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## SIX YEARS EXPERIENCE OF WRINKLED VASCULAR PROSTHESIS APPLIED FOR ASO

To secure the ischemic symptome or to salvage the limbs in high risk arteriosclerosis obliterance (ASO) patients, structural strength of the vascular prosthesis is important as well as its biocompatibility. Since extra anatomical bypass route is often selected, resistibility of the graft against external compression is required. Upon these concepts, by extending the fibril length, wrinkled ePTFE prosthesis with unique monolithic structure was developed and became compression resistant. We have chosen this material to the bypass operations in ASO and initial results up to six years were summarized. Ninety two wrinkled ePTFE grafts were implanted into 88 (male 82, female 6) ASO patients. Forty one (44%) grafts were implanted anatomically and remainings were extra anatomically routed. Twenty (22%) grafts were anastomosed sequentially. None of four late deaths during the follow up period were graft related. No graft failure was observed in anatomical group. In extra anatomical group, graft occlusion occurred in four grafts and one peri-graft seroma requiring graft replacement was reported. Actual event free ratio for this group was 85.5% at 72 months.

Above results reveal that the wrinkled ePTFE graft is clinically applicable to arterial reconstructions for ASO with satisfactory long term patency even in extra anatomical sequential bypasses.

M. Ishikawa, N. Konagai, Y. Obitsu, Y. Yao, H. Tsuchida, S. Motoyasu, T. Hirayama, S. Ishimaru, K. Furukawa
Tokyo Medical College

## THE COMPLIANT CORETHANE™/DACRON® COMPOSITE VASCULAR PROSTHESIS: COMPARISON WITH 4 MM ePTFE GRAFTS IN A CANINE MODEL

An important need in vascular surgery is for a small caliber (6mm and less internal diameter) vascular prosthesis with thromboresistance superior to existing Dacron® and ePTFE alternatives yet retaining comparable biostability with resistance to aneurysm formation. We have developed a composite vascular prosthesis with the inner blood-interfacing layer made of a porous elastomeric membrane of spun Corethane™ fibers (10 to 15 μm diameter, pore size 30-60 μm) impregnated with a gelatin-heparin complex and an outer soft tissue interfacing warp-knitted Dacron® sheath. Forty-eight Corethane™Dacron® composite (CDC) vascular grafts, of 4 mm inside diameter and 5 cm length, and 48 Gore-Tex® ePTFE vascular grafts of identical size were implanted bilaterally as end-to-end interposition grafts on opposite sides in the carotid and femoral arteries in dogs on low-dose (162 mg/day) aspirin. Patency was assessed by angiography and/or direct examination at explantation at 3 months follow-up with healing assessed by histology and scanning electron microscopy. Patency at 3 months was 37/48=77% for the ePTFE grafts and 44/48=91.7% for the CDC grafts with Fisher's exact test (2 tailed comparison) indicating the probability of superior CDC graft patency to be 95.5%. In the 7 pairs of grafts in which one graft was occluded, and the contralateral graft of other type was patent, the CDC graft was patent and the ePTFE graft was occluded in every instance. The better healing response of the Corethane™ layer of the CDC grafts showed greater collagenization, less residual platelet-fibrin and red blood cell deposits and more frequent mid-graft endothelialization than for the ePTFE grafts.

G.J. Wilson, *D.C. MacGregor, P. Klement, *B.A. Weber, A.G. Binnington and *L. Pinchuk
Toronto Hospital(General Division) and *Corvita Corporation

## ARE MICROPOROUS SMALL DIAMETER VASCULAR GRAFTS SUPERIOR TO SKINNED GRAFTS IN TERMS OF PATENCY?

Small diameter vascular grafts with a dense, non-porous polymer inner surface (skin) have been thought to be more refractory to early mural thrombosis than microporous grafts and therefore to exhibit a better patency rate. To test this hypothesis, skinned and microporous vascular prostheses, 1.5 mm ID, 15-22 mm long, were fabricated with either a polyurethane polydimethylsiloxane (PU-PDMS) or a polyvinylidene fluoride-trifluoroethylene (PVDF-TrFE) copolymer by the spray, phase inversion technique. Porosity was evidenced by scanning electron microscopy and measurement of hydraulic permeability. Overall 29 PU-PDMS grafts and 26 PVDF-TrFE grafts were implanted in the infrarenal aorta of 55 adult rats. The graft patency was checked by observation at implantation and explantation, and periodical assessment of blood flow through the femoral artery with either finger palpation or an ultrasonic flow detector. The numbers of grafts and patency rates at explantation were as follows:

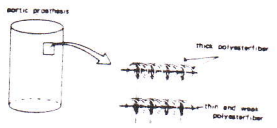
| | 1-3 days | 1-2 weeks | 3-6 months |
|---|---|---|---|
| **PU-PDMS** | | | |
| skinned | 2/3 (67%) | 0/8 (0%) | 0/1 (0%) |
| microporous | --- | --- | 13/17 (76%) |
| **PVDF-TrFE** | | | |
| skinned | 0/2 (0%) | --- | --- |
| microporous | 8/8 (100%) | 8/8 (100%) | 6/8 (75%) |

Skinned grafts, irrespective of graft materials, showed a poor early patency due to mural thrombosis, whereas microporous grafts were clearly superior. It appears that with small diameter vascular grafts polymer inner skin may cause a significant incidence of early mural thrombosis in the rat abdominal aorta replacement model.

Takafumi Okoshi, Giorgio Soldani*, Moses Goddard*, Henry Chen*, Pierre M Galletti*, Teikyo University, *Brown University

## DESIGN CONCEPT OF AN AORTIC PROSTHESIS FOR A CHILD

After long-term implantation of an aortic prosthesis into a child, the graft diameter becomes small because of the growth of the recipient aorta. It is ideal that a vacular prosthesis naturally enlarges in size as the patient grows, but quite difficult, because the growth rates of the patients are different from each other. The purpose of this study is to develop vascular prosthesis which is able to be dilated once by a percutaneous transluminal ngioplasty (PTA), whenever the implanted graft becoms the stenosis in the blood stream. The aortic proshthsis for a child is made of woven polyester fiber fabric. The design is as follows: ther transverse yarns of the woven polyester graft consist of two types of fibers; one is thin and weak, the other thick and spiraled around the former (Figure). A cutting-out of only thin fibers by a PTA procedure would result in enlargement of the graft, because the total length of the spirled thick fibers would regulate the next size of the graft. The graft with another latent diameter designed gy our concept might evade a risky reoperation. The in vivo experiment is now in preparation.




S.Satoh, S.Niu, K.Kanda, J.Hirai, T.Oka, K.Watanabe*
Kyoto Pref. Univ. of Med., Toray Ind*