

North American Gamma Knife Consortium



STEREOTACTIC RADIOSURGERY RESEARCH, EDUCATION AND PUBLISHING FOR THE PURPOSE OF IMPROVING PUBLIC HEALTH

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NAGKC Continues Growth

The North American Gamma Knife Consortium continues to grow with the addition of new members from Puerto Rico and from Northwestern University in Chicago. The Consortium is designed to facilitate both retrospective clinical trials for usage of the Gamma Knife and to stimulate the development of prospective clinical trials for important indications. The Consortium was founded in 2008 and is currently centered in Pittsburgh as the coordinating institution. Current participating sites include...

University of Pittsburgh Center for Image-Guided Neurosurgery

University of Virginia Radiosurgery Center

Mayo Clinic, Rochester MN

Cleveland Clinic Foundation

Hoag Memorial Hospital Gamma Knife Center

NorthShore University HealthSystem

Washington Hospital Healthcare System

Health Sciences Centre Winnipeg

Centre Hospitalier Universitaire de Sherbrooke

Barrow Neurological Institute

University of Kentucky Neuroscience Institute

NYU Langone Medical Center

Yale New Haven Gamma Knife Center

University of Pennsylvania Gamma Knife Center

University of California, San Francisco Gamma Knife Program

Northwestern Memorial Hospital Gamma Knife Radiosurgery Center

Puerto Rico Medical Services Administration Medical Center

The NAGKC seeks to foster analysis and publication of various indications for the use of the Leksell Gamma knife and has published two retrospective clinical trials (on chordoma and another on cluster headache). The retrospective outcome analysis of glomus tumors, authored by Jason Sheehan, is in press. A study on nonsecretory pituitary adenomas, also first authored by Jason Sheehan, is currently under review. Data collection is continuing related to craniopharyngioma under the direction of Dr. Niranjana and Dr. Kano.

Members of the Consortium are asked to define a particular clinical problem and to develop a de-identified patient spreadsheet (based on individual center retrospective chart reviews) containing all necessary data. We encourage members of the Consortium to continue to think about particular clinical indications, especially rare problems, where pooled data may be able to provide a much stronger study of outcomes related to stereotactic radiosurgery.

Regular Meetings of the Consortium

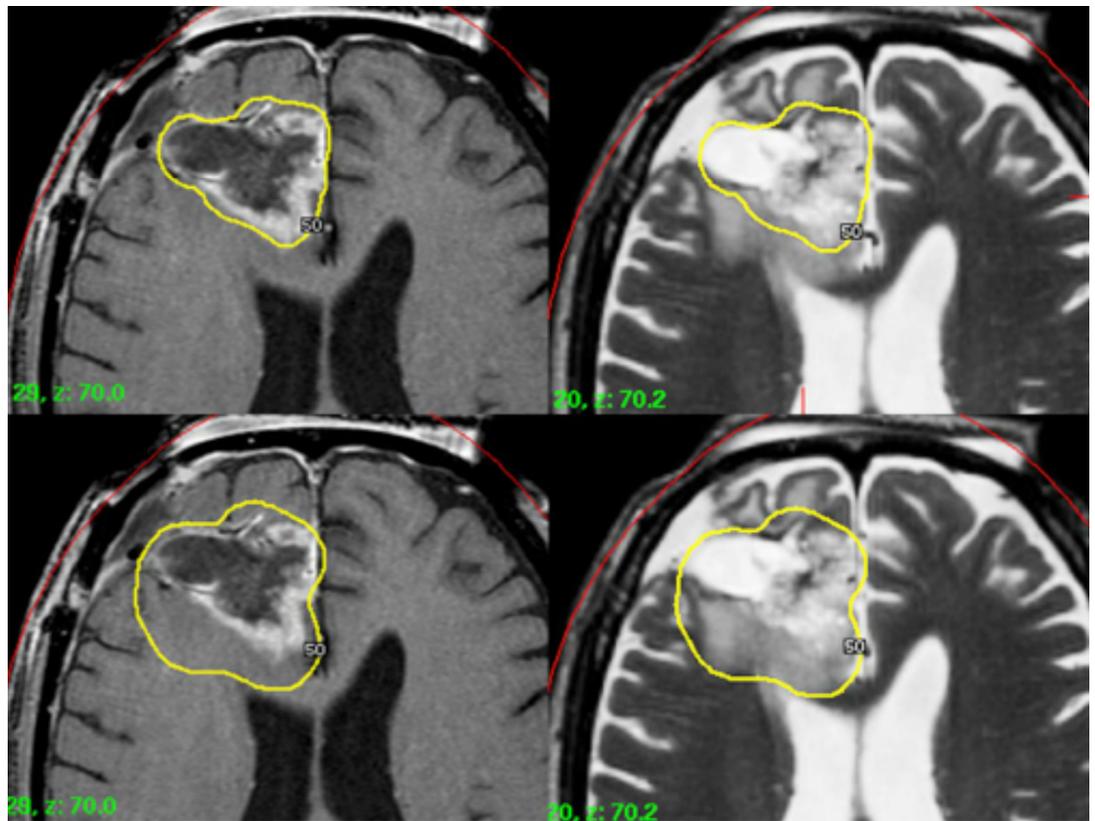
The North American Gamma Knife Consortium has regularly scheduled meetings of the board and attended by representatives of participating sites, usually in conjunction with major national or international meetings. The meetings are organized under the direction of Dade Lunsford and Doug Kondziolka and assisted by the administrative team of Rebecca Shapiro and Sharon DeCesare. Mr. Paul Stanick updates and maintains the NAGKC website (www.nagkc.pitt.edu). Copies of the current membership as well as bylaws are available on the website. Dr. Jason Sheehan, secretary/treasurer of NAGKC, has provided regular minutes for review which are also posted on the website.

Proposed Prospective Clinical Trials

Two proposed clinical trials are currently under evaluation by the NAGKC. The NAGKC 12-01 is a prospective clinical trial done to evaluate stereotactic radiosurgery for five or more brain metastases in comparison to whole brain radiation therapy. The primary end points are neurocognitive status as well as tumor response. This project is organized by Dr. David Larson and Dr. Igor Barani, and will be funded by Elekta AB. At the recent board meeting in conjunction with the AANS meeting in Miami, Dr. Barani described the organization and purpose of the clinical trial and received additional input from the attendees of the meeting. It is hoped that this clinical trial will begin very soon, as the practice of radiosurgery has continued to evolve with more and more centers and more and more patients with multiple brain metastases undergoing stereotactic radiosurgery. Preservation of neurocognitive function as well as brain-tumor control are important goals of radiosurgery, and this clinical trial will evaluate a novel neurocognitive online assessment tool. A parallel validation study is also planned under the direction of Dr. Barani comparing the online assessment tool to a subgroup of patients who undergo formal, more intense standard neurocognitive testing under the direction of a neuropsychologist.

A second trial (NAGKC 12-02) will be a phase II study on the usage of stereotactic Gamma Knife radiosurgery as a boost to the tumor bed border zone in conjunction with the usage of bevacizumab.

Border zone SRS GBM patient who underwent surgical resection followed by EBRT and Temozolomide chemotherapy developed tumor progression. (Upper) Gamma Knife planning for only Gd enhanced area. The target volume = 21.4 cc. (Lower) Border zone Gamma Knife planning for Gd enhanced area + T2 hyper intensity area. The target volume = 42.6 cc.



A clinical trial request has been submitted to Genentech for review. The trial anticipates an accrual of 40 patients over the course of 18 months at up to five participating centers. If funded and approved by Genentech, it is hoped that this clinical trial can begin in 2012. The primary outcome variable is overall survival at six months. Overall, survival from the time of diagnosis will also be assessed. Studies to date have not shown significant improvement in overall survival in patients where the target volume for radiosurgery is limited to the contrast-enhancing portion of the tumor. The hypothesis of this study is that glioblastomas progress in the adjacent border zone at the site of the cytoreductive surgical cavity. The target volume will be determined by the T2 volume, in some cases supplemented by coregistered MRS data. All participating patients will undergo boost radiosurgery after they have confirmed progression following initial diagnosis, radiation therapy, and temozolamide management.

Secretary/Treasurer Report

The secretary/treasurer's report indicates that the NAGKC maintains a satisfactory fund balance at the present time, based on initial membership fees and annual dues of \$2000.00 from each participating site. Participating sites in conjunction with the bylaws are required to supply cases for ongoing retrospective or prospective clinical trials. The administrative infrastructure of the NAGKC consists of the part-time assistance of Rebecca Shapiro, Sharon DeCesare (who handles regulatory affairs and serves as an honest broker), and Paul Stanick who helps to organize the NAGKC website.

University of Pittsburgh Medical Center (coordinating center for the NAGKC)

The Center for Image-Guide Neurosurgery at UPMC began performing gamma knife radiosurgery in August, 1987. Since that time, over 11,500 patients have undergone procedures and their initial and follow-up information entered into an imaging and data collection system. All gamma knife models have been utilized (U, B, C, 4C, Perfexion).

University of Pittsburgh Center for Image-Guided Neurosurgery staff.



A continuing commitment to outcomes research has led to the publication of over 400 peer reviewed reports. The center is the most prolific in radiosurgery publication and is #1 in reports with >100 citations. Over 50 visiting fellows from across the world have trained at UPMC, conducted research studies, and then assumed leadership positions at institutions across the world. Since 1995, over 90 training courses in gamma knife radiosurgery have been conducted which have helped to build clinical and research collaborations. The staff of the NAGKC include.

L. Dade Lunsford (neurosurgery)
Douglas Kondziolka (neurosurgery)
Ajay Niranjana (neurosurgery)
Johnathan Engh (neurosurgery)
John C. Flickinger (radiation oncology)
Yoshio Arai (radiation oncology)
Susan Rakfal (radiation oncology)
Melvin Deutsch (radiation oncology)

Jagdish Bhatnagar (medical physics)
Andy Xu (medical physics)
Mubina Quader (medical physics)
Greg Bednarz (medical physics)
Jong Kim (medical physics)
Michael Sheetz (radiation safety officer)
Jonet Vacsulka (head nurse)

Meetings of the NAGKC

Meetings of the NAGKC will be held in conjunction with future meetings. The next anticipated meeting to be held June 16, 2013, shortly before the Biennial International Stereotactic Radiosurgical Society meeting in Toronto.

Members and prospective sites are invited to correspond with questions relative to the NAGKC. Such questions can be addressed to Dade Lunsford or Sharon DeCesare at the University of Pittsburgh Medical Center.

NAGKC Published Articles

Kano H, Kondziolka D, Mathieu D, Stafford SL, Flannery TJ, Niranjan A, Pollock BE, Kaufmann AM, Flickinger JC, Lunsford LD. Stereotactic Radiosurgery for Intractable Cluster Headache: an Initial Report from the North American Gamma Knife Consortium. *J Neurosurg* 2011 Jun;114(6):1736-1743.

Kano H, Iqbal FO, Sheehan J, Mathieu D, Seymour ZA, Niranjan A, Flickinger JC, Kondziolka D, Pollock BE, Rosseau G, Sneed PK, McDermott MW, Lunsford LD. Stereotactic Radiosurgery for Chordoma: a Report from the North American Gamma Knife Consortium. *Neurosurgery*. 2011 Feb;68:379-389.

Sheehan JP, Tanaka S, Link MJ, Pollock BE, Kondziolka D, Mathieu D, Duma C, Young B, Kaufmann AM, McBride H, Weisskopf PA, Xu Z, Kano H, Yang HC, Lunsford LD. Gamma Knife Radiosurgery for the Management of Glomus Tumors: A Multicenter Study. *J Neurosurg* 2012 in press.