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CONTACT: Tom Rosenberger, APR
Communications Department
(513) 569-5260

CONTACT: Cindy Starr, MSJ
Communications Department
(513) 558-3505

***UC Brain Tumor Center study finds radiosurgery
of metastatic tumors is safe, effective without invasive head frame***

CINCINNATI – Stereotactic radiosurgery for metastatic brain tumors can be accomplished safely and effectively without immobilizing a patient’s head with an invasive head frame, researchers at the Brain Tumor Center at the University of Cincinnati Neuroscience Institute have found. Their findings are published in two manuscripts in the July issue of the *International Journal of Radiation Oncology, Biology, and Physics*.

Stereotactic radiosurgery, often referred to as “surgery without the knife,” involves the destruction of cancerous tissue with precisely targeted beams of radiation. Since the advent of radiosurgery, and up until now at most radiosurgery centers, the standard of care has required the fixation of a rigid, invasive stereotactic head frame to the skull in order to immobilize the patient and provide a frame of reference for targeting the radiosurgery.

The head frame is attached to the skull with surgically implanted pins and can be associated with patient discomfort, anxiety and increased recovery time.

The UC Brain Tumor Center team found that treatment accuracy and success in eliminating brain metastases for patients fitted with a fabricated, noninvasive mask were comparable to those experienced by patients whose treatment involved an invasive head frame. The researchers also determined that the mask system was adequate for patient mobilization.

John Breneman, M.D., Professor of Radiation Oncology, was principal investigator of the team’s paper that detailed clinical outcomes; Michael Lamba, Ph.D., a UC physicist, was principal investigator of a paper that evaluated technical aspects of image-guided positioning of the fabricated mask. Co-investigators were Ronald Warnick, M.D., Director of the Brain Tumor Center and a neurosurgeon with the Mayfield Clinic; Ryan Steinmetz, M.D., a radiation oncologist with Oncology Partners Network; and Aaron Smith, D.O., a neurosurgeon from Columbus, Ohio.

506 Oak Street • Cincinnati, Ohio • 45219-2552
513-221-1100 • 800-325-7787 • www.MayfieldClinic.com

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Their studies involved patients who were treated at the Precision Radiotherapy Center of West Chester, Ohio. Precision Radiotherapy is a partnership of the Mayfield Clinic and UC Physicians.

The Precision Radiotherapy team began developing “frameless” radiosurgery in mid-2005 and initially used the technology for only those patients who had tumors in areas of the brain not associated with critical functions such as language and reasoning. Over the following two years the success of this approach allowed expansion of the indications for “frameless” radiosurgery to a point where the team now treats all of its radiosurgery patients with this method.

The frameless method involves fabricating a clamshell mask that precisely fits the patient and is equipped with infrared fiducial reflectors to help monitor the patient during treatment. In preparation for treatment, CT scans and contrast-enhanced MRI scans are taken of the patient with the mask in place. Immediately prior to treatment, with the patient again wearing the mask, additional x-rays are acquired. With the patient aligned on the treatment couch, radiation is delivered in arcs that rotate around the target.

In preclinical studies, using a phantom instead of a real patient, Dr. Lamba and the radiosurgery team confirmed that frameless targeting was as accurate as radiosurgery with the invasive, fixated frame. In the subsequent study of 49 patients treated with frameless radiosurgery for one or more brain metastases between August 2005 and October 2006, local control of the patients’ lesions and patient survival at one year compared favorably to studies of patients treated with frame-based techniques.

With the frameless method, local control of brain metastases was 80 percent at 12 months and 78 percent at both 18 months and 24 months. Patient survival was 44 percent at one year, 29 percent at 18 months and 16 percent at 24 months. These figures were equivalent to other patient series using frame-based techniques as well as the researchers’ own previously reported outcomes.

Dr. Breneman and Dr. Warnick point to several benefits of the frameless technique. “In the most obvious benefit, it has eliminated the discomfort and anxiety caused by the head ring,” Dr. Warnick said. “Patients who have undergone stereotactic radiosurgery both with a head ring and without clearly preferred the latter method.”

“The frameless technique also facilitates the implementation of fractionated radiosurgery, which our team is currently studying,” Dr. Breneman said. “Preliminary indications suggest that this technique – the delivery of lower doses of radiation over a period of days -- can significantly reduce treatment complications in selected patients.”

Dr. Warnick added that the frameless technique has opened up radiosurgery “from a small select group to a greater universe of patients.” Where previously many patients were excluded, now virtually every patient with a brain metastasis can be treated painlessly with stereotactic radiosurgery. “For example, we can now treat patients with large numbers of metastases by enabling these patients to be treated in multiple sessions without the necessity of re-attaching a head ring,” Dr. Warnick said. “We have treated as many as 14 metastases in a single patient on three successive days.”

The Brain Tumor Center’s radiation oncology team used Novalis® technology, manufactured by BrainLAB AG, to perform their research. The Novalis® system is equipped with an image-guided

technology and real-time infrared fiducial tracking. The research team received approximately \$10,000 in the form of a nonrestricted educational grant from BrainLAB to support the development of their study of frameless radiosurgery. Warnick has received occasional honoraria from BrainLab in the past as a member of its speaker's bureau.

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The Precision Radiotherapy Center offers stereotactic radiosurgery for treatment of tumors both inside and outside the head. Candidates for treatment include patients with benign and malignant tumors of the brain, head, neck, spine, lung, liver, and prostate.

The Mayfield Clinic is recognized as one of the nation's leading physician organizations for clinical care, education, and research of the spine and brain. Supported by 20 neurosurgeons, three neurointensivists, an interventional radiologist, and a pain specialist, the Clinic treats 20,000 patients from 35 states and 13 countries in a typical year. Mayfield's physicians have pioneered surgical procedures and instrumentation that have revolutionized the medical art of neurosurgery for brain tumors and neurovascular diseases and disorders.

The UC Brain Tumor Center, under the direction of Dr. Warnick, treats hundreds of patients from the Greater Cincinnati region and beyond each year. The multidisciplinary center, which includes specialists in neurosurgery, radiology, radiation oncology, otolaryngology, internal medicine and physical medicine and rehabilitation, is committed to evidence-based medicine, compassionate care, research, and the utilization of emerging therapies and technologies.

The UC Neuroscience Institute, a regional center of excellence, is dedicated to patient care, research, education, and the development of new treatments for stroke, brain and spinal tumors, epilepsy, traumatic brain and spinal injury, Alzheimer's disease, Parkinson's disease, multiple sclerosis, disorders of the senses (swallowing, voice, hearing, pain, taste, and smell), and psychiatric conditions (bipolar disorder, schizophrenia, and depression).