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ORIGINAL ARTICLE

The pCONus Device in Treatment of Wide-necked Aneurysms

Technical and Midterm Clinical and Angiographic Results

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Abstract
Purpose A variety of devices for treatment of wide-necked bifurcation aneurysms are emerging. Here we report our results using the new pCONus device with special emphasis on the morphological and anatomical requirements for successful implantation.
Methods In this study we treated 21 patients with 22 aneurysms by endovascular interventions. After providing informed consent, patients were included according to the following criteria: aneurysm dome to neck ratio <2 or neck diameter >4 mm. The primary end points for clinical safety were the absence of death, absence of major or minor stroke and absence of transient ischemic attack.
Results A total of 22 aneurysms in 21 patients were treated with pCONus-assisted coiling. In 19 patients harboring 20 aneurysms the implantation of the device was successful and these aneurysms showed an adequate occlusion after 6 months in 95 %. The complication rate was low (5 %) with one case of minor neurological stroke. Analysis of the data showed that the difference in aneurysm angulation between successful (mean 45°) and failed implantations (mean 71.5°) was highly significant.
Conclusion Use of the pCONus device and coiling in wide-necked bifurcation aneurysms is safe and provides good occlusion rates but might be limited by the angulation between the aneurysm and the parent vessel.

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Keywords Aneurysm · Device · Coiling · Stent · Bifurcation

Introduction

A major determinant for the safe and complete coil occlusion of intracranial aneurysms is the geometry of the target aneurysm. Wide-necked aneurysms, defined by a neck diameter ≥4 mm, dome to neck ratios <2 and an aspect ratio ≤1.6, are less suitable for simple coiling and require adjunctive techniques [1–3]. Although the treatment of wide-necked aneurysms has been facilitated by new techniques including intraluminal balloon remodeling [4], stent-assisted coiling [5], flow diversion [6] and flow disruption [7] the treatment of wide-necked bifurcation aneurysms (WNBA) remains challenging. Recently, the pCONus Bifurcation Aneurysm Implant® (phenox, Bochum, Germany) was introduced for the treatment of intracranial WNBAs. The pCONus device is a dedicated neurovascular nitinol implant designed to protect the neck of WNBAs that would otherwise require stenting in Y-configuration. It is similar to the waffle-cone technique [8] as the main part of the device remains in the parent vessel and its tip holds the coils in the aneurysm. The device is CE marked since December 2012. Here, we report a consecutive, prospective single center experience for safety and efficacy of the pCONus implant in the endovascular treatment of 22 intracranial WNBA.

Materials and Methods

Patient Selection

Approval for prospective data collection of all interventional procedures reported in this study was given by the institutional review board of the university medical faculty. Patient informed consent for study inclusion was obtained from the patients or their legal representatives (in acute cases postprocedure within 48 h).

This prospective study included 21 patients harboring 22 aneurysms (mean age 52.7 ±12.1 years) who were treated with a pCONus bifurcation implants between December 2013 and September 2015. All patients were treated in a single institution by a team of three interventional neuroradiologists (MM, CH and MP). The decision to perform the endovascular procedure using pCONus was made at the discretion of the treating physician based on anatomical features of the target aneurysm.

pCONus Device

The pCONus device is a stent-like vessel implant shaped like a blossoming flower with four petals, which, once inside the aneurysm, bend outwards over the aneurysm neck and, together with polyamide fibers, prevent coil protrusion into the parent vessel. The stem, with a diameter of 4 mm and a length of 20 or 25 mm, remains in the parent vessel. To allow visual control under fluoroscopy the proximal end of the pCONus implant as well as the distal loops carry radiopaque markers. A range of six petal diameters (5, 6, 8, 10, 12 and 15 mm) is available, enabling the treatment of aneurysm necks ranging from 4–14 mm. The whole system is fully deployable and retrievable and is electrolytically detached.

Technique

Patients were treated under general anesthesia using a biplane digital subtraction angiography (DSA) unit (Axiom Artis, Siemens, Erlangen, Germany) and all patients received double antiplatelet therapy as per our institutional standards. From a femoral access, a 6 or 8 F guide catheter was inserted into the respective cervical vessel. Based on calibrated measurements of the neck width, the aneurysm width and the aneurysm height, the optimal pCONus size was selected to ensure complete coverage of the aneurysm neck by the petals. The diameter was chosen to be 1–2 mm oversized in correlation to the aneurysm neck. Delivery of the device was performed through microcatheters with an internal lumen of 0.021 inches. The distal end of the pCONus was placed within the proximal part of the aneurysm, the petals at the tip were expanded and the device was gently pulled back until the petals reached the aneurysm neck. With the device still attached to its delivery wire a second microcatheter was used to probe the aneurysm through the pCONus. Next, the aneurysm was filled with framing coils and remaining spaces were subsequently filled with long and soft filling coils. Finally, the coiling catheter was withdrawn and the device was electrolytically detached.

Antiplatelet/Anticoagulation Regimen

Patients were premedicated with clopidogrel 75 mg (loading dose 300 mg) and aspirin 100 mg 5 days prior to treatment. Platelet inhibition was tested using the light transmission aggregometry method before treatment. During the procedure standard heparin was administered to achieve an activated clotting time >250 s. Postprocedural medication included a daily dose of 100 mg aspirin for 6 months and 75 mg clopidogrel for 3 months. In patients with ruptured aneurysms, tirofiban was administered intravenously during the endovascular procedure and aspirin and clopidogrel were started after the procedure.

Data Collection

Patient age and gender; type of aneurysm, aneurysm location, size, dome to neck ratio and rupture status at presentation, degree of aneurysm occlusion as well as technical and clinical complications during or after pCONus deployment were recorded. Immediate angiographic outcome was determined using the final DSA series. Follow-up examinations were performed using magnetic resonance imaging (MRI, 3 T, Magnetom TRIO or VERIO, Siemens), time-of-flight (TOF) angiography/TOF with and without gadolinium diethylenetriamine pentaacetic acid (Gd-DTPA) contrast agent. In ambiguous cases on MRI, control DSA was performed (4 out of 20 cases). Aneurysm occlusion was determined using the Raymond occlusion classification (ROC) as complete occlusion (ROC 1), neck remnant (ROC 2) and aneurysm remnant (ROC 3) [9] which were dichotomized as adequate occlusion (ROC 1 and ROC 2) and insufficient occlusion (ROC 3), respectively. Clinical evaluation encompassed a detailed neurological examination noting any appearance of neurological symptoms. The examination was performed immediately after the procedure, at 2 h after the procedure, during clinical visit on the following day and finally at discharge and follow-up by a trained neurologist not blinded to the treatment. Morbidity and mortality were scored using the modified Rankin Scale (mRS) [10].

Table 1 Baseline characteristics of the 22 patients

No.	Clinical presentation	Location	Parent vessel diameter (mm)	Size (mm)	Width/neck [mm]	Treatment	pCONus size	Angle aneurysm/parent vessel (°)	Clinical outcome BP/FU	Aneurysm occlusion (PP/FU)
1	I, M	MCA	2.34	5.7 × 7.1 × 6.6	7.1/6.2	P	4-25-6	55	0/0	1/1
2	I, M	MCA	2.41	7.4 × 7.3 × 6.5	7.3/4.5	P	4-25-6	51	0/0	2/2
3	I, M	MCA	2.78	17 × 8.9 × 7.5	8.9/4.7	P	4-25-6	57	0/0	2/2
4	I, M	MCA	2.26	5.4 × 6.2 × 5.5	6.2/3.8	P	4-25-6	30	0/0	2/1
5	I	MCA	2.76	3.2 × 6.9 × 5.2	6.9/5.4	P	4-25-8	51	0/0	1/1
6	I	ACOMA	2.26	4.9 × 8.9 × 5.4	8.9/5.4	P	4-20-10* 4-20-8	50	1/1	1/1
7	I	ICA T	3.04	6.6 × 13.3 × 8.9	13.3/7.5	P	4-25-12	55	0/0	1/1
8	I	MCA	2.3	5.4 × 8.1 × 4.5	6.1/3.4	P	4-20-10* 4-20-8	45	0/0	2/1
9	I	MCA	2.06	8.0 × 8.8 × 8.2	8.8/4.6	P	4-25-8	50	1/1	2/1
10	I	ACOMA	1.9	11.8 × 12.3 × 11.7	12.3/8.5	P	4-20-12	43	0/0	2/2
11	SAH, M	MCA	2.73	5.8 × 3.7 × 4.1	3.7/3	P	4-20-5	52	1/1	1/1
12	I, M	MCA	2.87	9.8 × 10.5 × 8.6	10.5/6.1	P	4-20-10	50	0/0	2/2
13	I, M	MCA	2.54	5.7 × 10.4 × 7.6	10.4/4.2	P	4-20-10	57	0/0	2/2
14	I, M	MCA	2.32	8.6 × 5.7 × 5.4	5.7/4	P	4-20-8	37	3/3	2/2
15	R	ACOMA	2.47	5.8 × 11.7 × 9.1	11.7/6.4	P	4-20-12	34	0/0	1/3
16	I, M	MCA	2.1	4.4 × 6.4 × 5.7	6.4/4.3	P	4-20-6	52	0/0	2/1
17	I	MCA	2.55	9.0 × 11.6 × 9.3	11.6/8.2	P	4-20-15	55	0/0	3/2
18	I	BA	2.78	8.5 × 11.6 × 9.3	11.6/4.3	P	4-25-12	16	1/1	2/1
19	I	MCA	2.61	5.3 × 10.0 × 6.0	10.0/5.2	P	4-20-8	32	1/1	2/2
20	I, M	MCA	2.01	6.1 × 5.0 × 4.5	5.0/3.9	P	4-20-8	43	3/3	1/1
21	I	ACOMA	2.37	11.4 × 6.9 × 5.7	6.9/7.9	Y	–	70	0/0	1/1
22	I	MCA	2.82	5.6 × 7.9 × 5.9	7.9/6.9	WEB	–	73	0/0	3/3

I incidental, *M* multiple, *SAH* subarachnoid hemorrhage, *R* retreatment, *MCA* middle cerebral artery, *ACOMA* anterior communicating artery, *ICA T* t of the internal carotid artery, *BA* basilar artery, *P* pCONus device, *Y* y-stenting, *WEB* WEB device, * technical failure, *BP* before procedure, *FU* follow-up, *PP* postprocedure

Statistical Analysis

Data are presented as means and ranges for continuous variables and as frequencies for categorical variables. Primary end-point of the study was aneurysm occlusion (or recurrence) at 6 months and 1 year follow-up imaging. Values $p \leq 0.05$ were considered statistically significant. Statistical analysis was carried out with IBM SPSS Statistic 22.0®.

Results

A total of 22 aneurysms in 21 patients (mean age 53 years, 19 female and 3 male) were treated with the pCONus device. In two cases (9 %) deployment of the device was not possible. These patients were therefore separated in the subsequent data analysis.

Aneurysm Characteristics

Overall, 18 (90 %) incidental aneurysms were included, 1 patient (5 %) was treated in acute stage of subarachnoid hemorrhage (SAH) and in 1 patient (5 %) the aneurysm had previously been treated with coils. Of the aneurysms 15 (75 %) were located in the middle cerebral artery (MCA), 3 (15 %) in the anterior communicating artery (AComA), 1 (5 %) in the carotid T and 1 (5 %) in the basilar artery (BA). The average neck width was 5.0 mm (range 3.0–8.2 mm). The average dome to neck ratio was 1.7, ranging from 1.2 to 2.7. The mean aneurysm volume was 275.7 mm^3 (range 46.1–889.1 mm^3). The mean dimensions were 8.3 × 7.4 × 7.2 mm (width x depth x height). The vessel diameter at 5 mm proximal of the aneurysm neck was on average 2.5 mm, ranging from 1.9 to 3.0 mm. The angulation between the aneurysm and the parent vessel ranged from 16 to 57 °, with an average of 45 °.

Baseline patient and aneurysm characteristics are detailed in Table 1.

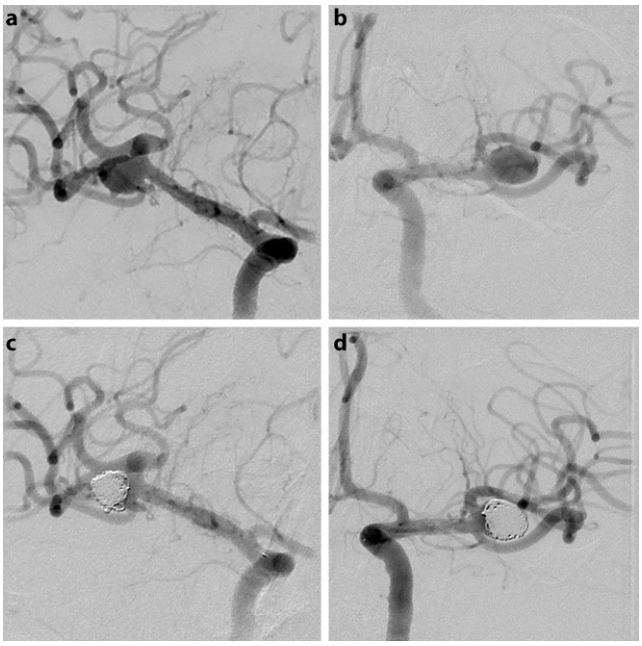

Fig. 1 Case of a 46-year-old female patient with bilateral MCA aneurysms both treated with pCONus (**a, b** before treatment, **c, d** after treatment)

Immediate Angiographic Results

The mean packing density of the coils was 45.8 %, this was determined from the total volume of the implanted coils and the aneurysm volume. In two cases the pCONus size (4-20-10; diameter – shaft length – crown diameter) chosen initially did not fit adequately and a smaller one (4-20-8) was used subsequently. Among the 20 patients successfully treated with pCONus the DSA immediately postprocedure showed complete occlusion in 7 subjects (35 %), a neck remnant in 12 aneurysms (60 %) and an aneurysm remnant in 1 case (5 %). An example is shown in Fig. 1.

Neuroradiological and Clinical Follow-up

A 6-month MRI follow-up was available for all patients [11, 12]. According to the 3-point ROC scale, 11 of the 20 aneurysms (55 %) were rated ROC 1 (complete), 8 (40 %) were graded as ROC 2 (neck remnant) and one was rated as ROC 3 (residual aneurysm perfusion). Using the dichotomous outcome, adequate occlusion was achieved in 95 % of the aneurysms. A 1-year follow-up was available in 15 of the 20 aneurysms (75 %). Among these 11 of the 15 aneurysms were rated ROC 1, while the remaining 3 were rated ROC 2 and 1 ROC 3. Between the 6-month follow-up and the 1-year follow-up 2 patients changed in ROC grading from 2 to 1, 1 patient showed partial occlusion of a remnant and was later rated ROC 2 and 1ne patient showed reperfusion of the aneurysm which changed the occlusion grade from ROC 2 to ROC 3. A comparison of the occlusion rates at different time points is shown in Table 2. An example is given in Fig. 2. The case that showed reperfusion after 12 months is presented in Fig. 3.

Complications

Overall complications associated with the endovascular procedure were noted in 5 patients (25 %): We observed one retroperitoneal hematoma where no further action was required, one clinically silent dissection of the vertebral artery in the V2 segment and two embolic events with transient neurological events and complete recovery at discharge. There was one embolic event during a procedure with a small (1–2 mm) lesion in diffusion-weighted imaging (DWI), this patient describes a subjective word finding disorder to date. However, the localization of the lesions does not explain the symptoms. Nevertheless, the primary endpoint (absence of new permanent deficit or death) was reached in 19 of 20 patients (95 %).

Technical Failure

The two aneurysms in which the pCONus procedure failed were located in the right MCA (size 7.9 × 5.9 × 5.6 mm, neck 6.9 mm, dome to neck ratio 1.14) with a volume of 136.7 mm^3 and the AComA (size 7.9 × 5.9 × 5.6 mm, neck 7.9 mm, dome to neck ratio 0.87) with a volume of 234.8 mm^3. The angle between the aneurysm and the parent vessel was 73° in the MCA aneurysm and 70° in the AComA aneurysm. The difference in angulation in failed (71.5°) vs. successful implantations (45°) was highly significant (p = 0.006). In both cases the device could not be placed in an adequate position due to the sharp angle. Subsequently, the MCA aneurysm was treated with a WEB

Table 2 Occlusion rates immediately postprocedure, at 6-month and 1-year follow up

	ROC1	ROC2	ROC3
Immediate angiography occlusion rate (20 aneurysms)	7 (35.0 %)	12 (60.0 %)	1 (5.0 %)
6-month MRI occlusion rate (20 aneurysms)	11 (55.0 %)	8 (40.0 %)	1 (5.0 %)
1-year MRI occlusion rate (14 aneurysms)	11 (79 %)	3 (21 %)	0

ROC Raymond occlusion classification: *ROC 1* complete occlusion, *ROC 2* neck remnant and *ROC 3* aneurysm remnant, *MRI* magnetic resonance imaging

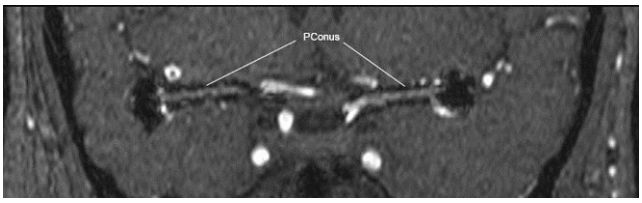

Fig. 2 Same patient shows adequate occlusion of both aneurysms after 12 months in contrast-enhanced MR time of flight angiography

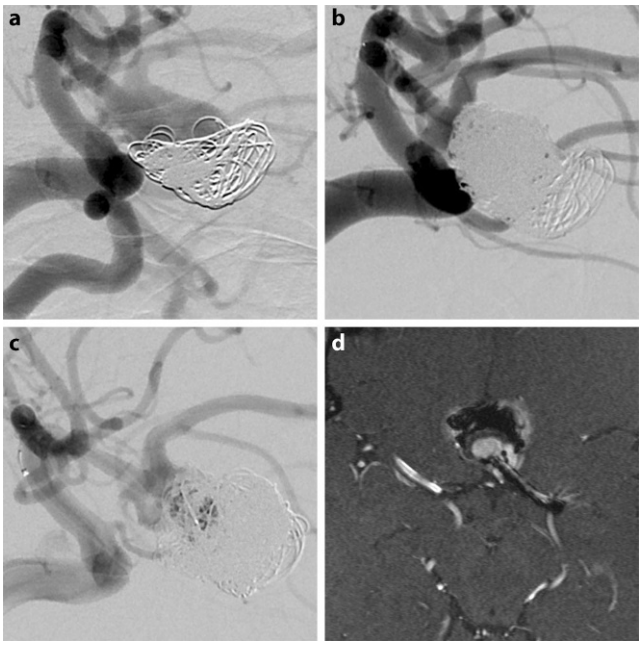

Fig. 3 Patient 15 who had been previously treated by coiling of an aneurysm of the anterior communicating artery where **a** shows the aneurysm before the pCONus treatment, **b** shows the result of the pCONus assisted coiling, **c** and **d** show DSA and CE-TOF in MRI after 12 months depicting an obvious reperfusion of the aneurysm. The aneurysm has since been successfully recoiled

device (Sequent Medical, Aliso Viejo, CA), the AComA aneurysm with a Y-stent assisted coiling.

Discussion

Wide-necked bifurcation aneurysms remain technically challenging to treat by the endovascular approach. Several methods and new devices with varying benefits and shortcomings have been developed for the endovascular treatment of this specific patient population. In this study we evaluated the safety and efficacy for the endovascular pCONus device for the treatment of WNBA at our institution. After a mean of 9.7 months the adequate occlusion rate was 93 %. Complications with a permanent deficit occurred in 5 % of the cases.

Stent techniques employing conventional stents for the endovascular treatment of WNBAs include Y or X stenting and single stenting. These techniques require the use of one or two stents in small vessels and seem to have a higher complication rate as Bartolini et al. have shown (approximately 10 % permanent neurological morbidity) [5]. The occlusion rates after 6 months are high (92.8 % ROC 1 or ROC 2) and in accordance with the results of our study. The pCONus device, in comparison, can provide an at least equivalent parent vessel protection with less material being placed in the cerebral bloodstream, possibly reducing the risk of thromboembolization and avoiding artificial stenosis as seen with Y-stenting. Furthermore, pCONus enables the treatment of aneurysms next to very small branches that are unsuitable for X or Y-stenting. Placing a microwire or a microcatheter in these branches is unnecessary with the pCONus device, possibly reducing the risk of perforation. With the pCONus it is generally recommended to first deploy the device and then place the microcatheter in the aneurysm, opposed to jailing the microcatheter. Navigating the coiling catheter through the device was unproblematic.

Flow diverters (FD) are dedicated devices which are used to redirect the blood flow away from the aneurysm and provide a scaffold for neoendothelialization across the neck of the aneurysm. They have been shown to be safe and effective devices for the treatment of aneurysms [13, 14]; however, in WNBAs the use of conventional FDs is limited by the fact that incomplete occlusion is likely when a branching vessel leaves the aneurysm or a bifurcation is involved.

Promising initial and mid-term results of the WEB flow disruptor for the treatment of WNBAs have been published with mid-term to long-term follow-up complete occlusion rates of 68.4 % [15–18]. Overall the occlusion rates using flow disruptors to treat WNBAs have been similar to the occlusion rate found in this study; however, due to the mere flow-disrupting effect of the device reperfusion might be less predictable and retreatment might be more difficult than in stent-assisted coiling.

The ‘waffle cone’ technique is the most similar approach to the intended use of pCONus, as a self-expanding stent is placed inside of the aneurysm instead of bridging the aneurysm neck [19]. Stent deployment may be combined with dual catheter techniques [15, 20–23]. Most studies using the waffle-cone technique had a very small sample size of 4–10 patients, occlusion rates varied (25–70 % complete occlusion) as did complication rates (0–17 %) and the reported frequency of aneurysm recanalization on follow-up (0–17 %). While the waffle-cone technique offers the benefit that less material is deployed within the cerebral bloodstream, the technical features of conventional stents may make them less suited for the task compared to pCONus,

Table 3 Comparison of available pCONus data

Author	Number of patients	Number of aneurysms	Mean FU time (months)	Adequate occlusion (%)	Complications (%)	Failures
Lubicz et al. [26]	18	19	9.5	75	5	2
Gory et al. [25]	40	42	6.8	78.8	5	0
Fischer et al. [28]	25	25	10.2	85.0	12	1
Aguilar-Perez et al. [24]	28	28	7.5	86.3	0	0
Our study	21	22	9.7	93.0	5	2

FU follow-up

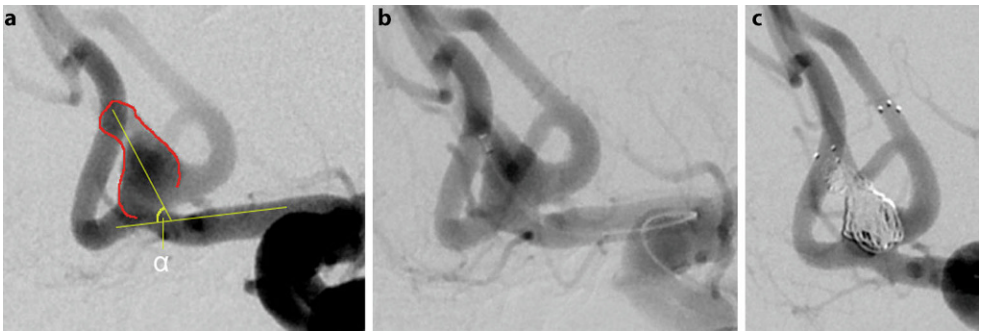

Fig. 4 Case of a failed pCONus implantation; **a** α = 70. **b** The microcatheter was placed in the aneurysm and showed a relatively sharp curve. Implantation of the pCONus was unsuccessful as either the petals prolapsed into the right A2 segment or the device left a gap to the left A2. **c** The aneurysm was then coiled with Y-stenting

which was designed and optimized for this purpose and may provide improved coil retention within the aneurysm.

In line with previous studies on the pCONus we experienced a safe application of the device, with a single case (5 %) of persistent neurological deficits and no mortality. Our study confirmed recent studies which had shown that the pCONus device offers a high level of adequate occlusion rates and is a valuable option for complex bifurcation aneurysms [24–27]. High occlusion rates could be observed immediately after the procedure. In our study, 35 % of the aneurysms were classified as complete occlusion (ROC 1) and 95 % as adequate occlusion (ROC 1 + 2), compared to a rate of 25–72 % complete occlusions and 61–83 % adequate occlusions seen in previous studies [24–26]. Similarly, follow-up surveys of the aneurysms treated with pCONus in this study confirmed prior ratings. In their initial report, Aguilar-Pérez et al. reported complete occlusion in 13 out of 22 cases (59 %), neck remnants in 6 out of 22 cases (27.3 %) and aneurysm remnants in 3 out of 22 cases (13.6 %) at follow-up periods between 2–19 months [24]. The follow-up study from the same group reported a rate of 45.5 % complete occlusion, 33.3 % neck remnants and 21.2 % aneurysm remnants, with 3 cases worsening within the last group at 3–6 months after treatment [25]. Lubicz et al. reported 75 % stable occlusion and 25 % recanalization rates at follow-up (2–24 months after endovascular treatment). In this study the complete occlusion rate at 1-year follow-up was 55 % and 40 % were classified as neck remnants resulting in an adequate occlusion rate of 95 % [26]. Other series reported technical failures: Fischer et al. [28] reported a detachment failure and Lubicz et al. [26] experienced 2 cases of pCONus-associated coil stretching. Available pCONus data are summarized in Table 3. Here, we report for the first time about possible anatomical limitations of the device and describe in which cases implantation might fail. In patients with successful device deployment the angle between the aneurysm and the parent vessel was 45° on average; however, the average angle was 71.5° in those patients where deployment failed, a statistically significant difference ($p = 0.006$) and an example is given in Fig. 4. The reason that pCONus deployment fails in aneurysms with these larger angles may be due to the fact that the petals deploy nearly orthogonally from the device stem. In highly angulated aneurysms, one petal connects with the aneurysm wall near the base, while a gap at the inside of the angle remains. This prohibits complete occlusion or may lead to coil protrusion; however, both issues can be recognized before detaching the device.

Our study had several limitations: the series had a limited number of patients and imaging follow-up at 1 year was not available for all patients. Furthermore, pCONus was not directly compared to other methods.

Conclusion

Deployment of pCONus device is safe and results in good initial occlusion rates; however, its use may be limited by the angle between the aneurysm and the parent vessel.

Compliance with Ethical Guidelines

Conflict of Interests C. Ulfert has received travel expenses from Bayer, Codman, Microvention and Stryker. J. Pfaff has received travel expenses from Siemens and Stryker. J. Bösel has received honoraria and travel expenses from Bard, Zoll, Seiratherm and Sedana Medical. M. Pham has received speaker fees and reimbursement of travel expenses from Penumbra, Covidien and Bayer. M. Bendszus has received fees and is consultant for Guerbet, Novartis, Codman and Roche. M. Möhlenbruch has received fees and is consultant for Acandis, Codman, Microvention, and Phenox and S. Schönenberger states that he has no conflict of interests.

Ethical standards All investigations described in this manuscript were carried out in accordance with national law and the Helsinki Declaration of 1975 (in its current revised form). Ethics approval was obtained from the ethics committee of the University of Heidelberg. Informed consent was obtained from all patients included in the study or the legal representative.

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