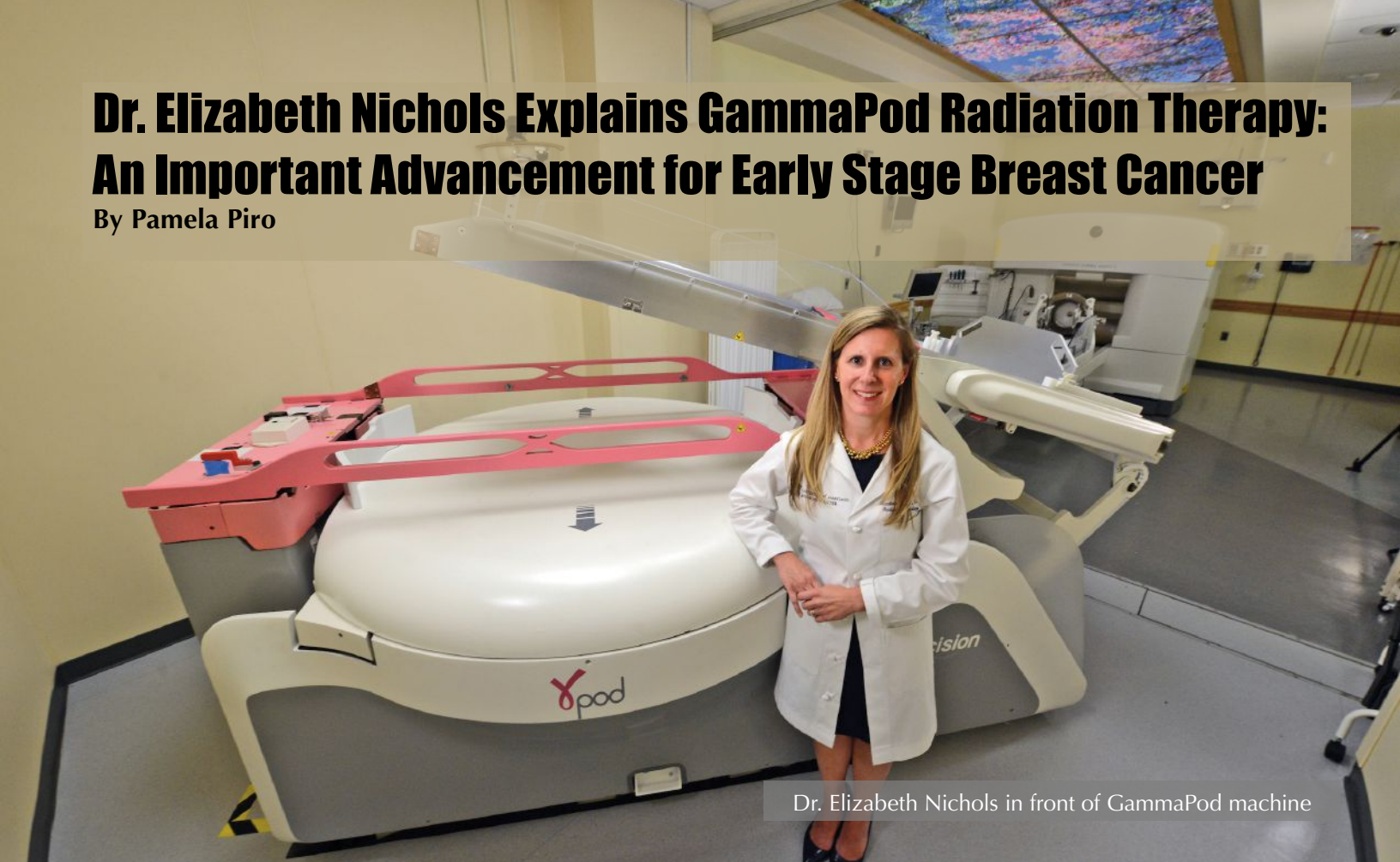


# Dr. Elizabeth Nichols Explains GammaPod Radiation Therapy: An Important Advancement for Early Stage Breast Cancer

By Pamela Piro



Dr. Elizabeth Nichols in front of GammaPod machine

Approximately 330,000 women will be diagnosed with breast cancer this year. Roughly two-thirds of these women will be diagnosed at an early stage, which has a high cure rate. Dr. Elizabeth Nichols, Associate Professor and Clinical Affairs Chair at the University of Maryland Department of Radiation Oncology states that at this stage, most women will be treated with a surgical lumpectomy, in which the surgeon removes the tumor plus an area around it to achieve negative margins. These patients will often undergo radiation therapy to reduce reoccurrence within the area where the cancer was previously located. Following standard protocol, radiation therapy will be delivered to the whole breast, usually 20 to 30 sessions.

Dr. Nichols explains that back in the 2000s, women diagnosed with breast cancer received the same, often overly aggressive treatment, whether they had Grade 1 or Grade 3, DCI or invasive. “Our chief of staff Dr. William Regine and then chief of physics Dr. Cedric Yu questioned that standard protocol and worked together to develop a technology that

addressed their concern. Their thinking was in alignment with the goal of personalized medicine: How do we maintain care rates while maintaining quality of life for and decreasing patients’ financial toxicity?”

That challenge led to their development of GammaPod radiation therapy, a concept which borrows from the Gamma Knife radiation technology used for brain metastasis and other small tumors, technology which has been used for decades. They applied for and received NIH grant funding for \$3.5 million for the development of the first GammaPod machine.

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“Our first trial with GammaPod radiation therapy started in 2015, which paved the way for FDA clearance in December 2017,” Dr. Nichols states. “At that point, we needed to change our radiation sources.” She explains the radiation source for GammaPod and Gamma Knife is Cobalt 60, which is radioactive. The Cobalt 60 decays over time, which provides the radiation source. Once we changed sources, we were ready to begin treating patients in 2018.”

The GammaPod radiation therapy system is designed specifically around the treatment of partial breast radiation for early-stage breast cancer patients. Dr. Nicholes explains: “With GammaPod we think about using it for women who have early-stage breast cancers, because once they have their surgeries to remove the tumor, their cavities are usually quite small, so we can specifically target that cavity.”

The GammaPod process involves a vacuum-assisted breast immobilization cup with a built-in stereotactic frame that prevents the breast from moving. The cup mold uses a slight suction seal to hold the breast in place, allowing pinpoint accuracy with the radiation beams.

The patient steps into a motor-drive treatment “couch,” which starts in a vertical position. The couch is then lowered into prone position. This allows the breast to be pulled away from the chest wall which helps protect the heart and lungs. This position also enhances patient comfort and ensures geometric consistency between breast imaging and treatment.

The treatment targets the surgical cavity where the tumor was located and the radiation is delivered through multiple different beam angles, typically over 100, which allows for a very high dose of radiation to the target and minimal dose of radiation to the normal breast tissue. This video provides excellent insight into the process: [The GammaPod: A New Way to Treat Early Stage Breast Cancer - YouTube](#).

Dr. Nichols, whose practice includes all types of radiation therapy, sees multiple benefits of GammaPod radiation versus standard partial radiation therapy for early-stage breast cancer. “GammaPod therapy was designed specifically for early-stage breast cancer. GammaPod requires fewer treatments and thus is less disruptive to patients’ everyday lives. The entire process from breast-cup fitting to radiation planning and treatment delivery is done on the same day and the typical protocol is five treatments versus five daily sessions for four to six weeks for standard radiation therapy.”

Additionally, she explains, “Because we’re delivering pinpoint radiation to the targeted area, the skin reaction is much less than I see with other techniques. I’m very pleased with the cosmetic outcome in terms of how the breast looks side to side and the decreased rates of fibrosis.” Additionally, the process was designed to reduce radiation exposure to vital organs, such as the heart and lungs.

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The [University of Maryland Medical Services](#) lists three high level criteria for patient eligibility for GammaPod therapy: patients who have early-stage breast cancer (stages 0, 1 or 2); patients ages 50 or older; and patients who are eligible for a lumpectomy.

Dr. Nichols refers to the [checklist](#) provided by the American Society of Radiation Oncology (ASTRO), which breaks criteria into three categories: Suitable, Cautious and Unsuitable. ASTRO is currently updating their guidelines and Dr. Nichols is a member of the committee responsible for these updates.

She highlights some of the criteria with commentary for determining a patient's suitability for GammaPod radiation therapy:

- Women who have lymph node positive disease are not good candidates for partial breast radiation treatment.
- Women who have genetic syndromes that could put them at an increased risk of developing breast cancer are not in the suitable category.
- Having a tumor of 3 centimeters or less, although most of us have a cutoff of approximately 2 centimeters.
- The criteria is less than 2.5 centimeters of DCIS and not palpable although we can actually treat DCIS (Stage 0 breast cancer) with partial breast radiation.
- It is important that the cancer be ER-positive, HER2-negative.

Dr. Nichols adds that she, like her peer specialists, will consider partial breast radiation if there is one of the factors in the "Cautionary" groups. "For example, I have a 49-year-old patient, an age which puts her in the cautionary group. I consider her a suitable candidate overall for GammaPod."

She continues, "We were pleasantly surprised to learn that we are able to treat patients who have had breast implants with GammaPod therapy. The shape of the implant is especially conducive to the shape of the cups." Breast size is also a consideration for GammaPod therapy. "The technique involves suction of the breast so there does need to be some breast tissue there, which could be challenging for a small breast. If the breast is too heavy, no amount of suction is going to hold everything in place. At our institution we haven't



Vacuum-assisted breast immobilization cup

had to turn anyone away for having too large or too small of a breast although I know another institution has. We are working with Xcision,<sup>1</sup> the manufacturing company, and they are in the process of developing additional size cups to address that."

The "we" refers to the GammaPod Consortium, which Dr. Nichols chairs. "As a consortium, we can continue to push this great new technology forward by all working together. Instead of each of us having our own clinical trials, we do our trials together to accrue patients faster, be able to publish with greater numbers, and also help all of us be on the forefront by sharing ideas, idea development, and new ideas on clinical trials. We have the common goal of advancing the science in a faster, more meaningful way."

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The consortium is made up of practitioners from each of the four institutions which have GammaPod equipment. “The University of Maryland Medical System was first, followed by UT Southwestern Medical Center in Dallas, which began treatment in March 2019. Unfortunately, with COVID, there were a lot of delays and then in 2021 a group in Italy started treating patients and Allegheny Health Network in Pittsburgh began treating with GammaPod radiation in January of this year.”

At a recent ASTRO meeting at UT Southwestern, the consortium discussed progress and goals for GammaPod therapy. “Between our institutions, we have probably seen around 200-250 patients so far. While contextually that’s not a huge number compared to our regular machines, we are consistently seeing that the quality of the radiation is excellent, the side effect profile is much less than whole breast radiation alone, and the patient satisfaction rate is high.”

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“One of the challenges with breast cancer is that you need patients to be out of treatment for a certain period of time before you can publish a lot, so we are just entering that era. Both our center and UTSW, who have been treating the longest, are planning to update our data and publish that in the near future. I can say that the local control rates have been very high, around 90%,” she says.

“All of us in the cancer community would agree that there are still a lot of patients who we overtreat and we want to reduce that. We think there are unique opportunities to continue to shorten treatment. Right now, we can deliver effective doses in five treatments, but we think we can deliver it in three or even one treatment.”

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Providing only radiation is also an option for the future. “We are moving forward the concept of doing radiation alone for appropriately selected patients. Right now, we’re in the first phase of trials where we’re giving a higher dose of radiation with the GammaPod, still following with surgery, but what we expect to find is that we’ll be able to eradicate the cancer in a large majority of women with these early stage, low risk breast cancers. The hope is that the next phase would be to do the radiation alone and then just follow with imaging. This has been successful for many types of cancers. There have been studies where we’ve actually been able to give high-level stereotactic radiation alone to patients with stage one lung cancer and they don’t have to have surgery,” she explains.

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“We all believe this will happen with early-stage breast cancer. Studies have already been done in Europe which show that this is feasible. This would be an amazing benefit for women. On a macroscopic level, in our country, where, after skin cancer, breast cancer is still the number one cancer with two-thirds in the early stage, it’s clear that there is a tremendous opportunity to reduce health care dollars if we’re able to do this.”

Dr. Nichols appreciates that with the Maryland model for health care reimbursements, she has not

experienced any significant issues with insurance approval for GammaPod therapy. However, there have been hurdles for some out-of-state patients coming to Maryland for GammaPod therapy and UTSW has experienced some challenges because of their different state insurance model. She says they are typically able to work through these insurance challenges because of the data from powerful studies on partial breast radiation that support its effectiveness.

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Delivering a message to cancer patients Dr. Nichols states, “While I wish physicians would advocate for this more, if your doctor doesn’t offer this, it’s okay to ask about this treatment. It’s okay to get a second opinion on this or any recommendation you receive. What’s most important for me is for the patient to feel right about their decision.”

Citation:

1. Dr. Nichols states, “Xcision is the company that makes the GammaPod machine. Dr.Yu, who was our original physicist, now owns that company, which is completely separate from us as the University of MD School of Medicine. They as a company are in negotiations with many other institutions for the GammaPod technology at this point.”



A former corporate executive, Pam Piro consults in building leadership development programs. In addition to her role as Board Chair of the Oncology Foundation of Maryland and the District of Columbia, Pam serves on the board as Past President of No More Stolen Childhoods, a Baltimore-based organization which is to engage all communities in the prevention of and healing from child sexual abuse.

## A Passion for Oncology

Dr. Nichols’s enthusiasm about the importance of GammaPod therapy reflects her passion for her work. “I’m lucky enough to say that I really love my job, I love what I do.”



Dr. Elizabeth Nichols

A Maryland native, her interest in oncology developed in high school. Her dad was a cancer researcher and she learned a lot from him. “Then when I went to medical school, I found that I really loved working with cancer patients and their families. I especially love being able to help women. I think I can help a lot of women because I can imagine what it feels like to go through what they’re going through. I can imagine why some women don’t want to have a mastectomy and they can be comfortable discussing with me the impact of hormone therapy on their sex lives,” she explains.

“I am an out of the box thinker. I always counsel my patients on the data but it’s not my job to force someone to have one therapy or another. I feel tremendous satisfaction that some of my patients are able to receive GammaPod therapy when it feels right for them. It’s very meaningful for me.”

A graduate of the University of Maryland School of Medicine, Dr. Nichols did her internship and residency at the University of Maryland Medical Center.

Outside of her practice, Dr. Nichols finds balance in her life with her husband and four children aged five to 11, running and gardening.