PRELIMINARY INVESTIGATION

A new vascular Endostaple: A technical description

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Objective: **The purpose of this report is to describe a new vascular Endostapling system.**
Methods: **The vascular Endostapling system can be passed through a 13F insertion sheath that is inserted through the femoral artery. An optical fiber and overlying Endostaple will penetrate a previously inserted endoprosthesis and the aortic wall at whatever points are desired. Once the optical fiber is withdrawn, the Endostaple assumes its preformed shape and acts like a through-and-through wire suture. As tissue ingrowth proceeds, the long-term security and stabilization of the coiled coil mechanism are likely to increase.**
Conclusions: **We think Endostaples can be useful in preventing endograft migration and in treating endoleak at the site of the aortic neck–proximal endograft interface. (J Vasc Surg 2001;34:565-8.)**

A vascular Endostaple is a single attachment unit that is delivered through the lumen of a blood vessel; it is used to penetrate the entirety of the luminal structure to increase the integrity of the structure or to secure an intraluminal prosthetic device to the full thickness wall of the luminal structure. Examples of possible application of Endostaples include the following: (1) sealing leaks ("endoleaks") of arterial blood flow between the aortic neck wall and the endograft in patients with abdominal aortic aneurysms being treated with endoluminal devices to exclude aneurysms; (2) preventing subsequent migration of endografts that do not have full thickness attachment at the proximal aortic neck attachment site; (3) attaching unsupported prosthetic bifurcation grafts to the proximal necks of abdominal aortic aneurysms; and (4) attaching unsupported tube grafts proximally and distally within the proximal and distal necks of abdominal aortic aneurysms.

The desirable attributes of an aortic Endostapling system include the following: (1) the insertion catheter should be small and flexible; (2) the delivery catheter head should be easily maneuvered; (3) the aortic wall should be penetrated easily, regardless of the degree of aortic wall calcification; (4) the Endostaple should resist dislodgment both immediately after insertion and thereafter for the entire life of the recipient; and (5) the intraluminal portion of the Endostaple should have a low profile. The purpose of this paper is to describe an Endostapling system that, on preliminary testing, meets these criteria.

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Competition of interest: Both HHT and HMT are board members of EndoVascular Associates, the company that owns the patents covering the Endostaple and delivery catheter described in this report.
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TECHNICAL DESCRIPTION

The Endostaples are composed of either interwound double coils of nitinol wire (0.007 in or 0.1778 mm diameter) or stainless steel wire (0.0065 in or 0.1651 mm diameter). The Endostaples are made of these two different shape memory metals so that a similar metal Endostaple can be chosen to avoid contact of dissimilar metals when used with supported endografts made of either nitinol or stainless steel. In the relaxed state the coils are themselves coiled, as illustrated in Fig 1. The primary coil of both Endostaples has an outer diameter of 0.038 in (0.9652 mm), whereas the secondary coil of both has a diameter of 0.135 to 0.150 in (3.43-3.81 mm).

When the Endostaples are loaded for delivery, six or more are serially aligned about a 530 to 540 μm ultralow hydroxyl, polyimide–coated optical fiber as shown, with three Endostaples, in Fig 2. The energy source is a Holmium:YAG laser; its particular wavelength vaporizes hydroxyl groups within the subject tissue on contact.

The delivery system is inserted through a 13F –internal diameter or larger insertion sheath (insertion sheaths are traditionally identified by the size of the catheter they are designed to accept). The delivery system is composed of an outer catheter (13F outside diameter) that can be deflected up to 100 degrees within a 15-mm artery and an inner catheter that houses the optical fiber and overlying Endostaples. For the treatment of endoleak or the prevention of migration, the delivery system can be inserted through an insertion sheath placed in a femoral artery and angled into position within the aortic neck of a patient who has already had an endograft inserted for treatment of an abdominal aortic aneurysm (Fig 3). The inner catheter is advanced so that its tip engages the endograft within the

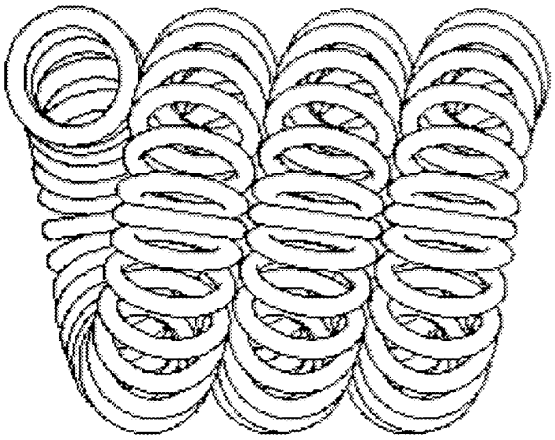

Fig 1. Endostaple in relaxed state.

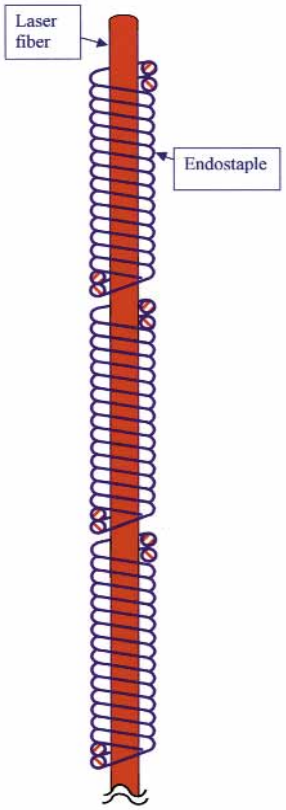

Fig 2. Three Endostaples aligned along a laser fiber.

aortic neck and is then further advanced until the portion of the outer catheter opposite the tip of the inner catheter is compressing the aortic neck wall (Fig 4). The laser is then turned on, and while the inner catheter remains fixed, the optical fiber and overlying 14-mm-long Endostaple (while aligned along the laser fiber) are advanced approximately 8 to 9 mm through the endograft and aortic wall (Fig 5). The inner sheath and accompanying optical fiber with the remaining overlying Endostaples are withdrawn inside the outer catheter, and the ejected Endostaple is left firmly attaching the endograft to the aortic wall (Fig 6). Fig 7 is an enlarged view of an Endostaple attaching a portion of prosthetic graft to the full thickness of an aortic wall. Note that only one Endostaple coil remains within the lumen, thus limiting its intraluminal profile to slightly less than 1 mm. This version is but one of a number of configurations that have been considered.[1,2] A common theme, however, is that the Endostaple, constructed in a shape memory alloy or material having similar performance characteristics, is introduced at the same time as the optical fiber and deforms to increase pullout resistance once the optical fiber is withdrawn.

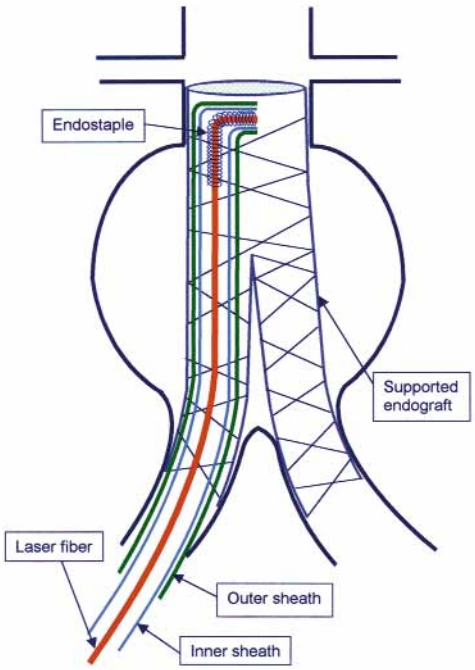

Fig 3. Supported bifurcation endograft inserted to exclude abdominal aortic aneurysm. Delivery system (shown) inserted through insertion sheath. Note that insertion sheath in each of Figs 3 through 7 has been omitted for clarity.

PRELIMINARY FEASIBILITY EVALUATION

All prosthetic grafts tested, including those made of polyester fiber (Dacron), expanded polytetrafluoroethylene, and polyesters, are easily penetrated with minimal adjacent graft damage by a relatively low-power laser ablation (< 10 W), as are highly calcified human explanted aneurysm walls. The laser will not transect metal struts made of nitinol or stainless steel. In acute feasibility experiments in sheep and calves, lasting up to 48 hours, with only Endostaples used for the proximal anastomosis, we have shown that a short-segment Dacron graft can be securely anastomosed to the

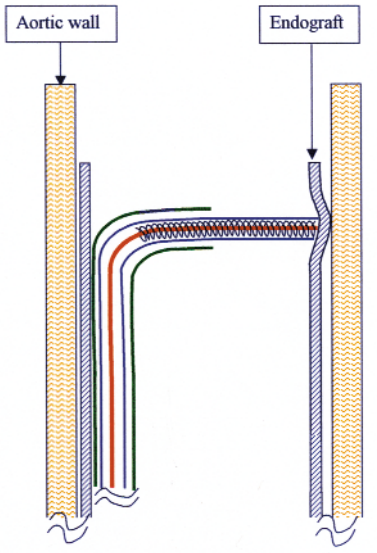

Fig 4. Delivery catheter compressing endograft against aortic wall.

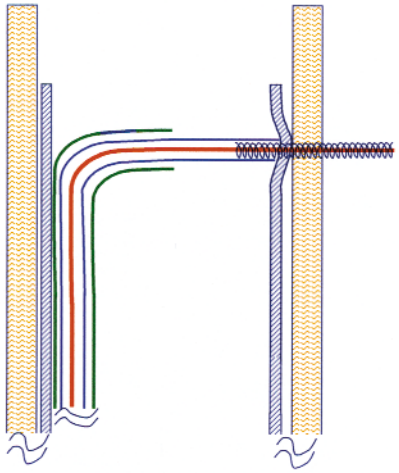

Fig 5. Laser fiber and overlying Endostaple inserted through endograft and aortic wall.

thoracic aorta with minimal bleeding at the time blood flow is restored and with the grafts remaining patent for the duration of the experiment.

DISCUSSION

The use of Endostaples that fully penetrate the aortic wall holds great promise in both the treatment of endoleak at the aortic neck/proximal endograft anastomosis and the prevention of migration (and subsequent reperfusion of the aneurysm) of the endograft from its aortic neck attachment site. The Endostaple that we describe acts as a wire suture or rivet that can be inserted through a 13F catheter and has the additional advantage of allowing tissue ingrowth within the interstices of its coils so that the security of the attachment increases as tissue ingrowth occurs. This approach may overcome some of the problems of devices currently approved by the Food and Drug Administration that are used for endograft repair of abdominal aortic aneurysms.

Treat proximal endoleak and prevent endograft migration. There are at least two major problems with the current generation of endovascular repair devices used for treatment of abdominal aortic aneurysms: migration and endoleak, particularly at the graft-aortic neck anastomosis.[3] A variety of strategies have been used to avoid one or both of these complications, including placing hooks on the endografts, using outward radial forces to attach self-expanding stent-grafts to the inner surface of the aortic neck, using fully supported stents to provide a rigid matrix with the intention that the graft would then not migrate, using suprarenal attachment with uncovered stent portions extending across the orifices of the renal arteries, and, when endoleaks occur, using additional stents or stented endografts to try to correct the underlying defect. None of these strategies has been entirely successful.[4] The biomedical engineering problems include the high probability that radially expanding forces of endografts against the intimas of relatively short and frequently diseased aortic necks are not likely to be a sufficiently durable attachment mechanism. It seems likely that, through the years after implantation, endograft migration will be problematic for an unacceptable number of endograft devices not attached to the full thickness of the aortic neck wall. Data to date from all endograft devices lacking full aortic wall penetration for proximal attachment suggest that the potential for migration and late endoleak continues for the life of the patient.[5-7] Neck dilatation, aneurysm shortening, or both[8] can also be destabilizing to the endograft. Hooks or other penetrating

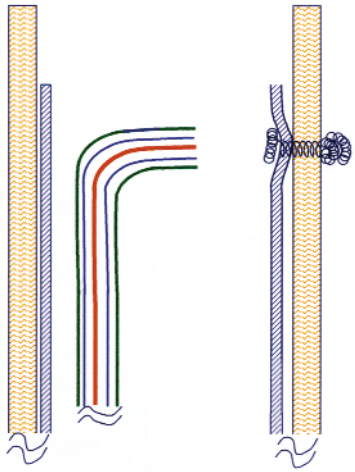

Fig 6. Laser fiber and inner sheath withdrawn. Endostaple acts as rivet.

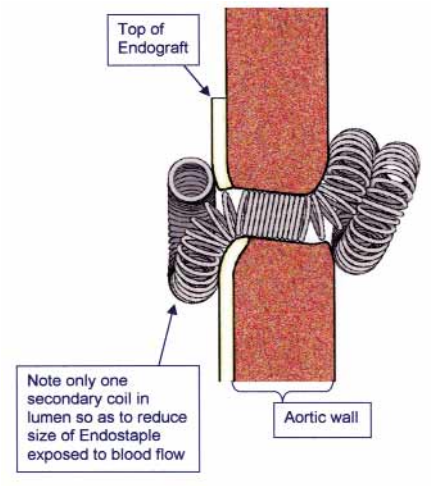

Fig 7. Endostaple holding endograft against aortic wall.

means attached to the endograft add unwanted dimensional bulk and may not penetrate a calcified aorta; indeed, they may serve to hold the endograft away from the aortic wall. It is possible that Endostaple placement through the full thickness of the aortic wall will be a remedy for many, if not all, of these problems.

Other possible uses. Although it is entirely speculative, a modular or sequential approach may allow the tube portion of an unsupported bifurcation prosthetic graft to be attached to the aortic neck with Endostaples with the bifurcation limbs being attached to the iliac arteries with stents or stent-grafts. Such an approach offers a number of possible advantages. First, because the graft has no support struts or attachment hooks, the insertion sheath can be smaller and more flexible and may thus be passed through smaller, moderately diseased, and more tortuous iliac arteries. Second, the attachment is more secure than with stented endografts because the Endostaple provides full thickness aortic wall attachment. Third, an endoleak can be treated more easily with the addition of more Endostaples without concern that the rigidity of a stented graft might prevent apposition of the graft to an eccentric aortic neck. Fourth, the unsupported nature of the graft allows postoperative contraction of the aortic aneurysm without adverse consequences. Finally, approximately 50% of all patients with an abdominal aortic aneurysm are currently thought to be eligible for endograft placement. The remaining 50% are excluded because of anatomical considerations (angulated, short-diameter, or large-diameter aortic necks; narrowed or aneurysmal iliac arteries). An endovascular approach that can be used in these currently excluded patients because of the greater security of the graft attachment to the aortic neck in some of these settings may substantially increase the number of patients with abdominal aneurysm eligible for an endovascular approach.

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