

Trinias Today

Construction of a Catheter Ablation Examination Room with the Trinias Bi-Plane Angiography System

Toyota Kosei Hospital Director of Cardiovascular Center





Department of Radiological Technology, Clinical Department

Kazuhiro Murayama



1. Introduction

Toyota Kosei Hospital began focusing on catheter ablation around 2000 and now handles about 550 cases annually (of which 90 % are for atrial fibrillation). Originally we worked with two bi-plane angiography systems, but due to the aging of the equipment, the hospital decided to install two Trinias systems designed by Shimadzu. Shimadzu Corporation is a long-established Japanese company known for successfully producing an X-ray image in 1896, just one year after Dr. Wilhelm Roentgen discovered X-rays.

One of these systems is a Trinias B8 unity edition, a bi-plane system with 8×8 -inch FPDs specifically for percutaneous coronary intervention (PCI) procedures for chronic total occlusion (CTO) and catheter ablation (ABL) procedures. The other system is a Trinias B12 unity edition, a bi-plane system with 12×12 -inch FPDs specifically for diagnostic coronary angiography (CAG), endovascular treatment (EVT), and pacemaker (PM) implantation procedures.

Since their introduction a little over a year ago, the new systems

have been in continuous and trouble-free use with no unplanned downtime. Even when minor issues were noticed soon after installation, they were immediately addressed with support from Shimadzu. A 24-hour support service with full-time engineers ready to take phone calls also brings peace of mind.

In this article, a physician performing catheter ablation procedures, Shinji Kaneko, presents his impressions of the image quality and image display upon receiving the new angiography systems, as well as images from actual cases. The article also describes the experiences of a radiological technologist, Kazuhiro Murayama, on constructing a catheter ablation examination room, how catheter ablation parameters are determined, how X-ray doses compare before and after updating the systems, and a comparison of exposure levels against national diagnostic reference levels (Japan DRLs 2020).





2. Fluoroscopy Performance and Image Quality

Most physicians are primarily interested in fluoroscopy performance and image quality, and as Director of Cardiovascular Center I am entirely satisfied in both of these respects. At first, when examining large patients, left anterior oblique (LAO) 60° fluoroscopy images of the B-plane were somewhat difficult to interpret but now, after fine-tuning the fluoroscopy parameters, such images can be interpreted without any problem. Even when using a 0.014-inch wire ahead of a monorail electrode catheter, good image contrast and visibility not only provide the potential to reduce cumulative fluoroscopy time but also lessen fatigue.

3. No Interference with 3D Mapping System

With some manufacturers' angiography systems, interference due to magnetic fields in 3D mapping systems can produce noisy fluoroscopy images. However, no interference or noise was found when the Trinias systems were used with EnSite precision[®] (Abbott) or Rhythmia[®] (Boston Scientific) mapping systems. Noise is a complex issue. It is not simply due to the angiography system but also depends on the electrical wiring, room configuration, and medical systems in adjacent rooms. The resistance of Trinias systems to noise seems to result from strong noise shielding on the main Trinias unit and the noise elimination software built into Trinias systems.

4. 58-Inch Monitors in the Catheterization Room

A large, 58-inch monitor was installed in the catheterization room. The large monitor ensures good visibility, while the SMART Touch (red outline in Fig. 1) touch screen control panel allows for smooth and stress-free image and layout switching. The topics of fluoroscopy image quality, X-ray dose levels, and innovative monitor layout in the control room are covered later in this article by a radiological technologist.



Fig. 1 Catheterization Room with SMART Touch Control Panel

5. Case Presentation

This section describes an example of a catheter ablation procedure performed in an obese patient.

The patient was a 70-year-old male, 181 cm in height, weighing 116 kg, and with a BMI of 35.4. The patient was admitted for clinical scenario 2 (CS2) heart failure (EF: 58 %, NT-proBNP: 857 pg/mL) due to sustained atrial fibrillation. One month after admission, the patient underwent ablation. Contrast-enhanced CT revealed a left atrial volume of 142 mL, and echocardiography revealed left atrial dimensions of 45.0 × 66.8 × 46.2 mm. After contrast enhancement of the left atrium (Fig. 2), ablation was performed with a posterior-anterior (PA) view in the A-plane and LAO 60° view in the B-plane. The

image quality of lateral view images was initially a concern after the new angiography systems were installed, but good visibility and good contrast resolution was achieved even in lateral view images of the high BMI patient, and the position of 3Fr coronary sinus catheters and Advisor[™] HD Grid (Abbott) electrodes was immediately discernible (Fig. 3). This patient had difficulty tolerating sedation, and he was more likely to need fluoroscopy in addition to 3D mapping to verify the position of the catheter. However, a circumferential pulmonary vessel isolation procedure was completed trouble-free and without recurrence. Image quality was also satisfactory though the patient was of large stature.



Fig. 2a, PA View

Fig. 2b, LAO 60° View

Fig. 3a, PA View

Fig. 3b, LAO 60° View

6. Constructing the Catheter Ablation Examination Room

In coordination with Shimadzu, the system replacement was used as an opportunity to optimize the ablation examination room in line with treatment objectives in terms of staff movement and other day-to-day challenges (layout of peripheral equipment, furnishings, and display monitor in the control room, etc.). While the performance of the equipment is a priority when introducing a new angiography system, good coordination with the equipment manufacturer prior to installation also opens the door to a variety of other improvements in the examination and control rooms. Three important improvements are described below.

(1) Moving the Electrocardiograph from the Examination Room to the Control Room

Previously, during ABL treatment, the clinical engineer (CE) who controls the electrocardiograph and the radiological technologist who controls the angiography system, records irradiation, and supplies items for the ABL procedure worked behind a lead radiation protection barrier inside the examination room. To further reduce X-ray dose levels for health care professionals, the electrocardiograph was moved to the control room.

Communication with the physician is very important in ABL treatment, hence some concerns were raised about moving the electrocardiograph to the control room, but a smooth workflow was established by installing an intercom and monitors. The change also made female CEs less anxious about X-ray dose levels.

(2) Large Control Room Monitors Dedicated to Electrocardiography Outputs

60-inch large monitor was also installed in the control room where they display the same outputs as in the examination room (often with the screen subdivided into five images. Red outline in Fig. 4). Physicians inside the control room find it difficult to discern ECG waveforms on a screen subdivided into five images, hence the ECG waveform is displayed alone on a separate dedicated monitor (blue outline in Fig. 4) to allow detailed viewing. The left monitor (green outline in Fig. 4) can also display multiple modalities as needed, such as intravascular ultrasound (IVUS), optical coherence tomography (OCT), and external outputs of other equipment.

Fig. 4 Monitors on Control Room Wall Left and right monitors are 40-inch displays, and the center monitor is a 60-inch display.



Bi-plane fluoroscopy images shown in top left, ABL analysis EnSite shown in bottom left, and electrocardiograph shown on right side

(3) Storage Space

The radiological technologist is tasked with retrieving items from storage, and a primary discussion was how to store items more efficiently and in a less time-consuming way. Catheters and sheaths used in ABL pose a particular challenge due to their length, and this was taken into consideration when preparing the design drawings for storage shelving. The medication cart and other items retrieved by the nurse were placed within arm's reach.



7. Determining Ablation Parameters of Fluoroscopy and its Performance

Although 3D mapping technology is advancing and treatment times are falling dramatically, X-ray fluoroscopy cannot be eliminated entirely from ablation treatment for arrhythmia. Trinias systems are equipped with the latest SCORE PRO Advance image processing engine, the principal feature of which is motion-tracking noise reduction technology. Toyota Kosei Hospital collaborated with an application specialist to investigate optimum parameters for fluoroscopy settings, including to what extent X-ray doses could be reduced. The hospital has always maintained a keen interest in fluoroscopy image quality and dose levels, and instead of the factory-default system settings, health care professionals collaborated with angiography system manufacturers to find the optimum X-ray dose and image quality for each procedure. Even prior to this system replacement, Toyota Kosei Hospital boasted of optimizing equipment settings for many years.

After the update, ABL parameters were adjusted by targeting a reference fluoroscopy dose rate (phantom entrance surface dose rate at patient entrance reference point (PERP value)) of 2 to 3 mGy/min with a 20-cm acrylic phantom. Trinias systems have three low-dose fluoroscopy modes (Low, ExLow, and Lowest). The X-ray dose of each mode is adjustable based on a density parameter, which has seven levels (+3 to -3) where each level is equivalent to an approx.

15 % change in dose. When investigating fluoroscopy parameters, examinations were performed with the lateral C-arm at LAO 60°, an angle that tends to involve difficult X-ray conditions in ABL procedures. Using the visibility of a 0.014-inch wire, one of the narrowest devices inserted in the coronary sinus, as an indicator, the PERP value was measured at different density settings (Table 1). This process was repeated with each image checked by a physician. In clinical settings, when an image is difficult to discern, the X-ray dose is readjusted, or the system is switched to a pre-configured default protocol.

Toyota Kosei Hospital uses its own ABL parameters: a radiography acquisition protocol of 7.5 f/Low -5 and fluoroscopy protocol of 6 pps/Lowest -1. The reference fluoroscopy dose rate (PERP value) for fluoroscopy performed at 6 pps/Lowest -1 was 2.34 mGy/min.

Table 1	Fluoroscopy	Parameters	Used to	Measure	Reference	Fluoroscopy	Dose Rate	(PERP	Value) w	vith 20-cm Ad	crylic Phantom
								·			

Fluoroscopy Protocol	Fluoroscopy Protocol Direction		FID (cm)		FOV (inch)		/oltage V)	Tube Currer (mA)	t Pulse Rate (Pulse/s)	e Pulse Width (ms)
6pps/Lowest-1	PA 1		00	7		90		67	6	3.2
Fluoroscopy Protocol	Inherent Filtration Aleq (mm)		Added Filter Al (mm) Cu (Area mm) Ale		Dosimeter	Total	Dose rate (mGy/min)	
	1	-)		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Cu	mm)		Y (mm)	meq (mm)	

(Dosimeter: RTI CT Dose Profiler, fluoroscopy time: 60 sec) (FID: 100 cm)



(Radiography images of pulmonary vein: PA view and LAO 60° view at 7.5 fps/Low -5)



(Fluoroscopy images of pulmonary vein: PA view and LAO 60° view at 6 fps/Lowest -1)

8. X-Ray Dose before and after System Replacement

Below, Table 2 compares the fluoroscopy time, fluoroscopy air kerma (AK) value, total AK value, and radiography AK value for paroxysmal atrial fibrillation (PAF) treatment performed by Toyota Kosei Hospital arrhythmia specialists before and after the system replacement.

	Fluoroscopy	F Fluoroscopy	L Fluoroscopy	Fluoroscopy	F Fluoroscopy	L Fluoroscopy
	Time (min)	Time (min)	Time (min)	AK (mGy)	AK (mGy)	AK (mGy)
Shimadzu (n = 41)	30.3	23.8	6.2	85.6	47.0	34.5
Company A (n = 46)	26.9	19.6	5.6	108.6	49.7	54.1
	Total	Frontal Total	Lateral Total	Radiography	F Radiography	L Radiography
	AK (mGy)	AK (mGy)	AK (mGy)	AK (mGy)	AK (mGy)	AK (mGy)
Shimadzu (n = 41)	Total	Frontal Total	Lateral Total	Radiography	F Radiography	L Radiography
	AK (mGy)	AK (mGy)	AK (mGy)	AK (mGy)	AK (mGy)	AK (mGy)
	91.2	50.9	41.2	5.9	1.6	4.1

Table 2 Comparing X-Ray Dose (during PAF Treatment) before and after System Replacement

Table shows median values. (Mean \pm SD; Shimadzu: height = 161.8 \pm 10 cm, weight = 63.4 \pm 13.8 kg; Company A: height = 160.1 \pm 11.8 cm, weight = 62.5 \pm 14.6 kg) (Data from PAF treatment performed by two skilled physicians)

(Note: Of procedures classified as ablation for atrial fibrillation, only PAF treatment cases are compared due to wide variability in procedure times for persistent atrial fibrillation and longstanding atrial fibrillation that affected fluoroscopy times in particular.)

(F: frontal, L: lateral. Clinically, "frontal" shows values equivalent to a PA view while "lateral" values are equivalent to an LAO 60° view.)

As shown in the above data, though fluoroscopy times are almost unchanged and there are no significant differences other than in lateral fluoroscopy AK (p = 0.02) and lateral total AK (p = 0.03), lateral fluoroscopy AK is around 40 % lower after the system replacement (Fig. 1). This finding shows that X-ray dose is reduced after the system replacement, even at high patient body thicknesses such as at LAO 60°. Further dose optimization may be achievable by varying the thickness of the acrylic phantom and ascertaining the behavior of the manufacturer's fluoroscopy dose control curve.



Fig. 1 Lateral AK Values (Fluoroscopy and Total) before and after System Replacement (Approx. 40 % Reduction)

When a Pro-Fluo150 acceptance and constancy test phantom (RTI) was placed onto an acrylic slab phantom and spatial resolution measured using fluoroscopy (6 pps/Lowest -1), the result was 1.6 lp/mm.

 μ = 1/2 d, where (μ : spatial frequency (lp/mm), d: line width and line space size (mm)) and d = 0.3125 (mm). A 0.014-inch wire is 0.3556

mm thick and therefore discernible. (A fluoroscopy dose rate equivalent to clinical fluoroscopy in the PA direction was achieved by placing the Pro-Fluo150 phantom on an 8-cm acrylic slab phantom and taking measurements at FID: 100 cm.)



9. Comparing X-Ray Doses against Japan DRLs 2020

The Japan DRLs 2020 diagnostic reference levels were published in July 2020. For Japan DRLs 2020, IVR examinations and treatments were separated by site and reference levels presented in greater detail. Thanks to this change, comparison with values obtained by Toyota Kosei Hospital allowed a more detailed understanding of X-ray dose levels. The Japan DRLs 2020 states that "DRLs are intended to be used for optimization and not simply for dose reduction," but comparing Japan DRLs 2020 data with Toyota Kosei Hospital data may lead to dose reduction.

Table 3 Comparing 50th Percentile Values from Japan DRLs 2020 and Toyota Kosei Hospital ABL Treatment

E D	Distribution (Quartile Point)									
Examination Region	DRLs	(50%)	DRLs	(75%)	Toyota Kosei Hospital (50 %)					
DRL Quantity	Ka,r[mGy]	PKA[Gy·cm2]	Ka,r[mGy]	Рка[Gy·cm2]	Ka,r[mGy]	PKA[Gy·cm2]				
Non-PVI RFCA	196	26.3	560	57	54	7				
PVI RFCA	317	40.8	645	89	150	22				

(ABL treatment: using 7-inch FOV)

(Fluoroscopy time: 45 min., system displayed AK value: 150 mGy)

Table 3 compares 50th percentile values from Japan DRLs 2020 and Toyota Kosei Hospital ABL treatment. The hospital X-ray dose levels for both non-PVI RFCA and PVI RFCA are substantially lower than the diagnostic reference level value: the hospital X-ray dose level for PVI RFCA is around half the diagnostic reference level 50th percentile value. Also, Toyota Kosei Hospital X-ray dose levels were captured not only by arrhythmia specialists but also by young physicians, hence the results show total X-ray dose levels at our hospital are very low. Similar results were also obtained for CAG and PCI for ischemic diseases.

10. Conclusions

When we first viewed images produced by a Trinias system several years ago on a demonstration unit, we were struck by the overall sharpness of the images, which made it easy to see the details of the blood vessels. This initial impression holds true to the present day. A Toyota Kosei Hospital cardiovascular ischemia specialist even remarked on the image quality and looked into the introduction of a Trinias system. Imaging protocols can also be easily configured on Trinias systems thanks to the easy-to-understand explanations provided by application specialists and service engineers. The Trinias unity edition systems introduced by Toyota Kosei Hospital have allowed X-ray doses to be reduced not only for the treatment of ischemic diseases but also for the treatment of arrhythmias, and the hospital now recommends Trinias unity edition to other facilities considering the purchasing replacement systems.



Founded in 1875, Shimadzu Corporation, a leader in the development of advanced technologies, has a distinguished history of innovation built on the foundation of contributing to society through science and technology. We maintain a global network of sales, service, technical support and applications centers on six continents, and have established long-term relationships with a host of highly trained distributors located in over 100 countries. For information about Shimadzu, and to contact your local office, please visit our website at www.shimadzu.com



Shimadzu Corporation

Headquarters

1, Nishinokyo-Kuwabara-cho, Nakagyo-ku, Kyoto 604-8511, Japan https://www.shimadzu.com/med/





Shimadzu Corporation Medical Systems Division has been certified by TÜV Rheinland as a manufacturer of medical systems in compliance with ISO9001:2015 Quality Management Systems and ISO13485:2016 Medical Devices Quality Management Systems.

Remarks:

- Every value in this catalogue is a standard value, and it may vary a little from the actual at each site.
- The appearances and specifications are subject to change for reasons of improvement without notice.
- Items and components in the photos may include optional items. Please confirm with your sales representative for details.
- Certain configurations may not be available pending regulatory clearance.
 Contact your Shimadzu representative for information on specific configurations.
- Before operating this system, you should first thoroughly review the Instruction Manual.