Prof. Ichiro Nakahara,
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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.

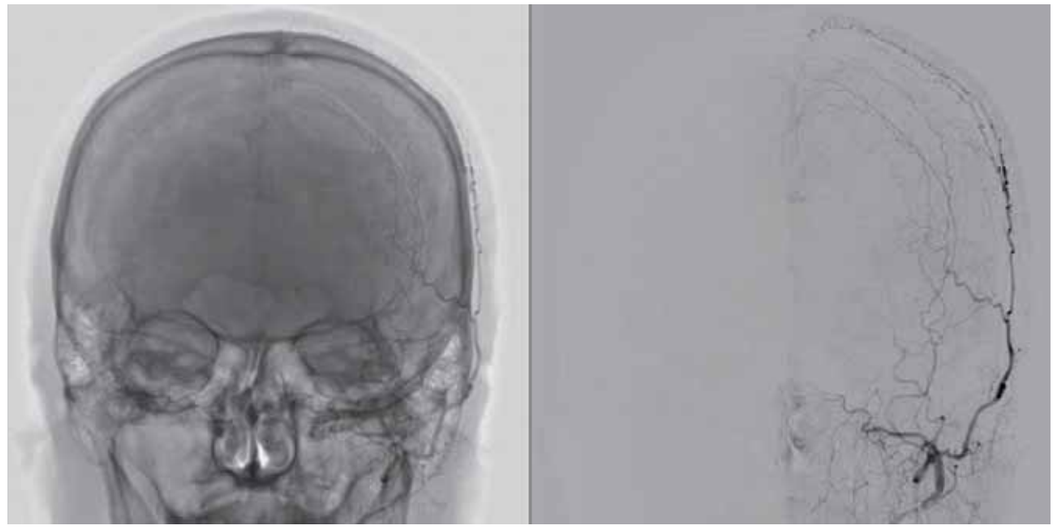
However, we previously have encountered cases in which the conventional angiography system was unable to provide adequate fluoroscopic, radiographic, or 3D images of sufficient high quality. For example, halation has been often observed near the area where a direct X-ray beam enters, making it difficult 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."

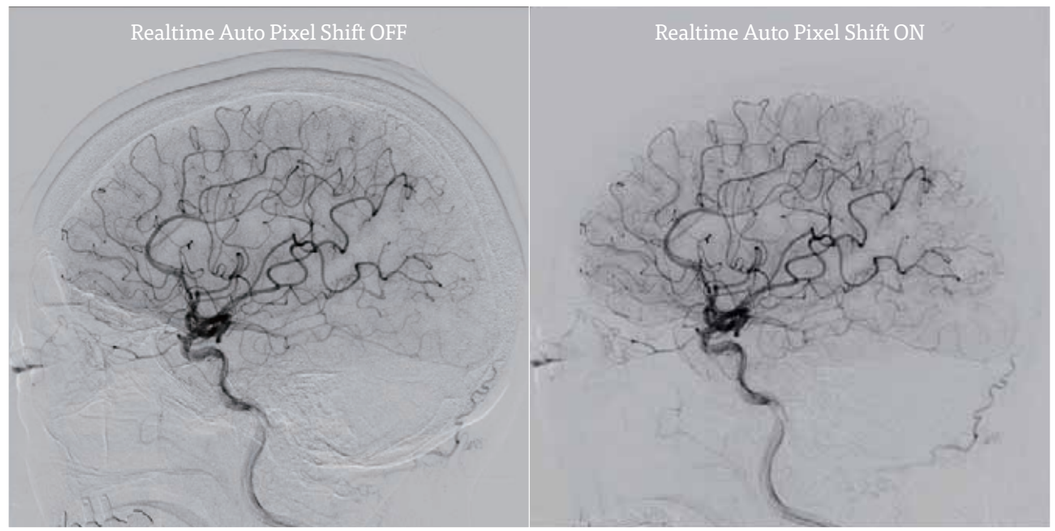


External Carotid Artery images.
Halation is not observed near the area where a direct X-ray beam enters, even without a compensation filter.

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. //