

The Past, Present and Future of Endovascular Aneurysm Treatment

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Abstract The technology available for the endovascular treatment of intracranial aneurysms is rapidly evolving. Both current and future devices are described. This includes, among others, UNO for parent vessel occlusion, the Medina device for saccular filling, the Comaneci device for remodeling, pCONus for assisted coil occlusion, and WEB and pCANvas for intrasaccular flow disruption. Perspectives of further development such as surface coating for increased radioopacity and decreased thrombogenicity are explained.

Keywords Aneurysm · Endovascular · Coil · Stent · Flow diversion

The Past

The idea to treat intracranial aneurysms from within the arterial system and avoiding surgical exposure was proposed in the 1960s [1]. Initial success was achieved by parent vessel occlusion using detachable balloons [2]. The intrasaccular balloon deployment, however, was associated with significant risks [3]. The dawn of endovascular aneurysm treatment started 25 years ago, when the first manufactured

endovascular devices became available. Until then, physicians assembled microcatheters and balloons on site under adventurous circumstances.

A major advance came with the development of electrolytically detachable coils [4]. For the first time, a controlled and atraumatic intrasaccular treatment became feasible. During the evolution of neuroendovascular treatment concepts and products it was common that the initially intended mode of operation (e.g., electrothrombosis) turned out to be inefficient [5]. The possibility to remove the coil from the aneurysm or to detach it added safety and efficacy to this treatment modality.

Subsequently, coil variants with different detachment mechanisms (e.g., electrothermal, hydraulic, etc.), featuring varying stiffness and different shapes became available. It soon became apparent that aneurysms with a neck of ≥ 4 mm were frequently less suitable for straightforward coil occlusion. Balloon remodeling [6] advanced the technique by providing balloon-assisted coiling, thus improving occlusion rates and packing density. An alternative was the deployment of a balloon expandable coronary stent [7]. Balloon-mounted stents were, however, stiff and the balloon inflation for stent deployment in front of an aneurysm was not without risk. This led to the development of a highly flexible, self-expanding open-cell design stent (Neuroform, Smart Therapeutics) [8]. Closed-cell, braided (Leo, Balt) and laser cut stents (Enterprise, Cordis [9]) and a detachable stent (Solitaire, ev3 [10]) followed thereafter. Other developments such as the first bioactive coil (Matrix, Boston Scientific [11]) and Onyx HD500 for aneurysms (ev3, Irvine [12]) were, at least in retrospect, failures.

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The Present

Coils

Coil treatment and coil technology have come to a mature status. In 2013, according to industry data approximately 5,400 and 28,000 aneurysms were treated by coil occlusion in Germany and Western Europe, respectively (compared to roughly 42,500 procedures in the USA) [13 and others]. The average physician expects reliable and instantaneous detachment and the full range of coil lengths, diameters, shapes, and stiffness grades. The German market in 2013 with a total volume of about 37,000 coils annually, including 29,800 coils per year for aneurysms was divided between Covidien (now Medtronic Neurovascular) (about 18%), MicroVention (about 35%), Stryker (about 25%), Codman (about 16%), and others (about 6%). The respective market shares for Western Europe and the USA were approximately Covidien (now Medtronic Neurovascular) (about 11% and 16%), MicroVention (about 21% and 14%), Stryker (about 34% and 40%), Codman (about 30% and 20%), and others (about 4% and 10%) for a total number of coil units of 173,000 for Western Europe and 230,000 for the USA (across all neurovascular coiling procedures) [13 and others]. Coil occlusion *per se* has gained an established role in the treatment of intracranial aneurysms and is considered as relatively straightforward. Aneurysm reperfusion of various degrees occurs in about one third of the patients but is infrequently a source of (re-)hemorrhage [14]. Evolutionary steps include the development of coil lines accepted by microcatheters with smaller inner diameters and with a detachment mechanism, which does not need a proximal marker (Kaneka Medix Corporation).

The Medina device (Medina Medical, Fig. 1) is a layered three-dimensional coil made from a radiopaque, shape set core wire, and shape memory alloy outer coil filaments (a

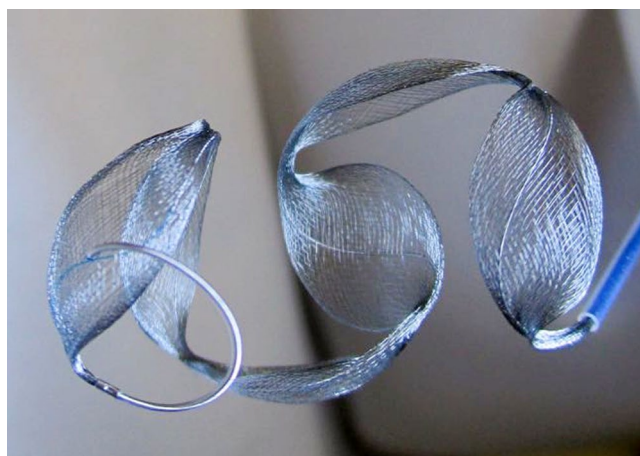


Fig. 1 Medina device (Medina Medical) for the intrasaccular occlusion of intracranial aneurysms

self-expandable mesh). The coil is accepted by any 0.021'' inner diameter microcatheter and is mechanically detachable. Early clinical experience confirmed efficacy and safety of this new coil [15]. Long-term aneurysm occlusion stability is not yet established.

Coils are far from ideal to achieve parent vessel occlusion. Precise coil positioning in a straight artery can be difficult since bare surface coils may not find enough grip on the vessel wall, possibly resulting in distal coil displacement. The thrombogenicity of coils is low and the remaining space between coil loops allows significant bloodflow even after dense packing of coils. For the occlusion of *extra cranial* vessels, the Amplatzer Vascular Plug (St. Jude Medical) can be used. The UNO Neurovascular Embolization System (Reverse Medical, now Medtronic Neurovascular) is an implant made for the targeted occlusion of *intracranial* arteries (Fig. 2). This stent-like structure, of which 80% is covered proximally with a PTFE membrane, is electrolytically detachable from an insertion wire. UNO-3 and UNO-5 can be used for 1.5–3 mm and 3–5 mm vessel diameters and are accepted by 0.021'' and 0.027'' inner diameter microcatheters, respectively. Initial experience shows reliable function.

Compliant Balloons and Alikes

Balloon remodeling during coil insertion of wide-neck aneurysms became an integral part of the interventional armamentarium. Very flexible low profile compliant balloons with a *single* lumen allow access to far distal target vessels (e.g., HyperGlide, HyperForm, Medtronic Neurovascular; Eclipse and Copernic, Balt). Dual lumen balloons (e.g., Eclipse 2 L, Balt; Scepter, MicroVention) can be used for balloon remodeling, followed by the deployment of a low profile self-expanding stent through the wire channel

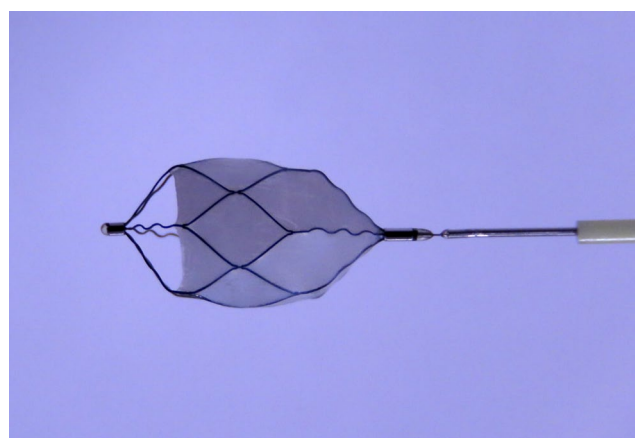


Fig. 2 UNO Neurovascular Embolization System (Reverse Medical, now Medtronic Neurovascular) for the targeted occlusion of intracranial arteries (parent vessel occlusion)

(e.g., LVIS jr., MicroVention; Baby Leo+, Balt) upon withdrawal of the balloon catheter.

The Comaneci Aneurysm Neck Bridging Device (Rapid Medical) is a stent-like structure made from radiopaque nitinol (Fig. 3). It is available with a length of 35 and 24 mm, with a distal tip wire and it is inserted through any 0.021" microcatheter [16]. It can be used in an analogous way like a remodeling balloon for temporary coverage of the aneurysm neck during coil insertion and is retrieved thereafter. One advantage is that bloodflow is maintained while the device is deployed. Clinical experience is still limited but promising.

Stents

All stents for assisted aneurysm coil treatment are currently self-expanding. About 900, 2,800, and 4,900 stent assisted coiling procedures were performed in Germany, Western Europe, and the USA in 2013, respectively, which accounts for 19% of all coil procedures in Germany and 17% in Western Europe, and the USA. With an annual volume of about 950 units in Germany, 2,900 units in Western Europe and 5,900 units in the USA in 2013 the market is shared between Solitaire AB (Medtronic Neurovascular) [10%/17% Germany/Western Europe], LVIS jr. (MicroVention) [25%/>1% Germany/Western Europe], Enterprise (Codman) [15%/39% Germany/Western Europe], Neuroform (Stryker) [20%/31% Germany/Western Europe], Leo+ and Leo+Baby (Balt) [20%/13% Germany/Western Europe], and others. In the USA, the market is shared between Stryker and Codman with 66 and 34%, respectively, in 2013 (estimated values based on various sources e.g., [13]). Development of the stent technology is characterized by a continuous process of modification and improvement

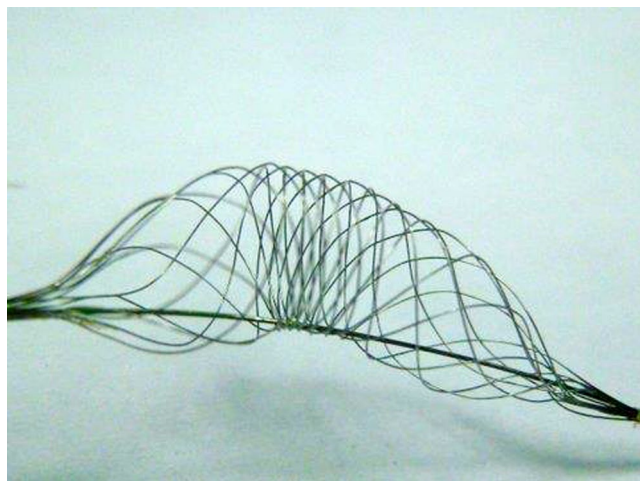


Fig. 3 Comaneci device (Rapid Medical) for the temporary coverage of wide-neck intracranial aneurysms during coil occlusion

(e.g., lower profile, better flexibility, increased radial force). For stent assisted coiling of wide-neck aneurysms, a variety of strategies such as staged procedures (i.e., deploying the stent and waiting 6–8 weeks until the stent is endothelialized prior to aneurysm coiling) or “jailed catheter” (i.e., inserting a microcatheter into the aneurysm and deploying a stent covering both, aneurysm and microcatheter) are used.

Crossing and Kissing Stents and Alikes

The reconstruction of vessel bifurcations with two stents can be technically demanding but is not infrequently used [17]. The two stents can be of the same or of different kinds (e.g., combination of Solitaire and Enterprise). The stents can be deployed in the afferent vessel either parallel (“kissing”) or one inside the other (“crossing”). Common to all variants of Y-stenting is the fact that both efferent vessels have to be catheterized, which is not always straightforward.

The Barrel Vascular Reconstruction Device (Reverse Medical, now Medtronic Neurovascular) is an electrolytically detachable self-expanding stent with a fusiform central part with enlarged diameter (Fig. 4). The stent is made for the treatment of wide-neck bifurcation aneurysms. It is deployed in one efferent vessel only through any 0.021" inner diameter microcatheter. This vessel is selected in a way that as much as possible of the aneurysm orifice will be covered by the stent. Once deployed, the central “belly” of the stent herniates inside the aneurysm orifice and can assist subsequent coil occlusion. Initial results confirm safety and efficacy of this interesting device [18].

pCONus (phenox) is an assisting device for the coil occlusion of wide-neck bifurcation aneurysms (Fig. 5). The stent shaft (20 or 25 mm long) is attached proximally to an insertion wire and can be detached electrolytically.

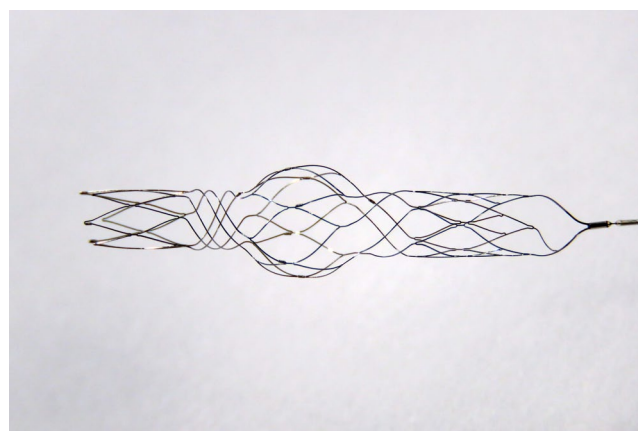


Fig. 4 Barrel Vascular Reconstruction Device (Reverse Medical, now Medtronic Neurovascular) for stent-assisted coil occlusion of wide-neck bifurcation aneurysms

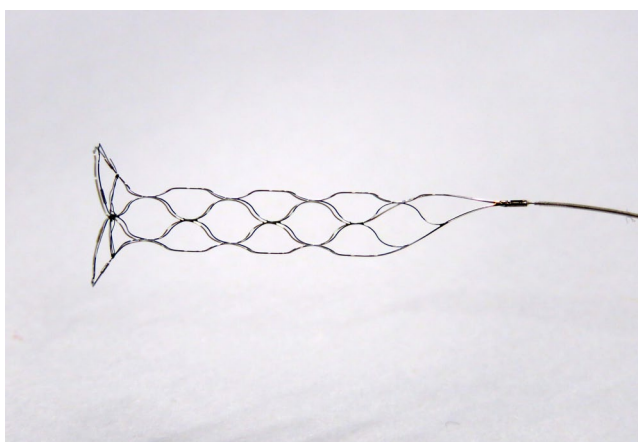
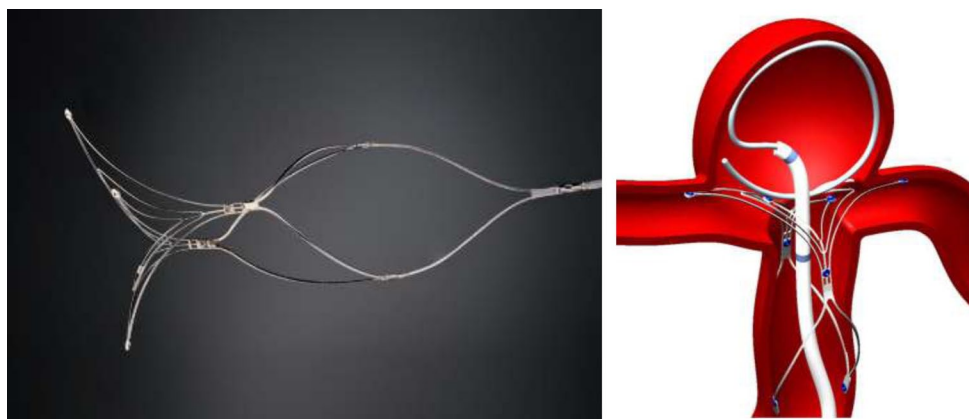


Fig. 5 pCONus (phenox), an assisting device for the coil occlusion of wide-neck bifurcation aneurysms, deployed *inside* the aneurysm sac

The distal end of this shaft carries four petals, which open outwardly when deployed. The device is compatible with 0.021" inner diameter microcatheters. The petal diameter is available from 4 to 15 mm. The petals are opened inside the aneurysm sac adjacent to the aneurysm neck. The shaft is deployed into the parent vessel. Thereafter, a second microcatheter is inserted into the aneurysm sac for coil occlusion. The device has no hemodynamic effect. The catheterization of the efferent vessels of a bifurcation is avoided and there is less metal in the bifurcation than with crossing stents. Procedural safety and efficacy are confirmed [19]. The aneurysm population pCONus is made for is prone to recurrence and may require eventual recoiling.

The PulseRider (Pulsar Vascular, distributed by Codman) is an open cell nitinol structure to support the coil occlusion of wide-neck bifurcation aneurysms, which can be delivered via 0.021" inner diameter microcatheters (Fig. 6). The device is deployed outside the aneurysm in the parent vessel bifurcation [20]. Two wings are expected to follow the course of the efferent vessels. The central part covers the aneurysm neck like a saddle and two "legs" anchor the device in the afferent

Fig. 6 PulseRider (Pulsar Vascular) for the assisted coil occlusion of wide-neck bifurcation aneurysms, deployed *outside* the aneurysm sac



artery. Repositioning is possible through partial or complete retrieval. Once properly in place the device can be detached electrolytically. At the time of writing marketing of the device in Germany has already started with some positive feedback.

Intraaneurysmal Flow Disruption

Obliterating the sac of an intracranial aneurysm with a single body instead of multiple coils is not new. Detachable balloons were used as intrasaccular flow disrupting implants in the 1980s [3]. An understanding of the limitations (i.e., difficulty with sizing, questionable permanency of occlusion) of the "single body" concept triggered the development of detachable coils, which are not perfect in terms of permanency in large and giant aneurysms. An attempt to establish a faster procedure, which would not require anticoagulation and antiaggregation and to improve the stability of aneurysm occlusion prompted the recent development of intrasaccular flow disruptors (Luna, NFocus Neuromedical, now Medtronic Neurovascular; WEB, Sequent Medical). The WEB device is a self-expanding sphere made of a nitinol wire mesh, introduced through microcatheters and electrothermally detached from an insertion wire (Fig. 7). Significant clinical experience is already available for WEB [21]. The device in its first version with two mesh layers ("dual layer") is no longer available. A single layer version (SL) with a more spherical shape (SLS) comes with a lower profile, enhanced visibility, better navigation and is offered in diameters of 4–11 mm. The 3–7 mm WEBs are accepted by 0.021" ID microcatheters, the 8–9 mm version needs a 0.027" ID and the 10–11 mm WEBs fit through a 0.033" ID catheter. WEB can be used with a high level of procedural safety. Early aneurysm occlusion is achieved in the majority of aneurysms. The issue of aneurysm recurrence, however, is not solved with this implant. Published follow-up results actually raised a number of concerns [22].

pCANvas (phenox) is a hemodynamically active derivate of the above described pCONus (phenox). A propri-

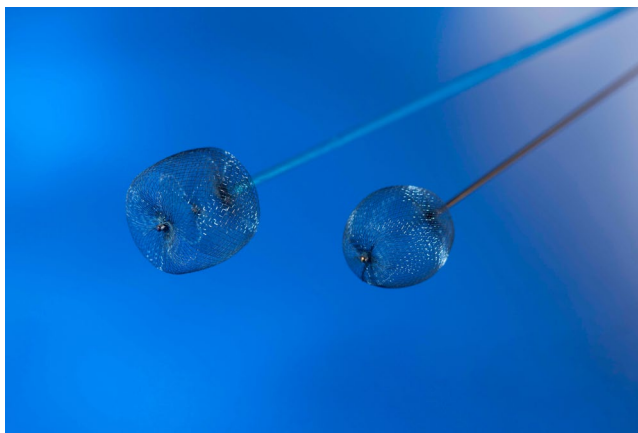


Fig. 7 Woven EndoBridge, WEB (Sequent Medical) for the intrasaccular flow disruption of mid-size and large intracranial aneurysms

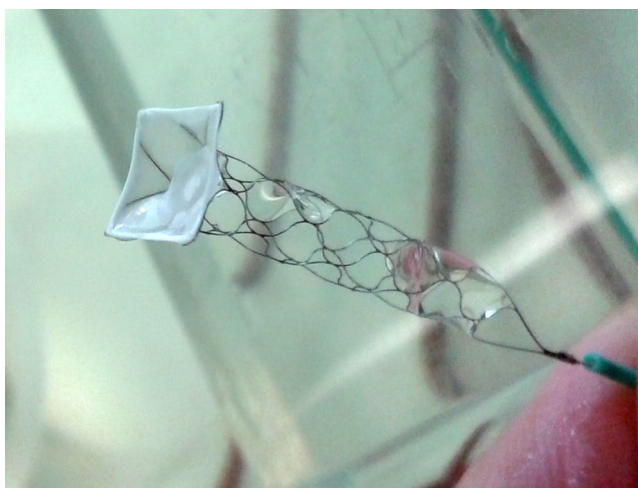


Fig. 8 pCANvas (phenox) for intrasaccular flow diversion in the treatment of wide-neck bifurcation aneurysms

etary membrane covers the petals (Fig. 8). Once deployed through a 0.027" ID microcatheter inside the aneurysm sac at the level of the neck the membrane blocks the bloodflow in the parent artery from the aneurysm. The membrane can also be penetrated with a regular microcatheter–microguidewire combination, which allows additional coil occlusion. The device is not yet commercially available.

Parent Vessel Flow Diversion

The concept of treating intracranial aneurysms through a hemodynamically active implant in the parent vessel has been discussed since the late 1990s. Dense metallic structures from braided wires were the most feasible solution. Silk, later Silk+, (Balt Extrusion) was the first device on the German market [23]. In an attempt to improve both efficacy and safety through greater mesh density, increased radial force, more flexibility, and higher radiopacity, a variety of devices were

made available, including Pipeline (Medtronic Neurovascular) [24], Surpass (Stryker) [25], p64 (phenox) [26], Fred (MicroVention) [27], and Derivo (Acandis). The features of these devices differ in many aspects; therefore the use of the term “flow diversion” in a generic sense is problematic.

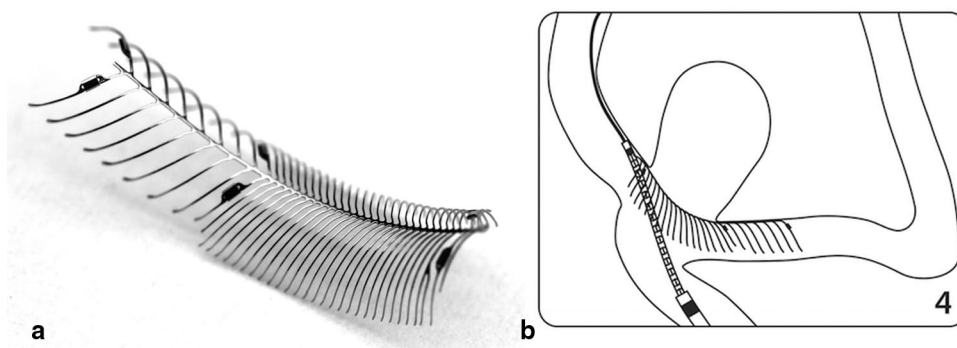
About 470, 2,300, and 3,000 flow diverter procedures are performed in Germany, Western Europe, and the USA in 2013, respectively. With an annual volume of about 600 units in Germany, 2,800 units in Western Europe and 4,800 units in the USA in 2013 the market was shared between Pipeline Embolization Device (Medtronic Neurovascular) (52%/51%/100% Germany/Western Europe/USA), Silk (Balt) (42%/44% Germany/Western Europe—device not FDA approved) and others (6%/4%—other devices not FDA approved) [13 and others].

Almost 10 years after we treated the first patient with a flow diverter (a precursor of Pipeline), we may draw some preliminary conclusions. Flow diversion has the potential to replace stent-assisted coil occlusion in the treatment of sidewall saccular aneurysms. With proper case selection, >50% of sidewall aneurysms will be completely occluded after 3 months and at 1 year achieve a complete occlusion rate of >80% [26]. The role of flow diversion in bifurcation aneurysms is less well established and it is certainly not yet the first choice strategy. In our experience, additional coil insertion, even with a very loose filling, accelerates the process of aneurysm obliteration. In large and giant aneurysms, delayed rupture after flow diversion remains a serious concern. Parenchymal hemorrhage distal to the target vessel might be related to debris from the device or microcatheter or is a sequel to microinfarcts from air bubble emboli [28]. Hyperresponse to ASA and/or Clopidogrel is another potential cause.

For the treatment of many fusiform aneurysms, flow diversion is the most appealing technical option [29]. In these frequently complex lesions, the complication rate is higher and the occlusion rate is lower than in saccular aneurysms. If several flow diverters have been deployed in a telescoping fashion and/or if the wall apposition of these implants is incomplete, endothelialization may take months or years and can even remain incomplete. Therefore extended (i.e., > 1 year) or lifelong dual antiaggregation may be required.

Apart from their original indication, flow diverters were found to be a very efficient device for the treatment of intracranial vessel dissections, dissecting aneurysms and blister aneurysms [30]. In dissections of the intracranial ICA, the main advantage of using flow diverters instead of balloon expandable stents is the better wall apposition. For intradural small vessel dissections and dissections with intracranial hemorrhage alternatives such as the use of self-expanding stents and parent vessel occlusion should be considered.

Fig. 9 eCLIPs (Evasc Medical Systems), intended for flow diversion and assisted coil occlusion of bifurcation aneurysms. The device (a) is anchored in one efferent vessel and positioned over the aneurysm orifice and the other efferent artery (b)



The above described flow diverting devices mainly address sidewall aneurysms. Hemodynamic influence on bifurcation aneurysms from outside the sac through an implant inside the bifurcation is a future concept. Pulsar Vascular is working on a derivate of the PulseRider with a membrane on the “saddle.” Peach et al. [31] described a device made of a nitinol wire but without a membrane, which is intended to be implantable in front of bifurcation aneurysms.

eCLIPs (Evasc Medical Systems) is a device for the endovascular treatment of bifurcation aneurysms, claiming hemodynamic effects (Fig. 9a). It may as well assist subsequent coil occlusion. The current version is different from a previously published concept [32]. It is a non-cylindrical nitinol structure with two sections, carrying six radiopaque markers. An anchor segment has to be placed in one efferent vessel and a cover segment is positioned over the aneurysm orifice (Fig. 9b) and in the other efferent artery. The device is fully retrievable with controlled detachment. Clinical results are not yet available.

The Future

The initial focus of endovascular treatment was on ruptured and otherwise symptomatic aneurysms, not suitable for surgery. Given the remaining high morbidity and mortality of aneurysm rupture, treating aneurysms prior to a hemorrhage and with the least procedural risk profile is the goal. The future of endovascular aneurysm treatment will comprise evolutionary and disruptive aspects. We expect further improvements both in coil and stent technology.

Coils

The failure of bioactive coils does not necessarily prove the uselessness of the concept. As a result of both financial and regulatory constraints, the applied bioactive substances (PGLA, PGA) might have been the wrong candidates and other substances may work instead. The coil technology *per se* has meanwhile come to a mature status and biological

activation of mechanically optimized coils is the logical step ahead. It is also conceivable that coils made of non-metallic materials (e.g., polymers, fibers, natural products) may offer different features. The original idea behind bioactive intraaneurysmal implants combining accelerated thrombus formation and induction of connective tissue formation remains intriguing.

Stents

The available low profile stents come with a limited outward radial force, which needs improvement. The closed cell laser-cut stents are notorious for issues like ovalization, poor wall apposition and difficult catheter navigation. All these aspects could be improved. True bifurcation stents with the ability to replace “crossing” or “kissing” Y-stenting procedures could find useful clinical applications. Stent-assisted coiling could be an ideal scenario for a bioabsorbable stent.

Intraaneurysmal flow disruption is a very promising concept. The issues of WEB should not discourage the industry from further developments in this regard. “Intraaneurysmal flow disrupting implant” is a generic term, which might have quite different technical solutions. Here, as in many other device categories, membrane technology and bioactivation is not yet available.

Endoluminal flow diversion is currently based on a variety of self-expanding braided implants made of different alloys (e.g., nickel titanium, cobalt-chromium). Other possible solutions might include membranes with calibrated holes or an intrinsic porosity. Apart from that, a further diversification of flow diverters is expected, especially concerning the porosity. For some indications (e.g., dissections), flow diverters could be bioabsorbable.

Some developments may affect both stents and flow diverters. Since most implants are made of materials with low radioopacity, they are difficult to control under fluoroscopy. Simply adding other components undermines the superelastic properties of nitinol and may in general impair the function of the device. Wire cores made of radiodense metal and (even more promising) ultrathin metallic surface

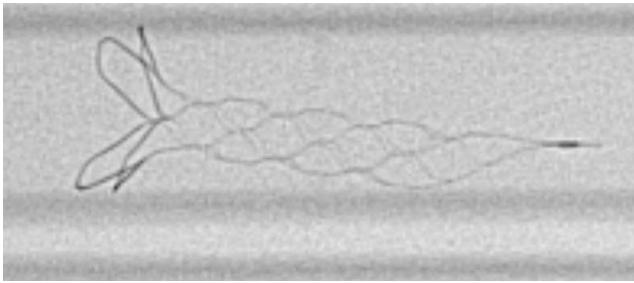


Fig. 10 pCONus (phenox) with coated petals to increase the radiopacity of the functionally most important component of the device

coatings with firm adherence to the underlying implant are solutions that are already underway (Fig. 10).

All existing stents and derivatives require dual platelet function inhibition for weeks or months and mono medication forever. Late thrombo-embolic complications are a severe issue with all flow diverting implants. A modification of the surface of these implants, which would avoid the need for dual or even mono antiplatelet medication, is rightly called “the holy grail” of future stent technology. Diamond-like carbon, polyzene-F and phosphorylcholine (Pipeline with Shield Technology) have been used clinically, but industry is years apart from having mastered this challenge.

Conflict of Interest Hans Henkes is co-founder and shareholder of phenox GmbH, which is producing neuroendovascular implants.

Werner Weber has consulting and proctoring contracts with Sequent Medical and phenox GmbH.

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