Vascular

Initial experience Using the Trinias B12 Package for Neuroendovascular Surgery

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1. Introduction

With the dramatic increase in endovascular procedures for cerebrovascular disorders in recent years, a variety of devices have been developed and advancements in angiography systems have provided a major contribution. In Japan, carotid artery stenting (CAS) technology was approved for treating carotid atherosclerosis in April 2008 and intracranial stents were approved for treating cerebral aneurysms in July 2010. Consequently, the number of these cases has been increasing each year.

Angiography systems have changed from using image intensifiers (I.I.) to flat panel detectors (FPD), which offer more functionality, high image quality, and low exposure dose levels. In addition, the environment for treating cerebrovascular impairments with endovascular procedures has changed dramatically as well, such as in terms of preoperative diagnosis, treatment applicability and strategy, selection of devices, evaluations during and after procedure. Various companies supply excellent FPDs, each with unique functions and features that are selectively utilized to maximum benefit in clinical application. The authors had an opportunity to use multiple brands of FPDs for endovascular treatment. The following is a preliminary report of our experience using a fully digital Shimadzu Trinias angiography system for CAS for carotid atherosclerosis and stent-assisted coil embolization for a cerebral aneurysm.

2. Trinias B12 Package

The system used was a Shimadzu Trinias B12 package released in August 2013 and installed at Nipponbashi Hospital in Osaka city in September of the same year **(Fig. 1)**. Developed as a crossover biplane system covering areas including the head and neck, thorax, heart, abdomen, and as far as the extremities, it features a 12 × 12-inch FPD on both the frontal and lateral sides, which allows switching between five field-of-view sizes from 4.5 to 12 inches. In addition to features common to all the FPDS, such as (1) a rectangular detector surface that allows capturing images that are as distortion-free at the edges as they are at the center and (2) a wide dynamic range that reduces the risk of halation even for large differences in permeability, an especially noteworthy feature of the Trinias is the SCORE PRO Advance system that significantly improves visibility. SCORE PRO Advance is Shimadzu's proprietary image processing technology that features real-time parallel processing, such as noise suppression and image parametric equalization, and a function for optimizing image data acquisition parameters based on the target treatment area or treatment method to simultaneously achieve both high image quality and low exposure dose levels. The wide variety of image display modes, such as SCORE CT and SCORE 3D, and operating mechanisms enable using simple operations to display various measurements while also clearly rendering the complicated blood vessel anatomy, which provides a treatment support system that is extremely useful for endovascular treatment in the head and neck.

Fig.1 Trinias B12 package

3. Current Status and Problems of CAS

In general, CAS is applicable in cases with at least 50 % symptomatic stenosis or at least 80 % asymptomatic stenosis and where a carotid endarterectomy would be difficult. However, in recent years, surgical treatment is often considered based on a qualitative diagnosis of plaque, more than the degree of stenosis. MRI plaque image or an echogram of the carotid artery is evaluated to determine whether or not plaque is unstable and then if the use of CAS is determined, then a filter, balloon, or other embolic protection device (EPD) is used with a technique that generates low debris levels during the operation to reduce the risk of ischemic complications. Some experiment reports indicate that using primary stenting that expands the stenosis to the target diameter with a balloon after placing the stent results in less debris, though results vary depending on the stenosis diameter before treatment. If using a filter with CAS, lower angioplasty levels (less than 30 % residual stenosis) are typically used to avoid complications from clogged filters initially experienced, referred to as "no-flow" or "slow-flow," rather than expanding vessels completely, which can generate large amounts of debris. A method called "seatbelt and airbag technique" is also used, which uses the proximal balloon catheter and flow reversal methods in combination with filters to benefit from the advantages of both methods during CAS. In cases of symptomatic stenosis where plaque has caused an inflammatory reaction, attention is paid not only to ischemic complications due to hard debris, but also to the effects of cytokine and other inflammation factors. For that reason, in symptomatic cases with severe stenosis due to large quantities of unstable plaque, it is necessary to adequately evaluate the lesion with images before operation, and the FPD system performance needs to be adequate so that various devices, including EPDs, are operated accurately.

Stents currently available for use in carotid arteries are the closed-cell type Carotid WALLSTENT (Boston Scientific) and the open-cell type Precise (Johnson & Johnson) and Protégé (ev3), which are all self-expanding models. Large amounts of debris generation or growth of plaque protrusions from strut gaps into the lumen are common in cases of severe stenosis with high volume soft plaque and is less likely to occur with closed cell type stents. On the other hand, the strut structure of open cell type stents provide higher radial forces, which makes them more suitable for hard stenosis or irregular bent lesions.

Various diagnostic imaging can be used for preoperative evaluation and measurements, such as vessel diameter, but once the stent is placed, it is difficult to view the stent lumen in detail. Therefore, intravascular ultrasound (IVUS) is often used before and after stent placement. However, because it is not officially applicable to carotid artery stenosis, the use of cone-beam CT with dilute contrast media is becoming more popular, which offers the advantage of clearly showing whether or not plaque protrusions are present. Furthermore, due to the large pulsations of the carotid artery, short exposure times are often used to avoid artifacts.

4. Current Status and Problems of Intracranial Stents to Treat Cerebral Aneurysms

Just as with CAS, either a closed-cell type self-expanding stent (Enterprise VRD from Johnson & Johnson) or an open-cell type self-expanding stent (Neuroform EZ from Boston Scientific) are available for use. In addition, a new generation of devices called flow diverting stents are scheduled for approval, which are used to prevent enlargement or bursting by reducing blood flow to cerebral aneurysms using only a stent.

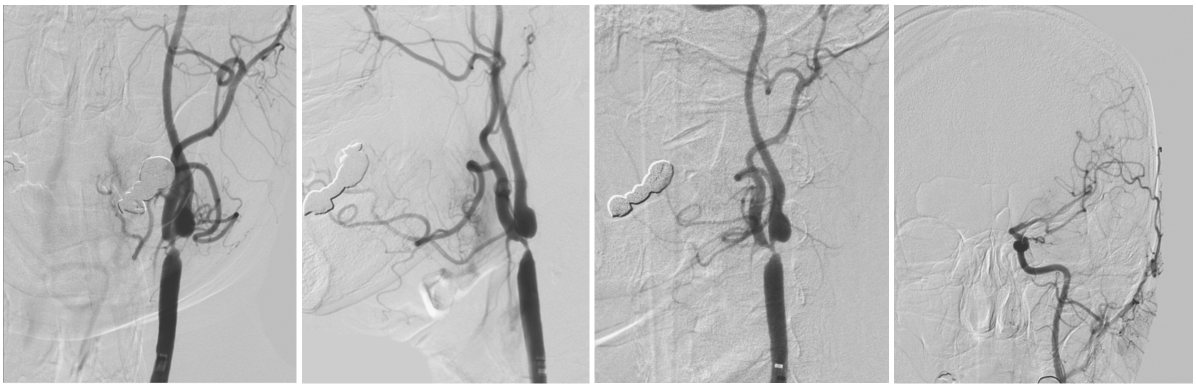
For Enterprise VRD and Neuroform EZ, it is necessary to use a dedicated microcatheter, which must be deployed and positioned properly among various markers. The stent position is verified using four radiopaque markers on the proximal and distal end of the stent. However, due to the small width and thickness (40 to 90 μm) of the struts and the typical spatial resolution of an FPD of about 200 μm, or 150 μm for even the newest models, it is difficult to visualize the strut deployment status using fluoroscopy or radiography monitors.

Closed-cell type stents offer the advantage of being recapturable if they are deployed in an unsuitable location, but also have the disadvantage of being prone to kinking or buckling in curved blood vessels. In contrast, open-cell type stents offer high compatibility with crooked blood vessels, but once deployment starts, they cannot be recovered even if the location is not suitable. Therefore, there are reports of complications, such as a stray strut protruding into the aneurysm or a coil escaping from a gap. There are two general methods of inserting the coil into the cerebral aneurysm. The trans-cell technique first places the stent and then inserts the microcatheter between the struts and into the cerebral aneurysm. The jailing technique first inserts the microcatheter into the cerebral aneurysm and then deploys the stent. Mention of other techniques will be omitted here, but in actual clinical practice, the jailing technique is the main method used. In addition, a one and a half round microcatheterization technique has been reported that involves rotating the coil insertion microcatheter inside the cerebral aneurysm and inserting the coil uniformly from the in-flow zone to the out-flow zone, which is the method often used by the authors for large to giant cerebral aneurysms.

The biggest problem with performing a highly curative and reliable coil embolization with a stent using a variety of techniques is not being able to confirm whether the struts of the placed stent are covering the neck of the cerebral aneurysm adequately or not in the fluoroscopy or radiography monitor, for the reasons indicated above. Consequently, angiographic computed tomography (CT) and cone-beam CT started being used to solve that problem. More recently, dilute contrast media and fusion imaging have become widely used for diagnostic imaging during operation. Considerable experience needs to be accumulated using the characteristics of each model before optimal imaging parameters can be determined. Therefore, a major issue imposed on new angiography systems is how much image quality can be improved, so that the relationships between the positions of the parent artery, cerebral aneurysm, intracranial stent, microcatheter, coil, and other elements can be sufficiently understood.

5. Case 1

This male in his fifties developed paresis on his upper and lower right limbs and aphasia. A CT/MRI scan revealed a relatively extensive cerebral infarction in the left middle cerebral artery and angiography from the left common carotid artery revealed delayed intracranial blood flow due to an 85 % stenosis in the carotid artery bifurcation **(Fig. 2 and 3)**. After administering two antiplatelet drugs, an 8Fr guiding system was inserted via the right femoral artery into the left common carotid artery, where a 3.5 mm - 5.5 mm FilterWire EZ system (Boston Scientific) was implanted in the internal carotid artery using a working angle of LAO 30 degrees for the frontal C-arm and the lateral side left unchanged. Though stenosis was severe and accompanied by large ulcerations, due to the clear road map image, inserting the guiding system and filter was easy. A 2.5 mm - 40 mm SHIDEN (Kaneka Medix) was used to pre-dilate, while checking for run-off, an 8 mm - 29 mm Carotid WALLSTENT was inserted and deployed, and then a 3.5 mm - 30 mm Sterling (Boston Scientific) was used for additional post-dilation **(Fig. 4)**. Due to concerns of hemorrhagic infarction in this case, minimal poststenotic dilation was performed, while also avoiding arterial hypotension and generating large amounts of debris. **Fig. 5** shows a 10 second



a: Frontal Image Before CAS　**b**: Lateral Image Before CAS　**c**: LAO 30 Deg. Before CAS　**d**: Frontal Intracranial Image Before CAS

Fig. 2 Case 1—Pre-CAS Images
The left common carotid artery image shows severe stenosis involving ulceration in bifurcation areas of the common, internal, and external carotid arteries. Therefore, a LAO 30 degree **(c)** was selected as the working angle for the front FPD. The preoperative intracranial blood flow was delayed and the anterior cerebral artery was not visualized **(d)**.

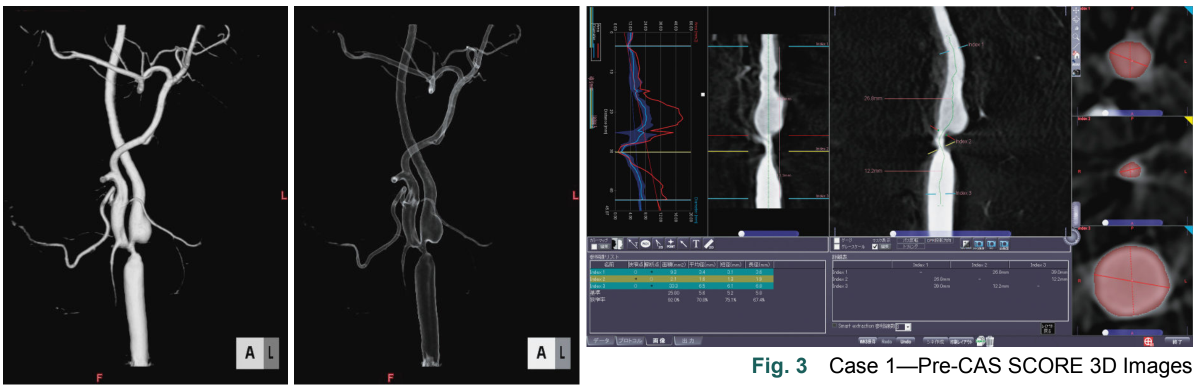
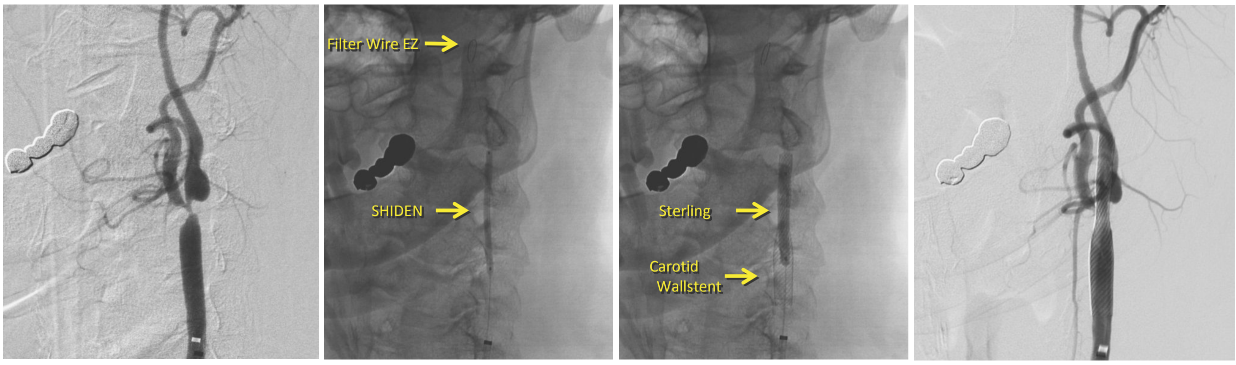


Fig. 3 Case 1—Pre-CAS SCORE 3D Images



a: Before CAS b: Pre-Dilation c: Stent Placement Post-Dilation d: After CAS

Fig. 4 Case 1—Images During CAS

These images were obtained during operation using a LAO 30 degree frontal working angle. Since this was a common carotid artery lesion, the 8Fr guiding system was carefully placed in the left common carotid artery using the road map image **(a)** and then the FilterWire EZ was deployed in distal internal carotid artery and pre-dilated with the 2.5 mm - 40 mm SHIDEN **(b)**. Next, the 8 mm - 29 mm Carotid WALLSTENT was placed and the 3.5 mm - 30 mm Sterling was used for slight additional poststenotic dilation **(c)**. Though ulcerations remained, CAS was ended at less than 30 % residual stenosis due to the need to avoid hemorrhagic infarctions and hyperperfusion syndrome **(d)**.

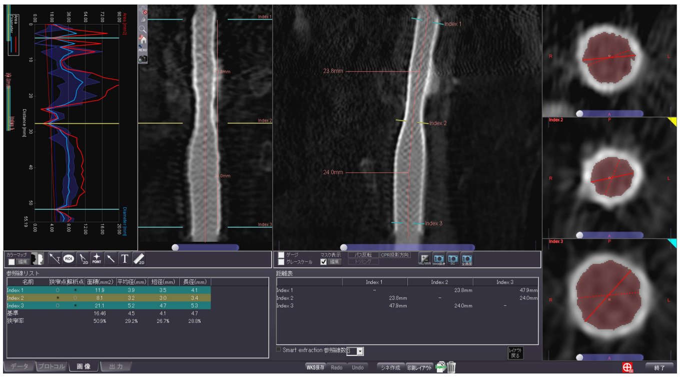
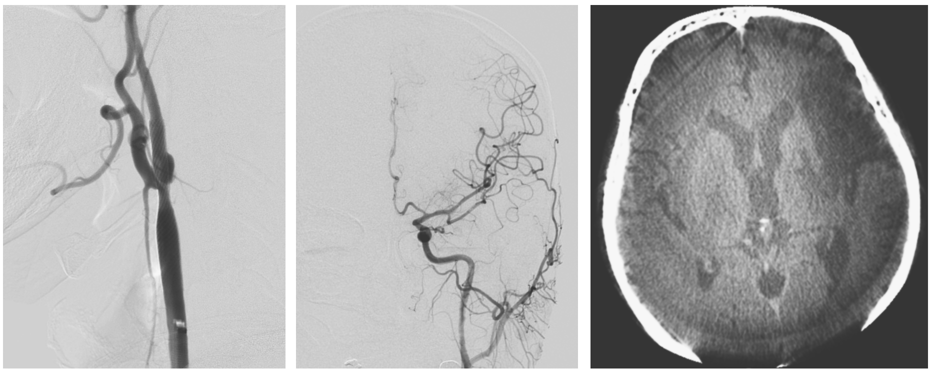


Fig. 5 Case 1—Post-CAS SCORE CT Images

This shows 10-second SCORE CT scan images using a 5-fold diluted contrast medium. These images obtained after CAS using a Carotid WALLSTENT show no plaque protrusions and show the highly circular shape after CAS. (Motion artifacts appeared because Carotid WALLSTENT stents are more prone to halation than other stents and due to the 10-second scan time. Hopefully, artifact levels will be reduced by 5-second or shorter scan modes planned to be released in the future.)



a: Lateral Cervical Image After CAS b: Frontal Intracranial Image After CAS c: SCORE CT Intracranial Image After CAS

Fig. 6 Case 1—Images After CAS

The post-CAS cervical image **(a)** shows that intracranial blood flow in the anterior cerebral artery and the middle cerebral artery area where the cerebral infarction occurred **(b)** has clearly increased, and the SCORE CT image confirms that it was not complicated by a hemorrhagic infarction **(c)**.

SCORE CT scan with a contrast medium diluted by five times. Though the stent and given radiography parameters are prone to artifacts, no plaque protrusions are shown and residual stenosis is less than 30 %, which is a generally good post-CAS condition. Intracranial blood flow clearly increased in post-CAS angiography, but the procedure was ended after confirming with SCORE CT that there was no bleeding in the cerebral infarction area **(Fig. 6)**.

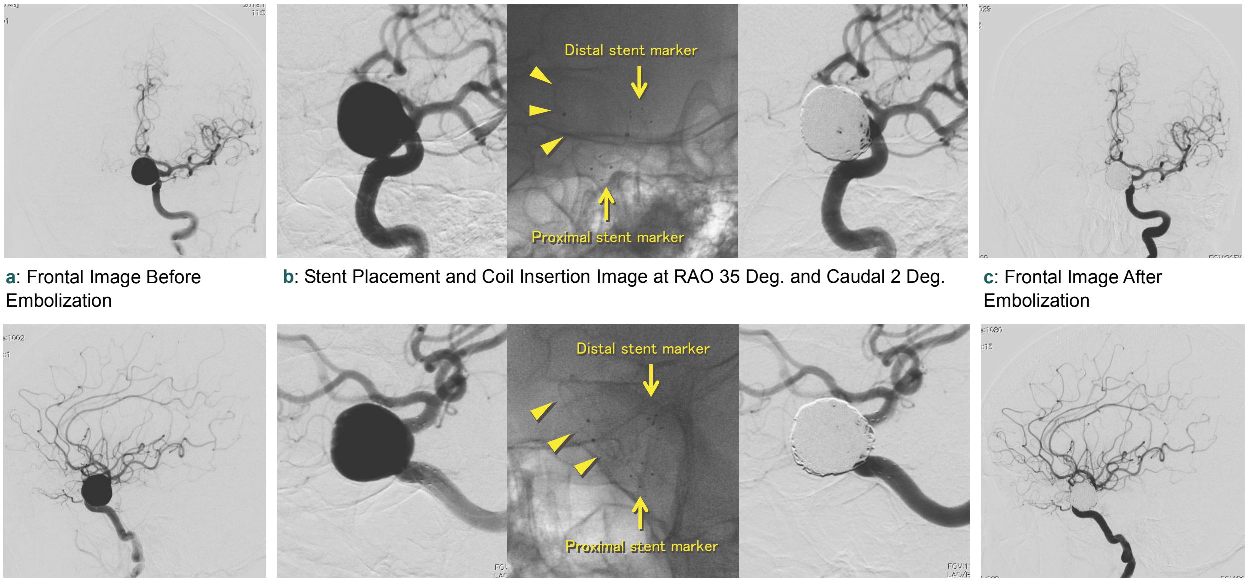
6. Case 2

This is a female in her fifties that developed a visual impairment in her left eye. Angiography from the left internal carotid artery showed a large cerebral aneurysm up to 17.8 mm in the bifurcation area between the left internal carotid artery and ophthalmic artery. After administering two antiplatelet drugs, a 6Fr guiding system was inserted via the right femoral artery into the left internal carotid artery, where the jailing technique and one and a half round microcatheterization technique were used to perform a stent-assisted coil embolization. Embolization was performed using a 4.5 mm - 30 mm Neuroform EZ, HydroFrame (Terumo), ED Coil (Kaneka), and VFC (Terumo), using a barrel view (tunnel view) with RAO 35 degree and caudal 2 degree for the frontal working angle and LAO 45 degree and caudal 25 degree for the lateral working angle, while also verifying the positional relationship between the starting point of the anterior choroidal artery and the stent maker at the distal end. Good embolization results were obtained with a volume embolization ratio (VER) of 20 % with bare platinum coil conversion and 26 % with hydro coil conversion **(Fig. 7)**.

Due to the high image quality of the fluoroscopy and road map images, it was easy to insert and deploy the Neuroform EZ accurately in the target implant location. In addition, **Fig. 8** shows preoperative SCORE 3D measurements and various SCORE CT images taken during the operation. These clearly show the stent struts, so that the positional relationship between the neck of the cerebral aneurysm, stent, and coil insertion microcatheter could be determined in detail as the procedure progressed.

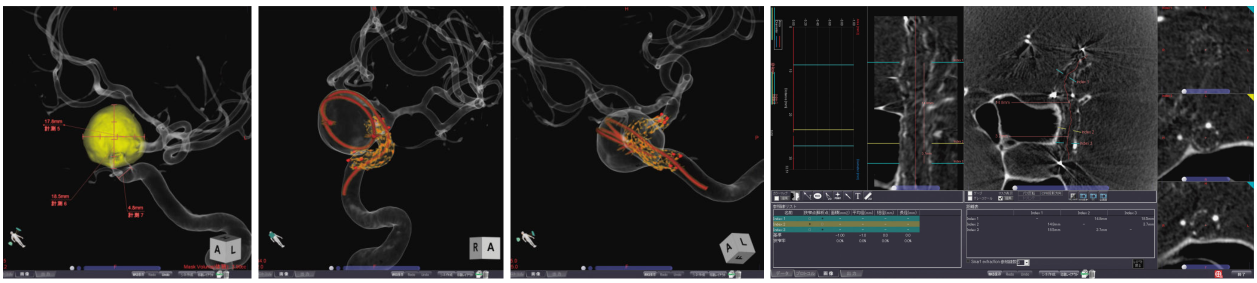
7. Case 3

This patient is a female in her sixties with right oculomotor palsy. Angiography from the right internal carotid artery showed a giant cerebral aneurysm up to 30.5 mm in the cavernous sinus segment of the right internal carotid artery. The same procedure as indicated in Case 2 was used to perform a stent-assisted coil embolization. Embolization was performed using a 4.0 mm - 30 mm Neuroform EZ and Penumbra Coil 400 (Penumbra), using a barrel view with RAO 25 degree and cranial 30 degree for the frontal working angle and the lateral working angle left in the lateral



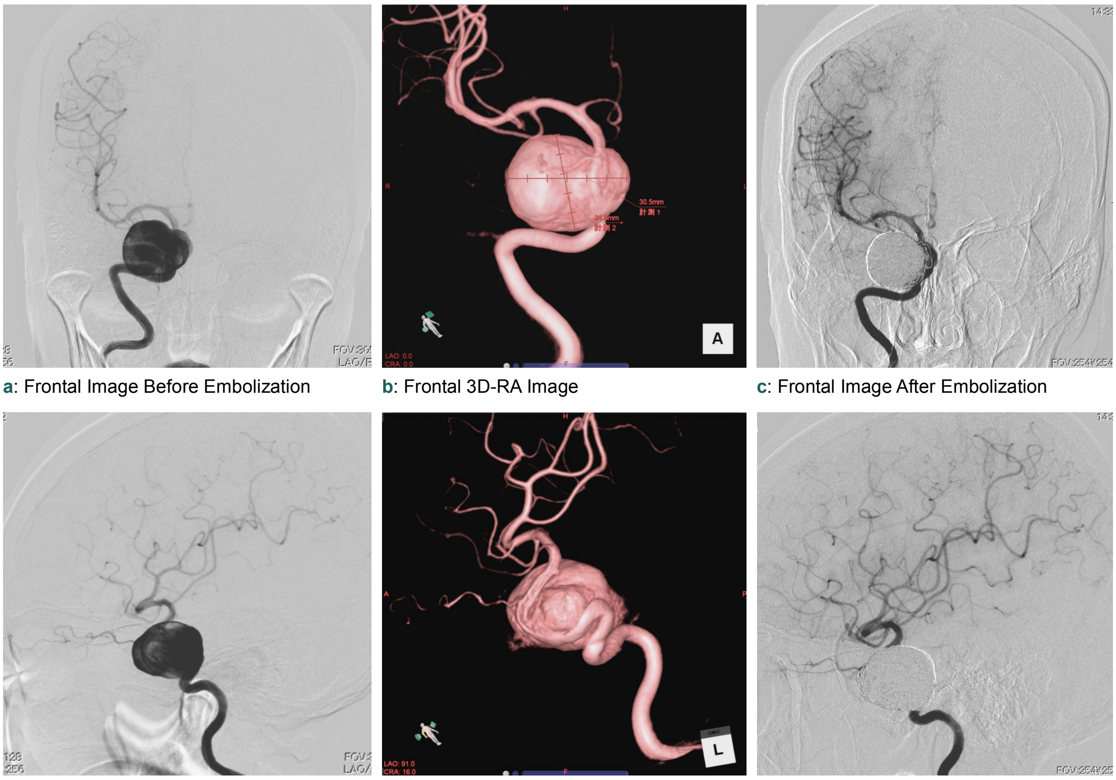
a: Frontal Image Before Embolization
b: Stent Placement and Coil Insertion Image at RAO 35 Deg. and Caudal 2 Deg.
c: Frontal Image After Embolization
d: Lateral Image Before Embolization
e: Stent Placement and Coil Insertion Image at RAO 45 Deg. and Caudal 25 Deg.
f: Lateral Image After Embolization

Fig. 7 Case 2—Stent-Assisted Coil Embolization
This shows front and lateral FPD images before embolization **(a and d)**, stent placement and coil insertion at given working angles **(b and e)**, and after embolization **(c and f)**. The images show good visibility of the distal and proximal stent markers and the microcatheter (indicated with arrowheads) inserted into the cerebral aneurysm in advance using the one and a half round microcatheterization technique, based on the fluoroscopy and road map images.



a: Preoperative Measurement **b**: SCORE CT (RAO/Caudal) **c**: SCORE CT (RAO/Caudal) **d**: Straight-View Image, CPR Image, and Short-Axis Images

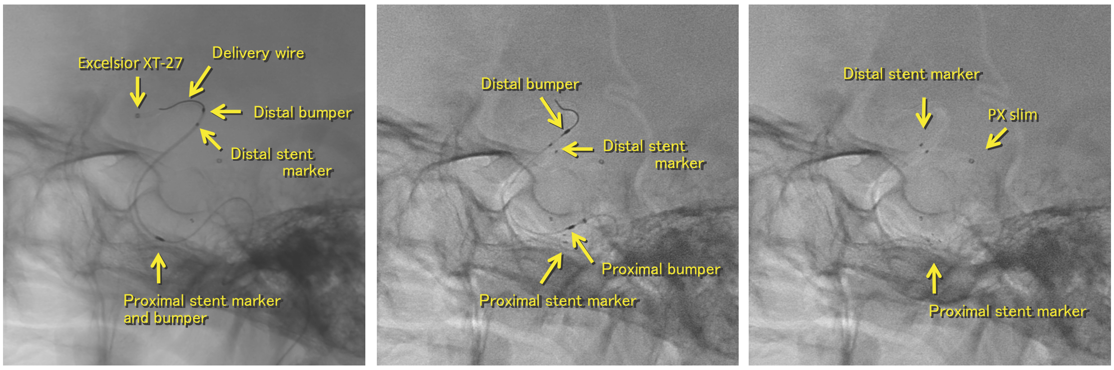
Fig. 8 Case 2— Stent-Assisted Coil Embolization
For the cerebral aneurysm with the maximum diameter of 17.8 mm in the preoperative measurement **(a)**, stent and microcatheter are clearly showed in SCORE CT images **(b and c)**. The stent deployment status could be determined in more detail from the straight-view, curved planar reconstruction (CPR), and short-axis images **(d)**.



a: Frontal Image Before Embolization b: Frontal 3D-RA Image c: Frontal Image After Embolization

d: Lateral Image Before Embolization b: Lateral 3D-RA Image c: Lateral Image After Embolization

Fig. 9 Case 3— Stent-Assisted Coil Embolization



a: Stent Insertion b: Stent Deployment c: Stent Placement

Fig. 10 Case 3—Visibility of Markers

The Neuroform EZ stent was inserted through the Excelsior XT-27 microcatheter (Boston Scientific), just beyond the neck of the cerebral aneurysm (a). The stent deployment in the target location was confirmed from the four distal and proximal stent markers expanding as the Excelsior XT-27 was pulled back (b). The PX SLIM microcatheter (Penumbra) for inserting the Penumbra Coil 400 was left in the aneurysm and the delivery wire and Excelsior XT-27 were removed (c). Visibility was good for each of the microcatheter markers, stent markers, stent delivery wire, positioning bumpers, and so on, both in the fluoroscopy (a) and road map (b and c) images.

position, while also verifying the positional relationships between the stent markers, coil insertion microcatheter, and coil removal markers. Good embolization results were obtained with 26 % VER (Fig. 9).

For cerebral aneurysms in this area, visibility of microcatheters and stents is poor due to the complex bone structure near the skull base that surrounds the area. Fig. 10 shows fluoroscopy and road map images of the stent from insertion to placement. An explanation of the markers and their names is omitted here, but the figure shows that image quality is more than adequate for reliably placing the stent in the target location. In this case, the giant cerebral aneurysm was pushing the parent internal carotid artery, resulting in concern that the stent was not deployed adequately. However, images obtained during the operation, such as the SCORE CT maximum intensity projection (MIP) images in Fig. 11, allowed confirming that adequate lumen diameter was achieved.

8. Other Trinias Features and Outlook

In addition to the SCORE Imaging ultra fast image processing technology, which includes SCORE PRO Advance, another outstanding feature of the

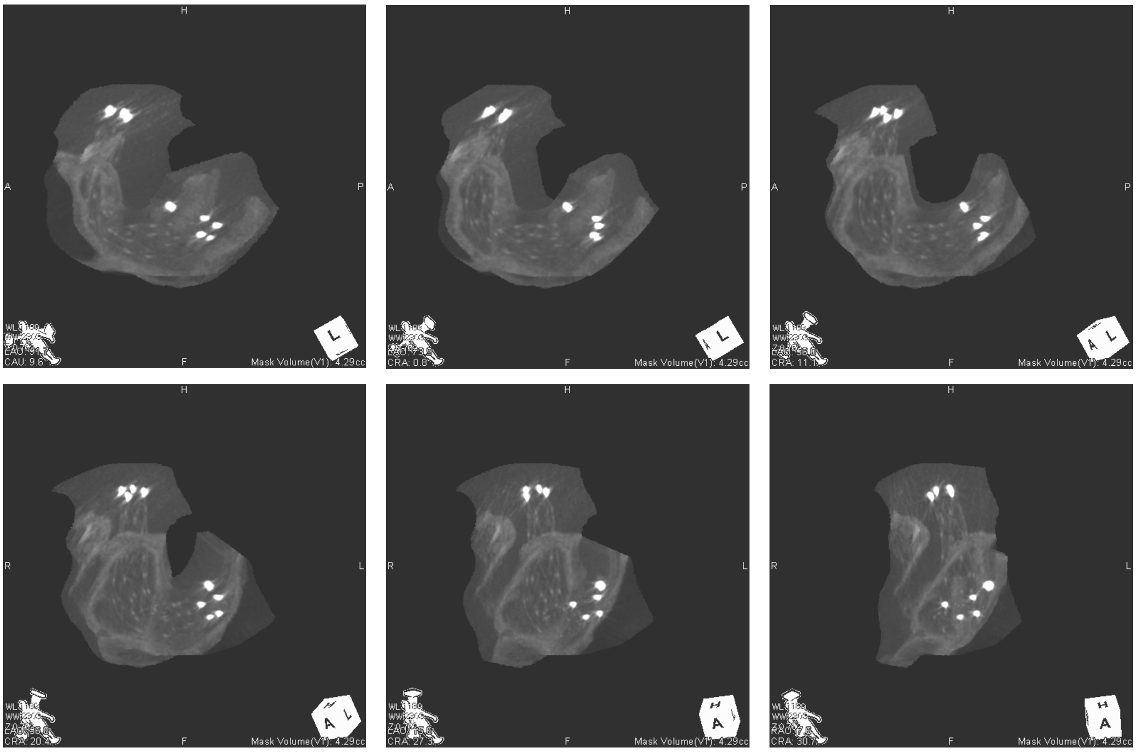


Fig. 11 Case 3—SCORE CT MIP Image
This shows SCORE CT MIP images after implanting the Neuroform EZ. These images were obtained at an early stage, before imaging parameters and image quality were properly adjusted, but they clearly show that the stent is adequately deployed inside the lumen of the parent artery.

Trinias is the improved operability provided by SMART Design. Due to SMART Access functionality, such as the fast lateral arm movement and the high degree of freedom provided by the 6-axis mechanism on the high speed C-arm, patients can be transported into the room, the arm positioned, and various imaging and treatment tasks performed smoothly even within a small angiography room. Other companies also offer FPD systems that feature state-of-the-art technologies, but the highly refined basic functionality of the Trinias, such as image quality and ease-of-operation, makes an excellent angiography system for actual clinical use.

Furthermore, the Trinias features SCORE StentView software that uses real time image processing technology to display even stents in pulsating coronary arteries in a stationary manner. By displaying images without dynamic motion at the same time, using balloon markers and other points as reference, this technology improves stent visibility. The utility for use with fixed cerebral aneurysms at the base of the skull is low, but for cerebral aneurysms that move significantly vertically, such as at the basilar artery bifurcation, or for carotid artery stent implants, which pulsate significantly due to their location, this technology is especially promising.

9. Conclusion

Generally positive initial results are reported from using the Shimadzu Trinias B12 Package for treating cerebral aneurysms with CAS and intracranial stent-assisted coil embolization. Since the days when image intensifiers were used, Shimadzu angiography systems have earned a reputation for durability and low image quality deterioration over time, compared to other brands in the same class. Therefore, we look forward to Shimadzu using their expertise and product support capabilities to develop reliable FPD systems with advanced technologies, such as multi-functionality, high image quality, and low exposure dose levels, but that are also based on the specific needs of the healthcare environment in Japan and that are trusted over the long term.