New Challenges in SRS/SBRT

New features of Gamma Knife Icon pose challenges to the workflow management in a traditional Gamma Knife Clinic

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Conflict of Interest Disclosure

- I have no conflict of interest to disclosure.

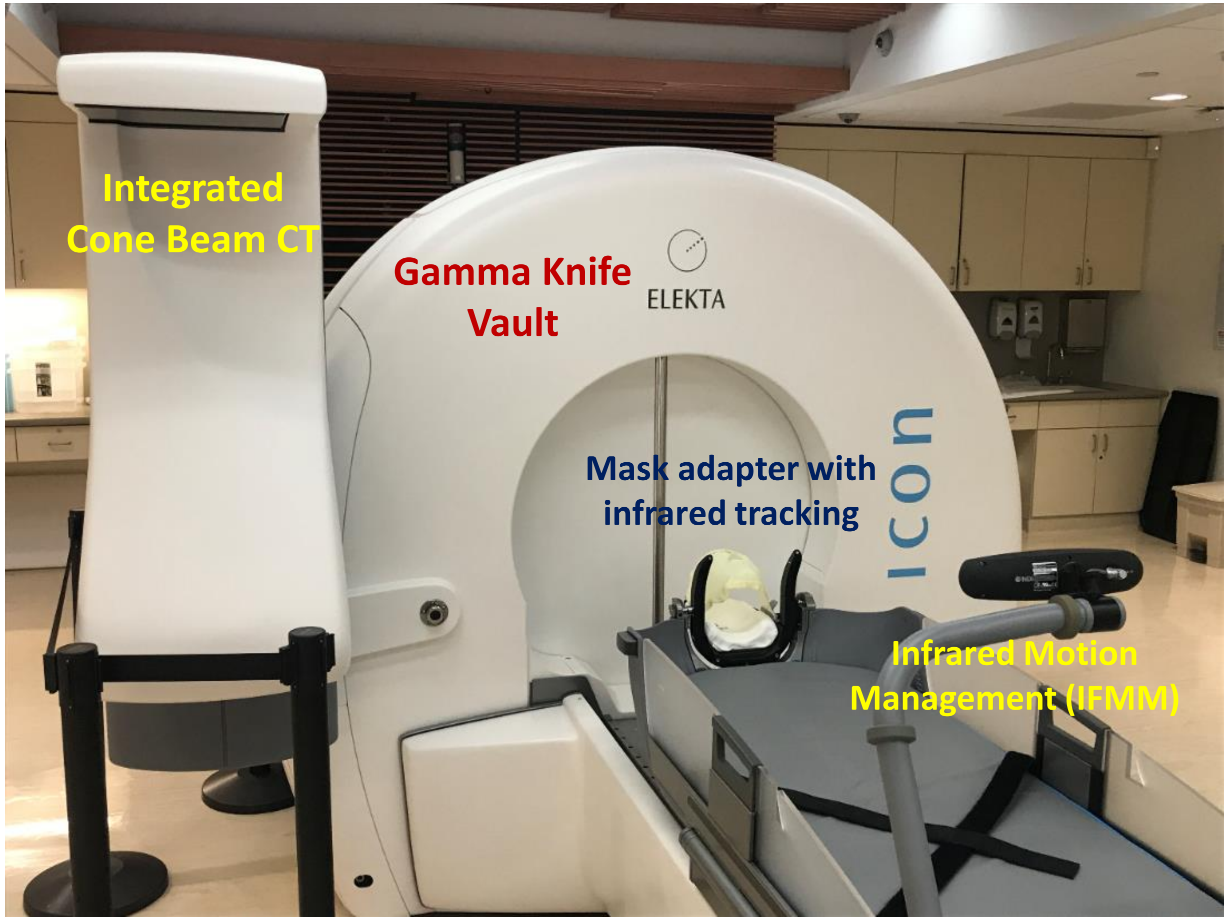
Outline

1. New features of Gamma Knife Icon
2. Technical challenges
3. Workflow issues
4. Quality Assurance
5. Summary

New features of Gamma Knife Icon^{TM}

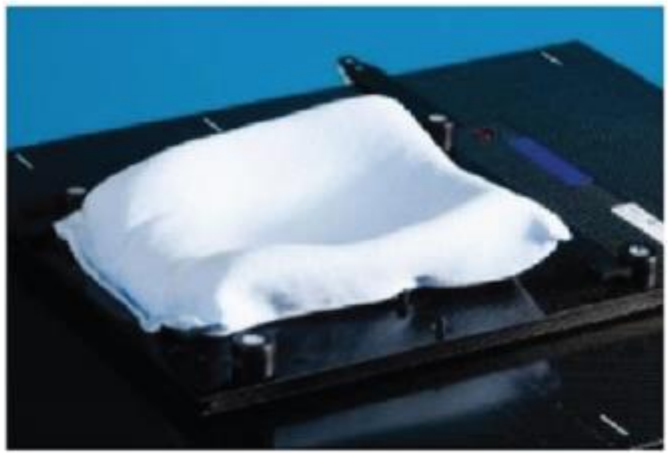
GAMMA KNIFE Icon™

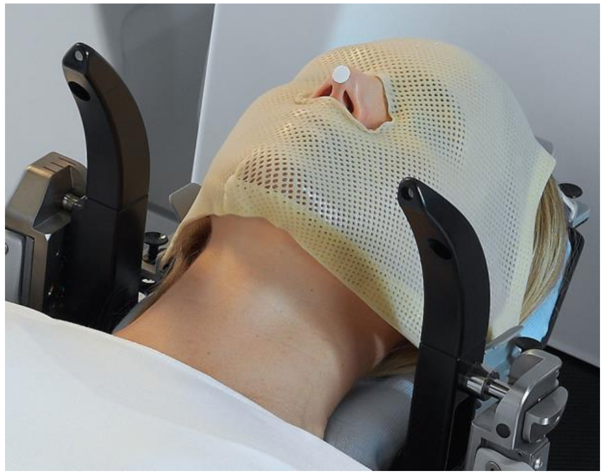
- Gamma Knife Icon™ (GKI)
  - Mask adapter for fractionated treatment
  - Onboard cone-beam computed tomography (CBCT) imaging and
  - Intrafraction motion management (IFFM).



GK Icon Immobilization System

- The thermoplastic mask system consisted of
  - A customized neck rest: thermoplastic-based or resin filled (activated with water)
  - A 3-point thermoplastic mask
  - The nose portion of the mask was cut out to allow placement of a single reflective optical marker on the patient’s nose





GK Icon Cone-beam computed tomography (CBCT)

- Characteristics:
  - SAD: 790mm, SDD: 1000mm
  - Recon. volume: 224 x 224 x 224mm^3
  - Cone angle: 15°, Fan angle: 16°
  - Scan time: 30s, Flex < 0.2mm
- Detector:
  - Layers: CsI, TFT (amorphous Si)
  - 780 x 720 pixels, pixel size = 0.368 mm
- X-ray tube:
  - Energy range: 70-120 kVp.
  - Spot size: 0.6 mm
  - Weight: 17kg

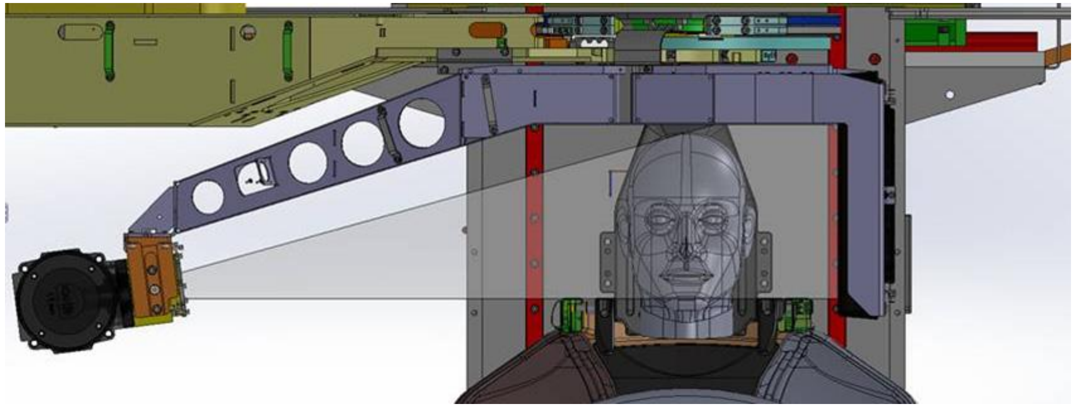


Figure 1. The X-ray field is aligned with the frame fixation

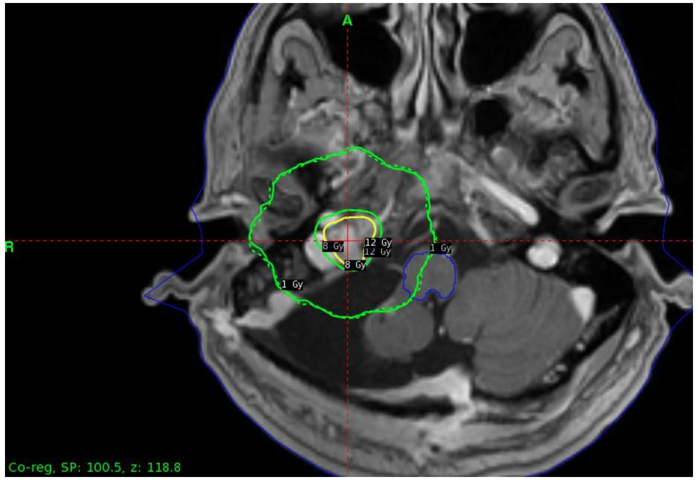
	Preset 1	Preset 2
mAs/projection	0.4	1.0
kVp	90	90
Number of projections	332	332
Image volume (voxels)	448^3	448^3
Voxel size	0.5mm	0.5mm
Resolution	7 lp/cm	8 lp/cm
CTDI	2.5mGy	6.3mGy
CNR	1	1.5

Table 3. The two presets.

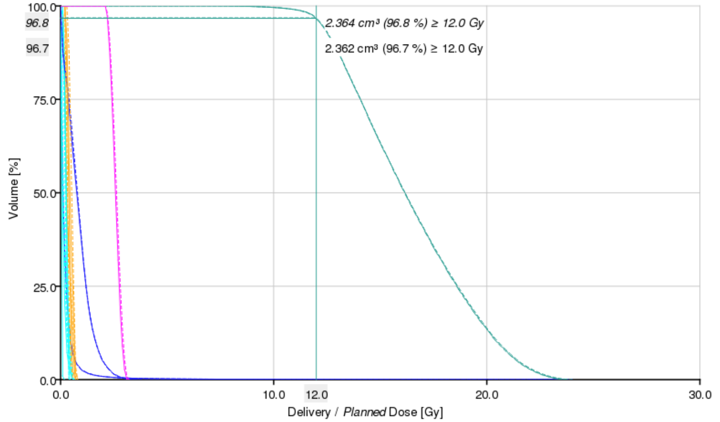
Elekta white paper "Design and performance characteristics of a Cone Beam CT system for Leksell Gamma Knife® Icon™"

GK Icon CBCT-guided setup using re-locatable mask

- CBCT-guided setup
  - Translational corrections according to the actual patient position from CBCT
  - No mechanical rotations of the patient.
  - Iso-center invariant relative to the anatomy
- Dose validation:
  - The delivery characteristics, i.e. beam-on times and collimators, are identical to the plan.
  - Dose after translational corrections is calculated based on the CBCT-imaged anatomy
  - Both planned (dotted line) and corrected delivery dose (solid line) are shown.



Head is rotated 5° around the z-axis).

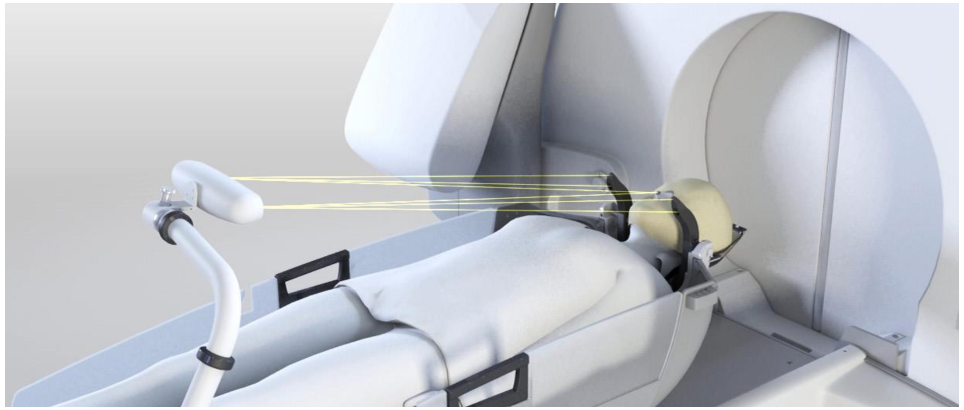


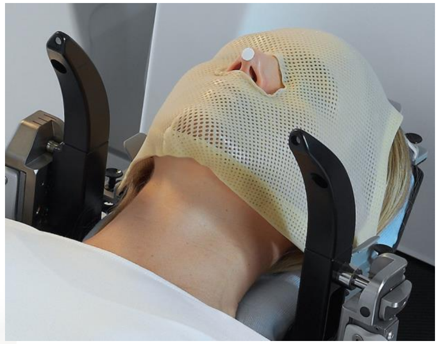
		Prescription dose	Min [Gy]	Max [Gy]	Vol. [cm³]	Cov	PCI	GI
	⊕	12.0 Gy @ 50%	6.6 *(6.7)*	23.7 *(24.0)*	2.442	0.97 *(0.97)*	0.90 *(0.90)*	2.67 *(2.66)*

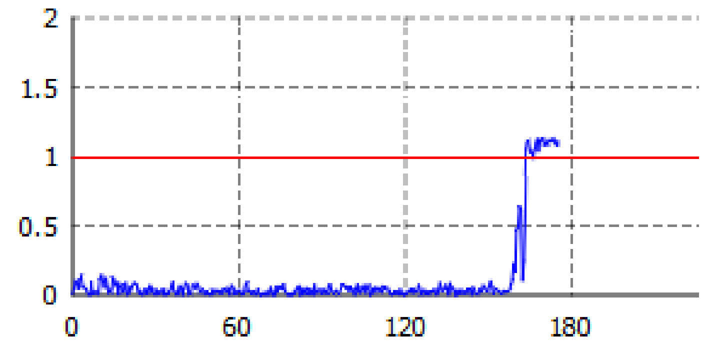
Elekta white paper “Automatic positional delivery correction using a stereotactic CBCT in Leksell Gamma Knife® Icon™ ”

GK Icon High Definition Motion Management (HDMM)

- HDMM system of consists of
  - An infrared stereoscopic camera,
  - A set of reference markers
  - A marker attached to the noise of the patient.
- Motion management:
  - Tracks at a frequency of 20Hz
  - Markers define a reference coordinate system in which the patient movements are measured.
  - System will hold of the treatment if the patient motion exceed the preselected threshold.
  - Treatment resumed again when the patient returns to the initial position



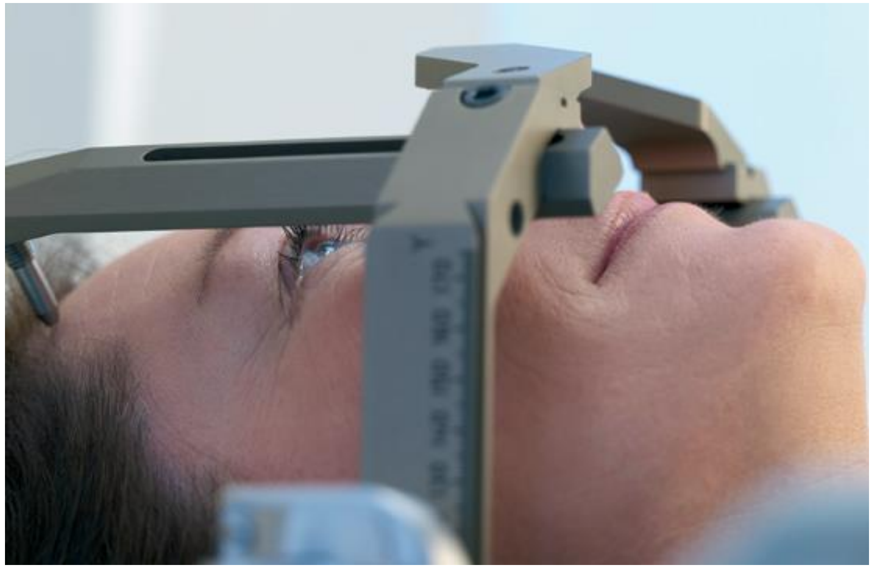




Elekta white paper "High Definition Motion Management - enabling stereotactic Gamma Knife® radiosurgery with non-rigid patient fixations"

Technical challenges

Adoption of mask for immobilization poses challenges to many GK centers



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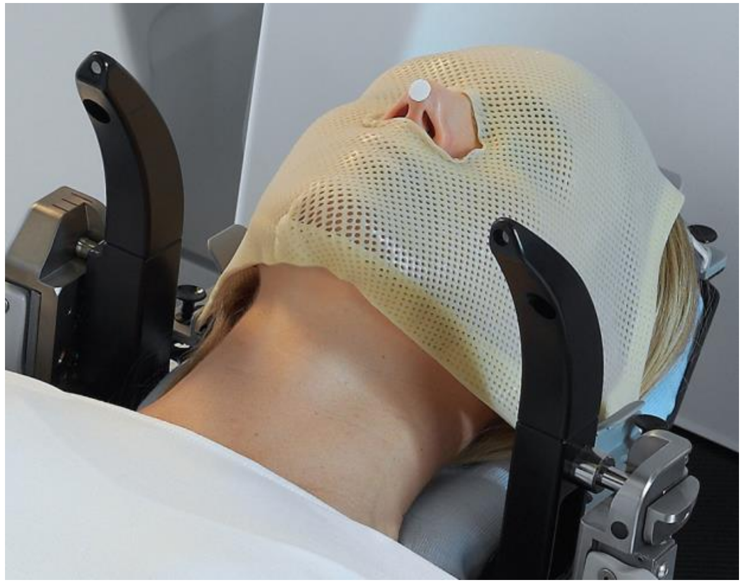


- Simple and efficient
- No intra-fractional motion
- Minimal uncertainty

- Non invasive
- Flexible
- Allow fractionated treatment

Are the additional complexities worth doing?

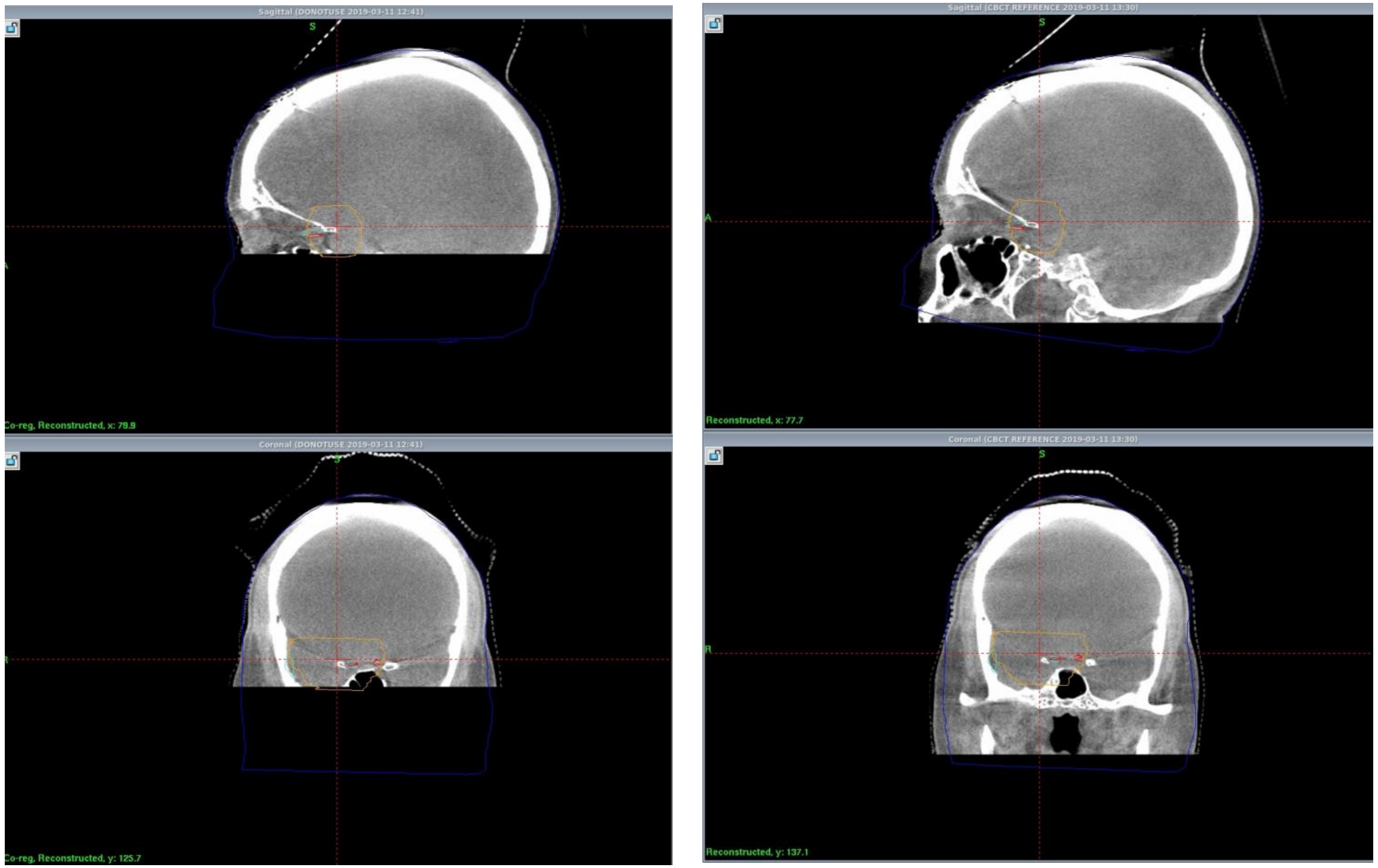
- There is no definitive answer but
  - Dr. Goenka’s talk demonstrates some clinical benefits,
  - Flexible scheduling will improve patient satisfaction and
  - Allow more planning time for complex cases.
- Therefore, if you have GK Icon at your clinic:
  - At least some, if not all, GK cases will be done with mask, and
  - You will get a lot of technical questions from the GK team members who might love, hate or be neutal about this approach.

Cost for the additional flexibility using mask

- Originally we thought mask will be more flexible than frame.
- It turns out that this expectation is generally true but there are caveats
- Collision is still a concern:
  - The head rest or patient might collide with the machine
  - Only 90^o gamma angle can be used (other angels not available)
- More limitations on planning :
  - External contour must be obtained from image segmentation, no manual measurement
  - Additional distance between shot and external contour needed to avoid shots that are not reachable

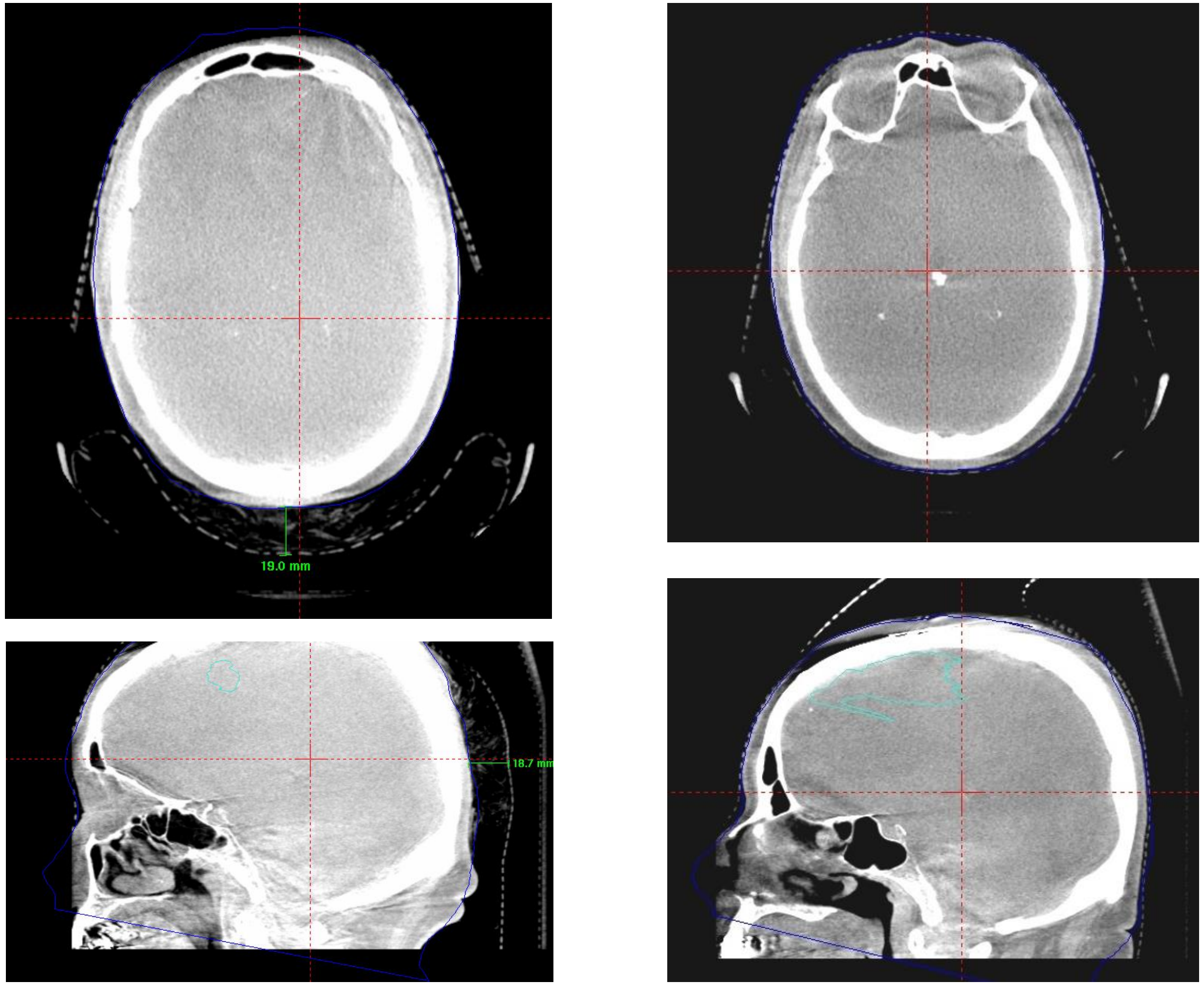
For mask cases, it is the responsibility of therapist/ physicist to make sure targets are within treatable range

- Used to be neurosurgeon’s responsibility when placing the frame.
- If not done properly:
  - Collision
  - Non-reachable position
- Confirm this immediately after the CBCT acquisition:
  - Remake the mask and re-CBCT If needed
  - There is no workaround



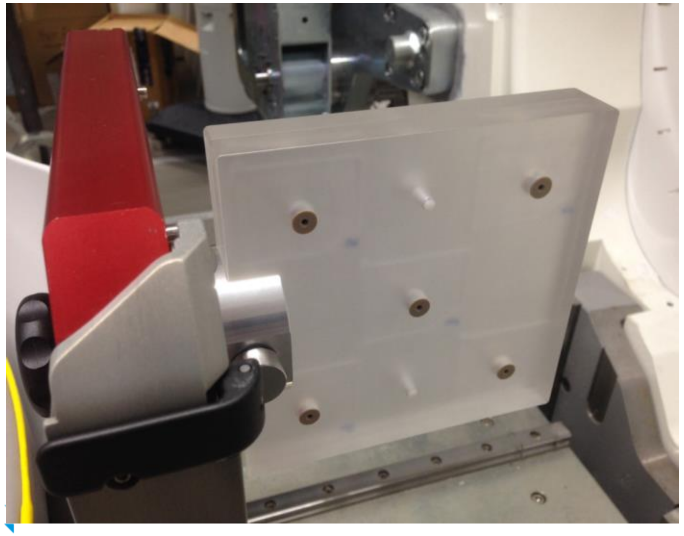
Treatable range is still limited for mask cases

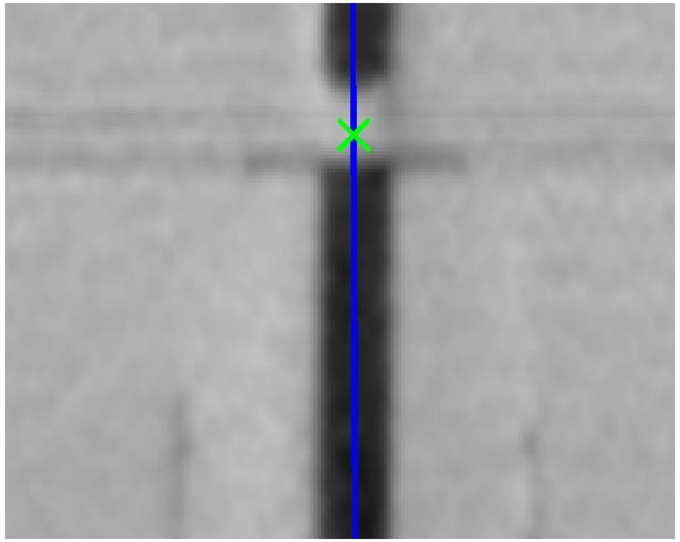
- Treatable range is the same as before ~(160, 180, 153) in mm.
- If frame is not done properly:
  - Collision
  - Unreachable shots
- Again, do not waste your time:
  - Remake the mask and re-CBCT If needed
  - There is no workaround

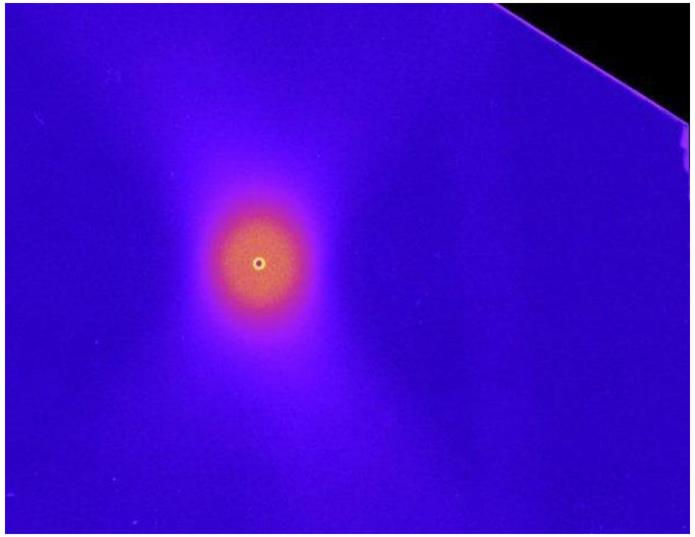


Apparatus accuracy of GKI CBCT is similar to frame

- Elekta white paper "Position accuracy analysis of the stereotactic reference defined by the CBCT on Leksell Gamma Knife® Icon™"
  - Major source uncertainty: couch sagging for very large patients (~0.18mm for a 210kg patient) and large temperature variations
  - Apparatus accuracy tested with 5 radiochromic films at various positions
  - Mean uncertainty < 0.2mm with a deviation < 0.1mm.





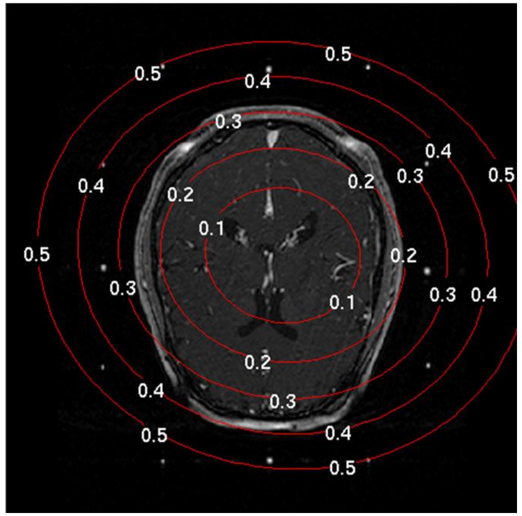


CBCT-MR registration accuracy is in general sub-mm

- Elekta white paper "Accuracy of co-registration of planning images with Cone Beam CT images"
- Mean Target Registration Error (TRE) for CBCT-MRI registration is ~0.3mm for an MRI resolution of $1mm^3$, higher for $1.5mm^3$.
- Large errors generally occur far from the center of the head
- CBCT-MR registration accuracy is less than for CT-MR registration

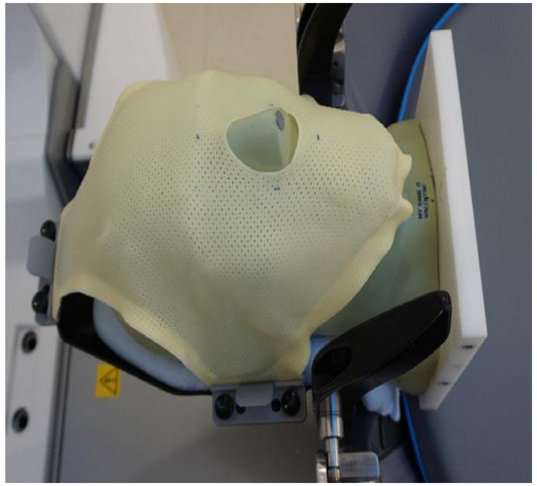
Patient	Estimated TRE (std dev) [mm]	
	CBCT-MR	CT-MR
Patient 1 (1 mm resolution)	0.35 (0.01)	0.16 (0.006)
Patient 2	0.33 (0.01)	0.19 (0.007)
Patient 3	0.31 (0.01)	0.17 (0.006)
Patient 4	0.34 (0.01)	0.16 (0.006)
Patient 5 (1.5 mm slice dist.)	0.54 (0.02)	0.26 (0.01)
Typical CBCT-CBCT/CT < 0.1 mm		

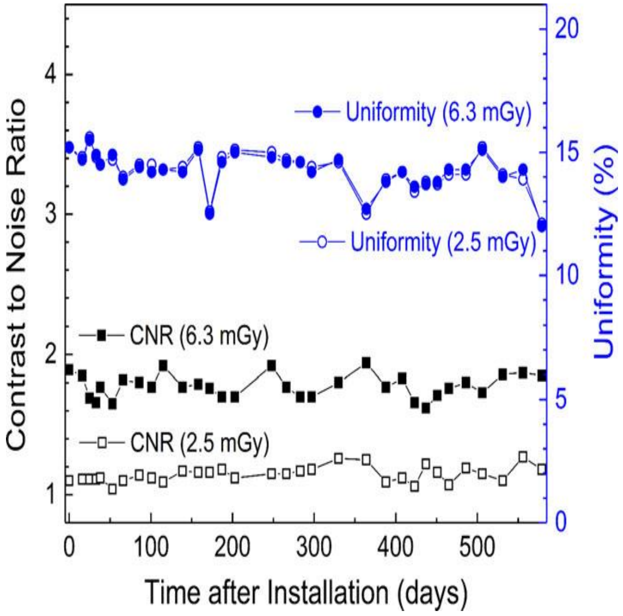
Table 1. Co-registration results for 5 different patients.

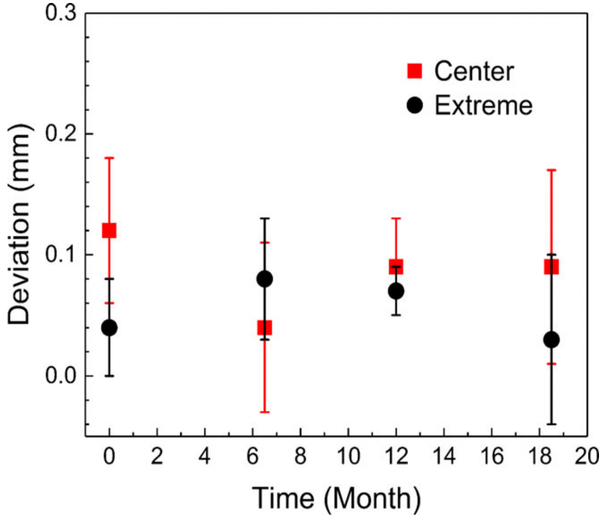


System stability and inter-fractional motion

- Chung, H.-T., et al., JACMP, 2018. **19**(4): p. 148-154.
- System stability for one and a half years :
  - CBCT coordinate system: 0.04 ± 0.02 mm.
  - Deviation bt. radiation isocenter and center of patient support system: <0.1 mm
- End-to-end accuracy (i.e., inter-fractional motion): 0.5±0.6 mm







F I G. 5. Deviations between the radiation iso-center and the center of the patient positioning system.

Intra-fractional motion evaluated on a linac

- Li et al, Cureus 8 (3), e531-e531 (2016).
- Intra-fractional motion of the target:
  - 0.34±0.25 mm, and
  - Maximum 1.5 mm.
- Intra-fractional motion (0.34±0.25 mm) is not insignificant in comparison to inter-fractional motion 0.5±0.6 mm
- Both inter-fractional and Intra-fractional motion need to be included when considering the CTV-to-PTV expansion.

Intra-fractional fraction motion of infrared marker

- Li et al, Cureus 8 (3), e531-e531 (2016).
- Intra-fraction motion of the nose tip:
  - 0.41±0.36 mm based on CBCT data
  - 0.56±0.51 mm using IR tracking.
- Maximum motion
  - 1.7 mm using CBCT and
  - 3.2 mm using IR tracking.
- Intra-fractional motion of the marker is larger than that of target.

Workflow issues

Staffing, scheduling

- Fractionated treatment demands
  - More machine time and
  - More man power: MDs, nurses, therapists, physicists.
  - Things can easily get out-of-control if not planned ahead.
- Education & Training are critical:
  - Clinical procedure for mask-based treatment
  - CBCT setup for mask and frame patients
  - Additional QA for CBCT
  - New treatment planning functions

Case handover

- Fractionated SRT cases are covered by different people:
  - The same plan is treated multiple times.
  - The patient might be simulated on one day, and treated a few days later with
  - The treatment plan being developed in between.
- Can be a challenge to a GK program new to GK Icon
  - “Who should do what and when?”
  - How to avoid something falling into cracks?

Potential solutions

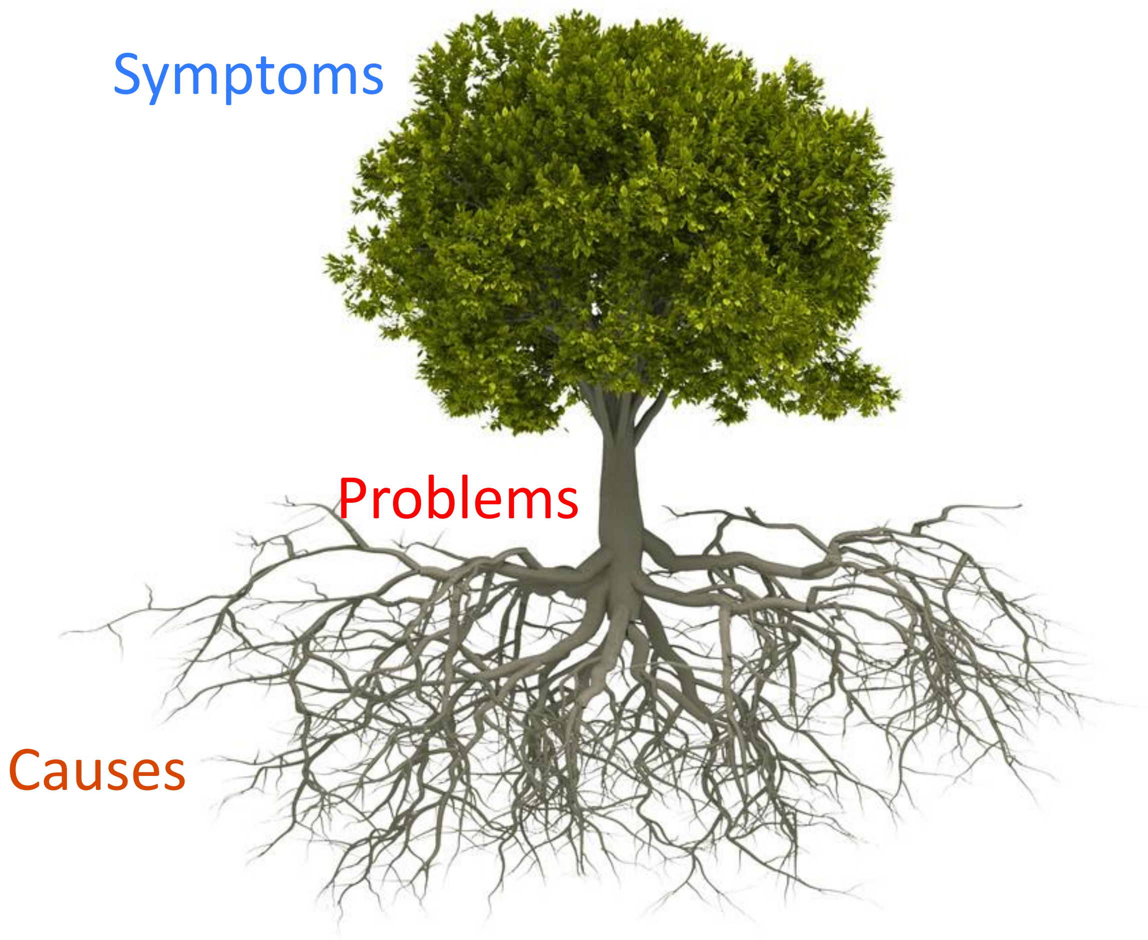
- Learn from how fractionated treatments are managed on linac
- Similar high-tech solutions can be used to manage GK treatments:
  - R&V: will increase the time between plan completion and treatment start
  - In-house electronic white board: need time and resources to develop
- Low-tech solutions work almost equally well:
  - Paper charts: we used to do it on linac.
  - Physical white board: cost ~$100, no software development

https://focus.elekta.com/2016/07/india-center-leaves-paper-based-workflow-behind/

Quality Assurance

RCA (root cause analysis)

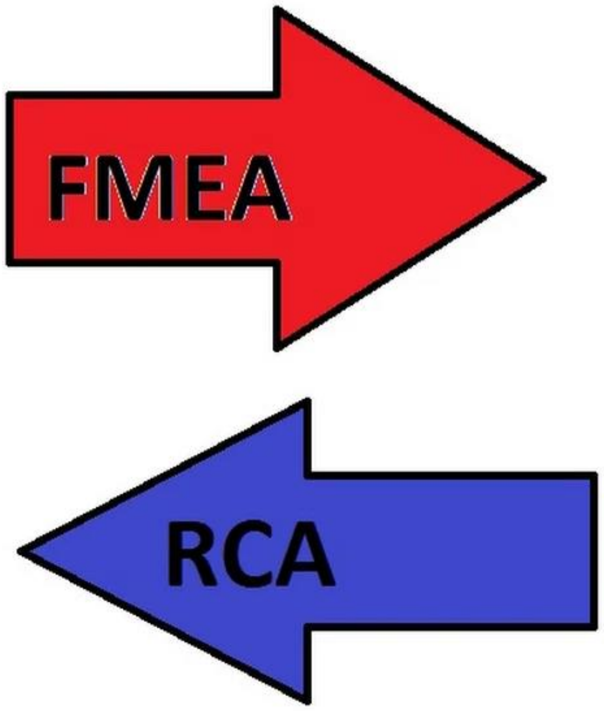
- A reactive process taking place after the harm has been done.
- Deal with actual failures
- Seeks to know the causal set of each of all possible effects.
- Looks backwards
- Commonly used in medicine to analyze serious adverse (e.g., sentinel) events



Senders J. FMEA and RCA: the mantras* of modern risk management. *Quality & safety in health care* 2004;13:249-250.

FMEA (failure mode and effects analysis)

- A proactive process aimed at predicting the adverse outcomes of various human and machine failures, and system states
- Deal with hypothetic failures
- Seeks to know the effects of each of all possible causal sets.
- Looks forward in time
- Less commonly used in medicine but are catching up



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FMEA for GK procedures using Perfextion/4C

- Xu et al. JACMP, 18(6), 152-168. doi:10.1002/acm2.12205.
  - A FMEA team formed with members from all involved expertise.
  - Process tree
  - Failure mode table
  - Scores for probability occurrence
  - Risk priority number (RPN)
- 86 failure modes identified:
  - 40 modes are GK specific; 46 common for all external beam RT techniques
  - High score modes: imperfect frame adaptor attachment, bad fiducial box assembly, unsecured plugs/inserts, overlooked target areas, and undetected machine mechanical failure during the morning QA process

Failure modes and effects analysis for Gamma Knife Icon™ frameless radiotherapy

- Jakubovic et al., 2019 AAPM Spring Clinical Meeting Poster Session.
  - A FMEA team formed with members from all involved expertise.
  - Process mapping
  - Failure mode and effect analysis
  - Fault tree analysis
  - Update quality management program
- Three focus areas specific to the frameless workflow
  - Simulation (12 steps)
  - Treatment Planning (15 steps)
  - Treatment (17 steps)
- 20 steps overlapped with framed Gamma Knife workflow

Process Map of Gamma Knife Icon^{TM} frameless radiotherapy

Simulation	Treatment Planning	Treatment
1. Machine daily QA (PH) 2. CBCT daily QA (PH) 3. Preheat oven (PH) 4. Patient identification and chart review (NC, RO) 5. Nursing assessment and documentation (NC) 6. Patient setup (TH, PH) 7. Mask fabrication (TH, PH) 8. Deployment of infrared camera (TH) 9. Documentation of setup, couch indices and mask position (TH) 10. CBCT acquisition (6.3 mGy CTDI) (TH) 11. CBCT registration and review (PH, RO) 12. Documentation of simulation (TH)	1. Transfer MRI to TPS (PH) 2. Generate skull geometry from images(PH) 3. Verify/modify reconstructed skull shape (PH) 4. Define pre-plan reference (PH) 5. Import and register previous treatments (PH) 6. Register pre-planning MRI to Simulation CBCT (PH, RO) 7. Contour the treatment volume and/or OARs (RO, NS, PH) 8. Enter and sign prescription (RO) 9. Entering prescription in TPS (RO, NS) 10. Planning (PH) 11. Plan review 2nd check (PH) 12. Plan approval (RO, NS, PH) 13. Print and sign the plan (PH, RO, NS) 14. Export to GK Treatment Console (PH) 15. Documentation of treatment plan with screenshots (PH)	1. Machine daily QA (PH) 2. CBCT daily QA (PH) 3. Nursing assessment and documentation (NC) 4. Prepare and transport patient to treatment room (PA) 5. Set up the patient on the couch (TH, NC, RO) 6. Confirm fraction number and treatment time (PH, TH, RO) 7. Align patient to left and right indices of the couch mattress from simulation (TH) 8. Secure mask (TH) 9. Set up any monitoring devices (if applicable) (NC) 10. Deploy infrared camera and attach infrared reflector to patient's nose (TH) 11. CBCT (2.5 mGy CTDI) acquisition (TH) 12. Register CBCT in TPS with CBCT Reference from simulation (PH) 13. Evaluate co-registration and dose (PH, RO) 14. Perform collision test if indicated by plan (PH) 15. Confirm data transfer with printed plan (PH, TH) 16. Beam on (TH, RO) 17. Patient monitoring (TH, PH, RO, NS)

Frameless Gamma Knife Workflow

- Legend
- NC: Nurse coordinator
- NS: Neurosurgeon
- PH: Physics
- PA: Patient assistant
- PH: Physics
- PA: Patient assistant
- TH: Therapist
- CC: Consult Coordinator

Jakubovic et al., 2019 AAPM Spring Clinical Meeting Poster Session.

Some key points

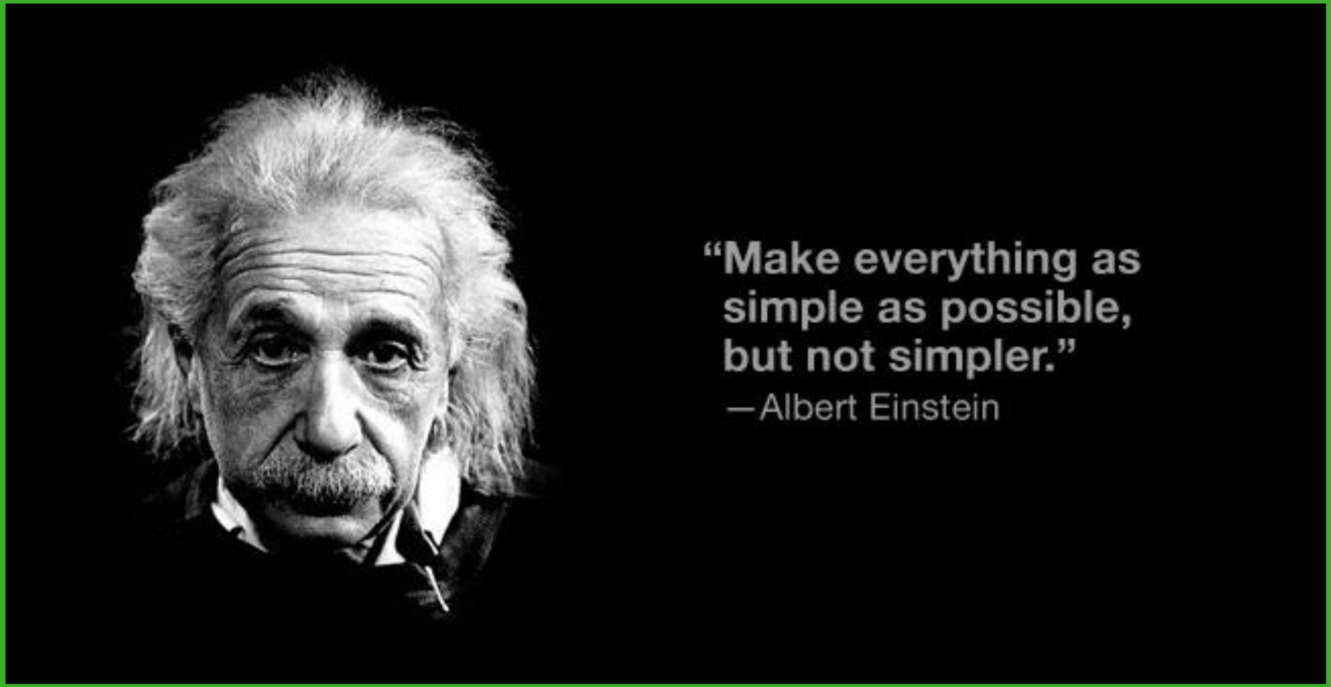
- Anatomical restrictions may limit ability of the HDMM system and should be tested at simulation
- Training of personnel is particularly important during the fabrication of the mask
- Patient comfort is crucial during simulation to ensure repeatability of patient positioning during treatment
- Use of CBCT and HDMM with the frameless introduces additional uncertainties which impact patient workflow and accuracy of treatment

Jakubovic et al., 2019 AAPM Spring Clinical Meeting Poster Session.

Conclusions

- GK Icon opens new opportunities for brain SRS/SBRT but also poses some challenges.
- There will be a learning curve when adopting GK Icon into clinic
- Physicists should have an open mind and be prepared to answer questions about this new technology .
- Workflow is much more complicated with GK Icon, which demands more clinical resources.
- A good QA program is critical.

Thank You!


"Make everything as simple as possible, but not simpler."
—Albert Einstein