IMRT severity scoring for TG-100: Do you really know?

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Introduction

With the present level of knowledge, training, and advanced technologies required for radiotherapy, a high level of safety, quality, and efficiency are expected. Several factors challenge these expectations. Accurate dose delivery requires a long, complicated chain of events, each of which may fail and contribute to dose delivery errors. In addition to the inherent risk that accompanies any medical procedure, complicated and compounding advanced treatment techniques increase demand on staff, hardware, and software. With the challenges of busier clinics, advanced treatment techniques, and increased patient risk, the radiotherapy community is taking on new approaches to improve quality management and patient safety. To more thoroughly, effectively, and efficiently address potential errors in radiotherapy and attempt to eliminate severe consequences from radiotherapy treatments, the perception of the entire field is shifting to include several prospective risk analysis and mitigation tools borrowed from other industries and other branches of medicine. One of these techniques is failure modes and effects analysis.

Failure Modes and Effects Analysis (FMEA)

Failure modes and effects analysis (FMEA) as defined in AAPM TG-100 has become a highly discussed concept throughout the radiotherapy community. After detailed process mapping, FMEA is performed by a panel of experts who assign values of probability of occurrence (O), lack of detectability (D), and severity (S) to each failure mode based on a predetermined ordinal scale such as that in Table 1. The product of these three values defines the risk probability number (RPN) which is used for QA task prioritization. Special attention is given to failure modes with high severity scores, as this is the most important variable with respect to patient safety.

This analysis is beneficial for overall process evaluation, however the primary limitation is the use of subjective, ordinal scoring to obtain risk information. The assigned scores lack evidence of accuracy and are often inconsistent and biased amongst the panel. Specific physical and quantitative information is lacking.

Objective

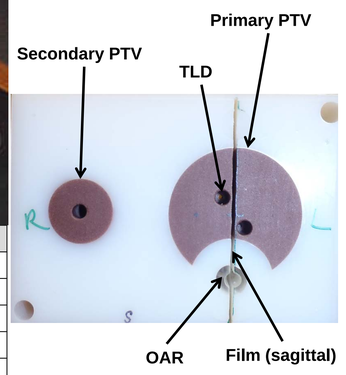
The objective of this work is to reduce the subjectivity of IMRT delivery FMEA severity scores for physics components by providing quantitative data on the effects of these failures. The rationale for this research is that even though severity scores are called for in the literature, quantitative values are not currently available and their application will improve the results of an FMEA for physics applications to radiotherapy quality management.

Materials and Methods

An IMRT delivery process map for physics-applicable processes was created and 12 physical failure modes were identified. To determine the magnitude of dose delivery errors for three of the physical failure modes (i.e., the severity of the failure mode), failure modes were induced and dosimetry measurements were performed on a Varian Clinac 2100CD accelerator going out of clinical service. Dosimetry measurements were made using both a standard (1948 MU, 90 segments, 0.482 modulation complexity score[2]) and complex (3533 MU, 216 segments, 0.181 modulation complexity score) H&N IMRT plan was delivered to the Radiological Physics Center's IMRT head and neck phantom (Figure 1). The plan was delivered as a baseline with no induced errors and then again with an MLC offset of +3 mm. Next the phantom was irradiated after adjusting the in-plane and cross-plane symmetry by 3.5% each independently. The beam was adjusted back to baseline performance and the beam quality was hardened by 1.1% (TMR ratio) by altering the bending magnet current and irradiated, then softened 0.6% and irradiate. Induced error magnitudes are summarized in Table 2. Output and beam quality (TMR ratio) were measured in solid water and the symmetry and flatness was evaluated with an ion chamber array each time the beam was adjusted. Radiochromic film in the axial plane and 6 TLD within the phantom target structures were used to analyze the 2D dose distributions and absolute doses. Paired t-test was used to evaluated the differences in baseline and failure mode deliveries for TLD absolute doses and distance to agreement in a high gradient region of the film with $p < 0.05$ showing significance..

Rank	Occurrence (O)		Detectability (D)		Severity (S)	
	Qualitative	Frequency	Qualitative	Est. probability of going undetected	Qualitative	Categorization
1	Failure Unlikely	0.01%	Never undetected	0.01%	No effect	
2		0.02%	Very low likelihood undetected	0.2%	Inconvenience	Inconvenience
3	Relatively few failures	0.05%		0.5%		
4		0.1%	Low likelihood undetected	1%	Minor dosimetric error	Suboptimal plan or treatment
5		< 0.2%		2%	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume
6	Occasional failures	< 0.5%		5%		
7		< 1%	Moderate likelihood undetected	10%	Recordable event, Potentially serious toxicity or tumor underdose	
8	Repeated failures	< 2%		15%		
9		<5%	High likelihood undetected	20%	Reportable event, Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume
10	Failures inevitable	> 5%	Always undetected	> 20%	Catastrophic	

Table 1: FMEA scoring scale adopted from AAPM TG-100 and Ford, *et al.*[1]



Structure	Dosimetric Criteria
Primary PTV	$D_{95\%} \geq 6.60$ Gy
	$D_{99\%} \geq 6.14$ Gy
Secondary PTV	$D_{95\%} \geq 5.40$ Gy
	$D_{99\%} \geq 6.03$ Gy
OAR	Max Dose < 4.50 Gy
Normal Tissue	Max Dose ≤ 7.26 Gy

Figure 1: RPC's IMRT head and neck phantom (left top), phantom dosimetric criteria of planning target volumes (PTV), organ at risk (OAR), and normal tissue (left bottom), and superior half of the phantom insert (axial plane) (center).

Failure Mode	Induced Error Magnitude
MLC Position	2 mm systematic, out
Beam Quality	+1.1% TMR ratio
	-0.6% TMR ratio
In-plane Symmetry	3.5%
Cross-plane Symmetry	3.5%

Table 2: Summary of magnitudes of induced failure modes

Results

Figure 2 depicts the general process map and the twelve physical failure modes identified for investigation.

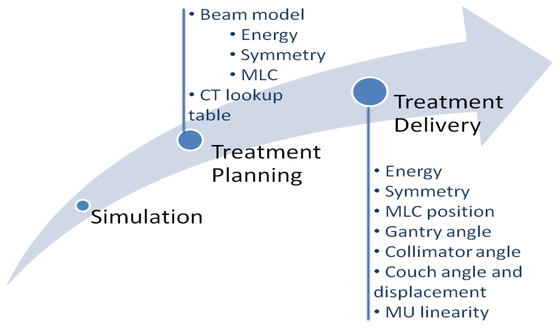


Figure 2: General IMRT delivery process map and physical failure modes

The difference in dose delivered to the IMRT H&N phantom from each of the three failure modes measured in this project relative to the baseline delivery is reported. Absolute dose differences measured in the PTV TLD are shown in Tables 3 and 4 for the standard and complex plans, respectively. The average difference of all six PTV TLD is shown in addition to the maximum difference seen in any of the TLD and the corresponding p-value. Differences in absolute dose delivery of up to 3.2% were seen for MLC positional errors, 3.5% for beam quality deviations, and 5.1% for symmetry errors. Additionally, differences in the distance-to-agreement (DTA) between the primary PTV and OAR are shown in Tables 3 and 4 along with corresponding p-values. Close to 1 mm statistically significant differences were seen in both the standard and complex treatment plan deliveries with MLC positional errors. Finally, the difference in percent of pixels passing a gamma analysis with 7%/4mm criteria (as performed at the RPC for this phantom) are shown.

Results (continued)

Standard Treatment Plan						
Failure Mode	Average Δabs dose	Maximum Δabs dose	p	Δ DTA (mm)	p	Δ%pp (7%/4mm)
MLC Position	1.4%	2.0%	*0.005*	0. 9	*0.029*	19%
Beam Quality	1.3%	2.2%	0.061	0.7	0.423	16%
	1.7%	2.2%	*0.042*	0.2	0.321	9%
In-plane Symmetry	2.0%	3.4%	*0.015*	0.2	*0.038*	13%
Cross-plane Symmetry	3.1%	4.3%	*0.004*	0.3	0.122	18%

Table 3: Summary of difference between baseline and failure mode deliveries for standard H&N treatment plan

Complex Treatment Plan						
Failure Mode	Average Δabs dose	Maximum Δabs dose	p	Δ DTA (mm)	p	Δ %pp (7%/4mm)
MLC Position	2.1%	3.2%	*0.004*	0.9	*0.006*	18%
Beam Quality	2.0%	3.6%	*0.020*	0.7	*0.002*	21%
	1.4%	2.2%	0.056	0.2	0.434	13%
In-plane Symmetry	2.7%	5.1%	0.058	0.5	*0.034*	15%
Cross-plane Symmetry	3.2%	3.8%	*0.031*	0.2	0.742	21%

Table 4: Summary of difference between baseline and failure mode deliveries for complex H&N treatment plan

Summary

Each of the failure modes induced in this study resulted in a notable difference in the dose delivery relative to baseline. Most of the maximum absolute dose and DTA differences were statistically significant. Differences in percent of pixels passing were generally between 10 and 20%. These differences were consistent at a tighter criteria of 5%/3mm.

Conclusion

Current FMEA practice for radiotherapy requires quantitative data in order to make accurate assessments associated with clinical QA programs. This study has shown examples of error magnitudes induced by IMRT physical FMs that can be used to quantify and rank FMEA severity scoring.

Future Work

The remaining failure modes identified will be assessed with physical measurement and/or computational studies. These data will then be used for quantitative severity scoring determination. These scores will be compared to subjective severity scores obtained through a conventional FMEA .

References

[1] Ford EC, Gaudette R, Myers L, et al. Evaluation of safety in a radiation oncology setting using failure mode and effects analysis. *Int J Radiat Oncol Biol Phys.* Jul 1 2009;74(3):852-858.

[2]McNiven AL, Sharpe MB, Purdie TG. A new metric for assessing IMRT modulation complexity and plan deliverability. *Medical Physics.* 2010;37(2):505-515.

Support

Work supported by grants CA10953 and CA81647 (NCI, DHHS).