Implantation of balloon-expandable intravascular grafts by catheterization in pulmonary arteries and systemic veins

Charles E. Mullins, M.D., Martin P. O'Laughlin, M.D., G. Wesley Vick III, M.D., Ph.D., David C. Mayer, M.D., Timothy J. Myers, R.R.T., Debra L. Kearney, M.D., Richard A. Schatz, M.D., and Julio C. Palma, M.D.

ABSTRACT The purpose of this investigation was to evaluate the efficacy and safety of implanting expandable intravascular stents in pulmonary arteries and systemic veins. Twenty-seven balloon-expandable grafts were placed in 13 mongrel dogs under anesthesia. A long sheath was introduced over a wire and catheter or dilator into the pulmonary artery or target vein. A collapsed stainless steel expandable mesh stent was placed over the balloon of an angioplasty catheter. The catheter with the mounted stent was advanced through the sheath. The stent expanded to the diameter of the balloon as the balloon was inflated, and remained expanded as the balloon was deflated. The stent was expanded further with a larger balloon in 11 instances. Eleven stents were placed successfully in pulmonary arteries (out of thirteen attempted), and 11 of 14 were installed in tributaries of the precava or postcava. Three inadvertent embolizations of the devices occurred. All three devices that embolized lodged in the pulmonary arteries and did not obstruct flow. Seven dogs were recatheterized at intervals ranging from 56 to 278 days. Twelve stents were patent and nonobstructive, and two were malpositioned, one of which was obstructed. Three animals were killed 2 months (two dogs) and 9 months (one dog) after the implantations. The stents (four in the pulmonary arteries and two in veins) were completely covered with neointima and were patent, without thrombosis. These stents hold promise for definitive dilation of congenital or postoperative vessel stenoses.


A number of congenital or postoperative vascular stenoses have been treated successfully with balloon dilation catheterization techniques. Balloon angioplasty, first described for use in pulmonary valve stenosis in 1982,1 has emerged as the treatment of choice for this lesion. The balloon dilation technique has been extended to treatment of aortic valve stenosis2 and coarctation of the aorta,3 and has recently been used for palliation of mitral and tricuspid valve stenosis.

There are many patients with hemodynamically significant narrowings of branch pulmonary arteries. These stenoses may occur as isolated congenital defects or in association with other anomalies. They are particularly common in Noonan syndrome,4 Alagille syndrome,5 Williams syndrome,6 and congenital rubella infection.7 Frequently there are narrowings of pulmonary arteries after repair of tetralogy of Fallot or other congenital heart lesions. These patients may require an aorta-to-pulmonary shunt in infancy to ensure adequate blood flow until they reach a size suitable for definitive surgery. By the time of this surgery, the pulmonary artery at the site of the shunt is often narrowed. Attempts at surgical revision of these stenoses are rarely satisfactory.8–10

Patients who have pulmonary branch narrowings after intracardiac repair of tetralogy of Fallot or other congenital heart defects have a poorer prognosis than those who do not. Significant pulmonary artery narrowing will cause increased right ventricular pressure. High right ventricular pressure after repair of tetralogy has been associated with a higher incidence of ventricular arrhythmias and sudden death.11

Balloon dilations of these stenoses of the pulmonary arteries distal to the pulmonary valve have met with less
than satisfactory results.\cite{12, 13} Although the stenotic vessels often can be dilated with angioplasty balloons, even to three or four times the original size of the narrowings, the stenoses frequently recur immediately after balloon withdrawal. The recurrence of obstruction after dilation is thought to be due to the natural elastic recoil of the tissue or to resilience and resistance of scar tissue in postoperative cases. Significant morbidity and mortality has been encountered in these dilations, possibly related to the large diameters to which the narrowed vessels were stretched in an attempt to avoid the restenosis.

Unfortunately, surgical treatment of these complicated stenoses generally is no more successful than balloon angioplasty. Additionally, the surgery carries a considerably greater morbidity and probably a greater mortality. The locations of the narrowings, often in the distal branch pulmonary arteries within the hilus or behind the aorta, make the lesions difficult to reach. When stenoses remain after previous intrathoracic surgery, reoperation is made more risky by the presence of adhesions and by the higher likelihood of severe bleeding.\cite{8, 9} Some patients have undergone operation for pulmonary artery branch stenosis only to have the narrowing persist or recur after the surgical revision.

Vein stenosis may pose a significant problem as part of congenital, postoperative, or acquired cardiovascular disease. Pulmonary vein stenosis has been notoriously unresponsive to balloon dilation techniques.\cite{14} Superior and inferior venae cavae obstruction or pulmonary venous channel obstruction may follow the Mustard or Senning operation.\cite{15, 16} Severe effects of significant superior vena cava obstruction are seen, including upper body edema and suffusion or communicating hydrocephalus.\cite{17} These complications necessitate some type of interventional therapy, usually a surgical revision of the baffle. Other diseases such as intrathoracic malignancies or mediastinitis may result in superior (or inferior) vena cava obstruction.

Recently, a device for correction of complicated vascular stenoses has been developed by Dr. Julio Palmaz and others.\cite{18-22} This device is a stainless steel tubular mesh expandable graft for supporting vascular walls after balloon dilation. The purposes of this study were (1) to devise a technique for the delivery and placement of these stents in both native pulmonary arteries and systemic veins in experimental animals and (2) to investigate the effects on the intravascular flow and on the vessel wall and surrounding tissue. The initial experience and results of this study are reported here.

**Materials and methods**

Twenty-seven balloon-expandable intravascular stents\cite{20} (Ethicon, Inc., Somerville, NJ) were placed in 13 dogs under anesthesia. The grafts or stents were constructed to specifications of stainless steel 0.076 mm in thickness. The prototypes were 3 cm in length (figure 1), and 3.4 to 3.7 mm in diameter before expansion. When the stents were machined, the diameter was predetermined by the manufacturer depending on the diameter desired when the graft is expanded. The grafts used in this investigation had 10 rows of staggered offset slots 6 mm long. For placement, the grafts were placed over the deflated balloon of a balloon dilation catheter (figure 2). The balloon catheters were advanced into position across the target area and the balloon (and stent) was expanded by inflation under pressure. The graft expanded with the balloon to the limit of expansion of the balloon. With expansion, the narrow slots opened to form diamond-shaped spaces whose dimensions determined the final diameter of the expanded graft.\cite{20} After placement, the free or open areas of the metal graft accounted for more than 90% of the surface of the graft. When the balloon was deflated, the

**FIGURE 1.** Stainless steel balloon-expandable intravascular graft (stent).
tubular mesh remained expanded, supporting the now-dilated area. The design of the stent prevented it from being crushed by the radial forces of the vessel. The wire and balloon catheter were then removed, leaving the implanted graft in place.

Mongrel dogs of either sex, 30 to 40 kg in weight, were sedated with acemopramine (TechAmerica, Elwood, KS) and atropine (Eli Lilly & Co., Indianapolis), and anesthetized with thiopental sodium (International Medication Systems, Ltd., So. El Monte, CA). Ventilation was maintained with a mechanical ventilator (Siemans-Elema ventilator, 900B, Siemans-Elema, Sweden). A No. 8F sheath (Bard, USCI Division, Billerica, MA) was placed in the right femoral vein and a 20 g 32 mm catheter (Cathlon, Critikon, Tampa, FL) was introduced into the femoral artery, both by percutaneous technique.

In the first seven dogs, the stents were placed in native nonobstructed vessels, either the left or right pulmonary artery or branches of the precava or postcava. In six dogs (Nos. 8 to 13), a left thoracotomy was performed and proximal left pulmonary artery branch stenosis was experimentally induced. Matress sutures were placed circumferentially in the arterial wall to narrow its diameter to 50% of the native diameter, and the artery was encircled with absorbable suture, in the method described by Lock et al. These animals recovered without difficulty.

On follow-up catheterization at 45 to 251 days (mean 181) after operation, however, no pressure gradients and only one angiographically detectable stenosis was found in the operated animals. Stents were placed in the proximal left pulmonary arteries in these animals, and venous stents were placed additionally in four. The results of these placements are summarized together with those in the unoperated dogs.

Stent placement. A No. 8F catheter was passed percutaneously from the femoral vein into the pulmonary artery or vein, depending on the site chosen for dilation. A 0.038 inch diameter Teflon-coated spring guidewire (Argon, Inc., Athens, TX) was inserted into the pulmonary artery or systemic vein and advanced distally. The catheter was removed, leaving the wire fixed in the distal vessel. A No. 12F (Cook, Inc., Bloomington, IN) or 14F (Universal Medical Instrument Corp., Ballston Spa, NY) long sheath and dilator or catheter were introduced over the wire into the pulmonary artery or target vein. The dilator or catheter was removed leaving the wire in place. A stainless steel expandable mesh stent was mounted on the balloon of an 8, 10, or 12 mm diameter balloon dilation catheter (Meditech/Mansfield Scientific, Inc., Mansfield, MA). The catheter and stent were advanced through the sheath into the pulmonary artery or systemic vein. When the balloon and stent were in position, the sheath was withdrawn off the proximal end of the balloon. The balloon was expanded to its maximal diameter with 4 to 6 atmospheres of pressure. The stent expanded as the balloon was inflated to the full inflation diameter and remained expanded when the balloon was deflated (figure 3). In 14 instances, the original smaller balloon was withdrawn over the wire and replaced with a larger balloon (15 or 18 mm). The graft was expanded further with the larger balloon. On occasion, the final expanded diameter was greater than the native vessel diameter (figure 4). At the end of the procedure all animals except one awoke without difficulty and recovered. The one animal appeared to suffer an anesthetic death and had no abnormalities of the heart or lungs at postmortem examination. The newly placed stent was unobstructed and in proper position.

Pressure measurements were obtained with Hewlett-Packard Model 1290A (Hewlett-Packard, Cupertino, CA) transducers, with zero set at midchest level. Recording was done with a Hewlett-Packard model 7700 monitor and Hewlett-Packard model 7758A recorder. Heparin sodium, 0.1 units/ml (Ivenex, Lypho Med, Inc., Rosemont, IL) was used in flush solution during placement catheterizations. No other anticoagulation was given to the animals during or after stent placement.

Seven animals have been recatheterized and the stents were examined by distal and proximal pressure recordings and by angiography. Three animals were killed with T-61 euthanasia solution (American Hoechst Corp., Somerville, NJ), given intravenously under anesthesia, to allow pathologic examination of the endovascular grafts 2 months after implantation (two cases) and 9 months after implantation (one). The last six animals are being maintained for long-term studies and have not been recatheterized.

All tissues were initially fixed in 10% phosphate-buffered formalin. Sections from endothelialized areas of each stent were fixed in 3% glutaraldehyde in 0.1M PIPES buffer, pH 7.2, postfixed in 2% PIPES-buffered osmium tetroxide, dehydrated in graded ethanol solutions. Specimens were embedded in Spurr’s resin with the use of propylene oxide (1,2 epoxypropane) as transition solvent. Sections 1 μm thick were cut with a Dupont diamond knife, stained with Polysciences Multiple Stain Solution, and evaluated by light microscopy. Paraffin-embedded sections of right and left lung were stained with hematoxylin and eosin and evaluated by light microscopy after conventional processing.

A section of the systemic venous stent from dog 2 was fixed in 3% glutaraldehyde in 0.1M PIPES buffer, pH 7.2, and processed for scanning electron microscopy. The tissue was postfixed in 2% PIPES-buffered osmium tetroxide, dehydrated in graded acetone solutions, and critical point dried from liquid CO₂. The tissue was then sputter coated with gold and viewed in a JEOL 100C scanning transmission electron microscope in the secondary electron imaging mode.
FIGURE 3. *Top left.* Unexpanded stent (arrow) on the balloon portion of the delivery catheter. Stent is in place in a branch of the precava. Right and left are marked (R and L). *Top right,* Balloon and stent being expanded. The balloon is being filled with dilute contrast material by hand inflation. Note that the balloon expands at both ends, then the stent expands from the ends toward the middle. *Bottom left,* The stent is expanded in the target vein. The diagonal pattern of the struts is seen. The guidewire has been left in place during withdrawal of the balloon catheter. *Bottom right,* Follow-up angiogram. There is complete opacification of the stented vein, with patent side branches. There was prompt and unobstructed drainage through the stented area into the precava and right atrium.

**Results**

**Placement.** Eleven stents were placed successfully in pulmonary arteries (out of 13 attempts), and 11 of 14 were implanted in tributaries of the precava or postcava. One animal died at catheterization after placement of a stent in a postoperative branch stenosis site, likely related to gas anesthetic overdose. There were no other significant complications of the catheterizations either during placement of the stents or on follow-up evaluation. There were no discernible adverse effects in the remainder of the animals. No excessive hemorrhage or arterial compromise was noted. One animal developed transient hind limb edema suggestive of venous stasis. This resolved without therapy.

In the native, fully patent vessels with no areas of obstruction against which to expand the grafts, three inadvertent embolizations of the devices have occurred. The very first device used became dislodged from the balloon catheter during attempted delivery without a sheath and moved more distally into the pulmonary tree. In that position, the balloon was reinserted, and the device was expanded and remained patent. Another stent was placed in a superior vena cava larger than the initial inflating balloon, and it too embolized into the pulmonary artery during removal of the original balloon. One device placed in a large, nonstenosed main pulmonary artery migrated into the right pulmonary artery during the exchange of the balloon catheters. All three devices that migrated lodged lengthwise in smaller distal pulmonary arteries and did not obstruct flow.

With one exception, the animals that had undergone attempted left branch pulmonary artery stenosis showed no discernible discrete stenosis. Stents were placed in the proximal left pulmonary arteries of these six dogs without difficulty. The stenotic site in the successfully operated animal was diluted with 8 and 12 mm diameter balloons, with the stent anchored pre-
FIGURE 4. Top, Main pulmonary artery angiogram before stent placement. There is a smooth outline of the proximal right pulmonary artery. Bottom, Postplacement angiogram. The stent is in place in the proximal right pulmonary artery. The artery has been dilated to greater than its native diameter, as can be seen by the proximal indentation (arrows). There is unobstructed filling of the right pulmonary artery and its branches.
TABLE 1
Results of stent placement in 13 animals

<table>
<thead>
<tr>
<th>Dog No.</th>
<th>Stent No.</th>
<th>Location</th>
<th>Balloon sizes (mm)</th>
<th>Complications</th>
<th>Duration (D)</th>
<th>Gradient (mm Hg)</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>MPA</td>
<td>12, 15</td>
<td>0</td>
<td>60D</td>
<td>Not measured</td>
<td>Patent</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>MPA</td>
<td>12</td>
<td>Embolize from RV to PA</td>
<td>60D</td>
<td>Not measured</td>
<td>Patent</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>RPA, foreleg vein</td>
<td>12, 18</td>
<td>0</td>
<td>56D</td>
<td>0</td>
<td>Patent</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>RPA</td>
<td>12, 18</td>
<td>Vessel disruption</td>
<td>56D</td>
<td>2</td>
<td>Patent</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>LPA</td>
<td>12, 18</td>
<td>0</td>
<td>273D</td>
<td>3</td>
<td>Patent</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>precava</td>
<td>12</td>
<td>0</td>
<td>273D</td>
<td>2</td>
<td>Patent</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>LPA</td>
<td>12</td>
<td>Embolize to RPA</td>
<td>104D</td>
<td>0</td>
<td>Patent</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td>12</td>
<td>Migrate to RPA</td>
<td>104D</td>
<td>1</td>
<td>Patent</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>Innominate vein</td>
<td>12</td>
<td>0</td>
<td>104D</td>
<td>3</td>
<td>Patent</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>L internal jugular</td>
<td>12, 18</td>
<td>0</td>
<td>91D</td>
<td>0</td>
<td>Patent</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>Innominate vein, R</td>
<td>12, 18</td>
<td>Vessel disruption</td>
<td>150D</td>
<td>Unable to be crossed</td>
<td>Partially thrombosed</td>
</tr>
<tr>
<td>7</td>
<td>2</td>
<td>renal vein</td>
<td>12, 15</td>
<td>0</td>
<td>150D</td>
<td>0</td>
<td>Patent</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>MPA</td>
<td>12, 18</td>
<td>Slight proximal migration</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>LPA</td>
<td>12</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>LPA</td>
<td>12, 18</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>10</td>
<td>2</td>
<td>LPA, precava</td>
<td>15, 18</td>
<td>Clot in lumen</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>11</td>
<td>1</td>
<td>LPA</td>
<td>12</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>11</td>
<td>2</td>
<td>LPA</td>
<td>8</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>11</td>
<td>3</td>
<td>LPA</td>
<td>15, 18</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
<td>LPA</td>
<td>12</td>
<td>Anesthetic death</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>13</td>
<td>1</td>
<td>LPA</td>
<td>8, 12</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>13</td>
<td>2</td>
<td>LPA</td>
<td>10</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>13</td>
<td>3</td>
<td>precava</td>
<td>18</td>
<td>0</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

The number of stents in each animal, their location, the balloon diameters used, and complications are shown under the heading “Immediate results.” With respect to follow-up, the duration of follow-up is given and any pressure gradient across the stent is shown, where measured. Results of angiography are listed. The specific complications are addressed in the text. No follow-up catheterizations have yet been performed on the final six dogs (Nos. 8 to 13).

R = right; L = left; M = main; PA = pulmonary artery; RV = right ventricle; D = days; 0 = none; Angio = angiographic appearance.

cisely across the segment. There was a slight residual narrowing or dent in the stent in the operated area that had been dilated to approximately two times its prestent diameter.

**Angiographic follow-up.** The intervals between placement of the stents and the follow-up catheterizations ranged from 56 to 278 days, with a mean interval of 107 days (table 1). On follow-up catheterization, there were two venous stents that had inadvertently been implanted and overexpanded partially through the small vein. One of these two stents (dog 7) could not be crossed with a catheter at follow-up, and was presumed to be thrombosed. The other venous and the pulmonary arterial stents were nonobstructive as determined by distal and proximal pressure recordings (table 1) and were noted to be patent by cineangiography (figure 5).

Three animals were killed at (dog 1) 2 months, (dog 2) 2 months, and (dog 3) 9 months after implantation and their hearts and lungs were removed for pathologic examination. The first animal had two stents placed in the pulmonary artery. The second and third animals had one stent each in a pulmonary artery and a systemic vein. The heart and lungs were removed immediately en bloc and immersed in 10% formalin solution. Gross external inspection of the heart and lungs partially including the areas of the stent placements was performed. The stents were incised lengthwise. Sectioning, staining, and microscopic examination were performed on the involved tissues from each animal.
Pathology

Gross. The stents in the pulmonary arteries and systemic veins were variably covered with neointima and were patent; there was no thrombosis in any angiographically patent stents (figure 6). The adventitial surfaces of all normally placed stents were unremarkable. The cephalic end of the foreleg venous stent from dog 2 had penetrated deep within the vein wall, which
FIGURE 6. **Top**, Exterior of the right pulmonary artery from dog 2 (2 month follow-up). The expandable intravascular graft may be seen through the thin pulmonary arterial wall. The configuration of the struts is seen clearly. The artery has been dilated to greater than its native diameter, as seen by comparison with the left pulmonary artery in the background. **Bottom**, The graft was patent without thrombosis. The process of covering with neointima was progressing (arrow).
showed localized fibrous thickening of the adventitia (figure 7). This was probably secondary to disruption of the vein by malposition of the stent and balloon overdistention during placement. Side branches of the arteries and veins in those areas of the implanted stents were patent. The systemic venous stent from dog 3 traversed the orifices of two side branches. One branch, 0.8 cm in diameter, was slightly narrowed by a 0.2 cm projection of neointima onto the stent.

Microscopic. Microscopically an oblique rectangular intimal defect with the “rolled” wire fragment along one edge indicated the position of both arterial and venous wire stents. The intima overlying and adjacent to individual “wires” was thickened with fibrous tissue that locally encircled the wire. The intimal fibrosis was mildly cellular with capillary proliferation in dog 2 (2 months) and densely fibrotic with few vessels and cells in dog 3 (9 months). Most cells appeared to be fibroblasts. The degree of intimal fibrosis was relatively uniform and did not correlate with the degree of changes in the underlying media.

Compression of the arterial media by the wire stent varied in different areas and ranged from 50% to 100%. With milder compression, medial fibrosis, loss of smooth muscle fibers, and fragmentation of the elastic lamellas were confined to the inner half of the media and did not extent beyond the lateral margins of each wire (figure 8). The outer media and adventitia were unaffected. With severe compression, the above-described changes involved the full thickness of the media, extended laterally to involve the adjacent media, and were accompanied by mild-to-moderate adventitial fibrosis. The full thickness of the venous media was compressed to the extent that a slight convex bulge was perceptible on the adventitial surface.

Sections from the right and left lungs from each dog were carefully examined for pulmonary thromboemboli. None were found.

The portion of systemic venous stent evaluated by scanning electron microscopy was selected from a transitional zone of endothelialization to nonendothelialized stent (figure 9). Smoothly contoured ridges on the intimal surface demarcated the underlying stent wires. A flap of apparent intima extended a short distance along the portions of bare stent wire that projected into the lumen.

Discussion

Over 20 years ago, in their landmark article, Dotter and Judkins,24 foresaw the development of endovascular grafts. “Once a pathway has been created across an occluded segment, repeated dilatation or the tem-

FIGURE 7. Interior of the stent from dog 2 placed in a tributary of the precava. This demonstrates irregular expansion of the stent and some fibrous adhesions (arrow) where the stent was overdistended inadvertently. There was no thrombosis, and the struts that did not lie against the vein wall were free of intimal covering or clots.
FIGURE 8. Light micrograph of right pulmonary artery stent showed in figure 6, cut in cross section. The impression of the graft wire (W) (sectioned steel rolled to side) is seen indenting the vessel wall. The neointima has formed over the stent, with the lumen above. The outer media and adventitia are intact and undisturbed (bottom of the figure). (Original magnification × 140.)

porary use of a Silastic endovascular (or, in some cases, paravascular) splint could maintain an adequate false lumen until the natural processes of fibrosis and re-intimalization had taken place.” In 1969, Dotter described transcutaneous placement of tubular coil-spring endovascular prostheses. These grafts were not expansile, and were designed to support an already-dilated vascular lumen. They had the disadvantage of being solid and thus not allowing for patent side branches.25

Recently developed endovascular prostheses described by Simon,26 Dotter,27 and Cragg28 and their colleagues have used nitinol wire coils whose characteristics include thermal memory. The grafts were shaped in a certain way and annealed by heating. For implantation, the wire required cooling for loss of its “memory,” then implantation and reheating in situ with hot saline delivered through the implantation catheter. This strategy seems unwieldy, and requires the dilation of the segment to be stented, either by balloon technique or by the radial expansion of the coil. The final expanded diameter must be known in advance for the coils to be chosen properly.

Expanding zigzag pattern stents described by Wright et al.29 and Charnsangavej et al.30 rely on the radial forces of the implanted coil to force open the vessel; continued expansion after implantation may have the potential of gradual erosion of or migration through the vascular wall.

A self-expanding stent recently has been used in humans by Sigwart et al.31 in Switzerland. This has shown promising results in peripheral vascular and coronary arterial stenoses. The small size of the devices described would limit their use in veins and pulmonary arterial branches. Again, this stent requires predilation of the stenotic area, and the final size of the arterial lumen determines the stent size required. The device described by these investigators has the advantage of flexibility, which may allow its use in curved portions of vessels.

The balloon-expandable intravascular graft described herein does not have a specific end-inflation diameter. Rather it will expand to the diameter of the inflated delivery balloon or to the limit of expansion allowed by the anatomic constraints of the stenosis to be dilated.

The length of the grafts to be implanted may be varied and chosen at the time of implantation. The stent must be long enough to traverse the stenotic segment; the 3 cm length has been convenient in these investi-
FIGURE 9. Scanning electron micrograph of the portion of the precaval stent in the transitional zone of endothelialization to nonendothelialized stent. The intima overlying the stent strut or wire shows smooth contours in the area of the metal (arrowheads). The process of neoendothelialization has covered the stent wire cut in cross section (arrow), but extends only a small distance along the metal, which is not in contact with the vessel wall. (Original magnification × 44.)

gations. The upper limit of length of stent has not yet been determined, but a very long segment would not be necessary to support a discrete stenosis in most cases. Should a long segment stenosis or multiple stenoses require dilation, two or more short stents could be installed in series. This approach would enable preservation of the curvature of the vessel while allowing stenting of a long segment.

The studies of Palmaz et al.\textsuperscript{18–22} have established the absence of thrombosis over long periods of time with aortic placements. Our preliminary results in the pulmonary artery are in agreement with this observation. This would suggest that anticoagulation is not necessary after placement of arterial stents. Because of the presumed thrombus formation in one of the venous stents examined, we will await further pathologic data on other venous stents. However, antiplatelet drugs such as aspirin or dipyridamole may prove useful in patients in whom the stent is placed in a vein stenosis.

The possibility of infection or colonization of the stented area must be considered. This was not encountered in the present study. Once the process of covering the stent with neoendothelium has been completed, the chance of infection may diminish. It might be prudent to administer a broad-spectrum antibiotic during stent placement and for a brief time thereafter to help prevent infection of the newly placed graft. After the installation of the device, prophylaxis against infective endocarditis, already suggested in the vast majority of these patients, would continue to be recommended during dental work or surgery.

These devices are distinguished by the ease of their placement. With the use of the long sheath, the delivery catheter and stent may be guided directly to the narrowed segment. The equipment required for placement is readily available in catheterization laboratories and familiar to cardiologists who perform balloon angioplasties. This feature is attractive when these grafts are compared with other devices that require special delivery systems.

As noted, the stents were redilated easily with larger balloon catheters after being delivered over a 12 mm diameter balloon. It remains to be seen whether the device will allow further dilation after a period of time in the vessel of a growing child. Further experimental work on this question is required.

Balloon-expandable intravascular grafts are extremely promising for dilation and postdilation support of complicated vascular stenoses. It is hoped that this
device and technique will be available for clinical trials in the near future.

We express our appreciation to the Baylor College of Medicine Pathology Department, Electron Microscopic Laboratory and thank the technicians who provided expert assistance, Susan Robbins and Mary Hsiao. The assistance and facilities of the Cullen Cardiovascular Surgical Research Laboratories are gratefully acknowledged.

References

Implantation of balloon-expandable intravascular grafts by catheterization in pulmonary arteries and systemic veins.
C E Mullins, M P O'Laughlin, G W Vick, 3rd, D C Mayer, T J Myers, D L Kearney, R A Schatz and J C Palmaz

Circulation. 1988;77:188-199
doi: 10.1161/01.CIR.77.1.188

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1988 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/77/1/188

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org//subscriptions/