Endovascular Prosthesis: Experimental Study and Clinical Use

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Introduction

Endovascular prostheses should be made of a special alloy capable of “remembering” shape. This characteristic requires the material, deformed at one temperature, to partially or completely restore its initial shape when warmed to a higher temperature; the phenomenon is based upon an invention by metallurgists in 1948 [5]. In 1983 scientists reported on the experimental use of a nitinol spiral which could support the lumen of a vessel [1, 2].

We began our first experiments in September 1983 [7]. It was necessary to develop an endovascular prosthesis which would meet the following medicotechnical requirements:

1. Be biologically inert
2. Be resistant to corrosion
3. Allow transcutaneous introduction into an angiographic cathether in the form of a stretched (uncoiled) wire
4. Allow correct positioning of the endoprosthesis under fluoroscopic control
5. Allow restoration of the initial shape by forming a spiral at body (blood) temperature
6. Allow regulation of the pressure on the vessel by elastic dilatation of the prosthesis without causing damage to the vascular wall
7. Be self-fixing within the vessel
8. Withstand compression from external squeezing

Materials and Methods

Experimental Experience

Endovascular prostheses developed by us (Fig. 1) were implanted during 32 acute and 21 chronic dog experiments using thoracic and abdominal sections of the aorta and renal, iliac, and femoral arteries (Table 1).

After implantation for a period of 12 to 16 months, the dogs showed no signs of disease or fever, and walking was not impaired. Control xeroradiograms did not reveal any displacement of the prostheses. The shapes of the stents were as
Table 1. Location of endovascular nitinol prostheses implanted in animals

<table>
<thead>
<tr>
<th>Type of experiment</th>
<th>Dogs (n)</th>
<th>Implanted vessels (n)</th>
<th>Total prostheses (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Thoracic aorta</td>
<td>Abdominal aorta</td>
</tr>
<tr>
<td>Acute</td>
<td>32</td>
<td>12</td>
<td>21</td>
</tr>
<tr>
<td>Chronic</td>
<td>21</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>16</td>
<td>37</td>
</tr>
</tbody>
</table>

Initially, serial xeroradiograms showed no signs of thrombosis or vascular lumen stenosis.

Microscopic studies demonstrated no signs of thrombosis or vascular lumen stenosis in all dogs. The entire spiral was covered by a thin layer of smooth intima through which the coils could be seen. Microscopic studies showed that after implantation of an endovascular prosthesis, threads of albumin and fibrin with elements of blood components collected on the surface of the spiral coils. These threads formed a smooth surface and signaled the beginning of intimal formation.

By the 14th day the inner layer was completely organized and the endothelium was formed. The inner surface of the prosthesis was lined with neointima which consisted of connective tissue, collagen, and endothelium (Fig. 2). Such neointima is nonthrombogenic. Its thickness at the site of the vascular lumen was 0.03–0.05 mm [9].