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Percutaneous Endovascular Graft: Experimental Evaluation[1]

An arterial endovascular graft was constructed by wrapping a Dacron cylinder around the Gianturco expandable metallic stent. The device was passed through an 11-F Teflon catheter into the normal abdominal or thoracic aortas of nine dogs. At follow-up of 7–35 weeks, all but one graft remained patent. At necropsy, the grafts were almost completely covered by neo-intimal proliferation. Similar proliferation was observed between the graft and the wall of the vessel.

Index terms: Aorta, grafts and prostheses, 56.45 • Arteries, grafts and prostheses, 94.456

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THE Gianturco expandable metallic stent has been placed successfully within the venous system and tracheobronchial tree in humans, indicative of its utility in expanding narrowed lumens (1, 2). Endovascular stents have also been placed in the arteries of animals, with eventual incorporation of the stents into the vessel walls (3, 4).

Another use of the Gianturco stent is as a vehicle for the intravascular placement of other materials. We developed such a modification to allow intravascular placement of a Dacron graft, using multiple Gianturco stents as a superstructure by which to anchor and support the graft. Such a device may find use in the treatment of aneurysms, as it allows creation of a new lumen within the aneurysm while sealing off the aneurysm outside of the device in a manner similar to a surgically placed graft. To evaluate the feasibility of the placement and short-term patency of this device, we studied it in the normal aortas of nine dogs.

MATERIALS AND METHODS

Stent Construction

The endovascular graft consisted of multiple stents in tandem connected to each other by metallic struts. The first stent was designated the lead stent; the last, as the trail stent (Fig. 1a). The Dacron tubing was wrapped around the outside of the middle group of stents, internalizing them within the Dacron graft. The lead and trail stents acted as anchors for the graft, while the internal stents served to open the Dacron tubing when the device was released from the catheter (Fig. 1c).

The lead and trail stents were constructed, as previously described (3), of stainless steel wire with a diameter of 0.016 inch. Each stent had six bends and no side barbs. The stents were approximately 2.5 cm long, with a diameter of approximately 1.0 cm. Internal stents were constructed, but wire of thinner gauge was used.

The graft tubes were made from thin, woven Dacron sheets. The graft was approximately 1.0 cm in diameter and usually 5.0 cm in length (range, 2.5–9.5 cm long). The ends of the graft were attached to the limbs of the lead and trail stents with 6-0 suture material. Once constructed, the devices were loaded into 12-F Teflon cartridges and gas sterilized with ethylene oxide.

Graft Placement and Follow-up Study

After intravenous induction of sodium pentobarbital into the dogs for general anesthesia and after systemic heparinization, an 11-F stent introduction assembly (Cook, Bloomington, Ind.) was introduced into the normal abdominal aortas of six dogs and the normal thoracic aortas of three dogs by a femoral arteriotomy procedure. Aortography was performed to document the size of the vessel. The grafts were then introduced through the cartridge and released under fluoroscopic guidance with the technique previously described for placement of a Gianturco stent (3). A second arteriogram was then obtained to enable evaluation of the immediate postplacement results. The animals were not given anticoagulants routinely following graft placement except for heparinization during follow-up studies.

Aortography was performed 1 week after graft placement in the first six dogs and prior to death in all dogs. No immediate or delayed complications related to the graft placement were observed clinically.

The dogs were killed by exsanguination under deep pentobarbital anesthesia at 7 weeks (two dogs), 8 weeks (four dogs), and at 10, 16, and 35 weeks (one dog each) after the procedure. At necropsy, the section of the aorta containing the graft was removed, together with the kidneys, if any portion of the device had bridged the renal arteries.

RESULTS

All grafts, with one exception, re-

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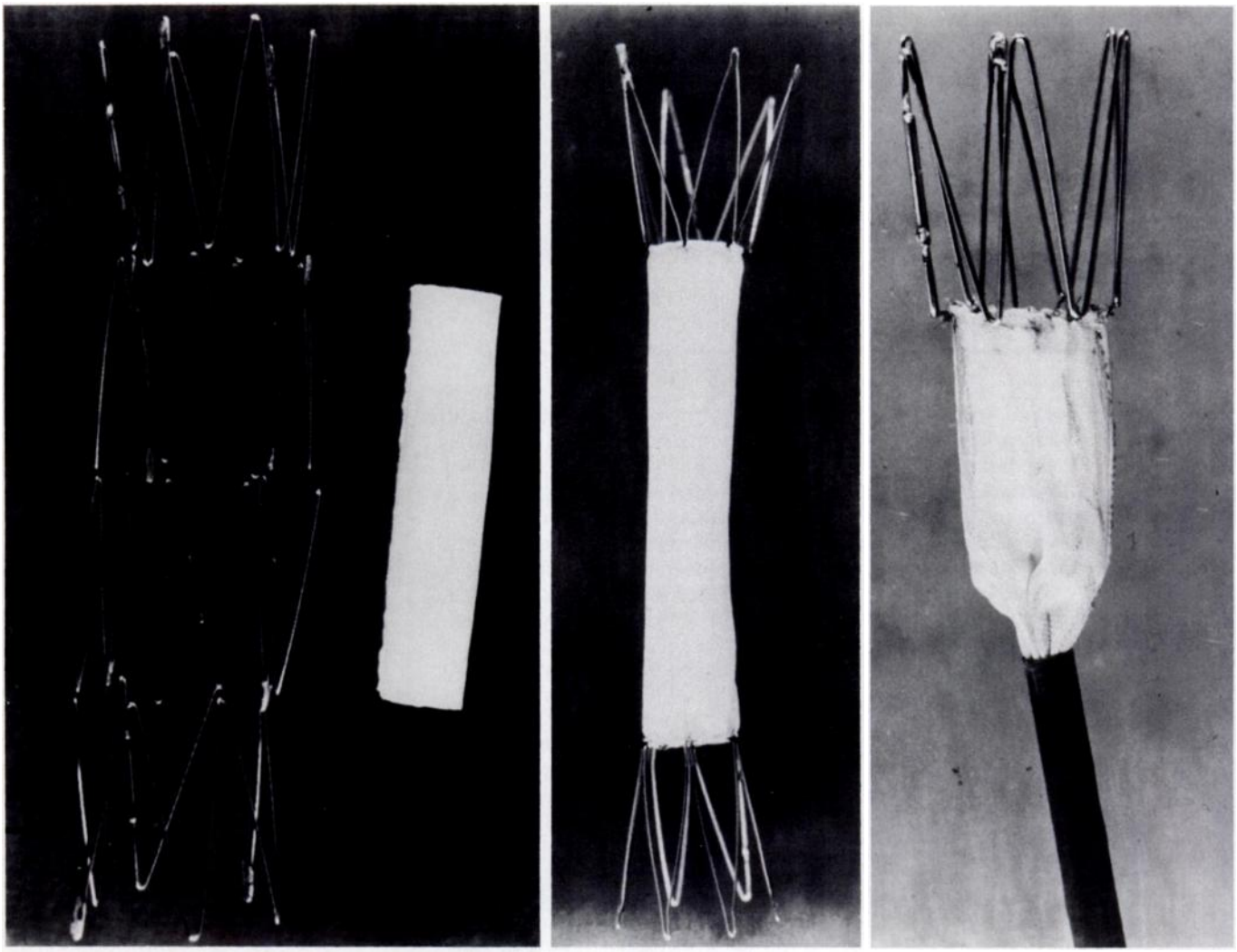


a. b. c.

Figure 1. **(a)** Photograph of components of the endovascular graft. Array of Gianturco stents forms basic superstructure of the device. The lead and trail stents (large arrows) act as anchors; the internal stents (small arrows) serve to open the Dacron graft (shown at right). **(b)** Assembled device, with Dacron graft around internal stents. **(c)** Device being released from 11-F sheath catheter.

of graft migration, and none of the stents broke or separated from each other. Perforation along the distal curvature of the aortic arch by a prong of a lead stent occurred in two animals; neither animal suffered any adverse effect, and subsequent aortograms showed no extravasation.

At arteriographic study it was noted that approximately 1 mm of luminal narrowing occurred immediately after placement of the device; this was related to the thickness of the Dacron graft itself. Further luminal narrowing between 1 and 3 mm in the region of the Dacron graft occurred over the follow-up periods. Occlusion of side branches of the aorta was observed in the areas where the Dacron graft was present, while side branches bridged by the metallic stents alone remained patent (Fig. 2).

On gross examination of the dis-

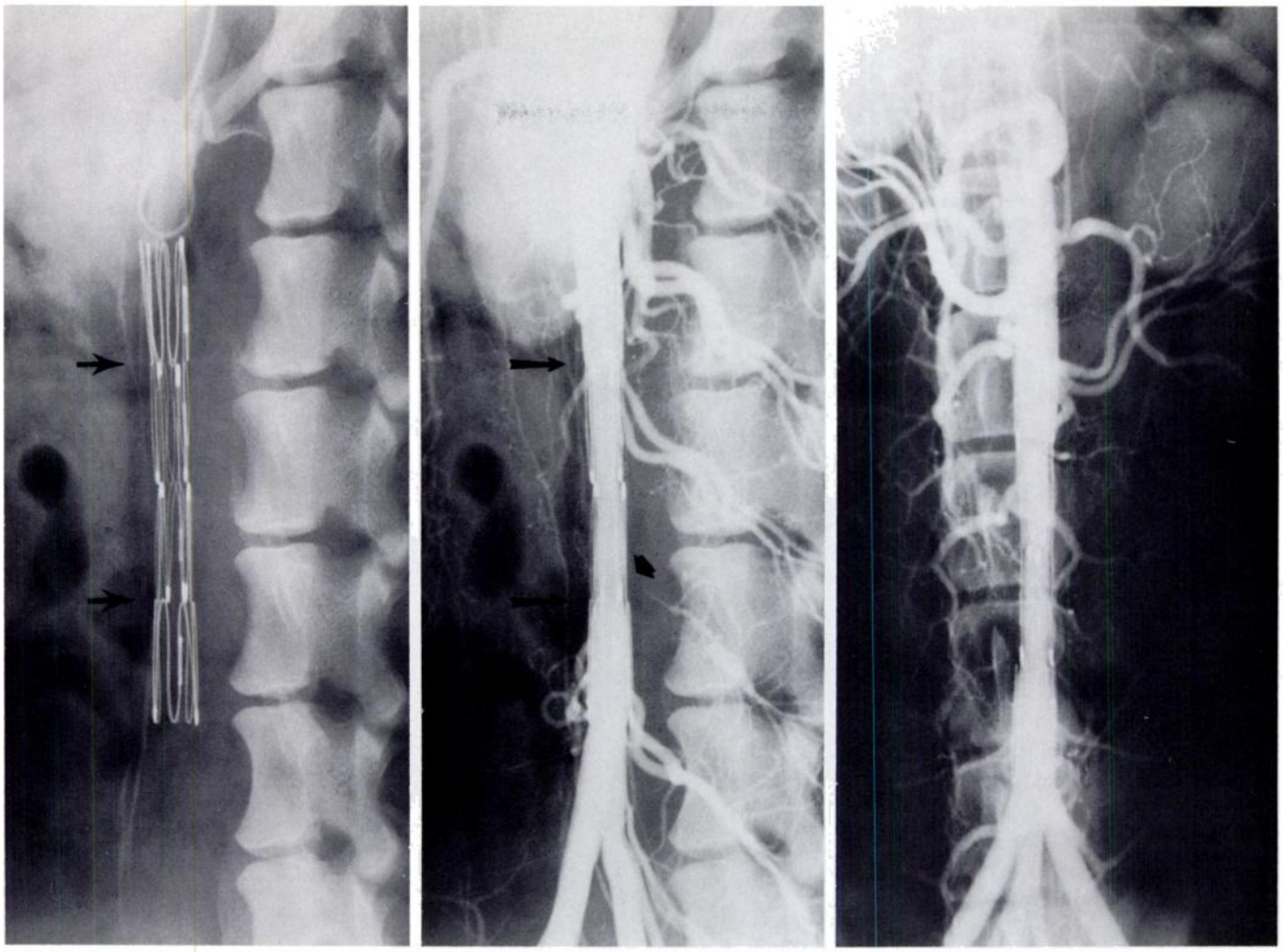
wall. A thin translucent covering was observed over the lead and trail stents, while a much thicker covering was present inside the lumen of the graft material. The extent of covering was nearly complete over both the graft and the metallic stents and was continuous with the native intima in most cases.

The Dacron grafts, most of which were larger in diameter than the native lumen, were longitudinally "pleated" inside the vessel lumen. This created spaces between the Dacron graft and the native vessel wall that were filled with proliferative tissue response similar to that seen inside the lumen of the graft. With pleating of the Dacron graft, neo-intimal growth response resulted in production of a smooth lumen, with the covering thicker in the crevices.

The side branches bridged by the

the wires. Examination of the kidneys in these cases showed no gross evidence of emboli or infarction. The two cases in which a renal artery was bridged by the Dacron portion showed infarction of the portion of the kidney supplied by the artery, with the vessel filled by organized thrombus. Lumbar and intercostal branches bridged by the Dacron also contained organized thrombus in their origins (Fig. 3).

At histologic study, the graft was found to be covered by fibroproliferative changes of various degrees. The process appeared well established at 7 weeks, which was the earliest time that the specimens were examined. The stages ranged from a loosely connected fibrin layer containing a few fibroblasts to densely packed layers of fibrocytes and collagen. A layer of cells resembling endothelium was



a. b. c.

Figure 2. **(a, b)** Radiographs from lateral abdominal aortogram of dog 8 weeks after placement of endovascular graft. Dacron portion is between two long arrows. There is mild luminal narrowing in the region of the graft as a result of neo-intimal proliferation. Note occlusion (short arrow) of origins of L-5 lumbar arteries by the graft, with reconstitution by collaterals. **(c)** Anteroposterior aortogram of same animal shows lead stent bridging left renal artery but not occluding it.

sia was observed in the neo-intima of one graft. The degree of organization did not appear to be related to length of time that the graft had been in place, as dense organization could be seen at 7 weeks, and loose organization was demonstrated at 35 weeks, and the various degrees could be observed in the same graft. Evidence of recanalization in the neo-intima was present in several specimens (Fig. 4).

Stenosis significant enough to produce hypertrophied collaterals developed in two grafts. One stenosis was related to use of an oversized graft, which nearly occluded the aorta. The other was caused by failure of the caudal end of the Dacron to open fully, as it was not bridged by an internal stent. Small, organized thrombotic vegetations were present on two of the devices (at 7 weeks and at 35 weeks) but were not seen in any of main patent had been disrupted by heat from inadvertent autoclaving before insertion. At necropsy, 16 weeks after placement, the graft was found to be layered against the anterolateral wall of the vessel and, interestingly, was completely covered with neo-intima.

DISCUSSION

The goal in the development of the endovascular graft was to produce a device that could be placed by a transcatheter approach to treat an aneurysm. The device should pass through a relatively small catheter and expand to fit the lumen of the vessel. When in place, the device should then act in the same way as a surgically placed graft, providing a new conduit for blood flow and supporting the weakened vascular wall. of dogs demonstrates that our design was easily placed through an 11-F catheter into the vessel. It was shown that the grafts occluded the side branches they bridged as well as producing a neo-intima similar to that seen in surgically placed grafts (5–11). The vessels bridged by stent wires alone demonstrated patency without evidence of distal emboli. This feature will allow placement of the lead stent across the renal arteries, permitting placement of the cephalic portion of the graft just below the level of the renal artery. Space between the graft wall and the native intima was filled, suggesting that the aneurysm may fill in with a fibroproliferative tissue response. Our future experiments will evaluate this.

Most of the complications (perforation, stenosis) that occurred were related to technical factors and are po-

tailoring the graft to the diameter of the vascular lumen. The presence of vegetation on two of the stents is bothersome and needs further evaluation.

While this endovascular graft was designed primarily for evaluation in aneurysms, other potential experiments include its use as a postangioplasty adjunct and as stents in the venous system and other organ systems. ■

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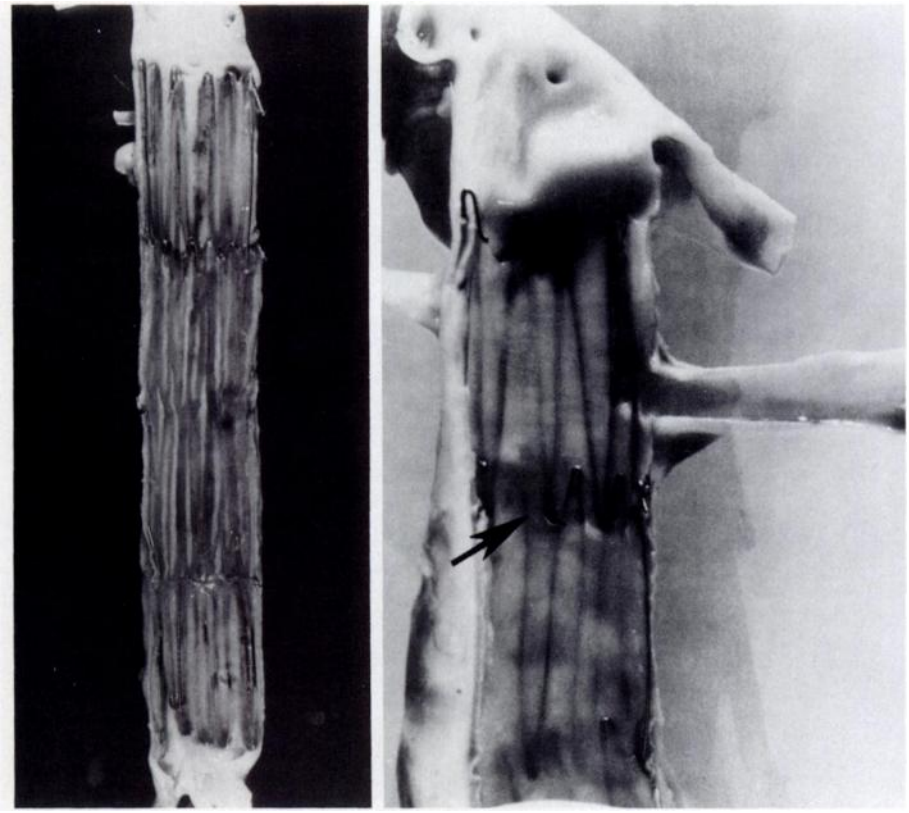
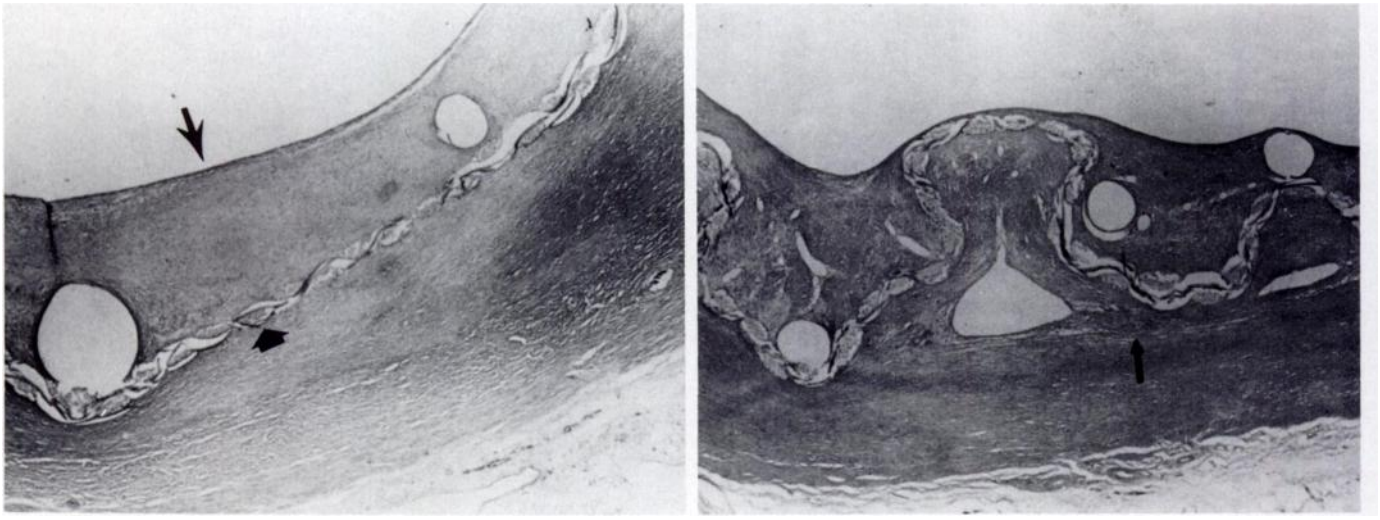


a. b.

Figure 3. **(a)** Gross specimen of device in abdominal aorta. There is nearly complete covering of the device by neo-intima. **(b)** Gross specimen shows lead stent wire bridging left renal artery. The vessel remains patent, and there is no neo-intimal covering over the portion of the wire bridging the artery. The Dacron graft and its junction with the native vessel (arrow) are completely covered with neo-intima.



a. b.

Figure 4. **(a)** Photomicrograph of cross section of abdominal aorta shows Dacron graft (short arrow) covered by thick neo-intima on its luminal surface. A layer of cells resembling endothelium is seen at the luminal surface of the neo-intima (long arrow). The large smooth holes in the neo-intima represent a cross section through the internal stent wires. **(b)** "Pleated" graft has longitudinal peaks and valleys. Note relatively more filling by the neo-intima in the valleys, in attempt to produce an even luminal surface. There is also recanalization within the