Vascular

Updating Clinical Practices with Trinias series Angiography System Featuring SCORE Opera AI Technology, Developed Based on Feedback from Users in the Field

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1. Introduction

Fukuoka Wajiro Hospital **(Fig. 1)** is located in a residential area about 30 minutes by car from the center of Fukuoka City and serves as a cornerstone for acute medical care in the region. The hospital operates 33 clinical departments and has 369 beds (including 18 ICU beds, 16 HCU beds, and 26 recovery beds). In 2023, it reported a total of 158,418 outpatient visits and provided care for 125,269 inpatients, while also accommodating 6,705 emergency ambulance arrivals and performing 4,000 surgical procedures. Our Department of Cardiology offers a wide range of services for ischemic heart disease, valvular disease, arrhythmias, peripheral vascular diseases (including varicose veins), and heart failure. Available diagnostic technologies include 320-slice cardiac CT, cardiac MRI, scintigraphy, transesophageal echocardiography, and exercise stress echocardiography. Procedures offered include PCI (percutaneous coronary intervention), TAVI (transcatheter aortic valve implantation), EVT (endovascular peripheral vascular procedure), laser treatment of lower limb varices, catheter ablation, pacemaker procedures (including for implantable cardioverter-defibrillators and biventricular pacemakers), percutaneous left atrial appendage closure, and the use of an Impella ventricular assist device for cardiogenic shock. In conjunction with the upgrade of angiography systems at other affiliated hospitals, we have now updated our own angiography system. This paper aims to discuss the innovative interface and advanced image processing capabilities of the newly introduced Shimadzu Trinias B8s angiography system with SCORE Opera **(Fig. 2)**.

Fig. 1 Exterior of Fukuoka Wajiro Hospital

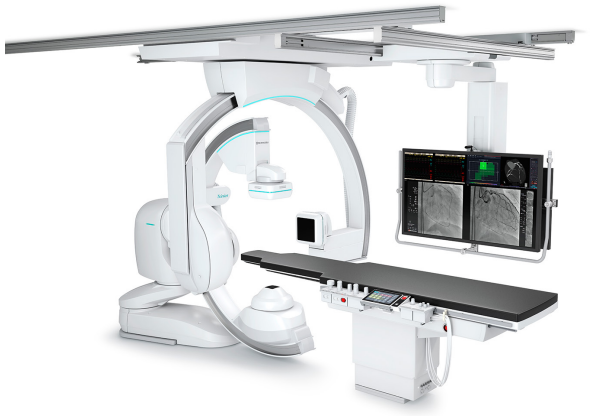

Fig. 2 Newly introduced Trinias B8s with SCORE Opera

2. Improved System Operability Aligned with Purchase Requirements

Our hospital has four catheterization rooms, and we have updated one room specifically dedicated to coronary interventions. The previous system was an old previous-generation Trinias series system (introduced in 2017) that already featured a low-dose high-quality image processing engine, effectively utilized for PCI procedures for complex lesions. The newly introduced Trinias series with SCORE Opera has revitalized the operator's working environment and incorporates the aforementioned AI image filters, achieving further advancements.

3. Enhancements in Operability

In coronary interventions, the requirements that operators seek from an angiography system include the following:

1. Low radiation exposure while maintaining high image quality.
2. The ability to quickly set up the C-arm and table in the desired position.
3. The capability to complete all operations from the operator's position.
4. The inclusion of applications that support performing procedures safely and rapidly.
5. Access to comprehensive after-service support.

The Trinias series with SCORE Opera is developed based on “Human-Centered Design (HCD)” principles, with a control module **(Fig. 3)** that allows even novice operators to quickly grasp how to perform operations. The touch panel (SMART Touch shown in **Fig. 4**) features various assigned functions that operators can use according to their preferences. Additionally, compared to previous models, the speed of C-arm movement has significantly increased, which is likely to astonish users. While, as interventionalists, ensuring safety during procedures is paramount, we must also address the challenge of reducing examination times. It is evident that improvements in operability contribute to that goal.

4. Utilization of SMART Dial

The new control module features another noteworthy characteristic: the SMART Dial, which can be installed at the bedside to allow operators to manipulate reference images by themselves. The dedicated lever has a dial mechanism that facilitates not only playing and pausing cine images but also intuitive frame-by-frame navigation. Though support from radiological technologists may be sought while reviewing necessary reference images during procedures, particularly in complex lesion procedures, operators often need to manipulate images frame by frame to evaluate collateral pathways in detail. This is enabled by the SMART Dial. Although operations are conducted via a sterile cover, it remains easy to handle. Actual usage will be discussed in section 5.3 of 5. Clinical Cases.

5. Clinical Cases

5.1 Low Radiation Dose Settings

At our hospital, we actively engage in treating complex vascular cases, which can result in prolonged procedure times, thus we consistently strive to minimize radiation exposure. Clinical images presented in **Fig. 5** show images with fluoroscopy dose settings reduced by 40% (7.5 PPS -1) and by 67% (7.5 PPS -3) from the standard setting. This involves a procedure where a wire is passed through the left anterior descending artery. When the fluoroscopy dose is reduced, the image may appear slightly darker and exhibit some granularity, but essential images for the procedure are still obtained without compromising the visibility of the device. In the past, when using previous systems, reducing the fluoroscopy dose sometimes resulted in after-images that affected the perception of wire behavior, but no such artifacts have been observed with the current system.

5.2 Application of SCORE StentView

The Trinias system includes an application called SCORE Stent View, which enhances stent visibility. Though SCORE StentView has been used in various contexts, the following describes a case from our hospital where the stent enhancement mode proved useful during IVL (intravascular lithotripsy) for highly calcified lesions **(Fig. 6)**. In IVL, energy is emitted from two locations at the center of the 4 markers (emitters) observed on the balloon. With StentView, the visibility of calcification and emitters is enhanced, allowing for precise positioning without the need for contrast confirmation, as demonstrated in this case.

Fig. 3 Control Module

Fig. 4 Display of SMART Touch

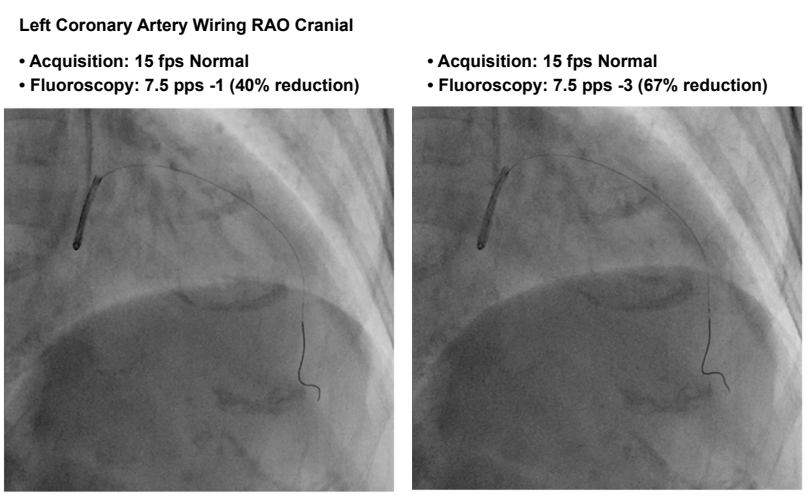

Fig. 5 Comparison of fluoroscopic images with reduced radiation dose levels

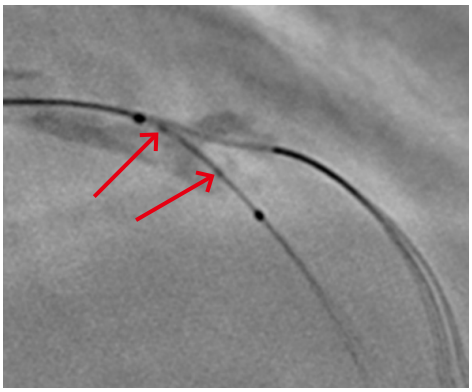

Fig. 6 Application in IVL (Red arrows indicate emitters)

5.3 Utility in CTO Procedures

SMART Dial

In retrograde approaches, wiring is performed using images of the distal coronary artery from the septal branch **(Fig. 7)**. Previously, operators often relied on technicians or assistants to capture these images. However, using the SMART Dial **(Fig. 8)**, operators can now freely control the reference image settings. The operability remains unaffected even when using sterile covers, allowing for stress-free setting configuration.

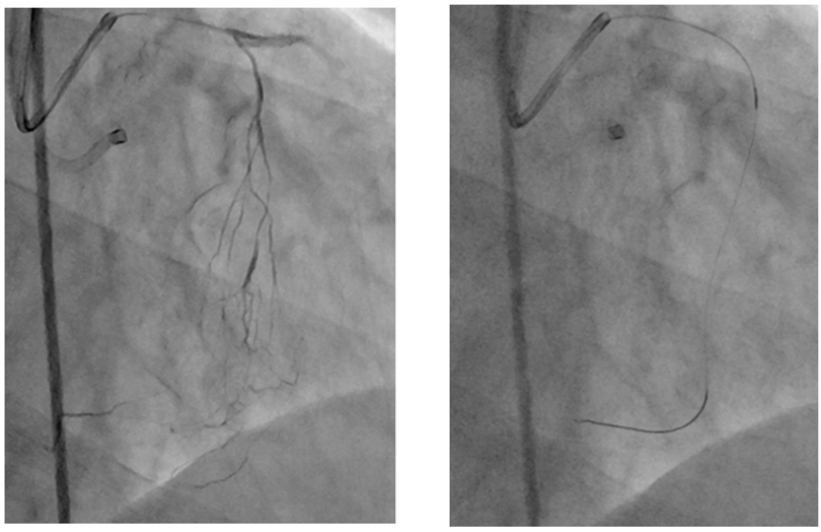

Fig. 7 Distal angiography image (left) and wiring fluoroscopy image (right)

Fig. 8 Frame-by-frame navigation using SMART Dial. This innovative dial operation supports stress-free image selection.

Low Dose Intervention

The CTO case shown in **Fig. 9** involved PCI using a retrograde approach combined with IVUS guidance, with a procedure time of 6 hours and 30 minutes. The fluoroscopy was conducted with a 50% dose reduction (7.5 PPS -2), resulting in a fluoroscopy time of 4 hours and 25 minutes, using a radiation dose of 4218 mGy. Although this is an extreme case, the ability to complete such a lengthy procedure at this radiation dose is noteworthy. Six months post-intervention, there have been no signs of radiation-induced skin damage, indicating a favorable outcome. Furthermore, we have now reduced the fluoroscopy conditions for CTO procedures to a 67% dose reduction (7.5 PPS -3). This further decreases radiation exposure during prolonged procedures and alleviates concerns regarding radiation-related complications.

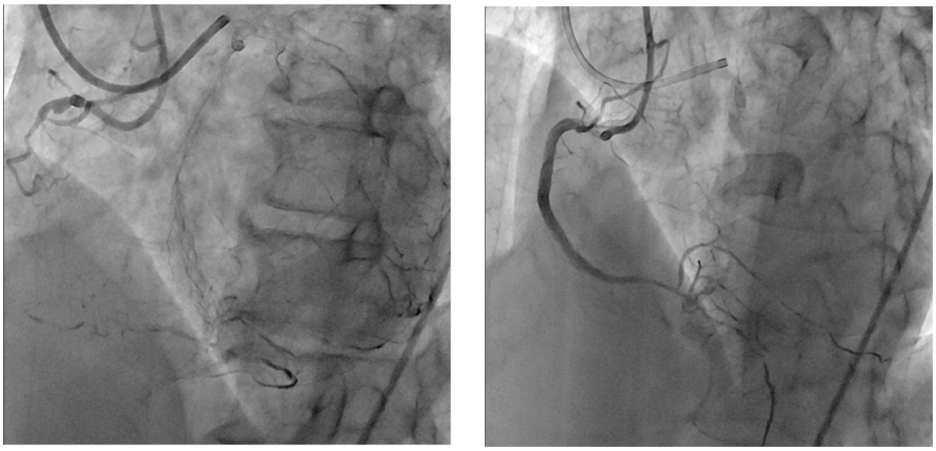

Fig. 9 CTO case with fluoroscopy conditions reduced by 50% (7.5 PPS -2)

6. Conclusion

As discussed above, the new product represents a significant update achieved by listening to feedback from the clinical field. It maintains high image quality while reducing radiation dose levels, features user-friendly machine speeds, and achieves a compact system configuration for a biplane system without compromising operability. The intuitive operability provided by the SMART Dial is one of the many functionalities that we hope users will experience. We look forward to further system updates through ongoing software development.