Surpass NeuroEndoGraft (SJN1301): Device and the State in Japan

Yasushi Matsumoto1 and Nobuyuki Sakai2

The flow diverter was developed with great expectations as a therapeutic device for intracranial aneurysms that have been difficult to treat to date. Placed in the parent artery of an intracranial aneurysm, it covers its neck, promotes complete occlusion, and prevents rupture of the aneurysm by reducing the blood flow to the aneurysm, inducing its thrombosation, serving as a scaffold for newly formed intimal tissue covering the neck of the aneurysm, and separating the aneurysm from the circulation of the parent artery.

Keywords ▶ flow diverter, Surpass NeuroEndoGraft, intracranial aneurysm

Introduction

Surpass NeuroEndoGraft (domestic clinical trial code: SJN1301, Stryker) is a flow diverter (FD) undergoing clinical evaluations in Japan and the United States. In Europe, non-clinical and clinical evaluations of SJN1301 have been implemented, and the device has acquired the CE mark (December 2010). In the United States, a clinical study is being conducted (as of December 2015). In Japan, SJN1301 is rated as a highly useful medical device by the evaluation committee concerning the early introduction of medical devices with high medical needs of the Ministry of Health, Labour and Welfare (MHLW), and a clinical trial is currently in progress.

In this article, clinical trials of SJN1301 are outlined, and typical cases that we encountered at Konan Hospital are presented.

The FD is a fine mesh-braided stent-like device for intracranial aneurysms, placed at parent artery and covered neck of aneurysm. FD reduces intra-aneurysmal flow followed by obliteration of the aneurysm. FD treatment is considered a good alternative for previously difficult to treat cases.

SJN1301 consists primarily of cobalt–chromium alloy wires, and marker wires made of platinum (92%) and tungsten (8%) are woven in it to improve the visibility under fluoroscopy. A dilated SJN is shown (Fig. 2). Marker wires are clearly identified, allowing confirmation of the state of expansion of the device.

SJN1301 is available in three different types of diameter: 3, 4, and 5 mm. The number of wires is 72 in the types 3 and 4 mm in diameter and 96 in the type 5 mm in diameter.
The device 5 mm in diameter consisting of 96 wires occasionally feels stiff in manipulations during delivery. As mentioned above, SJN1301 consists primarily of cobalt–chromium alloy wires, and marker wires made of platinum and tungsten are woven into them to improve the visibility under fluoroscopy. The number of marker wires is 12 regardless of the total number of wires. Pipeline is made of 48 wires consisting of 36 cobalt–chromium alloy wires and 12 platinum–tungsten marker wires regardless of the size.

The primary wires of both SJN1301 and Pipeline are made of cobalt–chromium alloy because of its excellent flexibility. In an early stage of its development, SJN1301 was made of cobalt–chromium wires alone, but some of them were replaced by platinum–tungsten marker wires as in the present form to improve the visibility within a range not affecting the performance.

### Sizes of SJN1301

SJN1301 is available in three diameters: 3, 4, and 5 mm in diameter. However, Pipeline is available in nine sizes ranging in diameter from 3.0 to 5.0 mm at intervals of 0.25 mm. This is considered to allow less precise selection of size in SJN1301 compared with Pipeline.

SJN1301 3, 4, and 5 mm in diameter are available in 3, 6, and 5 different lengths, respectively (Table 1). SJN1301 3 mm in diameter dilates to 3.5 mm or greater, that 4 mm in diameter dilates to 4.4 mm or greater, and that 5 mm in diameter dilates to 5.3 mm or greater in diameter, and the recommended vascular sizes are based on these values.

### Delivery Catheters for SJN1301

SJN1301 with a pusher wire mounted and inserted into the delivery catheter via a Y-connector is packaged aseptically as a set (Fig. 3). The delivery catheter houses and protects SJN1301 until it is advanced to the neck of the aneurysm, and the pusher wire pushes SJN1301 out of the delivery catheter and deploys it at an appropriate site. Since the distal end of Pipeline is protected by the polytetrafluoroethylene (PTFE) sleeve, the sleeve must be reversed to dilate the device, but no such manipulation is necessary with SSJN1301.

For Pipeline, a Marksman catheter 0.027 in internal diameter must be prepared separately.

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**Table 1** The list of SJN1301

<table>
<thead>
<tr>
<th>Indicated size</th>
<th>Diameter (mm)</th>
<th>Number of wires</th>
<th>Recommended vascular diameter (mm)</th>
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<tr>
<td>3 × 15</td>
<td>3.55–4.00</td>
<td>72</td>
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<tr>
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<td>4.45–5.00</td>
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<td>3.4–4.4</td>
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<tr>
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<td>96</td>
<td>4.3–5.3</td>
</tr>
</tbody>
</table>
The Dawn of the Flow Diverter in Japan

aspirin-reaction unit (ARU) was 429, and the P2Y12 reaction unit (PRU) was 152.

Anesthetic management: The patients were managed by general anesthesia.

Surgical findings: Fubuki Dilator Kit 6Fr (Asahi Intecc, Aichi, Japan) was placed in the cervical segment of the left ICA. A DAC catheter 5.2FR (Stryker Neurovascular) was advanced co-axially to the petrous segment. 3D angiography was performed from the DAC catheter, and the intended area of SJN1301 placement was measured. Both the proximal and distal diameters of the ICA were 3.8 mm, and the predicted length of deployment was 24.0 mm (Fig. 5). SJN1301 4.0 mm in diameter and 30 mm long was selected.

SJN1301 was placed in the intended area, and angiography was performed after the placement. The aneurysm was delineated by angiography immediately after surgery, and the findings of angiography one week after surgery were similar (Fig. 6).

The aneurysm disappeared in angiography six months after surgery (Fig. 7).

### Selection Criteria of SJN1301 for Patients in the Domestic Clinical Trial

Table 2 shows the patient selection criteria for the domestic clinical trial of SJN1301. Those for the domestic clinical trial of Pipeline are shown in the parentheses.

- Patients with aneurysms located in the internal carotid artery (ICA) including the terminal portion (ICA proximal to the division of the posterior communicating artery);
- Patients aged 20 years or above and 80 years or below (75 years or below);
- Patients in whom the vascular diameters of both the proximal and distal parts of the intended area of device placement are 2.5 mm or greater and 5.3 mm (5.0 mm) or less.

A marked difference in the selection criteria is that aneurysms at the bifurcation of the internal carotid and posterior communicating arteries and those at the bifurcation of the internal carotid and anterior choroidal arteries are included in the target lesions of the domestic clinical trial of SJN1301.

### Case

The patient was a 46-year-old female.

Preoperative angiography: A saccular aneurysm $10.4 \times 6.7 \times 6.5$ mm (neck length: 7.3 mm) protruding medioinferiorly from the medial side of the clinoid segment—suprACLoid segment of the left ICA was noted (Fig. 4). A small bleb protruding antero-mediainferiorly was observed.

Antiplatelet medication: The administration of aspirin at 100 mg/day and clopidogrel at 75 mg/day was scheduled to be initiated from five days preoperatively, continued for six months, and changed thereafter to aspirin alone. By the measurement using Verify Now system (Accumetrics Inc., San Diego, CA, USA) on the day of operation, the aspirin-reaction unit (ARU) was 429, and the P2Y12 reaction unit (PRU) was 152.

Anesthetic management: The patients were managed by general anesthesia.

Surgical findings: Fubuki Dilator Kit 6Fr (Asahi Intecc, Aichi, Japan) was placed in the cervical segment of the left ICA. A DAC catheter 5.2FR (Stryker Neurovascular) was advanced co-axially to the petrous segment. 3D angiography was performed from the DAC catheter, and the intended area of SJN1301 placement was measured. Both the proximal and distal diameters of the ICA were 3.8 mm, and the predicted length of deployment was 24.0 mm (Fig. 5). SJN1301 4.0 mm in diameter and 30 mm long was selected.

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Fig. 4 Preoperative angiogram shows a left internal carotid artery aneurysm. Left: Angiogram on working angle (RAO9/CAU9). Right: Angiogram on working angle (LAO80/CRA13).

Fig. 5 The diameter of proximal and distal ICA is 3.8 mm. We approximated the length of landing zone to be 24.0 mm.

Fig. 6 One week after SJN1301 placement, angiogram still shows a left internal carotid artery aneurysm.
The Present State and Future of SJN1301 (Surpass)

As mentioned above, SJN1301 already obtained the CE mark in June 2008 and is in clinical use in Europe, and its clinical trials are in progress in the United States and Japan. In Japan, the clinical trial is carried out at six institutions, registration of 30 cases has been completed between August 2014 and July 2015, and all patients except those who died are followed-up as of January 2016. The primary endpoint concerning the efficacy is the percentage of subjects in whom the target intracranial aneurysm was completely occluded (Raymond Class: 1), there is no clinically significant stenosis (stenosis rate ≤50%) in the parent artery, and no secondary treatment was performed for the target intracranial aneurysm 12 months after the procedure, and the primary endpoint concerning the safety was the percentage of subjects in whom death due to cranial nerve disorder or severe ipsilateral stroke occurred during the 12 months after the procedure.

Among the reports of clinical experience, there are two representative papers. De Vries et al. reported a prospective study of the early experience in treatment using Surpass at a single facility in 2003. Concerning the short-term (6 months) therapeutic results in 49 intracranial aneurysms (37 patients), no serious complications were observed, and the outcome was generally satisfactory.1) Wakhloo et al. reported the results of a prospective study in 190 aneurysms (165 subjects) in a multicenter. Surpass was successfully deployed in 98% of the lesions, 93.2% of the patients were followed-up over a mean period of six months, permanent complications were observed in 6%, and the mortality was in 2.7%. Angiographic evaluation was performed in 86.8% of the aneurysms, and the complete occlusion rate was 75%.2)

A clinical trial currently in progress in the United States is the Safety and Effectiveness of an Intracranial Aneurysm Embolization System for Treating Large or Giant Wide Neck Aneurysms (SCENT trial). Colby et al.3) reported the outcomes of 20 aneurysms (20 patients) registered in the SCENT trial and treated at their facility. The reports of the results of the SCENT trial and the clinical trial in Japan are awaited.

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Disclosure Statement

The first author and co-author have completed the self-report of COI to the Japan Neurosurgical Society. The COI that the first and second authors should disclose in connection with this paper is the payment of one million yen or
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References

