Original research

Woven EndoBridge device shape modification can be mitigated with an appropriate oversizing strategy: a VasoCT based study

Jildaz Caroff,[1] Jonathan Cortese,[1] Jean-Baptiste Girot,[2] Cristian Mihalea,[1] Guilherme Aguiar,[1] Jeickson Vergara Martinez,[1] Léon Ikka,[1] Vanessa Chalumeau,[1] Marcelle Rehem,[1] Sophie Gallas,[1] Augustin Ozanne,[1] Jacques Moret,[1] Laurent Spelle[1,3]

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[1]Department of Interventional Neuroradiology - NEURI Brain Vascular Center, Bicêtre Hospital, APHP, Paris, France
[2]Radiology Department, CHU Angers, Angers, Pays de la Loire, France
[3]Faculty of Medicine, Paris - Saclay University, Le Kremlin-Bicêtre, France

Correspondence to
Dr Jildaz Caroff, Department of Interventional Neuroradiology-NEURI Brain Vascular Center, Bicêtre Hospital, APHP, Paris, 94270, France; jildaz.caroff@aphp.fr

JCo and J-BG contributed equally.

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ABSTRACT

Background The Woven EndoBridge (WEB) shape modification (WShM) during follow-up may be a potential cause of poor angiographic outcomes. WShM predisposing factors have not yet been determined. Our systematic use of rotational cone beam computed tomography (VasoCT) imaging during follow-up allowed us to perform the first quantitative analysis of the shape of WEBs over time. Our goal was to identify possible strategies to reduce the occurrence of this phenomenon.

Methods All patients treated in our hospital with a WEB device between October 2015 and January 2019 were included. Using VasoCT acquisitions, systematically performed after implantation and during follow-up, we analyzed WEB morphology. WShM was defined as the percentage reduction in the distance between the two WEB markers.

Results Sixty-three aneurysms treated with a WEB device were finally included in this analysis. At the last follow-up (mean 15.5 months), mean WShM was 48%±24. The mean WShM was significantly higher in the aneurysm recurrence group than in the adequate occlusion group (51±6.5% vs 36±3.4%, difference 15% points (95% CI 0.7 to 30); p<0.05). Conversely, the extent of WShM did not directly correlate with occlusion rates. Indeed, 32% of completely occluded aneurysms presented severe WShM (≥50%). Importantly, the absence of WShM guaranteed complete occlusion in our study (n=12). We demonstrated that oversizing the width of the WEB significantly correlated with WShM reduction during follow-up (r=−0.38, p=0.002).

Conclusion WShM can be partly overcome by use of an appropriate width oversizing strategy that could lead to improved angiographic results.

INTRODUCTION

Flow disruption with the Woven EndoBridge (WEB) device (Microvention, Tustin, California, USA) is a promising technique to treat challenging intracranial aneurysms.[1] WEB embolization has proved to be highly feasible with a very good safety profile,[2] but the long term angiographic efficacy is still disputed and under evaluation.[3 4]

A potential cause of worsening of the initial aneurysmal occlusion has been attributed to WEB shape modification (WShM) during follow-up.[5] WShM corresponds to a decrease in WEB height, which can sometimes lead to aneurysmal recanalization. It is thought to be related to clot retraction during the healing process,[6] and this could be exacerbated by a high blood flow exposure.[7] A better understanding of WShM mechanisms is essential, because its prevention could potentially lead to higher rates of complete aneurysmal occlusion rates.

Cone beam CT has already proved to be a precise technique for cross sectional analysis of small endovascular devices with reduced radiodensity.[8 9] Our objective was to take advantage of our unique systematic use of cone beam CT (VasoCT, Philips, Best, The Netherlands) at implantation and during follow-up to perform the very first 'quantitative' assessment of the WShM phenomenon over time. Our goal was to report the prevalence and the parameters affecting WShM to subsequently identify possible strategies to reduce the occurrence of this phenomenon.

METHODS

Population

Between October 2015 and February 2019, 94 consecutive patients were treated with a WEB device in our hospital and included in a prospectively maintained register. The study was approved by the commission nationale de l'informatique et des libertés (CNIL) (No 20200525115905). Informed consent was obtained in each case. To assess WEB morphology over time, exclusion criteria for the study were: use of WEB in a previously coiled aneurysm, combined treatments (WEB with or without stents, with or without coils), and lack of post-delivery VasoCT or lack of DSA follow-up, including VasoCT acquisition and >3 months.

Antiplatelet regimen

In all unruptured cases, patients were premedicated with aspirin (160 mg) and ticagrelor (90 mg twice a day) 24 hours before treatment. Endovascular treatment was performed under general anesthesia and systemic heparinization (intravenous bolus of 50 IU/kg was administered after groin puncture, followed by a continuous 15 IU/kg/h intravenous injection). By the end of the procedure, heparin therapy was discontinued but not reversed. Antiplatelet

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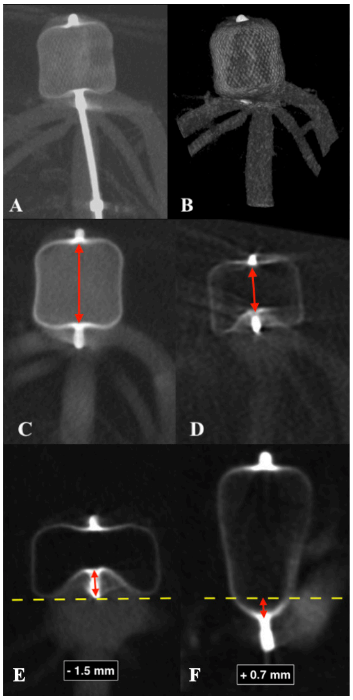

Figure 1 Cone beam computed tomography (VasoCT) of a basilar tip aneurysm treated with a Woven EndoBridge (WEB) SL device. (A) Pre-detachment evaluation. (B) Post-detachment three-dimensional rendering view. (C) Post-detachment cross sectional coronal view centered on the WEB markers (red arrows indicate measurement of the distance between the markers). (D) Seven month VasoCT follow-up, demonstrating 41% WEB shape modification. Oversizing WEB width generally leads to an ovalization of the initial device shape with a protrusion of the proximal marker. VasoCT was used to measure the protrusion of the proximal WEB marker under the line joining the two proximal WEB corners. (E) WEB proximal marker retracted inside the recess. (F) Oversized WEB device with marker protrusion.

medication was used postoperatively if needed, based on angiographic results (at least one antiplatelet medication in 35 cases).

WEB sizing

Over time, different generations of the WEB device were used.[10] The operator selected the device shape (the cylindrical WEB SL or the spherical WEB SLS) based on the anatomy of the aneurysm. Devices were delivered through VIA catheters (Microvention). Aneurysm measurements were extracted from three-dimensional rotational angiography and operators always tried to oversize the width of the WEB device by adding at least 1 mm to the average aneurysmal width on two orthogonal projections.

Imaging

VasoCT was performed systematically during endovascular treatment on WEB detachment but also during follow-up DSA scheduled at 3–6, 18, and 34 months.[9] Blinded from outcome, the cross sectional images were used to measure WEB height and width, and the distance between the two WEB markers (figure 1). The same working projection was always reproduced, and then a cross section passing through both WEB markers was selected for measurements.

In cases of retreatment, the last DSA follow-up considered was that measured on the day of retreatment. Aneurysmal occlusion was evaluated according to the [11]WEB Occlusion Scale (WOS) and Bicêtre Occlusion Scale Score (BOSS)[12] by two interventional neuroradiologists (including one external to our department) in consensus. Adequate occlusion[2] was defined by grouping the BOSS subgroups as 0, 0', 1, and 2.

WEB oversizing ratio

To assess WEB oversizing, we calculated in each case the ratio between the WEB's unconstrained width (given by the manufacturer) under the average width immediately after implantation measured by VasoCT (on two orthogonal views). Thus the higher this oversizing ratio was, the more laterally oversized the WEB was, with a ratio of 1 corresponding to a non-constrained device. WEB oversizing generally induces an ovalization of the device. To estimate this operator-induced shape modification, VasoCT was used to measure the protrusion of the proximal WEB marker under the line joining the two proximal WEB corners (figure 1).

Statistical analysis

Statistical analysis was performed using Prism software V.7.0 (GraphPad, San Diego, California, USA). A normality test was applied to assess the Gaussian distribution of data in all cases. Results are shown as mean±SD. Categoric variables were compared using the χ^2 or Fisher's exact tests, as appropriate. Correlations were determined using Pearson correlation coefficients. WShM as a function of time curve was generated using a locally weighted scatterplot smoothing (LOWESS) regression technique using R V.3.4.1 (R Foundation for Statistical Computing, Vienna, Austria). A p value <0.05 was considered significant.

RESULTS

Population

From 94 aneurysms treated with a WEB device, 63 were included in the final analysis (missing post-delivery VasoCT n=2, missing VasoCT follow-up n=22, combined treatment n=5, previously treated aneurysm n=1, mispositioning of the WEB n=1). Fifty-eight patients were treated, including 35 women (60%), and age range was 38–80 years (mean 55±11). Aneurysm locations were middle cerebral artery in 26 aneurysms (41.5%), anterior cerebral artery in 18 (28.5%), basilar artery in 6 (9.5%), internal carotid terminus in 7 (11%), posterior communicating artery in 5 (8%), and postero-inferior cerebellar artery in 1 (1.5%). Aneurysm size ranged from 2.5 to 13.1 mm (mean 6.4±2.5), and neck size ranged from 1.5 to 8.0 mm (mean 3.9±1.4). Aneurysm volume ranged from 0.01 to 0.8 mL (mean 0.14±0.16). Twenty-seven per cent of cases were treated in the acute phase of a subarachnoid hemorrhage. In 59% of cases, a fifth generation VIA 17 WEB device was used. WEB SLS devices were selected in 11% of cases. The mean length of follow-up was 15.9±3.9 months (range 1.3–24.9).

Angiographic results

At the initial follow-up (mean 6.1±3.5 months), complete occlusion was achieved in 41 cases (65%), neck remnant was depicted in 7 cases (11%), aneurysm remnant in 14 cases (22%), and isolated WEB opacification in 1 case. At the last follow-up (mean 15.5±8.3 months), complete occlusion was achieved in 38 cases (60%), neck remnant was depicted in 8 cases (13%), and aneurysm remnant in 17 cases (27%). By June 2020, seven aneurysms (11%) had been retreated and no WEB treated aneurysms had ruptured.

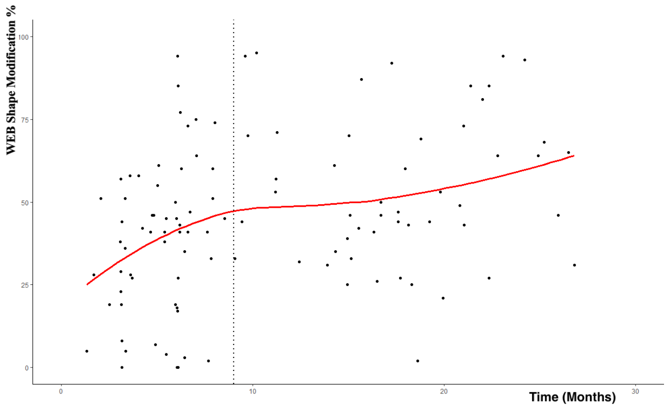

Figure 2 Woven EndoBridge (WEB) shape modification (WShM) as a function of time. The locally weighted scatterplot smoothing (LOWESS) regression technique demonstrates that WShM will mostly occur in the months immediately after implantation, with stabilization and a plateau of the phenomenon observed after 9 months.

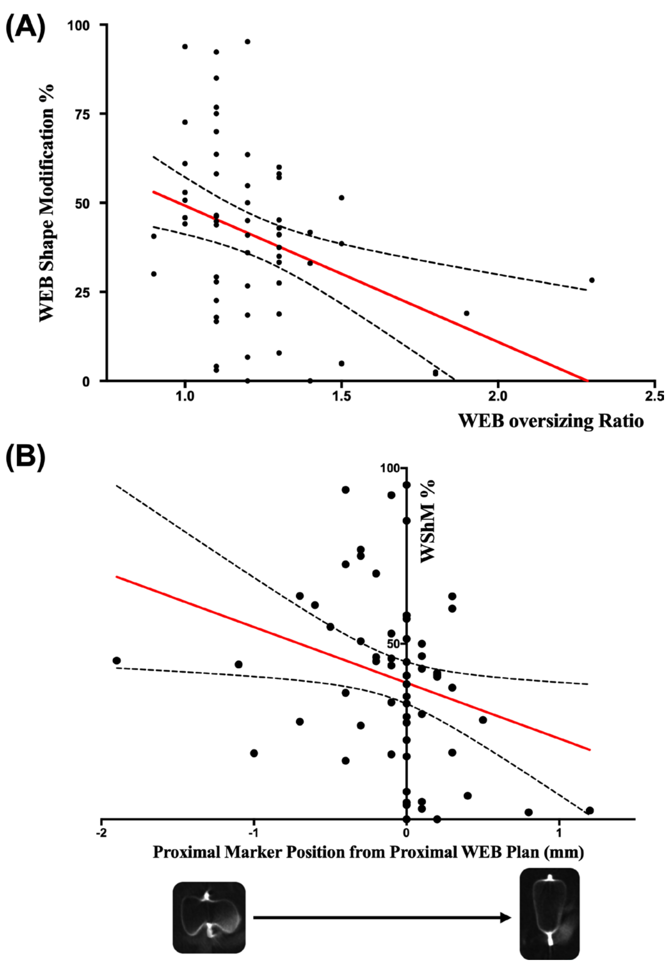

Figure 3 (A) Woven EndoBridge (WEB) shape modification (WShM) as a function of the WEB oversizing ratio (defined as the ratio of the WEB's unconstrained width given by the manufacturer to the width measured with cone beam CT immediately after implantation). The higher the ratio was, the less was the extent of WShM during follow-up. (B) WShM as a function of the position of the proximal marker from the line joining the two proximal WEB corners on detachment. The more ovoid the web shape was at implantation, the less likely WShM was to happen during follow-up.

WEB shape modification

Prevalence

At the initial follow-up (mean 6.1 months), mean WShM was 39.6±24% (range 0–95%) and 19 cases (30%) had a WShM of >50%. At the last follow-up (mean 15.5 months), mean WShM was 47.8±24% (range 0–95%), with 25 cases (39%) presenting with a WShM of >50%.

WShM as a function of time

The extent of WShM significantly correlated with the length of follow-up (r=0.26, p=0.006). From the smoothed scatterplot regression curve, it appeared that WShM mostly occurred in the early stages after implantation and that the phenomenon stabilized after 9 months (figure 2).

WShM as a function of WEB generation

There was no difference in WShM rates between the latest, fifth generation WEB 17 device, and previous WEB generations (41±4% and 37±4% of WShM, respectively) (p=0.57).

WShM as a function of aneurysm characteristic

WShM was not associated with aneurysm volume (p=0.57), maximum diameter (p=0.26), ruptured status (p=0.89), or location (p=0.52). However, WShM was significantly associated with an increased neck diameter (p=0.02). In addition, WShM was significantly less pronounced in aneurysms with the highest aspect ratios (height/neck) (p<0.001).

Impact of an oversizing strategy on WShM

The average WEB oversizing ratio was 1.24±0.2 (range 0.9–2.3). We found a significant association between width oversizing and a reduction of shape modification during follow-up (WEB oversizing ratio negatively correlated with the extent of WShM; r=−0.38, p=0.002) (figure 3A).

Mechanical hypothesis

To analyze the hypothesis that the ovalization of the native WEB shape could confer an increase in mechanical resistance, we studied the protrusion of the WEB marker. When the WEB develops an 'egg shape', the proximal marker moves from the WEB recess to a position under the line joining the two proximal WEB corners (figure 1). In our study, WShM significantly correlated with the position of the proximal marker at implantation. The more the marker protruded, the less likely WShM was to happen (r=−0.28, p=0.024) (figure 3B). The WEB SLS devices are designed with a predefined ovoid shape. Although not frequently used in this study, we detected a clear tendency toward lower WShM rates associated with their use. The mean WShM rates at first follow-up were 42% for the WEB SL devices (n=55) compared with 25% for the WEB SLS devices (n=8) (p=0.064).

Relationship between WShM and occlusion rates

Aneurysms were grouped according to the occlusion status at first follow-up: (1) complete occlusion; (2) adequate occlusion; or (3) aneurysm remnant. There was no difference in the time to first follow-up between the three different occlusion groups (6.3 ±4.1, 6.2±3.9, and 5.8±3.9 months, respectively; p>0.05). At the initial follow-up, the mean WShM rate was 34.8±3.8% in the complete occlusion group, 36.2±3.4% in the adequate occlusion group, and 51.4±6.5% in the aneurysm remnant group (figure 4). The difference was significant when comparing the aneurysm remnant group with the other two groups (p<0.05),

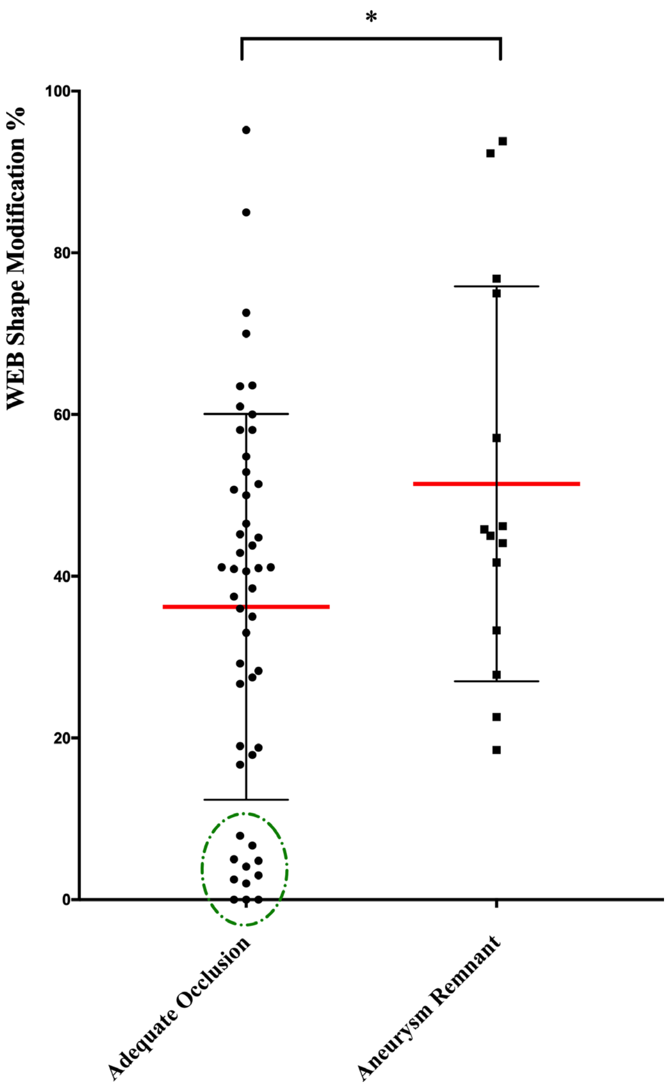

Figure 4 At first follow-up, the mean Woven EndoBridge (WEB) shape modification (WShM) rate was 36.2±3.4% in the adequate occlusion group and 51.4±6.5% in the aneurysm remnant group. All patients (n=12) with WShM <18% presented with complete aneurysmal occlusion (green circle). *p<0.05.

but not when comparing the complete and adequate occlusion groups.

However, it is very important to stress that there was no direct correlation between the extent of WShM and the angiographic outcome. Indeed, severe WShM (≥50%) occurred in 32% of completely occluded aneurysms.

DISCUSSION

WShM description

The WEB device has generated a lot of interest in the neurovascular community, as multiple studies[2 3] have demonstrated that it is a fast and safe approach for the treatment of complex intracranial aneurysms.[10 13–17] However, concerns were raised after some worsening of the initial aneurysmal occlusion was observed, secondary to a reduction in the WEB volume during follow-up,[5 18 19] with recurrence rates as high as 15%.[20]

Cone beam CT has proven to be a very efficient technique for the exploration of metallic intracranial implants.[8 9 21] Thanks to our systematic use of VasoCT during DSA follow-up, we were able to conduct, for the first time, quantitative assessment of WShM over time. Our analysis confirmed previous studies reporting that WShM is a frequent phenomenon, affecting to some degree a large majority of WEBs. Janot *et al* described WShM in 72.9% of cases.[19] We also showed that WShM occurs mostly during the first few months after implantation. Then, after approximately 9 months, and probably because of the healing of the aneurysms, WEB height stabilizes. Hence the first clinical implication of our work is that initial follow-up imaging should not be performed earlier than 9 months after implantation to better appreciate longer-term outcomes.

Association with occlusion rates

It is important to state that the extent of WShM did not directly correlate with angiographic outcomes. The impact of WShM on occlusion rates was moderate. At the initial follow-up, 32% of completely occluded aneurysms presented a severe WShM (≥50%). In fact, in some not infrequent cases, the aneurysmal neck was sealed, and the reduction in height of the WEB device occurred only from the dome, without leading to any worsening of the initial occlusion (online supplemental figure 1). However, we wish to emphasis the crucial need of WShM prevention to allow the WEB device to become a widespread part of the endovascular arsenal. Cagnazzo *et al*[22] described adequate occlusion in only 17.5% of cases when WShM was depicted. In our study, the absence of WShM was almost a guarantee of an excellent outcome. We found that 100% of the 12 cases that presented with almost no shape change (WShM <18%) achieved complete occlusion at first follow-up (figure 4).

WShM prevention

WShM does not appear to be inevitable. Some authors intuitively suggested that increasing a WEB's width could help reduce the likelihood of WShM occurring.[23] For the first time, we have confirmed clinically that oversizing the width of the WEB device could help prevent WShM.

Mechanical hypothesis

We have tried to better understand the underlying mechanism of WShM prevention. In our study, we observed lower rates of WShM: (1) in aneurysms with a high height/neck ratio; and (2) when the width of the WEB was oversized by the operator. Our hypothesis is that the lower prevalence of WShM observed in oblong aneurysms is linked to the device rather than the aneurysm. Regardless of size and type, all WEB devices are larger in width than in height. Therefore, when the aspect ratio increases, the operators have no choice but to oversize the width of the WEB to fill the entire aneurysmal sac.

Because of their softness, the laterally oversized WEBs will undergo a shape deformation with a proportional height increase (ovoid shape) and a consecutive proximal marker protrusion. In our study, the more this marker protruded, the less likely WShM was to happen. Therefore, we believe that it is through an induced 'egg shape' that an oversized WEB device could gain a compressive stress resistance, similar to that of arches that were used to support the weight of ancient cathedral roofs. Similarly, we have found a positive correlation between WShM and neck size, and we believe it could be related to a lesser stress resistance of shallow WEBs.

Clinical implications

We strongly recommend oversizing the WEB device by adding 1 or 2 mm to the average aneurysm width (in two orthogonal views) to induce increased mechanical resistance, subsequently preventing WShM. WEB SLS devices have a spontaneous ovoid design. Interestingly, we found a clear tendency (p=0.064) to a WShM reduction associated with their use, probably due to this different design. We therefore also recommend considering their use whenever the anatomy of an aneurysm allows it.

The final clinical implication of our study relates to the use of the latest generation of WEB devices. Although braided with fewer wires, the VIA17 WEB device was not more prone to WShM than previous generation WEB devices in our study. This important validation opens up the way for treatment of smaller, distal, and non-bifurcation aneurysms with this new generation of WEB devices.[10]

Limitations

The study was limited by its retrospective design and by the fact it included a relatively low number of patients although it is the largest study of WShM carried out to date.

CONCLUSION

Shape modifications impact on the angiographic outcomes after WEB treatment but with no direct relationship between the extent of WShM and occlusion rates. WShM was correlated with neck size and aspect ratio but with no other aneurysmal parameters. WShM can be partly overcome by use of an appropriate oversizing strategy that could lead to improved angiographic results.

Twitter Jildaz Caroff @jildazz, Cristian Mihalea @CRISTIANMIHALEA and Sophie Gallas @doc soph

Contributors JC contributed to the conception and design of the study, and drafting the manuscript. JC, JCo, and J-BG contributed to data collection and analysis. JC, JM, and LS contributed to revising the manuscript for important intellectual content. All authors approved the final version to be published.

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Competing interests JC has received educational scholarships from Medtronic Neurovascular and Microvention/Terumo in 2017. JM is a consultant for Microvention, Medtronic, and Balt. LS is a consultant for Stryker, Microvention, Medtronic, and Balt.

Patient consent for publication Not required.

Ethics approval The study was approved by the commission nationale de l'informatique et des libertés (CNIL) (No 20200525115905).

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ORCID iDs
Jildaz Caroff http://orcid.org/0000-0002-0029-1835
Jonathan Cortese http://orcid.org/0000-0002-1616-9113
Jean-Baptiste Girot http://orcid.org/0000-0002-2780-6907
Cristian Mihalea http://orcid.org/0000-0002-8260-8284
Guilherme Aguiar http://orcid.org/0000-0003-3206-2081
Vanessa Chalumeau http://orcid.org/0000-0002-7753-7186

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