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Multilayer Flow Modulator Stents in Brain Arterial Aneurysm Treatment

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ABSTRACT
Cerebral aneurysms are mostly asymptomatic. However, if left untreated, they can rupture and cause bleeding, ultimately leading to hemorrhagic stroke and death. Therefore, they may need treatment even if they are not ruptured to prevent these potentially serious complications. Conventional treatments are inadequate in specific or complex cases of cerebral aneurysm. Flow diverting modulator (FDM) stents have gained importance in the endovascular treatment of intracranial aneurysms in recent years. This article, based on current data, evaluates the general characteristics of FDM stents and their place in the treatment of cerebral aneurysms.
Several commercial FDM stents, including Stena® Stent Intracranial Current Converter (Invamed, Ankara, Turkey), are available for use in brain aneurysms. Even some newer surface-modified flow diverters, such as p64MW-HPC (Phenox GmbH, Bochum, Germany), have been introduced to reduce thromboembolic events.

Current studies show that FDMs appear to be effective and feasible in the treatment of unruptured cerebral aneurysms. Complete occlusion of the aneurysm is a relatively slow process, sometimes taking several months. More comprehensive and comparative studies are still needed.

Keywords: Cerebral Artery Aneurysm, Flow Diverting modulator Stents, Aneurysm Occlusion

Introduction
Cerebral aneurysms are common clinical entities that are mostly asymptomatic [1]. This ballooning in the weakened area of the wall of the arteries feeding the brain, also known as the brain and intracerebral aneurysm, can be symptomatic when it put pressure on adjacent structures [2,3]. The more important problem of brain aneurysms is that if left untreated, they may rupture and cause bleeding, especially in the subarachnoid space, eventually leading to hemorrhagic stroke and death. Most survivors of hemorrhagic stroke due to rupture of the aneurysm remain severely disabled [4].

Symptomatic or asymptomatic unruptured cerebral aneurysms may require treatment due to some potentially serious complications. Endovascular techniques have been widely used for the treatment of intracerebral aneurysms in recent decades, and even rapid progress has been made in this field [4]. Although intracranial aneurysm coil occlusion is widely used, it carries a serious risk of recanalization over long periods and the fact that aneurysms are sometimes untreatable has led scientists to search for alternatives, including stent-assisted coiling and balloon-assisted coiling [5-7]. However, complex anatomy-unruptured aneurysms, including wide-necked, fusiform, and too small aneurysms, may not be treated with this type of conventional coils [8]. Flow directing modulators (FDMs), which are new generation stents, are among the alternative techniques to traditional endovascular treatments. They are designed to isolate the lumen of the aneurysmal sac from the circulation to optimally treat cerebral aneurysms [4]. However, the indications and consequences of these devices need to be better defined [9].

In this article, the objective of this study was to assess the general characteristics of flow-disturbing modulator stents and their role in cerebral aneurysm therapy based on current data.

General Characteristics of Flow Diverting Modulators
The main objective of intracranial aneurysm treatment is to prevent rupture of the aneurysm and ultimately death [10]. In this context, in the treatment of FDM stents, the device is deployed in

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the main artery at the neck level of the aneurysm to reduce blood flow to the aneurysmal sac [9]. With their unique design, uncoated FDM stents laminate blood flow into the lumen of the parent artery. In this way, they reduce the flow rate of the aneurysmal sac, allow thrombosis to occur within the aneurysm sac, and ultimately cause the aneurysm sac to gradually shrink [11]. They also preserve blood flow into the branches and the perforators that feed the surrounding brain tissue remain patent [12].

Indications for cerebral aneurysm treatment and selection of the best endovascular procedure are still a matter of debate. Although the availability of FDM stents is relatively recent, experience with their treatment results are rapidly increasing [9]. Although today it is the most commonly used for aortic aneurysms, FDM was originally used for repair of unruptured intracranial aneurysm repair [3]. A variety of FDM stents are used in brain aneurysms, such as the SILK (Balt Extrusion, France), Pipeline Flex (Medtronic, USA), p64 Flow Modulation (Phoenix, USA) and Stena® Stent Intracranial Current Converter (Invamed, Ankara, Turkey). The Stena device that we developed is a newer product compared to others.

The FDM stents generally have similar basic features [13]. These stents have a unique design consisting of a 3D multilayer braided structure and are uncoated. They have a low profile and a self-expandable wire mesh structure. Therefore, FDM stents can easily adapt to the diameter, morphology, size, and course of the target artery [14]. Their porous design slows blood turbulence in the aneurysm sac, remodeling the main flow to the lumen of the stent. This eventually reduces the wall shear stress and pressure within the sac [15].

When we consider it based on the Stena® stent, this device is made of a knitted tubular multilayer network stent made of a super elastic platinum-nickel-titanium alloy. The device is designed to be delivered through a 0.027'' microcatheter. Being made of a self-expandable alloy, the stent has high radial strength and memory shape characteristic, making it possible to treat aneurysms of different locations, shapes, and sizes. It has a blood-compatible surface and provides aneurysm stabilization by causing thrombus regulation and reendothelialization. Due to the platinum content of its alloy, it can be easily visualized under the fluoroscope (Figure 1).

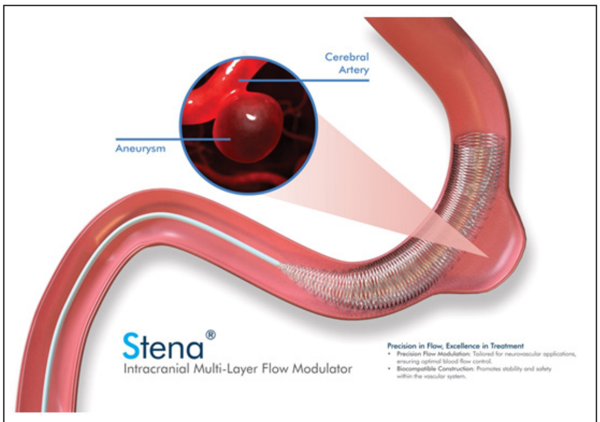

Figure 1: Schematic illustration of a cerebral artery aneurysm in which the Stena® Stent Intracranial Current Converter was deployed.

Challenge with Flow Diverting Modulators

FDM stents are now widely used worldwide in the treatment of intracranial aneurysms. But, on the other hand, there are some limitations to their use [8]. Importantly, the aneurysm occlusion process is often prolonged after placement of the FDM stent and can last up to several months [9]. To prevent thromboembolic complications, adjunctive dual antiplatelet therapy (DAPT) has been recognized as mandatory in FDM treatment in both preoperative and postoperative periods [16]. Although there is no consensus on the best strategies, DAPT is generally used long-term [17]. Because early discontinuation of DAPT treatment carries a high risk of thrombosis in both the stent and the main artery. On the contrary, long-term use of them increases the risk of hemorrhage, especially for large-sized aneursyms [9].

However, despite DAPT, thromboembolic and hemorrhagic complications can occur [18]. It is stated that in selected cases, reducing the dose of DAPT earlier and even using single antiplatelet therapy (SAPT) may reduce the risk of bleeding [16,19]. FDM stents with antithrombogenic surface modifications (such as those with hydrophilic polymer coatings based on glycans) have been designed and introduced to reduce the risk of thrombosis. Further studies are needed because it is not clarified how antithrombogenic surface modifications affect neo-endothelialization, thrombus formation, and in-stent stenosis [20].

The relatively high cost of FDM also prevents these products from becoming widespread [21]. More detailed cost studies are needed.

Discussion and Conclusions

The recommended therapeutic strategy for unruptured cerebral aneurysms is unclear. Conventional treatments are inadequate in specific or complex cases of cerebral aneurysm [4]. Despite significant advances in the field of treatment, important undesirable events such as stent or coil migration, thromboembolic events, and thrombosis in the stent after intracranial applications are not negligible [4,22].

FDMs are becoming an increasingly important option in the endovascular treatment of intracranial aneurysms, as studies support their safety and effectiveness [16,23,24]. With their low profile and unique design, they can be used even for arteries as small as 2.5mm in diameter. The flexibility and low profile provide FDM stents with their self-expandable feature. This ultimately makes it easier to place it in the target area, even in small-diameter arteries [20]. They can also be used for the treatment of aneurysms of different forms such as fusiform, saccular and dissecting [9].

Aneurysms in the internal carotid artery, anterior, middle, and posterior cerebral arteries, as well as vertebral and basilary arteries appear to be indications for the use of FDM [9,25]. Today, the treatment of non-ruptured intracranial aneurysms with FDM stents is performed as a routine procedure19. Studies confirm that FDM stents are a very effective technique and provide a very high total aneurysm occlusion rate. In a pooled data analysis of different trademarked FDM stents, the total occlusion rate was reported as 75.0%, 85.5%, 93.4% and 95.2% for 6-, 12-, 36- and 60-month follow-up, respectively [23].

In a systematic review by Briganti et al., which included 18 studies involving 1483 patients, the aneurysm occlusion ratio was reported to be 10.8%, 60%, 74.5% and 89.6% immediately after the intervention and at 3-, 6- and 12- month follow-ups, respectively [9]. These studies show that aneurysm occlusion is a relatively slow process, gradually increasing over time after intervention and sometimes requiring several months.

Although in some cases the flow in the aneurysm sac decreases immediately after the procedure, the long period until complete occlusion often makes the FDMs for the ruptured aneurysms dangerous [23,25]. Long-term need for dual antiplatelet therapy in FDM treatments also carries the risk of bleeding [12].

Non-negligible rates of occlusion or serious stenosis in the main artery (3.8% intraprocedural and 6.8% late), ischemic (4.1%) and hemorrhagic (2.9%) complications, neurological morbidity (3.5%) and mortality (3.4%) have been observed in the study by Briganti et al. These are the main limits of the FDM technique9. Furthermore, delayed rupture is a well-known complication that develops after FDS treatment of cerebral aneurysm [4,20].

Flow diverters with modified surface, such as the p64 Flow Diverter (phenox GmbH, Germany) with a surface coated with a hydrophilic polymer based on glycan, have become a promising alternative for patients who have contraindications to aggressive antiplatelet therapy [16]. The glycan polymer on the surface of the stent mimics the glycocalyx on the artery wall. Therefore, platelets do not perceive the surface of the stent as a foreign body and initial thrombus development is prevented. Safety and efficacy profiles have been reported to be comparable to those reported for other FDMs [20].

Based on recent clinical studies, flow-directing modulators appear to be effective and feasible for non-ruptured aneurysm treatments. The occurrence of total occlusion usually takes a relatively long time, sometimes requiring several months. The need to use long-term dual antiplatelet therapy increases thromboembolic events. Flow diverters with modified surface can extend the treatable lesion spectrum by the antithrombotic effect. However, more comprehensive and comparative studies are still needed.

Limitation of the Study: This study has some limitations. First, this study is a traditional type of review. There is no consensus on the management of cerebral aneurysms. The characteristics of the aneurysms and the FDMs used to treat the aneurysms differ from each other. The lack of comprehensive long-term follow-up data may have led to a poor confidence in their effectiveness and safety.

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Declaration of Conflicts of Interest: RD is the president of Invamed Company (Ankara, Turkey).

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