GammaTile®

Tile-Based Radiation Therapy: A New Approach to Tumor Control

Reconsidering timing and delivery in operable brain tumors

June 2026 | Rev. 2.1

Indication

GammaTile® is authorized for commercial distribution in the United States as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms.

Brain metastases: A multidisciplinary challenge

The Clinical Challenge

30%

Up to 30% of patients with cancer develop brain metastases[1]

Brain metastases negatively impact function, survival and systemic therapy

Treatment requires coordinated care: neurosurgery, radiation oncology, and medical oncology

Current SOC (Operable)

Surgical resection + SRT: the established, evidence-based standard of care

Published 12-month local control: 61–85%[2-7]

Supported by RCT: post-op SRT vs. resection + WBRT and post-op SRT vs. resection only [2,3]

1. Aizer AA, e al. *Neuro Oncol*. 24:1613-1646 (2022). 2. Patchell RA, et al. *N Engl J Med*. 322:494-500 (1990). 3. Mahajan A, et al. *Lancet Oncol*. 18:1040-1048 (2017). 4. Brown PD, et al. *Lancet Oncol*. 18:1049-1060 (2017). 5. Kocher M, et al. *J Clin Oncol*. 29:134-41(2011). 6. Eitz KA, et al. *Jama Oncol*. 6:1901-1909 (2020). 7. Lehrer EJ, et al. *Int J Radiat Oncol Biol Phys*. 103:618-630 (2019).

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Expanding options for care

Opportunities for Optimization

- Time between resection and SRT initiation is a recognized clinical challenge due to recovery, planning and access to care, leading to worse outcomes[1,2]
- Target delineation and cavity dynamics add complexity to post-operative planning[3-5]
- 12-month local control for tumors >3 cm: ~44%[6]
- No new randomized data for local management of resected brain metastases since 2017

Introducing ROADS Phase 3 RCT[8]

Multi-site RCT prospectively reviewed by independent blinded central readers

First RCT for local management of operable brain metastases with superior efficacy since 2017[6-8]

Cs-131 tile-based radiation therapy offers a new immediate option designed to address these challenges at the time of surgery

1. O'Brien, DAR, et al. *J Neurosurg.* 135:1695-1705 (2021). 2. Brennan C, et al. *Int J Radiat Oncol Biol Phys*. 88:130-136 (2014). 3. Shi S, et al. *Pract Radiat Oncol*. 10:e363-371 (2020). 4. Soliman H, et al. *Int J Radiat Oncol Biol Phys*. 100:436-442 (2018). 5. Jarvis LA, et al. *Int J Radiat Oncol Biol Phys.* 84:943-948 (2012). 6. Mahajan A, et al. *Lancet Oncol*. 18:1040-1048 (2017). 7. Brown PD, et al. *Lancet Oncol.* 18:1049-1060 (2017). 8. Weinberg J. *J Clin Oncol* 44, 2026 (suppl 17; abstr LBA2000).

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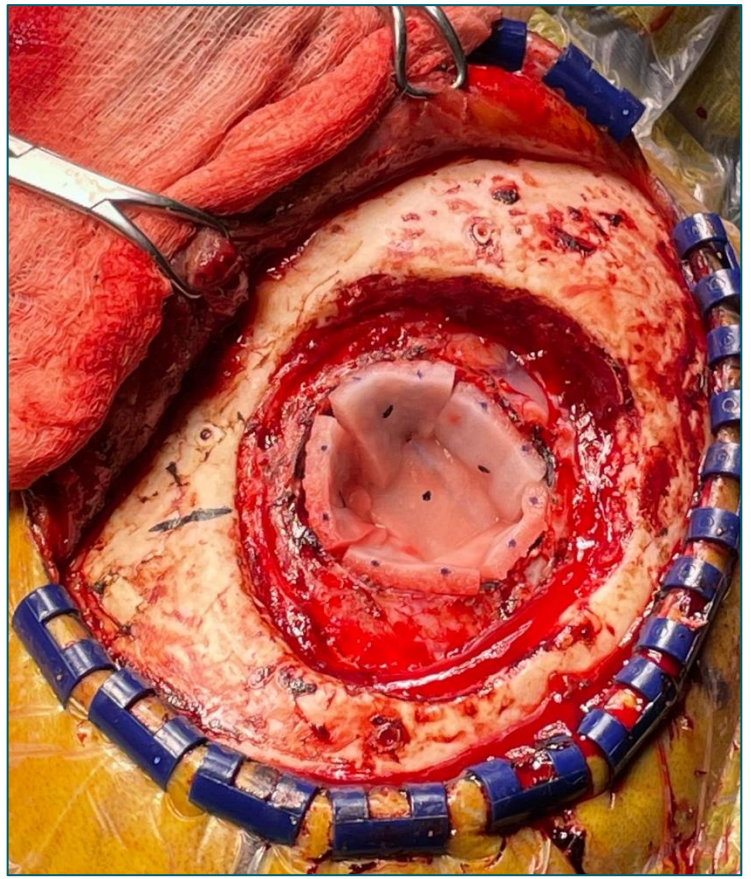
How GammaTile works

Mechanism of delivery

- Implantable radiation sources placed directly in the resection cavity
- Guaranteed immediate initiation of the prescribed dose at the time of surgery
- Localized, dose-escalated radiation delivered to the surgical margin with controlled dose distribution[1]

Treatment implication

- Eliminates the interval between surgery and radiation initiation
- Reduces dependence on post-op recovery and adherence



1. Kutuk T, et al. *Brachytherapy*. 23(6):751-760 (2024).

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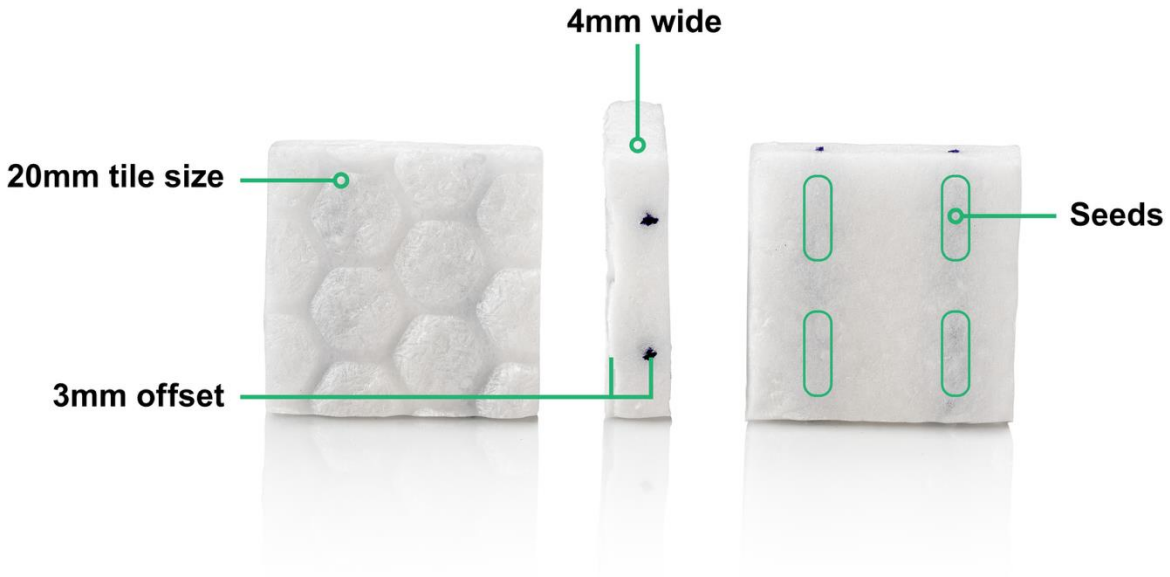
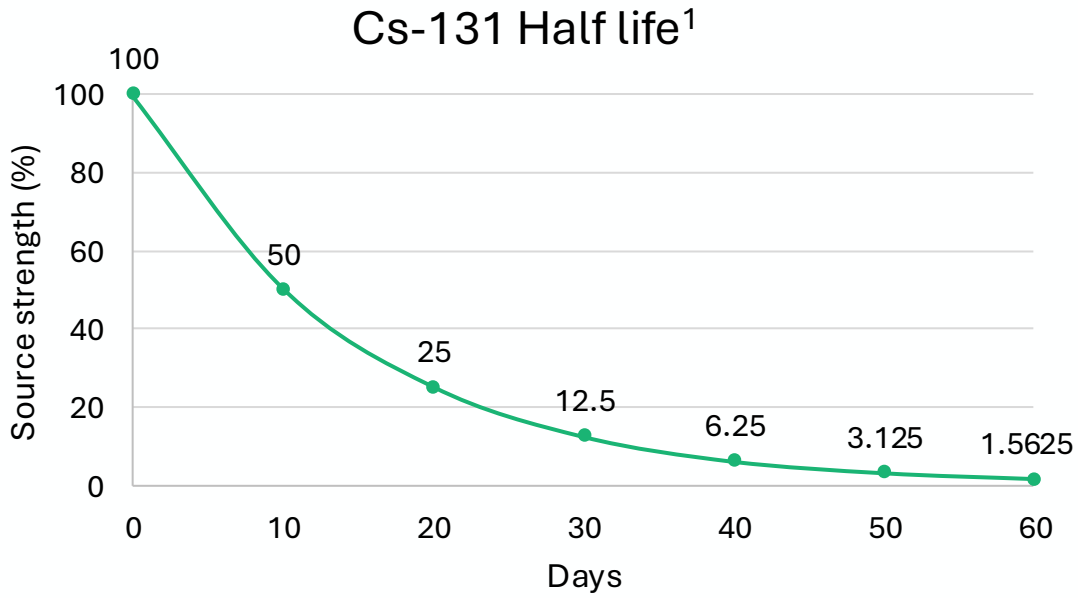
Design features enabling safe tile-based radiation delivery

Delivered in a standard operating room, no dedicated radiation treatment room required.

Tile-Based Radiation Delivery[1,2]

- Cesium-131 radiation sources (half life of 9.7 days) embedded in a bioresorbable collagen matrix
- Conforms to the resection cavity for margin-focused dose delivery
- Fixed source strength (3.5 U/seed) and predictable source spacing enable consistent dose distribution
- 0% reported reoperation for radionecrosis across peer-reviewed publications





1. Kutuk T, et al. *Brachytherapy and Radiation Principles in Clinical Practice*. 48:795-820 (2024). 2. Brachman DG, et al. *J Neurosurg*. 131(6):1819-1828 (2018).

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ROADS Full 230 Patient Analysis

Final results of a randomized, controlled, phase 3 trial comparing resection and post-operative stereotactic radiation vs. resection plus cesium-131 tile-based radiation for treatment of newly diagnosed brain metastases

Presented as a Late-Breaking Abstract at the 2026 ASCO® Annual Meeting
May 30, 2026

1. Weinberg J. ROADS: A randomized controlled phase 3 trial of resection plus post-operative stereotactic radiation versus resection plus cesium-131 tile-based radiation therapy for newly diagnosed brain metastases. Presented at: American Society of Clinical Oncology; May 30, 2026; Chicago, IL.

Key takeaway points / conclusions[1]

In patients with a newly diagnosed surgical brain metastasis, the phase 3 ROADS trial compared resection with tile-based radiation therapy to the standard of care resection followed by stereotactic radiation therapy.

Resection with tile-based radiation therapy demonstrated:

1

Superior
Time to Surgical Bed Recurrence

2

Superior
Surgical Bed Recurrence-Free Survival

3

Significantly Improved
Overall Survival

Superior efficacy did not come at the expense of increased toxicity.

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ROADS: A multi-site phase 3 RCT against the current SOC

Study Type

- Phase 3, randomized controlled (1:1), multicenter (32)

Objective

- Compare resection +SRT versus resection +TBRT for treatment of a single, newly diagnosed, surgical brain metastasis (index metastasis)

R+SRT Arm (standard of care)

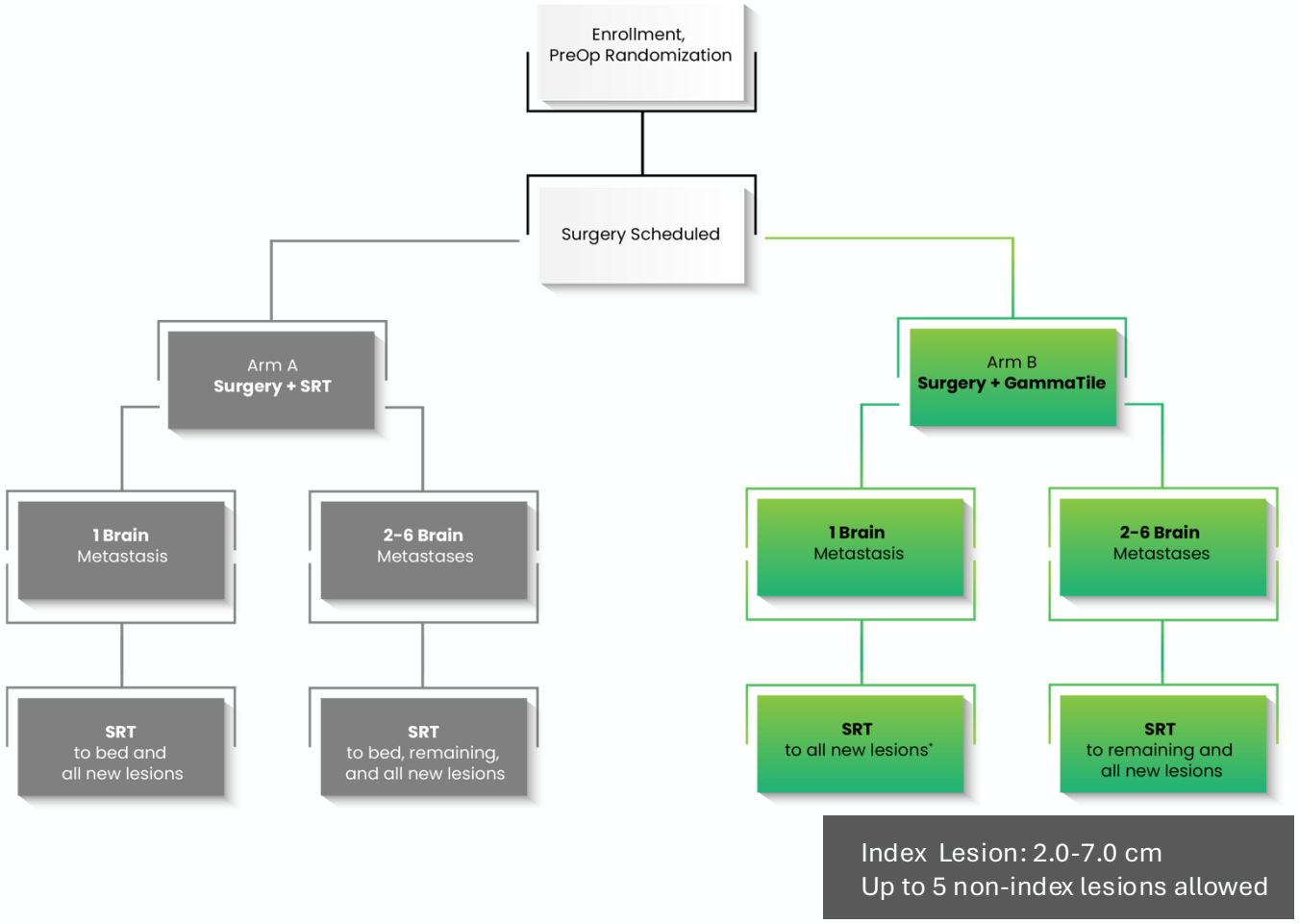
- Maximal safe resection
- SRT starting 21 ±7 days from surgery

R+TBRT Arm

- Maximal safe resection
- TBRT devices implanted at time of surgery

Non-index brain metastases (both arms)

- 1-5 additional non-surgical brain metastases allowed
- Treated using SRT starting 21 ±7 days from surgery



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Co-primary endpoints confirmed by prospective independent central review

Primary Outcomes*†

- Time-to-surgical bed recurrence (time-to-SBR)
- Surgical bed recurrence-free survival (SB-RFS)

Pre-specified modified intent-to-treat (mITT) population was used for efficacy analyses

- mITT = patients who had surgery, pathologic confirmed metastasis, any follow up information
    - This helps ensure that non-brain metastases histologies were not included

Secondary Outcomes

- Overall survival (OS)
- Functional status (KPS, Barthel-ADL)
- Quality of life (FACT-Br)
- Adverse events
- Development of leptomeningeal disease (LMD)†
- Assessment of radiation necrosis (RN)
- Factors that cause delays in SRT

* SBR = radiographic evidence of new or progressive contrast-enhancing metastasis within the surgical bed

† All reported SBR and LMD confirmed by central review by two independent neuroradiologists

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Rigorous hierarchical statistical testing used to control for multiplicity[1]

Primary Outcomes: Time-to-SBR and SB-RFS

- Non-inferiority design based on hypothesis that R+TBRT confers meaningful advantages for both convenience and access to care
- **If R+TBRT was statistically non-inferior, superiority testing was performed using hierarchical testing to control type I error in the following order:**

Non-inferiority for time-to-SBR → Non-inferiority for SB-RFS → Superiority for time-to-SBR → Superiority for SB-RFS

- Non-inferiority and superiority tests used Cox proportional hazards models with stratification variables as covariates
- Survival estimates were made using the Kaplan-Meier method

Key Secondary Outcome: Overall Survival

- If co-primary outcomes established superiority of R+TBRT, OS was compared using the same methodology

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Baseline characteristics: Well-balanced arms across a representative population

Median follow-up: **12.9 months**

Parameter	R+TBRT	R+SRT
Enrolled Patients (Total 230)	115	115
Modified Intent-to-Treat Population (Total 204)	103	101
Median age in years (range)	64 (34, 89)	63 (31, 89)
Sex, M:F	40:63	52:49
Race, %: White, Black, Asian, other/unknown	85.4 | 8.7 | 0.0 | 5.9	80.2 | 13.9 | 2.0 | 4.0
Duration of extracranial disease ≤ 3 months, %	52.4	54.5
Median resected tumor diameter, cm (range)	3.20 (2.0–6.1)	3.25 (2.1–5.8)
Mean number of brain metastases (standard dev)	1.8 (1.13)	1.8 (1.23)
Number of brain metastases, %: 1 | 2-3 | 4-6	58.3 | 34.0 | 7.8	55.4 | 33.7 | 10.9

Histology	R+TBRT (%)	R+SRT (%)
Lung	43.7	45.5
Melanoma	14.6	10.9
Breast	12.6	8.9
Renal	4.9	5.0
Colon	2.9	5.9
Other	21.4	23.8

R+SRT Arm	
Fractions: 1 | 3-5	**7.8% | 92.2%**
Median days from resection to SRT	27 (6–47)
Reasons for SRT delay	rehabilitation, weather, events, scheduling

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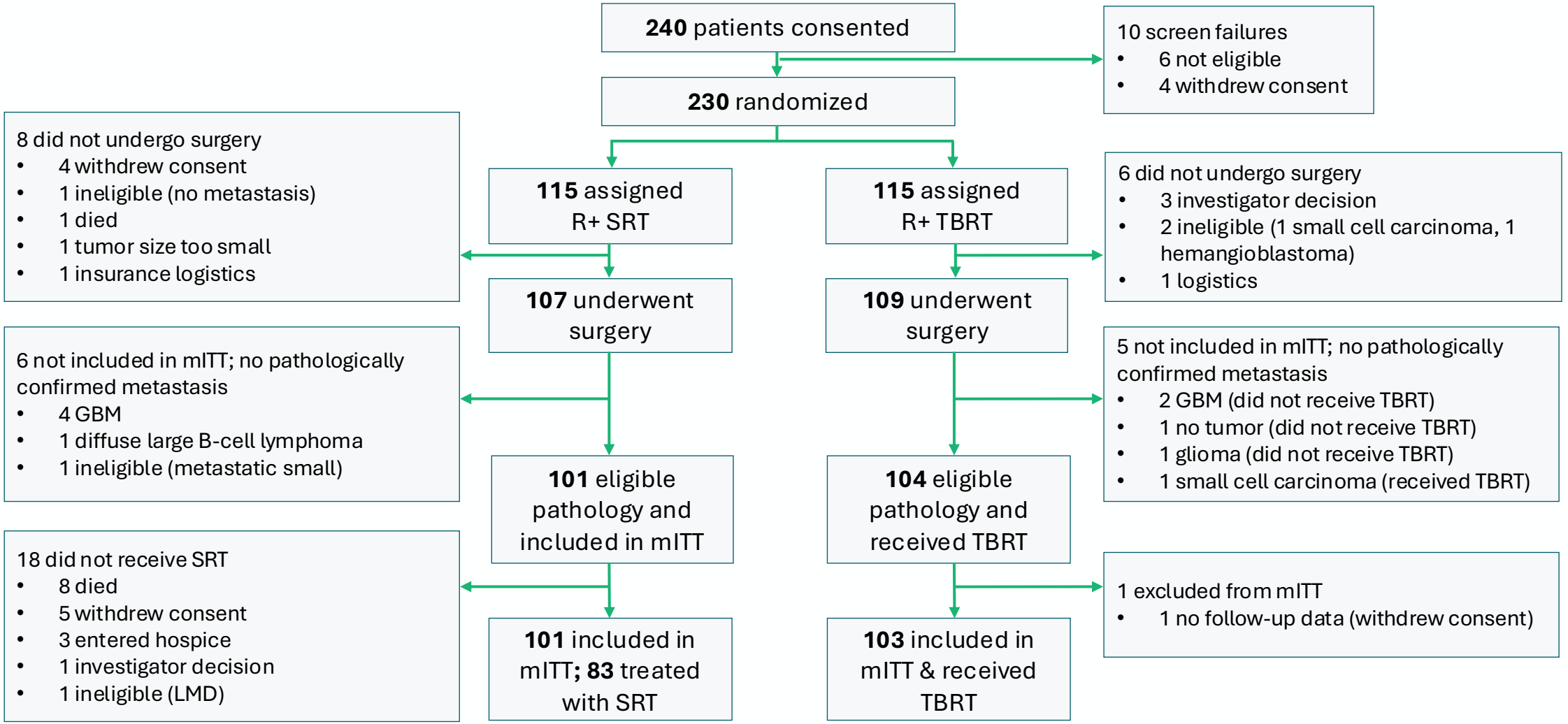
ROADS CONSORT: Randomization to treatment, 230 patients



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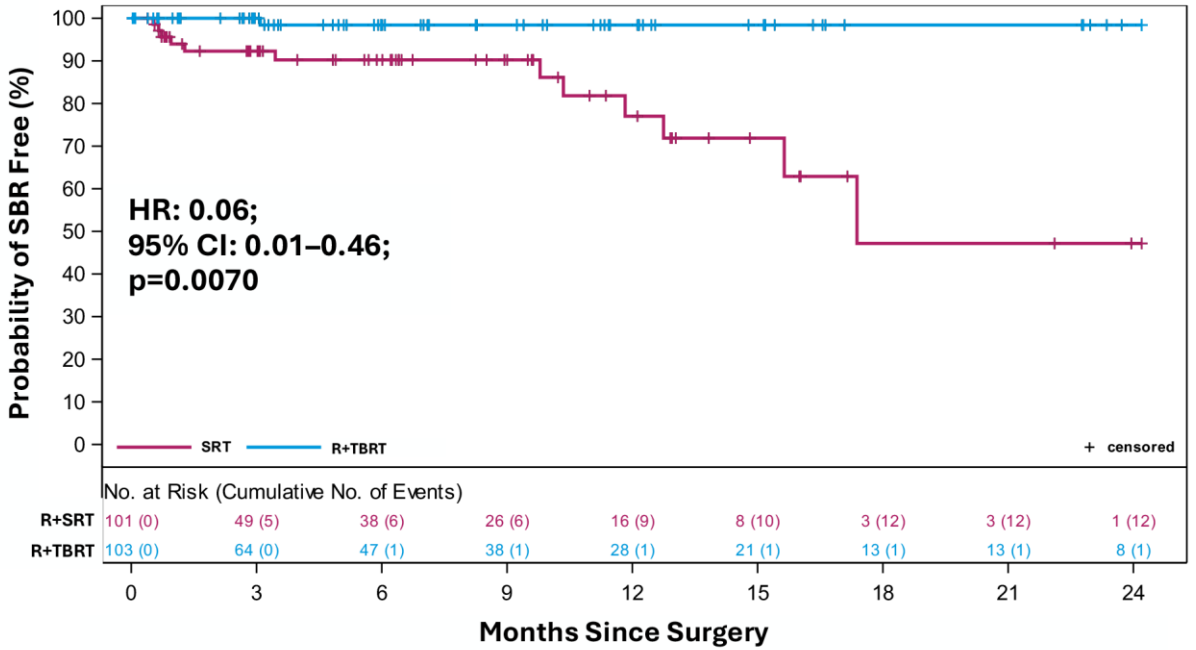
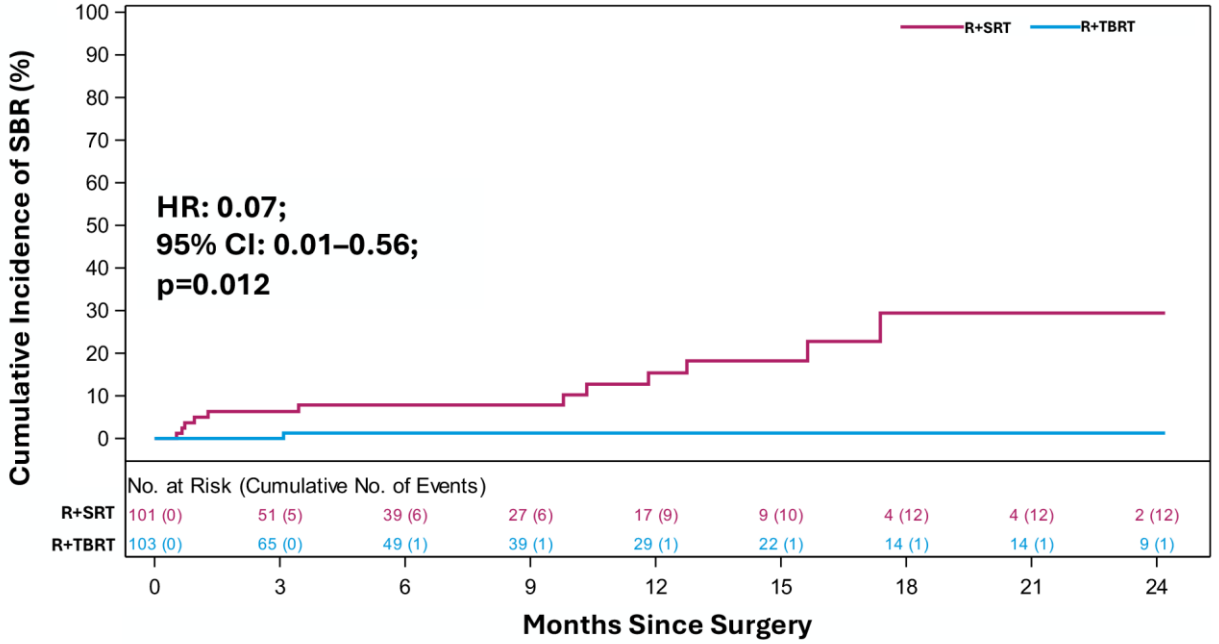
GammaTile demonstrated *superior* time to surgical bed recurrence (SBR)[1]

Time-to-SBR = time from surgery to SBR

- Median time-to-SBR was not reached in R+TBRT vs 17.4 months in R+SRT (p=0.0070)
- 12-month cumulative incidence of SBR was 1.3% in R+TBRT vs 15.4% in R+SRT (p=0.012)





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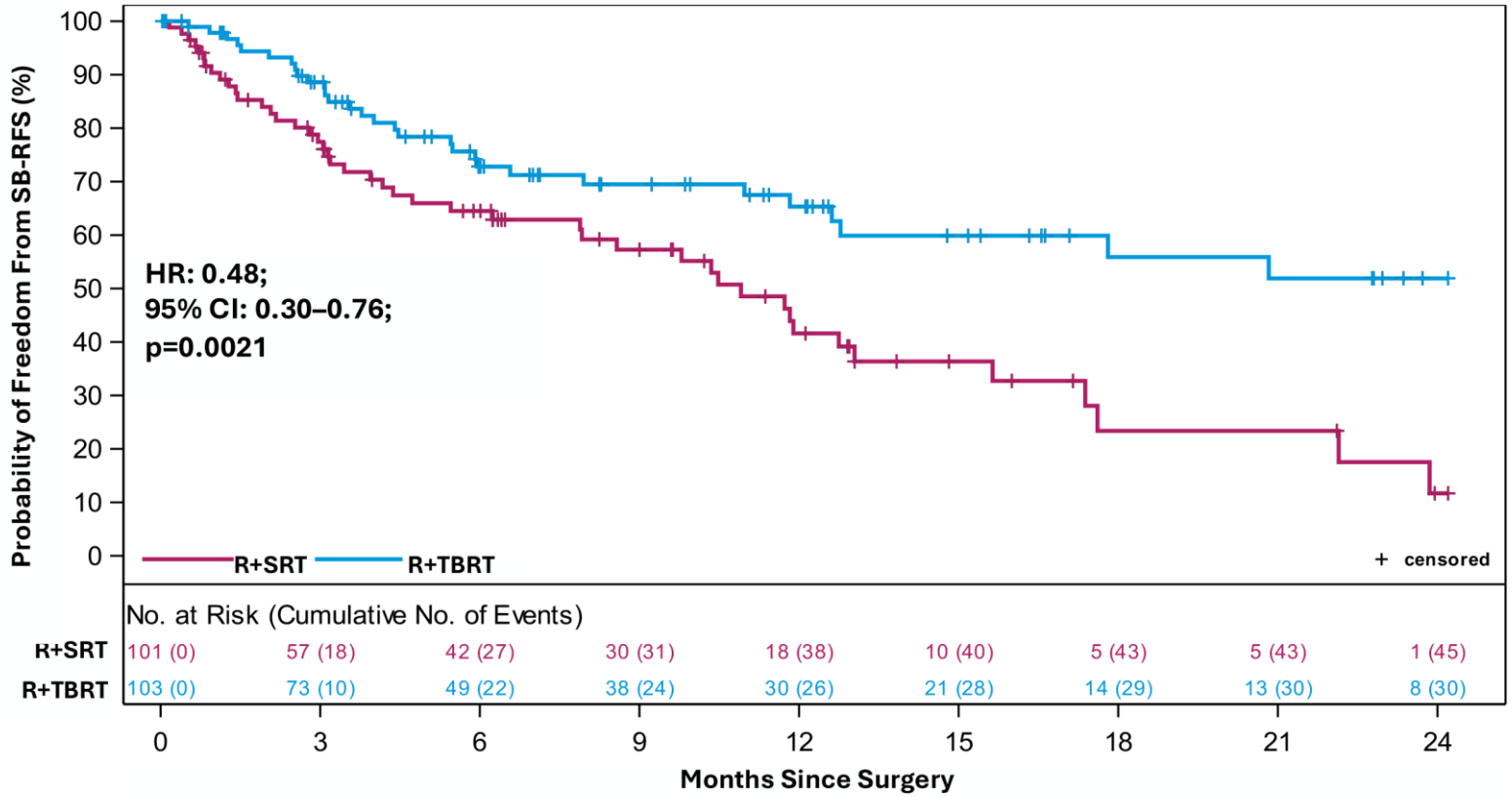
GammaTile demonstrated *superior* surgical bed recurrence-free survival (SB-RFS)[1]

SB-RFS = time from surgery to either SBR or death from any cause, whichever occurred first

- Median SB-RFS was not reached in R+TBRT vs. 10.9 months in R+SRT (p = 0.0021, HR:0.48)



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Post-operative SRT non-completion: A documented and reproducible clinical reality[1]

Patient Post-Operative Treatment Non-Adherence	
ROADS RCT Data	**Post-Op RCT Data**
17.9% of patients on RCT did not receive their intended SRT[2]	**20-27%** of patients on RCT never receive their intended SRT[3-4]

Median Days from Surgery to Beginning Radiation (Brain Mets)		
ROADS RCT Data		**Post-Op Meta-analysis**
No Delay GammaTile[2]	**27 days** Median post-op SRT gap[2]	**27.8 days** Median post-op SRT gap[5] Meta-analysis; n=1,338

1. Roth O'Brien DA, et al. *J Neurosurg.* 135:1695-1705 (2021). 2. Weinberg J. ROADS: A randomized controlled phase 3 trial of resection plus post-operative stereotactic radiation versus resection plus cesium-131tile-based radiation therapy for newly diagnosed brain metastases. Presented at: American Society of Clinical Oncology; May 30, 2026; Chicago, IL. 3. Yeboa DN, et al. *JAMA Oncol*. 11(8):890–899 (2025). 4. Brennan C, et al. *Int J Radiat Oncol Biol Phys.* 88:130–136 (2014). 5. Nwankwo A, et al. *Prac Oncol* (2023).

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TBRT remains superior even when removing patients on the SRT arm who did not receive SRT[1]

- An inherent challenge with postoperative SRT is that it is not guaranteed
- In previous trials, ~20% of trial patients do not receive assigned postoperative SRT[2,3]
- A sensitivity analysis was performed to remove patients on SRT arm that did not receive assigned SRT
- Even when removing patients who did not receive SRT on the SRT arm, primary endpoints remained significant

	R+TBRT	R+SRT
Patients in mITT who received intended treatment	N = 103	N = 83
Surgical Bed Recurrence		
Kaplan-Meier estimated median time-to-SBR (95% CI), months	Not met	17.4 (15.6, -)
Hazard ratio (95% CI)	0.06 (0.01,0.46)	
Non-inferiority p-value	0.0018	
Superiority p-value	0.0069	
Surgical Bed Recurrence-Free Survival		
Kaplan-Meier estimated median time-to-SB-RFS (95% CI), months	Not met	11.8 (9.8, 17.4)
Hazard ratio (95% CI)	0.57 (0.35, 0.93)	
Non-inferiority p-value	0.0008	
Superiority p-value	0.0245	

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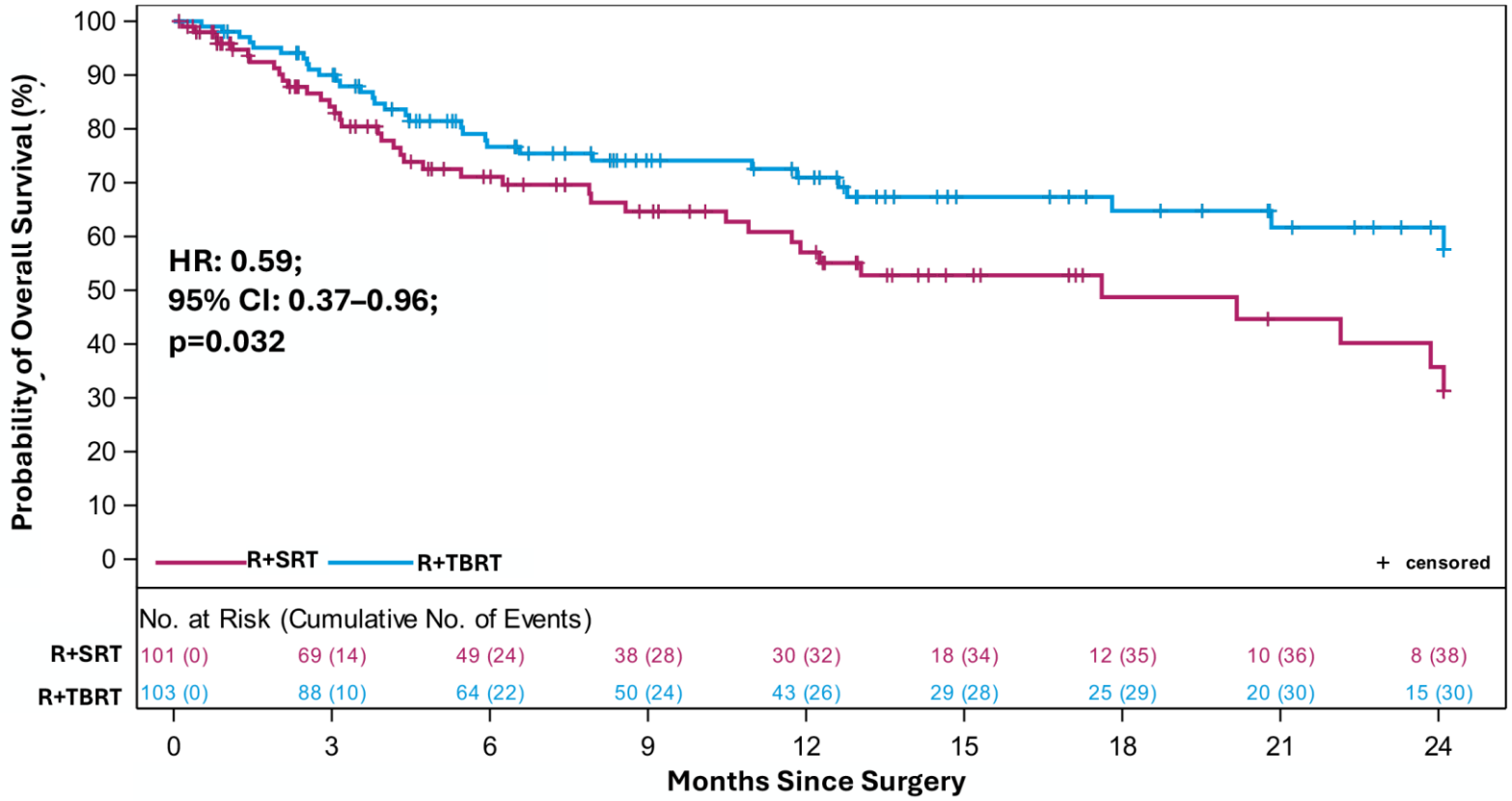
Secondary endpoint

GammaTile demonstrated *significantly improved* overall survival[1]

OS = time from surgery to death from any cause

- Median OS was 42.5 months in R+TBRT vs 17.6 months in R+SRT (p=0.032, HR:0.59)



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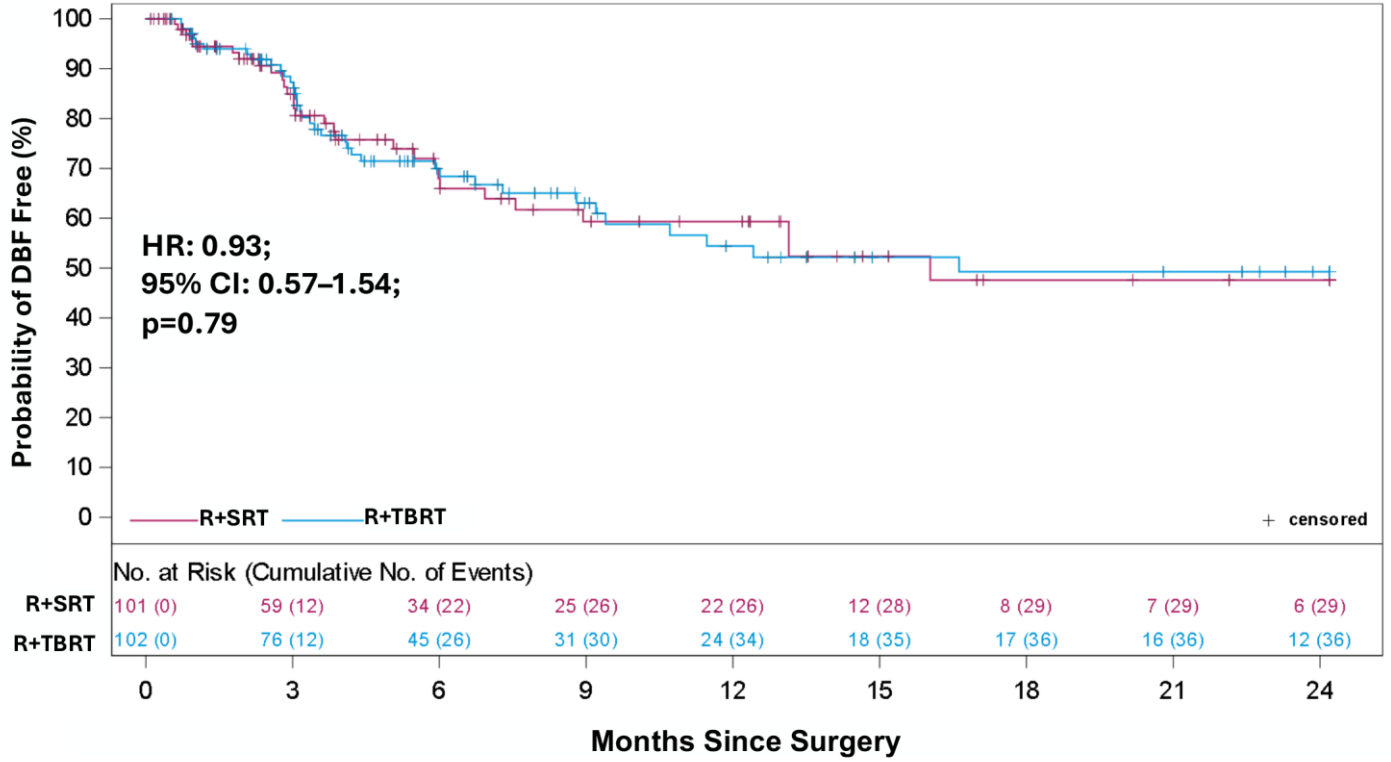
Distant brain failure was similar in each arm[1]

Distant brain failure (DBF) = development of any new brain metastases during the study

- Time-to-DBF = time from surgery to DBF
- No difference in time-to-DBF between arms (p=0.793)



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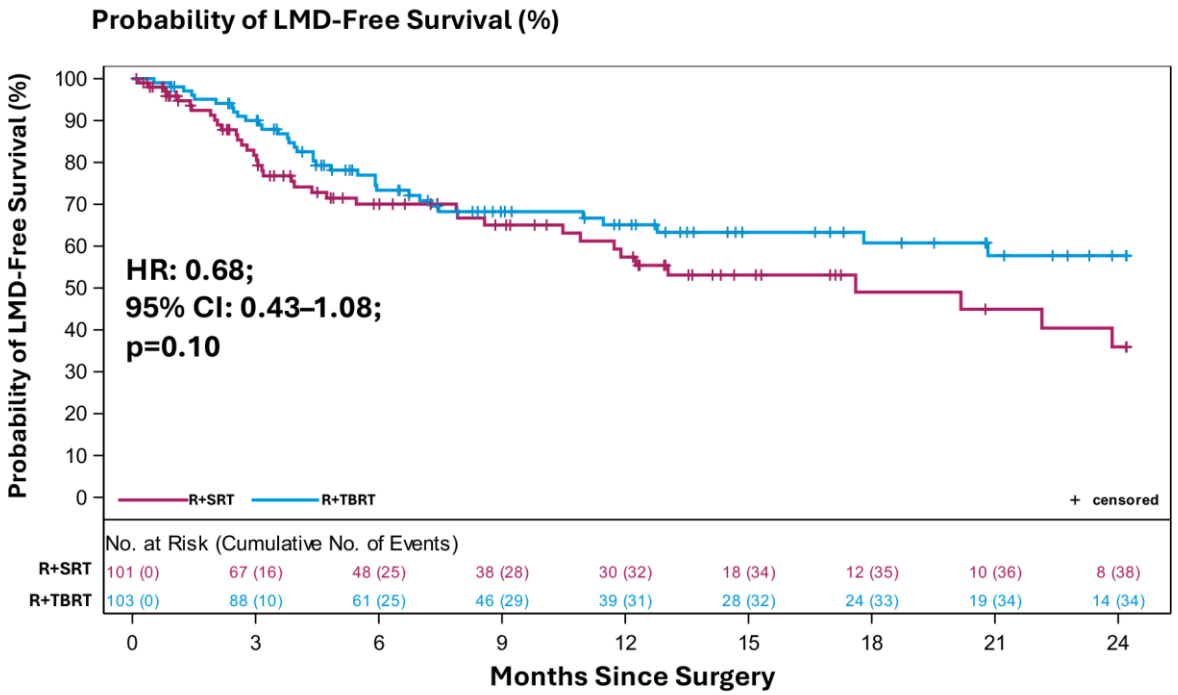
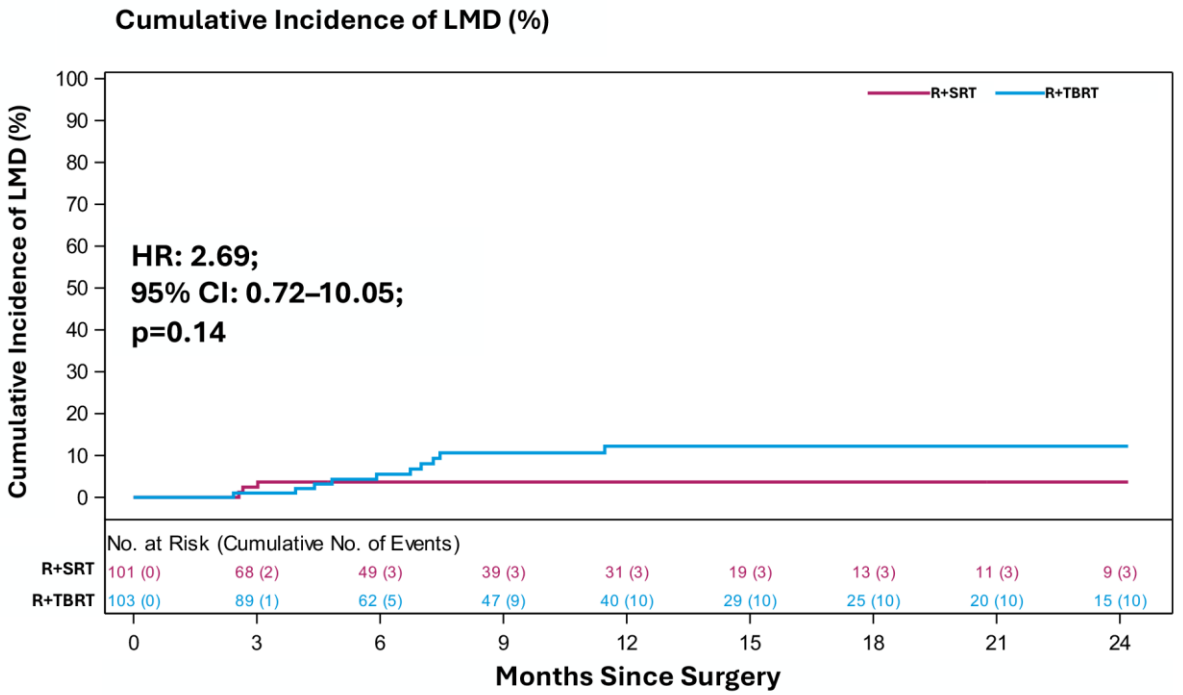
Secondary endpoint

Leptomeningeal disease (LMD) was similar in each arm[1]

- No difference in LMD-free survival (LMD or death, whichever occurs first) (p=0.10)
- No difference in cumulative incidence of LMD (p=0.14)





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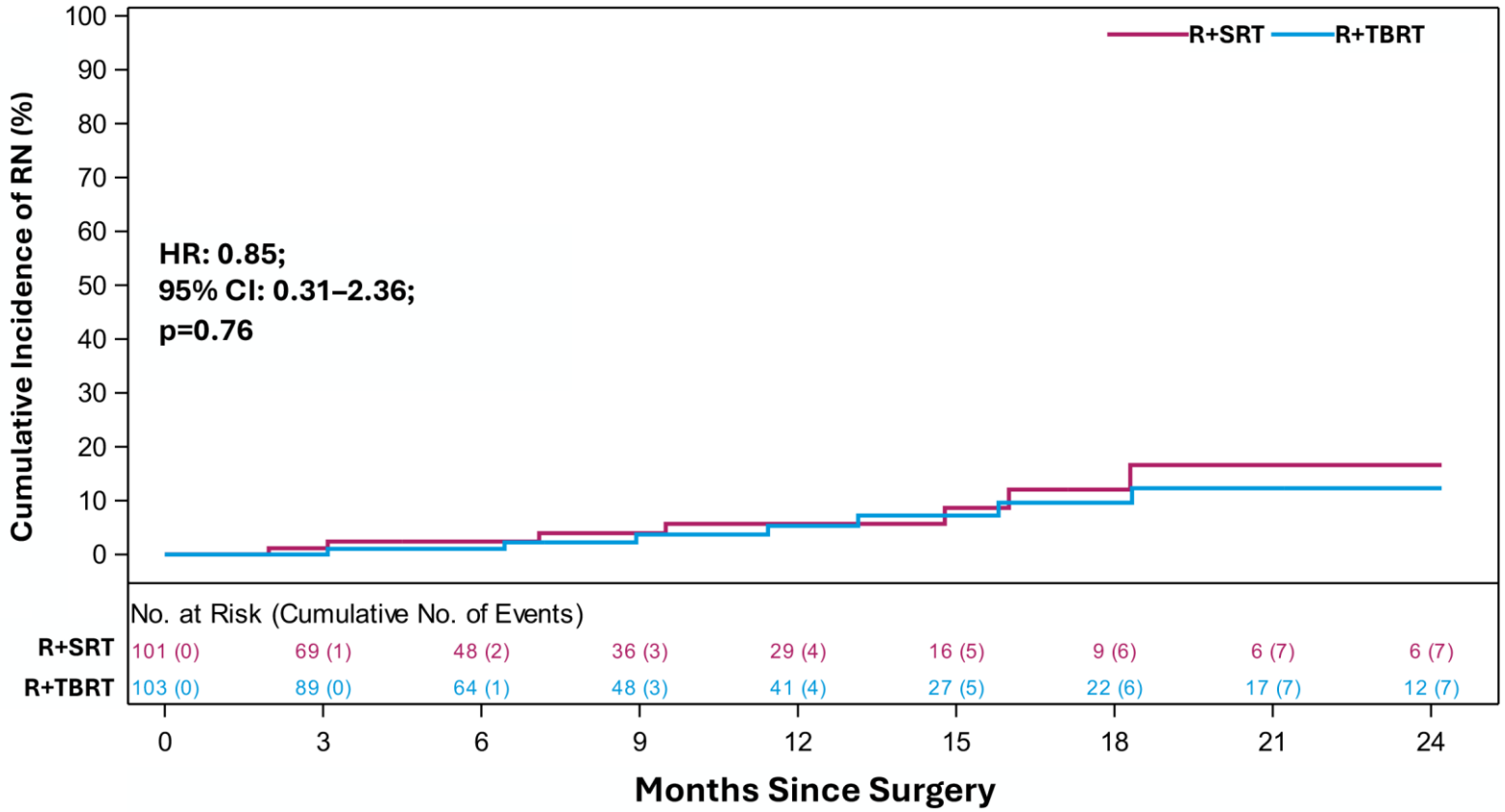
Secondary endpoint

Radiation necrosis was similar in each arm[1]

- 12-month cumulative incidence of RN was 5.3% (1.7-12.2) in R+TBRT vs 5.7% (1.8-13.0) in R+SRT
- No difference in cumulative incidence of RN between arms (p=0.76)



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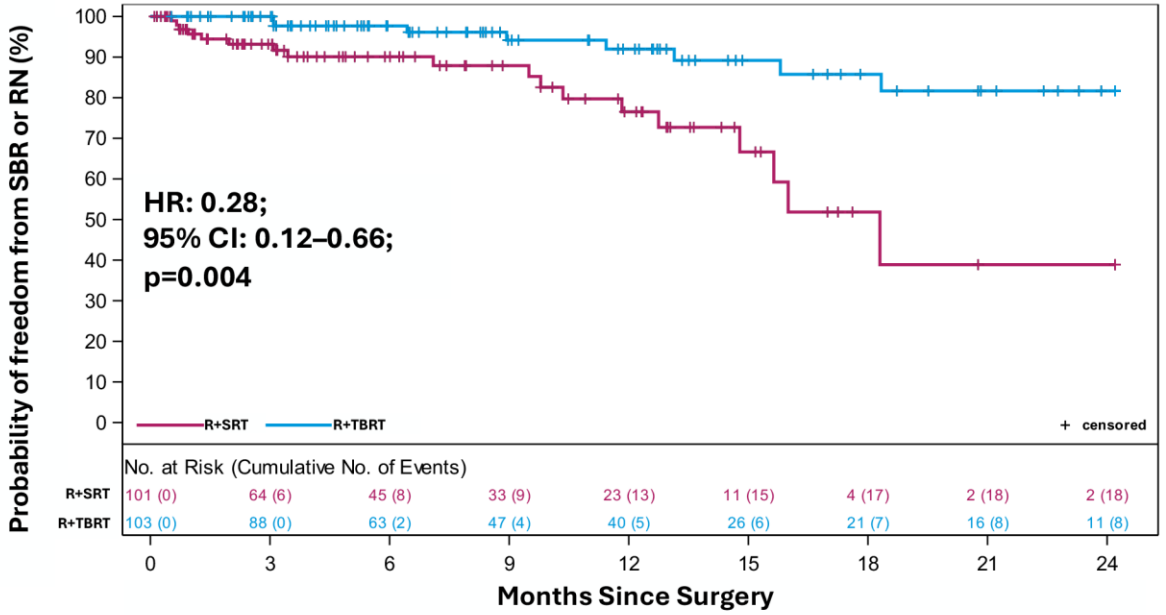
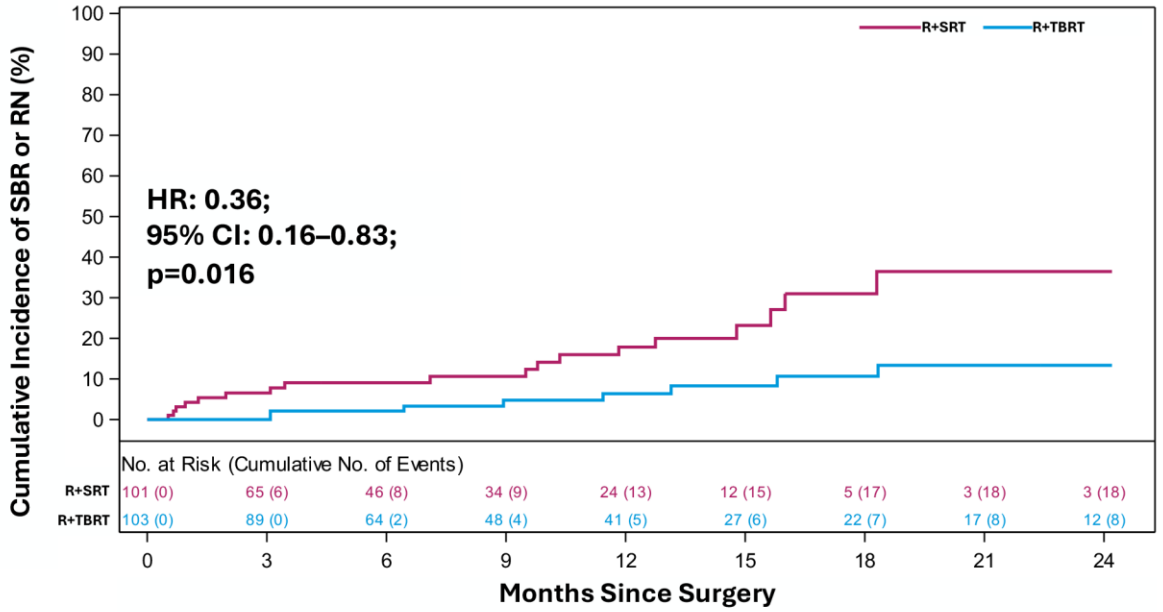
GammaTile led to significantly longer time to SBR or RN[1]

Time-to SBR or RN = time to either surgical bed recurrence or radiation necrosis, whichever occurred first

- This composite endpoint helps alleviate concern that SBR and RN could be mistaken for one another, a common diagnostic dilemma
- GammaTile showed superiority in overall protection from worrisome radiographic brain changes (both SBR and RN).





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There were no statistically significant differences among safety endpoints[1,2]

	p-value	R + TBRT	R + SRT
Radiation necrosis (RN)[1]	p=0.76	5.3%	5.7%
24-mo probability of being alive without LMD[2]	p=0.10	57.7%	35.9%
Leptomeningeal disease (LMD)[2]	p=0.14	9.7%	3.0%
All ≥Grade 3 treatment-related adverse events (TRAEs)[1]	NR	20.0%	21.7%

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Review: Improved outcomes did not come at the expense of increased toxicity[1]

	R+TBRT	R+SRT	
Co-Primary Endpoints (SBR and SBR-FS)			
Median time-to-SBR	**Not reached**	17.4 months	HR: 0.06; 95% CI: 0.01-0.46; p=0.007
12-mo cumulative incidence of SBR	**1.3%**	15.4%	HR: 0.07; 95% CI: 0.01-0.56; p = 0.012
Median SBR-FS	**Not reached**	10.9 months	HR: 0.48; 95% CI: 0.30-0.76; p = 0.0021
Secondary Endpoints			
Overall Survival	**42.5 months**	17.6 months	HR: 0.59; 95% CI: 0.37-0.96; p = 0.032
Estimated 24-month Overall Survival	**61.7%** (95% CI: 48.4-72.5)	35.7% (95% CI: 20.2-51.5)	
12-mo cumulative incidence of RN	**5.3%**	5.7%	HR: 0.85; 95% CI: 0.31–2.36; p=0.76
24-mo probability of being alive without LMD[2]	**57.7%**	35.9%	p=0.10
Cumulative incidence of LMD[2]	**9.7%**	3.0%	p=0.14
≥ grade 3 TRAE	**20.0%**	21.7%	-

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Lay summary (for patients and advocates) as presented at ASCO[1]

- For patients who had surgery to remove a new brain metastasis, tile-based radiation therapy, compared with standard treatment, showed:
  - The cancer was less likely to grow back in the treated area
  - Patients were less likely to have worrisome changes on their follow up brain MRIs
  - Patients lived longer
  - Treatment with tile-based radiation did not increase the chance of side effects

Scan for data

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Resection with tile-based radiation therapy demonstrated:

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Superior efficacy did not come at the expense of increased toxicity.

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Thank you

For product information or assistance, or to be connected with your GammaTile representative, contact:
GammaTile Customer Service Department
(833) 662-0044 | customerservice@gtmedtech.com

For adverse event reports and product complaint reports, contact:
GammaTile Medical Information Department
(833) 662-0044| feedback@gtmedtech.com

GammaTile® is indicated as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms. The potential for, and symptoms of, adverse events related to radiation exposure vary depending on the radiosensitivity of the exposed tissue, the amount of radiation delivered, and the placement of GammaTile(s). GammaTile should not be used for patients with a known history of hypersensitivity to bovine-derived materials. More information on indications, contraindications, warnings, and instructions for use can be found in the GammaTile Instructions for Use.

CAUTION: The law restricts these devices to sale by or on the order of a physician.

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