

In Situ Saphenous Vein Bypass Grafting in Peripheral Arterial Disease of the Lower Extremities

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Abstract

Objective: To evaluate the efficacy and safety of the valvulotome device used to cut venous valves and in situ bypass in the treatment of peripheral arterial disease (PAD) of the lower extremities.

Methods: In this study, the basic principles of in situ saphenous vein bypass are mentioned, specifically for a novel valvulotome device (NOD® Valvulotome device, Invamed/ Ankara/Turkey). In this context, the effectiveness of the method was evaluated by interpreting the results of some studies on in situ saphenous vein bypass.

Results: In situ bypass has an effective rate for long-term outcomes with approximately 80%, 90% and 95% for primary patency (no evidence of restenosis with a maximum systolic rate >2.5 or sonography-based occlusion), secondary patency (patency maintained by repeated intervention after complete bypass occlusion), and limb salvage (absence of major amputations), respectively. The side effects, including vessel perforation and intramural bleeding, are very low. The technical success rate is very high. Valvulotomes are easy to use by the surgeons and provide comfort for the patients.

Conclusions: In situ bypass is effective and safe in PAD treatment. Valvulotome provides ease of use for surgeons and comfort for patients.

Keywords: Peripheral Artery Disease (PAD), Valvulotomy, In Situ Vein Bypass, Great Saphenous Vein, NOD® Valvulotome

1. Introduction

Lower extremity peripheral artery disease (LE-PAD) is a circulation problem of the lower extremities that is progressive in nature [1]. This disease is a high burden on the public health system due to the increased risk of major cardiovascular events, high rates of morbidity, and an important cause of poor quality of life [2]. Atherosclerosis is the major cause of peripheral arterial disease (PAD). It most commonly affects the arteries that supply blood to the legs and feet. Although the clinical manifestation of PAD is generally benign, it can progress to life-threatening critical limb ischemia (CLI), which requires revascularization intervention [3]. Revascularization is achieved by open surgical techniques such as bypass grafting or endarterectomy,

or by endovascular methods such as stenting or angioplasty [4]. Endovascular methods are preferred to surgical techniques due to their minimally invasive properties. However, they are most effective for more localized occlusions in larger arteries. Open surgical techniques are considered when the blockage is too severe or endovascular methods are not feasible due to the lesion site [5]. Leg veins are commonly used for bypass grafting in PAD. However, the leg veins have multiple valves that direct blood flow to the heart, in the opposite direction of the arterial system. Therefore, they cannot be used directly as grafts. To overcome this challenge, reversed vein bypass or in situ bypass methods are used (Figure 1, A and B) [6,7].

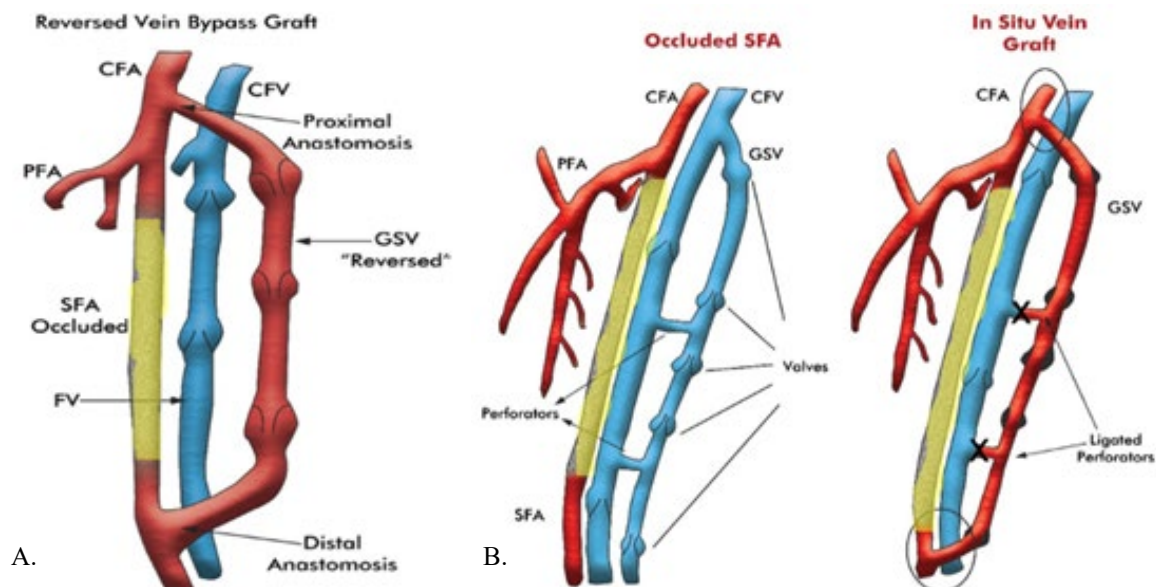


Figure 1A: Reversed Vein Bypass
Figure 1B: In Situ Vein Bypass Graft [8].

This review article focuses on the in-situ bypass treatment of PAD in the lower extremities, with a brief emphasis on other revascularization strategies.

2. Methods

In this study, the basic principles of in situ saphenous vein bypass are mentioned in order to bring the reader's attention, specifically to the NOD[®] Valvulotome device, developed Invamed (Ankara, Turkey). In this context, the effectiveness of the method was evaluated by interpreting the results of some studies on in situ saphenous vein bypass.

2.1. Basic Principle of In Situ Venous Bypass and Valvulotomy

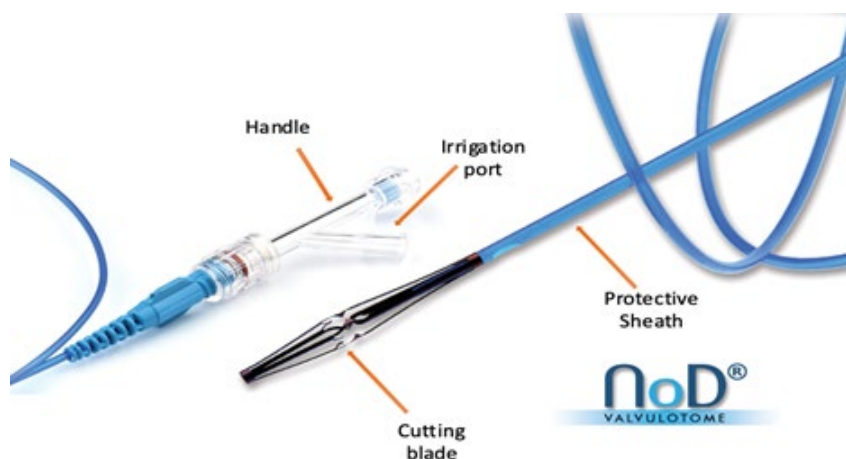
In situ vein bypass is to anastomose a vein to an adjacent artery by keeping it in its original vascular bed. Only the proximal and distal ends are mobilized in this technique. The other length of the vein used for bypass is left in its original anatomical position [8]. This appears to provide a higher patency and a higher rate of vein utilization. However, this procedure has special technical

challenges. For this reason, valve leaflets are cut separately to allow blood to flow downward valvulotomes. Valvulotomes are catheter-based surgical devices that are used to cut and disable venous valves. This provides a solution to direct blood flow in the grafted vein segment in the same direction as the artery [9]. The tributaries and perforators of the vein are also ligated by valvulotomes. The large and small end of the vein anastomosed to the large and small end of the artery, respectively (Figure 1B) [8].

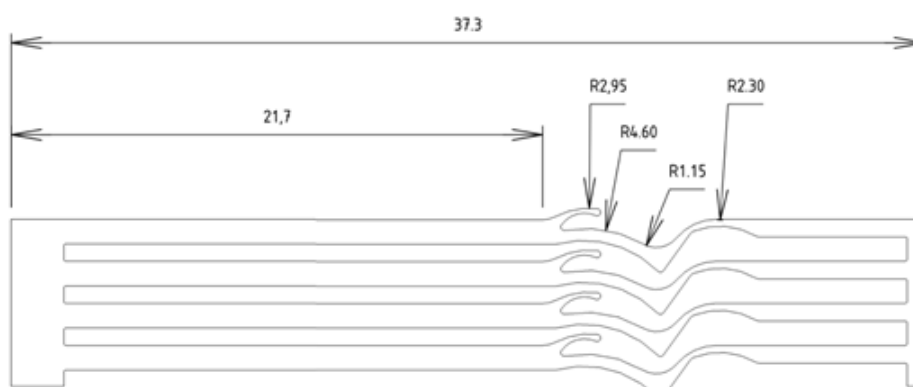
2.2. Technical Considerations for NOD[®] Valvulotome

The NOD[®] Valvulotome (Figure 2) allows an easy endovascular incision of the venous valves. The hydrophilic coating facilitates the intravenous insertion with minimal risk of intimal damage. It uses a long flexible catheter with a recessed cutting blade at the tip to destroy venous valves. It is well-positioned because of the unique self-sizing nitinol wire and self-centering pulley. In addition to these, it provides optimum valve cutting thanks to the four blades on-the-wire (OTW).

A.



B.



C.

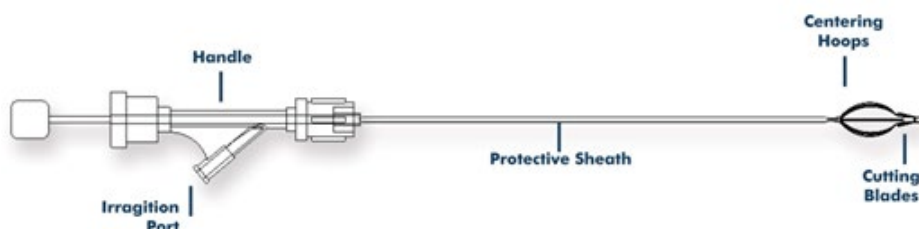


Figure 2A: Fundamental parts of NOD® Valvulotome

Figure 2B: Four cutting OTW* blades, enabling effective valve cutting,

Figure 2C: Schematic demonstration of common parts of NOD® and LeMaitre® Valvulotome devices.

*OTW: on-the-wire

2.3. Procedural Step

To destroy the valves of the vein, the valvulotome is inserted into the vein at its distal end with the catheter guide and then guided to the proximal end. After the blades are placed above the valve, the valvulotome opens and the valves are destroyed by the retracting motion of the blades. Then the valvulotome blades are closed and the device is taken out of the saphenous vein.

3. Results

According to reports from studies on valvulotomes, the estimated rates of long-term outcomes rates (> six months) of the studies used in situ bypass are approximately 80%, 90% and 95% for primary patency (no evidence of restenosis with a peak systolic rate >2.5 or occlusion based on sonography), second-

ary patency (patency maintained by repeated intervention after complete bypass occlusion), and limb salvage (absence of major amputations), respectively [9-11]. In addition to the technological characteristics that make the valvulotomes easy to use and provide comfort, the technical success and the arterial-venous end anastomosis rate are very high. Side effects, including vessel perforation and intramural bleeding, are very low.

4. Discussion

Delaying revascularization for PAD causes serious clinical conditions, including ischemia, gangrene, and can require leg amputation [4,12]. Both the severity of the disease and the anatomical location of the PAD strongly influence the revascularization strategy [13]. Optimal management is determined by a multi-

disciplinary team evaluation [4,12]. Especially during the treatment of long segment occlusions or heavily calcified arteries, endovascular treatment methods can cause some complications such as arterial rupture, arterial dissection, distal embolization, and access site injuries [14]. Due to such adverse events and the infeasibility for some lesions, peripheral bypass surgery still plays an important role in endovascular age [15]. On the other hand, early complications, such as postoperative cardiovascular events, wound complications, and late complications, such as anastomotic aneurysms, graft infections, and abdominal adhesions, are sometimes encountered in open surgical interventions [13,16].

An alternative strategy is to use leg veins with dysfunctional valves. The reverse vein bypass approach is one of the methods to disable the valves. In this method, the length of the saphenous vein surgically removed from the leg is reversed and implanted as a bypass by ligating and cutting its perforators and tributaries. However, the valves are not excised (Figure 1A) [8]. Of the alternative strategies, another approach is the in-situ bypass method, which commonly uses valvulotomes [9]. Some commercial valvulotomes are available for the in-situ bypass. The NOD® Valvulotome is technologically and operationally similar to the LeMaitre® Valvulotome (LeMaitre Vascular, Burlington, MA, USA), another commercial valvulotome device. Their self-sizing and self-centering close to the targeted valve provide ease of use for surgeons, high safety, and comfort for patients. During the intervention, damage to the vein intima is minimal due to the special design of the blade, and the valve leaves are cut traumatically without tearing. The devices contain a hydrophilic coating on the protective sheath to improve push ability by reducing friction.

Various studies have demonstrated in situ bypass, meanwhile the valvulotome, is effective for patency and limb salvage. In the LIMBSAVE registry, a multicenter study using the LeMaitre® Valvulotome, primary patency, secondary patency, and limb salvage were reported to be 78.1%, 92.1%, and 94.7%, respectively, at six-month follow-up. The study also reported the method was safe and technically successful [9]. Bergmark et al also reported a significantly higher patency (84%) after six months for the in-situ technique [10].

In a meta-analysis study, Guo et al found that the long-term patency of in situ bypass grafting was similar to reverse grafting [17]. In situ bypass grafting has even been reported to be superior for some subgroups, such as femoropopliteal bypass. In another study by Shah et al, the 30-day patency rate was 96%, while the cumulative secondary patency was 91% and 81% at 1 and 5, respectively [11]. Limb salvage rates using in situ bypass were 97% and 95% at 1 and 5 years, respectively. The in situ technique has several advantages over the reverse technique: for example, reduction in the number of interruptions (lower risk of dehiscence/infection at the surgical site); less manipulation of lymphatic structures (lower risk of postoperative lymphedema); lower risk of saphenous nerve damage (lower risk of postoperative dysesthesia); shorter intervention time; less manipulation of the great saphenous vein (lower risk of stenosis during fol-

low-up); and better anastomotic congruence (better circulatory dynamics), shorer hospital stay (decreased rate of major wound infection) and faster patient recovery [9,17].

5. Conclusion

Revascularization plays an important role in PAD therapy. Delay in revascularization may be associated with serious clinical conditions. The revascularization method is determined by a multidisciplinary team evaluation. To use valvulotome for in situ bypass is effective and safe. It also provides ease of use for surgeons and comfort for patients.

Declaration of Conflicts of Interest

Rasit Dinc is the president of INVAMED Company (Ankara, Turkey).

Ethics Approval Statement

This manuscript, which is a review article, does not include studies with human or animal participants.

Authors' Contributions

Rasit Dinc designed, conceptualized, searched for data, wrote and finalized.

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