ARTERIO-VENOUS FISTULAS CONSTRUCTED WITH FORMALIN-FIXED HUMAN UMBILICAL GRAFTS

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Summary
Since July 1976 we have implanted 18 umbilical vein grafts as haemodialysis shunts. Our experience shows that the umbilical vein is suitable for all shunt localisations. The formalin-fixed umbilical vein graft can be considered for vascular replacement. These can be removed in any clinic, prepared and stored under sterile conditions. The formalin conservation procedure is simple, inexpensive and possible everywhere without elaborate technical equipment.

Introduction
Autogenous saphenous vein is the optimal material for grafting. In the absence of a suitable vein, which occurred in about 12% of cases, prosthetic materials and heterologous tissue (bovine arterial heterograft) have been used as a substitute, but they have distinct limitations. In search of an improved vascular replacement for haemodialysis shunts, we considered the use of a formalin-fixed human umbilical vein.

The umbilical vein first used experimentally in 1973 by Dardik and Dardik [1] is a suitable basic material for the production of allogenous implants. Two years later, Dardik [2] published the first successful clinical results. Today, these grafts are commercially used as DARDIK grafts which are surrounded by a polyester mesh [1–5].

Materials and methods
The umbilical cords show a typical sinistral twisting of unknown origin. The lamina elastica is well developed [6] (Figure 1).
Figure 1. a: formalin-fixed umbilical cord; b: photomicrographs of the umbilical cord with the two arteries and the vein, surrounded by Wharton's jelly; c: variable shunt localisations; d and e: the implant 1 month and 20 months after the operation (left arm)
Characteristics of the umbilical vein are:

1. Average constant diameter of 5.8mm
2. Sufficient length of 22 to 48cm
3. No venous valves
4. No branches
5. No degenerative changes
6. Ample supply
7. Favourable mechanical qualities
8. Extensive immunological neutrality.

As a result of our experience with formalin-treated saphena implants in over 70 cases, we use 4% buffered formalin [7–9]. On the basis of our animal experiments, the following can be said about chemical preservation with formalin:

1. Formalin leads to sterilisation of contaminated vein segments within 5 hours. The treatment of the umbilical vein can thus be effected under non-sterile conditions.

2. 4% buffered formalin abolishes the antigenicity of vein implants over a period of at least 5 hours.

3. Formalin leads to an increase in the stability of the vein. The tensile strength is increased by formalin fixation. It is essential that an equilibrium exists between the resorption of the human umbilical cord and its incorporation. For example, when resorption takes place rapidly, the mechanical properties are worsened, resulting in an aneurysm.

4. Finally, formalin treatment causes a relaxation of the wall with an extremely porous vein surface. In our opinion, this promotes incorporation.

The implanted formalin-fixed veins induce a histogenous reaction. The organising tissue encloses the vein in a ‘sandwich-like’ manner (Figure 2). The outer layer exceeds the implant in thickness. There is no foreign body reaction to the formalin-fixed material, and no calcareous degeneration occurs. The implant is absorbed very slowly and even after 300 days, except for the adventitia, the implant media can be recognised as a framework. The implant adventitia is built into the neo-adventitia, and only remnants can still be recognised after a longer test period [7,10].

Preparation of the umbilical vein

The umbilical veins are stored in Ringer lactate solution immediately after delivery and prepared for our operative purpose within a few hours. All blood is washed from the cord and the venous channel is irrigated with normal saline. We test the veins with the aid of a pressure gauge at 300mmHg, in order to reject pervious umbilical veins from the beginning. The umbilical cords are drawn up onto glass rods with desired diameters between 4mm and 8mm and stored in 4% buffered formalin at 4°C [8,11] (Figure 2b).

After this procedure, the helical construction is no longer visible. The constant diameters of the umbilical vein practically excludes severe damage to the subinti-
Figure 2. a: the implant after 300 days: E = endothelium; NI = neo-intima; I = intima; NA = neo-adventitia. b: storage of umbilical vein in 4% buffered formalin.

mal tissue. Care has to be taken that glass rods of too small a calibre are not used. Formalin fixation induces shrinkage, which at wider diameters only results in a pleating of the vein wall. The endothelial layer remains intact for only about 2 hours; thereafter it will be rejected. The inner layer then consists of the subendothelium.
Clinical results

Formalin-fixed allogeneous umbilical vein implants were used as dialysis shunts in 16 patients. An average of 2 to 3 punctures were done per week. The first puncture was generally done after 4 to 6 weeks [10,12].

The longest functional period is now over 24 months. A fistula was established 14 times between the cubital artery and the brachial vein and twice between the radial artery and the cubital vein. In one patient, we implanted the umbilical vein in the lower arm in the form of a loop. In one case, the umbilical vein was implanted subcutaneously in the thigh between the popliteal artery and the femoral vein (Figure 3).

Figure 3. The umbilical vein implant in situ

The complications we saw were two early cases of thrombosis, one aneurysm after three months' use, and one transplant occlusion due to infection after eight months' use. Six patients died of their basic disorders with functioning dialysis shunts.

References

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