

# Long Term Results of Arterial Revascularization with Omniflow II® Biosynthetic Grafts: A Single Center Experience

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## Abstract

**Aim:** The aim of this study is to analyze the long-term outcomes of above-knee femoro-popliteal bypass procedures with Omniflow® II biosynthetic grafts. Primary patency and graft related complications were the end points of the study.

**Methods:** Between January 2012 and January 2021, a total of 50 patients (42 males, 8 females) were revascularized using an in-situ Omniflow® II graft. Demographic, clinical, operative and postoperative characteristics of the patients were analyzed retrospectively.

**Results:** Mean age was  $63.8 \pm 10.1$  (range 40-82) years. Fifty above-knee femoropopliteal bypass procedures were performed. Four patients (8%) were operated on due to a previous vascular graft infection where 8 (16%) were operated on due to a previous occlusion. Primary patency rate was 88%. Early graft thrombosis occurred in 2 (4%) patients where late graft stenosis unrelated to the anastomotic sites was encountered in 1 (2%) patient. An endarterectomy on either the proximal or distal site of the anastomosis were performed in 12 (24%) patients. Mean follow-up was  $32.9 \pm 20.8$  (range 12-90) months. Three (6%) patients died due to a COVID-19 infection. No graft infection nor mortality related to arterial bypass procedures was encountered.

**Conclusion:** The Omniflow® II biosynthetic graft provides superior results in treatment of above-knee femoro-popliteal bypass procedures with high patency rates and low incidence of graft infection and aneurysm formation.

**Keywords:** Biosynthetic graft, vascular grafting, revascularization, peripheral arterial disease

## 1. Introduction

Patients with peripheral arterial disease (PAD) have a poor circulation due to decreased arterial perfusion. The arterial blood flow to the distal extremity is restricted most frequently by systemic atherosclerosis. Its prevalence is 3-10% between 40-59 years and 15-20% over 70 years<sup>1</sup>. The most significant risk factors for PAD are diabetes mellitus (DM), hypertension (HT), hyperlipidemia (HL), chronic kidney disease (CKD), and smoking<sup>2</sup>. In addition, there is an increased rate of myocardial infarction, ischemic stroke, and cardiovascular death in patients with PAD<sup>3</sup>.

There is a remarkable elevated risk of adverse limb events like ischemic ulceration and gangrene unless treated. Revascularization deemed mandatory, particularly in patients with more advanced symptoms and presentations. Duplex ultrasonography, computed tomography angiography (CTA), magnetic resonance angiography or conventional peripheral angiography should be performed to diagnose and define the anatomy before revascularization. Though endovascular approaches have extended the invasive treatment modalities in peripheral arterial occlusive disease, surgical interventions must be considered especially for long occlusive disease, aneurysm formation, vascular graft infection and failure of endovascular treatment.

Despite the fact that superiority of the autogenous grafts are well-known, prosthetic grafts should be the selected conduit type in a variety of patients especially when autogenous grafts are not accessible, available or suitable<sup>4</sup>. Since 1983, the Omniflow® vascular grafts have been in clinical practice and advances in technology throughout this time period led to the current Omniflow® II vascular graft (OVG)<sup>5-7</sup>. Omniflow® II (Bio Nova International, Victoria, Australia) is created by using cross linked ovine collagen and an endoskeleton made of polyester mesh which

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Received: 03.04.2023, Accepted: 01.08.2023, Available Online Date: 31.08.2023

Cite this article as: Simsek B, Azboy D, Temiztürk Z. Long term results of arterial revascularization with Omniflow® II biosynthetic grafts: a single center experience. J Cukurova Anestezisi Surg. 2023; 6(2): 210-4. doi: 10.36516/jcass.1276127  
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