Endovascular Treatment of Popliteal Artery Aneurysms with the GORE® VIABAHN® Endoprosthesis
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**Popliteal Artery Aneurysms: Demographics and Symptoms**

Popliteal Artery Aneurysms (PAAs) are the most prevalent type of peripheral arterial aneurysm, accounting for 70 to 80% of all peripheral aneurysms.\(^1\) - \(^3\), \(^33\) The popliteal artery is considered aneurysmal once the diameter reaches either 1.5 cm or 1.5 times the size of the normal proximal artery. PAAs occur much more frequently in men than in women (20:1 ratio). PAA incidence increases with age, and approximately one-half of PAAs are bilateral.\(^4\) Studies have reported that an abdominal aortic aneurysm (AAA) is found in 36 to 50% of PAA patients, and about the same proportion have hypertension.\(^1\), \(^3\) - \(^5\)

The most frequent and severe symptoms of PAA are thromboembolism and thrombosis, which can lead to claudication, acute limb ischemia and major amputation. Symptomatic PAAs (i.e., claudicant or ischemic limb) account for approximately 40% of diagnosed PAAs and carry a risk of major amputation as high as 30 – 40%.\(^1\), \(^6\) - \(^8\)

The risk of thromboembolic complications in untreated, asymptomatic PAA ranges from 24% at one year to 74% at five years.\(^5\), \(^7\), \(^9\), \(^34\) Although PAAs expand at a growth rate of around 10% per year\(^10\), rupture is rare with an annual occurrence rate of 1.4%.\(^1\)

**Treatment Options**

There is general consensus that all symptomatic PAAs should be repaired regardless of size, and asymptomatic PAAs are recommended to be treated if the aneurysm diameter is greater than 2 cm, mural thrombus is present, or the patient has poor run-off.\(^1\), \(^9\), \(^11\) The current gold standard of PAA repair is saphenous vein bypass grafting with either ligation (most common) or endoaneurysmorrhaphy (resection of the aneurysm).\(^12\) When no suitable vein conduit is available, surgical ePTFE grafts are typically used, with reported primary patencies up to 30% lower than vein bypass at five and ten years.\(^13\), \(^14\)

In general, clinical outcomes are also negatively influenced by the presence...
faster recovery. In general, the reported GORE® VIABAHN® Endoprosthesis patency rates at two to six years in PAA (70% – 86%, Table 1) are comparable to those reported for surgical bypass at five years (69 – 88%).18 – 23 With its lower morbidity and mortality, the GORE® VIABAHN® Endoprosthesis provides an option for patients who are not good surgical candidates due to pre-existing co-morbidities. In general, endovascular repair of PAA does not preclude surgical bypass at a later date.19 – 23

Table 1: GORE® VIABAHN® Endoprosthesis primary patency reported in the literature

<table>
<thead>
<tr>
<th>Name</th>
<th>Limbs</th>
<th>1 Year Primary Patency</th>
<th>2 – 6 Year Primary Patency</th>
<th>Limb Salvage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rajasinghe</td>
<td>23</td>
<td>93%</td>
<td>—</td>
<td>100%</td>
</tr>
<tr>
<td>Antonello</td>
<td>21</td>
<td>81%</td>
<td>71% (6 years)</td>
<td>100%</td>
</tr>
<tr>
<td>Tielliu</td>
<td>73</td>
<td>84%</td>
<td>70% (5 years)</td>
<td>100%</td>
</tr>
<tr>
<td>Thomazinho</td>
<td>11</td>
<td>90%</td>
<td>—</td>
<td>100%</td>
</tr>
<tr>
<td>Curi / Jung</td>
<td>15</td>
<td>100%</td>
<td>83 (2 years)</td>
<td>100%</td>
</tr>
<tr>
<td>Midy</td>
<td>42</td>
<td>90%</td>
<td>86 (4 years)</td>
<td>96%</td>
</tr>
<tr>
<td>Ascher</td>
<td>15</td>
<td>82%</td>
<td>—</td>
<td>100%</td>
</tr>
</tbody>
</table>

* Primary patency definition revised from paper to include reinterventions (4 reinterventions)

— Indicates that the value was not reported
Making Treatment Decisions

The use of the GORE® VIABAHN® Device in the treatment of PAA can offer significant benefits for many patients; however, this treatment is not suitable for everyone.

To achieve optimal outcomes, it is recommended that a patient:

• Be a candidate for an interventional procedure.

• Have blood vessels with at least a 2 cm landing zone proximal and distal to the aneurysm (Figure 1).

• Not have a large difference in vessel diameter proximal and distal to the aneurysm to help minimize numerous device overlaps in points of flexion.

• Tolerate antiplatelet / anticoagulation treatment.

• At least one vessel run-off

Additionally, young and active patients who are good candidates for bypass (vein or synthetic) should preferentially be considered for surgical repair.

These recommendations are illustrated graphically in the following treatment algorithm shown in Figure 2.
PAA Anatomic Considerations:

PAAs have unique anatomical characteristics that impact their treatment with stent-grafts. The popliteal artery is anchored above the knee at the origin of the descending genicular artery, and is anchored below the knee at the level of the trifurcation. Figure 3 illustrates these locations. When the leg is straight, the popliteal artery is fully extended; however, as the knee bends, the distance between the two anchor points decreases by up to 25%. The popliteal artery accommodates this loss of length by
a combination of elastic shortening (predominant in younger patients) and the formation of bends or kinks in the artery (predominant in older patients).\textsuperscript{35}

The mechanical differences between the native vessel and implanted stent-graft must be considered with respect to these two anchor points. When selecting the location for the proximal and distal ends of the device, it is advisable to consider their relative position compared to the two anchor points. There may be increased risk of arterial kinking during flexion when the proximal or distal ends of the device fall short of the “anchor” sites.

**Device Description**

The GORE\textsuperscript{®} VIABAHN\textsuperscript{®} Device is comprised of an implantable endoprosthesis and a delivery system. The catheter consists of a deployment line, a constraining mechanism, and a catheter shaft with a hub assembly (Figure 4).

**Figure 4: GORE\textsuperscript{®} VIABAHN\textsuperscript{®} Device**
The GORE® VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal graft consisting of an expanded polytetrafluoroethylene (ePTFE) lining with an external nitinol (NiTi = Nickel: Titanium) support extending along its entire length (*Figure 5*). The endoprosthesis is compressed and attached to a dual lumen delivery catheter (*Figure 4*). To facilitate accurate graft placement, two radiopaque metallic bands are attached to the distal tip and transition of the catheter, marking the ends of the compressed graft.

The stent is attached to an ePTFE tube graft with a tape comprised of ePTFE and fluorinated ethylene propylene (FEP) (*Table 2*). The luminal surface of the graft has the same microstructure as the ePTFE vascular grafts commercialized by Gore, and provides a new conduit for blood flow.

The device is introduced over an appropriately sized stiff guidewire (0.035" or 0.018" / 0.014" for the low profile device) in small increments through the introducer sheath and advanced to the target site. The device is deployed by unscrewing the deployment knob and slowly pulling the deployment knob to unravel the restraining line. The device deploys from the tip to the hub, and should not appreciably shorten or jump if deployed as instructed. The device should be post-dilated to ensure full expansion and apposition to the wall of the vessel. For further instructions, please see the *Instructions for Use*. 
**Procedural Information**

Deployment of the GORE® VIABAHN® Endoprosthesis in a PAA follows the same basic steps as deployment in the SFA. However, there are some nuances with respect to deployment and technique specific to PAA treatment. Adherence to these recommendations are important in achieving safe and durable outcomes.

- **Pre-procedure planning:** Due to the tortuousity, potential for thrombus accumulation in the aneurysm, and change in vessel diameter, imaging prior to the procedure, such as CT/CTA or MRI/MRA are highly recommended to determine intended landing zones, vessel diameters, and potential overlap locations. Additionally, same-day preoperative duplex scanning may aid in pre-procedure planning.

- **Antiplatelet regimen:** The use of aggressive antiplatelet therapy (i.e., clopidogrel) is recommended for a minimum of six weeks following the repair of PAA with the GORE® VIABAHN® Endoprosthesis. Tielliu *et al.*, reported that treatment with clopidogrel was the only statistically significant predictor of success in his series of patients when reviewing patency at four years.  

- **Guidewire choice for device positioning and deployment:** The guidewire used in this application must be a stiff guidewire of the appropriate diameter and placed securely in a distal vessel. When the GORE® VIABAHN® Device is deployed in an aneurysm, the guidewire provides critical support to prevent the device from bending into the aneurysm during deployment. Inappropriate guidewire selection (incorrect diameter or stiffness) or insufficient anchoring of the guidewire distal to the lesion under some circumstances, has led to deployment inaccuracy and device shortening, as well as surgical bypass to remove devices that have completely folded into the aneurysm during deployment.

- **Speed of deployment:** In PAA, the GORE® VIABAHN® Device must be deployed relatively slowly to prevent deployment inaccuracy. It is
recommended that the clinician slowly deploy the device and watch on fluoro as the device opens to ensure safe and accurate deployment. When a fast, hard deployment is used, the force of pulling the line can pull the device into the aneurysm. This phenomenon is not observed when deploying a device in occlusive disease because the vessel walls minimize lateral movement.

- **Overlap distance**: When treating PAA with multiple devices it is recommended that there is at least 2 cm of overlap to minimize the risk of migration and endoleak. If unequal device diameters are used, the smaller device should be placed first and then the larger device should be placed inside of the smaller device. Overlapping devices should not differ by more than 1 mm in diameter, with one exception: If 13 mm and 11 mm devices are overlapped, the 11 mm device should be placed first and then the 13 mm should be placed inside of the 11 mm device.
• **Overlap location:** A hinge point zone has been shown to exist in the popliteal artery during knee flexion in many patients. Avoid ending an overlapping device zone in this hinge point zone, which is about 4 cm long and extends proximally from approximately 3 – 4 cm above the radiographic knee joint line (Figure 6). This is especially true when the distal margin of the aneurysm ends at the same level as the end of the overlap zone. This type of placement has resulted in stent fracture at the end of the overlapping region as reported in the literature.25, 36

• **Appropriate length selection:** Experience has shown that devices can shorten up to 10%21 as they are deployed within the aneurysm. When device lengths are selected, allow for this loss in length as the device is deployed. Additionally, the selected device diameter must correspond with the sizing recommendations provided (Table 1 of the Instructions for Use); Gore does not recommend additional oversizing to prevent migration.

• **Deployment location:** Select at least 2 cm of non-aneurysmal popliteal or SFA to serve as the proximal landing zone, and at least 2 cm of non-aneurysmal popliteal artery to serve as the distal landing zone (Figure 1). The endograft(s) should exclude all mural thrombus from the arterial lumen. Avoid unnecessary coverage of potential future proximal and distal anastomotic sites for surgical bypass. IVUS (Intravascular Ultrasound) may be helpful in verifying the landing zones, quality, and diameter intra-operatively. A longer proximal landing zone is preferable, if possible.

• **Flexion arteriography:** Flexion (bent-knee) arteriography post-implantation may be performed at the physician’s discretion to verify adequate device placement.
Failure Modes

There are two primary failure modes with the treatment of PAA — device thrombosis and endoleak.

Device thrombosis can occasionally happen with no apparent cause, but it is primarily related to one of three root causes, all of which limit blood flow through the device:

- **Disease progression:** Development or progression of occlusive disease distal or proximal to the device can limit blood flow and result in device thrombosis. This can be in the form of device-related edge stenosis, general disease progression in the SFA or elsewhere in the leg.

- **Arterial kinking:** Depending on where the margins of the device are placed, there is a potential for the artery to kink just proximal or distal to the device during extreme flexion, resulting in blood flow attenuation or stagnation (*Figure 7*). Careful device placement and a good proximal landing zone length may reduce this risk, as well as proper patient instruction to avoid long periods of time in positions of extreme flexion (i.e., kneeling or squatting.) Flexion (bent-knee) arteriography post-implantation may be performed at the physician’s discretion to verify adequate device placement.

*Figure 7: Possible arterial kinking in treatment of Popliteal Artery Aneurysms*
• **Device fracture:** In five published studies, one long-term series reported on the occurrence of stent fracture (16.7%) when the GORE® VIABAHN® Device was used in PAA.\textsuperscript{19–23, 36} With this experience, these investigators recommended avoiding overlap of devices at points of flexion. In this study, stent fracture did not have a significant adverse effect on patency.

**Endoleaks:**

• **Type I:** Type I endoleaks can occur post-implant as a result of improper device sizing or migration. Careful sizing and deployment with adequate landing zones will mitigate this risk. Late Type I endoleaks can also occur, related to progression of the aneurysmal disease (rare). Type I endoleaks can be treated with touch-up angioplasty or deployment of another device.

• **Type II:** Type II endoleaks are not uncommon in the treatment of PAA. When ligation is used during surgical repair, up to one-third of bypassed aneurysms may continue to enlarge due to the presence of geniculate arteries that feed the aneurysm.\textsuperscript{27, 28} Type II endoleaks similarly occur in patients treated with the GORE® VIABAHN® Device. Although few clinical implications are noted in the current GORE® VIABAHN® Device literature, serial monitoring is recommended. Endovascular techniques may be useful in ablating Type II endoleaks that are causing aneurysm sac enlargement.

**Figure 8: PAA Endoleaks**
• **Type III:** Type III endoleaks are caused by either improper sizing when overlapping devices (usually observed during post-deployment angiography) or by mechanical failure of the devices. Good procedural planning and technique can mitigate the risk of mechanical failure.

• **Type IV:** Due to the microstructure of the ePTFE used in the GORE® VIABAHN® Device, Type IV endoleaks rarely occur. Flow through the graft wall is possible if the graft material is compromised, which would be classified as a Type III endoleak.

In the series by Tielli (ref. 23), 6 (8.2%) endoleaks were reported. 2 Type I and 1 Type III endoleaks were treated by adding an additional stent graft. 2 Type II endoleaks were treated by thrombin injection, and 1 Type IV endoleak was treated with ligation and open bypass.

**Device Monitoring and Re-Intervention Options**

As with endovascular treatment of peripheral occlusive disease, serial monitoring of the patient offers the best route to successful long-term outcome. Gore recommends regular follow-up visits for PAA patients treated with GORE® VIABAHN® Device (1, 3, 6, 12 months, and then yearly). Unless symptoms recur, duplex ultrasound is adequate to monitor flow through the device. If flow is absent or significant endoleak is detected, a physician may opt to use angiography or some other imaging modality (i.e., CT / CTA, MRI / MRA) to determine the status of the PAA repair and decide on future patient treatment.

In the event of detection of thrombosis or an endoleak, endovascular and surgical options remain open to the patient, as well as conservative management.

• **Conservative management:** In the available reports of endovascular PAA treatment, most asymptomatic or minimally symptomatic (mild
claudication) device occlusions underwent no further treatment. These patients are no longer at significant risk of thromboembolism, the reason for which the PAA was originally treated. Similarly, a physician may choose not to intervene on patients with minor, asymptomatic Type II endoleak, although serial monitoring of aneurysm sac diameter is recommended.

- **Endovascular revision:** When a revision is necessary, endovascular techniques can often be used. In suitable candidates, thrombolytic techniques may be used to unmask the underlying cause of failure, and allow endovascular treatment of the culprit lesion. In most cases, placement of an additional stent-graft is used.

- **Surgical Revision:** If patency of a failed stent-graft cannot be re-established using endovascular techniques, surgical bypass using standard surgical techniques is recommended. Critical limb ischemia, including possible amputation, is a known hazard of both endovascular and surgical treatment of PAA.

While patency rates reported in the GORE® VIABAHN® Endoprosthesis literature are high, some cases of failed stent-grafts could not be revised by percutaneous methods.¹⁹–²³ These cases proceeded to either surgical bypass or conservative management (with stable claudication). There were no amputations reported in these series.
References


INTENDED USE / INDICATIONS: The GORE VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal prosthesis for endovascular grafting of peripheral arteries.

CONTRAINDICATIONS: Non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. \textit{Rx Only}

Products listed may not be available in all markets.

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