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◆ EXPERIMENTAL ◆

Endovascular AAA Exclusion: Will Stents With Hooks and Barbs Prevent Stent-Graft Migration?

Martin Malina, MD, PhD; Bengt Lindblad, MD, PhD; Krasnodar Ivancev, MD, PhD*; Mats Lindh, MD*; Janne Malina, MD†; and Jan Brunkwall, MD, PhD

Departments of Vascular Surgery, *Radiology, and †Pathology, Malmö University Hospital, Lund University, Malmö, Sweden

Purpose: To investigate if stents with hooks and barbs will improve stent-graft fixation in the abdominal aorta.

Methods: Sixteen- to 24-mm-diameter Dacron grafts were deployed inside cadaveric aortas. The grafts were anchored by stents as in endovascular abdominal aortic aneurysm repair. One hundred thirty-seven stent-graft deployments were carried out with modified self-expanding Z-stents with (A) no hooks and barbs (n = 75), (B) 4 5-mm-long hooks and barbs (n = 39), (C) 8 10-mm-long, strengthened hooks and barbs (n = 19), or (D) hooks only (n = 4). Increasing longitudinal traction was applied to determine the displacement force needed to extract the stent-grafts. The radial force of the stents was measured and correlated to the displacement force.

Results: The median (interquartile range) displacement force needed to extract grafts anchored by stent A was 2.5 N (2.0 to 3.4), stent B 7.8 N (7.4 to 10.8), and stent C 22.5 N (17.1 to 27.9), $p < 0.001$. Both hooks and barbs added anchoring strength. During traction, the weaker barbs were distorted or caused intimal tears. The stronger barbs engaged the entire aortic wall. The radial force of the stents had no impact on fixation, while aortic calcification and graft oversizing had marginal effects.

Conclusions: Stent barbs and hooks increased the fixation of stent-grafts tenfold, while the radial force of stents had no impact. These data may prove important in future endograft development to prevent stent-graft migration after aneurysm exclusion.

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Migration of stent-grafts used for abdominal aortic aneurysm (AAA) exclusion is a recognized complication of aortic endografting.[1–5] At our center, one third of the AAA patients treated with endografts containing Z-stents with four weak hooks and barbs presented with late migration of the proximal stent.[1] Stent-graft dislodgment ranged from minor (5 to 10 mm) to severe migration with complete descent of the stent-graft into the aneurysm sac, requiring late conversion to open surgery. Recently, other reports have appeared of simi-

Address for correspondence and reprints: Martin Malina, MD, PhD, Department of Vascular Surgery, Malmö University Hospital, S-205 02 Malmö, Sweden. Fax: 46-40-33-73-35

ing the Chuter bifurcated graft,[2] the Corvita endovascular graft (Dereume JP et al. 24th Annual Symposium on Current Critical Problems, New Horizons and Techniques in Vascular and Endovascular Surgery, New York, New York, USA, November 20–23, 1997), the Vanguard system (personal observation), and the Malmö system.[3,4] Late migrations have also been reported when balloon-expanded stents were used for graft anchoring.[5]

As most migrations are diagnosed ≥ 1 year after stent-graft insertion,[4] biological incorporation of endovascular grafts seems insufficient to resist the pulsatile forces present inside the aorta. These observations call for improved mechanical anchoring of stent-grafts. However, many new stent-grafts, such as the AneuRx, Corvita, and Talent devices, are anchored by smooth stents without hooks and barbs or by small barbs only (Vanguard system).

To our knowledge, only two groups have assessed the force needed to dislodge endovascular stent-grafts from cadaveric aortas. In the first study,[6] five different stent types were deployed in healthy porcine aortas, which obviated the assessment of stent function in atherosclerotic vessels. In the second experiment,[7] only Gianturco stents were used. The displacement force was exerted on both the distal and proximal stents of an endovascular stent-graft bridging an aneurysm. Therefore, no definite conclusions could be made about the specific anchoring of the proximal stent.

Prompted by incidences of stent-graft migration[1] and late proximal endoleaks[8] in endovascularly excluded AAAs, we designed this study to assess if stent-graft fixation can be improved mechanically by adding hooks and barbs to the graft-anchoring stents.

METHODS

Dacron grafts (Cooley Verisoft, Meadox Medicals, Oakland, NJ, USA) with diameters of 16, 20, and 24 mm were sutured to self-expandable Gianturco Z-stents (Cook Inc., Denmark), leaving a few millimeters of the stents protruding from the grafts proximally as is usually done for endovascular AAA exclusion (Fig. 1). The stents were 2.5 cm long and 4.5 cm wide in their uncompressed state and consisted of 10 bends of stainless steel wire.

Four different modifications of the Gianturco stents were examined (Fig. 1): (A) smooth stents without any anchoring appendages; (B) stents equipped with 4 weak hooks and barbs (5 mm long and 0.25 mm thick) similar to those used by several groups[4,9] in AAA repair; (C) stents with 8 stronger hooks and barbs (10 mm long and 0.3 mm thick); and (D) 8 reinforced hooks but no barbs. All barbs protruded out from the graft at an angle of about 30°.

The aortas of 15 human cadavers were exposed with minimal dissection and left in situ so as not to disrupt their attachment to surrounding tissue. The vessels were transected about 5 cm proximal to the aortic bifurcation, their proximal end thus mimicking an aneurysm neck. Stent-grafts were deployed 2.5 cm into the transected aortas, a distance corresponding to the length of many AAA necks encountered in clinical practice (Fig. 2). In each case, the entire stent was completely contained within the aorta, allowing all hooks and barbs to engage the vessel wall.

The median age of the cadavers was 66 years (range 46 to 84); half had been smokers and half had a previously diagnosed cardiovascular disease. The aortic walls were macroscopically classified into five groups: (I) nonatherosclerotic, (II) soft intimal thickening, (III) calcified plaques engaging part of the aortic circumference, (IV) circumferentially located calcified plaques, and (V) completely calcified, incompressible aortas.

The sample size of the different stent types was dictated by the experimental setting. Stents without hooks and barbs that did not disrupt the aortic wall were assessed first. Then, in the same aortic segment, stents with weaker hooks and barbs were tested. Because these stents caused damage to the aortic wall, only a limited number of trials could be performed in each aortic segment. Finally, the stents with reinforced hooks and barbs and hooks only were tested until the aortic wall was severely damaged. Thereby, stents with extra long and thick anchoring appendages were always assessed last, when the aortas offered the least anchoring support. In this manner, attachment of stents with hooks and barbs was not favored.

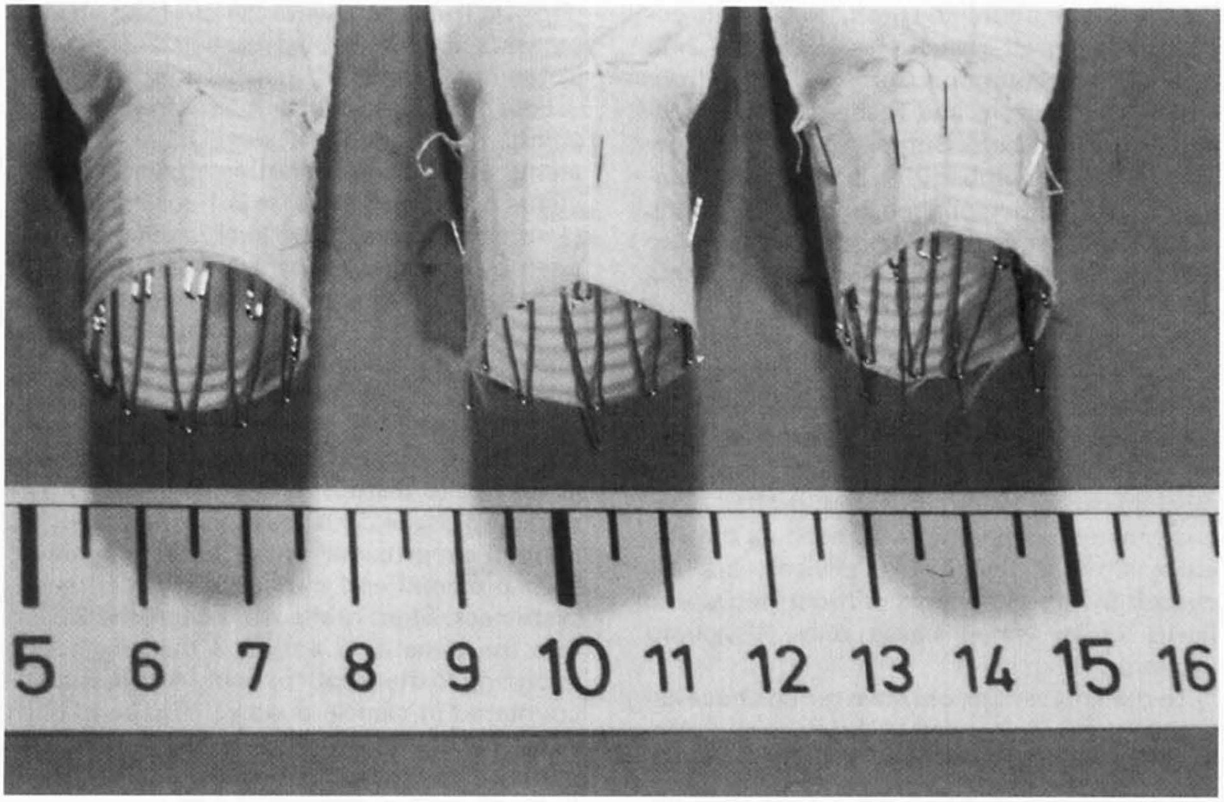

Figure 1 ◆ Three of the four types of Z-stents evaluated in this study: smooth stent (left), stent with four weak hooks and barbs (middle), and a stent with eight strengthened hooks and barbs (right). The barbs protrude through the grafts. Not pictured is the stent with eight reinforced hooks only.

Longitudinal traction then was applied to the distal end of the grafts (Fig. 2) and measured by a tensiometer. The traction was increased gradually by steps of 0.5 N until the stent-grafts were dislodged from the aorta, thereby defining the displacement force. After extraction from the aorta, the stents were examined for deformation of the appendages and the aortas for intimal or transmural injury. The damaged portion then was excised and additional measurements were taken more proximally. This was repeated until the level of the renal arteries was reached. In this fashion, the smooth stents were tested on 75 occasions, the design with 4 hooks and barbs in 39 instances, the model with 8 hooks and barbs 19 times, and the 8 hooks only were tested on 4 occasions.

The radial force exerted by the stents was assessed with a tonometer (Ophtalmo Dynamomètre du Dr Bailliart, Guilbert & Routit, Paris, France) by measuring the force required to compress the stents 2 and 4 mm (Fig. 3). The measurements were carried out with the stents compressed inside grafts that measured 16, 24, and 36 mm wide. To avoid lateral bulging during measurement, the sides of the graft were supported.

Nonparametric data were analyzed as median and interquartile range (IQR). The Wilcoxon rank sum test was used for comparing two groups; three or more groups were compared using the Kruskal-Wallis test. Differences were considered significant at $p < 0.05$.

RESULTS

Stent-grafts were implanted 137 times inside the 15 infrarenal aortas. The median force needed to extract the stent-grafts with smooth Gianturco stents was 2.5 N (IQR 2.0 to

3.4) (Fig. 4). The corresponding displacement force for the Gianturco stents with 4 weak hooks and barbs was 7.8 N (IQR 7.4 to 10.8), while the stents with 8 reinforced hooks and barbs required a median force of 22.5 N (IQR 17.1 to 27.9) ($p < 0.001$). Z-stents with 8 strong hooks but no barbs had a displacement force of 11.8 N (IQR 10.4 to 13.0) compared to 22.5 N for stents with both hooks and barbs ($p < 0.01$).

In every segment of cadaveric aorta, the stent-graft fixation was compared with the first and last time each type of stent was used. The median displacement force was slightly higher on the first occasion ($p = 0.2$). Hence, the fixation of the stents with hooks and barbs was not favored in this experimental setting because these stents were always assessed last.

The weaker hooks and barbs engaged the thickened media but did not penetrate the entire aortic wall. The dislodgment occurred by two mechanisms: upward distortion of the barbs upon traction until the angulation of the barbs was such that they could slide out of the aortic wall or by tearing of the intima. Often, pieces of atherosclerotic intima could be seen on the hooks and barbs of the extracted stents. In contrast, the reinforced hooks and barbs engaged the entire aortic wall, frequently perforating it and emerging outside the vessel wall (Fig. 2). Upon powerful traction, these barbs would also become deformed or cause a transmural tear of the aorta different from the limited intimal injury produced by the weaker barbs.

Oversizing the graft diameter increased slightly the displacement force but only for stents without hooks and barbs ($p < 0.01$). Stents with hooks and barbs retained their strength of fixation even when the grafts were undersized by 1 or 2 mm. Smooth stents had marginally stronger fixation in increasingly

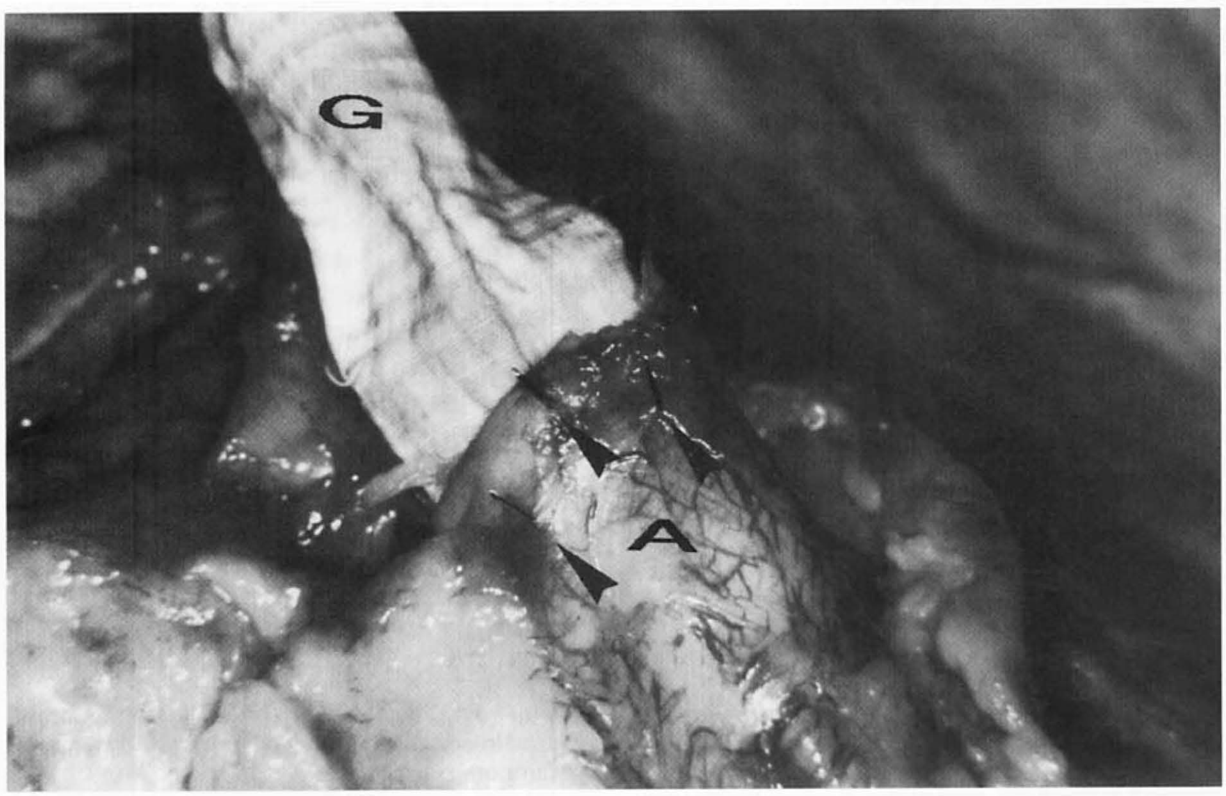

Figure 2 ◆ Stent-grafts were deployed 2.5 cm into transected cadaveric infrarenal aortas (A) in situ to avoid disruption of the aortic attachment to surrounding tissue. Longitudinal traction then was applied to the distal end of the grafts (G). Upon traction, the enforced barbs (arrows) penetrated the aortic wall.

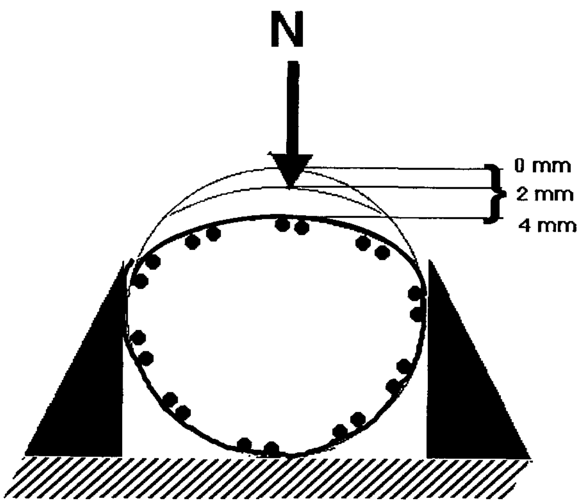

Figure 3 ◆ The radial force of stents at various states of compression was assessed by placing the stents inside grafts of different diameters: The force (N) needed to make a further 2- and 4-mm depression of the stents was measured by a tonometer. To avoid lateral bulging during measurements, the sides of the stent were supported.

atherosclerotic aortas, while the displacement force for stents with hooks and barbs was unaffected by the aortic calcification.

The radial force of the Z-stents was greater the more the stents were compressed (Fig. 5).

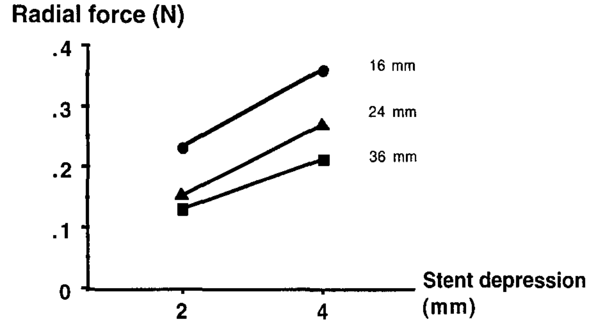

Figure 5 ◆ Radial force of stents contained within 16-, 24-, and 36-mm grafts. Stents compressed to a diameter of 16 mm exerted a radial force almost twice that seen when compressed to 36 mm. The force required to make a 4-mm depression into the stents was twice that of making a 2-mm depression regardless of the degree of compression. Each point is based on data from 6 registrations.

Thus, the radial force of stents contained within 16-mm grafts was almost twice that of stents in 36-mm grafts. Similarly, the force needed to compress the stents 4 mm with the tonometer was almost twice that needed to compress them 2 mm, regardless of the diameter of the graft containing the stent. By comparing the fixation of stents in aortas of differ-

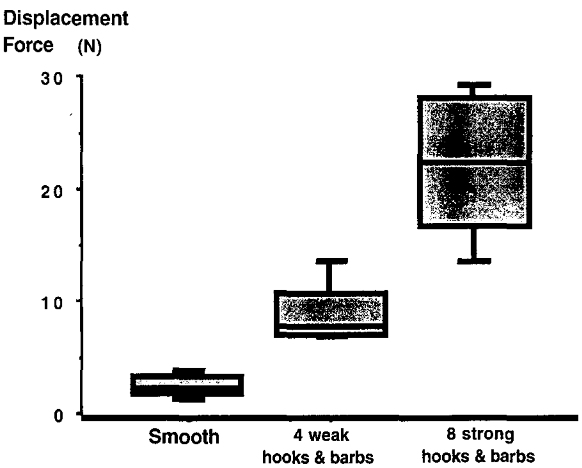

Figure 4 ◆ The force required to displace 3 different Z-stent modifications from cadaveric aortas (n = 75, 39, and 19, respectively). Medians, interquartile ranges (within box), and 10th and 90th percentiles (horizontal bars) are shown.

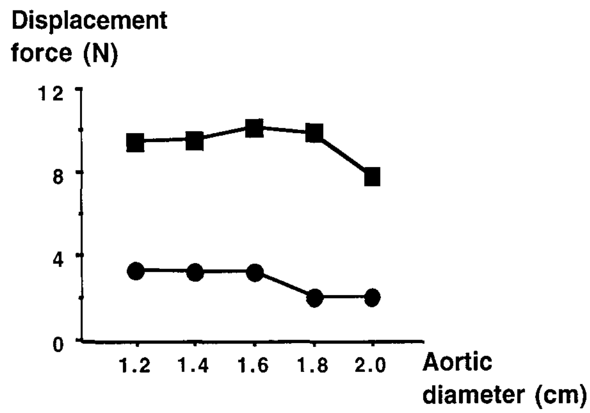

Figure 6 ◆ Displacement force for stent-grafts placed in aortas of various diameters and anchored by smooth stents (circles) or by stents with 4 hooks and barbs (squares). The stents (n = 72) exerted a greater radial force in small aortas, yet the displacement force was equal at all aortic diameters and therefore unaffected by the radial force of the stents.

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