

# Endovascular Treatment of Cerebral Aneurysms Using the Leo Stent: Long-Term Follow-Up and Expansion of Indications

Bernhard Kis<sup>\*1 2</sup>, Werner Weber<sup>\*3</sup>, Friedrich Götz<sup>4</sup>, Hartmut Becker<sup>4</sup>, Peter Berlit<sup>1</sup>, Dietmar Kühne<sup>3</sup>

## Abstract

**Purpose:** The authors share their extended experience using the Leo stent. Building on their earlier work, they present more cases, a longer follow-up period, and expansion of indications for use of the stent.

**Patients and Methods:** A total of 71 patients with 75 aneurysms were included in this study. 61 saccular and broad-necked intracranial aneurysms and twelve fusiform lesions were treated electively.

**Results:** Stent deployment was successful for 98% of the saccular aneurysms. Initial complete obliteration was achieved in 26 saccular aneurysms, a neck remnant in six, a residual aneurysm in four, while no immediate coil embolization was chosen for 25. Angiographic follow-up after 11 months available for 56 saccular aneurysms revealed unaffected parent arteries in 94%. Eleven saccular aneurysms exhibited spontaneous thrombosing after stent deployment without coiling and four lesions had recanalized (three residual aneurysms, one neck remnant). Regarding long-term follow-up  $\geq 12$  months, available for 26 saccular aneurysms, none of them showed parent artery affection. A recanalization was evident in three saccular aneurysms. All stents were successfully deployed for the fusiform aneurysms. Three patients with large fusiform aneurysms of the basilar artery had a lethal outcome. No clinical complications occurred in the remaining cases.

**Conclusion:** The authors confirmed the efficacy of the Leo stent for the treatment of saccular and broad-necked intracranial aneurysms. Mid- and long-term follow-up demonstrated intact parent vessels and stable occlusion rates in the majority of patients. This device is a treatment option for fusiform lesions, but may confer a higher periprocedural risk.

**Key Words:** Endovascular therapy · Intracranial aneurysm · Stent · Subarachnoid hemorrhage

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## Endovaskuläre Behandlung von intrakraniellen Aneurysmen durch den Leo-Stent: Langzeit-Follow-up und Erweiterung des Anwendungsbereichs

### Zusammenfassung

**Ziel:** Basierend auf ihrer bisherigen Arbeit in der Anwendung des Leo-Stents präsentieren die Autoren hier eine größere Fallzahl, ein längeres Follow-up sowie eine Erweiterung der Indikation zur Verwendung des Stents.

**Patienten und Methodik:** Insgesamt wurden 71 Patienten mit 75 Aneurysmen in diese Untersuchung aufgenommen. 61 sakkuläre und breitbasige intrakranielle Aneurysmen und zwölf fusiforme Läsionen wurden elektiv behandelt.

**Ergebnisse:** In 98% der Fälle war die Stentplatzierung erfolgreich. Durch anschließendes Coiling wurde bei 26 sakkulären Aneurysmen ein kompletter Verschluss erzielt, ein Resteinström war bei zehn Aneurysmen manifest, während bei 25 Aneurysmen die Coil-Okklusion bewusst zu einem späteren Zeitpunkt erfolgte. Das angiographische Follow-up war bei 56 Aneurysmen nach 11 Monaten verfügbar und ergab in 94% intakte Trägergefäße. Elf sakkuläre Aneurysmen wiesen eine spontane Thrombosierung nach alleiniger Stentplatzierung ohne Coiling auf, während vier Rezidive manifest waren. Das

<sup>1</sup>Department of Neurology and Clinical Neurophysiology, Alfried Krupp Hospital, Essen, Germany,

<sup>2</sup>Department of Psychiatry and Psychotherapy, University of Duisburg-Essen, Essen, Germany,

<sup>3</sup>Department of Radiology and Neuroradiology, Alfried Krupp Hospital, Essen, Germany,

<sup>4</sup>Department of Neuroradiology, Hanover Medical School, Hanover, Germany

\*Both authors contributed equally to this work

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Langzeit-Follow-up war für 26 Aneurysmen nach  $\geq 12$  Monaten verfügbar und wies in allen Fällen intakte Trägergefäße auf. Dabei traten drei Rezidive auf. In allen fusiformen Aneurysmen war die Stentimplantation erfolgreich. Drei Patienten mit einem großen fusiformen Aneurysma der Arteria basilaris verstarben, während in den übrigen Fällen keine klinischen Komplikationen auftraten

**Schlussfolgerung:** Die Autoren bestätigen in dieser Arbeit die Wirksamkeit des Leo-Stents in der Behandlung von sakkulären und breitbasigen intrakraniellen Aneurysmen. Das mittlere und Langzeit-Follow-up weist intakte Trägergefäße und stabile Verschlussraten in der Mehrzahl der Fälle auf. Die Behandlung von fusiformen Aneurysmen wird durch den Stent ermöglicht, beinhaltet jedoch ein höheres intraprozedurales Risiko

**Schlüsselwörter:** Endovaskuläre Behandlung · Intrakranielle Aneurysmen · Stent · Subarachnoidalblutung

## Introduction

Endovascular treatment of ruptured intracranial aneurysms with detachable coils has proven to be a favorable alternative to surgical clipping [1, 2]. Although no randomized clinical trial data on the treatment of unruptured lesions have been published, endovascular procedures have gained widespread acceptance. However, coil embolization has limitations in the treatment of complex or broad-necked aneurysms [3] because of possible coil migration into the parent vessel and long-term angiographic recurrence [4–6]. A variety of techniques and devices have become available in the last decade to treat these anatomically difficult aneurysms; the current practice includes nitinol microstents [7–10]. The latest research in this field resulted in the development of self-expandable nitinol stents with a closed-cell design [10–14]. In this paper, we present expanded data on elective endovascular treatment of saccular and broad-based aneurysms using the Leo stent (Balt, Montmorency, France), and also present the first long-term follow-up data. Additionally, we report our experience using the Leo stent to treat fusiform lesions.

## Patients and Methods

A total of 71 patients with 75 aneurysms were included in this study. 64 aneurysms were treated at the Alfried Krupp Hospital, and eleven at the Hanover Medical School, both Germany. Depending on aneurysmal anatomy, aneurysms were divided into two groups: (1) saccular aneurysms,  $n = 61$ , and (2) fusiform lesions,  $n = 12$ . Each patient in group 1 and 2 was in good-to-moderate clinical condition ( $MRS \leq 3$ ), and signed a written informed consent form at least 24 h prior to endovascular intervention. Data from 25 aneurysms in the saccular aneurysm group were presented in our previous study of the Leo stent [10].

## Saccular Aneurysm Group

The patient selection procedure was described previously [10]. In short, patients with saccular and broad-necked aneurysms with a dome-to-neck ratio  $< 2$  or a neck size  $\geq 4$  mm were included in this group.

57 patients aged  $54 \pm 12$  years (range 23–79 years) with 61 saccular aneurysms were treated between October 2003 and January 2006 (Table 1). 14 were male and 43 were female. Aneurysms were located as follows: 22 (36%) at the paraclinoid/paraophthalmic internal carotid artery; ten (16%) at the middle cerebral artery; eight (13%) at the cavernous carotid artery; eight (13%) at the basilar tip; five (8%) at the basilar trunk; three (5%) at the anterior cerebral artery; two (3%) at the anterior communicating artery; one (2%) at the posterior communicating artery; one at the intracranial vertebral artery (2%); and one (2%) at the posterior inferior cerebellar artery. 25 lesions were recurrences after primary endovascular treatment without stents: 20 were treated with bare coils, two with bioactive coils (Matrix, Boston Scientific, Fremont, CA, USA), two with the Onyx HD 500 liquid embolic system (Micro Therapeutics, Inc., Irvine, CA, USA), and one with the Onyx HD 500 and Matrix coils. Prior neurosurgical attempts had failed in three cases. 28 patients had incidental aneurysms, 16 had a SAH at least 3 months prior to current treatment, eleven developed cranial nerve palsies resulting from mass effect (one of them presented with an associated brain stem syndrome), and two had chronic headaches without proven SAH. Three patients had two aneurysms, each of them evolving vis-à-vis from the same vessel segment, and one patient had bilateral aneurysms of the paraclinoid carotid arteries. Five (8%) were giant aneurysms (diameter  $> 25$  mm) and 21 (34%) were large lesions (11–25 mm). All but ten lesions (84%) had at least one risk factor for angiographic recurrences based

**Table 1.** Patient and aneurysm characteristics (?): original size of recurrent aneurysm after surgical clipping is not known; ACA: anterior cerebral artery; \*: long-term follow-up  $\geq$  12 months; -: not available; (4.5 x 20): failed stent; AcomA: anterior communicating artery; BA: basilar artery; CNP: cranial nerve palsy; CO: complete occlusion; FU: follow-up; Hpl: intimal hyperplasia; i.a : intraarterial; ICA: internal carotid artery; ICA icr: intracranial carotid artery (paraclinoid or paraophthalmic); ICA cav: cavernous carotid artery; ICA occl: occlusion of the internal carotid artery; ICH: intracranial hemorrhage; Inc: incidental; IT: increased thrombosing after stent deployment; LPCA: left posterior cerebral artery; Max. diameter: maximal diameter (original size of a recurrent aneurysm is given in parenthesis); MCA: Middle cerebral artery; MRS: Modified Rankin Scale; NO: not occluded after single stent deployment; PcomA: posterior communicating artery; PICA: posterior inferior cerebellar artery; Post: Postint-erventional; Pre: Preinterventional; PSAH: previous subarachnoid hemorrhage; RPCA: right posterior cerebral artery; RN: residual neck; RA: residual aneurysm; V<sub>1</sub>: proximal part of the vertebral artery; Vis def: visual deficit

Patient no.	Location	Symptoms	Aneurysm dimension (mm)		Treatment Leo stent (mm)	Results	Follow-up and results retreatment	MRS		
			Max. diameter	Neck length				Pre	Post	FU
1	ICA cav	CNP	34	12	4.5 x 25	RN	Refused	1	2	-
2	BA trunk	Inc	10 (15)	9	4.5 x 25	CO	*CO	0	0	0
	BA trunk		6 (9)	6		CO	*CO			
3	ICA icr	Headache	9 (15)	8	4.5 x 25	RA	CO (ICA occl)	2	2	2
4	BA trunk	Inc	6	4	3.5 x 18	CO	*CO	0	0	0
5	ICA icr	Inc	4	4	4.5 x 20 (4.5 x 20)	CO	-	2	2	-
	ICA icr	PSAH	5	4		RN				
6	BA tip	Complex brain stem symptoms	18 (28)	8	3.5 x 25	CO	*RN	3	3	2
7	ICA cav	CNP	14 (30)	10	4.5 x 25	CO	*CO	1	1	1
8	ICA cav	CNP	7	8	4.5 x 20	RN	*RN	1	1	1
9	ICA cav	Vis def	18	14	4.5 x 40	RA	Refused	2	2	2
10	ICA icr	Headache	34	13	4.5 x 25	NO	CO	0	0	0
11	ACA	Inc	10	6	2.5 x 12	CO	*CO	0	0	0
	ACA		4	5		CO	*CO			
12	ICA icr	Inc	15 (20)	8	4.5 x 20	CO	*CO	0	0	0
13	AcomA	Inc	8	6	2.5 x 12	CO	CO	0	0	0
14	ICA icr	Inc	9	6	4.5 x 20	CO	*RN	0	0	0
15	ICA icr	Inc	5	5	4.5 x 25	CO	CO	0	0	0
16	ICA icr	Inc	7 (12)	5	4.5 x 20	CO	*CO	0	0	0
17	BA trunk	PSAH	2 (6)	5	2.5 x 12	NO	IT	0	0	0
	BA trunk		1 (6)	5		NO	IT			
18	ICA icr	PSAH	3 (10)	4	3.5 x 18	NO	CO	1	1	0
19	ICA icr	Vis def	18	10	4.5 x 25	CO	CO	1	1	1
20	BA tip	Inc	4	4	3.5 x 18	NO	*CO	0	1	0
21	MCA	PSAH	4 (9)	3	2.5 x 18	NO	*CO	0	0	0
22	BA tip	Inc	11 (11)	4	3.5 x 25	NO	CO	0	0	0
23	PcomA	Inc	20	8	4.5 x 25	CO	CO	0	0	0
24	V4	PSAH	9	2	3.5 x 18	CO	CO	4	3	0
25	ICA cav	CNP	18 (25)	12	4.5 x 25	CO	*RN	1	1	1
26	BA tip	Inc	2	2	2.5 x 18	NO	*CO	0	0	0
27	ICA icr	PSAH	5 (8)	6	4.5 x 25	NO	*RN	0	0	0
28	ICA icr	CNP	14	6	3.5 x 25	RN	CO	1	1	1
29	ICA icr	CNP	10	5	3.5 x 25	CO	CO	1	1	1
30	ICA icr	Inc	7 (13)	3	3.5 x 18	NO	CO	0	0	0
31	MCA	PSAH	5 (?)	4	2.5 x 12	CO	CO	0	0	0
32	MCA	Inc	18	13	2.5 x 18	RN	*CO	0	0	0
33	MCA	Inc	9	5	2.5 x 12	RN	*CO	0	0	0
34	ICA cav	Inc	15	9	4.5 x 25	CO	*CO	0	0	0

Continued next page

Table 1 Continued

Patient no.	Location	Symptoms	Aneurysm dimension (mm)		Treatment Leo stent (mm)	Results	Follow-up and retreatment Results	MRS		
			Max. diameter	Neck length				Pre	Post	FU
35	ICA icr	Inc	7	5	4.5 × 25	CO	*CO	0	0	0
36	BA tip	Inc	3	2	2.5 × 18	CO	*CO	0	0	0
37	MCA	Inc	7	6	2.5 × 18	CO	CO (Hpl)	0	0	0
38	MCA	PSAH	6 (32)	10	2.5 × 18	NO	CO	0	0	0
39	AcomA	PSAH	3	3	2.5 × 12	NO	*CO	2	2	2
40	MCA	PSAH	6 (11)	7	2.5 × 18	NO	RN	1	1	1
41	ICA icr	PSAH	6 (10)	5	4.5 × 25	CO	*CO	0	1	0
42	MCA	Inc	2	2	2.5 × 12	NO	CO	0	0	0
43	ICA cav	CNP	18	14	4.5 × 25	NO	RA	1	1	1
44	PICA	PSAH	3 (4)	2	3.5 × 18	NO	RA	1	1	1
45	ICA icr	Inc	25	13	3.5 × 25	RA	*CO	0	0	0
46	ICA cav	CNP	10 (21)	10	4.5 × 25	NO	CO	1	1	1
47	ICA icr	Inc	3	3	2.5 × 12	NO	*RA	1	1	1
48	ICA icr	Inc	5 (17)	5	3.5 × 18	NO	CO	0	0	0
49	BA tip	PSAH	10 (14)	6	3.5 × 18	RA	*RN	1	1	1
50	BA tip	PSAH	14 (21)	7	3.5 × 25	NO	CO	0	0	0
51	ICA icr	PSAH	3 (6)	2	3.5 × 18	NO	CO	0	0	0
52	ACA	PSAH	2	2	2.5 × 12	NO	CO	0	0	0
53	BA tip	Inc	10	10	3.5 × 25	CO	CO	1	1	1
54	MCA	Inc	4	3	2.5 × 12	NO	CO	0	0	0
55	MCA	Inc	3	3	2.5 × 18	NO	CO (Hpl)	0	0	0
56	ICA icr	Inc	6	4	3.5 × 25	CO	-	0	0	-
57	ICA icr	Inc	10 (14)	6	3.5 × 18	NO	CO	0	0	0

on published criteria [15]: aneurysm size  $\geq 10$  mm in 31 lesions, neck size  $> 4$  mm in 40, and previous rupture in 16. The average aneurysm neck length was  $6 \pm 3$  mm (range 2–14 mm), current average aneurysm size was  $9 \pm 7$  mm (range 1–34 mm), and the original average aneurysm size in 26 relapsing aneurysms was  $15 \pm 8$  mm (range 4–32 mm).

#### Fusiform Aneurysm Group

Twelve patients aged  $57 \pm 20$  years (range 10–88 years, six men and six women) with twelve fusiform aneurysms were included in this subgroup. There were five large aneurysms of the basilar artery, four large aneurysms of the internal carotid artery, and three dissecting aneurysms of the intracranial vertebral artery (average diameter:  $18 \pm 12$  mm, range 7–44 mm; average length:  $24 \pm 14$  mm, range 8–50 mm). Cranial nerve palsies or brain stem compression resulting from mass effect were evident in eight patients. Two aneurysms were incidental. Parent-vessel occlusion at the site of the aneurysm was not the first choice in all three patients with aneurysms of the intracranial vertebral artery because of contralat-

eral vessel hypoplasia in two cases and occlusion in one case. None of the patients have been pretreated by surgical or interventional procedure, mainly because their lesions had been classified as "untreatable".

#### Antiplatelet Premedication

Patients that were electively treated were given a loading dose of aspirin (500 mg/day) and clopidogrel (300 mg/day) 3 days before stent deployment. Daily doses of aspirin 100 mg and clopidogrel 75 mg were administered subsequent to stent deployment.

#### Stent Delivery and Deployment

The Leo stent (Balt, Montmorency, France) is a self-expandable stent manufactured with braided nitinol wires in a closed-cell design. The stenting technique was performed as previously described [10]. In brief, all treatments were performed under general anesthesia using intravenous heparinization to achieve an activated partial thromboplastin time at two to three times the basal value. In the first 21 patients, stents were delivered with a first-generation microcatheter (Vasco, Balt, Montmo-

rency, France). Since January 2005, our center has used the second-generation microcatheter (Vasco plus) for all Leo stent sizes. The microcatheter currently used for the 4.5-mm Leo stent is the Vasco plus 25, with a smaller outer diameter compared to the older one (the Vasco 28). This improved device has resolved the delivery problems that had resulted from extreme vessel curvature; also, the improved device does not usually require a coaxial double-guiding system. A 0.014 or 0.016 inch microguidewire (SilverSpeed, Micro Therapeutics, Inc., Irvine, CA, USA) was used to position the microcatheter. After removing the microguidewire, the stent is pushed within the microcatheter and finally detached at the intended position.

#### Endovascular Occlusion

Three different treatment options were evaluated in our first study and were continued here: (1) stent deployment and complete occlusion with coils; (2) stent deployment and partial occlusion resulting in residual neck or residual aneurysm; or (3) stent deployment without coil embolization [10]. As a result of our experiences in the first 21 patients treated with Leo stents [10], a staged procedure (option 2 or 3) was preferred in a larger group of patients. Indications for a staged or "wait and see" procedure were significant intraaneurysmal flow reduction after stent deployment, prevention of a deteriorating mass effect resulting from dense packing, or technical difficulties leading to stent dislocation. In all cases where coil embolization was performed, the aneurysmal cavity was probed through the stent strut by a microcatheter after the stent was finally deployed. A 1.7-French microcatheter (Excelsior SL-10, Boston Scientific, Fremont, CA, USA) was used in the majority of cases. Coil embolization was performed with bare coils or bare coils in combination with fibered coils (Sapphire, Micro Therapeutics, Inc., Irvine, CA, USA).

#### Postinterventional Management

Heparinization was stopped after the procedure, and femoral sheaths were removed. All patients were monitored in the stroke unit of the neurological department until the following day. Brain MRI scans (T2- and diffusion-weighted, DWI/MRI) were performed routinely within 48 h of intervention to determine clinically relevant and silent ischemic brain lesions [16]. Patients were discharged with instructions to take 100 mg aspirin daily for at least 1 year in combination with 75 mg clopidogrel daily for 8 weeks.

#### Angiographic Results

Anatomic results were recorded by selective contrast injections at multiple projections by the treating physician. The classification into complete obliteration, residual neck, and residual aneurysm has been described previously [17].

#### Follow-Up and Retreatment

The first angiographic follow-up examination was scheduled after a minimum of 3 months. An angiographic recurrence was defined as a change of classification of the angiographic results [17]. Clinical status was graded according to MRS by an independent neurologist. The second angiographic and clinical follow-up was scheduled depending on the results of the first examination. Adjunctive coiling was performed in patients with residual aneurysms, whereas residual necks were not retreated in most of the cases.

#### Results

##### Saccular Aneurysms

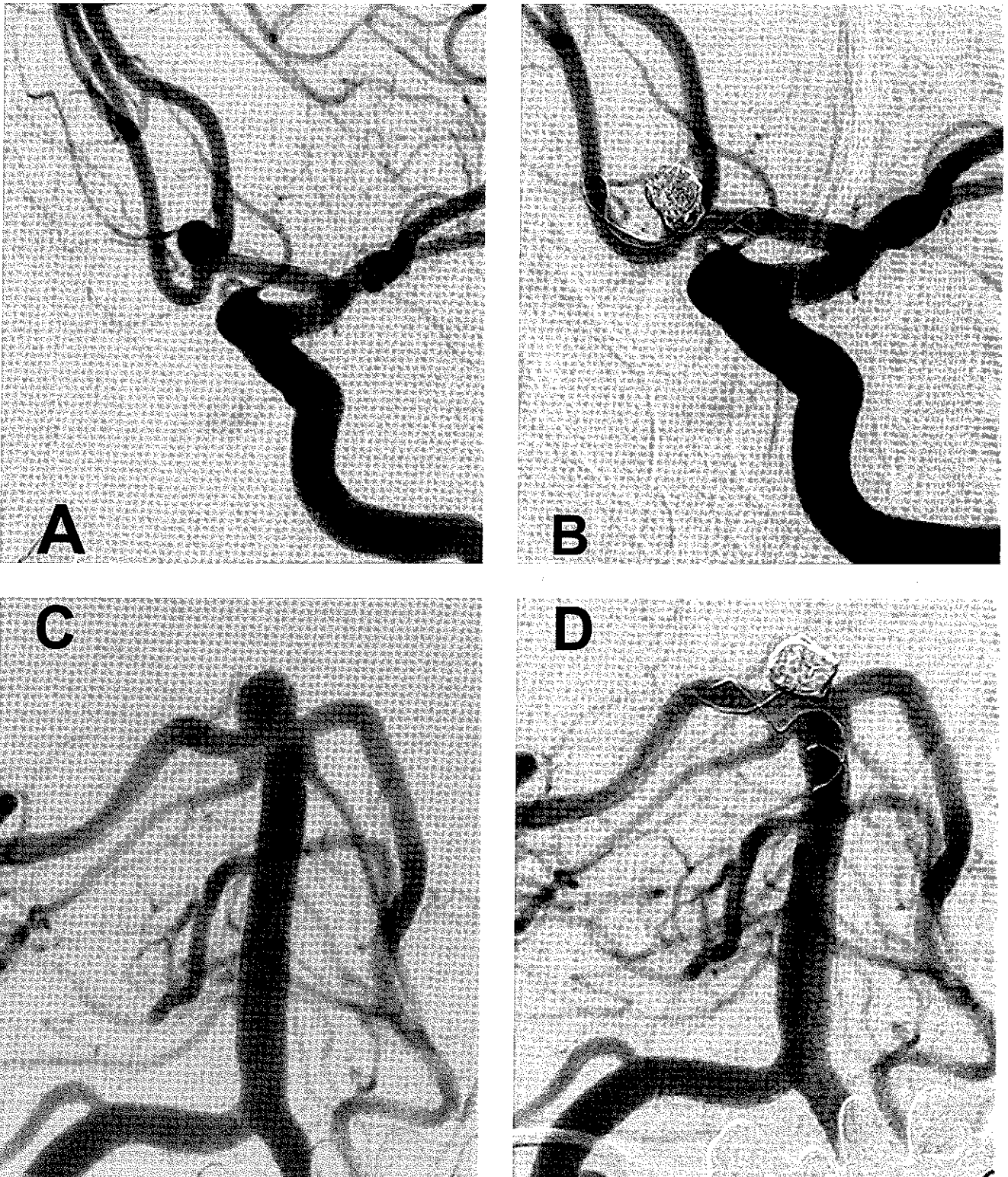
##### Immediate Results

Stent deployment was successful for all saccular aneurysms but one (98%). Stent sizes used are documented in Table 1. Coil embolization was performed with bare coils in 24 aneurysms and with bare coils in combination with fibered coils in nine. Bioactive coils were used in three large and giant aneurysms. Complete obliteration by stent deployment and coil embolization (treatment option 1) was achieved in 26 aneurysms (43%), a neck remnant in six lesions (10%), and a residual aneurysm (treatment option 2) in four cases (6%). No coil embolization immediately after stent deployment (treatment option 3) was chosen in 25 lesions (41%) because of significant contrast stasis in the aneurysmal sac, possibly leading to spontaneous thrombosing. Two exemplary cases are described in Figure 1.

##### Complications

Complications are listed in Table 2. We encountered delivery problems with the first-generation microcatheter (Vasco) in 16% of 25 aneurysms [10]. There were no complications with regard to stent delivery using the second-generation microcatheter (Vasco plus).

Two thromboembolic complications were encountered after Leo stent deployment when the aneurysmal sac was filled with coils [10]. In patient no. 29, a stroke in the territory of the ipsilateral middle cerebral artery occurred 6 weeks after stent deployment and complete



**Figures 1A to 1D.** Incidental wide-necked saccular aneurysm of the anterior communicating artery before stent deployment (A). Radiopaque platinum wires marked correct stent position across the aneurysm neck; aneurysmal sac was completely occluded with bare coils (B). Unruptured saccular and broad-necked aneurysm of the basilar tip (C) Stent is positioned in the basilar artery up to the right posterior cerebral artery; successful coil occlusion of the aneurysm (D).

**Table 2.** Periprocedural and delayed complications using the Leo stent to treat cerebral aneurysms. For abbreviations see Table 1

Patient no.	Periprocedural complications	Cause	Treatment	Clinical outcome
	<i>Thromboembolism</i>			
20	Stroke (PICA)	Deployment of carotid Wallstent to achieve endovascular access (extreme elongation of V <sub>1</sub> segment)		Transient vertigo and nausea
2	In-stent thrombosis (BA) intraprocedurally	Unknown	Abciximab i a.	Asymptomatic
6	Thrombosis RPCA intraprocedurally	Unknown (Leo stent deployed into LPCA)	Abciximab i a	Asymptomatic
	<i>Other</i>			
27	Ipsilateral visual deficit	Mass effect after coiling	Corticoid therapy	Resolved
	<i>Technical</i>			
5	Failure of stent deployment	Extreme vessel curvature	Single coil embolization	Asymptomatic
4	Stent positioning	Extreme vessel curvature		Asymptomatic
5	Stent positioning	Extreme vessel curvature		Asymptomatic
20	Stent positioning	Extreme vessel curvature		Asymptomatic
Patient no.	Delayed complications	Cause	Treatment	Clinical outcome
10	ICH	Unknown	Surgery	MRS 4
15 <sup>a</sup>	ICH	Hypertensive ICH		Death
3	Parent-artery occlusion	Unknown		Asymptomatic
29 <sup>a</sup>	Stroke (ipsilateral MCA)	Cessation of antiplatelet therapy 6 weeks after stent deployment into ICA	Antiplatelet therapy	MRS 2, resolved at FU

<sup>a</sup>cases described in detail in the *Results* section

occlusion of an aneurysm of the internal carotid artery. The patient suffered a mild hemiparesis. This was caused by cessation of the antiplatelet drugs due to a prescribing error by the general practitioner. Fortunately, all symptoms of stroke resolved and control angiography demonstrated a patent stent lumen. Delayed intracranial hemorrhages (ICH) occurred in patients no. 10 and no. 15. Case no. 10 has been reported in our previous publication [10]. In brief, the cause of the bleeding in this patient remains speculative but was unrelated to the stent deployment. In patient no. 15, control angiography 3 months after stent deployment and complete occlusion demonstrated no relapse of the aneurysm. Unfortunately, this 67-year-old female patient with known hypertension died after suffering an ICH 15 months later. The bleeding was located contralaterally to the occluded aneurysm and was classified as a hypertensive ICH.

Delayed occlusion of the parent artery was evident in patient no. 3 [10] but not in the following cases.

#### Follow-Up

Clinical and angiographic follow-up examinations were performed in 53 patients (93%) for 56 saccular aneurysms

after a mean time of 11 months (range 3–32 months). Assessment of clinical follow-up was performed in one patient by telephone interview who refused an angiographic follow-up.

*Stent deployment and coil embolization (treatment options 1 and 2)* Follow-up angiography of 31 aneurysms in 29 patients treated by stent deployment and coil embolization demonstrated 22 complete occlusions, six residual necks, and three residual aneurysms. Out of these, 27 lesions revealed a stable finding. Four lesions (7%) had recanalized (three residual aneurysms, one neck remnant). Seven aneurysms required retreatment.

*Stent deployment without coil embolization (treatment option 3)* Angiographic follow-up of 25 aneurysms in 24 patients that were managed by stent deployment without coil embolization showed 14 unoccluded lesions. Increasing spontaneous thrombosing in eleven aneurysms after stent deployment resulted in three complete occlusions and eight residual aneurysms. 19 lesions were retreated by coil embolization.

*Long-term follow-up.* Long-term clinical and angiographic follow-up  $\geq 12$  months was available in 26 aneurysms, on average at 17 months (range 12–32 months).

None of them showed affection of the parent artery. Recanalization was evident in three aneurysms

To date, complete obliteration was evident in 46 of 56 lesions (82%), residual neck in seven (13%), and residual aneurysm in three (5%).

**Complications.** Delayed complications are summarized in Table 2. Occlusion of the parent artery was found in patient no. 3 (Table 2), and asymptomatic intimal hyperplasia in patients no. 37 and no. 55. The clinical status was unchanged in 49 patients, was improved compared to that before treatment in three patients, and showed resolution of periprocedural deficits in two patients

#### Fusiform Aneurysms

16 stents were deployed successfully in twelve aneurysms. "Stent-in-stent" technique was used in three aneurysms: three stents (one 5.5 × 75, and two 5.5 × 50) were needed to bridge the aneurysm's neck in a lesion located at the basilar artery with a length of 50 mm (Figure 2), two stents (5.5 × 50, 5.5 × 35) were deployed in an aneurysm of the basilar artery with a length of 35 mm, and two stents (4.5 × 40, 4.5 × 20) in a lesion of the intracranial vertebral artery with a length of 20 mm. This technique was chosen for treating fusiform aneurysms and to induce restitution of normal blood flow. Deployment of "stent-in-stent" resulting in smaller stent meshes leads to a favorable hemodynamic effect. In addition, the parent artery is saved from coil protrusion in circumferential lesions. Coil embolization was performed with bare coils in eight aneurysms and with bare coils in combination with fibered coils in one. Complete obliteration by stent deployment and coil embolization (treatment option 1) was achieved in three aneurysms. Scheduled partial occlusion (treatment option 2) to prevent mass effect was performed in six lesions. No coil embolization immediately after stent deployment (treatment option 3) was chosen in three lesions, because of spontaneous thrombosing resulting in immediate complete occlusion in one case and partial occlusion in two lesions.

**Delivery problems** were evident only in the first patient of this subgroup with a large aneurysm of the basilar artery using the first-generation microcatheter (Vasco), however, the stent was deployed in the intended position. There were no complications with regard to stent delivery in the remaining cases.

**Periprocedural in-stent thrombosis** appeared after stent deployment and complete occlusion of the aneurysms with bare coils and fibered coils in one case with

a giant aneurysm of the internal carotid artery. After intravenous administration of abciximab the thrombus dissolved completely and no clinical deficit was evident. However, a DWI/MRI brain scan showed several embolisms distal to the aneurysm. No further thromboembolic events were noted in the other cases.

**Three patients with large fusiform aneurysms of the basilar artery** died in this study. Dysphagia and complex brain stem syndrome worsened in a patient with an aneurysm of the basilar artery after stent deployment, resulting in lethal pneumonia. The second death was caused by increasing mass effect after stent deployment and partial occlusion of a giant aneurysm of the basilar artery. A third patient with a giant aneurysm of the basilar artery that was treated by stent deployment and partial occlusion developed a severe SAH 2 days post-procedure (Figure 2). There were no new symptoms or clinical complications in the remaining cases.

**Clinical and angiographic follow-up examinations** were performed in the remaining nine cases after a mean time of 9 months (range 3–23 months). Two aneurysms remained completely occluded. Two partially coiled lesions were unchanged and were completely obliterated by coil embolization in succession. One partially occluded aneurysm of the basilar artery was not recoiled to prevent mass effect. Two aneurysms of the internal carotid artery, one of the basilar artery and one aneurysm of the intracranial vertebral artery (Figure 3) exhibited increasing spontaneous thrombosing after stent deployment 3 months previously. There was one recurrence of a giant aneurysm of the internal carotid artery. Retreatment was not performed in this cavernous aneurysm because cessation of clopidogrel after the control angiography may induce further aneurysmal thrombosing. To date, complete obliteration was achieved in four lesions and partial occlusion in five. The clinical status was unchanged in four patients and had improved in five patients.

## Discussion

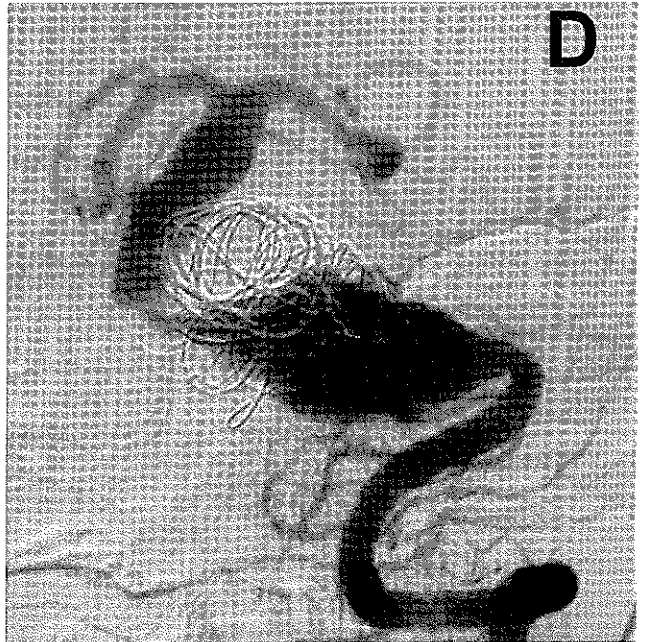
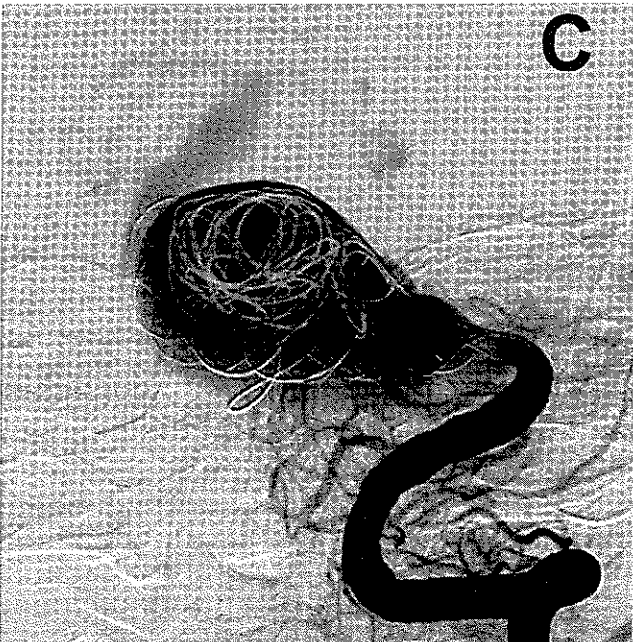
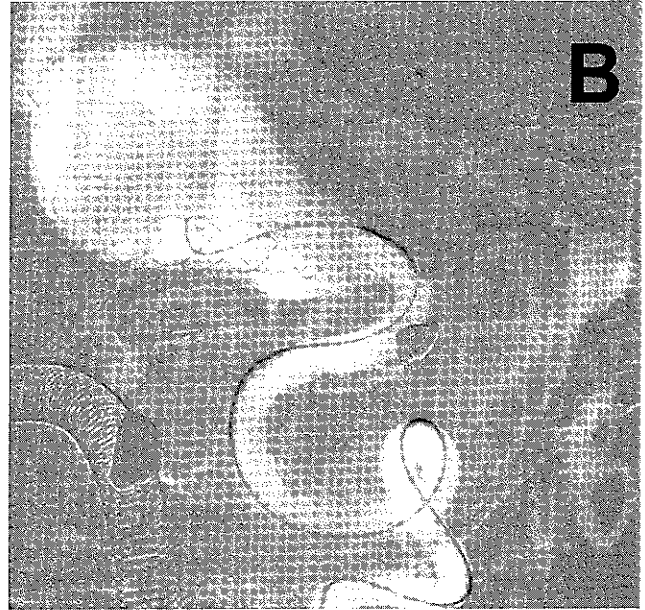
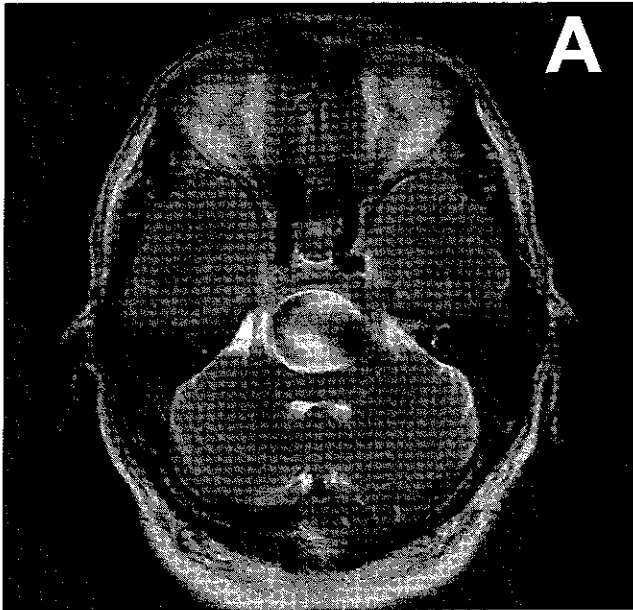
### Saccular Lesions

In a larger cohort of patients and with a longer follow-up period, we confirmed our previous results establishing the safety and effectiveness of the Leo stent for the treatment of saccular wide-necked aneurysms.

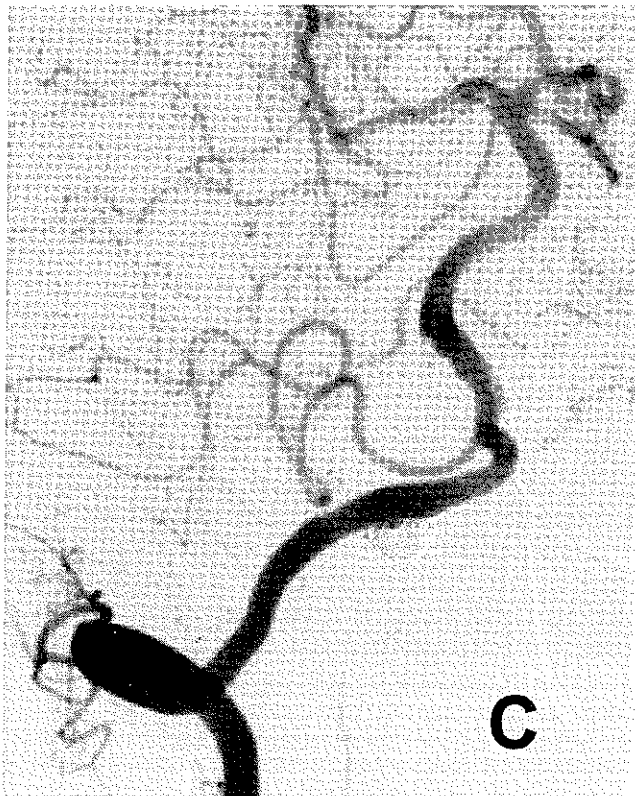
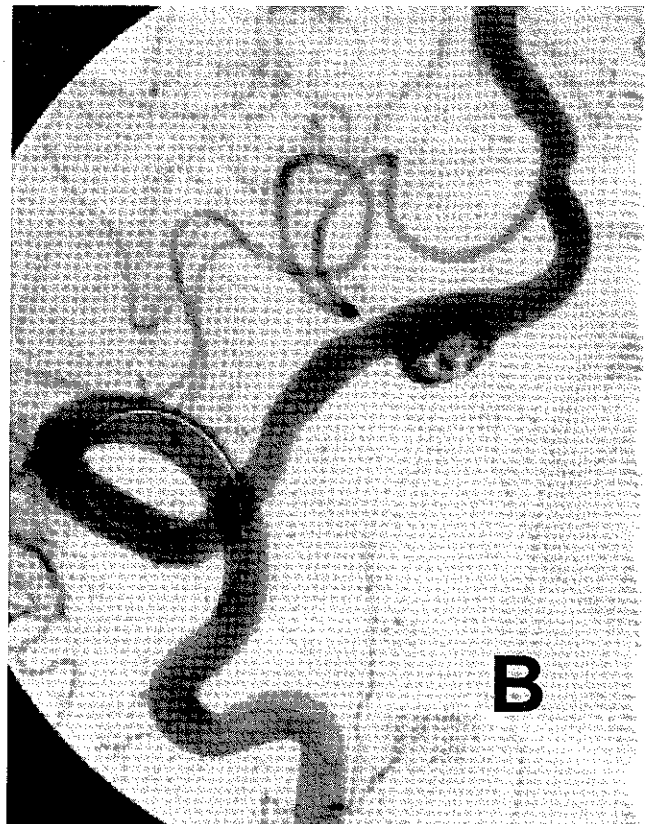
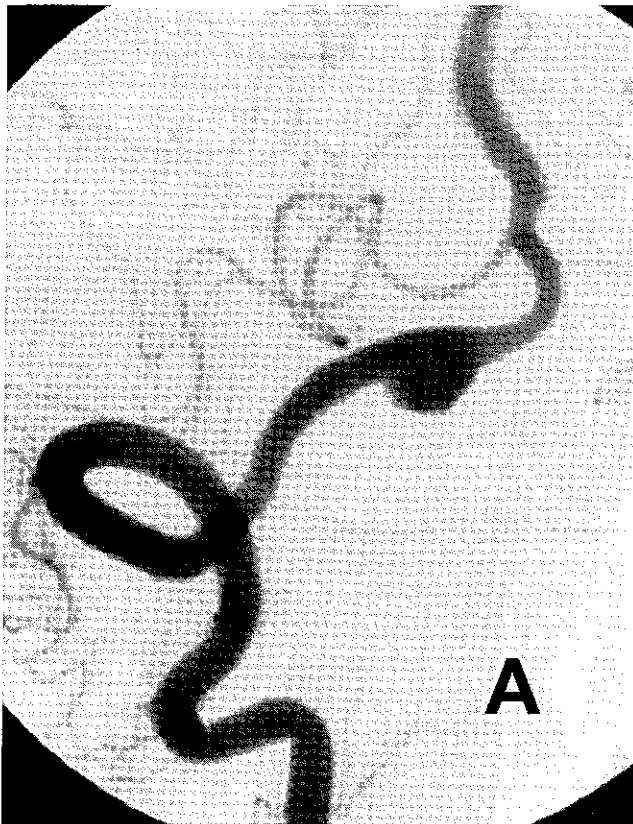
The previously reported delivery problems, experienced in our 21-patient study using the first-generation microcatheter [10], were not evident with the Vasco plus microcatheter. Altogether, the technical complica-

tion rate was 7% in the current study. Stent deployment difficulties with the triaxial Neuroform delivery system have been reported in 42–50% of cases [8, 9, 18], but have been improved by using newer generations of the Neuroform system [7–9, 14].

The rate of periprocedural thromboembolic events (3%) during stent deployment was improved when compared to our previous results (8%) [10]. This result is slightly better than the rate of 4–13% of cases reported for the Neuroform stent [7, 9, 14, 19]. We observed one



**Figures 2A to 2D.** Symptomatic giant aneurysm of the basilar artery causing brain stem symptoms in this male patient (A). Three Leo stents in a “stent-in-stent”-technique were needed to cross the aneurysm’s neck with a length of 50 mm (Leo 5.5 × 75 mm, and two Leo 5.5 × 50 mm; B). Adjunctive coil embolization is performed during the same procedure resulting in partial filling of the aneurysmal cavity (C). Postinterventional angiography after 24 h revealed slight reduction of the aneurysm. However, the patient developed a severe SAH 48 h post-procedure with lethal outcome (D).



**Figures 3A to 3C.** Asymptomatic fusiform aneurysm of the left intracranial vertebral artery (A) Stent is deployed to reconstruct parent vessel, adjunctive coiling is performed during the same intervention resulting in partial occlusion of the aneurysm (B) Follow-up angiography after 3 months demonstrated complete occlusion of the aneurysm by increasing thrombosing (C)

case of periprocedural clinical deterioration caused by mass effect of the coil packet after stent deployment, which resolved completely after antiedematous therapy. Further intraprocedural complications did not occur in our series of saccular wide-necked aneurysms, but have been infrequently reported with use of the Neuroform stent. Such complications have included coil protrusion into the parent artery [7, 19], intracranial hemorrhage [9, 19], and vessel dissection [9]. Recently, Benndorf et al. reported increased cell opening and prolapsing of struts of an open cell design stent (Neuroform 2) after placement in a curved vessel with a new imaging technique [20, 21]. The Leo showed fewer trends to kink but an inward crimping of its ends with more acute angles [21]. If these adverse stent mechanics may gain clinical importance has to be further investigated.

Up to now, two other groups have reported their preliminary results with the use of the Leo stent [13, 22], supporting its use in the treatment of wide-necked intracranial aneurysms. Both groups treated a total of 21 patients with broad-necked lesions. While Lubicz et al described excellent performance of the Leo stent without any complications [13], Pumar et al reported one significant stent delivery problem and one thromboembolic event in their series of ten patients [22]. Unfortunately, the antiplatelet premedication administered to the patients in this study was not described.

Follow-up angiography in nearly all of our treated patients demonstrated a recanalization rate of 7% after a mean time of 11 months. Asymptomatic intimal hyperplasia occurred in 4% of the aneurysms, and occlusion of the parent artery in 2%. Long-term follow-up of 26 saccular aneurysms revealed intact parent arteries in all cases and aneurysm recanalization in three lesions. Altogether, we had very favorable results when compared to the Neuroform series of stents: Fiorella et al collected follow-up angiographic and magnetic resonance angiographic data in 72% of all patients after a mean time of 5 months and reported aneurysm recanalization in 23% of cases and severe in-stent stenoses in 6% [14]; Lylyk et al found no recurrences and patent stents in 63% of all of their cases after 7 months [9]. A prospective 6-month study, which has not been published in a peer-reviewed journal, described ten wide-necked aneurysms treated with the Neuroform2 Treo stent [23]. This study reported one case with residual neck at six-month follow-up, but stable occlusion rates and intact parent vessels in the remaining cases.

Based on our experiences in the first 21 patients treated with Leo stents [10], we were encouraged to perform a staged procedure in a larger group of patients. 57% of all lesions were treated by stent deployment and partial or no coiling. Aneurysm thrombosing induced by stent placement may occur [24], but depends on aneurysm geometry [25] and stent porosity [9, 26]. In models of large-necked, sidewall, and bifurcation aneurysms, stent implantation induces intraaneurysmal loss of vortex coherence and flow reduction, and was found to be more important in the large-necked than in the small-necked aneurysm model [27–29]. This is clinically relevant as the mass effect of the intraaneurysmal coil packet may compromise the perivascular space, e.g., brain stem or cranial nerves. In our series, 18% of saccular aneurysms showed increasing spontaneous thrombosing after stent deployment without coil emboliza-

tion. In succession, coil filling of the aneurysmal cavity was performed in the majority of cases, which has been the experience with other stent systems as well [7, 9, 18]. No side effects of staged coil embolization or hemorrhages during the intervals occurred. In our opinion, the Leo stent offers a hemodynamic profile resulting in relatively low recanalization rates. In addition, the favorable reduction of intraaneurysmal flow induces the thrombosing of the aneurysmal sac.

#### Other Indications

The positive hemodynamic effect and size capabilities of the stent (up to 9.5 cm) allowed us to expand the indication of this stent. We reported the treatment of fusiform lesions in two groups: (1) five large aneurysms of the basilar artery, with fatal outcome in three cases, and (2) four large aneurysms of the internal carotid artery and three dissecting lesions of the intracranial vertebral artery with more favorable outcomes. In both groups, besides stent delivery difficulties in one case of a large fusiform aneurysm of the basilar artery and a thromboembolic event in a giant fusiform aneurysm of the internal carotid artery, there were no further technical complications. Despite the favorable technical feasibility of stent deployment in order to reconstruct dysplastic arteries, the group with large fusiform aneurysms of the basilar artery showed a fatal clinical outcome. Whether this subgroup of fusiform aneurysms should be treated at all is an unanswered question.

On the other hand, we achieved favorable angiographic and clinical results with an asymptomatic thromboembolic complication in the subgroup of fusiform aneurysms of the internal carotid artery and the intracranial vertebral artery. From our experience with this small subgroup, the application of the Leo stent may be advised in the treatment of fusiform aneurysms of the internal carotid and vertebral artery, in particular if the parent artery must be preserved. The radiopacity of the stent markers demarcates its lumen in these fusiform and often circumferential aneurysms. This is crucial in the case of adjunctive coil embolization, where proper coil placement through the stent struts is required. Therefore, the use of the Leo stent may be an alternative to balloon-in-stent techniques for constructive endovascular treatments [30].

Despite our general practice not to implant intracranial stent material into patients that are not adequately pretreated with standard antiplatelet drugs, the invention of the GP-IIb/IIIa inhibitor tirofiban (Aggrastat,

MSD Sharp & Dohme GmbH, Haar, Germany) makes it possible to use the Leo stent in cases of ruptured aneurysms. Up to now, we successfully used the combination of tirofiban plus intracranial Leo stent deployment to treat three carefully selected patients with acutely ruptured aneurysms; there were neither thromboembolic complications nor affection of the parent artery at follow-up (not reported in this paper).

Although all of these results are very promising with regard to intracranial stenting in the treatment of complex aneurysms, long-term monitoring of patients and a more rigorous scientific evaluation are required.

### Conclusion

We confirmed the feasibility and efficacy of using the Leo stent for primary and recurrent treatment of broad-necked saccular intracranial aneurysms. This first available long-term follow-up study found intact parent vessels and stable occlusion rates in the majority of patients. Complex and previously untreatable fusiform lesions can be treated with the Leo stent, but this treatment option may confer a higher periprocedural risk.

### Financial Disclosure

Werner Weber is the proctor for Leo™ treatments at other institutions for the German distributor of BALT. Bernhard Kis, Friedrich Götz, Hartmut Becker, Peter Berlit, and Dietmar Kühne have nothing to disclose.

### Authorship Requirement

All authors made a substantial contribution to the content of the manuscript, agreed to be named as an author, have read the full version of the paper, and have approved the manuscript for publication.

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**Address for Correspondence**

Bernhard Kis, MD  
Department of Psychiatry  
University of Duisburg-Essen  
Rheinische Kliniken Essen  
Virchowstraße 174  
45147 Essen  
Germany  
Phone (+49/201) 7227-190, Fax -310  
e-mail: bernhard.kis@uni-duisburg-essen.de