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Three Year Single Centre Experience with the AneuRx Aortic Stent Graft

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Objectives: to report the mid-term single-centre experience with the AneuRx self-expandable nitinol stentgraft for endovascular aneurysm repair.

Patients and Methods: between December 1996 and January 2000 a total of 128 patients were treated with an AneuRx bifurcated stentgraft. Of these, 77 patients had a minimum follow-up of 12 months. Patient operative and follow-up data were prospectively gathered.

Results: two (3%) conversions were necessary. Median hospital stay was 3 days. One superficial wound infection occurred. Periprocedural (30 days) mortality was 5% (four patients). Three graft occlusions were noted of which two required treatment. Fifteen patients developed 18 endoleaks (six type 1, eight type 2 and four type 3). Type 1 and type 3 endoleaks were treated by extension cuffs. Four type 2 endoleaks were treated with embolisation or direct lumbar puncture. Two-year freedom from endoleak was 76%. Graft migration occurred in six cases, resulting in a 2-year freedom from migration of 90%, kinking only once.

Conclusions: endovascular AAA treatment is feasible and so far mid-term results are without major problems. Extensive follow-up is essential as secondary problems may occur later. Long-term results are to be awaited.

Key Words: AAA; Endovascular repair; Stentgraft; Mid-term results; AneuRx; Endoleak.

Introduction

Since the first endovascular aneurysm repair in humans by Parodi in 1991¹ many different stentgrafts have been designed.^{2–12} It is still not clear which system provides the best long-term results. Of all the commercially available products the longest experience is with the EVT (currently named Ancure device) of Guidant Corporation and the Vanguard of Boston Scientific Corporation. Mid-term fixation stability results of the EVT device were published earlier.^{13,14} Most reports on the AneuRx device are descriptions of short-term results.^{15–17} The longest described experience is the FDA study published by Zarins *et al.*¹⁸ In many reports results are described of multicentred studies or with mixed data from registries. Advantage of these multicentred studies is the relatively large amount of patients included in a relatively short time span. Disadvantage is the variety of centres, each with different experience

and a large number of treating physicians. Each centre has to go through its own learning curve and this may influence outcome. In our opinion, although the numbers may be a little smaller, it is also very valuable single centre experiences. The aim of this study is to describe our experience with the AneuRx stentgraft.

Patients and Methods

As the AneuRx stentgraft has a maximum diameter of 28 mm and a delivery system of 21 Fr, inclusion criteria were a minimum diameter of the access vessels of 7 mm and a maximum diameter of the infrarenal neck of 25–26 mm. Preoperative evaluation included contrast enhanced helical CT scan (Philips Tomoscan SR 7000, Philips Medical Systems, Best, The Netherlands) and intra-arterial or intravenous DSA (Philips Integris C 3000, Philips Medical Systems, Best, The Netherlands). During implantation fluoroscopy, angiography (Philips OPC 9, Philips Medical Systems, Best, The Netherlands) and intravascular ultrasound (IVUS)

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with the Hewlett Packard HP 500 machine (Hewlett-Packard, Andover, Massachusetts, U.S.A.) and a 6.2 Fr/12.5 MHz IVUS monorail catheter (Sonicath, Meditech – Boston Scientific Corporation, Maple Grove, MN, U.S.A.) were used. Preoperatively, all patients received 1500 mg cefuroxime intravenously and a bilateral vertical groin incision was performed. For intraoperative angiography and IVUS measurements a 7 Fr introducer sheath was inserted by puncture in the common femoral artery followed by a transverse arteriotomy in the common femoral artery to introduce the delivery system of the stentgraft. After measurements, but before introduction of the delivery system, 5000 IU of heparin were given intravenously. A superstiff Backup Meier guidewire (Schneider Corporation – currently Boston Scientific Corporation, Bülach, Switzerland) was used. After deployment of the stentgraft and after satisfying completion angiography the arteriotomies were closed with a running Prolene 5.0 (Ethicon Inc., a Johnson & Johnson Company, Somerville, NJ, U.S.A.) suture. The wound was closed with a running Vicryl 4.0 (Ethicon) subcutaneous suture and a VicrylRapide 4.0 intracutaneous suture. No drains were left *in situ*. Follow-up consisted of early phase contrast enhanced CT scanning predischARGE (day 2) and at 3 months and 12 months postoperatively and annually thereafter. At 6 months duplex scanning was performed. Endoleaks were classified according to the classification proposed by White *et al.*^{19–21}

As the short-term one year results were published earlier the focus of this study is on the mid-term results and behaviour of the stentgraft. Therefore only patients with at least 12 months of follow-up were included in this study. Between December 1996 and January 2000 128 patients were treated with an AneuRx bifurcated stentgraft. A total of 77 patients had a minimum follow-up of 12 months. Of this group 75 were men and two women. Mean age was 70 (range 51–87) years. ASA classification was 54% ASA 2, 42% ASA 3, 4% ASA 4. Forty-five patients had follow-up of 24 months and 11 patients of 36 months. All patients were operated on under general anesthesia by a team consisting of one vascular surgeon and one interventional radiologist. In total only three different vascular surgeons and three different interventional radiologists were involved in all procedures. Intraoperative problems, hospital stay, wound complications, early and late graft occlusion, endoleak, graft migration, graft kinking and secondary interventions were prospectively noted. All data were put in the Eurostar registry and results of these data are published in this paper.

Results

During follow-up one patient was lost to follow-up, because of terminal pulmonary disease. Four (5%; 95% confidence interval: 1–13%) patients died within 30 days of the operation. Another 10 patients died within 1 year after the procedure, one died during the second and none died the third year of follow-up. None of the deaths were device or aneurysmal disease related. Fifty-three percent had cardiac related deaths, 47% died because of progression of co-existing disease (cancer or pulmonary dysfunction) or general condition (elderdom).

Intraoperative problems

Deployment of the graft was technically successful in all but three cases. In two (3%; 95% CI: 0–9%) cases intraoperative conversion was necessary. In one of these cases it appeared impossible to insert the deployment system past a bilateral very narrow and calcified external and common iliac artery. Predilatation could not resolve this problem. Conversion was performed uneventfully. In the other patient after deployment of the main segment of the modular stentgraft it appeared impossible to manipulate a guidewire past a very narrow distal aneurysmal neck. The deployed limb of the main graft already occluded the lumen of the distal neck. Efforts by using a brachial approach to manipulate the guidewire between graft and arterial wall were unsuccessful. At conversion attempts were made to manipulate the guidewire with manual assistance past the occluded lumen, but appeared impossible. Uneventful full conversion was completed. In a third case deployment was performed suprarenal and laparotomy was performed with the intention to perform a conversion. After laparotomy but before exposing and clamping the aorta it was decided to try to resolve the problem with endovascular techniques. We managed to pull the stentgraft to a just infrarenal position by inflating a 25 mm aortic balloon just above the flow divider of both limbs. With gently pulling forces it was possible to manipulate the stentgraft in the right position and a full conversion could be avoided. In this patient no postoperative renal impairment occurred.

Hospital stay

All patients underwent an in hospital predischARGE spiral CT scan. Median hospital stay was 3 days (range

1–44). Delayed hospital stay of more than 5 days occurred in 13 patients. Four patients because of fever without objective signs of infection, one patient had a small endoleak which was observed and resolved on duplex scanning on day 6, in one patient a *de novo* lung cancer was diagnosed and analysed, one patient had persistent hypertension and cardiac problems requiring in-hospital treatment, one patient had a superficial wound infection, one patient required a laparotomy because of renal artery occlusion by the stentgraft which was finally resolved with endovascular technique (see also sector intraoperative problems), one patient had neuralgia which prolonged hospital stay, one patient developed diverticulitis which was treated conservatively. Finally in two cases no explanation for prolonged stay could be found in the patient's records.

Wound complications

In all but one patient the groin incisions healed uneventfully. In one patient a superficial wound infection occurred. This was treated by removal of skin stitches and antibiotics. No deep infection or graft infection occurred, neither at follow-up.

Graft occlusion

At follow-up three limb graft occlusions were noted. One patient with a pre-existing tight iliac artery stenosis and extensive collateral circulation developed a limb occlusion with only slight increase of claudication symptoms. It was decided to accept this occlusion without further treatment. The other patient developed an acute occlusion of one limb 6 months after graft implantation, which was treated with fibrinolysis using urokinase. After successful fibrinolysis a narrowing of the graft was found at a pre-existing stenosis in the common iliac artery. This was treated with PTA and the vessel is patent up to now. Primarily at implantation this stenosis was recognised but considered as insignificant. This appears to have been a misjudgment. One patient required successful thrombectomy. This resulted in a primary patency of 98%, and secondary patency of 99% after 2 years.

Endoleak

For endoleak detection contrast enhanced spiral CT scan was used. In case a type-1 or type-3 endoleak

was found, the patient was scheduled for repair or intervention on a short time basis. In type-2 and type-4 endoleak our policy is either to perform an embolisation or use a wait and see policy. In seven patients (6%) six type-1 endoleak were found (one at 6 months, three at 1 year and two at 2 year follow-up) and four type-3 endoleak were found (one at 3 days, two after 1 year and one after 2 years). Three patients had both a type-1 and type-3 endoleak. In two patients it was discovered at the same time (after 1 year) in the other there was a time interval of 1.5 years between the two interventions. In one patient within one week after operation an extension cuff was placed at the connection between main body and iliac limb because of inappropriate placement of the iliac limb that was not noted at the time of operation. These type-1 and type-3 endoleaks were treated with either extension cuffs or interposition grafts (Fig. 1). All reinterventions were successful. A total of eight type 2 endoleaks were noted. Four patients are being evaluated. In four patients with a type-2 endoleak successful treatment was performed. Two patients were treated with direct CT guided translumbar puncture in the aneurysm and open lumbar artery and α -amino capronic acid was injected (Fig. 2). In two patients embolisation of the IMA was performed by selective catheterisation via the SMA and Riolan's arcade (Fig. 3). All secondary interventions were successful without recurrence of endoleak at the treated site at follow-up. No mortality was seen in association to reinterventions. No delayed ruptures of the aneurysm were seen. Two-year freedom from endoleak was 76% (Fig. 4).

Graft migration

Graft migration could be demonstrated in six patients (Fig. 5). In two patients a slight displacement at the proximal attachment sight was seen resulting in an endoleak. This was treated with an aortic extension cuff. In both patients the preoperative neck diameter was 26 mm and they were treated in the beginning of this series. Our policy since then is to include only patients with a maximum diameter of 25 mm. In one patient one iliac limb "popped" out of the common iliac artery into the aorta 6 months after the operation. In this patient the distal limb was placed too short in the common iliac artery resulting in only 5-mm attachment zone. At operation this was accepted but after shrinkage of the aneurysm it proved to be a too short anchoring zone and dislocation occurred. This was treated with an extension cuff.

In three other patients in whom a proximal endoleak

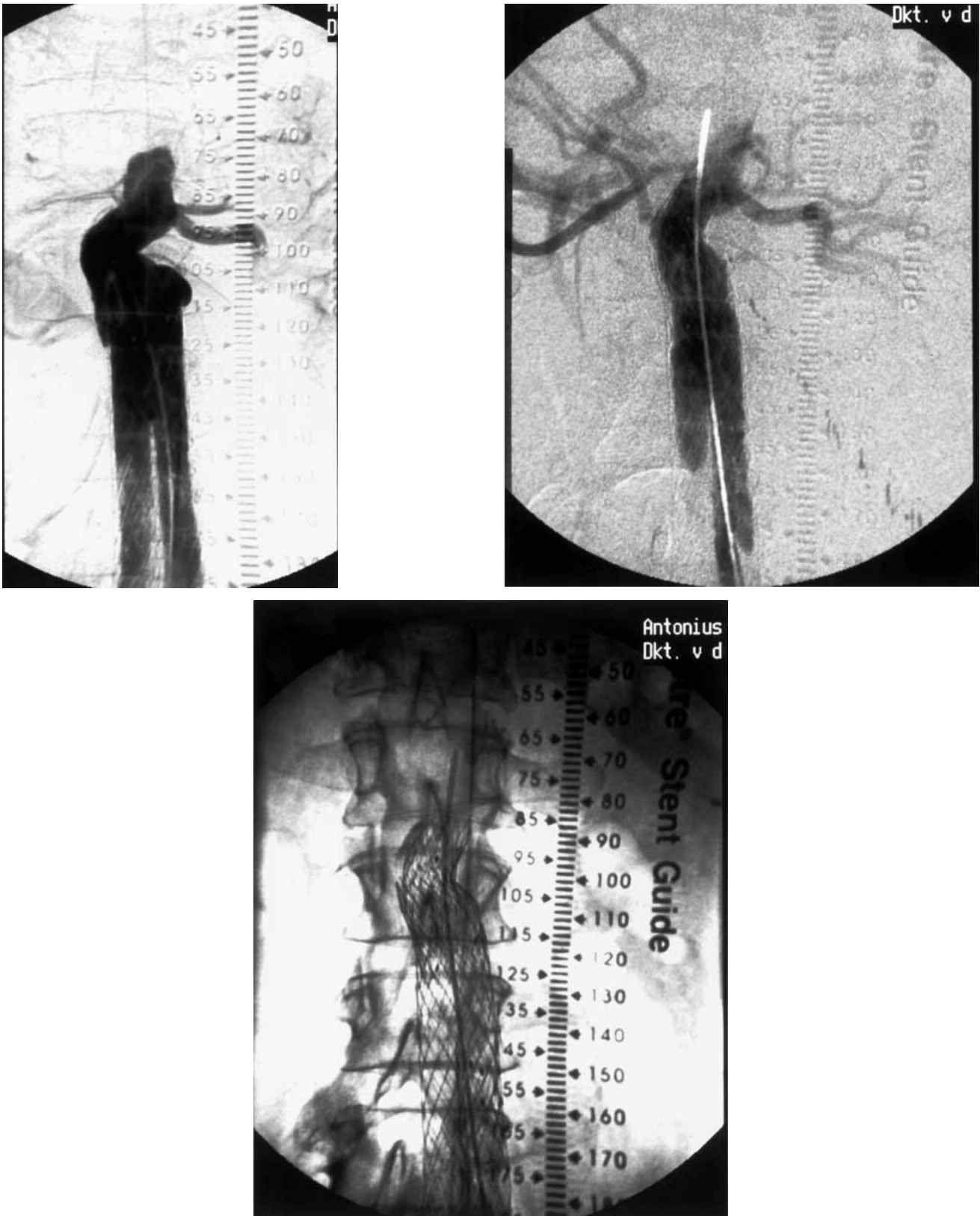


Fig. 1. Example of a type 1 proximal endoleak treated by placing a proximal aortic cuff stentgraft. Proximal endoleak is clearly visible on angiogram (A). After placement of the proximal aortic cuff, a good sealing is created up to the renal arteries (B). Plain X-rays show the skeleton of the stentgraft after (C) placement of the proximal cuff.

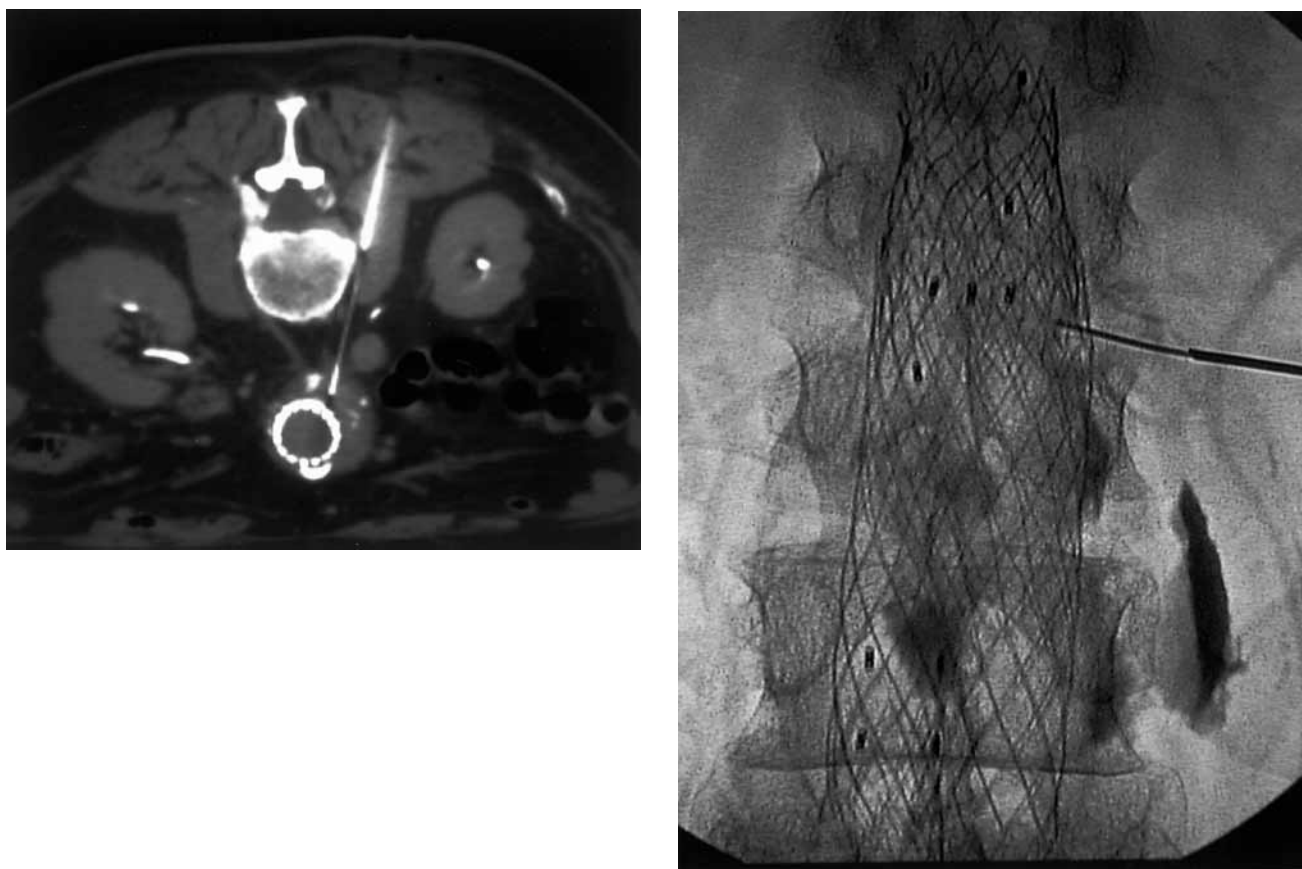


Fig. 2. Example of treatment of type 2 endoleak by means of direct puncture. CT-guided direct puncture of the aneurysm sac is performed at the level of the endoleak (A) in prone position. Patient is transported to the angiosuite and contrast is injected which is visualised as collections in the aneurysm sac (B). After the position of the needle is verified a sclerotic agent (in this case capronic acid) is injected to thrombose the endoleak.

occurred no displacement of the graft could be demonstrated.

In three patients an additional interposition stent-graft was placed at a connection of the modular system. Dislocation at the connection occurred probably because of shrinkage of the aneurysm, twice after 1 year and once after 2 years. Two-year freedom from migration was 90% (Fig. 5).

Graft kinking

Kinking of the graft occurred in only one patient. This happened after shrinkage of the aneurysm and resulted in a limb kink that was successfully treated by PTA.

Discussion

The high mortality and therefore "lost to follow-up" reflects the fact that most patients had serious comorbidity. Despite this, most patients were discharged within 3 days of surgery.

Morbidity was low. In general, the patients themselves were very enthusiastic about their fast recovery.

Both conversions could have been prevented. In one case the inclusion criteria were not strictly followed. In the other case inexperience with this problem was the reason for conversion. Since this second case, it is our policy (in the presence of a tight distal aortic neck) to make sure to have a contralateral guidewire or catheter in the aneurysm before deploying the main device of the stentgraft. Using this contralateral guidewire it is possible to guarantee access to the short limb of the ipsilateral placed main body and deploy the iliac limb.²² Usually after deployment of the iliac limb it is necessary to dilate the distal aortic neck slightly with the kissing balloon technique. In this way we managed to prevent conversion in two other similar cases.

In general, a prolonged hospital stay was due to postoperative problems which were non-device related.

Graft occlusions occurred only three times. In two cases a pre-existing iliac artery stenosis existed. We now tend to be more liberal in dilating the stentgraft

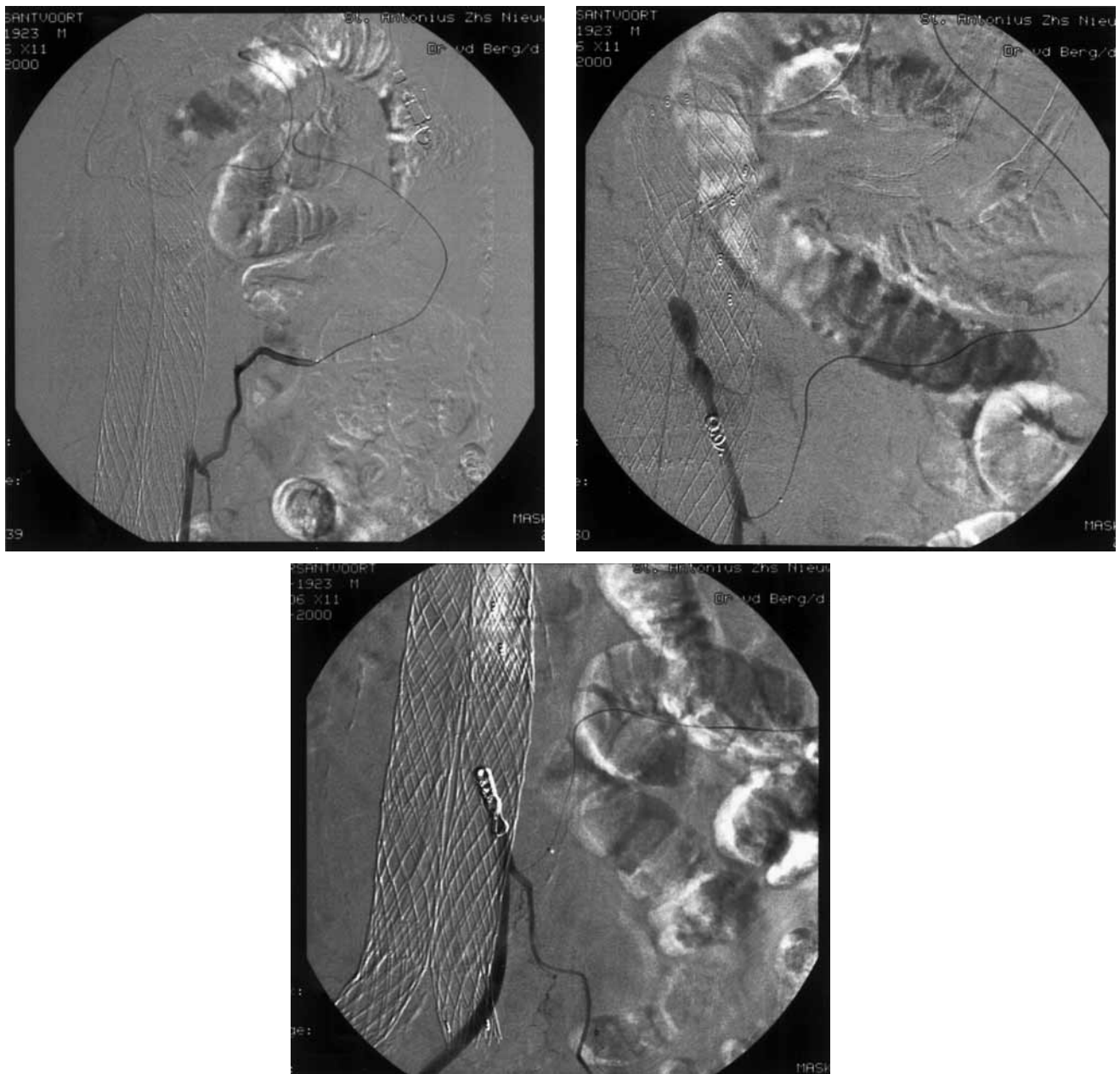


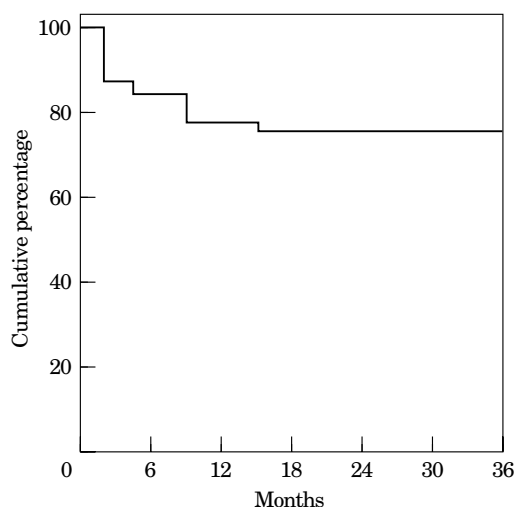
Fig. 3. Example of treatment of type 2 endoleak by means of selective embolisation. Selective embolisation by means of catheterising the SMA and Riolan's arcade. Contrast is injected and the endoleak is visualised (A), first coils are deployed at the origin of IMA near the aneurysm sac but the endoleak is still visible (B). Finally after deploying extra coils the leak is fully sealed (C).

if we notice a not fully deployed segment of the stentgraft, especially in pre-existing stenoses.

Endoleak in this series is in accordance with other publications.²³⁻²⁵ In our opinion, type-1 and type-3 endoleaks need to be treated immediately to eliminate the risk of rupture. In many cases it is possible to resolve the problem with an endovascular or minimal invasive technique. Adequate interventional experience is required however.

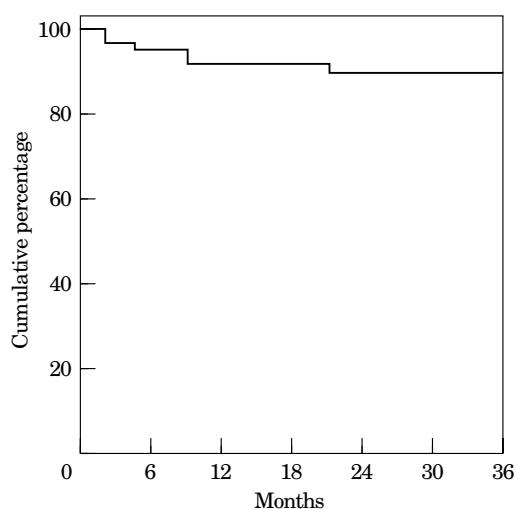
Graft migration did occur with this type of stentgraft.

It seems that proximal stentgraft migration leading to proximal endoleak is less frequent than dislocation at connections. In both patients with proximal graft migration the preoperative neck diameter was 26 mm and they were treated early in this series. Our policy since is to include only patients with a maximum diameter of 25 mm. Accurate preoperative measurements based on good quality images are the key to success. Intraoperative IVUS measurements can be of additional value.²⁶ If at the distal landing zone only



Number of patients under observation	77	49	35	11
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Fig. 4. Life table: freedom from endoleak.



Number of patients under observation	77	56	42	10
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Fig. 5. Life table: freedom from migration.

a short contact area between stentgraft and iliac artery exists, an extender cuff should be placed immediately. With this policy we could have prevented at least one re-intervention. The same applies for the connection zone of a modular system. With the AneuRx stentgraft this overlap should be at least 2 cm at the connection between main graft and contralateral limb and at least 1–1.5 cm between limbs and extender cuffs. At connection sites of the modular system we tend to perform a routine balloon dilatation to guarantee proper sealing.

As described in other series,^{27–30} shrinkage of an excluded aneurysm can cause kinking of the stentgraft.

In our series we found this kinking in only one patient,^{27–30} possibly because the stentgraft is fully supported over its whole length. Secondary interventions were necessary in 11 patients and occurred even after 2 years. This stresses the importance of performing extensive follow-up as the long-term results are not known.

As with other devices, the endovascular treatment of AAA's is not without problems, but most can be solved with a minimal invasive technique. These compatible extender cuffs are a worthwhile item of the AneuRx stentgraft system. It increases flexibility and offers bailout options, but on the other hand can introduce future problems at the connection site as a result of dislocation. The recently developed conversion kit offers even greater flexibility to handle late incompleteness or in some cases offers a bailout opportunity in case of an initial failure. Our mid-term experience and the general lack of knowledge in the long-term stresses the importance of performing extensive follow-up. Also it is important to put all data in a central registry like Eurostar. Only in this way we can learn of earlier mistakes and improve the results for future endovascular treatments.

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