Acta Neurochir (2016) 158:1545–1553
DOI 10.1007/s00701-016-2839-8

EXPERIMENTAL RESEARCH - VASCULAR

Stent-assisted coil embolization of challenging intracranial aneurysms: initial and mid-term results with low-profile ACCLINO devices

Derya Tureli[1] · Soheil Sabet[2] · Serkan Senol[3] · Nurten Andac[4] · Halil Donmez[3] · Serdar Geyik[5] · Feyyaz Baltacioglu[2] · Saruhan Cekirge[6]

Received: 19 December 2015 / Accepted: 10 May 2016 / Published online: 2 June 2016

Abstract
Background Stent-assisted coiling using low-profile, self-expandable and retrievable stents is a valid option in endovascular treatment of challenging intracranial aneurysms. This study aims to evaluate the feasibility and efficacy of ACCLINO 1.9 F and ACCLINO Flex stent systems, designed for use as adjunctive products in coil embolization of intracranial aneurysms.
Methods Case files of 47 patients, and 52 aneurysms in total, treated with at least one ACCLINO 1.9 F or ACCLINO Flex stent were retrospectively evaluated. Technical success, complications, and angiographic outcomes were assessed based on immediate post-procedural controls along with 6th and 12th month angiograms.
Results Mechanical untoward event rate, including asymptomatic complications, is 9.6 % (five out of 52 aneurysms). Failed dual-stenting attempt rate is 15.4 % (two out of 13). Overall procedure-related morbidity is 4.2 % with no neurologic sequelae. Initial occlusion rate is 90.4 % (47 aneurysms). One patient had residual filling in the aneurysm neck, which was stable throughout follow-up. The remaining four cases had spontaneous follow-up occlusion. Recanalization rate at 6th month is 2.1 % with one aneurysm requiring retreatment. One patient was lost to follow-up. There is no mortality associated with treatment.
Conclusions Stent–assisted coil embolization with ACCLINO stents in single or dual configurations is a feasible treatment option for challenging intracranial aneurysms. Follow-up results are encouraging; techniques were effective in complex cases and there were no clinically significant adverse outcomes.

Keywords Cerebral aneurysm · Stent-assisted coil embolization · Low-profile stent

The authors confirm that the manuscript has not been published elsewhere and is not under consideration by another journal. All authors have approved the manuscript and agree with its submission to Acta Neurochirurgica.

✉ Derya Tureli
deryatureli@yahoo.com

[1] Department of Radiology, Umraniye Training and Research Hospital, Elmalıkent M, Adem Yavuz C. #1, 34760 Umraniye, Istanbul, Turkey

[2] Department of Radiology, Marmara University School of Medicine, Istanbul, Turkey

[3] Department of Radiology, Erciyes University School of Medicine, Kayseri, Turkey

[4] Radiology Clinic, VKV Amerikan Hospital, Istanbul, Turkey

[5] Interventional Neuroradiology Clinic, Memorial Healthcare Group Hospitals, Istanbul, Turkey

[6] Interventional Radiology Clinic, Koru Hospital, Ankara, Turkey

Introduction

Endovascular coil embolization is a feasible treatment option for intracranial aneurysms [23]. However, wide-necked intracranial aneurysms remain technically challenging due to the increased risk of coil protrusion from the aneurysm sac into the parent artery. Contemporary endovascular treatment strategies for such aneurysms are balloon-assisted coiling, stent-assisted coiling, dual stenting, and flow diversion [31, 35]. Self-expandable intracranial stents, commercially available since 2002, have broadened the spectrum of aneurysms amenable to endovascular treatment with improved long-term success [4, 29, 33]. Stents function mechanically as scaffolds

preventing coil protrusion into arteries and stabilize both defective arterial wall segment and aneurysms sac; thus, angiographic recurrence is inversely correlated with the presence of a stent [26, 27]. Stents exert further biologic and hemodynamic effects by forming a matrix for orifice endothelialization, disrupting aneurysmal inflow, and increasing blood stasis within aneurysm sac promoting thrombosis. These effects are more pronounced with dual stenting [13, 14, 20, 26, 34].

Though downsizing of stent delivery systems is crucial for increased safety of procedure, delivery of self-expandable stents was only possible through 0.021 to 0.027-in. microcatheters until 2011 [5]. Introduction of new-generation stents deliverable via 0.0165-in. microcatheters enabled easier navigation in low-caliber delicate vessels and safer stenting [10, 11, 24]. Advanced neurovascular stents, such as LVIS Jr. (MicroVention, Tustin, California), LEO + Baby (Balt, Montmorency, France), and ACCLINO (Acandis, Pforzheim, Germany), with their low-profile, self-expandable and retrievable designs, provide better flexibility, maneuverability and overall effectiveness in endovascular treatment of complex or distal aneurysms. These stents also allow dual-stenting, which is often a necessity in cases of bifurcation aneurysms [5, 9, 17, 28]. ACCLINO 1.9 F and ACCLINO Flex stent systems, having received the CE mark in June 2012 and April 2014, respectively, for use in European countries with FDA approval pending, are the newest additions to the armamentarium of aneurysm treatment [1, 17]. This study aims to evaluate the feasibility of ACCLINO 1.9 F and ACCLINO Flex stents in endovascular treatment of challenging intracranial aneurysms in light of initial and mid-term results from four interventional neuroradiology centers.

Materials and methods

Case archives of four interventional neuroradiology departments were retrospectively evaluated by four experienced interventional neuroradiologists. Wide-necked intracranial aneurysms treated with at least one ACCLINO stent on an intention-to-treat basis between January 2013 and June 2015 were included. The study was in compliance with institutional review board guidelines. Interdisciplinary consensus among neurointerventional radiology, neurosurgery, and neurology departments was sought in each case. Written informed consent for endovascular treatment was obtained after discussing surgical and conservative management options with patients.

Patients and aneurysms

Forty-seven patients with a total of 52 aneurysms were treated. Aneurysms requiring stent-assisted coiling had at least two of the following characteristics: (a) Located in parent arteries with a diameter ≤3.5 mm, (b) dome/neck ratio <2, neck diameter >4 mm, and (c) any morphology not suitable for primary coiling. Aneurysm diameters ranged from 2.4 to 10.2 mm (mean = 5.2 mm) with an average neck width of 3.5 mm (range, 1.9–6.4 mm). Aneurysm locations were as follows: Twenty-one (40.3 %) at middle cerebral artery; six (11.6 %) at distal ICA segments; 19 (36.5 %) at anterior communicating artery and six (11.6 %) at basilar artery. All aneurysms were incidental and had not received any form of treatment previously. None of the patients had documented intracranial hemorrhage prior to treatment.

Antiplatelet regimen

Strict pre and post-procedural antiplatelet regimen and intraprocedural anticoagulation protocols were employed. Clopidogrel resistance was ruled out before the procedure and dual antiplatelet therapy was initiated with a loading dose of 450 mg clopidogrel and 300 mg aspirin. In one single patient with clopidogrel resistance, antiplatelet treatment was initiated with 40 mg prasugrel. Intraprocedural anticoagulation was achieved with 5000 IU heparin bolus intravenously at the time of femoral sheath placement and maintained by hourly 2500 IU i.v. push. Dual antiplatelet therapy with clopidogrel 75 mg/day and aspirin 100 mg/day was continued post-procedure for 6 months. Afterwards, a 100-mg/day aspirin monotherapy was resumed. Antiplatelet regimen in case of clopidogrel resistance comprised prasugrel 10 mg/day.

Devices

ACCLINO 1.9 F and ACCLINO Flex devices are low-profile, laser-cut microstents with electropolished surfaces. They are offered in diameters of 3.5 and 4.5 mm, both available in lengths ranging from 15 to 35 mm, in 5-mm increments. ACCLINO stents are available in various sizes recommended for vessel diameters from 2.0 to 4.0 mm [1, 17]. These self-expanding stents are compatible for delivery through 0.017-in. microcatheters. The micro-guidewire is removed after microcatheter placement; then, the stent is introduced and pushed through the microcatheter; and, via push-and-pull maneuvers, it is unsheathed across the aneurysm neck. Stent has three radiopaque indicators at both ends and a middle marker on the transport wire improving stent visibility during deployment. ACCLINO is of closed-cell design, which enables retrieval, resheathing, and redeployment even if the stent is unsheathed up to 90 % of its deployed length. Stent wall thickness is approximately 55 μm and strut width is 35 μm. Mesh pore size is approximately 1.8 mm, which obviates catheter exchange during aneurysm coiling with trans-cell technique [1, 2, 18].

Endovascular technique

Procedures were performed under general anesthesia. Transfemoral route was employed. Stent-assisted coiling of intracranial aneurysms is achieved using the jailing technique: First, the parent artery, and then the aneurysm sac is catheterized with 0.017-in. microcatheters over soft-tip 0.014-in. micro-guidewires. Microcatheters used were Acandis 1.9 F and Neuroslider 17 (both by Acandis, Pforzheim, Germany), Headway 17, Headway Duo and Scepter C (MicroVention, Tustin, CA, USA), and Echelon (ev3, Irvine, CA, USA). After that, the ACCLINO stent is deployed into the parent artery, across the aneurysm neck, thereby jailing the coil delivery microcatheter between the vessel wall and stent struts. Then, the aneurysm is coiled using bare platinum detachable coils until complete occlusion is achieved or further coiling is deemed unsafe.

For Y-stenting, the parent artery and its branch with the more acute bifurcation angle is catheterized using a 0.017-in. microcatheter. Then, the aneurysm sac is catheterized with another 0.017-in. microcatheter. After that, the first stent is deployed into the branch vessel, which is followed by catheterization and stenting of the other branch artery through the first stent's interstices using the same 0.017-in. microcatheter. Finally, the aneurysm is coiled using detachable coils.

Follow-up protocol

At the end of the procedure, immediate control angiograms, cranial CT, and diffusion-weighted MRI were obtained from all patients. Modified Raymond–Roy classification was used for grading occlusion status of coiled aneurysms [21]. Patients underwent DSA at the 6th and 12th month to reassess filling status of the coiled aneurysm, stent stenosis, and thrombosis. The modified Rankin scale was used for scoring neurologic status at discharge and follow-up.

Illustrative cases

Of particular note is one case with two left MCA aneurysms; one located at ostial level of superior trunk and other at bifurcation of inferior trunk. Both aneurysms were treated concurrently with coil embolization after deploying three stents in an alternate-branched Y configuration (Fig. 1).

One patient required stenting in order to restore diminished inflow to the left MCA superior trunk, which was due to compression by a woven endobridge device (WEB, Sequent Medical, Aliso Viejo, CA, USA) deployed into the neighboring bifurcation aneurysm (Fig. 2).

In another case, balloon-assisted coiling had to be concluded with stent-assisted procedure due to coil prolapse into parent artery after balloon deflation. ACCLINO Flex stent, proven to be deliverable through the balloon (Scepter C, MicroVention, Tustin, CA, USA), was deployed into the parent artery trapping coils inside the aneurysm.

Results

Forty-seven patients, 28 female and 19 male, with ages ranging from 29 to 72 and an average of 53 years, were treated. Forty-one aneurysms were treated with single stents, whereas 11 required Y stent-assisted coil embolization. In our series, the smallest vessel stented was of 1.2 mm in diameter with no observed short- or long-term complications.

Technical difficulties

Technical difficulties were encountered in five cases (9.6 %) none of which had significant angiographic or clinical adverse outcomes during follow-up. Two of these occurred during double-stenting of MCA bifurcation aneurysms: One was observed after stent deployment into superior branch while advancing the microcatheter through stent interstices. Proximal end of stent was displaced and folded into inferior branch resulting in U-shaped stenting of both trunks (Fig. 3). In another patient, the first stent migrated 4 mm proximally during microcatheter retrieval over the microguidewire. Both procedures were completed as single–stent assisted coiling. Twelfth-month control DSA of both cases showed patent MCA flow. Thus, double-stenting attempt success rate was 84.6 % (11 in 13 aneurysms).

The remaining three cases with technical difficulties were observed during single-stent assisted coiling: In two cases, the stent delivery microwire got stuck inside the fully expanded stent after deployment. The wire was entrapped inside the stent lumen at an acutely curved segment and could not be separated via gentle maneuvers. The microcatheter was advanced over the wire to gain leverage enabling removal of the wire from the stent following gentle backward and forward manipulation. During treatment of another aneurysm, the stent was inadvertently unsheathed, and expanded nearly completely, at a more proximal location than desired. ACCLINO stents are suitable for recapturing and repositioning, though deploying a brand new stent is more favorable than using the resheathed one if possible. Operator, in this instance, retrieved the stent by resheathing it into its delivery microcatheter, and redeployed the stent after repositioning the catheter at intended location. The remainder of the procedure was carried out uneventfully.

Immediate embolization results and angiographic follow-up

The modified Raymond–Roy classification was used for grading occlusion of treated aneurysms [21]. Immediate

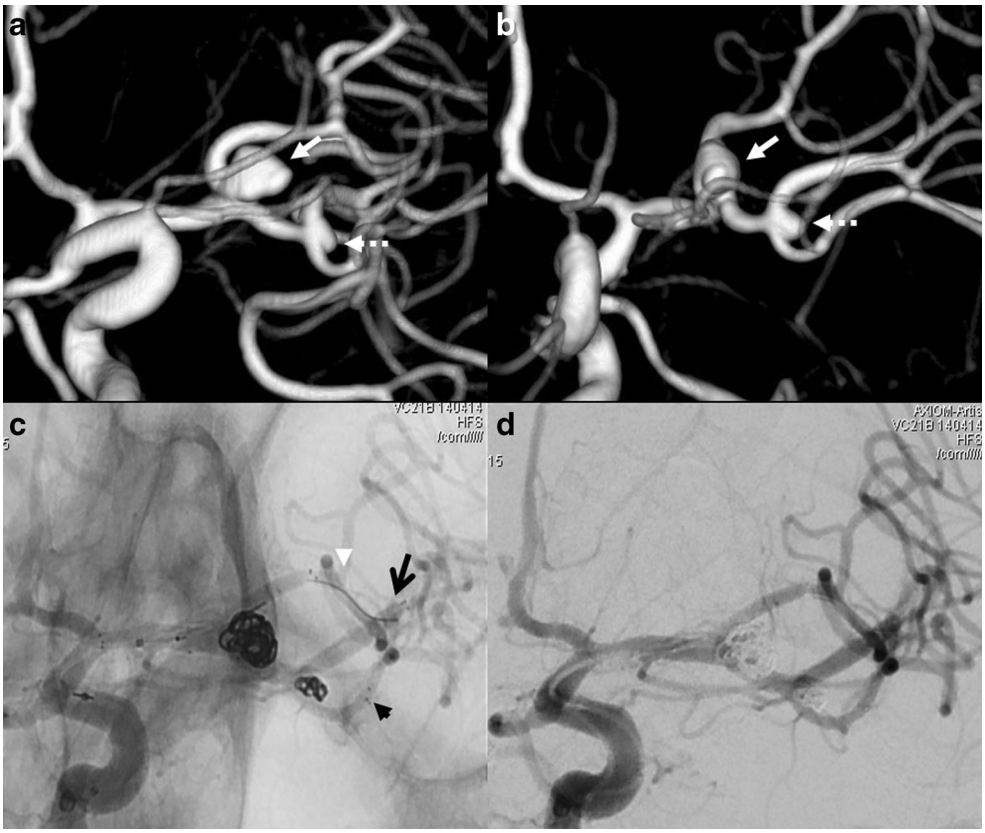

Fig. 1 **a**, **b** Left MCA bifurcation aneurysm (*solid white arrows*) and inferior trunk bifurcation aneurysm (*dashed white arrows*) treated with stent-assisted coiling in an alternate-branched Y configuration. **c**, **d** First a long stent (*black arrow*) is deployed from superior branch of inferior trunk to M1 segment. Then two short stents, one into inferior branch of inferior trunk (*black arrowhead*) and the other into the superior trunk (*white arrowhead*), are deployed

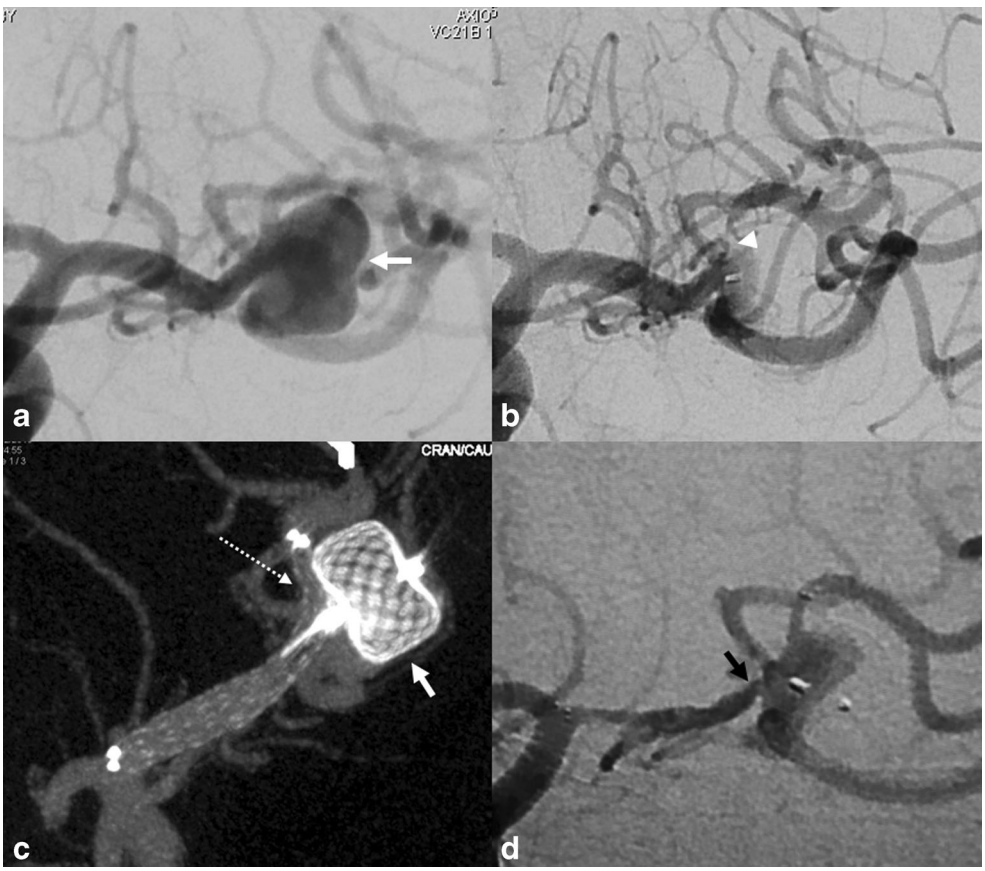

Fig. 2 **a** Wide-necked left MCA aneurysm (*white arrow*) occluded with Woven Endobridge (WEB) device. **b** After WEB deployment (*short white arrow*), a narrowing at the origin of the superior trunk (*white arrowhead*) is noted causing slow inflow. **c** ACCLINO stent placed into the superior trunk (*dashed white arrow* in angioCT). **d** Second month control angiogram shows moderate grade stenosis within the lumen (*black arrow*)

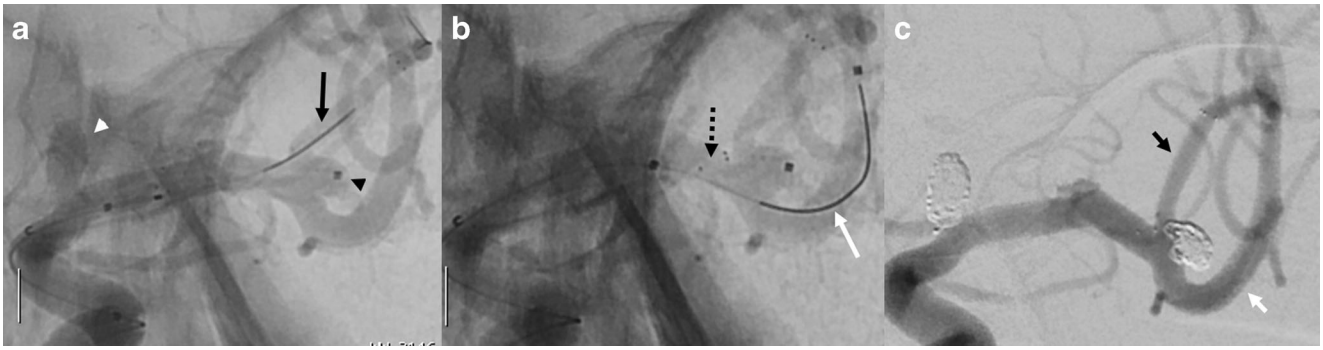

Fig. 3 **a** Aneurysms of ICA tip (*white arrowhead*) and left MCA bifurcation (*black arrowhead*). Y stenting is intended for the treatment of bifurcation aneurysm. A stent is deployed into the superior trunk first (*black arrow*). **b** During catheterization of the inferior trunk (*white arrow*), the proximal end of the stent migrated to the level of bifurcation (*dashed arrow*). **c** Flow patency is not compromised in both trunks (*black and white short arrows*) at the 1st year control

postprocedural angiographic results were as follows: Initial complete occlusion, i.e., class I, was achieved in 90.4 % of aneurysms ($n=47$). Four aneurysms showed residual neck, i.e., class II, opacification; and one aneurysm had contrast opacification within coil interstices of the residual aneurysm (class IIIa). There was no aneurysm with contrast opacification outside coil interstices, along aneurysm walls (class IIIb).

Three of the initially class II aneurysms and one class IIIa aneurysm were completely occluded by their 6th-month control angiograms. One class II aneurysm remained stable in size throughout the follow-up. The recanalization rate was 2.1 %; one initially class I occluded aneurysm showed class IIIa inflow at 6th-month control and had expanded by 12th-month DSA. This case was managed by simple coiling and complete occlusion was verified with the 18th-month control DSA. This, up until preparation of the manuscript, is the only patient requiring retreatment. All six patients had been treated with single stents. Complete occlusion was achieved in the rest of the cases (Figs. 4 and 5).

One patient was lost to follow-up. The remaining patients complied with their 6th- and 12th-month DSA follow-up protocols. At the time of this manuscript's preparation, the number of patients who had not yet undergone their 6th- and 12th-month DSA, due to recentness of their procedures, were two and six, respectively.

Complications

Intra-procedural complications arose in two cases; one hemorrhagic and one thrombotic, both during double-stenting. The hemorrhagic complication occurred during Y-stenting of an anterior communicating artery aneurysm. While advancing the second microcatheter into the second branch, the microguidewire punctured the aneurysm sac with subsequent subarachnoid hemorrhage. Bleeding was self-limiting and coil embolization was accomplished the next day in a separate session. The thrombotic complication emerged as an acute in-stent thrombosis within the unfavorably angled inferior trunk of a Y-stented left MCA bifurcation aneurysm. Total thrombolysis was achieved by prompt intra-arterial Tirofiban infusion. Post-procedure control angiography demonstrated complete luminal patency in this case.

Post-procedural complications were observed in two patients; one early thrombotic event and one moderate in-stent stenosis. Ten days after treatment of her M1 segment aneurysm, one patient experienced pure motor hemiparesis as part of a lacunar syndrome. The patient was hospitalized and enoxaparin therapy was initiated along with the routine dual antiplatelet regimen. She made excellent recovery without any neurologic sequelae to this date. Post-procedural in-stent stenosis was observed in one patient only. Second-month control DSA of the patient treated with WEB device showed moderate-grade stenosis within the stent lumen (Fig. 2). The patient is yet asymptomatic.

With one intra-procedure hemorrhagic and one early post-procedure thrombotic complication, the overall procedure-related morbidity was 4.2 % (two out of 47 patients). Apart from the case with intra-procedure hemorrhage, recovery from anesthesia was uneventful in all patients. No untoward event was observed during the hospital stay. There were no late post-procedure thromboembolic events. There was no procedure-related mortality.

Discussion

Prior to the introduction of advanced neurovascular stents, the spectrum of aneurysms amenable to stent-assisted endovascular treatment was rather limited. Mortality and morbidity associated with endovascular treatment of unruptured cerebral aneurysms were at best 1.2 and 4.7 %, respectively [25]. Availability of a new generation of advanced neurovascular stents has enabled neurointerventionalists to undertake treatment of more challenging aneurysms. Even with previously untreatable aneurysms, overall treatment-

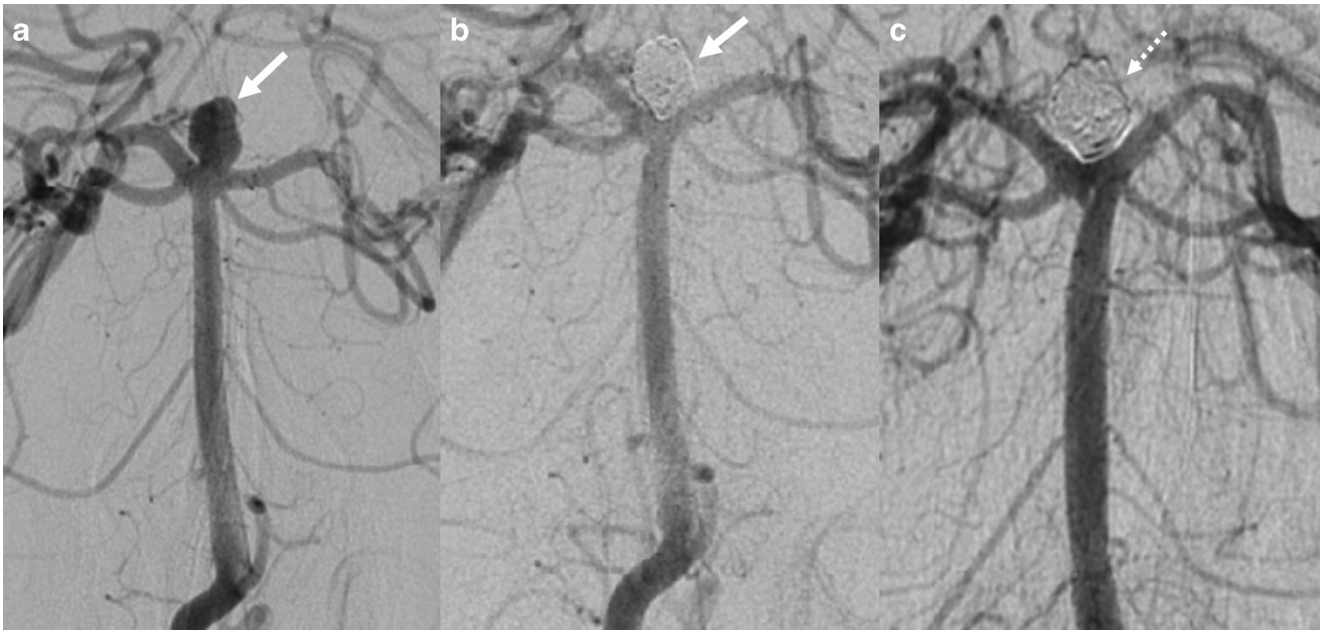

Fig. 4 **a**, **b** Basilar tip aneurysm (*solid arrows*) treated with Y stent-assisted coil embolization. **c** No recanalization is observed in 12th-month control angiogram (*dashed arrow*)

related morbidity and mortality of advanced stents is comparable to those of past series with earlier generation of stents. In our series, the overall procedure-related morbidity with ACCLINO was 4.2 %, an acceptably low figure, and the absence of any permanent neurological deficit is especially promising. A previous series of 14 aneurysms, both ruptured and unruptured, treated with ACCLINO reported 7 % complication rate [18]. Our complication rate was lower compared to those of LVIS Jr., i.e., 15 % in a series of 32 patients, but the mentioned series also contained ruptured aneurysms [6]. A study with LEO + Baby stents reported an overall complication rate of 11.3 %, including asymptomatic minor events; and there was 3.8 % permanent mild to moderate morbidity [5].

One major difference among the three new-generation intracranial stents is their mesh pore sizes. ACCLINO has a cell size of 1.8 mm when fully expanded, whereas those of LVIS Jr and LEO + Baby are 1.5 mm and 0.9 mm, respectively. It was previously inferred that LEO + Baby stent, due to its significantly smaller pore size, and higher surface coverage ratio, may create relatively higher flow-diversion capacity compared to others [3, 5, 18, 30]. However, flow-diversion is dependent on many other intrinsic characteristics of a stent's design and there are no studies directly comparing flow-diversion property of these three stents. Nevertheless, though not designed to provide flow-diversion, our experience implies that ACCLINO is capable of flow-modulation to a certain extent. Due to its larger cell size, ACCLINO has the potential advantage of easier double-stenting since there is more room for a second stent through the stent interstices, thus the constraint on the second stent is reduced at the stent intersection.

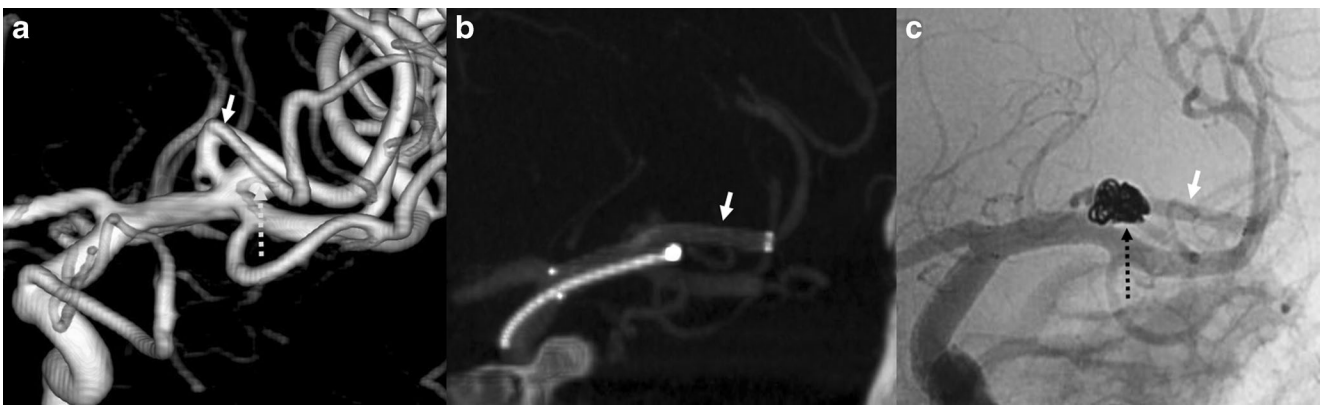

Fig. 5 **a**, **b**, **c** Left MCA bifurcation aneurysm (*dashed white arrow*) treated with single stent-assisted coiling (*dashed black arrow*). Stent's radial force is sufficient to straighten the superior trunk (*white arrows*)

The ACCLINO stent, in our experience, stands out due to its efficient deployability. It exhibits minimal foreshortening or recoil during deployment, which facilitates positioning and unsheathing. Due to ACCLINO's closed-cell design, force exerted at one end is immediately transferred to the other. In open-cell designs, on the other hand, each segment acts independently, which augments stent apposition to vessel walls but compromises transmission of force throughout the stent [5, 26]. LVIS Jr stents also have closed-cell design; LEO + Baby stents, on the other hand, with their sliding-strut structure, have hybrid features of both open and closed-cell designs [5].

The main disadvantage of the closed-cell design is that the stent may flatten or kink at vessel curvatures. This incomplete stent apposition is associated with thromboembolic complications [7, 12, 15, 16, 32]. ACCLINO's electropolished surface provides corrosion resistance while minimizing friction, intimal changes, and intraprocedural thrombogenicity. This decreased friction, on the other hand, warrants extra caution during manipulation of the jailed microcatheter due to potentially increased risk of stent displacements and cell impingements [1, 17, 19]. Though electropolished stents are less thrombogenic initially, lack of intimal changes may increase the risk of thromboembolic events in the long run [28]. In our series, the overall rate of thromboembolic events and in-stent stenosis was 4.2 %, whereas that of LVIS Jr, another closed-cell design stent, was reported between 5.8 and 9.1 % [6, 24, 28]. A meta-analysis of cases treated with older-generation stents between 2000 and 2011 revealed periprocedural in-stent thrombosis and thromboembolic event rate as 8.9 % and late in-stent stenosis rate as 5.3 % [22]. In a series of stent-assisted coiling with LEO + Baby, a hybrid cell design stent, in-stent stenosis rate was 15.6 %, though all were anatomically mild and asymptomatic [5].

With closed-cell stents, angular remodeling is more pronounced and shown to be a continuous post-treatment process [14]. Radial force of a stent is an important factor in parent artery stabilization and aneurysm neck remodeling. It enables stent's self-expansion and is, to a certain degree, determined by that stent's metal load. LEO + Baby stent contains 16 longitudinal wires and is reported to have lower incomplete expansion rates compared to LVIS Jr stent, which has 12 wires [3, 10]. ACCLINO, too, is composed of 12 longitudinal wires. Though there is no direct comparison in the literature regarding radial forces of LEO + Baby and ACCLINO stents, in our experience, ACCLINO has enough radial force to stabilize and remodel the parent artery despite its low metal-load (Fig. 5).

The major advantage of a closed-cell design is its ability to be resheathed into delivery microcatheter [26]. This allows stent retrieval unless fully expanded during deployment and enables the operator to optimize stent position. ACCLINO is retrievable until 90 % of its post-deployment length and this is a major improvement over non-retrievable open-cell stents and the previous generation of closed-cell stents such as Enterprise, which can be retrieved up to 70 % of its length. Another new-generation closed-cell stent, the LVIS Jr., can be withdrawn until it is 80 % released [24, 28].

Transport wire markers of ACCLINO are radiopaque for positioning and there are gold markers at the stent ends for visualization. Apart from those markers, the stent body, according to our experience, is hardly visualized under live fluoroscopy. This property, though desirable for a less obscured region of interest during fluoroscopy, may also impede optimal visualization of stent expansion, which is especially troublesome at acute curvatures of vessels where stents are more prone to incomplete expansion, recoil, or foreshortening. We think this was the case, at least in part, with the previously mentioned micro-guidewire entrapments inside stent lumina and in-stent thrombosis. Other laser-cut stents, such as NeuroForm (Boston Scientific, Natick, MA) and Enterprise (Codman Neurovascular, Ratham, MA), are also fluoroscopically visible only at their ends. On the other hand, LVIS Jr. and LEO + Baby stents, both braided not laser-cut, are visible throughout the entire stent body.

The ACCLINO 1.9 F Stent system was initially tested by the manufacturer for compatibility with the Acandis 1.9 F Microcatheter included in the set. For the ACCLINO Flex stent, on the other hand, the manufacturer recommends their more recently introduced NeuroSlider 17 microcatheter, which is sold separately [1, 9, 17, 19]. The ACCLINO Flex stent can be delivered with ease through Headway Duo microcatheters, which have 0.0165-in. internal and 1.6-F distal outer diameters; five cases were Y-stented using this microcatheter with no technical difficulties or complications. The ACCLINO Flex was also deliverable through Scepter Balloons, a feature initially emphasized for LVIS Jr stents.

A limitation of this study, due to it being retrospective and non-randomized, is the absence of a control group. One patient was lost to follow-up with 4.3 and 13.1 % of patients not yet undergone their 6th- and 12th-month control angiography by the time of manuscript submission. Another potential limitation is that none of our patients were treated in an acute setting of subarachnoid hemorrhage. This precludes generalization of our results to such context. Endovascular treatment in the acute phase of subarachnoid bleeding, despite positive outcomes reported in certain series, remains controversial. The need for dual antiplatelet therapy is also a potential cause for concern [8, 27, 31].

The lack of justifiable criteria for the introduction of novel neurointerventional devices is still a relevant problem in clinical practice. Prospective randomized trials, at least those

concerning neurointerventional devices, may not be the ideal solution since conducting them is very difficult, if not altogether impossible, due to the rarity of disorders requiring treatment with such devices, ethical or economic matters associated with employing novel techniques, and difficulties in managing underlying biases. On the other hand, FDA pathways for novel neurointerventional devices are very complex: Most of the new-generation low-profile intracranial devices in the market are still investigational and seeking pre-market approval, which only requires an efficacy trial, or Humanitarian Device Exemption, i.e., intended for rare diseases and merely demanding demonstration of safety, local review board approval, and monitoring. Some devices, already commercially distributed worldwide, only have Investigational Device Exemption, which allows use of the device solely in clinical trials. Regulatory standards and trade laws are not substitutes for well-founded ethical judgment. Thus, a CE marking cannot be considered a safety mark for patients, either. The authors would like to emphasize the necessity of standard protocols based on more strict criteria for pre- and post-market evaluation of novel neurointerventional devices and consensus between clinicians and companies.

ACCLINO, in summary, is a laser-cut, electropolished, low-profile, self-expanding, nitinol stent with a closed-cell design; it is deployable via 0.017-in. microcatheters and is retrievable unless fully expanded. Certain characteristics make ACCLINO a unique option among other neurovascular stents of its generation and stent-assisted coil embolization using ACCLINO device, either as single stent or in Y configurations, is a feasible treatment option for challenging intracranial aneurysms. Techniques were effective in complex cases; there were no clinically significant adverse outcomes and follow-up results are encouraging. Despite increasing clinical experience and technological improvements, stent-assisted coiling still has inherent risks of morbidity and, though not observed in our series, mortality. Similar to other intracranial stents, the effects of a learning curve is observable: The complication rates with the ACCLINO stents decrease over time as the operator's practice of stenting increases. Since most complications occurred during device manipulation, extra caution is necessary during operator's familiarization process with ACCLINO stents.

Compliance with ethical standards

Funding No funding was received for this research.

Conflict of interest The author(s) declare that they have no competing interests.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. For this type of study, i.e., retrospective, formal consent is not required. However, written informed consent for endovascular treatment had been obtained from all individual participants included in the study.

References

1. Acandis ACCLINO Flex Stent [brochure]. Acandis GmbH; Pforzheim, Germany. Available at: http://www.acandis.com/down/uploads/acandis-ACCLINO-folder-140916-v10-druck_647_1425634446.pdf Accessed 10 Nov 2015
2. Acandis ACCLINO Flex Stent [Instruction for Use]. Acandis GmbH; Pforzheim, Germany. Available at: http://kategorizacia.mzsr.sk/Pomocky/Download/RequestAttachment/46690. Accessed 15 Nov 2015
3. Akmangit I, Aydin K, Sencer S, Topcuoglu OM, Topcuoglu ED, Daglioglu E, Barburoglu M, Arat A (2015) Dual stenting using low-profile LEO baby stents for the endovascular management of challenging intracranial aneurysms. AJNR Am J Neuroradiol 36:323–329
4. Akpek S, Arat A, Morsi H, Klucznick RP, Strother CM, Mawad ME (2005) Self-expandable stent-assisted coiling of wide-necked intracranial aneurysms: a single-center experience. AJNR Am J Neuroradiol 26:1223–1231
5. Aydin K, Arat A, Sencer S, Barburoglu M, Men S (2015) Stent-assisted coiling of wide-neck intracranial aneurysms using low-profile Leo baby stents: initial and midterm results. AJNR Am J Neuroradiol 36:1934–1941
6. Behme D, Weber A, Kowoll A, Berlis A, Burke TH, Weber W (2015) Low-profile Visualized Intraluminal Support device (LVIS Jr) as a novel tool in the treatment of wide-necked intracranial aneurysms: initial experience in 32 cases. J Neurointerv Surg 7:281–285
7. Benndorf G, Claus B, Strother CM, Chang L, Klucznik RP (2006) Increased cell opening and prolapse of struts of a neuroform stent in curved vasculature: value of angiographic computed tomography: technical case report. Neurosurgery 58:ONS-E380; discussion ONS-E380
8. Bodily KD, Cloft HJ, Lanzino G, Fiorella DJ, White PM, Kallmes DF (2011) Stent-assisted coiling in acutely ruptured intracranial aneurysms: a qualitative, systematic review of the literature. Am J Neuroradiol 32:1232–1236
9. Brassel F, Melber K, Schlunz-Hendann M, Meila D (2015) Kissing-Y stenting for endovascular treatment of complex wide necked bifurcation aneurysms using Acandis ACCLINO stents: results and literature review. J NeuroIntervent Surg 1–10
10. Cohen JE, Melamed I, Itshayek E (2014) X-microstenting and transmesh coiling in the management of wide-necked tent-like anterior communicating artery aneurysms. J Clin Neurosci 21:664–667
11. Daluolio M, Calbucci F, Fioravanti A, Bortolotti C, Cirillo L, Princiotta C, Leonardi M (2013) Revascularized giant aneurysm of the anterior communicating artery after surgery and embolization, occluded by placement of a Leo + Baby intracranial stent. Neuroradiol J 26:320–326
12. Ebrahimi N, Claus B, Lee CY, Biondi A, Benndorf G (2007) Stent conformity in curved vascular models with simulated aneurysm weeks using flat-panel CT: an in vitro study. Am J Neuroradiol 28:823–829
13. Gao B, Baharoglu MI, Cohen AD, Malek AM (2013) Y-stent coiling of basilar bifurcation aneurysms induces a dynamic angular vascular remodeling with alteration of the apical wall shear stress pattern. Neurosurgery 72:617–628

14. Gao B, Baharoglu MI, Malek AM (2013) Angular remodeling in single stent-assisted coiling displaces and attenuates the flow impingement zone at the neck of intracranial bifurcation aneurysms. Neurosurgery 72:739–748
15. Heller RS, Malek AM (2015) Delivery technique plays an important role in determining vessel wall apposition of the Enterprise self-expanding intracranial stent. J NeuroIntervent Surg 3:340–343
16. Heller RS, Miele WR, Do-Dai DD, Malek AM (2011) Crescent sign on magnetic resonance angiography revealing incomplete stent apposition: correlation with diffusion-weighted changes in stent-mediated coil embolization of aneurysms. J Neurosurg 115:624–632
17. Innovations (2012) Acandis ACCLINO 1.9-F stent system. Endovasc Today 11:100
18. Kabbasch CLT, Faymonville C, Dorn F, Mpotsaris A (2014) Initial clinical experience with a new self-expanding nitinol microstent for the treatment of wide-neck intracranial cerebral aneurysms: the Acandis ACCLINO stent. J Vasc Interv Neurol 8:1–6
19. Krajewski S, Neumann B, Kurz J, Perle N, Avci-Adali M, Cattaneo G, Wendel HP (2015) Preclinical evaluation of the thrombogenicity and endothelialization of bare metal and surface-coated neurovascular stents. AJNR Am J Neuroradiol 36:133–139
20. Lawson MF, Newman WC, Chi YY, Mocco JD, Hoh BL (2011) Stent-associated flow remodeling causes further occlusion of incompletely coiled aneurysms. Neurosurgery 69:598–603
21. Mascitelli JR, Moyle H, Oermann EK, Polykarpou MF, Patel AA, Doshi AH, Gologorsky Y, Bederson JB, Patel AB (2015) An update to the Raymond–Roy occlusion classification of intracranial aneurysms treated with coil embolization. J Neurointerv Surg 7:496–502
22. McLaughlin N, McArthur DL, Na M (2013) Use of stent-assisted coil embolization for the treatment of wide-necked aneurysms: a systematic review. Surg Neurol Int 4:43
23. Molyneux AJ (2006) Ruptured intracranial aneurysms-clinical aspects of subarachnoid hemorrhage management and the international subarachnoid aneurysm trial. Neuroimaging Clin N Am 16:391–396
24. Möhlenbruch M, Herweh C, Behrens L, Jestaedt L, Amiri H, Pa R, Bendszus M, Pham M (2014) The LVIS Jr. microstent to assist coil embolization of wide-neck intracranial aneurysms: Clinical study to assess safety and efficacy. Neuroradiology 56:389–395
25. Naggara ON, Lecler A, Oppenheim C, Meder JF, Raymond J (2012) Endovascular treatment of intracranial unruptured aneurysms: a systematic review of the literature on safety with emphasis on subgroup analyses. Radiology 263:828–835
26. Piotin M, Blanc R (2014) Balloons and stents in the endovascular treatment of cerebral aneurysms: Vascular anatomy remodeled. Frontiers Neurol 5. doi:10.3389/fneur.2014.00041
27. Piotin M, Blanc R, Spelle L, Mounayer C, Piantino R, Schmidt PJ, Moret J (2010) Stent-assisted coiling of intracranial aneurysms: clinical and angiographic results in 216 consecutive aneurysms. Stroke 41:110–115
28. Poncyljusz W, Biliński P, Safranow K, Baron J, Zbroszczyk M, Jaworski M, Bereza S, Burke TH (2014) The LVIS/LVIS Jr. stents in the treatment of wide-neck intracranial aneurysms: multicentre registry. J NeuroIntervent Surg 7:524–529
29. Shapiro M, Becske T, Sahlein D, Babb J, Nelson PK (2012) Stent-supported aneurysm coiling: a literature survey of treatment and follow-up. Am J Neuroradiol 33:159–163
30. Spiotta AM, Miranpuri A, Chaudry MI, Turner RD, Turk AS (2013) Combined balloon stent technique with the scepter C balloon and low-profile visualized intraluminal stent for the treatment of intracranial aneurysms. J Neurointerv Surg 5(Suppl 3):iii79–iii82
31. Tahtinen OI, Vanninen RL, Manninen HI, Rautio R, Haapanen A, Niskakangas T, Rinne J, Keski-nisula L (2009) Wide-necked intracranial aneurysms: treatment with stent-assisted coil embolization during acute subarachnoid hemorrhage-experience in 61consecutive patients. Radiology 253:199–208
32. Valdivia y Alvarado M, Ebrahimi N, Benndorf G (2009) Study of conformability of the new LEO PLUS stent to a curved vascular model using flat-panel detector computed tomography (DynaCT). Neurosurgery 64:130–134
33. Wanke I, Doerfler A, Schoch B, Stolke D, Forsting M (2003) Treatment of wide-necked intracranial aneurysms with a self-expanding stent system: initial clinical experience. AJNR Am J Neuroradiol 24:1192–1199
34. Wanke I, Forsting M (2008) Stents for intracranial wide-necked aneurysms: more than mechanical protection. Neuroradiology 50: 991–998
35. Zanaty M, Chalouhi N, Tjoumakaris SI, Rosenwasser RH, Gonzalez LF, Jabbour P (2014) Flow-diversion panacea or poison? Front Neurol 5:1–8