

Preliminary Experience of the Surpass Streamline Flow Diverter for Large and Giant Unruptured Internal Carotid Artery Aneurysms

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Abstract

As of January 2021, the Surpass Streamline (SS) is the most recently approved flow diverter in Japan. A total of 28 Japanese patients, including 9 clinical trial patients, with 28 large or giant unruptured internal carotid artery (ICA) aneurysms, underwent SS embolization at Juntendo University Hospital. Procedural failure occurred in two patients due to the difficulty to navigate the device in the tortuous parent artery. Therefore, 26 patients with 26 aneurysms were available for clinical and anatomical assessments. Patients' mean age was 62.6 years (range 46-86), and 24 patients (92.3%) were female. Mean aneurysm size and neck width were 15.4 mm and 7.7 mm, respectively, with 20 saccular and 6 fusiform aneurysms. Seven aneurysms were symptomatic due to the aneurysmal mass effect. Twenty patients underwent a 6-month follow-up angiography to evaluate the degree of occlusion. Anatomical outcomes were 12 (60%) complete occlusion (CO), 4 (20%) residual neck (RN), and 4 (20%) residual aneurysm. Favorable aneurysm occlusion consisted of CO, and RN was achieved in 16 (80.0%). There were no significant device stenoses. Aneurysmal mass effect improved in one and was unchanged in eight patients. There were three device-related complications, namely, delayed aneurysm rupture, minor ischemic stroke, and device occlusion (11.5%). One patient with minor ischemic stroke fully recovered before 30 days, and our series showed 7.7% risk of major ipsilateral stroke and neurological death at 30 days. The SS embolization for large and giant unruptured ICA aneurysms offers satisfactory anatomical and clinical outcomes with a low risk of device-related complications.

Keywords: internal carotid artery aneurysm, flow diverter, surpass streamline, Japanese population

Introduction

Coil embolization is widely used as an endovascular strategy for intracranial aneurysms. However, it carries high risks of long-term recanalization and retreatment, particularly in large or giant aneurysms.¹⁾ Furthermore, coil embolization could not satisfactorily be used to treat fusiform aneurysms with parent artery preservation. Recently, flow diverter (FD) therapy has become an important alternative endovascular strategy for large or giant unruptured intracranial aneurysms.²⁻⁵⁾ Although various FDs made of different materials and with different delivery systems are available worldwide, there are currently three commercially

available flow diverters in Japan, namely, the Pipeline Flex (Medtronic, New York, NY, USA), the FRED (Terumo, Tokyo, Japan), and the Surpass Streamline (SS) (Stryker, Tokyo, Japan). The SS is the newest in Japan that was most recently approved in January 2021.

Materials and Methods

This was a retrospective study conducted in a single center. Authors obtained local research approvals, and the need for informed consent was waived by respective research committees due to the retrospective nature of the study (E22-0005).

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In January 2021, the SS flow diverter was approved in Japan. The SS is made of a cobalt chromium alloy with 12 platinum tungsten alloy marker wires, in a monolayer construction with 72 wires braided for the 3-mm and 4-mm diameter devices and 96 wires braided for the 5-mm diameter device. Unlike the Pipeline Flex and FRED, the SS is manufactured in diameters of 1-mm increments. The consistent mesh density ensures a more even effect on flow reduction, and the mesh density of the device ranges from 21 to 32 pores/mm².^{6,7)} The foreshortening percentage of the SS FD varies, depending on the device diameter and length. The SS has a strong kink and torque resistance with easy device opening. Different from the Pipeline Flex and FRED, the SS is preloaded in the delivery microcatheters, adding increased rigidity to the system. Therefore, higher manual push forces are required during the device navigation and deployment.^{8,9)} The combination of a long sheath and a large bore intermediate catheter is ideal for easy navigation of the delivery system beyond the aneurysm neck. A 0.014-inch microguidewire is coaxially placed through the center of the delivery system, an over-the-wire system, for added support and to facilitate navigation.

The SS is indicated for unruptured or chronically ruptured aneurysms of large to giant sizes (≥ 10 mm) and with wide neck (≥ 4 mm) morphology for aneurysms located between the petrous and supraclinoid segments of the ICA for patients in Japan.

All the authors retrospectively reviewed and analyzed the patients' medical records, outpatient charts, and operative records. Baseline neurological status was assessed using the modified Rankin scale (mRS)¹⁰⁾ and recorded at 30 days after the procedure. All procedure-related complications were recorded. Radiological follow-up studies were basically scheduled at 6 months after the procedure with digital subtraction angiography. Anatomical outcomes were assessed with a simplified Raymond 3-point scale (complete occlusion [CO], residual neck [RN], and residual aneurysm [RA]).¹¹⁾ Favorable aneurysm occlusion was defined as CO or RN. When the parent vessel narrowing was over 50%, it was defined as a significant device stenosis.

All the patients underwent the procedures under general anesthesia. A biplane angiographic system (Siemens Artis Q Biplane System, Siemens, Munich, Germany) with the three-dimensional (3D) rotational angiography was used in all the procedures. Selection of the most appropriate SS among the line of products was determined based on the parent artery caliber and implanting length with the final decision by the principal operator (H.O.). Because a Catalyst 5 intermediate catheter (Stryker Neurovascular, Fremont, CA) was not available in the clinical trial, we used a 6 French intermediate catheter (Cerulean DD6, Medikit, Tokyo, Japan), which is stiffer and has a larger bore than does the Catalyst 5 intermediate catheter. After patient approval, a coaxial system assembled with a 6 French guiding sheath and a Catalyst 5 intermediate catheter was

used with the transfemoral artery approach in all the procedures. The Catalyst 5 intermediate catheter is usually navigated distally beyond the aneurysm neck with the assistance of an AXS Offset delivery system (Stryker Neurovascular) designed to smoothly deliver large bore intermediate catheters using the less ledge effect. The SS deployment techniques included a few maneuver combinations, including delivery microcatheter unsheathing while pushing and pulling the catheter. Additional SSs were deployed in a telescoping fashion if the aneurysm neck was not fully covered with a single device. Additional coil embolization was performed through the jailed microcatheter when the aneurysm was located in the subarachnoid space with any of the anatomical risk factors of delayed aneurysm rupture: mass effect, saccular shape with a high aspect ratio >1.6 , and morphologic characteristics predisposed to an inertia-driven inflow.¹²⁾ Balloon inflation within the device using a TransForm Occlusion Balloon Catheter (Stryker Neurovascular) was usually performed. Finally, cone beam CT was performed to confirm the device opening and the vessel wall apposition.

During the procedure, the activated clotting time was extended to over twice the control value by administering a heparin bolus and controlled at 1-h intervals subsequently. After the procedure, the systemic heparinization was discontinued without the use of protamine sulfate. The effect of antiplatelet therapy was evaluated with light transmission aggregometry (LTA). The LTA values before starting dual antiplatelet therapy with adenosine diphosphate- and arachidonic acid-inducible platelet aggregation were the control. If the LTA values did not decrease to half of the control values, the VerifyNow P2Y12 Assay testing (Accumetrics, San Diego, CA, USA) was performed at the target reaction units of <550 for aspirin and <230 for clopidogrel. If the platelet inhibition did not achieve satisfactory levels, particularly suspected nonrespondent to clopidogrel, the patient received a loading dose of prasugrel of 20 mg immediately before the procedure. After the procedure, prasugrel was then continuously administered as an alternative drug for clopidogrel.

Results

Table 1 presents a summary of the patients and aneurysms. A total of 28 Japanese patients with 28 large or giant unruptured internal carotid artery (ICA) aneurysms underwent the SS embolization in Juntendo University Hospital. Nine patients (Cases 1-9) were enrolled in the clinical trial between August 2014 and April 2015. The remaining 19 patients (Cases 10-28) were treated after approval was secured between April 2021 and March 2022. Procedure failure occurred in 2 patients (Cases 8 and 27) due to the device navigation impossibility beyond the aneurysm neck due to the parent artery tortuosity. One patient (Case 8) underwent conservative therapy because of

Table 1 Summary of patient and aneurysm characteristics treated with the SS embolization device

Case No.	Age yrs	Gender	Aneurysm location	Aneurysm shape	Aneurysm maximum diameter	Aneurysm neck width	Symptom	Surpass size mm	Associated Coiling	Anatomical outcomes at 6 months	mRS just before procedure	mRS at 30 days	Adverse event
1	46	F	C4	Fusiform	24.0	20.0	Yes	4 × 50	No	CO	1	1	
2	65	F	C2	Saccular	16.5	6.7	Yes	4 × 40	No	RN	1	1	
3	78	F	C4	Fusiform	34.1	16.9	Yes	4 × 50	No	RA	1	1	
4	64	M	C4	Fusiform	18.5	18.0	No	4 × 50, 4 × 30	No	RN	2	2	
5	63	F	C2	Saccular	20.0	8.0	Yes	4 × 30	No	-	1	6	Posttreatment aneurysm rupture
6	57	F	C3	Saccular	10.5	6.5	No	5 × 25, 5 × 20	No	RN	0	0	
7	65	F	C3	Saccular	13.0	6.5	No	5 × 25	No	RA	0	0	
8	78	F	C4	Fusiform	30.0	18.7	Yes	-	-	-	-	-	Procedural failure
9	74	F	C3	Saccular	10.0	8.0	No	5 × 30	No	CO	0	0	Mild ischemic stroke
10	70	F	C4	Saccular	19.0	6.7	No	4 × 30	No	CO	0	0	
11	77	F	C3	Saccular	10.5	3.3	No	4 × 30	No	RN	0	0	
12	53	F	C4	Saccular	12.0	4.4	No	3 × 25	No	CO	0	0	
13	50	F	C4	Saccular	13.0	5.1	No	4 × 25	No	CO	0	0	
14	51	M	C4	Fusiform	22.5	11.4	No	4 × 40, 4 × 25	No	CO	0	0	
15	86	F	C4	Fusiform	27.2	11.4	Yes	4 × 40, 5 × 30	No	RA	1	1	
16	62	F	C2	Saccular	17.4	3.2	No	4 × 20	Yes	CO	0	0	
17	49	F	C2	Saccular	10.2	4.5	No	4.25 × 20	No	-	0	5	Device occlusion
18	80	F	C4	Fusiform	12.6	6.9	Yes	4 × 40	No	RA	1	1	
19	47	F	C2	Saccular	10.6	5.1	No	3 × 20	Yes	CO	0	0	
20	53	F	C2	Saccular	10.1	5.2	No	4 × 25	Yes	CO	0	0	
21	56	F	C4	Saccular	11.5	6.3	No	3 × 25	No	CO	0	0	
22	62	F	C1	Saccular	12.6	5.1	No	4 × 25	Yes	CO	0	0	
23	81	F	C1	Saccular	15.1	4.9	No	3 × 20	Yes	CO	0	0	
24	49	F	C4	Saccular	11.5	6.1	No	4 × 30	Yes	<6 months	0	0	
25	53	F	C1	Saccular	10.9	4.1	No	3 × 20	Yes	<6 months	0	0	
26	77	F	C5	Saccular	11.9	7.5	No	5 × 30	No	<6 months	0	0	
27	57	F	C3	Fusiform	24.8	12.3	Yes	-	-	-	-	-	Procedural failure
28	59	F	C2	Saccular	15.7	7.2	Yes	4 × 20	Yes	<6 months	1	1	

SS: Surpass Streamline, F: female, M: male, CO: complete occlusion, RN: residual neck, RA: residual aneurysm, mRS: modified Rankin scale

refusal to undergo further intervention, and another patient (Case 27) was successfully treated with FD therapy using the Pipeline Flex. As a result, 26 patients with 26 aneurysms were available for clinical and anatomical assessments. Patients' mean age was 62.6 years (range 46-86), and 24 patients (92.3%) were female. There were 20 saccular and 6 fusiform aneurysms. According to Fischer's classification of ICA segments, the aneurysms were located in C1 (3), C2 (7), C3 (4), C4 (11), and C5 (1).¹³ Overall, the mean aneurysm size and neck width were 15.4 mm and

7.7 mm, respectively. Mean aneurysm size and neck width of saccular aneurysms were 13.1 mm and 5.7 mm, respectively. Mean aneurysm size of fusiform aneurysms was 23.2 mm. The neck width of fusiform aneurysms, defined as the distance between the entry and exit of the aneurysm, was 14.1 mm. Seven patients were symptomatic due to the mass effect: optic nerve palsy (3), oculomotor nerve palsy (2), abducens nerve palsy (1), and trigeminal nerve palsy (1). The remaining 19 patients were asymptomatic. Twenty patients underwent a 6-month follow-up angiography to

evaluate the degree of aneurysm occlusion.

There were three device-related complications (11.5%). A 63-year-old female (Case 5) underwent the SS embolization for a symptomatic left ICA paraclinoid aneurysm. The procedure was successfully performed, and the patient was uneventfully discharged 4 days after the procedure without any worsening of visual disturbance. However, 10 days after the treatment, the patient was found dead (mRS 6) by a family member at her home. The medical examiner reported the cause of death as a subarachnoid hemorrhage. A 74-year-old female (Case 9) underwent the SS embolization for an asymptomatic right ICA cavernous aneurysm. The SS deployment was difficult but was eventually deployed. The patient experienced mild left hemiparesis just after the procedure. Posttreatment diffusion weighted images showed acute multiple ischemic lesions within the right cerebral hemisphere. The most likely causes were distal embolisms and mechanical vasospasm of a parent artery due to the repeated device deployment and a prolonged procedure. The patient underwent rehabilitation, and her clinical outcome at 30 days was mRS 0. A 49-year-old female (Case 17) underwent FD therapy using the SS for a left ICA paraclinoid aneurysm. The SS was successfully deployed, and the patient was discharged 4 days after the procedure without any new neurological deficits. On the following day, the patient was found by a family member lying unconscious at her home. Magnetic resonance imaging showed infarction in the territory of the left middle cerebral artery. Although the VerifyNow system (Accumetrics) testing just before the procedure showed an aspirin reaction unit of 441 and a PRU (P2Y12 purinergic receptor reaction unit) of 194 suggesting a satisfactory antiplatelet effect, the most likely cause of the ischemic stroke was an acute thrombus formation within the device. Her clinical outcome at 30 days and 6 months were both mRS 5. However, worsening of mRS occurred in 2 (7.7%) of 26 patients at 30 days after the procedure.

Other than for 8 patients (e.g., procedural failure in 2, delayed aneurysm rupture in 1, device occlusion in 1, and fewer than 6 months after the procedure in 4), 20 patients underwent a 6-month follow-up angiography to evaluate the degree of aneurysm occlusion. The anatomical outcomes showed CO in 12 (60%), RN in 4 (20%), and RA in 4 (20%). Favorable aneurysm occlusion consisting of either CO or RN was achieved in 16 patients (80.0%). There was no significant device stenosis. Sixteen patients with favorable aneurysm occlusion had a mean age of 60.5 years. Their mean aneurysm size and neck width were 14.5 mm and 7.5 mm, respectively. Four patients with RA had a mean age of 77.3 years. Their mean aneurysm size and neck width were 21.8 mm and 10.4 mm, respectively.

Abducens nerve palsy in one patient partially improved, but the remaining six patients showed no change in their cranial nerve dysfunction during the 6-month follow-up period.

Discussion

To the best of our knowledge, this study is the first case series of the SS embolization in a single center in the Japanese population. There were two large clinical studies of the SS embolization.^{8,14)} Wakhloo et al.⁸⁾ reported on their prospective multicenter study of 24 centers with 165 patients enrolled with 190 intracranial aneurysms including 85.5% with anterior circulation and 14.5% of posterior circulation locations. A 6-month follow-up angiography was available for 158 aneurysms. The follow-up angiography showed CO in 75% of the aneurysms. Particularly, in 98 ICA aneurysms, the 6-month follow-up angiography showed CO in 78.6%, RN in 4.1%, and RA in 17.3%. Meyers et al.¹⁴⁾ reported the Surpass Intracranial Aneurysm Embolization System Pivotal Trial to treat large and giant wide neck aneurysms (the SCENT) trial that was a multicenter study of 26 centers including 180 patients with 180 ICA aneurysms. The 1-year follow-up angiography showed CO in 66.1%. The 6-month follow-up angiography showed CO in 60.0% in the present study. There are two speculations for the insufficient rate of CO in the present series compared to those in the two previous studies. First, the mean aneurysm size and neck width in Wakhloo et al.'s study and the SCENT trial¹⁴⁾ were 12 mm and 5.1 mm and 10.4 mm and 6.0 mm, respectively. In the present series, the mean aneurysm size and neck width were 15.4 mm and 7.7 mm, respectively, which are remarkably larger than those in the two previous large studies. In the pipeline embolization device (PED) large studies of the PREMIER Study of small and medium intracranial aneurysms¹⁵⁾ and the PUFs trial of large and giant intracranial aneurysms,²⁾ the CO rates were 76.8% and 73.6%, respectively. Intracranial aneurysms with larger size and neck width tend to decrease the CO rate. Second, the mean age of the patients in the study of Wakhloo et al. and the SCENT trial¹⁴⁾ was 57.1 and 61 years, respectively. In the present series, patients' mean age was 62.7 years, which is older than those in the previous two large studies. Fujii et al. reported that elderly patients were a risk factor of poor aneurysm occlusion with the PED.⁵⁾ In the present series, nine patients 65 years or older had a low CO rate (33.3%). On the other hand, 11 patients younger than 65 years had a high CO rate (81.8%). The risk factor of incomplete aneurysm occlusion after the SS embolization for elderly patients was the same as that for the PED.

The study of Wakhloo et al.⁸⁾ showed that ischemic stroke at 30 days, subarachnoid hemorrhage (SAH) at 7 days, and intraparenchymal hemorrhage at 7 days were encountered in 3.7%, 2.5%, and 2.5%, respectively. The SCENT trial showed that 8.3% of 1-year follow-up patients suffered either major ipsilateral stroke or neurological death.¹⁴⁾ In the present series, SAH due to delayed aneurysm rupture at 4 days (Case 5) and ischemic strokes just after the procedure (Case 9) and at 30 days (Case 17) were encoun-

tered. Because Case 9 fully recovered before 30 days, our series showed 7.7% risk of either major ipsilateral stroke or neurological death at 30 days.

Although an additional coil embolization is thought to prevent delayed aneurysm rupture,^{16,17} Case 5 did not undergo the additional coil embolization because of the clinical trial regulation. Device deployment in Case 9 was difficult and required a prolonged procedure because the Catalyst 5 intermediate catheter and the AXS Offset delivery system (Stryker Neurovascular) were not available in the clinical trial. A complication occurred in only one patient (Case 17) after the approval (3.6%). The study of Wakhloo et al. showed new or worsening cranial nerve dysfunction in 2.7%.⁸ In the present study, only one symptomatic aneurysm showed improvement, while the remaining six were unchanged.

Procedural failure occurred in two patients in the present series. These patients had very tortuous vessel anatomy. The SS is a first-generation device. The significant drawback is its stiffness, which would likely present the risks of the impossibility to navigate the device into an adequate position, mechanical vascular spasms, and prolonged procedural time.

Regarding the technical considerations, the Catalyst 5 intermediate catheter should always pass across the aneurysm neck to the distal vessel. If that is not done correctly, the procedure may fail due to the inability of navigating the device to an appropriate position. Furthermore, there is a high risk of improper device navigation into the aneurysm sac in the treatment of wide-necked aneurysms located on the outer side of the parent artery curvature. When dealing with long lengths of PED and FRED devices, twisting tends to occur during deployment, particularly in the treatment of large fusiform and very wide neck aneurysms. Because the SS has a higher twisting resistance, due to the strong radial force, the use of SS could be recommended in high risk situations in which twisting often occurs during FD therapy. The selection of FD devices was decided by the principal physician (H.O.), with reference to the vascular anatomy, particularly in cases with severe tortuosity of the access rout and the parent artery. Therefore, 13 ICA large aneurysms were treated with PED, and no ICA large aneurysms were treated with FRED during the study except for clinical trial period.

In some other countries, the second-generation Surpass (the Surpass Evolve) (Stryker) is clinically available and has proven excellent technical success and procedural safety.¹⁸⁻²¹ An advantage of the SS is the possibility to treat aneurysms with a small number of devices. The numbers of SSs used in the study of Wakhloo et al. and the SCENT trial were 1.05 per aneurysm and 1.1 per patient, respectively.^{8,14} In the present series, the mean number of devices used was 1.3 per aneurysm. In the PUFs trial, 98.1% patients received more than one PED with a median average of three PEDs per aneurysm.² The smaller number of the



Fig. 1A 3D-DSA (digital subtraction angiography) translucency image of the right ICA showing an incidentally detected ICA cavernous fusiform aneurysm enlarged in a follow-up control (Case 14).

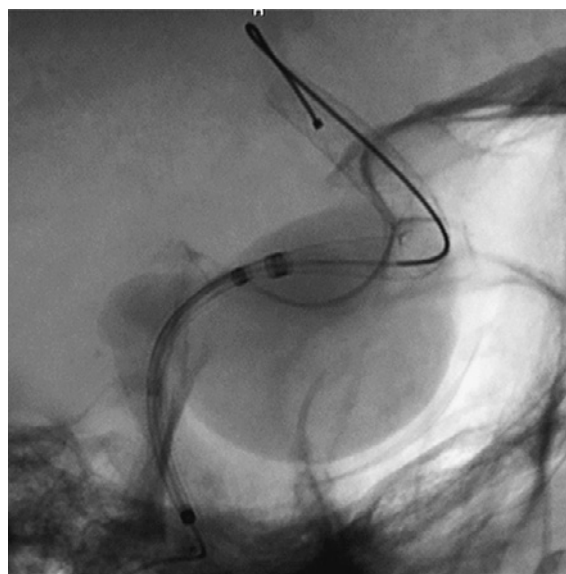


Fig. 1B Native image showing SS partially opened with support of 0.014-inch microguidewire coaxially placed through the center of the delivery system.

SSs used in treating aneurysms reduced the risk of telescoping. Furthermore, the OTW (over-the-wire delivery) system makes the SS a stable device during the deployment in the absence of an arterial wall situation such as that in the case of fusiform aneurysms (Fig. 1). Feigen et al.²² reported a retrospective matched study between the PED and the SS. In their study, 96 aneurysms were treated with the PED and 45 aneurysms were treated with the SS

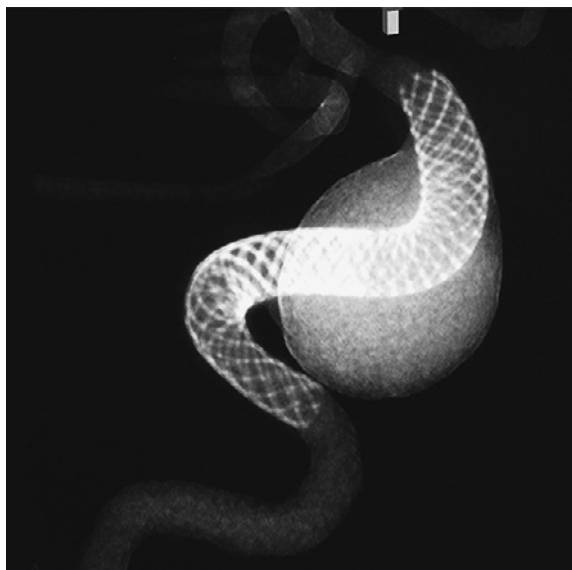


Fig. 1C Dyna-CT shows satisfactory coverage of the aneurysm with two telescoped SSs (4×40 mm and 4×20 mm).



Fig. 1D Six-month follow-up angiography showing CO of an aneurysm without device stenosis.

for a total of 126 patients.²²⁾ Because most intracranial aneurysms in the SS and PED cohorts were small size, those results would not necessarily apply to large or giant aneurysms. The authors advocated that the SS required frequent adjuvant balloon use for adequate apposition of the device to the parent vessel wall after deployment. In the present series, all patients underwent in-stent balloon inflation using the TransForm (Stryker) balloon catheters to achieve complete device opening and adequate vessel wall apposition.

The SS is a feasible FD for large and giant ICA aneu-

rysms with low procedural-related complications and high rates of occlusions.

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Conflicts of Interest Disclosure

Hidegori Oishi receives donations in the form of research funds as an endowed chair of his department from Terumo Co., Ltd., Stryker Co., Ltd., Medtronic Co., Ltd., and Kaneka Co., Ltd., consulting fees of over one million yen yearly from Medtronic Co., Ltd, Stryker Co., Ltd, Kaneka Co., Ltd., and Asahi Intec Co., Ltd., and a research grant of over one million yen yearly from Medikit Co., Ltd. The other authors declare no conflicts of interest.

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