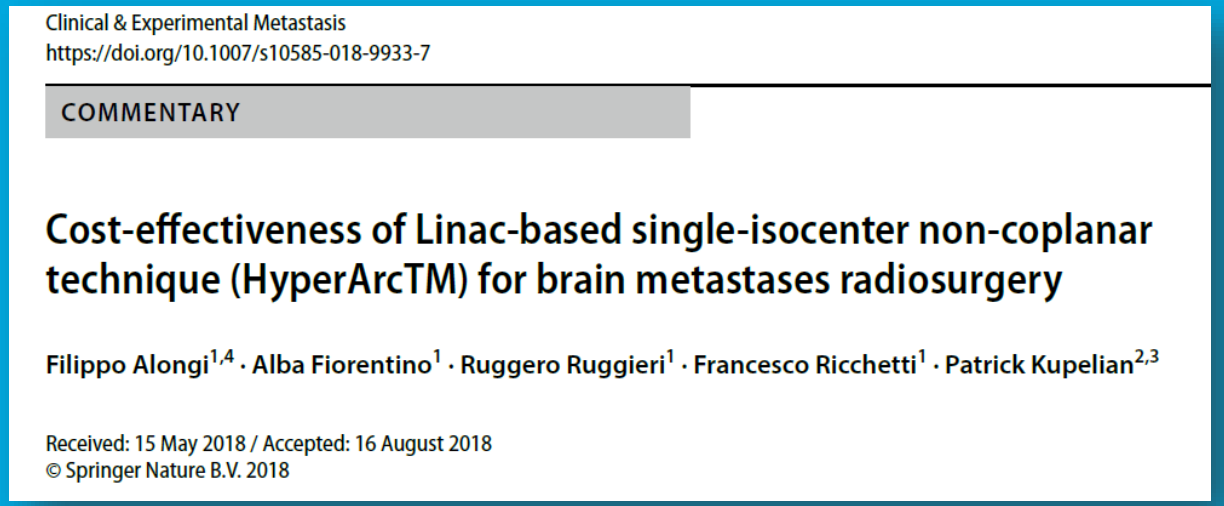
HyperArc Cost-effectiveness

With the increase in numbers of patients needing SRS, an efficient and effective solution such as HyperArc™ allows such BMs patients to be treated on a linac based platform without affecting the waiting time for other cancer patients treated on these versatile platforms.

Data provided by Sacro Cuore Don Calabria Cancer Care Center.



Clinical & Experimental Metastasis
https://doi.org/10.1007/s10585-018-9933-7

COMMENTARY

Cost-effectiveness of Linac-based single-isocenter non-coplanar technique (HyperArcTM) for brain metastases radiosurgery

Filippo Alongi[1,4] · Alba Fiorentino[1] · Ruggero Ruggieri[1] · Francesco Ricchetti[1] · Patrick Kupelian[2,3]

Received: 15 May 2018 / Accepted: 16 August 2018
© Springer Nature B.V. 2018

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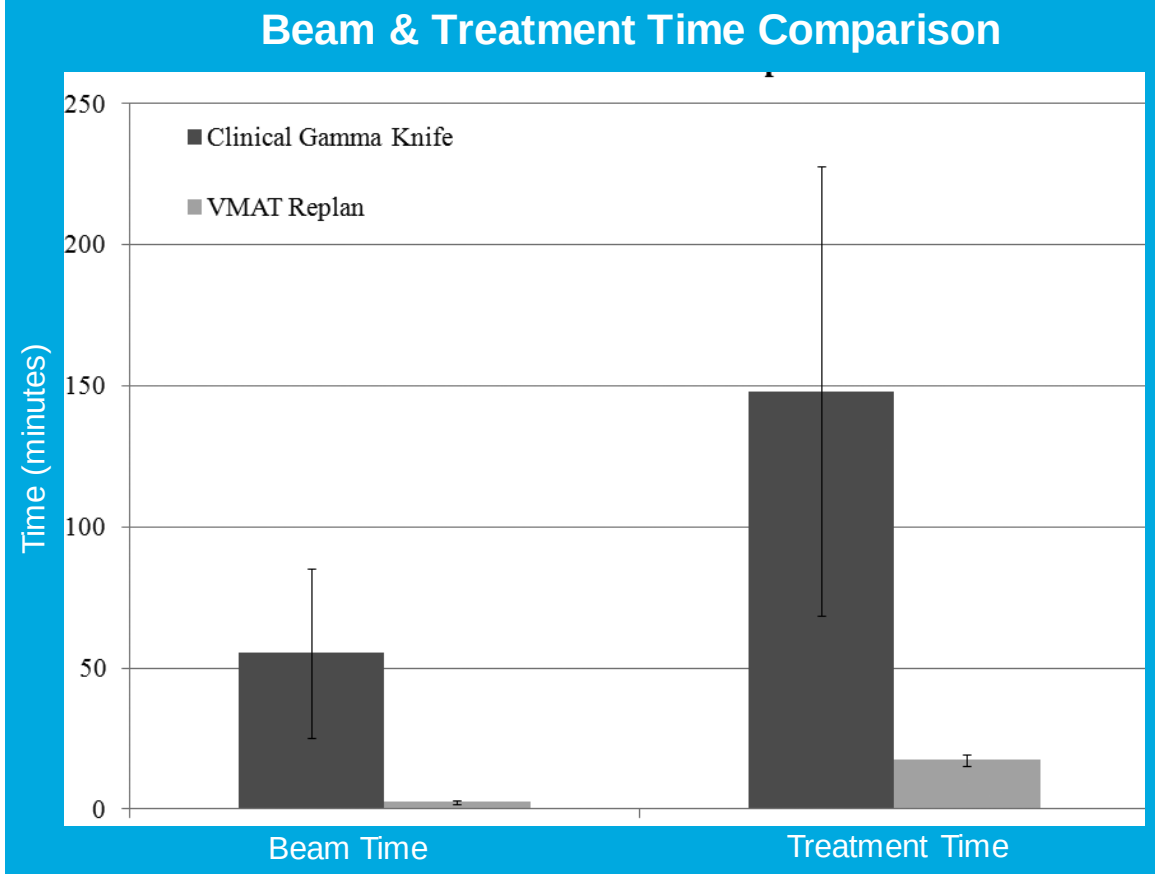
Linac vs. Gamma Knife

Treatment Efficiency

Multiple Target CNS Radiosurgery Can Be Performed in a Conventional Time Slot

- No cones
- High intensity mode (2400 mu/min)
- Single isocenter even for multiple targets



Thomas et al, Neurosurgery. 2014 Oct;75(4):409-17

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Vision:

A World Without Fear of Cancer

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