Refine and Redefine Intervention Using High-Definition (Hi-Def) Technology

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High-Definition (Hi-Def) Imaging

The ability to magnify the field of view while increasing inherent spatial resolution with Hi-Def technology enhances visualization during critical aspects of endovascular interventions and has the potential to translate into additional accuracy and precision in X-ray imaging guided procedures with enhanced real time visualization during complex endovascular procedures.

Canon Medical provides an innovative technology with the world's first Hi-Def detector—offering more than twice the spatial resolution of conventional flat panel detectors (FPD)—for resolving fine details. This unique hybrid 12" x 12" or 12" x 16" FPD combines high definition imaging technology based on CMOS that boosts spatial resolution up to 6.6 line pairs per millimeter (lp/mm) with 76 micron pixels (Figure 1). This unique Alphenix system offers the standard magnification modes 16", 12", 10", 8", 6" or 4.3" fields of view (FOV) and three additional Hi-Def modes with 3", 2.3" and 1.5" FOV, allowing increased spatial resolution without interruption of procedure workflow. At any given point in time, both modes are available, and when needed, the selection between the two modes can be quickly changed using an FOV switch, without adding additional delay to the procedure.

Modes Up to 2.5x Higher Spatial Resolution

Advancing minimally invasive treatments for neurovascular diseases such as stroke and aneurysms, places increasing demands for high definition real time imaging for aiding the interventionist in guiding the catheters upon identifying disease area, and to deploy treatment devices such as balloons, coils, stents, or flow diverters. Higher spatial resolution modes of the Hi-Def detector can provide sharper and visually improved images, as quantified using standard physical metrics, compared with those of traditional FPD images.[1] For example, the modulation transfer functions (MTFs) of the new detector under Hi-Def mode and the FPD mode demonstrate the ability of the Hi-Def magnification modes to image spatial frequencies that would otherwise be aliased (i.e. not visualized) by the FPD magnification modes. Inevitably, Hi-Def outperforms the FPD at all spatial frequencies.[5]

Visualization Like Never Before

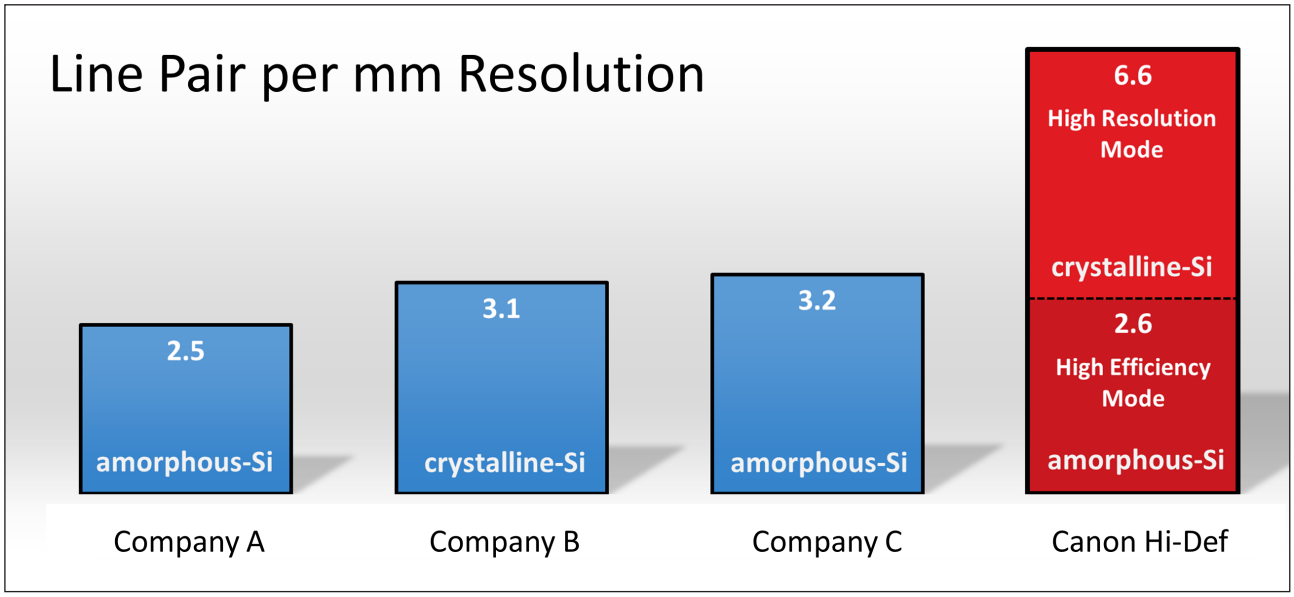
During intervention, using large FOV standard resolution FPD modes for coarse navigation, the catheter systems and devices are guided from the access site to just proximal to the lesion. Final placement and deployment of devices are performed under the magnified high-resolution Hi-Def modes with smaller FOVs (Figure 2). In a blinded-rater study that compared Hi-Def and FPD images, Hi-Def images were rated sharper and visually preferred [rated "much better" in 73% of instances] compared to the lower resolution images of the FPD.[3]

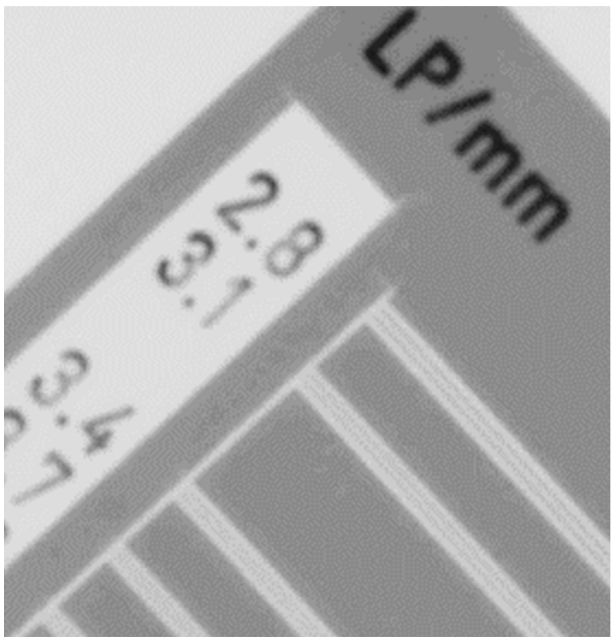
Case illustration[2]

A patient with no remarkable medical history presented to the emergency room with the worst headache of her life. Magnetic resonance angiography demonstrated a right carotid cavernous aneurysm measuring 11 × 7 mm. Lumbar puncture and head CT scan were negative for

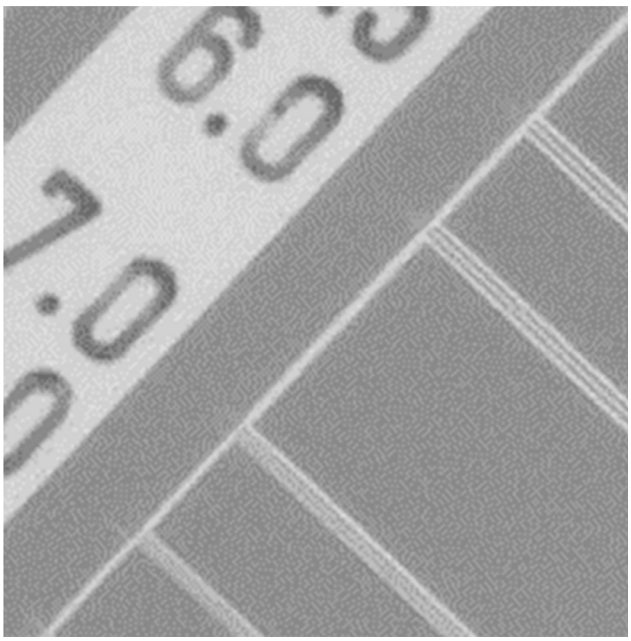
subarachnoid hemorrhage. The aneurysm size and location were confirmed with diagnostic cerebral angiography.

Under 2.3" x 2.3" FOV Hi-Def mode roadmap guidance, a 2.5Fr microcatheter over a 0.014" microwire was introduced and placed in the right distal M1 segment (Figure 3). An 2.4Fr microcatheter with a 45° angle was introduced concomitantly over the 0.014" microwire to cannulate the aneurysm neck. Under Hi-Def magnification, a single 9 × 33 mm coil was partially deployed into the aneurysm dome. Subsequently, a 4.5 × 23 mm LVIS Blue stent was introduced into the 2.5Fr microcatheter and deployment was started just distal to the aneurysm neck. Under 2.3" x 2.3" FOV Hi-Def mode, deployment showed good wall apposition throughout the curve of the cavernous carotid artery. The partially deployed coil was then fully deployed, followed by a second 5 × 20 mm coil. After the second coil deploy-





3.3" FPD



2.3" High Definition Mode

Figure 1 Multi-detector design maximizes efficiency and fundamentally offers more than 2x higher spatial resolution than any other available system.* Images of a line pair test object acquired using the standard resolution of 194 µm pixel FPD mode (left) and high-resolution 76 µm Hi-Def mode (right). Due to the larger pixel sizes of the FPD mode, only up to 2.6 lp/mm can be visualized without any aliasing. In the Hi-Def mode, due to the smaller pixel sizes, up to 6.6 lp/mm can be visualized without any aliasing or loss in information.

**Documented testing has demonstrated imaging capabilities with up to 2.5x greater resolution.*

"The Hi-Def mode of the new detector system is equivalent to a microscope that can be used during critical stages of the intervention."

— Adnan Siddiqui, MD, PhD, FACS, FAHA FAANS
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ment, DSA contrast runs were obtained and showed stasis in the aneurysm dome. The imaging mode was switched to large FOV, and a DSA contrast run was obtained to make sure the distal circulation was patent post-treatment. The patient was extubated and remained neurologically intact.

To assess the impact of improved visualization provided by the Hi-Def mode during cerebral aneurysm treatment a Pipeline Flow Diverter, a post-procedure physician survey was conducted in a single center study. Consecutive patients over a 10-month period treated with the use of the dual resolution imaging detector were included. A summary of the responses is presented in Figure 4 from a total of 25 cases.[4] In all the cases reported, 100% of the time physicians either agreed or strongly agreed that Hi-Def mode visualization during the procedure was improved compared with standard FPD.

One critical aspect of deployment of a Pipeline Flow Diverter is the visualization of the distal end of the flow diverter as it is deployed and the subsequent opening of the device. Due to lack of radial forces, the distal end of the device may not immediately open. Visibility of this detail can dictate the next steps of the deployment procedure for instance wait for the distal end to open or re-sheath and redeploy the flow diverter. The high resolution Hi-Def modes offer the interventionalist a definite advantage in accurate placement and deployment of devices.

No Observable Increase in Patient Dose

Advancements in medical device and imaging technology as well as accruing clinical evidence have accelerated the growth of endovascular treatment of cerebrovascular diseases. However, these procedures often necessitate the acquisition of many high-quality image sets and the use of long total fluoroscopy times, resulting in patients being potentially exposed to considerable radiation dose levels. And, with an increasing number of neurointerventional procedures being spurred by rapid advances in minimally invasive techniques and technologies for image guidance, this trend is likely to continue in the future. To mitigate this risk of unnecessary radiation exposure, and to provide data for decision support in justification and optimization, patient radiation dose tracking is considered to be of crucial importance. The ALARA principle, to limit radiation dose to "as low as reasonably achievable" should always be used; however, radiation doses should not be reduced at the expense of necessary image quality. Efforts focused solely on minimizing instantaneous radiation dose rates may paradoxically result in higher cumulative radiation dose delivered to the patient if there is an increase in overall irradiation time and/or increased utilization of higher dose acquisition modes to overcome inadequate visualization.

To quantify the clinical impacts and radiation dose of this novel dual-resolution detector, DICOM Radiation Dose

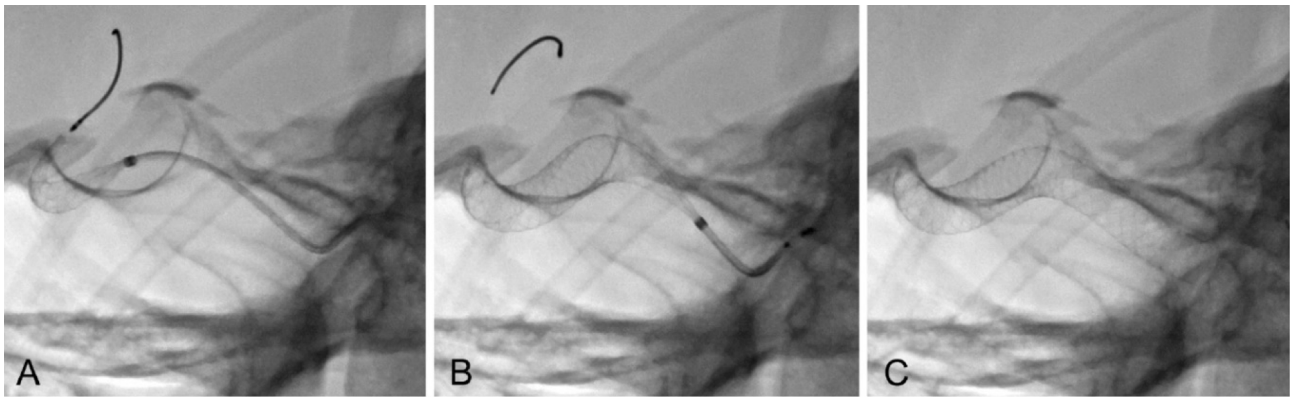


Figure 2 Images showing different phases of Pipeline embolization device (PED) deployment under Hi-Def 2.3" x 2.3" FOV guidance. (A) PED deployed one-third of the way. The cone-like structure of the partially deployed PED is visible and the distal end of the device is not completely open. (B) PED deployed halfway; the distal end of the device is open. (C) PED fully deployed.[4]

Physicians either agreed or strongly agreed, in 100% of situations, Hi-Def mode visualization was improved compared with standard FPD modes during the procedure and decision-making.

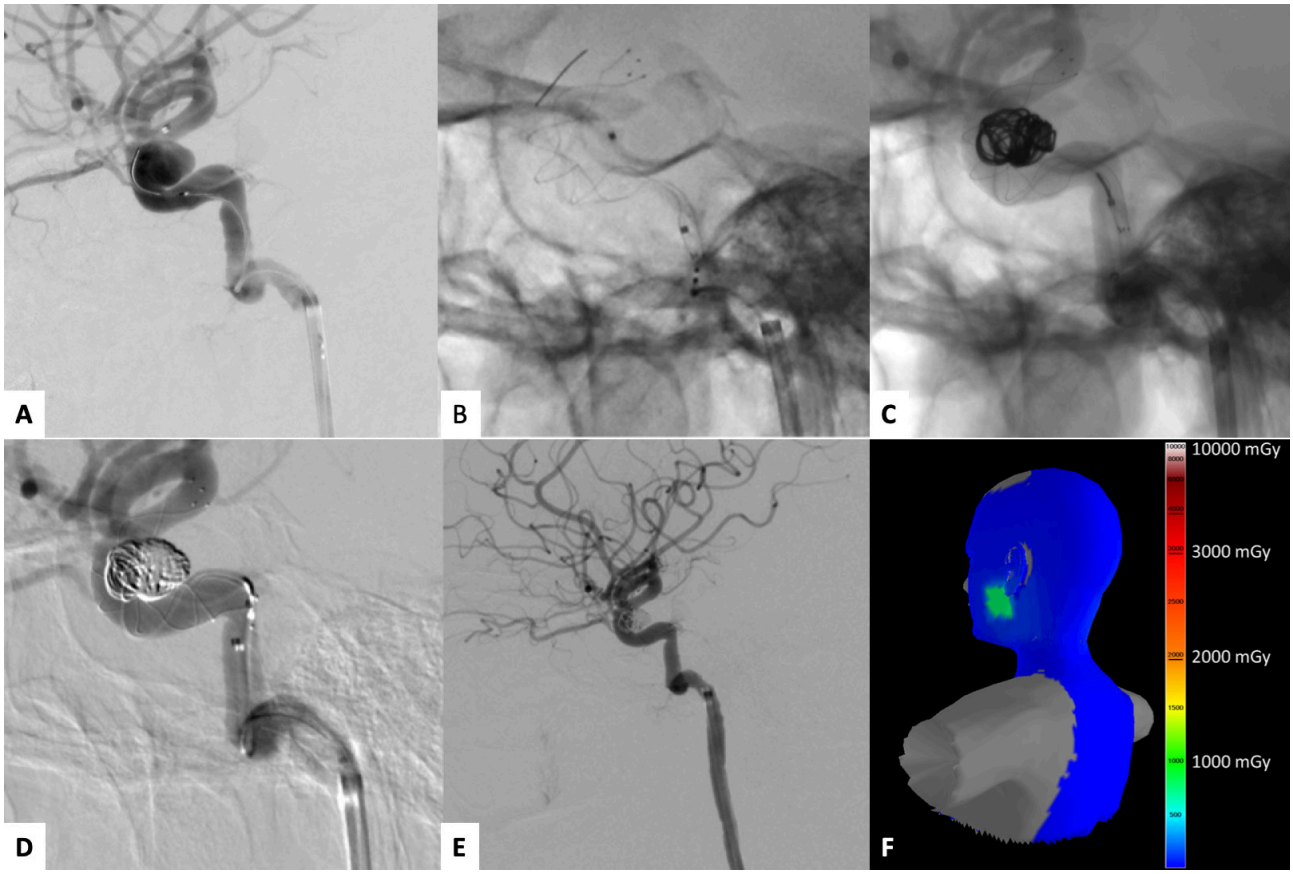


Figure 3 Digital subtraction angiography image acquired using (A) 3.0"× 3.0" FOV Hi-Def mode at baseline, (B) 2.3" x 2.3" FOV Hi-Def mode showing distal end of stent was not fully open, (C, D) 2.3" x 2.3" FOV Hi-Def mode showing coil mass were contained by the stent, (E) 10" x 10" flat-panel detector mode showing the distal circulation was patent post-treatment. (F) The peak skin dose recorded in real-time using Dose Tracking System (DTS) for the entire procedure was 815 mGy with 34 min of irradiation time.[2]

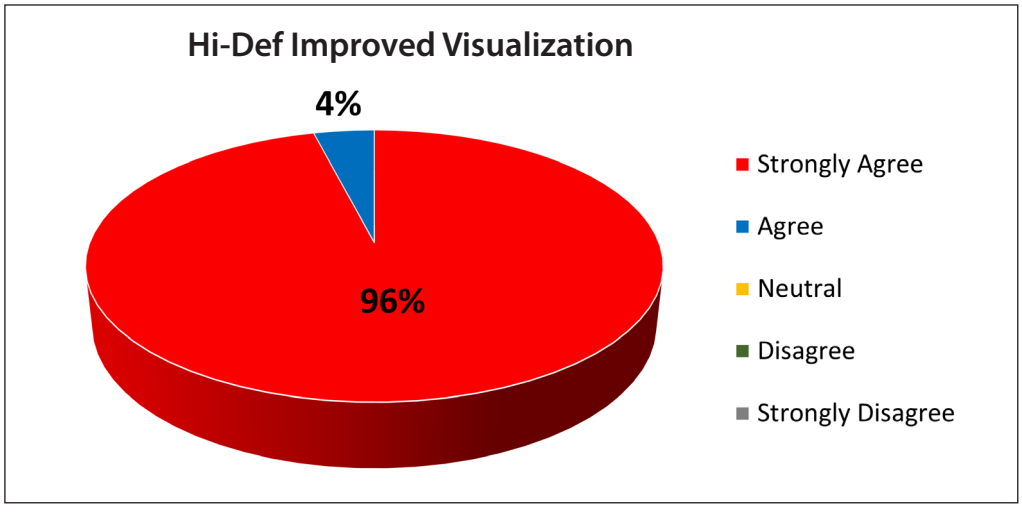
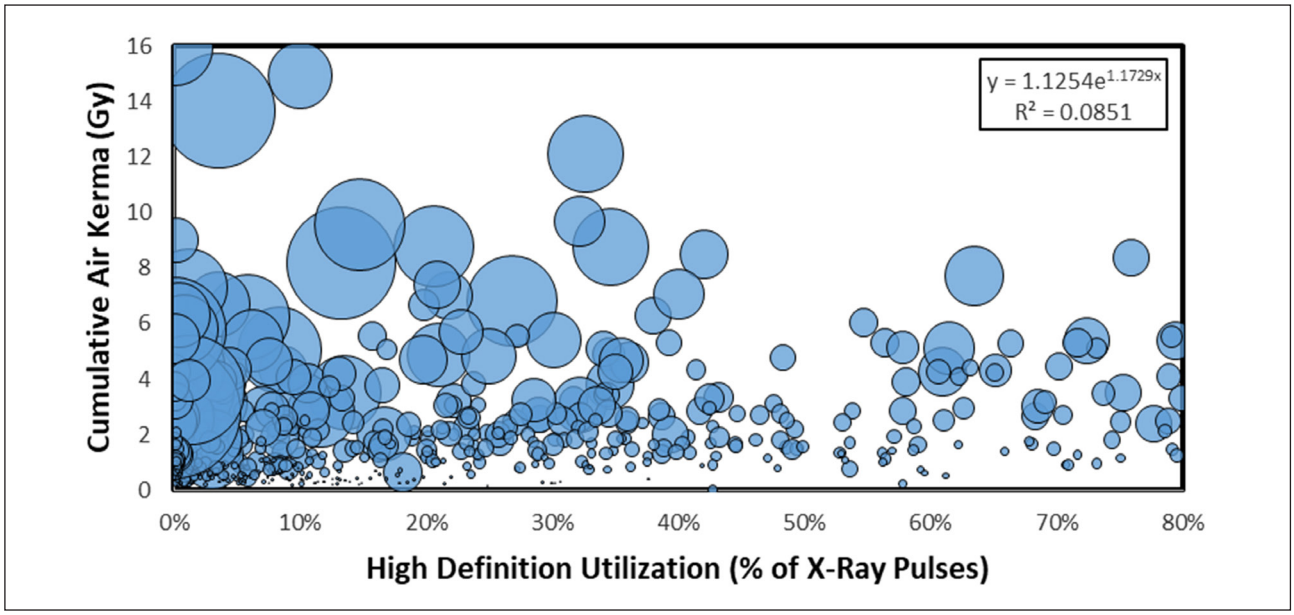


Figure 4
Summary of responses from post-procedure physicians' feedback survey that compared Hi-Def to standard FPD. Physicians either agreed or strongly agreed, in 100% of situations, Hi-Def mode visualization was improved compared with standard FPD modes during 9 different procedure and decision-making processes.[4]

Structured Report (RDSR) data was collected for all neurointerventional procedures performed before and after installation of the Hi-Def detector at a single center over a 45-month period. There were 1,702 pre- and 4,598 post-Hi-Def cases encompassing over 400,000 irradiation events in total. Normal and high-resolution magnification modes could be freely selected via the push of a button within the user interface. No other modifications were made to either the equipment or clinical protocols. Data from all cases were included and represented an equal mix of approximately 50% diagnostic and 50% interventions which remained consistent in both pre/post populations. A real-time patient skin dose tracking system (DTS) was used to monitor peak skin dose during the Hi-Def cases (Figure 5). A two-sample Student's t-test analysis was performed to compare various technical parameters included in the RDSR. And, to further investigate any potential impacts on radiation dose, the cumulative air kerma, dose area product, and peak skin dose were plot as a function of Hi-Def utilization as a percentage of the total number of irradiation events (Figure 6).

Hi-Def imaging modes were utilized in 22% of procedures post installation with an exponential increase of 12% to 52% from the shortest (simplest) to longest (most



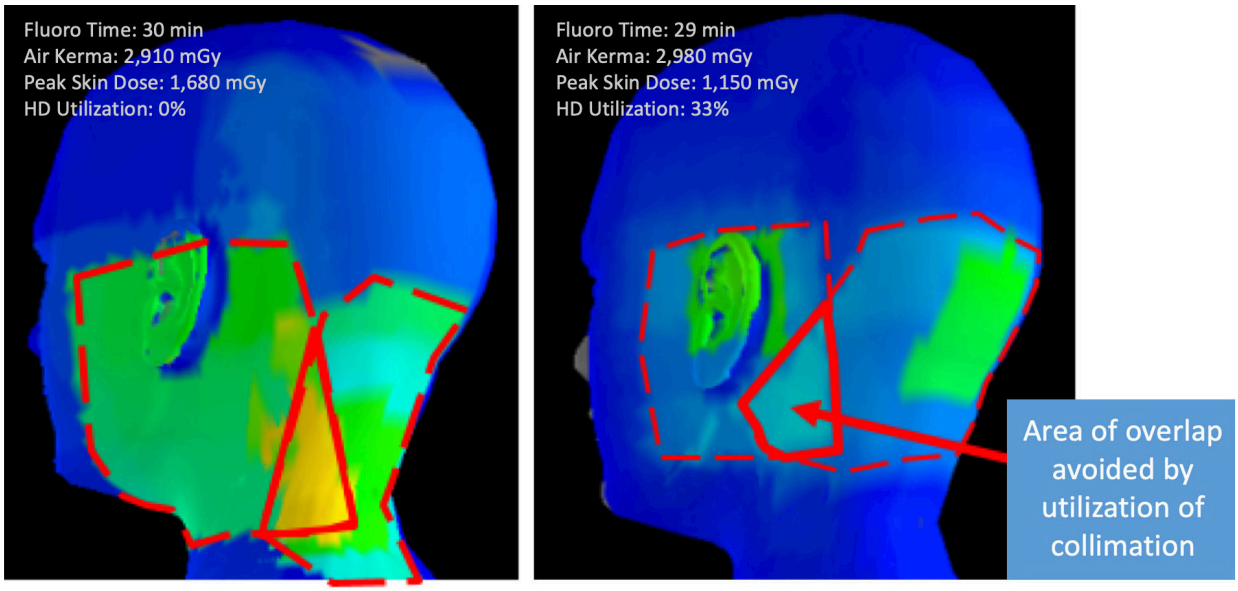


Figure 5 Overlapping exposure areas are more readily avoided by utilization of Hi-Def mode due to the smaller FOV sizes which may facilitate reductions in peak skin dose. The dashed red lines illustrate a normal FOV size and the solid red lines illustrate the potential overlap region that may be minimized utilizing smaller FOVs.

Average Value	Pre Hi-Def Era	Post Hi-Def Era	% Diff	p-value
Procedure time (min)	**43.15**	**39.18**	**-9.2%**	**< 0.001**
Cumulative Air Kerma (Gy)	**1.11**	**1.00**	**-9.6%**	**0.003**
Fluoro Time (min)	**19.12**	**17.48**	**-8.6%**	**0.004**
# of Pulses	**17,643**	**16,192**	**-8.2%**	**0.005**
# of 3D Spins	0.30	0.26	-12%	0.023
# of Irradiation events	85.0	82.2	-3.3%	0.059

Figure 6 With results from over 6,300 neurointerventional procedures highlighting reduced procedure time, cumulative air kerma, fluoro time, and number of X-ray pulses. There was no correlation observed between high definition utilization and cumulative air kerma (top). The bubble size relates to the total number of irradiation events. With results from over 6,300 neurointerventional procedures highlighting reduced procedure time, cumulative air kerma, fluoro time, and number of X-ray pulses (bottom).

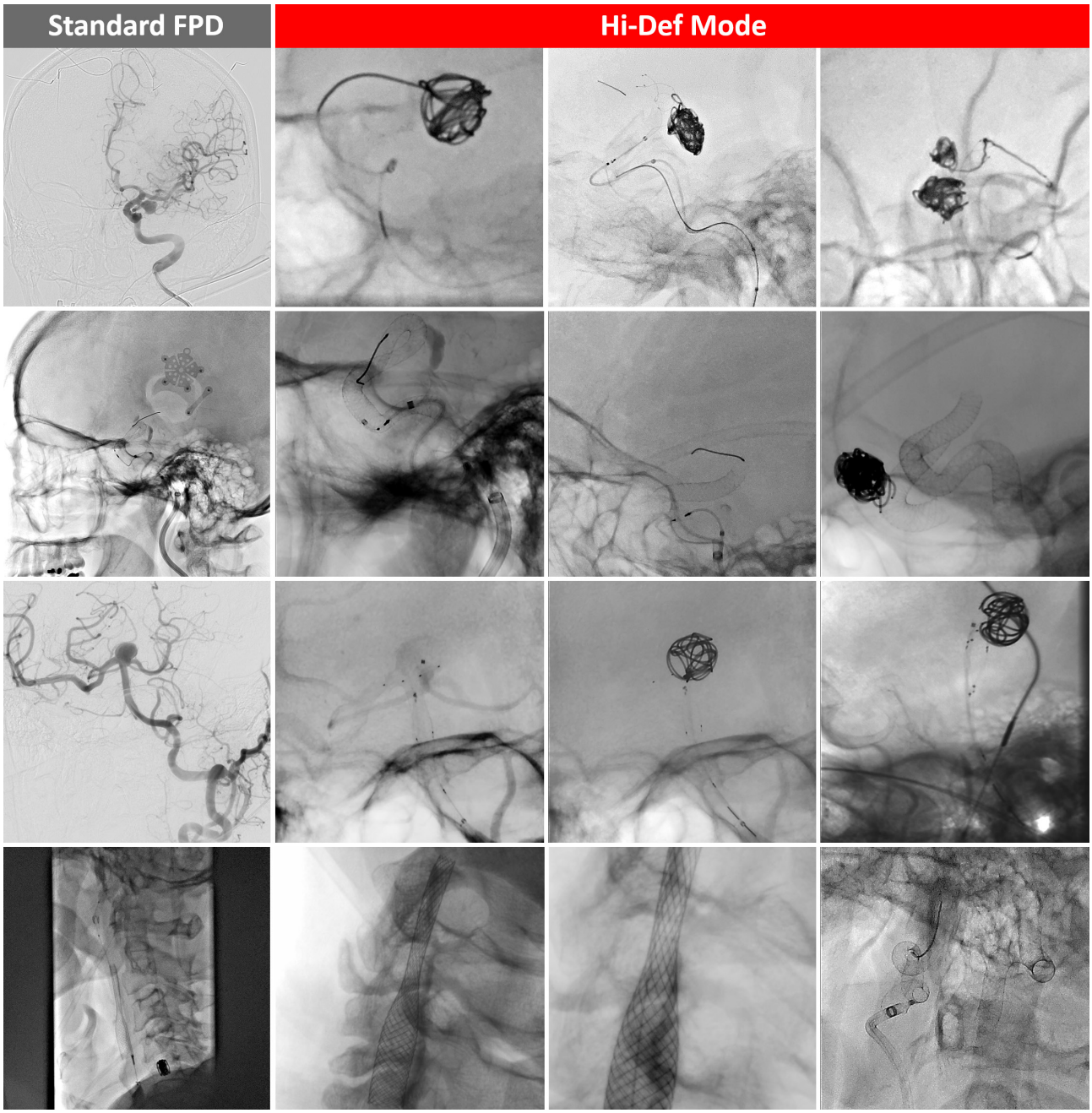


Figure 7 Standard FPD mode images (first column) and Hi-Def mode images from a variety of clinical examples.

Average procedure time, average fluoro time, the total number of X-ray pulses and cumulative air kerma were all significantly reduced by 8% or more.

complex) interventions. This suggests the greatest impacts of higher resolution were realized where additional information content may be of critical importance, for example in assessing vessel wall apposition of a device or the packing density of a coil mass. Hi-Def accounted for 26% of irradiation events on average, when utilized, across all modes of operation with 68% in fluoroscopy, 21% in DSA, 8% in DA and 3% in one shot modes. Statistically significant reductions ($p<0.03$) were observed in procedure time (-9.2%), cumulative air kerma (-9.6%), fluoro time (-8.6%), number of x-ray pulses (-8.2%) and 3D spins (-12%). Further, these metrics were 28 to 56% lower compared to available state-of-practice data.[6] Peak skin dose data was available for 1,518 cases with 97.7% and 99.5% of cases below 3Gy and 5Gy, respectively. No correlation was observed ($R^2 < 0.10$) using a best of all fits for all dosimetric indications as a function of Hi-Def utilization (Figure 6).

Significant improvements were observed with the new Hi-Def interventional system providing inherent spatial resolution capabilities up to 6.6 line pairs per mm (Figure 7). The clinical data outlined above shows that this enhanced visualization can result in reducing both procedure time and overall exposures required to complete a procedure.

The Best of Both Worlds: Consistent Low Dose Performance with Additional Hi-Def Modes

The ability of Canon Medical's Hi-Def technology to provide substantially increased spatial resolution modes can support complex endovascular procedures as clinical methods accessing smaller and more delicate structures are advanced and therapy moves towards more individualized, patient specific treatment. Hi-Def technology and increased visualization capabilities may well be fundamental in this next-generation era offering meaningful improvements to patient care.

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