USE OF A MULTILAYER FLOW MODULATOR IN THE TREATMENT OF ANEURYSMS
In the last 20 years the vascular surgeon has been capable of realizing the statement by Alexis Carrel “Man cannot predict the future but he can invent it”. His role in endovascular procedures is an example of what he meant. In fact, the excellent command of endovascular procedures, together with an essential training in open surgery, has allowed the vascular surgeon to offer a range of therapeutic options more adaptable and targeted, and therefore more efficient.

From this point of view, every new device is possibly a new piece of the therapeutic mosaic. However, novelty does not mean reliability and, for this reason, trials are needed to test new devices. This was our aim in using the multilayer stent, whose characteristics are enticing and results are certainly encouraging.

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Efficacious open surgery for aortic abdominal aneurysms pioneered by the French surgeon C. Dubost in 1951 was carried over to endovascular procedures by C. Dotter in the United States and J. Parodi in Argentina during the 1990s. Open surgery, which has proved feasible and effective in all vessels of the body, relies on established techniques and tested materials, whereas endovascular treatment is still evolving. A recently developed device for treating aneurysms is the multilayer stent termed the multilayer aneurysm repair system (MARS).

While generically considered a stent insofar as it is structurally similar to a conventional stent graft, its mechanism of action differs substantially from conventional stents. Whatever the material, architecture or morphology, because of their radial mechanical property, conventional stent grafts work by exerting continuous pressure on the endoluminal vessel wall or on another prosthesis to maintain their position or the results of angioplasty for an obstructive stenotic plaque. The MARS, because of its morphologic configuration based on hydrodynamics, induces gradual endosaccular thrombosis inside the aneurysm, preserving the patency of the native vessel and/or a branching vessel of the treated arterial segment. Endosaccular thrombosis leads to a reduction in aneurysm volume (shrinkage), as occurs by endoprosthetic exclusion.

Initial experience with the MARS in the treatment of peripheral aneurysms, chiefly popliteal aneurysms, has been extended to the treatment of abdominal and iliac aneurysms. Recently, the MARS has been used in procedures for treating thoracic and thoracoabdominal aneurysms (TAA). Should the novel stent graft prove effective also in the treatment of TAA, it would become an elective procedure with two innovative features: thrombosis with sac shrinkage and preservation of the spinal and abdominal branches.

**MORPHOSTRUCTURAL CHARACTERISTICS**

The MARS is composed of 2 to 5 concentric overlapping layers of cobalt (42%) alloy (grade II phynox). The alloy is highly resistant to stress and corrosion and does not release
toxic ions. Macroscopically, this highly flexible tubular stent graft resembles a common self-expanding coated stent. The stent graft’s flexibility derives from its particular structural characteristics. Unlike classical stents composed of a fine, laser-cut metallic matrix, the MARS is formed by wires originating from a single source and entwined in a single braid configuration according to programmed angles. The wires are round and the minimal blood contact surface is 40-50 μm; the helical design confers the stent radial resistance to pliability; the wires are not soldered and the mesh confers the stent its 3D tubular architecture. Highly flexible without prosthetic material, the stent is also ideally suited for treating arterial segments subject to continuous bending owing to its optimal torquability and pushability.

The MARS comes in a variety of designs according to the number of layers (2 to 5), number of wires, wire diameter, and type of fenestration (rectangular, square, lozenge). The stent’s porosity, which underlies its mechanism of action, is 60-65% and its mean permeability is 90%. Combining good radial force and flared ends, the helical coil shape is configured to self-anchor to vessel walls or other stents.

The stent’s radiopacity is satisfactory; it is compatible with magnetic resonance imaging and is readily visible on computed tomography and ultrasound scans. The MARS comes in a variety of diameters and lengths, so that it can be used in the

Figure 1  MARS release system.

Figure 2  A) MARS partially released. B) MARS completely released.
treatment of various different vessels in the body (Figs. 1-3).

**FUNCTIONAL CHARACTERISTICS**

The stent graft’s tubular 3D architecture, because it exploits hydrodynamic principles, permits:
- gradual thrombosis of the aneurysmal sac;
- maintenance of patency of the branching vessels of the aneurysm and/or those covered by the stent.

The MARS does this by combining two key characteristics:
- gradual thrombosis layered on the endoluminal wall of the sac resulting from laminarization, reduction of blood flow, and elimination of flow turbulence from the native vessel to the sac through the stent mesh (Fig. 4);
- canalization and laminarization of blood flow from the sac to the branching vessels (Fig. 5).

Besides activating these effects on the aneurysm, the stent accelerates blood flow, thus reducing the risk of intimal hyperplasia at the implant site on the wall of the main native vessel.

Laminarization and reduction of blood flow from the vessel to the sac is obtained thanks to the stent’s mean porosity (60-65%). The flow turbulence at the entrance to the sac is rendered linear, reducing blood flow velocity as the blood passes through the mesh. The concept of the stent’s effective porosity can be likened to that of the structure of a windbreak in agriculture:
- Low porosity windbreak. As the wind blows against a windbreak, large quantities of air move up and over the top and around the ends of the windbreak, generating turbulence on the leeward side. This barrier effect is like that created by a wall (Fig. 6).
- Medium porosity windbreak. The wind flows through the windbreak at 90% less than the original speed and is redirected in parallel laminar flows. On the leeward side, the wind flow pattern is modulated. By adjusting windbreak density, the length of the downwind protected area of crops is established (the downwind distance is 20 times the height of the windbreak). This laminar effect is like that achieved by the MARS (Figs. 7, 8).
- High porosity windbreak. The wind is not broken and flows through the open portions, creating high wind speed turbulence on the leeward
side. This effect is similar to that of a single-layer stent (Fig. 9).

The MARS mesh design is based on the principle of a medium porosity multiple row windbreak, with one row of trees spaced equally apart and a second row of trees positioned alternately with the space in one row filled by a tree in the other row. In this way, an effective barrier is established that permits the wind to pass through it, modulating the wind flow into a laminar pattern and reducing wind speed and turbulence on the leeward side.

Similarly, MARS acts on the blood flow from the vessel into the aneurysmal sac. The blood flow entering the sac increases in velocity and generates turbulence with unsteady vortices on the sac walls. The sac also alters the linear flow in the blood vessel; this change of direction generates tangential shear stress in the form of a vortex at the entrance of the distal pole (in the outflow direction) of the sac. MARS acts on the blood flow from the vessel to the sac: it realigns blood flow, rendering it laminar as it enters the sac, reducing its velocity and intensity. The MARS also redirects the flow from the proximal pole at the entrance to the sac. In this way an optimized hemodynamic condition is created which permits gradual stratification
**Figure 7** Example of medium porosity windbreak.

**Figure 8** Effects of a middle porosity windbreak.
of organized thrombus in concentric layers (Fig. 4). As thrombosis progresses, the layers build up in the sac, leading to sac depressurization and subsequent shrinkage.

Another particular characteristic of the MARS is that it preserves the patency of a branching vessel, with complete thrombosis of the aneurysmal sac (Fig. 5).

This is explained by the Venturi effect: as the speed of a moving fluid increases, the pressure within the fluid decreases and vice versa. For example, the flow through the narrow segment of a pipe decreases, the flow velocity increases and the flow pressure decreases. This is what occurs in an aneurysmal sac in which a MARS has realigned the blood flow: the blood flow velocity at the narrow ostium of the branch is increased, with a decrease in pressure and suction of blood flow from the branch. The flow is directed in the branch whose patency is maintained by the presence of endosaccular thrombosis.

The time needed for these processes varies depending on: the diameter of the aneurysmal sac; its morphology (fusiform or saccular); the arterial segment involved; the pre-existence and amount of endosaccular thrombotic material; the presence and number of branches emerging from the aneurysm.

Electron microscopy of MARS explanted from humans has shown colony formation on the stent’s internal surface of endothelial cells in a regular arrangement of a neoepithelium interrupted at the ostium of the branching vessels.

Intrastent endothelialization permits complete depressurization of the sac and renders the endoluminal surface of the stent impermeable to the external thrombus, impeding thrombus fissuring or canalization (Figs. 10, 11).

When thrombus formation and endothelialization are complete, the natural history of the aneurysmal sac treated with a MARS is similar to that of an aneurysmal sac effectively treated with a conventional stent graft.
 Macroskopically, this highly flexible stent graft resembles a common self-expanding coated stent. The wires are not soldered and the mesh confers the stent its particular 3D tubular architecture. The MARS is supplied prepacked together with its radiopaque delivery system. It is compatible with magnetic resonance imaging and is readily visible on computed tomography and ultrasound scans.

The MARS comes in a variety of diameters and lengths, so that it can be used in the treatment of aneurysms in all vessels of the body (cerebral, abdominal, aortoabdominal and thoracic). Stents up to 12 mm in diameter can be mounted on an 8 French introducer (placed via percutaneous access); larger stents up to 35-40 mm require introducers up to 20 French, in addition to surgical exposure of the vessel or the use of appropriate endovascular closure devices when completing the procedure.

Depending on stent diameter, the device is advanced to the landing zone on a guide: 0.014 to 0.018 inches for small diameters and 0.025 to 0.035 inches for larger diameters. Depending on the distance between the access site and the vessel segment under treatment, the stents can be arranged in delivery systems ranging from 80 to 110 cm in length.

After removing the device from the package and the proximal protection cap, the next step is to irrigate both the canal through which the guide will be inserted and the inside of
the delivery system with physiological heparinized solution to remove air from the system. This is done by operating the luer locks on the delivery system.

The system is now ready to be mounted on a guide and advanced to the landing zone. On reaching the landing zone, while holding the stylet of the delivery system firmly in the right hand, a pullback maneuver is executed, the external part of the delivery system is then retracted to deploy the stent which should expand to its nominal diameter. After deployment, using a reverse maneuver, the push rod is removed taking care to prevent it from rubbing against the distal end of the stent.

Should residual intrastent stenosis persist after stent implantation, the device can be manually dilated with low pressure using a non-compliant balloon to achieve correct stent expansion.