Conference paper

Clinical assessment of xenograft combined with knitted TiNi-based mesh implant in femoropopliteal bypass surgery: a Case Report

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Abstract

Treatment of patients with peripheral artery diseases is one of the most difficult issues in vascular surgery. The overall prevalence of peripheral arterial disease varies from 3-10% among the population aged 40-59 years old and among people over 70 years old - up to 15-20%. In the majority of cases atherosclerosis is the main cause of peripheral arterial disease. Autovein is considered a prosthesis of choice and is the most commonly used graft in the bypass surgery. However, it has been deemed impossible in 30% of cases due to its diameter, length or varicose lesions. Despite the technical advances, has not yet developed an ideal vascular prosthesis. Thus, there is a need of search for new materials and modifications of available materials, with the goal of creating a prosthesis for properties close to ideal. In this article we present first case report in the world about usage xenograft with protective external tubular mesh made from superelastic shape-memory nitinol as bypass material. This case shows that the xenoprosthesis with external tubular nitinol mesh support for prophylaxis of aneurysm formation can be used as vascular conduits in bypass surgery. Further randomized controlled trials needed.

1 Introduction

Treatment of patients with peripheral artery diseases is one of the most difficult issues in vascular surgery.

According to data, the overall prevalence of peripheral arterial disease varies from 3-10% among the population aged 40-59 years old and among people over 70 years old - up to 15-20%. In the majority of cases (75 - 90%) atherosclerosis is the main

cause of peripheral arterial disease. Femoropopliteal arterial segments are affected up to 65% of cases.

The steady increase of life expectancy and the prevalence of atherosclerosis of the aorta and lower limb arteries contributes to increase the number of performed reconstructive surgery and, accordingly, the number of postoperative complications.

The main role in the management of peripheral arterial occlusive disease takes a surgical treatment. There were 57,105 arterial surgeries performed in Russia in 2014 alone, which is an increase of 1,028 vascular interventions since 2013. This data shows a steady increase in the number of surgeries performed in the Russian Federation. Reconstruction of femoral-popliteal-tibial segment occupied 2nd place – 13,508 operations, second only to operations in lesions of brachiocephalic arteries - 20,458, including endovascular intervention. In addition to the above methods there are various methods of endarterectomy and lumbar sympathectomy.

A pioneer in the field of vascular prosthesis, T. Gluck, was the first to perform an experimental transplantation of venous conduit into the carotid artery of a dog in 1898 [1]. However, his work did not get as much publicity as similar studies of A. Carrel, who used venous grafts for transplantation in different parts of the arterial system [2]. In 1912 these studies earned him The Nobel Prize in Physiology or Medicine. Subsequently, a large number of different vascular prostheses have developed, among which autografts, synthetic prostheses and xenografts are most commonly used. Autovein is considered a prosthesis of choice and is the most commonly used graft in the bypass surgery. However, it has been deemed impossible in 30% of cases due to its diameter, length or varicose lesions.

The ideal graft must have the following properties: be strong; be non-thrombogenic; be biocompatible; be resistant to infection; be flexible; have elastic properties of the normal arterial wall; there should be no physical or chemical degeneration of the wall of the prosthesis; be inert to surrounding tissues; prosthesis must not damage the blood contents; have a long-term patency; not occluded when flexed. Unfortunately, the ideal vascular prosthesis has not yet been invented. Thus, it is necessary to look for new materials and modifications among already available ones to create the prosthesis which will be approximate to the ideal one. From this point of view, decellularized vascular grafts, which retain most of the properties of living tissues, seem quite interesting.

Due to the high frequency of development of prosthetic aneurysm in the postoperative period xenografts is not gain high popularity. This complication occurs in an average of 6% of cases, but modern technological advances in manufacture of xenografts

have reduced the percentage of aneurysms to 4.1%, which is still high[3].Studies aimed at xenografts improvement and elimination of their deficiencies, in particular the development of aneurysm, are encouraging.

In this clinical case, we have described our clinical experience and techniques in the case of a femoropopliteal bypass surgery using xenograft with protective external meshmade from superelastic shape-memory nitinolas bypass material (Fig.1) on patient who suffers peripheral artery disease and in doing so, hope to contribute to this exciting area of vascular surgery. To our knowledge, this is the first case report that describes using xenograft with protective external nitinol mesh as bypass material in the world.

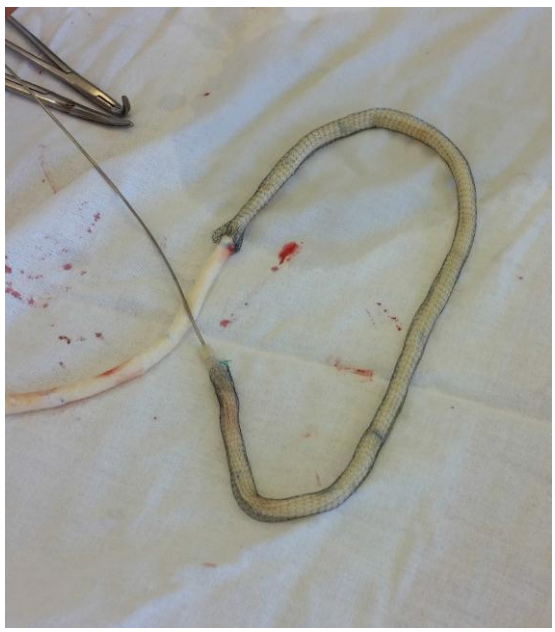

Fig. 1. – Xenograft with protective external nitinol mesh as bypass material

2 Case Summary

66-year-old Caucasian female admitted to the Department of Vascular Surgery of Tomsk Regional Clinical Hospital complaining of persistent pain in her left foot. The examination revealed occlusion of the femoropopliteal segment of the left lower extremity due to atherosclerotic lesion. Also, the patient had hypertension, obesity, type 2 diabetes mellitus and permanent form of atrial fibrillation.

Two days later we performed the femoral-popliteal bypass surgery. Surgery site was treated with antiseptic solutions. An incision in the left groin was performed, superficial femoral artery occluded from the bifurcation. Revision of the popliteal

artery showed atherosclerotic change suitable for bypass surgery. Arteriotomy was performed, retrograde blood flow from popliteal artery was satisfactory. Then distal anastomosis between the xenoprothesis and popliteal artery end-to-side was done with Prolene 5-0 (Ethicon, Somerville, NJ, USA). Then the intersection of the superficial femoral artery distal to the bifurcation of the common femoral artery was performed. The distal end of the superficial femoral artery was ligated. The proximal end of the superficial femoral artery was cut longitudinally and endarterectomy was. Proximal anastomosis between the xenoprothesis and superficial femoral artery end-to-end using Prolene 5-0 was done (Fig. 2). After that blood circulation has started. Shunt worked satisfactory. Hemostasis. Closed the surgery wound. Aseptic gauze bandage was applied.

Postoperative period had no complications. Sutures are removed in 20 days. At discharge shunt was functioning (Fig. 3). Blood pulse was determined on the posterior tibial artery of the left lower extremity. Discharged from the Department in a satisfactory condition.

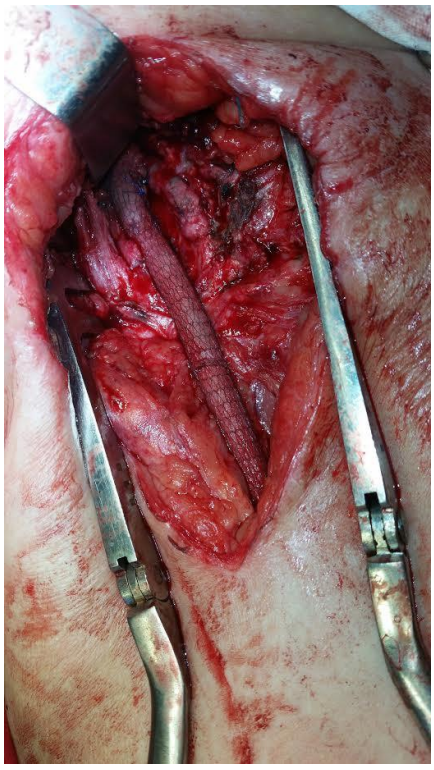

Fig. 2. – Xenograft after remove vascular clamps.

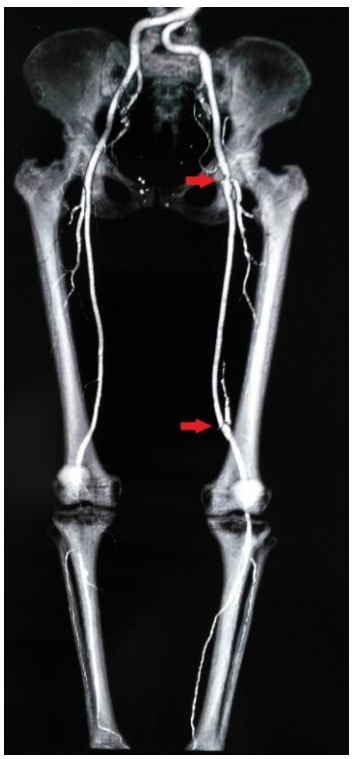

Fig. 3. – Lower extremity CT angiography on Aquilion 64 (Toshiba, Japan) after surgery. Red arrows indicate the locations of the proximal and distal anastomoses.

3 Discussion

Xenograft is defined as agraft of tissue taken from another species, usually from pigs or cattle. In the past, this type of graft causes immense immunological reaction. Modern xenograft is treated with proteolytic enzymes to remove cellular components and retaining nonantigenic collagen tube.

Today xenografts have increased interest for researchers, as recently in medicine it has been actively developing a new area - tissue bioengineering based on restoration of tissues and organs by using stem cells. Unfortunately, today it is technically difficult to create an artificial three-dimensional structure of collagen, some researchers prefer decellularization of organs and tissues that follows by treatment with stem cells. Thus, in the future xenografts may be used to treat human endothelial cells for the formation of high-grade biocompatible vascular prosthesis.

E. Hopfner - a pioneer in the field of vascular xenograft, was the first to perform the experimental transplantation of blood vessel from rabbits to dogs in 1903 [4]. Following experimental data showed high rate of either thrombosis or aneurysmal formation in vascular xenograft. Vascular xenograft drew much attention after the publication of the report on enzyme-modified heterografts by Rosenberg, Gaughran, Henderson, Lord and Douglas in 1957 [5].They treated bovine carotid artery by proteolytic enzymes ficin with subsequent formaldehyde fixation. Further experiments on animals by de Takats, Thompson and Dolowy showed that these grafts still frequently degenerated into aneurysms [6]. Rosenberg modified the manufacturing process with deactivation of enzyme and subsequent crosslinking with dialdehyde starch. After that modified xenografts retain their strength for long periods of time without antigenic responses [7]. In 1966 N. Rosenberg and colleagues were the first to report the result of human artery replacement using modified bovine xenografts, showing that 13 of 18 xenografts had remained their patency for 32 months without development of aneurysm [8].

Subsequently treated by enzymes of the carotid artery of cattle have become possible for commercial purposes as a vascular graft Artegraft (Artegraft, North Bruswick, NJ, USA), however, some studies have shown high incidence of thrombosis and aneurysm formation associated with the use of this vascular conduit. The quality improvement in the production of Artegraft has led to the fact that recent studies have shown good results its using as a dialysis access.For example, P. Kennealey and his colleagues compared the xenografts with PTFE as a permanent access for hemodialysis. After 1 year, there was a statistically significant difference in the incidence of graft patency. Therefore, patency rate in xenografts was 60.5% compared to 10.1% patency in PTFE

[9]. Similar data was obtained by Harlander-Locke M. et al., they used decellularized porcine carotid arteries as an access for hemodialysis, after 18 months patency was observed in 73.3% of cases [10].

In our report, we used the first Russian commercially available vascular xenograft - KemAngioprotez (NeoCor, Kemerovo, Russia). These prosthesis' are used in vascular surgeryfrom 1993 to the present day.KemAngioprotez represents the internal thoracic artery of bovine treated with diepoxide. In our unpublished data, these prosthesis' show good results in femoropopliteal bypass surgery below the knee, but the rate of development of aneurysm remains high. To solve this problem, we decided to use external support mesh as other authors do [11].Within the last decade, it has also been noticed that external support reduces intimal hyperplasia; in theory, this happens because external stenting reduces wall tension and endothelial cells stretching [12]. As supporting material, we chose knitted nitinol tubular mesh because of its properties: it is a strong, flexible, biologically inert material with superelastic shape-memory properties (Fig. 4). This material has been widely used in vascular surgery for many years. We use TN-10 brand (TiNi alloy, at wt %: nickel, 50.0; titanium, 48.4; ferum, 0.5; molybdenum, 0.5; cobalt, 0.3; cuprum 0.2; and aluminium 0,1) nitinol tubewith 40 мm-thick wires which were knitted using a knitting machine, inner diameter of the tube was 0,77 cm (Research Institute of Medical Materials and Shape Memory Implants, Tomsk, Russia) [13].

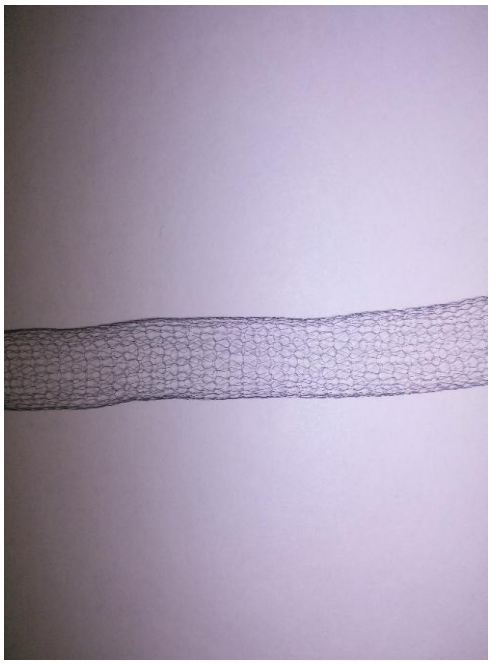

Fig. 4. – Knitted tubular TiNi mesh

Our operative time and blood loss was similar with 'traditional' infrainguinal bypass surgery. Operating time for the case was 160 minutes, and blood loss was 250 ml. We didn't meet any trouble with tubular mesh fixation. No other complications were noted in the post-surgery examination within eight months time frame.

4 Conclusion

The number of operations performed on the periphery artery is large and growing and the surgeon should have a choice of methods when treating a patient, depending on individual circumstances. Unfortunately, it is not always possible to use autovein as vascular conduit and use of synthetic prosthesis, particularly in bypass surgery below the knee, are still show poor result.

This case shows that the xenoprosthesis with external tubular nitinol mesh support for prophylaxis of aneurysm formation can be used as vascular conduits in bypass surgery. Further randomized controlled trials needed.

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