Vascular

Flex-APS and New SCORE StentView

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1. Introduction

Balloons were the prevailing device used for PCI in the 1980s, but after entering the 1990s a variety of new devices emerged and rapid progress was made in interventional radiology (IVR) for the coronary artery. Of these devices, the emergence of bare-metal stents (BMS) saw the clinical prognosis for PCI drawing level with that of CABG, and rapid adoption of this device throughout Japan. This was followed by the use of IVUS, frequency-domain optical coherence tomography (FD-OCT), and other preoperative and postoperative methods of assessing the intravascular lumen, and a change in procedure strategy from only treating the site of stenosis or occlusion, towards a strategy more cognizant of long-term prognosis and the reduction of restenosis. Furthermore, procedure strategies changed to take into account myocardial viability by using fractional flow reserve (FFR) in the procedure of moderate lesions and other techniques. The evolution of devices did not stop there, and for stents in particular the emergence of drug eluting stents (DES) saw substantial improvement in restenosis rates, with DES continuing to evolve into second generation and third generation devices. A number of performance improvements have been made to DES design, with stent strut thickness having a major contribution in these improvements. Reducing stent strut thickness is thought to promote endothelial coverage of the stent by quicker re-endothelialization. Nevertheless, it goes without saying that as strut thickness is reduced, decreased stent visibility on fluoroscopy and angiography performed during procedure becomes an issue. In light of this, improvements in image quality are essential to ensuring the safety of PCI. The number of cases of coronary artery and other endovascular treatments (EVT) is also increasing in recent years, with a corresponding increasing number of challenging cases of critical limb ischemia. Lesion length and the scope of lesions subject to procedure in the lower extremities is also increasing, with increasing procedure times due to many cases of complete occlusion. This, of course, is also accompanied by increasing fluoroscopy times and the number of acquisitions. As various new devices emerge on the market, with these changes comes the demand for reduced radiation exposure, improved image quality, and the image quality improvements of DSA becoming essential for peripheral areas in particular.

2. Emergence of Dynamic StentView

Image processing tools for improving stent visibility had actually already emerged by around 2004, but at that time, stents were more easily visible than today, and the application technologies could only apply image processing to data after acquisition, which only produced still images. Such shortcomings prevented the technology from leading to efficiency of stent enhancement and blanket adoption seen today. However, the need for image processing increased as DES evolved, PCI techniques became more diversified, and as PCI was applied in more complex cases. Shimadzu therefore released the long-awaited PCI support tool Dynamic StentView **(Fig. 1)**.

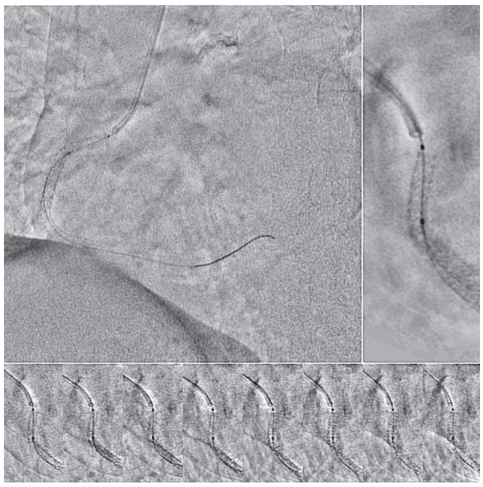

Fig.1 Dynamic StentView

Dynamic StentView displays the world's first stent enhancement dynamic images in real time, and as a result has been adopted widely in clinical practice. The greatest advantage of Dynamic StentView is its real-time performance, which is an extremely important factor in the use of enhanced stent images. Real-time performance is important since it is a necessity for making decisions and implementing procedure immediately, such as for stent positioning, balloon dilatation after placement, and checking overlap after additional stenting **(Fig. 2, 3, 4)**. In actual clinical practice, Dynamic StentView also allows the operator to change the position of balloon markers and stents during ongoing angiography. Other characteristic elements that are important for the application are the ability to perform imaging at the same radiation dose as normal imaging modes, allowing operators to easily change between imaging modes, displaying images in real time, and automatic transfer and storage to PACS in real time.

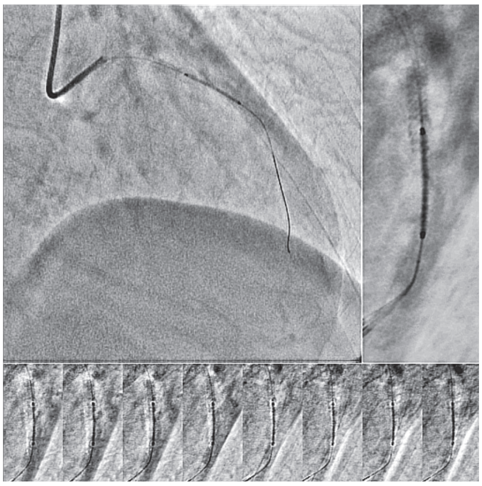

Fig.2 Stent Positioning

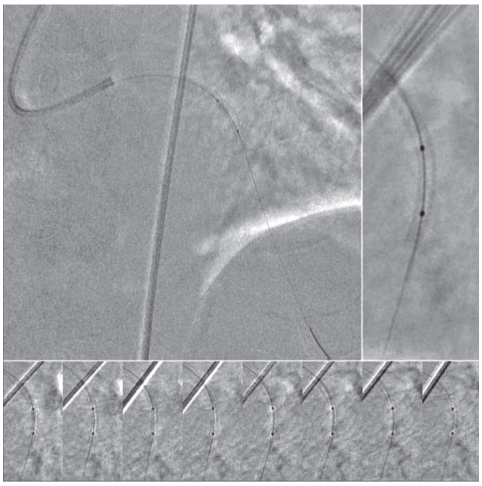

Fig.3 Balloon Dilatation After Placement

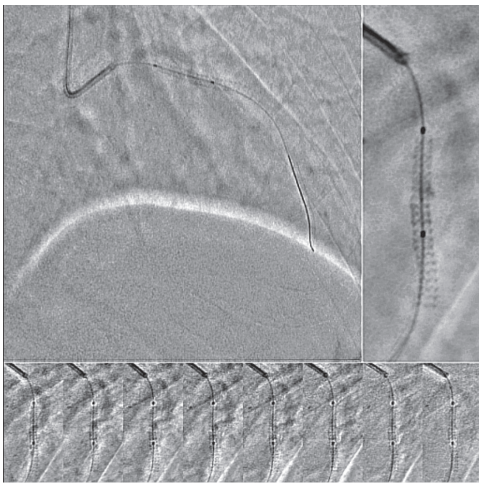

Fig.4 Additional Stenting

3. New SCORE StentView

Although the original Dynamic StentView was brilliant technologically, a number of issues were encountered with its real-time performance. One of these issues was the orientation of the displayed image. The application created enhanced stent images by automatically recognizing 2 balloon markers and correcting movement-induced distortions based on those markers, but on occasion the proximal and distal balloon marker would switch over. The second issue was misrecognition of features that were not balloon markers or misrecognition of multiple balloon markers, such as pacemaker leads, distal protection devices, or when 2 balloons were used for the kissing balloon technique (KBT), in which cases the application was unable to display an image correctly **(Fig. 5)**. The third issue was with the layout of the images being displayed. The area used to display the enhanced stent image (StentView area), which was the area of greatest interest, was actually relatively small. The original display layout was arranged into 3 areas: the StentView area displaying the area of

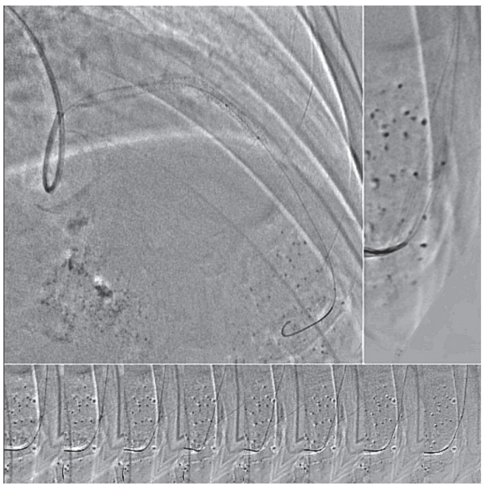

Fig.5 Unable to Distinguish and Display Balloon Markers

interest at fixed magnification, the Dynamic View area displaying the entire image area, and the Detective View area displaying marker detection status **(Fig. 6)**. However, just as device and PCI technology advanced, these issues with Dynamic StentView were resolved. The region of interest became configurable to any size, and it became possible to select regions of interest that contained balloon markers. These changes were developed for the current Trinias system and have reduced the frequency of misrecognition. Furthermore, the new SCORE StentView redesign improves visibility further by allowing full-screen display of the enhanced stent image, and by allowing the clinical orientation of the stent to be fixed within the region of interest on the stent-stabilized image **(Fig. 7)**. Further visibility improvements are also desired in areas of rapid movement, such as the right coronary artery.

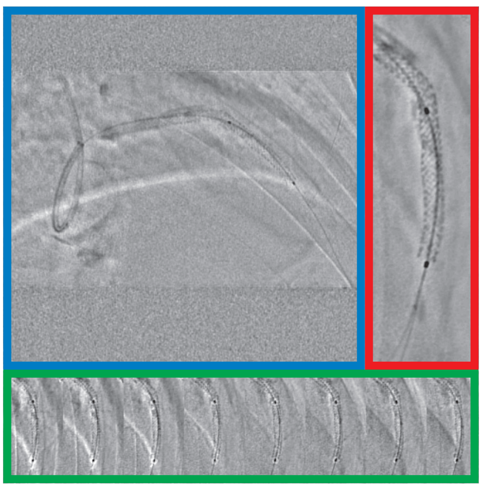

Fig.6 Previous display layout. Enhanced stent image is displayed in a small area (red outline) despite being the image of greatest interest.

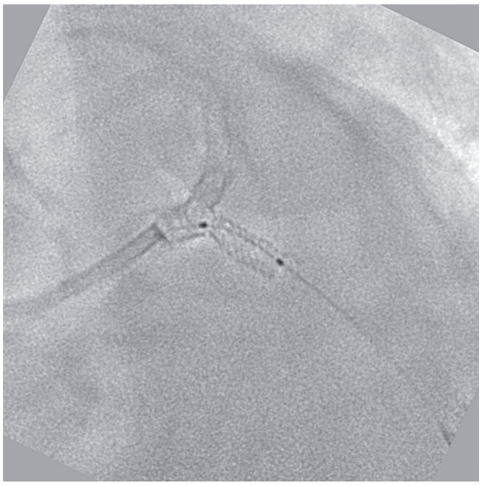

Fig.7 New SCORE StentView Spider View Orientation

4. Additional Features: SCORE StentShot

StentView images are created by combining 8 separate images, but the newly developed SCORE StentShot application improves visibility even further by increasing the number of separate images combined. SCORE StentShot combines all acquired images, so these images cannot be acquired while changing the positioning of a device, such as while moving balloon markers. However, this feature is highly effective for observing more detailed features, such as checking for broken stents, and dividing tasks between SCORE StentShot and the new SCORE StentView will help to improve PCI procedures even further **(Fig. 8)**. Of course, SCORE StentShot retains other features of SCORE StentView mentioned earlier, such as real-time performance, real-time display, and transfer and storage to PACS.

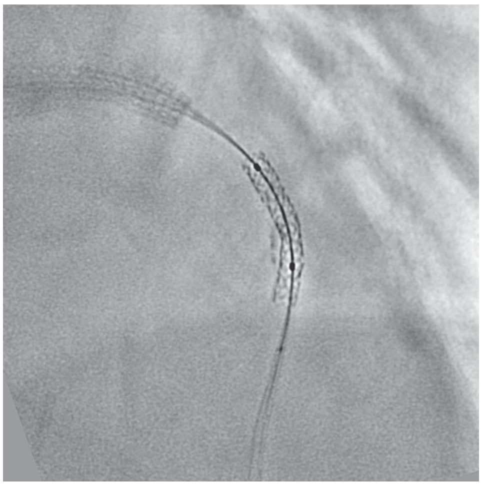

Fig.8 SCORE StentShot

5. Use in Actual Clinical Practice

We often used the previous version of the Dynamic StentView application to check distal and proximal positioning during balloon dilatation after stent placement, for balloon dilatation during in-stent restenosis, and to check overlap during additional stenting. Currently, depending on the circumstances, we either use the new SCORE StentView or the SCORE StentShot function. The new SCORE StentView is used in areas that were already well-visualized using the previous version of the Dynamic StentView application. SCORE StentShot is used in situations that require greater emphasis on visualization, and is used with the assumption that balloon markers will not be moved. This allows more effective utilization of this application, and is what we recommend to operators.

6. Flex-APS in Support of EVT

DSA imaging is frequently used for lower extremity EVT in cases when visualization is difficult due to overlapping bone and blood vessels. Since only a limited area can be imaged in a single exposure, different system manufacturers use different techniques to allow observation of the entire lower extremity. We use SCORE RSM, a proprietary technology developed by Shimadzu that uses frequency subtraction processing, to give us an overview of the entire lower extremity. DSA imaging is still needed for detailed observations of lesion morphology and to display fine blood vessels for procedure. Problems we encounter during lower extremity EVT that may prevent the acquisition of good images are that many diseases manifest with pain and make immobilizing the patient difficult, lesions can often affect a large area and lengthen procedure times, and body movement is common during imaging or procedure due to the sensation of heat caused by contrast media and pain felt during vessel dilatation. Flex-APS (Flexible-Active Pixel Shift) has been introduced to resolve these issues. Flex-APS corrects for complex subject movement by using pattern recognition technology and motion tracking technology to analyze movement in live images relative to a mask image. This technology is expected to reduce the number of difficult cases and reduce the number of repeat acquisitions. In a clinical setting, Flex-APS has been particularly effective in the area below the knee. Due to the compatibility of Flex-APS with DSA imaging, it can be easy to take the additional effect for granted when they are used together, though this additional effect is substantial **(Fig. 9)**. At our hospital, the Peak Hold function is often used to reduce contrast media usage, but movement in source images can have an important effect on Peak Hold. Consequently, the improvement in images provided by Flex-APS can be utilized in many parts of the body.

Further experimentation and verification of clinical data will be needed to determine to what extent Flex-APS can compensate for movement, and the effectiveness of Flex-APS in areas other than the lower extremities, such as for gas in the abdomen.

7. Conclusions

Flex-APS and the new SCORE StentView both demonstrated effective results after introduction to a clinical setting. Due to the manufacturer's capacity for development combined with feedback from performance in the field, we expect Shimadzu will produce even better products in the future. Client needs will always be highly demanding, and improvements will never satisfy these needs completely. While a trade-off exists between reducing radiation dose and improving image quality, both are necessary for IVR, and we look forward to even further technological improvements.

References

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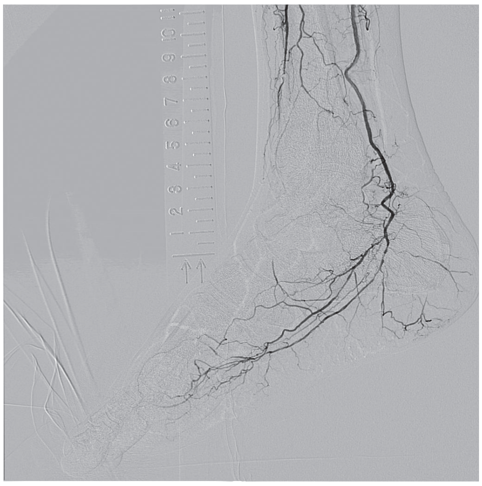
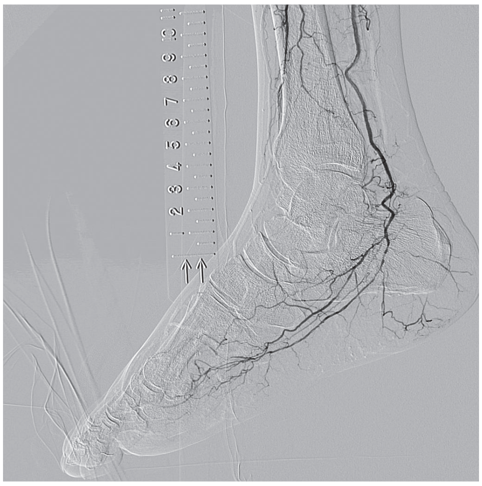


Flex-APS ON



Flex-APS Off

Fig.9 Flex-APS