

Benefits Using High-Definition (Hi-Def) Technology in Complex Neurovascular Procedures

Professor Adnan Siddiqui

The increased use of minimally invasive techniques for the treatment of hemorrhagic stroke, such as intracranial aneurysms and arteriovenous malformations (AVMs), has steadily increased worldwide over the years due to various underlying benefits. New breakthroughs in cerebrovascular treatment devices, necessitates advanced imaging technologies for safer and more accurate deployment.

For over a decade, our collaborative scientific, and clinical partnership with Canon Medical Systems (previously Toshiba Medical Systems) contributed to the core Hi-Def technology designed for neurointerventional therapies, and was recently piloted at the Gates Vascular Institute (GVI).



University of Buffalo Neurosurgery (UBNS) at Gates Vascular Institute

(Photo Credit: Doug Levere)



Professor Adnan Siddiqui,
University of Buffalo Neurosurgery (UBNS) at Gates Vascular Institute

(Photo Credit: Kaleida Health)

Clinical and Industry collaborative partnering

Image-guided neuroendovascular intervention is used in modern day minimally invasive treatment of cerebrovascular diseases such as strokes and aneurysms. With the increasing complexity of treatment devices, such as intraluminal and intrasaccular flow diverters, aneurysm bridging stents, and intrasaccular coils used, have tiny sub millimeter sizes with fluoroscopic markers. During intricate deployment of such devices, it is critically important to precisely and accurately visualize the treatment area.

Professor Adnan Siddiqui leads the University of Buffalo's Department of Neurosurgery (UBNS) at the Gates Vascular Institute, which was ranked 7th in academic impact in North America by the Journal of Neurosurgery. Dr. Siddiqui is also the head of Neuroendovascular Research and Stroke Service at the Canon Stroke & Vascular Research Center, where he serves as a reviewer for Stroke, Neurosurgery, Journal of Neurosurgery and Journal of Neurointerventional Surgery as well as many others. He has over 100 peer reviewed publications, more than 50 chapters and has been invited to more than 200 national and international lectureships.

GVI treats more strokes than any other hospital in New York State. We deliver stroke care that brings patients the best chance of recovery, from a designated emergency pod for stroke to a dedicated team of neurologists and neuroendovascular surgeons offering full treatment options utilizing the latest technology. The multidisciplinary team of neurologists, endovascular neurosurgeons and dedicated specialized staff at Gates Vascular Institute, diagnose, treat and manage patients with neurological and endovascular disorders and diseases and all cerebrovascular conditions.

Through the affiliation with University at Buffalo Neurosurgery (UBNS) and the Jacobs School of Medicine and Biomedical Sciences, our teams are selected to be a part of national clinical trials, and often the principal investigator, in developing new methods for treating and preventing strokes.

What is Hi-Def?

The high definition technology from Canon Medical is based on the concept that a better resolving flat panel detector that detects images drastically better than current flat panel technology can significantly facilitate device visualization during complex endovascular procedures. The ability to view a region of interest all the way down to 76 microns using a 1.5" field of view (FOV) resolution which translates into a much more accurate and precise live visualization of devices as neurosurgeons position and deploy them during complex Neuroendovascular procedures.

"All these various and critical surgical intricacies during the procedure are much better seen with the such accurate resolution than with the standard flat panel detector technology that is used in common angiography systems."

Hi-Def Technology Evaluation:

The researchers located here at the Canon Stroke and Vascular Research Center, University at Buffalo, SUNY performed a preliminary Hi-Def pilot evaluation for a future Alphenix interventional system. In addition to the evaluations, the research resulted in a scientific publication on this new proprietary detector, which had high resolution (Hi-Def) capability coupled with the flat panel detector (FPD) built into one unified housing whose physical appearance was like that of the original FPD. The new detector implementation enabled

rapid switching by the operator between Hi-Def and FPD modes. Semi-quantitative subjective studies involving qualitative clinician feedback on images of interventional devices such as a Pipeline Embolization Device (PED) were acquired in both Hi-Def and normal FPD modes.



Figure 1b: New detector system both the Hi-Def and FPD detector in one single panel.

Live Visualization of Pipeline™ Embolization Device (PED)

The pipeline embolization procedure is a relatively new, less invasive approach to treating unruptured cerebral aneurysms, especially including many that were historically considered too risky to treat. Instead of treating aneurysms directly, flow diversion procedures focus on restructuring or reconstructing the artery itself. In a pipeline procedure, a braided wire mesh sheath called a pipeline embolization device is inserted into the artery at the site of an aneurysm to block its flow of blood. The PED allows blood to flow normally through the artery, so that in the weeks and months after surgery, the aneurysm shrinks and eventually disappears. The pipeline embolization procedure is a revolutionary, less invasive approach to treating unruptured cerebral aneurysms, including many that were previously considered too difficult to treat. The pipeline embolization device, or PED, offers an effective and relatively safe alternative to aneurysm clipping and coiling procedures, but this procedure is not without risks of its own.

An image pair consisting of a Hi-Def image and FPD image of the same PED object, FOV and exposure conditions were acquired using the setup described above. A total of 10 different image pairs were obtained by changing PED's of different sizes, configurations and

its positions in the 3D printed neuro-vasculature placed within the skull.

Figure 4 and 5 gives an example of two different image pairs shown to the neuro-interventionalists. Fig. 4a and 5a are the Hi-Def images, and Fig. 4b and 5b are the corresponding FPD images. The images were displayed at their native resolution with a matrix size of 1024 x 1024 pixels.

Image pairs were presented to the neuro-interventionalists, who were asked to select their preferred image within the pair and were asked to rate their choice in comparison with the other image with the following three options: Similar (~), Better (>), or Superior (>>). For a fair and unbiased comparison, the position of the Hi-Def and FPD images within an image pair was not the same but was randomized for all the pairs and was not made known to the raters.

Conclusions:

Due to the higher resolution of the Hi-Def technology, images are sharper, and hence are visually improved compared to the images of the FPD. This is supported by the positive results of the comparative physician observer preference study presented here. These results suggest that the improved imaging provided by the HRF can provide

an advantage during neurointerventions. The new detector having both Hi-Def and FPD modes can offer an advantage in the clinical setting compared to the existing conventional commercial FPD-only detector systems used in typical interventions.

Why Hi-Def?

Although any surgery, especially to the brain, poses risks, some of the risks related to pipeline embolization can be reduced or avoided altogether. These procedural complications bring attention to the importance of an experienced endovascular surgeon, clinical support staff, and research institution with extensive training in performing these is a key factor in reducing the risk of adverse procedural outcomes. It is for these procedural reasons the Hi-Def technology was purposefully engineered for enhanced, precise live intraprocedural visualization.

Dr. Siddiqui mentioned in a recent interview

Hi-Def imaging is most beneficial during the critical parts of the case where you are utilizing high magnification imagery to deploy a complex intravascular device. The best examples of that are currently deployment of coils, deployment of stents, deployments of intraluminal flow diverters, endosaccular flow disrupters, or anything where you really need to appreciate how the device is behaving in

Figure 4a



Figure 4a



Figure 4b

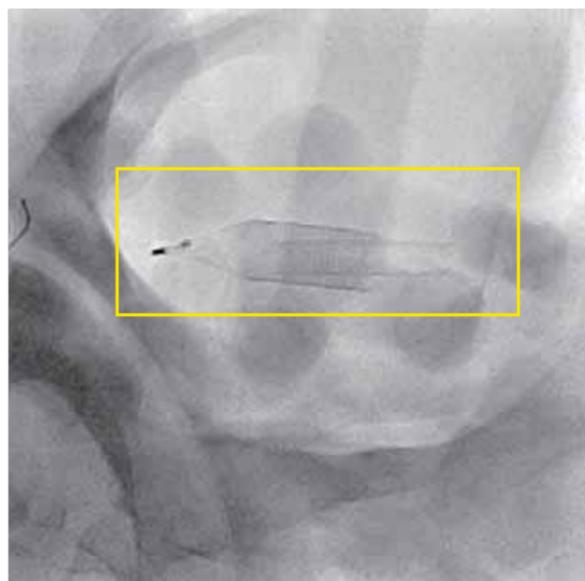


Figure 4b



Figure 4: Sample image pairs presented to the neuro-interventionalist for a qualitative image comparison study. A-Hi-Def image, B- FPD images. The images are presented at their native resolution (1024 x 1024 pixels each). For the reader to appreciate the difference between the Hi-Def and the FPD, the stent portion of each image is zoomed in and presented under the corresponding image.

Figure 5a



Figure 5a



Figure 5b

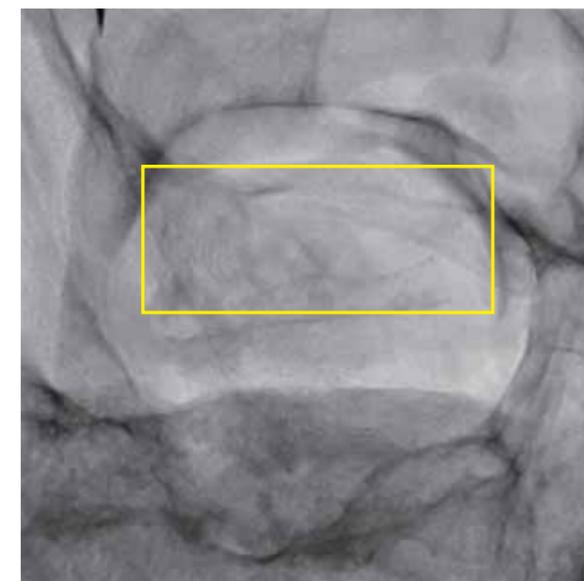


Figure 5b



Figure 5: Sample image pairs presented to the neuro-interventionalist for a qualitative image comparison study. A-Hi-Def image, B- FPD images. The images are presented at their native resolution (1024 x 1024 pixels each). For the reader to appreciate the difference between the Hi-Def and the FPD, the stent portion of each image is zoomed in and presented under the corresponding image.

a small space and it is of critical implication, there's nothing that comes close to the ability to visualize these implements than Hi-Def technology.

The ability to transform the field of view with Hi-Def technology in my mind is like what the operating microscope did with open neurosurgery. Prior to the availability of the operating microscope, surgeons would use loops to magnify the visualized anatomy and it was grossly inadequate and the complication rates were very high. The operating microscope opened an entire new era of open neurosurgery, I relate Hi-Def technology to the same kind of transformation when it comes to complex endovascular procedures because it allows us to see things better than we ever saw before, perforators, smaller details in the anatomy, vessel wall apposition. As we start becoming more advanced with materials and methods to access these smaller more delicate structures, Hi-Def technology will make that possible for us.

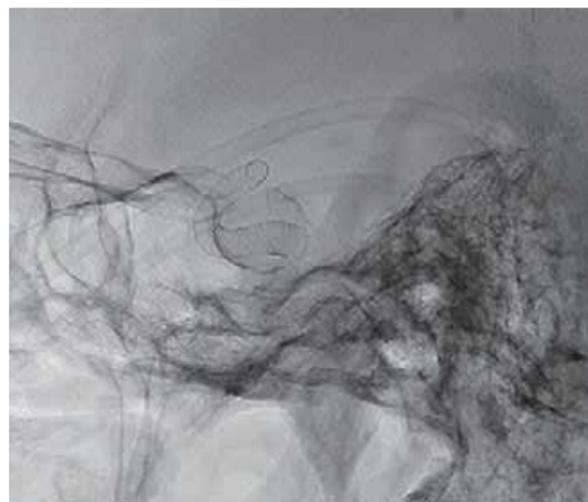


Image of Hi-Def: Pipeline Stent

This is especially true for appreciating nuances such as perforators and small distal branches arising in the brain. Which has more to do with our ability to visualize the current devices and its proper placement within vessel anatomy. As these technologies further develop, I suspect that we will develop means to be able to access these smaller distal blood vessels in the brain, we would develop means to develop asymmetric devices, which deal with the aneurysm and only the aneurysm rather than trying to treat the entire blood vessel that includes even the healthy tissue. Currently all the device therapies we use are based on symmetry, all devices are visualized at either ends with the difficulty to see what is happening at the middle. As interventional imaging technology develops such as Hi-Def, we should be able to develop tools that can precisely treat the injured segments.

Hi Def vs. Exposure:

A very common question that's posed to me often is, what kind of increase tradeoff in radiation exposure is a result to this improved and increased visualization? It stands to reason clinicians believe that there would be an increased radiation exposure to the patient, however in this case this is a false statement.

Given the improved collimation and the considerably smaller Hi-Def fields of view (FOV), the average amount of radiation being exposed to the patient and staff is even lower than with conventional standard flat panel (FPD) technology for the same procedure case. In addition, the procedures are more precise, making them faster, more accurate and ultimately safer in the end. When considering all the benefits of the Hi-Def technology factored together, the clinician is getting improved visualization, without the penalty in the total radiation being exposed to the patient, in fact in most cases a reduction.

When we think of neuro interventional procedures we think of treating brain aneurysms, treating AVMs, treating strokes, these are the very early phases of utilizing Neuroendovascular access to treat brain diseases. While these are the common applications currently, I believe that our Hi-Def technology is one of many profound clinical



Images of Hi-Def with Stent-Assisted Coiling - LVIS & Coils



tools evolving towards the enhancement of treating cerebrovascular brain diseases through endovascular therapy.

Hi-Def's Future in Neurointervention:

Based upon my experience and expertise in neurointervention, the Hi-Def technology by Canon Medical, provides a new visualization gateway to clinically expand the horizons of neuro intervention beyond the standard conventional imaging technology today. These clinically-driven features and tools to treat the neurovascular brain and its related affecting diseases, are currently not common to neuroendovascular surgery.

I believe there is potential for this type of enhanced live visualization technology to be utilized in other circulatory beds, be it the kidneys to modulate high-blood pressure, the heart to affect functional change or ablation procedures, or other procedures in other parts of the body where intricate detail is critically important. Hi-Def technology allows you to see things better than you have ever been able to before and I believe this technology feature will be equally useful in other vascular beds or other solid organs as it is in the vascular brain.//

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