Vascular

Development of Trinias FPD-Equipped Angiography System

Medical Systems Division, Shimadzu Corporation **Yoshiaki Miura**

1. Introduction

Shimadzu has developed Trinias (one ceiling-mounted type C12 package, and one floor-mounted type F12 package), a new angiography system equipped with a 12×12 inch flat panel detector (FPD) (Fig. 1). The new "crossover" system supports interventions in many diagnostic fields, and can be used over the entire body, from vessels in the head, to the heart, abdomen and extremities (Fig. 2).

The "Tri" in "Trinias" represents the three central concepts of this product, "next generation intervention guidance," "superior operability" and "safety and peace of mind." The "as" in "Trinias" also represents the concept of building a better tomorrow for patients, medical staff and equipment manufacturers alike ("as" from "asu" means "tomorrow" in Japanese).



Fig. 1 Trinias F12 Package

1.1. Next Generation Intervention Guidance

SCORE Imaging – Experience the Next Frontier of Intervention

SCORE: Shimadzu Challenge Of REvolution

SCORE Imaging is a set of original guide functions developed in the pursuit of "real time processing and one-action support," and inspired by the phrase "Experience the Next Frontier of Intervention." SCORE Imaging is comprised of the functions below.

- SCORE PRO, a new image processing engine that provides high-quality images in various diagnostic fields and improves dramatically the visibility of interventional devices by reducing image noise over previous technology.
- PCI support guide SCORE StentView that provides assistance in the provision of safe and accurate treatment by displaying a stent in a static position in dynamic movement caused by heartbeat and enhancing its display to make the stent more visible

Crossover (A single, multi-capable unit)

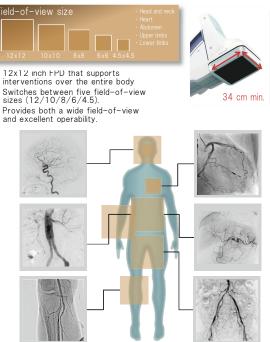


Fig. 2 Crossover System Concept

- Interventional support guide SCORE RSM that uses a Shimadzu's original frequency subtraction method
- 3D guide SCORE 3D and C-arm CT guide SCORE CT that allow for one-action three-dimensional image reconstruction

These functions are collectively referred to as SCORE.

1.2. Superior Operability

SMART Design – Change the Way. Make It Possible SMART: Shimadzu Makes Advanced Remarkable Technology

SMART Design that strives to realize the motto of "Change the Way. Make It Possible" by incorporating a flexible C-arm design, one-action operations, and world-beating response speeds. SMART Design manages to reduce examination times substantially, so reducing the burden on the patient. SMART Design is comprised of the functions below.

- SMART Access, consisting of a flexible C-arm design capable of full body coverage, and supporting for multi accesses and radial approaches
- SMART Assist, consisting of a bedside console that facilitates one-man operation, and a next-generation control console with world-beating response speeds that enable one-action control
- SMART Display, consisting of the display of various types of image information as required in various fields

1.3. Safety and Comfort

SMILE Concept – Safety + Comfort = SMILE SMILE: Shimadzu Makes Innovation in Life for Everyone

SMILE Concept is a total solution that strives to incorporate both safety and comfort into equipment design with regards for both the patient and the operators. The product is equipped with SMILE Dose-eye, which is functionality based on seven mechanisms, including SCORE PRO, that reduces dose and delivers an approximate 40 % maximum reduction in exposure dose relative to previous products. It also incorporates the SMILE Recovery backup function with multiplexing of critical components to ensure a high level of confidence in equipment performance, and the integrated manufacturing techniques and comprehensive implementation of quality control at Shimadzu's leading-edge production plant that was newly completed in 2010 deliver on the promises the label of "Made in Japan" implies.

2. Technical Commentary

The concepts of "next generation intervention guidance," "superior operability" and "safety and peace of mind" will be explained in technical terms below.

2.1. SCORE PRO

SCORE PRO image processing is mainly comprised of the two types of image processing mentioned below (Fig. 3).

- a. Dynamic multifrequency processing
- b. Object enhancement and noise reduction processing using neural network processing

The information in each captured image frame is analyzed for particular characteristics (histogram, frequency information, and movement components) in real time using dynamic multifrequency processing, where each frequency band is resolved into the image parameters that contribute to object enhancement (lines, contrast) and noise reduction (movement components), whereupon neural network processing is used to optimize the image.

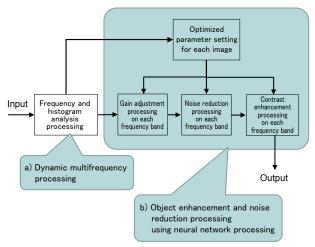


Fig. 3 SCORE PRO Processing Outline

Details of dynamic multifrequency processing, and object enhancement and noise reduction processing using neural network processing are described below.

a. Dynamic multifrequency processing

Dynamic multifrequency processing is performed on the captured image. This comprises frequency analysis and histogram analysis on each frame to resolve the image information into frequency information and histogram information. Next, using this resolved frequency and histogram information, neural network processing is implemented to determine the optimum image processing parameters for each image. Neural network processing uses an identification model employing stochastic variables that resemble the mechanisms of the neural network of the brain.

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The model is run repeatedly, and as the stochastic variables change iteratively an arithmetic algorithm is produced that calculates the optimum solution. This technique is a method for solving a problem that presents various different uncertainties. The technique is used as a derivation approach to obtaining the parameters that will create optimum final image quality.

b. Object enhancement and noise reduction processing using neural network processing

Object enhancement and noise reduction processing using neural network processing are processed from original images and the quantitative image information. SCORE PRO processing uses frequency information of images and histogram information of frequency to derive the parameters that will produce an optimum image quality. Compared to previous methods, this form of processing reduces image noise and improves the visibility of interventional devices.

2.2. SCORE StentView

SCORE StentView, Shimadzu's original software that supports cardiovascular interventional procedure, applies object enhancement and noise reduction by neural network processing mentioned above when describing SCORE PRO, but for marker detection. This method has succeeded in reducing marker detection times. The number of marker searches that can be performed is doubled so various types of balloon markers can be detected, improving marker detection ability substantially as a result. How this works is outlined below.

To improve stent visibility, SCORE StentView implements additive signal averaging while correcting for the distortion caused by the movement of blood vessels over time due to the heartbeat.

This processing is performed in one frame-time at a maximum frame rate of 30 frames/second (33 msec) in real time and it allows acquiring and viewing an enhanced image of the stent during ongoing treatment without post-processing. This processing technique can also be used to show clearly the relative positions of a marker on an existing implanted stent and a marker on a new stent that will be placed (**Fig. 4**).

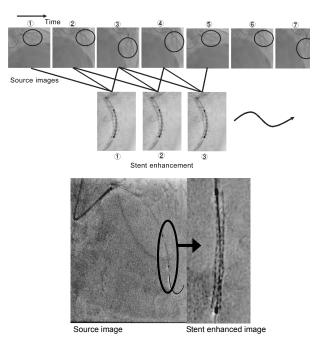


Fig. 4 Operating Principle of SCORE StentView

Fig. 5 shows how markers are detected from a source image containing wires and markers. Markers are indicated by arrows.

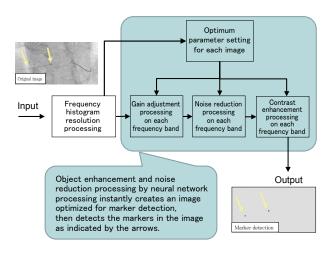
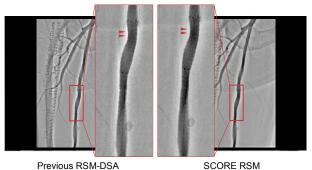


Fig. 5 Marker Detection Using Neural Network Processing

2.3. SCORE RSM

Shimadzu's original frequency subtraction RSM-DSA has also been evolved, and can now remove the overshoot artifacts from around high-contrast elements caused by the effects of frequency processing. Similar to SCORE PRO, this processing employs dynamic multifrequency technique processing to perform real time processing with a combination of multiple spatial filters to create a more natural image. Fig. 6 compares images produced using the previous RSM-DSA and the new SCORE RSM. In the RSM-DSA image, overshoot artifacts are present in the form of white hemming around very dark areas, while overshoot artifacts are almost invisible in the SCORE RSM image.

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(Artifacts are substantially reduced.)

Fig. 6 RSM-DSA and SCORE RSM

To remove the overshoot artifacts, dynamic multifrequency processing is applied to control in real time a combination of a spatial filter that creates a low frequency mask and a spatial filter that removes overshoot artifacts (Fig. 7).

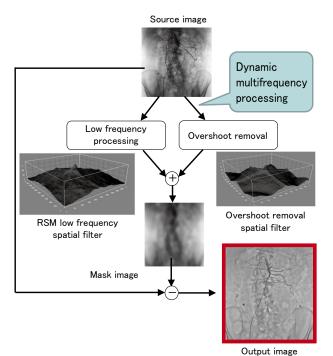


Fig. 7 SCORE RSM Processing Overview

2.4. SCORE 3D/SCORE CT

Image transfer times have been reduced substantially by using a data transmission method developed by Shimadzu. Furthermore, reconstruction times have also been reduced substantially (SCORE 3D: 15 sec minimum, SCORE CT: 30 sec minimum).

Workstation software has been developed with "one action" as a major driving force so a variety of operations are now easy to perform. These original functions consist of a seamless linkage function between the C-arm and 3D image, a back view function that calls up the opposite working angle in a single operation, and Palette Function, a control customization function that customizes operations for the operator. **Fig. 8** shows some clinical examples.

3D Guidance: SCORE 3D Workstation

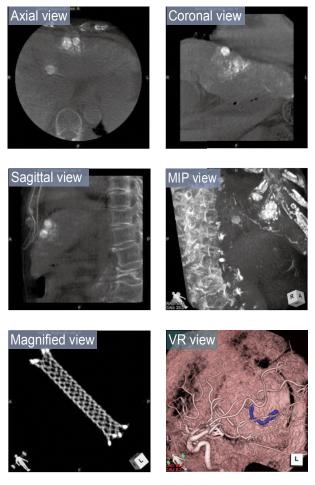


Fig. 8 SCORE 3D Operation Overview

2.5. SMART Assist

SMART Assist is updated next-generation operation software optimized for 64-bit Windows 7. Full parallel processing has been implemented for operations that encompass image, file, C-arm, and X-ray generator control, resulting in world-beating response speeds. In addition, system operation has been simplified where possible, and operation can be customized to suit the operator. This is referred to as one-action operations, while frequently used operations can be assigned to specific operation buttons at the bedside or to create keyboard shortcuts in the control room. Also the assignment of functions to particular buttons is fully customizable and the controller shape is selectable from lever or grip type controllers. These features deliver superior system operability (Fig. 9).

One-Action Functions

Assigning short cuts control for frequently used functions onto keyboard function keys

- "Fluoroscopy: 15 pps/H"
- "Radiography: LVG30f"
- "Radiography: SCORE RSM"
- "SCORE StentView"
- "Fluoroscopy image save"
- "MAP mask setup," etc.
- \Rightarrow Simple switching between techniques
- \Rightarrow Optimum fluoroscopy mode selection



Console Supports One-Man Operations



Fig. 9 SMART Assist

2.6. SMART Display

SMART Display consists of functions for implementing integrated management and distribution of the various types of image information required in various interventional procedures. Based around a 56-inch high-definition color monitor system, SMART Display is capable of real time layout and distribution of multiple video signal inputs. It also includes functions that enable the synthesis and distribution of a variety of video signal formats and supports digital inputs, analogue inputs, and multimedia inputs (Fig. 10).



Fig. 10 SMART Display

2.7. SMILE Dose-eye

An integrated radiation dose management function that encompasses dose reduction, dose management, and DICOM-RDSR functions (Fig. 11)

Seven Mechanisms for Dose Reduction: SMILE Dose-eye



 IMBH Filter
 Effectively eliminates unnecessary soft X-rays.

 Pulsed Fluorescopy
 Select from 10 rates depending on the procedure.

 Grid Control
 Blocks unnecessary soft radiation.

 Virtual Collimation
 Enables collimation without fluorescopy.

 Fluorescopy
 SCORE PRO ensures lower dose and higher image quality.

 Fluorescopy Video Recording
 High-definition fluorescopy can substitute for radiography.

 Area Dosimeter
 The monitor displays the actual dosage in real time.

Fig. 11 SMILE Dose-eye

2.8. SMILE Recovery

Functions that improve reliability including backup filaments, image data mirroring, and high-speed setup completed within 2 minutes (minimum) (Fig. 12)

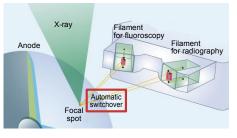
High-Speed Setup Function

All functions are available within 2 minutes after the power is turned ON.



Backup Filament Function

If the filament burns out during an examination, it will be replaced to another filament automatically so the examination can continue.



Data Mirroring Function

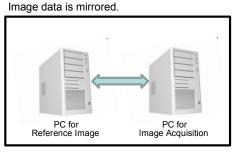


Fig. 12 SMILE Recovery

3. Conclusion

The Trinias angiography system profiled above was developed based on the concept of a "crossover" system tailored to the current diversification of vascular interventional procedures and compatible with vascular interventional procedures over the entire body. By employing digital image processing technologies that improve processing speeds, we have realized the practical application of image processing techniques whose real time implementation was once thought impossible, including pattern recognition processing and image processing using neural networks. Based on these leading-edge technologies, we have introduced SCORE Imaging, SMART Design, and SMILE Concept all of which aim to deliver the key concepts of "next generation intervention guidance," "superior operability," and "safety and peace of mind." In concluding this profile of Trinias, we hope these latest technologies will be of real use to our customers and patients alike. We would also like to take this opportunity to express our sincere gratitude to the staff of Chikamori Hospital, of the Chikamorikai Medical Group, who have performed clinical evaluation and provided valuable advice during the development of this software.