Gammapod targets early-stage breast cancer

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An experimental innovation in cancer treatment from the Department of Radiation Oncology at the University of Maryland School of Medicine could provide a new, high-precision, noninvasive method of treating early-stage breast cancer. The GammaPod was invented by Cedric Yu, M.S., D.Sc., the Carl M. Mansfield Endowed Professor in the Department of Radiation Oncology, who patented the technology in 2006. Although the device has not yet been cleared by the Food and Drug Administration (FDA) to be used on patients, the manufacturer is actively seeking that approval and the department hopes to begin clinical trials as soon as October 2013.

Dr. Yu's research was funded initially by $3.5 million in Small Business Innovation Research grants from the National Institutes of Health (NIH). With support from the University of Maryland, Baltimore's Office of Research and Development (ORD), he founded a new company called Xcision Medical Systems, LLC, to pursue the development of the GammaPod. In 2010, Dr. Yu received the University System of Maryland's Entrepreneur of the Year award for his research leading to the development of the GammaPod. "I am so happy that this university encourages entrepreneurship and recognizes the importance of translational research that converts new knowledge into new products," says Dr. Yu.

The GammaPod enables a proven technology called stereotactic body radiation therapy (SBRT) to be used for breast cancer. SBRT has been used to successfully obliterate inoperable brain tumors and hard-to-reach lung and liver cancers. However, SBRT technology has not been applied

to breast cancer. GammaPod system is the first device created specifically for the treatment of breast cancer. It is designed so that patients can receive external radiation treatments while lying on a comfortable treatment couch. The device uses tens of thousands beams of radiation from 36 rotating sources to focus the radiation to the tumor.

The affected breast is fitted into a patented two-layer, vacuum-assisted cup that immobilizes the breast during imaging and treatment. The breast cups come in 28 sizes to provide a proper fit. Such immobilization allows the radiation to strike only the tumor with pinpoint accuracy and minimizes damage to surrounding healthy tissue and adjacent major organs such as the heart and lungs. Treatment will take anywhere from 5-40 minutes, depending on the treatment plan. "We want to make sure the treatment process is as comfortable for women as can be," says Dr. Yu.

"Dr. Yu's accomplishments represent the type of extraordinary innovation and entrepreneurial spirit that we foster here at the School of Medicine," says E. Albert Reece, M.D., Ph.D., M.B.A., Vice President for Medical Affairs at the University of Maryland and John Z. and Akiko K. Bowers Distinguished Professor and Dean of the School of Medicine. "His research is turning groundbreaking discoveries from the laboratory into potentially lifesaving solutions for patients. He is an outstanding research scientist, and we are hopeful that his work will revolutionize the field, changing the way that radiation oncologists approach breast cancer treatment."

Although it has yet to be tested on breast cancer patients, Dr. Yu hopes that the GammaPod will one day offer an alternative to invasive surgery in those with early-stage tumors. "With standard therapy, breast cancer patients often have surgery to remove the tumor, followed by five to seven weeks of radiation treatments to destroy any residual cancer cells," says Dr. Yu. "We hope that GammaPod will dramatically reduce the

treatment time to a few treatments that can be done over the course of a week. There is potential that the need for surgery could be eliminated altogether, meaning no needles, no knives, no anesthesia and no scars."

Clinical trials are a critical next step to bringing the GammaPod to patients. Principal investigator on the trials at the School of Medicine is Steven Feigenberg, M.D., Associate Professor, Director of Clinical Research and Co-Director of the Program of Excellence in Technology-Based Translational Research in the Department of Radiation Oncology. He is currently seeking approval from the Institutional Review Board (IRB) for the trials, although they will not be able to start until the FDA approves the device for clinical testing.

"Patients in the clinical trial will be treated with the GammaPod system before they have a lumpectomy to remove the tumor," Dr. Feigenberg explains. "We want to see if GammaPod can neutralize the tumor and will check for any traces of cancer in the area around the tumor. Patients will, of course, still have the option of partial or whole-breast irradiation, if it is needed."

Another common treatment for breast cancer involves brachytherapy, or "internal" radiation, to treat the cancer with radioactive seeds placed inside the breast through small catheters. Dr. Yu hopes the GammaPod will offer an alternative to this procedure, in which 10-20 catheters are placed, requiring an operating room and general anesthesia for the patient. "I had participated in many of these procedures, and I knew there had to be a better way to get the same or better results without putting women through these invasive treatments," Dr. Yu says.

"One hundred thousand women a year are receiving breast conservation therapy (BCT), traditionally a lumpectomy followed by weeks of radiation therapy," says William F. Regine, MD, the Isadore & Fannie Schneider Foxman Professor and Chair in the Department of Radiation

Oncology. "An even greater number could receive BCT if treatment could be done in a matter of 1-3 days and with less radiation exposure. We hope the GammaPod will meet the challenge of developing a simpler and safer treatment for early-stage breast cancer that will help women avoid the self-image distortion that too often is a result of current treatment approaches."

Dr. Yu, who has been at the School of Medicine since 1997, has a Masters in Electrical Engineering and a PhD in medical physics from Washington University in St. Louis. He holds 10 patents and has invented a number of other technological advances that are now used in the field of radiation oncology. Among those is Intensity Modulated Arc Therapy, which delivers radiation directly to a tumor two to eight times faster than conventional intensity-modulated radiation therapy (IMRT). His other innovations include direct aperture optimization (DAO), an enhancement of IMRT therapy and Translational Tomosynthesis Mammography.

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