Vascular

Our Experience with Trinias Biplane and Hybrid Operating Room Systems

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1. Overview of the hospital

The Mitsubishi Kyoto Hospital was established in 1946 as a company hospital for the employees of Kyoto Machinery Works, Mitsubishi Heavy Industries Ltd. The hospital is currently affiliated with Mitsubishi Motors Corporation, a spinoff from the parent company in 1970. Located in the southwest part of Kyoto city, the Mitsubishi Kyoto Hospital is a 188-bedded hospital (general ward, 174 beds; ICU/CCU, 8 beds; and NICU, 6 beds). Ever since its establishment, the hospital has played a vital role as a central hospital in the region, which caters to not only the Mitsubishi employees and their families but also the general public living in the area. Immediately after its inception, it served as the nodal hospital for the treatment of tuberculosis and other communicable diseases. However, due to subsequent changes in disease trends, the treatment facilities were expanded and aligned to contemporary needs. The year 2007 saw the rebirth of the hospital as the first earthquake-proof hospital in Japan, using only electricity as its source of energy, and stocked with an emergency underground supply of water and a dedicated helipad. All our employees are dedicated toward providing healthcare services driven by our fundamental philosophy of sophisticated and friendly healthcare service delivery.

Fig. 1

2. Background

Our cardiovascular internal medicine physicians work closely with cardiovascular surgeons for treatment of a wide range of cardiovascular disorders. In the fiscal year 2014, we performed 306 percutaneous coronary interventions (PCI), 160 endovascular treatments (EVT) (including shunt PTA), 84 pacemaker surgeries (including biventricular pacing and ICD), 122 cardiovascular surgeries, and 14 aortic stent graft procedures. In the recent years, there has been a steady increase in the number of conditions that are amenable to percutaneous interventions via catheters. Moreover, because of the aging population, the need for less invasive interventions is increasing. Given the demographic trends, a hybrid operating room where surgery and percutaneous interventions can be performed simultaneously confers a significant advantage. To address this need, a new hybrid operating room was installed at our hospital in April 2015.

With the establishment of the new hybrid operating room, we decided to replace the previously used angiography system (biplane system) in the cardiac catheterization room. After a detailed evaluation of the available options, we opted for the Shimadzu angiography system, with a ceiling mounted C-arm (12 × 12 inches) in the hybrid operating room, and a biplane system (8 × 8 inches) in the cardiac catheterization room.

Fig. 2

3. Equipment overview

Both systems have unique features, but the SCORE PRO Advance image processing technology, which enables low exposure doses, and the StentView+Plus software for supporting PCIs are especially useful. These features are described below with examples of actual cases.

The biplane system **(Fig. 3a)** includes 8 × 8-inch FPDs specifically designed for cardiac applications. The system can be used in a biplane configuration, whenever necessary, for diagnostic and therapeutic interventions. The biplane configuration has been particularly useful for complex PCIs, such as those for chronic total occlusion (CTO), and catheter ablation procedures. Due to its compact size and easy operability, it allows a stress-free operation. The frontal C-arm provides a broad movement range that allows extremities to be imaged without repositioning the patient. The SCORE RSM frequency subtraction process is well suited to lower limbs, provides excellent image quality, and allows DSA to be performed while moving the patient, making it very user-friendly. The FPD field of view is slightly small for EVT but it does not seem to limit its utility.

The hybrid operating room system **(Fig. 3b)** was introduced in combination with a ceiling-mounted C-arm, a 12 × 12-inch FPD, and a portable operating table. This C-arm also provides for a broad movement range, and the main monitor can be rotated to almost 360°. This offers considerable leverage to operate the system in conjunction with any other type of equipment without feeling constrained. The HEPA filter for maintaining air cleanliness in the operating room and surgical field can be installed inside the C-arm rail, which allows for a vertical laminar flow system for conditioning the air.

Fig. 3 a)

Fig. 3 b)

Table 1 Components of the biplane system

Component		Specifications/Features
C-Arm	Frontal	Floor-mounted, six-axis triple-pivot, maximum 25°/s rotation, and direct memory
	Lateral	Ceiling-mounted, switches between LL and RL, and vertical movement at ISO center
FPD		Frontal: 8 × 8 inches Lateral: 8 × 8 inches
Fluoroscopy/radiography image processing		SCORE PRO Advance motion tracking noise reduction
Application software		SCORE StentView+Plus SCORE RSM
Monitor		SMART Display (58 inches, with 27 channels)
Applicable cases		PCI, EVT, EP, etc.

Table 2 Components of the hybrid operating room system

Component	Specifications/Features
C-Arm	Ceiling-mounted
FPD	12 × 12 inches
Operating table	Mizuho table with manual floating tabletop movement
Fluoroscopy/radiography image processing	SCORE PRO Advance motion tracking noise reduction
Application software	TraceMAP, SCORE 3D, Navi+Plus
Monitor	SMART Display (58 inches, with 27 channels)
Applicable cases	StentGraft, PaceMaker, TACE

4. Biplane system

The biplane system is mainly used for PCI and EVT, as described above. A total of 306 PCI procedures and 160 EVT procedures, including shunt PTA, were performed using the system in 2015.

This system includes SCORE PRO Advance image processing software, which has allowed fluoroscopy to be performed at a low-dose exposure with an excellent visibility. Because of low image persistence, the fluoroscopy frame rate can be reduced without inhibiting catheter operability. Consequently, at our hospital, we set the frame rate to 7.5 fps, which is below 10 fps recommended by Shimadzu. The frame rate can be increased, whenever necessary, for a particular procedure or for individual patients depending upon the size and shape of their bodies.

The system also includes StentView+Plus software for assisting with stent placement during PCI. Shimadzu released StentView approximately four years ago with features, such as the ability to recognize two markers on the balloon or other device, and real time image processing capability that allows both enhancing stents and showing them in a fixed position on the screen, which makes the stent appear stationary and unaffected by cardiac beat, at the same time. With stent images unaffected by cardiac beat, it is easy to understand the relationship between the positions of stent edges and markers, which is immensely helpful in positioning overlapping stents or during balloon inflation after stent implantation.
This feature has truly lived up to our high expectations from the system. In particular, the current model features StentView+Plus, an improved version of StentView, which considerably improves marker detection rates by specifying regions of interest (ROI) for image processing **(Fig. 4)**. The ROI mode is slightly more difficult to operate than the normal automatic recognition mode. However, because of the extra certainty it offers, we use it as the default mode at our hospital. For more details, please refer to Shimadzu literature.

Fig. 5 shows a case where the StentView+Plus software was particularly useful.

These images are from post-coronary bypass surgery and biventricular pacemaker surgery, where PCI was performed to treat significant stenosis between the left main trunk and the high lateral branch.

Lower limb interventions are also frequently performed at our hospital for which the system's SCORE RSM feature is very convenient to use, as mentioned earlier. For EVT procedures, we use this radiography mode in combination with DSA and fluoroscopy recording features. In patients with CTO, use of the biplane system allows for simultaneous confirmation of wire movement from two directions at the same time. This has improved the procedural success rate and helped shorten the time required for the procedure. **Fig. 6** shows a case of CTO of the popliteal artery, where the biplane system was found to be particularly useful.

5. Hybrid OR system

5.1 Primary applications

The hybrid OR system is mainly used for stent grafting in the thoracoabdominal aorta, but it is also being used for liver TAE, coil embolization, and pacemaker implantation surgery. We are considering its use for transcatheter aortic valve replacement

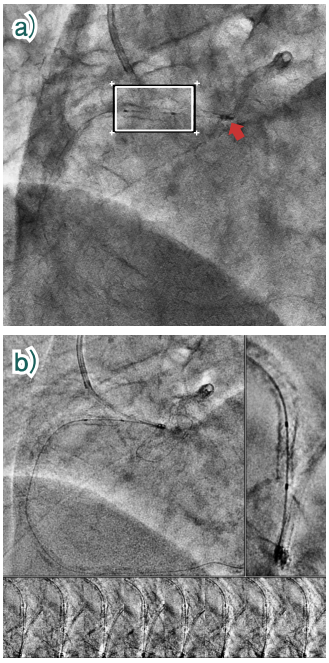


Fig. 4 **a)** ROI was specified to avoid incorrect detection of the area indicated with a red arrow (where the wire overlaps with the catheter tip and appears like a marker).
b) The extent of stent inflation is clearly visible using StentView+Plus to successfully detect the markers in the specified ROI.

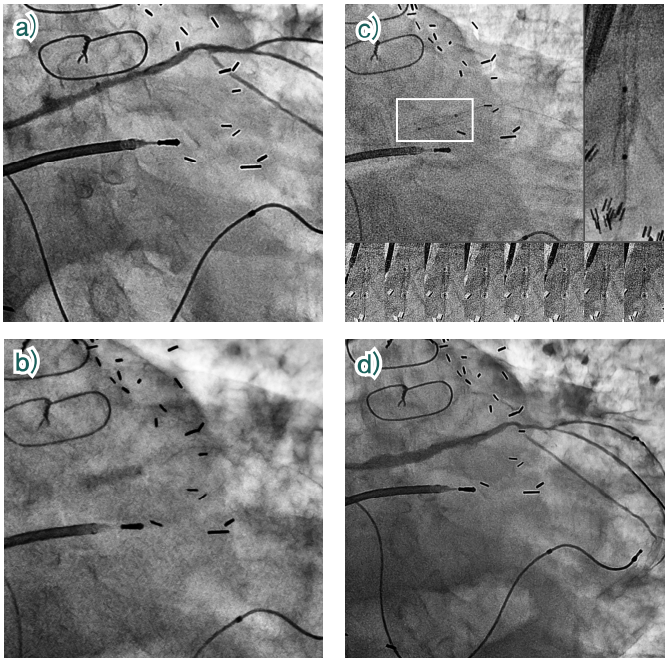
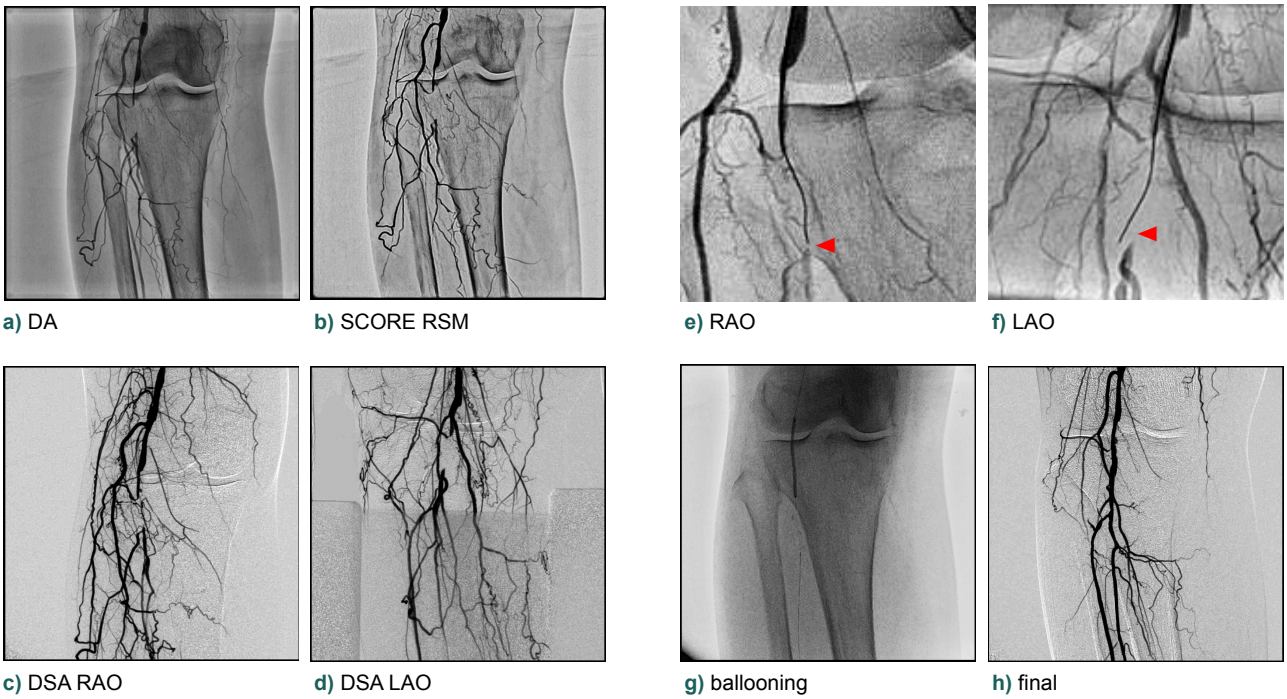


Fig. 5 **a)** Due to interference, for example, from a sternal wire and/or multiple clips used during coronary bypass graft surgery or from lead wires from the pacemaker in the same field of view, detection with the previous StentView software would have been difficult.
b) ROI was specified in a manner that avoided the sternal wire, clips, and pacemaker lead wires prior to the use of StentView+Plus to obtain the image. It clearly shows the position of both ends of the stent and also that the stent interior is not inflated properly.
c) High-pressure inflation with a balloon was able to resolve the inadequate inflation inside the stent.
d) The last contrast enhanced image shows adequate inflation inside the stent.



a) DA **b)** SCORE RSM **e)** RAO **f)** LAO

c) DSA RAO **d)** DSA LAO **g)** ballooning **h)** final

Fig. 6
a) DA
The larger closer blood vessels are rendered well, but peripheral capillaries are hidden behind the bone shadow and difficult to clearly visualize it.
b) SCORE RSM
This image is close to DSA and clearly shows, while moving, capillaries extending till the extremities.
c) DSA RAO
d) DSA LAO
The biplane mode was used to obtain DSA images from two directions to delineate the path of the serpentine blood vessels in three dimensions.
e) In the RAO view, the wire appears to be in the true lumen at the edge of the occluded vessel.
f) The LAO view shows that the wire is somewhat shifted forward from the true lumen of the occlusion. The occlusion is slightly bent, so operating the wire from only one side can easily result in inserting the wire in a false lumen.
g) Using both RAO and LAO views during insertion, we successfully navigated the wire into the true lumen of the occlusion. Subsequently, a balloon was inflated at the site of occlusion.
h) Contrast enhanced image (DSA) showing restoration of blood flow.

(TAVR) surgery and other procedures. We have just started operating the system. The initial impressions of the system and its features are described below. The basic functionality is similar to that of the biplane system; however, the key differences include a larger 12 × 12-inch field of view for the chest and abdomen areas and the portable operating table. It also includes a 3D workstation for C-arm CT radiography or for fusion with MDCT. Presumably, fusion with MDCT would also be useful for stent grafting, but we have not tried it yet. We hope to use it in future and examine how conveniently we can use it.

5.2 Pacemaker implantation

In the past, we used a mobile fluoroscopy system to guide pacemaker implantation; however, after installation of the hybrid operating room, we routinely use the hybrid system for all such procedures. Biventricular pacemaker implantation requires contrast-enhanced scan from multiple directions, which requires use of the cardiac catheterization room. However, we now perform the implantation in the hybrid operating room. The hybrid operating room allows the fluoroscopy system to be operated in a clean operating room environment in a manner similar to that in the catheterization room. Therefore, it provides an ideal surgical environment for implantation of pacemakers, stent grafts, or other artificial implants in the cardiac blood vessels.

The 58-inch monitor **(Fig. 7)** allows the operator to simultaneously monitor the fluoroscopic image, electronic medical records, polygraph, and the intracardiac electrocardiogram from the pacemaker programmer **(Fig. 8)** on the same screen, which helps enhance the procedural efficiency.

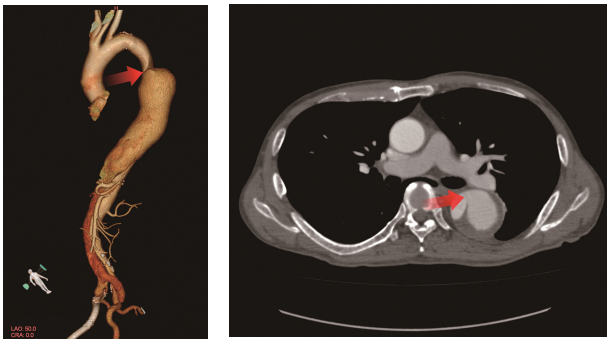
5.3 TraceMAP 2D guidance for implantation of aortic stent grafts

In the past, aortic stent graft surgery **(Fig. 9)** was performed using a mobile fluoroscopy system in the operating room; however, the hybrid system is currently used for all cases. The hybrid OR system allows the C-arm to be inserted from a variety of angles, which reduces the physical stress on operators during procedures and provides a comfortable environment for anesthesiologists to provide perioperative care.

Fig. 7 Large 58-inch monitor screen

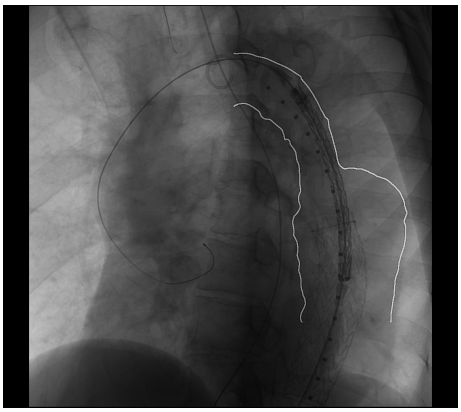
Fig. 8 Intracardiac electrocardiogram (lower right area of screen)

Fig. 9 Aortic stent graft surgery



a) Preoperative CT images

b) TraceMAP: Auto-trace vascular walls in peak hold DSA image



c) TraceMAP: Fluoroscopy image with overlaid trace lines; simple and easy to understand.

d) Post-operative DSA image

Fig. 10

The system also includes TraceMAP software, which incorporates a 2-D guidance functionality that is helpful during thoracic aortic stent grafting **(Fig. 10)**. TraceMAP automatically traces the walls of blood vessels in DSA images of the aorta and then overlays the trace lines on fluoroscopy images. Conventionally, vascular walls were marked directly with a water-based marker pen or an inverted DSA image was laid over the fluoroscopy image. Each method has its pros and cons, and neither system is ideal. Recently, use of TraceMAP function seemed like a good substitute to those techniques. Further, the ability to trace the blood vessels using the peak hold DSA function

implies that map images can be created with relatively small amounts of contrast media, which makes it a very patient-friendly function. In addition, sketch lines can be freely drawn on fluoroscopy images. Therefore, we hope to collaborate with other hospital personnel in considering useful applications for this functionality.

6. Summary

In this article, we presented our experience of the use of the Trinias biplane and hybrid OR systems. We are extremely pleased with the performance of these systems, which have allowed us to obtain more vivid images, with lower radiation dose. In particular, the StentView+Plus software for PCIs and SCORE RSM software for EVT have been especially useful. In addition to high quality fluoroscopic images, it is important that a hybrid OR system provide a layout that does not interfere with the surgical procedures or anesthesia, including a large monitor screen for simultaneous access to a variety of information. In this regard, the Shimadzu system satisfies all criteria and provides a user-friendly and ergonomic surgical environment.