ENDOVASCULAR AND SURGICAL TECHNIQUES

A Telescopic Stent-graft for Aortoiliac Implantation

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Objectives: To test a new delivery system for a telescopic stent-graft.
Materials: Variable overlap between the components of this stent-graft combination allows length adjustment. This device differs from other multi-component stent-grafts in that both components are contained within a single delivery system.
Methods: The stent-graft was implanted in the distal thoracic to suprarenal aorta of five pigs (35-50kg), where the arterial diameter falls by almost 50%. The proximal and distal components of the stent-graft were targeted to bony landmarks in the vertebral column.
Results: Inspection of completion angiograms showed both proximal and distal stent-grafts to be within 1 mm of their target locations in all five experiments. Overall combined stent-graft length varied from 13.5cm to 16.1cm depending on the location of the bony landmark chosen as the distal target, and on the size of the pig.
Conclusions: This system may be useful for the repair of abdominal aortic aneurysm whenever preoperative sizing is difficult due to aortic tortuosity, or precluded due to the urgency of the procedure.

Key Words: Endovascular; Aneurysm; Stent-graft; Telescopic.

Introduction

Preoperative graft sizing for endovascular aneurysm repair can be difficult, when the aorta is tortuous, the implantation sites are short, or the time available is limited by the condition of the patient. Of the many stent-grafts in clinical use for aortic aneurysm repair,1-5 only those which employ a multicomponent approach6 permit much intraoperative adjustment of length. In this approach the components are introduced separately and assembled in situ. By choosing components of different lengths, and varying the degree of overlap, it is possible to adjust the overall length of the device. Indeed, variability in the degree of overlap is enough, by itself, to generate a range of graft lengths suitable for the majority of cases of AAA.

We have developed a system which employs this "variable overlap", or "telescopic", principle, yet introduces the two components inside a single delivery system. We believe that one-step delivery of such a graft has clear advantages, particularly in the emergency setting.

The purpose of this study was to assess the feasibility and accuracy of this method of multi-component stent-graft delivery.

Method

The system for one-step delivery of a variable length stent-graft was developed through a series of in vitro experiments, followed by preliminary animal experiments, during which the design was further modified. To evaluate the final system, a series of five implantations were performed in pigs, ranging in weight from 36 to 50 kg, using standardised apparatus and technique. The experimental procedures were approved by the animal ethics committee of Lund University.

The stent-graft spanned the distal thoracic to suprarenal aorta, where the diameter tapers from approximately 18 mm to 9 mm. The target for proximal stent-graft implantation was the same in all experiments, whereas the target for distal stent-graft implantation...
varied, in order to mimic the varying length requirements of the clinical setting. The criteria of success were:

1. Accurate implantation, proximally and distally.
2. Exclusion of aortic branches in the region of the stent-graft, including the celiac and superior mesenteric arteries.

**Stent-graft**

The system has many features in common with other Gianturco-based stent-grafts for aneurysm repair, but the telescopic (variable length) capability is new. This capability was produced by the combination of two stent-graft components, one inside the other; each with its own sheath and independent position control mechanism. The two stent-grafts will be referred to as the proximal and distal, although they could equally be called inner and outer. The difference between this and other modular systems is that while the component stent-grafts of other systems are entirely separate, and must be inserted one after the other, the component stent-grafts of this system are both loaded into the same sheath, and are introduced simultaneously.

The proximal stent-graft had a single barbed Gianturco Z-stent mounted inside its proximal orifice. The fabric sleeve was a hand sewn tube of woven polyester, which tapered from 22 mm to 12 mm in diameter immediately below the stent. The total length of the proximal stent-graft was 11 cm, 3 cm of which was 22 mm in diameter and 7 cm of which was 12 mm in diameter. Although the distal end of the fabric sleeve had no stent, it was marked by a single link of gold chain, which was highly radio-opaque. The distal stent-graft had two Gianturco Z-stents; one within each orifice. The proximal stent had caudally oriented barbs. The fabric sleeve was a hand sewn tube of woven polyester, with a constant diameter of 13 mm, and a length of 7 cm.

**Delivery system**

Both proximal and distal stent-grafts were attached to a single carrier by short suture loops (Fig. 1a, b and d). These loops were tied around a small inner catheter in the lumen of the carrier. Complete release of both stent-grafts was accomplished by removing the inner catheter. Partial release, or release of only the proximal stent-graft, could be accomplished by partial withdrawal of the inner catheter (to level A on Fig. 1a).

When only the proximal stent-graft was released, the position of the distal stent-graft could be controlled independently to make precise adjustments in the overall length of the stent-graft combination.

Independent movement of the distal stent-graft was also facilitated by enclosing it in a separate sheath (16 French O.D.). When the system was loaded, the proximal stent-graft occupied the space between the main sheath of the delivery system (20 French O.D.), and the sheath that surrounded the distal stent-graft.

The stages in loading were as follows:

1. The small sheath was mounted on the carrier (Figs. 1a and b).
2. The distal stent-graft was tied to the carrier (Fig. 1b).
3. The small sheath was advanced over the distal stent-graft, and locked in position by tightening the fitting at its outer end (Fig. 1c).
4. The proximal stent-graft was tied to the carrier (Fig. 1d).
5. The proximal stent-graft, and carrier, were loaded into the large sheath using the Teflon cone (Fig. 1e).

**Procedure**

The distal aorta, inferior mesenteric artery and adjacent lumbar arteries were isolated through a transperitoneal incision. Five thousand units of heparin were administered intravenously (first three experiments only). Proximal control was obtained using a loop snare, and distal control with clamps. An angiographic catheter was introduced through a longitudinal incision, and passed over a guidewire into the proximal aorta. Following digital subtraction angiography, the catheter was exchanged over a guidewire for the delivery system.

The delivery system was advanced, under fluoroscopic control, until the proximal margin of the proximal stent (of the proximal stent-graft) was level with the proximal margin of the second to last thoracic vertebral body (Fig. 2). The position of the proximal stent was maintained through its attachment to the carrier while the outer sheath of the delivery system was withdrawn completely, allowing the proximal stent to be deployed. The inner catheter was withdrawn until its tip was between the attachment points of the two stent-grafts (position A, on Fig. 1a). This left the proximal stent-graft free of attachment to the delivery system. The distal stent-graft, however, remained attached; its position could be adjusted by moving the carrier.
Fig. 1. Steps in loading the stent-graft into the delivery system. Note that several components are not shown at their full length. (a) The carrier. (b) Attachment of the distal stent-graft. (c) Ensheathing the distal stent-graft. (d) Attachment of the proximal stent-graft. (e) The loaded system.
The target location for the distal stent-graft varied (Fig. 2). In the three experiments, the distal stent graft was positioned so that the proximal margin of its proximal stent was aligned with the proximal margin of the second lumbar vertebral body. In the two experiments, the distal stent graft was positioned so that the proximal margin of its proximal stent was aligned with the middle of the first lumbar vertebral body. The distal stent-graft was deployed in this location by withdrawal of the smaller (14 French) sheath. Stent-graft release was completed by removal of the inner catheter, whereupon the delivery system was removed altogether. The result was assessed by completion angiography, after which a lethal dose of barbiturate was administered intravenously.

Results

Inspection of completion angiograms showed both proximal and distal stent-grafts to be within 2 mm of their target locations in all five experiments. Overall combined stent-graft lengths depended on the location of the bony landmark chosen as the distal target, and on the size of the pig (Fig. 2). When the distal stent-graft was targeted to the L2 vertebral body, the combined lengths varied from 14.8 cm to 16.1 cm ($n = 3$, mean = 15.5 cm). The longest being in the 50 kg pig, which of course had the longest vertebral bodies. When the distal stent-graft was targeted to the middle of the L1 vertebral body, the combined lengths were 13.5 cm and 14.3 cm ($n = 2$, mean = 13.9 cm). Again the longer of the two was in the largest pig (50 kg).

In the first three experiments, initial angiograms showed brisk leakage of contrast into the celiac and superior mesenteric arteries. This ceased approximately 15–30 min after the injection of Protamine. The fourth and fifth experiments were performed without heparin, no Protamine was given, and there were no signs of leakage within approximately 5 min of implantation.

| Overall stent-graft length (cm) | 15.7 | 14.8 | 16.1 | 13.5 | 14.3 |
| Weight of pig (kg) | 41 | 40 | 50 | 36 | 50 |

Fig. 2. The positions of proximal and distal stent-grafts relative to the bony targets, the weight of the pigs, and the resulting overall length of the stent-graft.
Discussion

Both the proximal and distal stent-graft components were implanted accurately in all five animals. The initial leakage was attributed to the presence of a hand-sewn suture line down the length of both grafts, and the high porosity of the polyester fabric used. Protamine and time resulted in complete haemostasis. The system therefore satisfied our criteria of success in all cases.

Most importantly, the overall length of the stent-graft could be adjusted by varying the degree of overlap between the components, enabling a graft with a constant initial length of 12.5 cm to have a final length between 13.5 and 16.1 cm, depending on the location of the preselected distal target. Although the increase in length demonstrated here was relatively modest, the potential is clear. Indeed, this stent-graft was partly extended at the time of insertion. Its fully collapsed length was 11 cm, and its fully extended length was 17 cm. Assuming the length of the wide (22 mm) and tapered segments, at the proximal end of the proximal stent-graft, have a constant length of 4 cm, and assuming a minimum of 1 cm overlap is maintained between the two stent-graft components, the relationship between fully collapsed (c) and fully extended (e) lengths (in centimetres) is given by the formula $e = 2c - 5$. Perhaps the most useful stent-graft would be the one with a range of 12–19 cm, since the distance from the renal arteries to the internal iliac artery origin is rarely less than 12 cm and the distance from the renal arteries to the proximal common iliac artery is rarely more than 19 cm.

The graft diameters used in this study, 22 mm proximal end and 13 mm at the distal end, would be too small to be implanted in the aortoiliac position in the majority of patients with aortic aneurysm. However, this size was dictated by the requirements of the model, not the volume of the delivery system. A graft, tapering from 30 mm to 15 mm, would be more appropriate for clinical use. The delivery system can easily accommodate stent-grafts of this size if it is constructed with thin-walled fabrics, such as that manufactured by Meadox Medicals (Oakland, NJ, U.S.A.) for endovascular use.

The presence of a stent-graft to stent-graft connection is a potential site for leakage, and a cause for concern, as it is in all multicomponent stent-graft designs. However, some degree of preoperative sizing would often allow the approximate range of graft length to be narrowed. A slightly oversized stent-graft could then be selected with the expectation that it would function at the lower end of its full range. If this were the case, the overlap between components would be quite long, and the proximal component would often reach the orifice of the common iliac artery by itself. The long overlap and the location of the stent-graft junction in the common iliac artery would both tend to lessen the risk of leakage into the aneurysm.

The main advantage of this system, over current multicomponent systems, is one step delivery of both stent-graft components. The development of this system was prompted by an emergency case, in which none of the available stent-grafts were long enough. A
two system modular approach was ultimately successful, but it was neither easy nor quick. If stent-grafts are ever to be used widely in emergency cases, the flexibility afforded by a variable length stent-graft will be important, and so will the speed afforded by one-step delivery.

References


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