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SPECIAL

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// EDITORIAL

Dear Reader,

coexistence.

era'.

It is a severe and uncertain situation, and I would like to express my deepest gratitude to all medical professionals, who continue to work hard and give their best under great pressure.

as well as safe, secure systems.

This is the sixth edition of VISIONS Special – Interventional X-ray, which brings you stories from users of our Angiography systems. In this edition, we feature the innovative technologies and the functionality that is provided by our Alphenix systems, and explore the ways that the systems are used in actual clinical practice from the customer perspective.

In addition, as 2022 marked the 30th anniversary of the birth of Angio CT systems, this edition includes the fascinating development story behind Angio CT from the engineers who were involved at the time.

I hope you enjoy reading this edition of VISIONS.

Made for patients. Made for partnerships. Made for you. Made for Life.

Kunitoshi Matsumoto General Manager, Vascular Systems Division, Canon Medical Systems Corporation

We are now in the third year of the coronavirus pandemic. Many countries and regions have already shifted from their early strategies of total containment to

At the same time, with worldwide concern as economic growth has slowed this year since the Spring due to the unstable global situation, we are reminded that we are truly in the midst of a 'VUCA (volatile, uncertain, complex and ambiguous)

At Canon Medical Systems, we believe that it is our constant mission and our responsibility to continuously deliver better medical technologies and solutions,

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Assuming the Mission in a Critical Situation — Bravery in the Face of Difficulty — The Story of How an Alphenix System Started Operation at The People's Hospital of Tonghua City in Jilin Province

In mid-March 2022, Jilin Province in China experienced a surge in coronavirus infections. In Tonghua City, which is located in the southern part of the province and shares borders with Liaoning Province and North Korea, emergency measures were taken to isolate persons who were close contacts of infected people.

Since the spread of COVID-19, The People's Hospital of Tonghua City has been solely responsible for providing medical services to all non-COVID-19 patients in Tonghua City and its adjacent areas. This is because Tonghua Central Hospital, located in the same area, has become the designated medical facility for COVID-19 patients. Under these circumstances, a Canon Angiography system was scheduled to be installed at the Hospital.

Mr. Du Lizhong and Mr. Tao Hongwei arrived at The People's Hospital of Tonghua City to install the new Alphenix Angiography system. Which is used for cardiac operations, peripheral vascular interventional procedures, neuro interventional procedures, and diagnosis and treatment of cardiovascular diseases.

On March 13, the system arrived at the Hospital amid heavy snowfall, and Mr. Du and Mr. Tao unloaded the system with the help of a logistics operator.

The installation work began on March 15, but auxiliary equipment necessary for the installation of the system had not arrived yet due to the COVID-19 lockdown. Despite this, the two engineers began their work with the firm determination that the work should not be delayed, and the system should be in operation as soon as possible.



Test operation of the system finally began



Installation is finally finished! (Completion date: March 29, 2022) Left to right: Mr.Du Lizhong, Dr. Wang Xu of the People's Hospital of Tonghua City, Mr. Tao Hongwei

"There are only two of us, but we are a team!"

The two men overcame difficulties together

The installation of Angiography systems requires careful attention to detail. However the installation schedule requested by the Hospital was very tight, so Mr. Du and Mr. Tao proceeded without wasting a single moment. The COVID-19 situation became even more severe. Borders between the regions in the entire Jilin Province were closed, so the engineers in charge of installation of the peripheral devices were not able to go to the Hospital. The installation of peripheral devices to an operating room for interventional procedures requires special expertise. It is difficult for local engineers to install them by themselves, but Mr. Du and Mr. Tao did not give up! They got in touch with the expert engineers and received remote instructions from them. As a result of this effort, they were able to successfully complete the installation of the peripheral devices. There were also other challenges caused by the policy

response to COVID-19. Hotels in Tonghua City were designated as isolation facilities for close contacts of infected people, so Mr. Du and Mr. Tao had to stay 30 kilometers away from the Hospital. For almost a month, they spent over an hour each way commuting to the Hospital. Despite this, they stayed on task and maintained the belief that "hard work pays off".

On March 29, they finally completed the installation, and test operation of the system began on April 7.



The much-anticipated Alphenix system. How did test operation turn out?

Since the spread of COVID-19, The People's Hospital of Tonghua City has been responsible for the diagnosis and treatment of all non-COVID-19 patients in Tonghua City and its adjacent areas. Because of this situation, the existing system (one of our previous systems) had been used heavily. So the Alphenix system was highly anticipated and attracted much attention. The senior management of Tonghua City's health committee, which oversees the medical system in the city and adjacent areas, gave high priority to the installation and operation of the system, and cooperated closely with the Hospital's executives and the medical staff from each clinical department.

As expected, the Alphenix system started operating successfully and exhibited excellent image quality. The burden on the existing system was quickly reduced after installation of the new system, and interventional procedures could now be performed more smoothly. Mr. Du and Mr. Tao proudly told us, "The hospital originally planned to use the Alphenix system for an operation to check its performance, but they changed their plan and decided to use the system for four emergency operations because the system was operating successfully in all aspects and the images were excellent." The functionality of the system received high praise from the Hospital staff. Furthermore, the two engineers received an award from the Hospital for their efforts in installing and operating the system.

"Customer first, life first." Competition to save lives

Installation procedures for Angiography systems, from arrival and unloading of cargo to test operation, usually take about half a month to complete. This time however, it took 10 or more extra days to finish the installation work due to the many challenges. We asked Mr. Du and Mr. Tao, "You have not seen your family for almost a month. How do you feel?" Mr. Du replied on Mr. Tao's behalf with humor, "Mr. Medical staff watching the test operation of the system with keen interest

Tao's kid is only one and a half years old and soon will not remember him." Then Mr. Du explained with a smile, "I am an experienced engineer with over 20 years of experience. I regularly make phone calls and video calls to my family while on business trips, they are already used to it." (After this, Mr. Du may have to isolate again for the third

time. If so, when will he be able to return home?) The two engineers further commented:

We must ensure that our systems operate normally. Our job is like a competition to save lives. Many healthcare professionals are using our systems every day to save lives despite the spread of COVID-19 or the occurrence of a sudden flood. This means that our responsibility is great. We are on the front line to ensure stable and normal operation of the systems for healthcare professionals and patients! Even if we face a critical situation again in the future, we will do our best for our users and for society without hesitation.

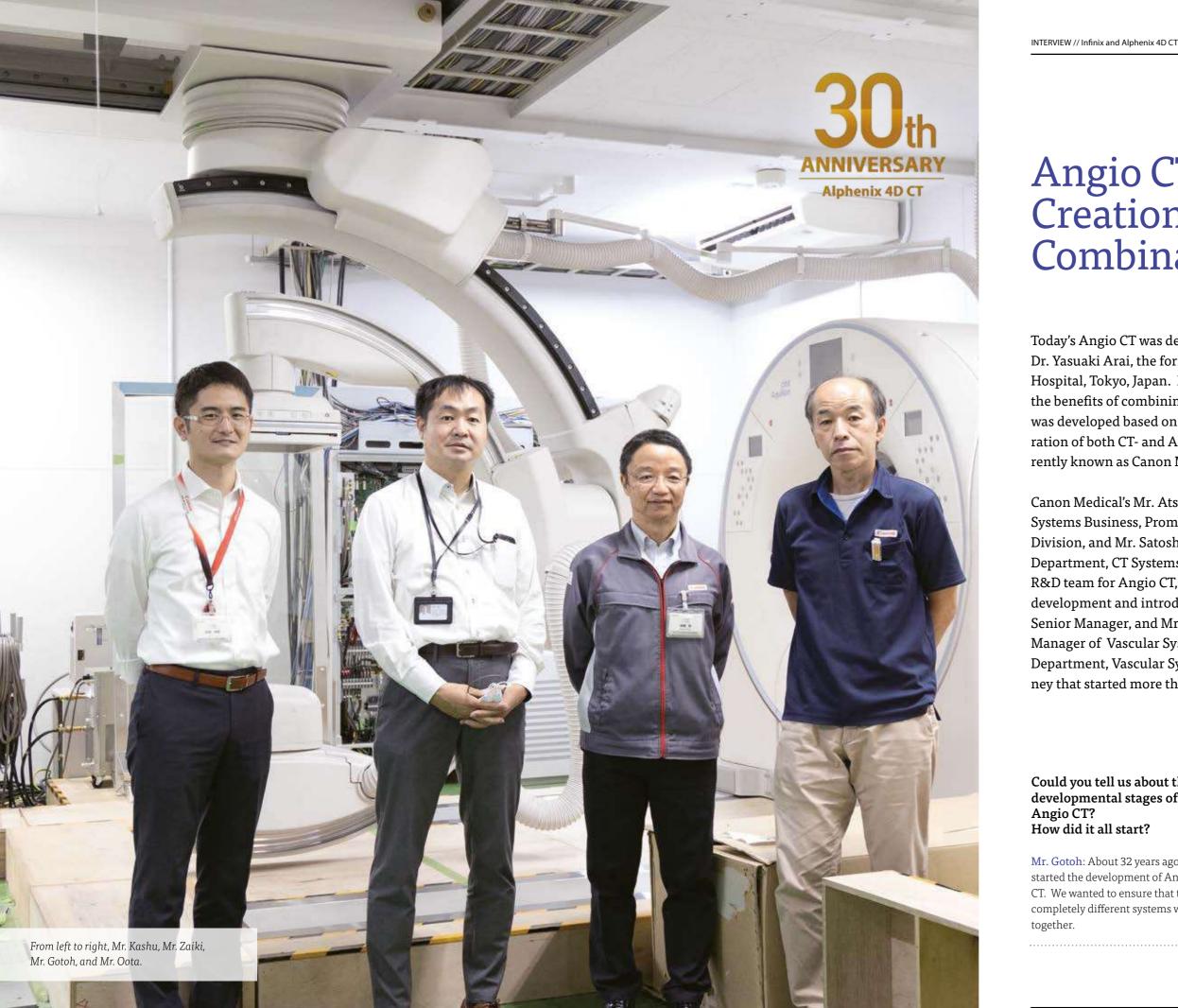
(Mr.Du Lizhong returned safely to his home in Shenyang on April 10, 2022. Mr. Tao Hongwei returned safely to his home in Zhengzhou on April 16, 2022.)

Conclusion

Mr. Du and Mr. Tao are typical examples of Canon Medical Systems staff, and many of our colleagues are also working at the forefront of medical care. They are just like Mr. Du and Mr. Tao, sometimes they have to sacrifice time with their families, but they are working in critical situations and contributing to the company which is like a large family for us. They sometimes talk enthusiastically about our systems, but they rarely talk about the difficulties they experience. They are aware that it is their responsibility to deal with such difficulties.

It is our important mission to ensure timely delivery of services to our users. To achieve this mission, Canon Medical Systems engineers assume the responsibility to stand at the front line. We would like to express our sincere respect to all of our colleagues and the medical professionals who are working at the forefront of medical care. *#*

July 14, 2022 CMC / Vascular Systems Marketing and Promotion Department / International Sales Division, China group



Today's Angio CT was developed from the original concept of Dr. Yasuaki Arai, the former Director of National Cancer Center Hospital, Tokyo, Japan. From as early as the 1980s, he realized the benefits of combining a C-arm with CT. The first 'Angio CT' was developed based on Dr. Arai's idea together with the collaboration of both CT- and Angio Teams from Toshiba Medical (currently known as Canon Medical Systems) in 1992.

Canon Medical's Mr. Atsushi Gotoh, Senior Manager, X-ray Systems Business, Promotion Department, X-ray Systems Division, and Mr. Satoshi Oota, CT Systems Development, Department, CT Systems, Division, are former members of the R&D team for Angio CT, who worked on the system's initial development and introduction. Together with Mr. Ryuji Zaiki, Senior Manager, and Mr. Kashu Yuto Senior Global Marketing Manager of Vascular Systems Marketing and Promotion Department, Vascular Systems Division., they reflect on the journey that started more than 30 years ago.

Could you tell us about the developmental stages of Angio CT? How did it all start?

Mr. Gotoh: About 32 years ago, we started the development of Angio CT. We wanted to ensure that the two completely different systems worked together.

Angio CT : The Creation of a Dynamic Combination



What technical challenges were encountered in this project?

Mechanical synchronization was our first challenge The CT team had a lot of technical challenges to deal with. Our CT engineers had to develop a mechanism to move very heavy objects mounted on the gantry. The main challenge for the Angiography system engineers was to rotate the ceiling C-arm structure layout by 90°.*

Of course, there were some functional changes needed.

CT systems are gantry-based, and development related to the gantry requires a great deal of careful design, including deciding how the sensor needs to be, and how the rails can be laid completely level with the floor. We also invested a lot of effort into careful site-planning and construction work.

We had to make sure that the rails are embedded with no protrusions, in order to avoid creating a trip hazard and prevent objects from catching on protrusions.

In addition, as the systems are installed at hospitals, where there is the possibility of liquids, such as disinfectants or blood, entering the rail grooves, we also had to factor in a way to keep the rails clean.

We had to make sure that liquids could be easily removed using swabs or mops. This was particularly challenging in the development of the Angio CT. Engineers came up with a special design for the rails, in which liquids are prevented from entering the rail grooves easily, and yet, the liquids that do enter can easily pass through to the bottom.



*: In Canon Medical's Alphenix 4D CT, the ceiling C-arm lands perpendicular to CT gantry rail, so the C-arm can be fully parked without disturbing CT fluoro procedures

What is most rewarding to you in this project?

Mr. Gotoh: When I receive positive comments from users of our systems, such as "The system was very easy to use," or "This system changed the whole examination procedure." One physician from Chicago University in the USA remarked that the system is economically extremely efficient. These comments indicate that our initial objectives for design of the system have been successfully achieved in real clinical settings.

When I hear these things, I regard the development as a success.

Are there any other achievements that you are particularly proud of in the development?

Mr. Gotoh: Yes. The Angiography system controls travel of the CT system. Not the operation of the system itself, but the movement of the CT from one place to another.

The motors and other mechanisms related to movement are installed in the CT, but the command is sent from the Angiography system. During the developmental stage, we found it exciting to see if the system

would travel appropriately according



Figure 1

to the retraction command or traveling

command.

for us.

communication.

This requires the separate CT system and Angiography system to communicate with each other. Successfully programming the commands was one of the most important achievements

We designed the circuit -the printed wiring board (PWB) - to enable this

And as we needed to make sure that the program worked appropriately before attempting to move a huge system, like a CT, we created models to simulate the CT (Figure 1). Using these models, we simulated communication with the CT system via the circuit that we designed. According to the communication rules that were established collaboratively by the CT- and Angio teams, we first performed a simulation separately for the CT system and the Angiography system using the model. Then we combined the two models and performed a simulation. After confirming that communication worked successfully, we then set up the actual CT and Angiography systems in the test bay. Seeing the actual system starting to

move was a very happy moment. As an engineer, it was very rewarding and encouraging.

We then moved on to detailed design.

"These comments indicate that our initial objectives for design of the system have been successfully achieved in real clinical settings."

> Mr. Atsushi Gotoh, Senior Manager, X-ray Systems Business Promotion Department., X-ray Systems Division.

Anecdotes behind the development.

What further changes were made during the detailed design process?

Mr. Gotoh: We adapted the blue LED to

our latest controller when we updated

the first generation Angio CT to Infinix

generation because the blue LED was

invented and was introduced as a new technology of the world. (Figure 2) You designed this, didn't you?

Mr. Oota: Yes.



Figure 2



Angio CT system with multi-slice CT in 2003.

Mr. Gotoh and Mr. Oota were members of the original development team for the Angio CT. They describe history behind the invention.

What was the most challenging part of the development?

Mr. Oota: In the beginning, the CT team had not previously extensively collaborated with teams from other modalities, and as a consequence, did not know everything about the other systems.

Mr. Gotoh: Yes, both CT- and Angio teams were developing at the same time. When something failed, we would begin a discussion to find out which was the responsible modality.

Mr. Oota: The Angio team got into many deep discussions with the CT team back then. When an issue came up at the hospital, we investigated thoroughly to find out exactly what was happening.

Mr. Oota: One particular issue was in constructing the interface, because it was difficult to ascertain which system was responsible for what in the tests. It was a lot of fun to build something together with another modality.

Although I now 'belong' to the CT team, it's still fun to collaborate with the Angio team, from the 'other side'. as it were.

Do you have any comments on

thanks to these developments? Mr. Oota: It's nice to know that Angio CT has developed in the way that it has. Back then, it was a totally new concept, and we couldn't imagine how it would be implemented in the future. However, now it's become a standard. That's a pleasant surprise!

Mr. Gotoh: The success has been made possible by Dr. Arai's passion.

Mr. Oota: Yes. Thanks to this, we were able to form the connection with the hospital and share information with them towards developing the system by implementing it in clinical environment. The Angio CT could only be created with the ideas, expertise and help of Dr. Arai.

"Back then, it was a totally new concept, and we couldn't imagine how it would be implemented in the future."

> Mr. Satoshi Oota, Senior Principal Engineer, CT Systems Development Department.,

the systems that we now have

Mr. Zaiki: The CT - and Angio teams are working even closer together now.

Mr. Oota: Yes. That has intensified since we formed the 'IVR CT project team'. It inspired us to work more closely together.

Mr. Zaiki: There is a difference in the CT images for diagnosis and for treatment.

Mr. Oota: Oh yes, the requests are different. And this makes a lot of sense. Their purpose is different and utilization as well. So there are special needs that the CT team has to respond to.

Mr. Oota: I spent a lot of my efforts on site planning, I also had to go to the construction site to collect the data of the floor construction.

Mr. Oota: So we changed the depth of the floor installation rail.

Mr. Gotoh: Yes, it was deeper, but was made shallower.

CT Systems Division.







Mr. Zaiki: However, thanks to that, when some competitors couldn't fit their systems in the room because they needed a taller room, the customer came to us for a solution.

Mr. Oota: Yes, and they have a large box of cables in the ceiling. We are the only manufacturer to produce a system without anything above. It's all inside the floor.

Mr. Gotoh: We sometimes call competitor's structure a 'chimney' and it moves with the system's arm.

So, our system is all embedded in the floor?

Mr. Oota: Exactly.

Then you must be involved with the construction of the room?

Mr. Kashu: Yes, the construction and planning. Other systems require use of the ceiling.

So, it's easier for the hospital to have the floor modified rather than the ceiling?

Mr. Oota: It's not easy. For the ceiling installation, it's simpler to install and faster, but they must reinforce the ceiling and have the space.



Mr. Gotoh: Yes, they can't install the surgical lighting system in the ceiling in exchange.

Mr. Gotoh: All cables of our system CT is installed in the floor. (Figure 4)



Figure 4

You mentioned that there were more challenges asides from the mechanical ones, could you tell us more about them?

Our next challenge after the mechanical part was the integration of imaging and clinical concept.

We received a lot of requests from Dr. Arai concerning inclusion of positional information etc. Dr. Arai has a unique perspective that is totally different from ours. For example, there was one request on linkage between CT and Angiography images. This was very tough to solve. These were challenging issues, but they have now all been resolved, making fusion of CT and Angiography images possible. This achievement was not only the result of inspiration, but also

collaborative efforts between multiple departments.





What expectations do you have for the future of Angio CT?

Mr. Gotoh: The future also involves Dr. Arai. While our systems are premium class, Dr. Arai has always strongly believed that a wonderful system like this should be used in many countries around the world.

To make this possible, Dr. Arai always had in mind that the system should be available in budget-oriented versions so that it can also be used in developing countries, as well as developed countries. This made us realize how much potential the system has.

Is there anything you'd like to say to the users of our systems?

Mr. Gotoh: I want to say thank you. Thank you for using our systems! It is not our role to specify in what way the system should be used. This is totally up to the users. Our system is still evolving, and has great potential. If our users come up with new and innovative ideas of how the system can be used therapeutically, we'd be more than happy to work with

them on it. I want to explore what can be done if the combination of CT and Angiography is further strengthened and used at a higher level. I will strive to realize ideas that can deliver further innovation in

In Japan alone there are over 200 systems installed since it was

invented.

healthcare.//

This is all made possible thanks to input from the users of our systems. Achieving a combined Angiography system and CT system is an example of an innovation that has been driven from the customer side.

We value 30 years of partnership, and look forward to collaborate with clinical care team to transform global health care.



Atsushi Gotol Senior Manager, X-ray Systems Business Promotion Department., X-ray Systems Division.



Division

Satoshi Oota Senior Principal Engineer, Senior Manager, Vascular CT Systems Development Systems Marketing and Department., CT Systems Vascular Systems Division



Promotion Department.,

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Senior Global Marketing

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Manager, Vascular Systems



Amalia Airi Asai Global Integrated Marketing munications specialist VL/XR, Clinical Solutions & Modality Marketing Group., Global Marketing Departmen

Canon **CANON MEDICAL**

Quickly diagnose, treat and verify with confidence.

Alphenix 4D CT seamlessly integrates our flexible Alphenix 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, Alphenix 4D CT helps you prioritize safety, speed and efficiency during complex interventions.





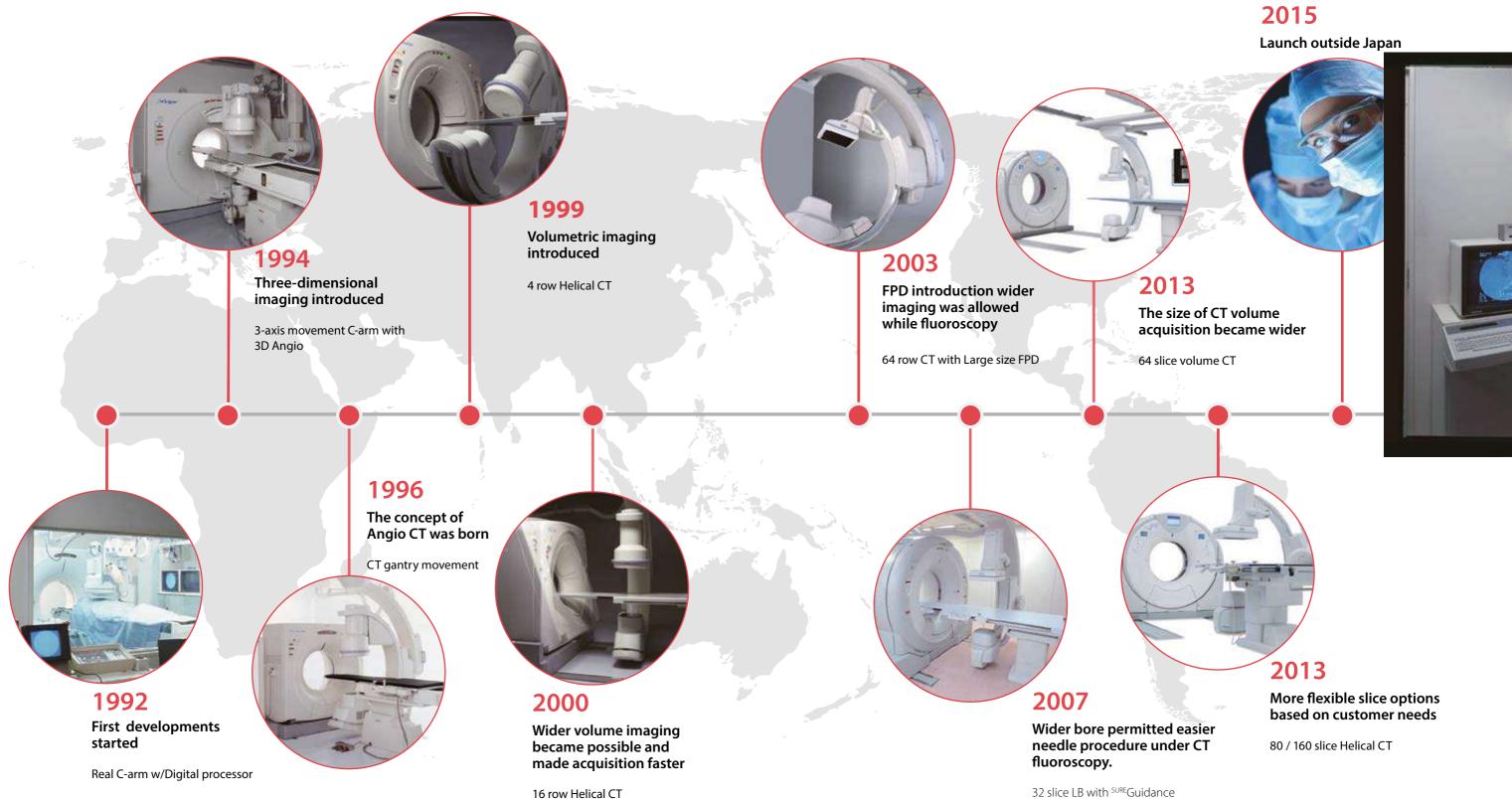
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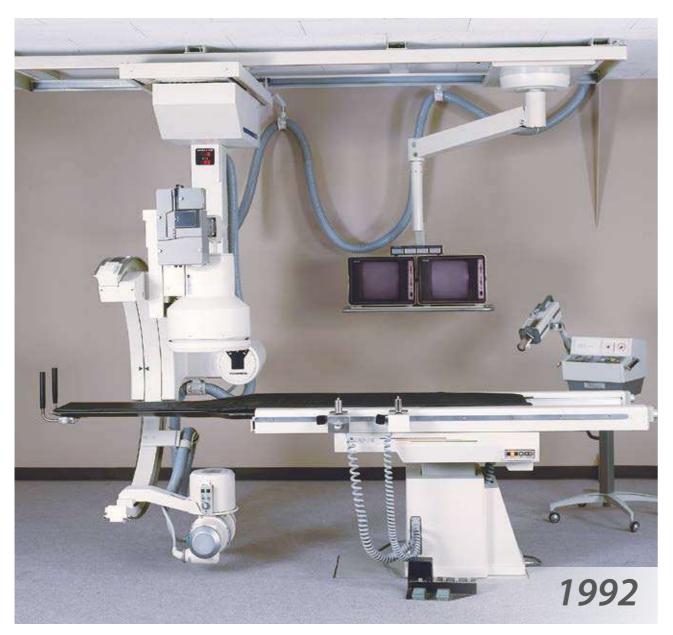
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Timeline of Development of Angio CT



From Concept to Clinical Practice -Following The Technical Evolution of Angio CT

Angio CT was born from an idea first conceived 30 years ago by Dr. Yasuaki Arai, former director National Cancer Center, Tokyo, Japan. Over the years, its initial technical evolution has been driven by Canon Medical expertise. Mr. Atsushi Gotoh, Former Angio CT team leader at Canon Medical, describes the key features of the system and milestones in the early development period.



Angiography system in 1992.

1992 - The birth of an innovation driven by patient needs

The idea for Angio CT originated from the desire to improve imaging and interventional procedures for patients. I joined the Angio CT story in (1994) as a member of the development team. Work to create the system had already begun in 1992. One of our starting points was an Angiography system, like this one (Figure 2).



Figure 2

Let me explain the mechanism of this 1992 system. This is a CT-based system.

The first generation utilized a CT-based table and not a catheter table.

The X-ray tube is not visible, because it is inside the CT table. Above it is a large detector called an "I.I.", (Imaging Intensifier) that comprises of a vacuum tube and an X-ray enhance electron.

It is amplified, and provides an output image on the fluorescent screen which is suspended from the ceiling. It uses a vacuum tube and is equivalent to the FPD in current systems. At the time, CT systems were floor-mounted and not movable.

Three-dimensional C-arm rotation was not possible then.

Dr. Arai (Figure 3) first came up with the Angio CT hybrid idea. This was during the period when he was working at Aichi Cancer Center in Japan.

His main focus was to avoid moving the patient.

Dr. Arai has always emphasized the importance of not moving patients.

Moving the patient takes a lot of effort and requires support from a number of hospital staff. For example, there are

X-ray tubes, ECG electrodes, other cables, and tubes involved in Angiography systems. If these have to be disconnected to move the patient, it places a great burden on them, as well as the staff members involved.

It is also time consuming. Therefore, it is important that all the procedures can be performed while sharing one table between Angiography and CT scan.

CT is used to examine the lesion in advance. While the

Angiography C- arm is mostly used to confirm the results of the examination, and to evaluate results before and after the examination.

The need to perform Angiography and CT using the same patient table within a single room led to the concept for the world's first Angio CT system. At the time, the initial development was mainly handled by the CT team rather than the VL team.



Figure 3: Dr. Arai

1994 - Introduction of the C-arm

This is when the C-arm was first introduced in the Angiography system. This C-arm was an ancestor of the Alphenix. Originally, the arm was suspended from the ceiling. This not only allowed scanning of the patient from the front, but also made it possible to perform scanning from various angulations.

However, the CT was still fixed to the floor, requiring a specially designed patient table. This is why the tabletop is long. Unlike current Angio CT systems in which the CT system can move, a CT system fixed to the floor was used in combination with a long tabletop like the one shown in Figure 4 (1996). However, limits as to how far the tabletop could be extended, restricted coverage of the region of interest for the CT system.

This is just an example of how the system looked. during the. period of technological transition.



Figure 4: The Angio CT system installed in 1994.



figure 5: The Angio CT system produced in 1996. The CT gantry is now movable on the floor rail. The basic design of the well-known Angio CT system was invented at this time.

1996 - First movable CT

We identified that there was a problem in the movement range for the C-arm, and so decided to rotate the ceiling rail layout perpendicular to the Cath table.

In 1996, we tackled this technical challenge and were able to develop the first movable CT.

The ceiling travel rails are not visible in figure 5 of a system from 1996, the duct hoses are mounted on the ceiling, the system began to resemble the current Alphenix C-arm. Ingenuity was required to create this feature. The layout of this C-arm was designed very carefully. Generally, for the C-arm for Angiography systems, if it is used

as a general vascular system, two rails are installed in the longitudinal direction, so that the C-arm can be moved in the patient head/foot direction.

The movement range was wider in the longitudinal direction.

As the C-arm suspended from the rails, if it is moved along the rails, it cannot be retracted sufficiently if used as is in combination with the CT system.

To address this problem, the layout was and the direction of the C-arm is perpendicular to the catheter table. This ensured a longer movement range in the lateral direction than the longitudinal direction.



The CT base can move on the floor to realize the helical scan. This unique concept was born by Toshiba/Canon in 1996.



Figure 7: The ceiling C-arm can park perpendicular to the table and CT gantry. This unique design doesn't disturb patient approach from both right and left side of the patient

In this way, the C-arm can be completely retracted beyond the movement range of the CT gantry. (Figure 7) With this layout design, it was intended that both the Angiography system and the CT system could respectively fulfill their maximum capabilities when used individually. A great deal of thought went into development of the system, with the focus from the very beginning on finding solutions to the many challenges.

This layout design has basically been maintained up to the present.



This required the most effort. And this was all possible thanks to input from many physicians.

As the Angio CT system was first developed in Japan, where examination rooms are generally small, we considered various ways to design a compact layout that would provide an optimal fit.

Mass production started with the 1996 version of the system.



The Flat Panel Detector was adopted for C-arm in 2003.

After we went into mass production, the system was installed at many sites. This seems to have been a key year. For the launch of the "3-axis movement C-arm with 3D Angio".

As shown in Figure 7, a common table designed for a helical CT system was first installed at National Cancer Center, Japan in 1996.

A multi-angle-approach C-arm and a ceiling-suspended C-arm were installed at NCC Hospital East. Rotational DSA and an Angio CT monitor were also installed.

Angiorex was the original name for the Canon Medical Infinix back then.

The present concept was already established by this time, including its structure, movement, and layout.



2003 - Launch of the Infinix and Alphenix

The VL BU released the Infinix series, with the name changed from Angiorex. This is now known as Alphenix.

Although it's been 20 years since then, we have provided updates to the CT- and Angiography systems as we continued with development. Progress through this kind of steady effort has achieved a great deal.

Conclusion

Now, after many changes and improvements, Alphenix 4D CT has achieved the stage where the features allow users to deliver safer and effective procedures with Hi-Def Angio, ONE-beat Cardiac, Dynamic 4D Brain, Whole Organ Perfusion, Spectral CT and more. All of this under dose management and deep learning reconstruction for efficient imaging and less dose.

Aquilion ONE combination of the Alphenix 4D CT now provides a full 50 cm scan FOV with up to 16cm of wide



Canon's latest Alphenix 4D CT in 2022. Combination of the Alphenix Sky+ arm and the Aquion ONE / GENESIS edition.

Z-coverage, and patient specific mA modulation. Also the recent technology permits to harness the power of deep learning reconstruction that delivers excellent energy separation for spectral analysis with high resolution. These reconstructed spectral images are then delivered directly to your reading station for immediate review.

This is all possible thanks to Vitrea, our interactive station, that analyze the image including quantification of perfusion data for more confident diagnosis with the wide range of applications. //



Dr. Toshihiro Tanaka, Professor and Chair, Department of Diagnostic and Interventional Radiology, Nara Medical University, Nara, Japan



Radiology

Dr. Toshihiro Tanaka has taken on many new challenges in expanding the range of clinical applications of interventional radiology (IR), starting from tumor vascular embolization, to AVM coil embolization, and then to transcatheter arterial micro-embolization (TAME) for pain management. He serves as professor of diagnostic and interventional radiology based on his personal philosophy, "Harmony is to be valued." We asked him to discuss the equipment features and functions he has found to be indispensable when performing IR procedures.

Angio CT simplifies complicated clinical routines

I served as a resident at Aichi Cancer Center, where Dr. Yasuaki Arai was playing a leading role in the field of IR in Japan and was engaged in joint research to develop Angio CT with then Toshiba Medical Systems

Hi-Def Detector and 320-row Area Detector CT Open up New Possibilities in Interventional

Corporation (now Canon Medical Systems Corporation). In fact, the world's first Angio CT system was installed at Aichi Cancer Center. This novel system featured an Angiography system and a CT scanner which were installed in the same room and shared a single patient couch. I found the



Angio CT system to be extremely convenient when I had a chance to actually use it, and it was my belief that such systems would eventually become the clinical mainstream. At that time, routine clinical practice at Nara Medical University Hospital was to transfer patients back and forth between the Angiography room and the CT room on stretchers. In patients with liver cancer, Angiography was used to determine the number of tumors and evaluate blood flow dynamics. The patient was first sent

to the Angiography room, where catheters were introduced into the superior mesenteric artery and the hepatic artery, and portal venography was performed via the superior mesenteric artery. The patient was then transferred to the CT room, where contrast CT images were acquired via the hepatic artery to visualize the arterial supply. So we made the diagnosis during this phase of the overall process of transarterial chemoembolization (TACE). After diagnosis, the patient was transferred back to



the Angiography room to perform the actual TACE procedure. This clinical routine, in which the patient needed to be transferred between rooms several times, not only placed a severe burden on the patient but also made it difficult to manage the CT room efficiently. When patients were transferred from the Angiography room, the CT examinations scheduled for all other patients had to be suspended, even when the room was fully booked.

Seamless integration with CT in a wide range of clinical research

In 2003, a long-awaited Angio CT system with a 16-row CT scanner (Aquilion LB) was finally installed at Nara Medical University Hospital. The system was immediately found to be useful for a wide variety of clinical applications. At that time, one of my research interests was the treatment of pancreatic cancer using a method in which anticancer agent is injected directly into the tumor. Pancreatic cancers also tend to have a large number of feeding vessels, and in order to identify the most effective vessel for injecting anticancer agent, it is necessary to introduce a catheter into each individual vessel, obtain contrast CT images, and then check the pattern of contrast enhancement in the tumor to evaluate the drug distribution. We have found Angio CT to be extremely useful for performing these complex procedures.

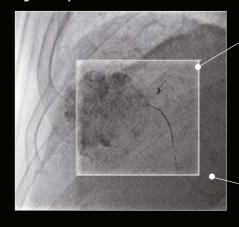
4D navigation pioneered by 320-row CT

In 2019, the system was upgraded by installing Alphenix 4D CT with the latest 320-row Area Detector CT (ADCT) scanner, Aquilion ONE. In a later upgrade, a high-definition detector (Hi-Def Detector) was installed. Alphenix 4D CT is provided with a variety of new functions for improving workflow. One of these new functions, Semi-Auto Registration, allows 3D CT images to be superimposed on Angiography images. Because the Angiography system and the CT

scanner share the same patient couch. there is no need to manually adjust the positions of the two images to achieve precise registration. The 3D CT information is used as a roadmap to confirm the locations of devices such as guidewires during the procedure. Auto Table is another useful function that allows the couch position and the C-arm position and angle to be automatically returned to the same settings as before by simply selecting a previously acquired image. This is extremely helpful for cases in which the working angle needs to be changed repeatedly, and we now consider this function to be indispensable in our daily clinical practice.

The SPOT Fluoro dose-reduction function is also very effective. When X-rays are emitted to cover the entire field view, the exposure dose is increased not only for the patient but also for medical staff due to scattered X-rays. When SPOT Fluoro is used, X-rays are limited to the area of interest while retaining the information for surrounding areas. This makes it possible to perform procedures safely with the lowest possible radiation dose (Figure 1). We have found 320-row CT to be of great value in both vascular and nonvascular IR. For example, in complicated cases, it can be difficult to clearly understand blood flow dynamics during navigation when vascular IR procedures are performed using Angiography alone. By performing 4D CTA (i.e., ADCT with temporal information), we can precisely visualize very fast blood flow in 3D images that provide stereoscopic views of blood flow dynamics as well as vascular structures. We use this function in many of our cases. For example, in patients with arterial dissection, 4D CTA allows us to assess the blood flow in the true lumen and that in the false lumen even when the blood flow is separated into two layers due to the dissection. As another example, in patients with arteriovenous malformations, blood flow from the arteries to the veins is extremely fast. It can therefore be

Figure 1. Spot Fluoro



shunt



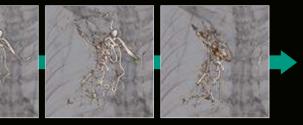


difficult to depict the structure of the shunts using Angiography alone. 4D CTA offers very fast scanning speeds, making it possible to obtain a detailed understanding of blood flow dynamics (Figure 2). Challenging cases like these can be diagnosed thanks to 4D CTA. In nonvascular IR, we have found the

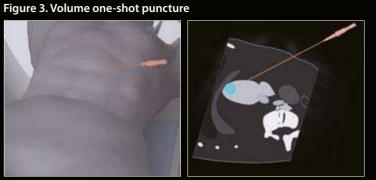
X-rays are limited to the area of interest (inside the white box). Unlike conventional collimation the area of interest can be set at any desired location, not only at the center of the image.

Fluoroscopic image informatio obtained immediately beforehand is displayed the area of interest (outside the white box), allowing previously acquired information of surrounding areas to be viewed or refence

Figure 2. 4D CTA in a patient with bronchial artery-pulmonary artery



4D CTA makes it possible to acquire angiographic images together with temporal information, providing a clearer understanding of complex blood flow dynamics.



A width of up to 16 cm can be scanned at one time, so the entire course of the needle can be displayed during puncture even if it is tilted in the craniocaudal direction.

> volume one-shot puncture technique to be particularly effective. When the conventional method is employed, the needle needs to be introduced perpendicular to the CT cross-sectional slice in order to display the entire course of the needle. With ADCT, on the other hand, a total width of up to 16 cm can



be scanned at one time, allowing the course of the needle to be displayed even if it is tilted in the craniocaudal direction (Figure 3).

Future expansion of IR into many new areas

It is my belief that IR is a continually evolving treatment method with a wide range of future applications. For example, transcatheter arterial micro-embolization (TAME) can be performed as a palliative treatment for bone and joint pain. We have treated a few patients with TAME at Nara Medical University and have found it to be quite effective. Symptomatic treatment is also required in oncology, and the importance of not only curative treatment but also palliative care in cancer patients is now widely recognized. The time has come for IR to take on a larger role in the treatment of such patients. One example would be the management of cancer patients with bone metastases. Patients with low back pain or bone pain may benefit from vascular embolization or radiofrequency ablation. Although such treatments do not cure the





cancer itself, they will be performed more frequently because they can help to improve the patient's quality of life (QOL).

I was appointed professor in the Department of Diagnostic and Interventional Radiology in February 2022. Looking at the current situation at our hospital, I feel we have established excellent relationships with doctors in other specialties in terms of clinical care. The next step is to elucidate therapeutic approaches whose mechanisms are currently unknown, including basic research, and to develop new treatment methods and medical devices. With regard to more intangible assets, we enjoy strong relationships with our outstanding radiological technologists and nurses. This is essential for the provision of quality care. To take full advantage of the latest Alphenix 4D CT functions described above, we need to work in close collaboration with our radiological technologists. Traditionally, their main role was to operate the equipment and acquire images. But their role has been steadily expanding to include creating the navigation images used for treatment, displaying the images and communicating with

the doctors during the procedure, and working together as a team with doctors in treating patients. The doctors operate the catheters during the procedure while constantly communicating with the radiological technologists to set the optimal view angles and navigate to the target vessels. When visitors from other institutions come to our hospital, they often remark how much they envy us for having such excellent technologists. This is due not only to their outstanding individual skills and capabilities



but also, as mentioned before, to the fact that we work in close collaboration, which allows us to inspire each other to achieve even higher levels of professional performance. I place the greatest value on working together as a team and ensuring a positive atmosphere in the workplace.

*Some of the comments and information in this article are the personal opinions and impressions of Dr. Tanaka.



A year in which doctors, technologists, and a manufacturer worked as one team

Dr. Toshihiro Tanaka (TT): We've

been working together with Canon Medical to conduct joint research in a variety of areas. Embolization Plan was one research project that focused on accurate identification of the feeding vessels of hepatocellular carcinomas. When I heard about the Hi-Def function currently incorporated into the Alphenix 4D CT, I was very much interested and had high expectations for its clinical value.

Mr. Yoshiyasu Hayashi (YH): We were also very happy when you decided to participate in this joint research because we felt Hi-Def was a very ambitious function and an exciting new challenge. We're very grateful for your participation. Nara Medical University has been taking the lead in IR under the guidance of a number of key opinion leaders (KOLs) in the field, starting with Dr. Tanaka. The university actively participates in international congresses, and we expect that the results of this research will be presented to a global audience. That's the background when we proposed this joint research.

TT: What was the aim of Hi-Def development?

YH: Although some clinical experience had already been gathered for the brain, this was the first attempt to employ Hi-Def in the abdomen. The key advantage of Hi-Def is its extremely small and precise pixel size, which allows the acquired images to be greatly enlarged. To make the best possible use of this advantage, we first needed to develop innovative approaches in all aspects of imaging to fully exploit the performance capabilities of Hi-Def in the abdomen as well. We developed a dedicated X-ray tube and also optimized image processing techniques to ensure that Hi-Def could perform at its full potential. Our final goal was to ensure that doctors could clearly see the embolic materials, such as coils, as well as minute blood vessels during IR procedures. Various teams in the development department worked closely together to achieve this goal. Not only the development team but also sales representatives, application specialists, and service engineers were able to receive detailed feedback from doctors, which helped us to improve the quality of Hi-Def when used in the clinical setting. For a full month after system installation, we worked together with the doctors to fine-tune the images and ensure that the system was operating at peak performance. I'm very pleased and grateful that all the stakeholders were able to work in

close collaboration as one team.

TT: Yes, I remember. When I was shown images of cerebral aneurysm coiling in the brain, I expected something like that in the abdomen, and when I actually experienced it in clinical practice, it fully met my expectations. Hi-Def is undoubtedly effective for coil embolization. One of the unique benefits of Hi-Def is that we can identify the location of the microcatheter in coils. That is, even if a lesion appears to be completely filled with coils, Hi-Def allows us to see any gaps in the coils and identify areas where additional coils can be placed. In addition, when I was studying in Germany, I was involved in research focusing on the embolization of liver cancers using microspheres, embolic material consisting of tiny spheres with a diameter of only 40 µm. The depiction of minute objects with Hi-Def is an extension of that research, and I have very high hopes for its future development.

YH: Hi-Def has a pixel size 76 µm, and we took on the challenge of applying it to the abdomen after having gained substantial experience in the brain. However, we couldn't apply it to the abdomen in exactly the same way because the abdomen is thicker than the brain. It was very difficult to fine-tune the system and determine the optimal dose settings and image processing parameters. We were finally able to optimize the parameters and achieve the current high level of

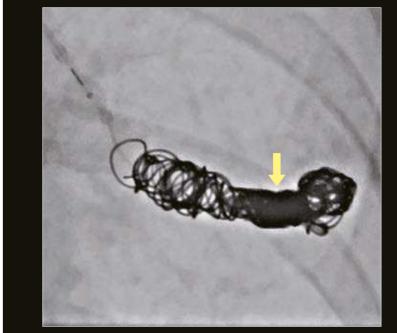
performance after installation thanks to the suggestions and guidance we received from Dr. Tanaka and the technologists at the hospital.

TT: Yes, parameter setting was difficult at first. To be honest, when I saw it the first time. I had some doubts. I wondered, "Is this going to be usable?" However, we doctors, our technologists, and the staff of Canon Medical worked together as a tight cross-disciplinary team until our efforts paid off. The improvements were remarkable, and I started to have the feeling, "This will really work!"

YH: In what areas do you think Hi-Def can really demonstrate its full potential?

TT: As I mentioned before, the first thing that comes to mind is coiling. even in the abdomen. Also, pulmonary arteriovenous malformations are considered to have a high recurrence rate. And even when coil embolization is performed properly, they may recur over the long term. To minimize the risk of recurrence, we try to achieve extremely dense coil embolization. Hi-Def allows us to clearly see any gaps between the coils and fill in the gaps completely (Figure 4). In addition, I think it will prove to be extremely useful for tumor embolization and for evaluating the feeding vessels of tumors. Although it's still in the research phase, a new treatment approach using an angiogenesis inhibitor is being developed. The initial findings of this research have shown that the angiogenesis inhibitor can normalize the abnormal cancer vessels, and this method has already been successfully employed in a number of clinical cases. I expect that this will be an area in which high-definition vascular imaging with Hi-Def will prove to be particularly effective.

YH: I really hope you can apply Hi-Def to a wide range of procedures where it's effective.

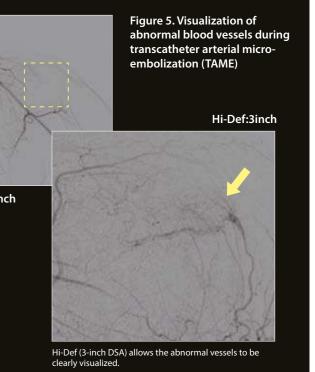




FPD:12×16 inch

Figure 4. Coil embolization in a patient with a pulmonary arteriovenous malformation

Hi-Def (3-inch Fluoro) helps to ensure more complete coil embolization.



catheter into a smaller vessel, we use Hi-Def 3-inch enlargement. After that, going back to 6 inches is a disappointment. We feel that information is lost at 6 inches because Hi-Def allows us

to see extremely minute structures. It's often the case that we notice things we hadn't noticed before. For example, with regard to musculoskeletal pain, we've used Hi-Def to evaluate vessel size in patients with Moyamoya disease, and abnormal vessels measuring 100-200 µm can be clearly depicted. Compared to 6-inch and 8-inch images, Hi-Def 3-inch images clearly show the differences in the blood vessels (Figure 5).

YH: I'm very happy to hear your positive comments. Our goal is to develop and produce equipment that helps you perform your clinical work. First, we want to ensure that the equipment provides the highest quality images. Also, because the equipment uses X-rays, it's essential to minimize radiation exposure to both patients and medical staff. And finally, we want to maximize operability. We plan to make further improvements in all these areas in the future. At the same time, we'd like to further explore the possibility of multi-modality collaboration to better support your clinical needs. Do you have any requests you'd like to share with us today?



TT: Let me first mention the things I'm really satisfied with. The main thing is the degree of responsiveness. I appreciate your prompt responses and how you carefully consider our requests and try to make improvements. I look forward to working closely with you in the future and developing exciting new technologies. I hope to address not only ease of use in routine clinical practice but also our future visions, including the future evolution of IR, working together with Canon Medical so we can move forward together into a new era.

YH: Thank you very much for taking time from your busy schedule to talk with us today. //



Nara Medical University, Nara, Japan

*Some of the comments and information in this article are the personal opinions and impressions of Dr. Tanaka.

* This article was originally published in Alphenix Magazine Vol.3 2022.

Dr. Tanaka's profile

Dr. Toshihiro Tanaka, professor and chair, Department of Diagnostic and Interventional Radiology, Nara Medical University, Nara, Japan

Specializing in minimally invasive IR treatment of malignant tumors (cancer). Actively involved in joint research and device development with manufacturers. Appointed chairman of the Japanese Society of Interventional Radiology in 2020.

Biography

1996: Completed clinical training and graduated from Nara Medical University. 1998: Served as resident at Aichi Cancer Center.

 2000: Appointed assistant professor, Department of Radiology, Nara Medical University.
2009: Served as visiting research fellow, Institute of Applied Medical Engineering, Aachen University, Germany. 2010: Named CIRSE Fellow, Department of Radiology, Maastricht University, the Netherlands. 2015: Appointed associate professor, Department of Radiology, Nara Medical University. 2022: Appointed professor and chair, Department of Diagnostic and Interventional Radiology, Nara Medical University,



Interviewer



Yoshivasu Havash Senior Engineer Vascular Systems Development Department, ular Systems Division



Hybrid Angiography-CT Room: A Unique Environment for Expanding the Frontiers of IR

Dr. Carlos Abath

INTRODUCTION

The evolution of Interventional Radiology (IR) began over 60 years ago with a simple question. Could be used the same diagnostic imaging tools that have revolutionized the practice of medicine to guide the real-time treatment of disease? It became obvious that imaging could be used better to enable certain patients to undergo targeted procedures, eliminating the need for major surgery, and others could undergo procedures for previously unsolvable problems. Since its advent, IR has expanded to encompass treatment of various diseases across multiple body systems. Interventional procedures are minimally invasive, based on image-guided techniques, such as US, CT, MRI, or DSA, and can be classified as vascular and non-vascular procedures. Vascular interventions are performed by an endovascular route, utilizing catheters, wires, and special devices to reach the target and achieve the treatment objective. The techniques used include: angioplasty and stenting of a stenotic or occluded vessel, implant of vena cava filter to prevent pulmonary embolism, delivery of embolic agents for tumor shrinkage, to stop bleeding and to occlude aneurysms and vascular malformations, or endoprosthesis introduction for aortic aneurysm repair. All these interventions are done with DSA, in an angiographic sterile operating room. Non-vascular procedures include percutaneous direct stick of cavities, organs, ducts, or tumors, for purposes of drainage, stenting, biopsy, or ablation. These types of procedures are more frequently guided by US, CT, or a combination of both. They are usually carried out in the Diagnostic Imaging Department. Therefore, the IR teams performing all the spectrum of interventional procedures, like ours, are obliged to split their professional activities into two different and separate ambiances, resulting in a considerable logistic problem for professionals and patients.



Diagnostic Imaging Department × Cath Lab

Normally, imaging facilities are designed to receive many patients, allocated in several rooms that each contain a specific diagnostic imaging modality, such as X-ray, ultrasound, CT, MRI or densitometry. Most diagnostic imaging exams, even the more sophisticated, are quick and simple, with a high turn-over of patients. In contrast, some non-vascular interventions, performed under general anesthesia, can last morethan one hour, which can slow the flow of the imaging



Figure 1a: Challenging CT guided pancreatic biopsy

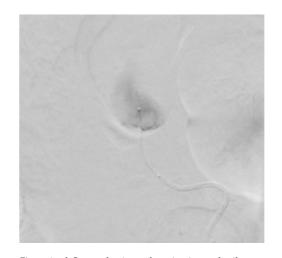
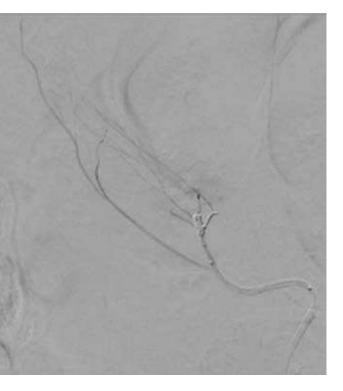


Figure 1c, d: Superselective catheterization and coil embolization of the false aneurysm

facility. Alongside this, if complications occur, like inadvertent arterial branch puncture with bleeding, the patient must be transferred urgently from the diagnostic imaging environment to the Cath Lab for embolization. So, the potential advantages of doing non-vascular interventions in the Cath Lab are obvious: sterile ambiance, trained team, equipment facilities, and catheters and devices availability to manage complex cases and life-threatening complications (Figure 1).



Figure 1b: Active bleeding detected at CT scan post biopsy



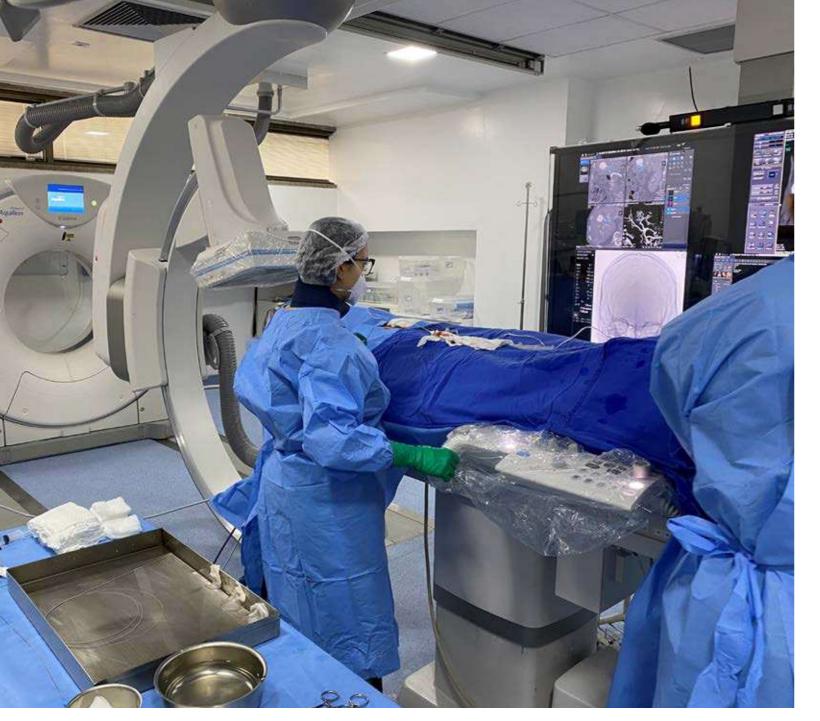


Figure 2: Alphenix 4D CT, installed at Hospital Português do Recife

Alphenix 4D CT, a rational solution

This is a powerful hybrid imaging system which has a fully operational ceiling mounted angiography system combined with an advanced dynamic volume CT scanner. It is an elegant and practical solution for more complex imageguided interventional procedures. The 4D CT has a specially designed extendable top table 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 Real Hospital Português de Recife, which was founded in 1855, is the biggest private hospital in the Brazilian Northeast region. It has 850 beds. It's Department of Cardiovascular and Interventional Radiology has always been at the cutting-edge of IR, and it is one of the most active reference centers on medical assistance and training in Brazil. Four angiography systems are currently in operation at Hospital, but only one of them incorporates a CT scanner: the Alphenix 4D CT system produced by Canon Medical Systems Corporation, Japan. This system was installed in October 2020, to meet the Hospital's needs in the rapidly expanding field of IR, and provide facilities for all kinds of interventional procedures in just one single dedicated operating room. From October 2020 until June 2022, almost 1,700 patients were treated in this hybrid room (Figure.2).

Emergency clinical cases: When time really matters

There are a special set of patients, with life-threatening clinical conditions, for whom prompt and precise interventional procedures can save lives and prevent disabling sequelae. This group, represented by patients who present with multiple traumas, massive pulmonary embolism, ruptured aortic aneurysm, major gastrointestinal bleeding, and others, require rapid diagnostic confirmation and treatment strategy planning based on CT findings, followed by an immediate endovascular intervention in the Cath Lab. The Alphenix

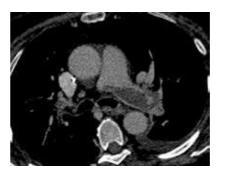


Figure 3a: CT scan showing large thrombus at the main pulmonary arteries

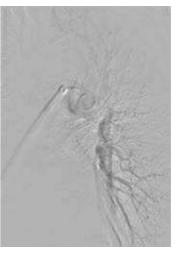


Figure.3b: Pigtail thrombus



4D CT is an unbeatable workflow, in order to avoid wasting time with the transfer of the patient from the CT room to the Angio suite and change of the respective professional team. At our Hospital we are trying to modify the PERT (Pulmonary Embolism Response Team) protocol, for patients with suspected massive and sub massive pulmonary embolism. They are then directly admitted in the hybrid room, where they can receive CT scans and immediate endovascular thrombus aspiration and thrombectomy (Figure. 3).

A patient with ruptured aortic aneurysm submitted to the

Figure.3b: Pigtail Catheter inside the

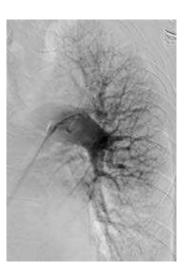


Figure 3c: Left pulmonary angiography after mechanical fragmentation, aspiration and r-TPA infusion

Alphenix 4D CT, for detailed anatomical evaluation, measurements, and EVAR planning and execution (Figure. 4).

Precision, efficacy and safety

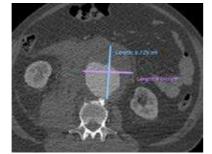


Figure 4a: CCT displaying a large ruptured AAA, with a right retroperitoneal hematoma on the right sidee



Figure 4b: EVAR planning based on the CT images

Figure 4c: Angiography after EVAR

the development of diagnostic imaging equipment that can identify culprit lesions, guide catheters and needles to the target, and evaluate treatment effectiveness. The Canon Medical 4D CT has transformed our ability to perform interventional oncology procedures. Now, we can acquire high quality CT images quickly, that are not possible to obtain using "cone beam" technology. In this way, we can accurately confirm treatment areas and recognize sources of non-target embolization, by performing fluoroscopic selective catheterization of the arterial branch that is believed to feed the lesion, and moving the table to obtain CT axial images, after intra-arterial administration of diluted iodinated contrast. If the tumoral nodule is not completely opacified, it means that another arterial feeder exists and must be found, catheterized and embolized, to avoid an incomplete response to the treatment (Figure. 5). However, if the CT scan shows opacification of a normal vital tissue or organ, a more selective catheterization must be done to avoid non-target ischemic complications.

IR has advanced in precision, efficacy and safety, thanks to

Another advantage of the Alphenix 4D CT is the possibility to carry out multiple sequential procedures in the same room. It enables two or more Interventional procedures that require guidance through different imaging modalities to be performed without moving the patient from the table. The best example is the approach of certain HCCs that could

benefit from the association of TACE and CT guided ablation (Figure. 5).

Final considerations

Hybrid Room Angiography - CT technology is bringing Interventional Radiology to a new level of performance. This is the perfect environment for a full-time interventional team, that cover all the spectrum of vascular and visceral interventional procedure. There is need to travel between the Diagnostic Imaging Department to the Cath Lab, and vice-versa, which wastes time and money, and exposes patients to unnecessary risks. In addition, the use of a high-quality CT integrated to DSA, provides an opportunity to implement new and innovative approaches for various diseases across multiple body systems. The correlation of CT, US and angiographic findings enable the physician to have a better comprehension of the pathologic process and rigorous judgement of the treatment effectiveness. Maybe, in the future, this technology will help to develop new treatment protocols, algorithms, and workflows, after scientific validation of the cumulative data.

Definitively, this hybrid CT-Angiography room will expand the horizons of Interventional Radiology, empowering even more the specialty among the population and medical community. //



Figure 5a: 3D reconstruction of the hepatic arterial tree, after CT scan with intra arterial contrast infusion. Electronic lines represent the tumor's arterial feeders. This image is superimposed on the fluoroscopic screen, and works as a roadmap to quide superselective microcatheterization

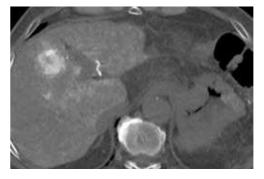


Figure 5c: CT scan after intra arterial infusion of contrast, showing enhancement of the whole nodule



From left to right Dr. Jailton Luiz Cordeiro Junior (Anaesthetist), Dr. Ruth da Silva Pinheiro (IR), Dr. Carlos Abath, Dr. John Christian Alva Saavedra (IR).



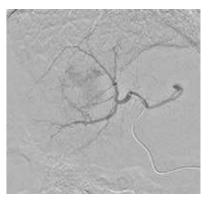


Figure 5b: Angiography performed after microcatheterization of the segment IV arterial branch

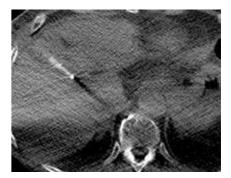


Figure 5d: After TACE, CT guided puncture for RF ablation



VISIONS spoke with SEARCH (Sandnes Education And Research Center Hoyland), a research laboratory in Sandnes, Norway, about their experiences with the Alphenix 4D CT.

Searching for New Horizons with the Alphenix 4D CT

SEARCH (Sandnes Education And Research Center Hoyland) is a new research laboratory in Sandnes, Norway. It was established to provide state-of-the-art resources for public research institutions and private companies to scientifically test products and techniques from a broad range of sectors, including medical and veterinary fields. This research has the potential to enhance scientific knowledge on diseases, diagnostic tools and treatment methods that have the potential to benefit human- and/or animal health globally. Highly advanced imaging is essential. One of the first priorities in setting up the lab was to install an Alphenix 4D CT from Canon Medical. Marianne Oropeza Moe, Manager, and Frode Johannessen, Senior Radiologist at SEARCH, explain how the advanced system opens up a wide range of research opportunities.

riginally formed from a collaboration between the Norwegian University of Life Sciences (NMBU), Stavanger University Hospital (SUS) and the University of Stavanger (UiS), SEARCH is currently run by five core staff with access to the

wider scientific expertise of medical and veterinary specialists from these institutes. Over the last five years, the facility has evolved from a concept into a fully functional laboratory which will welcome its first research customers later this year.



"We have high expectations for the system, as well as the alliance with Canon Medical and Tromp Medical."

Marianne Oropeza Moe – Manager at SEARCH, Sandnes, Norway.

Aiming to be the best

SEARCH Laboratory has been established for use by public research institutions and private companies for testing techniques, medical equipment etc. using models, simulators or fresh frozen specimens.

Construction of the lab began in 2017. The core operational team was appointed in 2020 and immediately set about equipping the new lab. One of the first priorities was to acquire state-of-the-art imaging equipment. The lab purchased an Alphenix 4D CT system from Canon Medical Systems Europe and Tromp Medical.

"We are a small core team, but we aim to be the best experimental lab in Europe!" remarked Frode Johannessen. "There were many reasons why we chose Canon Medical and the Alphenix 4D CT," said Marianne Oropeza Moe. "Firstly, the quality and advanced capabilities of the equipment itself – the 4D CT with the 16cm Wide-Area Detector CT, combined with a highly flexible Angio system. A shared coordinate system between the CT and Angio system for optimal communication. And the fact that this



From left to right: Christel Ailin Eide Espeland, Frode Johannessen, Silje Nes and Marianne Oropeza Moe (SEARCH, Sandnes, Norway).

What is Canon Medical's Alphenix 4D CT?

The Alphenix 4D CT is an integrated system that combines premium CT and ceiling-mounted Angiography technology. It provides the perfect diagnostic and treatment set-up for procedures across various interventional segments such as Interventional Oncology, Trauma / Neuro / Stroke, General Vascular or for use as an additional or backup CT. The system is available with two different CT configurations: Aquilion ONE/ GENESIS Edition and Aquilion Prime SP.



Nils Petter Oveland, Medical Advisor at SEARCH, Sandnes, Norway.



system fitted well into our lab, which occupies a relatively small area."

"In addition, the professionality of the vendors during the purchase in process and in subsequent negotiations impressed us," she added. "The participation of top leaders from both Tromp Medical Norway and Canon Medical made it possible to come to conclusions and agreements during the negotiations in a smooth way and their willingness to commit to a partnership with us."

Versatility

SEARCH require the Alphenix 4D CT for many different kinds of CT examinations and interventions. For example, to scan animal models, to offer the highest quality imaging and live videos of anatomical structures and pathological processes in animals and humans (i.e. as part of specific research projects), to train many medical and veterinarian specialists, and to develop new imaging software.

"Our imaging activities will start off with evaluations of the cardiovascular system on animal models," said Frode Johannessen. "We have a project scheduled this autumn together with Topigs Norsvin (a world leading company in pig breeding and genetics) called: "A Heart for a Pig". This is a



Frode Johannessen, Senior Radiologist at SEARCH, Sandnes, Norway.



survival study with ten, fast-growing, pigs which we will examine with CT from the weight of 40 kg until slaughter weight 120 kg (three months). Our main objective in the project is to acquire more knowledge regarding development of the cardiovascular system and heart function in fastgrowing pigs. For this we plan to use Canon's software - CT Cardiac Functional Analysis."

Two different research groups, one from Sweden and one from Finland, also wish to conduct their experiments on detection of intracranial bleeds at SEARCH. And other customers have expressed an interest in conducting survival studies after implanting new medical devices at the lab. The Alphenix 4D CT system will also be used as the gold standard in a PhD project to evaluate the diagnostic potential of microwaves for detection of internal bleeding.

"We are also planning to offer a wide range of Interventional Radiology courses. Anything from elementary level to more advanced courses, such as embolization, TIPS, TAVI and spine intervention," said Frode Johannessen.



Frode Johannessen, Senior Radiologist at SEARCH, Sandnes, Norway.

A new spectrum of possibilities

The Alphenix 4D CT opens up a whole new spectrum of possibilities for SEARCH.

"We have high expectations for the system, as well as the alliance with Canon Medical and Tromp Medical,"

Sandnes, Norway added Marianne Oropeza Moe. "We are convinced that it was a smart move to base the acquisition of the system on a collaborative approach. Our experience with multidisciplinary teams is that they result in new synergies and alternative approaches to solve

problems." //

Silje Nes,





Department engineer at SEARCH,



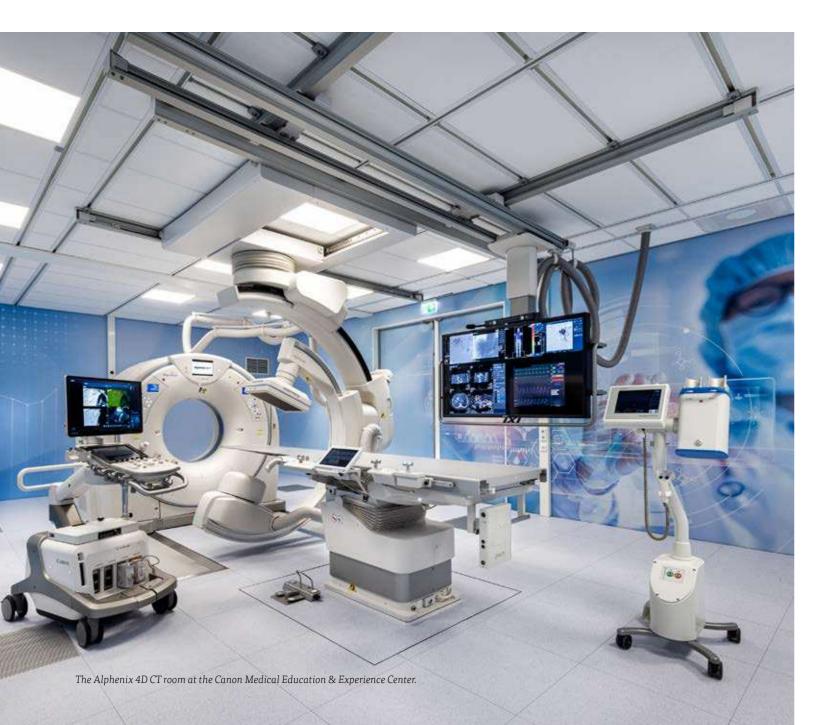
Christel Ailin Eide Espeland Research technician at SEARCH, Sandnes, Norway

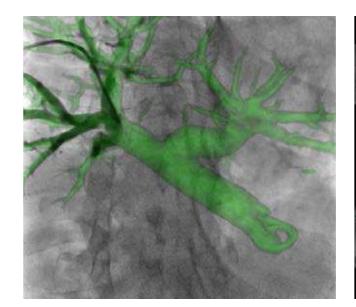


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Enhancing Knowledge on Latest Innovations

Canon Medical continually develops new technologies to improve product performance. Upgrading our products means that we can provide new functionality, help our customers benefit from the latest technology, and extend the longevity of their systems, but we need to keep our customers and our own staff up-to-date with developments. Our Education & Experience Center at European Headquarters, in The Netherlands, is a key resource in this.





Prof. Guiu – CHRU St. Eloi, Montpellier Multimodality Roadmap: Overlay of 3D volumes onto fluoroscopy to improve confidence, reduce the amount of contrast and examination time.

The facility was recently extended with the addition of a unique Alphenix 4D CT. The Center is now fully equipped with an Alphenix 4D CT. It welcomed its first trainees in 2021: specialists and technicians from one of Canon's customer hospitals, who traveled from France to learn more about the new features available on their own, newly upgraded Alphenix 4D CT system in a dedicated training session.

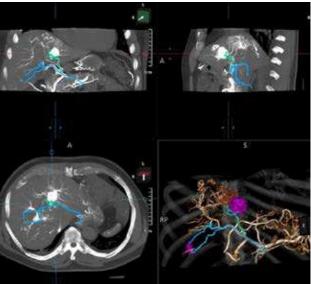
Busy schedule

The Center will be used to enhance the knowledge of Canon Medical's own specialists and engineers, as well as customers. During the course of 2022, it is anticipated that the Center will host approximately ten training sessions for Canon's own Application Specialists in Interventional applications, 15 training sessions for Canon Service Engineers, around three customized service training sessions for hospital engineers, up to five customer



"The Alphenix 4D CT in the Education & Experience Center represents our dedication in investing in an innovative multimodality solution that will improve clinical outcomes, lead to workflow optimization, patient outcome and increased cost efficiency."

Erwan Ladsous, European Director Interventional Radiology, Canon Medical Systems Europe.



Embolization Plan software: Semi-automatic tumor segmention and feeder detection to optimize workflow during i.e TACE procedures.

application training sessions, on request. Potential customers can also visit the Center to experience the Alphenix 4D CT 'live' or utilize full livestreaming possibilities remotely. The Center is also creating a range of sales support and application materials, such as videos and user-instructions.

"When we introduce new products, such as the Alphenix 4D CT Angiography suite, we work together in close collaboration with our "We are extremely pleased with such a great training center which features a unique hands-on or livestream experience for potential and actual customers."

"The training center gives us a vital opportunity to test new software, optimize protocols and train our European application colleagues with tailor-made courses"

Yves Pijlman – European Clinical Specialist Interventional Radiology, Canon Medical Systems Europe.

customers to gather their experiences and their feedback as to what may help them and their patients even further. Our partnership with customers fuels continual innovation, which manifests in upgrades and new products." said Thomas Grossmann, Canon Medical's Modality Manager.

"Training with the upgraded system is important," he added. "It enables users to become familiar with new features before they start clinical practice with the upgraded system and ensure that its introduction does not affect workflows. It also means they become aware of the full range of possibilities available to them with the upgrade."

The first customer training was attended by three staff members from one of Canon's customers, who learned how upgrades to their

Alphenix 4D CT (running on a Canon Medical Aquilion ONE / GENESIS Edition CT system) would be to used in practice. The training was held over one full day and was facilitated by Canon Medical Trainers, Xavier Carvin, Naoufel Marzak, and Yves Pijlman.

New features

In August 2021, the Alphenix 4D CT software was upgraded together with the installation of the new CT Fluoro console. The new CT Fluoro console has been designed to optimize workflow with a new touch panel and joystick design, and an improved image data display for CT Fluoro examinations.

In addition, the Alphenix 4D CT software was upgraded to implement the following improvements:

- New computer hardware with improved hard-disk capacity (3.3x more data capacity).



- Image quality improvements for 2D Roadmap imaging.
- ^{SURE}Guidance and Embolization Plan software have been optimized on the Alphenix 4D CT series.
- A new feature called 'Alphenix Auto Registration', which features full, automatic image registration for 3D Roadmap, a big step forward in workflow.
- Alphenix Auto-table functionality, C-arm and table positions can be easily restored based on previous images.
- Improved flexibility to set and adapt 58" monitor layouts in the examination room with the Alphenix tablet.
- Optimized Needle Guidance workflow, up to five needle paths can be set and used at the same time. The complete workflow is accessible from the tableside with the Alphenix tablet.
- Upgraded embolization plan software which enables analysis of ten tumors at the same time and improved workflow.
- General workflow improvements for the Alphenix Angio Workstation.
- · Improved dose management for Alphenix' SPOT Fluoro dose-saving feature.
- Enhanced functionality for Dose Tracking System, allowing the generated dose reports to be transferred to PACS and/or any other network server.



(European Senior Product Manager), Erwan Ladsous (European Director Interventional Radiology), and Yves Pijlman (European Clinical Specialist).



Naoufel Marzak – Application Specialist Interventional Radiology, Canon Medical Systems France.

Canon Medical Systems Europe's Interventional Radiology Team (from left to right): Ed van der Vliet (European Clinical Specialist), Sjoerd Iken

"Potential customers can also visit the Center to experience the Alphenix 4D CT 'live' or utilize full live-streaming possibilities remotely."

"The Canon CT scanners improve the accuracy and efficiency of our Interventional procedures."

Xavier Carvin – VL Clinical Expert Interventional Radiology, Canon Medical Systems France.



Enhancing product value

The Alphenix 4D CT is an innovative, multimodality solution that will improve clinical outcomes, patient safety, clinical workflow and cost-efficiency.

"Providing the right training for users after upgrades will enhance the system's value in the clinical workplace and is an important part of our commitment to ensure that our customers can continue to deliver optimal patient care," said Xavier Carvin, Clinical Expert Interventional Radiology at Canon Medical Systems France. //





"We work together in close collaboration with our customers to gather their experiences and their feedback as to what may help them and their patients even further."

Thomas Grossmann – Modality Manager Interventional Radiology, Canon Medical Systems France.



New features available with the Alphenix 4D CT

^{SURE}Guidance

CT and Angiography without moving the patient improves workflow. The unique ^{SURE}Guidance feature in Canon Medical's Alphenix 4D CT system provides a fast and accurate position linkage of the target exposure area between CT and Angiography. The CT gantry, Angiographic C-arm and table can move automatically to an indicated target position, improving workflow and saving procedure time.

3D Roadmapping

Canon Medical's 3D Roadmapping feature utilizes an unsubtracted or subtracted 3D acquisition, CT or MR volume. Such a volume can be overlaid onto live Fluoroscopy which provides better guidance during the interventional treatment phase, as it always keeps the correct spatial alignment of the 3D volume with the real anatomical background irrespective of any potential C-Arm or table movement, FOV and SID changes.

The 3D/2D synchronization works in two ways: 1.) C-Arm follows the 3D volume orientation changes. 2.) 3D volume follows the C-Arm orientation changes.

Alphenix Auto Registration

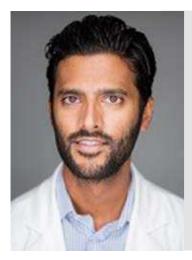
Full, automatic image registration between CT data and fluoroscopy, which represents a big step forward in workflow.

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Utility of 4D CT Technology During Prostate Artery Embolization (PAE)

Nainesh Parikh, MD, MBA Associate Member, Diagnostic Imaging & Interventional Radiology H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL with Florida, USA.

Yiemeng Hoi, PhD, Dale Marek, RT(R) Mark Hohn, Andrew Kuhls-Gilcrist, PhD, DABR Medical Affairs, Interventional X-ray Canon Medical Systems USA, Inc.



Dr. Nainesh Parikh, a Board-Certified Interventional Radiology, pioneers the PAE program at H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL with Florida, USA. He focuses on utilizing PAE for men with lower urinary tract symptoms (LUTS) from benign prostatic hyperplasia (BPH) who may or may not have concurrent prostate cancer. Dr. Parikh earned his undergraduate degree from Columbia University in New York City, USA, and subsequently worked as an Investment Banker after graduation. After deciding that he wanted to have a significant impact on the daily lives of patients, he obtained MD and MBA degrees from Tufts University School of Medicine in Boston, Massachusetts, USA. He then completed diagnostic radiology residency at NYU Medical Center in New York City, and a fellowship in Angiography and Interventional Radiology at the Brigham and Women's Hospital – Harvard Medical School Boston, Massachusetts, USA

"4D CT is helpful during PAE for confirmation of PA origin, quantification of prostatic parenchyma, and identification of intra-prostatic collaterals. The ability to visualize these things with exceptional image quality allows for increased confidence during embolization with respect to safety and outcomes."

Nainesh Parikh, MD, MBA

4D CT: True CT and Angiographic Imaging for Advanced Image Guided Therapy

The Canon Medical Alphenix 4D CT system combines two complimentary imaging modalities within the same environment - a sliding computed tomography (CT) scanner system with a state-of-the-art interventional fluoroscopic C-arm. This enables utilization of CT and fluoroscopic

images during diagnostic and therapeutic interventions during the same procedure.

This potentially leads to more accurate image-guided interventions with reduced procedure time, providing on-demand true CT imaging during interventional procedures. ^{1,2}

BPH, sometimes referred to as 'an enlarged prostate', is

one of the most common medical conditions in older men. effecting 70% of men in their 70s and 80% of men in their 80s.³ Recently, Prostate Artery Embolization (PAE) was recommended by four multidisciplinary medical societies as a "valuable minimally invasive option for patients who cannot tolerate or who have failed medical therapy, and those who are poor surgical candidates or refuse invasive surgery."4 Detailed knowledge of prostatic arterial anatomy is necessary during PAE in order to minimize the risks of 'non-target' embolization that can cause ischemic complications to major pelvic organs, such as the urinary bladder, rectum and penis.⁵ Thus, identification of the prostatic artery origin as well as collaterals supplying pelvic viscera, is paramount.

As part of the PAE program at Moffitt Cancer Center, Dr. Parikh and his team have treated over 150 patients for lower urinary tract symptoms. In order to specifically evaluate the utility of 4D CT during PAE, the team conducted a pilot study

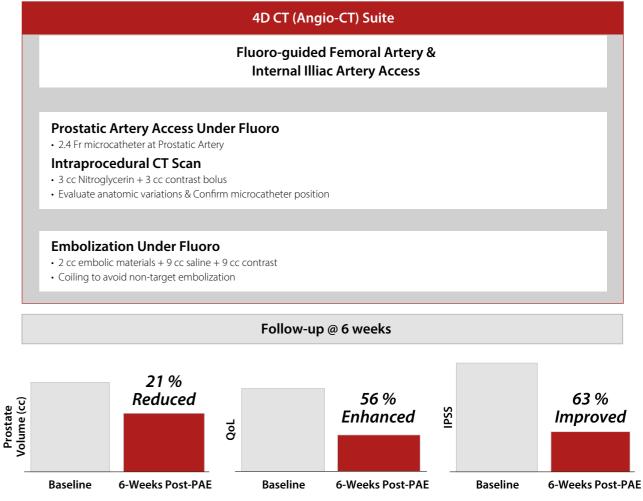


Figure 1: Clinical improvement was significant in patients treated with PAE using the 4D CT system, with mean prostate volume reduced 21%, mean QoL enhanced 56%, and mean IPSS improved 63%.⁶

of 10 consecutive patients who underwent technically successful bilateral PAE in the 4D CT suite between September 2017 and February 2020 to evaluate short term clinical success, as well as to demonstrate efficiency of the 4D CT system during PAE.⁶ Short-term clinical success was evaluated by comparing prostate volume, International Prostate Symptom Score (IPSS) and Quality of Life (QOL) scores before treatment and at six-week follow-up. Efficiency of 4D CT was measured by calculating time required to perform 4D CT for each PA as a percentage of total procedure time. Results demonstrated that PAE with use of 4D CT was safe, clinically effective and efficient. Intraprocedural 4D CT of bilateral PAs is valuable for confirming PA origin, identifying pelvic visceral collaterals, and optimizing volume of embolic delivered. Acquisition of intraprocedural CTA of bilateral PAs consumed only 12% of total procedure time.⁶

Clinical Report

Nainesh Parikh, MD, MBA,

H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL with Florida, USA.

Patient 1

History: A 70-year-old man presented with PI-RADS®4 MRI found to represent, Gleason 3+4 favorable intermediate risk prostate cancer (Gleason Grade Group 2) with a baseline IPSS of 29, QOL 3 and prostate volume 94 cc from radiation oncology clinic prior to definitive radiotherapy.

Procedure: Via right common femoral artery approach, both prostatic arteries (PA) were catheterized using a 2.4Fr microcatheter. The left PA (LPA) arose from the obturator artery and a clear intra-prostatic penile collateral was seen during Angiography (Figure 2). After successful coil embolization, the microcatheter was retracted into the main LPA and pelvic CTA was performed after hand injection of 3 cc contrast and 5 seconds delay (120kV, ^{SURE}Exposure, 0.5s rotation time, 0.5 mm x 80, AIDR* 3D) using the 4D CT system. CT imaging was helpful for identifying persistent penile collateral (Figure 3) which was subsequently successfully coil embolized (Figure 3C). After retracting the microcatheter into the main LPA, 5 cc diluted embolic material (2cc 300-500 μ m Embosphere® microspheres in 9 cc saline and 9 cc contrast) was delivered into the LPA under fluoroscopy. The right PA (RPA) was also successfully embolized with 5 cc of diluted embolic material, for a total of 10 cc. No access site or post-procedure complications were seen.

Outcome: The patient's IPSS and QOL improved to 4 and 1, respectively at 6 weeks; prostate volume decreased from 94 cc to 49 cc at 6 weeks. The patient had persistent continued improvement at 12 week follow up and successfully underwent 60 Gy image-guided radiotherapy (RT) in 20 fractions over 4 weeks without acute genitourinary toxicity.

*: Adaptive Iterative Dose Reduction

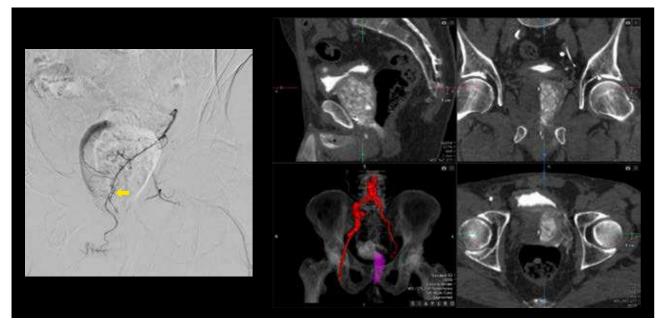


Figure 2: Digital subtraction Angiography (DSA, a) and 3D reconstruction of (b) of the left prostatic artery demonstrating an intra-prostatic penile collateral (yellow arrow)

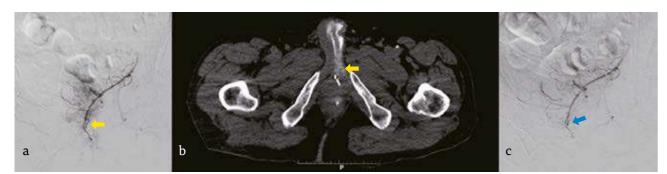


Figure 3: Digital subtraction Angiography (DSA, a) showing persistent intra-prostatic penile collateral (yellow arrow) confirmed on 4D CT imaging (b). CT imaging was helpful for identifying and confirming persistent penile collateral which was subsequently successfully coil embolized (c, blue arrow).

Patient 2

History: A 80-year-old man presented in urinary retention from long-standing BPH with a left total hip arthroplasty and was referred for PAE.

Procedure: Via right common femoral artery approach, both tortuous internal iliac systems were selected and both PAs were catheterized using a 2.4Fr microcatheter. Pelvic CTA of each PA was performed after hand injection of 3 cc contrast and 5 seconds delay (120kV, ^{SURE}Exposure, 0.5s rotation time, 0.5 mm x 80, AIDR 3D) using the 4D CT system. Intraprocedural CT imaging was helpful for being able to exclude intra-prostatic penile collaterals in addition to evaluating the entire enlarged prostate even in the face of the significant streak artifact from the left total hip arthroplasty (Figure 4, 5). Successful embolization was performed under fluoroscopy with a total of 15 cc diluted embolic material (2cc 300-500 μ m Embosphere[®] microspheres in 9 cc saline and 9 cc contrast) was injected. No access site or post-procedure complications were seen.

Outcome: The patient successfully passed voiding trial at 6 week follow up with mild LUTS (IPSS 6; QoL 1) post catheter removal.

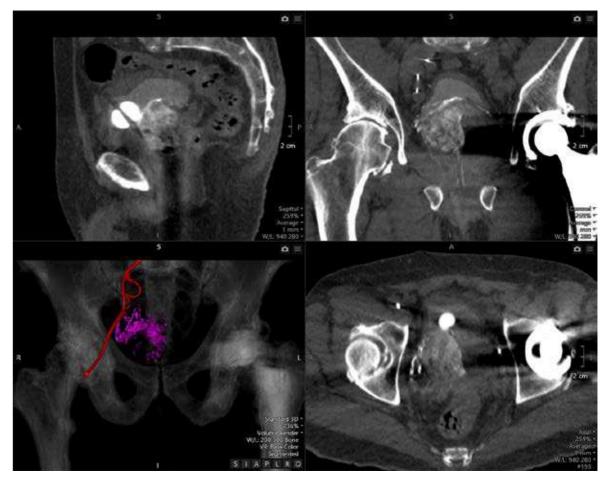


Figure 5: 3D CT reconstruction after contrast injection into the right prostatic artery demonstrates excellent image quality for visualization of the right hemi-prostate in the face of significant streak artifact secondary to the left total hip arthroplasty

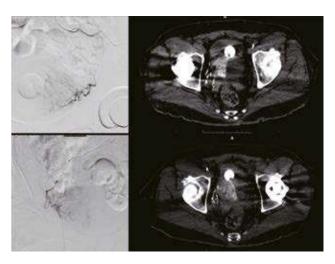


Figure 4: Digital subtraction angiogram (DSA) (left) and CT (right) of left prostatic artery (top) and right prostatic artery (bottom). Intraprocedural 4D CT imaging was helpful for exclusion of intra-prostatic penile collaterals as well as for full evaluation an enlarged prostate given significant streak artifact from the left total hip arthroplasty.

Patient 3

History: An 82-year-old man with a history of Gleason 4+4 high risk (Gleason Grade Group 4) prostate cancer status presented in acute urinary retention approximately 6 months post completion of radiotherapy. Baseline prostate volume was 68 cc.

Procedure: Via right common femoral artery approach, both prostatic arteries (PA) were catheterized using a 2.4Fr microcatheter. Both PAs arose from a common cysto-prostatic trunk. Pelvic CTA of only the right PA was performed after hand injection of 3 cc contrast and 5 seconds delay (helical scan, 120kV, ^{SURE}Exposure, 0.5s rotation time, 0.5 mm x 80, AIDR 3D) using the 4D CT system. CT imaging was helpful for identifying reflux into the cystic branches resulting in very deliberate embolization (Figures 6). A total of 9 cc diluted embolic material (2cc 300-500 µm Embosphere® microspheres in 9 cc saline and 9 cc contrast) was injected under fluoroscopy between both PAs. No access site or post-procedure complications were seen.

Outcome: The patient successfully passed voiding trial at 6 week follow up with mild LUTS (IPSS 5; QoL 0) post catheter removal.

Multimodality For Better Patient Care

PAE is a complex, technically challenging procedure that requires intimate knowledge of the pelvic arterial anatomy. Intra-procedural CT is helpful to confirm prostatic artery origin in addition to intra-prostatic collateral vasculature, particularly to the penis. Visualization of these details allows for safe, effective, optimal treatment. For example, identification of PA origin in conjunction with confirmation of the lack of intra-prostatic penile collateral allows for embolization with the maximal amount of embolic material resulting in optimal clinical outcome. Streamlined 4D CT allows for full visualization of the pelvic viscera, particularly in large or tall patients; conversely, cone-beam CT is limited by the detector panel size in addition to patient size. In addition, 4D CT allows for excellent image quality during the procedure. Dr. Parikh would like to extend his warmest thanks to the staff of the Department of Interventional Radiology at H. Lee Moffitt Cancer Center & Research Institute for their continued support in the development of the prostatic artery embolization program. //

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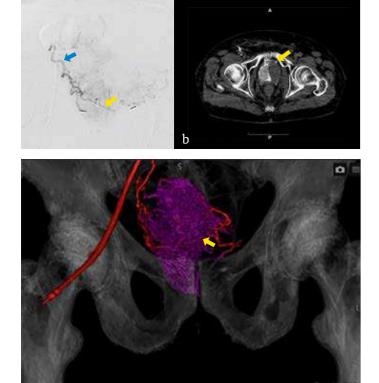


Figure 6: Digital subtraction Angiography (DSA, a), CT (b) and 3D reconstruction (c) after contrast injection into the right prostatic artery (blue arrow). Reflux into a cystic branch was clearly identified on both Angiography and CT (yellow arrows), resulting in very deliberate but complete embolization.

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