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Percutaneous Endovascular Stents: An Experimental Evaluation[1]

Percutaneous, expanding, endovascular stents were constructed of stainless steel wire formed in a zig-zag pattern. Stents were placed for varying periods of time in the jugular vein, vena cava, and abdominal aorta in each of five adult dogs. The dilating force of the stents could be controlled by different wire size, number and angle of wire bends, and stent length. In addition, multiple stents could be placed one inside the other or one after the other, depending on the circumstance. The stents distended the vessels and increased their diameter. No flow defects, luminal narrowing, or occlusion were noted in any of the stented vessels, even after 6 months. Side branches bridged by the stents remained patent and showed no indication of narrowing. Stent wires became encased by a proliferation of the tunica intima where they contacted the vessel wall. Encasement was slower and less extensive in the abdominal aorta. No vascular erosion or clot formation was found to be associated with any of the stents.

Index terms: Arteries, prostheses, 9.456 • Veins, prostheses, 9.456

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In 1969, Dotter et al. reported on the experimental use of coiled, stainless steel, wire stents placed in the popliteal arteries of dogs (1). This was the first report of nonoperative, endarterial placement of wire stents. Although the coils exhibited long-term patency, significant narrowing of the lumen occurred within them, and only small coils could be passed percutaneously (1).

Three laboratories reported on the use of a new type of endoprosthesis constructed of a thermal shaped memory alloy, nitinol, which can be passed through a catheter (2–4). However, these stents require ice water and heated saline for placement, and they have produced luminal narrowing within 4 weeks because of fibrin deposition on the stent wires (2–4).

Recently, the use of expanding, spring, steel spirals was reported (5). The spirals were stable and did not produce stenosis, thrombosis, or perforation, providing an adequate technique was used. The major disadvantage associated with these endoprostheses was the requirement of a large-access applicator for introduction and placement.

We describe a new type of percutaneous, expanding, endovascular, stainless steel stent that can be tailored to the vessel and to the need. The technique for introduction and preliminary results obtained in canine arteries and veins are also discussed.

MATERIALS AND METHODS

Endovascular stents were constructed in two sizes (5.5 cm in length × 3.5 cm in diameter fully expanded and 3.0 cm in length × 2.0 cm in diameter fully expanded) from stainless steel wire (0.018 inch) bent in a zig-zag pattern (Fig. 1). They were placed for varying periods of time in the jugular vein, precava and postcava, and abdominal aorta of five dogs (Table 1) and were evaluated with regard to ease of use, dilating force, migration, patency, thrombogenicity, and local vascular changes.

Five adult, mongrel dogs (20–26 kg) were used in the study. They were anesthetized with an intravenous injection of 30 mg/kg sodium pentobarbital (Nembutal; Abbott, North Chicago, Ill.). The jugular vein, femoral vein, and femoral artery were surgically isolated. An incision was made in each vessel, and a 12-F Teflon sheath containing a 12-F Teflon catheter with a tapered tip was inserted. Under fluoroscopic monitoring, the catheter was advanced just beyond the area of interest. The stent was compressed and placed within a Teflon cartridge that fit inside the adaptor of the 12-F sheath. The 12-F catheter was removed, the cartridge was placed in the sheath adaptor, and the stent was advanced through the sheath with flat-ended 12-F polyethylene tubing. When the stent reached the end of the sheath, the polyethylene tubing was held while the sheath was withdrawn. This freed the stent, allowing it to expand and hug the vessel wall. In some cases, stents were placed one inside another or one after another (Table 1). Angiography was performed immediately after the procedure, again after 1 week, and then at monthly intervals, to document stent position and vascular anatomy. The dogs were killed at the end of the study by exsanguination under deep sodium pentobarbital anesthesia, and a complete necropsy was performed.

RESULTS

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inside another or one after another. No distress was observed in any of the dogs during the study.

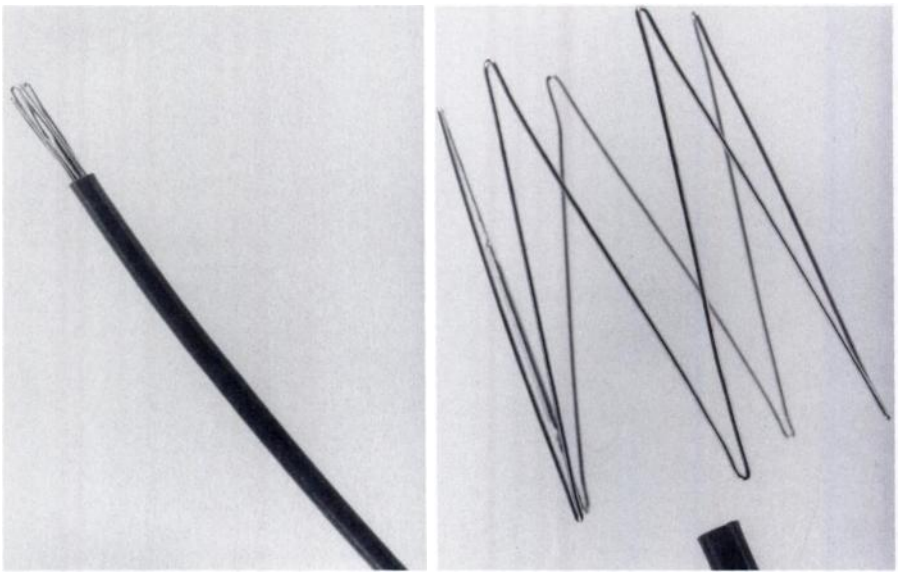
The expansile strength of the stents was found to be dependent on stent length, diameter of stent wire, the number and angle of bends in the wire of each stent, and the number of stents placed on inside another. Specifically, expansile force increased with decreased stent length, increased stent wire diameter, increased number of wire bends, larger angle formed by wire bends, and increased number of stents used.

Angiograms made of the stented vessels showed that the stents distended the vessels, increasing their diameter. No flow defects, luminal narrowing, or occlusion was noted. Blood vessels bridged by the stents remained patent and showed no indication of narrowing even after 6 months (Fig. 2). No migration was noted with 29 of the 30 stents placed. One long stent (5.5 cm) placed alone in the postcava migrated 1.6 cm cranially during the first week following placement, but no further movement occurred and no complications were encountered because of this migration.

Postmortem examinations showed that cellular proliferation occurred around the stents where the wires contacted the vessel wall (Fig. 3). Within 4 weeks following placement, venous stents were almost completely (80%) covered while aortic stents were just beginning (30%) to be incorporated. By 12 weeks, all stents were covered with tissue where the wires contacted the vessel wall. After 6 months, some cell growth was noted on wire segments that bridged the renal veins (Fig. 3b). No erosion of the vascular walls was noted, and no clot formation was seen on any of the stents.

Microscopically, stent wires were found to be located deep within the vessel wall and encased by an extension of the tunica intima (Fig. 4). Immediately surrounding the wires were multiple layers of endothelium covered by a layer of fibrous connective tissue that was similar in thickness to that found in the adjacent unstented intima. Finally, a single layer of endothelium lined the vascular lumen.

Figure 1



a. **b.**

Expanding stainless steel stent.
a. Collapsed stent beginning to exit 12-F Teflon sheath.
b. Stent fully expanded after being pushed from sheath.

Table 1
Summary of Vascular Stent Placement in Five Adult Dogs

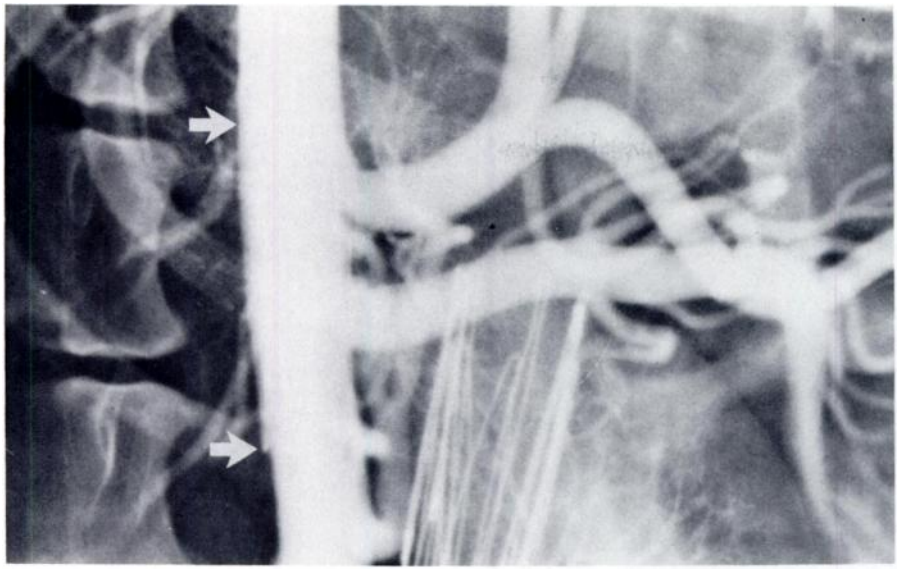
Weight (kg)	Stent Size (cm)	No. Used	Vascular Placement	Duration (mo)
22	5.5	5	Two placed one inside the other in abdominal aorta (AA) bridging the celiac, cranial mesenteric, and right renal arteries Two placed one inside the other in precava at level of right atrium One placed in the postcava bridging both renal veins	1
	3.0	3	One placed in right jugular 8 cm above precava, and two placed one inside the other in left jugular 8 cm above precava	
20	5.5	3	One placed in AA bridging the celiac, cranial mesenteric, and right renal arteries Two placed one inside the other in postcava bridging both renal veins	3
	3.0	3	Two placed one inside the other in precava at level of right atrium, and one placed 2.3 cm above the right atrium	
20	5.5	2	One placed in AA bridging the cranial mesenteric and both renal arteries One placed in postcava bridging both renal veins	4
26	5.5	5	Four placed one after another in AA beginning at T-11 (diaphragm) and ending at L-5 One placed in postcava at level of diaphragm	5
	3.0	3	One placed inside last long stent in AA at level of L-4–L-5 Two placed one after another in postcava between the hepatic and renal veins	
21	5.5	5	One placed in AA bridging the celiac, cranial mesenteric, and phrenicoabdominal arteries Two placed one inside the other in precava at level of right atrium Two placed one inside the other in postcava bridging both renal veins	6

DISCUSSION

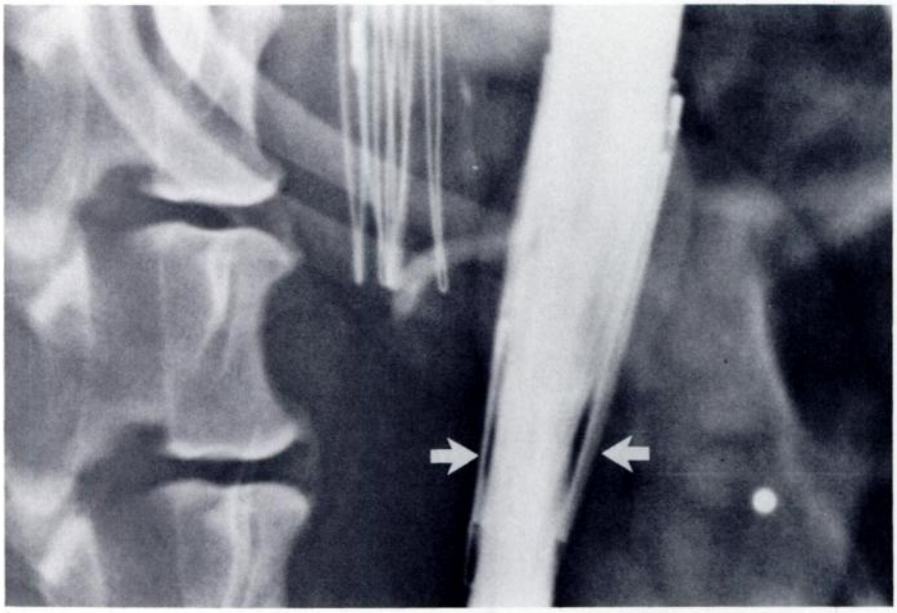
Percutaneous, expandable, endovascular stents can be made of various diameters and lengths from stainless steel wire formed in a zig-zag pattern. They are easy to place percutaneously, require the use of ice water or hot saline as do nitinol coils (2–4), or a large (21-F) introducer as do spring steel spirals (5, 6).

Two factors were important in the successful placement of the stent. First, the tubing used to advance the stent was held while the sheath was withdrawn; the stent was not pushed from the introducer. Second, the diameter of the fully expanded stent had to be

Figure 2



a.



b.

Angiograms obtained 6 months following placement of stents.

a. Aortogram showing patency of bridged side branches and lack of aortic narrowing. The stent is located between the arrows. Additional stents seen to the right of the aorta are located in the vena cava.

b. Angiogram of vena cava showing patency of bridged renal veins (arrows) and lack of caval narrowing even though two stents were placed one inside the other. Because stent wires were covered by a layer of endothelium, some appear to be outside the vena cava.

to prevent immediate migration.

The expansile pressure of the stent was not determined in our study because it varies depending on the diameter of the fully expanded stent in relation to that of the recipient vessel (i.e., the smaller the vessel, the greater the expansile pressure for a given stent) and on the intrinsic dilating force of the stent itself. The dilating force of the stent can be varied by manipulating the wire size, the number and angle of wire bends, and the

does the diameter of the collapsed stent, which necessitates use of a larger catheter for placement. Decreasing the stent length and increasing the number of wire bends or the angle formed by the bends also increases the dilating force. Therefore, stainless steel vascular stents can be tailor-made with regard to length, diameter, and expansile force.

Multiple stents can be employed depending on the circumstance. If the area of interest is longer than one

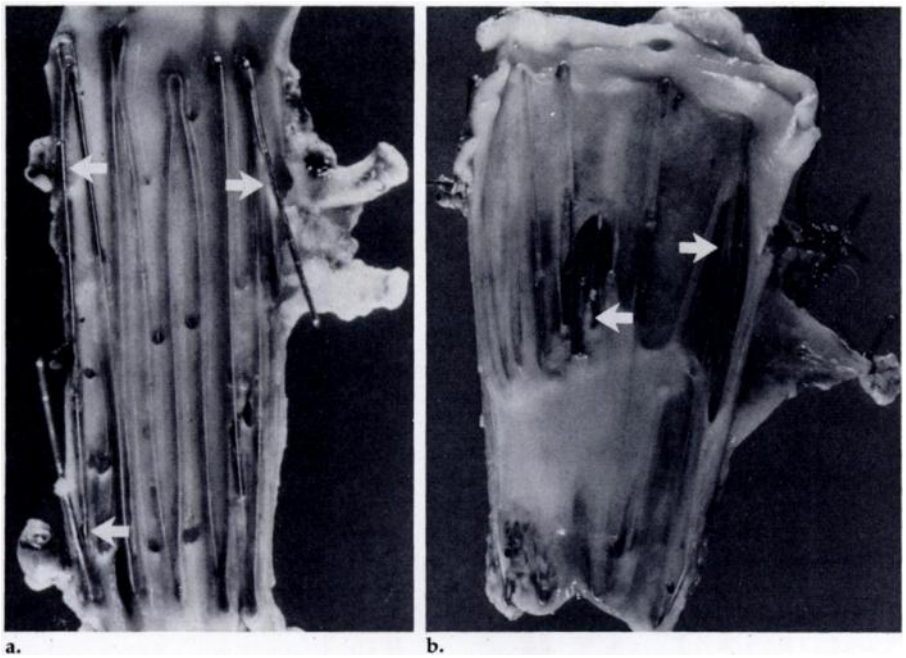
the ends. In addition, if the expansile strength of one stent is not sufficient, several stents can be placed one inside another to increase the dilating force at a specific point.

Following placement in a blood vessel, the stent gradually becomes incorporated into the vascular wall by a proliferation of the tunica intima where the wires contact the wall. This is similar to what has been noted in other studies in which steel wire has been placed in the vascular system (5–7), but differs from results obtained with nitinol wire, which becomes covered with fibrin (2–4). Radiographic studies indicated that by 1 week after placement of the stent, sufficient intimal encasement had occurred to prevent migration, but during this first week, displacement was possible although not probable. After being in place for 1 month, the venous stents were approximately 80% encased, while the aortic stents were only partially covered (30%). This difference is probably due to the greater blood flow and pressure in the aorta. By 3 months, all stent wires contacting the vessel wall were completely encased. This incorporation into the vascular wall reduces thrombogenicity (3), but no clot was found, even on the bare wires after 6 months. This differs from steel spirals, which showed sporadic cases of thrombus attachment and development in the infrarenal vena cava within the first 2 weeks following placement (5). Occasional cellular growth was noted on stent wires bridging side branches, especially in the vena cava. However, all branches remained patent even when crossed by multiple stents. This is similar to the results obtained by Maass et al. (5), but has not been reported for other types of endovascular stents (2–4). Thus it appears that the stainless steel stents can be placed anywhere in the vascular system that will accommodate them.

No luminar narrowing was noted during angiography in the stented vessels even after 6 months. Again, this is similar to the results reported for spring steel spirals (5) but differs from the nitinol endovascular stents, which have been shown to produce luminal narrowing within 4 weeks because of fibrin deposition on the stent wires (1–4).

No clot formation was found on any of the stents at the time they were removed. This is similar to previously reported results (1–4). No vascular erosion was seen, probably because the vessels were normal and able to expand, thus reducing the force of the

Figure 3

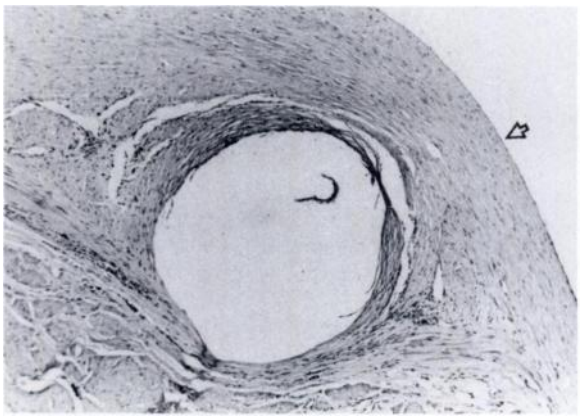


Specimens collected from the dog in Fig. 2. Stents had been in place for 6 months.

a. Abdominal aortic stent. Note that stent wires are covered only where they contact the vessel wall. Wires bridging the celiac trunk, the superior mesenteric artery, and some vertebral arteries are devoid of cell growth (arrows), and no narrowing of the vascular origins can be seen.

b. Two stents placed one inside the other in the vena cava bridging both renal veins. The stents are covered where they contact the vessel wall. Some cell growth can be seen on the stent wires bridging the renal veins (arrows).

Figure 4



Photomicrograph of a cross section made through an encased vena caval stent wire 3 months following placement. The large, discrete, endothelium-lined space is where the wire was located. Note that the encasement is due to a proliferation of the tunica intima, and that a single layer of endothelium lines the luminal surface of the vessel (arrow). Hemotoxylin and eosin, ×100.

cate that these expanding stents should have several clinical applications. These may include reestablishment of flow in veins compressed by neighboring tumor (superior vena cava syndrome), maintenance of vascular patency after percutaneous balloon dilatations, repair of dissecting aortic aneurysms, and correction of incomplete, long, irregular, vascular stenoses. ■

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References

1. Dotter CT. Transluminally placed coil-spring endarterial tube grafts: long-term patency in canine popliteal artery. Invest Radiol 1969; 4:329–332.
2. Simon M, Kaplow R, Salzman E, et al. A vena cava filter using thermal shaped memory alloy. Radiology 1977; 125:89–94.
3. Dotter CT, Buschmann RW, McKinney MK, Rosch J. Transluminal expandable nitinol coil stent grafting: preliminary report. Radiology 1983; 147:259–260.
4. Cragg A, Lund G, Rysavy J, Castaneda F, Castaneda-Zuniga W, Amplatz K. Nonsurgical placement of arterial endoprostheses: a new technique using nitinol wire. Radiology 1983; 147:261–263.
5. Maass D, Zollikofer CL, Largiader F, Senning A. Radiological follow-up of transluminally inserted vascular endoprostheses: an experimental study using expanding spirals. Radiology 1984; 152:659–663.
6. Maass D. Reaction of the aortic wall to expanding metal implants. Thorac Cardiovasc Surg 1983; 31 (special issue I): 38.
7. Gianturco C, Anderson JH, Wallace S. A new vena cava filter: experimental animal evaluation. Radiology 1980; 137:835–837.