# The Square Stent-based Large Vessel Occluder: An Experimental Pilot Study[1]

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**Index terms:** Stents and prostheses • Interventional procedures, experimental • Embolization

**JVIR 2000;** 11:1227–1234

**Abbreviations:** LVO = large vessel occluders, SIS = small intestine submucosa

**PURPOSE: The purpose of this study is in vitro and in vivo experimental evaluation of a square stent-based vascular occlusion device for large vessels.**

**MATERIALS AND METHODS: Square stent-based large vessel occluders (LVO) 5 mm–50 mm in size were constructed from stainless-steel square stents covered by porcine small intestine submucosa (SIS). The LVOs with two back-side barbs were delivered through a guiding catheter. The LVOs with two back-side barbs and two frontal barbs were front-loaded and delivered coaxially. A pusher with a retention mechanism at its end was used for deployment. In vitro testing for competency was performed with use of a flow model with pressure increases. In an experimental pilot study in seven pigs and five dogs, 16 LVOs were placed into the aorta ($n$ = 4), common iliac artery ($n$ = 2), pulmonary artery ($n$ = 4), and medial sacral artery ($n$ = 6). Four animals received two LVOs in different locations. Angiography was performed before and after placement of each LVO. Animals were followed for as long as 3 months with use of angiography and were then killed for gross and histologic evaluation.**

**RESULTS: In vitro LVOs with two and four barbs were easily collapsed and pushed through or front-loaded into guiding catheters (6-F for a 5-mm occluder, 10-F for a 50-mm occluder). A 20-mm LVO adapted to tubular structures 10–15 mm in diameter, forming polygons 17–18.5 mm in length. In the flow model, LVOs endured pressure increases to 300 mm Hg. In vivo, the LVOs self-expanded and adapted to the vessel without migration in all cases. The locking pusher allowed precise LVO placement and engagement of its barbs into the vessel wall before complete deployment, preventing dislodgment by blood flow. Complete arterial occlusion occurred within 10–20 minutes and arteries remained occluded until the animal was killed in all cases. After 2 months, histologic evaluation revealed replacement of SIS by host tissue and its remodeling with variable fibrocytes, fibroblasts, and some inflammatory cells. Complete endothelialization was seen on both sides of the LVO.**

**CONCLUSION: The SIS LVO is effective and reliable for acute and chronic occlusion in a high flow model in an experimental animal.**

EXPANDABLE stents have been used commonly for more than 10 years for treatment of obstructions in vascular and nonvascular systems. Expandable stents also have great potential as carriers for percutaneously placed intravascular occluders. Self-expandable Wallstents (Boston Scientific/Meditech, Watertown, MA), balloon-expandable Palmaz stents (Cordis, Warren, NJ), and self-expandable Gianturco

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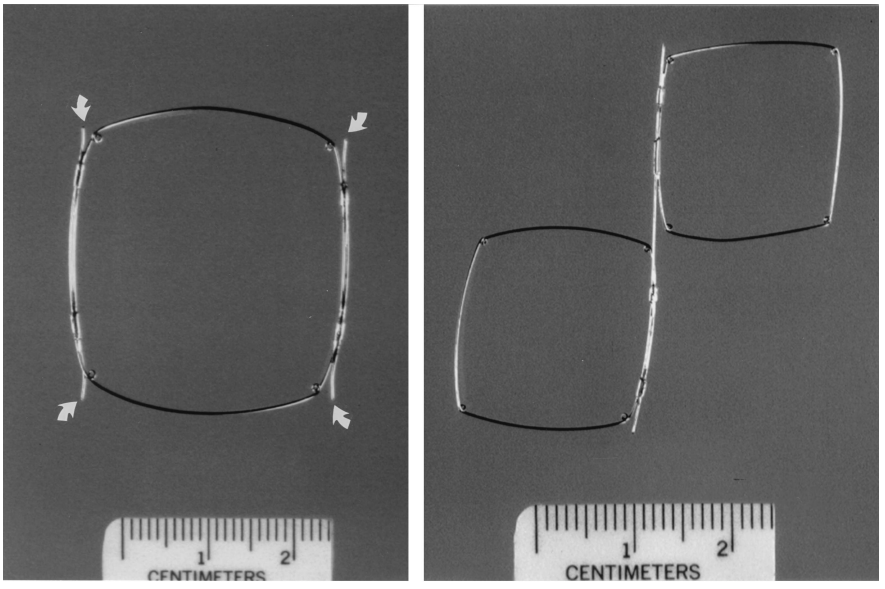



a. b.

**Figure 1.** The square stents. **(a)** Single square stent 28 mm in length with four barbs for self-attachment to the vessel wall (arrows). **(b)** Two square stents 18 mm in length connected by an elongated barb into square stent combinations.

Z-stents (Cook, Bloomington, IN) have been explored for this purpose (1–5). We present a preliminary report of a new self-expandable square stent and its potential as a carrier for a large vessel occluder (LVO). The new cover material, small intestinal submucosa (SIS), is derived from the middle layer of the small intestine of pigs. It provides an acellular framework that is remodeled by host tissue while degrading and reabsorbing over the course of time (6). This report describes the square stent and the square stent-based LVO and summarizes the results of our tests of them in vitro and in pilot animal experimental studies.

## MATERIALS AND METHODS

The protocol for the animal studies was approved by the Oregon Health Sciences University Animal Care and Use Committee. All animal facilities are accredited by the American Association for the Accreditation of Laboratory Animal Care and meet all federal (Public Health Service and National Society for Medical Research) guidelines for animal care.

### • Square Stent

Square stents were constructed in our research laboratory of stainless-steel wire 0.006–0.018 inches in diameter. Selection of the wire diameter depends on the desired size and degree of expansile force of the square stent. The selected wire is hand-formed on a wooden template with fixed metal pegs, enabling the wire to be bent into an exact square. The distance between the pegs determines the size of the square stent. Stent sizes ranged from 5 mm to 50 mm. The corners of the square stent were formed into a coil to reduce stress and fatigue of the wire. The wire ends were joined by a metal cannula. For better fixation of the stent, we added 2 or 4 barbs. The square stents with two barbs had both wire ends extended 1–2 mm over the stent frame, forming barbs on opposite corners. On stents with four barbs, two anchoring barbs were attached to the other sides of the stent frame with metal cannulas. To ensure stability of the square stent and the barbs, the cannulas were crimped and soldered. Square stents were created as single stents or connected to other stents with elongated barbs **(Fig 1)**. When introduced to the tubular structure, the square stent self-expanded with complete wall contact to take the shape of the tubular structure **(Fig 2)**.

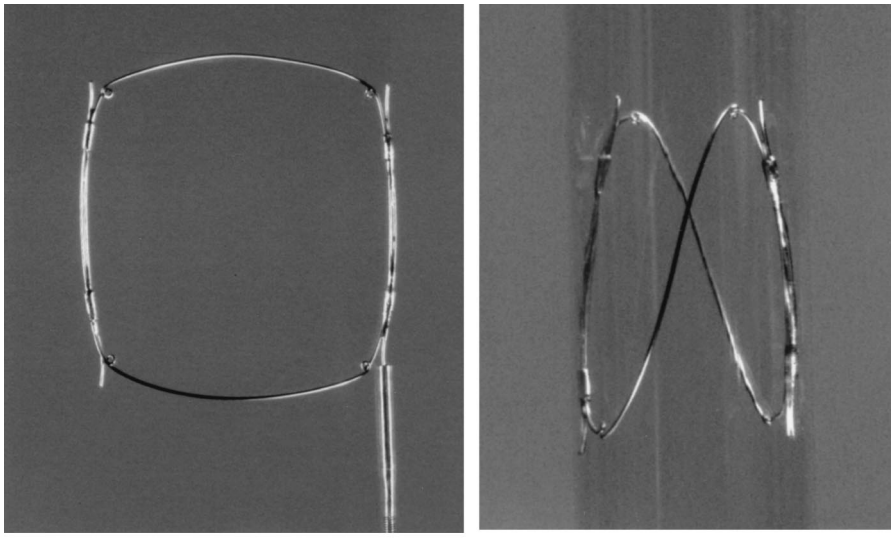
### • Large Vessel Occluder

A square frame with two or four barbs, when covered with low-porosity material such as porcine SIS, becomes an occluder **(Fig 3a)**. A double LVO is composed of two SIS-covered square stents connected by an elongated barb.

To determine an ideal fit in an artery with a circumference of $2\pi r$, the diagonal axis of the square stent was constrained to the length of $\pi r$, forming a diamond. An artery 7 mm in diameter required a 12-mm square stent, the diagonal axis of which was constrained to 13–15 mm; a 14-mm artery required a 20-mm square stent with a diagonal axis constrained to 20–22 mm **(Fig 3b)**. The covering was attached to the corners with 7.0 Prolene (Ethicon, Somerville, NJ) monofilament suture. The sides of the covering were then folded back around the wire and continuously sutured to the stent frame. When sutured to the square frame, the layer of SIS had a flap approximately 2 mm wide, allowing a better seal between the artery wall and the LVO. Large vessel occluders were made in various sizes from 5 mm to 50 mm and were connected with combinations of two or three occluders.

### • Deployment

The square stent, LVO, or the combination of the two was delivered through a 5–10-F guiding catheter or sheath, depending on the size of the stent, wire diameter, and the amount of SIS. Square stents, LVOs without barbs, and LVOs with only proximal barbs were delivered through a single guiding catheter. Square stents and LVOs with distal barbs were delivered coaxially. For deployment, a modified locking wire guide pusher was



a. b.

**Figure 2.** Deployment of a square stent 28 mm in length. **(a)** Square stent retained by a wire pusher connected to one barb. **(b)** Square stent deployed into a tube 20 mm in diameter.

used with a Bird's Nest filter (Cook, Bloomington, IN). The stent or LVO was folded by bringing its opposite bends together. The collapsed square stent or LVO without barbs or with only back-side barbs was loaded into a cartridge. From the cartridge, a pusher wire then pushed the device into the delivery catheter and to the site of its placement. The square stent or LVO with frontal barbs was front-loaded into the guiding catheter with the back barbs protected with cannulas. The guiding catheter with the device and introduced pusher was then coaxially advanced through a sheath to the desired position. Delivery in both instances was accomplished by withdrawing the guiding catheter or guiding catheter and sheath while holding the pusher. The square stent or LVO self-expanded and adapted to the tubular structure of the artery when delivered. The locking pusher assured placement of the square stent or LVO in the proper position and prevented its dislodgment by blood flow before its barbs engaged into the vessel wall. When the device was anchored against the vessel wall, it was released and the pusher and catheter with the retention wire were removed.

### • In Vitro Testing: Dry

To test the compressibility of folded stent profiles and LVOs, we used 5-mm and 50-mm square stents made of stainless-steel wire, 0.0075 inches and 0.018 inches, respectively. Square stents and LVOs were folded gently without force, avoiding deformation of the coiled bends. The minimum inner diameter of the guiding catheter or sheath was determined as the diameter at which a device with back-side barbs or without barbs could be delivered smoothly or a square stent and LVO with four barbs could be front-loaded without deforming the coiled corners.

For self-expansion, wall contact, metal-to-surface ratio, and expansile force, 20-mm stainless-steel stents 0.0075, 0.010, and 0.012 inches in diameter were tested. They were tested in rigid and elastic transparent plastic tubes 10–20 mm in diameter.

The equation $SA = L \times 2\pi r$, where L is the length of deployed square stent, yields the surface area of the cylinder. The equation was used for measurement of the metal-to-surface ratio. For measurement of the expansile force of the square stent, a similar method to that described by Fallone et al (7) for Gianturco Z-stents was used. Testing was done at room temperature.

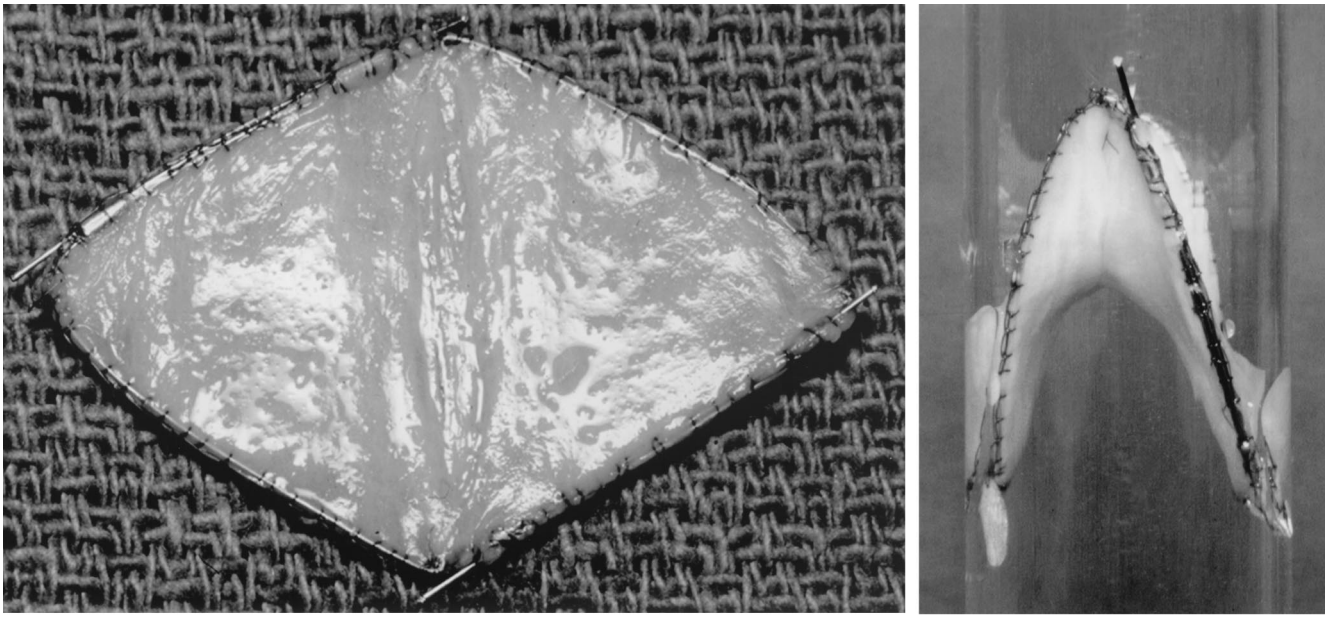
### • In Vitro Testing: Wet

A model with a flow rate of 2.5 L/min was used to test LVO competency and stability with pressure measurement proximal and distal to the occluder. The test system was constructed from a plastic tube flow loop with an internal diameter of 15 mm. A pump with a flow rate of 2.5 L/min was connected by side arms to the lower end of the flow model. At rest without flow, the occluders were exposed to hydrostatic pressure of 60 mm Hg provided by a 70-cm water column in a plastic tube above the occluders. Two LVOs with four barbs were repeatedly tested with pressure increases to 300 mm Hg. Testing was done at room temperature with the flow model in a vertical position.

### • Animal Experiment

Sixteen LVOs 8–20 mm were tested in vivo in seven pigs and five dogs. Seven young pigs weighing 25–40 kg were used for acute ($n$ = 4) and chronic studies ($n$ = 3); five adult dogs weighing 24–36 kg were used for chronic studies. Each animal was sedated with Telazol 3–6 mg/kg intramuscularly (Fort Dodge Laboratories, Fort Dodge, IA) and Atropine sulfates 1 mL intramuscularly (American Regent Laboratories, Shirley, NY). The animals were ventilated by mask with isoflurane (Burns Veterinary Supply, Rockville Center, NY) and were subsequently intubated and ventilation was maintained at 2% isoflurane with 2 L/min of $O_2$.

After induction of general anesthesia, a cut-down was performed to access the left or right femoral or carotid artery and a 9-F Teflon sheath (Cook) was inserted for LVO delivery into the arterial system. For single or coaxial LVO placement, a 7–9-F LuMax guiding cath-



a. b.

**Figure 3.** Large vessel occluder 20 mm in length covered with SIS. **(a)** Unrestricted previous introduction. **(b)** LVO after deployment into tubular structure 14 mm in diameter.

eter (Cook) was advanced through the sheath into the aorta. A percutaneous transjugular puncture was used to access the pulmonary artery. A 9-F Teflon sheath was introduced and an 8-F LuMax guiding catheter was advanced through it into the pulmonary artery for LVO placement.

Four animals received one LVO in their systemic arterial system and two animals received one additional pulmonary LVO to evaluate short-term delivery, stability, and efficiency of LVO placement. In an acute experimental pilot study in four pigs, six LVOs were studied in the abdominal ($n = 1$) and thoracic aorta ($n = 1$), common iliac artery ($n = 1$), pulmonary artery ($n = 2$), and medial sacral artery ($n = 1$). Two barbed LVOs were placed into medial sacral and pulmonary arteries. The other LVOs had four barbs. For longer-term testing in three pigs and five dogs, 10 LVOs were placed into the abdominal aorta ($n = 2$), common iliac artery ($n = 1$), pulmonary artery ($n = 2$), and medial sacral artery ($n = 5$) to evaluate long-term stability and efficacy of the LVOs in different large-diameter arteries. Two animals received LVOs in systemic and pulmonary arteries. Follow-up arteriography was performed immediately, 15–45 minutes after deployment, and at the time the animals were killed. Animals were followed by angiography at 6 weeks ($n = 5$), 8 weeks ($n = 2$) and 3 months ($n = 1$). They were killed with an overdose of pentobarbital sodium (Euthasol; King Pharmaceuticals, Bristol, TN) administered intravenously, and necropsy with histologic examination was performed.

Gross examination concentrated mainly on the occluded aortas and arteries and surrounding structures. After a minimum of 48 hours of fixation in buffered 10% formalin, the specimens were further sectioned into tissue cassettes, processed through alcohol and xylene, and embedded in paraffin. Five-micron paraffin sections were cut and stained with hematoxylin and eosin or with Masson's trichrome stain. Digital photomicrographs were made on a Zeiss Axiophot microscope equipped with a Polaroid Digital Microscope camera (Carl Zeiss, Jena, Germany).

## RESULTS

### • In Vitro Study: Square Stent

*Compressibility-folded stent profile*.—The guiding catheter had to have an inner diameter of at least 1.8 mm (6 F) for 5-mm square stents or LVOs and at least 3 mm (10 F) for 50-mm square stents or LVOs.

*Self-expansion and wall contact*.—A square stent, after being collapsed, did not return to its initial shape. Its shape changed to that of a four-sided polygon. The square stent's diagonal axis actually shortened from 28 mm to 25 mm and the four 90° angles changed to two 80° and two 100° angles. This deformation was the same for both wire sizes tested. When introduced to the tubular structure with a diameter half that of the diagonal axis of the square stent, the square stent shortened slightly, self-expanded, centered, and adapted, with complete wall contact, to the shape of the tubular structure. A 20-mm square stent with a diagonal axis of 28 mm fit into tubular structures 10–15 mm in diameter, forming a

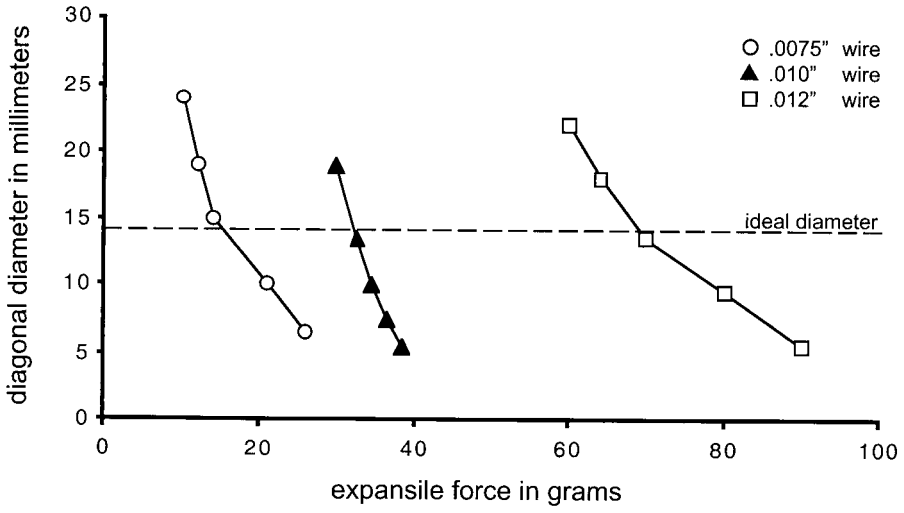



**Figure 4.** Expansile force of square stents 20 mm in length for an ideal tube diameter of 14 mm made of different wire sizes. Graph shows reduction of the square stents' diagonal diameter as a function of increased radial pressure.

cylinder 17–18.5 mm in length. In tubular structures 16–20 mm in diameter, square stents with barbs anchored well against the wall but did not achieve complete wall contact because their shortened diagonal axes exceeded the vessel diameter. Stents without barbs had a tendency to move in tubes larger than 15 mm in diameter. These characteristics were the same for both wire sizes.

*Metal-to-surface ratio.*—It was calculated that, because of the square stent's low profile, only 5%–7% of the vessel surface is covered by metal.

*Expansile force.*—Expansile force was measured by attaching weights to the coiled corners of the folded stent. Values of these measurements are plotted graphically in **Figure 4**. Force of expansion depended on wire diameter, constrained stent diameter, and length of the square stent. Under increasing external pressure, the square stents changed shape, forming a four-sided polygon. After this deformation, stents were completely elastic and compliant and they retained their original diameter after removal of the load.

*Flow model.*—Results of testing in the flow model showed that the LVOs endured pressure increases to 300 mm Hg and there was no fracture of the material.

### • In Vivo Study

All 16 LVOs were easily introduced via either the femoral artery ($n$ = 6), common carotid artery ($n$ = 6), or jugular vein ($n$ = 4) into the abdominal aorta ($n$ = 3), thoracic aorta ($n$ = 1), common iliac artery ($n$ = 2), middle sacral artery ($n$ = 6), or pulmonary artery ($n$ = 4). Large vessel occluders with proximal barbs were delivered through a single guiding catheter ($n$ = 10). The LVOs self-expanded, centered, and adapted properly in large vessels after placement in all animals. The locking pusher allowed precise LVO placement and enabled its barbs to engage the vessel wall in all cases. The introduced LVOs remained stable and no migration was observed. Arteriography immediately after placement revealed minimal leak around the LVOs. Follow-up arteriography performed 20 minutes postprocedure showed complete arterial and aortic occlusion with no leaks around the LVOs.

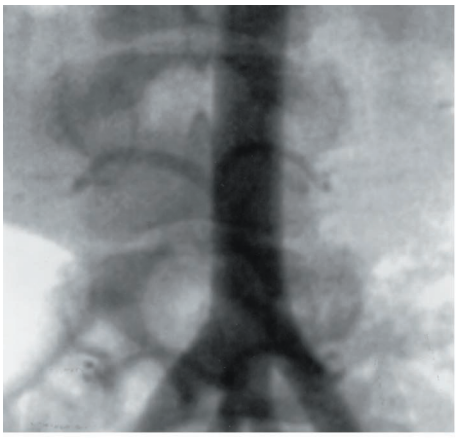
In all cases, the position of the LVO immediately after placement was identical to the position on follow-up arteriography at the time the animal was killed. In all eight animals followed for 3 months, follow-up arteriography performed at 6 weeks ($n$ = 6), 8 weeks ($n$ = 3), and 3 months ($n$ = 1) showed complete permanent occlusion of two aortas, eight systemic or pulmonary arteries with multiple collateral vessels around the excluded vessel segments, and excellent distal filling **(Figs 5a, 6)**. No evidence of recanalization of occluded arteries was found on follow-up arteriography.

### • Pathologic Examination

Postmortem examination of four animals that had been treated acutely showed that the LVO was securely anchored against the aorta or arterial wall by the barbs and no damage to the surrounding structures was noted. The aorta or arteries were occluded and the LVOs were covered with thrombus and fibrinous apposition, filling the space around the device. Traces of barbs penetrating into the arterial wall were seen after removal of the LVO. Necropsies of the eight animals undergoing longer-term follow-up revealed incorporation of the SIS LVO into the aortic or arterial wall. Smooth, shiny vascular surface was seen on both sides of the LVO in all animals **(Fig 5b)**. There was no sign of stainless steel corrosion or fracture. Histologic evaluation revealed SIS replaced by host tissue and remodeled with variable fibrocytes, fibroblasts, some inflammatory cells, and vascular endothelial cells. The suture lines of the LVO were inflamed with foreign-body reaction. There was complete endothelialization of the LVO covered by endothelialized neointima on both sides **(Fig 5c)**.

## DISCUSSION

To serve efficiently as a device carrier, an expandable stent should have a low enough profile to be introduced through a small catheter but should have sufficient expansile force to securely attach to the arte-



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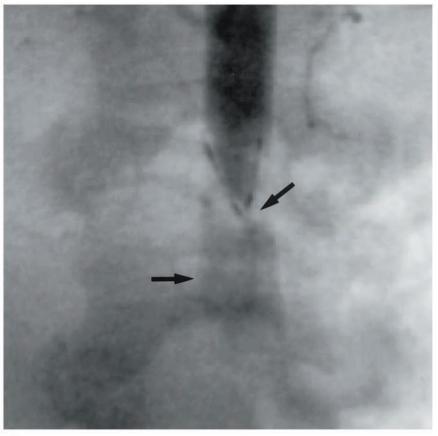

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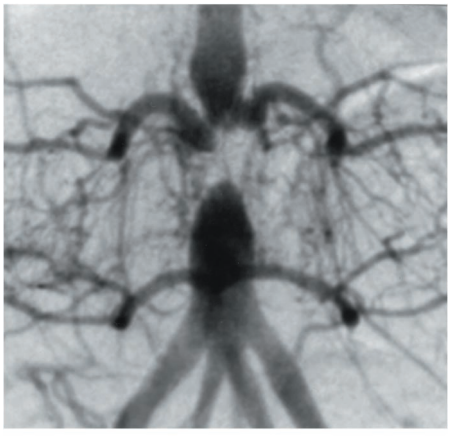

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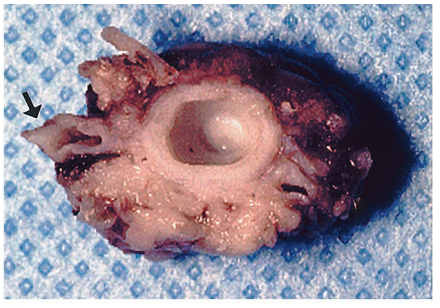

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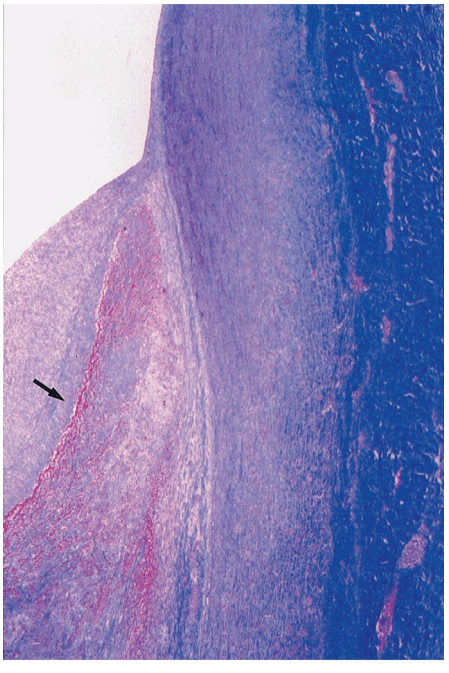


e.

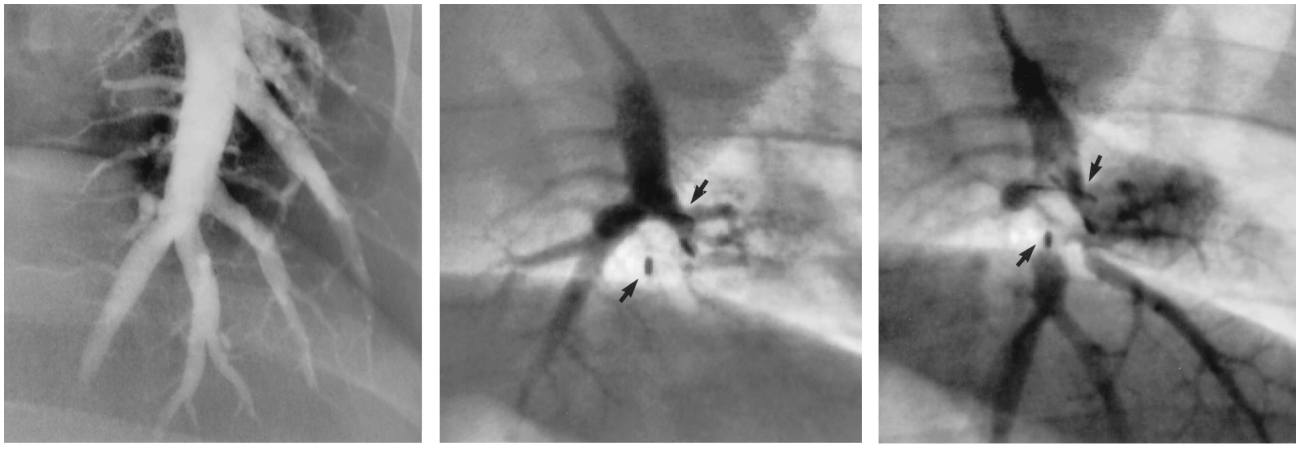
**Figure 5.** Placement of LVO into abdominal aorta. **(a)** Baseline aortogram. **(b)** Follow-up aortogram immediately after LVO placement shows occlusion of aorta with minimal leak (arrows). **(c)** Aortogram 2 months after placement shows complete aortic occlusion with extensive collateral circulation with filling of aorta and its branches distal to occlusion. **(d)** Autopsy specimen of the occluded aorta shows neointima completely covering the occluder. Large collateral lumbar arteries (arrow). **(e)** Photomicrograph of a longitudinal cross section of aortic SIS occluder. The area of loose connective tissue in the left half of the image corresponds to organized thrombus, which was lined by intact endothelium when viewed at high power. This area includes the region in which the SIS material was originally present (arrow), but the SIS is no longer distinguishable from the host tissue. The adjacent elastic wall of the vessel shows slight compression, but there are no significant changes within the adventitia. [Trichome stain, original magnification 25×].

rial wall in high-volume, high-pressure flow. The self-expandable square stent fulfills these conditions and has potential to be a suitable carrier for intravascular and intracardiac devices.

To construct an LVO, we covered the square stent with a biologic material, porcine SIS, which is very thin and does not significantly increase the size of guiding catheters used for introduction. Depending on their size, LVOs can be introduced through 6–10-F catheters. Even though it is very thin, SIS cover is durable, and when attached to a square stent with two or four barbs, it forms an LVO that is stable and withstands high-volume, high-pressure flow. However, it is essential that the LVO is properly sized in relation to the vessel that will be occluded. In our experience, the formula that half the diagonal axis of the square stent represents the optimal diameter for the tubular structure to be occluded is valuable in estimation of the proper LVO size. Complete contact between the diamond-shaped stent frame and the cylindrical vessel and a flap of overhanging SIS material provided a good seal between the LVO and the vessel wall. The SIS overhang also provided a basis for ingrowth of native intimal tissue from the vessel.

Large vessel occluders are radiopaque and easy to place. The tendency of a single-body LVO to spring out of the catheter during release is eliminated by a retention mechanism attached to a wire pusher. In all our 16 LVO placement procedures in animal studies, we did not observe any misplacement during release. Also, all LVOs stayed in place during the study with no evidence of migration.

As a biomaterial capable of promoting reconstructive tissue response rather than nonspecific scar tissue formation (11–17), SIS has several advantages over other covers for LVOs, such as Dacron, polytetrafluouroethylene, silicone, or polyurethane. Present experience with these materials show that they do not remodel (1,3,5,8,9). Therefore, no ingrowth of host cells is



a. b. c.

**Figure 6.** Placement of LVO in the pulmonary artery. **(a)** Pulmonary arteriogram before occluder placement. Pulmonary arteriograms 6 weeks after occluder placement show complete pulmonary artery occlusion, with extensive collaterals and filling of artery distal to occlusion. **(b)** Early phase. **(c)** Late phase.

possible, and this may be a reason that these prosthetic materials occasionally fail and recanalize in long-term studies (8,10). In addition, they are thicker and require a larger introducing catheter. As an acellular biomaterial, SIS has been shown to be a bioscaffold with excellent strength in animals and humans in intraarticular ligament grafts (11,12), articular cartilage repair (13), vascular grafts (14), dermal grafts (15), and grafts for urinary (16) and hernia repair (17). With immunohistochemical analysis of SIS-remodeled aortic tissue, Hiles et al (6) demonstrated that SIS material degrades and reabsorbs over the course of time. Like previous studies, our experimental study demonstrated the endovascular remodeling ability of SIS with vascular tissue in two different species. Although SIS comes from a biologic source, studies to date have demonstrated no problems with rejection (6,14,16). The LVO remodeled as an ingrowth of the host cells, incorporating it into the vascular wall and making it less likely to fail.

The ability of SIS to stimulate the body to endoluminally build its own new tissue suggests great potential for future research with SIS-covered square stent-based devices such as vascular occluders, venous and aortic valves, and branched adapter stent-grafts.

## SUMMARY

Our experience has shown that the self-expandable square stent is a good carrier for intravascular devices, particularly the LVO. It has a low profile, is easy to place, and its barbs keep it in stable position. LVOs covered with SIS are very efficient and durable occlusive devices for medium-sized and large vessels in a high-flow model and in experimental animals. Possible clinical applications include occlusion of iliac and other large-diameter arteries during endoluminal aortic and arterial aneurysm repair, occlusion of the aorta, occlusion of large-diameter patent ductus arteriosus, and percutaneous treatment of large arteriovenous fistulas. However, more experience in animals other than pigs will be necessary to document the long-term potential of SIS-covered square stents as LVOs before their clinical application.

**Acknowledgment:** The authors thank Martina Basin Pavcnik and Sheri Imai for their assistance.

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