- Board of Continuing Professional Development and Standards (RACS)
- Ethics committee of the RACS
- EUROSTAR registry*
- National Death Index at the Australian Institute of Health and Welfare (AIHW)

* Links established through the AAA reference group.

Supporting documentation

Documents produced during the audit include: a patient information brochure, patient consent form, project plan, protocol, audit manual, and project reports (produced 6 monthly). The reports, patient consent form, AAA brochure and patient information sheet are available for download from the ASERNIP-S website or are available on request from the ASERNIP-S office.

Data collection

This section describes the methods used to facilitate accurate and complete data collection.

Participating surgeons

As part of RACS, ASERNIP-S has access to the contact details of vascular surgeons in Australia. During the period of initial data collection around 80 surgeons were performing the EVAR procedure and have continued to submit their data. It is anticipated that during the next 12-months all vascular surgeons will be surveyed to determine whether patterns of practice have changed in the intervening period.

Data input

Data has been submitted using: paper-based forms, electronic forms, Access database and the Internet. Internet submission is encrypted using public key cryptography.

On arrival at ASERNIP-S the information is entered into a password-protected database created using Access 2000. Most of the data is double-checked to ensure data integrity. The date of data entry and checking is logged.

Surgeons are asked to provide information using three separate forms:

- Operative form – information obtained in the period immediately prior and during the procedure

- Discharge form – including information obtained post-operatively, up to 30 days from the time of the procedure
- Follow-up form – aimed to collect information at regular follow-up intervals of 3 months, 6 months, 12 months, then on an annual basis.

Copies of each form are included in Appendix 2. The forms do not include any universal identifiers such as the Medicare or Veterans Affairs Numbers as stipulated by the Privacy Amendment (Private Sector) Act 2000, in National Privacy Principle 7.1. Changes were made to the forms in 2004 to identify type III and type IV endoleaks.

Data received

ASERNIP-S was required to collect procedures performed privately in Australia between November 1999 and May 2001. An estimate of the number of private procedures performed was obtained from the Health Insurance Commission (HIC), and a comparison with ASERNIP-S data indicates that around 90% of these cases were submitted.

As noted in previous reports, the follow-up of patients by surgeons is not standard, and varies from surgeon to surgeon. To account for this the following follow-up intervals have been adopted: 1-3 months, 4-8 months, 9-14 months, 15-19 months, 20-29 months, 30-41 months, 42-54 months and 55-67 months.

A number of patients are regarded as lost to follow-up, although this number has decreased slightly since the November report. Reasons for losing patients include: cases where the surgeons have retired (or in one case died) and our inability to establish the surgeon or GP responsible for these patients; the advanced age and/or increasing frailty of patients has necessitated their movement to nursing home care; other patients move to be closer to family members and become lost to follow-up; the follow-up of regional patients is often problematic as this is often done by different surgeons and/or general practitioners; some patients simply refuse further follow-up. Barriers to follow-up include worsening health, distance, cost and movement between service providers.

Information received from the National Death Index (AIHW), has meant that the number of deaths reported has increased dramatically since the last report. Enrolments and mortality are shown in Table 2.

Table 2: Enrolments

Data		Total	Percentage
Operative data set		961	
	Public	284	30%
	Private	677	70%
Lost to follow-up		75	8%
Deceased		263	
	Early*	17	1.8%
	Late	246	26%

* Early death is death within 30 days of the procedure, and is sometimes referred to as perioperative death. Late death implies death occurring more than 30 days post procedure.

Figure 1 shows the number of follow-up forms received and Figure 2 shows the overall number of follow-up forms received for patients.

Figure 1: Follow-up forms received by time interval

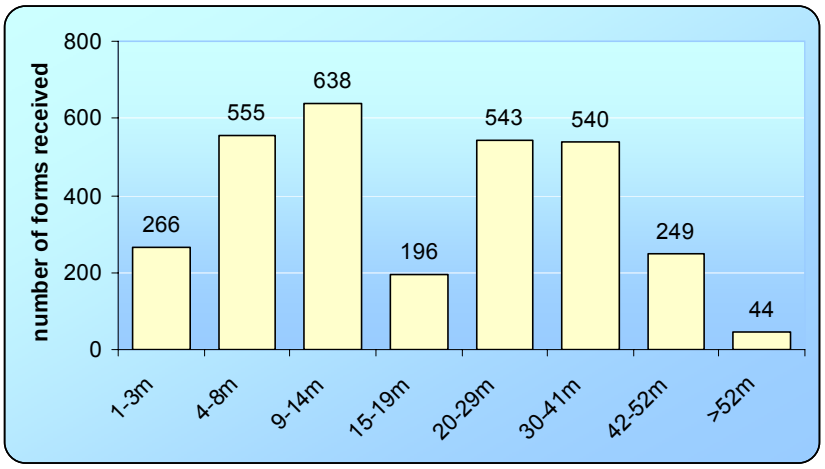
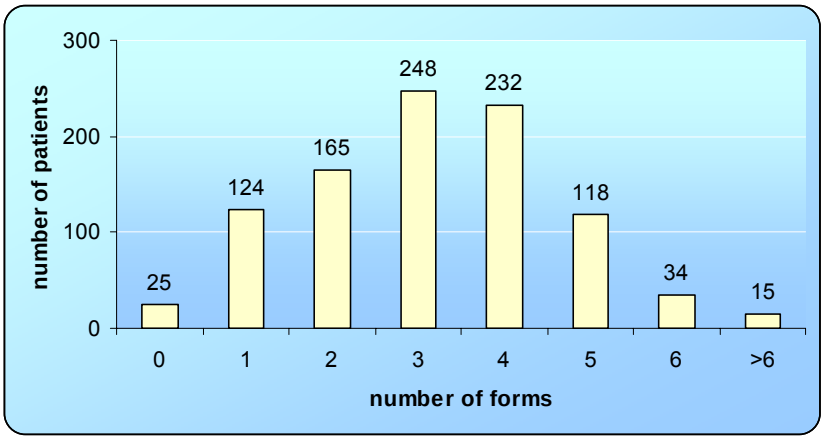


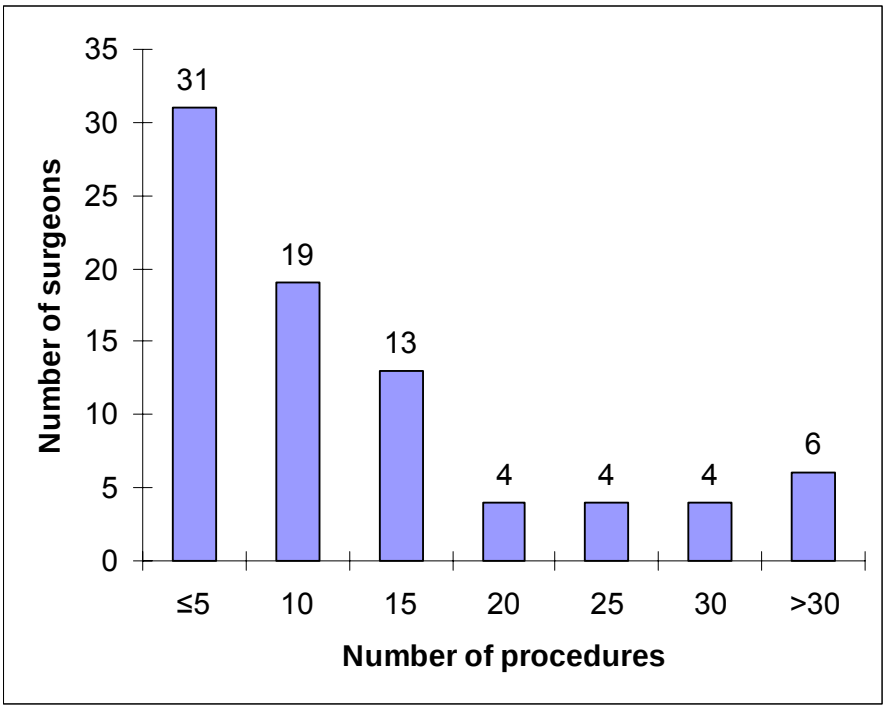
Figure 2: Follow-up forms received by patient



Number of procedures performed by surgeons

Figure 3 shows the number of procedures performed by surgeons during the audit period. In some cases more than one surgeon was listed as having performed the procedure. In this situation the procedure was ascribed to the follow-up surgeon.

Figure 3: Number of procedures submitted by surgeons



Reportage

Surgeons participating in the audit receive an updated list of their audit information every two months. This ensures surgeons remain informed if follow-up information is due.

In June 2004 all participating vascular surgeons received a copy of the May 2004 audit report.

The progress of the audit is reported at each ASERNIP-S Management Committee meeting. The most recent took place on the 6 May 2005. An update of audit activities is provided to the Council of the RACS three times each year. Audit reports are submitted to the Australian Government Department of Health and Ageing at six-monthly intervals.

Publications and presentations related to the audit are shown below:

Conference Presentations

2005

- **Fitridge R**, Boult M, Babidge W, Maddern G. *ASERNIP-S audit of endoluminal repair of abdominal aortic aneurysms in Australia.* Annual Scientific Congress of the Royal Australasian College of Surgeons. Perth, Australia. May 2005.

2004

- **Fitridge R**, Boult M, Babidge W, Maddern G. *Endoluminal repair of abdominal aortic aneurysms – contemporary Australian experience.* Annual Scientific Congress of the Royal Australasian College of Surgeons. Melbourne, Australia. May 2004.
- **Fitridge R**, Boult M, Babidge W, Maddern G. *Endoluminal repair of abdominal aortic aneurysms – Australian audit*. ISCVS World Congress, Hawaii. April 2004.

2003

- **Fitridge R**, Boult M, Babidge W, Maddern G (for the ASERNIP-S Reference Group for endoluminal graft repair). *The Australian Audit of the Safety and Efficacy of Endoluminal Grafts for the Repair Of Abdominal Aortic Aneurysms.* Annual Scientific Congress of the Royal Australasian College of Surgeons. Brisbane, Australia. May 2003.

2002

- **Harris J.** *Australian audit of endoluminal and open repair of abdominal aortic aneurysms.* 15th Annual International Congress for Endovascular Interventions. Phoenix, Arizona USA. February 2002.
- **Fitridge R**. *ASERNIP-S follow-up data.* Annual Scientific Congress of the Royal Australasian College of Surgeons. Adelaide, Australia. May 2002.
- Boult M, **Babidge W**, Coburn D, Maddern G. *Data collection on a new technology to inform funding decision making by the Australian Government*. (Poster). 18th Annual Meeting for the International Society of Technology Assessment in Health Care (ISTAHC). Berlin, Germany, June 9-12, 2002.
- **Boult M**, Babidge W, Maddern G. *The role of audit in improving health outcomes*. Australasian Health Research Data Managers Association, Brisbane, Australia, 21-22nd August 2002.
- **M Denton,** R Fitridge, M Boult, W Babidge & G Maddern (for the Endoluminal Reference Group) *Highlights from the ASERNIP-S Registry; What are the important*

findings for clinical practice? International Endovascular Symposium. Sydney, Australia, December 5-7, 2002.

2001

- **Maddern G and Fitridge R.** Annual Scientific Congress of the Royal Australasian College of Surgeons. Canberra, Australia. May 2001.
- **Boult M**, *Ethics and the Law - Some Issues involved in Data Collection*, Australasian Health Research Data Managers Association, Melbourne, Australia, 13-14th September 2001.

Publications

2005

.

- Boult M, Babidge W, Maddern G, Barnes M, Fitridge R. Predictors of success following endovascular aneurysm repair: mid-term results *European Journal of Vascular and Endovascular Surgery* 2005: In press

2004

- Boult M, Babidge W, Maddern G, Fitridge R, on behalf of the Reference Group. Endoluminal repair of abdominal aortic aneurysm – contemporary Australian experience. *European Journal of Vascular and Endovascular Surgery.* 2004: 28(1); 36-40.

2002

- Boult M, Babidge W, Anderson J, Denton M, Fitridge R, Harris J, Lawrence-Brown M, May J, Myers K, Maddern G. Australian audit for the endoluminal repair of abdominal aortic aneurysm - the first 12-months. *Australian and New Zealand Journal of Surgery.* 2002. 72(3) 190 - 195.
- Boult M, Babidge W, Roder D, Maddern G. Issues of consent and privacy affecting the functioning of ASERNIP-S. *Australian and New Zealand Journal of Surgery.* 2002; 72:580-582.

2001

- Fitridge R. Evaluation of aortic stent grafting – the Australian experience. In: Whittemore A (Ed). *Advances in Vascular Surgery.* 2001, volume 9 pp55 – 65.

Accreditation of the ASERNIP-S audit

The RACS Board of Continuing Professional Development and Standards has approved the EVAR audit for the purposes of their Continuing Professional Development Programme. The audit is listed on the RACS website under approved audit activities: http://www.surgeons.org/Content/NavigationMenu/FellowshipandStandards/ProfessionalStandards/FAQS/surgical_audit_peer_review_2005.pdf

3. RESULTS

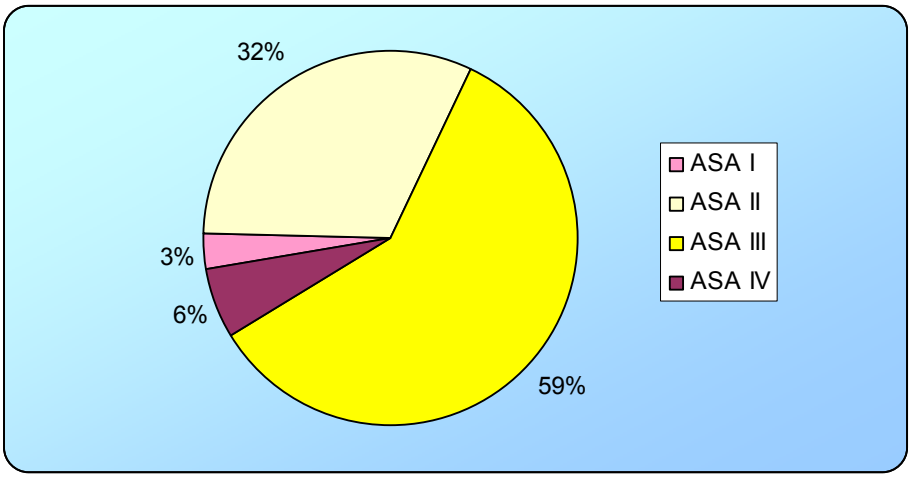
This section summarises patient demographics, procedural and follow-up results and aims to provide answers to the research questions (shown in Table 1). All data for calculating results were received prior to **1 April 2005**.

Up to 1 April 2005, a total of 961 EVAR procedure patients were enrolled in the audit of which 70% (677/961) were performed in the private sector and the remainder in the public system. The 677 private patients represent around 90% of all procedures performed privately in Australia. Fifty five percent (495/906) of patients were considered suitable for open repair.

Preoperative patient demographics and anatomical features

Most patients in the audit are male (86%, 827/961). The mean age (± SD) of patients at the time of the procedure was 75.0 ±6.9 years and 57% (546/961) of patients were 75 years or older. Patient fitness was measured using the American Society of Anaesthesiology (ASA) rating. Thirty four percent of patients were listed as healthy or had only mild systemic conditions (i.e. ASA I or II), the majority of patients (59%) were ASA III (559/945). Figure 4 shows the proportion of ASA rating for EVAR patients.

Figure 4: ASA values for EVAR patients



The number of systemic conditions diagnosed for patients prior to surgery ranged from 0 to more than 10 per patient (55% ≤ 3 conditions). Few patients were listed as current smokers (10%, 89/892).

Mean preoperative aneurysm diameter was 57.5mm (± 10.4mm). Where maximum aneurysm diameter was reported, a total of 44% (411/931) of aneurysms measured less than 55mm in diameter, with 27% (255/931) ≤50mm in diameter.

Ten percent (83/870) of patients had an infrarenal "neck" length less than 15mm. Thirty four percent of patients had a neck length between 15 and 20mm (300/870). An infrarenal neck diameter ≥ 28mm was recorded in 16% of cases (143/877). Significant aortic neck angulation was noted for 229 patients (24%), but the angle size provided varied between 10^{o} and 90^{o}. A neck angle > 45^{o} was noted in 8% of patients (13% were ≥ 45^{o}). Significant aneurysm angulation was noted for 57 patients (6%) with angle size ranging between 5^{o} and 90^{o}. An aneurysm angle of greater than 60^{o} was recorded for only 1% of patients (1.5% were ≥ 60^{o}). Twelve percent (105/884) of patients had thrombus in the neck of the aneurysm, 22% had a saccular aneurysm (186/869) and 29% had an iliac aneurysm (249/871). Occlusive aorto-iliac disease was noted in 12% of patients (104/851). Iliac tortuosity was severe in 13% of patients (115/898) and moderate in a further 28% of patients (247/898); iliac calcification was severe in 5% of patients (41/868) and moderate in 20% of patients (171/868). The aorta was the artery affected by aneurysm in 72% of patients (646/901), whilst a further 26% of aneurysms affected the aorto-iliac arteries (236/901).

Forty five percent of patients (411/914) were regarded as unsuitable candidates for the open repair. For this group, the main reason given was co-existent morbidity (77%), whilst 'hostile abdomen' and 'unfit for general anaesthetic' were given as further or additional reasons for 37% of patients. The patients who were considered suitable for open repair were significantly fitter (ASA I/ASA II = 13% v 51%; $p<0.05$) with fewer comorbidities (3.5 v 2.2; $p<0.05$).

Summary statistics for females enrolled in audit

The average age for the 134 female patients was 75.4 [7.0] years at the time of the procedure. Thirty four percent had an ASA I or II, and 57% had ≤ 3 conditions prior to surgery. The pre-operative aneurysm diameter was 55 [9.0mm], and 55% of aneurysms measured less than 55mm; 39% measured ≤50mm.

Fourteen percent had an infrarenal neck length <15mm (17/125); 46% had a neck length between 15 and 20mm (n=57). Infrarenal neck diameter was ≥ 28mm in 10% of females treated (13/126). Significant aortic neck angulation was noted in 55 females (41%) with sizes ranging from 15° to 90°; an aortic neck angulation of >45^0 was noted in 20% of patients (n=26). Significant aneurysm angle was recorded in 17 women (13%) ranging between 30 ° and 90 °; an angle >60 ° was present in two patients (1.5%). In the female group, thrombus was noted in 15/129 patients (12%); the aneurysm was reported as saccular in 30/123 patients (24%) and iliac in 18% of patients (23/134). Occlusive aorto-iliac disease was indicated in 12% of women (14/120). Iliac tortuosity was severe in 10% of women, whilst iliac calcification was severe in 9% of women. The aorta was the aneurysm affected artery for 80% of women (102/128).

Open repair was not considered suitable for 43% of women (58/134), mostly due to co-existent morbidities (71%).

Imaging

On average, two imaging techniques were used preoperatively (mean number of imaging techniques=2.1 [0.62]). Most commonly this involved the two techniques spiral CT and angiography (57%, n=538/943), but these two imaging techniques were used in combination with other imaging techniques in a further 20% of cases. Spiral CT was used in 94% of imaging and angiography was used in 83% of cases. Spiral CT on its own accounted for 11% (n=100/943) of imaging.

For follow-ups that took place after 30 months, the mean number of imaging techniques used was 1.3 [0.66]. Imaging typically involved CT, ultrasound, or the two techniques in combination as shown in Table 3:

Table 3: Imaging techniques used at follow-up

Imaging technique	30- 41 months (n=487)	>41 months (n=234)
Spiral CT alone	147 (29%)	69 (30%)
Other CT alone	23 (5%)	7 (3%)
Spiral CT + x-ray	54 (11%)	34 (14%)
Spiral CT + ultrasound	16 (3%)	13 (6%)
Ultrasound alone	128 (26%)	49 (21%)
Ultrasound + x-ray	53 (11%)	23 (10%)
No imaging listed	28 (6%)	22 (9%)
Other imaging	38 (8%)	17 (7%)

Surgical details

Most procedures were performed in an angiography or endovascular suite (66%, 611/921); the rest were performed in a surgical theatre. Around 74% (690/933) of procedures were performed under general anaesthesia, and epidural/spinal anaesthesia was used in 25% (235/933) of cases (only 1% of patients had local anaesthesia). The most commonly used main access vessel is the femoral artery (96%, 908/945), and access is usually open (92%, 865/941) rather than percutaneous. The main type of graft used in Australia during the period of audit was the Zenith graft (Cook Australia) (82%, 787/957). The other types of graft used were: Ancure (Guidant) 1.5% (n=14), AneuRx(Medtronic) 7.0% (n=67), Excluder (W L Gore) 4.5% (n=43), Talent (World Medical) 3.8% (n=36), and Vanguard (Boston Scientific) 0.7% (n=7). Three grafts were of mixed origin (AneuRx and Talent). The aorto-bi-iliac-bifurcated design is the most common configuration (92%, 874/949). Sixteen fenestrated grafts were used during the audit period.

30-day technical and clinical success

Technical and clinical success rates were calculated according to reporting standards established by the Ad Hoc Committee for standardized reporting practices in vascular surgery.[2] Details are shown in Table 4, and additional information is provided in Appendix 3.

Table 4: Definition of technical and clinical success

	Description
Technical success	Primary technical success based on intent-to-treat basis • Successful access to the arterial system using a remote site • Successful deployment of the endovascular graft with secure proximal and distal fixation • Absence of the following: death, conversion to open repair, type I or III endoleaks, or graft limb obstruction • Use of the following: additional planned components, stents, angioplasty or adjunctive surgical procedures constitutes success.
Assisted primary success*	• Additional unplanned endovascular procedure
Secondary technical success*	• Additional unplanned surgical procedure
Clinical success	• Successful deployment of device at intended location • Absence of the following: aneurysm-related death, type I or III endoleak, graft infection, thrombosis, aneurysm expansion ≥ 5mm, aneurysm rupture, conversion to open repair, graft migration, failure of device integrity
Assisted clinical success	• Additional endovascular procedures to achieve ongoing clinical success
Secondary clinical success	• Additional surgical procedures to achieve ongoing clinical success

* The Australian audit data does not distinguish between planned and unplanned procedures undertaken during the peri-procedural (24h) period.

Table 5 shows the time interval covered by technical and clinical success:

Table 5: Time interval for technical and clinical success

	Time interval
Technical success	Peri- and post-operative to 24 hours
Clinical success	
• Initial	Up to 30 days postoperative
• Short term	30 days to 6 months
• Mid term	6 months to 5 years
• Long term	> 5 years

Technical success for Australian patients enrolled in the audit was 93% (890/961)

Clinical success is shown in Table 6. As several follow-up forms were received for each patient during the mid-term period (6 month to 5 years), clinical success was based on the most recent follow-up. Where additional endovascular or surgical procedures (excluding conversion to open) have been performed at any time during follow-up, success is described as assisted or secondary on a continuing basis. It should be noted that patients may alternate over time between clinical failure and success if: additional procedures are performed; a type 1 endoleak disappears; the sac size decreases. As recommended by the *ad hoc* Committee for Standardized Reporting Practices in Vascular Surgery[2], the proportion of patients classified as clinical successes that harbour a type II endoleak are indicated.

Table 6: Clinical success

	Clinical success (total)	Assisted clinical success	Secondary clinical success	Type II endoleaks with no associated increase in sac size
Initial success (961)	89% (853)	[++]	[++]	4.6% (41)
Short term success (350)	92% (321)	1.7% (6)	1.4% (5)	6.8% (24)
Mid-term success (819)	91% (744)	6% (49)	1.5% (12)	4% (33)

[++] Assisted and secondary success is not shown; the operative questionnaire does **not** distinguish between planned and unplanned procedures.

Endoleaks

Prior to discharge, 24 patients (2.5%) were recorded with type I endoleaks, four patients (0.5%) with type I and II endoleaks and a further 64 patients (6.5%) had type II endoleaks only. Table 7 provides the follow-up information for the patients with type I endoleaks.

Table 7: Endoleaks recorded < 30 days

Type I endoleaks (only)	**24**	**Comments**
Normal at first follow-up	15	1 patient had a type I endoleak at 2nd follow-up
Type II endoleaks only at first follow-up	3	
Type I endoleak treated	3	1 treated following rupture due to contralateral limb separation at 3 years
Deceased	1	septicaemia < 30 days
Converted to open	1	following rupture at 6 days
Unknown	1	

For the four patients who had type I **and** type II endoleaks recorded prior to discharge, one was clear of both at all subsequent follow-ups, one was clear until two years when the type II leak was observed again, and two reported continuing type II endoleaks (but not type I) throughout all follow-ups.

During mid-term follow-up, 35 patients were diagnosed with type I endoleaks. Twenty four had additional interventions, (including three who were converted to open repair, one conversion followed aneurysm rupture), six patients declined further treatment or were too frail for a further intervention, two patient's leaks resolved, two patients died following rupture of the aneurysm and the outcome for one is unknown as yet. Ten patients with type I endoleak also recorded stent migration. Out of these 35 patients with type I endoleak at mid-term follow-up, a total of seven patients have subsequently died (20%), a slightly lower proportion than for the cohort as a whole (27%).

Type II endoleaks were noted in 123 patients at some point during their mid-term follow-up. Information relating to these patients is shown in the Table 8:

Table 8: Mid-term type II endoleaks

Type II endoleak at some point during follow-up	123
Resolved	44 (36%)
Ongoing	49 (40%)
Other	30 (24%)
Ruptured aneurysm and deceased	3
Deceased (no cause provided for 12 patients)	22
Ruptured aneurysm and repaired	1
Converted to open	3
Type III endoleak and migration	1

Type III endoleaks were not originally specified on the questionnaire, but were added as data points in 2003. To date only three type III endoleaks have been reported. One of these patients died at 24 months when an intra-sac injection dislodged the contra-limb. The second was diagnosed at 48 months and an extension limb was inserted endoluminally. The third was reported at 60 months and was awaiting an additional procedure at the time of data submission.

Complications (not including endoleaks)

Graft related complications noted immediately following the procedure included failed access, access vessel complications, failed and misplaced deployment of endografts, imperfect seal, twist/kink/obstruction and embolisation. For the 4% of patients whose aneurysms were not successfully excluded (n=41) the following reasons were specified (Table 9):

Table 9: Complications, excluding endoleak where aneurysm not excluded

Imperfect seal	18
Failed access	4
Access vessel complications + imperfect seal	2
Failed deployment	1
Misplaced deployment	1
Failed deployment + imperfect seal	1
Misplaced deployment + imperfect seal	1
Misplaced deployment + imperfect seal + embolisation	1
Not specified	12

A further 8% of patients (n=76), whose aneurysms were successfully excluded, had the following complications recorded (Table 10):

Table 10: Complications, excluding endoleak where aneurysm excluded

Imperfect seal	25
Twist/kink/obstruction	18
Access vessel complications	14
Misplaced deployment	8
Failed access and access vessel complications	3
Embolisation	3
Failed deployment	2
Misplaced deployment + imperfect seal	2
Failed access	1

Prior to discharge 18 patients (2%) had graft related complications (Table 11):

Table 11: Graft related complications prior to discharge

Thrombosis	6
Stenosis	4
Migration	3
Kinking	2
Migration + thrombosis	1
Migration + kinking	1
Graft infection	1

Surgeons noted a range of systemic complications (excluding pyrexia) prior to discharge in 182 patients (19%); the leading cause was attributed to cardiac-related complications (7%, n=70).

Access site and lower limb complications were experienced by 8% (n=74) of patients, with bleeding, haematoma and false aneurysm being the major problem (4%, n=36).

Complications noted in the short-term (30 days to 6 months) and mid-term follow-up, excluding endoleaks, were as follows (Table 12):

Table 12: Short-term and mid-term complications (excluding endoleak)

	Short-term complications (350)	Mid-term complications (819)
Kinking	2	9
Stenosis	5	12
Thrombosis	10	7
Migration		12
Infected graft		1
Displaced graft struts		1
Mesh widened in graft		1
Separated wires		1
Serous fluid in aneurysm sac		1
Total	17 (5%)	45 (5%)

Ruptured aneurysms

To date, 13 patients have had aneurysms that have ruptured (1.4%). Information relating to these events is summarised in the Table 13:

Table 13: Ruptured aneurysms

Total number of rupture events recorded	13	
Patients deceased	7	One at time of procedure; others at 11 months, 12 months, 22 months, 30 months, 31 months and 35 months
Patients alive	6	2 episodes converted to open repair early, 3 converted late, 1 treated endoluminally

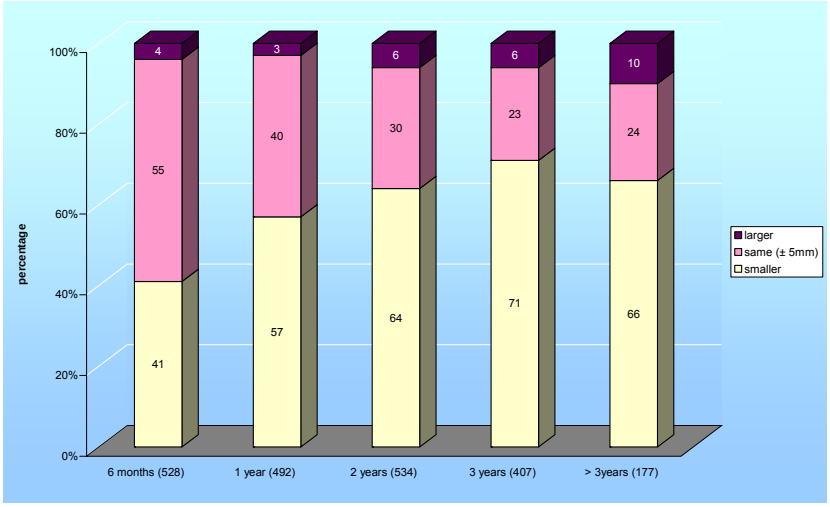
Occluded graft limbs

In order to evaluate how many patients have experienced occluded graft limbs, information was derived from several of the follow-up questions, including where 'thrombosed' was ticked, or the words occlusion, occluded, thrombectomy, embolectomy, thrombus in graft, graft blocked or fem-fem crossover graft appeared in any of the text fields. To date, 29 patients (3%) appear to have experienced occluded graft limbs.

Changes in aneurysm sac size

Figure 5 shows changes in aneurysm size over time. Aneurysms were deemed to be the same size if they were within 5mm of the original (pre-operative) measurement.

Figure 5: Changes in aneurysm size (±5mm)



Additional interventions

Three types of intervention are reported:

- additional procedures performed at the time of the original procedure (often referred to as secondary procedures)
- interventions performed after the initial procedure but prior to discharge
- interventions recorded at follow-up (shown in Table 7 - clinical success)

To date there have been 16 (1.7%) patients whose EVAR repair has been converted to open repair. Of these, 10 (1.0%) had early conversions (<30 days post operative) and 6 (0.6%) had a late conversion, as shown in Table 14:

Table 14: Cause of conversion to open repair

11 months	Enlarging aneurysm
20 months	Following rupture
22 months	Graft infection
27 months	Migration and type I endoleak
29 months	Aneurysm enlargement and type II endoleak
52 months	Following rupture (tear in fabric)

At the time of the procedure 23% of patients had an additional endovascular procedure (n=226), and 4% of patients had an additional surgical procedure (n=37). An additional 1.7% of patients had endovascular interventions following the original procedure but prior to discharge (n = 16), and 1.9% had surgical interventions (n=17).

Table 15 shows the number of open and endovascular interventions reported at follow-up. Most patients requiring an additional procedure during follow-up have endovascular procedures.

Table 15: Additional open and endoluminal procedures performed during follow-up

	Open	*Endoluminal*
<12m	8 patients: 9 procedures	26 patients: 28 procedures
12 – 24m	6	29
24 – 36m	6	23 patients: 24 procedures
> 36m	4	20
Total	24 patients; 25 procedures	98 patients; 101 procedures

Number of follow-up forms received: <12m=951; 12-24m=851; 25-36m=528; >36m=433.

Mortality

ASERNIP-S has been notified that 263 patients in total have died. The large increase in numbers follows information received from the National Death Index (AIHW). The number of patients who died within 30 days of the operation was 17 (1.8%), and 263 (27%) in the >30 day postoperative period. The reasons given for early death and postoperative days to death are shown below:

Table 16: Cause of early mortality and days to death

Cause of early death	Days to death
Retro-peritoneal haemorrhage and MI	0
Cardiac and acidosis	1
MI	2 at 3 days
Ischaemic bowel	3
Chronic IHD	3
Pulmonary embolus	6
Renal failure	7
Acute bowel rupture	10
Sepsis	11
Cardiac failure + renal failure	13
Rupture	14
Cerebral haemorrhage	14
Brain stem haemorrhage	18
Septicaemia from infected drip	19
Ischaemic gut	21
MI	21
Dissection thoracic aorta	27

Twenty-one patients died during the "short-term" period (30 days to six months), mostly due to cardiac causes (12/21). As described previously, two deaths were related to aneurysm rupture.

Mid-term mortality fell into the following categories:

Table 17: Cause of mid-term mortality

Total number of patients	225	
Unknown causes	92	41%
Cardiac	46	21%
Cancer	34	15%
Respiratory	16	7%
Stroke	9	4%
Sepsis	5	2%
Rupture	4	2%
Miscellaneous	19	8%

Time spent in hospital

Time spent in hospital was calculated for those patients where admission date and date of discharge were provided. Details of these results are shown in Table 18.

Table 18: Summary statistics for length of stay (days)

n	Mean	SD	Median	Min.	Max
932	7.3	7.6	5	0*	130

n = number of patients, SD = standard deviation, Min = minimum, Max = maximum
* Patient died during procedure

Comparison of Australian data with Eurostar[1] data registry results

Table 19 compares the Australian audit data with the Eurostar results reported in January 2005. Eurostar has been in effect since 1996; however they have recently stopped reporting their "older device data". Current devices reported include: Ancure (after 1/7/98), AneuRx, Fortron, Excluder, Lifepath, Talent and Zenith. Follow-up for Eurostar is up to 7 years post procedure. A total of 6264 patients are included in the data set.

[1] **Euro**pean Collaborators Group on **S**tent-graft **T**echniques for **A**bdominal Aortic Aneurysm **R**epair

Table 19 - Comparison of Australian and European audit data

	EUROSTAR[4]	Australian data
Male	94%	86%
Age (mean)	72	75
Aneurysm size (mean)	58mm	58 mm
ASA I	8%	3%
ASA II	41%	32%
ASA III	43%	59%
ASA IV	7%	6%
Classification of AAA		
A	16%	24%
B	47%	45%
C	14%	11%
D	8%	8%
E	6%	4%
Asymmetric	6%	8%
Study period	1996-2005*	1999-2005
Most common graft:		
Zenith (Cook) endograft	35%	82%
Device configuration:	90%	91%
Bifurcated		
Anaesthesia		
General	70%	74%
Regional	25%	25%
Local	5%	<1%
Perioperative mortality	2.4%	1.8%
Conversion to open (early)	1%	1%
Conversion to open (late)	1%	0.6%
Rupture (early)	0.02%	0.1%
Rupture (late)	0.7%‡	1.3%
Endoleak (discharge)		
Type I endoleak	4.3%	2.9%
Type II endoleak	9.6%	7%
Type III endoleak	2.1%	NA
Endoleak at 3 years (total)	9.3%	15%
Length of stay (mean and std dev)	5.8±7.9 days	7.3±7.6 days

n= 6264 (Eurostar), 961 (Australian data)

* grafts entered into the Eurostar audit between 1996 and 1998 appear to have been excluded from the study.

‡ Figure taken from Peppelenbosch et al[3] for 4392 patients enrolled in Eurostar registry, 1996-2002.

4. STATISTICAL ANALYSIS

The CSIRO Division of Mathematical and Information Sciences analysed de-identified data provided by ASERNIP-S and have produced a report detailing the full statistical analyses. This report is available as a separate document.

Analyses were performed to answer the following questions.

1. What pre-operative variables affect success?
2. Does presence of type I or II endoleaks affect the likelihood of another procedure?
3. What aneurysm morphology variables affect the likelihood of type I and II endoleaks?
4. Is Whites grading system* a better predictor of success than ASA?
5. Does graft type and device correlate with outcomes and endoleaks?

The results are summarized for each question below.

1. The pre-operative variables which affect success are shown in Table 20. Shaded cells indicate a statistically significant relationship, and the table is ordered by the number of statistically significant relationships. **Pre-operative aneurysm diameter** was found to statistically explain more variation in the different success measures than any other predictor variable.

a) ASA rating, graft type, number of ever-diagnosed conditions, operation site and maximum aneurysm diameter were statistically significantly correlated with initial graft complications (prior to discharge). Small aneurysms, few pre-existing conditions, open suitability and private patients statistically significantly correlate with fewer migrations.

b) Graft type, number of ever-diagnosed conditions, device/manufacturer, open suitability and operation site statistically significantly correlate with re-interventions.

c) The following factors statistically significantly correlate with less type I endoleaks; small aortic neck angle, longer infrarenal neck length, certain devices, small aneurysms. For fewer type II endoleaks predictors were graft type, low ASA and female gender.

d) The following factors were found to statistically significantly correlate with technical success; small aneurysms, low ASAs, small aortic neck angle and long infrarenal neck length. For clinical success the factors were young patients and small aortic neck angle.

e) The following factors were found to statistically significantly correlate with few early deaths; small aneurysms, small aortic neck angle, young patients and low Whites Grade Score. For few late deaths the factors were small aneurysms, low ASAs, few pre-existing conditions, open suitability and young patients.

* A full description of 'Whites grading system' is provided in Appendix 4.

2. Type I or II endoleaks did appear to affect the likelihood of a patient requiring another procedure.

3. The aneurysm morphology variables affecting the likelihood of type I endoleaks were found to be infrarenal neck length, aortic neck angle and maximum aneurysm diameter.

4. White's Grading Scale does not appear to be a better predictor of success than ASA. ASA was found more often to statistically significantly contribute to explain variations in success measures. Interestingly, White's Grade was a better predictor of early deaths.

5. Graft type and device do appear to correlate with outcomes and endoleaks. Device name statistically significantly ($p=0.04$) helped explain variation in additional interventions and initial type I endoleaks. Type of graft (bifurcated, crossover, tube) statistically significantly contributes to explain the variation in initial interventions, graft complications, and type II endoleaks. Site of procedure statistically significantly contributes to explain the variation in initial interventions, initial graft complications and perhaps early death.

The full report of these results is available from the ASERNIP-S office.

Table 20: Predictors of success

Predictor variable	Technical Success	Interventions		Graft Comp		Migrations	Conversion to open	Rupture	Endoleak Type I		Endoleak Type II		Clinical Success		Deaths	
		Initial	Mid-term	Initial	Mid-term	Mid-term			Initial	Mid-term	Initial	Mid-term	Initial	Mid-term	Early	Late
Max aneurysm diameter	0.020			0.035		0.002	0.006	0.011	0.056	0.032					0.004	<.001
Graft type		0.012		0.008	0.041						0.013	0.023		0.082		
ASA	0.034	0.057		0.016		0.100	0.092				0.028					<.001
Device	0.054	0.014	0.023	0.051				0.009	0.007					0.089		
Pre-existing morbidities		0.001		0.020	0.056	0.046		0.058			0.059					<.001
Site of procedure		0.042	0.051	0.036			0.049	0.024								
Aortic neck angle	0.024								0.048				0.024		0.021	
Age				0.078								0.064	0.018		0.017	<.001
Open suitability		0.034				0.048			0.088	0.086						<.001
Infrarenal neck length	0.006								0.012						0.087	
Whites Grade Score	0.088	0.061											0.082		0.047	
Public Private					0.065	0.034						0.060				
Gender											0.008					
Infrarenal neck diameter															0.076	
Aneurysm angle																
Smoking																

Red shading denotes 5% statistical significance ($p < 0.05$) Yellow shading denotes 10% statistical significance ($p < 0.10$)
Table shows Chi-squared p-value for terms included one at a time with intercept model

5. DISCUSSION

The EVAR audit has captured data for 90% of patients who received a graft under the Australian private health system between 1 November 1999 and 16 May 2001. In addition to the 677 **private** patients there is information on a further 284 patients who received the procedure under the **public** health system. The Australian audit provides a realistic means of evaluating the mid to long-term safety and effectiveness of the grafts used for EVAR.

Most Australian surgeons performed <15 EVAR procedures during the period 1999-2001, whilst a small number of surgeons appeared to offer the procedure to a high proportion of their patients. Surgeons will be surveyed during 2005 to determine whether patterns of surgical care for AAA have subsequently changed.

Of the 770 patients who entered the three year follow-up phase (i.e. 191 patients died prior to their three year follow-up), follow-up information has been received for 582 patients (76%), of whom 72 (9%) patients have subsequently died. ASERNIP-S has been notified that 10% (75) of patients are lost to follow-up. Patients become 'lost to follow-up' for a number of reasons but can be classified according to whether the patient is not contactable, has refused further follow-up, or where the surgeon has died or retired and the surgeon responsible for the ongoing care of the patients is unknown. Comments from surgeons suggest that public and rural patients are harder to follow.

The problem of losing patients during the follow-up period should be recognised by surgeons when they enrol patients for the EVAR procedure. Regular follow-up is known to be an important aspect of care; especially for certain sub-groups of patients who are at increased risk of complications. Peppelenbosch et al [3] identified worse outcomes for patients with larger aneurysms and this appears to be true for Australian patients, where initial aneurysm size is the most significant predictor of success measures. Longer follow-up periods will also be necessary for younger patients.

The peri-operative (30 day) death rate for this cohort of Australian patients is 1.8% (n=17) and late mortality is currently 26% (n=246). The perioperative death rate reported here is similar to that reported for other series:

- Eurostar:
  Poppelenbosch et al[3] reported 2.5% (108/4392)
  Eurostar Progress Report[4] reported 2.4% (152/6264)
- The Dutch Randomised Endovascular Aneurysm Management (DREAM) trial of EVAR vs open repair[5,6] reported 1.2% (2/171) for EVAR vs 4.6% in the open group (8/174)

- The Endovascular Aneurysm Repair Trial 1 (EVAR-1) of EVAR vs open repair [7,8] reported 1.7% (9/531) for EVAR vs 4.7% in the open repair group (24/516).
- 2001 Nationwide Inpatient Sample (national administrative database) identified 1.3% (33/2565) for EVAR vs 3.8% (176/4607) for open repair

The 30-day mortality reported for EVAR patients in the EVAR-2 trial (EVAR vs no intervention)[10] was considerably higher (8.7%, 13/150, vs 2.1%, 1/47 for the open group). Patients in this study had been deemed unfit for open repair and the study suggests that EVAR is not suitable for such high-risk patients.

During the four year follow-up period of the Australian audit, 126 additional open and endovascular procedures were performed on 97 patients (10%) with a mean time to initial placement of 23 months. In a French study conducted between 1995 and 2002, Becquemin et al [11] reported that 27% of patients (68 patients/250) required secondary procedures, with a mean time from initial placement of 18 months. The 2005 Eurostar report [4] indicates that 9.1% of European patients have required secondary interventions (572/6264) over 7 years. The EVAR-1 trial results[7] indicated that 20% of EVAR patients required interventions by 4 years (compared with 6% in the open group).

Additional statistical analysis of the audit results was undertaken by the CSIRO Division of Mathematical and Information Sciences; the executive summary of which is shown in section 7. A full report of the results is available on request.

The most significant predictor of success, as determined by this statistical analysis, is smaller pre-operative aneurysm size, a conclusion that was also drawn by the Eurostar group[3] and from the EVAR-1 trial[7,8].

Being less invasive than open repair, the EVAR procedure was originally deemed to be of benefit to higher risk patients. However, our statistical analysis shows worse outcomes for patients who have higher ASA values, patients considered unsuitable for open repair, and patients with higher numbers of pre-existing morbidities. This also appears to have been the case in the EVAR-2 trial[10] and as indicated above, the EVAR-1 trial has shown higher rates of reintervention for EVAR patients than for patients who have open repair. In other words, success is higher in patients with smaller aneurysms, who are fit for open repair and have lower ASA values. However, this group of patients could reasonably expect longer life-expectancies and are opting for a treatment whose long-term benefits are not yet known, but which necessitates regular follow-up and the expectancy of additional procedures over time.

The statistical analysis assessed various morphological features as predictors of outcome (i.e. aneurysm diameter, aortic neck angle, aneurysm angle, infrarenal neck length and infrarenal neck diameter). As noted before, aneurysm size was the most significant predictor, statistically significantly affecting technical success, initial graft complications, mid-term migrations, likelihood of conversion to open, risk of rupture, endoleaks I and II and early and late deaths. Other morphological predictors of success were longer infrarenal necks

and smaller aortic neck angles. These appeared to affect the risk of developing type I endoleaks, technical success and to a lesser extent early death.

Lastly, aspects of the graft and the site of operation were assessed to determine whether these correlated with outcome measures. According to the analysis the likelihood of rupture increased for AneurRx stents and combination AneuRx/Talent stents. These combination stents also had significantly higher rates of type I endoleaks, and secondary interventions. Ancure devices showed significantly higher rates of secondary interventions.

Most devices used are of the aorto-bi-iliac-bifurcated (trouser) configuration. Other configurations include aorto-aortic tube and aorto-uni-iliac+crossover. Crossover configuration stents appear to be more significantly associated with additional interventions at the time of the procedure.

There also appeared to be some correlation in terms of outcome measures with the operating facility used. For instance there were more graft complications seen in patients whose procedure was undertaken in a surgical theatre.

The audit of this cohort of EVAR patients is continuing until mid 2006. Considerable effort will be put into obtaining and checking the follow-up data for all surviving patients during the next few months to ensure this data set is as complete and accurate as possible.

6. REFERENCES

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Appendix 1 – Patient information and consent forms

CONSENT TO RELEASE OF INFORMATION

1. **I**……. of (address) …….
……
……
……

GIVE CONSENT TO:

the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical ("ASERNIP–S"), on behalf of the Royal Australasian College of Surgeons, to obtain information from medical records concerning my endoluminal grafting for abdominal aortic aneurysm, to enable the Medical Services Advisory Committee ("MSAC") to conduct an evaluation of the procedure.

2. **I UNDERSTAND THAT:**

- Any report compiled for the purpose of this audit and evaluation will not use information that could identify me.
- MSAC may authorise ASERNIP-S to release information to other organisations, but this will not include any information that could identify me.
- ASERNIP-S is strongly committed to protecting my privacy and maintains high levels of security.

……..
Signature

……..
Witness signature

……/……/……
Date

Endoluminal Grafting for Abdominal Aortic Aneurysm
PATIENT INFORMATION SHEET

What is an Abdominal Aortic Aneurysm?

Aging and certain diseases can cause weakening of the aorta (the main artery from the heart to the lower body), which may become enlarged (a condition known as abdominal aortic aneurysm) and could burst. As the aneurysm gets larger it becomes more likely that it will burst. Bursting of an aneurysm usually results in death. It is generally recommended that aneurysms greater than 5cm be treated if the risk of rupture is greater than the risk of operating. There are two treatment options that may be available, depending on the patient's suitability: open surgical repair and endoluminal grafting.

Open surgical repair

Open surgical repair is a procedure that has been well tested over 40 years with excellent long-term results.

The conventional operation involves a large abdominal incision. The diseased part of the aorta is replaced by a synthetic fabric tube (called the prosthesis or graft). The graft prevents rupture by replacing the weakened, enlarged aorta.

Open surgical repair is a major operation requiring deep general anaesthesia with 1–2 days in intensive care and then 7-14 days in a general hospital ward. The operation carries the risk of serious complications, including an approximate 5% risk of death. The risk of complication is greater in patients with severe lung, heart or kidney disease.

Endoluminal grafting

Endoluminal grafting has only been in clinical use for less than 10 years. The endoluminal grafting procedure usually involves inserting the graft by way of a small thin plastic tube (catheter) through an incision in one of the groin arteries. The graft is guided into position using x-rays, then expanded and secured in place to restore a more normal blood flow through the aorta.

It is a less major procedure, but it does require the same period in the operating theatre as open surgical repair. It is usual to spend 4-7 days in a general hospital ward, with no time spent in intensive care. The overall risks of the procedure in suitable patients are different, and possibly less severe than those for open surgical repair, at least in the short term. Available evidence suggests that mortality rates associated with the endoluminal repair of small aneurysms at the time of the operation are similar to those of open repair. Similarly, complication rates for endoluminal repair are different but as frequent as those for conventional open repair. Complications associated with the endoluminal procedure include blockage of arteries or veins, internal blood leaks from the upper or lower join of the graft into the aneurysm, and even failure to insert the graft. If the graft cannot be placed, or if one of the major arteries is blocked, then open surgery may be required to correct these problems, frequently at the same operation.

While the endoluminal grafting procedure appears effective in the short term, it is a relatively new procedure and the long-term success of the grafts is uncertain and is the main concern for the method.

Appendix 2 - EVAR data entry forms

Available from ASERNIP-S web site
http://www.surgeons.org/asernip-s/audit.htm

ASERNIP-S

ENDOLUMINAL
Abdominal Aortic Aneurysm Repair
Operative Data Set

PO Box 553
Stepney
South Australia 5069
Telephone: (08) 8363 7513
Facsimile: (08) 8362 2077
Email: mboult.asernip@surgeons.org
Form updated 3 May 04

Baseline details

Identifying data or place a name label

1 Patient's name

Family name

Given name

2 Address

City/Town

State Postcode

3 Telephone numbers

Home

Work

4 Date of birth

Day Month Year

5 Gender

Male ☐ Female ☐

6 Hospital

7 Medical record number

8 Patient Type

Private ☐ Public ☐

9 Admission date

Day Month Year

Question 10: no longer required

11 Smoking status (tick one)

Current ☐ Ever ☐ Never ☐

12 Creatinine

μmol/L

Baseline details (continued)

13 Physical condition: ASA (tick one)

ASA I ☐
Normal healthy patient with localized condition requiring surgery

ASA II ☐
Patient with mild or well controlled systemic condition, e.g. mild hypertension

ASA III ☐
Patient with severe systemic condition limiting lifestyle, e.g. angina

ASA IV ☐
Patient with severe systemic condition threatening life, e.g. advanced cancer

ASA V ☐
Moribund patient not expected to survive 24 hours with or without operation

14 Has the patient ever been diagnosed with, or experienced, any of the following:

	Yes	No
Hypertension	☐	☐
Angina	☐	☐
Myocardial infarction	☐	☐
Heart failure (CCF)	☐	☐
Arrhythmia	☐	☐
Stroke	☐	☐
Transient ischaemic attack	☐	☐
Peripheral vascular disease	☐	☐
Diabetes	☐	☐
Cancer (non-skin)	☐	☐
Asthma	☐	☐
COAD	☐	☐
Renal failure	☐	☐
If **yes**, requiring dialysis?	☐	☐
Hepatic disease	☐	☐
Haematologic disease	☐	☐
Specify		
Previous abdominal surgery	☐	☐
Other	☐	☐
Specify		

Aneurysm morphology

15 Imaging technique (tick all that apply)

- Spiral CT ☐
- Other CT ☐
- Abdominal x-ray ☐
- MRI ☐
- Angiography ☐
- Ultrasound ☐
- Other ☐

Specify ☐

16 Maximum aneurysm diameter

☐ mm

17 Length of infrarenal neck

☐ mm

18 Diameter of infrarenal neck

☐ mm

19 External iliac artery diameter

☐ mm

20 Is there thrombus in the neck?

Yes ☐ No ☐

21 Saccular aneurysm

Yes ☐ No ☐

22 Iliac aneurysm

Yes ☐ No ☐

23 Is there occlusive aorto-iliac disease?

Yes ☐ No ☐

24 Iliac tortuosity *(tick one)*

- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐

25 Iliac calcification *(tick one)*

- None ☐
- Mild ☐
- Moderate ☐
- Severe ☐

26 Artery affected by aneurysm *(tick one)*

- Aorta ☐
- Aorto-iliac ☐
- Iliac ☐
- Other ☐

Specify ☐

Aneurysm morphology (continued)

27 Length of common iliac artery

Left ☐ mm

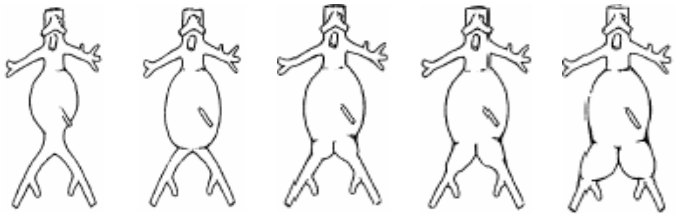
Right ☐ mm

28 Significant angulation *(sharpest angle in AP or side projection*

	Significant angulation? Yes	No	If YES, specify angle (°)
Aortic neck	☐	☐	☐
Aneurysm	☐	☐	☐
Right iliac	☐	☐	☐
Left iliac	☐	☐	☐

29 Classification AAA *(If iliac involvement is asymmetric: check two boxes A-E)*

A ☐ **B** ☐ **C** ☐ **D** ☐ **E** ☐



30 Patency of IMA

- Patent ☐
- Occluded ☐
- Unknown ☐

Comments ☐

Suitability for treatment

31 Is the patient suitable for open surgical repair?

Yes ☐ No ☐

If No, specify reasons *(tick all that apply)*

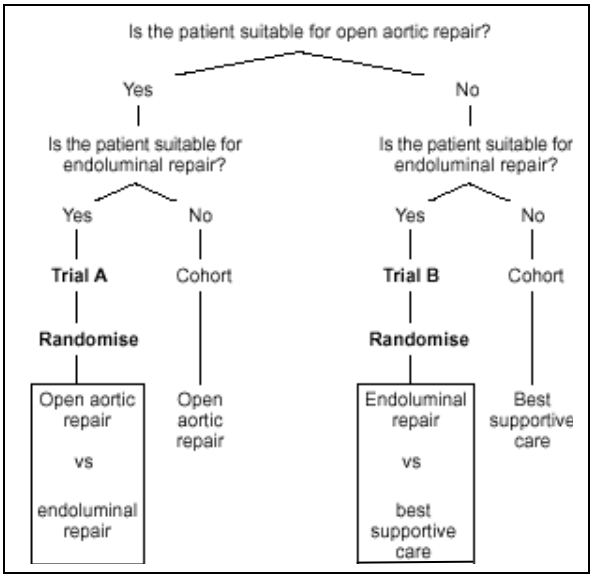
- Coexistent morbidities that preclude open surgical repair ☐
- Hostile abdomen ☐
- Unit for general anaesthesia ☐
- The risk of rupture does not exceed the risk of operating ☐
- Other ☐

Specify ☐

Procedure Details

32 Could this patient theoretically be randomised?

Randomised trials comparing treatments for abdominal aortic aneurysm are being considered. One model is presented in the diagram below.



Yes, could be randomized **Trial A** ☐

Yes, could be randomized **Trial B** ☐

No, could not be randomised ☐

33 Surgeon

34 Date of procedure

Day | Month | Year

35 Site of procedure *(tick those that apply)*

Angiography suite ☐

Surgical theatre ☐

Endovascular suite ☐

36 Type of anaesthesia used *(tick one)*

Local ☐

Epidural/spinal ☐

General ☐

37 Main Access Vessel *(tick one)*

Femoral ☐

Iliac ☐

Other ☐

Specify

Procedure details (continued)

38 Contralateral Access Vessel *(tick one)*

None ☐

Femoral ☐

Iliac ☐

Other ☐

Specify

39 Access technique for body of graft (endoluminal)

Open ☐

Percutaneous ☐

Other ☐

Specify

40 Access technique for second limb (endoluminal)

Open ☐

Percutaneous ☐

Other ☐

Specify

41 Name of device (and manufacturer) *(tick one)*

Ancure (Guidant) ☐

AneuRx (Medtronic) ☐

Lifepath (Baxter) ☐

Talent (World Medical) ☐

Vanguard (Boston Scientific) ☐

Zenith (Cook) ☐

Excluder (W L Gore) ☐

Other ☐

Specify

42 Type of graft *(please attach graft label to page 4 Q.47)*

Aorto-aortic tube ☐

Aorto-bi-iliac-bifurcated ☐

Aorto-uni-iliac + crossover ☐

Other ☐

Specify

43 Duration of procedure

Hours : Minutes

44 Immediate outcome

Was the aneurysm successfully excluded?

Yes ☐ No ☐

Procedure details (continued)

45 Complications at the time of the procedure

(tick all that apply)

- Failed access ☐
- Access vessel complications ☐
- Failed deployment ☐
- Misplaced deployment ☐
- Imperfect seal ☐
- Twist/kink/obstruction ☐
- Embolisation ☐
- Death ☐
- Other ☐

Specify

Procedure details (continued)

46 Additional procedure/s *(tick those that apply)*

- No additional procedures ☐

or

- Conversion to open repair ☐
- Secondary intervention during the procedure (e.g. twist corrected) ☐
- Additional endovascular procedure ☐

Specify

- Additional surgical procedure ☐

Specify

Comments

47 Graft Label *(Attachment or Description)*

ASERNIP-S

ENDOLUMINAL
Abdominal Aortic Aneurysm Repair
Discharge/30-Day Follow-up

***BLOCK LETTERS TO BE USED FOR HAND WRITTEN FORMS**

PO Box 553
Stepney
South Australia 5069
Telephone: (08) 8363 7513
Facsimile : (08) 8362 2077
Email: mboult.asernip@surgeons.org

Last update 3 May 2004

Discharge Evaluation

Identifying data

Surgeon:

1 Patient's name

Family name

Given name

2 Medical record number

3 Patient status

Alive ☐ - Go to Q6

Deceased ☐

4 If deceased, date of death

Day Month Year

5 If deceased, cause of death

6 Creatinine

µmol/L

7 Discharge date

Day Month Year

8 Admitted to ICU

Yes ☐ No ☐

9 If admitted to ICU specify

a) Date and time admitted

Day Month Year Time (24 hour Clock)

a) Date and time discharged

Day Month Year Time (24 hour clock)

10 Transfused blood products within 48 hours of procedure

mls

Discharge Evaluation (continued)

11 Complications prior to discharge *(tick all that apply)*

a) Procedures and device related complications

Graft migration ☐
Graft thrombosis ☐
Endoleak – Type 1 ☐
Endoleak – Type 2 ☐
Endoleak – Type 3 (fabric tear / module separation) ☐
Endoleak – Type 4 (graft porosity) ☐

Details

b) Systemic complications (*tick box then specify details*)

Cardiac ☐
Cerebral ☐
Pulmonary ☐
Renal ☐
Hepatobiliary ☐
Bowel ☐
Sepsis ☐
Pyrexia ☐
Graft infection ☐
Other ☐

Details

c) Access site and lower limb complications

Bleeding, haematoma, false aneurysm ☐
Arterial thrombosis ☐
Peripheral emboli ☐
Limb loss ☐
Other ☐

Specify

Discharge Evaluation (continued)

12 Were there any interventions following the procedure

Yes ☐ No ☐

13 If Yes, specify details of procedure

a) Open procedure

Yes ☐ No ☐

If **yes**, give date and details — Day | Month | Year

Details

b) Endovascular procedure

Yes ☐ No ☐

If **yes**, give date and details — Day | Month | Year

Details

c) Other procedure

Yes ☐ No ☐

If **yes**, give date and details — Day | Month | Year

Details

Aneurysm Evaluation

14 Imaging technique *(tick all that apply)*

- Spiral CT ☐
- Other CT ☐
- MRI ☐
- Angiography ☐
- Ultrasound ☐
- Abdominal x-ray ☐
- Other ☐

Specify

15 Result of Imaging *(tick all that apply)*

- Normal findings ☐
- Endoleak – Type 1 ☐
- Endoleak – Type 2 ☐
- Endoleak – Type 3 (fabric tear / module separation) ☐
- Endoleak – Type 4 (graft porosity) ☐
- Kinking ☐
- Stenosis ☐
- Migration ☐
- Thrombosis ☐
- Graft infection ☐
- Other ☐

Specify

16 Position of stent

- Same ☐
- Migrated ☐
- Broken wires ☐

17 Maximum aneurysm diameter

mm

ASERNIP-S

ENDOLUMINAL
Abdominal Aortic Aneurysm Repair
Follow-up

*BLOCK LETTERS TO BE USED FOR HAND WRITTEN FORMS

PO Box 553
Stepney
South Australia 5069
Telephone: (08) 8363 7513
Facsimile : (08) 8362 2077
Email: mboult.asernip@surgeons.org

Form updated 8 March 2005

Identifying details

1 Patient's name

Family name

Given name

2 Medical record number

3 Date of procedure

Day Month Year

4 Surgeon

5 Current follow-up

<12 months ☐ 50-60 months ☐
12-20 months ☐ 60-70 months ☐
20-30 months ☐ 70-80 months ☐
30-40 months ☐ >80 months ☐
40-50 months ☐

Patient details

6 Patient status

Alive ☐ - Go to Q8

Deceased ☐

7 If deceased,

a) Date of death

Day Month Year

b) Cause of death

8 If alive, date of examination

Day Month Year

9 Readmission to hospital

Day Month Year

Patient details (continued)

10 Cause for readmission

11 Creatinine

µmol/L

Aneurysm Evaluation

12 Imaging technique *(tick all that apply)*

Spiral CT ☐
Other CT ☐
MRI ☐
Angiography ☐
Ultrasound ☐
Abdominal x-ray ☐
Other ☐

Specify

13 Result of Imaging *(tick all that apply)*

Normal findings ☐
Endoleak – Type 1 ☐
Endoleak – Type 2 ☐
Endoleak – Type 3 (fabric tear / module separation) ☐
Endoleak – Type 4 (graft porosity) ☐
Kinking ☐
Stenosis ☐
Migration ☐
Thrombosis ☐
Graft infection ☐
Other ☐

Specify

14 Position of endoluminal graft

Same ☐
Migrated ☐
Broken wires ☐

15 Maximum aneurysm diameter

mm

Interventions

16 Have there been any interventions for the aneurysm since the last follow-up?

Yes ☐ No ☐

17 If Yes, specify details

a) Open procedure

Yes ☐ No ☐

If **yes**, give date and details Day Month Year

Details

b) Endovascular procedure

Yes ☐ No ☐

If **yes**, give date and details Day Month Year

Details

c) Other procedure

Yes ☐ No ☐

If **yes**, give date and details Day Month Year

Details

Interventions (continued)

18 Comments

Appendix 3 – Explanation of ‘technical’ and ‘clinical’ success, and White’s grading system

Technical success[2]

Technical success relates to the first 24 hours after the procedure and implies the following qualifying details:

- Successful access to the arterial system using a remote site
- Successful deployment of the endoluminal graft
- Absence of type I or III endoleak
- Patent endoluminal graft without significant twist, kinks or obstruction.

The standards delimit three subgroups of technical success according to the planned or unplanned use of additional modular components or surgery: primary technical success, assisted primary success and secondary technical success. Primary technical success can include the use of additional modular components, stents, angioplasty or adjunctive surgical procedures. The unplanned use of endovascular components is described as assisted primary technical success and unplanned additional surgical procedures is described as secondary technical success.

Clinical success[2]

"Clinical success requires successful deployment of the endovascular device at the intended location without death (as a result of aneurysm-related treatment), type I or III endoleak, graft infection or thrombosis, aneurysm expansion (diameter >=5mm or volume >=5%), aneurysm rupture, or conversion to open repair. Moreover, the presence of graft dilatation of 20% or more by diameter, graft migration, or a failure of the device integrity classifies a case as a clinical failure. Clinical success can be claimed for those cases with a type II endoleak only in the absence of aneurysm expansion. As long as the significance of a type II endoleak and its implication as a marker for late clinical failure remains an area of active investigation, it is recommended that reports clearly indicate the proportion of patients classified as a clinical success that harbour a type II endoleak.

Initial or 30-day clinical success encompasses 30-day data. Short term clinical success includes outcome measures reported within a 30 days to 6 month time frame. Mid term clinical success refers to all outcome measures that are statistically significant up to 5 years after endograft implantation. Long-term clinical success refers to all outcome measure that are statistically significant beyond 5 years.

Primary clinical success is clinical success without the need for an additional or secondary surgical or endovascular procedure. Assisted primary success is clinical success achieved with the use of an additional or secondary endovascular procedure. Secondary clinical success is clinical success obtained with the use of an additional surgical procedure."

Clinical success was calculated for the Australian data for discharge and 30day follow-up.

White's grading system[12]

Table 21 shows the grading system White developed to predict degree of difficulty for endovascular AAA repair:

Table 21 – Whites grading system[12]

Morphology	Extent	Points
Proximal Neck		
Length	<15mm	3
Angulation	$>45^0$	3
Thrombus layer	>2mm thick	3
Aortic Sac		
Angulation	$>60^0$	3
Iliac Tortuosity		
Tortuosity	Tortuous or $> 60^0$	3
Stenosis	Requires dilation to pass sheath	3
Circumferential calcification	Severe	3

"*Other features (e.g. patency of the inferior mesenteric artery, presence of eccentric thrombus in the lumen, etc) could be allocated relative values of 1 or 2 points or more to produce a more complete system.*"[3]

White graded patients using a points system:

Grade I	1-2 points
Grade II	3-5 points
Grade III	>5 points