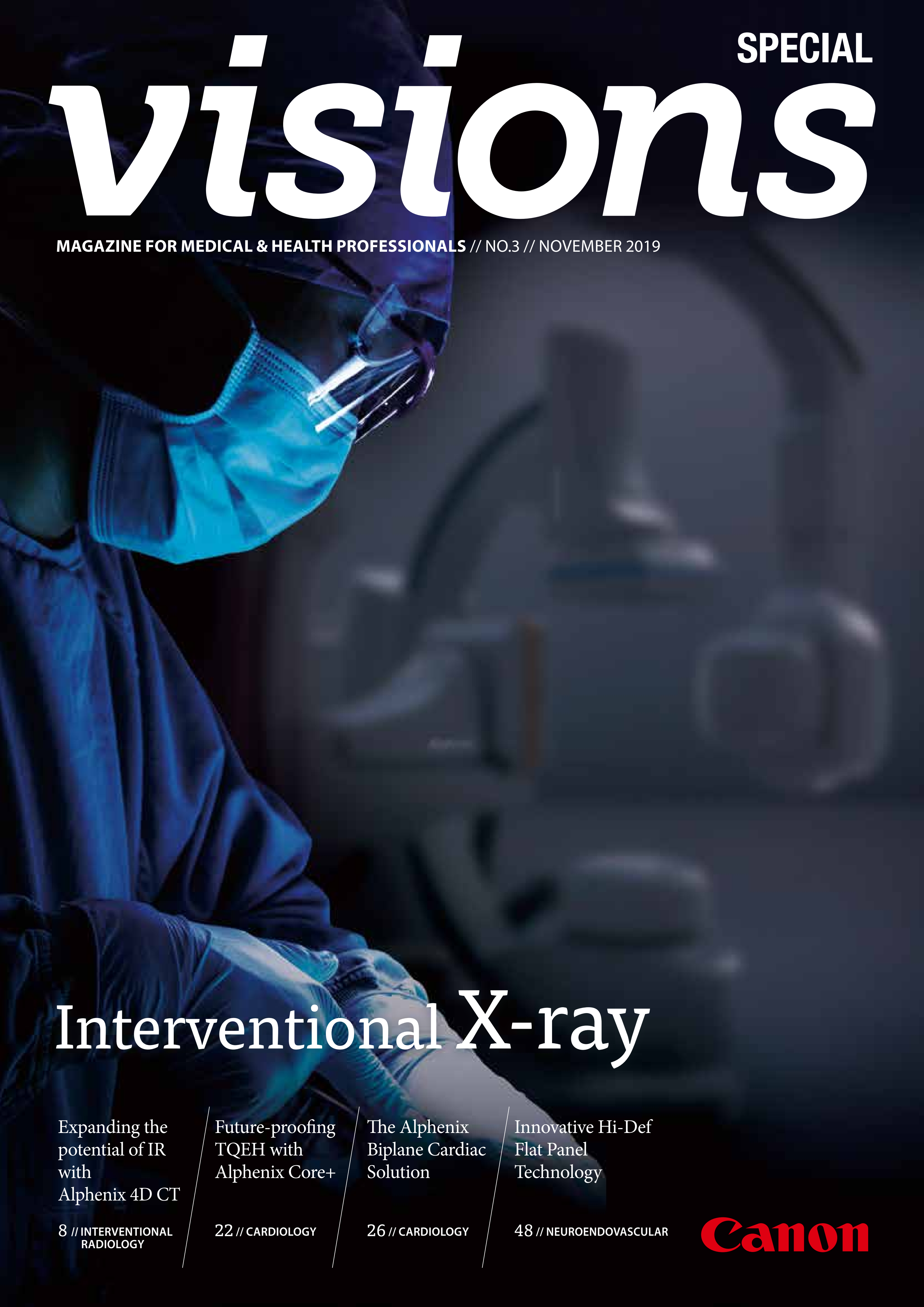

SPECIAL

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MAGAZINE FOR MEDICAL & HEALTH PROFESSIONALS // NO.3 // NOVEMBER 2019

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// EDITORIAL

Dear Global Healthcare Partners,

I would like to welcome readers to this special edition of VISIONS Magazine and thank our valued customer partners for their continued interest and contribution towards our angiography solutions. Our vision is to develop technologies around the clinician's needs so that you can treat patients better and safer. The spirit of collaboration is well and truly alive, and we are well placed to achieve great things together.

This clinical-focused mindset will continue to drive and expand throughout the organization, including our global sales and marketing teams that serve you. The purpose of the VISIONS Special magazine is to provide Canon Medical Interventional users a forum to share your clinical voice, research cases and success stories. We hope to forge a deeper partnership based on the relationship between our clinical research partners, our technology staff, and those who use and appreciate our solutions.

At Canon Medical Systems, we are committed to providing our customers with the very best imaging solutions available. But to do this, we require the input of a range of partners to ensure we're meeting their needs and delivering the capabilities they're looking for. For example, we are grateful to Drs. Kichikawa and Tanaka from Nara Medical University Hospital, Japan, who as long-time customers of Canon Medical's hybrid angio-CT solutions are excited with the potential of Alphenix 4D CT in innovative treatment of pain or prostate cancer.

Being part of a strong and enduring partnership is fundamental to our shared success in providing world-class healthcare solutions to patients. Nowhere is that more evident than with the development and clinical research partnerships we have with clinicians across the globe. Much appreciation to the many global partners that have contributed to the clinical articles, white papers, and case studies in this magazine that demonstrate our unique technology features that benefit procedures leading to better patient outcomes.

Here's to a bright future for everyone.

Izumi Watanabe
Manager of Vascular Systems
Canon Medical Systems Corporation

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// NEWS

Innovative Technology Designation for the Alphenix Platform

Canon Medical Systems USA, Inc. announces its Alphenix family of interventional angiography systems has received a 2019 Innovative Technology designation from Vizient, Inc., the largest member-driven health care performance improvement company in the USA.
The designation was based on the recommendations of health care experts serving on a member-led council who interacted with the product shown at the Vizient Innovative Technology Exchange.

The council determined the technology had the potential to enhance clinical care, patient safety, health care worker safety or improve business operations of health care organizations.

The innovative line of interventional systems delivers images with greater clarity and precision. It combines industry-leading dose optimization technologies, enhanced workflow and a new set of features to help clinicians provide patients with safe, accurate and fast imaging.

The Alphenix Biplane and Alphenix Core + systems also include the Hi-Def Detector (High-Definition Flat Panel Detector) with the highest image resolution in the market to help clinicians see fine details during complex interventional procedures such as stent positioning and stent apposition, wire and catheter navigation through the stent struts, and observation of coil deployment.

"Canon Medical is proud to be recognized for our commitment to innovation in medical imaging technology through the Alphenix family, a platform that is redefining what is possible in intervention," said Casey Waldo, managing director, Vascular Business Unit, Canon Medical Systems USA, Inc. "This product line represents an important advancement in improving clinical care and patient safety by enabling health care providers to prioritize clinical decisions and patient outcomes through higher quality imaging."

Innovation Celebration for the Alphenix Platform

The Alphenix platform is one of the medical innovations that was showcased in front of thousands of healthcare providers at Premier Inc.'s 2019 Breakthroughs Conference and Exhibition on June 18.

Canon Medical's Alphenix family of interventional systems was debuted during the conference's 11th annual Innovation Celebration, an event recognizing advancements in healthcare and highlighting suppliers dedicated to furthering innovation and improving patient outcomes in the industry.

"Canon Medical shares Premier's commitment to providing valuable products to our alliance members that are high-quality and cost-effective," said David A. Hargraves, Senior Vice President of Supply Chain, Premier.
"These innovations can truly benefit providers in our shared work to transform healthcare."

Clinicians and other health system members of Premier selected the Alphenix platform to be showcased at the Innovation Celebration due to its uniqueness, ability to have an impact on unmet clinical needs and potential to improve patient care.

Toshihiro Tanaka, M.D., Ph.D.
Associate Professor, Dept. of Radiology, IVR Center
Nara Medical University

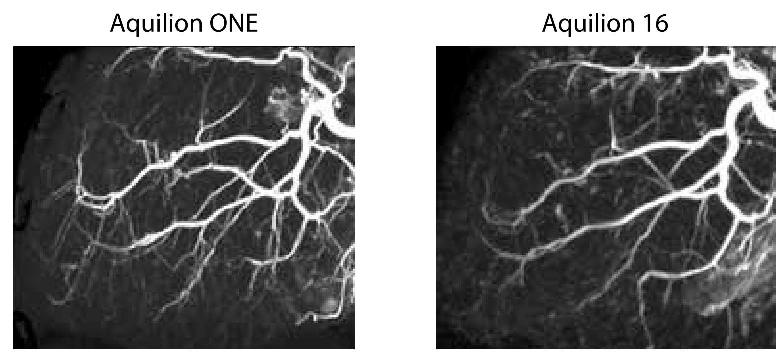
Kimihiko Kichikawa, M.D.
Vice-President of Nara Medical University Hospital
Professor & Chairman of Dept. of Radiology
Director of Interventional Radiology Center, Nara Medical University
President of Japanese Society of Interventional Radiology (JSIR)

Expanding the potential of IR with Canon Medical's Alphenix 4D CT

The Department of Radiology at Nara Medical University has always been on the cutting-edge of interventional radiology (IR). As it stands, they perform more than 1,500 IR procedures annually, covering virtually all areas except for the cardiac region. Three angiography systems are currently in operation in the Department of Radiology, but only one of these systems incorporates a CT scanner: the Alphenix 4D CT system produced by Canon Medical Systems Corporation, Japan.

This system was installed in March 2019 as a replacement for their Infinix-i 4D CT system (incorporating a 16-row CT scanner) which had been in use for 16 years.

To meet the needs of the rapidly expanding field of IR, they wanted a new system that could provide wider single-scan coverage, improved image quality, and reduced dose.



Aquilion ONE vs Aquilion 16
Fundamental image quality is improved.

Nara Medical University

We recently sat down with Dr. Kimihiko Kichikawa (a Professor in the Department of Radiology) and Dr. Toshihiro Tanaka (an Associate Professor in the same department) to find out more about their experience with the Alphenix 4D CT system and how they expect the relationship between hybrid angiography-CT and IR to evolve.

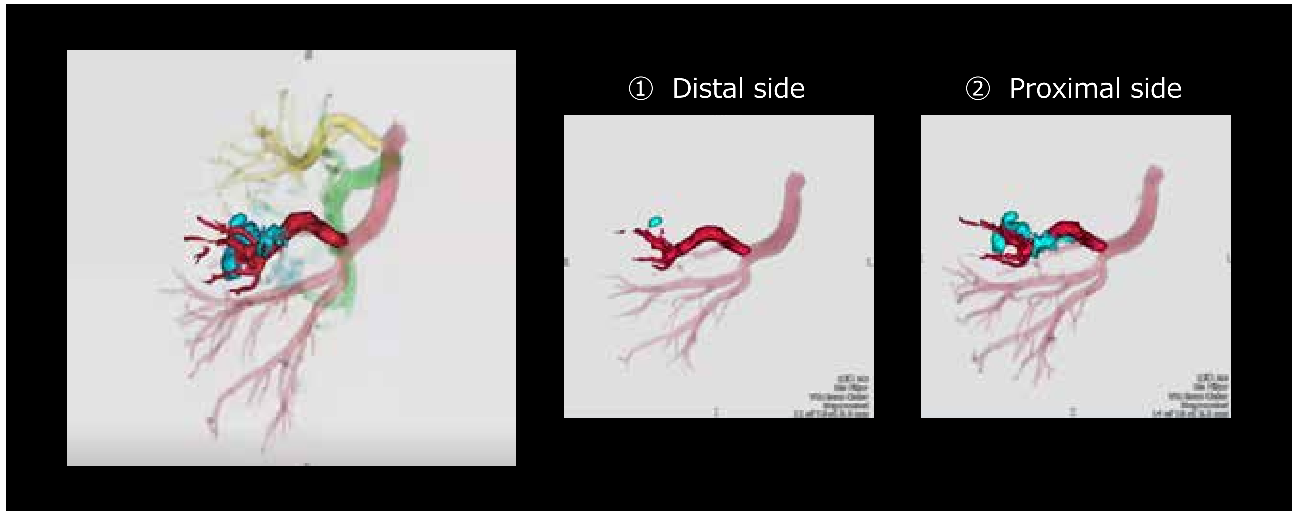
Q1: Why did you choose the Alphenix 4D CT system?
Dr. Kichikawa: We chose the Alphenix 4D CT for a couple of reasons. Firstly, it is an extremely dynamic, high-performance system that features the largest area detector available. The importance of this cannot be underestimated as it enables us to acquire volumetric data over a range of 16 cm. Secondly, 4D CT data is changing everything in the IR space. Not only does it help us decide whether or not IR is a reasonable therapeutic option, it also helps us create effective treatment plans that incorporate the right therapeutic strategy. In addition, Dynamic Volume CT helps us to obtain a clearer understanding of blood flow dynamics, with a particular focus on the feeding vessels.

Dr. Tanaka: With the Alphenix 4D CT system, conventional 3D imaging is far superior with higher scanning speeds and a quicker display of reconstructed images. Different types of reconstructed images are available, and the system allows us to select the most suitable reconstruction for a range of cases, including those that require immediate confirmation or a more detailed perspective. The 4D CT is especially effective in vascular IR for patients with fast blood flow in whom we need to obtain the required information without delay. It has also proven to be a significant advance in non-vascular IR because it allows us to introduce the needle at a craniocaudal angle during puncture procedures. This means that we can now match a specific reconstruction to the clinical needs of each patient. For example, when we require highly detailed images, we can use Dynamic Volume CT, and when we simply need to scan quickly in order to view images while performing a procedure, we can use the low-dose cone-beam CT.

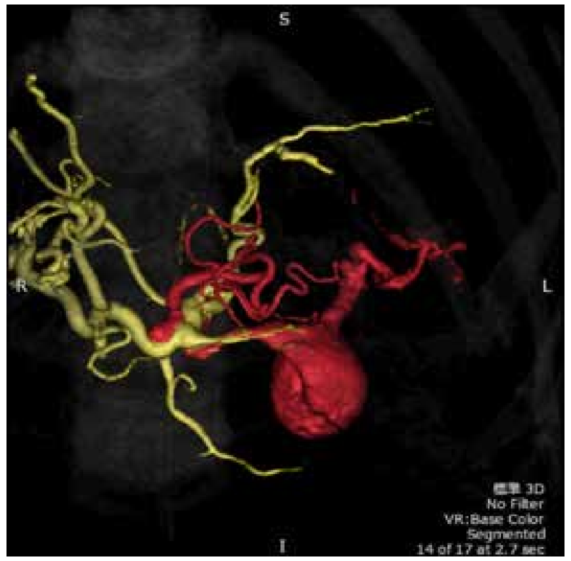
Alpha CT reduces 90% dose comparing to conventional CBCT.

Q2: What changes have you seen since installing the Alphenix 4D CT system?
Dr. Kichikawa: The hybrid angiography-CT solution is essential for identifying tumor vessels and determining the extent of embolization in transcatheter arterial embolization procedures. In particular, we have found the Alphenix 4D CT system to be indispensable when performing extremely fine and selective arterial embolization, a method that was first introduced and is currently being refined by Dr. Tanaka.

Dr. Tanaka: In patients with complicated blood flow dynamics, such as those with an arteriovenous malformation or arterial dissection, we first obtain 4D CT data and carefully evaluate the reconstructed images. Next, we decide on the optimal therapeutic strategy before commencing the procedure. When we use a needle to drain an abscess, Dynamic Volume CT is an essential tool for obtaining clear images that are free of artifacts, allowing us to clearly visualize the position of the needle relative to surrounding structures. In my experience, there are serious limitations when such procedures are performed using only cone-beam CT. Alphenix 4D CT has made it possible to formulate precise therapeutic plans and to ensure the accurate implementation of IR.



A renal arteriovenous malformation case



A celiac-splenic arterial dissection case

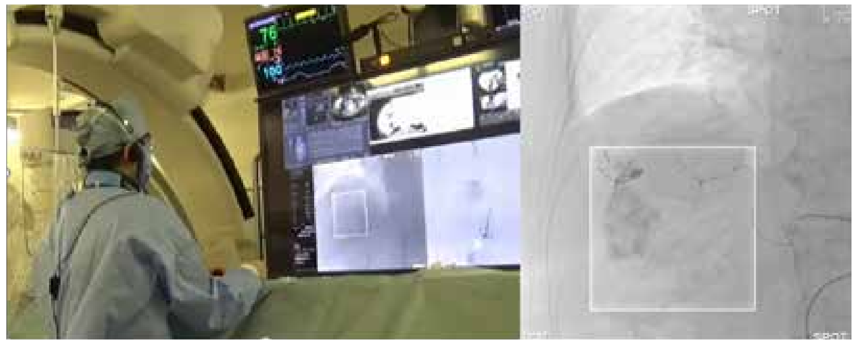
“The Alphenix 4D CT system is indispensable when performing extremely fine and selective arterial embolization, a method first introduced and currently being refined by Dr. Tanaka.”

Kimihiko Kichikawa, M.D.
Vice-President of Nara Medical University Hospital
Professor & Chairman of Dept. of Radiology
Director of Interventional Radiology Center
President of Japanese Society of Interventional Radiology (JSIR)

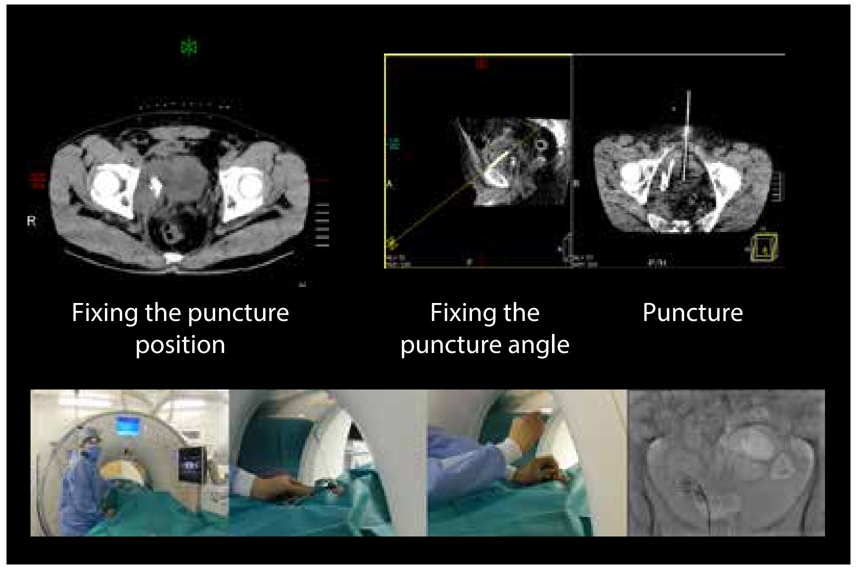
Q3: Have you seen a reduction in dose?
Dr. Tanaka: Compared to other conventional systems, the Alphenix 4D CT system significantly reduces the exposure dose to both patients and operators. With the SPOT ROI feature, the standard level of radiation exposure is used only in the area where precise visualization is required, and a lower level of radiation exposure is used in surrounding areas. As a result, the areas outside the ROI do not appear completely black but are shown with a certain degree of useful visual information. This allows the operator to perform procedures more comfortably.

In conventional procedures, we usually introduce the biopsy needle straight into the target under real-time CT fluoroscopic guidance. However, with Dynamic Volume CT, it is possible to slowly advance the needle while confirming the angle under MPR imaging based on the volume data, which minimizes the exposure dose (Direct MPR function).

Dr. Kichikawa: Radiation exposure has long been a challenge in CT-guided procedures, and the ability to perform such procedures in real-time without the need for fluoroscopy is, therefore, a significant benefit. In addition, the Dose Tracking System (DTS) of the angiography unit provides real-time exposure dose display, which helps limit the dose even further. When we perform angiography, we select the appropriate dose for the particular case and communicate with the technician to inform him or her whether precise visualization or only rough guidance is required. In addition, we are cautious to adjust the angle of the protective plate so that it is placed in proper contact with the patient. We also use goggles to protect the lenses of the eye from radiation exposure.



Spot FluoroscopyReducing scattered radiation.



Q4: How can the Alphenix 4D CT system help with puncture procedures?
Dr. Kichikawa: The development of advanced puncture techniques has led to higher precision in puncture procedures. I expect this will also improve the accuracy of embolization for the management of endoleaks following stent placement in patients with aortic aneurysms.

Dr. Tanaka: I believe it will expand the range of possibilities in puncture procedures by allowing the needle to be introduced at oblique angles. In the conventional method, we could only introduce the needle in the x-axis or y-axis direction, but we can now insert the needle from a wide range of angles, making it easier to avoid sensitive anatomical structures. Previously, a puncture in the z-axis direction was only possible using the tilt method, and the angle was therefore limited to 30 degrees. Moreover, in vascular IR, the acquisition of 4D data is expected to expand the potential of this technique and to drive the development of new therapeutic methods in the future.

Q5: How would you like to see the Alphenix 4D CT system improved?
Dr. Kichikawa: Personally, I would wish for the availability of 3D fluoroscopy. Nowadays, we take 3D and 4D imaging for granted, but fluoroscopy is still limited to 2D.

Dr. Tanaka: From the viewpoint of puncture procedures, I would wish for faster real-time 3D reconstruction. I would also like to see advances in puncture angle guidance technology so that everyone can perform such procedures accurately and consistently.

Q6: What do you believe the future has in store for IR?
Dr. Kichikawa: Recently, there have been many reports on the use of IR in pain management. Percutaneous vertebroplasty has already been used to treat patients with vertebral compression fractures, and there have been some clinical trials involving the embolization of new blood vessels responsible for causing pain.

Dr. Tanaka: There have also been many studies conducted overseas to assess the potential efficacy of IR in patients with prostate cancer, in which extremely fine vessels need to be approached.
I am extremely pleased to learn that the hybrid angiography-CT solution, which was first developed in Japan, is now widely recognized and is rapidly expanding worldwide.

Dr. Kichikawa: I believe it is inevitable that the hybrid angiography-CT solution will gain widespread acceptance in all parts of the world. This is because it is essential for taking IR to the next level. I look forward to continuing my work in order to further improve the system in collaboration with Canon Medical Systems and to expand the future potential of IR. //

“The Alphenix 4D CT makes it possible to formulate precise therapeutic plans and to ensure the accurate implementation of IR.”

Toshihiro Tanaka, M.D., Ph.D.
Associate Professor
Dept. of Radiology, IVR Center

New & Emerging Possibilities Using Angio 4D CT in IR

– The University of Chicago Medicine

Brian Funaki, M.D., FSIR, FCIRSE, FAHA, Osmanuddin Ahmed, M.D., Rakesh Navuluri, M.D., Steven M. Zangan, M.D., Samuel E. Guajardo, RT (R) (VI)
Department of Radiology, Section of Vascular and Interventional Radiology University of Chicago Medicine, Chicago, IL, USA
Betty Ashdown A.R.R.T. (R) (CV) (CT) RCIS, FAVIR, FSICP, Canon Medical Systems USA, Inc. Strategic Development Manager
Yiemeng Hoi, Ph.D., Canon Medical Systems USA, Inc., Medical Affairs Manager

You can do multiple sequential procedures in the same room without going back and forth between the CT and IR room…The procedures can be done sequentially without the patient ever getting off of the table….
Gives you a unique ability to handle some of the complications that you might encounter for CT guided procedures.

An internationally recognized expert in vascular and interventional radiology, Brian Funaki, MD, Chief of Vascular and Interventional Radiology at the University of Chicago Medicine, performs the full range of vascular and non-vascular interventions, including angioplasty, stenting, thrombolysis and embolization, as well as transplant-related procedures. He is a former member of the Executive Council of the Society of Interventional Radiology. An avid writer, he has authored over 200 publications, two books and 11 book chapters. Dr. Funaki is an associate editor of the Journal of Vascular and Interventional Radiology. He also served as editor-in-chief for Seminars in Interventional Radiology from 2004-2011 and is the co-editor in chief of Updates in Interventional Radiology.

Brian Funaki, M.D., FSIR, FCIRSE, FAHA

Osmanuddin Ahmed, M.D.

The Canon Medical 4D CT has transformed our ability to perform interventional oncology procedures. The ability to obtain diagnostic quality CTs quickly has allowed us to accurately confirm treatment areas, optimize dosimetry planning, and recognize sources of non-target embolization.

Osmanuddin Ahmed, MD is a board-certified radiologist with extensive experience on diagnostic and interventional radiology at The University of Chicago, Section of Vascular and Interventional Radiology. He has been an editorial board member and social media editor of Journal of Vascular and Interventional Radiology since 2017. Dr. Ahmed has published numerous articles, is an invited reviewer of many high-impact journals and provides various lectures worldwide. He has been recognized as Top Reviewer of JVIR since 2016 and by the international Alpha Omega Alpha Honor Medical Society.

The Canon Medical 4D CT system has transformed our workflow and increased our throughput by giving us the ability to treat a patient using two modalities in a single suite.

Samuel E. Guajardo, RT (R) (VI) is an experienced and accomplished interventional radiology technologist with over fifteen years of experience. As a Senior IR Tech at the University of Chicago Medicine, Sam is responsible for training and teaching new technologist in interventional radiology. He actively develops teaching tools and training modules for new employees, fellows, residents, technologists and nurses on products and procedures in Interventional Radiology. He also participated in the development and implementation of Y90, trauma and research protocols.

Samuel E. Guajardo, RT (R) (VI)

Better patient care in one Interventional Lab/CT solution with Canon Medical's 4D CT

Canon Medical Systems' 4D CT is a powerful hybrid imaging system which has a fully operational ceiling mounted angiography system combined with an advanced dynamic volume CT scanner. This combination in one suite delivers an exceptional solution for more complex image-guided interventional procedures. The 4D CT has a specially designed extendable table top that easily slides into position during imaging for either the angiography C-arm or the CT scanner. The uniqueness of the 4D CT is the ability of clinicians to prioritize the patient experience and streamline their workflow during interventional procedures in a single clinical setting. The combination of both systems within one integrated imaging suite enables physicians to eliminate patient transfer during intricate procedures and confirm the effectiveness of the procedure.

The Canon Medical 4D CT ceiling mounted C-arm has a high resolution flat panel detector with compact housing to enable unprecedented flexibility of positioning the C-arm 270 degrees around the patient. The CT system offers low contrast detectability and high contrast resolution for either volume or helical examinations to create thin slices with high precision 3D and MPR images.

The history of the University of Chicago Medicine dates back to 1927 and is a not-for-profit academic medical health system located on the campus of the University of Chicago in Hyde Park. The Department of Radiology, Vascular and Interventional Radiology team installed Canon Medical's 4D CT in April 2018. The physicians have learned the capabilities of the system and the various types of procedures performed continue to grow.

The procedures in this article are due to the efforts of the physicians and staff at the University of Chicago and is intended to highlight countless categories of procedures that are being performed.

University of Chicago 4D CT PRIME system (Photo Credit: Mark Hohn)

Renal Aneurysm Embolization

71 year old man with a past history of esophageal cancer had two renal aneurysms discovered incidentally on abdominal CT performed to evaluate tumor response. The smaller one was 1.8 cm and the larger one 3.6 cm in diameter. Initial DSA (digital subtraction angiography) series performed at 3 frames per second (fps) showed two aneurysms originating off of the Lt renal artery as well as a large cyst. The neck of the aneurysms were not delineated by DSA alone so a helical CT scan was performed with an intra-arterial injection of the Lt renal artery. The multiplanar views obtained from the CT aided in localizing the origin of the neck of both aneurysms. An additional CT scan was then performed using delayed scanning of 6 seconds to capture the left renal vein to confirm the aneurysms did not encroach on the vein. The larger one was treated using 2 long detachable packing coils to completely fill the aneurysm with preservation of all vessels. Post coiling both a DSA and a CT scan were done to check the effectiveness of the coils. The smaller aneurysm was not treated during this procedure.

Image 1: DSA Lt renal artery shows two aneurysm

Image 2: 3D volume rendering and Coronal MPR oblique view depicts neck of aneurysm and renal cyst (red)

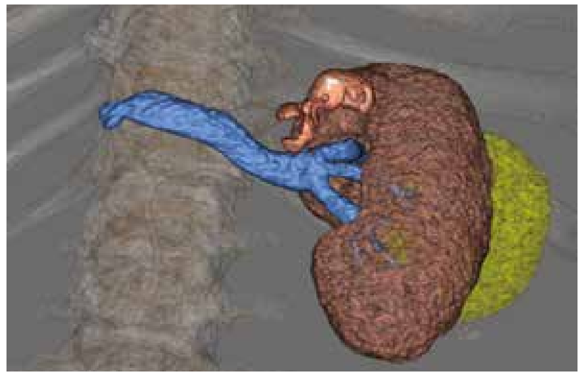


Image 3: CT late venous phase to check encroachment

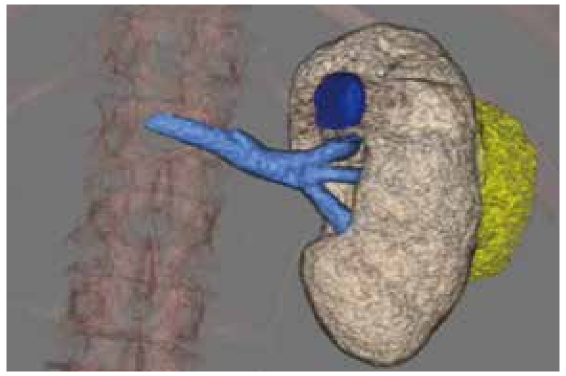


Image 5: DSA post 2nd coil of larger aneurysm. The darker blue represents the coils

Image 4: Fluoro record during first coil placement

Yttrium-90 Mapping

A 64 year old with a history of metastatic colon cancer in the liver, was brought to the 4D CT room for Y-90 mapping. A 5 French catheter was inserted into the patient's right femoral artery and advanced to the celiac artery. An intraarterial injection DSA did not highlight the common hepatic artery. The common hepatic artery was found as a separate branch off of the aorta. A DSA through a 5 French catheter showed the vessels which were supplying the tumor in the late venous phase. A 2.4 French microcatheter was then advanced to the common hepatic artery and a DSA was done with an injection of 1 ml per second for a total of 11 ml.
To highlight the tumor, a tri-phasic CT scan was done with an intra-arterial injection through the 2.4 French microcatheter to identify a significant lesion in the upper right lobe of the liver. Contrast injection of 0.5 ml per second for a total of 6 ml was used with a 2 second scan delay for the arterial phase, a 6 second scan delay for the early venous phase, and then a 10 second scan delay for the late venous phase.

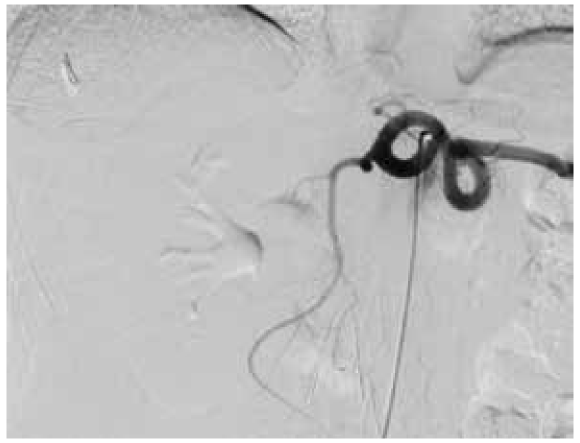


Image 1: DSA of celiac origin

Image 2: DSA of common hepatic origin

Image 3: Helical CT of common hepatic showing Coronal, 3D VR and Sagittal views

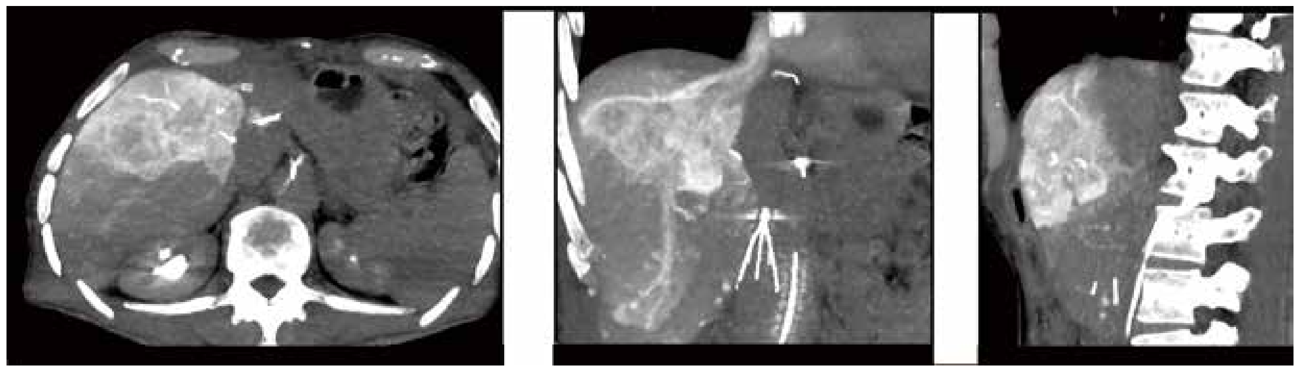


Image 4: Helical CT with injection through 2.4 French microcatheter placed in the common hepatic artery. Venous phase of axial, coronal, and sagittal MPR highlights contrast washout of the tumor area.

Arterial Bleed Embolization

A 23 year old man that came into the emergency room after a straddle injury and high flow priapism which developed post injury. Patient was brought to the 4D CT room and CT scan identified an arterial cavernous fistula from the right internal Pudendal artery. The communication was embolized using two microcoils and his condition resolved over the subsequent week.

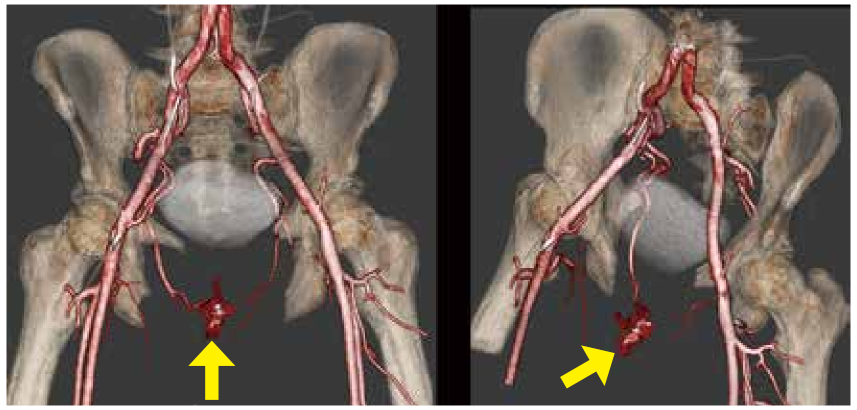


Image 1: CT of Aortic bifurcation. 3D Volume rendered AP and Oblique views

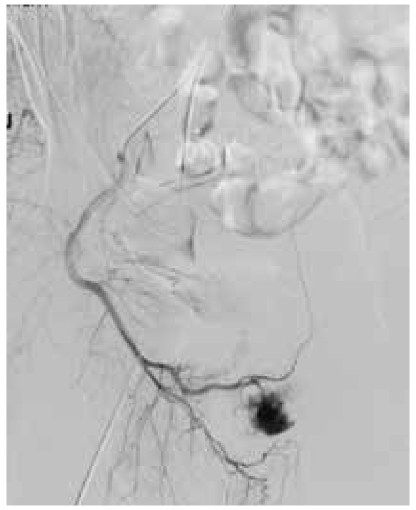


Image 2: DSA of right pudendal artery

Image 3: CT of super selection of internal pudendal artery.

Image 4: Image on left shows microcatheter in position. Image on right shows coil placement

Pelvic Mass Cryoablation With Biopsy

A 55 year old brought into the 4D CT room for possible cryoablation in the pelvis. The helical CT scan of the pelvis was done and a large mass was seen. A biopsy was necessary to specify what category of pathology. Once the biopsy needle was advanced to the mass, a CT scan was done with an intra venous injection to ensure that the needle had missed the arteries in the pelvis. A cryoablation of the mass was then performed.

Three cryoprobes were inserted into the area mass. CT provided the necessary information during this procedure without the need for fluoroscopy.The patient was able to have both procedures in the same room, on the same day without being transferred from one room to another.

Image 1: Depicting CT-guided positioning of the cryoprobes with ice ball development.

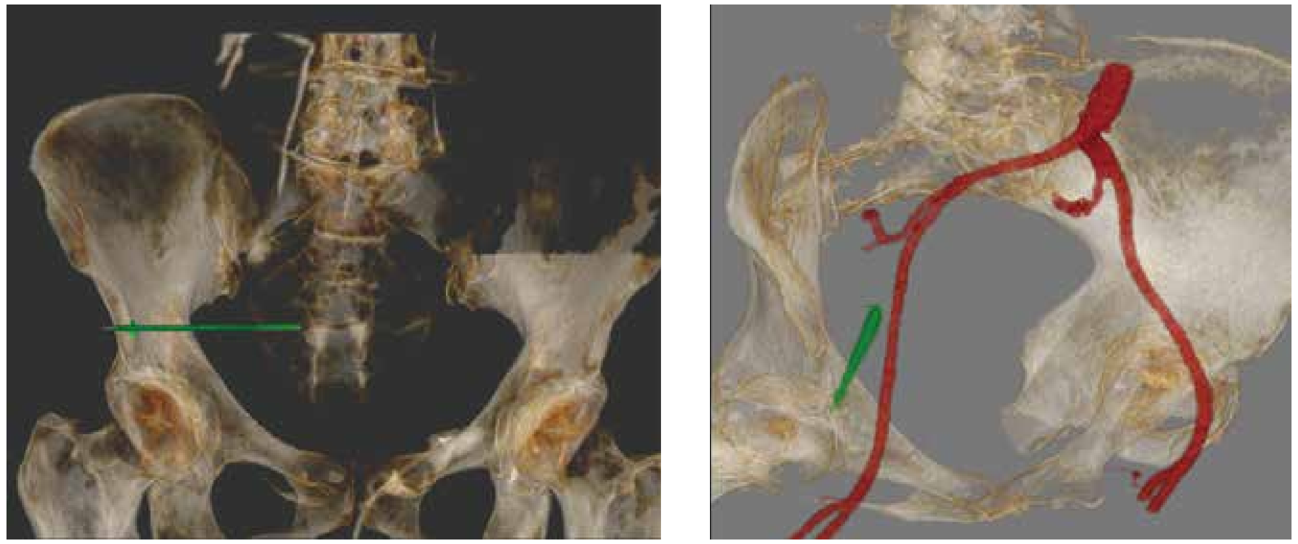


Image 2: Image on left shows the biopsy needle insertion. Image on right is the CT with IV contrast injection to check the needle pathway

Image 3: CT scan shows axial, sagittal, and coronal MPR views of the probes for cryoablation

Type 2 Endoleak Repair

A 72 year old who had undergone an endovascular aortic aneurysm repair (EVAR). Physician suspected an endoleak outside lumen of the patient's endoluminal stent graft. The procedure was done in the 4D CT room in anticipation of the need to perform CT scanning for localization of the area of the leak. A 5 French catheter was inserted into the right femoral artery and a DSA of the aorta was obtained.

A helical CT scan was then performed and 3D volume rendered image was used along with the MPR views to try to visualize the endoleak. The patient was found to have a Type 2 endoleak demonstrated by a dynamic CTA. The sac was accessed in retrograde fashion from the SMA into ascending left colic and then the inferior mesenteric artery. The sac and IMA ostium was embolized using microcoils.

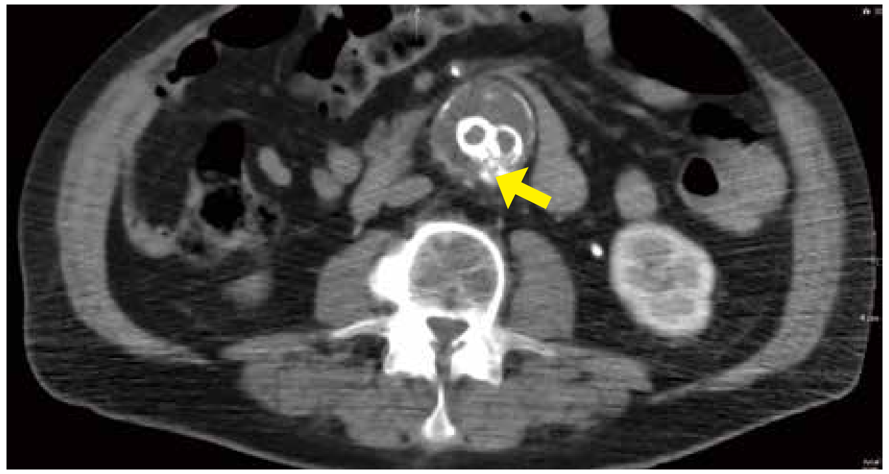


Image 1: CT scan helped to confirm area of endoleak.

Image 3: Coil placement through microcatheter to repair the endoleak

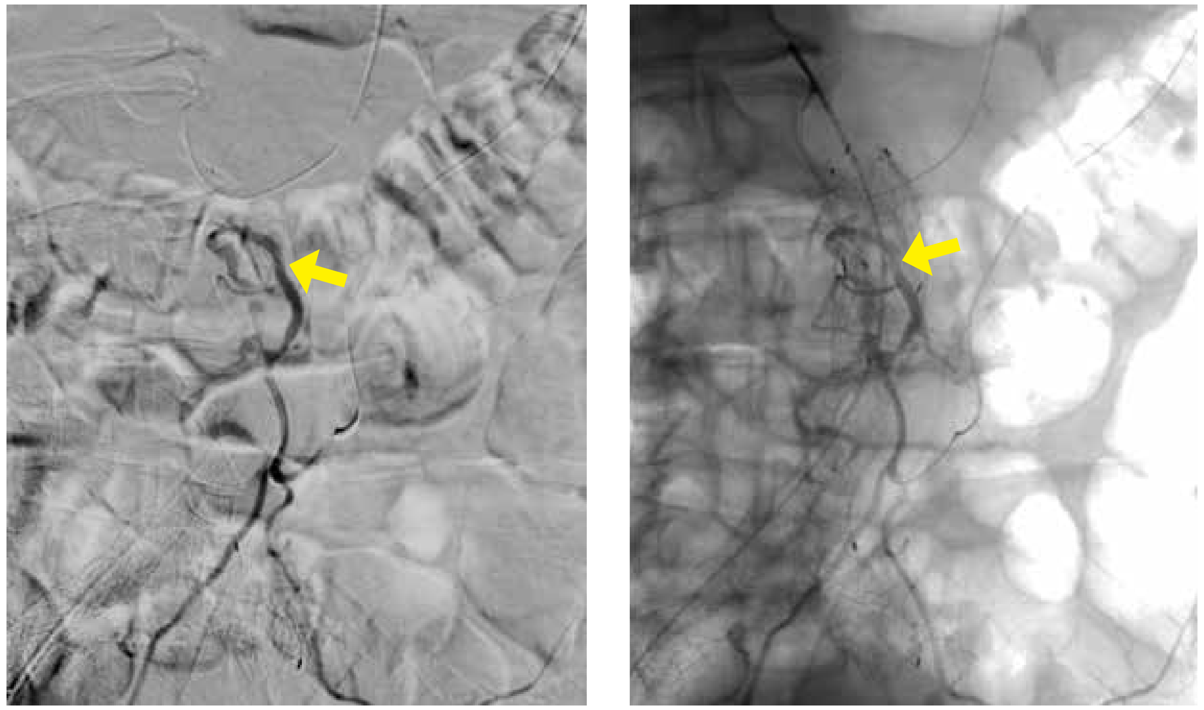


Image 2: Image on the left is a DSA through the microcatheter. Image on the right is DSA with land-marking. Leak was not distinguishable due to patient motion and bowel gas.

Procedural Parameters*1

Due to the amount of procedures the University of Chicago has performed and the number of staff that need to be trained, Sam Guajardo has collected information for intra-arterial injections during CT scanning that are used consistently. The following parameters are used for intra-arterial injections acquired with CT imaging

Vessel	Cath Fr	Cath Position	ml/s & total ml	Scan Delay	Scan Condition	Image Recon
SMA	5 Fr, end hole (EH)	Proximal	3 ml/s for 24 ml total	Arterial Phase Delay: 2 sec	Helical scan	3x3 for all
Celiac	5 Fr, EH	Proximal	3 ml/s for 24 ml total			
Common Hepatic	Micro 2.4 Fr, EH	Mid	1 ml/s for 11 ml total	Venous Phase Delay: 6 sec	120kV, MA modulation (MAM)	5x5 for EMAR*2
Proper Hepatic	Micro 2.4 Fr, EH	Mid	1 ml/s for 11 ml total			
Lt / Rt Hepatic	Micro 2.4 Fr, EH	Mid	0.5 ml/s for 6 ml total	Late Venous Phase Delay: 10 sec	Pitch 0.813 Rotation 0.5 sec	AIDR 3D*3 enhanced
Lt / Rt Gastric	Micro 2.4 Fr, EH	Proximal	0.5 ml/s for 6 ml total			
Phrenic	Micro 2.4 Fr, EH	Proximal	0.3 ml/s for 4 ml total			

**1 : The above chart is provided by the University of Chicago as a reference to the presented literature. Canon Medical is not endorsing or promoting the use of contrast agents outside of the drug insert.*

**2 : Single Energy Metal Artifact Reduction (SEMAR)*

**3 : Adaptive Iterative Dose Reduction 3D (AIDR 3D)*

Conclusion

The Canon Medical 4D CT efficiently integrates CT and IR imaging into one seamless solution. The use of real CT imaging available on demand helps reduce motion and breathing artifacts due to short acquisition times and provides enhanced soft tissue visualization. The 4D CT seamlessly integrates our flexible interventional system with the advanced Aquilion CT imaging suite into one versatile solution. With the ability to see, diagnose, plan, treat, and verify in the same room, the 4D CT helps you prioritize safety, speed, and efficiently during complex interventions. Physicians are envisioning more and more ways to use the 4D CT system, while being able to change the treatment of the patients and provide a more comfortable environment during interventional procedures. //

University of Chicago 4D CT PRIME system (Photo Credit: Mark Hohn)

Prof.Christopher Zeitz
Director of Cardiology
The Queen Elizabeth Hospital
(Central Adelaide Local Health Network)
He has more than 25 years' experience as an interventional cardiologist, and his special interests include acute coronary syndrome and coronary vasodynamic reactivity.

Future-proofing TQEH with Alphenix Core+

The number of patients presenting with cardiovascular or ischemic heart disease has drastically increased over the years, and with it, so has the demand for cardiac catheterization labs to perform complex procedures on high-risk individuals. For our team at The Queen Elizabeth Hospital (TQEH), the most significant challenges posed, are those by Australia's aging population, an ever-increasing range of co-morbidities, and an overall rise in patient BMI.

Clinical excellence requires constant evolution

To address these issues head-on, we chose to focus our strategic efforts on sourcing a solution that would enable our team to achieve optimal diagnostic imaging to treat a range of complex cardiac pathologies – particularly in the acute setting. Having previously invested $4 million in the re-development of our cardiac services, it was essential that this solution could quickly adapt and future-proof our clinical efficacy as the market evolves.

After much discussion, it was decided that the Alphenix Core + by Canon Medical was the ideal choice. We had already been using the Infinix-i for several years, but now it was time to invest in an upgrade that would successfully service this complex set of patient needs.

A triumph from the start

Since opening the new cardiac catheterisation lab, the Alphenix Core + has exceeded all expectations. Firstly, we have seen incredible image quality thanks to Canon Medical's Illuvis Image Processing Technology, which reduces frames from 15 per second to 10. We have also been able to reduce dose by up to 85% with built-in Spot ROI technology.

Secondly, when performing PCI procedures with stents, the new Alphenix Stent Mode protocols enables extra enhancement with dynamic acquisitions, as well as providing real-time visualization without any artefacts from balloon markers during instant replay.

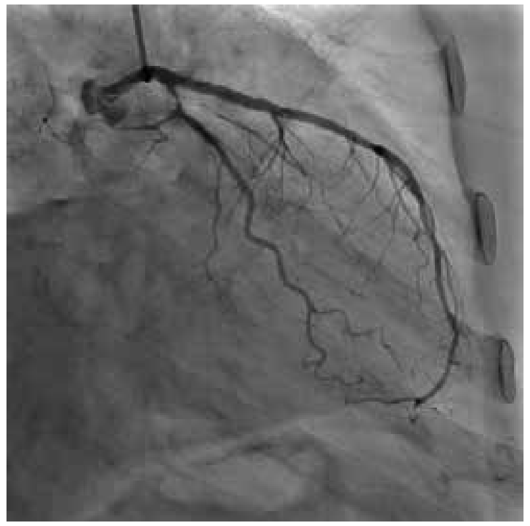


Image 1 Low dose protocol

Image 2 Stent Mode with Spot ROI positioning stent in stent

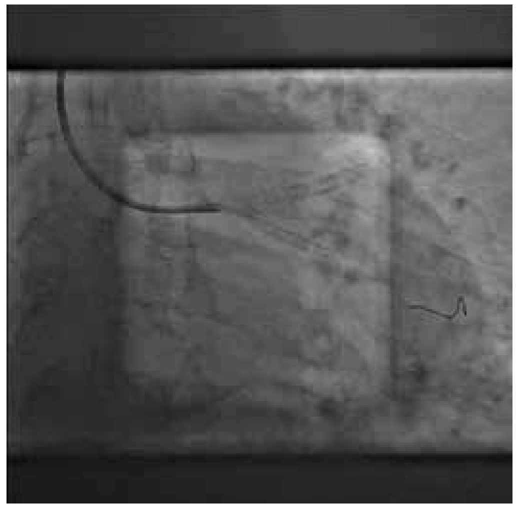
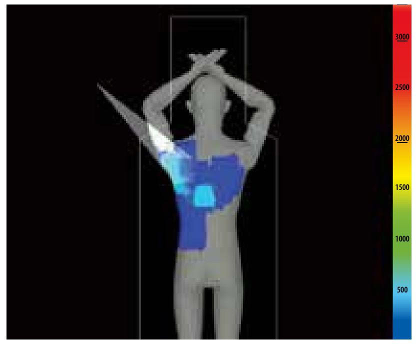


Image 3 Stent Mode with Spot ROI post stent deployment

Image 4 Final image Stent Mode

> *"We have also been able to reduce dose by up to 85% with built-in Spot ROI technology."*
>
> *Prof.Christopher Zeitz*
> *Director of Cardiology*

Finally, advanced Dose Tracking System (DTS) software provides comprehensive awareness of the local dose being administered at the point of treatment, as well as instant feedback and repositioning options to lower the chance of radiation-induced injury.



Dose Tracking System

Improved operations across the board

Mr. Khoa Doan, Head Medical Radiology Technician, describes from an operational perspective, the Alphenix Core+ has delivered a number of workflow, accessibility and IT benefits for our entire team, including:

1.Improved ergonomics and patient accessibility

The system's table movements allow for head up/head down lateral tilt and table rotation for improved flexibility during anaesthetic cases. The table has a weight limit of 250 kg to accommodate bariatric patients, and the flexible positioning of the c-arm allows for complete and unrestricted access to the patient's head. In addition, head-to-toe and fingertip-to-fingertip coverage means staff no longer have to move or reposition patients during complex procedures with anaesthetic support.

2.Seamless integration with other modalities

With the help of Canon Medical's skilled engineers, integration of OCT, IVUS and other third-party products have been seamless. All systems have been fully integrated and can present required data on the large display at the touch of a button. Layouts and inputs can also be changed mid-procedure without having to stop work.

3.Enhanced workflows

Our team of radiographers have been very impressed with the new tablet and its ability to simplify workflow. Buttons can be clearly labelled and customized to your needs, and clinical radiology technicians who have not used the machine for several weeks can quickly re-familiarize themselves with the system. Furthermore, the intuitively placed auto-angle buttons allow operators to select the ideal angle for any patient during any procedure.

Mr Khoa Doan
Head Radiographer
Angiography/Fluoroscopy
South Australia Medical Imaging (SAMI)

Prof. Zeitz concludes

Overall, we feel that we have made the right choice with a flexible and versatile system that provides the required tools to conduct expert interventional procedures. With its increased image quality and low dose parameters, we are confident that we can deliver the very best care to our patients now and long into the future.//

The Queen Elizabeth Hospital Cardiac Team
TQEH is a 311-bed acute care teaching hospital that provides inpatient, outpatient, emergency, and mental health services to a population of more than 250,000 in Adelaide, South Australia. It is supported by 24 cardiologists, including 12 interventional specialists.

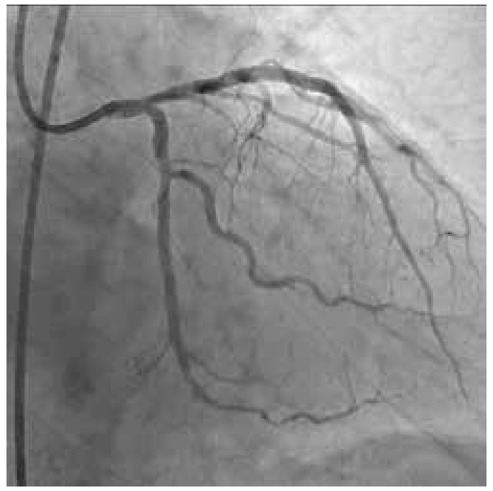
Dr. Kenya Nasu
Director of Cardiovascular Medicine
Toyohashi Heart Center
He specializes in cardiac endovascular treatment and is recognized as a leader in this field both in Japan and overseas.

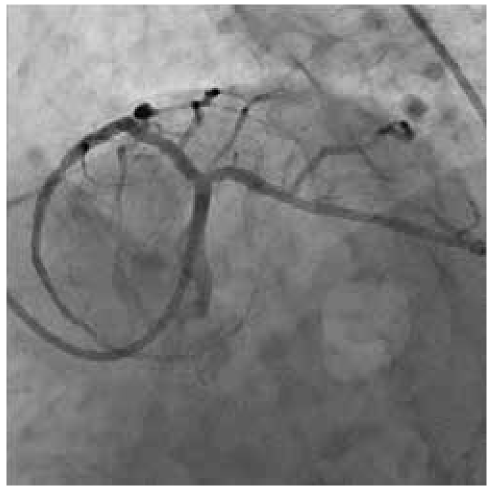
The Alphenix Biplane Cardiac Solution: Toyohashi Heart Center Delivers High Image Quality and Lower Dose Exposure

In June 2018, the world's first installation of the new Alphenix Biplane was completed in Cath Lab 1 at the Toyohashi Heart Center in Japan. For Dr. Kenya Nasu and his team, it was the start of something truly remarkable.

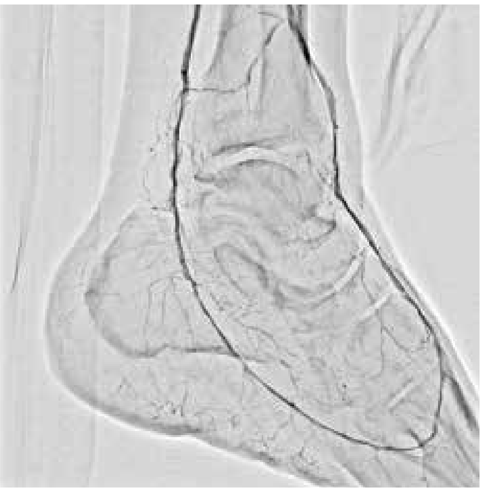
I can't deny that the Alphenix Biplane came at precisely the right moment for me and my team. Every day, we diagnose and treat a large number of patients with cardiovascular disease, and while our current Infinix-i system was doing a great job, we always felt that it wasn't quite hitting the spot in terms of image quality and exposure dose. We needed something more advanced.

Having used the Alphenix Biplane for more than a year now, I am pleased to report that we got exactly what we needed and more. Overall, the system has achieved both better image quality and lower exposure dose. In addition, we have been more than satisfied with its performance during routine clinical practice, endovascular treatments, percutaneous coronary interventions, and procedures for structural heart disease.

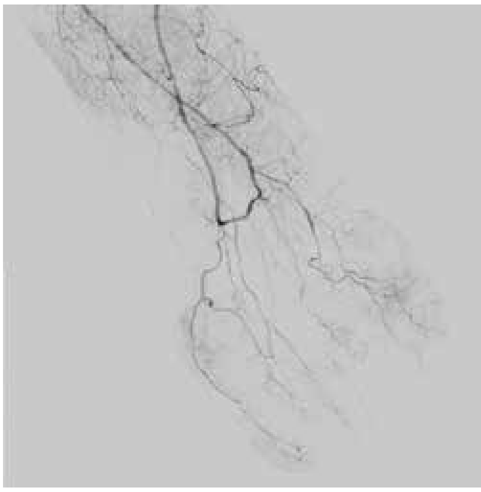




Even at extreme angles, vessels can be visualized in detail while maintaining good contrast.



DSA-like images can be obtained.



Small vessels in the toes are depicted with auto-pixel shift.

Here are some of the highlights we have experienced:

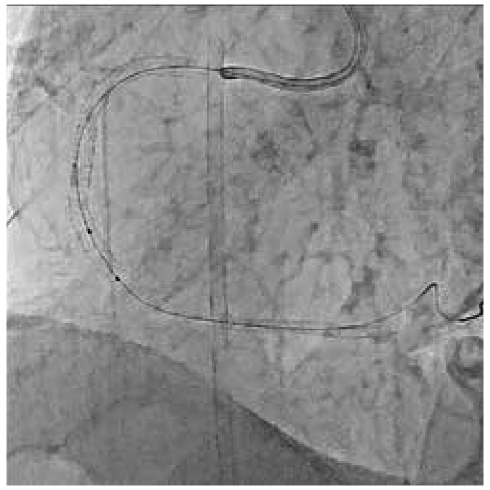
Drastically improved image resolution

I have now performed several PCI procedures on the Alphenix Biplane. In comparison with the Infinx-i system, it provides significantly enhanced visibility and improved contrast at vascular margins. This is particularly useful for channel tracking chronic total occlusion.
With the conventional system, we used a frame rate of 15 fps, but with the Alphenix Biplane, a rate of 7.5 fps was perfectly acceptable for most patients. What's more, image lag near vascular margins was suppressed to minimal levels, even with view angles strongly affected by cardiac motion, and the system's performance was further improved by a standard update, installed in October 2018.

A new Stent Mode for routine practice

The Alphenix new Stent Mode enhances signals from devices such as stents through high-speed image processing, thus improving the visualization of these devices in real-time. Stent images can be improved with or without the use of a balloon marker, and there is no need to fix or add the stent. This feature is particularly helpful because it allows us to perform all procedures according to our standard workflow.

In addition, we now employ Stent Mode routinely in our clinical practice. When a stent fracture is suspected in diagnostic cardiac catheterization, Stent Mode is extremely effective because it allows the stent to be clearly seen. Other manufacturers offer similar functions, but these cannot match Canon Medical's real-time visualization capabilities, permitting the balloon site and overlapping stent to be fully visualized.



The edges of stents are enhanced without affecting the dose (marker-less application).

Minimal dose during fluoroscopy

Designed to maintain the required level of visualization at a much lower dose, Spot ROI and Spot Fluoroscopy are both intuitive breakthrough technologies only available for Alphenix interventional systems.

With Spot ROI, the standard level of radiation exposure is used only in the region of interest, while a substantially lower level of radiation exposure is used in surrounding areas – in some cases, 60-70% less. In addition, Spot ROI minimizes scattered radiation and reduces exposure not only to the patient but also to the operators by limiting it to the area in which intervention is performed.

What's more, I frequently use Spot ROI in situations where I need to focus on a limited area, such as in bifurcation wiring procedures. With the conventional system, when we attempted to reduce the exposure dose by collimating the area to be treated, the areas outside the ROI were completely black, and there was a risk of structures or devices moving out of the frame due to cardiac motion. Operators were also forced to maintain a high level of concentration when viewing through a small hole in a totally black background. With Spot ROI, on the other hand, the surrounding reference areas appear as if seen through frosted glass, and the entire image moves in synchronization.

"The C-arm movement through various positions during a set of routine examination procedures, was around one minute and forty seconds – considerably far less than it took for other systems."

Dr. Kenya Nasu
Director of Cardiovascular Medicine

A new Dose Tracking System to visualize real-time estimated skin dose

The Dose Tracking System (DTS) is considered to be particularly helpful for inexperienced operators, who tend to perform entire procedures without changing the imaging exposure angle. DTS can assist the operator by providing a visual warning of potential hot spots. Plus, the estimated exposure dose to the patient's skin is calculated in real-time and displayed as a color-map on a patient model.

Smooth C-arm movement

Toyohashi Heart Center currently has four catheterization labs: one with an Alphenix Biplane, and three with systems from other companies. Compared to the systems from other manufacturers, the Alphenix Biplane's C-arm is considerably faster and smoother. In fact, the time required to move the C-arm through various positions during a set of routine examination procedures, was around one minute and forty seconds – considerably less than the two minutes or more it took for the systems from other companies.

Easy-to-use controls

The Alphenix Biplane features a tablet console (Alphenix Tablet) that allows a variety of operations to be performed easily by pressing a single key or button. I have not yet used this tablet, but it definitely appears to reduce the workload for our radiology technicians. When new functions are added to a device or system, operation tends to become more complicated, but Alphenix has successfully streamlined the process by offering simple and intuitive touch-panel operation.

Expert support from Canon Medical

We find it easy to communicate with Canon Medical because it is a Japanese company. We enjoy excellent support and follow-up, and the company provides a meticulous service.

When the Alphenix Biplane was installed at our hospital, it was first assembled at the Canon Medical factory and then minimally disassembled for shipment. The system was installed in an astonishingly short period of time, and we have not encountered any problems since. I appreciate the pride of the company as a manufacturer of high-quality equipment.

Looking towards the future

As our partnership with Canon Medical moves forward, I am particularly interested in the combined use of angiography and CT to improve diagnostic accuracy, for example, to achieve precise phase synchronization in both diastole and systole.

I would also like to see closer integration of angiography and ultrasound and improved integration with intravascular ultrasound (IVUS) and optical coherence tomography (OCT). It is my hope that it will soon become possible for sites of interest that have been identified by IVUS to also be pinpointed in angiography images.

Another area for future improvement could be finding the optimal balance between the size of an angiography system and its performance capabilities. At present, angiography systems are very large and consume a lot of power. Hopefully, we can expect further improvements in the future, allowing us to see the same things with less power.

Of course, it is also important to continue our efforts to obtain even more detailed information than we can now. Today, artificial intelligence (AI) is being introduced in a wide range of technologies, and I have high hopes regarding the usefulness of AI in angiography – especially when it comes to obtaining optimal views and controlling the dose in an even smaller area of the patient.//

The world's first commercial installation of Alphenix Biplane.

Toyohashi Heart Center is one of Japan's top hospitals specializing in cardiac disease. It was founded by Dr. Takahiko Suzuki, Hospital Director, where he was the first to pioneer the treatment of interventional cardiology in Japan. The center provides community healthcare services and contributes to medicine within and outside Japan.

VISIONS spoke with Eric van Antwerpen, Chief Commercial Officer at Fysicon.

A Complete, In-House Solution for Cardiology

With the acquisition of Fysicon over a year ago, Canon Medical is now able to provide the best image quality with an intuitive hemodynamic monitoring solution, a powerful combination in cardiac care. Eric van Antwerpen, Chief Commercial Officer at Fysicon, discusses how in areas such as interventional radiology and stroke Canon Medical's solutions and its sister company can better fit the needs of the customer and improve patient outcomes.

With the inclusion of Fysicon, Canon Medical now has a broad range of solutions across different modalities, clinical scenarios and workflow systems designed to add real value to the services offered by the hospital. This ability to provide a complete, in-house solution is one of the company's strongest points, according to Eric. "We are the only ones who can supply a complete portfolio; a one-stop-shop. Having a single solution means you don't have any integration issues. Everything works together seamlessly."

Improving and expanding cardiac care

Fysicon's most well-known product is QMAPP®, a hemodynamic monitoring system. QMAPP beautifully completes the powerful Alphenix interventional system with cardiac workflow, cardiovascular reporting system and database, to deliver our best possible cardiac imaging and workflow solution. "Today everything inside the hospital is IT-connected. Fysicon adds greater IT connectivity and workflow management to enhance our cardiac solution," he said.

QMAPP attached on Canon Medical's X-Ray system Alphenix.

Combined with the Alphenix cardiovascular X-ray system, QMAPP provides a complete solution for the cardiac lab. For hemodynamic applications, the system typically needs to be replaced after seven years.

The average lifetime of cardiac or X-ray equipment in a dedicated lab or X-ray room, is between eight to ten years. Everything can be planned directly with the customer, to renew equipment and IT when it best makes sense, on a case-to-case basis.

Used in combination with the Alphenix Core, QMAPP also enables to perform cardiac imaging inside a catheter lab, which may prove a smart business decision for small hospitals, Eric explained: "In a general district hospital you facilitate 300 to 350 procedures a year. In a cath lab, that's too expensive. But by having a system like the Alphenix Core and an upgrade kit such as QMAPP, you can perform cardiac care in this setting, and save money for your hospital."

Information on stents, balloons, devices, valves and any implants are also stored on QMAPP, and can be sent to registries. If companies have an issue with their product, they can consult QMAPP data to find out.

If a facility performs 320 procedures per year in their cath lab, they would break even within approximately five years, while it usually takes a decade for a cardiac lab to generate benefits. "With optimal workflow, customers can add one or two patients per day, which is good from a budget perspective. For patients, it means shorter waiting times before they can have their procedures done," he added.

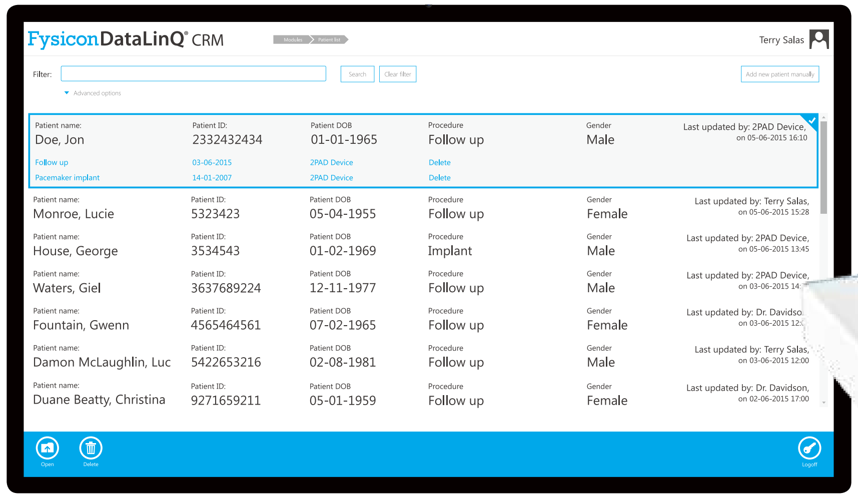
DataLinQ™ is another workflow management system used to facilitate a paperless pacemaker clinic and make pacemaker follow-ups more efficient and less costly. Usually, pacemakers are implanted in the cardiac catheter lab. Fysicon facilitates an IT solution where all the data from the pacemaker is directly fed into the database. Pacemaker follow-ups are usually performed once or twice a year. In the past, all the data generated by the pacemaker in that time was printed on paper, in 4-12 pages-long reports, which were then put into files. When the patient returned to the hospital for a follow-up, the physician don't have time to go through the long reports and would typically read only the first pages.

"An IT system, allows you to directly access all key information on battery state, lead wires, settings etc. and, if necessary, plan a replacement in time based on the trends. You can better follow-up patients and track any changes in their behavior. These trends become evident as all the data on the patient's wellbeing is stored in the system," Eric explained.

With DataLinQ Remote Device Management it is also possible to integrate data from remote device systems into DataLinQ Cardiac Rhythm Management. A message is automatically displayed in the inbox when data from remote device systems are delivered through the hospital server. Both follow-up as well as remote follow-up data are integrated into one database. All the data generated by DataLinQ is exported to national registries, helping to collect data to activate alerts and appropriate chain of actions in case a defect is spotted.

Future applications

The burden of cardiovascular disease (CVD) is set to increase drastically over the next decades. CVD is already the most common cause of death in Europe, responsible for 3.9 million deaths each year. It is a major cause of disability and reduces quality of life. Longevity, improved survival, obesity and the rapidly increasing prevalence of diabetes will continue to boost the number of patients with CVD.



These factors directly have an impact on rising costs for healthcare and put further strain on healthcare resources. It is currently estimated that CVD costs € 210bn a year to the EU.[1]

Optimized workflows and improved resource utilization are crucial to help buckle the trend. The combination of Alphenix and QMAPP can help detect CVD at an early stage, before any complications, such as stroke, arise. Other modalities can also be used to help in the early diagnosis of CVD. The focus should now be on multimodality sales and along clinical pillars - i.e. cardiology, oncology.

"Selling modalities doesn't work anymore. It's important to think across the clinical pillar because we can offer a whole approach, for example a complete cardiac solution. You can't do everything with one device and that's why you need to use the whole portfolio."

Canon Medical has several high profile academic sites equipped with Alphenix 4D CT, a sliding CT system integrated with an interventional system that can also be combined with ultrasound. This one-room solution avoids the complications and time delays of patient transfer.

"We are continuously looking for opportunities to make the current workflow more efficient, by combining additional modalities, and improving integration and usability," Eric said.

Stroke and oncology are areas in which Canon Medical combined with Fysicon have a lot to offer. Interventional radiology is another area to explore and grow, as procedures are getting more complicated and greater patient monitoring is required.

Connectivity is another important direction with regard to workflow and interoperability, and Fysicon continues to acquire experience in this field.

Smarter, safer and cheaper image transfer

Since 2004, Fysicon develops products based on real world needs, for example, from observations made in hospitals. "We saw a nurse walking by in a cardiac thoracic center with a shopping trolley full of CDs and film scans. These imaging studies were being returned by mail to the hospital that created the images, where, according to Dutch legislation, they had to be stored. We thought: this is a wasteful practice. We have to facilitate the transfer of images, and make it more reliable and efficient," Eric said.

That was the inception of EVOCS™. EVOCS is an image and document sharing system, which transmits images from one hospital to another over a secure Internet connection. With EVOCS, the risk of losing or damaging the images disappears, transfer process is expedited and the data anonymized.

The network was created for cardiology, but could be extended to other departments, which are still using CDs and USB sticks to transfer images – for instance oncology. Oncology would be an interesting area as images from

> *"With the inclusion of Fysicon, Canon Medical now has a broad range of solutions to add real value to the services offered by the hospital."*

Eric van Antwerpen
Joined the Fysicon team in 1996 as freelance application specialist. Before that he had been working as a radiographer, specializing in angiography and diagnostic cardiac care for over ten years.

different hospitals are used in expert panels, for example, in university medical centers involved in large studies and concentrating the data of patients with certain types of cancer.

Stroke is another potential use for EVOCS. Time is brain in stroke management, and EVOCS can help make a difference. "We can help save time when a patient CT information is sent to the neurovascular reference center, to help the neurosurgeon to get the data as soon as possible and trigger the appropriate chain of actions - i.e. keep the patient in observation or prepare the OR right away, when there's a major bleed that needs to be coiled. This is a much more efficient and cheaper workflow compared to current processes." EVOCS proved its benefits in the Mr Clean Study, which is the fundament for the Dutch Stroke program.[2]

Cybersecurity

Cybersecurity is an essential consideration in all IT systems, especially when the systems are exposed to the internet. Fysicon was the first company in the Netherlands that provided data-processor agreements as part of its EVOCS contract. Today such agreements are a commodity.

"We periodically perform penetration tests to ensure that the data is secure."

Cybersecurity in pacemaker follow-up is crucial. DataLinQ does not communicate with the devices itself, but with the pacemaker programmer and the Remote Monitoring Devices. This prevents any possibilities for a breach.

Data acquired on all Fysicon solutions is encrypted. The used encryption algorithm is the same as with banking and credit card transactions. SSL and network certificates are being used and the access to all systems is secured though username, passwords, user groups and rights, and in some cases even two-factor authentication. These security measures are approved by the US Department of Defense.

Cybersecurity is everyone's concern inside the hospital: the equipment and IT providers, but also the staff. "We do our software part but expect the hospital to do something. We still see passwords written directly on the computer in some hospitals. Such behavior endangers data security. We must all make appropriate efforts," he concluded. //

Fysicon
creating medical solutions

About Fysicon
Fysicon designs and develops applications as well as a manufacturing services for Canon Medical. Fysicon was founded 25 years ago as a third-party vendor, which provided systems in combination with all brands to get best of breed for the end-user. Fysicon was acquired by Canon Medical in March 2018, to combine the best of both companies.

Fysicon may not be available in all regions or countries, please contact your local Canon representative for more details.

[1] *World Health Organization www.who.int/cardiovascular_diseases/en/*
European Cardiovascular Disease Statistics 2017 http://www.ehnheart.org/cvd-statistics/cvd-statistics-2017.html.
European heart health charter http://www.heartcharter.org

[2] *https://www.mrclean-trial.org/*
https://www.spoedzorgnet.nl/sites/default/files/documents/protocol_regionale_inrichting_beroertezorg_strokenet_-_final_juli_2018.pdf

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The Next Advance Is Now in Sight Alphenix Biplane

Kenya Nasu, MD, Department of Cardiology, Toyohashi Heart Center, Aichi, Japan

Alphenix provides higher image quality, lower exposure dose, and improved operability

For the 12 years prior to the installation of the new Alphenix system, we were using an Infinix-I INFX-8000V. However, all angiography systems will inevitably deteriorate over the course of time, and the failure rate will tend to also increase as a result.

Compared with the newer models housed in our other catheterization laboratories, the Infinix-i delivered much higher doses in radiography and fluorography examinations, putting it at a strong disadvantage overall. Therefore, we felt it was time to install a new system.

The new Alphenix system provides many benefits, including reduced exposure dose, advanced image processing capabilities, a user-friendly design, and significantly improved image quality.

In fact, one of our patients, who has been receiving care at the clinic since its establishment, has been examined with three different systems over the years: the Infinix system (1999), an Infinix-i system (2014), and the Alphenix system (2018).

Figure 1 shows images of this patient acquired with these three systems. The Alphenix image shows a much clearer contrast between structures, such as vascular margins. This is an excellent example of the higher resolution that can now be achieved thanks to Canon Medical's technological advances.

Alphenix new Stent Mode is clinically effective and 7.5-fps fluorography is free of image lag.

The Alphenix's new Stent Mode is an effective tool suitable for routine clinical use. When we perform diagnostic catheterization procedures in patients with suspected stent fracture, the use of Stent Mode allows the stents to be clearly visualized, making it much easier to determine the presence or absence of stent fracture. The stent visualization enhancement functions in systems produced by other companies employ a marker for a fixed display of the stent, but this can interfere with visualization. Alphenix's Stent Mode, on the other hand, permits the status of the stent to be confirmed easily in a conventional image. Clear images can be obtained even when the stent overlaps the diaphragm and is difficult to see.

We have, therefore, found the new Stent Mode to be very useful in our clinical practice.

Another benefit of Alphenix is its excellent image quality, even when fluorography is performed at low pulse rates. For example, this imaging method was found to be extremely effective in a patient with chronic total occlusion (CTO) of the left anterior descending artery (LAD). First, a guidewire was advanced under fluorographic guidance at 7.5 frames per second (fps).

Tip injection was then performed, and the catheter could be clearly depicted.

In addition, the large and rapid cardiac movements observed in right anterior oblique (RAO) and RAO caudal views often lead to image lag, which interferes with visualization of the guidewire, making it difficult to determine the direction the tip is facing and how it is moving. For vascular surgeons, this is one of the most frustrating limitations of angiography systems. The Alphenix system overcomes this limitation because it is virtually free of image lag, allowing the tip of the guidewire to be clearly visualized at all times. It can, therefore, be expected to improve the precision of such interventions, while shortening procedure times.

Minimizing exposure dose

Minimizing radiation exposure during fluorography is an important goal. In particular, when a time-consuming procedure is conducted in a left anterior oblique (LAO) caudal view (LAO 40°, caudal 30°; the so-called spider view), there is an increased risk of excessive X-ray exposure. For example, one patient who was treated at our institution developed severe radiodermatitis that required skin grafting. To avoid such adverse events in the future, the actual exposure dose was measured in each of our four catheterization laboratories, under the same conditions.

A 20-cm acrylic plate was placed at the examination position, and measurements were obtained while the fluorography and radiography programs were run on the four different systems, using the same parameters as in routine clinical practice. The dose measurements obtained for Alphenix were equal to or lower than those obtained from the other three systems. Compared to the Infinix system we had used previously, Alphenix showed dose reductions of approximately 60% and 50% in fluorography and radiography, respectively. This is truly a remarkable improvement. When the thickness of the acrylic plate was increased to simulate a larger patient, the dose during image acquisition was increased by a factor of three to seven in all the systems, but Alphenix was found to have the lowest dose.

Alphenix also provides a tool known as the Dose Tracking System (DTS), which measures and displays the patient estimated peak skin dose in real-time. This function makes it easy for the operator to identify 'hot spots' and take appropriate measures to avoid them as much as possible. Furthermore, while DTS improves awareness of high-exposure areas where the radiation dose should be reduced, another function known as SPOT ROI has also been found to be effective in routine clinical practice.

Various functions that allow the operator to collimate the region of interest (ROI) within the overall field of view are available in the systems produced by other companies, but these functions tend to be rather difficult to use because the area outside the ROI is displayed in black. The SPOT ROI function in Alphenix, on the other hand, continues to show the surrounding anatomy. It is like covering the image with a thin cellophane film with an opening that matches the area of the ROI (Figure 2).

Using this function, the image quality within the ROI is maintained at the usual level, and surrounding areas can also be observed to some degree. This means that the operator can perform procedures at a lower radiation dose while still being able to observe changes that may occur quickly. In fact, the measurement results showed that Spot ROI can reduce the dose in surrounding areas by 65-85%. It is also easy to operate the ROI, which minimizes the burden on the operator and makes it possible to perform less-invasive therapeutic procedures.

The speed of C-arm movement is another critical factor during cardiac imaging, in which images must be acquired from various angles. The four systems produced by different companies were compared in terms of the time needed to move the C-arm to specified positions during a set of routine examination procedures. Alphenix was found to be the fastest, at one minute 40 seconds, resulting in more efficient operation. The time needed for the systems produced by the other companies was two minutes or more. One of the reasons for the higher speed of Alphenix is that its flexible wide arm opening minimizes interference (Figure 3).

Figure 1 Images of the same patient acquired using three successive systems at Toyohashi Heart Center

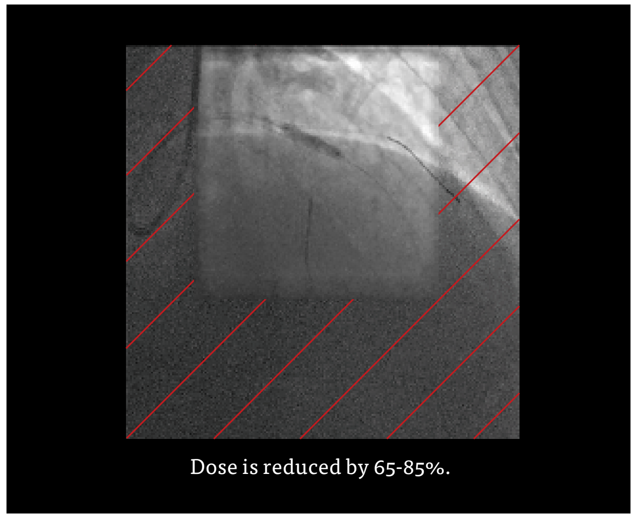


Figure 2 SPOT ROI

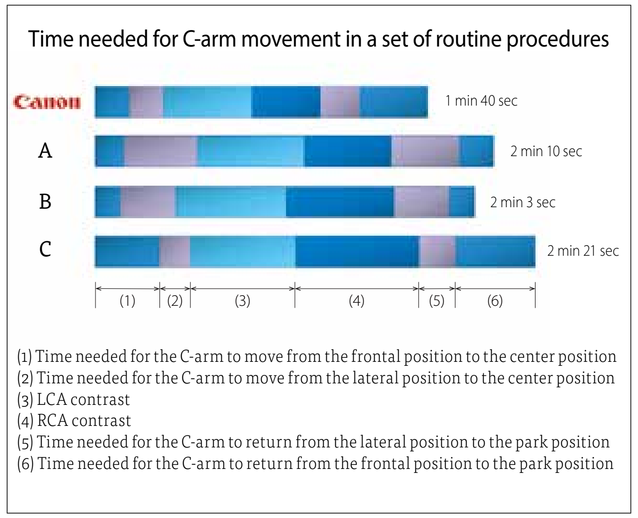


Figure 3 Comparison of C-arm movement speeds

Alphenix also allows the operator to simulate the working angle based on 3D CT data obtained before the procedure is started. For example, in patients with severe renal dysfunction, who need to be examined with the smallest possible amount of contrast agent, the most effective angle for observing a lesion can be identified by reviewing previously acquired 3D CT data. This information can then be preloaded into Alphenix, allowing the lesion to be easily observed from the optimal angle. Consequently, the number of image acquisitions is reduced, and the amount of contrast medium is minimized, resulting in a less invasive interventional procedure (Figure 4).
What's more, Alphenix which comes with an optional tablet console, allowing a variety of operations to be performed easily by pressing a single key or button on the tablet. For example, the viewing mode can be changed through one-touch operation to change the monitor display settings. In addition, the arm angle can be registered in advance and visually indicated on the display. Even though the operator may not remember the actual settings, the desired angle can easily be selected. The workstation can also be operated using the tablet.
For example, the operator can rotate and view 3D images to determine the optimal working angle. This design allows the operator to work at the tableside in many situations that are encountered in actual clinical practice.

Installation of the first "Alphenix Biplane" system

Toyohashi Heart Center was established in 1999 as a 'clinic' (a medical institution with 0-19 beds, as defined by the Medical Care Act of Japan). The center initially provided services from just two catheterization laboratories; however, the number of beds were later increased, and the center was reclassified as a 'hospital'. Toyohashi Heart Center now provides services with total of four catheterization laboratories. Since its establishment, the center has used angiography systems produced by a range of manufacturers – one by Canon Medical Systems (previously known as Toshiba Medical Systems), and another three by a variety of companies. It was under this arrangement that the Alphenix Biplane system (a state-of-the-art solution from Canon Medical Systems) was installed in Cath Lab 1. As of October 26th 2018, this was the company's first commercial installation of the Alphenix Biplane in the world, and the system has been in operation at the Toyohashi Heart Center ever since.

Conclusion

First, there is no doubt that image quality has been markedly improved. We usually perform fluorography at 7.5 fps, which provides acceptable image quality and allows procedures to be conducted comfortably and efficiently, even in complicated patients with chronic total occlusion (CTO). The exposure dose is equal to or lower than that of the systems produced by other companies and has been found to be completely acceptable in clinical use. The system also provides advanced functions such as DTS, which allows the operator to be fully aware of the exposure dose, and SPOT ROI, which allows the dose to be further reduced. Alphenix offers many advantages for both patients and operators, and we look forward to making the best possible use of the system. We have high expectations for this system in the future due to its outstanding benefits, including high-speed C-arm movement and improved workstation operability. //

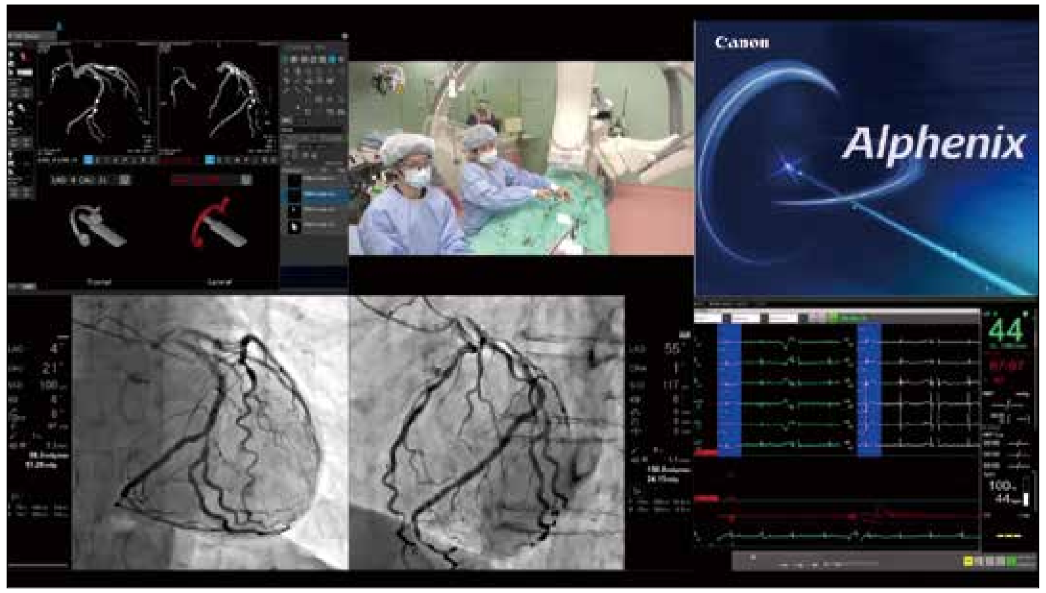
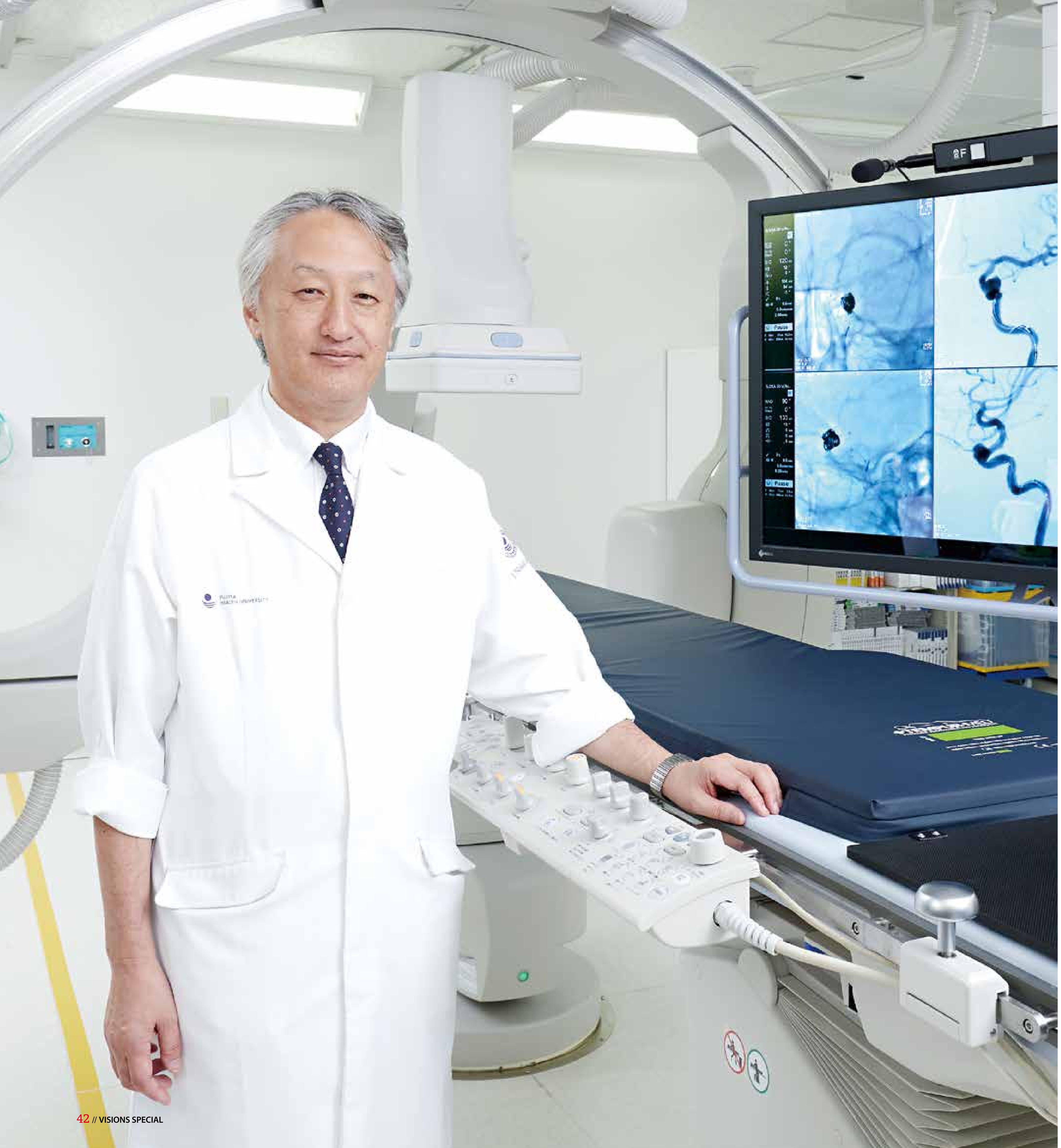


Figure 4 Evaluation of arm movement



Prof. Ichiro Nakahara
Department of Comprehensive Strokology
Fujita Health University Hospital

Transforming Neuroendovascular Therapy with the Alphenix Hi-Def Detector and Workstation

It's no exaggeration when I say the Alphenix Hi-Def Detector and Alphenix Workstation have entirely changed the clinical practice for me and my team – not to mention the thousands of patients we treat every year.

Until recently, stroke treatment at our hospital had always been delivered in a nonintegrated silo: only the neurosurgical team was managing surgical treatment, and the department of neurology was managing all things medical. However, with neuroendovascular therapy growing and awareness increasing, the need for a more integrated approach was becoming evident. It was clear that in order to strategize the future of our practice, we needed technology that could bridge the divide between surgery and medicine, as well as provide patients with the best-in-class neuroendovascular treatment they need.

We currently have five hybrid operating rooms, each equipped with an angiography system from various vendors. Of all the existing systems, I mainly prefer to use the Alphenix Biplane system manufactured by Canon Medical Systems Corporation, which was installed at our hospital for imaging the head and neck.

A strategic solution for the long term

In March 2019, we had decided to install the Alphenix Hi-Def Detector and Alphenix Workstation.

As a neurovascular surgeon, it is my job to perform both neurosurgery and neuroendovascular therapy, and I can tell you from experience, the new Alphenix platform solution have changed the way we practice intervention for us. Here's why:

Seeing device details can be incredibly effective.

The Alphenix Hi-Def Detector has achieved the world's smallest pixel size (at 76 µm) for a detector used in any angiography system. To put this in context, this is more than half the pixel size of any other detector in the market, allowing the system to provide high-definition images in both fluoroscopy and radiography. Now, a field size as small as 1.5 inches (3.89 cm × 3.89 cm), which is the minimum FOV of the Alphenix Hi-Def Detector, can be enlarged and displayed as extremely sharp images on the large monitor.

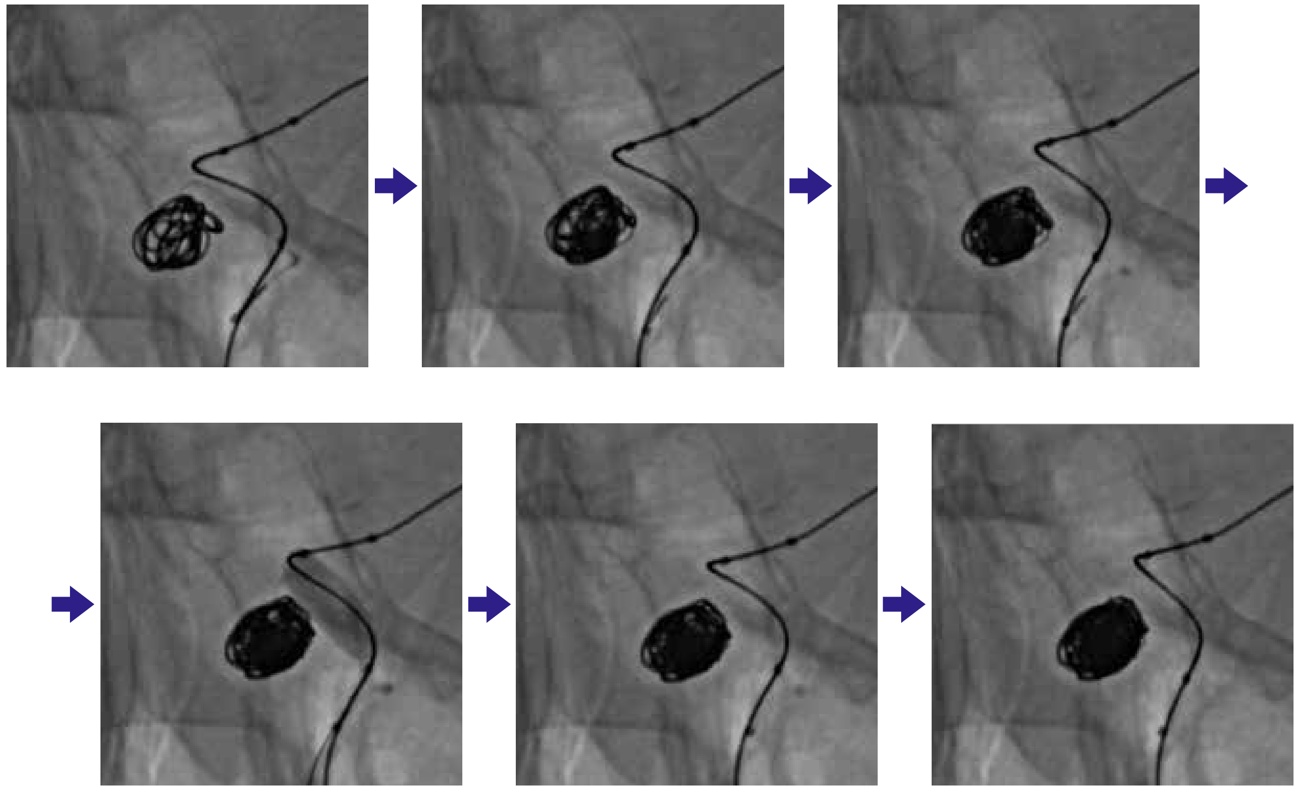
Enhances our surgical case experience

I first used a prototype of the Alphenix Hi-Def Detector about two years ago and was amazed at how clearly it could depict small microcatheters. I had the same feeling when I used the system installed at our hospital. The position of a microcatheter introduced into an aneurysm can be precisely determined, and the coils placed in the aneurysm can be distinctly visualized. Indeed, the ability to view the placement of the framing coil in the aneurysm is far superior to anything we had experienced in the past. In the course of our practice, we often employ flow-diverter stents for large/giant aneurysms, and the detector allows even the finest struts of such stents to be visibly depicted.

I believe that the main advantage of the Alphenix Hi-Def Detector is its high definition zoom capability, which makes it possible to observe extremely small structures in enlarged views (down to 76 µm pixels) on the large monitors and ensures extremely fine control by the surgeon for increased precision.

Assists us with treating cerebral aneurysms

By using the Alphenix Hi-Def Detector, it makes it possible to increase the packing density in coil embolization procedures for aneurysms. Even when surgeons feel that much of the space within an aneurysm has been packed with coils, viewing an enlarged Hi-Def detailed image of the aneurysm often reveals remaining space for the placement of additional coils.



Hi-Def 1.5-inch coiling demonstration (OneShot)
Even though the space appears to be completely packed with coils in the later stages of the procedure, Hi-Def allows us to see that there is still some remaining space between the coils.

It is my opinion that the coil packing ratio of aneurysms could be increased from the usual 30% to around 40%, or even 50%, by employing this simple technique. This, of course, requires further study for verification, but I am planning to conduct research on this matter in the future.

During postoperative follow-up, the use of the Alphenix Hi-Def Detector can increase accuracy in evaluating recanalization. And in the placement of flow-diverter stents, the images acquired using the Alphenix Hi-Def Detector are totally different visual experience from those acquired using a conventional detector. When the Alphenix Hi-Def Detector is used, it is possible to place the stent at the optimal position in closer contact with the vessel wall, and even small perforating vessels to be conserved can be depicted, allowing us to determine the optimal position for placement of the flow-diverter stent.

Outside Japan, a new endovascular flow disruptor device, known as the WEB (Woven Endo Bridge) by Microvention, for reducing blood flow within an aneurysm has been introduced in clinical practice, and it is anticipated that this device will also be introduced in clinical practice in Japan within the next few years. Alphenix's Hi-Def imaging would also be useful for further enhancing such novel treatment methods, and the Alphenix Hi-Def Detector is expected to play a significant role in this field.

Its potential future for neuroendovascular therapy.

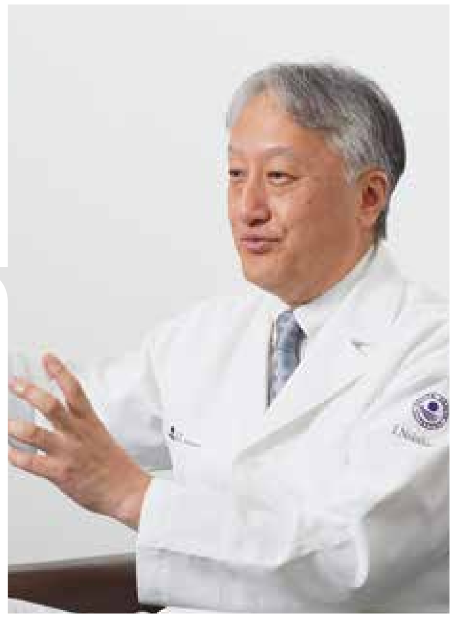
The ability of the Alphenix Hi-Def Detector to provide Hi-Def images may expand the application of neuroendovascular therapy to treat finer vessels in the future. In addition to the treatment of the cerebral arteries as discussed above, the detector may also help physicians accurately determine the extent of shunt flow in a variety of conditions, such as cerebral arteriovenous malformations and dural arteriovenous fistulas (d-AVF).

The Alphenix Workstation with 3D applications improves our case workflow

In neuroendovascular therapy, shortening the procedure time can help reduce the amount of anesthesia required, as well as the risk of ischemic complications due to thrombosis. The Alphenix Workstation can help address these clinical needs with a wide range of applications and features that support neuroendovascular therapy, including the direct link function between the workstation and the angiography system, automated analysis applications, and road mapping. I believe that the Alphenix Workstation can play an essential role in achieving these goals, especially with the following range of features at our fingertips:

> *"Only after experiencing cases in Hi-Def, you truly appreciate the detailed visual and clinical advantages it provide. Now it's difficult to go back using a conventional detector again."*

Professor Ichiro Nakahara
Department of Comprehensive Strokology

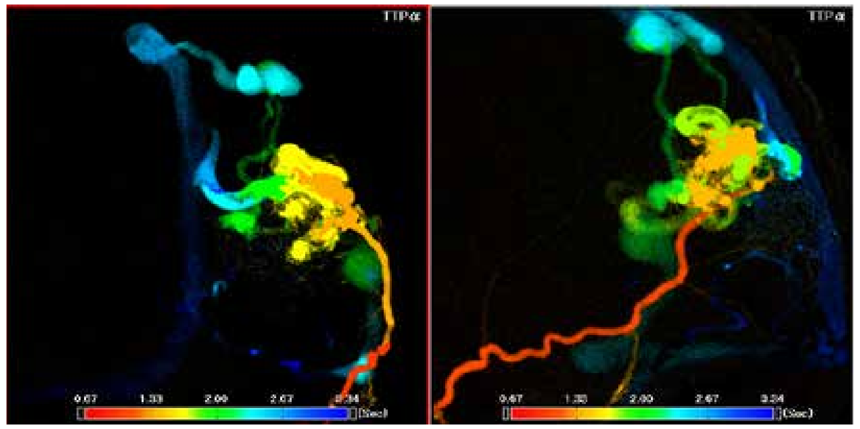


• **The working angles of the biplane system** can be automatically set in advance by simply pressing a button on the workstation, or new tablet.

• **The Parametric Imaging (PI) function** uses the time-density curve for each pixel acquired by pre-and post-digital subtraction angiography (DSA) to display the changes in pixel values in different colors according to characterize the contrast media dynamics and to allow easier visual flow evaluation in a single composite image.

• **Color-Coded Circulation (CCC)** is a function that simultaneously shows both the anatomical course of blood vessels and blood flow by displaying color information as a dynamic image based on the contrast medium arrival time.

I believe that the effectiveness of neuroendovascular therapy could be evaluated by using both PI and CCC in preoperative and postoperative imaging.



Diagnosis of AVM using PI

• **In Cerebral Aneurysm Analysis (CAA)**, aneurysms are semi-automatically detected in 3D images acquired using Alpha CT (cone-beam CT imaging). When the neck of an aneurysm is selected, the parent blood vessel is segmented and the measurement results are displayed. The size and volume of the aneurysm are measured automatically, and the results can be used to evaluate the embolization ratio.

The Workstation and Hi-Def Detector integrate beautifully

The images acquired using Alpha CT (CBCT) with the Alphenix detector are significantly superior to those acquired using other conventional detectors, and I look forward to additional progress in the future. It is my firm hope that the Alphenix Hi-Def Detector will undergo further development to achieve high-definition Alpha CT (CBCT) using the high-definition detector technology. Such high-definition 3D images would lead to more accurate diagnosis and treatment for clinicians.

Concerning workstation functions, such as CFD (computational flow dynamics analysis) and 4D-Perfusion (flow dynamics analysis on the temporal axis), these could be further improved. Ultimately, it would be advantageous if the entire course of stroke care, including all the steps in evaluating and determining infarction, neuroendvascular treatment, and post treatment follow-up could be conducted with solely the angiography system used for stroke patients admitted in emergency cases.

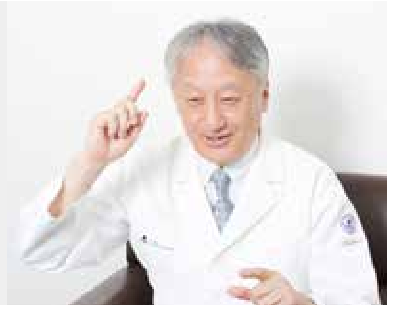
Looking to the future

As a user of an Alphenix Biplane system, I feel that the angiography systems manufactured by Canon Medical, including those with the Alphenix Hi-Def Detector and the Alphenix Workstation, have undergone dramatic improvement recently.

Although I have experience using angiography systems from other manufacturers, I currently feel very comfortable and relaxed using our Alphenix system.

It is reasonable to say that the Alphenix Hi-Def Detector, which provides very sharp images even at a minimum FOV of 1.5 inches, is an essential feature for physicians who perform neuroendovascular procedures, as even a single millimeter matters in the treatment of cerebral aneurysms. It is my belief that the Alphenix Hi-Def Detector and the Alphenix Workstation will play leading roles in the further development of neuroendovascular therapy in the future.//

Professor Ichiro Nakahara heads the Department of Comprehensive Strokology at Fujita Health University School of Medicine. The Department of Comprehensive Strokology was established in April 2016 to provide comprehensive care for stroke patients. Currently, the hospital has five hybrid operating rooms, each equipped with an angiography system: two systems for imaging of the heart, one for the head and neck, one for the abdomen, and one for the head and abdomen.



Fujita Health University Hospital

Innovative High-Definition Flat Panel Technology in the Treatment of Cerebrovascular Disease

Adnan H. Siddiqui MD, PhD, FACS, FAHA, FAANS, Gates Vascular Institute, Kenneth V. Snyder, MD, PhD, FAANS, Gates Vascular Institute, Betty Ashdown, Senior Clinical Marketing Manager, ARRT(R), (CV) (CT), RCIS, FAVIR, FSICP, Canon Medical Systems, USA

Today more and more clinicians are performing endovascular stenting and coiling for treatment of intracranial aneurysms. Newer devices are being developed using materials that are more flexible to provide better durability, which allow the structural design of the devices to be smaller in size to improve patient outcomes.

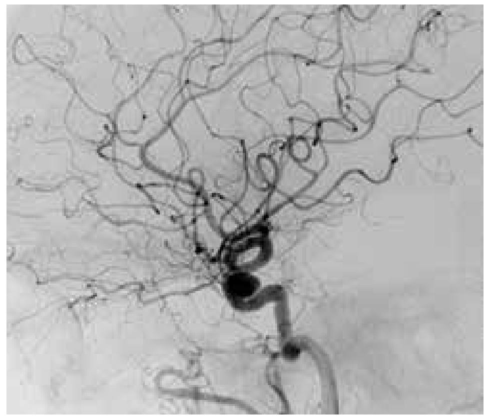
Technology

Traditional flat panel detectors have difficulty in visualization of the newer devices being used today during minimally invasive interventional procedures. Digital Live Zoom can be used to increase image display size in real time during both fluoroscopy and digital acquisitions, from 1.2 to 2.4 times standard field of views (FOV: 12", 10", 8", or 6"). However using the highest live zoom modes tend to create digital distortion and pixilation in the image. Canon Medical's new, technologically advanced High Definition detector technology boosts visualization and increases spatial resolution to facilitate the clinician in delivering safe patient care during interventional procedures.

History

A 30-year-old female arrived at the emergency department complaining of the worst headache of her life. A CT scan of the head and a lumbar puncture were done, both were negative for the possibility of a subarachnoid hemorrhage. She then went for magnetic resonance angiography, which showed her to have an 11 mm right carotid cavernous sinus aneurysm.

Pre-Intervention Images



12" FOV coned to region of interest (ROI)

6" FOV coned to ROI

3" High-Definition DSA

Procedure

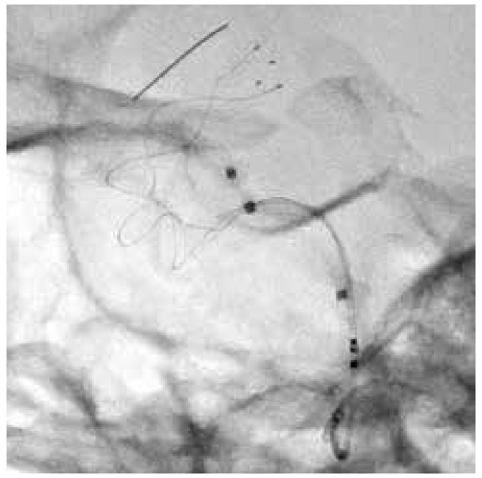
The physician decided to perform endovascular treatment of the aneurysm using a neurovascular stent and coils to prevent rupture. After femoral arterial access was obtained, a catheter was advanced to the right common carotid artery and digital subtraction angiography (DSA) was done. DSA imaging was used to obtain intra-arterial measurements of the carotid cavernous sinus aneurysm. The guidewire was then threaded through the carotid artery and a stent was positioned to cover the neck of the aneurysm. High-definition magnification modes of 3.0 and 2.3 inches were used to amplify visualization which aided in accurate insertion of the small coils through the stent struts and into the aneurysmal sac. Two long coils were necessary to pack the entire aneurysm volume.

Conclusion

Canon Medical's unique hybrid 12-inch flat panel detector design enables operators to maximize efficiency during interventional procedures and provides up to 2.5 times greater spatial resolution. Magnification modes of 3 inch, 2.3 inch, and 1.5 inch are now obtainable with remarkable resolution of the image. In this case, High Definition helped with stent positioning, ensuring the stent opened as expected, allowing for easy wire and catheter navigation through the stent tines, and allowed improved observation of coil deployment.//

Images courtesy of Dr. Adnan Siddiqui at Gates Vascular Institute in Buffalo, NY.

Device Deployment Images



2.3" High-Definition FOV: Image A is post stent deployment

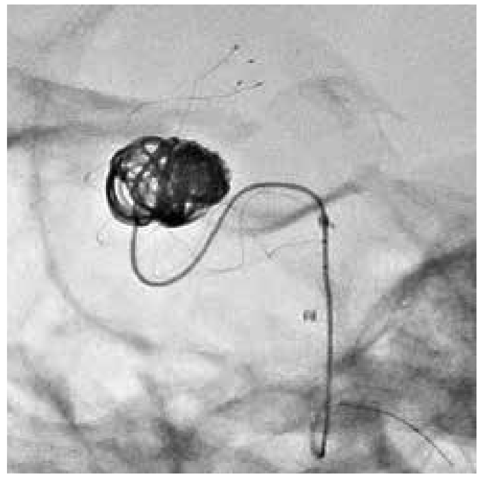
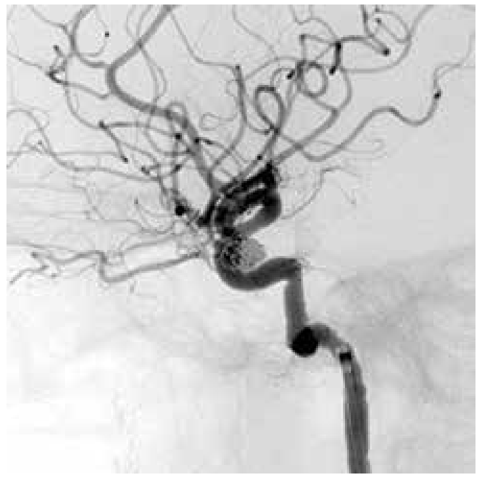


Image B is post second coiling

Post-Intervention Images



6" FOV with DSA post intervention coned to ROI

2.3" High-Definition DSA post intervention

High-Definition Zoom Mode, a High-Resolution X-Ray Microscope for Neurointerventional Treatment Procedures: A Blinded-Rater Clinical-Utility Study

S.V. Setlur Nagesh, V. Fennel, J. Krebs, C. Ionita, J. Davies, D.R. Bednarek, X M. Mokin, X A.H. Siddiqui, and X S. Rudin

ABSTRACT

BACKGROUND AND PURPOSE: Quality of visualization of treatment devices during critical stages of endovascular interventions, can directly impact their safety and efficacy. Our aim was to compare the visualization of neurointerventional procedures and treatment devices using a 194-mpixel flat panel detector mode and a 76-mpixel complementary metal oxide semiconductor detector mode (high definition) of a new-generation X-ray detector system using a blinded-rater study.

MATERIALS AND METHODS: Deployment of flow-diversion devices for the treatment of internal carotid artery aneurysms was performed under flat panel detector and high-definition-mode image guidance in a neurointerventional phantom simulating patient cranium and tissue attenuation, embedded with 3D-printed intracranial vascular models, each with an aneurysm in the ICA segment. Imagesequence pairs of device deployments for each detector mode, under similar exposure and FOV conditions, were evaluated by 2 blinded experienced neurointerventionalists who independently selected their preferred image on the basis of visualization of anatomic features, image noise, and treatment device. They rated their selection as either similar, better, much better, or substantially better than the other choice. Inter- and intrarater agreement was calculated and categorized as poor, moderate, and good.

RESULTS: Both raters demonstrating good inter- and intrarater agreement selected high-definition-mode images with a frequency of at least 95% each and, on average, rated the high-definition images as much better than flat panel detector images with a frequency of 73% from a total of 60 image pairs.

CONCLUSIONS: Due to their higher resolution, high-definition-mode images are sharper and visually preferred compared with the flat panel detector images. The improved imaging provided by the high-definition mode can potentially provide an advantage during neurointerventional procedures.

ABBREVIATIONS: DA digital angiography; FPD flat panel detector; Hi-Def high definition; PED Pipeline™ Embolization Device; RP reference point

The technologic advances in neuroendovascular devices have led to fluoroscopically guided endovascular treatment of intracranial aneurysms becoming the preferred treatment. The constantly evolving design of stents and coils, and recent developmentof new technologies such as flow diversion and intrasaccular and bifurcation devices now offer neurointerventionalists a variety of treatment options. However, the commercial X-ray imaging detector technology used during neuroendovascular interventions has not kept up with the increased requirements of image resolution.

The flat panel detector (FPD) used in most angiographic and fluoroscopy suites consists of an array of square pixels based on thin-film transistor technology, with sizes varying from 140 to 200 μm.[1] During the most critical steps of aneurysm treatment, such as deploying or repositioning a stent or flow-diversion devices or manipulating the microcatheter within a coil mass to achieve optimal coil structure, it is critical to have high-quality images of the treatment area to guide device deployment. To provide such improved imaging, a new detector system (On-line Fig 1) consisting of the conventional large-FOV regular-resolution FPD mode (194-μm pixel size at the detector) and a smaller FOV high-resolution complementary metal oxide semiconductor high-definition (Hi-Def) mode (76-μm pixel size at the detector) has been developed.

Early experience with the Hi-Def mode in imaging a standard line-pair phantom (On-line Fig 2) demonstrated improved spatial resolution over the standard FPD mode, with line pairs as high as 5.6 line pairs/mm distinctly visualized without loss in information in the Hi-Def images. However, the objective evaluation of how this new technology with improved performance affects the decision-making during neurointerventional procedures and, specifically, aneurysm embolization with the flow-diversion approach has not been performed. In this study, we present a blinded-rater study comparing the visualization of neurointerventional procedures and treatment devices using the 194-μm pixel FPD and 76-μm pixel Hi-Def mode of the new-generation X-ray detector system.

Methods and Materials

Detector Description

The new X-ray imaging system has both a regular-resolution 194-μm pixel FPD mode and a high-resolution 76-μm pixel Hi-Def mode in 1 single unit. The FPD mode has larger FOVs, varying from 30 × 30 cm to 15 ×15 cm. Smaller FOVs up to 6.3 × 6.3 cm are available using digital interpolation. In the high-resolution Hi-Def mode, only smaller FOVs are available, ranging from 8.9 × 8.9 to 3.8 × 3.8 cm.

At any given point in time, 1 of the 2 modes is active, and when needed, the image acquisition between the 2 modes can be quickly changed using an FOV switch, without adding any additional delay to the procedure.

Intervention Model Description

An X-ray image is formed by the differential attenuation of the X-ray beam within a patient's body. During an endovascular neurointervention, the major sources of X-ray attenuation are the human bone (skull) and the soft tissue (including the human cerebral cortex and skin tissue). To simulate this, a neurointervention phantom was developed by placing a human skull (simulating bone attenuation) in-between a total stack of five 1-inch acrylic layers (simulating tissue attenuation[2]). To simulate the cerebral circulation, we embedded a 3D-printed model of patient-based intracranial vasculature, consisting of the internal carotid artery segment, the middle cerebral artery, and the anterior cerebral artery segments closely representing the human circle of Willis region, inside the skull and connected it to a pulsatile flow loop, with water used as circulation fluid. The process of fabricating 3D-printed phantoms was previously described in Ionita et al[3] and Russ et al.[4] The neurointervention phantom setup and its attenuation comparison with 3 commercially available anthropomorphic phantoms are presented in the On-line Appendix.

Neurointerventional Treatment Simulation

For this study, endovascular treatment of intracranial aneurysms of the internal carotid artery with the flow-diversion approach using the Pipeline Embolization Device (PED; Covidien, Irvine, California) was simulated.[5] Five different 3D-printed models with aneurysms in the ICA segment were fabricated and treated with a 4.75 × 30 mm PED. Due to limitations in the availability of the PED and its high cost, we only partially deployed the device to approximately 50% of its length and then resheathed and reused it for subsequent simulated interventions.

Image Acquisition and Display Setup

The main purpose of the study was to qualitatively evaluate the simulated clinical image sequences of PED deployment acquired using both FPD and Hi-Def modes of the new detector system. The image acquisitions were divided into the following 2 categories:

Deployment Image Sequences. First for a particular aneurysm geometry, a PED was partially deployed using a background (bone) subtracted roadmap and an unsubtracted (native) image guidance from 1 of the 2 detector modes (FPD or Hi-Def). The stent was then resheathed and repositioned to its initial location before deployment. Then, the PED was partially redeployed under road-mapping and native image guidance from the other detector mode. During clinical neurointeventions, the roadmap images and the native images complement each other and are displayed and viewed simultaneously. For comparison, the roadmap images along with the corresponding native images from 1 detector mode form a deployment image sequence.

For the same aneurysm geometry, the 2 deployment imaging sequences, 1 from each detector mode, are considered an image sequence pair.

For a total of 5 aneurysm geometries with 2 C-arm views per geometry (anteroposterior [frontal] and posteroanterior [lateral]), a total of 10 image-sequence pairs under fluoroscopy and 10 image pairs under digital angiography (DA) exposure conditions were obtained. On-line Fig 4 shows frames obtained from a sample image sequence pair acquired under fluoroscopic conditions, and On-line Fig 5 shows frames obtained from a sample image sequence pair acquired under DA conditions. On-line videos 1 and 2 show the PED deployment sequence acquired using Hi-Def and FPD modes, respectively, for the anatomy and exposure conditions presented in On-line Fig 5.

DSA Image Sequences. For a particular aneurysm geometry, with the PED partially deployed, DSA image sequences using the FPD and Hi-Def modes each were acquired. 80% iodine and 20% water were used as a contrast agent. Similar to the deployment image sequences, the bone-subtracted image along with the unsubtracted native image from 1 detector

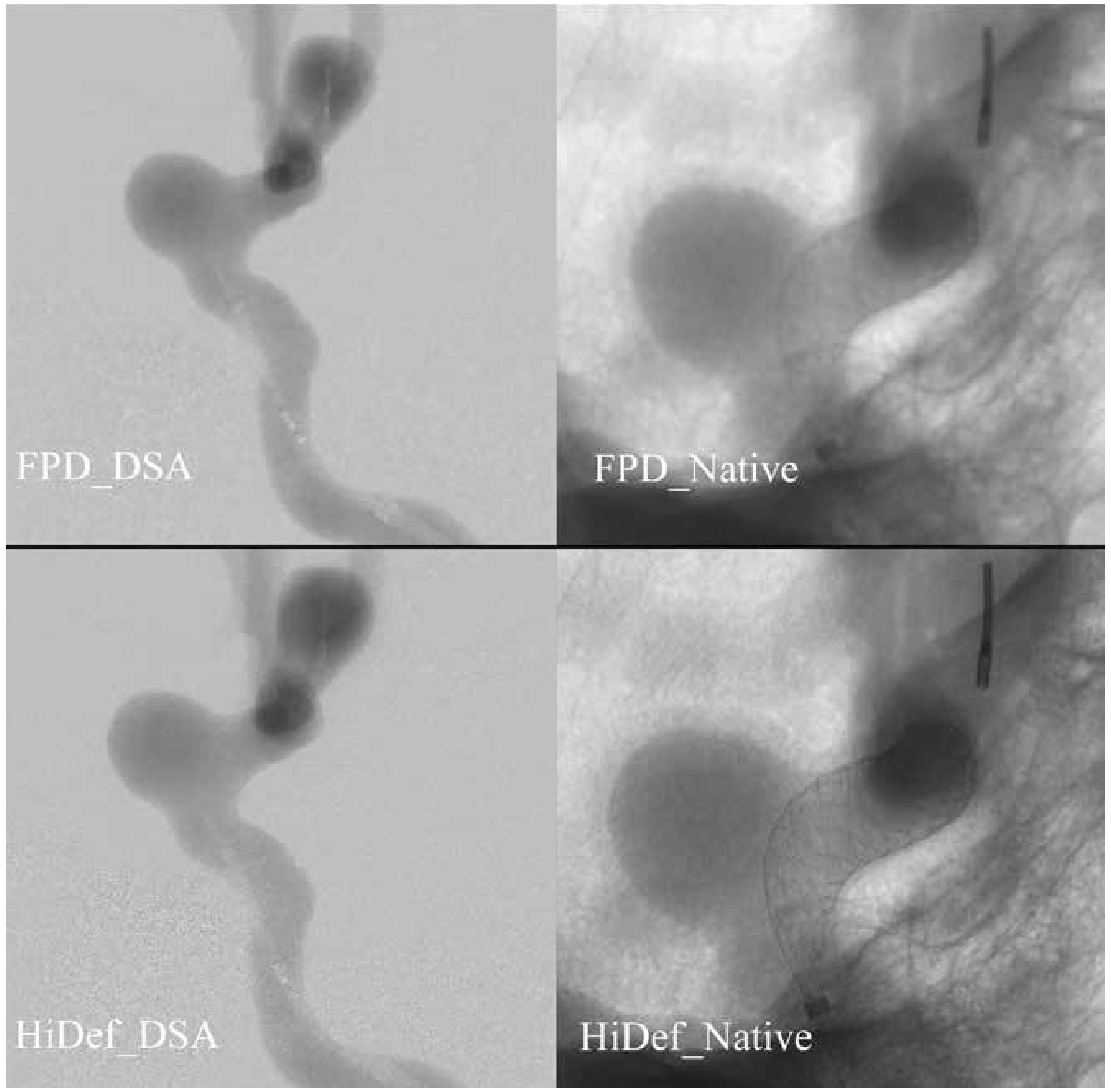


Figure 1: Sample single-image sequence pair acquired under DSA exposures. The average RP air kerma per frame for DSA was calculated to be 1.40 mGy for the FPD mode and 1.34 mGy for the Hi-Def mode. Due to more quanta reaching the detector, the image quality is improved for both the FPD and Hi-Def modes compared with On-line Fig 4 and On-line Fig 5. The amount of information available in the Hi-Def native image is higher than in the FPD native image. For the reader to appreciate the difference between Hi-Def and FPD images, especially the visualization of the stent, the native images are zoomed-in to the ROI showing the stent area.

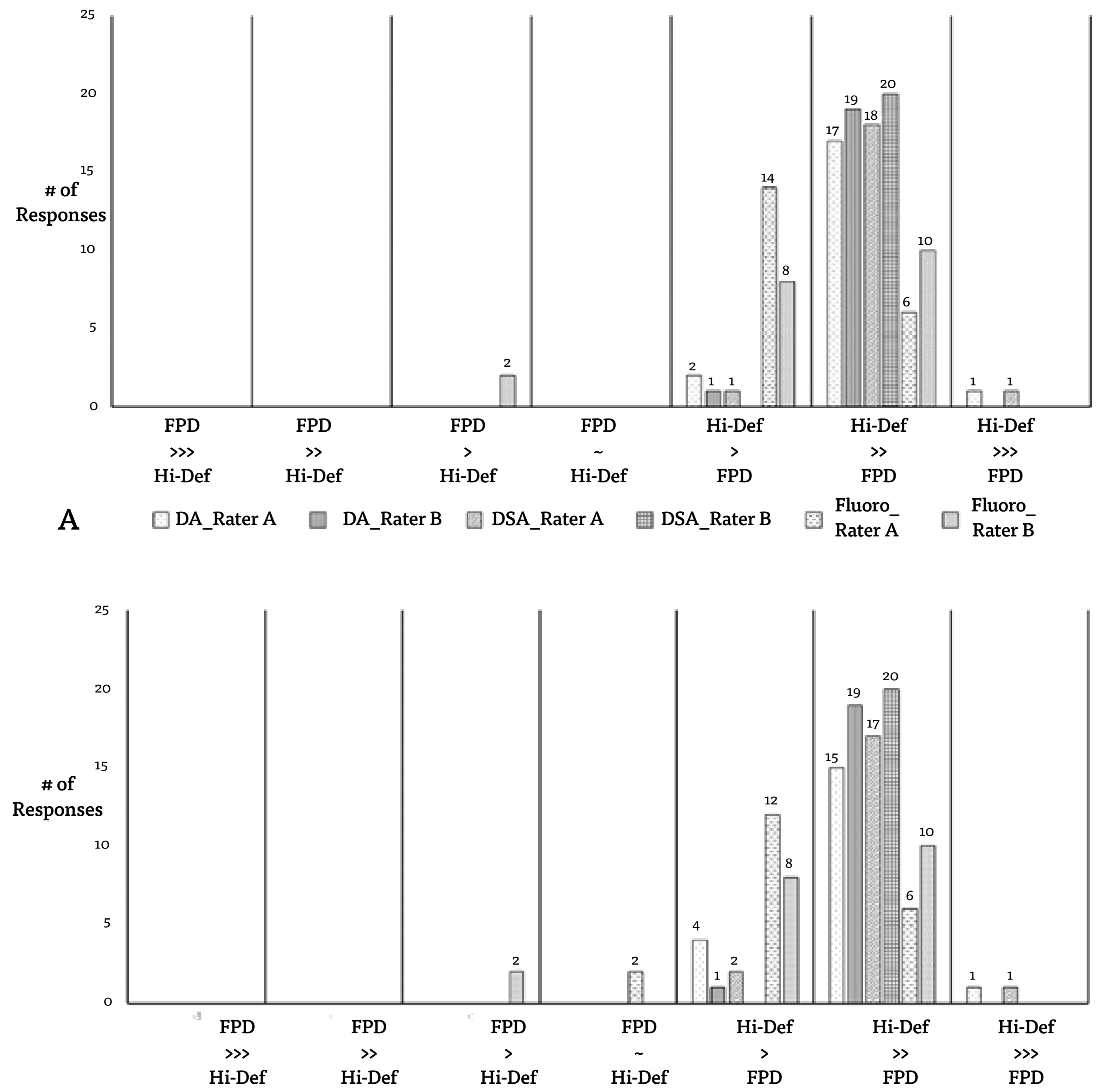


Figure2: Histogram distribution of rater-assigned scores (raters A and B) for all 5 aneurysm geometries, A, The first criterion: overall image preference in terms of visualization of anatomic features and image noise. B, The second criterion: visual quality of the stent for all 3 exposure modes: fluoroscopy (Fluoro), DA, and DSA. The raters were asked to score their image preference as either similar (~), better (>), much better (»), or substantially better (» >) than the other image.

formed a DSA image sequence. For the same aneurysm geometry, the 2 DSA image sequences, 1 from each detector, were considered an image-sequence pair.

Ten DSA image sequence pairs were obtained. Similar to On-line Fig 5 (and On-line Fig 4), Fig 1 shows a sample image-sequence pair acquired under DSA conditions.

A 0.3-mm focal spot size and an average geometric magnification of 1.2 were maintained for all the acquisitions. Within an image-sequence pair, the distance between the neurointervention phantom and the detector panel and the view angle (C-arm angle) were kept the same. The exposure conditions as determined by the automatic exposure control of the imaging system were also kept similar.

For each acquisition, by dividing the cumulative reference-point (RP) air kerma (reported by the angiography machine at a reference point 15 cm from the isocenter toward the X-ray source to approximate the patient entrance air kerma) by the number of frames in the acquisition, we calculated the reference point air kerma per frame. The average of the RP air kerma for both FPD and Hi-Def modes for fluoroscopy, DA, and DSA acquisitions is reported in the beginning of the Results section.

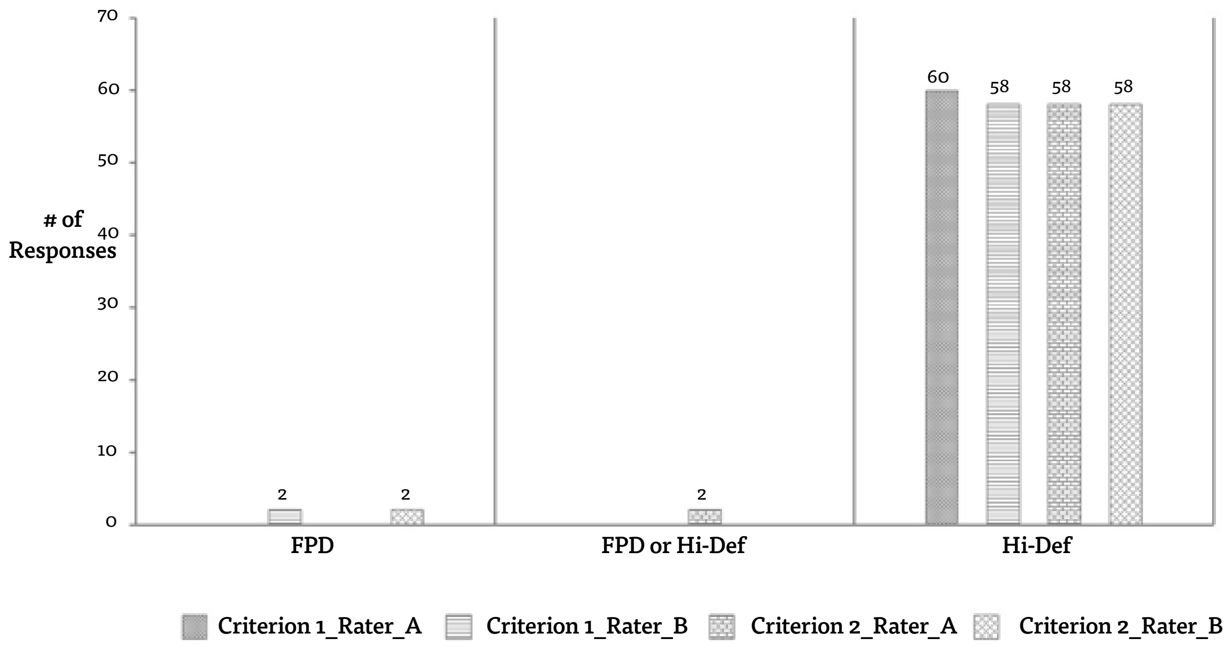


Figure3: Distribution of detector preference scores for 60 image sequence pairs (all 5 aneurysm geometries) for both criteria. On the basis of the rater-assigned scores (Fig 2), the detector from which the selected image was acquired was recorded as the preferred detector

Table 1:
Statistical test results—binomial exact CI test for intrarater agreementa[a]

Criteria	Rater-Assigned Scores							
	Interrater Agreement						1-Sample *T* Test	
	Rater 1			Rater 2			Rater 1 *P* Value	Rater 2 *P* Value
	P(agr)	95% LC	95% UC	*P*(agr)	95% LC	95% UC		
C1	.7	0.50	0.85	.83	0.65	0.94	<.001	<.001
C2	.56	0.37	0.75	.83	0.65	0.94	<.001	<.001

Note:—P(agr) indicates probability of agreement; LC, lower confidence; UC, upper confidence; C1, overall image preference in terms of visualization of anatomic features and image noise; C2, the visual quality of stent.
a: One-sample t test for analysis of the scores.

Table 2:
Statistical test results—binomial exact CI test for interrater agreementa[a]

Criteria	Detector-Preference Scores				
	Interrater Agreement			1-Sample *T* Test	
	P(agr)	95% LC	95% UC	Rater 1 *P* Value	Rater 2 *P*Value
C1	.96	0.82	0.99	<.001	<.001
C2	.9	0.73	0.97	<.001	<.001

Note:—P(agr) indicates probability of agreement; LC, lower confidence; UC, upper confidence; C1, overall image preference in terms of visualization of anatomic features and image noise; C2, the visual quality of stent.
a: One-sample t test for analysis of the scores.

Image-Quality Evaluation

For rater evaluation, 30 image sequence pairs were acquired, 10 in fluoroscopy, 10 in DA, and 10 in DSA. With each image-sequence pair repeated twice, 60 image-sequence pairs were presented to 2 experienced practicing neurointerventionalist raters. The raters were asked to select their preferred image sequence within a pair based on a comparison of the following 2 criteria—C1: overall image preference in terms of visualization of anatomic features and image noise and C2: the visual quality of the stent.

Different raters can perceive the difference between the images within a pair differently; thus, the raters were asked to score (rater-assigned scores) their selected image as either similar, better, much better, or substantially better than the other image. By means of this rater-assigned score, the detector from which the selected image was acquired was recorded as the preferred detector (detector-preference scores).

Image Display

Two display monitors with the same pixel resolution and similar brightness and contrast levels were used to display the image pairs. For a fair and unbiased comparison, the display monitor stations showing the Hi-Def and FPD images within an image sequence pair were not the same but were randomized for all the pairs and not made known to the raters.

The detector FOV between the FPD and Hi-Def modes was kept comparable, 6.3 × 6.3 cm in the FPD mode and 5.8 ×5.8 cm in the Hi-Def mode. The display brightness and contrast between the 2 image sets were adjusted to be similar to avoid any bias. The raters were also free to choose and adjust the display brightness and contrast for each image pair independently. For a fair image comparison, the image processing was kept similar for both Hi-Def and FPD modes.

Statistical Analysis

For each of the criteria, histogram analysis was performed on the rater-assigned scores as well as the detector-preference score. Intrarater agreement for the rater-assigned scores and interrater agreement for the detector-preference scores for each of the criteria were determined using the binomial exact confidence interval test. Assessment of the degree of agreement was based on the 95% upper confidence values (0–0.49 = poor, 0.50–0.74 = moderate, 0.75–1.0 = good). To establish statistical significance between the FPD and Hi-Def modes, we conducted a 1-sample t test on all rater-assigned scores and the detector preference scores for all criteria. For each of the criteria and all the image pairs, an assumption that both raters would select similar image quality between the 2 detector modes within an image pair was used as the null hypothesis. A P value < .05 was considered statistically significant.

Results

The average RP air kerma per frame for fluoroscopy was 0.02 mGy for the FPD mode and 0.03 mGy for the Hi-Def mode; for DA, it was 0.16 mGy for the FPD mode and 0.17 mGy for the Hi-Def mode; and for DSA, it was 1.40 mGy for the FPD mode and 1.34 mGy for the Hi-Def mode.

The histogram distribution of the rater-assigned scores for the 2 criteria for fluoroscopy, DA, and DSA exposures is presented in Fig 2. For fluoroscopic exposures, rater A selected the Hi-Def imagesas better than FPD images with a frequency of at least 60% for both criteria, whereas rater B selected the Hi-Def images as much better thanFPDimages with a frequency of50%for both criteria. For DA and DSA exposures, both raters selected the Hi-Def images as much better than FPD images with an average frequency of 90%.

Combining the rater-assigned scores for both criteria and all 3 exposure modes, both raters, on average, rated the Hi-Def images as much better than FPD images with a frequency of 73% for both criteria.

The distribution for the detector-preference scores is shown in Fig 3. In all 3 exposure modes for both criteria, both raters preferred Hi-Def images over FPD images with a frequency of at least 95%.

The results from the binomial exact CI test and 1-sample t test are summarized in Tables 1 and 2. For all criteria, both raters had good intrarater agreement and were consistent. From the detector-preference scores for each criterion, good interrater agreement was determined, further substantiating the results from Fig 3 that both raters generally preferred the Hi-Def images over the FPD images.

From the 1-sample t test for all rater-assigned scores and detector-preference scores for both criteria, a P value < .001 was calculated for both raters. This indicates that the null hypothesis assumption that the image quality of Hi-Def and FPD images is similar is wrong and statistically they are significantly different.

Discussion

The improvement in visualization due to use of a surgical microscope was one of the key reasons for its adoption during open craniotomies for treatment of vascular diseases such as brain aneurysms in the late 1960s and 1970s.[6] Similarly, the optimization of laparoscopic visualization has ushered in the standardization of minimalist approaches compared with major open laparotomy procedures during general urologic and gynecologic surgery.[7] Likewise, enhanced visualization during critical aspects of endovascular interventions, such as during microcatheterization and stent or coil deployment, directly impacts the safety and efficacy of neurointerventional procedures.

Previously, high-resolution fluoroscopy systems based on charge-couple devices[8] and complementary metal oxide semiconductors[9] were developed to provide improved imaging of the treatment area compared with existing FPD systems during neurovascular interventions. Successful use of the high-resolution fluoroscopy systems based on charge-couple devices during 2 clinical neurointerventional studies was reported.[10,11] In both cases, high-resolution fluoroscopy provided improved visualization of the endovascular devices. Another study[12] reported that the high-resolution fluoroscopy was particularly beneficial during the treatment of partially thrombosed aneurysms. However, the high-resolution fluoroscopy detector systems were separate from the FPD panels and were mounted on a mechanical changer. Whenever high-resolution imaging was needed, the high-resolution fluoroscopy was deployed into the active FOV using the changer system.

In the new detector system presented in this work, the higher resolution Hi-Def mode and the regular-resolution mode are available in 1 single unit and can be selected by an FOV switch, which gives it a distinct advantage over the high-resolution fluoroscopy systems. From On-line Fig 2, it can be seen that due to smaller pixel size, the high-resolution Hi-Def mode has a distinct advantage over the regular-resolution FPD mode and up to 5.6 line pairs/mm can be easily visualized. The aim of our study was to determine whether this added advantage provided by the Hi-Def mode can actually improve imaging of a treatment device such as a PED, a flow-diverter stent used for the treatment of intracranial aneurysms. When deployed, the PED induces a modification of blood flow within and around the inflow zone of an aneurysm that leads to gradual intra-aneurysmal thrombosis and subsequent atrophy, while preserving flow in the parent vessel and perforating branches.[13]

The subjective assessment of 2 comparable clinical images using image-quality rating scores is a standard practice and has been previously used to compare images from 2 different detectors such as comparing computed radiography with screen films[14] and in comparing selenium-based digital radiography with conventional film-screen (100-speed) radiography.[15]

From the detector-preference score distribution shown in Fig 3, both raters in good agreement (interrater agreement in Tables 1 and 2) preferred the Hi-Def images over the FPD images for both criteria. For both criteria, from the rater-assigned scores shown in Fig 2, it can be seen that in fluoroscopic exposures, both interventionalists, on average, rated the Hi-Def image quality as better compared with the FPD quality, whereas in DA and DSA exposures, they rated the Hi-Def image quality as much better compared with the FPD quality. This is consistent because the image SNR in DA is higher than in fluoroscopy, and in DSA, it is higher than in DA due to increased quanta reaching the detector. During an intervention, it is critical for interventionalists to have optimal visualization of devices such as stents and flow diverters to ascertain their placement along the course of the vessel, ensure proper deployment and wall apposition of the treatment device, and recognize impending kinking or twisting, which can result in unexpected complications.[16]

From On-line Fig 4 acquired in fluoroscopy-exposure conditions, it can be seen that due to higher spatial resolution, visualization of stent and other anatomic features is better in the Hi-Def mode compared with the regular FPD mode. When we compared On-line Fig 5 when the PED is deployed with DA with On-line Fig 4 for the same aneurysm geometry, it can be seen that due to higher quanta reaching the detector, while the image quality is improved in both FPD and Hi-Def images, the amount of information available in Hi-Def images, especially the visualization of the stent structure including the individual struts, is greater compared with the corresponding FPD image. Such information can be critical during the intervention because devices such as the PED place additional constraints on imaging technology because manipulations during deployment induce changes in the structure of the PED, which may affect treatment outcomes.

For instance, with the information provided in Hi-Def images in On-line Fig 5, one could selectively compress the device to preferentially increase its metal coverage over the aneurysm ostia to induce higher mesh attenuation, aiding occlusion without inducing compression over side branches and perforators, preventing the risk of branch occlusion and postprocedural stroke.[17,18] In the DSA exposure mode shown in Fig 1, the image quality in both FPD and Hi-Def images is further improved due to higher quanta; however, the information available in Hi-Def images is much higher than in the FPD images. During the deployment process, a DSA with contrast injection is performed to visualize the flow in the aneurysm and proximal and distal vasculature. With the information in Hi-Def images, one could visualize the flow not only inside the stent but also around the stent walls in places with poor stent-to-vessel wall apposition.

Furthermore, from the P values presented in Tables 1 and 2 for both the rater-assigned and detector-preference scores, it can be deduced that for all criteria, both raters concluded that PED images from the Hi-Def mode were significantly improved over those from the FPD mode.

Intracranial arteries range from 5 to <1 mm in diameter; and because the treatment devices are continually evolving to enable greater accuracy of treatment in such areas, the imaging technology should also evolve. Flow-diversion devices are being increasingly used for distally located aneurysms with smaller diameter parent arteries.[19,20] With the conventional FPD imaging systems, the images can be digitally interpolated to provide a zoomed-in view of the treatment area and devices when needed. However, the resulting image might still have poor resolution and lower image quality. In the new detector system, when a zoomed-in view is needed, the high-resolution Hi-Def mode can be turned on electronically. The results of the study show that the Hi-Def-mode images are significantly improved over the zoomed-in FPD mode. This improvement gives the new detector system a unique advantage over the conventional FPD systems.

The purpose of the study was to evaluate X-ray image quality of the new detector system during neurointerventional treatment. To that extent, the use of a 3D "patient-specific" printed model with appropriate X-ray attenuation simulation can offer a viable alternative to preclinical animal studies. With the advancement in 3D printing technology, an accurate replica of the human vasculature can be easily reproduced. Use of animal studies could provide more information about the actual treatment procedure, such as the biologic interaction of the treatment device and the blood vessels, but this is not within the scope of this work. In this study, we assumed that the treatment would be performed with the patient under general anesthesia, similar to treatment in the study of Nelson et al,[5] thus minimizing patient motion. In both FPD and Hi-Def modes at high image magnifications, significant patient motion could affect the visibility in background subtracted images due to mask misregistration. Studies involving other neurointerventional treatment devices such as coils, high-porosity stents, and balloons are currently being performed.

Conclusions

The Hi-Def mode of the new detector system is equivalent to a microscope that can be used during critical stages of the intervention when superior imaging over the magnified view of the treatment area and devices is required. Due to the high resolution of the Hi-Def mode, the images are sharper and visually preferred compared with the lower resolution images of the FPD. This is supported by the results of the comparative study presented. Neurointerventions may be performed with a greater degree of accuracy using the improved imaging provided by the new detector system. //

Disclosures:
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References

1 *Nickoloff EL. AAPM/RSNA physics tutorial for residents: physics of flat-panel fluoroscopy systems—survey of modern fluoroscopy imaging: flat-panel detectors versus image intensifiers and more. Radiographics 2011;31:591–602 doi:10.1148/rg.312105185 pmid:21415199CrossRefPubMedGoogle Scholar*
2 *Schropp L, Alyass NS, Wenzel A, et al. Validity of wax and acrylic as soft-tissue simulation materials used in in vitro radiographic studies. Dentomaxillofac Radiol 2012;41:686–90 doi:10.1259/dmfr/33467269 pmid:22933536Abstract/FREE Full TextGoogle Scholar*
3 *Ionita CN, Mokin M,Varble N, et al. Challenges and limitations of patient-specific vascular phantom fabrication using 3D Polyjet printing. Proc SPIE Int Soc Opt Eng 2014;9038:90380M doi:25300886 pmid:25300886CrossRefPubMedGoogle Scholar*
4 *Russ M, O'Hara R, Setlur Nagesh SV, et al. Treatment planning for image-guided neuro-vascular interventions using patient-specific 3D printed phantoms. Proc SPIE Int Soc Opt Eng 2015;9417 doi:10.1117/12.2081997 pmid:26778878CrossRefPubMedGoogle Scholar*
5 *Nelson PK, Lylyk P, Szikora I, et al. The Pipeline Embolization Device for the intracranial treatment of aneurysms trial. AJNR Am J Neuroradiol 2011;32:34–40 doi:10.3174/ajnr.A2421 pmid:21148256Abstract/FREE Full TextGoogle Scholar*
6 *Uluc K, Kujoth GC, Baskaya MK. Operating microscopes: past, present, and future. Neurosurg Focus 2009;27:E4 pmid:19722819PubMedGoogle Scholar*
7 *Rassweiler JJ, Teber D. Advances in laparoscopic surgery in urology. Nat Rev Urol 2016;13:387–99 doi:10.1038/nrurol.2016.70 pmid:27215426CrossRefPubMedGoogle Scholar*
8 *Jain A, Bednarek DR, Ionita C, et al. A theoretical and experimental evaluation of the microangiographic fluoroscope: a high-resolution region-of-interest X-ray imager. Med Phys 2011;38:4112–26 doi:10.1118/1.3599751 pmid:21859012CrossRefPubMedGoogle Scholar*
9 *Jain A, Bednarek DR, Rudin S. Experimental and theoretical performance analysis for a CMOS-based high-resolution image detector. Proc SPIE Int Soc Opt Eng 2014;9033:90333P doi:10.1117/12.2043053 pmid:25300571CrossRefPubMedGoogle Scholar*
10 *Kan P, Yashar P, Ionita CN, et al. Endovascular coil embolization of a very small ruptured aneurysm using a novel microangiographic technique: technical note. J Neurointerv Surg 2013;5:e2 doi:10.1136/neurintsurg-2011-010154 pmid:22266790Abstract/FREE Full TextGoogle Scholar*
11 *Binning MJ, Orion D, Yashar P, et al. Use of the microangiographic fluoroscope for coiling of intracranial aneurysms. Neurosurgery 2011;69:1131–38 doi:10.1227/NEU.0b013e3182299814 pmid:21694658CrossRefPubMedGoogle Scholar*
12 *Starke RM, Turk A, Ding D, et al. Technology developments in endovascular treatment of intracranial aneurysms. J Neurointerv Surg 2016;8:135–44 doi:10.1136/neurintsurg-2014-011475 pmid:25412618Abstract/FREE Full TextGoogle Scholar*
13 *Eller JL, Dumont TM, Sorkin GC, et al. The Pipeline embolization device for treatment of intracranial aneurysms. Expert Rev Med Devices 2014;11:137–50 doi:10.1586/17434440.2014.877188 pmid:24506298CrossRefPubMedGoogle Scholar*
14 *Swee RG, Gray JE, Beabout JW, et al. Screen-film versus computed radiography imaging of the hand: a direct comparison. AJR Am J Roentgenol 1997;168:539–42 doi:10.2214/ajr.168.2.9016243 pmid:9016243CrossRefPubMedGoogle Scholar*
15 *Piraino DW, Davros WJ, Lieber M, et al. Selenium-based digital radiography versus conventional film-screen radiography of the hands and feet: a subjective comparison. AJR Am J Roentgenol 1999;172:177–84 doi:10.2214/ajr.172.1.9888764 pmid:9888764CrossRefPubMedGoogle Scholar*
16 *Mitchell B, Jou LD, Mawad M. Retrieval of distorted Pipeline embolic device using snare-loop. J Vasc Interv Neurol 2014;7:1–4 pmid:25566333PubMedGoogle Scholar*
17 *Xiang J, Damiano RJ, Lin N, et al. High-fidelity virtual stenting: modeling of flow diverter deployment for hemodynamic characterization of complex intracranial aneurysms. J Neurosurg 2015;123:832–40 doi:10.3171/2014.11.JNS14497 pmid:26090829CrossRefPubMedGoogle Scholar*
18 *Shapiro M, Raz E, Becske T, et al. Variable porosity of the Pipeline embolization device in straight and curved vessels: a guide for optimal deployment strategy. AJNR Am J Neuroradiol 2014;35:727–33 doi:10.3174/ajnr.A3742 pmid:24072622Abstract/FREE Full TextGoogle Scholar*
19 *Nossek E, Zumofen DW, Setton A, et al. Treatment of distal anterior cerebral artery aneurysms with the Pipeline Embolization Device. J Clin Neurosci 2017;35:133–38 doi:10.1016/j.jocn.2016.10.041 pmid:27863970CrossRefPubMedGoogle Scholar*
20 *Puri AS, Massari F, Asai T, et al. Safety, efficacy, and short-term follow-up of the use of Pipeline Embolization Device in small (<2.5 mm) cerebral vessels for aneurysm treatment: single institution experience. Neuroradiology 2016;58:267–75 doi:10.1007/s00234-015-1630-5 pmid:26700827CrossRefPubMed*

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