

# Surgically Targeted Radiation Therapy (STaRT) for brain metastases: Initial Experience from a Prospective Multi-institutional Registry (NCT04427384)

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## PURPOSE/OBJECTIVES

- Resection and intraoperative brachytherapy for patients with large, operable brain metastasis allows for both relief of mass effect and the delivery of radiotherapy (RT) to the resection cavity with a favorable dosimetric profile in comparison to external beam radiotherapy.
- The objective of this study was to analyze early patterns-of-care and treatment-related toxicity outcomes for brain metastasis patients treated with surgically targeted radiation therapy (STaRT) using a novel brachytherapy carrier.

## MATERIALS/METHODS

- Patients with brain metastasis, de novo and recurrent disease, who enrolled onto a prospective multi-institutional observational study (NCT04427384) were the subject of this analysis.
- Patients underwent resection and immediate implantation (Fig 1.) of bioresorbable, conformable, 20 mm x 20 mm x 4 mm collagen tile brachytherapy device(s) containing four uniform-intensity Cesium-131 sources (Fig 2.).
- Toxicities were categorized using the CTCAE v5.0 adverse event (AE) criteria.
- Descriptive data regarding patient factors, tumor dimensions and implantation details, and early toxicity outcomes were obtained.

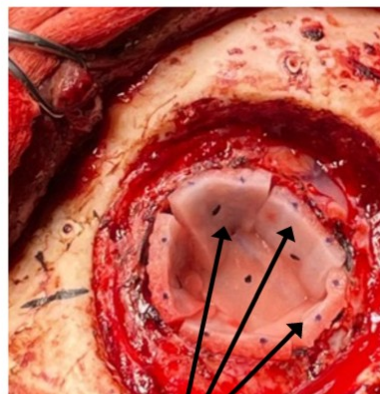


Figure 1. Multiple tiles implanted in resection cavity.

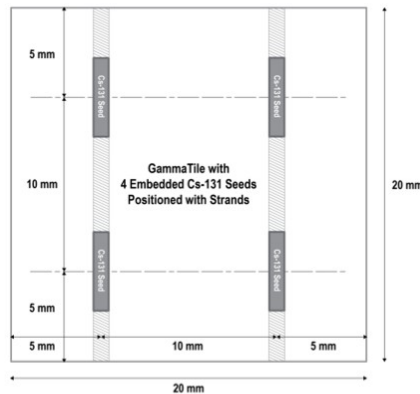


Figure 2. Engineering drawing of GammaTile.

## RESULTS

- From 10/2020 to 01/2023, 14 participating sites enrolled and treated 48 patients with 51 metastases (13 with de novo and 35 patients with recurrent brain metastases), and 3 patients had 2 lesions implanted at the same procedure.
- Median age was 61 years (range: 28 to 80), 52% were female, and the most common primary types were lung (56%) and breast (13%).
- The median maximum pre-operative dimension was 3.4 cm (range: 1.7 to 5.7) and median pre-operative tumor volume 13.7 cm<sup>3</sup> (range: 1.7 to 132).
- 64% had received prior RT with a median time from last RT to STaRT of 14.6 months (range: 3.5 to 57.3).
- Median Karnofsky performance score (KPS) at screening was 80 (range: 50 to 100), and remained stable at post op visit (80, range: 50 to 100), and at 3-months following treatment (80, range 50 to 100), respectively ( $p > 0.05$ ).
- The median time for implantation was 3 minutes (range: 0.4 to 30).
- At a median follow-up of 4 months (range: < 1 to 18), no patient experienced a radiation-attributed AE, and only 1 attributable Gr > 3 AE was noted (Gr 5 intracerebral hemorrhage deemed probably related to surgery and unrelated to the implanted device).

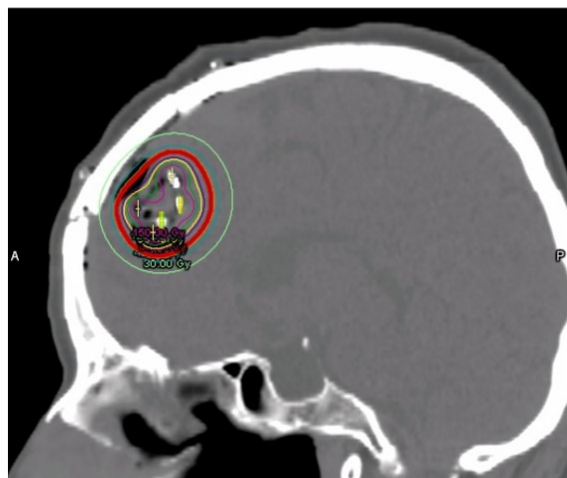


Figure 3. Post-surgery CT scan of collagen tile implants with Cesium-131 seeds.

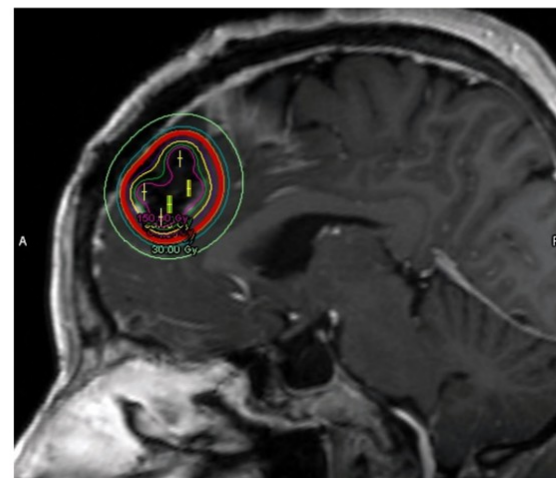
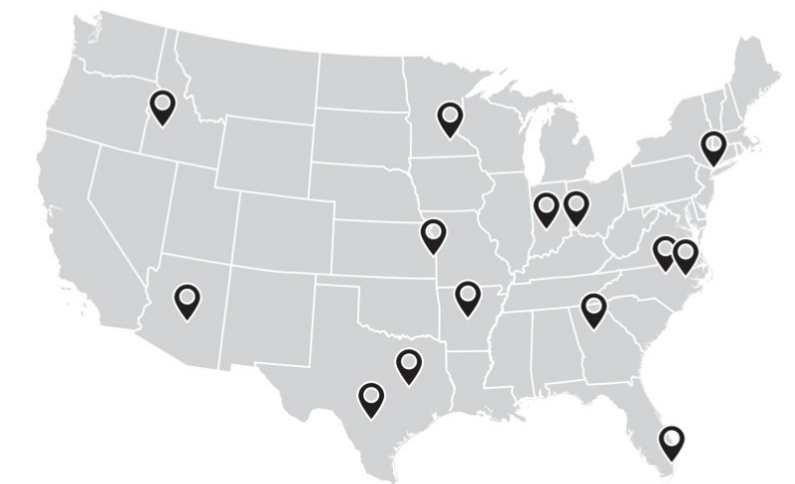


Figure 4. Post-surgery MRI scan of collagen tile implants with Cesium-131 seeds.

Characteristics	Mean $\pm$ SD (Median) (Min – Max)
Age	61.1 $\pm$ 9.8(63) (28-80)
BMI	Median = 26.3
Male	n=23
Female	n=25
Ethnicity	Hispanic - 11
	Non-Hispanic - 35
	Prefer not to answer - 0
	Not yet identified - 2
Race	White - 43
	Asian - 0
	Black - 4
	Native Hawaiian or Pacific Islander - 0
	American Indian or Alaska Native - 0
	Prefer not to answer - 0
	Other race - 1

48 patients enrolled into a multi-institutional observational study (NCT04427384) with 14 sites: ECU Health, Emory Healthcare, HonorHealth Scottsdale Osborn, Indiana University Health, Mayfield Brain & Spine, Miami Baptist, St. Alphonsus, UAMS Medical Center, University of Kansas Medical Center, University of Minnesota Health, University of North Carolina Health, University of Texas Southwestern, UT Health San Antonio, and Westchester Medical Center.



## CONCLUSIONS

- Early results from this prospective multi-center trial demonstrate the feasibility and safety of STaRT.
- The lack of radiation-related AE, even with short follow-up, is intriguing given the relatively large lesion size and proportion of patients treated for recurrent, previously irradiated disease.
- Additional follow-up will provide data on tumor control outcomes and radiation necrosis rates using this novel technique.

## CONTACT INFORMATION

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