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Original research

Retrospective multicenter analysis of the Trenza Embolization Device for endovascular therapy of intracranial aneurysms: initial results and short-term follow-up

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ABSTRACT

Background Intrasaccular devices are increasingly used in endovascular therapy of intracranial aneurysms, in particular wide-necked and ruptured aneurysms. The Trenza Embolization Device (TED) is an innovative intrasaccular device for medium- to large-sized aneurysms. Currently, literature about the TED is scarce.

Methods In eight participating European centers, 25 aneurysms (3 ruptured) in 25 patients (18 females, mean age 62.4 years) treated with the TED outside the currently recruiting prospective, post-market, multicenter study were included in this retrospective, multicenter analysis. Primary endpoints for clinical safety were the absence of stroke and death. Primary endpoint for technical success was implantation of TED without necessity of adjunct stenting. Primary and secondary endpoints for efficacy were adequate angiographic occlusion according to the Modified Raymond–Roy Classification (MRRC) immediately after the procedure and at first follow-up (FU).

Results Stent-assistance was required in two cases. Thus primary endpoint for technical success was reached in 23/25 (92%) cases. With one symptomatic thrombotic event, primary safety endpoint was reached in 24/25 (96%) cases. At the end of the procedure, complete occlusion (MRRC I) was achieved in 12/25 (48%), and a small residual neck (MRRC II) remained in 13/25 (52%) cases. In 19 cases FU (mean 6 months) was available, showing adequate occlusion in 17/19 (89.5%) cases (MRRC I in 8/19 and stable MRRC II in 9/19 cases) and relevant reperfusion MRRC IIIa with indication to retreatment in 2/19 (10.5%) cases.

Conclusions The results of this first retrospective, multicenter experience with the TED appear promising. Further prospective, multicenter studies with larger patient cohorts, as well as long-term FU, are required.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Since their introduction, intraaneurysmal devices are an increasingly utilized option in endovascular therapy (EVT) of intracranial aneurysms. Their increased stability compared with simple or balloon-assisted coiling allows treatment of wide-necked aneurysms. As, contrary to stent-assisted coiling, no foreign material is left in the parent vessel, patients treated with intrasaccular devices normally should not require dual antiplatelet therapy (DAPT), allowing their use in patients with acute subarachnoid hemorrhage and in patients with other contraindications for DAPT or long-term single antiplatelet therapy (SAPT). The published literature on the novel Trenza Embolization Device (TED) so far only includes a single-center case series with short-term follow-up, while a prospective, post-market, multicenter study is still recruiting.

WHAT THIS STUDY ADDS

⇒ This study is the first multicenter analysis of initial experience and short-term follow-up of the TED, a novel intrasaccular device combining features of a braided intrasaccular flow disruptor, and a three-dimensional framing coil. In this study, the TED shows efficacy and safety comparable to currently available intrasaccular devices.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These data encourage further prospective and multicenter evaluation of this innovative device as it expands the armamentarium of EVT of wide-necked aneurysms in both elective and subarachnoid hemorrhage cases.

INTRODUCTION

For more than two decades, endovascular treatment (EVT) by coiling has been an established therapy for ruptured[1 2] and unruptured[3] intracranial aneurysms. Historically, only intracranial aneurysms with simple configuration and relatively narrow neck were eligible for coiling, while wide-necked aneurysms (WNA) required surgical clipping.

As materials and techniques evolved from simple coiling to balloon-assisted- (BAC) and stent-assisted coiling (SAC), to flow diversion with flow diverting stents (FDS), and intrasaccular flow disruptors, EVT of WNA and complex-configured aneurysms was increasingly enabled

and has become the preferred therapy for the majority of cerebral aneurysms. Nonetheless, EVT of WNA remains frequently challenging, as coils tend to dislocate into the parent artery. BAC may stabilize the coil basket but has limitations when the dome-to-neck ratio (DNR) is too unfavorable.[4] In such cases, SAC has been shown to be effective,[5] but even contemporary low-profile, laser-cut stents require sufficient inhibition of platelet aggregation, usually with temporary double antiplatelet therapy (DAPT) and followed by long-term single antiplatelet therapy (SAPT). The implantation of FDS is associated with increased thrombembolic complication rates and demands antiplatelet medication as well, usually DAPT, while only in selected cases with surface-modified FDS at least SAPT might be safe and efficient as well.[6 7] As inhibition of platelet aggregation is unfavorable in patients with acute subarachnoid hemorrhage (SAH) in general, intraaneurysmal embolization devices or flow disruptors, not leaving material in the parent artery and thus making antiplatelet therapy superfluous, are advantageous in SAH cases, and other conditions when antiplatelet therapy is considered contraindicated.

The Trenza Embolization Device (TED) is a novel device for dedicated intraaneurymatic implantation, allowing its use in ruptured aneurysms as well. The current literature about the TED is scarce, as recently only one single-center case report with 12 consecutive cases has been published,[8] while a prospective, post-market, multicenter study named TREAT (ClinicalTrials.gov ID NCT04380350) is still recruiting. To date, no multicenter results of the TED have been published.

In contrast to braided intrasaccular flow disruptors on the market, like the first introduced and currently best studied one, the Woven Endobridge (WEB) (Microvention),[9] or the newer devices Contour (Stryker, previously Cerus Endovascular),[10] or Artisse (Medtronic),[11] the implantation of a single TED is not supposed to sufficiently disrupt the flow inside the aneurysm but to deliver a stable basket with good neck coverage and wall apposition for consecutive coil embolization.

METHODS

We contacted several neuroradiological centers across Europe that were already using the TED outside the currently recruiting, prospective, post-market study in order to perform a retrospective multicenter evaluation of safety as well as initial and short-term efficacy of these first cases with this novel device. Demographic, clinical, angiographic, and procedural data were collected retrospectively. All personal patient data remained exclusively at each contributing center; only anonymized data were sent to the evaluating center. Thus, ethical approval was waived by the leading institution's ethics committee.

Patient population

Between July 2022 and December 2023, in all eight participating centers, the TED was utilized in 25 intracranial aneurysms (3 ruptured, 22 incidental) of 25 patients (18 males, 7 females; mean age 62.4 years, ranging from 39 to 83 years) outside the TREAT study. Those centers that also had been or later became involved in the TREAT study only contributed those cases that were performd before joining the TREAT study and with exclusion crtiteria for the TREAT study.

The decision regarding implantation of the TED was taken by the treating neurointerventionalist based on the clinical and angiographic presentation of the aneurysm. In table 1, patient demographics and baseline clinical features are shown.

Table 1 Patient demographics, clinical presentation, and aneurysm localization

Gender	n (%)
Female	18 (72)
Male	7 (28)
Age, mean (range), years	62.4 (39–83)
Clinical status	
Incidental	22 (88)
Subarachnoid hemorrhage (SAH)	3 (12)
Aneurysm location	
Internal carotid artery (ICA)	4 (16)
Posterior communicating artery (PComA)	4 (16)
Middle cerebral artery (MCA)	8 (32)
Anterior communicating artery (AComA)	2 (8)
Pericallosal artery	1 (4)
Basilar tip	5 (20)
Posterior cerebral artery (PCA)	1 (4)

All data are given as numbers and percentages unless otherwise stated.

The Trenza Embolization Device (TED)

The CE-certified TED by Stryker is a novel intrasaccular device, combining the flexibility of coils with the increased stability of intraaneurysmal devices. It is designed as a 1.25 mm-wide braid of 24 nitinol-platinum wires and a short coil segment at the distal tip, like traditional three-dimensional (3D) framing coils taking up a spherical configuration when leaving the microcatheter (figure 1), but providing superior wall apposition and a more stable basket for consecutive coil embolization. It is available in the following sizes (secondary outer diameter (mm) × total implant length (cm)): 6×11, 7×13, 8×15, 9×16, 10×18, 11×19, and 12×21. The radiopaque proximal end is connected to the target delivery wire of 185 mm in length, with fluorosave markers and proximal InZone Detachment (figure 1). The delivery of the TED is provided via the Excelsior 1018 (Stryker), a microcatheter of 150 cm length in total (115 cm proximal shaft with three layers of stainless steel braid for sufficient support, 33 cm mid-shaft transition and braid of helical coil transitions for enhanced trackability, and 12 cm distal segment of stainless steel helical coil reinforcement for lumen integrity, stability, and flexibility) and 0.48 mm (0.019 inch) inner diameter. Like conventional microcatheters for coiling, the Excelsior 1018 has two radiopaque markers, one at the tip (distal marker) and one 3 cm proximal to the tip (proximal marker). The TED is electrolytically detachable via Stryker's InZone Detachment system. The TED is suitable for aneurysms with spherical configuration or at least a spherical part at the base of the aneurysm. Sizing of the TED is comparable to sizing of a 3D framing coil. The size of the appropriate TED can be calculated as one-third of the sum of the aneurysm diameters in three dimensions. In smaller and ruptured aneurysms, slight undersizing is recommended.

Antiplatelet therapy

As the TED is designed for intraaneurysmal implantation, there is no systematic recommendation for the use of antiplatelet therapy, but of course antiplatelets reduce the risk of thromboembolic events and can become necessary when stent-assistance as bailout strategy is chosen. Thus, the use of antiplatelet medication relied on the discretion of the neurointerventionalist and was inhomogenous in our retrospective, multicenter series. In

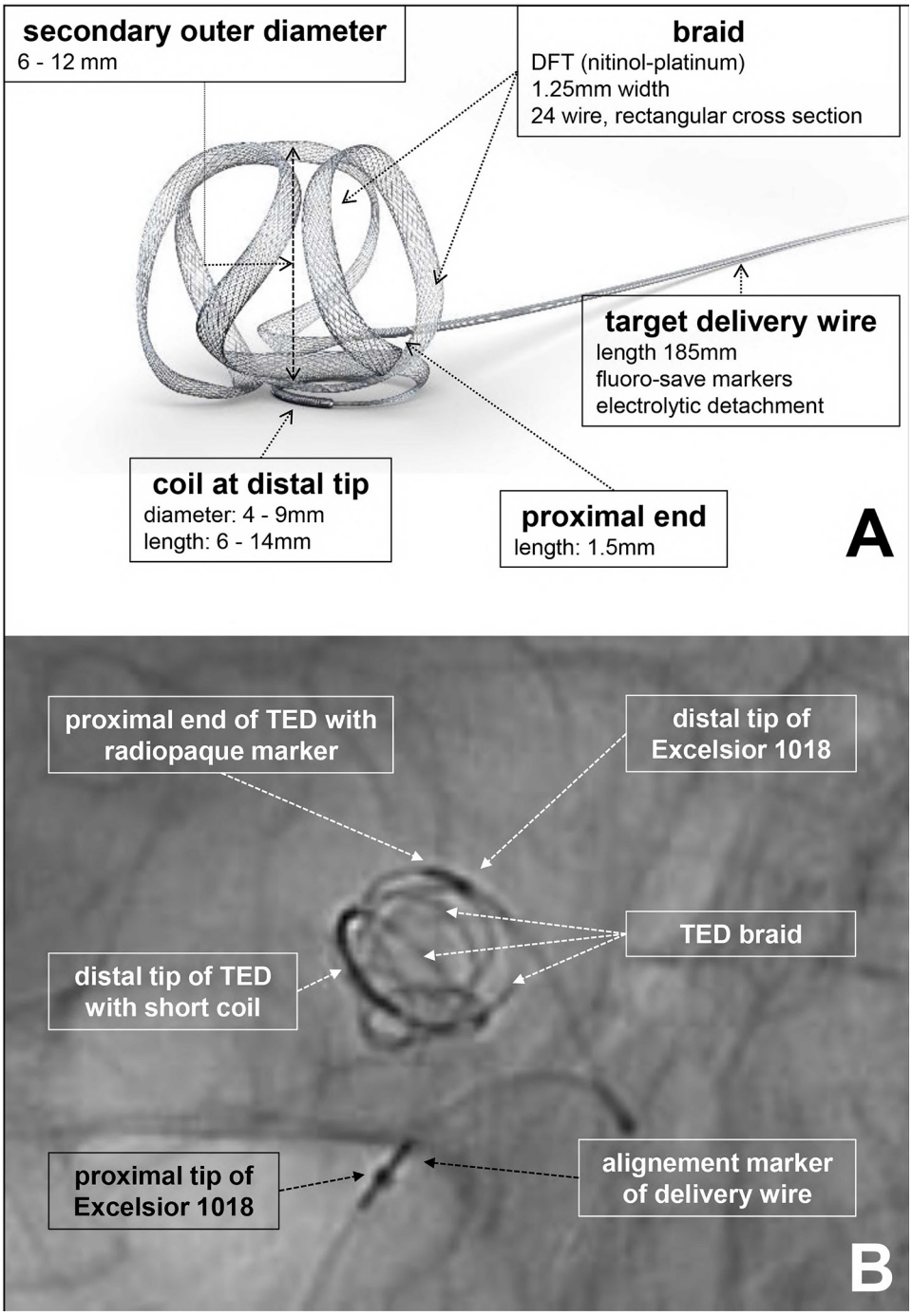

Figure 1 Trenza Embolization Device (TED). A: Technical overview (courtesy of Stryker). B: In vivo.

two of the three SAH cases, 500 mg acetylsalicylic acid (ASA) was administered intravenously (IV) once during the procedure, whereas in the other SAH case no antiplatelet medication was administered. In the 22 elective cases, 11 procedures were performed under DAPT, 10 under SAPT, and only one without any antiplatelet medication but only IV heparin. Standard DAPT regimen was daily dose of 100 mg ASA and 75 mg clopidogrel, with start at least 5 days prior to the procedure or application of a loading dose of 500 mg ASA and 300 mg clopidogrel. In the case of clopidogrel non-response, daily 10 mg prasugrel was used (this was required in two cases), and started at least 5 days prior to the procedure as well. After the procedures with adjunctive stenting (n=2), DAPT (ASA and clopidogrel) was continued for at least 3–6 months, and then SAPT with ASA was continued permanently. The periprocedural antiplatelet regimen is illustrated in table 2. In the majority of cases without additional stenting, antiplatelet medication was ceased after the procedure. However, this decision relied on the discretion of the interventionalist. In all cases, an IV bolus of standard heparin (70–100 IU/kg) initiated anticoagulation, maintained through IV administration to sustain an activated clotting time of 250–300 s, or 2–2.5 times the baseline value during the endovascular procedure.

Endovascular procedures

All endovascular interventions were performed using state-of-the-art, biplane angio suites under general anesthesia. Access via coaxial or triaxial catheters was at the discretion of the treating neurointerventionalists, depending on the anatomy and

Table 2 Antiplatelet medication during the procedures

Cases (n (%))	Antiplatelet medication
SAH cases	
2/3 (66)	ASA intraprocedurally
1/3 (33)	No antiplatelets
Elective cases	
9/22 (41)	Standard DAPT (ASA and clopidogrel)
2/22 (9)	Modified DAPT (ASA and prasugrel)
5/22 (23)	SAPT with ASA
4/22 (18)	SAPT with clopidogrel
1/22 (4.5)	Anticoagulation with apixaban
1/22 (4.5)	No antiplatelets

ASA, acetylsalicylic aci; DAPT, double antiplatelet therapy; SAH, subarachnoid hemorrhage ; SAPT, single antiplatelet therapy.

tortuosity of vessels. The optimal working projection was identified on standard biplane projections, as well as 3D rotational angiography. Using standard 0.014 inch microwires, the Excelsior 1018 microcatheter was positioned inside the aneurysm. Selection of the size of the TED was based on the measurements on the 3D rotational angiograms. The TED and consecutive coils were deployed via Excelsior 1018 microcatheter. In two cases where no stable intraaneurysmal position of the TED and/or consecutive coils could be achieved, adjunct stent-assistance or balloon- and stent-assistance was used. After implantation of the TED device, consecutive coiling was performed with Stryker coils (Target XL, Target 360 soft, Target 360 ultra, and/or Target Nano), compatible with Stryker's InZone Detachment system as well. The size of the TED, diameter and length of the first and last coil, as well as total number of implanted coils are listed in table 3.

A representative case is illustrated in figure 2.

Endpoints

Primary endpoint for technical success of the procedure was implantation of the TED without the necessity of additional stent-assistance. The efficacy of the procedure was evaluated by the interventionalist according to the MRRC[12] at the end of the procedure and at first FU. MRRC type I and stable type II were deemed adequate aneurysm occlusion. Neurological examination was performed immediately after the procedure, at discharge, and at first FU. Any procedure-related death or stroke with permanent neurological deficit was regarded as missing of primary safety endpoint.

RESULTS

Patients and aneurysm characteristics

Some 25 aneurysms in 25 patients (18 females, mean age 62.4 years, ranging from 39 to 83 years) treated with the TED were suitable for our evaluation. Three (12%) of these patients presented with aneurysmatic SAH and were treated in an emergency setting, while the intervention in 22 patients with incidental aneurysms was performed electively. In the three SAH cases, two patients presented with Hunt and Hess (HH) grade 2 and one with HH grade 3. Location of the aneurysms was as follows: four aneurysms were located at the internal carotid artery (ICA; 16%), another four aneurysms were located at the posterior communicating artery (PComA; 16%), eight aneurysms originated from the middle cerebral artery (MCA; 32%), and two aneurysms originated from the anterior communicating artery (AComA; 8%). In table 1, patient demographics and baseline clinical features are shown. Mean aneurysm diameter was 9.38 mm (ranging from 6.5 to 20.0 mm) and mean DNR was 1.74 (ranging from 1.00 to 3.00). In table 3, aneurysm features and details of neurointerventional procedures are shown.

Technical results and effectiveness

An initially selected TED was implanted in 24/25 (96%) cases; in one case, the initially selected TED was considered to be undersized and the next larger device was successfully implanted. In 6/25 (24%) aneurysms, two TED were implanted. No inopportune release or misdetachment was reported. In 2/25 (8%) cases with unfavorable DNR of 1.25 and 1.00, respectively, adjunct devices were necessary; in one case stent-assistance, and in the other both balloon- and stent-assistance. Thus the endpoint of technical success was reached in 23/25 (92%) cases. Initial aneurysm occlusion at the end of the procedure was adequate in 25/25 (100%), MRRC I in 12/25 (48%), and MRRC II in 13/25 (52%) cases. In 19 cases, FU (mean 6 months, range 3–11 months) was available, showing adequate aneurysm occlusion in 17/19 (89.5%), MRRC I in 8/19, and stable MRRC II in 9/19 cases, while 2/19 aneurysms (10.5%) with initially occlusion MRRC II showed relevant reperfusion MRRC IIIa with indication to re-therapy.

Safety and outcomes

In one of the elective cases (1/25, 4%), under standard DAPT preloaded with ASA and clopidogrel, in a procedure where adjunct stent-assistance as a bailout was necessary, a symptomatic thrombembolic event occurred. Immediately postprocedure until discharge, the affected patient's modified Rankin Score (mRS) was 2, and improved to 1 until clinical follow-up after 3 months. Except for this thrombembolic event, no further complications or adverse events occurred in this series. The three patients with SAH presented with preprocedure mRS 0, 0, and 1, at discharge mRS 0, 0, and 5, and at follow-up mRS 0, 0, and 1, respectively. The third SAH patient's apparent clinical deterioration after the procedure and at discharge can be explained by the clinical course and is not related to the procedure. During the EVT, no complications occurred, but in the postinterventional course an external ventricular drain and finally a ventriculoperitoneal shunt were necessary. Since the patient remained intubated in the intensive care unit throughout the entire postinterventional hospital stay and during transfer to the rehabilitation clinic, an adequate neurological assessment was not possible. Therefore, mRS 5 was scored postinterventionally and at discharge. After weaning from mechanical ventilation during the rehabilitation treatment, the patient showed satisfactory recovery and presented with mRS 1 at the FU examination.

DISCUSSION

In this retrospective, multicenter evaluation, the TED could be implanted in 100% of cases, but in 8% of cases with unfavorable DNR, additional stent-assistance was necessary. Except for one symptomatic thrombembolic event (4%), no further relevant complications were observed, and so from this small series we assume the TED to be relatively safe. Adequate aneurysm occlusion MRRC I or II at the end of the procedure was achieved in 100% and remained stable in 89.5% of cases during short-term (mean 6 months) FU.

In Raj and Numminen's single-center series of 12 consecutive aneurysms (two ruptured) treated with the TED, the incidence

Table 3 Aneurysm features and details of neurointerventional features

Case	Clinical presentation	Location	Maximum diameter (mm)	Neck (mm)	DNR	TED size(s) (mm x cm)	Additional coils (n)	Diameter x length of first coil (mm x cm)	Diameter x length of last coil (mm x cm)	Adjunct devices	Complications	MRRC initial	Months until first FU	FU modality and month	MRRC FU	Indication to re-therapy
1	Elective	PComA	7.5	4	1.25	6×11	7	5×10	2×4	Stent	No	I	6	DSA	I	No
2	Elective	AComA	7.5	5	1.5	7×13	8	6×15	2×4	No	No	I	6	DSA	I	No
3	Elective	Basilar tip	11	4	2.25	10×18, 7×13	6	5×15	4×12	No	No	I	6	DSA	I	No
4	Elective	Basilar tip	6.5	3.5	1.42	6×11	3	5×10	3×6	No	No	II	5	DSA	II	No
5	Elective	ICA	7	5	1.4	6×11	6	5×10	2×3	No	No	I	6	DSA	I	No
6	SAH (HH 2)	MCA	19	6	3	11×19, 10×18	14	9×30	2×4	No	No	II	9	DSA	II	No
7	SAH (HH 2)	PComA	8	4	2	7×13	5	5×15	1×3	No	No	II	7	DSA	II	No
8	SAH (HH 3)	AComA	9	6	1.5	9×16	10	7×20	2.5×4	No	No	II	9	DSA	II	No
9	Elective	Basilar tip	7	4	1.5	6×11	4	5×10	3×8	No	No	II	8	DSA	II	No
10	Elective	Basilar tip	11	12	1	11×19, 9×16	12	8×30	3×8	Balloon, stent	Symptomatic thromboembolic, dissolved at 3- month clinical control	II	11	MRI	II	No
11	Elective	MCA	16	6	2	12×21, 11×19	18	12×45	2.5×6	No	No	II	6	DSA	II	No
12	Elective	MCA	7	5	1	6×11	4	5×10	3×8	No	No	II	3	MRI	I	No
13	Elective	MCA	8	5	1.6	7×13	9	6×30	1.5×4	No	No	I	3	MRI	I	No
14	Elective	PComA	7	4	1.5	6×11	7	5×15	1×3	No	No	I	4	MRI	I	No
15	Elective	ICA	8	4	1.7	7×13	3	5×20	4×8	No	No	I	8	DSA	I	No
16	Elective	ICA	8	5	1	8×15, 7×13	3	5×20	4×15	No	No	II	6	DSA	II	No
17	Elective	MCA	10	6	1.4	8×15	5	6×20	4×10	No	No	II	5	DSA	IIIa	Yes
18	Elective	MCA	7	2	2.5	7×13	3	6×15	4×15	No	No	II	NA	NA		
19	Elective	MCA	8	2.5	2	9×16	3	7×30	2.5×6	No	No	I	6	DSA	II	No
20	Elective	MCA	8	2.8	1.8	8×15	3	6×20	4×15	No	No	I	NA	NA		
21	Elective	Basilar tip	7	3	2	7×13	4	6×20	3×10	No	No	I	NA	NA		
22	Elective	PCA	7	2	3	7×13	3	6×20	3×6	No	No	I	NA	NA		
23	Elective	Pericallosal artery	11	6.5	1.3	9×16	3	7×20	4×12	No	No	II	NA	NA		
24	Elective	PComA	9	8	1	8×15	6	6×20	2×4	No	No	I	NA	NA		
25	Elective	ICA	20	7	2.57	12×21, 10×18	14	12×45	4×15	No	No	II	6	DSA	IIIa	Yes

AcomA, anterior communicating artery; DNR, dome-to-neck ratio; DSA, digital subtraction angiography ; FU, follow-up; HH, Hunt and Hess; ICA, internal carotid artery; MCA, middle cerebral artery; MRI, magnetic resonance imaging; MRRC, Modified Raymond–Roy Classification; NA, not available; PComA, posterior communicating artery; SAH, subarachnoid hemorrhage; TED, Trenza Embolization Device.

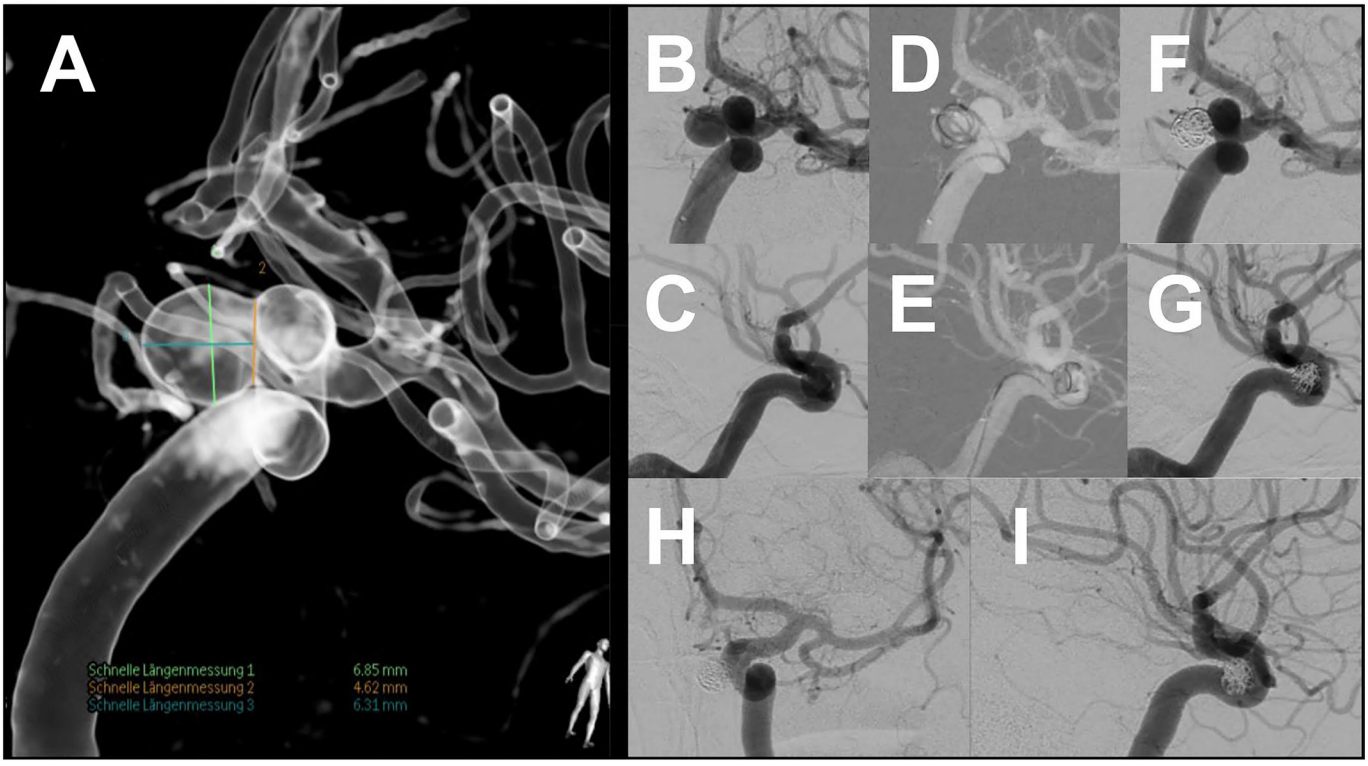

Figure 2 Illustrative case of a wide-neck left internal carotid artery aneurysm with dome-to-neck ratio of 1.4. A: Translucent three-dimensional (3D) rendering after 3D rotational angiography; B–G: Biplane digital subtraction angiography (DSA) in working projection prior (B and C), after positioning of the Trenza Embolization Device (D and E), and after consecutive packing with platinum coils (F and G). (H and I): Biplane DSA after 6 months follow-up shows stable complete occlusion of the aneurysm (Modified Raymond–Roy Classification (MRRC) I).

of major complications was higher. In their study, in 3/12 cases (25%) major ischemic complications were reported, in 2/12 patients (17%) with permanent, and in 1/12 patients (8%) with transient neurological deficit.[8] Furthermore, fatal rupture of a treated aneurysm occurred in 1/12 cases (8%) of Raj and Numminen's cases 1.6 months after initial treatment. Adequate aneurysm occlusion at first FU (mean 6.5 months) was achieved in 10/12 cases (83%), and in 2/12 cases (17%) retreatment was indicated.[8]

It is worth mentioning that the only symptomatic thromboembolic event in our series of 25 patients occurred despite DAPT after preloading with ASA and clopidogrel but during a challenging procedure with bailout stent-assistance. As the TED is designed for intraaneurysmal implantation, there is no systematic recommendation for the use of antiplatelet therapy, but of course antiplatelets reduce the risk of thromboembolic events, and should be considered when an unfavorable DTN ratio indicates a high probability of need for adjunct stenting.

In our study, adequate aneurysm occlusion was achieved in 100% of cases at the end of the procedure and remained stable in 89.5% of cases during the short FU interval. Thus, retreatment after 6 months was indicated in 10.5% of our cases and in 17% in Raj and Numminen's series. Currently, there exists no reliable published data on aneurysm reperfusion after initial therapy with the TED, and no published data about the safety and efficacy of recoiling in these cases at all.

The concept of TED differs from that of available intraaneurysmal flow disruptors like the WEB, Contour, and Artisse, which are designed to disrupt the flow into the treated aneurysm, and are intended to lead to stasis and consequently thrombosis after the implantation of one single device. Due to its braided design, the TED has certain flow-diverting effects, but these are neither sufficient nor intended to independently occlude the aneurysm. Instead, the device provides a stable basket for subsequent dense packing with coils.

To date, the WEB by far is the most used and best studied of these intraaneurysmal devices, as its first-generation device was introduced in 2010. The initial version of this electrolytically detachable braided nitinol cage was the WEB-DL (dual layer), and in 2013 the lower profile WEB-SL (single layer) and WEB-SLS (single layer spherical) were introduced. Several large retrospective and prospective case series, as well as meta-analyses, of the WEB have already been published.

The Woven Endobridge Intrasaccular Therapy (WEB-IT) study is a pivotal, prospective, single-arm, investigational study for evaluation of the safety and effectiveness of the WEB. In the WEB-IT procedural and 30-day safety results, only one primary safety endpoint in 150 patients (0.7%) occurred, a delayed parenchymal hemorrhage 22 days after treatment. The rate of minor ischemic strokes was 4.7%, of transient ischemic attacks 2.7%, and of minor SAH 1.3%.[13] After 30 days through 1 year, no further primary endpoints were observed, and angiographic 12-month FU showed complete aneurysm occlusion in 53.8% and adequate occlusion in 84.6% of cases.[14] During the 5-year FU, none of the treated aneurysms bled or rebled; and after 1 year, no procedure- or device-related complications occurred. At 5-year FU, complete occlusion was observed in 58.1% and adequate occlusion in 87.2% of cases.[9] Thus, in the WEB-IT study, aneurysm occlusion rates achieved at 1 year remained durable until the 5-year FU, as rates of progressive thrombosis exceeded aneurysm recurrence.[9]

In a recent retrospective, multicenter evaluation of the World Wide WEB Consortium, 671 patients with 683 aneurysms (26.2% ruptured) treated with the WEB were included.

Thrombembolic complications occurred in 7.5% of cases, of which only 4.0% were symptomatic and 2.0% permanent. Hemorrhagic complications occurred in 3.0% of cases. During FU (median 11 months), 85.7% adequate occlusion and 57.8% complete occlusion was reported.[15]

Long-term outcomes of the WEB in recent systematic reviews and meta-analyses were reported as 87.1%, 91.2%, and 88.9% adequate occlusion at 1 year, beyond 1 year, and at/beyond 2 years FU, respectively. Retreatment rate increased from 3.5% at 1 year to 7.1% beyond 1 year FU.[16]

In the combined population of the two prospective, multicenter studies WEBCAST and WEBCAST-2, mortality at 5 years was 7% but was not related to the WEB, while 1% were related to the procedure and 6% to other conditions. Adequate aneurysm occlusion at 5-year FU was 77.9%, and retreatment rate at 5 years was 11.6%.[17]

The Contour is another, later introduced, electrolytically detachable, intraaneurysmal device with a bowl-shaped mesh structure that is implanted at the aneurysm neck and acts as an intraaneurysmal flow disruptor and a flow diverter. Compared with the WEB, sizing of the Contour appears easier and faster, as Gärtner *et al* report a lower number of necessary device changes and assume that using the Contour demands less extended training.[18] In another direct comparison, both devices showed the same satisfying adequate occlusion rates of 90%, but the percentage of complete occlusion at last FU was higher in the Contour group (75% vs 63.3% in the WEB group).[19] Furthermore, the WEB showed higher retreatment rates and significantly longer deployment times than Contour.[19] In the pre-market CERUS study,[10] the Contour device was implanted in 32/34 (94.1%) aneurysms in the intention-to-treat group. Two patients (5.9%) met the primary safety endpoint of major stroke or non-accidental death. Regarding efficacy, total occlusion was achieved in 44% of cases at 6 months, 69% at 12 months, and adequate occlusion in 84% at last FU, while one patient (3.1%) was retreated during the FU period.[10]

In two single-center case series with 14[20] and 60[21] endovascularly treated intracranial aneurysms, Contour was successfully implanted in 11/14 (78.6%) and in 54/60 (90%) cases. In the smaller series by Akhunbay-Fudge *et al*, with 11 successfully implanted Contour devices, thrombembolic events occurred in 18.1% of cases without causing permanent sequelae. In 12 months' FU, complete occlusion was 55.6% and adequate occlusion was 44.4%.[20] The larger series of Biondi *et al* with 54 successfully implanted Contour devices showed thrombembolic events in 6.7% of cases, also without permanent neurological deficit or death.[21] Biondi *et al* evaluated aneurysm occlusion immediately postprocedurally, at 24 hours, at 3 months, and 12 months, showing adequate occlusion of 31.5%, 62.3%, 81.4%, and 89.3%, respectively.[21] However, for Contour, the results of long-term FU beyond 12 months are still pending.

For the electrolytically detachable, braided nitinol-cage Artisse, another intraaneurysmal flow disruptor, literature about its safety and efficacy profile is still scarce. To date, only a small, single-center series with nine subjects has been published in 2022 by Piotin *et al*,[11] reporting adequate aneurysm occlusion in 66.7% of cases at 6 months and 56.2% at 36 months. As relevant procedure-related complications, 22.2% major strokes were reported. For Artisse's predecessor version, Luna (Medtronic), data from a post-market, prospective, multicenter study including 64 aneurysms were published in 2018 by Piotin *et al*[22] as well. In this large series, adequate aneurysm occlusion rates of 78.0% and 79.2% at 12 and 36 months FU, respectively, were reported. Major stroke occurred in 3.2%, minor stroke in 1.6%, and intracranial hemorrhage in 3.2% of cases prior to the 12-month FU. Morbidity was 0% and 1.8% at 12 and 36 months FU, respectively.

Regarding its design, the TED probably shows the most similarities with the Medina device (Medtronic), which consists of a 3D coil core that is covered with a metal mesh. It is supposed to spherically configure inside the aneurysm, acting as an intraaneurysmal flow disruptor by covering the neck. However, adequate aneurysm occlusion is supposed to be achieved by one Medina device alone, without the necessity of further coiling. With the Medina device, adequate aneurysm occlusions of 83.0%,[23] 90.9%,[24] 75.0%,[25] and 71.4%[26] at short-term FU have been reported. Long-term FU (mean 17.7 months) data, showing an adequate aneurysm occlusion rate of 80.0%, have only been published by Haffaf *et al*.[25] Although designed to adequately occlude the aneurysm alone, in some series high percentages of conjunct devices were used to achieve these satisfying occlusion rates. Sourour *et al* report 85.0% aneurysms additionally treated with conventional coils,[23] and Aguilar *et al* report 71.4% use of adjunctive devices.[24] An optimal device configuration with sufficient coverage of the aneurysm neck is important and may require several attempts at deployment, and Frölich *et al* have demonstrated in flow models that the intraaneurysmal flow disruption of the Medina device correlates with neck coverage and total neck area.[27] However, the Medina device could not prevail on the market and is no longer available.

In our initial and short-term experience, the TED shows a satisfying safety and efficacy profile, comparable to available competing intraaneurysmal devices, and seems to be a promising additional option in the armamentarium of EVT of cerebral aneurysms, in particular WNA. Sizing and handling of the TED are comparable to a very stable framing 3D coil, affording careful deployment with often several repositionings to achieve sufficient wall apposition and, particularly, neck coverage. In our series, no device-related complications occurred. Of course, further data from prospective, multicenter studies with larger patient cohorts, and long-term FU in particular, are required.

Limitations

This study has several limitations, due to the retrospective design and relatively small number of included patients (n=25) with incomplete FU data (19/25) and relatively short FU interval. Moreover, the baseline, intra- and postinterventional imaging were not core-laboratory evaluated, and consistent reporting of complications and adverse events was not ensured by a central clinical events committee, potentially resulting in heterogeneity.

CONCLUSIONS

This study is the first multicenter analysis of initial experience and short-term FU of the TED, a novel, intrasaccular device combining features of a braided intrasaccular flow diverter and a 3D framing coil. Due to its braided design, the TED has certain flow-diverting effects, but these are neither sufficient nor intended to independently occlude the aneurysm. Instead, it provides a stable basket for subsequent dense packing with coils. Sizing and handling are more similar to a framing coil than to any of the available intraaneurysmal flow diverters. In our analysis, the TED demonstrated safety and efficacy comparable to available intrasaccular devices. These data encourage further prospective and multicenter evaluation of this innovative device as it expands the armamentarium of EVT of WNA in both elective and SAH cases.

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