

# Embolization of Intracranial Aneurysms with the HydroSoft and HydroFrame Coils: A Single-Center Experience

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## ●Abstract●

**Objectives:** The HydroSoft and HydroFrame coils are a new generation of coils designed to further improve the safety and durability of aneurysm coiling using hydrogel technology. The authors report their experience using the HydroSoft and HydroFrame coils for the treatment of intracranial aneurysms.

**Methods:** Immediate and follow-up angiographic results, procedure-related complications, and retreatments were retrospectively analyzed for 106 intracranial saccular aneurysms in 103 patients treated with the HydroSoft and HydroFrame coils during a 50-month period.

**Results:** The incidence of thromboembolic complications was 5.7%. Procedure-related morbidity and mortality rates were each 0.9%. None of the patients with unruptured aneurysms developed hydrocephalus. Immediate post-procedure angiograms showed complete aneurysm occlusion in 34.9% of cases, neck remnant in 36.8%, and incomplete occlusion in 28.3%. Angiographic follow-up was obtained in 51.9% (55 of 106 aneurysms; average, 16 months; range, 6–45 months). In these 55 aneurysms, the rate of immediate complete occlusion was 27.3% after treatment, which increased to 50.9% on follow-up, and the overall recanalization rate was 14.5%. No recanalization was observed in the 8 aneurysms treated with stent-assisted coiling in combination with HydroSoft and HydroFrame coil placement.

**Conclusions:** The overall safety profile of the HydroSoft and HydroFrame coils appears to be acceptable. Preliminary midterm observation suggests that these new-generation hydrogel coils will improve the durability of angiographic occlusion, when compared with immediate post-embolization results, and can reduce the rate of aneurysm recanalization.

## ●Key Words●

coiling, endovascular treatment, hydrogel coil, intracranial aneurysm

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## Introduction

Endovascular coil embolization of intracranial aneurysms has become a widely accepted treatment alternative to surgical clipping<sup>10,11</sup>. However, aneurysm recanalization remains the major limitation of endovascular treatment compared with surgical clipping<sup>12,16</sup>. This limitation has led to the development of second-generation coils coated with biodegradable polymers (such as polyglycolic acid [PGA] or polyglycolic combined with polylactic acid [PGLA]) and hydrogels. In our clinical experience, treatment of human aneurysms

with PGLA-coated coils has yielded disappointing results, with more prevalent recanalization, leading us and many others to stop using these coils<sup>13</sup>. The HydroCoil (MicroVention TERUMO, Tustin, CA, USA) was developed to improve volumetric filling with an expandable hydrogel that should fill more of the aneurysm lumen than bare platinum coils<sup>8</sup>. The HydroSoft and HydroFrame coils are new generation coils designed to further improve the safety and durability of aneurysm coiling with hydrogel technology. Unlike HydroCoils, which are platinum coils coated with hydrogel, these coils are platinum coils with a hydrogel

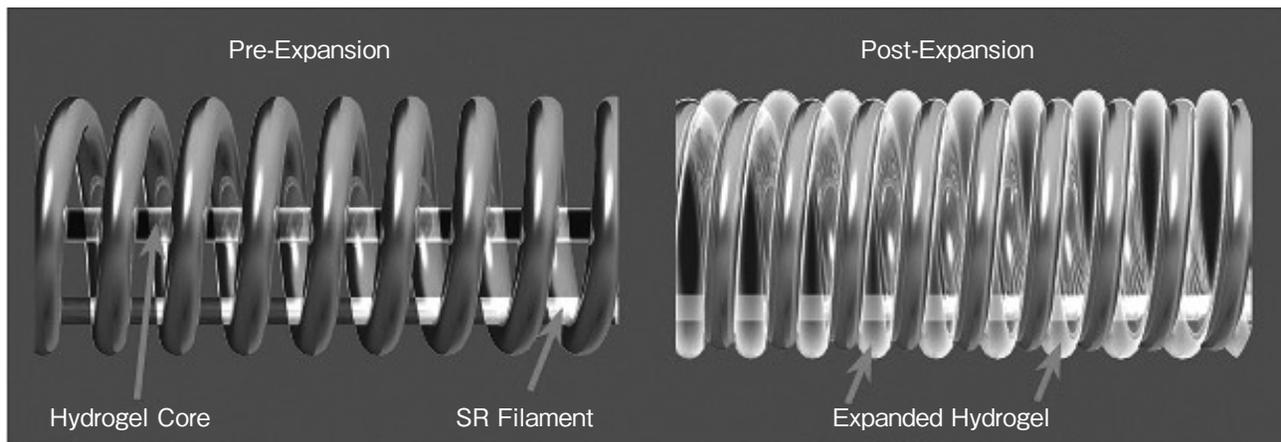


Fig. 1

The HydroSoft and HydroFrame coils are platinum coils with an inner hydrogel core and a stretch-resistant filament.

core (Fig. 1). The HydroSoft coil is a soft helical coil, and can be used as a finishing coil. The HydroFrame coil has a 3D spherical structure with various loop sizes and lengths suitable for framing. We began to use HydroSoft coils in September 2007 and HydroFrame coils in February 2010 in our institution. In the present study, our single center experience is reported including the midterm follow-up results of using HydroSoft and HydroFrame coils.

## Methods and Materials

Between September 2007 and October 2011, a total of 106 consecutive aneurysms in 103 patients were treated either totally or partially using HydroSoft and HydroFrame coils at our institution. Fusiform and dissecting aneurysms, and those previously treated with HydroCoils or by parent artery occlusion were excluded from the study. Endosaccular coiling of an aneurysm was performed when it was considered as the best treatment option based on discussions among members of the endovascular surgery and cerebrovascular surgery. The use of HydroSoft and HydroFrame coils was decided arbitrarily by the operator without strict criteria. Other coils including HydroCoils were used in addition to the HydroSoft and HydroFrame coils based on operator preference. Aneurysms were divided into 4 categories<sup>1,12</sup>: small narrow-necked (S/S; <10 mm, neck <4 mm), small wide-necked (S/W; <10 mm, neck  $\geq$  4 mm), large (L;  $\geq$

10–25 mm), and giant (G;  $\geq$  25 mm) aneurysms.

### 1. Endovascular Treatment

The technique for endovascular coil treatment has been previously described<sup>6</sup>. All procedures were performed using a biplane angiography system (Siemens, Erlangen, Germany) under general anesthesia and with systemic anticoagulation. Dual antiplatelet premedication (75 mg of clopidogrel and 81 mg of aspirin 5 days prior to treatment) was used in those cases where a stent was thought to be needed. In all patients, inhibition of platelet activity was checked. Typically, HydroFrame coils were used as framing and filling coils and HydroSoft coils were used as filling and finishing coils. In 22 aneurysms (20.8%), chiefly large aneurysms (13 of 22), HydroCoils were used as filling coils in addition to the HydroSoft and HydroFrame coils. The balloon-remodeling technique was used in 10 (9.4%) procedures. Stents (Enterprise VRD: Codman Neuroendovascular, Johnson & Johnson, Miami, FL, USA) were used to support coiling in 14 (13.2%) procedures. The double-microcatheter technique was used in 2 (1.9%) procedures.

### 2. Complications

Adverse events of the endovascular treatment were recorded as procedure-related complications along with its clinical consequences. These included thromboembolic stroke, hemorrhage during the procedure, delayed hemorrhage, and development of hydrocephalus in unruptured aneurysms. Procedure-related neurological

morbidities were defined as minor if temporary and major if permanent.

### 3. Angiographic Evaluation

Angiographic results were recorded immediately after treatment and on the last follow-up visit. Multiple projections with selective contrast injections were reviewed for assessment of angiographic occlusion grade. We used the Raymond-Roy classification of angiographic results<sup>17</sup>: class 1, complete occlusion, defined as no contrast filling within the aneurysm dome and neck; class 2, persistence of any portion of the original defect of the arterial wall as seen on any single projection but without opacification of the aneurysm sac; and class 3, aneurysm sac opacification. Although for HydroSoft and HydroFrame coils (which are designed to increase volumetric filling), assessment of the packing density in the aneurysm sac is reasonable, the calculation of packing density may be incorrect because it relies on certain assumptions about the physical dimensions of aneurysms and the behavior of the hydrogel. Therefore, analyses on the aneurysm packing density were omitted from the study.

### 4. Follow-up Strategy and Evaluation

For all patients with treated aneurysms, follow-up skull x-rays were requested at 3 months. If the 3-month skull x-ray showed evidence of coil compaction, an angiogram was recommended immediately. Otherwise, a 6-month follow-up angiogram was recommended for ruptured aneurysm patients, and a 1-year follow-up angiogram for unruptured aneurysm patients. Further angiograms were recommended at the 3-year and 5-year follow-up visits.

To better compare recanalization results with those of Guglielmi detachable coil (GDC; bare platinum coil) treatment, we used the same definition of recanalization as that used in the 11-year University of California at Los Angeles (UCLA) study<sup>12</sup>: recanalization was defined as >10% increase in contrast filling of the aneurysm; a <10% increase in filling was defined as unchanged.

## Results

### 1. Patient Population

Table 1 summarizes patient and aneurysm

Table 1 Patient and aneurysm characteristics

No. of patients	103
Sex (Female : Male)	82 : 21
Age (Mean ; Range)	56.0 ; 27-79
No. of treated aneurysms	106
Ruptured aneurysms	44 (41.5%)
Hunt and Hess grade I	22 (20.8%)
Hunt and Hess grade II	6 (5.7%)
Hunt and Hess grade III	8 (7.5%)
Hunt and Hess grade IV	8 (7.5%)
Unruptured aneurysms	62 (58.5%)
Incidental	48 (45.3%)
Mass effect	7 (6.6%)
Others	3 (2.8%)
Pretreated aneurysms	4 (3.8%)
Aneurysm location	
Internal carotid artery	57 (53.8%)
Anterior cerebral artery	25 (23.6%)
Middle cerebral artery	9 (8.5%)
Posterior circulation	15 (14.2%)
Aneurysm size	
S (<10 mm) / S(neck<4 mm)	67 (63.2%)
S (<10 mm) / W(neck≥4 mm)	19 (17.9%)
L (10 mm<25 mm)	20 (18.9%)
% hydrogel coils in length (Mean; Range)	52.9% ; 6.8%-100%
Adjunctive use	
HydroCoil	22 (20.8%)
Balloon	10 (9.4%)
Stent	14 (13.2%)
Double microcatheter	2 (1.9%)

characteristics. There were 22 males and 81 females. The mean age was 56 years. Sixty-two aneurysms were unruptured or in the chronic phase of hemorrhage, and 44 aneurysms were in the acute phase. Four aneurysms were treated previously: 3 by coiling and 1 by clipping. Aneurysms were located in the anterior circulation in 91 cases and posterior circulation in 15 cases. S/S, S/W, and L aneurysms occurred in 63.2%, 17.9%, and 18.9% of cases, respectively. There was no G aneurysm in this series.

On average, 52.9% (range, 6.8-100%) of the total length of deployed coils within the treated aneurysms was hydrogel coils (HydroSoft and HydroFrame coils and HydroCoils). In 20.8% of aneurysms (22 of 106), HydroCoils were used in addition to the HydroSoft and HydroFrame coils. Ninety-nine aneurysms (93.4%) were treated using HydroSoft coils, which were used as finishing coils in 50 aneurysms (50.5%). Thirty-three

Table 2 Procedure-related complications

	No.	Morbidity	Mortality
Aneurysm perforation	0	0	0
Thromboembolism	6	1	0
Early rehemorrhage	1	0	1
Total	6* (5.7%)	1 (0.9%)	1 (0.9%)

\*Fatal rehemorrhage occurred immediately after intraarterial ReoPro injection due to thromboembolic complication in one patient

aneurysms (31.1%) were treated using HydroFrame coils, which were used as framing or first coils in 28 aneurysms (84.8%).

## 2. Clinical Outcome

Table 2 summarizes procedure-related complications. No aneurysm perforation occurred during the procedure, but thrombus formation occurred during 6 procedures (5.7%), causing 1 permanent neurological deficit (0.9% morbidity) and 1 fatal rehemorrhage after thrombolysis (0.9% mortality).

In a 39-year-old woman who presented with subarachnoid hemorrhage, a left internal carotid artery bifurcation aneurysm was embolized using HydroSoft and HydroFrame coils. A post-procedure angiogram demonstrated thrombus formation at the site of a small coil loop protrusion in the left M1 segment. After intra-arterial abciximab (ReoPro) injection, there was complete resolution of the thrombus. Nevertheless, the patient had a minor stroke due to distal embolism, but she recovered to walk with a cane.

In a 48-year-old woman, a ruptured small anterior communicating artery aneurysm was completely occluded using two GDCs and a HydroSoft coil. However, the procedure was complicated by thrombus formation and occlusion of the left anterior cerebral artery. This was treated with intra-arterial Reopro injection that resulted in partial recanalization. However, CT scan performed 3 hours later demonstrated a subarachnoid hemorrhage and enlargement of the left frontal lobe hematoma. The patient died within one month of the treatment.

The remaining 4 patients with thrombus formation were treated with intraarterial ReoPro injection and recovered without neurological sequelae. In one of them, deployment of a stent across the neck of the aneurysm

was also needed to prevent recurrent thrombus formation. No delayed rehemorrhage was observed during the follow-up period. None of our patients with an unruptured aneurysm developed hydrocephalus.

## 3. Immediate Angiographic Outcome

The immediate post-procedure angiogram demonstrated complete aneurysm occlusion (class 1) in 34.9% (37 of 106 cases), residual neck (class 2) in 36.8% (39 of 106), and residual sac (class 3) in 28.3% (30 of 106). Table 3 summarizes angiographic results for S/S, S/W, and L aneurysms. Total or subtotal occlusion of the aneurysm (class 1 or 2) was obtained in 79.1% (53 of 67) of S/S aneurysms, in contrast to 59.0% (23/39) of S/W aneurysms and L aneurysms (S/W and L).

## 4. Follow-up Angiographic Outcome

Follow-up angiographic results were obtained in 53 patients with 55 aneurysms treated with HydroSoft and HydroFrame coils (51.9%) at a mean of 16 months (range, 6-45 months). Table 3 shows the sizes and initial occlusion classes of these angiographically followed aneurysms. Table 4 shows the change in angiographic occlusion class. In all the 55 aneurysms with follow-up data, comparison of the occlusion class immediately after treatment with that at the last follow-up demonstrated improvement of the aneurysms in 41.8% (23 of 55 cases), no change in 43.6% (24 of 55 cases), and worsening in 14.5% (8 of 55 cases). The rate of class 1 aneurysms increased from 27.3% immediately after treatment to 50.9% on the last follow-up. Improvement in angiographic occlusion class at the last follow-up was seen in 16 (59.3%) of 27 aneurysms treated with  $\geq 50\%$  hydrogel coils in length but only 7 (25.0%) of 28 aneurysms treated with  $<50\%$  hydrogel coils in length.

Eight aneurysms were treated with stent-assisted

Table 3 Immediate angiographic result according to aneurysm size

All (n=106)				
	S/S	S/W	L	Total
Class 1	27 (40.3%)	6 (31.6%)	4 (20.0%)	37 (34.9%)
Class 2	26 (38.8%)	5 (26.3%)	8 (40.0%)	39 (36.8%)
Class 3	14 (20.9%)	8 (42.1%)	8 (40.0%)	30 (28.3%)
Total	67	19	20	106
With follow-up (n=55)				
	S/S	S/W	L	Total
Class 1	12 (33.3%)	2 (20.0%)	1 (11.1%)	15 (27.3%)
Class 2	17 (47.2%)	3 (30.0%)	4 (44.4%)	24 (43.6%)
Class 3	7 (19.4%)	5 (50.0%)	4 (44.4%)	16 (29.1%)
Total	36	10	9	55

Table 4 Angiographic change in occlusion class at immediately post-procedure and at the last follow-up

	Immediate angiogram			Follow-up angiogram			Change in occlusion class			Recanalization	Retreatment
	Class1	Class2	Class3	Class1	Class2	Class3	Better	Same	Worse		
Overall (n=55)	15 (27.3%)	24 (43.6%)	16 (29.1%)	28 (50.9%)	20 (36.4%)	7 (12.7%)	23 (41.8%)	24 (43.6%)	8 (14.5%)	8 (14.5%)	5 (9.1%)
≥50% hydrogel coils (n=27)	6 (22.2%)	12 (44.4%)	9 (33.3%)	15 (55.6%)	11 (40.7%)	1 (3.7%)	16 (59.3%)	7 (25.9%)	4 (14.8%)	2 (7.4%)	0 (0.0%)
<50% hydrogel coils (n=28)	9 (32.1%)	12 (42.9%)	7 (25.0%)	13 (46.4%)	9 (32.1%)	6 (21.4%)	7 (25.0%)	17 (60.7%)	4 (14.3%)	6 (21.4%)	5 (17.9%)
With stent (n=8)	1 (12.5%)	2 (25.0%)	5 (62.5%)	5 (62.5%)	3 (37.5%)	0 (0.0%)	7 (87.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

coiling in combination with placement of the HydroSoft and HydroFrame coils. Five of these aneurysms were S/W, two were L, and one was S/S. The stent deployed in the S/S aneurysm was for rescue from thrombus formation. The average percentage of hydrogel coils used in these 8 aneurysms was relatively high compared to the 47 aneurysms without stents (70.9% versus 50.3%). Although the immediate angiography showed class 1 in 1, class 2 in 2, and class 3 in 5 of the 8 aneurysms, follow-up angiography demonstrated class 1 in 5 and class 2 in 3 aneurysms. No class 3 aneurysm was observed on follow-up. Even if the coils appeared to be loosely packed immediately after treatment, neither coil compaction nor contrast filling was observed in that compartment on follow-up (Fig. 2).

Delayed asymptomatic parent artery occlusion occurred in 3 cases. Two aneurysms located in the internal carotid artery bifurcation resulted in occlusion of the A1 segment of the anterior cerebral artery after embolization. In one of these patients, delayed coil herniation into the parent artery was found on the follow-

up angiogram (Fig. 3). In the other patient, although the cause was unclear, bilateral anterior cerebral arteries were originally supplied predominantly from the contralateral internal carotid artery. In the third patient with a left paraophthalmic artery aneurysm treated with stent-assisted coiling, the 6-month follow-up angiogram showed complete occlusion of the aneurysm with patency of the internal carotid artery and ophthalmic artery, but the 2-year follow-up angiogram showed occlusion of the left internal carotid artery at the cavernous segment. This occlusion may be stent related because the proximal end of the stent was in the cavernous segment. The coils including the HydroSoft and HydroFrame coils were thought to be unrelated to the occlusion because the distal internal carotid artery was reconstituted through the anastomosis between the external carotid artery and the ophthalmic artery originating near the neck of the aneurysm.

## 5. Aneurysm Recanalization

In 55 angiographically followed aneurysms, the overall recanalization rate was 14.5% (8 of 55), with rates of

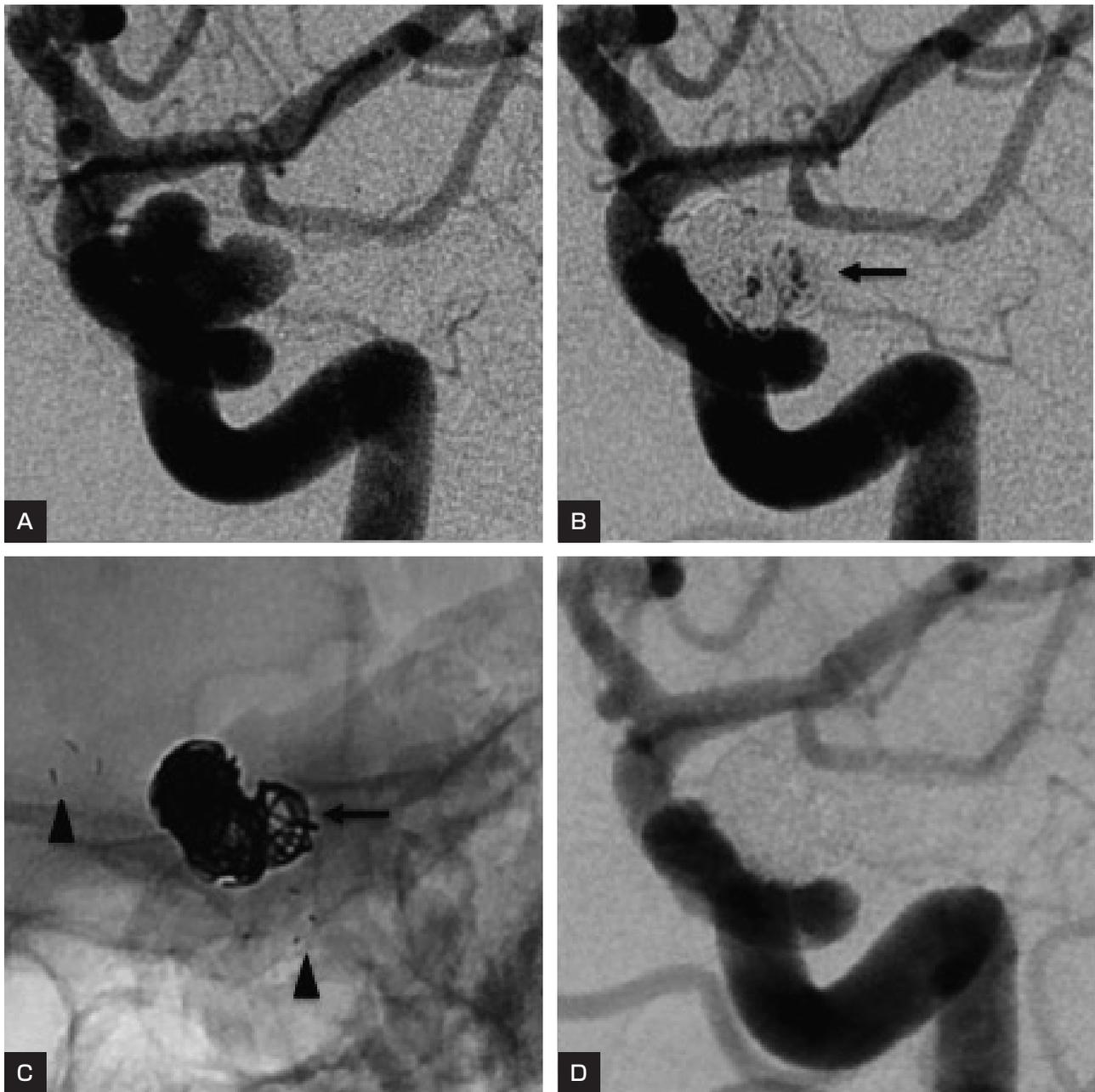


Fig. 2

- A : 65-year-old woman with an unruptured left paraclinoid internal carotid artery treated with stent-assisted coiling. Pre-embolization angiogram demonstrates a bilobed wide-necked aneurysm in the left paraclinoid internal carotid artery.
- B : After stent-assisted coiling using 2 HydroFrame coils and 3 HydroSoft coils, an angiogram shows residual filling into the proximal sac (arrow).
- C : There is a loosely packed compartment in the proximal sac (arrow). The stent is placed across the neck of the aneurysm (arrowheads).
- D : A 12-month follow-up angiogram shows complete aneurysm occlusion.

13.9% (5 of 36) for S/S, 10% (1 of 10) for S/W, and 22.2% (2 of 9) for L aneurysms, respectively. The retreatment of the aneurysm due to recanalization was performed in 5 cases (9.1%): 3 by surgical clipping, 1 by coiling, and 1 by

stent-assisted coiling. Table 5 shows characteristics of the 8 recurrent aneurysms. The average percentage length filled by hydrogel coils in the recanalized aneurysms was relatively low compared to the



**Fig. 3**

- A :** 70-year-old woman with an unruptured left internal carotid artery bifurcation aneurysm treated with balloon-assisted coiling. A. Pre-embolization angiogram demonstrates a small-size aneurysm at the bifurcation of the left internal carotid artery.
- B :** A 3-D rotational angiogram demonstrates an aneurysm with a few lobules and relatively wide neck.
- C :** After coil embolization with 1 HydroFrame coil, 1 HydroSoft coil, and 3 bare platinum coils, an angiogram shows successful subtotal occlusion of the aneurysm (Class 2).
- D :** There is a minimal protrusion of the second coil tail into the M1 segment without clot formation or flow restriction (arrow).
- E :** A 12-month follow-up angiogram shows occlusion of the A1 segment (arrow).
- F :** There is a significant coil protrusion into the A1 segment (arrow).

Table 5 Characteristics of 8 recurrent aneurysms

No.	Age/Sex	Presentation	Location	Type	Class	Hydrogel coils (%)	Retreatment
1	51/F	Incidental	ICA bifurcation	S/S	2 to 3	51.4	–
2	54/M	SAH grade 1	ACoM	S/S	2 to 3	12.1	clipping
3	43/F	Incidental	ICA bifurcation	S/S	1 to 2	76.1	–
4	61/F	3rd nerve palsy	PCoM	S/S	3 to 3	27.3	stent-assisted coiling
5	45/M	SAH grade 2	Basilar tip	L	3 to 3	6.8	coiling
6	65/F	Incidental	Pericallosal	L	3 to 3	40.3	clipping
7	27/F	SAH grade 1	ICA bifurcation	S/S	2 to 3	42.9	clipping
8	60/F	SAH grade 1	Pericallosal	S/W	2 to 3	49.4	–

aneurysms that did not recanalize (38.3% vs. 55.9%). The recanalization rate was 7.4% in the group of 27 aneurysms containing  $\geq 50\%$  hydrogel coils. In contrast, it was 21.4% in the group of 28 aneurysms containing  $<50\%$  hydrogel coils. No aneurysm recanalization was observed in the cases treated with stent-assisted coiling in combination with HydroSoft and HydroFrame coil placement.

## Discussion

Many clinical studies have demonstrated the efficacy of the HydroCoil embolization system in reducing aneurysm recurrence<sup>1,3,4,14</sup>. Recently, the HydroCoil endovascular aneurysm occlusion and packing study (HELPS) trial, a multicenter randomized controlled study comparing HydroCoils and bare platinum coils, demonstrated fewer major angiographic recurrences in the HydroCoil group than in the control group (24% vs. 33%)<sup>20</sup>. However, the HydroCoil system has some technical limitations. The HydroCoil is a platinum coil coated with synthetic polymeric hydrogel, is slightly stiffer than a bare platinum coil, and requires prehydration for softening. The positioning time of this coil is limited to 5 minutes because the coil progressively expands over 20 minutes. The HydroSoft and HydroFrame coils were developed to overcome these shortcomings. These coils are platinum coils with an inner hydrogel core and a stretch resistant filament (Fig. 1). They are softer, contain less hydrogel, and swell more slowly (up to 1.7 times the original volume). Consequently, repositioning and retrieval of these coils do not have time restrictions.

Our data suggest that the overall safety profile of the HydroSoft and HydroFrame is acceptable. Procedure-

related morbidity and mortality were each 0.9% (1 of 106). There was no incidence of aneurysm perforation during the procedure. The incidence of thromboembolic complications was 5.7% (6 of 106), which is slightly higher than that of bare platinum coils but lower than that of second-generation coils. The thromboembolic event rate associated with bare platinum coil use in aneurysms is reported to be 2.4–5.2%<sup>5,12</sup>. In a recent systematic review of the literature regarding second-generation coils, the rate of thromboembolic events was 10.6%, 9.8%, and 6.9%, respectively, in patients treated with PGLA-, PGA-, and hydrogel-coated coils<sup>19</sup>. In our previous HydroCoil series, the incidence of thromboembolic complications was 8.7%, and it was considered that this slightly higher incidence might be due to the larger expanded size of the HydroCoils rather than to thrombogenicity of the hydrogel material<sup>1</sup>. Less expansion of the HydroSoft and HydroFrame coils because they contain less hydrogel may account for the decreased incidence of thromboembolic complication.

Delayed hydrocephalus is a potential complication related to the HydroCoil. In the HELPS trial, the risk of hydrocephalus was 4.5% in the HydroCoil group and 0.9% in the control group, although the difference was not statistically significant<sup>20</sup>. The cause of HydroCoil-associated hydrocephalus is unknown but suspected to be an inflammatory reaction induced by trapping of a thrombus within the aneurysmal dome but not by the hydrogel itself. Moreover, HELPS indicated that the risk of hydrocephalus could be more related to mechanical effects associated with large basilar tip aneurysms than any other factors<sup>20</sup>. None of our patients with unruptured

aneurysms treated using HydroSoft and HydroFrame coils developed hydrocephalus. This difference from the HydroCoils treatment may be at least partially explained by less expansion of the HydroSoft and HydroFrame coils compared to the HydroCoils and consequently explained by less mechanical effects.

In the present study, based on angiographic follow-up in 51.9% of cases (average, 16 months), the overall recanalization rate of aneurysms treated with HydroSoft and HydroFrame coils was 14.5% (8 of 55), with recanalization rates of 13.9%, 10.0%, and 22.2% for S/S, S/W, and L aneurysms, respectively. In the 11-year UCLA experience, angiographic follow-up revealed an overall recanalization rate of 20.9% of the GDC-treated aneurysms (5.1% for S/S, 20% for S/W, 35.3% for L, and 59.1% for G aneurysms)<sup>12</sup>. Raymond et al. reported that major recurrences after endovascular GDC treatment were found in 20.7% of cases, and the most important factors associated with recurrences were treatment after rupture, aneurysm size >10 mm, and incomplete occlusion<sup>16</sup>. In the systematic review of second-generation coils, the rates of incomplete occlusion on follow-up were 25% for PGLA-coated coils and 17% for hydrogel-coated coils<sup>19</sup>. Our previous HydroCoil study demonstrated an overall recanalization rate of 20.8%<sup>1</sup>. Although its statistical significance is unknown, our result was slightly better than findings with bare platinum coils, PGLA-coated coils, and HydroCoils. In our series, aneurysm size had less of an effect on recanalization rate than it did in previous reports. The better result with S/W aneurysms may be due to the high rate of stent-assisted coiling (5 of 10).

At least two articles have addressed the efficacy of HydroSoft coils and include follow-up results. In the series of Guo et al, initial angiographic results showed complete occlusion in 63% of the aneurysms treated with HydroSoft coils compared with 51% of aneurysms treated with HydroCoils<sup>7</sup>. The recanalization rate was 2.3% in the HydroSoft group and 10% in the HydroCoil group. A recent prospective multicenter observational study of patients treated with HydroSoft coils for 127 intracranial small size aneurysms (<10 mm)<sup>15</sup> showed complete

aneurysm occlusion in 69% of cases on immediate angiography. Although 77% of the follow-up data were obtained from magnetic resonance angiograms (not conventional angiograms), the overall recurrence rate was 3% at a mean of 11 months follow-up.

The HydroCoil endovascular aneurysm occlusion (HEAL) study of cases drawn from a prospective multicenter registry demonstrated a reduced recurrence rate when greater than 75% of the aneurysm length was filled with HydroCoils and when the final coil was a HydroCoil<sup>4</sup>. O'Hare et al. found significantly greater occlusion rates on follow-up when >70% of the total coil length used in an aneurysm is HydroCoils than when <20% of that length is HydroCoils<sup>14</sup>. In the present study, the recanalization rate was lower in the group of 27 aneurysms with hydrogel coils filling  $\geq 50\%$  of the total coil length used in an aneurysm than in the group of 28 aneurysms with hydrogel coils filling <50% of that length (7.4% vs. 21.4%). These results suggest that, when a large proportion of hydrogel coils are used, the recanalization rate will decrease, similar to our previous experience with first-generation HydroCoils<sup>1</sup>.

All 8 patients treated with stent-assisted coiling in combination with placement of HydroSoft and HydroFrame coils demonstrated either complete occlusion or improved occlusion class on follow-up. This may be due to benefits attributable to both stent and hydrogel coil placement. It can be speculated that this combination provides a more robust scaffold at the neck, fostering neointima formation and endothelialization. Brisman et al. reported the technical feasibility of stent-assisted coiling in combination with HydroCoil placement in 7 patients with wide-necked aneurysms<sup>2</sup>. However, the HydroCoils were used as filling coils, and the bare platinum coils were used in the final stage of coiling to prevent contact between the hydrogel and the stent. The HydroSoft and HydroFrame coils are used even in the final stage of coil packing because they are more flexible and slower to expand. Therefore, these coils may be used to greater benefit at the neck of the aneurysm.

In an experimental study using canine bifurcation aneurysms as a model, HydroCoils showed less coil

compaction and thicker neointima formation compared with bare platinum coils<sup>21</sup>). Tsumoto et al. showed the feasibility of the HydroSoft coil as a finishing coil in the same model<sup>18</sup>). No significant difference in aneurysm histology was found between the HydroSoft and HydroCoil groups except for the thicker neointima in the HydroCoil group. Endothelialization and neointima formation at the neck surface was complete in most aneurysms. The study by Killer et al. (comparing angiographic and histological findings in rabbit bifurcation aneurysms embolized with bare platinum coils, HydroCoils, HydroSoft coils, and biodegradable polymer coils) demonstrated increased angiographical occlusion at follow-up in the HydroCoil and HydroSoft groups<sup>9</sup>). The average aneurysm volume was significantly larger in the HydroCoil group than in the other groups including the HydroSoft group. The expansion of the hydrogel in the HydroCoil and HydroSoft groups achieved durable embolic occlusion without increasing thrombus organization. Thus, the HydroSoft and HydroFrame coils seem to provide occlusion durability without increasing aneurysm volume.

Limitations of the study in addition to its nonrandom uncontrolled retrospective method include the small number of treated aneurysms, the relatively low percentage of patients with angiographic follow-up, and the short duration of angiographic follow-up. As a tertiary center with a larger number of referrals from remote sources, return visits for clinical and angiographic follow-up could not be uniformly achieved.

## Conclusions

The overall safety profile of the HydroSoft and HydroFrame coils appears to be acceptable. Preliminary midterm follow-up results suggest that these new-generation hydrogel coils can reduce the rate of aneurysm recanalization. Because of the properties of less stiffness and slower expansion, the HydroSoft and HydroFrame coils can be used near the neck of aneurysms. Therefore, these coils in the neck are expected to provide a scaffold that fosters neointima formation and results in less aneurysm recanalization.

Especially, these coils seem to be useful for packing in stent-assisted coiling. Longer and more complete follow-up is warranted to validate the durability of the HydroSoft and HydroFrame coils.

## Disclosure

Alejandro Berenstein has consulting interests in MicroVention TERUMO. All remaining authors have declared no conflicts of interest.

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