SPECIAL

visions

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Interventional X-ray

Canon

// EDITORIAL

Dear Global Healthcare Partners,

Working with our partners allows us to resolve unmet clinical needs. Being part of strong and enduring partnerships is fundamental to our shared success in providing world-class healthcare solutions to clinicians and their patients. Nowhere is the benefit of these partnerships more evident than with the collaborative development programs we have with clinicians across the globe. One of the many great outcomes as a result of these collaborations was the launch of a hybrid solution, Angio CT. Our Angio CT (4D CT) seamlessly combined our pioneering flagship CT technology for outstanding diagnostic imaging with our best flexible interventional X-ray for surgery, into one pragmatic solution. This clinical concept allows diagnosis and treatment in only one room without moving the patient nor any triage. By doing so we provide clinicians a safer and better clinical workflow, resulting in better patient outcomes. The system was designed with a focus on the patient and supports all the clinical requirements.

Before I took the X-ray Systems Division General Manager role last April, I was deeply involved in development projects for over ten years, collaborating with key clinical research partners and forming cohesive clinical partnerships with medical societies. Above all, I gained an appreciation of how crossing institutional and organizational barriers is critical to success. We are very proud and excited to introduce "Alphenix", a completely new Interventional system which incorporates superior high-definition imaging technology, the first of its kind in the world.

Our vision is to develop technologies around the clinician's needs so that patients can receive better and safer treatment. We listened to you, our customer, as you challenged us to push the boundary of what can be done to evolve minimally-invasive diagnosis and treatment. Developments resulting from our shared vision has enabled clinicians using today's evolving therapy devices and technologies, to treat patients more effectively and in less time. Thanks to research partnerships with neuro interventionalists, we have made strides using Ultra-high Definition imaging to improve the treatment methodology and workflow, thereby enabling advanced safer treatment using combined multiple modalities effectively, while reducing radiation exposure and shortening the patient procedure time.

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 clinical magazine is to provide the Canon Medical Interventional user a forum to share your clinical voice, research cases and success stories. We hope to forge a deeper partnership based on the clinical relationship between our research partners, our technology staff, and those who use and appreciate our solutions.

Kind regards,

Izumi Watanabe
General Manager
X-ray Systems Division
Canon Medical Systems Corporation

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(Photo Credit: Doug Levere)

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

Experience using the New Alphenix Interventional System for Neuro-endovascular Therapy

Prof. Ichiro Nakahara was appointed as a Professor and Chairman in the Department of Comprehensive Strokology of the School of Medicine of Fujita Health University in 2016. He is recognized as one of the leading medical experts in Japan, and his areas of special expertise include general neurosurgery, the surgical treatment of cerebrovascular diseases, Neuroendovascular Intervention, and stroke care. Prof. Nakahara is also extremely active as a director or council member of a variety of medical congresses and plays a leading role in healthcare both inside and outside of Japan.

The Department of Comprehensive Stroke is a new department established in April 2016 at Fujita Health University Hospital. Previously, our approach to the care of hemorrhagic stroke patients was direct surgery performed by the Department of Neurosurgery, along with medical treatment provided by the Department of Neurology. However, due to the emergence of neuroendovascular therapy treatments (i.e., catheter-based therapeutic procedures), the need for a new approach that integrates seamless and precise craniotomy, neuroendovascular, and medical therapy into stroke care. In considering this vision, the new department was established with the objective of providing comprehensive stroke care to our patients.

Fujita Health University Hospital currently performs 200 to 250 neuroendovascular procedures each year, and approximately the same number of open neurovascular surgeries. Although we could perform a larger number of neuroendovascular procedures, the volumes are nearly the same due to consideration in evaluating and prioritizing the best treatment option for these different therapeutic approaches.

Fujita Health University Hospital

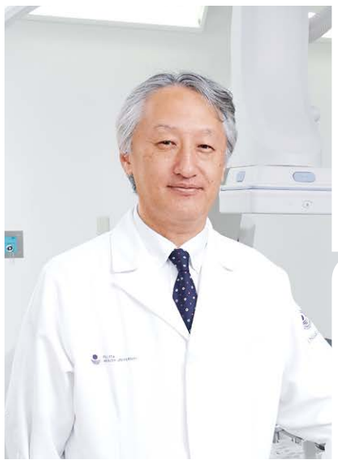
Critical Requirements for an Angiography System

Our most important requirement in considering a new angiography system is the ability to clearly visualize vessels and the tissues around vessels in both fluoroscopy and radiography. In addition, a sufficient range of functions are needed to support effective treatment, such as the growing importance of catheter-based procedures in current stroke care. Specifically, for 3D Angiography and the associated integrated workstations, as well as the various software applications supporting catheter-based procedures are considered essential.

However, we previously have encountered cases in which the conventional angiography system was unable to provide adequate fluoroscopic, radiographic, or 3D images of sufficient high quality. For example, halation has been often observed near the area where a direct X-ray beam enters, making it difficult to assess accurate information concerning the extracranial vessels and skull base. We also felt that there was a need for further improvement in the functionality of cone beam CT technology.

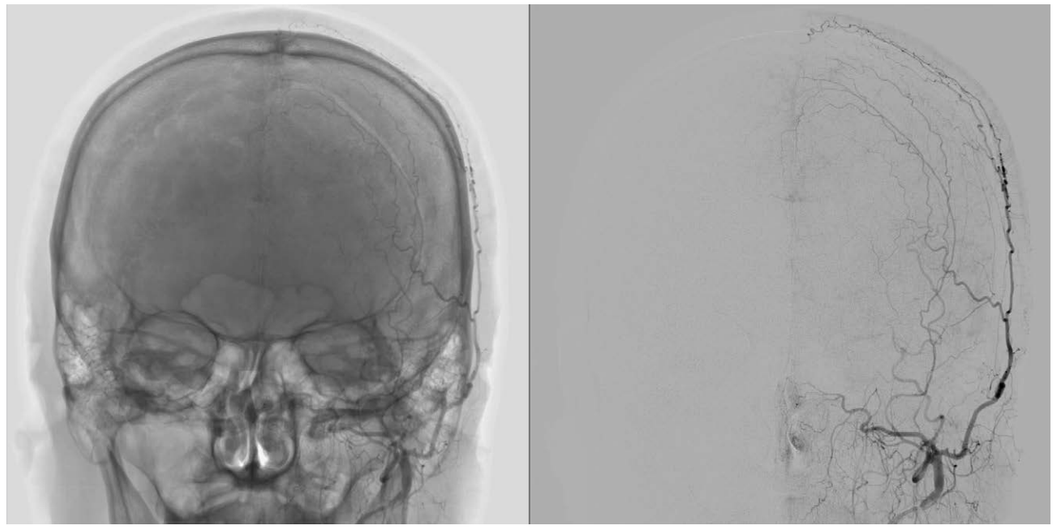
Features of the Alphenix System

The Alphenix system has been introduced to the market as a new angiography system driven by clinical needs and a development process focused on addressing and overcoming the above mentioned clinical limitations. Now with the detailed imaging information being provided, the necessary preciseness for proper clinical treatment of stroke can easily be attained.



Prof. Ichiro Nakahara

"During neurovascular therapy being able to see the intricate details in anatomy, and access devices gives us the confidence to quickly and better treat our patients with less chance of complications."

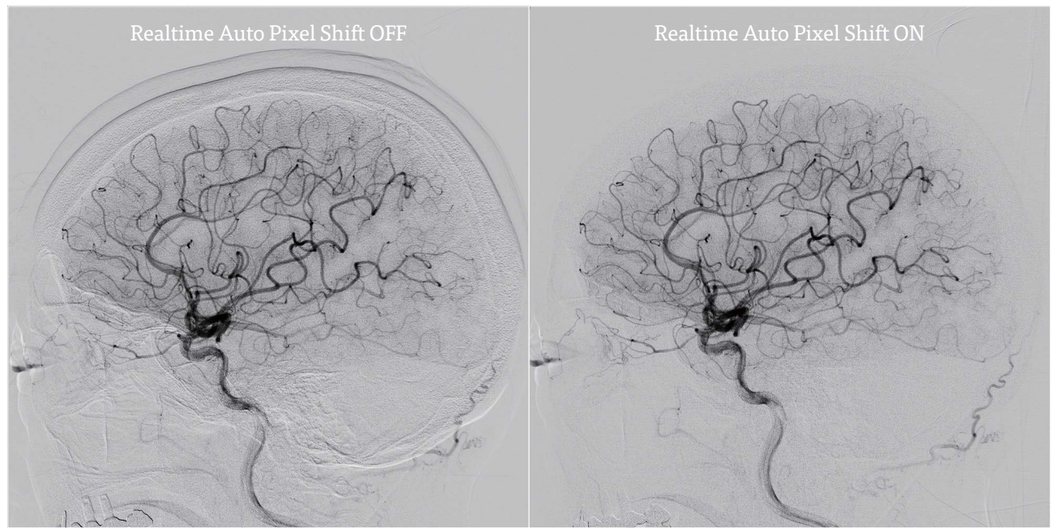


External Carotid Artery images.
Halation is not observed near the area where a direct X-ray beam enters, even without a compensation filter.

We are strongly confident that the Alphenix system can be utilized for all varieties of neuroendovascular procedures at a wide range of medical institutions around the world.

(1) Fluoroscopy/Radiography

When using fluoroscopy on the Alphenix system, you notice the enhanced contrast in fluoroscopic images of the skull base. This makes it easier to clearly observe the precise movements needed to gain catheter access to tortuous vessel anatomy, the treatment zone, and the deployment behavior of the stent. Being able to visualize each platinum marker during the intracranial placement of flow-diverter stents can also be performed with greater confidence and ease. One of the useful features of this system is the advanced Auto-Pixel Shift function. The system instantly detects even the slightest patient movements and performs real-time pixel shifting to provide optimized subtraction images. This eliminates the time needed for the technologist to manually adjust the images, allowing the operating staff to focus on patient care, minimize surgical time, reduce complications, or to prepare for the next procedure immediately after the acquisition is completed.

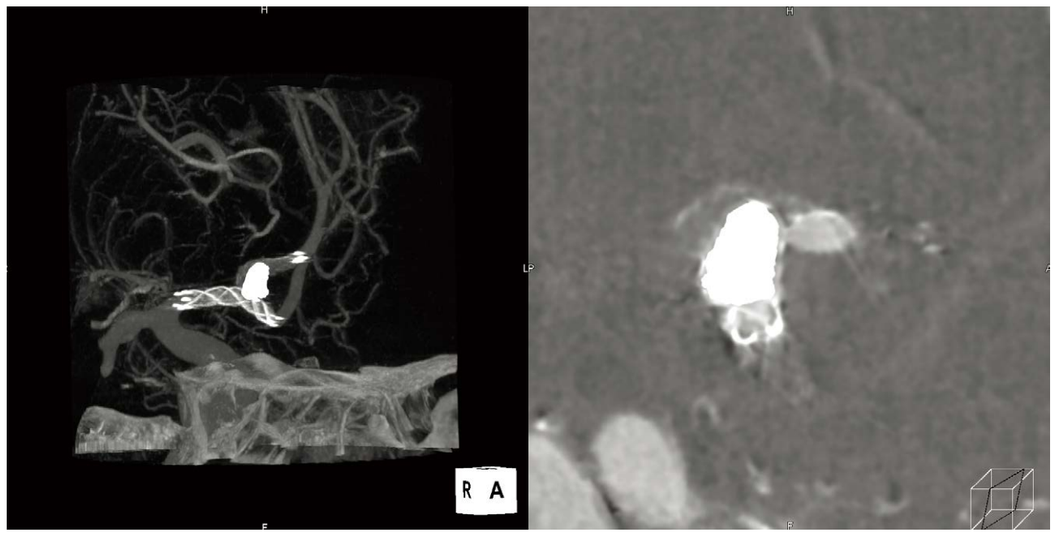


Effects of Realtime Auto Pixel Shift

One of the Biplane system at the Fujita Health University Hospital.

(2) 3D / Cone-Beam CT

Cone-beam CT technology plays a very important role in current neuroendovascular therapy. There is great need for a sophisticated cone-beam CT system with smart features for confirming precise stent placement and vessel wall apposition, as well as for observing fine perforator vessel anatomy.
The current functional capabilities of cone-beam CT in conventional systems are considered inadequate for confirming the absence of intracranial hemorrhages during post treatment. However, thanks to the enhanced diagnostic performance of the Alphenix system, the presence or absence of a intracranial hemorrhage after treatment can be determined using our cone-beam CT function known as Alpha CT, which is currently in use at our facility. The most remarkable feature of Alpha CT is its capability to eliminate metal artifacts. When imaging a vessel in which endovascular coils have been placed, the artifacts caused by the coil elements can be eliminated, allowing the deployed stent placed in the vessel to be clearly visualized. In addition, images are generated at a higher speed, making it conveniently possible to quickly determine the current treatment status and proceed to the next step of the therapeutic procedure.



Alpha CT eliminates Metal artifact

Ichiro Nakahara, Professor and Chairman, Department of Comprehensive Strokology, School of Medicine, Fujita Health University.
After graduating from the School of Medicine of Tokyo Medical and Dental University in 1983, Prof. Nakahara earned a Ph.D. from Kyoto University and specializes in the surgical treatment of cerebrovascular diseases, Neuroendovascular intervention, and stroke care as a practicing neurosurgeon.
In 1990, he studied at Massachusetts General Hospital, which is affiliated with Harvard Medical School. After holding key positions at Kyoto University, the National Cerebral and Cardiovascular Center, and Kokura Memorial Hospital, he was appointed as a professor in the Department of Neurosurgery of the School of Medicine of Fujita Health University in 2015, assuming his current position in 2016. Prof. Nakahara has published many papers in the field of Neuroendovascular treatment. He is also actively involved as a director or council member of a variety of congresses and is a leader in clinical healthcare in Japan as a supervising physician. His contributions are widely recognized both inside and outside of Japan.

(3) Flexible Operability

In neuroendovascular procedures, it is very important to set the appropriate working angle and to make use of the roadmapping function. In the Alphenix system, the working angle can easily be set from the 3D image in a single operation. In addition, a roadmap overlay can be generated instantly, as well a function for automatically generating the optimal mask image is also available. These functions are extremely effective, significantly reducing the clinical case workload on the operator as well as the time required for the therapeutic procedure.

Assessment of the Alphenix system

I believe the most prominent and purposeful Alphenix system feature is its ability to provide superior neuro anatomical fluoroscopic images of regions that are critical for ensuring precise treatment and accurate diagnosis. Due to the 3D-related limitations of conventional systems being deemed un satisfactory, we have been using a single-plane systems from other manufacturers instead.
However, now having experienced the Alphenix system in our clinical neuroendovascular treatment cases, it has since become our first choice. I have come to appreciate the fully-featured effectiveness of the Alphenix system, and I believe the same would be true for many other physicians who perform neuroendovascular procedures. Given the great technological advances in neuroendovascular therapy and the intricate devices, the requirements for an angiography systems technology must also evolve.
Angiography systems are not limited to use in the field of neurosurgery, but are often used in the field of cardiology and interventional radiology as well. We hope that angiography systems will continue to clinically evolve in parallel with the future progress of neurosurgical treatment and neuroendovascular procedures. Throughout the technical development process of the Alphenix system, I have contributed my clinical feedback and unbiased suggestions to help make critical feature improvements to the previous conventional system. The Canon Medical development and clinical applications teams took my feedback and suggested improvements from a clinical operator perspective very seriously. I believe that their sincere and responsive attitude has led to the developmental success of such a new intuitively dynamic and robust system. //

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

Professor Adnan Siddiqui

The increased use of minimally invasive techniques for the treatment of hemorrhagic stroke, such as intracranial aneurysms and arteriovenous malformations (AVMs), has steadily increased worldwide over the years due to various underlying benefits. New breakthroughs in cerebrovascular treatment devices, necessitates advanced imaging technologies for safer and more accurate deployment.
For over a decade, our collaborative scientific, and clinical partnership with Canon Medical Systems (previously Toshiba Medical Systems) contributed to the core Hi-Def technology designed for neurointerventional therapies, and was recently piloted at the Gates Vascular Institute (GVI).

University of Buffalo Neurosurgery (UBNS) at Gates Vascular Institute *(Photo Credit: Doug Levere)*

CANON STROKE & VASCULAR RESEARCH CENTER
UNIVERSITY AT BUFFALO

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

(Photo Credit: Kaleida Health)

Clinical and Industry collaborative partnering

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

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

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

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

What is Hi-Def?

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

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

Hi-Def Technology Evaluation:

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

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

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

Live Visualization of Pipeline™ Embolization Device (PED)

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

An image pair consisting of a Hi-Def image and FPD image of the same PED object, FOV and exposure conditions were acquired using the setup described above. A total of 10 different image pairs were obtained by changing PED's of different sizes, configurations and its positions in the 3D printed neuro-vasculature placed within the skull.

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

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

Conclusions:

Due to the higher resolution of the Hi-Def technology, images are sharper, and hence are visually improved compared to the images of the FPD. This is supported by the positive results of the comparative physician observer preference study presented here. These results suggest that the improved imaging provided by the HRF can provide an advantage during neurointerventions. The new detector having both Hi-Def and FPD modes can offer an advantage in the clinical setting compared to the existing conventional commercial FPD-only detector systems used in typical interventions.

Why Hi-Def?

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

Dr. Siddiqui mentioned in a recent interview

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

Figure 4a

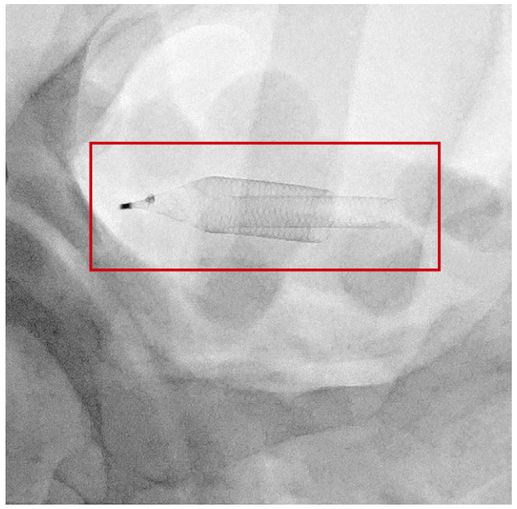


Figure 4a

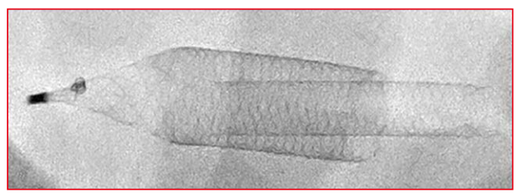


Figure 4b

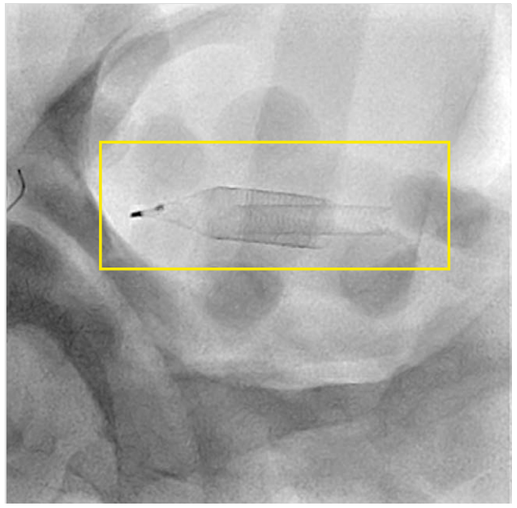


Figure 4b

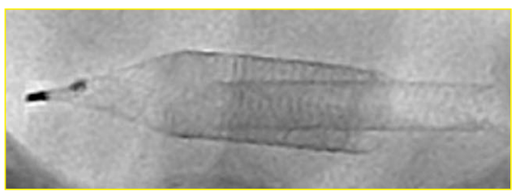


Figure 4: Sample image pairs presented to the neuro-interventionalist for a qualitative image comparison study. A-Hi-Def image, B - FPD images. The images are presented at their native resolution (1024 x 1024 pixels each). For the reader to appreciate the difference between the Hi-Def and the FPD, the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

Figure 5a

Figure 5a

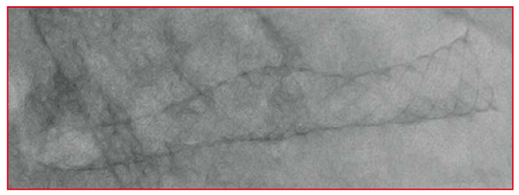


Figure 5b

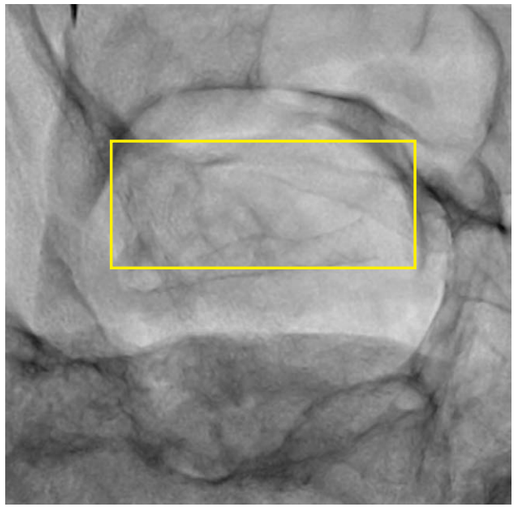


Figure 5b

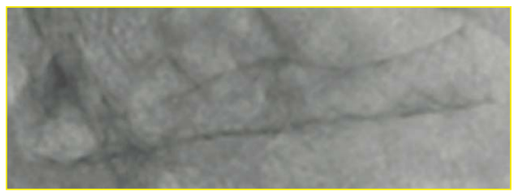


Figure 5: Sample image pairs presented to the neuro-interventionalist for a qualitative image comparison study. A-Hi-Def image, B- FPD images. The images are presented at their native resolution (1024 x 1024 pixels each). For the reader to appreciate the difference between the Hi-Def and the FPD, the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

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

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

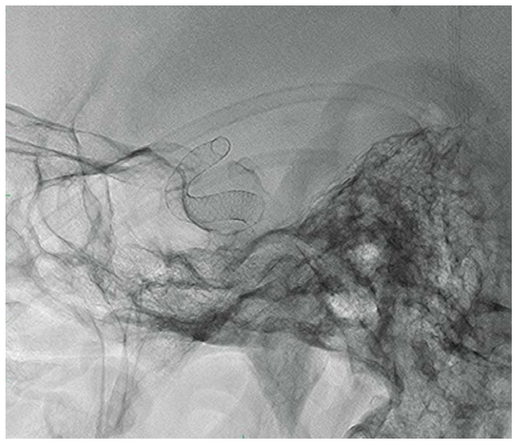
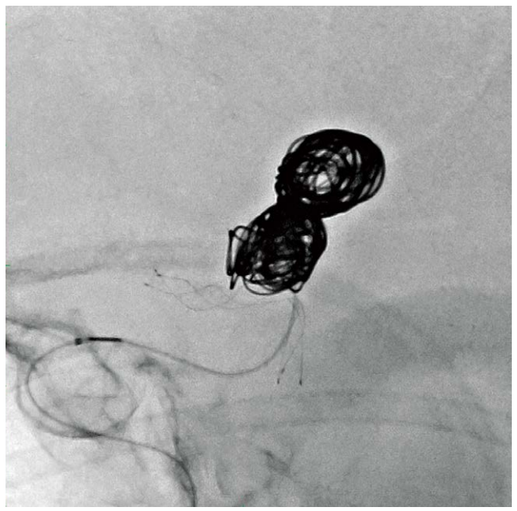
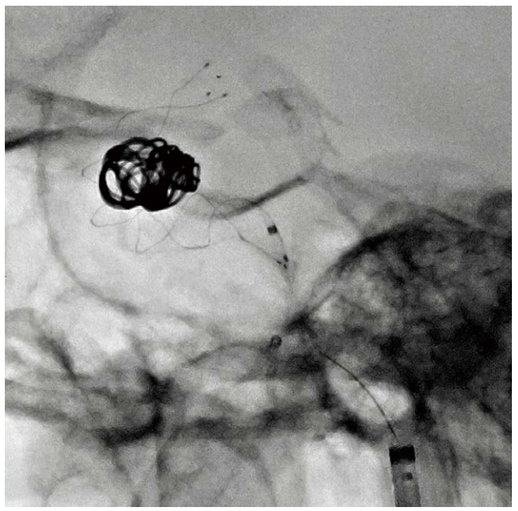


Image of Hi-Def: Pipeline Stent





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

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

Hi Def vs. Exposure:

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

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

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

Hi-Def's Future in Neurointervention:

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

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

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VISIONS spoke with Prof. Gangi, Dr. Garnon, Mr. Gautier and Mr. Gigleux, from the University Hospital Strasbourg, about their experiences with the Infinix-i 4D CT and Ultrasound system Aplio i800.

Expanding horizons in Interventional Oncology in a state-of-the-art Angio-CT environment

Since the installation of the Infinix-i 4D CT and Aplio i800 ultrasound system in last November, the University Hospital Strasbourg has been able to expand its research program in Interventional Radiology with several advanced techniques that could bring about major changes in the discipline.

The University Hospital of Strasbourg is one of the most prestigious University Hospitals in Europe. Affiliated to the University of Strasbourg, it forms part of a medical technologies campus with growing expertise in R&D using cutting-edge technologies in healthcare. The Hospital employs more than 12,000 people, including 3,000 physicians and leads groundbreaking global research in several disciplines, including transplantation, minimally-invasive surgery, Immunology and Interventional Radiology.

An emerging world-class specialist facility

The Radiology Department's highly specialized Interventional Imaging Service has grown steadily since 2011.

"Interventional Radiology is of crucial importance for our University Hospital for several reasons, and we have invested significantly in this field," remarked Mr. Gautier, General Manager of the Hospital. "Most importantly, it brings numerous benefits to our patients. It drastically improves the treatment of specific tumors, patients benefit from less invasive procedures, with improved outcomes and shorter hospitalization and it has also proved useful in pain treatments."

Led by Prof. Gangi, Head of Interventional Radiology, and Chairman of the Radiology and Nuclear Medicine Department, the large Interventional Radiology Department has grown in recent years and is currently staffed by nine Interventional Radiologists and 10 Radiology Technicians.

"Thanks to the dedication of Prof. Gangi and his Team to our patients, and to their research interests, the University Hospital has established an outstanding reputation in Interventional Radiology, at national- and international levels," continued Mr. Gautier.

"High-quality true CT scanning during a complex intervention is key for us."

Prof. Gangi - University Hospital Strasbourg.

"We are very proud indeed of their technical and medical accomplishments."

This skilled team carry out hundreds of interventional procedures every year (including spinal injections, biopsies, TACE, cementoplasty, ablation and embolization) using a range of imaging equipment based in three dedicated Interventional Radiology rooms. Alongside rooms housing an interventional MR and a C-arm based system with cone-beam CT capability, the latest suite to be added is equipped with an Infinix-i 4D CT and Aplio i800 ultrasound system from Canon Medical Systems.

The Radiology Team chose these systems specifically to increase the range of Interventional Radiology procedures possible at the Department, as well as reduce patient waiting-time.

Groundbreaking concept

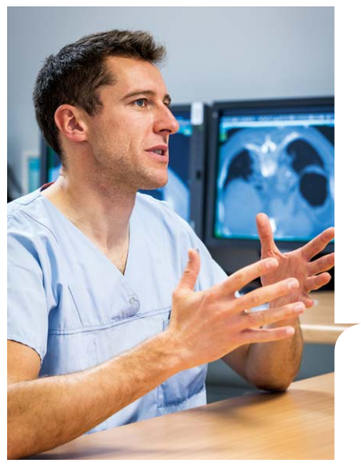
"We were one of the first research institutes in the world to combine fluoroscopy and CT modalities in the same room," said Prof. Gangi. "When I was a Resident Radiologist back in 1990, I could already see the advantage of placing a mobile C-arm in front of the CT-scanner. At first, people questioned what it could bring, but it proved so successful in imaging that it eventually became a new concept, and was ultimately adopted commercially by Canon Medical Systems."

The Hospital's Interventional Imaging Service performs an increasing range of interventional procedures ranging from simple infiltration to complex therapeutic treatments, sometimes combined with surgery.

When it came to creating an additional Interventional Radiology suite to provide the resources to keep up with growing demand for new imaging services, the Hospital turned to Canon Medical Systems for a solution.

A uniquely integrated solution

"The Infinix-i 4D CT combines two different imaging modalities within the same environment, which will allow us to treat new medical indications in the different fields with pioneering Interventional Radiology techniques," said Mr. Gautier.



Dr. Garnon - University Hospital Strasbourg.

"We are convinced that installing this high-level CT system will help us reach our main goal, which is to continuously enhance the quality and safety of the healthcare that we offer to our patients."

"We chose the Infinix-i 4D CT initially on the basis of the exceptionally high-quality CT scanning that is possible with the system. It is key for us. It's the heart of the system," added Prof. Gangi. "There are not many systems as mature as the Infinix-i 4D CT available on the market. Both angio and CT modalities communicate and work together, enabling our Interventional Radiologists to use them with maximum ease-of-use. They can move from one system to another without any steps. A seamless combination of top CT scan and high-end level angiogram: an ideal option for us."

The new equipment replaced a 128-slice CT system and a mobile C-arm. Installation of the Infinix-i 4D CT and the Aplio i800 ultrasound system was carried out in collaboration with the Canon Medical Systems project management team. Installation of the new imaging suite required considerable planning.

"When we decided to change our CT-suite, we were hoping to achieve many objectives: to improve the quality of our CT-imaging; to combine high-quality fluoroscopy and CT; to optimize ease-of-use and versatility in one machine; to reduce radiation significantly; and to support new procedures," said Dr. Garnon, Interventional Radiologist at the Hospital. "The new system meets all of these needs."

"The range of possibilities is huge."

Radiology Team at the University Hospital Strasbourg.

Mr. Gautier – General Director University Hospital Strasbourg.

> *"Infinix-i 4D CT will help us to improve patient outcomes and shorten hospitalization time."*

"Given the context of our expanding research, we realized that replacing our mobile C-arm with a motorized ceiling-suspended C-arm with Flat Panel Detector, would allow us to push our current limits, cover new indications and enable us to perform complex vascular-, as well as percutaneous procedures," said Mr. Gigleux, Biomedical Engineer. "Our choice focused on the Infinix-i 4D CT, because of its versatility. In addition to the advantages of the C-arm in interventional work, the system offers great flexibility, for example, the C-arm can assume a dedicated parking position for procedures that require use of the CT only."

Combining two modalities in one room

Previously, the Interventional Radiology Team used to carry out angiographs in one room, and then moved the patient into a second room for the CT. This step is no longer necessary with the higher quality Infinix-i 4D CT.

"The implementation of the solution combining two modalities in a single room was one of the first points that we studied together with Canon Medical Systems project management team when installing the system," said Mr. Gigleux. "Implementation of the project was quite complex, but the collaboration between the Hospital's technical teams, the various sub-contractors and the entire Canon Medical Systems Team was excellent."

"As the modalities are combined in one system with the Infinix-i 4D CT, many procedures that we were previously performed in two steps can now be completed in one," remarked Prof. Gangi. "The system will not only improve the quality and safety of our standard Interventional Radiology procedures, but will increase the number of indications that we are able to treat."

Infinix-i 4D CT with Aplio i800.

"Our work includes vascular- and percutaneous interventions, and our Team includes specialists in these techniques. In many cases, the procedures are performed separately, but when both approaches are required, we can work together, side-by-side, with the new system. The Infinix-i 4D CT clearly offers new perspectives in combined therapies and enables us to perform much more complex procedures in this field," added Dr. Garnon.

Infinix-i 4D CT: State-of-the-Art in CT

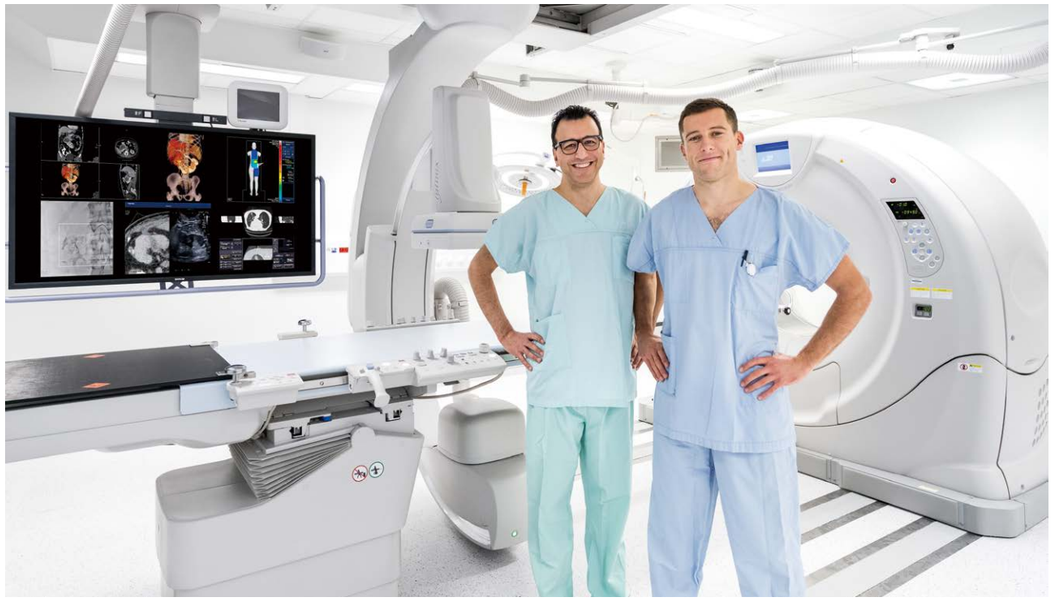
"There are plenty of new possibilities on the horizon," said Prof. Gangi. "We plan to introduce real, combined procedures, including angiographic-, percutaneous- and surgical procedures. So, we'll have specialists from three disciplines working together in the same room. This is what will make the difference: the ability to perform multi-modality, multi-discliplinary, interventional procedures."

The advanced CT imaging and fluoroscopy capabilities of the Infinix-i 4D CT will enable the team to combine procedures, such as ablation and embolization, or ablation and bone consolidation, alongside use for more regular Interventional Radiology procedures.

"We want to perform true hybrid interventions, which involve Interventional Radiology, but also other specialties, such as surgery, pneumology, or others, depending upon the case," said Dr. Garnon. "The range of possibilities is huge: image-guided coelioscopy, real-time image-guided fibroscopic biopsies, and potentially many other applications. The goal is to overcome the limitations of each technique by combining everything together."

Aplio i800: The ultimate in ultrasound

Along with the Infinix-i 4D CT, the new Interventional Radiology suite at the Hospital is equipped with an Aplio i800 ultrasound system from Canon Medical Systems.
Prof. Gangi and his team are impressed with the image quality of this additional system and the potential new options that it brings to complex Interventional Radiology work.



Prof. Gangi and Dr. Garnon.

Mr. Gigleux - Biomedical Engineer University Hospital Strasbourg.

"Complex implementation requires excellent collaboration with a partner."

"As someone who didn't believe much previously in ultrasound when I was younger, I have to admit that I have been impressed by the huge amount of progress made in ultrasound over the last three- or four years. Today, the diffusion capabilities with ultrasound are substantial.

We cannot now carry out interventional procedures without a high-end ultrasound in the room," he said. "The quality of the Aplio i800 is so good. Despite not really using much ultrasound previously, I am now happy to have the Aplio i800 nearby the CT- and angio systems. It gives me a lot of confidence - the ultrasound is a really important part of the suite."

"The Aplio i800 is a game-changer in ultrasound guidance. The image quality is really incredible and the system includes features that are perfectly suited to Interventional Radiology, such as dedicated micro-convex probes, fusion imaging, and needle-tracking," added Dr. Garnon. "With the help of fusion and small probes, we can perform procedures that were previously not thought to be within the scope of ultrasound-guidance, including some lung biopsies, mediastinal biopsies, and even selected bone biopsies. Liver ablation capabilities are definitely improved with the Aplio i800, as the optimal approach can be selected with fusion, and the quality of ablation can be checked with contrast. Pre- and post ablation images can be compared to ensure that safety margins have been included with ultrasound fusion."

Expanding research horizons

Combining the outstanding capabilities of the Aplio i800 and Infinix-i 4D CT has potential for application in other organs, such as kidney and soft-tissues.

"Used alone, the Aplio i800 is of great value, but in combination with use of the Infinix-i 4D CT, is, of course, even better. By combining the high contrast quality of the ultrasound system with the high-precision 3D of CT, the optimal approach to treating target lesions in liver or soft-tissues could be chosen to ensure with 100% confidence that ablation with safety margins have been completed in all directions," said Dr. Garnon.

"For kidney and bone there is still much progress to make in applications using the two modalities," added Prof. Gangi. "There are still many challenges to overcome with multi-modality, multi-disciplinary approaches, but with the new systems in place, the potential of these techniques looks very promising."

Supporting advances in Interventional Radiology Faced with the challenge of an increase in patient throughput of approximately 18-20% each year, Prof. Gangi and his team are certain that the investment in the Infinix-i 4D CT and Aplio i800 will help them to make significant progress.

"I believe ultimately that we can advance Interventional Oncology with the Infinix-i 4D CT," said Dr. Garnon. "It should help us to reduce the waiting time for an intervention, whatever the procedure is. And that's a critical point when dealing with patients, especially in Oncology."

"I have collaborated with Canon Medical Systems for many years and my experience has always been very positive," said Prof. Gangi. "With the installation of the Infinix-i 4D CT and Aplio i800, we are able to develop something very new in our department. I am fully confident that the dynamic of our team and that of Canon Medical Systems, our continued collaboration and the accumulation of knowledge and expertise, will ensure that this is a success."

"We are extremely proud to have acquired an Infinix-i 4D CT," said Mr. Gautier. "Only three other hospitals in Europe currently benefit from this technology. The system helps to confirm our position at the forefront of Interventional Radiology." //

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Prof. Yasuaki Arai
Executive Advisor to the President
Interventional Radiology Center
Department of Diagnostic Radiology
National Cancer Center Hospital

Prof. Yasuaki Arai is a leading interventional radiologist in Japan and is the pioneer and expert of Angio CT technology who has also developed several new techniques and other breakthroughs in medical devices over the years.
In addition he is the founder of the Japan Interventional Radiology in Oncology Study Group (JIVROSG), which gathers and analyzes clinical evidence in the field of interventional radiology. In 2017, he was honored by being named a Distinguished Fellow of the Cardiovascular and Interventional Radiological Society of Europe (CIRSE).
Prof. Arai is widely recognized as a medical expert both inside and outside of Japan, and he is frequently invited to speak at seminars at more than 30 international academic conferences annually. He also plays an instrumental role in supporting the Ministry of Health, Labour and Welfare of Japan in the development and approval of safety requirements for medical devices.

Expanding Use of Interventional Radiology in Clinical Practice

The National Cancer Center, which is one of the National Centers for Advanced and Specialized Medical Care, serves as a hub for cancer treatment and research as a member of the National Research and Development Agency of Japan. Its mission is to provide clinical care, conduct research, promote technological development, oversee clinical trials, perform investigations, formulate policy proposals, foster human resources, and issue accurate information concerning cancer and malignant tumors.

In the first five years of my career as a physician, I focused on the field of internal medicine. At that time, the medical treatment for patients with cancer was solely chemotherapy. In many cases, survival rates were not as high as today. I feel fortunate to be skilled in very intricate procedures, therefore I have made extra effort in ways to help patients using catheter-based interventional methods.

A major turning point in my Interventional Radiology career was when I was transitioning to a new hospital, I was unexpectedly assigned to the radiology department, rather than staying in my field, further improving my internal medicine skillset. Around the same time Interventional Radiology (IR) was introduced and evolving in Japan, I had come to the realization what I had been seeking to pursue and achieve was in the field of IR specialty itself. This is how I ended up specializing in IR. I have always sought to challenge myself and achieve new things that have never been done before, or considered impossible in medicine, therefore my strong desire was a new field that offered many new challenges to be faced.

Development of the first Angio CT

When I started IR, various types of diagnostic imaging equipment, including X-ray angiography, ultrasound, MRI, and CT systems were already heavily used in many fields. IR procedures were performed and used in various imaging combinations relative to each clinical case setting. The imaging systems and therapeutic devices used in those early days were not as sophisticated and available today, however the basic concept of IR has not changed much in the current environment where Angio CT is available.
In the 1980s, Professor Osamu Matsui (present Professor Emeritus) of Kanazawa University, demonstrated the effectiveness of selective contrast CT imaging for the diagnosis of hepatoma. As a result, CT imaging during angiography became indispensable for accurate diagnosis, treatment planning and the evaluation of therapeutic outcomes in patients with hepatoma. This allowed me to truly appreciate the clinical value of Angio CT.

"At that time, angiography systems and CT scanners were installed in separate rooms, but I always wished that I could perform angiography and CT in the same room. I talked with a number of companies, including Toshiba Medical Corporation (present Canon Medical Systems Corporation) to see if they would be able to produce an Angio CT. At that time, only Toshiba Medical took my idea seriously, considering such an unusual request. As a result, the very first Angio CT was introduced in 1992 which was only two years after the start of development."
My initial reaction when I used the Angio CT for the first time was, "It is absolutely amazing!" The entire system truly turned my dream into reality. Prior to the advent of the Angio CT, moving a patient between the angiography and CT rooms would take 30 minutes, in addition to the required assistance of countless hospital staff. On the other hand, with having both angiography and CT installed as one system in the same room, cases can now be performed in only a few minutes without moving patients from one room to another. I was extremely gratified to see that my requested vision, led to such great clinical advantages and benefits.

A Whole New World Awaits

What exceeded even my initial expectations, was the ability to acquire CT images during interventional procedures, which then began a whole new era of 3D visualization. With conventional 3D images frequently utilized today, we take for granted not fully appreciating the importance of this technology, until applying this functionality in clinical practice. The result of this significant clinical impact and innovation make it possible for improved accuracy during treatment, as well as significant expansion in the range of IR procedures.
For example, when using conventional methodology, IR procedures are performed using catheters which are introduced into luminal structures such as blood vessels, the digestive tract, or the airways. However, with Angio CT, therapeutic procedures can easily be performed for lesions even though there isn't luminal access. For instance, such unique procedures include nerve blocks and tumor biopsies which are considered to be an indispensable process of cancer treatment today. Particularly, the greater accuracy of biopsy procedures has significantly enabled and improved the therapeutic outcomes of cancer patients.

Infinix-i 4D CT at National Cancer Center Hospital.

Angio CT: A Breakthrough role in Oncology?

The most reliable imaging method during puncture procedures today, in my opinion, is X-ray fluoroscopy. However, X-ray fluoroscopic images only provide limited 2D information, hence there exists a critical need to obtain CT images to confirm and verify essential information, such as the direction and distance of the needle as it advances precisely to the exact location.
The main advantage of Angio CT is that procedures can be performed while quickly switching between the X-ray fluoroscopic image and the CT image along with the requirement for confirmation. In addition, operability is much easier with Angio CT as compared to one of Cone Beam CT (CBCT). My experience is mainly in the field of oncology, but at the very least, the Angio CT has proven itself to be an extremely versatile device in this field.

My clinical opinion regarding the Angio CT's practical use is that interventional pro-

Prof. Yasuaki Arai

cedures can now be performed accurately based on X-ray fluoroscopy, coupled with CT imaging, which plays an invaluable confirmatory role. However, this may depend on each individual operator, regardless whether fluoroscopy or CT is considered the primary modality. The most important advantage when using the Angio CT is that both the angiography and CT system can be used flexibly and simultaneously according to the operator's requirements. It is like the way we use both, our right and left hands together. The things we can do with only one hand are very limited, however the things we can do with both hands is quite infinite in comparison. This system allows us to use both modalities freely, seamlessly and interchangeably rather than placing a primary emphasis on one or the other at one time.

Furthermore, there is no limit on the range of applications with Angio CT in the field of IR. Instead of thinking in terms of what Angio CT can be used for, we should focus on the creative clinical possibilities of how we can help each individual patient outcome in the IR procedure. It is crucial for us to maintain as clinical specialists to consider how Angio CT can be applied in IR. If we focus only on the Angio CT itself without considering furthering clinical possibilities, we limit our treatment capabilities and achievements.

The Future of Interventional Procedures:

My hope is the future of IR will utilize clinical practice more frequently. Contrary to popular belief, IR procedures are not typically the expensive therapeutic option. IR procedures are relatively less invasive and can significantly reduce medical costs. For these reasons, I hope that IR will be more widely employed and gain growing acceptance in emerging countries, as well as in developed countries.

As an interventional radiologist, I have always believed in the great potential of treating diseases better using IR procedures and have worked many years to achieve this goal. With IR, our ability to cure diseases is improving, and even though a cure is not always possible, we can often times mitigate symptoms and improve the patient's quality of life regardless. The clinical challenges that now can be treated using Angio CT in IR procedures is only the tip of the iceberg. I am looking forward to learning more about the new and surprising possible IR applications that will be developed in the future, thanks to the new possibilities of widespread IR procedures around the world. //

Prof. Yasuaki Arai with Infinix-i 4D CT

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