Clinical Impact Study of a New High Resolution Fluoroscopic Imager: Analysis of 400,000 Irradiation Events

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INTRODUCTION

A new high resolution fluoroscopic imager has been implemented in a variety of clinical applications[1-3] that provides imaging modes with more than **double the spatial resolution** (Figures 1 and 2) compared to other available technologies. To ensure optimal system performance, technical data was collected over a sustained period of utilization both pre and post implementation, and protocol adjustments were iteratively performed with an objective to optimize study-level metrics.

Figure 1. The new high definition detector provides 76 micron pixel imaging modes that can resolve 6.6 line pairs per mm (lp/mm).

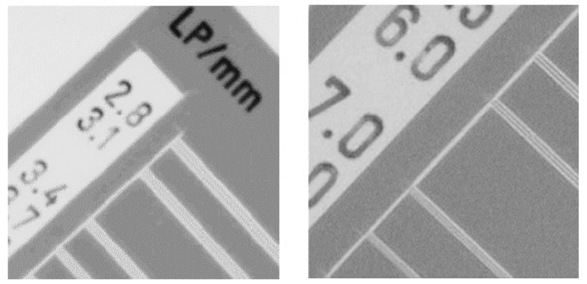

Figure 2. Images of a line pair test object acquired using the standard resolution of the FPD mode (left) and high-resolution Hi-Def mode (right).

AIM

To quantify clinical impacts of a **next generation fluoroscopic imager with 76 micron pixel high-definition (hi-def) imaging modes** using DICOM Radiation Dose Structured Report (RDSR) data from over 400,000 irradiation events (IEs).

METHODS

A DICOM destination was configured to receive RDSRs from multiple interventional fluoroscopy systems performing complex procedures at a single institution (1,702 pre and 4,136 post implementation).

Study and IE data were extracted and staged in a relational database.

Aggregated and non-aggregated data was exported to an Excel compatible format for further analysis that included comparison of procedural results pre/post implementation.

During the investigation, system technique factors utilized when in hi-def modes were monitored using IE data to support protocol adjustments towards optimization of overall study-level performance.

RESULTS

Both mean procedure time and number of IEs per case significantly reduced from 43 to 39 minutes and 85 to 78 instances, respectively. This indicates:

Improved visualization provided by hi-def modes had a positive impact in increasing procedural efficiencies.

During the study, adjustments to hi-def protocols included modifications to pulse width, beam filter, focal spot and dose rate settings to maximize physician satisfaction while also monitoring procedural results, ensuring improvements realized were also observed at the study-level.

In general there was a preference across operators towards settings that provided higher image quality and instantaneous dose rates to maximize imaging efficiency.

With an ability to more readily visualize anatomy and device detail that was otherwise difficult/impossible to resolve, less IEs were required resulting in a decrease in overall mean cumulative air kerma (p = 0.16).

A representative image comparison between a traditional imaging mode on a standard flat panel detector (frontal c-arm, 15 x 15cm FOV, 194 micron pixels) and the new hi-def mode (lateral c-arm, 3.8 x 3.8cm FOV, 76 micron pixels) at the same instance in time on a biplane acquisition is shown in Figure 3 and 4, demonstrating increased visualization of device details. Aggregated RDSR data was used to quantify clinical impacts pre/post implementation of the hi-def technology with results shown in Table 1.

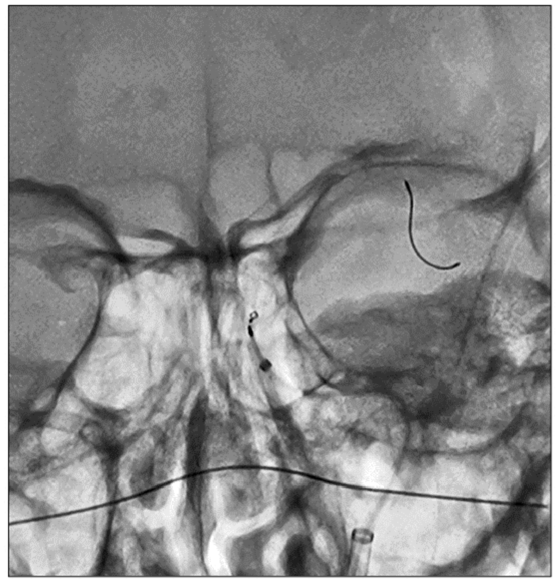

Figure 3. Standard flat panel detector image (194 micron pixel size). Technique: 77kVp, 387mA, 8ms, middle focus, 0.2mm Cu added beam filter; Air kerma rate: 83 mGy/min.

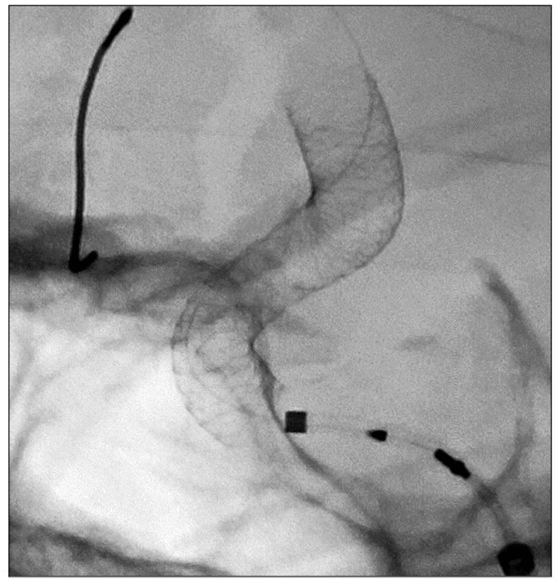

Figure 4. Hi-def detector image (76 micron pixel size). Technique: 99kVp, 131mA, 8ms, small focus, 0.2mm Cu added beam filter; Air kerma rate: 62 mGy/min.

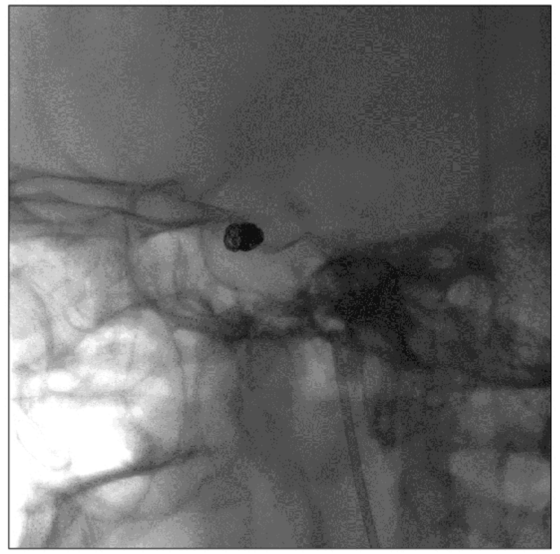

Figure 5. Standard FPD image in 6" FOV.

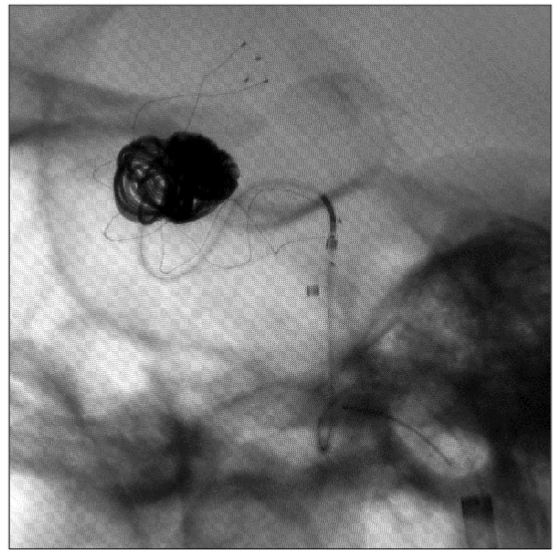

Figure 6. Hi-def image in 2.3" FOV

Average Value	Pre Hi-Def	Post Hi-Def	% Difference	p-value
Procedure Time (min)	43.1	39.3	-9%	< 0.001
# Irradiation Events	85.0	77.8	-9%	< 0.001
Fluoro Time (min)	19.1	17.9	-6%	0.06
Air Kerma (Gy)	1.11	1.05	-5%	0.16

Table 1. Monitoring procedural results supported protocol optimization to ensure effective implementation with improved procedural efficiency, reduction in procedure time and less overall imaging.

Hi-Def protocols were adjusted based on physician subjectivity and outcomes with a mean air kerma (DAP) rate of 1.9x higher (3.5x lower) with no net increase to total patient dose at the end of the procedure (Figure 7). Due to its smaller field-of-view (FOV), utilization of hi-def modes facilitates potential reductions in peak skin dose (PSD) when overlap of irradiation areas are avoided (Figure 8).

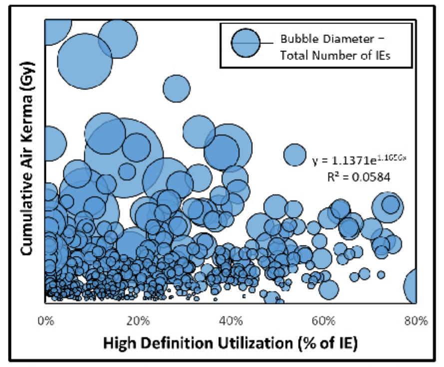

Figure 7. There was no correlation observed between hi-def utilization and cumulative air kerma with a best of fits R^2 value less than 0.06.

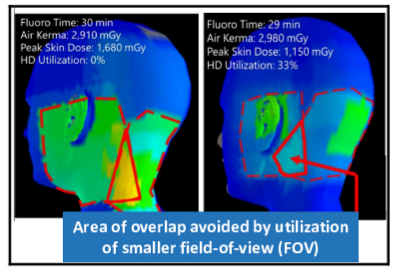

Figure 8. Example of potential peak skin dose reduction with utilization of the smaller FOV of the hi-def for a similarly matched procedure. Hi-def was used for 33% of IEs and PSD was 32% lower.

CONCLUSIONS

This work demonstrates a systematic way of leveraging RDSRs to optimize system parameters and the potential clinical impact of substantially increased limiting spatial resolution of 6.6 lp/mm. **Moving beyond physics level testing into monitoring and analysis of clinical data and performance helped to ensure this new hi-def technology produced clinically meaningful quality and that its benefits were maximized within the framework of actual clinical utilization.**

REFERENCES

1. SVS Nagesh et al., High Definition Imaging Reduces Procedure Time Without Impacting Patient Dose in Image-Guided Neuro Interventional Procedures. *Radiologic Society of North America; SSG10-09 (2019)*
2. SVS Nagesh et al., Single-center experience of using high definition (Hi-Def) imaging during neurointervention treatment of intracranial aneurysms using flow diverters. *Journal of Neurointerventional Surgery; doi: 10.1136/neurintsurg-2019-015551 (2020)*
3. SA Arain et al., Initial Experience Using A Novel High Definition (Hi-Def) Imaging Systems in Interventional Cardiology. *JACC* ***75*** *(11) 3637 (2020)*

CONTACT INFORMATION

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