Chapter 2
Evolution of Endovascular Technique

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From the advent of digital subtraction angiography and diagnostic angiography to early device development, the field of neurointervention has made great strides in neurovascular disease diagnosis and treatment. We will detail some of the most prominent advances in the field, which have shaped the current state of practice as they relate to vascular lesions including vascular malformations, aneurysms, vascular tumors, and ischemic stroke-related large vessel occlusions.

Introduction of Digital Subtraction Angiography and Early Diagnostic Angiography

The first attempt at angiography in 1896 followed the invention of X-ray in 1895. Using an amputated cadaver hand, Hascheck and Lindenthal first described the visualization of the vascular network using a mixture of mercuric sulfide, petroleum, and quicklime as a contrast agent [1]. Years later, in 1927, Moniz is known for performing the first cerebral angiogram using iodinated contrast composed of 25% sodium iodide solution. Angiography during his initial attempt was performed with percutaneous access and direct injection into the carotid artery in the context of transient carotid ligation/occlusion [2]. Cerebral venography followed by Moniz in 1931 who by that time became proficient at performing cerebral angiography in patients with a wide range of neurological disease. The idea of separating

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confounding anatomical background from angiographic signal was first introduced in 1934 by Ziedses des Plantes as an initial concept termed film subtraction angiography [3]. Hand in hand with the development of radiographic technology, enhancing signal obtained from the vessels continued to be investigated including the possibility of intravenous rather than intra-arterial iodinated contrast injection; however, given the dilution in contrast and subsequently signal, arterial injection became a more favorable choice [4]. Until the 1950s, percutaneous access of the carotid artery and brachial artery for opacification of the vertebral artery had been the method used for cerebral vessel catheterization [5]. This of course later evolved with the evolution of catheter technology. Another pivotal development in angiography was the construction of a real-time digital fluoroscopic image processor at the University of Wisconsin which was described by Kruger et al. in 1977 [6]. This processor yielded 30 subtraction images per second and permitted the elimination of bony structures and soft tissues for the first time, in an interactive manner [6]. The evolution of digital subtraction angiography continued over the course of the years to include further refinement in resolution and has been further enhanced by the development and current use of three-dimensional, rotational angiography. The precise visualization yielded by the advancement in cerebral vascular imaging has served as a founding platform for the understanding and subsequent targeted therapeutic treatment across a wide range of neurovascular disease.

Advancing Access to the Cerebral Circulation

Surgically inoperable lesions including challenging arteriovenous malformations, fistulas, and aneurysms served as the driving factor in the development of more advanced catheters and microcatheters with the ability to reach the target lesion.

Gaining Precise Access and Targeted Treatment of Intracranial Vascular Lesions

Catheters and Microcatheters

The navigation of catheters endovascularly, particularly in the tortuous and small caliber of the cerebral circulation, poses unique challenges. Early efforts of Luessenhop and Velasquez in 1964 demonstrated the first successful cerebral catheterization [7]. Silastic tubing was inserted into the internal carotid artery by way of a glass chamber which was surgically connected to the external carotid artery. In 1966, the microcatheter described by the name of para-operational device (POD) was engineered as a combination of polyethylene proximally and silicone rubber distally forming a soft 7 cm tip of 1.3 mm in outer diameter [8]. Additionally, the distal tip of the microcatheter included a 1 mm micro-magnet which allowed for

pull and vibration achieved by the application and manipulation of an external magnetic field. Another technical strategy introduced by these early scholars was use of a guide catheter which Frei and colleagues termed by the name of plastic T [8]. This concept continued to propagate in 1968 where Yodh et al. [9] developed six iterations of a microcatheter with an implanted 1.3 mm magnet in the silastic microcatheter tip, some of which were designed to detach. These detachable constructs contained 0.5 mm cooper wire wrapped in ten turns and attached by paraffin wax which was intended to melt upon the introduction of heat via electric current. One year later, in 1969, the first report of middle cerebral artery catheterization was published describing access using the POD catheter through percutaneous carotid puncture [10].

Iterations of the POD catheters continued to evolve and included the POD with incorporated detachable balloon [11]. Later in the 1970s, detachable balloons were described by Serbinenko [12] and Debrun [13] for the endovascular treatment of carotid-cavernous fistulas. To better understand the technique, Debrun et al. described the methodology of detachable balloon synthesis using latex sleeves created using stainless steel molds, steam-treated in two different iterations, Type I and Type II, which differ in the balloon catheter construction [13]. The former did not involve firm attachment of the balloon to the catheter nor does it need a second catheter for detachment, while the latter involved the balloon being tied to the catheter by a latex thread, was self-sealing, and required a coaxial catheter for detachment. Although their results were favorable for carotid-cavernous and vertebra-vertebral fistulas, less favorable results were seen with aneurysm treatment with a risk of morbidity, mortality, and recanalization of the aneurysms that was seen in a subset of their patients [13]. Calibrated-leak balloon catheters and flow-directed microcatheters were also described for the treatment of arteriovenous malformations using bucrylate, hydroxyethylmethacrylate, or isobutyl 2-cyanoacrylate [13–17].

The next significant turning point in microcatheter evolution occurred in the 1980s with the development of the Tracker microcatheter which occurred as a modification to an existing Target Therapeutics product by one of its biomechanical engineers by the name of Erik Engelson [18]. This new microcatheter distinguished itself by a property of variable stiffness owing to varying consistency of polyethylene. He continued to advance the use of existing microcatheters by also developing shapeable tip microwires which were more navigable as well as adding a radiopaque marker in the distal portion of the microcatheter to allow for visualization. This essentially marked the beginning of the so-called “over-the-wire” catheterization.

Microcatheter technology continued to improve and expand to include flow-directed microcatheters. The Balt Magic (Montmorency, France) provided a more flexible alternative to the Tracker catheter owing to its polyurethane and silicone composition [19]. The Balt Magic, along with the Marathon (EV3, Irvine, California) microcatheter, has been particularly useful in tortuous distal vessel access. In addition to the flow-directed microcatheters, further modifications have been made to aid in the safe delivery of embolic agents whereby the Apollo (EV3, Irvine, California) and Sonic (Balt, Montmorency, France) microcatheters also include a

detachable tip, which can be safely retained after embolization and catheter withdrawal. A valuable addition to the current microcatheters which is particularly helpful in the treatment of high flow lesions is the Scepter balloon (Microvention, Tustin, California). This dual lumen microcatheter which has a balloon at the catheter tip, which allows for concurrent inflation of the balloon for flow arrest and injection of embolic material through its inner lumen.

Embolic Agents

The evolution of endovascular embolization with polyvinyl alcohol (PVA) particles (Boston Scientific/Target Therapeutics, Cordis J&J Endovascular, Miami, FL, USA) began with use of sponge material for embolization in 1974 [20, 21]. In the late 1970s, Irv Kricheff described flow-directed bead embolization to reduce vascular flow to arteriovenous malformations [22, 23]. Also useful in the preoperative embolization of richly vascularized head and neck tumors, the ability of these particles to decrease tumor blush angiographically often translates into a surgical benefit during excision [24–28]. Typically made of foam sheet which is vacuum dried and ground, particles are subsequently sieved and are manufactured in sizes as small as 100 uM and as large as 1100 uM; their irregularity in shape promotes their aggregation when reconstituted in suspension [29]. The mechanism by which they contribute to vascular embolization includes lodging into small vessels correlating with their selected size and adherence to vessel wall which both contribute to flow stagnation and therefore embolization of the vessels targeted [30]. Nontarget embolization must be avoided as the PVA particles are known to accumulate in the catheter hub [31].

Isobutyl 2-Cyanoacrylate (IBCA) and N-Butyl-2-Cyanoacrylate (NBCA) Glue

Early on, IBCA was used as an embolic agent in cerebral vascular lesion embolization; however due to its handling characteristics, it was later replaced with NBCA glue [32]. In the year 2000, the FDA approved NBCA glue (TruFill, Cordis, Miami Lakes, Fl) as a synthetic agent for arteriovenous malformation (AVM) embolization. The embolization agent mix is composed of NBCA, which polymerizes when exposed to an anionic environment [33]; ethiodized oil (Savage Laboratories, Melville, NY, USA), a vehicle for retardation of polymerization and opacification; and tantalum powder which also allows for radiographic visualization. Pretreatment of the catheter with dextrose 5% in water (D5W) is essential to avoid premature polymerization due to contact with anionic material. Following NBCA glue injection, the catheter tip is swiftly withdrawn to avoid catheter adherence to the vessel being treated. The glue material creates a permanent cast within the vasculature and, in generating inflammation in the vessel wall, leads to fibrosis to achieve embolization [33].

Ethylene Vinyl Alcohol Copolymer (Onyx)

Soon following FDA approval of NBCA for cerebral AVM embolization in 2004, in 2005, the FDA approved ethylene vinyl alcohol copolymer (EVOH) (Onyx, Micro Therapeutics, Inc., Irvine, CA), although first introduced in 1990 [34]. The agent precipitates in aqueous solutions and thus is prepared with dimethyl sulfoxide (DMSO), which acts as its solvent. Once the DMSO rapidly disperses, the EVOH mixture precipitates. Akin to NBCA preparation, tantalum powder is used for radiographic visualization. The Onyx preparations differ in viscosity with the commonly used Onyx-18 and Onyx-34 with lower concentration correlating with lower viscosity. Catheter pretreatment is accomplished by the use of DMSO flush. Catheter dead space is then filled with Onyx, and endovascular delivery is performed under fluoroscopy, which forms a visible vascular cast. Longer injection times can be performed as compared to NBCA glue, and the risk of catheter tip adhesion in the event of reflux is considerably less, although catheter tip entrapment is still possible, and thus the advantage of using detachable tip microcatheters. Given suspension in DMSO, initial injection rate is <0.3 ml over greater than 40 seconds to avoid the risk of DMSO-related vasospasm and necrosis.

Absolute Alcohol

Ethanol embolization may also be utilized particularly in the case of venous and venolymphatic malformations. The alcohol serves to induce thrombosis and fibrosis and has been described in use for neck and oral/facial slow flow malformations [35–37]. Given its ability to widely diffuse, it has the risk of damage to the surrounding tissue, including possible skin necrosis when used percutaneously, and as such should be used with precaution.

Evolution of Endovascular Aneurysm Treatment

Early attempts at endovascular aneurysm embolization with balloon occlusion occurred as early 1974 as described by Serbinenko [38]. Four years later, Debrun reported the use of silicone-filled latex balloons in aneurysm embolization, and even later, silicone detachable balloons were developed by Hieshima and Interventional Therapeutics (ITC). However, radiographic recanalization of balloon-treated aneurysms was seen in a significant number of cases [13]. In the 1980s, a study reporting results of balloon occlusion in over 100 aneurysms addressed the inability to effectively treat wide-necked aneurysms, small aneurysms, and in ruptured aneurysms as well as in cases of vasospasm [39]. Aneurysm rupture and its associated morbidity/mortality also became a concern as the relatively non-compliant balloons filled with hydroxyethylmethacrylate preserved their

own shape rather than adapting to the shape of the fragile aneurysms. As such, the endovascular community searched for the next technical advance in aneurysm treatment.

First introduced in 1988, the idea of pushable coils for use in embolization of cerebral aneurysms was a desirable one that was unfortunately limited by the stiffness and irretrievable nature of these early coils [40, 41]. As such, the development of soft platinum coils by Guglielmi in 1989 dramatically changed the course of endovascular aneurysm embolization. The naissance of the GDC system occurred as a research continuum from bench side to the AngioSuite at the University of California, Los Angeles (UCLA). Several integral members of the development team along with Guglielmi included neurointerventionalist Vinuela and Target Therapeutic engineer Ivan Sepetka [42–44]. The structure of these coils consisted of a soft, platinum detachable material ranging in length from 2 to 30 cm, connected to a stainless steel pusher wire. The technique involves the over wire navigation of the microcatheter to the aneurysm, followed by delivery of these platinum coils and their subsequent electrolytic detachment. The first human use of GDC coil occurred at UCLA in 1990 [45], and now, coil embolization of aneurysm is a standard for endovascular aneurysm embolization. Detachment methods for the currently utilized coils include both electrolytic and mechanical means. Decades later, the trend for increase in endovascular treatment of aneurysms has grown as the leading method of treatment when anatomically feasible and continues to grow with less adjusted morbidity as compared with surgical clipping [46, 47]. The need for effective treatment of wide-necked aneurysms which are not amenable to primary coil embolization further advanced the field to include stent-assistive devices beginning with open-cell, Neuroform (Stryker, Kalamazoo, MI, USA) stent which received FDA approval under Humanitarian Device Exemption (HDE) in 2002. In 2007, the first closed-cell stent approved by the FDA for the adjunctive treatment of intracranial aneurysms in the United States was the Enterprise (Cordis Neurovascular, Miami, FL) stent. Many groups have described their embolization experience in the treatment of wide-necked aneurysms with each of these stents [48–50]. Other stents described as aneurysm stent-assistive devices in Europe have included the Leo (Balt, Montmorency, France) and detachable Solitaire (Covidien, Irvine, California) stent, among others [51, 52].

However, even with aneurysm stent-assistive devices, wide-necked aneurysms continue to be a challenge, as persistent flow can continue to impact the coil construct and remodel the coil mass or even lead to aneurysm growth. To address these issues, lower porosity stents and flow-diverting devices have been developed. To accommodate for smaller vessel calibers and with a degree of decreased stent porosity than its predecessors, Microvention's (Tustin, CA, USA) Low-profile Visualized Intraluminal Support device, LVIS Jr., along with its larger version LVIS, was approved for use under HDE in 2014. Intra-saccular flow-diverting devices, which have yet to gain FDA approval, include the WEB device produced by Sequent Medical, which consists of a microbraided structure intended for delivery within the aneurysm and functions to stagnate flow in a similar fashion to a dense coil mesh.

Compared to the purely intra-saccular treatment of aneurysm, the introduction of flow-diverting stents including the Pipeline embolization device (EV3, Covidien, CA, USA) and Surpass flow diverter (Stryker, Kalamazoo, MI, USA) relies on low porosity (30–35% metal surface area coverage versus 6.5–9.5% in stents used for Neuroform/Enterprise, 18–22% LVIS/LVIS Jr.) [53, 54]. The flow diversion is thought to change the parent vessel hemodynamics and decrease blood flow into the aneurysm leading to thrombosis. This is particularly useful in lesions where the anatomical pathology is complex or the disease involves portions of the parent vessel extending outside of the aneurysm sac [55–61].

Evolution of Endovascular Stroke Treatment

The endovascular treatment of acute stroke has considerably evolved since its inception beginning with intra-arterial urokinase infusion in the late 1980s/early 1990s [62, 63]. Investigators continued to assess the efficacy of IA thrombolysis with pro-urokinase/urokinase [64–66] and tissue plasminogen activator (tPA) [67, 68]. The use of IA thrombolytic therapy was aimed at delivering a more concentrated dose of these agents in direct proximity to the clot in an effort to achieve more effective recanalization, thereby reducing systemic exposure. In spite of the effective recanalization demonstrated by thrombolysis in acute myocardial infarction (TIMI) score in the intra-arterial treatment group, clinical improvement defined as a modified Rankin Scale (mRS) of 0–1 in PROACT and 2 or less in PROACT II was not significantly different from placebo in spite of a trend toward improvement in morbidity [64]. Combined thrombolysis using intravenous (IV) tPA in conjunction with IA tPA was further investigated in multiple trials including Emergency Management of Stroke (EMS) [69] and Interventional Management of Stroke (IMS) [68].

With a lack of positive clinical results, the technical advances in the field continued to evolve to meet the clinical need. Endovascular treatment of stroke next addressed mechanical thrombectomy in combination with thrombolysis. Clouded by a small sample population and possible selection bias, the RECANALISE trial assessed 53 patients, a subset of whom were treated with mechanical thrombectomy if IA tPA was unable to achieve a desirable TIMI [2, 3] recanalization [70]. No significant difference in 90-day Rankin scores was identified in the patient study group [70].

From a technical perspective, mechanical thrombectomy efforts began with the development of both aspiration and retriever devices which have continued to be refined since inception. In 2004, the first mechanical thrombectomy device FDA approved for stroke was the Mechanical Embolus Removal in Cerebral Ischemia (MERCI, Concentric Medical, California, USA) device [71].

The major initial randomized control trials addressing the possible benefit of endovascular intervention for large vessel acute ischemic stroke including IMS-III [72], SYNTHESIS [73], and MR RESCUE [74] did not demonstrate a statistically significant clinical benefit of endovascular therapy. Several confounding factors which likely contributed to the lack of benefit noted include less refined imaging

inclusion/exclusion criteria, the use of IA thrombolysis and first-generation thrombectomy devices, as well as significant time delays in endovascular treatment with time of up to 381 minutes of mean time to groin puncture in the MR RESCUE trial [75].

The biggest shift in paradigm occurred beginning in 2014 with the validation of endovascular thrombectomy as the standard of care in ischemic stroke caused by large vessel occlusion, presenting within 6 h of symptom onset. After the results of the MR CLEAN trial were announced at the World Stroke Conference in 2014 [76], a number of trials followed suit confirming the clinical benefit [76–80]. Patients had a more advanced imaging selection criteria in some of the trials including perfusion data, received standard doses of IV TPA when eligible, and confirmed proximal large vessel occlusions prior to enrollment. The positive results were also owed in part to the development of more effective second-generation stent retrievers including the Solitaire FR (EV3/Medtronic, California, USA) and TREVO (Concentric Medical/Stryker, California, USA) devices [81, 82]. Achieving more effective recanalization from the first-generation devices [81, 83, 84], small construction differences are seen with an open-ended basket of the Solitaire FR stent retriever and a closed-ended and stent wire radiopaque nature of the TREVO. Others in the market which are also constructed of nitinol memory wire include CATCH (Balt Extrusion, Montmorency, France) and REVIVE (Codman & Shurtleff Inc., Massachusetts, USA). In terms of aspiration, the penumbra (Penumbra Inc., California, USA) system initially developed as a multicomponent system with a reperfusion catheter, separator, and thrombus removing ring [85]. While aspiration is currently used in clinical practice alone or in conjunction with stent retriever devices, no evidence of clinical efficacy for aspiration has been demonstrated in a randomized trial. The THERAPY trial designed for addressing the question of aspiration benefit was halted after the positive endovascular study results were published in 2014 and 2015. As such, the 108 patients enrolled in the THERAPY trial underpowered the study for an ability to show significance in their primary endpoint of 90-day mRS 0–2, correlating to functional independence [86]. Additional efforts at reducing distal emboli and improving clot thrombectomy have shown the clinical benefit of proximal balloon guide use during clot retrieval [87]. More recently, a number of reperfusion catheters have been in use adjunctively in the clinical setting with second-generation stent retrievers, although no data currently exists for their efficacy. Studies aimed at investigating efficacy of thrombectomy in acute ischemic stroke have mostly focused on anterior circulation occlusions. Given the small percentage of posterior circulation occlusions, no dedicated study has evaluated the efficacy of any of the specific thrombectomy or aspiration devices exclusively in the vertebrobasilar or posterior cerebral artery infarcts. The improvement and evolution of endovascular thrombectomy devices over the past years since MERCI was approved in 2004 has positively affected treatment outcomes and has allowed endovascular thrombectomy to become the standard of care, at this interval in patients presenting within 6 h of symptom onset. Further trials evaluating late presentation past the current 6-h time point are ongoing, which include DAWN and POSITIVE.

Summary

Since the 1960s with the first reported endovascular catheterization, the diagnostic and therapeutic horizon of neurointervention has continued to expand. This is in part due to the conception, development, and rapid evolution of catheter, device, and embolic materials. Endovascular treatment of fistulas, arteriovenous malformations, aneurysms, and acute ischemic stroke due to large vessel occlusion has become more refined and increasingly widespread. The persistent refinement of these tools will serve to challenge the field in seeking further continued improvement in patient outcomes.

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