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Novel Suture-Less Vascular Anastomotic Device (BYFix) in Femoro-Popliteal Surgery, Early Clinical Experience

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Abstract

Objectives: To evaluate the early experience of using the BYFix-innovative anastomotic device for creating suture-less vascular anastomosis in major and peripheral arteries surgery. **Design:** Uncontrolled prospective study. **Materials:** The BYFix anastomotic device for suture-less vascular anastomosis with surgical tools and standard vascular grafts. **Methods:** 7 patients, age 63.6 ± 9.2 years, with peripheral vascular occlusion above the knee scheduled for surgical repair were operared. They underwent the surgical procedure using the BYFix anastomotic device for creating proximal anastomosis and the conventional manual suturing for creating the distal anastomosis of the implantable vascular graft. **Results:** The anastomoses by using BYFix anastomotic device were successfully created in all patients. The duration of anastomosis creation was significantly shorter by using BYFix device, compared to conventional manual suturing, 5:10 ± 1:50 minutes compared to 33 ± 17:40 minutes respectively. No adverse events related to BYFix anastomotic device were observed, during the surgical procedure or recovery period. One year follow up revealed no complications related to BYFix anastomotic device. **Conclusions:** The BYFix anastomotic device enables the creation of efficient vascular anastomosis in peripheral vascular occlusions. It shortens the time needed for creating vascular anastomosis and thus reducing the operation time and might reduce distal complications related to the vascular procedure. Further clinical trials are needed to establish the results.

Keywords: Anastomosis, Peripheral Vascular Surgery, BYFix Device

1. Introduction

Lower extremity peripheral arterial disease affects a large proportion of most adult populations worldwide [1]. The prevalence of lower extremity peripheral arterial disease has been defined by a series of epidemiological investigations, that have used either claudication as a symptomatic marker of lower extremity peripheral arterial disease, or an abnormal ankle-to-brachial systolic blood pressure to define the population affected [2].

Patients with symptomatic PAD have significantly reduced mobility and poor quality of life, claudicating results in a reduced physical component quality of life score-lower than for arthritis, cancer or chronic lung disease [3].

Furthermore, PAD patients were more likely to have widespread atheromatous disease in multiple vascular beds (62%), than patients with either CHD (25%) or stroke (40%) [4]. As the presence of PAD is a red alert for the existence of widespread atherothrombosis it should provide a powerful stimulus for action. However, despite these compelling statistics, PAD remains under diagnosed and patients often do not get proper care until the associated heart disease becomes evident. Progression of PAD can result in critical limb ischemia, manifested by ischemic pain at rest or in breakdown of the skin (ulcers or gangrene). Severe PAD can result in tissue ischemia in the lower extremities, causing gangrene and requiring amputation in 3% to 8% of patients [5,6]. Aggressive investigation for revascularization options, either surgical or percutaneous, are warranted in such instances. Only a small proportion of patients with severe disease ultimately require a major amputation.

In managing PAD, it is critically important to deal

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with the high risk of developing severe and often fatal cardiovascular complications. The first priority is to aggressively modify risk factors that enhance the progression of atherosclerosis and atherosclerotic complications. Treatments may include lifestyle modification; smoking cessation; dietary management to decrease weight and control serum lipid levels; physical training and exercise therapy are recommended for patients with intermittent claudication. Antiplatelet and lipid-lowering therapies are effective in decreasing the risk of cardiovascular morbidity and improving long-term survival, endovascular treatment and bypass surgical intervention [7].

The goal of surgical intervention in patients is the elimination of clinical manifestations of severe lower extremity peripheral arterial disease, whether rest pain, ischemic ulcers, or distal ischemic gangrene. Surgery for the treatment of severe lower extremity ischemia (as for endovascular treatment) must be based on specific goals, such as the relief of rest pain or healing of ulcers, prior revascularization attempts, the type of procedure required to accomplish the goals, and the patient's overall ability to successfully recover from the effort.

The innovative BYFix device (HDH Medical, Israel) and method are intended for creating sutureless vascular anastomosis, and by that reduction surgery complication, thus improves the effectiveness of the surgical procedures on various blood vessels.

2. Materials and Methods

2.1. Study Design

This study is a prospective, multi-center and uncontrolled.

Three centers in Germany, Israel and Russia have participated in the study.

2.2. Patients

During the period from January 2008 until November 2009, 7 patients had been enrolled in the study, 3 in Germany, 2 in Israel and 2 in Russia. All patients were diagnosed to have peripheral vascular occlusion above the knee, scheduled for occlusion surgical repair and fulfill the inclusion criteria of the study: diameter of femoral artery $\geq$ 5 mm, patient with severe stenosis or occlusion of SFA (superficial femoral artery) requiring femoral-popliteal bypass above the knee, artery that is relatively free of calcium and atheromathosis, TACS II-C, D, Fontaine IIb, ASA I, II, III and patient's physical condition allows performing general anesthesia.

All patients signed informed consent form.

The study protocol was approved by the local ethical committee at each medical center as well as by the ethical committee of Ministry of Health in Israel.

2.3. The BYFix Device

The BYFix device is intended for creating sutureless vascular anastomosis in various blood vessels (**Figures 1**, **2**).

The BYFix device is accompanied with tools for its insertion: the measuring device (**Figure 3**) and the inversion device (**Figure 4**) for connecting of the vascular graft to BYFix.

The BYFix is long term implantable device intended to be used to rapidly and permanently connect any standard artificial vascular graft to any blood vessel which has a diameter of more than 5 mm, for treatment of aortic and peripheral aneurysms, arterial occlusions and blood vessel traumas.

The full details of the BYFix device and the technical bases of using it for creating anastomoses was described in previous paper by B. Yoffe *et al*. [8]. The BYFix implanted device diameter was determined by artery measurements, using measuring devices and by pre-operative imaging.

Figure 1. The BYFix device attached to different vascular grafts.

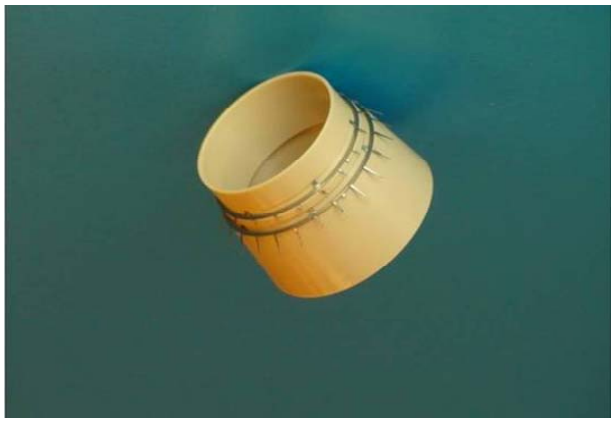

Figure 2. The BYFix device.

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Figure 3. The measurement device.

Figure 4. The inversion device.

2.4. The Surgical Procedure

The standard surgical approach was performed to expose and prepare the affected vascular segment for grafting. The incision was performed in the superficial femoral artery, immediately above the occlusion with endarterectomy, if needed. Vessel diameter was measured by insertion of measuring device into the proximal direction from smaller diameters to larger, up to visible deformation of the vessel wall without its tear. The proximal side of the vascular graft was attached to the BYFix device using the inversion device and the BYFix graft (vascular graft with attached BYFix device) was inserted into the proximal part of the vessel digitally or with a grasper in a parallel direction to the vessel long axis, up to the fixation point (**Figure 5**). The proximal vascular clamp then was moved from the proximal part of the vessel to the vascular graft for testing the hermetic quality of the proximal anastomosis.

The distal anastomosis was created by a standard procedure (manual suturing).

Throughout the procedure the duration of clamping time and the time for creating each anastomosis were recorded. Observational data regarding success of implanting BYFix device, blood loss and anastomosis efficacy was documented.

2.5. Follow Up

The patients had been followed up with pre-discharge evaluation that included: ABI measurement, Doppler test of lower extremities, claudication distance and Duplex to assess the position of implanted device and anastomosis leakage, and then follow up visits at 1 week after hospital discharge, at 1, 3, 6 and 12 months after surgery. The

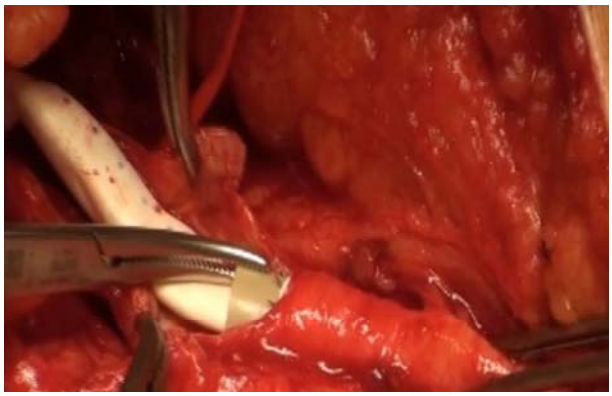

Figure 5. The BYFix graft insertion into the femoral artery.

visits included routine physical examination, documentation of postoperative adverse events, postoperative imaging and Lab tests as needed.

3. Results

The 7 enrolled patients underwent the study procedure, completed follow up period of 12 months, up to December 2010, and were included in the analysis. The study population consists of 7 male, age 63.6 ± 9.2 years (range 55 - 78 years), and weight 76 ± 7.9 kg (range 70 - 85 kg).

All patients had undergone the surgery using BYFix device for common femoral artery or SFA occlusion.

Seven anastomoses (all proximal) were created using BYFix anastomotic device. The distal anastomoses (n = 7) were created by manual suturing. The vascular grafts used were made from PTFE.

The anastomoses by using BYFix anastomotic device were successfully created in all patients. The duration of anastomosis creation was significantly shorter by using BYFix device, compared to conventional manual suturing, 5:10 ± 1:50 minutes compared to 33 ± 17:40 minutes respectively. No serious adverse events related to BYFix anastomotic device were observed during the surgical procedure or recovery period at hospital.

During the 12 months follow up period, no complications or serious adverse events were observed according to the monitoring follow up visits. Throughout the follow up period, the imaging procedures revealed no evidence of leakage from anastomosis, stenosis or displacement of the BYFix.

4. Discussion

BYFix device is an innovative device, intended for creating suture-less vascular anastomosis. The device was tested to be feasible and efficient in preclinical studies on vascular samples, cadavers and animals. This clinical

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study was designed and conducted to test the BYFix device in clinical practice, its feasibility in creating peripheral vascular anastomosis and the potential adverse events or complications.

The study demonstrates the feasibility and safety of BYFix device in creation of anastomoses in the arteries of lower extremities. The BYFix device was demonstrated to be useful in the repair of artery occlusion of lower extremities.

In the current study the advantages of BYFix device over sutured anastomosis were demonstrated in clinical practice. The creation of anastomosis is simple and fast, the anastomoses are standardized, thus the duration of vascular clamping is shortened. These advantages would be even more pronounced as vascular surgeons become more familiar with the technique and gain experience in using it. This technique as it eliminates the need for suturing, is of special value in the repair of technically difficult aneurysms and suitable for laparoscopic surgery. In the current study both types of anastomoses sutured as well as suture-less were created in each patient.

Throughout the follow up period, the imaging procedures revealed no evidence of leakage from anastomosis, displacement of the BYFix or restenosis.

5. Conclusions

In conclusion, the BYFix anastomotic device enables safe and efficient anastomosis between arteries of lower extremities to a conventional graft. It can be applied easily and significantly shorten the time, that needed for creating anastomosis.

Although BYFix device and method is not less invasive than the manual suturing method, it has the potential to shorten the duration of the surgical procedure and to be applied in laparoscopic surgery.

Controlled clinical trials are required to establish the results, which have been achieved in this study.

6. References

[1] M. H. Criqui, J. O. Denenberg, R. D. Langer, *et al*., "The Epidemiology of Peripheral Arterial Disease: Importance of Identifying the Populationat Risk," *Vascular Medicine*, Vol. 2, No. 3, 1997, pp. 221-226.

[2] J. M. Murabito, R. B. D'Agostino, H. Silbershatz, *et al*., "Intermittent Claudication. A Risk Profile from the Framingham Heart Study," *Circulation*, 1997, Vol. 96, pp. 44-49.

[3] R. A. Linsky, K. S. Korr and I. Sadiq, "Contemporary Management of Peripheral Arterial Disease: A Review," *Medicine and Health Rhode Island*, Vol. 91, No. 10, 2008, pp. 305-308.

[4] A. T. Hirsch, Z. J. Haskal, *et al*., "ACC/AHA Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal Mesenteric, and Abdominal Aortic): Executive Summary: A Collaborative Report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Vascular Medicine and Biology, Society of Interventional Radiology and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients with Peripheral Arterial Disease," *Journal of the American College of Cardiology*, Vol. 47, No. 6, 2006, pp. 1239-1312.

[5] M. D. McDaniel and J. L. Cronenwett, "Basic Data Related to the Natural History of Intermittent Claudication," *Annals of Vascular Surgery*, Vol. 3, No. 3, 1989, pp. 273-277. doi:10.1016/S0890-5096(07)60040-5

[6] A. M. Imparato, G. E. Kim, T. Davidson and J. G. Crowley, "Intermittent Claudication: Its Natural Course," *Surgery*, Vol. 78, No. 6, 1975, pp. 795-799.

[7] N. N. Dagher and J. G. Modrall, "Pharmacotherapy before and after Revascularization: Anticoagulation, Antiplatelet Agents, and Statins," *Seminars in Vascular Surgery*, Vol. 20, No. 1, 2007, pp. 10-14.

[8] B. Yoffe, *et al*., "Experimental Study of a Novel Suture-Less Aortic Anastomotic Device," *European Journal of Vascular and Endovascular Surgery*, Vol. 34, No. 1, 2007, pp. 79-86. doi:10.1016/j.ejvs.2007.02.004

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