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Experimental Assessment of Proximal Stent-graft (InterVascular™) Fixation in Human Cadaveric Infrarenal Aortas

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Objectives: *this paper investigates the radial deformation load of an aortic endoluminal prosthesis and determines the longitudinal load required to cause migration in a human cadaveric aorta of the endoprosthesis.*
Design and methods: *the endovascular prosthesis under investigation was a 24 mm diameter, nitinol, self-expanding aortoaortic device (InterVascular, Clearwater, Florida, U.S.A.). Initially, a motorised digital force gauge developed an incremental load which was applied to the ends of five stent-grafts, to a maximum of 10 mm (42%) compression. Secondly, using a simple bench model, each end of four stent-grafts were deployed into 10 cadaveric experimental aneurysm necks and a longitudinal load applied to effect distraction.*
Results: *increasing load produced increasing percentage deformation of the stent-grafts. The mean longitudinal distraction load for an aneurysm neck of 20 mm was 409 g (200–480 g), for 15 mm was 277 g (130–410 g) and for 10 mm was 218 g (130–340 g). The aneurysm diameter and aortic calcification had* p *values of 0.002 and 0.047, respectively, while the* p *value for aneurysm neck length was less than 0.00001.*
Conclusions: *these results suggest that there is a theoretical advantage of oversizing an aortic prosthesis and that sufficient anchorage is achieved in an aortic neck of 10 mm to prevent migration when fully deployed.*

Key Words: Aneurysm neck; Length; Diameter; Radial expansion force; Migration.

Introduction

Initial fixation of the deployed stent-graft within the proximal aneurysm neck depends on a number of factors relating to the aorta and the stent-graft: the shape and size of the proximal neck, the constitution of the aortic wall, the presence of thrombus, the size and shape of the stent-graft, the area of the stent-graft in contact with the aortic wall, the ability of the stent to provide a radial spring force and a number of other features specific to the particular stent-graft in question, including balloon or self-expanding, hooks and barbs.[1] Although listed separately, it is quite obvious that these parameters in combination determine the strength of the initial fixation. It is being increasingly recognised that the comparative performance of the radial deformation of a stent-graft is an important performance characteristic. The purposes of the stent in a stent-graft system are to provide adequate fixation forces to prevent migration of the device once deployed and establish a seal for the graft.[2]

This paper investigates the load required to radially deform a 24 mm diameter nitinol self-expanding stent device (InterVascular, Clearwater, Florida, U.S.A.) by focusing on the terminal portions of the stent because of the specific interest in the initial fixation forces at the proximal aneurysm neck. Secondly, it investigates the longitudinal load required to cause migration of this stent-graft when deployed in the proximal "aneurysm neck" of a human cadaveric aorta, with respect to variables including aortic diameter, degree of mural calcification and aneurysm neck length.

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Methods

Experiment 1

To measure the load (force) applied to the nitinol stent (Fig. 1), a commercially available digital force gauge (Chatillon, Greensboro, NC, U.S.A.) was used. A tip extension provided the interface between the force gauge and the stents tested. The force gauge was mounted to a motorised displacement measuring test stand to provide vertical load and displacement measurement. The stent was placed into a constant

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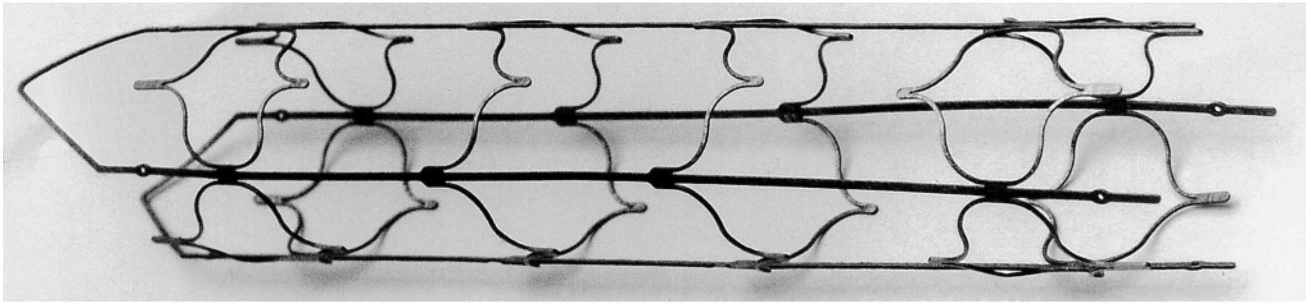

Fig. 1. Stent configuration of the Intervascular stent-graft showing supporting cells.

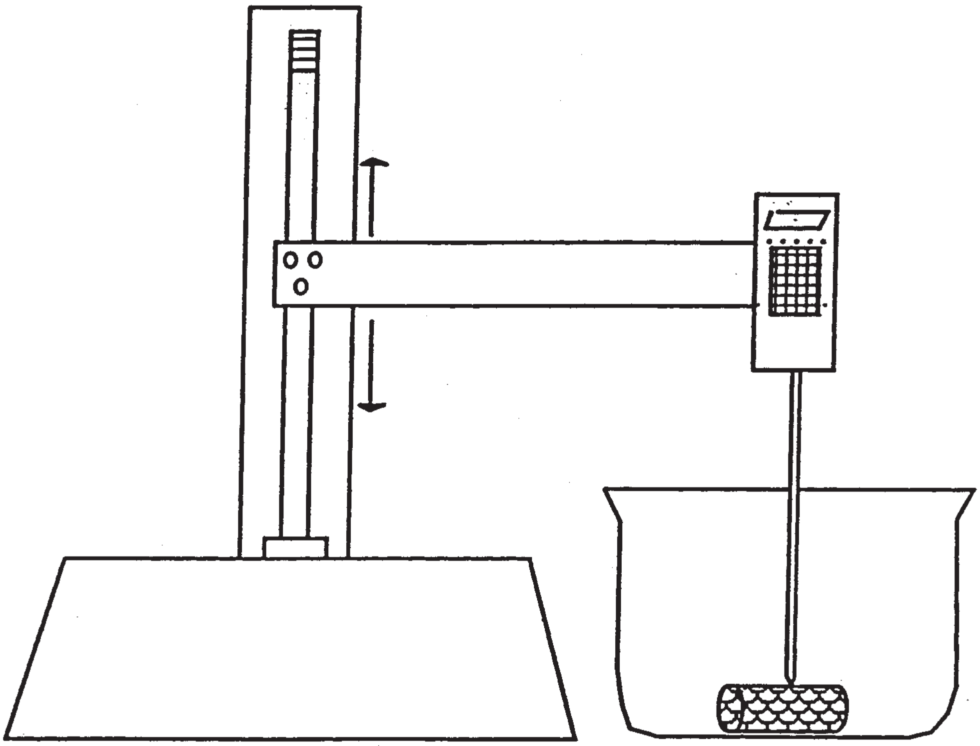

Fig. 2. Radial spring force test rig with Chatillon digital force gauge.

temperature water bath at 37 °C, which was positioned under the force gauge (Fig. 2). A small weight (10 g) was placed on the interior surface of the stent, opposite the portion being tested, to secure the device. The force gauge was aligned to the centre of the proximal or distal sealing ring of the stent. Using the motorised test station to provide downward displacement, incremental compression was applied to the stent to a maximum of 10 mm (42%) stent compression. This is within the limits that a stent-graft would be oversized during the endovascular treatment of abdominal aortic aneurysm.

Experiment 2

A stent-graft comprising a 9 cm long, 24 mm diameter shape memory alloy nitinol stent inside a dacron graft was investigated. Using a simple bench model, the weight required to cause migration of the stent-graft from human cadaveric infrarenal aortas was measured (Fig. 3). Following dissection from the retroperitoneum, each aorta was prepared by removing attached tissue and displaying the vessel from the coeliac axis to the bifurcation. The amount of calcification present in the infrarenal portion was es-

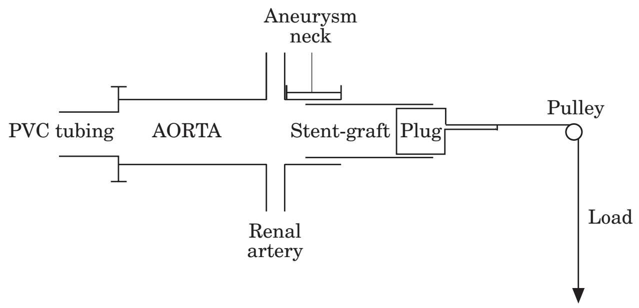

Fig. 3. Diagrammatic representation of the stent-graft distraction apparatus.

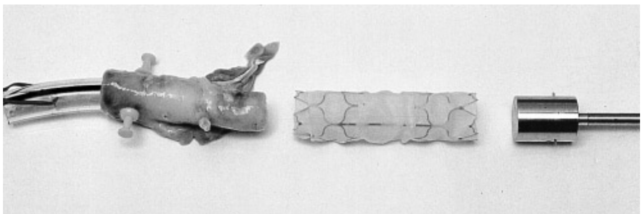

Fig. 4. Aorta with prepared "aneurysm neck", stent-graft and customised plug.

timated and graded as minimal, mild or heavy. The suprarenal aorta was fixed proximally to PVC tubing which in turn was fixed to a stanchion. The infrarenal abdominal aorta was cut such that 20 mm of aorta was left beneath the inferior edge of the lowest renal artery creating an experimental "aneurysm neck". The internal diameter of the "neck" was measured and recorded.

Each stent-graft was placed in iced water, compressed and deployed into the "aneurysm neck". The end of each stent-graft was positioned immediately below the inferior edge of the lowest renal artery. The preparation was then placed in a water bath at 37 °C to effect reconstitution of the stent-graft. A customised plug was placed in the free end of the stent-graft to which a load was applied (Fig. 4). A length of cord, which ran over a pulley, was attached to a bucket into which water was added in 20 ml increments (20 g load). The end point was taken to be the weight of water added to the traction apparatus to produce dislodgement of the aortic/stent-graft interface by 5 mm, to a maximum of 500 ml (500 g). These measurements were repeated three times for each end of each stent-graft in each of the 10 aortas. The "aneurysm neck" length of each aorta was then reduced to 15 mm and finally 10 mm and the measurements repeated.

Between measurements, the stent-graft was removed from the test aorta and placed in the water bath to ensure full reconstitution of shape prior to reinsertion into the iced water to enable moulding and redeployment. The order in which the stent-grafts were used during the experiment and whether the proximal or distal end was used first was randomised to reduce bias. The aneurysm neck lengths were inevitably studied sequentially, starting on each occasion with 20 mm.

Table 1. Required load applied to produce radial deflection.

Deflection (mm)	Deflection (%)	Load (g)	Load S.D. (g)
1.0	4.2	20.4	7.8
2.0	8.3	41.7	13.7
3.0	12.5	59.5	20.5
4.0	16.7	74.7	25.8
5.0	20.8	88.8	30.9
6.0	25.0	99.3	34.7
8.0	33.3	116.8	38.9
10.0	41.7	132.3	41.2

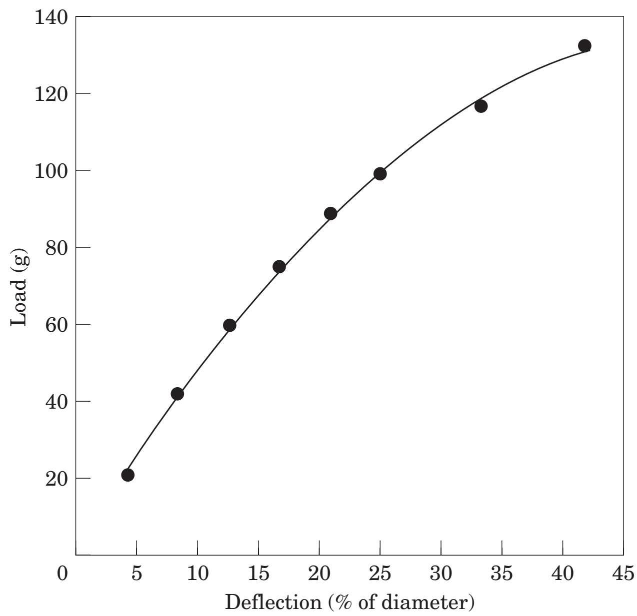

Fig. 5. Load required to radially deform the stent plotted as a function of the radial deflection.

Results

Experiment 1

In the radial deflection study, five 24 mm stents were investigated. Each end of each stent was tested twice and the results averaged. Values for the incremental deflection of the stent are shown (Table 1). It can be seen that incremental load applied produces increasing deformation of the stent which can be demonstrated graphically (Fig. 5).

Table 2. Characteristics of the experimental aortas.

Subject	Gender	Age (years)	Internal diameter (mm)	Grade of calcification
1	F	85	19	Mild
2	F	87	19	Mild
3	M	49	17	Heavy
4	F	80	19	Mild
5	M	85	22	Mild
6	M	76	20	Heavy
7	F	76	18	Minimal
8	M	73	21	Mild
9	M	86	19	Minimal
10	M	76	21	Heavy

Table 3. Summary of the data broken into categories of "aneurysm neck" length, stent-graft, stent-graft orientation and aortic diameters.

	Mean Pull (g)	
Category	All observations	Selected observations
Neck length (mm):		
10	218 (130–340)	225 (125–340)
15	277 (130–410)	290 (145–415)
20	409 (200–480)	425 (205–490)
Stent-graft:		
1	300	306
2	270	299
3	310	311
4	318	322
Orientation:		
P	291	312
D	308	311
Aortic diameter:		
<20	305	336
>20	292	305

Experiment 2

In the aortic bench model, 10 fresh cadaveric abdominal aortas were used (Table 2). There were six male and four female specimens, mean age 77 years (range 49–87 years). Using each end of four stent-grafts, 696 traction values of a potential 720 values (97%) were made. Twenty-four values (3%) were unobtainable in subject 3, as it was not possible to deploy the 24 mm stent-grafts into the 17 mm diameter lumen of the 20 mm length "aneurysm neck". This subject was excluded from further analyses. Ninety-six observations (14%) were removed from the initial data to exclude those traction forces which were associated with "crossed strut", "fractured strut" or "stent failed to fully expand". One hundred and twenty-one of the 696 observations (17%) reached an end point at 500 g. The mean weight to produce displacement for the 20 mm "aneurysm neck" was 409 g (200–480 g), for 15 mm was 277 g (130–410 g) and for 10 mm was 218 g (130–340 g) (Table 3: all observations).

Table 4. Test statistics and *p* values for the stent-graft, aortic diameter, aortic calcification and "aneurysm neck" length factors.

Source	Test statistic	*p* value
Stent-graft	1.73	0.10
Aortic diameter	9.92	0.002
Aortic calcification	3.34	0.047
"Aneurysm neck" length	207.47	<0.00001

The aim of the analyses was to determine which of the measured explanatory variables (aortic diameter, degree of calcification, stent-graft, "aneurysm neck" length) affect the load needed to remove the deployed stent-graft from the test aorta. The statistical technique used in selection of the model and significant effects was an analysis of variance (ANOVA). In the reduced data set, the traction load for the 20 mm neck length was 425 g (205–490 g), for 15 mm was 290 g (145–415 g) and for 10 mm was 225 g (125–340 g) (Table 3: selected observations).

The aortas were classified as narrow (less than 20 mm internal diameter) or wide (diameter greater than or equal to 20 mm) and graded as minimally, mildly or heavily calcified. Under these conditions, ANOVA was performed on the selected observations. The results show that the "aneurysm neck" length was highly significant ($p<0.00001$). The aortic diameter effect and the calcification was significant with p values of 0.002 and 0.047, respectively (Table 4). The stent-graft used was not significant. This statistical model showed that the wider diameter aortas needed less load to remove the stent-graft, compared with the narrower aortas; a 95% confidence interval (C.I.) for this difference was (11, 54). The differing calcification levels had a lesser effect on the load needed. The fitted model estimated a 95% C.I. for the extra weight needed by a 15 mm neck over a 10 mm neck to be (60, 128) while a 95% C.I. for the extra weight needed by a 20 mm over a 15 mm neck was (87, 126).

Discussion

It has been proposed that the minimum length of the proximal neck of an abdominal aortic aneurysm compatible with endoluminal stent-grafting is 20 mm.[3] The clinical results of the implantation of endovascular devices up until now would support this but with time, centres are reducing the neck length. It is not clear, however, on what scientific observations these conclusions have been reached. Andrews reported that a mean longitudinal load of 220 g could be applied to three stents suitable for endoluminal stenting of infrarenal abdominal aortic aneurysms (Palmaz, Gianturco, nitinol coil), provided the whole length of the stent was in contact with porcine aortic wall.[4] The traction load was reduced to 166 g and 59 g when the stent/aortic interface was reduced to 20 mm and 10 mm, respectively, by the application of a graft to the outside of the stent. Another seies of experiments investigated proximal neck fixation in human cadaveric aortas.[5] Barbed stent-grafts were deployed and traction applied to achieve longitundinal displacement. It was found that the less severely diseased vessels appeared to withstand less force to cause displacement.

Even when good initial fixation has been achieved, progression of the aneurysmal process has been described.[6] Some experimental work has been performed suggesting self-expanding stents are superior to balloon-expandable in a growing porcine aortic model[7] but further work is required in this field. The distal neck requirements are less clear cut. It had been suggested that there may be no requirement to fix the distal graft of an endoluminal prosthesis[8] but this has subsequently been disproved.[9] With the development of bifurcated prostheses[10] and aorto-uni-iliac stent-grafts combined with a femorofemoral crossover graft,[11,12] abdominal aortic aneurysms with no distal neck or aneurysms extending into the iliac arteries can be managed by endovascular surgery. Indeed, few authorities now advocate the use of aortoaortic devices.

The radial deformation behaviour of one specific stent type and one specific type of deformation is described in this paper. Previous studies have documented several different test methods.[13] These have included a contracting sleeve, a point load (similar to the procedure described here), compression between flat surfaces and external fluid pressure. The method described in this paper differs from other tests measuring the deformation over the entire length of the device[14] and was chosen because the interest was in the forces related to the proximal non-sutured anastomosis. A direct comparison of these data with other published or unpublished data is difficult because of the differences in methodology and equipment used. It is currently uncertain if any of these tests represent any clinically useful information regarding device performance because of the complex loading conditions that exist on the stent-graft *in vivo.* This straightforward deformation test is a relatively simplistic method of characterising relative device performance and can only supply data that can then be considered to be one element of total device performance *in vivo.* Since the nitinol stent is self-expanding, these results suggest that there is a greater radial expansion force produced as the degree of deflection increases. This further supports the theoretical advantage of oversizing the prosthesis.

During the distraction experiment, the most significant factor was found to be the length of the "aneurysm neck" in all analyses. It was to be expected that the longer the "aneurysm neck" the greater would be the weight required to produce migration and this has been confirmed. The predictive effect of the degree of calcification was less obvious and it would appear from these experiments to have only a small effect ($p = 0.047$) and should be viewed cautiously. Only one diameter of stent-graft was used in all subjects and this will have had an effect because of non-uniform under-expansion in the smaller diameter aortas and presumably a reduction in the radial force applied to the "aneurysm neck". It is of relevance that even with only a 10 mm neck length, a mean weight of 215 g was required to produce migration of the stent-graft in this model. This is comparable with the results obtained for the Palmaz, Gianturco and nitinol coil stents described by Andrews[3] when a complete stent was in contact with the aorta.

An end point was described when a 500 g load was applied to the stent-graft and migration did not occur. A greater mean weight would have been achieved if load had continued to be applied until migration had occurred. The repeated deployment and distraction of the stent-grafts into the aorta may have altered the aortic characteristics and had an effect on the traction values, which has not been taken account of in these calculations. The sequential nature of the experiment could raise concern that the shorter necks might be giving low-biased results. This seems unlikely as within each individual cell of values, there was not a pattern of reducing weights. In addition, the result is so strongly significant ($p<0.00001$) that there is not really any doubt as to the validity of this data for this parameter. Despite this, the stent-graft distraction load with a 10 mm "aneurysm neck" length is greater than those forces recorded by Andrews in his study with a stent/aortic interface of 20 mm. It is difficult to relate the values obtained from a pulley system *in vitro* to the longitudinal, pulsatile traction force of a non-Newtonian fluid, blood, *in vivo*, but such a model is difficult to design.

In conclusion, this particular self-expanding nitinol stent-graft appears to produce sufficient anchorage in an aortic neck length of 10 mm to prevent migration when fully deployed in this experimental model. This may have profound consequences upon the number of aneurysms suitable for endoluminal stent-grafting.

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