

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

An intracranial aneurysm is a bulge in a blood vessel in the brain, caused by a weakness in the blood vessel wall. In this procedure, a wire-mesh device is inserted through a thin tube (catheter) into the brain via a large blood vessel (endovascular) in the groin. It is guided into the aneurysm (intrasaccular) and left there to act as a plug (a blood clot forms in the device). The aim is to block the flow of blood into the aneurysm to reduce the chance of it rupturing or to stop further bleeding from an aneurysm that has already ruptured.

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IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in January 2019.

Procedure name

- Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm.

Specialist societies

- UK Neurointerventional Group
- Society of British Neurological Surgeons
- The British Society of Neuroradiologists
- Royal College of Radiologists.

Description of the procedure

Indications and current treatment

An intracranial aneurysm is a bulge in a blood vessel in the brain caused by a weakness in the blood vessel wall, usually where it branches. Most brain aneurysms only cause noticeable symptoms if they rupture. However, large aneurysms may cause local compression symptoms before they rupture, such as headache. Rupture of intracranial aneurysms causes subarachnoid haemorrhage and is associated with a very poor prognosis. About 10% of people die before reaching hospital and a further 50% die within 4 weeks. About 50% of people who survive a subarachnoid haemorrhage have a persistent neurological deficit.

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If an intracranial aneurysm is detected before it ruptures, treatment may be recommended to prevent it rupturing in the future. This is typically only done if the risk of a rupture is particularly high.

Current options for managing intracranial aneurysms include coiling, often with stent placement (stent-assisted coiling), neurosurgical clipping through a craniotomy (with or without bypass procedures), parent vessel occlusion (by open neurosurgery or by endovascular means) and conservative management. Flow diverter embolisation devices, which are placed in the parent blood vessel to divert blood flow away from the aneurysm itself, may be an option for some people with intracranial aneurysms.

What the procedure involves

Endovascular insertion of an intrasaccular wire mesh blood-flow disruption device for intracranial aneurysm is used for the embolisation of ruptured and unruptured intracranial aneurysms. It may be particularly suitable for people with wide-necked aneurysms. The procedure is usually done under general anaesthesia. A catheter is inserted into the femoral artery and advanced into the cerebral circulation under X-ray guidance. A second, smaller catheter is put inside the first and is inserted into the aneurysm. A basket-like device made of fine wire mesh is then pushed through the second catheter and placed into the aneurysm sac. The mesh device covers the aneurysm neck and obstructs blood flow into the aneurysm sac, creating blood stasis and promoting endothelial growth across the neck of the aneurysm. The appropriate device size is selected according to the aneurysm width and height.

The aim is to prevent the aneurysm from rupturing or to stop further bleeding from an aneurysm that has already ruptured.

Outcome measures

Modified Rankin Scale (mRS)

This is a functional assessment scale that measures the degree of disability or dependence of people who have suffered a stroke.

The scale runs from perfect health without symptoms to death:

- 0: no symptoms
- 1: no significant disability; able to carry out all usual activities, despite some symptoms

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- 2: slight disability; able to look after own affairs without assistance, but unable to carry out all previous activities
- 3: moderate disability; needs some help, but able to walk unassisted
- 4: moderately severe disability; unable to attend to own bodily needs without assistance, and unable to walk unassisted
- 5: severe disability; needs constant nursing care and attention, bedridden, incontinent
- 6: dead.

Efficacy summary

Technical success

In a systematic review of 940 patients, successful placement of an intrasaccular blood-flow disruption device was achieved in 97% of procedures (95% confidence interval [CI] 95% to 99%).¹

In a case series of 48 patients, successful device placement was achieved in 96% (50/52) of procedures.⁴

In a case series of 39 patients, the technical success rate was 100% (39/39).⁶

Need for additional devices

In the systematic review of 940 patients, 10% of patients needed additional devices, such as coils or stents, to complete the procedure (95% CI 5% to 15%, $I^2=76%$).¹

In the case series of 48 patients, additional devices were needed in 22% (11/52) of procedures (10 stent insertions and 1 coiling).⁴

In the case series of 39 patients, adjunctive stent placement was needed in 5% (2/39) of procedures.⁶

Aneurysm occlusion

In the systematic review of 940 patients, adequate occlusion (defined as either complete occlusion or neck remnant) was reported in 81% (95% CI 73% to 88%) of patients.¹

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In a case series of 113 patients, adequate occlusion was reported in 84% (82/98) of patients at 6-month follow up. In those patients who only had an intrasaccular wire-mesh blood-flow disruption device, the rate of adequate occlusion was 90% (64/71).³

In the case series of 48 patients, adequate occlusion was reported in 96% of aneurysms at short-term follow up (mean 5 months, n=45) and 100% at long-term follow up (mean 39 months, n=25).⁴

In the case series of 39 patients, adequate occlusion was reported in 87% of patients at short-term follow up (3 to 6 months, n=38) and 88% of patients at long-term follow up (18 months or longer, n=24).⁶

In a case series of 16 patients, total occlusion immediately after device insertion was 75% (12/16) and 19% (3/16) of patients had neck remnants. At long-term follow up (median 36 months), 4 of the 8 patients who did not have retreatment had total occlusion and 3 patients had neck remnants.⁷

Retreatment

In a case series of 168 patients, retreatment was needed in 7% (11/160) of patients (4 stent and coils, 4 flow diverters, 1 stent, 1 intrasaccular blood-flow disruption device and stent, and 1 intrasaccular blood-flow disruption device).²

In the case series of 113 patients, retreatment was reported in 15% (15/98) of patients (4 coiling, 7 stent-assisted coiling, 3 flow diversion, 1 additional intrasaccular blood-flow disruption device).³

In the case series of 48 patients, retreatment was needed after 16% (8/49) of procedures (11 retreatments: 5 stent-assisted coiling, 3 intrasaccular blood-flow disruption device insertion, 2 coiling and 1 flow diverter stent placement).⁴

In the case series of 39 patients, retreatment was needed after 5% (2/39) of procedures.⁶

In the case series of 16 patients, retreatment was needed in 47% (7/15) of patients by the end of follow up (median 36 months).⁷

Clinical outcome

In the case series of 113 patients, a favourable clinical outcome (mRS score 2 or less) was reported in 81% (92/113) of patients at 6-month follow up. The rate was higher for patients with unruptured aneurysms compared with those with ruptured aneurysms (96% and 49% respectively).³

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In the case series of 48 patients, 92% (44/48) of patients had a good clinical outcome (mRS score 2 or less) at last clinical follow up (mean 25 months).⁴

Aneurysm recurrence

In the case series of 113 patients, aneurysm recurrence was reported in 15% (15/98) of patients at 6-month follow up; 7 were minor and 8 were major recurrences.³

Safety summary

Thromboembolic complications

Thromboembolic complications were reported in 10% (91/940) of patients in the systematic review of 940 patients.¹

Thromboembolic complications were reported after 6% (3/52) of procedures in the case series of 48 patients. Two patients had intravenous abciximab and stent placement with no further consequences. In the third patient with a ruptured aneurysm, abciximab was not given to avoid haemorrhagic complications. There was a subsequent occlusion of a temporal M2 branch, resulting in temporo-parietal ischaemia with right hemiparesis and dysphasia (mRS score 4). The patient gradually recovered with slight hemiparesis at follow up (mRS score 2).⁴

Thromboembolic events were reported in 8% (3/39) of patients in the case series of 39 patients: 2 patients had no clinical deficit and 1 patient had a permanent deficit related to stent placement.⁶

A major stroke was reported in 1 patient in a case series of 150 patients; a delayed ipsilateral parenchymal haemorrhage, unrelated to the treated aneurysm, happened on day 22 after the procedure. Minor ischaemic stroke and transient ischaemic attack were reported in 5% (7/150) and 3% (5/150) of patients respectively. Arterial thrombosis in parent or branch vessels near the device was reported in 2% (3/150) of patients.⁸

Haemorrhage

Procedure-related haemorrhage was reported in 2% (14/940) of patients in the systematic review of 940 patients.¹

Intraprocedural subarachnoid haemorrhage was reported in 1% (2/150) of patients in the case series of 150 patients (both patients were discharged without neurological symptoms).⁸

Aneurysm rupture during procedure

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Intraprocedural rupture was reported in 1% (2/167) of patients in the case series of 168 patients.²

Aneurysm rupture during device placement was reported in 1 patient in the case series of 48 patients. This was treated by coils and glue; subsequent symptomatic vasospasm resulted in a hemiplegia that remained stable at follow up, with an mRS score of 3.⁴

Other vascular damage

Cervical artery dissection was reported in 4% (2/48) of patients in the case series of 48 patients: 1 case was identified during the procedure and treated by stenting with no clinical consequences. The other was diagnosed 24 hours after the procedure because the patient showed mild left hemiparesis, and was then treated by stenting. The patient had left upper limb paresis at follow up (mRS score 2). Femoral artery dissection was reported in 1 patient in the same study; this was treated by surgical bypass with no further clinical consequences.⁴

Inflammatory response

Inflammatory response around the blood-flow disruption device was reported in 1 patient in the case series of 16 patients. This was seen on MRI as perianeurysmal oedema from 10 months after the procedure, and constantly increased thereafter. The patient also had an increasing neck remnant, which needed clipping.⁷

Mortality

Mortality was 5% (95% CI 1% to 10%) at last clinical follow up in the systematic review of 940 patients.¹

Mortality was 3% (3/113) at 6-month follow up in a case series of 113 patients; 1 death was procedure related.³

One patient died from aneurysm rupture 3 years and 10 months after the original blood-flow disruption device insertion, in the case series of 16 patients. There was progressive aneurysm growth with increasingly slow circulation between the Woven EndoBridge (WEB) device and the aneurysm wall. This patient had the largest aneurysm of the series, originating from the basilar tip.⁷

Other safety issues

Hydrophilic polymer embolism after intrasaccular blood-flow disruption device insertion was described in a case report. The patient developed status epilepticus and pneumonia and died 24 days after admission. The cause of death was certified as 'intracerebral and subarachnoidal haemorrhage from ruptured IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

aneurysm of the left anterior cerebral artery'. The authors noted that the precise role of hydrophilic polymer embolism in the sequence of events leading to death remain a matter for speculation.⁹

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers listed the following anecdotal adverse events: displacement of a deployed device from the aneurysm sac into the lumen of the parent artery, the need for an additional intravascular device such as a stent, groin haematoma, clot formation and aneurysm rupture. They considered that the following were theoretical adverse events: delay in time to treatment if treatment is for a ruptured aneurysm, and risks from the use of antiplatelet therapy.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endovascular insertion of an intrasaccular wire mesh blood-flow disruption device for intracranial aneurysm. The following databases were searched, covering the period from their start to 8 January 2019: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the internet were also searched. No language restriction was applied to the searches (see the [literature search strategy](#)). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	People with an intracranial aneurysm.
Intervention/test	Endovascular insertion of an intrasaccular blood-flow disruption device.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on about 1,200 patients from 1 systematic review, 7 case series and 1 case report (there is some patient overlap between the studies).¹⁻⁹

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in the [appendix](#).

Table 2 Summary of key efficacy and safety findings on endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Study 1 Tau N (2018)

Details

Study type	Systematic review
Country	Europe and US
Recruitment period	Search date: December 2017
Study population and number	n=940 (12 studies) Patients with bifurcation intracranial aneurysms, either ruptured or unruptured
Age and sex	Mean 57 years; 69% female
Patient selection criteria	Studies of any design were included, without language restriction, except for commentaries, letters, technical notes, case reports and case series with fewer than 10 patients. The population of interest was patients with bifurcation aneurysms, either ruptured or unruptured, with any aneurysm anatomic characteristics. The intervention was endovascular treatment with any of the WEB devices.
Technique	Endovascular treatment with any WEB device (Sequent Medical, US).
Follow up	Clinical follow up: median 7 months (range 1 to 13.8)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Losses to follow up were not discussed in the review.

Study design issues: The review was reported according to the 'Preferred Reporting Items for Systematic Reviews and Meta-analyses' (PRISMA) guidelines. When an overlapping cohort was identified, only the most comprehensive and latest report was included in the final analysis. If the reviewers were unable to verify the uniqueness of participating patients, the paper was excluded from final analysis. Study quality was assessed using the 'Quality Assessment Tool for Case Series Studies' published by the National Institutes of Health. All studies were uncontrolled case series. There were 7 prospective, 4 retrospective and 1 combined retrospective and prospective. Three studies were single centre and 9 were multicentre. Five studies were rated as 'good', 1 was 'poor' and 6 were 'adequate'. The authors noted large heterogeneity between studies.

Study population issues: The most common aneurysm location was the middle cerebral artery bifurcation (37%), followed by anterior communicating artery (25%), basilar artery (22%), and internal carotid artery (8%). The aneurysmal neck was more than 4 mm in 75% to 100% of patients. Two studies exclusively included patients with ruptured aneurysms, while in other studies the proportion of patients with ruptured aneurysms was less than 50%.

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Key efficacy and safety findings

Efficacy	Safety
<p>Number of patients analysed: 940</p> <p>Successful placement of device=97% (95% CI 95% to 99%)</p> <p>Proportion of patients needing additional devices (such as coils or stents)=10% (95% CI 5% to 15%; I²=76.4%)</p> <p>Adequate occlusion (defined as either complete occlusion or neck remnant)=81% (95% CI 73% to 88%)</p> <p>There were no significant differences according to the duration of follow up. Angiographic evaluation was done at a median of 7 months (range 3 to 28).</p>	<p>Periprocedural complications=14% (130/940) (95% CI 9% to 19%, I²=76.9%)</p> <ul style="list-style-type: none"> • Thromboembolic complications, n=91 • Procedure-related haemorrhage, n=14 • Other complications included intracranial aneurysm rupture and brain oedema. <p>Mortality</p> <p>At last clinical follow up, mortality was 5% (95% CI 1% to 10%) and was increased in studies with higher proportions of patients with ruptured intracranial aneurysms.</p>
<p>Abbreviations used: CI, confidence interval; WEB, Woven EndoBridge</p>	

Study 2 Pierot L (2018)

Details

Study type	Case series (3 single-arm prospective multicentre studies: WEBCAST, WEBCAST-2 and French Observatory)
Country	Denmark, France, Germany, Hungary
Recruitment period	2010 onwards
Study population and number	n=168 (169 aneurysms) Patients with bifurcation intracranial aneurysms, ruptured or unruptured
Age and sex	Mean 56 years (range 27 to 77); 67% female
Patient selection criteria	Inclusion criteria: age 18 years or over, ruptured (Hunt and Hess grade I, II, or III) aneurysms or unruptured aneurysms in the basilar artery, middle cerebral artery, internal carotid artery terminus or anterior communicating artery complex, diameter suitable for WEB use, dome-to-neck ratio ≥ 1 . The French Observatory study also specified recanalised aneurysms as an inclusion criterion and the WEBCAST studies also specified neck size ≥ 4 mm and no additional implant. Exclusion criteria: age over 75 years, more than 1 aneurysm to be treated within 30 days, microcatheter could not reach target aneurysm, tumour or arteriovenous malformation. The WEBCAST studies also specified subarachnoid haemorrhage or intracranial haemorrhage within 3 months of treatment as an exclusion criterion for unruptured aneurysms.
Technique	The WEB-DL (Sequent Medical, US) device was initially used. This was subsequently replaced by WEB-SL, which has a barrel shape, and WEB-SLS, which is spherical. The most recent evolution of the device (WEBEV) has enhanced visualisation, which incorporates composite wire strands made from nitinol and platinum. Different microcatheters were also used throughout the studies. Treatment with ancillary devices (balloon, coils and stents) could be done, if necessary, in the French Observatory. In the WEBCAST trials, the use of ancillary devices was authorised as a rescue treatment only.
Follow up	1 year
Conflict of interest/source of funding	All 3 studies were funded by Sequent. A number of authors are consultants for companies including Sequent, Balt, Microvention, Neuravi, Penumbra, Medtronic, Stryker, Codman, Covidien and Cerus Endovascular.

Analysis

Follow-up issues: 91% (153/168) of patients were clinically evaluated with a mRS scoring at the 12-month follow up. Of the remaining 15 patients, 2 withdrew consent, 6 patients did not have a WEB device implanted, 5 patients had retreatment, 1 patient was lost to follow up and 1 patient missed the follow up.

Study design issues: Cumulative population of 3 single-arm, prospective, consecutive, multicentre studies. Clinical data, including all adverse events, were independently monitored and analysed by the same medical monitor. Thromboembolic events were diagnosed intraoperatively by angiography. Postoperative thromboembolic events were diagnosed by MRI or digital subtraction angiography done in patients with sudden neurological compromise. An expert interventional neuroradiologist independently evaluated aneurysm location on the initial angiogram, and aneurysm occlusion at the last angiographic follow up, using a previously validated 3-grade scale: complete occlusion, neck remnant and aneurysm remnant.

Study population issues: At baseline, 8% (14/169) of aneurysms were ruptured, 89% (150/169) were unruptured and 3% (5/169) were recanalised (after coiling). Aneurysm locations were: middle cerebral artery (51%), anterior communicating artery (21%), basilar artery (18%), and internal carotid artery terminus (10%). Aneurysm size was 2.8 to 17.0 mm (mean 7.6 ± 2.5 mm). Aneurysm neck size was 2.4 to 13.8 mm (mean 5.2 ± 1.6 mm). The neck was wide (≥ 4 mm) in 85% (144/169) of aneurysms.

Other issues: Study is included in systematic review by Tau et al. (study 1).

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Key efficacy and safety findings

Efficacy					Safety																																																	
Number of patients analysed: 168					Adverse events, morbidity and mortality at 1 month																																																	
Successful device placement=96.4% (163/169) (causes of failure were protrusion and subsequent retrieval of the device in 2 aneurysms, lack of appropriate device sizing in 3 aneurysms, and inability to deploy device in 1 aneurysm)					<table border="1"> <thead> <tr> <th>Event type</th> <th>All (n=167)</th> <th>WEB-DL (n=80)</th> <th>WEB-SL/SLS (n=87)</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td>Thromboembolic events</td> <td>24 (14.4%)</td> <td>15 (18.8%)</td> <td>9 (10.3%)</td> <td>0.130</td> </tr> <tr> <td>- asymptomatic</td> <td>11 (6.6%)</td> <td>9 (11.3%)</td> <td>2 (2.3%)</td> <td>0.027</td> </tr> <tr> <td>- symptomatic without sequelae</td> <td>8 (4.8%)</td> <td>4 (5.0%)</td> <td>4 (4.6%)</td> <td>1.00</td> </tr> <tr> <td>- symptomatic with sequelae</td> <td>5 (3.0%)</td> <td>2 (2.5%)</td> <td>3 (3.4%)</td> <td>1.00</td> </tr> <tr> <td>Intraoperative rupture</td> <td>2 (1.2%)</td> <td>1 (1.3%)</td> <td>1 (1.1%)</td> <td>1.00</td> </tr> <tr> <td>Intracranial haemorrhage</td> <td>1 (0.6%)</td> <td>1 (1.3%)</td> <td>0 (0%)</td> <td>0.479</td> </tr> <tr> <td>Morbidity*</td> <td>5 (3.0%)</td> <td>3 (3.8%)</td> <td>2 (2.3%)</td> <td>0.671</td> </tr> <tr> <td>Mortality</td> <td>0 (0%)</td> <td>0 (0%)</td> <td>0 (0%)</td> <td>-</td> </tr> </tbody> </table>					Event type	All (n=167)	WEB-DL (n=80)	WEB-SL/SLS (n=87)	p value	Thromboembolic events	24 (14.4%)	15 (18.8%)	9 (10.3%)	0.130	- asymptomatic	11 (6.6%)	9 (11.3%)	2 (2.3%)	0.027	- symptomatic without sequelae	8 (4.8%)	4 (5.0%)	4 (4.6%)	1.00	- symptomatic with sequelae	5 (3.0%)	2 (2.5%)	3 (3.4%)	1.00	Intraoperative rupture	2 (1.2%)	1 (1.3%)	1 (1.1%)	1.00	Intracranial haemorrhage	1 (0.6%)	1 (1.3%)	0 (0%)	0.479	Morbidity*	5 (3.0%)	3 (3.8%)	2 (2.3%)	0.671	Mortality	0 (0%)	0 (0%)	0 (0%)	-
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Adjunctive devices were used in 7.4% (12/163) of aneurysms (coils alone in 7, stents of flow diverters in 5).					* defined as an mRS score >2 if baseline ≤2, mRS +1 or more if baseline >2, mRS >2 and ruptured at baseline.																																																	
Aneurysm occlusion at 1 year follow up					The intraoperative ruptures and intracranial haemorrhage (related to antiplatelet treatment) were asymptomatic.																																																	
	All (n=153)	WEB-DL (n=72)	WEB-SL/SLS (n=81)	p value	Morbidity was related to a thromboembolic event in 2 patients (mRS score 3) with device protrusion in 1 patient, to initial aneurysm rupture in 2 patients (mRS scores 3 and 4), and to worsening of pre-existing aneurysm mass effect in 1 patient (mRS score 3). Morbidity was related to the device in 1 patient, to the procedure in 1 patient and to the disease in 3 patients.																																																	
Complete occlusion	81 (52.9%)	38 (52.8%)	43 (53.1%)	1.00	Mortality at 1 year																																																	
Neck remnant	40 (26.1%)	19 (26.4%)	21 (25.9%)		3.3% (5/153) of patients died between the 1-month and 1-year follow up: 3 were unrelated to aneurysm disease or treatment (2 cancer and 1 cirrhosis), 1 from worsening of pre-existing mass effect and 1 as a consequence and complication of a retroperitoneal haematoma during the index procedure.																																																	
Aneurysm remnant	32 (20.9%)	15 (20.8%)	17 (21.0%)		All-cause mortality at 1 year=3.3% (5/153)																																																	
					Neuro-related mortality at 1 year=0.7% (1/153)																																																	
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Evolution of aneurysm occlusion between postoperative DSA and 1-year follow up					Morbidity at 1 year																																																	
	All (n=153)	WEB-DL (n=72)	WEB-SL/SLS (n=81)	p value	All-cause morbidity at 1 year=1.3% (2/153)																																																	
Improved	94 (61.8%)	46 (63.9%)	48 (60.0%)	0.911	Neuro-related morbidity at 1 year=0% (0/153)																																																	
Stable	53 (34.9%)	24 (33.3%)	29 (36.3%)		Procedure-related morbidity at 1 year=1.3% (2/153)																																																	
Worsened	5 (3.3%)	2 (2.8%)	3 (3.8%)																																																			
No neck or aneurysm remnant was associated with bleeding or rebleeding during the follow-up period.																																																						
Retreatment=6.9% (11/160) (4 stent and coils, 4 flow diverters, 1 stent, 1 WEB and stent, and 1 WEB).																																																						
Abbreviations used: DL, double layer; DSA, digital subtraction angiography; EV, enhanced visualisation; mRS, modified Rankin Scale; SL, single layer; SLS, single-layer sphere; WEB, Woven EndoBridge																																																						

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Study 3 Kabbasch C (2018)

Details

Study type	Case series
Country	Germany (3 centres)
Recruitment period	2011 to 2018
Study population and number	n=113 (114 aneurysms) Patients with intracranial aneurysms, ruptured or unruptured
Age and sex	Mean 59 years; 66% (75/113) female
Patient selection criteria	Not described
Technique	All procedures were done using a transfemoral approach with the patient under general anaesthesia. The single-layer, double-layer, and single-layer sphere WEB devices were used (Sequent Medical, US). The use of additional devices was left to the neurointerventionalist's discretion. 77% of aneurysms were treated by WEB only and 23% were treated in conjunction with coiling or additional devices (stents or flow diverters).
Follow up	6 months
Conflict of interest/source of funding	2 authors are consultants for Acandis GmbH (Germany) and 1 is a proctor for Microvention Inc./Sequent Medical (US).

Analysis

Follow-up issues: An additional 8 patients had treatment during the study period, but were excluded from the study cohort because the implantation procedure failed. 86% (98/114) of aneurysms were available for the 6-month angiographic follow up.

Study design issues: Retrospective, multicentre, observational study of consecutive patients. Functional outcome was evaluated by the mRS score at 6-month follow up. Unfavourable outcome was defined as mRS score >2. The study aim was to evaluate factors influencing aneurysm occlusion and aneurysm recurrence after WEB embolisation.

Study population issues: 32% (36/114) of aneurysms were ruptured and were treated within 24 hours after ictus. 9% (10/113) of patients had recurrent aneurysms that had been previously treated with other modalities. 7 aneurysms were partially thrombosed and 13 had a lobular shape. 34% of aneurysms were located at the basilar tip, 28% at the anterior communicating artery and 14% at the middle cerebral artery bifurcation. 80% (91/114) of aneurysms were located at a bifurcation and 20% (23/114) were sidewall aneurysms. The maximum aneurysm diameter ranged from 3 to 27.2 mm (mean diameter 8.6±4.6 mm). The mean dome width was 7.3±3.6 mm, the mean aneurysm height 7.9±4.4 mm, the mean neck width 4.6±1.8 mm and the mean dome-to-neck ratio 1.7±0.8. A total of 104 (91%) aneurysms were classified as wide necked.

Other issues: There may be some patient overlap with Pierot L et al., 2018 (study 2)

Key efficacy and safety findings

Efficacy	Safety
<p>Number of patients analysed: 113 (114 aneurysms)</p> <p>Immediate angiographic outcomes after device insertion</p> <ul style="list-style-type: none"> • Complete occlusion=57.0% (65/114) • Neck remnants=19.3% (22/114) • Aneurysm remnants=23.7% (27/114) <p>Angiographic outcome at 6-month follow up</p> <ul style="list-style-type: none"> • Complete occlusion=62.2% (61/98) • Neck remnants=21.4% (21/98) • Aneurysm remnants=16.3% (16/98) • Adequate occlusion=83.7% (82/98) <p>In multivariate analysis, aneurysm size (OR 1.2, 95% CI 1.01 to 1.38, p=0.034) was an independent risk factor for aneurysm remnants. Among the procedure-related factors, recurrent aneurysms (OR 7.5, 95% CI 1.5 to 37.3, p=0.013) and treatment by WEB and coiling (OR 7.9, 95% CI 1.8 to 33.9, p=0.005) were independently associated with aneurysm remnants.</p> <p>Angiographic outcome at 6-month follow up for aneurysms treated by WEB device only</p> <ul style="list-style-type: none"> • Complete occlusion=67.6% (48/71) • Neck remnants=22.5% (16/71) • Aneurysm remnants=9.9% (7/71) • Adequate occlusion=90.1% (64/71) <p>Aneurysm remnants were more often seen in male patients (21.9%) than in female patients (0%, p=0.003) and the rate of adequate occlusion was higher in patients with immediate complete occlusion. These factors were not statistically significant in multivariate analysis.</p> <p>Favourable clinical outcome at 6-month follow up (mRS≤2)</p> <ul style="list-style-type: none"> • Overall=81.4% (92/113) • Unruptured aneurysms=96.2% (75/78) • Ruptured aneurysms=48.6% (17/35) (1 unfavourable outcome was procedure related and the others were related to subarachnoid haemorrhage itself.) <p>Aneurysm recurrence at 6 months=15.3% (15/98) (7 were minor and 8 were major recurrences)</p> <p>Recurrence was statistically significantly associated with partial intrasaccular thrombosis (p<0.001), increasing aneurysm size (p=0.005) and additional coiling (p=0.001). In multivariate analysis, aneurysm size (OR 1.2, 95% CI 1.02 to 1.41, p=0.032) and additional coiling (OR 7.8, 95% CI 1.9 to 31.7, p=0.004) remained as independent predictors of recurrence.</p> <p>Aneurysm recurrence at 6 months for aneurysms treated by WEB device only=11.3% (8/71) (6 minor and 2 major)</p> <p>Recurrent aneurysms had a larger height (p=0.008) and aspect ratio (p=0.012) than aneurysms without recurrence (factors were dependent in multivariate analysis).</p> <p>Retreatment=15.3% (15/98) (4 coiling, 7 stent-assisted coiling, 3 flow diversion, 1 additional WEB device). Retreatment was feasible in all patients.</p>	<p>Mortality</p> <p>At 6-month follow up, there were 3 deaths (2.7%), 1 of which was procedure related.</p>
Abbreviations used: CI, confidence interval; mRS, modified Rankin Scale; OR, odds ratio; WEB, Woven EndoBridge	

IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Study 4 Mine B (2018)

Details

Study type	Case series
Country	Belgium (3 centres)
Recruitment period	2010 to 2015
Study population and number	n=48 (49 aneurysms) Patients with intracranial aneurysms
Age and sex	Mean 57 years (range 35 to 76); 73% (35/48) female
Patient selection criteria	Not reported. The indication and modality of treatment were based in multidisciplinary discussion for all patients.
Technique	All procedures were done under general anaesthesia and systemic heparinisation. Overall, 52 WEB devices (Sequent Medical, US) were implanted: 33 WEB-DL, 15 WEB-SL, 4 WEB-SLS An additional device was used in 22% (11/52) of procedures.
Follow up	Mean 25 months (range 3 to 72)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Imaging follow-up protocol consisted of digital subtraction angiography (DSA) at 3, 6 and 12 months. MR angiography (MRA) was done at 12-month follow up and then every 2 years for unruptured aneurysms and yearly for ruptured aneurysms. In 1 procedure, the device was retrieved because of a major protrusion in the parent artery and in another procedure the device could not be implanted because of an acute angle between the parent artery and the aneurysmal neck. These 2 aneurysms were excluded for anatomical evaluation. Anatomical results were available for 74.5% (35/47) of aneurysms at 12-month follow up and 53.2% (25/47) of aneurysms at long-term follow up (mean 39 months, range 24 to 72).

Study design issues: Retrospective analysis of prospectively maintained database from 3 centres. All patients who had a WEB device inserted for an intracranial aneurysm were identified from the database. Clinical outcome was assessed using the mRS. Aneurysm occlusion was evaluated on DSA using a 3 point scale: grade I, complete occlusion; grade II, almost complete occlusion – neck remnant; grade III, incomplete occlusion – aneurysm remnant. Aneurysm occlusion was evaluated by 2 senior neuroradiologists, reaching consensus.

Study population issues: Mean aneurysm diameter was 8.6 mm (range 4 to 22) and mean neck diameter was 4.9 mm (range 2 to 10). There were 41 unruptured aneurysms, 3 recurrent aneurysms after treatment with coils, and 5 ruptured aneurysms. 59% (29/49) of aneurysms were located on the middle cerebral artery, 14% (7/49) on the basilar tip, 10% (5/49) on the anterior communicating artery, 4% (2/49) on the posteroinferior cerebellar artery and 2% (1/49) on the vertebral artery.

IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Key efficacy and safety findings

Efficacy	Safety																				
<p>Number of patients analysed: 48 (49 aneurysms)</p> <p>Successful device placement=96% (50/52) of procedures Two devices were needed in 2 procedures. Two aneurysms needed more than 1 procedure: 1 needed a second WEB placement because of a significant remnant after the first procedure and the other needed 3 procedures because of persistent growth (in a previously ruptured and recanalised giant partially thrombosed anterior communicating artery aneurysm).</p> <p>Additional devices=22.4% (11/52) Of the 10 stent placements, 1 was planned before the procedure and 9 were decided during the procedure because of a WEB protrusion or clot formation. In 1 patient, additional coiling was done because of a significant aneurysm remnant after WEB placement.</p> <p>Clinical outcome At discharge, 83% (40/48) of patients had a normal (n=38, mRS=0) or unchanged neurological examination. 8.3% (4/48) of patients had neurological deterioration, 3 of whom showed a good clinical evolution at follow up (2 had an mRS score of 0 and 1 had mRS score of 1). One patient retained left paresis (mRS 3).</p> <p>mRS score at last clinical follow up (mean 25 months)</p> <ul style="list-style-type: none"> 0=79.2% (38/48) 1=6.2% (3/48) 2=6.2% (3/48) 3=4.2% (2/48) 6=4.2% (2/48) <p>Permanent neurological morbidity=6.2% (3/48) Good clinical outcome (mRS≤2)=92% (44/48)</p> <p>Retreatment=16.3% (8/49) (11 retreatments: 5 stent-assisted coiling, 3 WEB placement, 2 coiling, 1 flow diverter stent placement)</p> <p>Anatomical outcomes – aneurysm occlusion grade (including retreatments)</p> <table border="1" data-bbox="110 1205 993 1432"> <thead> <tr> <th>Follow up</th> <th>Grade I</th> <th>Grade II</th> <th>Grade III</th> <th>Adequate occlusion (grade I and II)</th> </tr> </thead> <tbody> <tr> <td>Short term (mean 5 months), n=45</td> <td>68.9%</td> <td>26.7%</td> <td>4.4%</td> <td>95.6%</td> </tr> <tr> <td>Mid term (12 months), n=35</td> <td>74.3%</td> <td>20%</td> <td>5.7%</td> <td>94.3%</td> </tr> <tr> <td>Long term (mean 39 months), n=25</td> <td>72%</td> <td>28%</td> <td>0%</td> <td>100%</td> </tr> </tbody> </table> <p>Occlusion was stable between mid-term and long-term follow up in 82.6% (19/23) of aneurysms.</p> <p>Overall occlusion at latest available follow up (mean 25 months, range 3 to 72)</p> <ul style="list-style-type: none"> Grade I=72.3% (34/47) Grade II=27.7% (13/47) 	Follow up	Grade I	Grade II	Grade III	Adequate occlusion (grade I and II)	Short term (mean 5 months), n=45	68.9%	26.7%	4.4%	95.6%	Mid term (12 months), n=35	74.3%	20%	5.7%	94.3%	Long term (mean 39 months), n=25	72%	28%	0%	100%	<p>Unexpected procedural events=14% (7/52) of procedures</p> <ul style="list-style-type: none"> Thromboembolic complications=6% (3/52) Aneurysm rupture during device placement, n=1 (treated by coils and glue; subsequent symptomatic vasospasm resulted in a hemiplegia that remained stable at follow up with mRS score of 3) Cervical artery dissection, n=2 (1 was identified during the procedure and treated by stenting with no clinical consequences. The other was diagnosed 24 hours after the procedure because the patient showed mild left hemiparesis, and was then treated by stenting. The patient had left upper limb paresis at follow up, mRS score 2) Femoral artery dissection, n=1 (treated by surgical bypass with no further clinical consequences) <p>The 3 thromboembolic complications were clot formation at the neck: 2 were treated by intravenous abciximab and stent placement with no further consequences. In the third patient with a ruptured aneurysm, abciximab was not given to avoid haemorrhagic complications. There was a subsequent occlusion of a temporal M2 branch, resulting in temporo-parietal ischaemia with right hemiparesis and dysphasia (mRS score 4). The patient gradually recovered with slight hemiparesis at follow up (mRS score 2).</p> <p>Mortality 2 patients died from unrelated causes during follow up.</p>
Follow up	Grade I	Grade II	Grade III	Adequate occlusion (grade I and II)																	
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IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Study 5 Lawson A (2018)

Details

Study type	Case series
Country	UK (14 centres)
Recruitment period	2012 to 2014
Study population and number	n=109 (109 aneurysms, 112 procedures) Patients with intracranial aneurysms
Age and sex	Mean 56.5 years; 69% female
Patient selection criteria	Not described. Patients were selected after a multidisciplinary meeting among clinicians. Selection criteria were related to aneurysm and aneurysm neck size, aneurysm location, and whether a neurosurgical option was available. Aneurysms suitable for standard coiling or clipping were excluded, unless the patient refused the surgical option.
Technique	3 types of WEB device (Sequent Medical, US) were used: WEB-DL, WEB-SL and WEB-SLS. The procedure was elective in 83.5% (91/109) of patients and acute in 16.5% (18/109). There was no consistent antiplatelet regimen used across the different centres.
Follow up	Minimum 3 months (range 3 to 16 months)
Conflict of interest/source of funding	Sequent Medical funded Axiom Fusion eClinical Suite to build the WEB UK study database and provided funding for the statistical analysis. Five authors are consultants for Sequent Medical. Two are also consultants for other companies, including Covidien, Medtronic, Stryker and Pulsar Vascular.

Analysis

Follow-up issues: Follow-up results were available for 92% (100/109) of patients.

Study design issues: Data were collected retrospectively until March 2014 and prospectively after this date. Two independent interventional neuroradiologists classified all reported adverse events into 5 categories: device-related, procedure related, aneurysm disease related, ancillary device related, or related to another incidental condition. Clinical outcome was assessed using the modified Rankin Scale (mRS).

Study population issues: 7% (8/109) of patients had partial thrombosis of the aneurysm. Basilar aneurysms were the most common at 40% (44/109), followed by middle cerebral artery (36%), internal carotid artery (8%), anterior communicating artery (7%), posterior communicating artery (4%), posterior cerebral artery (1%), and anterior cerebral artery (4%). All patients had difficult to treat aneurysms that would not be suitable for unassisted coiling. 86% (84/109) had a wide neck, 45% (49/109) were bifurcation aneurysms, and 19% (21/109) of patients were not surgical candidates. Aneurysms were incidental in 59% (64/109) of patients, 17% (18/109) of patients had acute subarachnoid haemorrhage, and 18% (20/109) of patients were symptomatic. 6% (7/109) of patients had recurrent aneurysms. The maximum aneurysm diameter ranged from 3.8 to 18.4 mm (mean 8.2 mm) and the maximum diameter of the aneurysm neck ranged from 2.4 to 11.4 mm (mean 6.2 mm).

Other issues: Study is included in systematic review by Tau et al. (study 1).

IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Key efficacy and safety findings

Efficacy	Safety																																							
<p>Number of patients analysed: 109</p> <p>Successful device placement=95% (103/109)</p> <p>1 patient had 2 successful procedures on separate occasions.</p> <p>8 procedures were abandoned because of access issues.</p> <p>Modified Rankin Scale score</p> <table border="1" data-bbox="110 451 889 745"> <thead> <tr> <th rowspan="2">Follow up</th> <th colspan="7">mRS score</th> </tr> <tr> <th>0</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> <th>5</th> <th>6</th> </tr> </thead> <tbody> <tr> <td>Preoperative, n=109</td> <td>73.4%</td> <td>10.1%</td> <td>4.6%</td> <td>3.7%</td> <td>3.7%</td> <td>4.6%</td> <td>0%</td> </tr> <tr> <td>At discharge, n=109</td> <td>78.9%</td> <td>8.2%</td> <td>6.4%</td> <td>5.5%</td> <td>0.9%</td> <td>0%</td> <td>0%</td> </tr> <tr> <td>>3-month follow up, n=100</td> <td>77.0%</td> <td>8.0%</td> <td>6.0%</td> <td>4.0%</td> <td>0%</td> <td>0%</td> <td>5.0%</td> </tr> </tbody> </table>	Follow up	mRS score							0	1	2	3	4	5	6	Preoperative, n=109	73.4%	10.1%	4.6%	3.7%	3.7%	4.6%	0%	At discharge, n=109	78.9%	8.2%	6.4%	5.5%	0.9%	0%	0%	>3-month follow up, n=100	77.0%	8.0%	6.0%	4.0%	0%	0%	5.0%	<p>Overall morbidity at discharge=1.8% (2/109) (increase in mRS score to >2)</p> <p>1 patient had thromboembolism secondary to the procedure and vasospasm from an acute subarachnoid haemorrhage. The other patient developed right cerebellar infarcts and cerebellar ataxia 5 days after the procedure.</p> <p>Overall morbidity at follow up=6.0% (6/100)</p> <p>In addition to the patient with cerebella ataxia described above, there were 5 patients who died.</p> <p>No morbidity was associated with complications specific to the WEB device.</p> <p>Mortality before discharge=0%</p> <p>Mortality at follow up=5.0% (5/100)</p> <p>None of the deaths was considered to be device related. 2 patients had delayed rupture, 1 of a different aneurysm (at 300 and 336 days after the procedure respectively), 1 patient had hydrocephalus, subarachnoid haemorrhage and died 259 days after the procedure, 1 patient had a delayed thromboembolic event 279 days after the procedure and 1 patient died because of comorbidities 306 days after the procedure (no association with the procedure or device).</p> <p>Total adverse events=36.7% (40/109)</p> <ul style="list-style-type: none"> • Procedural, n=14 • Device related, n=17 • Ancillary device related, n=5 • Disease related, n=6 • 'other', n=2 <p>Thromboembolism=15.6% (17/109) (7 symptomatic and 10 asymptomatic)</p> <p>10.1% (11/109) of patients had persistent clinical sequelae related to an adverse event.</p> <p>Incorrect sizing of device was recorded as an adverse event in 4 patients.</p>
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IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Study 6 Herbreteau D (2016)

Details

Study type	Case series
Country	France
Recruitment period	2012 to 2015
Study population and number	n=39 Patients with intracranial aneurysms
Age and sex	Mean 59 years; 59% (23/39) female
Patient selection criteria	Not described. The decision for treatment and its technique was decided by a multidisciplinary team that included neurosurgeons and interventional neuroradiologists. The decision for treatment with the WEB device was made on the basis of aneurysm characteristics (location, size, and neck size).
Technique	The WEB-DL device (Sequent Medical, US) was initially used, but was later replaced by WEB-SL and WEB-SLS. All procedures were done under general anaesthesia with intraoperative heparin, and a single femoral approach. Antiplatelet therapy regimens before, during and after procedure varied.
Follow up	6 to 18+ months
Conflict of interest/source of funding	One author received payment from Sequent Medical for writing or reviewing the manuscript.

Analysis

Follow-up issues: 1 patient was lost to follow up at the short-term follow up (3 to 6 months). Mid-term and long-term follow-up data were available for 62% (24/39) of aneurysms.

Study design issues: Retrospective analysis of prospectively collected data from a single centre. The aim of the study was to analyse the safety and efficacy of the WEB device in long-term follow up in relation to WEB shape modification. Morbidity was defined as an mRS score >1 when the preoperative mRS was 1 or lower (or in ruptured aneurysms) and as an increase of 1 point when the preoperative mRS score was higher than 1. Aneurysm occlusion was evaluated using the 3-grade scale (complete occlusion, neck remnant, aneurysm remnant) immediately at the end of the procedure and at follow up. Adequate occlusion was defined as complete occlusion or neck remnant. Modifications of the WEB device were evaluated by comparing angiographic views of the distance between the distal and proximal markers of the device and evaluating the concavity of the distal and proximal surfaces.

Study population issues: 90% (35/39) of aneurysms were unruptured. No aneurysm had been previously treated. Aneurysms were located at the middle cerebral artery bifurcation (54%), the anterior communicating artery (23%), the basilar tip (13%), the internal carotid artery terminus (5%), the pericallosal artery (3%) and the posterior communicating artery (3%). Aneurysm mean diameter ranged from 4.3 to 9.5 mm (72% were ≥ 5 mm). Neck size was <4 mm in 18% of aneurysms and ≥ 4 mm in 82% (32/39) of aneurysms. All except 1 met the definition of wide-neck bifurcation aneurysms.

Other issues: 14 patients were also included in the case series described by Pierot L et al., 2018 (study 2).

IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Key efficacy and safety findings

Efficacy	Safety																																																												
<p>Number of patients analysed: 39 Technical success=100% (39/39) Adjunctive stent placement=5.1% (2/39) (because of WEB protrusion)</p> <p>Aneurysm occlusion by follow-up period</p> <table border="1" data-bbox="110 373 868 630"> <thead> <tr> <th></th> <th>3 to 6 months n=38</th> <th>1 year n=24</th> <th>≥18 months n=24</th> </tr> </thead> <tbody> <tr> <td>Complete occlusion</td> <td>60.5% (23/38)</td> <td>50.0% (12/24)</td> <td>54.2% (13/24)</td> </tr> <tr> <td>Neck remnants</td> <td>26.3% (10/38)</td> <td>33.3% (8/24)</td> <td>33.3% (8/24)</td> </tr> <tr> <td>Aneurysm remnants</td> <td>13.2% (5/38)</td> <td>16.7% (4/24)</td> <td>12.5% (3/24)</td> </tr> <tr> <td>Adequate occlusion</td> <td>86.8% (33/38)</td> <td>83.3% (20/24)</td> <td>87.5% (21/24)</td> </tr> </tbody> </table> <p>Retreatment=5.1% (2/39) (1 patient had an unruptured aneurysm treated with an undersized WEB, retreated at 8 months with stent placement and coiling. The other patient had an unruptured aneurysm treated with an appropriately sized WEB, and was retreated at 14 months for an aneurysm remnant.)</p> <p>Device sizing and shape medication The WEB device was undersized (according to the rule of +1 mm/-1 mm) in 28.2% (11/39) of patients. Among the 38 patients with short-term angiographic follow up, 10 (26.3%) had an undersized device and 28 (73.7%) had an appropriately sized device.</p> <p>Occlusion rates according to device sizing – short-term follow up</p> <table border="1" data-bbox="110 1012 868 1268"> <thead> <tr> <th></th> <th>Undersized device</th> <th>Appropriately sized device</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td>Complete occlusion</td> <td>50.0% (5/10)</td> <td>64.3% (18/28)</td> <td>0.67</td> </tr> <tr> <td>Neck remnants</td> <td>20.0% (2/10)</td> <td>28.6% (8/28)</td> <td>Not reported</td> </tr> <tr> <td>Aneurysm remnants</td> <td>30.0% (3/10)</td> <td>7.1% (2/28)</td> <td>Not reported</td> </tr> <tr> <td>Adequate occlusion</td> <td>70.0% (7/10)</td> <td>92.9% (26/28)</td> <td>0.10</td> </tr> </tbody> </table> <p>WEB shape modification=31.6% (12/38) of patients at short-term follow up. At long-term follow up, 1 additional patient had WEB shape modification.</p> <p>Occlusion rates according to WEB shape modification – short-term follow up</p> <table border="1" data-bbox="110 1402 868 1688"> <thead> <tr> <th></th> <th>WEB shape modification</th> <th>No WEB shape modification</th> <th>p value</th> </tr> </thead> <tbody> <tr> <td>Complete occlusion</td> <td>25.0% (3/12)</td> <td>76.9% (20/26)</td> <td>0.004</td> </tr> <tr> <td>Neck remnants</td> <td>58.3% (7/12)</td> <td>11.5% (3/26)</td> <td>0.004</td> </tr> <tr> <td>Aneurysm remnants</td> <td>16.7% (2/12)</td> <td>11.5% (3/26)</td> <td>Not reported</td> </tr> <tr> <td>Adequate occlusion</td> <td>83.3% (10/12)</td> <td>92.3% (24/26)</td> <td>0.64</td> </tr> </tbody> </table>		3 to 6 months n=38	1 year n=24	≥18 months n=24	Complete occlusion	60.5% (23/38)	50.0% (12/24)	54.2% (13/24)	Neck remnants	26.3% (10/38)	33.3% (8/24)	33.3% (8/24)	Aneurysm remnants	13.2% (5/38)	16.7% (4/24)	12.5% (3/24)	Adequate occlusion	86.8% (33/38)	83.3% (20/24)	87.5% (21/24)		Undersized device	Appropriately sized device	p value	Complete occlusion	50.0% (5/10)	64.3% (18/28)	0.67	Neck remnants	20.0% (2/10)	28.6% (8/28)	Not reported	Aneurysm remnants	30.0% (3/10)	7.1% (2/28)	Not reported	Adequate occlusion	70.0% (7/10)	92.9% (26/28)	0.10		WEB shape modification	No WEB shape modification	p value	Complete occlusion	25.0% (3/12)	76.9% (20/26)	0.004	Neck remnants	58.3% (7/12)	11.5% (3/26)	0.004	Aneurysm remnants	16.7% (2/12)	11.5% (3/26)	Not reported	Adequate occlusion	83.3% (10/12)	92.3% (24/26)	0.64	<p>Adverse events</p> <ul style="list-style-type: none"> Intraoperative aneurysm rupture=0% (0/39) Thromboembolic events=7.7% (3/39) (2 patients had no clinical deficit and 1 patient had a permanent deficit related to stent placement) <p>There were no delayed adverse events.</p> <p>Procedure and device-related morbidity (mRS 2)=2.6% Procedure and device-related mortality=0%</p>
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	WEB shape modification	No WEB shape modification	p value																																																										
Complete occlusion	25.0% (3/12)	76.9% (20/26)	0.004																																																										
Neck remnants	58.3% (7/12)	11.5% (3/26)	0.004																																																										
Aneurysm remnants	16.7% (2/12)	11.5% (3/26)	Not reported																																																										
Adequate occlusion	83.3% (10/12)	92.3% (24/26)	0.64																																																										
Abbreviations used: DL, double layer; mRS, modified Rankin Scale; SL single layer; SLS, single-layer sphere; WEB, Woven EndoBridge																																																													

IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Study 7 Khalid Z (2018)

Details

Study type	Case series
Country	Norway
Recruitment period	2012 to 2015
Study population and number	n=16 Patients with ruptured or unruptured intracranial aneurysms
Age and sex	Median 59 years (range 39 to 71); 56% (9/16) female
Patient selection criteria	Not described. Mode of treatment was decided by a vascular team consisting of neurosurgeons and neurointerventionists.
Technique	A single WEB device was implanted in all procedures: 3 WEB-DL, 11 WEB-SL and 2 WEB-SLS
Follow up	Median 36 months (range 13 to 49)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: 1 patient was lost to follow up.

Study design issues: Retrospective analysis of prospectively collected data in a single centre cohort study. Data were obtained from the institutional prospective quality registry. Follow-up imaging was routinely done by CT angiography within a few days of the procedure and after 3 months. MR angiography was also done for all but 1 patient shortly after device insertion. Conventional angiography was only done on selected patients. Changes in size and shape of the device were assessed qualitatively on follow-up imaging, together with measurements of the distance between markers at the poles of the device.

Study population issues: At the time of intervention, 81% (13/16) of the aneurysms were unruptured (6 were symptomatic and 7 were incidental). Aneurysms were located at the basilar artery bifurcation (56%), anterior communicating artery (38%), and the middle cerebral artery (6%). Most of the aneurysms were ≥ 10 mm and the smallest aneurysm was 8.1 mm. 93.8% of the aneurysms were wide necked with a neck diameter ≥ 4 mm. Eleven aneurysms had an aspect ratio lower than 1.6 and 5 had an aspect ratio lower than 1.2. One aneurysm had previously been treated with coils. The authors noted that the population included a high number of aneurysms with circulated blebs or irregular configurations, which make it more difficult to obtain complete occlusion.

Other issues: the authors noted that the sizing recommendations from the device producer have been revised after gathering more experience into oversizing at the level of the neck. They stated that a large fraction of the failures in this study may be attributed to not oversizing the WEB device.

IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Key efficacy and safety findings

Efficacy	Safety
<p>Number of patients analysed: 16</p> <p>Occlusion immediately after device insertion</p> <ul style="list-style-type: none"> Total occlusion=75.0% (12/16) Neck remnants=18.8% (3/16) Aneurysm remnant=6.2% (1/16) <p>Occlusion at follow up (median 36 months) excluding patients who had retreatment</p> <ul style="list-style-type: none"> Total occlusion=4/8 Neck remnants=3/8 Aneurysm remnant=1/8 <p>Retreatment=46.7% (7/15)</p> <p>All retreatments were for increasing circulation inside the aneurysm sac. In 3 of the retreated aneurysms, there were signs of shortening/retraction of the WEB device over time (1 of which also had compaction of coils from initial coiling treatment). In 2 aneurysms, there were signs of distal dislocation of the WEB without shortening.</p> <p>There were also signs of shortening in 3 WEB devices in aneurysms that were not retreated.</p> <p>Of the 7 patients who had retreatment, 5 had total occlusion at the end of follow up and 1 had an aneurysm remnant (for 1 patient, only the immediate status of retreatment was available, which showed complete occlusion).</p> <p>WEB size evolution</p> <p>In the aneurysms that ruptured at 3 years and 10 months after initial treatment, the WEB device had increased by 25%.</p> <p>26.6% (4/15) of WEB devices collapsed over time and had decreased in size by an average of 44.5% (range 35.9 to 59.1%). All of them had developed significant new circulation and needed retreatment.</p> <p>In the 9 aneurysms that were completely occluded at follow up, there was a successive slight decrease in WEB device size with an average of 13.2% (0 to 22.9%) at latest follow up.</p>	<p>There were no procedural or postprocedural thromboembolic events.</p> <p>1 patient developed an inflammatory response around the WEB device. This was seen on MRI as perianeurysmal oedema from 10 months after the procedure and constantly increased thereafter. The patient also had an increasing neck remnant, which needed clipping.</p> <p>Mortality</p> <p>1 patient died during follow up from aneurysm rupture, 3 years and 10 months after the original WEB device treatment. There was progressive aneurysm growth with increasing slow circulation between the WEB device and the aneurysm wall. This patient had the largest aneurysm of the series, originating from the basilar tip.</p> <p>Retreatment procedures led to complications in 2 patients: 1 patient had a subdural haematoma after craniotomy that could be managed conservatively and 1 patient had a right-sided infarction of the A2 territory after aneurysm clipping (the same patient who developed an inflammatory response around the WEB device).</p>
Abbreviations: DL, double layer; SL single layer; SLS, single-layer sphere; WEB, Woven EndoBridge	

Study 8 Fiorella D (2017)

Details

Study type	Case series (WEB-IT)
Country	US, UK, Hungary, Turkey (31 centres)
Recruitment period	2014 to 2016
Study population and number	n=150 Patients with intracranial wide-necked bifurcation aneurysms
Age and sex	Mean 59 years (range 29 to 79); 73% (110/150) female
Patient selection criteria	Ruptured or unruptured saccular aneurysms, located at the basilar apex, middle cerebral artery bifurcation, internal carotid artery terminus, anterior communicating artery complex, dome-to-neck ratio ≥ 1 , wide-necked intracranial aneurysm with neck sized ≥ 4 mm or dome-to-neck ratio < 2 , diameter appropriate for treatment with the WEB device per instructions for use. Patients with ruptured aneurysms were required to be neurologically stable with a Hunt & Hess score of 1 or 2. Key exclusion criteria included: vascular tortuosity or morphology which could preclude safe access and support during treatment with WEB, and modified Rankin Scale (mRS) score ≥ 2 at baseline or prior to rupture.
Technique	A WEB device was implanted in all procedures: 19 WEB-DL, 107 WEB-SL and 22 WEB-SLS
Follow up	30 days
Conflict of interest/source of funding	Study was funded by Sequent Medical Inc. The primary investigators for the WEB-IT trial received institutional salary support for study related activities. Investigators in the WEB-IT trial also received payment for proctoring cases within the context of the trial.

Analysis

Follow-up issues: Follow up for safety data was only to 30 days.

Study design issues: Prospective multicentre single-arm study. The aim of the study was to report adverse events within the first 30 days after the procedure.

Study population issues: At the time of intervention, 9 of the aneurysms were ruptured. With respect to aneurysm characteristics, 91 (61%) were in the anterior circulation and 59 (39%) in the posterior circulation. The mean dome width was 6.4 mm (range 3.6 to 11.4), mean dome height was 6.1 mm (range 3.1 to 10.3), mean neck size was 4.8 mm (range 2.0 to 8.2), and mean dome-to-neck ratio was 1.3 (range 1.0 to 2.0).

IP overview: Endovascular insertion of an intrasaccular wire-mesh blood-flow disruption device for intracranial aneurysm

Key efficacy and safety findings

Efficacy	Safety
<p>Number of patients analysed: 150</p> <p>Technical success=98.7% (148/150)</p> <p>Device insertion was unsuccessful in 2 patients; 1 because of anatomic tortuosity and 1 because of improper device size availability. Adjunctive stenting was done in 2 patients where the WEB device appeared to impinge upon the parent artery or adjacent branch. Adjunctive balloons were used to assist WEB positioning in 5 patients.</p>	<p>Technical events related to device</p> <ul style="list-style-type: none"> • Failure to open or twisted on deployment, n=3 • Device detachment system failure, n=3 • Kinked pusher, n=2 • Multiple attempts needed for detachment, n=2 <p>There were no patient sequelae and a device was successfully implanted in all of these patients.</p> <p>Primary safety events=0.7% (1/150)</p> <p>A delayed ipsilateral parenchymal haemorrhage unrelated to the treated aneurysm, happened on day 22 after the procedure. The event was adjudicated as a major stroke, most likely related to antiplatelet medication and underlying cerebrovascular disease. At last follow up the patient's mRS score was 4.</p> <p>Additional safety outcomes</p> <ul style="list-style-type: none"> • Minor ischaemic stroke=4.7% (7/150) (5 resolved without sequelae and 2 were mRS 1 at 30 days. Of these, 1 was device-related, 4 were procedure related and 2 were neither) • Transient ischaemic attack=2.7% (5/150) • Arterial thrombosis in parent or branch vessels near the WEB device=2.0% (3/150) • Intraprocedural subarachnoid haemorrhage=1.3% (2/150) (both patients were discharged without neurological symptoms) <p>There were 136 adverse events in 65 patients, of which 24 were categorised as serious (9 device-related, 68 procedure-related). 125 of these resolved without sequelae, 8 remain ongoing and 3 incurred sequelae.</p> <p>Other common events in the 30 day follow up included headache (n=21, 15.4%), nausea (n=7, 5.1%) and vessel puncture site pain (n=5, 3.7%).</p>
<p>Abbreviations: DL, double layer; SL single layer; SLS, single-layer sphere; WEB, Woven EndoBridge</p>	

Study 9 Tikka J (2018)

Details

Study type	Case report
Country	Finland
Recruitment period	Not reported
Study population and number	n=1 Patient with ruptured aneurysm of the anterior cerebral artery.
Age and sex	'woman in her 70s'
Patient selection criteria	N/A
Technique	The WEB-SL device (Sequent Medical, US) was used.
Follow up	None
Conflict of interest/source of funding	None

Key efficacy and safety findings

Case report: left cerebral hemisphere hydrophilic polymer embolism

The device insertion procedure was uneventful, but the patient remained unconscious. A CT scan 6 hours after the procedure showed rebleeding and ischaemic changes in the brain tissue surrounding the aneurysm with compression of the lateral ventricles. A ventriculostomy was done the next day. The patient then developed status epilepticus and pneumonia and died 24 days after admission.

Tissue samples from the left cerebral hemisphere showed foreign particles surrounded by multinucleated cells, suggesting a foreign-body reaction. The findings were consistent with 3-day to 2-month old polymer emboli.

The cause of death was certified as 'intracerebral and subarachnoidal haemorrhage from ruptured aneurysm of the left anterior cerebral artery'.

The authors noted that the precise role of hydrophilic polymer embolism in the sequence of events leading to death remain a matter for speculation.

Abbreviation: SL single layer; WEB, Woven EndoBridge

Validity and generalisability of the studies

- No comparative studies were identified.
- Most studies were retrospective.
- There are different devices used for the procedure, which may have different safety and efficacy profiles.
- The patient populations are heterogenous for size and location of the aneurysms, although most aneurysms were classified as wide necked.
- The evidence includes both ruptured and unruptured aneurysms.
- Antiplatelet regimens vary within and between studies.
- Patient selection criteria were not described in detail in several studies.
- Some of the studies include the first patients to have treatment with the procedure.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Supraorbital minicraniotomy for intracranial aneurysm. NICE interventional procedures guidance 84 (2004). Available from <http://www.nice.org.uk/guidance/IPG84>
- Coil embolisation of ruptured intracranial aneurysms. NICE interventional procedures guidance 106 (2005). Available from <http://www.nice.org.uk/guidance/IPG106>

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- Coil embolisation of unruptured intracranial aneurysms. NICE interventional procedures guidance 105 (2005). Available from <http://www.nice.org.uk/guidance/IPG105>

Medical technologies

- Pipeline Flex embolisation device with Shield Technology for the treatment of complex intracranial aneurysms. NICE Medical technologies guidance 10 (2012, updated 2019). Available from <http://www.nice.org.uk/guidance/mtg10>

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by specialist advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Three Specialist Adviser Questionnaires for intrasaccular blood-flow disruption device insertion for intracranial aneurysm were submitted and can be found on the [NICE website](#).

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 3 companies who manufacture a potentially relevant device for use in this procedure. NICE did not receive any completed submissions.

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Issues for consideration by IPAC

Ongoing studies:

- WEB Clinical Assessment of IntraSaccular Aneurysm Therapy (WEBCAST); NCT01778322; Denmark, France, Germany, Hungary; prospective cohort study; n=100; estimated study completion date: June 2020
- The WEB-IT Clinical Study (WEB-IT); NCT02191618; US, Canada, Denmark, Germany, Hungary, Turkey; prospective cohort study; n=150; estimated study completion date: March 2021
- The WEB®-IT China Clinical Study (WEB-IT China); NCT03207087; China; single group assignment; n=150; estimated study completion date: June 2019
- CLARYS: CLinical Assessment of WEB® Device in Ruptured aneurYSms (CLARYS); NCT02687607; France; observational (registry); n=50; estimated study completion date: June 2018

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References

1. Tau N, Sadeh-Gonik U, Aulagner G et al. (2018) The Woven EndoBridge (WEB) for endovascular therapy of intracranial aneurysms: Update of a systematic review with meta-analysis. *Clinical Neurology & Neurosurgery* 166: 110–5
2. Pierot L, Moret J, Barreau X et al. (2018) Safety and efficacy of aneurysm treatment with WEB in the cumulative population of three prospective, multicenter series. *Journal of Neurointerventional Surgery* 10: 553-559
3. Kabbasch C, Goertz L, Siebert E et al. (2018) Factors that determine aneurysm occlusion after embolization with the Woven EndoBridge (WEB). *Journal of Neurointerventional Surgery* 24
4. Mine B, Goutte A, Brisbois D et al. (2018) Endovascular treatment of intracranial aneurysms with the Woven EndoBridge device: mid term and long term results. *Journal of Neurointerventional Surgery* 10: 127-132
5. Lawson A, Molyneux A, Sellar R et al. (2018) Safety results from the treatment of 109 cerebral aneurysms using the Woven EndoBridge technique: preliminary results in the United Kingdom. *Journal of Neurosurgery* 128: 144–153
6. Herbreteau D, Bibi R, Narata AP et al. (2016) Are Anatomic Results Influenced by WEB Shape Modification? Analysis in a Prospective, Single-Center Series of 39 Patients with Aneurysms Treated with the WEB. *American Journal of Neuroradiology* 37: 2280–86
7. Khalid Z, Sorteberg W, Nedregaard B et al. (2018) Efficiency and complications of Woven EndoBridge (WEB) devices for treatment of larger, complex intracranial aneurysms-a single-center experience. *Acta Neurochirurgica* 13: Dec 13
8. Fiorella D, Molyneux A, Coon A et al. (2017) Demographic, procedural and 30-day safety results from the WEB Intra-saccular Therapy Study (WEB-IT). *Journal of Neurointerventional Surgery* 9: 1191–96
9. Tikka J, Gardberg M, Rautio R et al. (2018) Left cerebral hemisphere hydrophilic polymer embolism associated with endovascular WEB treatment of a ruptured aneurysm of the anterior cerebral artery. *Legal Medicine* 35: 66–68

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Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	08/01/2019	Issue 1 of 12, January 2019
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	08/01/2019	Issue 1 of 12, January 2019
HTA database (CRD website)	08/01/2019	
MEDLINE (Ovid)	08/01/2019	1946 to January 07, 2019
MEDLINE In-Process (Ovid) & MEDLINE Epubs ahead of print (Ovid)	08/01/2019	January 07, 2019
EMBASE (Ovid)	08/01/2019	1974 to 2019 Week 01
BLIC (British Library)	08/01/2019	n/a

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Intracranial Aneurysm/
2	((intracranial or brain* or cerebral or wide-neck or 'basilar artery' or berry) adj4 aneurysm*).tw.
3	((intracranial or brain* or cerebral or wide-neck or 'basilar artery' or berry) adj4 (unrupt* or thin* or bulg* or weak* or balloon* or bubbl* or dilat* or puls* or swell*)).tw.

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4	1 or 2 or 3
5	((intrasaccular or endosaccular) adj4 flow* adj4 (disrupt* or divert* or diversion or alter* or redirect* or change*)).tw.
6	'woven endobridge'.tw.
7	((intrasaccular or endosaccular or embolization or embolisation) adj4 (system* or device* or therap* or technique*)).tw.
8	(WEB or WEB-IT or Luna or artisse).tw.
9	or/5-8
10	4 and 9
11	Animals/ not Humans/
12	10 not 11

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Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/ follow up	Direction of conclusions	Reasons for non-inclusion in table 2
Anil G, Goddard AJ, Ross SM et al. (2016) WEB in Partially Thrombosed Intracranial Aneurysms: A Word of Caution. American Journal of Neuroradiology 37: 892–6	Case series n=4	This small, select case series shows that WEB placement with adjunctive stent placement may be an effective treatment in the management of partially thrombosed intracranial aneurysms, which merits further validation. However, exclusive intrasaccular flow disruption may have an adverse influence on the natural history of this disease.	Larger studies are included.
Armoiry X, Turjman F, Hartmann DJ et al. (2016) Endovascular Treatment of Intracranial Aneurysms with the WEB Device: A Systematic Review of Clinical Outcomes. American Journal of Neuroradiology 37: 868-72	Systematic review n=7 articles	Endovascular treatment of bifurcation wide-neck aneurysms with the WEB device is feasible and allows an acceptably adequate aneurysm occlusion rate; however, the rate of neck remnants is not negligible. The WEB device needs further clinical and anatomic evaluation with long-term prospective studies, especially of the risk of WEB compression. Prospective controlled studies should be encouraged.	A recent update of the review is included (Tau et al, 2018)
Asnafi S, Rouchaud A, Pierot L et al. (2016) Efficacy and Safety of the Woven EndoBridge (WEB) Device for the Treatment of Intracranial Aneurysms: A Systematic Review and Meta-Analysis. American Journal of Neuroradiology 37: 2287-2292	Systematic review n=565 (15 studies)	Early evidence derived from uncontrolled studies suggests that Woven EndoBridge treatment has a good safety profile and promising rates of adequate occlusion, especially given the complexity of aneurysms treated. Further prospective clinical trials are needed to confirm these results and better define the risks and benefits of use of the Woven EndoBridge device in treating wide-neck and wide-neck bifurcation aneurysms.	A more recent systematic review is included (Tau et al, 2018)
Behme D, Berlis A and Weber W (2015) Woven EndoBridge Intrasaccular Flow Disrupter for the Treatment of Ruptured and	Case series n=55 FU=3 months	A favourable angiographic result at 3 months was achieved in 29/44 (66%) cases, whereas the percentage of good anatomic	Studies with more patients or longer follow up are included.

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Unruptured Wide-Neck Cerebral Aneurysms: Report of 55 Cases. American Journal of Neuroradiology 36: 1501-6		results increased from 40% in 2012 to 75% in 2014.	Study is included in systematic review by Tau et al, 2018.
Bhogal P, AlMatter M, Hellstern V et al. (2018) The Combined Use of Intraluminal and Intracardiac Flow Diversion for the Treatment of Intracranial Aneurysms: Report of 25 Cases. Neurointervention 13: 20-31	Case series n=25 FU=mean 10 months	The Medina Embolic Device can be successfully used in combination with intraluminal flow diverter stents (FDS) and in selected aneurysms this may represent an alternative to FDS and adjunctive coiling.	Studies with more patients or longer follow up are included.
Bozzetto Ambrosi P, Gory B, Sivan-Hoffmann R et al. (2015) Endovascular treatment of bifurcation intracranial aneurysms with the WEB-SL/SLS: 6-month clinical and angiographic results. Interventional Neuroradiology 21: 462-9	Case series n=10 FU=6 months	From this preliminary study, treatment of bifurcation intracranial aneurysms using WEB-SL is feasible. WEB-SL treatment seems safe at 6 months; however, the rate of neck remnants is not negligible due to compression of the WEB-SL. Further technical improvements may be needed in order to ameliorate the occlusion in the WEB-SL treatment.	Studies with more patients or longer follow up are included.
Caroff J, Mihalea C, Da Ros V et al. (2017) A computational fluid dynamics (CFD) study of WEB-treated aneurysms: Can CFD predict WEB "compression" during follow up? Journal of Neuroradiology 44: 262-268	Case series n=22 FU=mean 17 months	The mechanisms underlying the worsening of aneurysm occlusion in patients who had a WEB because of device compression are most likely complex as well as multifactorial. However, it is apparent from our pilot study that a high arterial inflow is, at least, partially involved.	Studies with more patients or longer follow up are included.
Caroff J, Mihalea C, Dargento F et al. (2014) Woven Endobridge (WEB) Device for endovascular treatment of ruptured intracranial wide-neck aneurysms: a single-center experience. Neuroradiology 56: 755-61	Case series n=6 FU=3 months	From this preliminary study, the high feasibility rate and lack of need for systematic antiplatelet agents favour the WEB device providing a solution for endovascular treatment of ruptured wide-neck bifurcation aneurysms during the acute phase. However, further studies are needed to evaluate the complication rate and long-term efficiency.	Studies with more patients or longer follow up are included.
Caroff J, Mihalea C, Klisch J et al. (2015) Single-Layer WEBs: Intracardiac Flow Disrupters for Aneurysm Treatment-Feasibility Results from a European Study. American Journal of Neuroradiology 36: 1942-6	Case series n=95 FU=3 months	The feasibility and safety of the single-layer WEB device was comparable with that of the double-layer. However, further studies are needed to evaluate long-term efficacies.	Studies with more patients or longer follow up are included. Study is included in systematic review by Tau et al, 2018.

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Caroff J, Mihalea C, Neki H et al. (2014) Role of C-arm VasoCT in the use of endovascular WEB flow disruption in intracranial aneurysm treatment. American Journal of Neuroradiology 35: 1353-7	Case series n=12	High-resolution contrast-enhanced flat panel detector CT (VasoCT) allowed a precise evaluation of the WEB sizing and its relation to the parent vessel. Such information very likely enhances the ability to safely use this device, avoiding potential thromboembolic events in cases of protrusion in the parent arteries.	Study focuses on imaging technique.
Clajus C, Strasilla C, Fiebig T et al. (2017) Initial and mid-term results from 108 consecutive patients with cerebral aneurysms treated with the WEB device. Journal of Neurointerventional Surgery 9: 411-417	Case series n=108 FU=mean 13 months	Thromboembolic complications occurred in 10% (11/110) of interventions, with a new permanent deficit in 1 patient. Re-rupture after WEB treatment was detected in 2 aneurysms (4%), which had both initially presented with subarachnoid haemorrhage. Angiographic follow up revealed adequate occlusion in 76% (68/90) of aneurysms. Fifteen aneurysms required retreatment.	Studies with more patients or longer follow up are included. Study is included in systematic review by Tau et al, 2018.
Cognard C, Januel AC (2015) Remnants and recurrences after the use of the WEB intrasaccular device in large-neck bifurcation aneurysms. Neurosurgery 76: 522-30	Case series n=15	Compression of the WEB cage was seen at first follow up in 57% (8/14) and in an additional 43% (3/7) of cases at second control. Last angiography showed complete occlusion in 7% (1/14), neck remnant in 57% (8/14) and residual aneurysm in 36% (5/14) of cases.	Studies with more patients or longer follow up are included. Study is included in systematic review by Tau et al, 2018.
Colla R, Cirillo L, Princiotta C et al. (2013) Treatment of wide-neck basilar tip aneurysms using the Web II device. Neuroradiology Journal 26: 669-77	Case series n=4 up to 12 months	Preliminary results suggest that the WEB II is a suitable device for endovascular treatment of unruptured wide-necked basilar tip aneurysms.	Studies with more patients or longer follow up are included.
Da Ros V, Bozzi A, Comelli C et al. (2018) Ruptured Intracranial Aneurysms treated with Woven Endobridge Intrasaccular Flow Disruptor (WEB): a multi-center experience. World Neurosurgery 27	Case series n=33 FU=mean 14 months	Overall WEB-related complication was 27% (5 device-protrusion; 2 sac-perforation; 2 thromboembolism) with a WEB-related mortality of 12% and 3% of permanent neurologic deficit. At follow up, no early or delayed aneurysm re-ruptured were seen; complete occlusion was obtained in 7/21 patients (33%), neck remnant in 8/21 (38%), residual aneurysm filling in 6/21 (29%) patients with an mRS 0-2 seen in 17/21 patients (80%).	Studies with more patients or longer follow up are included.
Gawlitza M, Soize S, Januel AC et al. (2018) Treatment of recurrent aneurysms using the	Case series n=17	Permanent morbidity due to a thromboembolic complication occurred in 1 patient. There was	Studies with more patients or longer

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Woven EndoBridge (WEB): anatomical and clinical results. Journal of Neurointerventional Surgery 10: 629-633	FU=12 months	no mortality. Rates of complete occlusion, neck remnant, and aneurysm remnant were 33%, 40%, and 27%, respectively.	follow up are included.
Gherasim DN, Gory B, Sivan-Hoffmann R et al. (2015) Endovascular treatment of wide-neck anterior communicating artery aneurysms using WEB-DL and WEB-SL: short-term results in a multicenter study. American Journal of Neuroradiology 36: 1150-4	Case series n=10 FU=1 month	One patient developed a procedural thromboembolic event. Angiographic control was obtained in all patients, including 6 adequate aneurysm occlusions (3 complete occlusions and 3 neck remnants) at short-term follow up.	Studies with more patients or longer follow up are included.
Haffaf I, Clarencon F, Shotar E et al. (2018) Medina embolization device for the treatment of intracranial aneurysms: 18 months' angiographic results. Journal of Neurointerventional Surgery 24	Case series n=19 FU=18 months	Medina embolisation device is a hybrid device, combining properties of a conventional coil with those of an intrasaccular flow disrupter. Our series shows a satisfactory long-term occlusion rate. Larger series with longer angiographic follow-up times are warranted to confirm these preliminary results.	Studies with more patients or longer follow up are included.
Kabbasch C, Mpotsaris A, Reiner M et al. (2016) WEB as part of a multimodality treatment in complex, large, and partially thrombosed intracranial aneurysms: a single-center observational study of technical success, safety, and recurrence. Journal of Neurointerventional Surgery 8: 1235-1239	Case series n=43	All 8 of the complex, large, wide-neck aneurysms were treated successfully and without periprocedural adverse events. At follow up, the 2 non-thrombosed aneurysms were completely occluded, but all 6 partially thrombosed aneurysms recurred and were retreated. There was no morbidity or mortality in these 8 patients.	Studies with more patients or longer follow up are included.
Klisch J, Sychra V, Strasilla C et al. (2011) The Woven EndoBridge cerebral aneurysm embolization device (WEB II): initial clinical experience. Neuroradiology 53: 599-607	Case series n=2 FU=8 weeks	In both cases, complete aneurysm occlusion was seen within minutes of device deployment. Short-term angiographic follow up confirmed stable complete occlusion at 8 weeks.	Studies with more patients or longer follow up are included.
Lawson A, Goddard T, Ross S et al. (2017) Endovascular treatment of cerebral aneurysms using the Woven EndoBridge technique in a single center: preliminary results. Journal of Neurosurgery 126: 17-28	Case series n=22	The technique is safe, and short-term results show effective occlusion of complex aneurysms with minimal complications associated with the procedure. Long-term efficacy, however, still needs to be assessed.	Studies with more patients or longer follow up are included.
Lescher S, du Mesnil de Rochemont R, Berkefeld J (2016) Woven Endobridge (WEB) device for endovascular treatment of complex unruptured aneurysms-a single-	Case series n=22	Follow-up angiographic imaging proved total or subtotal occlusion of the aneurysm in 19 of 22 cases. Two minor recurrences remained stable during a period of 15 months. One patient with a partially	Studies with more patients or longer follow up are included.

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center experience. Neuroradiology 58: 383-90		thrombosed giant middle cerebral artery aneurysm had a major recurrence and was retreated with a second WEB in combination with coiling.	
Liebig T, Kabbasch C, Strasilla C et al. (2015) Intracranial Flow Disruption in Acutely Ruptured Aneurysms: A Multicenter Retrospective Review of the Use of the WEB. American Journal of Neuroradiology 36: 1721-7	Case series n=47	This retrospective series showed good procedural safety, feasibility, and stability of mid-term occlusion in ruptured wide-neck bifurcation aneurysms.	Studies with more patients or longer follow up are included. Study is included in systematic review by Tau et al, 2018.
Limbucci N, Leone G, Rosi A et al. (2018) Endovascular Treatment of Unruptured Intracranial Aneurysms by the Woven EndoBridge Device (WEB): Are There Any Aspects Influencing Aneurysm Occlusion? World Neurosurgery 109: e183-e193	Case series n=24 FU=median 18 months	Endovascular treatment with WEB is a safe treatment for unruptured cerebral aneurysms, also resulting in a good adequate occlusion rate in aneurysms that would otherwise require complex assisted coiling techniques. However, results are less favourable in cases of very large aneurysmal neck.	Studies with more patients or longer follow up are included. Study is included in systematic review by Tau et al, 2018.
Lubicz B, Klisch J, Gauvrit JY et al. (2014) WEB-DL endovascular treatment of wide-neck bifurcation aneurysms: Short- and midterm results in a European study. American Journal of Neuroradiology 35: 432-438	Case series n=45 FU=median 13 months	The results suggest that the WEB endovascular treatment of wide-neck bifurcation aneurysms offers stable occlusion in a class of aneurysms that are historically unstable.	Studies with more patients or longer follow up are included.
Lubicz B, Mine B, Collignon L et al. (2013) WEB device for endovascular treatment of wide-neck bifurcation aneurysms. American Journal of Neuroradiology 34: 1209-14	Case series n=19 FU=12 months	Angiographic controls were obtained in all patients (mean 6 months), and they showed stable or improved results in all except 4 cases, including 2 complete occlusions, 15 near-complete occlusions, and 2 incomplete occlusions.	Studies with more patients or longer follow up are included.
Lv X, Zhang Y, Jiang W (2018) Systematic Review of Woven EndoBridge for Wide-Necked Bifurcation Aneurysms: Complications, Adequate Occlusion Rate, Morbidity, and Mortality. World Neurosurgery 110: 20-25	Systematic review n=935 (19 studies)	The thromboembolic complication rate was 8% (95% CI, 6%-11%). The overall bleeding complication rate was 2% (95% CI, 1%-3%). The adequate occlusion rate was 81% (95% CI, 76%-85%). Morbidity during follow up was 3% (95% CI, 1%-4%) (I ² =30%), and mortality was 2% (95% CI, 1%-3%).	A review with a more recent search date is included (Tau et al, 2018).
Mine B, Tancredi I, Aljishi A et al. (2016) Follow-up of intracranial aneurysms treated by a WEB flow disrupter: a comparative study of DSA and contrast-enhanced MR angiography. Journal of	Case series n=15	Contrast-enhanced MRA is a useful tool for the follow up of intracranial aneurysms (IAs) treated with a WEB-DL. However, early follow up with digital subtraction angiography	Study focuses on imaging techniques.

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Neurointerventional Surgery 8: 615-20		remains mandatory to detect inadequately occluded IAs.	
Muskens IS, Senders JT, Dasenbrock HH et al. (2017) The Woven Endobridge Device for Treatment of Intracranial Aneurysms: A Systematic Review. World Neurosurgery 98: 809-817.e1	Systematic review n=687 (19 papers)	Thromboembolic events were described in 71 patients (10% of all patients) and infarctions in 8 patients (1% of all patients). Despite initial promising results, the WEB device should be used with caution given its potentially large learning curve and because it has primarily been investigated only in wide-neck and bifurcation aneurysms.	A review with a more recent search date is included (Tau et al, 2018).
Papagiannaki C, Spelle L, Januel AC et al. (2014) WEB intrasaccular flow disruptor-prospective, multicenter experience in 83 patients with 85 aneurysms. American Journal of Neuroradiology 35: 2106-11	Case series n=83 FU=mean 5 months	Periprocedural complications=11% (9/83), leading to permanent neurologic deficits in 3 (4%). Morbidity and mortality at 1 month were 1% and 0%, respectively. Complete aneurysm occlusion was seen in 37/65 aneurysms (57%); neck remnant, in 23/65 (35%); and aneurysm remnant, in 5/65 (8%).	Studies with more patients or longer follow up are included.
Pierot L, Costalat V, Moret J et al. (2016) Safety and efficacy of aneurysm treatment with WEB: results of the WEBCAST study. Journal of Neurosurgery 124: 1250-6	Case series n=51 FU=6 months	The WEBCAST study showed good procedural and short-term safety of aneurysm treatment with WEB and good 6-month anatomical results.	Results from this study are included in Pierot et al, 2018 (study 2)
Pierot L, Gubucz I, Buhk JH et al. (2017) Safety and Efficacy of Aneurysm Treatment with the WEB: Results of the WEBCAST 2 Study. American Journal of Neuroradiology 38: 1151-1155	Case series n=55 FU=1 year	WEBCAST 2 confirms the high safety and efficacy of WEB aneurysm treatment showed in the WEBCAST and French Observatory studies.	Results from this study are included in Pierot et al, 2018 (study 2)
Pierot L, Klisch J, Cognard C et al. (2013) Endovascular WEB flow disruption in middle cerebral artery aneurysms: preliminary feasibility, clinical, and anatomical results in a multicenter study. Neurosurgery 73: 27-34	Case series n=33 FU=2 to 12 months	Mortality of the treatment was 0% and morbidity was 3% (intraoperative rupture with modified Rankin Scale score of 3 at the 1-month follow up). In short-term follow up, adequate occlusion (total occlusion or neck remnant) was seen in 83% of aneurysms.	Studies with more patients or longer follow up are included.
Pierot L, Klisch J, Liebig T et al. (2015) WEB-DL Endovascular Treatment of Wide-Neck Bifurcation Aneurysms: Long-Term Results in a European Series. American Journal of Neuroradiology 36: 2314-9	Case series n=45 FU=median 27 months	Long-term aneurysm occlusion in the 19 patients had the WEB only and did not have retreatment during follow up was complete occlusion in 68% (13/19) of patients, including aneurysms with opacification of the proximal recess in 9/19 patients (47%), neck remnant in 3/19 patients (16%), and aneurysm remnant in 3/19 patients (16%).	Studies with more patients or longer follow up are included.

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Pierot, L, Liebig T, Sychra V et al. (2012) Intracranial flow-disruption treatment of intracranial aneurysms: preliminary results of a multicenter clinical study. American Journal of Neuroradiology 33: 1232-8	Case series n=20 FU=2 to 8 months	One patient (5%) experienced transient clinical worsening (mRS 1 at 1 month, mRS 0 at 3 months) related to a thromboembolic event. Inadvertent detachment of the WEB was seen, and the WEB was retrieved in 1 patient, without adverse effects. In the short-term follow up, adequate occlusion (total occlusion or neck remnant) was seen in 80% of aneurysms.	Studies with more patients or longer follow up are included.
Pierot L, Moret J, Turjman F et al. (2016) WEB Treatment of Intracranial Aneurysms: Clinical and Anatomic Results in the French Observatory. American Journal of Neuroradiology 37: 655-9	Case series n=62 FU=1 year	This prospective French Observatory study showed very good safety of aneurysm treatment with the WEB, with a high rate of adequate aneurysm occlusion at 1 year (79%).	Results from this study are included in Pierot et al, 2018 (study 2)
Pierot L, Moret J, Turjman F et al. (2015) WEB Treatment of Intracranial Aneurysms: Feasibility, Complications, and 1-Month Safety Results with the WEB-DL and WEB-SL/SLS in the French Observatory. American Journal of Neuroradiology 36: 922-7	Case series n=62	This comparative study shows increased use of WEB treatment in ruptured, small, and anterior communicating artery aneurysms when using WEB-SL/SLS. There was a trend toward fewer thromboembolic complications with the WEB-SL/SLS. With both the WEB DL and WEB-SL/SLS, the treatment was safe, with low morbidity and no mortality.	Study focuses on comparison of different devices.
Pierot L, Spelle L, Molyneux A et al. (2016) Clinical and Anatomical Follow-up in Patients With Aneurysms Treated With the WEB Device: 1-Year Follow-up Report in the Cumulated Population of 2 Prospective, Multicenter Series (WEBCAST and French Observatory). Neurosurgery 78: 133-41	Case series n=113	The analysis in this large cumulated population of studies confirms favourable safety and efficacy of WEB treatment.	Results from these studies are included in Pierot et al, 2018 (study 2)
Piotin M, Biondi A, Sourour N et al. (2018) The LUNA aneurysm embolization system for intracranial aneurysm treatment: short-term, mid-term and long-term clinical and angiographic results. Journal of Neurointerventional Surgery 10: 12 e34	Case series n=63 FU=36 months	There was one instance of mortality (1/63, 2%). Morbidity was 0% (0/63) and 2% (1/63) at the 12-month and 36-month follow ups, respectively.	Studies with more patients or longer follow up are included.
Popielski J, Berlis A, Weber W et al. (2018) Two-Center Experience in the Endovascular Treatment of Ruptured and Unruptured Intracranial	Case series n=101 FU=12 months	Procedural complications occurred in 5% (5/102). Of these, 4 were thromboembolic events and 1 was an intraprocedural rupture.	Studies with more patients or longer follow up are included.

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Aneurysms Using the WEB Device: A Retrospective Analysis. American Journal of Neuroradiology 39: 111-117		Angiographic follow up showed a sufficient aneurysm occlusion in 81% (63/78) at 3 months and 78% (38/49) at 12 months. Delayed aneurysm ruptures have not been seen during the follow-up period to date.	
Raj R, Rautio R, Pekkola J et al. (2018) Treatment of Ruptured Intracranial Aneurysms Using the Woven EndoBridge Device: A Two-Center Experience. World Neurosurgery 18	Case series n=33 FU=6 months	For anatomically suitable ruptured IAs, WEB device treatment seems to be safe and results in acceptable occlusion rates. Still, larger studies with long-term results are needed before recommendations can be made.	Studies with more patients or longer follow up are included.
Sivan-Hoffmann R, Gory B, Riva R et al. (2015) One-Year Angiographic Follow-Up after WEB-SL Endovascular Treatment of Wide-Neck Bifurcation Intracranial Aneurysms. American Journal of Neuroradiology 36: 2320-4	Case series n=8 FU=1 year	Endovascular therapy of intracranial aneurysms with the WEB-SL device allows treatment of wide-neck aneurysms with a high rate of neck remnant at 1 year, at least partially explained by WEB compression. Initial size selection and technologic improvements could be an option for optimisation of aneurysm occlusion in WEB-SL treatment.	Studies with more patients or longer follow up are included.
Sourour NA, Vande Perre S, Maria FD et al. (2018) Medina Embolization Device for the Treatment of Intracranial Aneurysms: Safety and Angiographic Effectiveness at 6 Months. Neurosurgery 82: 55-162	Case series n=12 FU=6 to 9 months	One case of thromboembolic complication was seen in a ruptured anterior communicating artery aneurysm, without any clinical consequence at follow up. Grade A occlusion rate was 83% at follow up. Two cases (17%) of recanalisation were documented angiographically.	Studies with more patients or longer follow up are included.
van Rooij SBT, Peluso JP, Sluzewski M et al. (2018) The New Low-Profile WEB 17 System for Treatment of Intracranial Aneurysms: First Clinical Experiences. American Journal of Neuroradiology 39: 859-863	Case series n=40 FU=3 months	The WEB 17 is safe and effective for both ruptured and unruptured aneurysms. The WEB 17 is a valuable addition to the existing WEB size range, especially for very small aneurysms.	Studies with more patients or longer follow up are included.
van Rooij SBT, van Rooij WJ, Peluso JP et al. (2017) WEB Treatment of Ruptured Intracranial Aneurysms: A Single-Center Cohort of 100 Patients. American Journal of Neuroradiology 38: 2282-2287	Case series n=100 FU=3 months	Treatment of small ruptured aneurysms with the Woven EndoBridge was safe and effective. The Woven EndoBridge proved to be a valuable alternative to coils without the need for stents or balloons.	Studies with more patients or longer follow up are included.
van Rooij SB, van Rooij WJ, Peluso JP et al. (2018) The Woven EndoBridge (WEB) as primary treatment for	Case series n=51 FU=3 months	WEB treatment is safe and effective in selected unruptured aneurysms suitable for the	Studies with more patients or longer follow up are included.

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unruptured intracranial aneurysms. <i>Interventional Neuroradiology</i> 24: 475-481		device, regardless of neck size or location.	
van Rooij S, Peluso JP, Sluzewski M et al. (2018) Mid-term 3T MRA follow-up of intracranial aneurysms treated with the Woven EndoBridge. <i>Interventional Neuroradiology</i> 24: 601-607	Case series n=52 FU=mean 20 months	WEB-treated aneurysms with adequate occlusion at three-month angiography remained stable during serial 3T MRA follow up of 18-36 months. One aneurysm reopened during the 6- to 18-month interval. Once the WEB-treated aneurysm is adequately occluded in the short term, later reopening is uncommon.	Studies with more patients or longer follow up are included.
van Rooij WJ, Peluso JP, Bechan RS et al. (2016) WEB Treatment of Ruptured Intracranial Aneurysms. <i>American Journal of Neuroradiology</i> 37: 1679-83	Case series n=32 FU=3 months	WEB treatment of small ruptured aneurysms was safe and effective without the need for anticoagulation, adjunctive stents, or balloons. Our preliminary experience indicates that the WEB may be a valuable alternative to coils in the treatment of acutely ruptured aneurysms.	Studies with more patients or longer follow up are included.

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