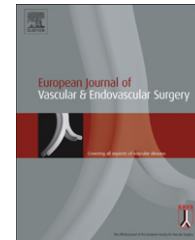




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The Anaconda™ AAA Stent Graft System: 2-Year Clinical and Technical Results of a Multicentre Clinical Evaluation

S.G.J. Rödel^a, R.H. Geelkerken^{a,*}, R.J. Prescott^b, H.J. Florek^c,
P. Kasprzak^d, J. Brunkwall^e, on behalf of the ANA 004 study group

^a Department of Vascular Surgery, Medical Spectrum Twente, PO Box 50000, 7500 KA Enschede, The Netherlands

^b Medical Statistics Unit, University of Edinburgh, Edinburgh, Scotland, UK

^c Department of Vascular Surgery, Klinikum für Dresden-Friedrich-Stadt, Dresden area, Germany

^d Department of Surgery, Klinikum der Universität Regensburg, Regensburg, Germany

^e Department of Vascular Surgery, Klinikum der Universität, Cologne, Germany

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Abstract *Introduction:* This study reports the technical and mid-term clinical results of the second-generation Anaconda™ AAA Stent Graft System endovascular device for treatment of abdominal aortic aneurysm (AAA). The design of the Anaconda™ AAA Stent Graft System is characterised by a three-piece system consisting of two proximal independent saddle-shaped nitinol self-expandable rings with hooks fixation, zero body support and vacuum-cleaner tube leg design.

Methods: From July 2002 to April 2005, a total of 61 patients with AAA were enrolled in a multicentre, prospective, non-randomised controlled design study. All patients received a second-generation Anaconda™ AAA Stent Graft System. They entered a standard follow-up protocol at discharge for 3, 6, 12 and 24 months. Follow-up data included survival; rupture-free survival; incidence of aneurysm rupture, death from aneurysm rupture, aneurysm-related death; freedom from aneurysm expansion; freedom from Types I and III endoleaks; endograft patency and technical and clinical success rates.

Results: Successful access to the arterial system was achieved in all patients. The primary technical success was 59 out of 61 and the primary assisted technical success was 60 out of 61. All endovascular grafts were patent without significant twists, kinks or obstructions. Migration was not observed in any of the grafts. During the first 30-day period, two serious adverse events (3%), both not related to the procedure, were observed. Nine patients (15%) needed a secondary intervention; two of these interventions were related to stent graft (3%). The mean aneurysm sac diameter decreased significantly from 57 mm pre-operative to 45 mm after 24 months, without aneurysm growth. There was one Type I endoleak at initial implantation,

* Corresponding author. Tel.: +31 53 4872510; fax: +31 53 4872526.

E-mail address: r.geelkerken@ziekenhuis-mst.nl (R.H. Geelkerken).

which was corrected using a proximal extension cuff. In total, three Type II endoleaks were still present after 24 months without any signs of aneurysm growth.

Conclusion: The design features of the second-generation Anaconda™ AAA Stent Graft System are effective in the treatment of AAAs on mid-term evaluation.

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With the primary objective to exclude the abdominal aorta aneurysm (AAA) sac from the arterial circulation and to consequently eliminate the risk of aneurysm rupture, several endovascular graft devices were developed during the past 2 decades. The basic concept of endoluminal AAA exclusion has not changed during this period but the failure modes observed during this era inspired companies and clinicians to reappraise the endograft design configurations.

First-generation homemade devices were custom-made endografts using off-the-shelf stents combined with various graft materials used for conventional vascular procedures.¹ Clinical experiences were rapidly gained with second-generation, commercially available endoprotheses in the 1990s, which were used in the USA and Europe depending upon regulatory approval status.^{2,3} Various failure modes of these stent grafts were identified. The two most clinically significant failures are endoleak (particularly Types I and III) and migration,^{4–6} ranging between 10% and 30% 1 year after graft placement depending on endograft type.

The first-generation Anaconda™ AAA Stent Graft System was developed without hooks and completely relied on friction sealing for proximal fixation. The second-generation Anaconda™ AAA Stent Graft System has been redesigned with the intention of addressing the failure modes observed in the earlier generations of stent grafts, including the first-generation Anaconda.^{6–9} The two major modifications were the introduction of proximal hooks connected to the proximal two-ring stents and the introduction of the zero body support of the graft, both with the intention to decrease the chance of migration. The name Anaconda™ was chosen because of the similarity between the shape of the proximal ring stent and a snakes' mouth. The second-generation Anaconda™ AAA Stent Graft System was CE marked in April 2005.

This study reports on the technical and the mid-term clinical results of the second-generation Anaconda™ AAA Stent Graft System for the treatment of AAA.

Materials and Methods

Study design

From July 2002 to April 2005, a total of 61 patients with AAA were enrolled in a multicentre, prospective, non-randomised controlled study (Anaconda 004 study). Each patient underwent a detailed pre-operative screening to ensure that the general medical condition was satisfactory for conversion from endovascular aneurysm repair (EVAR) to conventional repair, if necessary. The information collected consisted of a general health analysis including the Society of Vascular Surgery–International Society of Cardiovascular Surgeons (SVS–ISCVS)¹⁰ risk scores for diabetes, smoking, hypertension, hyperlipidaemia, cardiac status, carotid disease, renal status, pulmonary status and

American Society of Anesthesiologists (ASA) classification. pre-operative AAA assessment included detailed spiral computed tomography (CT) scanning and standard contrast arteriography as detailed in the Core Laboratory Protocol. The selected medical and anatomical inclusion and exclusion criteria are listed in Table 1.

Study hypothesis and definitions

The primary objectives of this study were to examine the technical and clinical success of the Anaconda™ AAA Stent Graft System for the treatment of AAA. The following definitions, in line with the suggestions of Chaikof et al., were used.¹¹

Technical success was defined as successful access to the arterial system using a remote site, successful deployment of the stent graft with secure proximal and distal sealing and fixation of the attachment devices, demonstrating safe and effective exclusion of the AAA without Type I or III endoleak and patent endoluminal graft without significant

Table 1 Anaconda 004 AAA stent graft study.

Inclusion criteria

- Patients aged 18 years–85 years
- Patient willing and available to comply with follow-up requirements
- Patient can comply with instructions and give informed consent
- Life Expectancy >2 years
- Patient is a candidate for open surgical repair
- AAA >50 mm in diameter
- Infrarenal proximal neck diameter 18–31.5 mm
- Infrarenal proximal neck length >15 mm
- Distal Iliac fixation site diameter <16 mm and >30 mm in length
- Access vessels >7.5 mm in diameter

Exclusion criteria

- Ruptured AAA
- Symptomatic AAA
- Juxta or suprarenal extension of aneurysm
- Presence of serious concomitant medical disease or infection
- Known allergy to contrast medium, nitinol or polyester
- Inability to preserve at least one hypogastric artery
- Connective tissue disease
- ASA Grade IV or V
- Need for surgical reconstruction of other visceral arteries
- Infrarenal aortic angulation >45°
- Presence of >50% continuous calcification of proximal neck
- Presence of >50% thrombus in proximal neck
- Presence of conical infrarenal neck
- Other unsuitable anatomy

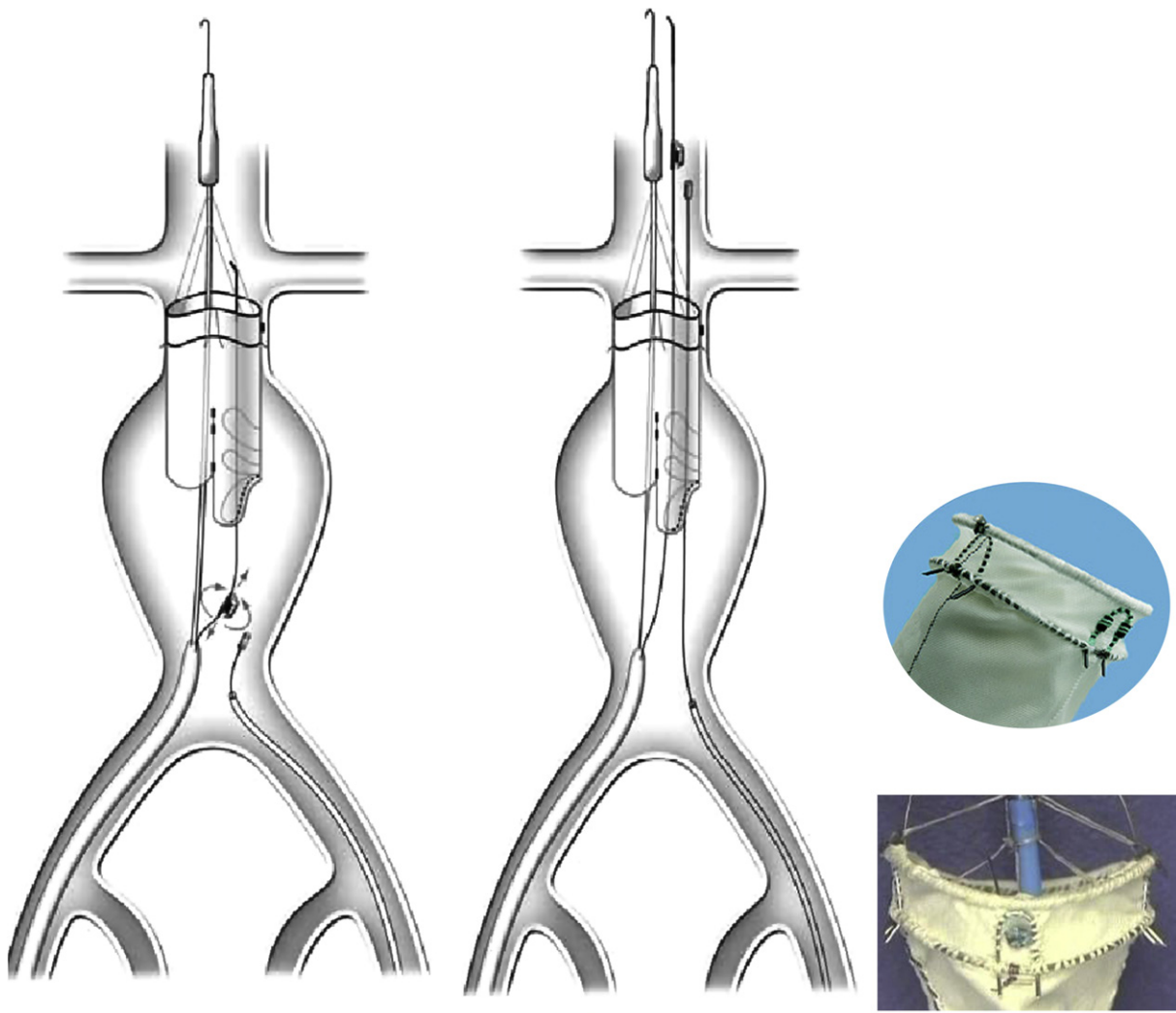


Figure 1 The Anaconda™ AAA Stent Graft System (Vascutek, Terumo, Inchinnan, Scotland) is a three-pieces endovascular device made of multiwire twisted nitinol stents combined with woven graft material. The proximal ring stent is anchored in an infrarenal position by four pairs of nitinol hooks that prevent device migration. The cannulation of the contralateral gate of the body is facilitated by a unique magnet system.

twists, kinks or obstruction by intra-operative angiography measurements periprocedural and in the first 24-h period. In case of unplanned endovascular or surgical procedures, it was defined as assisted primary or secondary technical success.

Clinical success was defined as successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, Types I and III endoleak, graft infection or thrombosis, aneurysm expansion (diameter ≥ 5 mm, or volume $\geq 5\%$), aneurysm rupture or conversion to open repair. In cases with Type II endoleak, clinical success was only claimed in the absence of aneurysm expansion. *Primary clinical success* is clinical success without the need for an additional or secondary surgical or endovascular procedure. *Secondary clinical success* is clinical success obtained with the use of an additional or secondary surgical procedure.

Clinical failure included a failure to deploy the endovascular device at the intended location, the presence of a Type I or III endoleak, graft thrombosis or infection, graft

dilatation of 20% or more by diameter, graft migration, failure of device integrity, aneurysm expansion or rupture, conversion to open repair or death.

A *serious adverse event* was defined as any clinical event, which resulted in death, or was life-threatening, produced permanent or significant disability/incapacity, resulted in-patient hospitalisation or prolongation of existing in-patient hospitalisation, is a cancer or required medical or surgical intervention to prevent permanent impairment of function or permanent damage to a body structure.

Clinical success is reported as short-term clinical success (30 days) and mid-term clinical success (2-years' follow-up).

Device description

The Anaconda™ AAA Stent Graft System (Vascutek, Terumo, Inchinnan, Scotland, UK) is a three-piece endovascular device made of multiple element nitinol stents combined with woven polyester graft material. The top of the graft

consists of a dual-ring stent design, which provides haemostatic sealing against the vessel wall. The proximal ring stent is anchored in an infrarenal position by four pairs of nitinol hooks, which prevent device migration (Fig. 1). The body is unstented, resulting in zero column strength, which is comparable to conventional bifurcated prosthesis design. The iliac legs are fully supported with independent nitinol ring stents, which provide flexibility and prevent kinking in tortuous anatomy. The cannulation of the contralateral gate of the body is facilitated with a magnet system (Fig. 1). The delivery device of the body is flexible, kink resistant and allows multiple rotational, proximal and distal repositioning (Fig. 2). The delivery system of the main body has an outer diameter of 20.4 or 22.5 French (6.8–7.5 mm), depending on the stent graft neck diameter used. The delivery system for the iliac legs has an outer diameter of 18.3 French (6.1 mm).

AAA sizing and stent-graft selection were in line with the recommendations of the Anaconda™ AAA Stent Graft System and sizing reference chart. The oversizing at the level of the infrarenal neck was between 7.3% and 21.8%, and at the level of the common iliac artery between 5% and 28.5%, respectively.

Operative procedure

The operation was performed under local, epidural or general anaesthesia in the operating room with a radiolucent table under fluoroscopic guidance. The procedure required surgical exposure of the femoral arteries or common iliac arteries and was performed by surgical cut down and formation of an arteriotomy. During the procedure, intravenous heparin 5000 IU or 100 IU heparin per kg body weight was required in accordance with standard endovascular procedures. The surgical technique was carried out in accordance with the Vascutek Limited Instructions for Use (see www.vascutek.com). All the necessary operative details, overall outcome of the procedure as well as any adverse events during the operation were recorded using the case report form.

Follow-up protocol

All patients were enrolled in a standard follow-up protocol at discharge and at 3, 6, 12 and 24 months. Each patient underwent a postoperative contrast-enhanced computed tomography (CT) scan and plain abdominal radiograph. All radiological data were independently reviewed by a core lab (Cleveland Clinic, Cleveland, OH, USA).

Recorded follow-up data included survival, rupture-free survival, incidence of aneurysm rupture, death from aneurysm rupture, aneurysm-related death, freedom from aneurysm expansion, freedom from Types I and III endoleaks, endograft patency and technical and clinical success rates.

Statistical analysis

Results are reported as mean \pm standard deviation (SD; range) or with a 95% confidence interval where appropriate. Student's *t*-test was used to compare continuous variables. Significance was assumed at a *P* value of less than 0.05. The

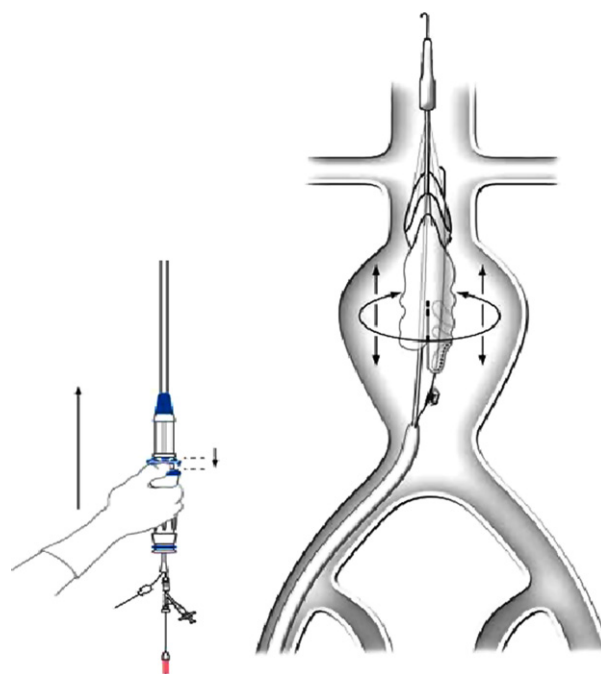


Figure 2 Repositionable proximal neck.

Kaplan–Meier curves and log-rank tests were used to plot survival over time. The statistical analyses of this study were carried out by an independent statistician.

Results

Demographics

Relevant patient characteristics are presented in Table 2. The patients' age ranged between 51 and 87 years with a mean of 71 years. The average aneurysm sac diameter was 57 mm (range: 50–83 mm).

Technical success

The technical results are summarised in Table 3. In all patients, successful access to the arterial system was achieved. In all cases the body of the Anaconda™ AAA Stent Graft System could be precisely positioned and, if necessary, repositioned using the delivery device. One implantation could not be completed due to the accidental loss of the guide-wire of the main body during operation. The local physician decided to convert to conventional open repair. Access to the contralateral gate was quick and easy. Intraoperatively, there was one Type I endoleak, which was treated successfully with a proximal extension cuff. There were no Type III endoleaks. All endoluminal grafts were patent without significant twist, kinks or obstruction.

Short-term clinical success

The short-term clinical outcome is summarised in Table 3.

During the first 30-day period, there were two serious adverse events resulting in death: one patient died due to

Table 2 Anaconda 004 AAA stent graft study; patient characteristics.

Demographic		Present study, number of patients (range or %)
Age (years)	Mean (Range)	71.2 (51–87)
Gender	Male	60 (98.4)
	Female	1 (1.6)
ASA grade	I	3 (4.9)
	II	38 (62.3)
	III	19 (31.1)
	Unknown	1 (1.6)
Diabetes	Only diet controlled	9 (14.8)
Hypertension	None	16 (26.2)
	Drug controlled	43 (70.5)
	uncontrolled	2 (3.3)
Hyperlipidaemia	Normal	26 (42.6)
	Mild	20 (32.8)
	Diet and or drugs	14 (23)
	Not recorded	1 (1.6)
Cardiac status	Normal	30 (49.2)
	Asymptomatic - MI angina etc.	18 (29.5)
		13 (21.3)
Renal disease	Normal	57 (93.4)
	Increased	4 (6.6)
Pulmonary disease	Normal	48 (78.7)
	Mild	9 (14.8)
	Moderate/severe	4(6.5)

a cardiac arrest 8 days after EVAR and another died as a result of a severe lung bleeding 12 h after an uncomplicated EVAR. The cause of death in the second patient was a ruptured bronchial artery in a necrotic lung segment due to radiotherapy for bronchial carcinoma 2 years earlier, which could not be foreseen. At autopsy, it was confirmed that the AAA exclusion with the Anaconda™ Stent Graft was uncomplicated in both cases. Other early serious adverse events were not experienced.

Mid-term clinical results

The mid-term clinical outcome is summarised in Tables 3 and 4 and Fig. 3.

The 2-year loss to follow-up was zero. There were seven serious events including four additional deaths after 30 days (heart failure (2), carcinoma and CVA) and one patient with occlusion of an iliac device leg, treated successfully with a PTA procedure. There were no aneurysm-related deaths. There were no device fixation failures at the proximal neck, specifically no wire or hook fractures or migrations at 2 years. Nine patients needed a secondary intervention; two of these interventions were related to graft.

The mean aneurysm sac diameter decreased significantly from 57 mm (± 7 mm) pre-operative to 45 mm

Table 3 Anaconda 004 AAA stent graft study: technical success and clinical success.

	30 days	2 years
Primary technical success	96.7% (59/61) ^{a,b}	
Primary assisted and secondary technical success	98% (60/61) ^a	
Primary clinical success	93% (57/61) ^{c,d,e,f}	72.1% (44/61)
Secondary clinical success	95% (58/61) ^c	88.5% (54/61)
Serious adverse events	3.2% (2/61) ^{e,f}	11.4% (7/61)
Clinical failure	4.9% (3/61) ^{d,e,f}	11.4% (7/61)
All cause mortality		9.8% (6/61)
Aneurysm-related mortality		0% (0/61)
Freedom from re-intervention		85.2% (52/61)
Freedom from migration		100% (60/60)

^a One conversion due to loss of the guide-wire.

^b One Type I endoleak. Proximal extension cuff resolved endoleak.

^c Type I endoleak during operation, proximal extension cuff needed.

^d One conversion due to loss of guide-wire. Clinical failure.

^e Death due to cardiac arrest, not device related. Clinical failure.

^f Severe lung bleeding. Not device related. Clinical failure.

(± 11 mm) after 24 months evaluation ($p \leq 0.0001$). At 24 months no patient had an increase of the aneurysm sac diameter, eight patients remained stable and 39 patients had a decrease of the aneurysm sac of 5 mm or more. Eight patients were not evaluated at 24 months, but all these patients showed no increase at 18 months' follow-up.

Endoleak

Neither Type III nor Type IV endoleaks were observed during the 2-years' follow-up.

One Type I endoleak occurred during operation, which was corrected intra-operatively using a proximal extension cuff and Palmaz balloon-expandable stent. Retrospectively, less than 6% oversizing of the Anaconda stent caused this problem. Eight Type II endoleaks, seven lumbar artery and one inferior mesenteric artery were observed intra-operatively. One patient with a Type II endoleak died 8 days after discharge due to cardiac arrest. In two other patients with stable aneurysm diameter, coiling of a Type II endoleak was performed at 3 months. One Type II endoleak disappeared spontaneously after 18 months and another after 24 months. A new Type II endoleak was discovered at 12 months follow-up and disappeared spontaneously at 18 months follow-up. In total, three Type II endoleaks were still present after 24 months without any signs of aneurysm growth.

Table 4 Anaconda 004 AAA stent graft study; re-interventions.

Patient	Re-intervention	Details	Follow-up
25	Coiling	Patient had persistent Type II lumbar endoleak. Elective angiography with attempt to coil.	3 m
23	Coiling	Patient has a new Type II collateral vessel endoleak. Collateral vessels coiled.	3 m
1	Iliac Extension to treat aneurysm.	Patient had distal iliac aneurysm successfully treated with an Anaconda iliac extension.	10 m
47	Iliac Extension to treat dilatation.	Increased diameter of left CIA.	12 m
5	Fem Fem	Right iliac obstruction with stenosis in external iliac artery.	3 m
33	Thrombendarterectomy & SFA Proximal Vein Patch Plasty	Occlusion of artery access.	15 m
3	PTA	Femoral artery occlusion. High grade stenosis of common femoral artery.	12 m
58	PTA	Internal iliac occlusion.	12 m
27	Thrombectomy & Stent	Right iliac device obstruction	16 m

Discussion

The second-generation Anaconda™ AAA Stent Graft System was introduced in the clinic 6 years ago. The present report focusses on the technical and the mid-term clinical success of this new device.

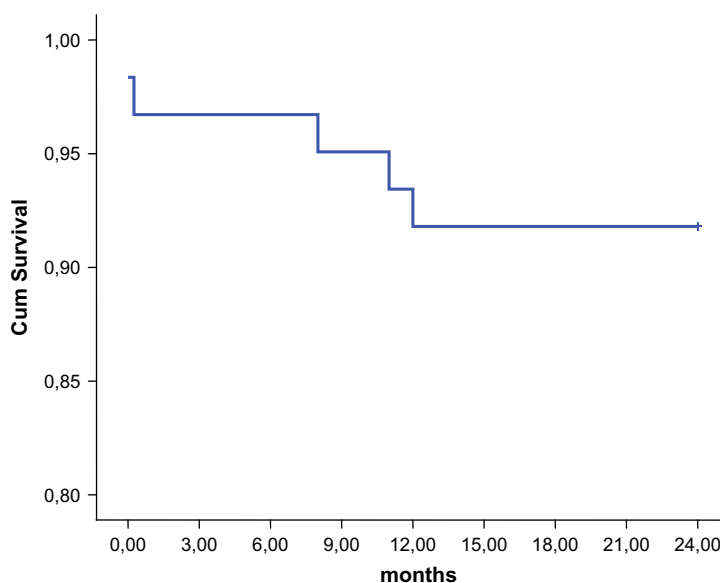
Including the 61 patients in this present study, until now technical success has been reported in 173 out of 175 patients (99%) receiving an Anaconda™ stent graft.^{12–14} These results are comparable with the Zenith and Excluder trials recently published.^{6,15}

The only conversion in the present series was due to loss of guide-wire access while no additional endovascular equipment, such as long wires for a brachial approach, a goose neck or a shepherd's hook catheter, was available at the local site to resolve the problem. In our opinion, lack of technical success in this case was not related to any failure of the Anaconda™ system.

The present multicentre prospective, core lab-controlled study determined the mid-term clinical outcome of AAA patients treated with the Anaconda™ AAA Stent Graft System. In line with the in- and exclusion criteria, selecting anatomically and physically favourable patients, excellent outcomes should be feasible. The 2-year overall mortality rate of 10%, none related to aneurysm, was comparable with the DREAM trial,¹⁶ although 30-day mortality in our group was slightly higher (3.2% vs. 1.1%). In particular, the low incidence of Types I and III endoleaks, the absence of migration, the absence of increase of aneurysm diameter and the 100% rupture-free survival were considered to be excellent and comparable with the Zenith and Excluder trials.^{6,15}

One special feature of the Anaconda™ AAA Stent Graft System is the possibility of using the magnetic docking system for cannulation of the contralateral gate. Although time to access to the contralateral gate was not part of the study protocol, the personal experience of the participants was that the magnetic system significantly reduced the cannulation time of the contralateral side compared with standard cannulation techniques. Other single-centre studies reported a mean contralateral cannulation time of 4 min (range: 3–22 min) with a magnetic coupling success rate of 94–100%.^{12–14} After modification with stronger magnets in the year 2005, a further reduction of the cannulation time of the contralateral body was achieved according to Stehr.¹³

Another special feature of the Anaconda™ AAA Stent Graft System is the possibility of repositioning the two proximal sealing and fixation stent rings. This feature allowed accurate infrarenal placement in angulated necks as well. Repositioning rates reported in the literature varied between 38% and 10% to achieve more satisfactory stent-graft positions.^{12–14} The Anaconda AAA Stent Graft System is not more difficult in stent placement than are other systems, and getting the most optimal result using a repositioning system during the intervention is attractive and forgiving in first-time suboptimal stent placement. Most stents do not have this feature and stent replacement could be difficult to achieve. The saddle-shaped proximal ring design facilitates adaptation to local anatomy, also during the first few days after implantation. If this occurs, the valley of the proximal stent ring could migrate a few millimetres upstream. If the Anaconda is placed juxtarenal with the valleys functioning as scallops around the renal orifices,



Months	N=0	3	6	9	12	15	18	21	24
Patient at risk	60	58	58	57	56	55	55	55	54
No Deaths	2	0	0	1	1	1	0	0	1
Cumulative survival	96.7%	96.7%	95%	95%	93.3%	91.7%	91.7%	91.7%	90%
Cumulative mortality	3.3%	3.3%	5%	5%	6.7%	8.3%	8.3%	8.3%	10%

Figure 3 Kaplan–Meier survival curve survival.

we advise placement of short balloon-expandable stents in these orifices to prevent renal artery stenoses or occlusion.

It is noted that although the number of leg occlusions observed was reasonably low and comparable to other devices, the majority of occlusions in the current worldwide Anaconda experience is observed in the combination of small body diameter (<25 mm) and relatively large diameter legs. Consequently, the sizing and reference chart concerning the body leg combination was recently adjusted to this latest worldwide experience and, on short notice, the docking zone diameter of the small bodies will be enlarged.

The secondary intervention rate of 15%, including coil embolisation of a Type II endoleak in two patients with stable aneurysm diameter, was comparable with other prospective studies and represents the known difference between conventional surgical repair, with a low incidence of secondary interventions, and EVAR.¹⁷ Most vascular centres do not advise coil embolisation in asymptomatic patients with a Type II endoleak in case of stable aneurysm diameter.

We conclude that the design features of the second-generation Anaconda™ Stent Graft System allow easy placement of the stent and are effective in the mid-term in the treatment of AAAs in patients with straightforward anatomy. Studies focussing on patients with challenging

AAA anatomy and patients with rupture AAA will shed further light on the additional clinical value of the Anaconda™ AAA Stent Graft System design.

Conflict of Interest

None.

Authorship Statement

Conception and design: SR, RG
 Analysis and interpretation: SR, RG, RP
 Data collection: RP, SR
 Writing the article: SR, RG
 Critical revision of the article: HF, PK, JB
 Final approval of the article: SR, RG
 Statistical analyses: RP, SR, RG
 Obtained funding: Overall responsibility: SR, RG

Acknowledgements and disclosure

Participants in ANA 004 study and number of patient included

Participant	Clinic	Number of patients included
Wolff W. Stelter, MD, PhD	<i>Department of Surgery, Städtische Kliniken; Germany</i>	4
Hans Joachim Florek, MD, PhD	<i>Department of Vascular Surgery, Klinikum für Dresden-Friedrich- Stadt; Germany;</i>	9
Jan Brunkwall, MD, PhD	<i>Department of Vascular Surgery, Klinikum der Universität Köln,</i>	7
Klaus Balzer, MD, PhD	<i>Department of Vascular Surgery, Evangelisches Krankenhaus;</i>	3
Gernot Wozniak, MD, PhD	<i>Department of Surgery, Krankenhaus Knappschafts,</i>	3
Peter Kasprzak, MD, PhD	<i>Department of Surgery, Klinikum de Universität Regensburg;</i>	8
Ingo Flessenkämper, MD, PhD	<i>Department of Vascular Surgery, DRK-Kliniken Mark;</i>	5
Peter Taylor, MD, PhD	<i>Department of Surgery, London Health Science Centre;</i>	4
Robert H. Geelkerken, MD, PhD, Rob J. Det, MD, Pieter de Smit, MD, PhD, D.G. Gerrits, MD, Ad.B. Huisman, MD, PhD	<i>Department of Vascular surgery and interventional radiology Medical Spectrum Twente; Enschede, The Netherlands.</i>	18

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ANA-004 Investigators

Centre no.	Investigator	Address
001	Herr Prof. Dr. med. Wolff Stelter	Städtische Kliniken Frankfurt - Höchst Gotenstrasse 6-8 65929 Frankfurt GERMANY
002	Herr CA Dr. med. Hans -Joachim Florek	Städtisches Klinikum Dresden-Friedrichstadt Gefässchirurgie Friedrichstrasse 41 01067 Dresden GERMANY
003	Herr Prof. Dr. med. Jan Brunkwall	Klinikum der Universität Klinik und Poliklinik f. Viszeral und Gefäßchirurgie Leitender Arzt der Sektion Gefäßchirurgie Postfach 50924 Köln GERMANY
007	Herr Dr. med. Klaus Balzer	Evangelische Krankenhaus Chefarzt d.Gefäßchirurg Klinik Wertgasse 30 45468 Mülheim GERMANY

(continued on next page)

(continued)

Centre no.	Investigator	Address
009	Herr Priv. Doz. Dr. med. Gernot Wozniak	Knappschafts Krankenhaus Gefäßchirurg. Klinik Osterfelder Straße 157 46242 Bottrop GERMANY
010	Herr Chefarzt Dr. med. Peter Kasprzak	Klinikum der Universität Klinik f. Gefäßchirurg. Klinik Josef-Straße-Allee 11 93053 Regensburg GERMANY
014	Herr Chefarzt Dr. med. Ingo Flessenkämper	DRK-Kliniken Mark Brandenburg CA der Gefäßchirurgie Drontheimer Str. 39-40 13359 Berlin GERMANY
015	Robert H Geelkerken, MD, PhD Pieter de Smit, MD, PhD Rob J. van Det, MD Ad B. Huisman, MD, PhD	Medisch Spectrum Twente Department of Surgery PO BOX 50.000 7500 KA Enschede THE NETHERLANDS
021	Mr Peter Taylor	Consultant Vascular Surgeon 3rd Floor Special X-ray Guy's Tower Guy's Hospital St Thomas Street London SE1 9RT, United Kingdom

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