Quality Assurance, Planning and Clinical Results for Gamma Knife Radiosurgery

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1. Brief Overview of Gamma Knife

• First invented in 1968 in Stockholm
• Commercially introduced in US in 1987
• Cobalt-60 sources (roughly 30Ci each) at 40cm SSD with 4, 8, 14
  and 18mm diameters
• APS introduced in 2001
• Gamma Knife Perfexion introduced in 2007
• 350,000 patients treated worldwide thru 2005

Review of Models

Gamma Knife Model 4C
Rotating Gamma Units

New manufacturers:

<table>
<thead>
<tr>
<th>GammaARM Orbiter</th>
<th>GammaStar</th>
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<tbody>
<tr>
<td>Cancer Care International</td>
<td>Shenzen, China</td>
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<tr>
<td>42 Co-60 sources, 6000Ci</td>
<td>6500 Ci Co-60</td>
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<td>Total body capability</td>
<td>4D chair</td>
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2. Traditional Gamma Knife QA

• Numerous clinical papers over the years
• See special “QA of Radiation Therapy” issue of Red Journal
  for detailed list
• AAPM Report 54 “Stereotactic Radiosurgery” (Task Group
  42): Published in 1995, covered Gamma Knife, linac and
  protons
• TG 54 report needs to be updated

Other Gamma Knife QA Resources

- ASTRO/AANS Consensus Statement on stereotactic radiosurgery quality improvement, 1993
- RTOG Radiosurgery QA Guidelines, 1993
- European Quality Assurance Program on Stereotactic Radiosurgery, 1995
- DIN 6875-1 (Germany) Quality Assurance in Stereotactic Radiosurgery/Radiotherapy
- AAPM Task Group 68 on Intracranial stereotactic positioning systems, 2005

This is what you don’t want:

“Patient Speaks Out After Wrong Side Of Brain Treated”
Headline from newspaper in Midwest, October, 2007

The Radiosurgery process

• See patient in clinic, assess usefulness of GK radiosurgery
• Pre-op patient visit
• Day of Treatment: apply the frame
• Obtain thin slice high resolution imaging
• Construct treatment plan
• Administer treatment
• Follow up over long term

How it works:

Axial Imaging Study

• High resolution CT and/or MRI scan required
• Fiducial box allows image registration

Planning with proprietary planning system

• High speed workstation
• Hospital ethernet connection
• RS 232 link to computerized treatment console
Same Day Treatment
Treatments last 5 minutes to 5 hours

Acceptance Testing and Commissioning
• Qualified Medical Physicists needs to perform rigorous acceptance testing
• Manufacturer recommends output factors for helmets/collimators: difficult for typical user to measure reliably
• Manufacturer also does radiochromic film analysis
• Typical users can obtain radiochromic film and attempt to scan in flatbed scanner

Imaging QA Essential
• Must validate accuracy for MRI and angio or digital angiography
• Quality assurance phantom essential
• CT can serve as “Gold Standard”
• Encourage hospital to obtain ACR certification for all modalities.

How accurate do you need to be?
• Must hit 3mm diameter nerve consistently with 4mm beam diameter
• Massager: correlated FU MRI with treatment planning and found deviation of 0.91mm; Int J Radiation Oncol Biol Phys, Dec. 2007 (69) 1514-20

MRI Imaging Phantoms
Manufacturers: Elekta Inc.
CIRS Radiosurgery Head Phantom
Standard Imaging LUCY phantom
Phantom Laboratory RSVP Phantom Head
Elekta “Plastic” Phantom Problems with Dosimetry

- Gamma Knife is one of several modalities that does not “comply” with TG51
- AAPM Working Group on Dosimetry Calibration Protocol for Beams that are Not Compliant with TG-51, chaired by Jan Seuntjens
- Charge is to offer input into a future IAEA dosimetry protocol
- Therapy Physics Committee considering creation of new GSR Task Group

3. Gamma Knife Clinical Results
Over 400,000 patients treated worldwide at 250 Gamma Knife Centers thru 2006 from Leksell Society:
- 54,000 vascular (14%)
- 139,000 benign tumors (35%)
- 172,000 malignant tumors (43%)
- 30,000 functional (8%)

A. Pain relief from Trigeminal Neuralgia
- ¾ of San Diego Gamma Knife Center patients had “Grade 1 or 2” results
- Grade 1: relief of pain while still on meds
- Grade 2: relief of pain without meds
- 34 of 426 (8%) patients had previous surgery (microvascular decompression)
- Longhi (Neurosurgery, 2007): 61% Grade 1 and 29% Grade 2

B. Non Malignant Acoustic Neuromas
- Acoustic neuromas (acoustic neurinomas, acoustic schwannomas) are tumors of 8th cranial nerve
- Open surgery extremely complex and hazardous
- Chopra (IJROBP July 2007) reported 10 year control rate in 216 patients of 98.3%, w 71% hearing preservation
- Marginal dose decreased in 1990 to reduce risk of complications
C. Metastatic Brain Tumors
• Paradigm changing for some primary tumors
• Radiation oncology dogma: whole brain for every brain met patient
• Neurosurgery dogma: WBRT causes dementia
• Local tumor control of 87% reported by U of Pittsburgh (Neurosurgery 2004)

D. Now you see it, now you don’t Obliteration of AVMs
• Greater than 30 year history of treatment w Gamma Knife: Steiner at Karolinska
• Highly successful with both operable and inoperable lesions
• Flickinger quoted 75% obliteration rate for 250 pts w 3 to 11 year follow-up
• Open surgery may be risky

4. Elekta Perfexion Controversy
• New Elekta unit
• Moving sources
• No helmets
• Couch is precision movement device

Perfexion at work
NRC Advisory Committee on Medical Use of Isotopes (ACMUI)
• Elekta obtained 510 (k) from FDA
• Also listed Perfexion on NRC Sealed Source and Device Registry
• NRC still put Perfexion into Part 35.1000 (essentially for experimental devices); not in Part 35.600 for GSR devices
• ACMUI objected to this
AAPM Rides to Rescue
• S. Goetsch and Lynne Fairobent created questionnaire and sent to first nine Perfexion sites
• Asked whether sites complied with NRC “License guidance for Perfexion”
• New AAPM Task Group 172 formed in February, 2008

New Part 35.600
• ACMUI proposed re-writing Part 35.600 to include Perfexion and rotating gamma units
• Discussed at semi-annual meeting April 28-29
• AAPM TG 172 had a chance to review and comment on proposed new regs
• Rotating gamma units also included in new proposed Part 35.600

4. Conclusions
▪ “The price is freedom is eternal vigilance” Thomas Jefferson
▪ Radiosurgery is a one time event: no second chance
▪ Get outside audit before you begin
▪ Much work remains to be done with new technologies and dosimetry

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