Fenestrated and branched endografts: assessment of proximal aortic neck fixation

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ABSTRACT

Objective: To investigate proximal fixation characteristics of different aortic endograft designs: a supra-renally placed fenestrated endograft, a modular branched endograft, an infrarenal endograft with suprarenal bare stent fixation, and the gold standard, a conventional hand-sewn anastomosis.

Methods: Ten human cadaveric aortas were obtained at autopsy and transected 20 mm below the renal arteries to mimic an infrarenal aneurysm neck. In random order, the infrarenal, fenestrated, and branched endografts were deployed into the aorta. Using a hydraulic material-testing machine, longitudinal load was applied to the distal end of each endograft until migration occurred, thus defining the displacement force (DF). Subsequently, a hand-sewn infrarenal anastomosis was tested in a similar manner.

Results: The median DF was 4.67 N (3.82-6.37) for the infrarenal endograft, 9.17 N (8.03-10.81) for the fenestrated endograft, and 16.95 N (14.78-19.67) for the branched endograft. The differences in DF between the infrarenal and fenestrated endografts and between the fenestrated and branched designs were statistically significant (both p=0.005). The median force to dislodge the graft from the conventional anastomosis was 89.16 N (71.24-105.23).

Conclusion: Supra-renally placed endografts, especially with additional branch grafts, provide improved proximal fixation compared to an infrarenal endograft with suprarenal bare stent fixation. However, none of the tested endografts approached the optimal, time proven fixation, the hand-sewn anastomosis.
Introduction

Long-term performance of a vascular graft in open abdominal aortic aneurysm (AAA) repair depends on the durability of the anastomosis and graft material. With the introduction of endovascular aneurysm repair (EVAR), the anastomosis changed, and, in the process, introduced doubt with regard to its long-term durability. One of the worrisome complications in EVAR is endograft migration, which can lead to late type I endoleak, aneurysm enlargement, and eventually rupture.\textsuperscript{1,2}

Currently available endografts rely on radial force, appendages such as hooks and barbs, and suprarenal bare stent deployment for improved fixation. Midterm results for these devices show migration rates varying from 0% to 13%.\textsuperscript{3–6} However, the incidence of device migration seems to increase with length of follow-up,\textsuperscript{7,8} so longer term data are needed.

Fenestrated and branched endografts might have a role in improving proximal fixation. Because they can be deployed further into the non-aneurysmal section of the aorta without impairing blood flow to the renal and visceral arteries, larger surface contact between the graft and aortic wall is created. Such complex endografts are not yet available in regular practice. In future, they might enlarge the pool of aneurysms anatomically suitable for EVAR. They might also improve EVAR success in terms of migration for infra-renal aneurysms currently being treated with standard endografts.

The purpose of this study was to investigate proximal fixation of a fenestrated endograft and a modular branched endograft in comparison with an infrarenal endograft with suprarenal bare stent fixation and a conventional hand-sewn anastomosis.

Methods

Endografts

Three different endograft designs (Fig. 1) based upon the Talent endograft (Medtronic Vascular, Santa Rosa, CA, USA) were tested for proximal fixation capacities: (1) an infrarenal endograft with suprarenal bare stent fixation, (2) an endograft with fenestrations aligning with the renal artery orifices, and (3) a
branched endograft. The branched endograft was a modular system composed of a tubular main graft customized with 2 fenestrations to accommodate the separate renal branch grafts. Branch grafts were composed of a 20-mm-long Bridge Assurant balloon-expandable stent (Medtronic Inc., Santa Rosa, CA, USA) with a 6 or 7 mm diameter. The stent was covered with an extended polytetrafluoroethylene (ePTFE) tube over which was molded a silicone flange (Fig. 2). The ePTFE was held to the stent system by an additional constraining suture that broke when the integrated stent was balloon expanded. The silicone flange was designed to easily slide into the fenestration, lock into place, and create a fluid-tight seal between the main graft and the proximal end of the branch graft (Fig. 3).

Figure 1: (A) An infrarenal endograft placed with the fabric below the lowest renal artery, (B) a fenestrated endograft, and (C) branched endograft.

Figure 2: The branch graft is made of an e-PTFE tube with a silicone flange (arrowhead) molded over it; the PTFE is held to the stent system with a constraining suture (arrow) that breaks during stent expansion.
Figure 3: Both branch grafts are locked into place and seated within the fenestrations of the main graft, creating a fluid-tight seal.

Harvesting and preparation of the aortas

At autopsy, 16 human postmortem non-aneurysmal abdominal aortas were obtained. After harvesting, the aortas were macroscopically classified following the scoring system proposed by Malina et al.\(^8\): (I) non-atherosclerotic, (II) soft intimal thickening, (III) calcified plaques along part of the aortic circumference, (IV) circumferential calcified plaques, and (V) completely calcified, incompressible aorta. The aortic diameter of each specimen was measured.

For the experiment, aortas classified as II or III were considered suitable for proximal aortic neck fixation in EVAR. From among the 16 specimens, 10 aortas harvested from 6 men and 4 women (median age 69 years, range 60-75) were selected. To mimic an infrarenal aneurysm neck, the aortas were transected 20 mm below the orifice of the lowest renal artery. Both renal arteries were preserved, with a minimum length of 20 mm each. The aortas were stored in a saline fluid and maintained below 4° C until tests were performed (mean delay 11.4 hours).
Experimental set-up

Endografts were deployed in the 20-mm aortic neck similar to clinical practice. Over sizing (20%) and post-deployment dilation (6 atmospheres) were performed. The implanted grafts were flushed with saline solution at 37°C to promote graft expansion.

Using a hydraulic material testing machine (model 8872, 250-N load cell; Instron Corporation, Norwood, MA, USA), longitudinal traction was applied to the distal end of each endograft. The aorta showed elastic elongation due to increasing tension load. At maximum load, static friction changed into dynamic friction, and the endograft began to migrate; the force being applied when this point was reached was defined as the displacement force (DF), given in Newton (N) (Fig. 4).

The 3 endografts were tested in random order, once in each of the 10 aortas. After each extraction, the aorta was macroscopically examined for injury and, if necessary, excluded from the test. Thereafter, a 3.0 Prolene hand-sewn anastomosis was made with each aorta using a Dacron graft, and the force to dislodge the graft was measured (Fig. 5).

Figure 4: Longitudinal tension load curve of a branched endograft. Notice the increase in force due to elastic elongation. At maximum tension load, static friction changed into dynamic friction; this point is defined as the displacement force (DF).
Figure 5: A conventional anastomosis is placed into the hydraulic material testing machine and longitudinal traction is applied.

Statistical analysis

The results are presented as the median (range) of the 10 measurements. Multiple groups were compared using the Friedman test. The Wilcoxon signed rank test was used to compare 2 devices. P < 0.05 was considered statistically significant. Statistical analyses were performed with SPSS software (version 11.0; SPSS, Chicago, IL, USA).

Results

The median DF ranged from 4.67 N (3.82- 6.37) for the infrarenal endograft to 16.95 N (14.78- 19.67) for the branched endograft (Fig. 5). DF for the fenestrated endograft was 9.17 N (8.03- 10.81). Statistical analysis showed a significant increase in the DF between the infrarenal and the fenestrated endografts (p=0.005), as well as between the fenestrated and the branched designs (p=0.005). The median force to dislodge the graft from the conventional anastomosis was 89.16 N (71.24- 105.23), which was about 5 times higher than
the branched endograft. During displacement of the endografts, no macroscopic damage was seen in the aortic segments; however, displacement of the conventional anastomosis tore the aorta along the suture line.

Discussion

Successful EVAR requires secure proximal endograft fixation; if it fails, then late type I endoleak, aneurysm enlargement, and rupture can occur. Factors influencing proximal endograft fixation are aortic neck dilatation due to progressive aneurysm disease, stent oversizing, pulsatile blood flow causing longitudinal repetitive displacement forces, and, in certain cases, unfavorable neck morphology. While biological incorporation into the aortic wall is generally inadequate, endograft manufacturers have sought to overcome this deficiency by introducing mechanical fixation techniques. Besides radial force, currently available endografts rely on appendages, such as hooks and barbs, and on suprarenal bare stent deployment for increased surface contact.

Several experimental studies using human cadaveric aortas showed improved endograft fixation with the addition of hooks and barbs. These results are supported by low incidences of migration in patients treated with infrarenal endografts with proximal barbs. However, enthusiasm about hooks and barbs is somewhat tempered by reports of hook fractures due to material fatigue in EVAR patients. Long-term concerns may also arise with hooks and barbs penetrating the aortic wall and surrounding structures, although no such event has been reported to date.

Another important development is suprarenal stent placement. By placing a proximal uncovered portion across the orifices of the renal arteries, a larger attachment area is created. According to large series from various centers, short to medium-term results for suprarenal bare stent placement are satisfactory. Due to these favorable results, suprarenal bare stent placement is increasingly applied in EVAR. However, concerns remain that stent struts across the renal ostia, with or without foreign body–induced neointimal hyperplasia, might alter renal blood flow and renal function. Renal infarction and occasional renal artery occlusion have been reported in some patients. More long-term information about these issues is essential to ensure the safety of suprarenal endograft implantation.
A combination of both techniques, i.e., hooks or barbs with suprarenal fixation, has been described as the best possible fixation in ex vivo experiments, with a DF of \(-25\) N.\(^{16}\) This observation has also been confirmed by multicenter data reporting a low incidence of migration with suprarenal barbed endografts.\(^{3,30}\)

To overcome the potential shortcomings of transrenal stent struts, some investigators have suggested the use of fenestrated endografts.\(^{31,32}\) By creating holes in the fabric of the graft, blood flow can be preserved to the renal and, if needed, visceral arteries. The concept of endograft fenestration has been developed into successful clinical application.\(^{33,34}\) Nonetheless, this type of aneurysm repair is associated with a risk of adverse renal events,\(^{35}\) and when these grafts are applied to treat aneurysms with very short or absent infrarenal necks, the risk of endoleak remains. This concern has given rise to the development of branched endografts with fluid-tight seals between the main and branch grafts. Reports have been mostly limited to animal studies and incidental case reports.\(^{36-38}\) These procedures have proven technically challenging and time consuming and are therefore probably less suitable for use in a conventional endovascular unit. Nonetheless, the modular branched endograft-system described in this study, although still in pre-clinical development, has proved it can be deployed in a reliable, predictable, and timely manner.\(^{39}\)

The current study revealed improved proximal fixation for the fenestrated endograft (median DF 9.17 N) owing to an increased attachment area (with 35 mm length) at the proximal neck compared to the 20-mm neck of the infrarenal graft. The increased attachment area and anchorage afforded by the two branch grafts in the renal arteries resulted in an even better proximal fixation (median DF 16.95 N). However, in this study, the proximal fixation provided by the endografts was significantly less reliable than that afforded by the conventional hand-sewn anastomosis.

**Limitations**

Although effort was made to reproduce the clinical situation, there are several limitations to this study design. Similar to other in vitro migration studies, we used a continuous longitudinal force instead of pulsatile blood flow with repetitive pulling and pushing forces.\(^{5,16,17}\) Regarding the suitability of the cadaveric aortic neck, we believe that our selection of atherosclerotic postmortem aortas at the level of the renal arteries with a short delay between harvest and test was the optimal means of mimicking the clinical situation in a living human being. Because of the absence
of hooks and barbs in these endografts, no impairment of the aortic wall was discerned. Moreover, all endograft types were tested in a random order, avoiding selection bias. Nevertheless, caution is warranted when comparing our results with the other studies.9,16,17 First, we positioned our devices in the exact location with regard to the renal arteries similar to the clinical situation, while other studies used varying aortic neck lengths (2–5 cm) without taking into account the increased attachment area of the bare suprarenal part.9,16,17 Secondly, while even minimal displacement in fenestrated and branched endografts could affect renal perfusion, we selected the start of displacement as the important force factor; other studies measured the force to completely dislodge the grafts from the aorta.9,16,17

Conclusion

Although still technically challenging, fenestrated and branched endografts provide enhanced proximal fixation strength. As endograft migration and vulnerable renal perfusion are persisting concerns in EVAR, expansion of the endovascular field with the introduction of fenestrations and branched endografts in clinical practice seems worthwhile. Fenestrated endografts, especially with the addition of branch grafts, combined with adjacent hooks or barbs might approach the gold standard, the hand-sewn anastomosis.

References