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The Safety and Effectiveness of the Contour Neurovascular System (Contour) for the Treatment of Bifurcation Aneurysms: The CERUS Study

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BACKGROUND: The Contour is a novel intra-aneurysmal flow disrupting device to treat intracranial aneurysms.
OBJECTIVE: To evaluate the safety and effectiveness of the Contour device for treatment of nonruptured intracranial bifurcation aneurysms through a prospective, multicenter, single-arm study.
METHODS: Thirty-four patients were enrolled. Primary end points were successful occlusion at 6 mo for efficacy and any major stroke or nonaccidental death up to 30 d or major disabling stroke within 6 mo for safety. Secondary end points were occlusion at 12 mo, retreatment rate, procedure time, and procedure-related/device-related adverse events. Procedural and follow-up imaging was reviewed by an independent core laboratory. Adverse events were reviewed and adjudicated by a clinical events committee.
RESULTS: In total, 32 of 34 aneurysms were successfully implanted and, 2 of 34 in the intention-to-treat (ITT) group did not receive the Contour and were excluded from follow-up after 30 d. In addition, 2 of 32 were lost to angiographic follow-up and regarded as treatment failure. The primary safety end point was met in 2 patients in the ITT group. In the perprotocol (PP) group, complete occlusion was seen in 14 of 32 (44%) at 6 mo and 22 of 32 (69%) at 12 mo. Adequate occlusion (Raymond–Roy [RR] 1 and 2) was reached in 84% at a last available follow-up. One patient from the ITT group and 1 from the PP group received additional treatment during follow-up.
CONCLUSION: The Contour seems to be both safe and effective in the treatment of intracranial bifurcation aneurysms.

KEY WORDS: Contour, Aneurysm, Endovascular, Bifurcation, Intrasaccular, Flow diversion

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Endovascular aneurysm treatment has become standard of care for certain anatomic locations and geometries.[1,2] Limitations of coiling[3] were overcome by balloon[4] and stent use.[5,6] Recent flow-diverting techniques[7-9] aim at fluid dynamic disruption of the aneurysm and parent vessel.[10] Flow diverters covering the aneurysm orifice also cover neighboring branches, potentially resulting in branch occlusion[11] and mandating antiplatelet medication.[12] Such a barrier at the neck, inside the aneurysm,[13-16] eliminates the risk of branch occlusion and potentially the need for antiaggregation.[17] Endosaccular flow disruptors include the Woven-EndoBridge (WEB, MicroVention),[18] the LUNA-AED (Medtronic),[19] and—most recently—the Contour (Cerus Endovascular Ltd).[20,21] WEB and LUNAs spherical braid fill the aneurysm dome while the Contour is a planar braid,[22] entirely positioned at the neck (Figure 1). The aim of this multicenter trial was to evaluate the safety and efficacy of the Contour to achieve conformité européenne mark (granted in July 2020).

ABBREVIATIONS: EC, Ethical Committee; **ITT,** intention to treat; **PP,** perprotocol; **RR,** Raymond–Roy; **sAPT,** single antiplatelet therapy; **SCA,** superior cerebellar artery; **WEB,** Woven-EndoBridge; **WOS,** WEB Occlusion Scale.

METHODS

A single-arm, premarket, prospective, multicenter trial to evaluate the procedural, short-term and midterm safety and effectiveness of the Contour in unruptured saccular bifurcation aneurysms was conducted at 6 European sites in accordance with the Declaration

of Helsinki, approved by the Ethical Committee (EC) of the Medizinische Fakultaet der Christian-Albrechts-Universitaet zu Kiel and all local ECs. The trial has been registered at ClinicalTrials.gov under NCT03680742.

Inclusion criteria were as follows: age 18 to 80 yr, aneurysm unruptured, untreated, neck 2 to 8 mm, and no adjunctive devices (unless bailout). Patients were selected by local principal investigators without sponsor interference. The participating centers were chosen by the sponsor based on previous experience particularly with intrasaccular devices but without a need to meet a specific safety/efficacy profile established ahead. All first treatments were entered into the trial without a lead-in phase. The sample size was defined by the conformité européenne mark criteria.

Primary end points were as follows: technical success, occlusion at 6 mo, and death or disabling stroke within 30 d/at 6 mo. Secondary end points were as follows: occlusion at 12 mo, instrumentation time, number of deployment attempts, and retreatment rate. Follow-up modified Rankin Scale (mRS) and National Institute of Health Stroke Scale were obtained at discharge, 1, 6, and 12 mo. Angiographic status was obtained at the end of the procedure and 6 and 12 mo.

Images were evaluated by an independent core laboratory (Eppdata) using the Raymond–Roy (RR) occlusion scale and the Bicetre-refined WEB Occlusion Scale (WOS).

The Contour

The Contour is a circular, dual-layered structure of 2 × 72 nitinol wires (Figure 1A) with 1 platinum marker (Figure 1B). It is radiopaque and retrievable until electrolytically detached. On deployment, it adapts to the lower half of the aneurysm, covering the neck (Figure 1C). It deploys through 0.027″ microcatheters. Sizing is performed to the aneurysm neck width and diameter, disregarding height, with 5, 7, 9, and 11 mm in diameter available.

Procedural Data

Procedures were performed on biplane angiosuites under general anesthesia through a transfemoral approach. In 14 of 34 cases, a triaxial system with an intermediate catheter was applied. Periprocedural medication was managed autonomously at each center. The most common combination was acetylsalicylic acid for single-antiplatelet therapy (sAPT in 7/34) and additional clopidogrel or ticagrelor for dual-antiplatelet therapy (in 25/34), mainly to allow for bailout stenting.

Data Collection

Each center collected an electronic patient file. Adverse events were collected even if no treatment was needed and without clinical worsening. Images were anonymized and transferred through cloud picture archiving and communication system (Cimar Inc) and analyzed by 2 independent neuroradiologists (10 and 15 yrs' of experience, not involved in treatment). Disagreements were solved by consensus. The results were recorded using a computerized system compliant to good clinical practice standards (Eppdata). Preoperative, postoperative, 6-mo, and 12-mo images were rated using the Raymond–Roy scale[23] and an adaptation of the Bicetre-refined WOS.[24] Applying both scales was performed to account for situations where there was coverage of the neck but contrast filling beyond the mesh—a constellation that occurs with braided implants, not coils.

RESULTS

Between October 2018 and July 2019, 34 patients were recruited at 6 centers in Austria, Denmark, and Germany. The mean age was 58 ± 11.4 yrs; 19 of 34 patients were male. Individual risk factors included hypertension (56%), current (47%)/past smoking (29%), previous stroke (18%), hyperlipidemia (18%), coronary artery disease (9%), peripheral vascular disease (9%), and diabetes, arrhythmia, afib, previous myocardial infarction, or seizures (3% each). Five patients had previous aneurysm treatment, and 2 patients previously had subarachnoid hemorrhage (SAH) from a nontarget aneurysm.

Per protocol analysis was based on 30 complete data sets including follow-up. Some of the 12-mo follow-ups fell within the COVID-19 pandemic and could thus only be performed by remote interview. Two patients in the intention-to-treat (ITT) group were not implanted with the Contour. In 1 patient, after 4 attempts that did not result in an angiographically satisfactory result; the aneurysm was finally stent-coiled, complicated by a thromboembolic stroke. Another patient in the ITT group suffered a superior cerebellar artery (SCA) aneurysm perforation on microcatheter probing and was treated with balloon-assisted and stent-assisted coiling. Both patients were followed up to 1 mo and disregarded from the perprotocol (PP) analysis for efficacy outcome.

Information on aneurysm geometry, location, and procedural details is summarized in Table 1. The device sizing chart is presented in Table 2.

Procedure

Technical success was achieved in 32 of 34 patients (94%) and, 2 of 34 were not treated with the Contour (see above). In 21 of 32 patients (66%), the Contour was implanted and detached at the first attempt and, in 11 of 32 (34%), it was deliberately retrieved and redeployed or replaced with a different size. One case demanded the use of a remodeling balloon as the sole adjunctive device in an index procedure. Instrumentation time ranged from 5 to 67 min (mean 19.8). The most common sizes used were 7 and 9 mm.

Clinical Outcome

The safety end point was met in 3 patients in the ITT group. Two were excluded from the PP analysis because they did not receive the Contour. One suffered a microcatheter perforation of an SCA aneurysm before device delivery. The other had a middle cerebral artery (MCA) bifurcation aneurysm where 4 attempts

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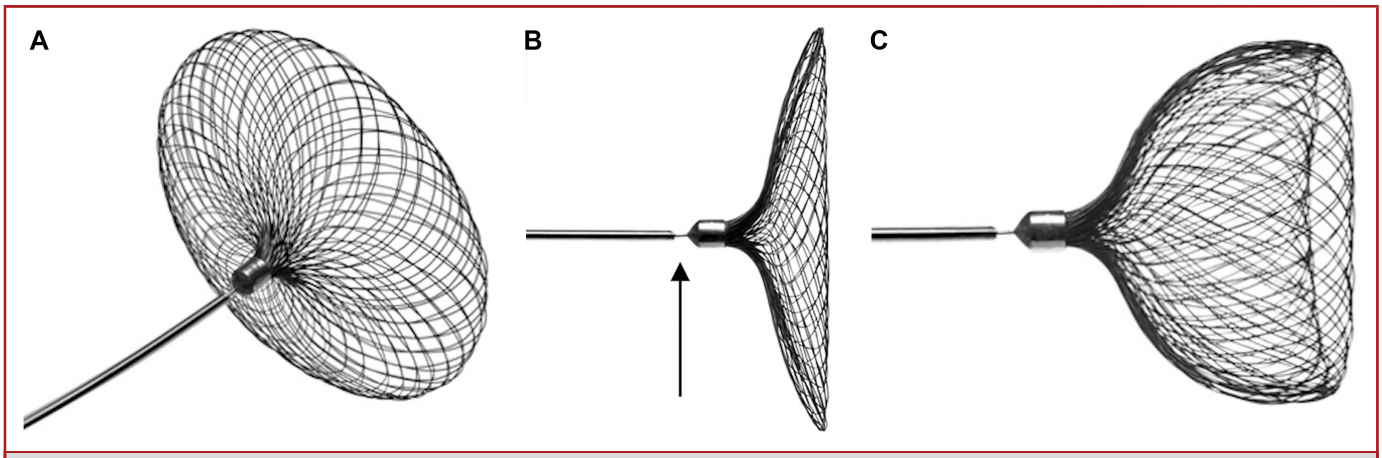

FIGURE 1. *The Contour is* A*, a dual layer circular braided construct with* B*, its proximal platinum marker connected to the introducer wire at the detachment zone.* C*, Inside the aneurysm, it typically adapts to the lower half of the sphere with its largest diameter at the equator level.*

placing various sizes of Contour did not result in a satisfactory angiographic result. The treating physician proceeded with stent-assisted coiling, complicated by disabling a thromboembolic stroke 90 min after the last Contour was removed. Both events were procedure-related but not device-related and had clinical sequelae up to 30 d when follow-up was discontinued.

In the PP group, 1 patient with an MCA aneurysm suffered a basilar perforator stroke on day 27, unrelated to treatment (mRS 3 at 1 mo and mRS 0 at 6 and 12 mo).

Nondisabling thromboembolic events occurred in 4 patients: 2 periprocedural, one 24 h after the procedure, and 1 on day 63. The first 3 were regarded as procedure-related and, the latter was likely device-related. In this patient, treatment was performed for an anterior communicating artery (AComA) aneurysm with both A2 segments filling from the left A1. This patient was on sAPT, prescribed before and independent from aneurysm treatment, but stopped for spinal surgery. Diffusion-weighted imaging/magnetic resonance imaging revealed a 5-mm area of restricted diffusion in the right precentral gyrus as a correlate of acute stroke that was responsible for lower extremity paresis. Angiographically, the aneurysm was reduced in size but partially perfused while there was no evidence of clot outside the implant. All 4 patients had complete resolution of their symptoms at the time of the next follow-up.

One patient experienced an unexplained SAH on day 3 after treatment of an internal carotid artery aneurysm, which at the time of the event was angiographically occluded but exhibited a neck remnant that appeared unchanged since the end of the procedure. Although not believed to be the source of hemorrhage, the neck remnant was successfully occluded with platinum coils. The patient had no clinical sequelae from this event.

At 12 mo, 30 of 32 patients in the PP analysis were mRS 0 and, 1 patient was entered into the study at mRS 2 and remained stable throughout. Another patient who was mRS 0 until 6 mo had no entry for the 12-mo follow-up (see Table 1).

Efficacy

Independent core laboratory occlusion status evaluation at the end of the procedure and 6 and 12 mo used the RR scale (Table 3) and Bicetre-refined WOS (Table 4). In patients unavailable to perform the 12-mo follow-up, the 6-mo occlusion status was carried forward. Completeness of follow-up was interfered with by the COVID-19 pandemic because some of the 12-mo follow-up visits fell within the first lockdown period. In total, 30 patients were imaged at 6 mo and 21 at 12 mo.

Two patients received additional treatment for the target aneurysm: one with additional coiling of a neck remnant and another with a positive family history of aneurysmal SAH and multiple aneurysms, some surgically clipped, suffered from an anxiety disorder and demanded treatment for a small neck remnant of an AComA aneurysm, angiographically stable at 6 mo and successfully treated with WEB. One patient with a large partially thrombosed AComA aneurysm showed recurrence after the Contour moved up into the aneurysm because the intra-aneurysmal thrombus adjacent to the neck had dissolved, essentially eliminating surface contact for the implant. This patient was rated WOS 3 at follow-up and should have been retreated but did not consent to this.

DISCUSSION

We conducted the first multicenter trial on Contour for intracranial bifurcation aneurysms at 6 different centers in Europe. There was no lead-in phase of the trial; none of the operators had previously used the study device in a patient. Patient selection was performed without interference by the sponsor. This has to be kept in mind, especially when comparing the results with those of other studies (Table 5).

TABLE 1. Patient, Aneurysm, and Procedural Demographics

	Mean	Min-max
Patient age (yr)	58 ± 11.4	32-81
Aneurysm height (mm)	7.1 ± 3.4	3.3-16.8
Aneurysm width (mm)	6.3 ± 2.4	2.5-10.7
Aneurysm neck width (mm)	4.3 ± 1.4	2.4-7.4
Dome-to-neck ratio	1.4 ± 0.4	0.9-2.6
Parent vessel diameter (mm)	2.6 ± 0.5	1.8-3.6
Total duration of procedure (min)	97.1 ± 56.8	30-270
Device instrumentation time (min)	19.2 ± 13.6	5-67

	AComA	MCA	ICA-PO	ICA-T	BA	IC-PC
Aneurysm location	13	10	1	1	8	1

	1	2	3	4
Deployment at number of attempts (n)	22	11	0	1

	5 mm	7 mm	9 mm	11 mm
Implanted device sizes (n)	5	9	14	4

	ITT analysis (n = 34)			PP analysis (n = 32)	
Clinical status	Preimplant	Discharge	1-mo follow-up	6-mo follow-up	12-mo follow-up
mRS 0—no symptoms	32	30	28	30	30
mRS 1—no significant disability		1	2	1	
mRS 2—slight disability	1	2	1		1
mRS 3—moderate disability			1		
mRS 4—moderately severe disability	1	1	1		
mRS 5—severe disability					
mRS 6—dead					
Missing entry[a]	—	—	1	1	1

AcomA, anterior communicating artery; BA, basilar artery; ICA-PO, paraophthalmic segment of internal carotid artery; ICA-T, internal carotid artery terminus; IC-PC, internal carotid artery at origin of posterior communicating artery; ITT, intention to treat; MCA, middle cerebral artery; PP, perprotocol.
[a]One patient was mRS 2 preimplant, discharge at 12 mo but missing entries at 1 and 6 mo. One patient was mRS 0 preimplant and up to 6 mo but missing 12-mo entry.

Intrasaccular Flow Disruption

Flow diversion and flow disruption have been applied to treat intracranial aneurysms since the advent of braided stents. It is conceptually different from volumetric displacement (ie, with coils) that counteracts aneurysm shrinkage, while implants exposed to the forces of clot retraction may deform, subsequently resulting in aneurysm reperfusion.[25] Implant conformability may be limited by the complexity of aneurysm shape. Sizing has to take into account the 3-dimensional aneurysm properties. Stent-type flow diverters achieve high long-term occlusion rates[7,26] exceeding 90%[27] and even induce aneurysm shrinkage.[28] However, they may cover branching vessels, resulting in luminal reduction, thromboembolism, or branch occlusion,[29] and typically mandate long-term antiplatelet therapy.[12] Insufficient dampening of the pulse pressure may result in rupture before thrombosis or neointima-formation occurs—a limitation in ruptured aneurysms.[30]

Intra-aneurysmal flow diverters are conceptually aiming at creating a border at the level of the neck, but from the sac and with no implant in the parent artery. So far, 3 different intrasaccular devices have been introduced into the field: WEB, LUNA/AED, and, most recently, the Contour. Existing evidence is very good for WEB with several good clinical practice studies[14-16] and numerous case series.[31,32] There is only 1 study available on the use of LUNA,[19] plus 1 single-center series, few case reports, and oral presentations.

TABLE 2. Recommended Implant Size

REF (catalog number)	Aneurysm neck (mm)	Aneurysm width (mm)
CNS05—5 mm	2.0-3.0	2.0-3.5
CNS07—7 mm	3.0-5.0	3.0-5.5
CNS09—9 mm	4.0-6.0	5.0-7.5
CNS11—1 mm	5.0-8.0	7.0-8.5

These recommendations follow the manufacturer's instructions for use. The device should be large enough to completely cover the neck, even if it comes to position itself "off center" with the marker directed to 1 side of the neck. Oversizing for aneurysm width helps to stabilize its position at the level of the neck. Aneurysm height can be used to allow additional oversizing but may otherwise be disregarded.

TABLE 3. Perprotocol Analysis of Aneurysm Occlusion Rate Using the Raymond Roy Scale at Key Time Points

Occlusion	End of procedure		6-mo follow-up (n = 30)		12-mo follow-up (n = 21)		12 mo/LOCF	
RR 1	3/30	10%	14/30	47%	15/21	71%	22/30	73%
RR 2	0/30	0%	9/30	30%	4/21	19%	5/30	17%
RR 3	27/30	90%	7/30	23%	2/21	10%	3/30	10%

LOCF, last observation carried forward; RR, Raymond–Roy.
In the LOCF analysis, for patients who were not available for their 12 mo follow-up, the result at 6 mo was used instead).

TABLE 4. Aneurysm Occlusion Rate Using the Web Occlusion Scale at Key Time Points (LOCF, in Patients Who Were Not Available for Their 12-mo Follow-up, the Result at 6 mo was Used Instead, Perprotocol Analysis)

Occlusion	End of procedure		6-mo follow-up (n = 30)		12-mo follow-up (n = 21)		12 mo/LOCF	
WOS 0	2/30	7%	13/30	43%	13/21	62%	20/30	67%
WOS 0′	2/30	7%	2/30	7%	2/21-	7%-	2/30	7%
WOS 1	22/30	73%	9/30	30%	1/21	5%	3/30	10%
WOS 2	-		5/30	17%	4/21	19%	4/30	13%
WOS 3	4/30	13%	1/30	3%	1/21	5%	1/30	3%

LOCF, last observation carried forward; WOS, WEB Occlusion Scale.

Although WEB and LUNA/AED are designed to fill the aneurysm and are sized based on volumetric measurements, the Contour essentially has no volume itself but adapts to the neck plane in a semi-2D fashion. Sizing is easy with just 4 sizes to choose from currently. Preimplant 3D imaging with extra contrast and radiation is less crucial when compared with planning a WEB procedure where anatomic analysis and selection of the optimal (WEB) device configuration and size require a considerable commitment of time and cognitive effort before the case.[33] The follow-up results of some earlier WEB series were inferior to those of the later trials (ie, WEB-IT), mainly because of sizing issues resulting in compression rates as high as 57.2% at the first follow-up.[31] This was also seen with WEB in recurrent aneurysms,[34] and other series demonstrating only 66% of favorable angiographic results at 3 mo[32] interpreted as indicating that experience is a prerequisite, especially for sizing.[35] In our study, there was only 1 case of device movement from the neck plane into a partially thrombosed aneurysm when thrombus dissolved. There was no evidence for compaction or deformation because of undersizing or clot retraction—a potential advantage of a nonvolumetric concept. Noteworthy, all participating physicians were experienced in the use of intrasaccular devices, mainly WEB, which was believed to be an advantage. Still, in 11 of 34 ITT group cases,

TABLE 5. Overview of Study Results for Intrasaccular Flow Disruptors (WEB, LUNA, and CONTOUR)

Study	No. of patients	Neck width	Adjunctive devices	Complete occlusion 6 mo	Complete occlusion 12 mo	Thromboembolic event	SAH (n)	Remarks
WEBCAST	51	All wide neck	8.3%	56.1%	—	17.7%	0	
FROBS	62	90.5% wide neck	11.3%	—	51.7%	12.9%	1	19% ruptured
WEBCAST 2	55	Mean 4.6 mm	1.8%	—	54%	14.5%	1	4 ruptured
WEB-IT	150	All wide neck	—	—	53.8%	0	2	6% ruptured
LUNA	63	Mean neck width 3.9 mm		41.7%	45.8%	3.2%	2	Mainly small aneurysms
CERUS	34 (ITT) 32 with implant	Mean 4.3 mm (29 of 32 were >4 mm)	3%	47% (PP)	73% (PP)	11% (ITT)	2 (ITT)	1 SAH and 1 thromboembolism in the ITT group with no device implanted

ITT, intention to treat; SAH, subarachnoid hemorrhage; WEB, Woven-EndoBridge.

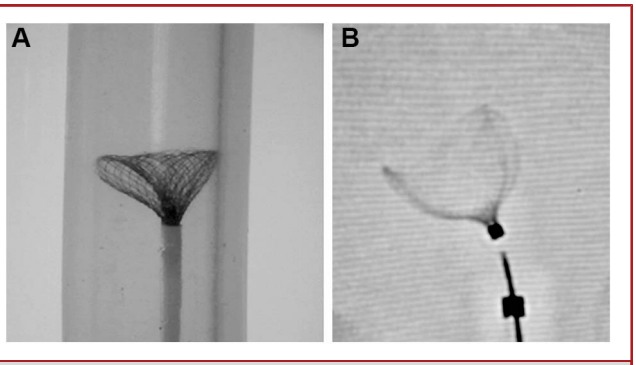

FIGURE 2. *During deployment, the 2 layers of the Contour typically separate, often resulting in* **A**, *a teardrop-shaped double outline visible in vitro but also under* **B**, *fluoroscopy. Persistence of this configuration can be an indicator for oversizing. Note that the mesh is made from drawn filled tube; hence, the entire implant is radiopaque, and there is just 1 proximal marker.*

the initial implant was replaced with a different size. However, fewer sizes to choose from and a nonvolumetric approach allow for a quick learning process for sizing. Although undersizing resulting in dislocation on careful traction is self-explanatory, an indicator of oversizing and incomplete opening seen in some cases can be seen in Figure 2: During opening, the 2 layers of the Contour separate on exiting the microcatheter to realign once it comes to lie in its final position. If the implant was chosen too large, persistent separation of the 2 layers may be seen fluoroscopically as a teardrop shape.

Core laboratory evaluation of 12-mo follow-up was compared favorably with previous series of wide neck bifurcation aneurysms (WNBAs). Although immediate occlusion (Figure 3) was found in only 7%–10%, depending on the scale, an increasing percentage of complete occlusion was found with time, comparable with flow diverter series. This should be kept in mind when considering the Contour for ruptured aneurysms. Increasing occlusion over time was also seen with WEB.[16] Our results with the Contour at 12 mo with 69% RR1 and 84% RR1+2 are comparable with multicenter trials on WEB and thus superior to those of conventional therapies for WNBAs. A wide neck was not a prerequisite in the study. However, a mean neck width of 4.3 mm and 29 of 32 aneurysm cases with a neck width >4 mm make our results comparable with other trials on WNBAs.[36]

Procedural Aspects and Adverse Events

In half the cases, the device handling time was 15 min or less; 20 of 32 cases in the PP group were performed in less than 90 min total. There were 2 procedural SAEs as described above, both unrelated to Contour, but attributed to the general risk of treatment. There were 2 minor strokes[37] that were related to treatment but with their symptoms resolved at the next follow-up visit. Finally, there was 1 unexplained SAH 3 d after treatment and with successful angiographic exclusion of the aneurysm where a neck remnant was coiled without clinical sequelae. The primary safety end point was met in 1 patient in the PP group, but unrelated to treatment. Overall, the safety profile of the Contour is acceptable and most likely comparable with other endovascular treatment options.

Limitations

The main limitations are small sample size, nonrandomization, and that patients were not excluded because of poor pretreatment clinical status or partial thrombosis of the aneurysm. There was no case selection process in place, which, on the other hand, represents a more realistic scenario and might make these results reproducible outside a study.

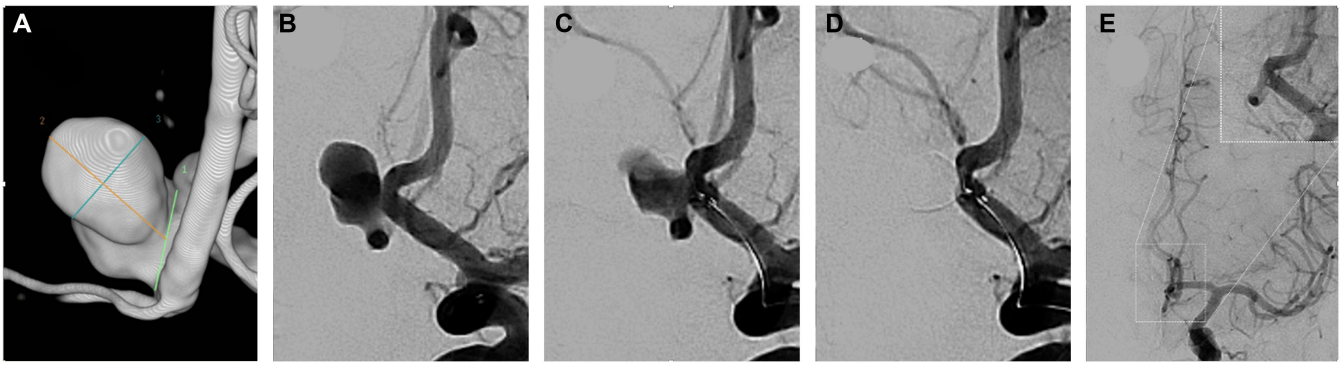

FIGURE 3. *Example case of the anterior communicating artery (AComA) aneurysm treatment.* **A**, *The dimensions on the 3D-rotational angiography were 8.3 mm × 5.8 mm × 5.45 mm (height × width × neck).* **B**, *The right A2 was filling predominantly from the right A1 and was partially arising from the aneurysm neck. Immediately after placement of a 9-mm Contour and before detachment there was marked inflow reduction with* **C**, *the right A2 now filling from right A1 only,* **D**, *followed by full stasis within 3 min, and* **E**, *with complete occlusion of the aneurysm, patency of the AComA and re-established cross flow at 6 mo.*

CONCLUSION

The Contour device shows encouraging results for the treatment of nonruptured intracranial bifurcation aneurysms. Our results are compared favorably with existing studies on intrasaccular devices and especially to those of conventional therapies of WNBAs. Further systematic evaluation is warranted in the light of possible future iterations of the study device and to better understand its full potential.

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Disclosures

Dr Liebig proctors and consults for Cerus Endovascular outside this study, and within the past 3 yr, he has proctored or received service-related fees from MicroVention, Sequent, Phenox, Stryker, Medtronic, and Pfizer. Dr Fiehler receives research support from EU, BMBF, BMWi, DFG, Acandis, Medtronic, MicroVention, and Stryker and holds an executive function at Eppdata and stock in Tegus. He consults for Acandis, Cerenovus, Medtronic, MicroVention, Penumbra, Phenox, and Stryker. Dr Jansen receives research support from BMBF and DFG. During the past 3 yr, he consulted for Acandis, Cerenovus, Cerus Endovascular, MicroVention, Philips, Radiologie Holding, Route 92, and Stryker. Dr Berlis has no conflicts with Cerus Endovascular outside this study, and within past 3 yr, he has proctored or received service-related fees from MicroVention (proctor), Sequent Medical (proctor), Phenox (lecture honorary, CEC), Stryker (proctor, lecture honorary), and Penumbra (lecture honorary). Dr Killer-Oberpfalzer consults for Cerus Endovascular outside this study, and within the past 3 yr, she has received service-related fees from MicroVention, Medtronic, and Stryker. Dr Wodarg proctors and consults for Cerus Endovascular outside this study, and within the past 3 yr, he has proctored or received service-related fees from MicroVention, Acandis, Cerenovus, Route 92, and Daiichi Sankyo. Dr Dorn receives research support from Cerenovus and proctors and consults for Cerus Endovascular outside this study, and within the past 3 yr, she has proctored or received service-related fees from Phenox, Cerenovus, Acandis and Balt Germany. Dr Schramm receives research support from Siemens and Penumbra, consults for Cerus Endovascular, and within the past 3 yr, he has proctored or received service-related fees from Penumbra, Phenox, and Stryker. Dr Gal proctors for Cerus Endovascular.

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COMMENTS

Adding to the armamentarium of intra-saccular flow-disrupting devices, this study presents preliminary data on the safety and efficacy of the Contour device (Cerus Endovascular, Ltd.). The authors report the results of a single-arm, prospective, multicenter trial designed per Ethical Committee (EC) mark criteria for the purposes of clearance in the European Union. The primary efficacy outcome was occlusion at 6 mo, and safety outcome was death or disabling stroke within 30 d and 6 mo. Thirty-four patients were enrolled across 6 sites, but only 32 patients were included in the final per protocol analysis due to failure to implant the device in 2 patients. The safety end point was met in 3 of the 34 patients in the intention-to-treat cohort, but 2 of these patients did not have Contour implanted. Efficacy was comparable to that of the WEB. By design, patient selection was done by the local PI without sponsor involvement, only under the guidelines of age 18 to 80, unruptured aneurysm, and neck 2 to 8 mm. There was no lead-in phase for device training either. Thus, the study resembles more of a phase IV post-market surveillance study rather than a clinical trial to establish safety and efficacy. While a more rigorous trial may be warranted to better characterize device performance, the study design is suitable for its purpose of EC mark and the data from its use in a more "real-world" situation shed light on how patients will fare when this device comes to market.

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This is a prospective multicenter single arm study to assess safety and efficacy of the novel Contour flow disruption intrasaccular device for bifurcation aneurysms. This device apposes the neck of saccular aneurysm and is sized according to the neck diameter. In this study of 34 patients conducted in intrasaccular device deployment experienced European centers, the success rate of deployment was 94% with 4 cases of deployment related complications (3 minor and 1 major stroke). The device itself appears to sit safely in most cases despite its nonvolumetric profile with only 1 migration in a lesion with resolving partial thrombosis. Complete occlusion was achieved in 48% at 6 mo and 73% at 12 mo, which appears comparable with WEB and LUNA devices (40%-50% range). While it appears to show promising results on safety and efficacy, patient selection will be paramount. It remains uncertain of its potential application in ruptured aneurysms given only <10% immediate occlusion. In addition, the current cohort selection was done by saccular device experts with limited information on their selection criteria which may not be representative of real-world practice variability. Overall, the Contour device represents another alternative in the category of intrasaccular flow disruptors.

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