

Company

GT Medical Technologies, Inc.

Drug or Device Name

GammaTile®

Category

Medical Technology

Compound/Technical Name

Cesium-131 embedded in bioresorbable collagen matrix

Trade Name

GammaTile

Date of Approval

07/06/2018

Therapeutic Categories

Radiation therapy for newly diagnosed malignant and recurrent intracranial neoplasms

Indications

GammaTile® is indicated as a treatment for patients with newly diagnosed malignant intracranial neoplasms and patients with recurrent intracranial neoplasms.

Background

In oncology, some of the poorest outcomes today are experienced by patients with aggressive brain tumors of any type (e.g., gliomas, brain metastasis, meningiomas). The current standard of care is to undergo surgery to safely remove as much of the tumor and surrounding involved brain tissue as possible, and then wait 3-6 weeks for surgical healing before starting radiation treatments. External Beam Radiation Therapy (EBRT) is the most common form of treatment and is provided using a medical linear accelerator to aim radiation beams outside of the body inward, consequently traversing innocent bystander tissue. Inevitably there are side effects associated with this, which include fatigue, hair loss, skin changes, nausea, vomiting, brain swelling, and even permanent neurocognitive changes. Even with these treatments, life expectancies in the US are most often measured in months. This has not improved significantly in decades. One of the fundamental problems with the current treatment paradigm is the need for a several-week wait post-surgery before starting EBRT. External radiation started immediately after surgery does not give the wound (skin, bone, internal tissues) sufficient healing time, and significant complications occur. During this wait, residual tumor cells can rapidly multiply. This regrowth very significantly lessens the chance that a safe radiation dose will be sufficient to eradicate the increased tumor burden present after the waiting period. GammaTile Therapy was developed to deliver radiation therapy intraoperatively, allowing targeted and immediate treatment, unlike EBRT. GammaTiles are comprised of Cesium-131 radiation sources embedded in a bioresorbable

collagen tile, which serves as a structural offset to prevent the radiation seeds not only from migrating but also from delivering supratherapeutic radiation doses at the seed-brain interface, thus potentially minimizing complications. Clinical data demonstrate that immediate radiation improves local tumor control and can extend survival in patients who are treated with surgery plus GammaTile.

Development

Driven to overcome the limitations of current treatments for brain tumors and raise the standard of care, a team of brain tumor specialists joined forces and formed GT Medical Technologies, creators of GammaTile, with the purpose of improving the lives of patients with brain tumors. In 2010, a radiation oncologist and department chairman specializing in brain tumor treatment was saddened and desperate from the lack of progress in his field. Thus, the conception of a collagen tile/internal radiation treatment idea was born. The thought behind this novel device was to precisely imbed small radioactive sources within a biocompatible, resorbable collagen tile to be permanently implanted at the time of tumor removal. The target area would receive a therapeutic dose of radiation, allowing therapy to be initiated at the time of surgery to minimize regrowth of tumor cells. The radiation oncologist and a team of four other brain tumor specialists used their understanding of radiation oncology, brain tumor clinical needs, neurosurgical practice, and physics to integrate their specific disciplines to develop GammaTile. A prototype device was created, physics aspects were optimized, and a manufacturing process was devised. Eventually, a clinical trial with the prototype led to initial FDA clearance in 2018, with an expanded clearance in 2020. Despite radiation having been used in cancer treatment since ~1910 (and in brain tumors since the ~1930s), patent offices in multiple countries saw the non-obviousness of the invention clearly: +20 US patents have been granted, with additional patents granted in Canada, the UK, the EU, and Japan. This new treatment is just taking hold. 1000+ patients have been treated to date. It is routinely used in centers large and small, including Memorial Sloan Kettering Cancer Center and MD Anderson Cancer Center, and multiple hospitals across the country.

Innovation

Fundamentally different from EBRT, GammaTile Therapy is a "one-and-done" treatment, implanted at the time of brain tumor removal surgery in <5 minutes using collagen-based tiles embedded with optimally spaced radiation sources. Radiation begins immediately before cancer cells have a chance to replicate. With traditional EBRT, patients typically must not only wait for the surgical wounds to heal before starting treatment but once treatment begins, patients and families are faced with the daily burden of time and travel to the medical center for up to 6 weeks. Sadly, with surgery plus EBRT alone, 50-90% of patients suffer a tumor recurrence within 12 months, in addition to experiencing typical radiation side effects like fatigue and hair loss. GammaTile can safely generate 2.5 times the energy within this cavity than can be achieved by EBRT, which has proven to be highly lethal to residual tumor cells. The shorter half-life radioisotope, Cesium-131, versus traditionally used Iodine-125, enables this rapid radiation dose delivery. Clinical studies have shown improved local tumor control and progression free survival, and the potential for improved overall survival with GammaTile. In addition, quality of life for the patient is greatly improved. GammaTile Therapy spares healthy brain tissue and can eliminate both hair loss and repeated radiation treatments. Patients receive their course of radiation while going about their daily lives, requiring no additional trips to the hospital for treatment. There hasn't been an improvement to the standard treatment care protocol for patients with brain tumors in over 10 years. As the incidence and recurrence rates of brain tumors and other cancers continue to rise, there is an ever-growing need to improve radiation options by making the treatments safer and more effective. GammaTile Therapy is shaping the future for oncological research and

improvements, while concurrently improving the lives of patients with brain tumors.

Pubmed

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Brachman D, et al. Resection and permanent intracranial brachytherapy using modular, biocompatible cesium-131 implants: results in 20 recurrent, previously irradiated meningiomas. J Neurosurg 131, 1819–1828 (2019).

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Smith K, et al. Safety and patterns of survivorship in recurrent GBM following resection and surgically targeted radiation therapy: Results from a prospective trial. Neuro-oncology 24, S4–S15 (2022).

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Odia Y, et al. Surgically targeted radiation therapy (STaRT) trials for brain neoplasms: A comprehensive review. Neuro-oncology 24, S16–S24 (2022).

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Attachments

- 1655326335K190839.pdf
- 1655326351K180515.pdf
- 1655326361K190296.pdf
- Executive Summary GT Medical Technologies.pdf