An *in vivo* comparative study of the e-polytetrafluoroethylene vascular prostheses: Vitaflon and Gore-Tex

N. B. DOBROVA, A. J. GORODKOV*, E. S. SIDORENKO, A. B. SCHEKHTER,
Bakulev Scientific Center of Cardio-vascular Surgery, 135, Rublevskoye schosse, 121552 Moscow, Russia

C. BAQUEY
INSERM U.443-146, rue Leo-Saignat, 33076 Bordeaux, France

A comparative study was performed in order to validate new Russian e-PTFE vascular prostheses Vitaflon (St. Petersburg, Russia). The Gore-Tex prostheses were chosen as a referential model. The prostheses were implanted in the venous and arterial positions in 13 dog experiments. After the implantation time was over a comprehensive histological and histochemical examination of excized specimens was performed. It was demonstrated that there is no difference in healing and functional properties between the two studied prostheses.

1. Introduction

The worldwide popularity and high quality of e-polytetrafluoroethylene (PTFE) vascular prostheses, in association with their limited availability because of relatively high price, have determined the necessity of development of such prostheses elsewhere than in the USA. In St. Petersburg (Russia) the analogous prostheses were worked out by the ''Ecoflon'' society under the ''Vitaflon'' trade mark. These prostheses have revealed the same properties as other e-PTFE grafts. A comprehensive study of physicomechanical properties (water permeability, rupture testing, scanning electron microscopy) and biocompatibility testing (*in vivo* subcutaneous and vein implantation in dogs) was performed and published previously [1]. The main goal of this work was to confirm the sufficient functional properties of the Vitaflon vascular prostheses in comparison with currently used analogous models (Gore-Tex, W. L. Gore & Ass. Inc., USA).

2. Materials and methods

A total of 13 *in vivo* implantation experiments were performed in mongrel dogs under general barbiturate anesthesia. For the venous implantation sites the dogs' weights were 10–12 kg ($n = 4$), and for the arterial implantation sites the dogs' weights were 20–25 kg ($n = 9$) were used.

The prosthesis sample of 8 mm diameter and 3 cm length was implanted in the venous position into the intrathoracic segment of the caudal caval vein via the fifth right intercostal space under the artificial respiration. The host vessel section was irrigated with papaverine solution (5%). ''End-to-end'' anastomoses were performed with Prolene 6/0.

Three Vitaflon and one Gore-Tex prostheses were implanted for 3, 6, 12 and 7 months, respectively.

The arterial implantation was performed in the contralateral common carotid arteries and common femoral arteries in such a way that the Vitaflon and the Gore-Tex prostheses were parallel. In two experiments only carotid implantation was performed. The specimens used were 5 mm diameter and 25–30 mm length. The prostheses were sewed ''end-to-end'' with Prolene 6/0.

A total of nine experiments was performed, and 32 prostheses (16 Vitaflon and 16 Gore-Tex) were implanted. During the surgery two Gore-Tex prostheses were ligated because of technical complications (bleeding). The implantation time was from 15 days to 6 months.

During and after the surgery neither anticoagulants nor anti-aggregants were applied. All the administrations were treated with anaesthetic, analgesic and antibacterial therapy.

After the implantation time was over the dogs were sacrificed with an overdose of barbiturate, the prostheses were excized, and detailed histological and histochemical examination of the specimens was performed. The cellular reaction, capsule maturity, elastic elements and acid glycosaminoglycan contents were studied.

*Author to whom correspondence should be addressed.

3. Results

3.1. Comparative characteristics of the Vitaflon and Gore-Tex vascular prostheses

There was no difference in the microstructure of two prostheses that present a fiber-nodal stroma, with approximately 25–30 μm fiber length. The only visible difference was that the reinforcing external membrane of the Vitaflon prosthesis was thicker and denser than the Gore-Tex one. The strength properties measurement demonstrated a significant anisotropy of the Vitaflon prostheses (Table I). The water entry pressure varied for the both prostheses from 250 to 300 mmHg.

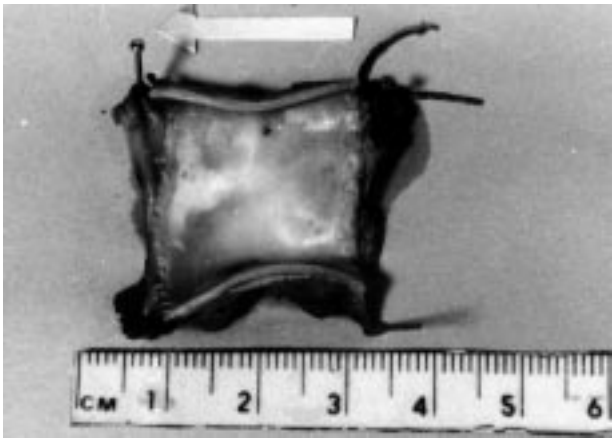

Figure 1 Gore-Tex prosthesis after 7 months of implantation in the caval vein.

3.2. Venous implantation

All the prostheses remained patent in the venous position (Table II). According to the principal criteria of healing no significant differences were noticed between Vitaflon and Gore-Tex. The internal surface of all prostheses was covered with thin smooth and glistening tissue, that changed color depending on the implantation period, from red at 1 month to white at 6 months. The external capsule was thin enough that it did not change the rigidity of prosthesis (evaluated by hand) (Figs 1 and 2).

The histological study showed a very weak inflammatory reaction compared to other synthetic vascular prostheses. The synthetic matrix of the prostheses was not penetrated by connective tissue cells from the exterior or interior side. However, the connective tissue capsule was well fixed on to the synthetic matrix, even during the histological sections preparation. The external connective tissue was very thin. In the 3 month period it was sufficiently matured. Spindle-form fibroblasts were oriented along the prosthetic surface (Fig. 3).

TABLE I Strength properties of Vitaflon and Gore-Tex prostheses

	Vitaflon (ϕ10 mm, $n = 6$)	Gore-Tex (ϕ10 mm, $n = 6$)
In longitudinal direction		
Tensile strength (MPa)	12.0 $\pm$ 0.7	14.8 $\pm$ 0.8
Break elongation (%)	43.9 $\pm$ 10.8	46.3 $\pm$ 12.1
In circumferential direction		
Tensile strength (MPa)	10.2 $\pm$ 1.1*	20.7 $\pm$ 0.9
Break elongation (%)	248.5 $\pm$ 84.6*	49.8 $\pm$ 15.0

*$P < 0.05$.

TABLE II Results of implantation of Vitaflon and Gore-Tex prostheses in dogs

No.	Implantation time	Implantation position	Vitaflon	Gore-Tex
Venous implantation				
1	3 months	Caval vein	+	
2	6 months	Caval vein	+	
3	7 months	Caval vein		+
4	12 months	Caval vein	+	
Arterial implantation				
5	15 days	Carotid artery	+	+
		Femoral artery	−	Ligated
6	15 days	Carotid artery	−	−
		Femoral artery	−	Ligated
7	15 days	Carotid artery	−	−
8	15 days	Carotid artery	+	+
		Femoral artery	+	−
9	15 days	Carotid artery	+	−
		Femoral artery	−	−
10	1 month	Carotid artery	+	+
		Femoral artery	−	−
11	1 month	Carotid artery	−	−
12	3 months	Carotid artery	+	+
		Femoral artery	−	−
13	6 months	Carotid artery	+	+
		Femoral artery	+	+

+ Patent prosthesis; − obstructed prosthesis.

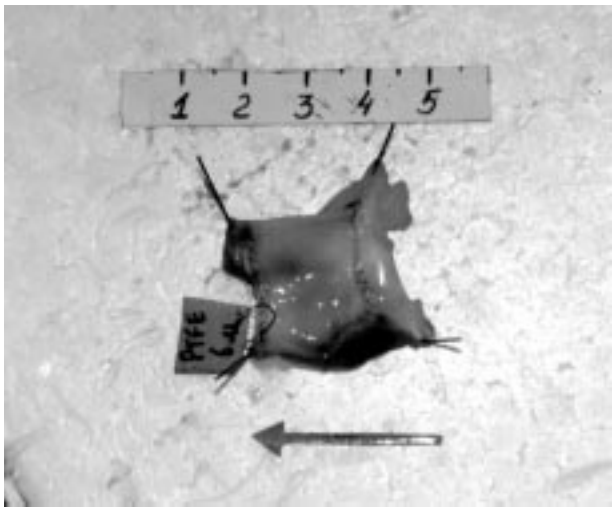

Figure 2 Vitaflon prosthesis after 6 months of implantation in the caval vein.

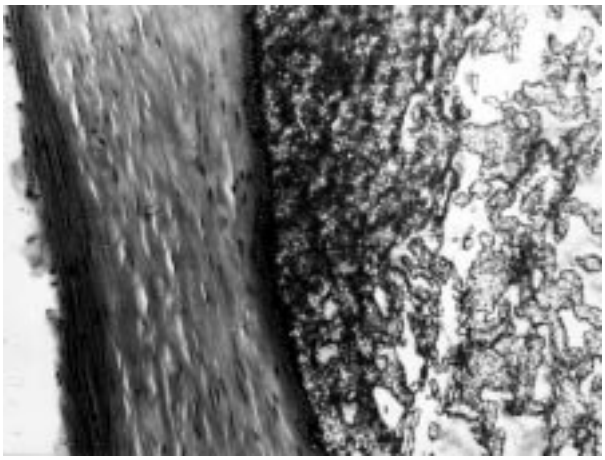

Figure 4 Gore-Tex prosthesis excized from the caval vein after 7 months. Fully endothelialized internal capsule (70–100 μm after 3 months), smooth muscular cell layer. Haematoxylin and eosin, × 250.

The internal connective tissue capsule was formed and nourished from the host vein sections. The endothelial growth was spread from the anastomotic sites. The full endothelialization of the 3 cm specimen was achieved in 3 months. Just under the endothelial layer one could see the thin layer of smooth muscular cells. Nevertheless, the internal capsule was poorly vascularized and was relatively thin, especially in the middle portion of the prosthesis (Fig. 4).

Hyperplastic signs were not found in Vitaflon nor in Gore-Tex specimens.

3.3. Arterial implantation

Since the common carotid artery and common femoral artery in dogs are small, and one should use prostheses of small diameter, this method of vascular prosthesis evaluation is very rigorous. Thus, almost 50% of all implanted prostheses were thrombosed despite the time of implantation (Table II). However, the number of patent prostheses for both models is comparable and one could not choose the best prosthesis. The resulting rating of each model was followed: from 16 implanted Vitaflon prostheses eight (50%) were patent or contained thin, near-wall thromboses; for the 14 Gore-Tex prostheses that were implanted without technical complications, six prostheses (43%) remained patent. Implantation in the femoral position is less favorable than the arterial one. Seven implanted Vitaflon and five Gore-Tex prostheses resulted in two (29%) and one (20%) patency rates, respectively, whereas for carotid implantation this ratio is 8/6 (75%) for Vitaflon, and 6/5 (83%) for Gore-Tex.

In the patent prostheses the internal capsule was red or rose at the early healing stages, and white and glistening at 6 months. The external capsule was moderately thick and increased slightly the rigidity of prosthesis (evaluated by hand) (Fig. 5). In arterial implantation the connective tissue capsule was not sufficiently fixed onto the synthetic matrix at 6 months.

The maturation of the connective tissue capsule that formed around both prostheses was typical. A thin fibrous capsule was substituted with connective tissue that spread from the host artery sections. The inflammatory reaction was very weak. On the early stages of the

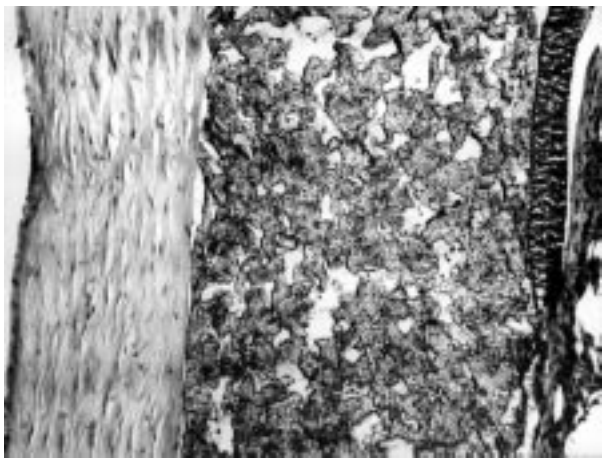

Figure 3 Vitaflon prosthesis excized from the caval vein after 6 months. Well-matured, thin connective tissue capsule (70–100 μm after 3 months); full endothelialization of the inner capsule. Haematoxylin and eosin, × 20.

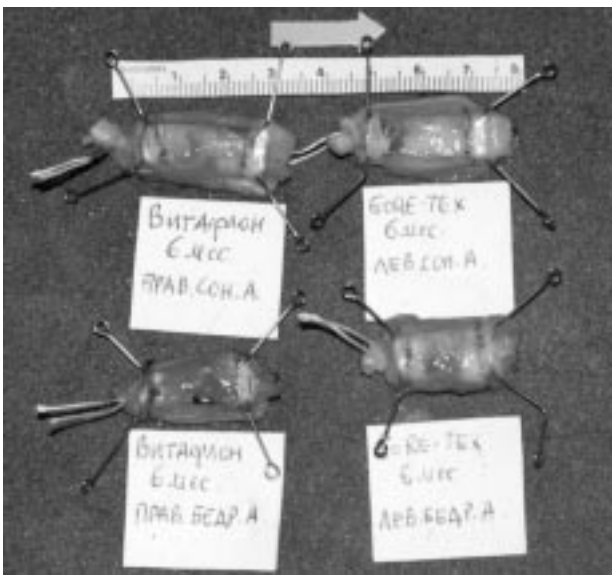

Figure 5 Vitaflon (left) and Gore-Tex (right) excized from the common carotid arteries (top) and common femoral arteries (bottom).

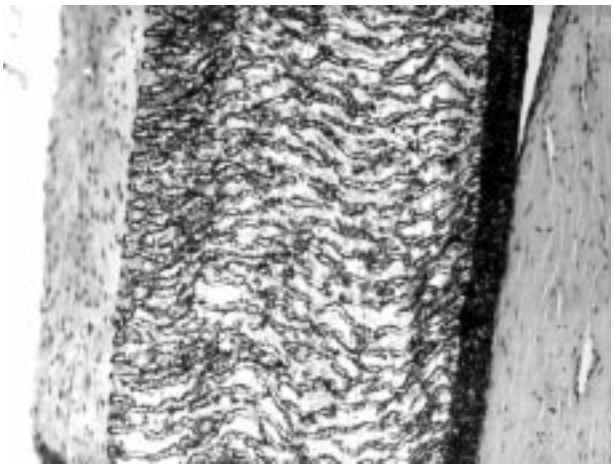

Figure 6 Vitaflon prosthesis excised from the right carotid artery after 6 months. Thin and dense fibrous capsule (70–100 μm after 3 months). Internal capsule is thin and fully endothelialized. Haematoxylin and eosin, × 200.

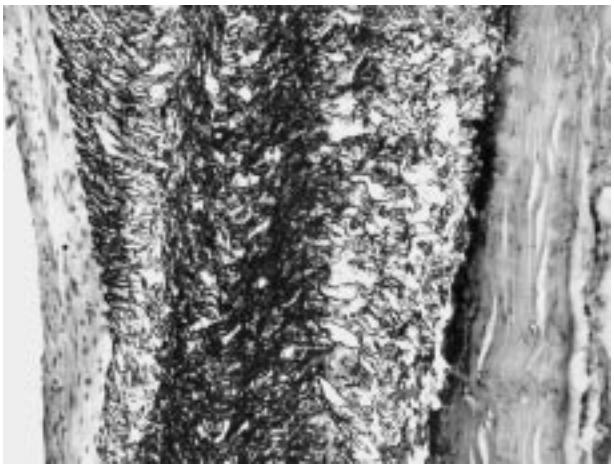

Figure 7 Gore-Tex prosthesis excised from the left carotid artery after 6 months. Mature external capsule (70–100 μm after 3 months). Internal capsule is fully endothelialized. Haematoxylin and eosin, × 200.

capsule formation a thin layer of macrophages was observed at the margin of the synthetic material. However, this layer thinned with the capsule maturation and the observed small amount of macrophages did not lead to giant foreign body cell formation. No penetration of connective tissue was observed via the pores of the wall of prostheses from either the exterior or the interior side. Only a small amount of macrophages and leukocytes was found at the entry portion of the pores from the interior side. After 3 months of implantation the prostheses were fully endothelialized and contained the thin, subendothelial smooth muscular layer. The endothelial cells spread from the host artery sections. However, the moderate thinning of the internal capsule was observed on both prostheses after 6 months of implantation. This was explained by the lack of vascularization in the middle portion of the graft (Figs 6 and 7).

4. Discussion

The results obtained from routinely performed vascular prostheses examination demonstrated that the Vitaflon prostheses can be used with equivalent prognostics as the other e-PTFE prostheses (Gore-Tex, Impra, and others). In some items the Vitaflon prostheses revealed even better properties, but this is disputable. Thus the structural and physical anisotropy of the prosthetic wall suggests better compliance properties; an external membrane that is more solid and dense may prevent excessive dilation. The *in vivo* experiments showed a slightly higher tolerance of Vitaflon during the arterial implantation, of 50% compared to 43% tolerance of Gore-Tex. However, this difference is not significant.

Nevertheless the Vitaflon prostheses do not resolve the principal problems existing now in vascular surgery. That is why the main goal of future investigations should be concentrated on the advancement of the tolerance of these prostheses in substitution of the small vessels.

5. Conclusion

No differences in patency or in biocompatibility were detected between the Vitaflon and Gore-Tex vascular prostheses. Both models revealed very similar properties in venous and arterial canine implantation.

Reference

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