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Frame Dislocation of Body Middle Rings in Endovascular Stent Tube Grafts

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Objectives: *to understand the cause, and propose a mechanism for frame dislocation in endovascular grafts.*
Materials and methods: *five tube grafts were explanted due to secondary distal leakage 15–21 months after operation. One bifurcated graft was removed during emergency operation after aortic rupture caused by secondary leakage. A second bifurcated graft was harvested from a patient with thrombotic occlusion of one limb, who died after transurethral prostatic resection. The inside of the grafts were examined endoscopically. The stent was inspected after removal of the fabric, broken ligatures were counted and examined by scanning electron microscopy. The fabric strength was tested by probe puncture.*
Results: *we found 17–44% of the stent ligatures of the body middle rings to be loose. The knots were intact. Degradation of the polyester textile was not observed.*
Conclusions: *continuous movements in the grafted aorta and blood pressure impose permanent stress to the stent frame and the polyester fabric resulting in morphological changes in the body middle ring of grafts. The clinical implications of the suture breakages are unknown although they may be related to distal secondary leakage in tube grafts.*

Key Words: Endovascular stent grafts; Dislocation; Secondary leakage.

Introduction

The endovascular repair of abdominal aortic aneurysms has rapidly increased since the successful implantation of an aortic stent graft by Parodi 1990.[1–5] In order to learn more about the future fate of endovascular grafts implanted in humans explanted grafts require close examination. The mechanism of failure depends on the type of device used. In this paper we present our first findings on explanted Stentor™ (MinTec, Bahamas) endovascular aortic grafts. We attained the explants from three centres; in the Department of Vascular Surgery, Städtisches Klinikum Süd in Nürnberg, 96 tube grafts and 19 bifurcation grafts were implanted between August 1994 and August 1996, in the Department of General and Vascular Surgery, Städtische Kliniken Frankfurt-Höchst, Frankfurt am Main, 10 tube grafts and 80 bifurcation grafts were implanted between August 1994 and July 1996, and in the Department of General, Vascular and Thoracic Surgery, General Hospital of Harburg, Hamburg four Stentor™ bifurcation grafts were implanted until July 1996.

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Materials and Methods

One of the late complications observed has been secondary leakage due to dislocation of the distal portion of the graft.[7,8] Conventional X-ray examinations (Fig. 1) have shown marked kinking of the prostheses and distraction of adjacent stent frames resulting from suture breaks.

Between 1996 and 1997 we collected seven explanted Stentor™ grafts, which are listed in Table 1. All grafts had been implanted in the infrarenal aorta because of AAA. In five cases secondary leakage led to the reoperation and explantation of the graft after 15–21

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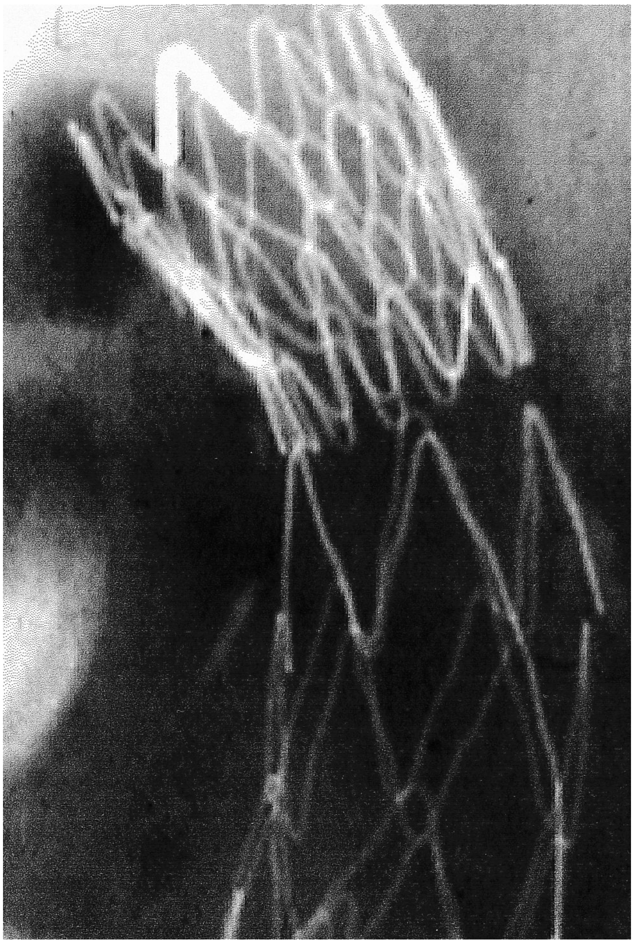

Fig. 1. A conventional X-ray of a dislocated graft during post-operative follow-up.

months (average 18 months). In one of these cases a leak lead to the reperfusion and rupture of the AAA after 16 months. In a further case one limb of a bifurcation graft occluded during transurethral prostate resection, presumably due to the extreme flexion in the hip joint for approximately 1 h combined with low flow due to considerable hemorrhage.

Explant cleaning and endoscopic examination

The outside of the formalin fixed, explanted grafts was photographed. The inspection of the inside was performed using a resectoscope (Storz, Tuttlingen, Germany) and the entire examination was captured on video. The explants were surrounded by tissue. Larger pieces were carefully removed using forceps before washing the graft. For the washing procedure we used an enzyme-detergent (TERG-A-ZYME, Alconox, New York, U.S.A.). This cleaning procedure has been proposed for polyester grafts by Berger and

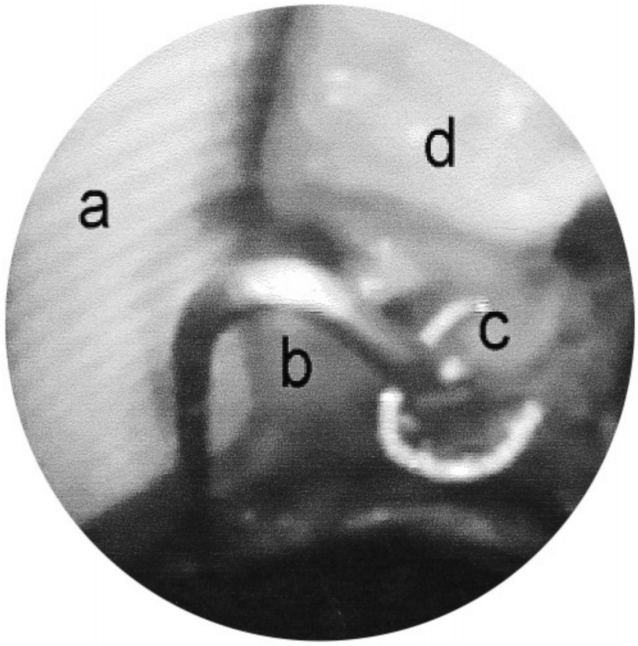

Fig. 2. An endoscopic view of the inside of an explanted stent graft with an incomplete layer of tissue (d) revealing the polyester textile (a), a disconnected wire frame (b) and a loose, fractured ligature (c).

Sauvage.[9] As recommended, 3.75 g of detergent were dissolved in 500 ml of water. The grafts were left in this solution at 45 °C for 5 days. The clean specimens were then thoroughly rinsed in cold water and dried at room temperature for at least 24 h. To examine the stent, the covering polyester textile was removed. The ligatures were viewed with a stereo microscope. Intact and broken or missing ligatures were counted.

Scanning electron microscopy

Scanning electron microscopy (SEM) was performed to investigate the fractured ligatures. Images were acquired on a Leitz ISI scanning electron microscope (Leitz, Germany) using an accelerating voltage of 10 kv. Gold coating was necessary. Multiple random photographs were obtained at several magnifications.

Probe puncture test

The polyester textile covering of the grafts was fixed by ligatures on the upper and lower body ring and the large part in between could then easily be removed for examination. The probe puncture test is described in ISO 7198–2 for cardiovascular implants and tubular vascular prostheses.[6] The modified test device was set

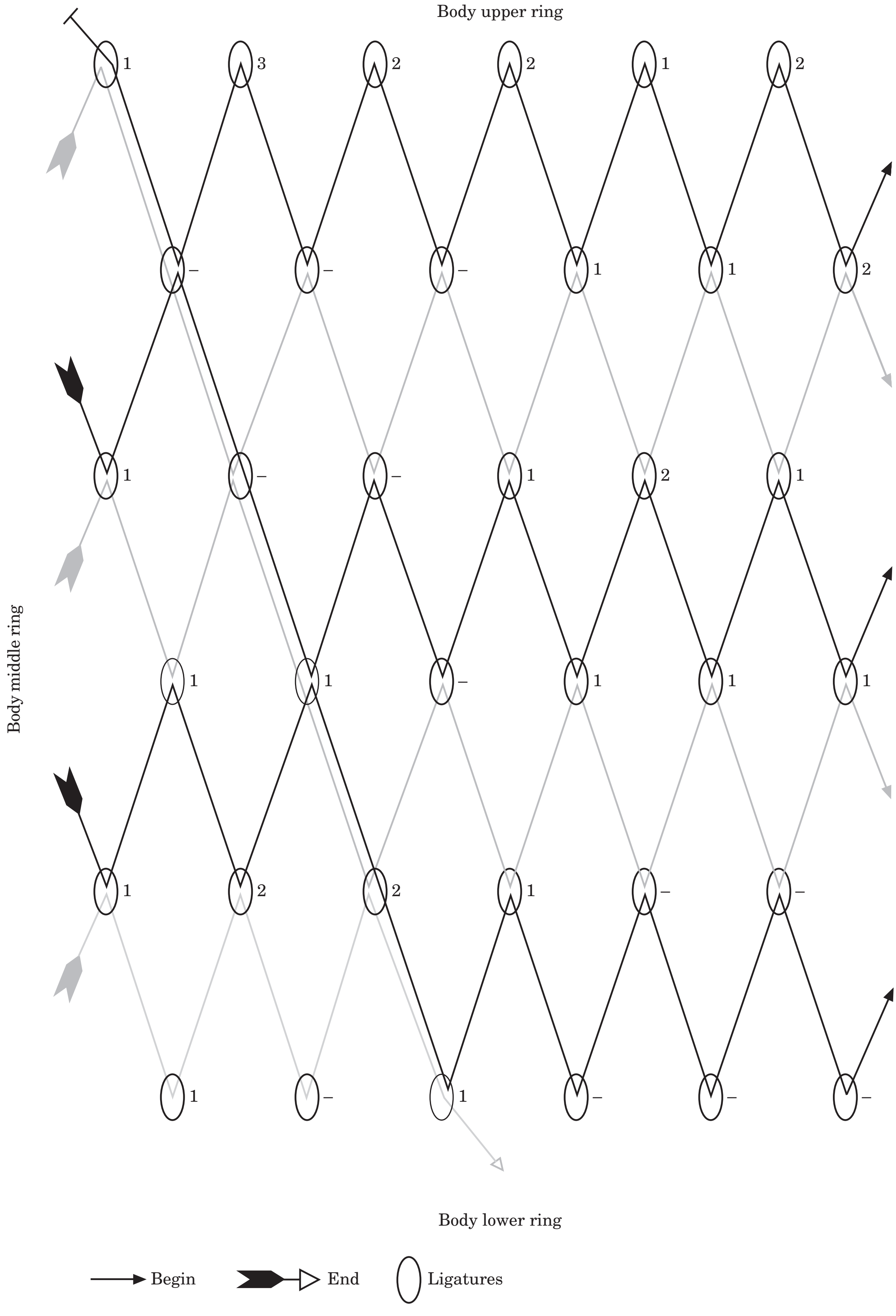

Fig. 3. The scheme of a longitudinally cut open body middle ring showing the continuous "zig-zag" of the stent wire and the connecting ligatures. The numbers next to the ligatures indicate the number of missing ligatures in the four examined explants.

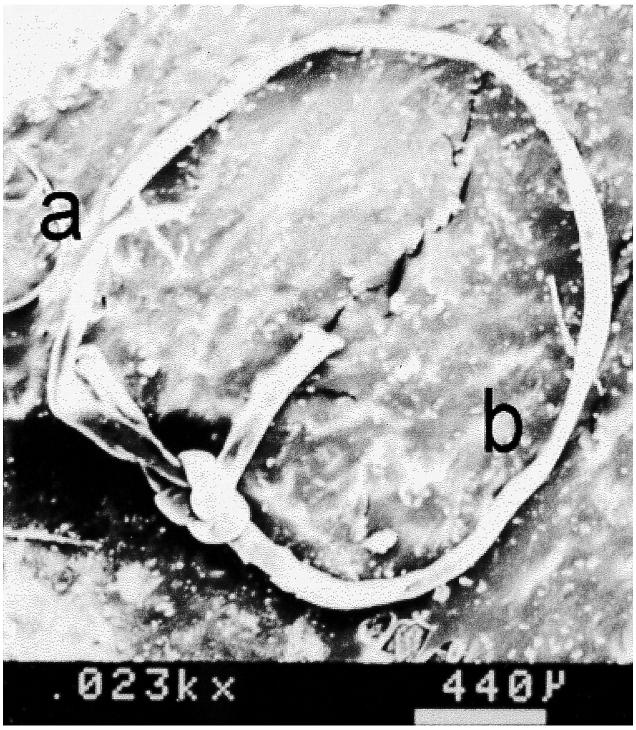

Fig. 4. Scanning electron microscopy of a ruptured ligature showing the location of the rupture (a), the intact knot and the thinned segments (b).

up on a ZWICK 1120 material testing machine (Zwick GmbH & Co, Ulm, Germany). The cylinder-shaped indenter measured 48 mm in diameter and had a polished, hemispherical ending. The circular specimen holder was equipped with a polyvinylchloride ring to prevent slipping of material. The indenter penetrated the material with a velocity of 70 mm/min. Three tests were performed on each of the samples.

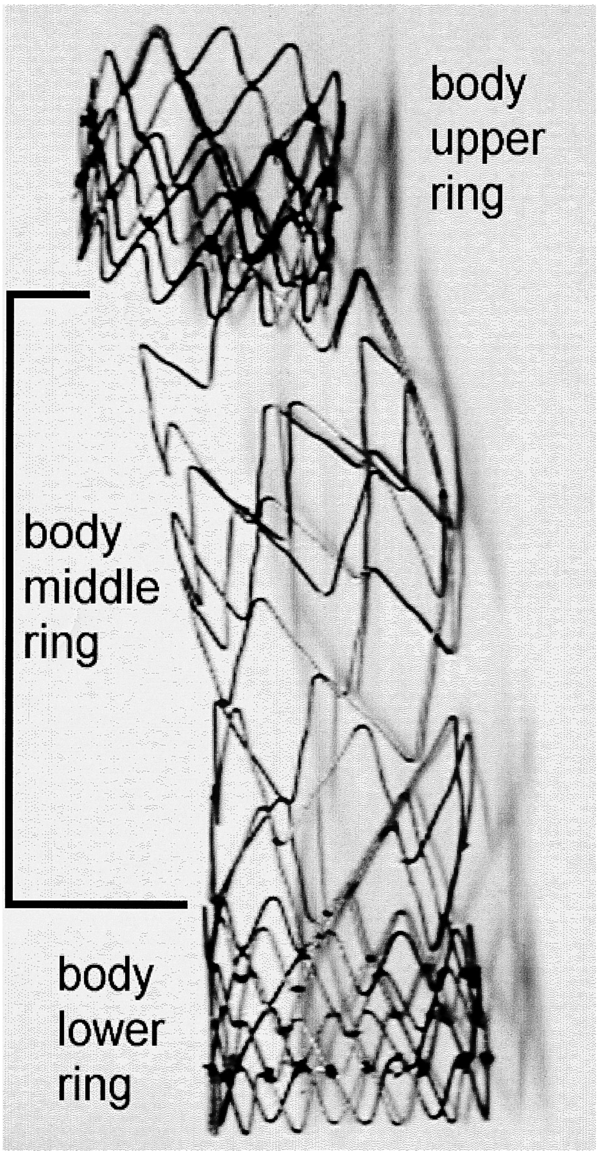

Fig. 5. An explanted, 15-month-old endovascular graft (Stentor™, MinTec, Bahamas) after removal of the outer polyester fabric, showing the kinking of the graft and multiple dislocated frames.

Results

Endoscopic explant examination

The endoscopic examination was performed on the formalin-fixed explants before the cleaning procedure. The internal walls of the grafts were mostly covered by a layer of pseudointima. In some areas, where the graft was kinked, the covering was very thin or broken up, revealing bare stent wire and the outside polyester textile. Where there was a missing ligature, some of the stent wires protruded far into the lumen of the graft (Fig. 2).

The examination of the ligatures revealed that damaged or missing ligatures were only found in the body middle ring. Six of the explants had body middle rings. Four of these could be examined (Nos 179, 252, 254 and 264). The other two explants (Nos 251, 236) were destroyed during explantation or examination. The 5-month-old bifurcation graft (No. 179) showed no destroyed ligatures. The three tube graft body middle rings each had 36 possible ligatures, of which 17–44% were missing (Table 2). In Fig. 3 the location of the missing ligatures is shown on an illustration of a longitudinally cut open body middle ring. The highest number of missing ligatures was observed on the junction to the body upper ring. The body upper ring is fixed to the artery by small barbs.

Table 1. The seven explanted Min Tec™ Stentor™ grafts, their duration of implantation and the cuase of explantation.

No	Age (months)	Graft type	Cause of explantation
179	5	Stentor™ bifurcation	Occlusion after transuretral prostate resection, death
190	5	Stentor™ tube	Limb of bifurcation No. 179 (see 179)
236	20	Stentor™ tube	Dislocation, secondary distal anastomosis leakage
251	16	Stentor™ bifurcation	Secondary leakage, AAA rupture
252	20	Stentor™ tube	Dislocation, secondary distal anastomosis leakage
254	21	Stentor™ tube	Dislocation, secondary distal anastomosis leakage
264	15	Stentor™ tube	Dislocation, secondary distal anastomosis leakage

Table 2. The results of the probe puncture test using a 48 mm thick cylindrical, hemispherically tipped indenter, penetrating at 70 mm/min. The max. burst strength is stressed in $n \pm$ standard deviation. Furthermore, the thickness of the polyester and the percentage of missing ligatures is listed.

No	Age (months)	Wall thickness (mm)	Missing ligatures	Max. burst strength (n)
179	5	0.16	0%	114.5 ± 7.8
252	20	0.16	28%	114.3 ± 3.0
254	21	0.16	44%	109.9 ± 8.2
264	15	0.16	17%	118.9 ± 5.3

Scanning electron microscopy

The electron microscopy of several damaged ligatures showed that intact knots and ruptures of the ligatures outside the knot (Fig. 4). Apart from the rupture, the ligatures also had segments which were visibly thinner than others.

Probe puncture test

This test does not reproduce the physiological loading on an implanted graft. It allows the comparison of the mechanical properties of explant material of different ages, looking for differences due to degradation during implantation. Four of the seven explants in this study could be tested (Table 2). The results showed no difference between the maximum burst strength of the 5-month-old and the 15, 20 and 31-month-old explants.

Discussion

Stentor™ (MinTec, Bahamas) endovascular aortic stent grafts (Fig. 5) consist of an internal, self-expanding stent and an approximately 0.16 mm thin, woven polyester fabric on the outside. The stent is constructed of a zig-zag shaped nitinol wire spiral, held in place by multiple approximately 0.09 mm thick polypropylene ligatures. These ligatures are wound around the wire three times and closed with knots, which are fused by heat to prevent unravelling. Three different segments of the stent are defined. The body upper ring has external hooks for fixation of the proximal anastomosis and small gaps between the wire zig-zag of approximately 6×10 mm size. The body middle ring has wide gaps of approximately 11×22 mm size between the wires. This section of the stent prevents collapse or torsion on the surrounding fabric during the implant procedure. The body lower ring is similar to the upper ring, but has no external hooks. Tube grafts consist of a longer body middle ring than bifurcation grafts.[10]

Amongst the examined explants, frame dislocation was only observed in the body middle ring of aortic tube grafts. We found 17–44% of the ligatures of the body middle ring to be loose. It was previously supposed that the ligatures would stay in a "pig-tail" shape on the wire beneath an internal pseudointima.[10] The endoscopic examination of the explants contradicts this. Figure 2 shows the broken up pseudointima, revealing a dislocated wire frame, ligation and uncovered, outer polyester material. It is not known if the missing ligatures were lost during the explantation despite the careful treatment of the explant. Complications due to distal embolisation of ligatures have so far not been reported.[10]

Degradation of the polyester fabric is known to take

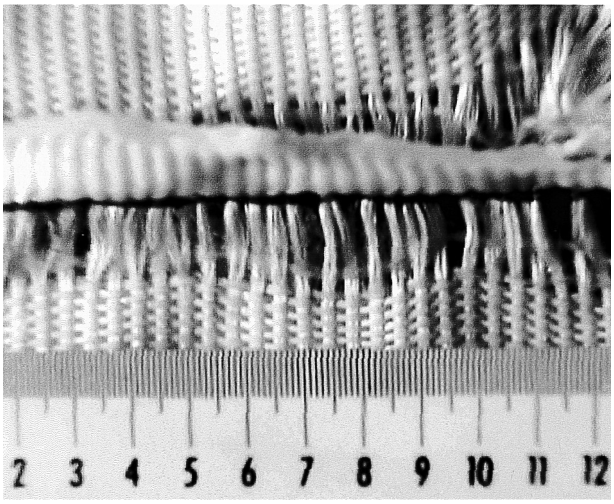

Fig. 6. The seam of the polyester fabric of a stent graft with multiple holes (scale in mm).

place in conventional surgery after 10–20 years of implantation, weakening the textile material and leading to rupture.[11] In our probe puncture examinations we found no sign of degradation of this polyester material within 21 months of implantation. The woven polyester textile is turned into a tube using a polypropylene suture. Along the suture line multiple holes were seen (Fig. 6).

In the light of our findings we wish to propose a mechanism of tube stent graft failure. The pulsatile blood circulation and movement of aorta lead to micromovements of the stent wires. The most movement takes place in large frames of the body middle ring. The twisting of the wires within the ligatures leads to wear and finally fatigue with rupture of the ligatures of the frames of the body middle ring. These suture breaks may play a role in secondary graft failure. The longitudinal strength of the graft is weakened and kinking may become more likely. It was postulated (Raithel) that this instability allows the distal anastomosis, which in contrast to the body upper ring has no external fixation mechanism, to slip up, causing a secondary leakage and a Z-shaped kinking of the graft. This kinking of the stent can be observed in conventional X-ray examinations (Figs 1 and 5).

Theoretically this failure mechanism could be prevented by a better fixation of the distal anastomosis either by similar barbs as used proximally, or a continuous narrow gapped stent structure in the body middle as used in the upper and lower ring or the limbs of bifurcation grafts. The elasticity of the ligatures material must be addressed. The security of the distal anastomosis also depends on the suitability of the distal neck of the infrarenal aneurysm. An unsuitable, short and conical neck leads to a high risk of dislocation.[10] In general, bifurcated grafts should be preferred for endovascular grafting. Only small and saccular aneurysms seem to be suitable for straight tube grafts, as follow-up reveals.

Damage to the explants during reoperation is possible. The grafts 179 and 190 (Table 1) were explanted post-mortem. Graft 251 was removed during an emergency operation and thus damaged. The grafts 236, 252, 254 and 264 were explanted by the same surgeon. The aorta was clamped subdiaphragmal, the stent grafts were carefully loosened digitally in order to prevent damage by instruments. A preoperative conventional X-ray demonstrating frame dislocation was not performed routinely on the early follow-ups. Today the conventional X-ray has become an irreplaceable part of the postoperative follow-up, showing *in vivo* stent frame dislocations (Fig. 1).

The Stentor™ endovascular graft has been implanted several hundred times worldwide. Although the device has been modified into the Vanguard™ graft, it is important to know about the possible fracture of ligatures of the stent dislocation in order to be able to interpret conventional X-ray findings during the follow-up of Stentor™ graft. The ability of the stent wires to slip diagonally within the intact ligatures is an intentional property of the graft design and must be differentiated from the stent wire dislocation due to fracture of ligatures.

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