Aneurysm Formation in Modified Human Umbilical Vein Grafts

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Objectives: Aneurysm formation in Human Umbilical Vein Grafts has been reported to be as high as 65% after 5 years. One of the causes might be the structure of the Biograft-wall and in 1985 a new method of processing the graft was begun. In Groningen this new improved Biograft has been used since late 1986.

Design: Duplex scanning was used to examine the frequency of aneurysm formation in the new improved Biograft.

Materials: Sixty-nine patent Biografts have been examined in a period up to 6 years after implantation.

Main Results: Aneurysms were found in only 17% of grafts although the frequency increased with time. Dilatation was common but may be due to a more elastic graft.

Conclusion: These findings justify the continued use of the new Biograft as a substitute for arterial femoropopliteal reconstructions.

Key Words: Biograft; Aneurysm; Duplex-scanning; Femoropopliteal reconstructions.

Introduction

Since the introduction of the glutaraldehyde-tanned Human Umbilical Vein Graft (Biograft) as an arterial substitute for revascularisation of the lower limb in 1975, considerable knowledge has been gained concerning patency rates and the behavior of this graft.

A point of great concern has been aneurysm formation in this biological graft, as described in several papers. The reported incidence of aneurysm formation depends on the definition of aneurysm, the diagnostic methods and the methods of analysis of the material, which may explain the variation in frequency from 3 to 65%.

The manufacturers of the Biograft (Meadox Medical Inc. and since 1989, Bio-Vascular Inc.) introduced several improvements in the processing steps of the Biograft, in an attempt to prevent dilatation:

1. Improved glutaraldehyde fixation results in greater thermal stability and a decrease in mural dissection of the wall, improving resistance to degradation.

2. The exterior excess tissue surrounding the umbilical cord is mechanically stripped with a lathe, which results in a thinner and more consistent wall thickness.

3. The Dacron mesh surrounding the Biograft is knitted with tighter interstices, giving more strength to the supportive structure of the graft.

At the University Hospital of Groningen the modified Biograft has been used since late 1986. The purpose of this study was to investigate the incidence of dilatation and aneurysm formation in the new Biograft.

Patients and Methods

Between October 1986 and January 1992 a series of 105 femoropopliteal bypass procedures with a Biograft were performed for atherosclerotic occlusive disease. Sixty-seven patients (56 male and 11 female) with 69 patent bypasses were available for the study and were examined with a Duplex scanner. The mean age was 73 years for men and 64 years for women.

Indications for operation were short-distance and disabling claudication in 48 cases and limb-threatening ischaemia in 13 cases. Seven cases were secondary operations as a replacement of the Biograft due to occlusion (n = 2) or aneurysm formation (n = 5) of an old Biograft. In one case a femoropopliteal bypass procedure was performed because of a popliteal artery aneurysm. The proximal end-to-side anastomosis was usually to the common femoral artery and in three
cases to the distal end of a previously inserted proximal bypass. The distal end-to-side anastomosis was to the popliteal artery, above the knee in 61 cases and below the knee in eight cases. For above knee reconstructions a 6mm. Biograft was used and for below knee reconstructions a composite 6 and 5 mm. Biograft was inserted. All patients received antiocoagulant therapy (acenocoumarin) for 6 months postoperatively.

Since June 1990 patients with a patent graft have been screened yearly with Duplex ultrasonography to detect dilatations and aneurysms. Because the study started in 1990 and the new type of Biograft has been used since 1986, not all patent grafts could be scanned after 1, 2, or 3 years. A high-resolution Duplex scanner (Ultramark 5, Advanced Techniques Laboratories, USA) was used, having a 7.5 MHz and a 10 MHz transducer to visualise every graft in both transverse and longitudinal planes. Every limb was divided in 6 zones: zone I was at the proximal anastomosis, zone IV above the popliteal space where the distal anastomosis was located in case of above knee procedures and zone VI at the distal popliteal artery where the distal anastomosis of below knee procedures was located (Fig. 1). All other zones were equally spaced between the proximal and distal zones. Measurements of the graft were taken 5 mm above and below every zone.

Before insertion the Biograft has an inner diameter of 6 mm, or of 6 mm and 5 mm in the case of a composite graft. The outer diameter before insertion is 8 mm in the case of above knee procedures, and 8 mm and 7 mm in composite grafts. Our Duplex equipment has a resolution of 1 mm. We defined a Biograft to be aneurysmal if the outer diameter was 150% (i.e. 12 mm or 10.5 mm) of its original size or more. Grafts with diameters between 10 and 12 mm were defined as dilated but not aneurysmal. Aneurysms have been described to be diffuse or localized. An aneurysm was considered to be diffuse if its length was at least one third of the total length of the graft. All other aneurysms were classified as localized and were sometimes multiple. There are two categories of localized aneurysms i.e. fusiform and saccular. A fusiform aneurysm is concentric with a symmetrically distended graft-wall. A saccular aneurysm is eccentric with a normal graft wall on one side.

**Results**

Sixty nine patent grafts were examined at least once (Table 1). After 1 year one above knee bypass was found to be diffusely aneurysmal (14, 15 and 14 mm at zones II, III and IV). The 6 mm part of a composite graft was also aneurysmal (14, 15 and 14 mm at zones I, II and III). Seven grafts were found to be dilated (5 localized and 2 diffuse). After a period of 2 years (n = 25) one patient was found to have a localized

![Fig. 1. Schematic diagram, showing scanning zones.](image-url)

<table>
<thead>
<tr>
<th>Zone</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>V</th>
<th>VI</th>
</tr>
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<td>Fig. 1. Schematic diagram, showing scanning zones.</td>
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**Table 1. Diameters found during Duplex scanning of all 69 Biografts. The percentage of aneurysm at each year of examination is shown in brackets**

<table>
<thead>
<tr>
<th>Postop. years</th>
<th>n</th>
<th>&lt;10mm</th>
<th>&gt;10mm loc.</th>
<th>&lt;12mm diff.</th>
<th>&gt;12mm diff.</th>
<th>Aneurysm</th>
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<tbody>
<tr>
<td>1</td>
<td>15</td>
<td>6</td>
<td>5 2</td>
<td>1 2</td>
<td>2 (13%)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>25</td>
<td>16</td>
<td>2 6 1</td>
<td>1 2 3</td>
<td>1 2 (14%)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>25</td>
<td>19</td>
<td>1 2 3</td>
<td>1 2 1</td>
<td>1 (12%)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>16</td>
<td>10</td>
<td>1 2 1</td>
<td>1 2 6 1</td>
<td>1 (13%)</td>
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<tr>
<td>5</td>
<td>19</td>
<td>12</td>
<td>1 1 1</td>
<td>1 2 1 1</td>
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<tr>
<td>6</td>
<td>8</td>
<td>5</td>
<td>1 1 2</td>
<td>1 2 1 1</td>
<td>1 (13%)</td>
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</tr>
</tbody>
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Aneurysm (13 mm). Eight grafts were dilated. At 3 years (n = 25) 3 patients had a localized fusiform aneurysm (13 mm) and three grafts were dilated.

Four years after implantation (n = 16) one patient had a local aneurysm (17 mm). In another patient a fusiform aneurysm (13 mm) and three grafts were dilated. At 5 years (n = 19) there were six cases of localised, fusiform aneurysm formation. One of these grafts had a fusiform aneurysm of 23 mm at one zone, but no clear disruption of the Dacron mesh could be detected. One year previously, this graft had an aneurysm at the same location of 17 mm. Eight grafts were examined after 6 years. The same 23 mm aneurysm seen at 5 years had now grown to 27 mm. No inner wall structure could be detected, and there seemed to be a rupture of the Dacron mesh at one point.

Anastomotic aneurysms were not seen in any graft. 50% of all aneurysms were located in zone II and 50% in zone III. In two cases we saw dilatation of a composite graft between zone IV and V.

Discussion

Of all grafts examined we found a frequency of aneurysms of 17%, although the frequency increased with time. In his study Boontje\(^6\) found a frequency of 3.5% aneurysm formation after 6 years among 257 Biografts of the older type, diagnosed by clinical assessment alone. All aneurysms originated from a defect in the graft wall. Boontje\(^6\) also described a frequency of 46% diffuse or local ectasia of grafts after 3–5 years with follow-up angiography. After 6 years Dardik \(^7\) found 7.7% dilatation of the older type of Biografts at angiographic assessment.

Our study was based on screening with Duplex scanning because previous studies have shown that this is the preferential method.\(^6\),\(^9\),\(^10\) Karkow \(^6\) et al., Nevelsteen \(^9\) et al. and Sommelings \(^10\) have also performed a screening with Duplex scanning, but these studies were of the old Biograft and the frequencies of aneurysm formation were high, (65%, 40%, and 50% respectively after more than 5 years). Out of 64 Biografts, Karkow found seven grafts to have a diameter more than 30 mm ranging up to 57 mm. The largest diameters measured in our series were two Biografts with an outer diameter of 27 and 28 mm in which there was a defect in the Dacron mesh. All other aneurysms had a maximum diameter of 17 mm but without any sign of inner wall loss, or Dacron mesh rupture. Our policy is to intervene surgically only if the diameter of an aneurysm is larger than 30 mm, unless the patient is asymptomatic. Both patients with large aneurysms of their Biografts are asymptomatic and without compromise to the distal circulation.

Karkow \(^6\) et al. and Sommelings \(^10\) describe the outer diameter of newly implanted old type Biografts to be 8 mm. We never found this as Biografts of the new type seem to dilate to a diameter of 9–10 mm within 1 week of implantation. On the other hand, all not-dilated Biografts of the old type previously scanned at our vascular laboratory had an outer diameter of 8 mm. It seems as if the modified Biograft is more elastic, which might be explained by the changed method of harvesting the umbilical vein mechanically, which results in a thinner and smoother wall. In contrast with the results of many other authors we did not detect any anastomotic aneurysms\(^3\),\(^5\),\(^6\).

In conclusion, although there is a tendency for dilatation in the new modified Biograft, there seems to be a substantially lower incidence of significant aneurysm formation compared to the old type Biograft. The modified Biograft seems to be an improvement in its use as an arterial substitute for femoropopliteal reconstructions.

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References


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