

ONLY AT UMGCCC: GAMMAPOD OFFERS STEREOTACTIC RADIOTHERAPY FOR EARLY-STAGE BREAST CANCER

A stereotactic radiotherapy device developed specifically to treat early-stage breast cancer is making its worldwide debut at the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center (UMGCCC) in Baltimore. The GammaPod aims high doses of external beam radiation at the tumor site with state-of-the-art precision that spares healthy tissue. Compared to other forms of partial breast irradiation, this new approach has the advantage of being noninvasive and faster: Treatment takes days, not weeks.

“With this breast-specific treatment system, we deliver high-dose radiation to a tumor while minimizing damage to normal breast tissue and—even more importantly—to major organs such as the heart and lungs,” says **William F. Regine, MD, FACR, FACRO**, the Isadore and Fannie Schneider Foxman Chair and professor of radiation oncology at the University of Maryland School of Medicine (UMSOM). GammaPod was invented by Dr. Regine and colleague **Cedric Yu, DSc, FAAPM**, the Carl M. Mansfield, MD, Professor in Radiation Oncology at UMSOM. Dr. Yu has invented several radiation technologies for treating cancer, including intensity-modulated arc therapy, used daily around the world.

GAMMAPOD DEVELOPED AT UMGCCC

Developing the GammaPod took about 10 years. It started when Dr. Regine, now chief of radiation oncology at UMGCCC, questioned whether one of his post-lumpectomy patients, who was undergoing standard partial-breast radiation, needed to have so much exposure of surrounding normal breast tissue to excess radiation, given the small size of her tumor. Concerned that many women might be receiving more treatment than necessary, he started talking with Dr. Yu.

The professors hoped to harness technology used elsewhere in the body to improve care for early-stage breast cancer. Studies show that, for certain patients, stereotactic body radiation therapy (SBRT) prevents tumor recurrence as effectively as more traditional approaches that require

several weeks of daily irradiation. SBRT has long been used to treat tumors of the lung and liver, and even to treat breast cancer metastases, but not within the breast.

That changed when Dr. Regine and Dr. Yu invented the GammaPod. Subsequently, Dr. Yu founded, and now serves as chief executive officer of, Xcision Medical Systems, LLC, which makes the device.

CREATED FOR BREAST CANCER PATIENTS

One of the things that makes the GammaPod special is that it was designed completely around the treatment of breast cancer, says **Elizabeth Nichols, MD**, assistant professor of radiation oncology and clinical director of the UMSOM Department of Radiation Oncology.

“One of the guiding principles behind stereotactic radiosurgery is that we need to know exactly where our target is at all times,” Dr. Nichols says. However, breast tissue moves as patients breathe, and large, pendulous breasts might lie differently from one day to the next.

“Part of the reason the GammaPod technology came about and can be successful is that it offers an immobilization device, or a way to fixate the breast so that it doesn’t move while we’re delivering treatment,” says Dr. Nichols.

The GammaPod achieves that with an integrated breast-cup system, consisting of a custom-fitted inner cup,



Cedric Yu, DSc, FAAPM



William F. Regine, MD, FACR, FACRO

a rigid outer cup, and a silicone flange. The flange connects the two cups and adheres to the skin. A fiducial wire sends coordinates to a computer so it can map the breast. Vacuum pressure pulls the breast into the inner cup and holds it in place.

“It’s not painful,” Dr. Nichols says. She tells patients the device applies less pressure than commercial breast pumps.

To keep the heart and lungs away from the gamma rays, the device treats

GAMMAPOD OFFERS STEREOTACTIC RADIOTHERAPY

patients in the prone position. Gravity separates the breast from the chest wall.

On treatment day, patients stand against the GammaPod table wearing the breast cup, which locks into a hole in the device. The table rotates them into a prone position, and a separate computed tomography machine scans the breast. It sends images to the GammaPod treatment-planning system, which uses computational geometry to chart a path that covers the target while avoiding healthy tissue. Once the radiation

oncologist finalizes the treatment plan, patients return to the GammaPod, which positions them for treatment.

SAME RADIATION, BUT BETTER AIM AND FEWER SESSIONS

The GammaPod delivers the same effective radiation dose as conventional treatment, but in fewer sessions at a higher dose per session.

"It's the same radiation that we've always given, but it's delivered in a more focused way," says Dr. Nichols. During

treatment, 25 rotating sources of cobalt radiation form a limitless number of arcs, all converging within the breast at the planned target.

"We don't see the 'hot spots' that we typically see with whole breast radiation, or even with other forms of partial breast radiation," Dr. Nichols says. "The dose is more uniform throughout the whole target."

GOOD EARLY OUTCOMES

The GammaPod received US Food and Drug Administration clearance in 2017, based on findings from a clinical trial conducted at the UMGCCC. Dr. Nichols, a lead investigator in that trial, said radiation devices go through a different process than do chemotherapy drugs.

The study enrolled 17 patients, age 60 and over, who had undergone lumpectomy for stage 1 or 2 breast cancer. Study personnel were able to fit 15 of them with the immobilization unit. Those patients received one boost to the tumor bed from the GammaPod before receiving their regular whole-breast radiation.

"What that trial showed is that the device is safe and feasible to use," says Dr. Nichols. Furthermore, a survey found patients to be highly satisfied with GammaPod treatment.

"One of the biggest things that patients really appreciated was the fact that it was shortening the overall treatment course," she says.

"Women undergoing traditional radiation typically need 16 to 35 sessions," says Dr. Yu. "The GammaPod has the potential to significantly shorten the treatment time to a few sessions or possibly even one treatment, saving patients time and saving health care dollars."

Dr. Nichols notes that all of the preclinical studies that compared GammaPod radiation plans to other radiation plans deemed the GammaPod better for delivering radiation to the

BELOW: Dr. Nichols cares for many of the breast cancer patients who will benefit from GammaPod.



KEY POINTS

- Two UMSOM professors invented and developed the first stereotactic radiotherapy system optimized for early-stage breast cancer. GammaPod received US Food and Drug Administration clearance in 2017.
- The new GammaPod delivers higher doses of the same, effective radiation typically used for breast cancer, but focuses it with greater precision on the planned treatment site.
- Many patients need only one to five of the noninvasive treatments, an advantage over other forms of partial breast irradiation.
- Prone positioning of patients and a breast immobilization unit help the gamma rays reach their target, while protecting healthy breast tissue and nearby organs.
- Currently, only UMGCCC offers GammaPod treatment, although other hospitals will follow.

“If we’re using the same type of radiation, we have no reason to think that local control should be different than with our other therapies,” Dr. Nichols says. Furthermore, in studies, partial breast radiation compares favorably with whole breast radiation for preventing recurrence.

target and not to the remaining normal breast tissue, heart and lungs. Moreover, the device dispenses much less radiation to the skin than brachytherapy does.

Researchers have not yet determined how well the GammaPod controls local recurrence.

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BENEFICIAL EFFECT ON QUALITY OF LIFE

Dr. Nichols does not expect the GammaPod to improve the already high survival rate for early-stage breast cancer, but it should enhance patients’ quality of life in multiple ways. First, it may lessen fatigue and skin reactions. Second, fewer treatments means less time off from work and other activities, reducing stress for patients. Third, because some women choose mastectomy to avoid disruptive daily radiation treatments, the shorter course of GammaPod care offers an important option that might help them keep their breast.

While UMGCCC is the first to offer this treatment, three other hospitals in the United States and Canada plan to offer it in the near future. Meanwhile, UMSOM has launched the GammaPod Consortium, a group of institutions, chaired by Dr. Nichols, that will collaborate on GammaPod research.

A TARGETED APPROACH FOR THE RIGHT PATIENTS

“The GammaPod is not going to be the right treatment for all breast cancer patients,” says Dr. Nichols. It cannot replace whole breast radiation, nor can it help everyone who qualifies for partial breast radiation.

According to Dr. Nichols, women who have a single tumor less than about 3 centimeters in size are eligible for GammaPod treatment. The device might not fit those with very small or very large breasts, although Xcision wants to add cup sizes. Women who are extremely obese or who cannot lie comfortably on their bellies cannot undergo GammaPod treatment.

BELOW: Patients lie in prone position on the GammaPod, allowing gravity to separate the breast from the chest wall.

PARTNERING WITH REFERRING PHYSICIANS

Patients who want to receive GammaPod treatment need not give up their primary breast-health team.

“We want to develop great partnerships with our referring physicians, and we’re happy to work with them as part of their team,” says Dr. Nichols.

Whether the GammaPod will transform care for early-stage breast cancer remains to be seen, but early results bode well.

“I’ve been involved in this project for years and years. To finally see it come to fruition gives all of us a big sense of accomplishment and excitement, too. I think this is going to be a great therapy for a lot of women,” Dr. Nichols says.

To read more, including a video showing GammaPod in use, as well as published clinical and research trials, visit our page for physicians: umgccc.org/GammaPodMD

