Jour. of Radiosurgery and SBRT, Vol. 7, pp. 115-125
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Clinical Investigation

Failure mode and effects analysis (FMEA) to enhance the safety and efficiency of Gamma Knife radiosurgery

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(Received: January 13, 2020; Accepted: June 25, 2020)

ABSTRACT

This risk analysis describes our Failure Mode and Effects Analysis (FMEA) for Gamma Knife stereotactic radiosurgery at our community hospital. During bi-monthly meetings over 5 months, our FMEA team mapped a detailed Gamma Knife process tree and identified potential failure modes, each were scored a Risk Priority Number (RPN) for severity, occurrence, detectability. In our process tree of 14 subprocesses and 177 steps, we identified 31 potential failure modes: 7 high scoring (RPN ≥150) and 3 modes (<150) selected by clinicians for mitigation strategies. Eighteen months later, rescoring of high-risk failure modes showed significant reduction in RPN scores, thus confirming the benefit of our FMEA mitigation strategies. Our study provides a roadmap to achieve high-quality Gamma Knife radiosurgery that can be utilized by new centers as a starting point for their quality management program. Five quality control documents were developed that can be customized by any Gamma Knife center.

Keywords: FMEA, Gamma Knife, quality assurance, radiosurgery, risk analysis

INTRODUCTION

Gamma Knife radiosurgery utilizes a stereotactic head frame and highly collimated radiation beams to accurately treat intracranial diseases such as tumors, vascular malformations, and trigeminal neuralgia. This minimally invasive, multistep procedure involves a multidisciplinary team of physicians, nurses, and physicists. The high complexity of Gamma Knife radiosurgery requires strict attention to accuracy and safety throughout the process. A prospective risk analysis can identify high-risk process steps before failure occurs providing the opportunity to establish preventive measures.

In stereotactic radiosurgery, early risk analysis focused on quality assurance of the treatment unit, stereotactic accessories, and imaging.[1] We now have a greater understanding about the importance of process design, information flow, staff training, and documenta-

tion in preventing an undetected error that could result in patient injury.

Failure Mode and Effects Analysis (FMEA) is a well-recognized tool for conducting a systematic, proactive analysis of a complex process in which harm may occur. Developed in 1949 by the United States Department of Defense, FMEA was subsequently utilized by many industries including aerospace, automotive, and healthcare.[2] This type of analysis was also applied to modern radiation oncology for intensity modulated radiation (IMRT), stereotactic body radiation therapy, linear accelerator (LINAC) stereotactic radiosurgery, and Gamma Knife radiosurgery, mainly at academic medical centers.[3-8] Nonetheless, the Nuclear Regulatory Commission recorded seven critical medical events over the past 5 years involving Gamma Knife radiosurgery, thus pointing to the need for a more in-depth clinically-oriented analysis.[9-16]

Toward this aim, this study documents our implementation of FMEA for Gamma Knife radiosurgery at a community hospital, including the creation of the multidisciplinary team, development of a process tree, and identification of critical failure modes (i.e., any event that could potentially lead to an undesired treatment outcome). We review the interventions implemented to address the riskiest of these potential events and the reassessment 18 months later. The results provide a roadmap for clinicians launching a Gamma Knife radiosurgery program or existing centers that wish to enhance their quality management program.

METHODS AND MATERIALS

Radiosurgery treatment process

Since our radiosurgery team began using the Gamma Knife Perfexion® (Elekta Instrument AB, Stockholm, Sweden) in March 2013, we have treated 1,400 patients with brain tumors, vascular malformations, and trigeminal neuralgia. At our center, the procedure begins with placement of a stereotactic headframe under conscious sedation by the neurosurgeon. Diagonal pins are tightened in a sequential fashion using a torque wrench calibrated to 0.4 nM (3.5 in-lb). Patients then undergo magnetic resonance imaging (MRI) with a stereotactic localizer. Patients with skull base tumors (e.g., vestibular schwannoma) or trigeminal neuralgia also undergo computed tomography (CT) scans. Next, images are imported into the treatment planning workstation and defined in stereotactic space. With contouring of the skull, targets, and critical structures by the physicians, a treatment plan is generated and approved by the neurosurgeon, radiation oncologist, and medical physicist. After receiving intravenous steroids, the patient is positioned and secured onto the treatment table, and monitored throughout treatment delivery by the physicians and nurses. Lastly, the nurses remove the stereotactic frame and the patient receives discharge instructions.

Overview of the FMEA process

Our FMEA project was initiated in February 2017 after we had treated 610 patients. Our working group consisted of a neurosurgeon, radiation oncologist, nurse, medical physicist, MRI technologist, and four hospital quality experts, one of whom was highly experienced in the FMEA process. The team met biweekly for a 5-month period and then again 18 months later to review the effectiveness of the quality management program. Our analysis included creation of a process tree, identification of possible failure modes, scoring of failure modes, and development of mitigation strategies.

Development of a Gamma Knife process tree

During the initial meeting, the working group reviewed the FMEA protocol, drafted an initial high-level process tree for Gamma Knife radiosurgery that began with the initial consult and ended 2 weeks after the procedure. During nine subsequent meetings, the team members further detailed each subprocess. Our resulting Gamma Knife process tree consisted of 14 subprocesses including: (S1) initial consult, (S2) scheduling of procedure, (S3) pre-procedure chart, (S4) patient registration, (S5) pre-frame tasks, (S6) frame placement, (S7) imaging, (S8) treatment planning, (S9) physics quality assurance (QA), (S10) treatment delivery, (S11) frame removal, (S12) post-procedure chart, (S13) post-procedure call, and (S14) post-procedure visit (Table 1 and Supplement 1). Each subprocess was then subdivided into individual steps.

Identification and scoring of possible failure modes

With identification of the individual steps of the process map, team members then identified and scored potential failure modes by consensus using a 10-point scale adapted from the Institute for Healthcare Improvement FMEA toolkit (Table 2).[17] The Risk Priority Number (RPN) for each failure mode was calculated by multiplying the individual scores for severity (S), occurrence (O), and detectability (D) (i.e., 10 = highest severity, highest occurrence, lowest detectability). Miti-

Table 1. Subprocesses, steps, and failure modes for Gamma Knife radiosurgery

Subprocess	Description	Steps	Failure Modes
S1	Consult	6	8
S2	Scheduling of procedure	14	3
S3	Pre-procedure chart	18	2
S4	Patient registration	4	1
S5	Pre-frame tasks	17	4
S6	Frame placement	10	3
S7	Imaging	8	3
S8	Treatment planning	22	4
S9	Physics quality assurance (QA)	32	1
S10	Treatment delivery	20	1
S11	Frame removal	8	1
S12	Post-procedure chart	6	0
S13	Post-procedure call	5	0
S14	Post-procedure visit	7	0

Within the 14 subprocesses before (blue), during (green), and after (gold) the procedure, our FMEA analysis identified 177 steps and 31 failure modes.

gation strategies were developed for all failure modes with RPN scores ≥150 (similar to Younge et al.[6]) and for three additional failure modes <150 selected by the clinicians (Table 3).

Creation of mitigation strategies

The team's strategies to increase the detectability of potential failure modes and reduce the likelihood of occurrence included various process controls, specifically standardized forms, mandatory pauses, and time-out documents. Special emphasis was placed on redundant measures (e.g., multiple overlapping time-outs) that could reduce the possibility for a single undetected error resulting in harm to the patient.

Implementation and follow-up

New process controls approved by the working group were immediately implemented. Therefore, some mitigation strategies were initiated early in the 5-month FMEA project whereas others were added later. Eighteen months after completing the FMEA project, the working group reconvened to re-score the RPN for each high-risk failure mode and assess the effectiveness of these new quality management tools.

Table 2. FMEA scoring guidelines adapted from the Institute for Healthcare Improvement FMEA toolkit[17]

SEVERITY RATING	
1	No effect on patient
2	Slight system problem – may annoy patient
3	Moderate system problem – may affect patient
4	Moderate system problem – may affect patient and delay or alter treatment
5	Major system problem – begins to affect patient adversely
6	Major system problem – additional effect on patient
7	Major system problem – begins to cause temporary harm to patient, additional monitoring and intervention required
8	Major system problem – moderate temporary harm to patient, aggressive monitoring and intervention required
9	Major injury, permanent harm, surgical intervention required
10	Terminal injury or death
OCCURRENCE RATING	
1	Remote chance of occurring – no known occurrence
2	Remote chance – may occur, once a year
3	Low possibility of occurring
4	Increasingly higher chance of occurring – several times a year
5	Moderate probability – monthly
6	Moderate probability – several times a month
7	High probability – occurs frequently, weekly
8	Occurs frequently – several times a week
9	Occurs very frequently – daily
10	Happens all the time – several times a day
DETECTION RATING	
1	Error highly detectable – very obvious
2	Error highly detectable
3	High detectability – we will likely catch it
4	High detectability – we should detect
5	Moderate likelihood of detection – we might detect
6	Moderate detectability
7	Low-moderate detectability
8	Low likelihood of detection – we probably will not catch
9	Very low detectability
10	Detection not possible – we will never catch it

Table 3. High-scoring and clinician-selected failure modes identified within subprocesses (S) before (blue) and during (green) the Gamma Knife procedure that were targeted for mitigation strategies.

	Failure Mode		Severity (S) × occurrence (O) × detectability (D) = Risk priority number (RPN)		Mitigation Strategies				
S	RPN ≥150	Potential Effect(s)	S × O × D	RPN	Patient intake form	Pre-procedure checklist	Frame placement time-out	Physics Check-list	Treatment delivery time-out
S1	Incomplete documentation of prior head/neck radiation	Excessive dose to critical structure	9 × 4 × 5	180	✓	✓			
S1	Failure to review MRI in Gamma Plan (previously treated patients)	Wrong target, over- or under-treatment	9 × 5 × 8	360	✓	✓			
S3	Incomplete documentation of prior cranial surgery	Pin penetration into brain	9 × 3 × 8	216	✓	✓			
S6	Incomplete time-out procedure	Missed critical step	9 × 4 × 9	324	✓	✓	✓	✓	✓
S7	Inconsistant identifier information on DICOM images	Incorrect MRI imported into patient's plan	9 × 10 × 4	360				✓	
S8	Incorrect registration of DICOM images	Under-treatment of tumor or excessive dose to critical structure	9 × 2 × 9	162				✓	
S10	Failure to administer pre-procedural medications	Adverse events (e.g., perilesional edema, seizures)	8 × 5 × 7	280					✓
	Clinician-selected RPN < 150								
S2	Failure to take appropriate outpatient medications	Adverse events (e.g., perilesional edema, seizures)	8 × 4 × 1	32	✓	✓			
S2	Lack of recent glomerular filtration rate (GFR)	Nephrogenic systemic sclerosis	8 × 3 × 4	96	✓	✓			
S5	Failure to confirm side of trigeminal neuralgia	Treatment of incorrect trigeminal nerve	6 × 2 × 3	36			✓		✓

RESULTS

Process tree

Our FMEA identified a process tree with 14 subprocesses (S1-S14) before, during, and after the Gamma Knife procedure (Figure 1 and Supplement 1). Subprocesses represented the pre-procedure period (n=3), day of procedure (n=9), and postoperative period (n=2). Each subprocess consisted of 4 to 32 steps, totaling 177 individual steps from consult to post-procedure visit (Table 1).

Failure modes

Thirty-one potential failure modes were identified for the pre-procedure period (n=13), frame placement (n=8), imaging (n=3), treatment planning/quality assurance (QA) (n=5), treatment delivery (n=1), frame removal (n=1), and post-procedure period (n=0) (Table 1 and Figure 1). The significant number of failure modes in the pre-procedure period reflected concerns that lack of a full clinical history (e.g., prior surgery or radiation) or inadequate preparation (e.g., failure to prescribe medications) could propagate the potential for patient injury throughout the procedure.

Of 10 high-risk failure modes, 7 had RPN ≥150 related to preoperative preparation (n=3), frame placement (n=1), imaging (n=1), treatment planning (n=1), and treatment delivery (n=1) (Table 3 and Figure 1). Mean RPN score of these high-scoring failure modes was 269 (range 162-360). Three failure modes with RPN < 150 (mean 55, range 32-96) were selected for further study at the clinicians' discretion. Overall, two of the high-risk failure modes were specific to Gamma Knife (i.e., incomplete documentation of prior cranial surgery, inconsistent identifier information on DICOM images) whereas the remaining 8 high-risk failure modes were common to framed and frameless stereotactic radiosurgery (e.g., failure to administer pre-procedural medications).

Creation of mitigation strategies

All 10 high-risk failure modes were addressed with mandatory pauses and overlapping time-out documents that achieved a level of redundancy. Supplement 2 contains the five quality control documents that were developed or were revisions of existing documents: Patient Intake Form (at scheduling), Pre-Procedure Checklist (on arrival to hospital), Frame Placement Time-Out (just before frame placement), Physics Checklist (at completion of treatment planning), and Radiation Delivery Time-Out (just before treatment delivery). Table 3 illustrates the use of these documents to address each high-risk failure mode.

Mitigation strategies were developed for each high-risk failure mode within subprocesses S1-S14 and for clinician-selected failure modes with <150 RPN.

S1 Consult: Incomplete documentation of prior head/neck radiation (RPN 180). Knowledge of the timing, dose, and field of prior head/neck radiation is important

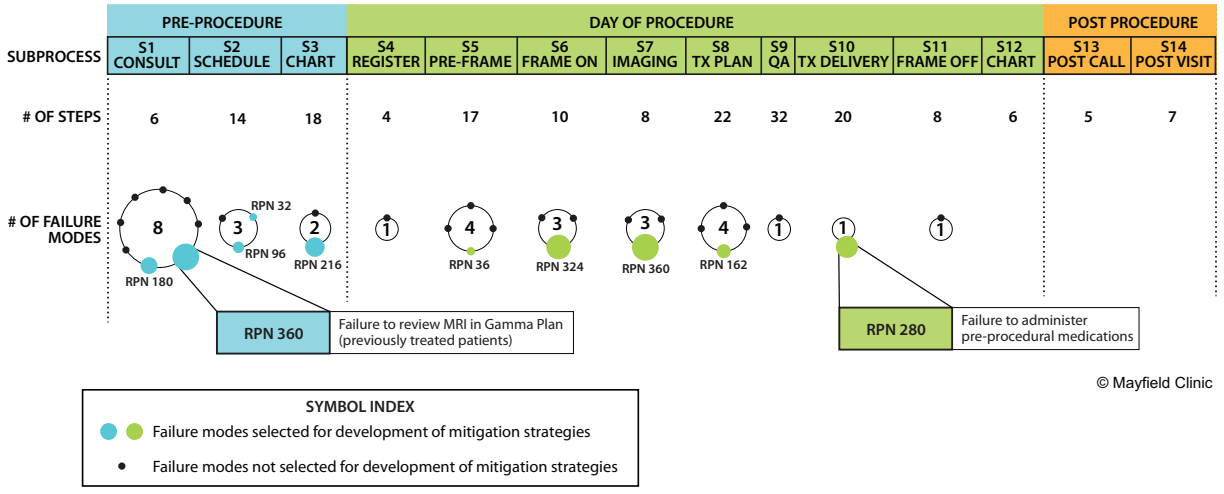

Figure 1. Infographic depicts our initial Gamma Knife process tree that consisted of 14 processes before, during, and after the procedure. Our FMEA team examined the 177-step process to reveal 31 potential failure modes, each of which scored a Risk Priority Number (RPN) based on severity, occurrence, and detectability. Mitigation strategies were developed for 7 high-scoring (RPN ≥150) failure modes (blue and green circles) and 3 clinician-selected failure modes (RPN <150); other failure modes were not considered high risk for mitigation (black circles). Two example RPNs of 360 and 280 are shown. (Figure with permission from Mayfield Clinic).

during patient selection for radiosurgery and also for developing safe, effective treatment plans. This potential failure was addressed in the Patient Intake Form and Pre-Procedure Checklist ("Has the patient ever received radiation to the head or neck? If so, are the radiation records available?") (Supplement 2). Additionally, we required radiosurgery plans in DICOM format for all patients who previously underwent radiosurgery at outside institutions.

S1 Consult: Failure to review MRI in Gamma Plan (previously treated patient) (RPN 360). Determination of treatment response and tumor recurrence can be challenging in patients with multiple brain metastases who have undergone multiple sessions of Gamma Knife radiosurgery. A risk exists for inadvertently retreating a tumor or failing to detect new lesions. Therefore, our center requires that all follow-up MRI scans be imported into Gamma Plan and then fused with prior treatment plans to assess tumor response and determine if the patient will undergo additional radiosurgery. Potential omission of this critical review was addressed in both the Patient Intake Form and Pre-Procedure Checklist ("Has the MRI been reviewed in Gamma Plan?") (Supplement 2).

S3 Preoperative chart: Incomplete documentation of prior cranial surgery (RPN 216). The neurosurgeon must be cognizant of the location and extent of any prior cranial surgery before placing the stereotactic frame to avoid pin penetration into the brain through a bony defect. The Patient Intake Form triggered request for information ("Previous craniotomy? If yes, "Is the operative report in the chart?"), and the Pre-Procedure Checklist queried the patient ("Has the patient ever had surgery on the head?"). Additionally, the neurosurgeon must mark the incision and bone flap of any prior craniotomy, a step that is confirmed by the Pre-Procedure Checklist ("Is the craniotomy site marked?"). If the neurosurgeon was uncertain of the proximity of the craniotomy, markers were placed at the proposed pin sites and the patient underwent a cone-beam CT scan before frame placement.

S6 Frame placement: Incomplete time-out (RPN 324). During the FMEA process, the working group expressed concern that a critical step could be missed during completion of the five quality control documents. This was resolved by developing templates in the electronic medical record (EMR) that required completion of all fields in each document before signature was allowed into this record. Although this failure mode is listed under the frame placement subprocess, both the failure mode and mitigation strategy apply to all five documents.

S7 Imaging: Inconsistent identifier information on DICOM images (RPN 360). The format of the patient's name may differ; specifically, Gamma Plan has no field for middle name (or initial) whereas the DICOM format usually includes a middle initial from the EMR. This discrepancy resulted in an error message for every DICOM import. Although the user could override this, it raised the concern of alert fatigue wherein the user becomes desensitized to safety alerts and fails to respond appropriately to the warning (e.g., inadvertently override the warning and import another patient's MRI scan). We resolved this discrepancy by adding the patient's middle initial in the field for the first name in Gamma Plan, and confirmed patient identifiers on the MRI on the Physics Checklist (Supplement 2) ("Proper imaging studies requested and imported? Patient identifiers correct in Gamma Plan?").

S8 Treatment planning: incorrect registration of DICOM images (RPN 162). Imported MRI image sets must be registered in stereotactic space using the stereotactic localizer fiducials. This process generates mean and maximum errors and provides a visual depiction of any magnetic distortion. However, a registration could be accepted that exceeds the tolerance (mean <0.6 mm), which would degrade the accuracy of the radiosurgery procedure. We safeguarded against this potential failure mode by requiring the user to enter the mean error of registration for each imaging sequence on the Physics Checklist.

S10 Treatment delivery: Failure to administer preprocedural medications (RPN 280). Dexamethasone 4 mg is administered intravenously immediately before treatment delivery, except for patients with trigeminal neuralgia. The morning of treatment, patients with supratentorial tumors also receive levetiracetam 500–1,000 mg orally. For tumors within the motor cortex, lorazepam 0.5–1 mg is given orally before the procedure. Failure to administer the appropriate pre-procedural medications could result in adverse events (e.g., perilesional edema and/or seizures). We addressed this potential failure mode with two questions on the Radiation Delivery Time-Out (Supplement 2) ("Has the patient received intravenous dexamethasone? Does the patient require Keppra or Ativan prior to treatment delivery?").

S2 Scheduling: Failure to prescribe appropriate outpatient medications (RPN 32). Outpatient medications are at the discretion of the treating physician. At our center, dexamethasone 4 mg po bid is started 1 day before the procedure and levetiracetam 500 mg po bid 3 days before treatment. To ensure this, the Patient Intake Form prompts the nurse to request specific medication orders from the neurosurgeon or radiation oncologist when scheduling the procedure. Electronic prescriptions generated and documented in the chart are confirmed on the morning of the procedure in the Pre-Procedure Checklist ("List the procedure-specific medications taken by the patient this morning.").

S2 Scheduling: Lack of recent glomerular filtration rate (RPN 96). The relationship between gadolinium-based contrast agents and nephrogenic systemic sclerosis was first described in 2006.[18] Our radiology department uses the following guidelines based on glomerular filtration rate (GFR): < 30 mL/min → no gadolinium, 30-59 mL/min → single-dose gadolinium, and ≥60 mL/min → double-dose gadolinium (for brain metastases). We require a GFR within 30 days of the procedure. To ensure against an omission, we developed a triple check: documentation of this value on both the Patient Intake Form and Pre-Procedure Checklist ("What is the patient's GFR?"), and the MRI technologist's confirmation of the GFR and MRI order with their written guidelines.

S6 Pre-procedure: Failure to confirm side of trigeminal neuralgia (RPN 36). Confirmation of the side of pain is essential in patients with trigeminal neuralgia because there is usually no structural abnormality visualized on the MRI scan. Bilateral trigeminal neuralgia, though rare, can be particularly confounding. The Nuclear Regulatory Commission reported a wrong-sided Gamma Knife radiosurgery procedure in 2014 for a patient with bilateral trigeminal neuralgia.[9] For this reason, the neurosurgeon must review the clinic note and consent form on the morning of the procedure, query the patient regarding the side of pain, and affix a vitamin E capsule to the treatment side to ensure its visualization on the MRI scan as a final check during treatment planning. This check was addressed in both the Frame Placement Time-Out and Radiation Delivery Time-Out by two questions ("What side are we treating? Is the side marked for laterality?)" (Supplement 2).

Follow-up scoring of high-risk failure modes

The physicians and nurses of the original working group reconvened 18 months after completing the FMEA to re-score the high-risk failure modes and assess the new quality control measures. For the seven failure modes with an initial RPN ≥150, the mean score decrease from 269 (range 162-360) to 47 (range 9-81) signified a positive result from the FMEA mitigation strategies (Table 5). Scores for severity remained

Table 4. Comparison of RPN scores based on severity (S), occurrence (O), and detectability (D) before and after FMEA process.

	Failure Mode	Before FMEA				After FMEA			
Subprocess	**RPN ≥150**	**S**	**O**	**D**	**RPN**	**S**	**O**	**D**	**RPN**
S1 Consult	Incomplete documentation of prior head/neck radiation	9	4	5	180	9	3	3	81
S1 Consult	Failure to review MRI in Gamma Plan (previously treated patients)	9	5	8	360	9	3	3	81
S3 Pre-procedure chart	Incomplete documentation of prior cranial surgery	9	3	8	216	9	2	2	36
S6 Frame placement	Incomplete time-out procedure	9	4	9	324	9	1	1	9
S7 Imaging	Inconsistant identifier information on DICOM images	9	10	4	360	9	4	2	72
S8 Treatment planning	Incorrect registration of DICOM images	9	2	9	162	9	2	2	36
S10 Treatment delivery	Failure to administer pre-procedural medications	8	5	7	280	8	1	2	16
	Mean	**8.9**	**4.7**	**7.1**	**269**	**8.9**	**2.3**	**2.1**	**47**
	Clinician-selected RPN <150								
S2 Scheduling	Failure to take appropriate outpatient medications	8	4	1	32	8	4	1	32
S2 Scheduling	Lack of recent glomerular filtration rate (GFR)	8	3	4	96	8	1	1	8
S5 Pre-frame tasks	Failure to confirm side of trigeminal neuralgia	6	2	3	36	6	1	1	6
	Mean	**7.3**	**3**	**2.7**	**55**	**7.3**	**2**	**1**	**15**

the same, frequency of occurrence decreased from mean (range) 4.7 (2-10) to 2.3 (1-4), and detectability decreased from mean (range) 7.1 (4-9) to 2.1 (1-3). Thus, strengthening our existing documentation and the introduction of new time-out procedures improved our ability to detect these potential failure modes, which resulted in lower detectability scores. This seems counterintuitive but is made clearer by examining the scoring of this parameter in Table 2 (i.e., low detectability score equates to a higher level of detectability).

For the three clinician-selected failure modes, mean RPN decreased from 55 (range 32-96) to 15 (range 6-32), further confirming the benefit of our FMEA process (Table 4). Scores for severity scores remained the same, mean frequency of occurrence decreased from 3 (range 2-4) to 2 (range 1-4), and mean detectability decreased from 2.7 (range 1-4) to 1 (range 1-1). "Failure to take appropriate outpatient medications" showed no change in RPN after the FMEA interventions. The working group discussed additional strategies and ultimately recommended calling the patient the day before the procedure to confirm their medications.

DISCUSSION

Our Gamma Knife radiosurgery center conducted an FMEA with input from multiple disciplines to address this complex, multi-stage procedure with aim to reduce the risk of an undetected error that could result in patient death or injury. The Nuclear Regulatory Commission requires Gamma Knife users to report critical medical events, such as, total delivered dose > 20% higher than prescription dose or any dose to the wrong patient.[12] During the past 5 years, seven Gamma Knife misadventures reported to the Commission included treatment of the wrong patient (1 event) or wrong side (2 events), stereotactic frame slippage (2 events), incorrect table docking of patient (1 event), and misalignment of treatment table (1 event).[9-16] Therefore, the Gamma Knife community needs more robust quality management programs to minimize the occurrence of these events.

Our center's 5-month FMEA process achieved the goals of strengthening our Gamma Knife quality controls and cultivating a culture of excellence in our organization. Our Gamma Knife process tree, including 14 subprocesses and 177 individual steps, revealed 31 potential failure modes; 7 high-scoring failure modes (RPN ≥150) and 3 other clinician-selected modes (RPN <150) for problem-solving interventions. Other potential failure modes not selected were deemed highly detectable because of existing quality controls developed during the initial 4 years of our Gamma Knife program.

Notably, six potential failure modes chosen for mitigation strategies were in the preoperative period (e.g., office consultation, scheduling phone call, discussion prior to frame placement). One failure mode (each) was related to frame placement, imaging, treatment planning, and treatment delivery. We believe that this reflects the evolution of our quality management program during the period from Gamma Knife installation to the FMEA project. At the launch of our center, we focused on optimizing frame placement, obtaining high-resolution and distortion-free MRI scans, optimizing Gamma Knife treatment plans, and confirming the mechanical precision of the treatment unit. Thereafter, our FMEA process focused on the potential for human failure and implementation of standardized procedures (mandatory pauses, time-out procedures) to reduce the likelihood of a mistake or error going undetected. Our 18-month follow-up evaluation affirmed the value of these interventions: all high-scoring failure modes had become highly detectable, and therefore, were unlikely to be propagated and result in patient harm.

Previous FMEA studies in radiation oncology

The seminal 2016 report by Huq et al. and the Task Group 100 (TG-100) of the American Association of Physicists in Medicine (AAPM) outlined the framework for using FMEA as the primary tool for quality management in radiation oncology.[3] Their application for IMRT was comprehensively described including development of a process tree, identification and scoring of failure modes, fault tree analysis, and mitigation strategies. They also provided a practical guide to performing FMEA and introductory exercises for process mapping, FMEA, and quality management design.

Among recent publications about FMEA for cranial stereotactic radiosurgery, Masini et al. identified two high-risk failure modes (RPN ≥125) (i.e., incorrect collimator size, incorrect double-check of target coordinates) associated with framed LINAC radiosurgery.[5] The authors implemented corrective measures that increased the likelihood of their detection, and also commented on the overall increased awareness of quality and safety among the FMEA participants (halo effect).

Younge et al. reported their experience with FMEA implementation before launching their frameless LINAC stereotactic radiosurgery program.[6] Their five high-risk failure modes (RPN > 150) related to imaging (incorrect patient orientation during MRI), treatment planning (contours accidentally changed), and treatment delivery risks specific to frameless radiosurgery (inadequate mask immobilization, patient movement

during treatment). Interestingly, team members selected their presumed high-risk failure modes before initiating the FMEA project: only one item was borne out by the FMEA process (incorrect patient orientation during MRI). In the second FMEA publication on frameless LINAC radiosurgery, Manger et al. identified 10 high-risk failure modes (RPN ≥180) in the areas of imaging (n=1), treatment planning (n=5), and treatment delivery (n=4).[7] The preponderance of failure modes in the treatment planning and delivery may have reflected the composition of the FMEA team (four medical physicists, one physician).

In the one previous publication on the use of FMEA for Gamma Knife radiosurgery, Xu et al. applied recommendations from the AAPM TG-100 report to framed radiosurgery with the Gamma Knife 4C and Perfexion® platforms.[8] Their 2017 study identified 86 potential failure modes: 40 items specific to Gamma Knife and 46 items common to all radiosurgery technologies. Notably, only one failure mode scored RPN >100 (frame adapter not properly attached, RPN 123). Several failures modes with the highest severity scores did not rise to the level of further analysis because occurrence and detectability scores were low as a result of previously implemented quality assurance procedures. These results are not unexpected when one considers the long history of the Pittsburgh Gamma Knife center (launched in 1987), its high patient volume (> 600 patients/year), and the senior author's involvement in the AAPM Task Group 100.

Our study differed from the 2017 Pittsburgh publication[8] in several important ways. First, our Gamma Knife program is based at a community (non-academic) hospital and the FMEA project was initiated early in our clinical experience (after 4 years and 610 patients). Second, our multidisciplinary FMEA team included four hospital quality experts with expertise in FMEA. Third, our analysis focused on a single Gamma Knife platform (Perfexion®). These differences may explain why we identified seven high-scoring failure modes (vs. Pittsburgh's one) with the majority in the pre-procedure period (vs. none). Their single high-scoring failure mode (improper frame adapter attachment) did not reach an RPN ≥150 in our analysis because an Elekta field notice had raised our awareness of this pitfall (i.e., lowered the detectability score). Therefore, one should expect that each institution's FMEA output will uniquely reflect the technology platform, maturity of the radiosurgery program, composition of the FMEA team, and depth of existing quality management processes. We predict that our results and guidelines are more applicable to newly established Gamma Knife centers than the unique findings of the Pittsburgh group.

FMEA roadmap for new Gamma Knife Centers

New Gamma Knife centers are provided considerable manufacturer support during technology installation and launch of the clinical program. Physicians, nurse coordinators, and medical physicists must complete a Gamma Knife introductory course at an approved training center. Elekta also provides on-site mentorship by an experienced Gamma Knife physician during the first week of treatment. The available policies and procedures focus primarily on image acquisition, treatment planning, and quality control of the treatment unit and stereotactic accessories. However, less emphasis is placed on patient clinical care before and during the procedure. New centers are expected to develop their own quality management program at a point when they have limited experience with the Gamma Knife procedure.

Our study provides a roadmap to achieve high-quality Gamma Knife radiosurgery that can be applied by new centers as a starting point for their quality management program. We describe the methodology, high-risk failure modes, and mitigation strategies that can reduce the risk of an adverse event. A straightforward set of mandatory pauses and overlapping time-out documents provide a level of redundancy that reduces the likelihood of a mistake or error going undetected. These five quality control documents in Supplement 2 can be customized to the needs of each Gamma Knife center.

Limitations of our study

Our FMEA working group's scoring system adapted from the Institute for Healthcare Improvement FMEA toolkit differed from studies that used the scoring system recommended in the AAPM TG-100 report.[3,17] The two systems differ in the descriptors used for rankings of severity, occurrence, and detectability; this difference could result in RPN scores that are not directly comparable. Our strategy of generating an RPN score for each failure mode by consensus during our biweekly FMEA meetings was similar to that used by Manger et al.[7] and Masini et al.[5] but unlike that of Younge et al.[6] and Xu et al.[8] who relied on individual RPN scoring and averaging without group discussion. It is possible that group scoring could be unduly influenced by one or more dominant voices.

Ideally, an FMEA project produces mitigation strategies that would be implemented on a specific date to measure the incidence of adverse events before and after that date. In our study, if deemed important for patient safety, the recommended process controls were implemented immediately after the working group's approval. Given that some mitigation strategies were initiated early during the 5-month project and others were added later, we cannot compare adverse events before and after their

implementation. Instead, our working group reconvened 18 months after completing the FMEA project to re-score the RPN for high-risk failure modes and assess the benefit of the new quality management tools.

Lastly, our FMEA analysis applies to the Gamma Knife Perfexion® and was performed at a community hospital after an initial 4-year clinical experience with 610 patients. We believe that the findings of our FMEA are generalizable to all Gamma Knife centers and the protocols in Supplement 2 can be easily modified to suit the needs of an individual center.

CONCLUSIONS

We applied FMEA to Gamma Knife Perfexion® stereotactic radiosurgery to identify high-risk failure modes and thereby develop effective mitigation strategies. The majority of high-risk failure modes related to preoperative patient care that may reflect our pre-existing quality processes focused on other steps in the procedure (e.g., imaging, treatment planning, treatment unit). Rescoring of these high-risk failure modes 18 months later showed significant reduction in risk scores thus confirming the value of FMEA. Our process tree (Supplement 1) and protocols (Supplement 2) can function as a roadmap for new Gamma Knife centers that wish to strengthen their quality management program.

ACKNOWLEDGEMENTS

The authors thank medical illustrators Martha Headworth and Tonya Hines for infographic design and figures, and Mary Kemper for medical editing. The authors received no grant or other financial support for this work. The information presented has not been previously presented or published.

Supplementary information to this paper can be accessed from the electronic version.

Authors' disclosure of potential conflicts of interest

The authors have nothing to disclose.

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