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Original Article

Morphological factors and device deformation associated with recurrence in intracranial aneurysms treated with the contour neurovascular system

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ABSTRACT

Background and Purpose: The Contour Neurovascular Device is an intrasaccular flow disrupting device designed for the treatment of wide-neck intracranial aneurysms and has been shown to be a safe and effective treatment option. Mid- and long-term results are still scarce, and data on morphological risk factors and device deformation have not been published yet. In this study, we investigate the association of aneurysm-related morphologic parameters and device deformation with recurrence after treatment of intracranial aneurysms with Contour.

Materials and Methods: All patients with unruptured and ruptured aneurysms that were treated with Contour in our institution were retrospectively identified. Only patients with 3D-rotational angiography, flat-panel detector-CT or CTA on pre-interventional, 24 h post-interventional, and at least one follow-up imaging were included. Morphological parameters and Contour deformation on longitudinal imaging were tested for an association with aneurysm occlusion status.

Results: 63 aneurysms were analyzed, the median follow-up time was 17 (range, 2–67) months. Adequate occlusion (BOSS 0–2) on longest follow-up occurred in 79 %, and Contour deformation in 57 %. The parameters neck diameter ($p = 0.005$, OR 3.1), Contour migration ($p = 0.017$, OR 9.3) and lateral impression ($p = 0.033$, OR 5) were significantly and independently associated with deterioration of occlusion status on follow-up imaging. Deformation mostly occurred within a 4 to 6-month follow-up period.

Conclusions: Larger neck diameter and Contour deformation are significantly associated with recurrence after treatment with Contour irrespective of the dome-neck ratio. Assessment of Contour deformation on 3D follow-up imaging seems advisable.

Introduction

Intrasaccular flow disrupting devices have emerged as a useful tool for the endovascular treatment of saccular intracranial aneurysms, complementing the neurointerventional armamentarium particularly for the treatment of wide-neck aneurysms.¹ Several devices have become available, including the Contour Neurovascular System (Stryker, Portage, USA), which has been reported to be safe and effective for the treatment of ruptured and unruptured aneurysms.^{2–9} However, data describing aneurysm-related risk factors for recurrence on mid- and long-term follow-up are still scarce, and it has not yet been investigated how frequently Contour deformation occurs and whether it contributes to a higher risk of recurrence. The aim of this study is to investigate the association of aneurysm morphology and device deformation with aneurysm recurrence.

Material and methods

This study was approved by the local ethics committee. All patients who underwent treatment of an intracranial aneurysm with the Contour Neurovascular device in our institution between 2018 and 2025 were retrospectively identified from our prospectively collected internal intervention database. Inclusion criteria were 1) successful implantation of a Contour, 2) availability of a pre-treatment 3d rotational angiography (3D-RA), 3) post-treatment 3D-RA, flat-panel detector-CT (FD-CT) or CT-angiography (CTA) within 24 h after implantation, and 4) at least one follow-up imaging with 3D-RA, FD-CT or CTA. 3D-RA and FD-CT images were obtained on a biplane angiography system (Azurion, Philips, Amsterdam, The Netherlands), reconstructed voxel sizes ranged from 0.16 – 0.33 mm for 3D-RA and FD-CT, respectively. CTAs were conducted on a Spectral CT 7500 (Philips, Amsterdam, The Netherlands), images reconstructed with a voxel size of $1 \times 0.35 \times 0.35$ mm

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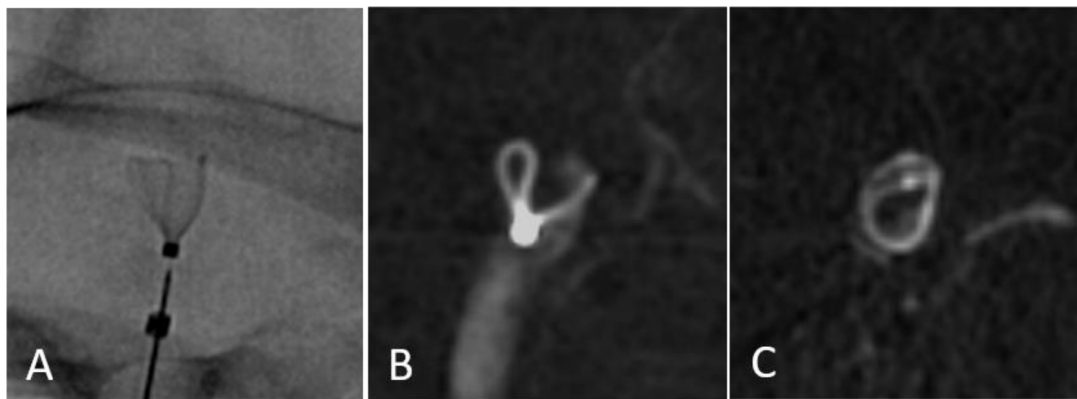


Fig. 1. teardrop deformation. A: Angiography and B,C: 3D-rotational angiography 24 h post-treatment of a basilar tip aneurysm with a 7 mm Contour showing incomplete expansion of the device resulting in a double-layer, teardrop-shaped structure.

were used for analysis. Only patients who signed the institutional broad consent form were included. Exclusion criteria were 1) any previous treatment of the same aneurysm, and 2) implantation of additional devices to treat the target aneurysm in the same session.

The following parameters were collected on multiplanar reconstructions of 3D-RA, FD-CT, and CTA datasets. Deformation category and occlusion status were independently assessed by two neuroradiologists with an experience >10 years (N.L., F. G.), differences were resolved in a consensus reading session.

Pre-treatment 3D-RA

- maximum aneurysm neck diameter
- maximum aneurysm dome diameter, measured in a plane perpendicular to the longest axis of the aneurysm
- aneurysm height, measured as the longest axis of the aneurysm

24 h post-treatment 3D-RA, FD-CT or CTA

- Contour area: area of a region of interest corresponding to the plane bounded by the distal rim of the device
- incomplete expansion of the device, “teardrop-deformity” (Fig. 1)

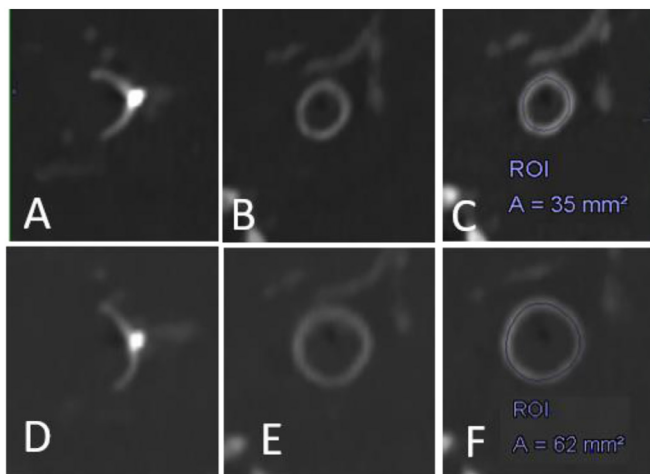


Fig. 2. flattening and lateral impression. Multiplanar CT-angiography images after implantation of a 11 mm Contour in a middle cerebral artery bifurcation aneurysm, A,B,C: 24-hours follow-up, A: images reconstructed parallel to the long axis of the device B,C: images reconstructed perpendicular to the long axis* of the device at the level of the distal rim, without and with a region of interest bounded by the distal rim of the Contour, showing an area of 35 mm². D,E,F: 30-month follow-up, showing a Contour area of 62 mm², flattening and increase of the proximal angle of the device. * Long axis is defined as the line that intersects the proximal marker, and the plane of the distal rim at a right angle

Longest available follow-up 3D-RA, FD-CT or CTA

- Contour area: area of a region of interest corresponding to the plane bounded by the distal rim of the device
- Contour deformation: change of the shape of the device compared to 24 h post-treatment imaging (nominal scale, multiple assignment possible) (Figs. 2–5)
 - flattening
 - lateral impression (any focal deviation from a circular or elliptic shape of the device towards the center on any cross section perpendicular to the long axis of the device)
 - distal migration
 - inversion

For determination of Contour area, the distal rim was visualized on multiplanar reformatted images in a PACS viewer (DeepUnity Viewer, Dedalus, Milan, Italy) and marked with a circular or freehand region of interest (Fig. 2).

The occlusion status was assessed on 24 h post-treatment and longest available follow-up imaging using the Bicêtre occlusion scale score (BOSS).¹⁰

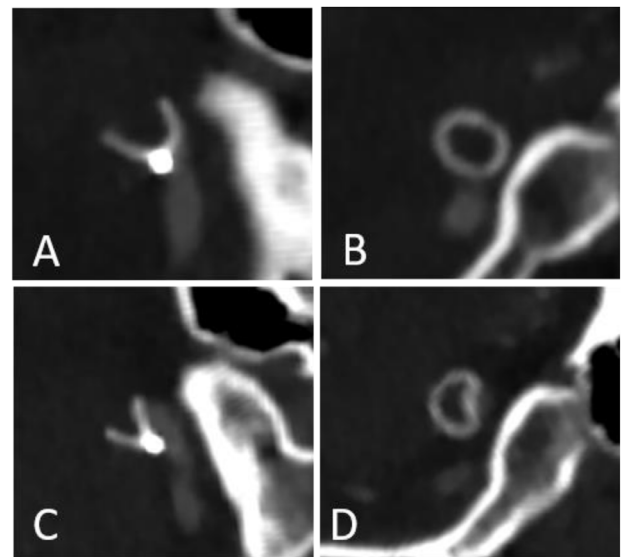


Fig. 3. lateral impression. Multiplanar CT-angiography images after implantation of a 9 mm Contour in a PICA-aneurysm, A,B: 24-hours-follow-up, A: images reconstructed parallel to the long axis of the device, B: images reconstructed perpendicular to the long axis of the device. C,D: 7-month follow-up, unilateral compression of the device is noted

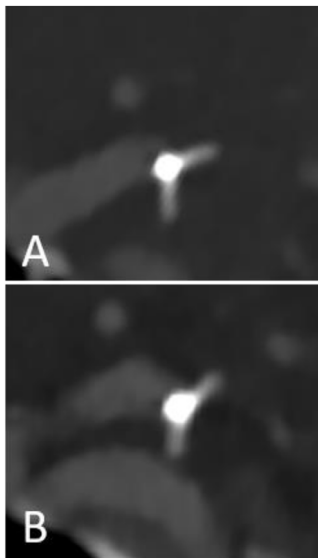


Fig. 4. Distal migration. Multiplanar CT-angiography images after implantation of a 9 mm Contour in a posterior communicating artery aneurysm, A: 24 h after implantation. B: migration of the device into the aneurysm sac at 42-month follow-up

Area ratio was calculated as the ratio of the Contour area on longest follow-up divided by the Contour area on 24 h follow-up.

Patient age and sex, aneurysm rupture status, aneurysm localization (anterior, posterior circulation), aneurysm type (bifurcation, side wall), size of implanted Contour, time between treatment and longest available follow-up time in months were extracted from the patients' records.

Time between implantation and worsening of occlusion status, and occurrence of retreatment were assessed on all available follow-up imaging datasets of a patient.

Contour size/neck diameter, Contour size/dome diameter, and Contour size/height ratios were calculated. The size of the implanted Contour was compared with the recommended device size according to the manufacturer's sizing chart (Fig. 6). A device was defined as oversized, if maximum aneurysm width and/or maximum neck diameter was below the range of the proposed size-category. Cases were determined as undersized, if maximum aneurysm width and/or maximum neck diameter exceeded the upper limit of the proposed category.

Recommendations of the manufacturer for sizing of the Contour Neurovascular System with ranges for maximum aneurysm width measured at the equator, and neck width.

Patients were divided into two groups based on longest available follow-up imaging, 1) stable occlusion status, 2) aneurysm recurrence or progression of a remnant. Aneurysms with progression of a neck or aneurysm remnant were attributed to group 2 even if the BOSS category did not change. Differences between the two groups were tested with the Mann-Whitney *U* test for continuous variables, and with the χ^2 -test

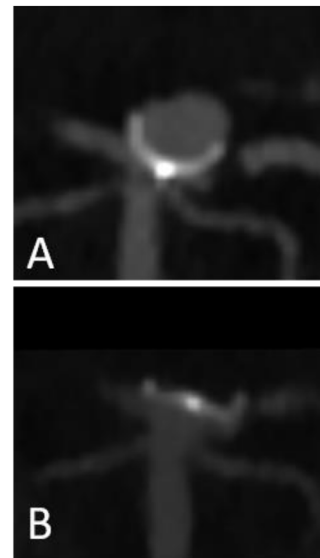


Fig. 5. Inversion. Multiplanar CT-angiography images after implantation of a 9 mm Contour in a basilar tip aneurysm, A: 24 h after implantation. B: inversion of the Contour at 19-month follow-up

for nominal and categorical variables. The significance level was set to $\alpha = 0.05$. Highly significant ($p < 0.001$) morphological variables were entered into a multivariate logistic regression model.

Furthermore, an association of Contour deformation with the occlusion status (BOSS category) was tested with a Pearson Chi-square test.

Results

Cohort

Of a total of 144 aneurysms treated with Contour in our center, 81 were excluded due to incomplete image data or the use of multiple devices. 63 aneurysms in 62 patients were included in the analysis, 47 (76 %) were female, 15 male (24 %), with a median age of 59 years. Locations were intradural internal carotid artery (ICA) in 9 cases, posterior communicating artery (PcomA) in 4, ICA-terminus in 8, middle cerebral artery in 14, anterior communicating artery in 12, and pericallosal artery in 3. In the posterior circulation, 11 were located at the basilar tip, 1 at the posterior cerebral artery and 1 at the posterior inferior cerebellar artery.

Median longest follow-up time was 17 months, with a range of 2–67 months. In 61 (97 %) cases, follow-up imaging after 6 or more months was available, in 40 (64 %) after 12 or more months, and in 15 (24 %) after 24 or more months.

In 25 (40 %) cases, a recurrence or progression of a remnant was noted, there was no significant difference in patient age, sex, and longest

Device diameter (mm)	Maximum aneurysm width (mm)	Maximum aneurysm neck (mm)
5.0	2.0-3.5	2.0-3.0
7.0	3.0-5.5	3.0-5.0
9.0	5.0-7.5	4.0-6.0
11.0	7.0-8.5	5.0-8.0
14.0	8.0-10.5	7.0-10.0

Fig. 6. Contour neurovascular system sizing chart.

time of follow-up between the groups (no recurrence versus recurrence). 3 (5 %) underwent retreatment. No rebleeding occurred.

Aneurysm-related parameters

For the results of univariate testing for an association of aneurysm-related parameters with recurrence, see Table 1.

Assessment of the accuracy of the parameter “neck diameter” yielded an area under the receiver operating characteristic curve of 0.793, with the highest accuracy (sensitivity 0.68, specificity 0.8) for a cut-off value of 3.45 mm.

When testing aneurysm-related parameters for an association with Contour deformation, we found a highly significant result for neck diameter and dome diameter, ($p < 0.001$), and a significant result for aneurysm height ($p = 0.005$).

Device deformation

A teardrop-deformity was present on 24-hours imaging in 9 cases (14 %) and persisted in all but one case until last follow-up. Teardrop-

Table 1

Aneurysm-, device- and treatment-related parameters in aneurysms without and with deterioration of the occlusion status.

	stable <i>n</i> = 38 (60 %)	progression <i>n</i> = 25 (40 %)	Total <i>n</i> = 63
neck diameter, median [mm]	3	4.1	3.5**
dome diameter, median [mm]	4.7	5.9	5.2*
aneurysm height, median [mm]	5.2	6.5	5.5*
dome/neck ratio, median	1.6	1.5	1.5
ruptured			
no	34 (90 %)	19 (76 %)	53 (84 %)
yes	4 (10 %)	6 (24 %)	10 (16 %)
localization			
anterior	32 (84 %)	18 (72 %)	50 (79 %)
posterior	6 (16 %)	7 (28 %)	13 (21 %)
type			
bifurcation	31 (82 %)	18 (72 %)	49 (77 %)
sidewall	7 (18 %)	7 (28 %)	14 (23 %)
initial occlusion status (BOSS)			
0/0'	20 (53 %)	14 (56 %)	34 (54 %)
1	14 (41 %)	6 (24 %)	20 (32 %)
2	4 (6 %)	3 (12 %)	7 (11 %)
3	0	1 (4 %)	1 (2 %)
1 + 3	0	1 (4 %)	1 (2 %)
follow-up occlusion status (BOSS)			**
0/0'	29 (76 %)	0	29 (46 %)
1	5 (13 %)	0	5 (8 %)
2	4 (11 %)	12 (48 %)	16 (25 %)
3	0	11 (44 %)	11 (18 %)
1 + 3	0	2 (8 %)	2 (3 %)
Contour size			*
5	13 (34 %)	2 (8 %)	15 (24 %)
7	18 (47 %)	11 (44 %)	29 (46 %)
9	5 (13 %)	8 (32 %)	13 (21 %)
11	2 (5 %)	3 (12 %)	5 (8 %)
14	0	1 (4 %)	1 (2 %)
Contour size/neck ratio	2.2	2.0	2.1*
Contour size/dome ratio	1.4	1.4	1.4
Contour size/height ratio	1.4	1.3	1.3
teardrop-deformity	5	4	9 (14 %)
Contour deformation (multiple assignment possible)			
none	27 (71 %)	0	27 (43 %)**
flattening	7 (18 %)	14 (56 %)	21 (33 %)*
impression	2 (5 %)	11 (44 %)	13 (30 %)**
migration	4 (11 %)	15 (60 %)	19 (21 %)**
inversion	0	1 (4 %)	1 (2 %)
area, median [mm ²]	10.5	18	13**
area ratio, median***	1,1	1,2	1,1

* $p < 0.05$

** $p < 0.001$

*** cases with teardrop-deformity, impression and inversion were excluded.

deformity was not associated with over-, undersizing or aneurysm recurrence ($p = 0.563$).

In all cases with Contour deformation ($n = 36$, 57 %), morphological change was noted on the first follow-up examination (≤ 4 months in 3, 6 months in 33 cases, respectively). In cases where multiple follow-ups were available ($n = 27$), further progression of the deformation was observed in 13 (48 %).

In 2 patients only short-term follow-up of 1 and 2 months, respectively, was available, where there was no evidence of deformation or recurrence.

In all cases requiring retreatment ($n = 3$), lateral compression and migration of the Contour was noted.

There was a highly significant association between the parameters follow-up occlusion status BOSS 2, 3 and 1 + 3, and Contour deformity (yes/no) ($p > 0.001$).

For the results of univariate testing for an association of device-related parameters with recurrence, see Table 1.

Contour size

For the results of univariate testing for an association of treatment-related parameters with recurrence, see Table 1.

Comparison of the size of the implanted Contour with the recommended device size according to the manufacturer's sizing chart did not yield any significant association of undersizing or oversizing with recurrence ($p = 0.628$ and $p = 0.592$, respectively), or with BOSS on longest follow-up ($p = 0.186$). 27 aneurysms (43 %) could not be adequately categorized following the recommendation on the sizing chart.

There was no significant association of Contour size/neck ratio with device migration and/or lateral impression ($p = 0.327$).

Multivariate analysis

After multivariate testing that included all parameters that were tested highly significant in univariate analysis, the following parameters remained independent predictors for aneurysm recurrence: neck diameter ($p = 0.005$, OR 3.1), Contour migration ($p = 0.017$, OR 9.3) and lateral impression ($p = 0.033$, OR 5).

Discussion

Aneurysm morphology

For the Contour Neurovascular Device, several retrospective studies have reported short- and mid-term safety and efficacy results,^{2–9} the largest to date published by Griessenauer et al., including 279 aneurysms with a median follow-up time of 12 months.⁷ They reported a higher odds ratio for recurrence with increasing aneurysm height, while the other studies did not report aneurysm-specific risk factors for recurrence. In our study, we also found neck diameter, aneurysm height and dome diameter associated with recurrence, and neck diameter to be the only independent risk factor. The discrepancy can be explained by the fact, that in our study, we categorized any progression of a remnant or recurrence as deterioration, even if it did not lead to a progression on the BOS scale. Moreover, we exclusively analyzed high-resolution 3D-RA, FD-CT, or CTA datasets for the assessment of recurrence, while in the study conducted by Griessenauer et al., occlusion status was evaluated on 2D digital subtraction angiography (DSA). The sensitivity for small remnants or recurrences is probably higher on 3D imaging, while the sensitivity of 2D imaging for recurrences is related to aneurysm size.

Contour size

A previous in vitro- and in silico study investigated the impact of Contour size and positioning on the reduction of intra-aneurysmal flow in patient data-derived basilar tip aneurysm flow models compared to the pre-interventional state.¹¹ The analysis showed a more pronounced reduction of intra-aneurysmal flow with smaller Contour sizes. While

the results of this study must be regarded with caution due to the small sample size and the ex vivo design, they correspond to the finding of the present study that smaller Contour sizes are associated with non-progression in univariate analysis. This phenomenon could be related to the microstructure of the Contour, that is constructed in petal-like shapes converging at the central marker with the struts overlapping more densely at the center of the device. The Contour comes in a variety of sizes that are constructed from the same number of wires, resulting in a different cell area for each device size possibly enabling a more complete flow disruption with small devices. In narrow-neck aneurysms, the ostium is mainly covered by central denser parts. In contrast to that, large devices in wider necks have a larger proportion of the peripheral aspect of the device exposed to inflow from the parent vessel. This concept was also suggested by Mostafa et al., who investigated the safety and efficacy of the treatment of narrow-neck aneurysms with Contour.¹² Therefore, additional coiling of wide-necked aneurysms including shallow low height-wide neck morphologies treated with Contour could positively affect the treatment efficacy. The technique and feasibility of this method has been reported by Wodarg et al.¹³

Moreover, a lower Contour size/neck diameter ratio was also associated with recurrence on this study. This finding is in accordance with previous results for intrasaccular treatment, and the issue of optimal sizing needs to be discussed. The extent of oversizing is limited by the height of the aneurysm, leaving shallow wide-necked aneurysms most difficult to seal completely from inflow. For another widely used intrasaccular flow disrupting device, the WEB Embolization System (Microvention/Terumo Neuro, Aliso Viejo, USA), oversizing is considered to be associated with better angiographic outcome.¹⁴ In this study, however, we did not find a significant association of undersizing or oversizing with deterioration of angiographic outcome. Here, under- and oversizing was defined according to the recommendations on the sizing-chart provided by the manufacturer, which can only account for differences in individual aneurysm morphologies in a simplified manner. This is supported by our observation that the aneurysm neck and dome dimensions of 43 % of the treated aneurysms did not fit into any of the categories proposed on the sizing chart. Therefore, interventionalists should not strictly adhere to the sizing chart, carefully check for signs of undersizing such as flattened appearance of the device before detachment, and in that case consider an exchange for the next larger Contour size.

Contour deformation

In this study, the Contour deformation categories “lateral impression” and “distal migration” were significantly associated with neck diameter and a deterioration of the occlusion status. Furthermore, we found a highly significant association of Contour deformation with BOSS categories 2 and 3. None of the previous studies systematically reported morphological changes of the Contour device. The only reports on Contour deformation to date have been published by Bhogal et al. and Bellanger et al., describing distal migration and inversion of a 9 mm Contour occurring after 1 month, and between 6- and 18-month follow-up, respectively.^{15,16}

For the WEB, morphological changes have been extensively investigated.^{17–20} WEB shape modification (WSM) was observed frequently and associated with worse angiographic outcome.^{19,20} Conversely, some studies found no association of WSM with recurrence^{17,18} suggesting that WSM could also be attributed to thrombus organization and aneurysm healing in some cases.

It could be hypothesized that growth of the aneurysm sac caused by inflammatory and associated wall-degrading mechanisms induced by the intraluminal thrombus can lead to migration of the Contour device into the aneurysm sac, exposing the aneurysm neck, corresponding to the finding in this study that distal migration of the Contour is associated with recurrence. In contrast to that, in studies investigating WSM, the missing association with recurrence was attributed to the formation and maturation of intraluminal thrombus, with the aneurysm dome covered

and thereby protected by the distal part of the WEB device, preventing sac growth and promoting aneurysm healing.¹⁷ It is not known however whether this healing process occurs similarly in aneurysms treated with the Contour, that does not directly interact with the wall of the aneurysm dome.

We found flattening of the Contour to be a frequent finding, that was significantly associated with recurrence only in univariate, but not in multivariate analysis. This finding suggests that this type of deformation, if not occurring together with a distal migration or lateral impression, is not a specific marker for a higher risk of recurrence. Lateral impression of the Contour represents failure to resist hemodynamic forces of a part of the device at the aneurysm ostium and neck. Future hemodynamic studies investigating the influence of angulation and centrality of Contour placement on the susceptibility to deforming forces could further elucidate factors predisposing for recurrence.

In 9 cases, a so-called teardrop-deformity was visible, that was noted already during the intervention in all cases. This deformity is generally ascribed to incomplete expansion of the device, but was not associated with a higher risk of recurrence in our cohort, and can therefore most likely be regarded as tolerable during intervention and should not prompt an exchange for a smaller device.

Our results suggest a strong role of Contour device deformation in recurrence, occurring probably most frequently 3 to 6 months after treatment and tending to deteriorate further over time. This effect appeared to be independent of the neck diameter, future studies should evaluate further parameters, including hemodynamic measures and platelet inhibition regimens, for an influence on device deformation. On the other hand, a stable Contour device without deformation on follow-up imaging is associated with a stable occlusion status according to our results.

Limitations

Limitations of this study include the retrospective study design, leading to an inhomogeneity in follow-up durations available for the included cases, and a possible selection bias, since patients with Contour deformation detected during the intervention, on baseline or in any follow-up imaging were more likely to receive 3D-imaging evaluation and thus be eligible for inclusion in this study. Moreover, the small sample size excludes adequately powered subgroup analyses, that could possibly elucidate further associations of patient-specific parameters as rupture status and anti-platelet medication with risk of recurrence. The observation of longer follow-up periods is warranted to better assess the influence of the factors investigated in this study on retreatment and rebleeding rate, and long-term occlusion.

Conclusion

Deformation of the Contour device occurs frequently and already within the first 6 months and tends to deteriorate further on longer follow-up. On 6-month follow-up, lateral impression and distal migration of the device are associated with recurrence, while the absence of Contour deformation is associated with a stable occlusion status. Close assessment of Contour deformation on 3D follow-up imaging using 3D-RA, FD-CT, or CTA seems advisable.

Furthermore, recurrence is associated with a larger neck diameter and does not depend on the dome/neck ratio.

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