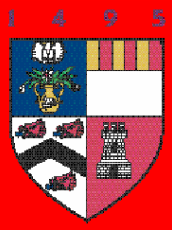

A systematic review of the recent evidence for the efficacy and safety relating to the use of endovascular stent-graft (ESG) placement in the treatment of thoracic aortic disease

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A systematic review of the recent evidence for the efficacy and safety relating to the use of endovascular stent-graft (ESG) placement in the treatment of thoracic aortic disease.

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Lisa Jones	Lead reviewer responsible for writing the report, study selection, data extraction, validity assessment and writing the final report.
Lynda Ayiku	Devised the search strategies and carried out the literature searches. Wrote the search methodology sections of the report.
Richard Wilson	Contributed to the writing of the scope and final editing of the completed report.

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Executive summary

Background

Thoracic aortic disease, that may be treated using stent grafts, covers a variety of diagnoses including aneurysms of different aetiologies, dissections, traumatic ruptures (aortic transection), intramural haematoma, and penetrating ulcer. The main conditions considered in this review are thoracic aneurysms and thoracic aortic dissection. A thoracic aortic aneurysm is defined as a condition in which the aorta develops a weakness with accompanying localised dilatation of the vessel at least 50% greater than its normal diameter. Aneurysms may be the result of atherosclerosis or also, for example, be traumatic, mycotic or post-surgical in origin. Based on the Stanford classification, aortic dissections may be type A or type B dissections. Type A dissections are characterised by involvement of the ascending aorta and require immediate surgery. Unless complications occur, patients with type B dissection typically do not undergo surgery and are treated medically.

Endovascular stent grafting for thoracic aortic disease was first described in 1996 for the treatment of thoracic aortic aneurysm, and there are a number of different ways to carry out the procedure, using a variety of commercially-developed devices. The potential advantages of endovascular aneurysm repair are that it is a less invasive procedure, and may have a lower operative mortality and reduced rate of post-operative morbidity compared to open surgical repair of the aorta.

Objectives

The objective of the review was to systematically assess the evidence for the efficacy and safety of the use of endovascular stent-graft (ESG) placement in the treatment of thoracic aortic disease as outlined above.

Methods

Electronic searches were conducted in the following electronic bibliographic databases: BIOSIS, Cinahl, Central Database, Cochrane Database of Systematic Reviews (CDSR), Centre for Reviews and Dissemination (CRD) Databases, Embase, Health Technology Assessment (HTA) Database, Medline, Medline in Process, NHS Economic Evaluations Database (NHS EED), Science Citation Index, Social Sciences Citation Index. In addition, the reference lists of relevant articles were checked. Searches were restricted to English language articles and papers published from the year 2000 onwards.

Study selection and quality assessment

Studies of any design (with the exception of case reports) that assessed the efficacy and/or safety of ESG placement were considered relevant. Only stent-graft devices commercially-available in the UK were included. The main efficacy issues were the technical success rate, exclusion of the aneurysm sac, aneurysm enlargement rate, rupture of the aneurysm, and mortality. All adverse events reported in the included studies were documented. One reviewer, using an adapted checklist assessed the quality of the included studies.

Results

A total of 29 studies were identified for inclusion in the review. The majority of the included studies were case series. Two comparative observational studies were identified that compared open surgical repair and endovascular stent grafting, but patients were not comparable in terms of their demographic and clinical

characteristics. Therefore, only the results for ESG patients were reported for these two studies.

Efficacy

Data from the included studies indicated that technical success was achieved in around 93% of cases. In 3 studies that provided a definition, which included freedom from endoleak, the technical success rate was around 84%. The overall rate of conversion to open repair during or after surgery was around 3%. Changes in aneurysm size were not well documented by the included studies. Patients experiencing an increase in aneurysm size ranged from 0% to 7%. In one large study, with over 12 months of follow-up, the rate of patients experiencing an increase in aneurysm size was 5%. Rate of aneurysm rupture was also reported in this study and was 5%. Length of hospital stay ranged from 3 to 10 days in the included studies and overall, patients spent an average of 6.3 days in hospital.

Safety

Across the included studies, the 30-day mortality rate after ESG placement was 5% and the overall mortality rate was 12% over a mean follow-up period of 14 months. Where reported, 30-day mortality rates for elective and emergency patients were 3% and 11%, respectively. Overall mortality rates were 11% for elective patients and 15% for emergency patients over an average follow-up of 18 months. The most commonly occurring technical complications related to the stent-graft device were endoleaks (13%), injury to the access site (6%), and stent fracture (6%). Where reported, type I endoleaks (perigraft leak at the graft attachment site) were the most frequent type of endoleak occurring. Stent fracture and stent migration occurred in 6% and 2% of patients in the included studies, respectively. The most commonly occurring non-technical complications experienced by patients undergoing ESG placement were wound complications associated with the access site (10%) and the need for mechanical ventilation for at least 24 hours (8%). The incidence of stroke and paraplegia were 6% and 2%, respectively. The majority of cases of paraplegia were reported to be transient and to have resolved over follow-up.

Conclusions

The evidence base for the assessment of the safety and efficacy of ESG placement for the treatment of thoracic aortic aneurysms is poor. The majority of the studies identified for inclusion in this systematic review were case series. In two studies that did compare endovascular stent grafting with open surgical repair, patients were not comparable in terms of their demographic and clinical characteristics. The results of the quality assessment showed that studies included heterogeneous groups of patients and that reporting of outcomes was incomplete. However, despite the quality of the evidence, the safety of ESG placement needs to be assessed in light of the fact that mortality is very high if patients presenting with thoracic aortic aneurysms are untreated. There was insufficient evidence to enable a comparison of the safety and efficacy of ESG placement with open surgical repair.

Data from the included case series indicated that ESG placement was technically successful in the majority of cases (approximately 84%) and had a 30-day mortality rate of 5%. Patients treated as emergency cases in the included studies experienced a greater 30-day mortality rate compared to patients treated electively (11% versus 3%, respectively). Conversion to open repair was performed in around 3% of patients and the length of stay in hospital averaged 6.3 days. The rate of aneurysm rupture was reported in one study only and was 5%. The most common complication experienced

by patients related to the stent-graft device was endoleak, (particularly type I endoleaks) and the most common non-technical complication was wound complications. Rates of stroke and paraplegia were 6% and 2%, respectively.

Well-designed, prospective studies are needed to more adequately assess the safety and efficacy of ESG placement for the treatment of thoracic aortic aneurysms. The types of patients selected for inclusion needs to be carefully considered to enable subgroup analyses of homogenous groups to be undertaken. Studies should also aim to include appropriately matched controls, as up-to-date studies comparing ESG placement to alternative treatments are currently lacking. In addition, long-term data are required to assess the durability of ESG devices over a number of years.

1 OBJECTIVE OF THE REVIEW

The objective of the review was to systematically assess the evidence for the efficacy and safety of the use of ESG placement in the treatment of thoracic aortic disease. The review focussed on thoracic aortic aneurysm and dissection.

2 BACKGROUND

2.1 The interventional procedure under review

2.1.1 Description of the interventional procedure

Stent-graft placement is a minimally invasive alternative to open surgical replacement of the aorta. In this procedure a stent-graft (a metallic stent covered with graft material) is inserted into the aorta to line the aorta from within (endoluminal placement). The aim in aneurysmal disease is to exclude the aneurysm sac from the circulation by placing the stent from normal proximal aorta into a normal segment of the distal thoracic aorta. This is usually achieved by using catheterisation of the femoral arteries or abdominal aorta. In order to exclude the sac of the aneurysm, the stent-graft device is positioned and deployed using x-ray guidance. The procedure is often known as Endovascular Aneurysm Repair (EVAR). Endovascular stent grafting for thoracic aortic aneurysm was first described in 1996, and there are a number of different ways to carry out the procedure, using a variety of commercially developed devices.

In thoracic aortic dissection, the stent-graft is used to cover the primary intimal tear (usually just beyond the origin of the left subclavian artery) and to increase flow into the true lumen of the dissection. This will often improve distal perfusion and may allow the false lumen to thrombose and remodel. If this occurs then the risk of long term dilatation of the false lumen may be reduced.

Traumatic aortic transection treated using stent-grafts are often reported with other cases treated using ESG, but these patients form a separate group in terms of likely outcomes. These patients may have multiple injuries, and as a result often have a high morbidity and mortality from these associated injuries, independent of the outcome of ESG placement.

The potential advantages of endovascular repair are that compared to open repair it is a less invasive procedure, and may have a lower operative mortality and reduced rate of post-operative morbidity. Endovascular aneurysm repair may also be a possible treatment in high risk patients for whom open surgery would not usually be an option.

2.1.2 Proposed clinical indications/contraindication and putative impact of the procedure

Treatment for asymptomatic aneurysms is usually advised in patients with aneurysms greater than 6 cm in diameter, because the risk of rupture increases with larger sized aneurysms. Symptomatic aneurysms are treated regardless of size. Contraindications for endovascular repair include: insufficient length of normal aorta proximal and distal to the aneurysm to adequately anchor the stent graft, excessive diameter of the aneurysm neck (proximal or distal), and the presence of thrombus within the distal or proximal neck likely to prevent exclusion of the aneurysm.[1] In thoracic dissection, stent-graft treatment is usually only required if there are peripheral complications of

the dissection, such as poor visceral or limb perfusion. However, there are some who advocate using stent-grafts to try and reduce long term problems of dilatation of the false aortic lumen following dissection of the descending thoracic aorta.

Aortic injury producing aortic transection usually occurs following high energy injury, such as during road traffic accidents. Most cases are immediately fatal, and of these that survive to reach hospital, rapid diagnosis and treatment, either surgically or with ESG placement, is required.

2.1.3 Personnel involved (e.g. surgeons, anaesthetists, nurses) and skill/experience required

Prior to an endovascular repair, patients are assessed for suitability for EVAR using computerised tomography (CT) scanning. In some cases this is supplemented by catheter angiography. These investigations are performed and analysed by a consultant vascular radiologist. Endovascular aneurysm repair for thoracic aortic aneurysms is a Consultant-led service, usually with involvement from a vascular interventional radiologist, a cardiothoracic surgeon and/or a vascular surgeon, depending upon the set-up of each centre. A consultant anaesthetist is present throughout the procedure and is responsible for general or regional anaesthesia.

Typically access to the femoral arteries is provided by a vascular or cardiothoracic surgeon via a surgical cut-down. Placement of the endovascular stent is carried out by either the radiologist or the surgeon, and a radiology assistant is required for this stage of the procedure. Nursing staff involved include a scrub nurse, and 2 support nurses to act as runners. An operating department assistant (ODA) is present to help the anaesthetist. Finally two radiographers are required to operate the radiology equipment. The surgeon or radiologist will typically have undergone a period of training in vascular interventional radiology.

2.1.4 Current use in the UK

There are currently around 60 centres in the UK undertaking EVAR for abdominal aortic aneurysms (AAA) and these centres also have experience in undertaking EVAR for thoracic aortic aneurysms. Most of these are teaching centres and the majority are participating in a national controlled trial which aims to assess the efficacy and safety of EVAR in the treatment of AAA.[2]

2.1.5 Equipment or devices required

There are a number of commercially-available ESG devices currently being sold in the UK. These are summarised in Table 1.

Table 1. Endovascular prostheses for thoracic aortic aneurysms currently being sold in the UK

Commercial name (Manufacturer)	Stent material	Graft material
Endofit (Endomed Inc.)	Nitinol	PTFE
Gore TAG (WL Gore & Associates)	Nitinol	PTFE
Talent (AVE/Medtronic)	Nitinol	Polyester
Zenith (William Cook)	Stainless steel	Polyester

2.2 Description of underlying health problem

2.2.1 Epidemiology

The estimated incidence of descending thoracic aortic aneurysms is approximately 6 cases per 100,000 persons per year. The risk of rupture in such patients is reported to range from 46 to 74%, with 5-year survival rates estimated between 9 to13%.[1] The incidence of aortic dissection is around 1-2 cases per 100,000 persons per year.[3]

2.2.2 Aetiology, pathology and prognosis

Thoracic aortic disease covers a variety of diagnoses including dissections, traumatic ruptures and aneurysms of different aetiologies.

Thoracic aortic aneurysms

A thoracic aortic aneurysm is defined as a condition in which the aorta develops a weakness with accompanying localised dilatation of the vessel at least 50% greater than its normal diameter. A large number of aneurysms are the result of atherosclerosis but they also may, for example, be traumatic, mycotic or post-surgical in origin. The condition may be asymptomatic in its early stages, but the aneurysm may continue to enlarge with the risk of rupturing, resulting in internal bleeding. When rupture occurs it is usually a fatal complication.

Aortic dissection

Aortic dissection occurs when there is a tear within the aortic wall, which causes the layers of the aortic wall to separate.[4] Based on the Stanford classification, aortic dissections may be type A or type B. Type A dissection is characterised by involvement of the ascending aorta, with or without involvement of the more distal aorta. Type B dissections are those in which the dissection does not involve the ascending aorta. Dissections are categorised as acute if the patient presents within 2 weeks of onset, or chronic if the onset is longer.[4] Patients with dissecting thoracic aneurysms may present with chest and back pain. The aims of stent grafting differ in patients with type A and B dissections.

2.2.3 Current management and alternative procedures

The conventional treatment for thoracic aortic aneurysm is a surgical operation to insert a bypass graft within the dilated aorta. This is a major operation with 30-day mortality rates of 5% to 20%.[5] In the case of aortic dissection, patients with type A dissection have been shown to be best treated with surgery. Early mortality rates following surgical repair range from about 20% to 35%.[6] As open surgery is associated with a very high rate of morbidity and mortality (35% to 50%[1]) in patients with type B dissection, they are usually treated medically with hypertensive drugs and ß blockers, unless complications associated with the condition occur. However, the mortality rate in patients with medically treated type B dissection remains around 20%.[7]

The risks of surgery may be increased by various co-morbidities that are common in patients with this condition. These need to be weighed against the risks of rupture of the aneurysm, which are dependent upon its size. Current practice is to consider surgery if there are signs that the aneurysm is continuing to enlarge. Of those patients whose aneurysms rupture most do not survive to undergo surgery. Of those patients that do, the operative mortality is greater than 50%.

3 METHODS FOR REVIEWING THE EVIDENCE ON EFFICACY AND SAFETY

3.1 Search strategy

Electronic searches were conducted in 12 electronic bibliographic databases, covering biomedical, health-related, science, and social science literature. The following databases were searched and full details of the search strategies used in the major databases are included in Appendix 1.

- BIOSIS
- Cinahl
- Central Database
- Cochrane Database of Systematic Reviews (CDSR)
- Centre for Reviews and Dissemination (CRD) Databases
- Embase
- Health Technology Assessment (HTA) Database
- Medline
- Medline in Process
- NHS Economic Evaluations Database (NHS EED)
- Science Citation Index
- Social Sciences Citation Index

In addition, the reference lists of relevant articles were checked.

Search terms

A combination of free-text and thesaurus terms were used. 'Population' terms (e.g. thoracic aortic aneurysm) were combined with 'intervention' terms (e.g. EVAR, endovascular aneurysm repair, endovascular stent).

The searches were restricted to the English language articles and to papers published from the year 2000 onwards, in accordance with ReBIP policy.[i]

3.2 Inclusion and exclusion criteria

Two reviewers independently screened all titles and abstracts. Full paper manuscripts of any titles/abstracts that were considered relevant by either reviewer were obtained where possible. The relevance of each study was assessed according to the criteria set out below. Studies that did not meet all of the criteria were excluded and their bibliographic details listed with reasons for exclusion. One reviewer assessed full paper manuscripts for inclusion.

a) Interventions

This review covers the efficacy and safety of ESG placement. Only commercially-available stent-graft devices were considered relevant for this review.

b) Participants

Participants with a primary thoracic aortic aneurysm of any aetiology including atherosclerotic, dissecting, and traumatic were considered relevant to this review. The review was limited to patients presenting for elective or emergency surgery.

[i] Policy agreed with NICE to limit the amount of literature to be reviewed.

c) Study design

Systematic reviews of the literature, randomised controlled trials, controlled clinical trials, comparative observational studies, case series, and population-based registries assessing the efficacy and/or safety of ESG placement were relevant. Case reports and abstracts were excluded.

d) Outcomes

The main efficacy issues were the technical success rate of introducing a stent-graft and excluding the sac of the aneurysm, and the long term results in preventing further enlargement and rupture of the aneurysm. Both 30 day and longer term mortality and severe morbidity rates were reviewed for ESG placement, open repair and conservative management for the different pathologies involved.

All adverse effects reported in the included studies were documented, including the rate of conversion to open repair and early and late complications of the procedure, especially relating to the long term integrity of the stents.

3.3 Data extraction and quality assessment strategy

Data relating to both study design and quality were extracted by one reviewer into an Access database. The quality of the individual studies was assessed by one reviewer into an Access database. The quality of the comparative observational studies and case series were assessed according to separate criteria based on CRD Report 4[8] and Down's and Black.[9]

3.4 Methods of analysis and synthesis

The results of the data extraction and quality assessment for each of the included studies were presented in structured tables and as a narrative summary.

4 RESULTS

4.1 Quantity and quality of research available

A total of 400 papers were identified from the literature searches and screened for inclusion in the review. Of the titles and abstracts screened, 81 studies were ordered as full papers and assessed in detail. A summary of the study selection process is shown in Figure 1.

4.1.1 Number and type of included studies

A total of 29 primary studies were identified for inclusion.[4, 7, 10-36] This included 27 case series[4, 7, 10-16, 18-29, 31-36] and 2 comparative observational studies.[17, 30] The main characteristics of the included studies are shown in Table 2.

The number of participants in the included studies ranged from 4 to 94 (total n=875) and the mean age, where reported, ranged from 46 to 75 years. The number of patients who received elective or emergency surgery, where reported, ranged from 0 to 73 and 0 to 26, respectively.

Mean months of follow-up ranged from 5.5 to 25 months. Thirteen studies[11, 12, 14, 15, 18, 20, 25-27, 30, 31, 34, 36] had a mean follow-up of 12 months or more, 3 of which,[12, 18, 25] had a mean follow-up of at least 24 months.

The majority of studies included participants with aortic aneurysms of various aetiologies. Additionally, some studies reported on patients with specific types of aneurysm (e.g. traumatic aneurysms, type B aneurysms).

4.1.2 Registry data

No data from population-based registries was identified in the literature searches. However, through personal communication with the Database Administrator we were able to access data from the Registry for Endovascular Treatment of Thoracic Aneurysms and Dissections. These data are presented in an Addendum.

4.1.3 Summary of excluded studies

A total of 43 studies were excluded; in addition, 9 studies[5, 37-44] were excluded on the basis that they were subsets, or earlier reports, of patients in included studies. Any data not reported in the main publications were extracted. Full bibliographic details of these studies are presented in Appendix 3.

The majority of the studies were excluded as the stent-graft under investigation was custom-made by the investigators and/or is not commercially-available in the UK. Full bibliographic details of the excluded studies and reasons for exclusion are reported in Appendix 4. Seven studies were ordered as full papers but were unavailable.[45-51]

Figure 1. Process of study selection

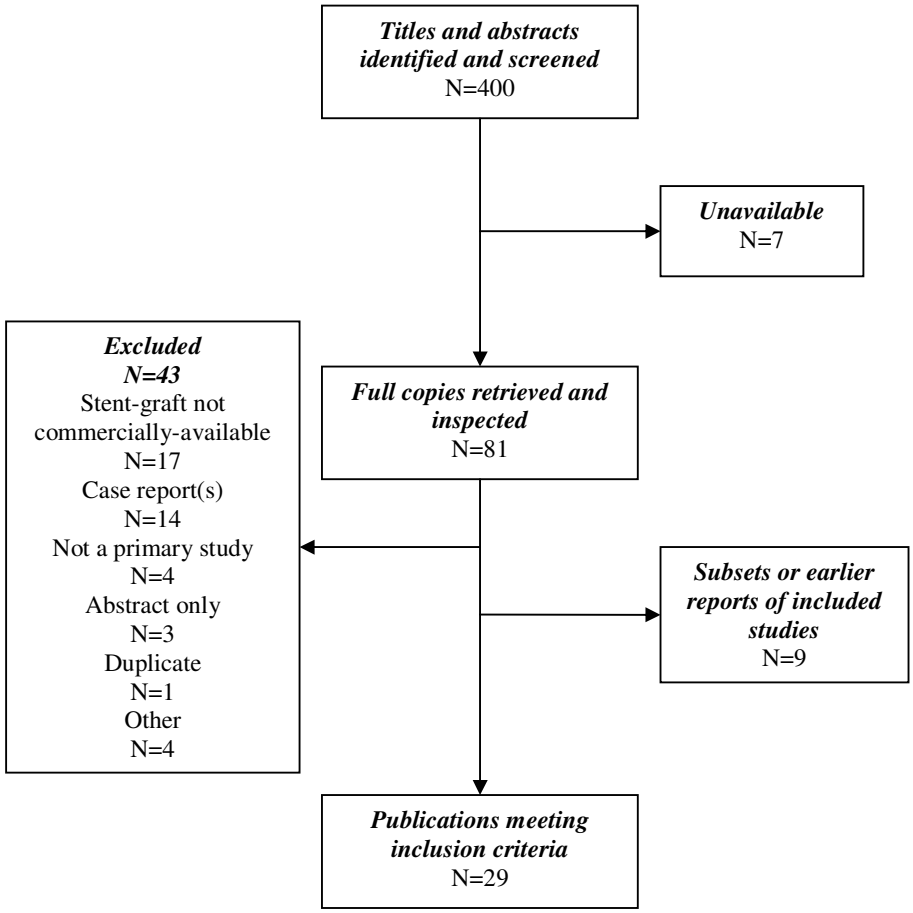

Table 2. Summary of included studies

Study ID	Design	Participant characteristics				
		Total	Elective	Emergency	Mean age (range)	Mean follow-up (range)
Alric 2002[10]	Case series	10	NR	NR	75 years (49-85 years)	7.9 months (4-22 months)
Bell 2003[11]	Case series	67	42	25	72[a] years (17-90 years)	17 months (2-64 months)
Bergeron 2003[12]	Case series	33	NR	NR	70 years (35-88 years)	24 months (1-40 months)
Bortone 2001[13]	Case series	16	NR	NR	NR (21-77 years)	6.2 months (NR)
Criado 2002[14]	Case series	47	NR	NR	NR (33-88 years)	18 months (1-44 months)
Czermak 2000[4]	Case series	7[b]	NR	NR	67 years (43-80 years)	14 months (1-25 months)
Czermak 2002[15]	Case series	18	0	18	62 years (19-80 years)	17.4 months (0-38 months)
Daenen 2003[16]	Case series	7	NR	NR	NR	9 months (1-18 months)
Doss 2003a[17]	Comparative study	26	NR	NR	ESG: 61.1 years (NR)	NR
Fattori 2003[18]	Case series	70	NR	NR	NR (19-80 years)	25 months (1-60 months)
Gerber 2003[19]	Case series	17	NR	NR	NR (26-80 years)	NR
Grabenwoger 2003[20]	Case series	19	18	1	61 years (20-85 years)	17.2 months (3-63 months)
Haulon 2002[21]	Case series	14	10	4	45.8 years (20-78 years)	7.25 months (2-12 months)
Heijmen 2002[22]	Case series	27	27	0	70 years (50-82 years)	NR
Herold 2002[23]	Case series	34	30	4	68.6 years (58-84 years)	NR
Krohg-Sørensen 2003[24]	Case series	20	NR	NR	NR years (22-81 years)	8 months (1-24 months)[a]
Lambrechts 2003[7]	Case series	26	NR	NR	64 years (30-84 years)	8 months (1-18 months)
Lamme 2003[25]	Case series	21	NR	NR	55.6 years (19-86 years)	24 months (5-44 months)
Lepore 2002[26]	Case series	43	20	23	67 years (17-82 years)	19 months (0-34 months)
Marin 2003[27]	Case series	94	NR	NR	74 years (NR)	15.4 months (NR)
Marty-Ane 2003[28]	Case series	9[c]	0	9	52.3 years (23-78 years)	NR (4-20 months)
Morgan 2002[29]	Case series	4	NR	NR	NR	6.3 months (1-16 months)
Najibi 2002[30]	Comparative study	19	NR	NR	70.6 years (59 -78 years)	12 months (3-22 months)
Orend 2003[31]	Case series	74	48	26	65 years (12-87 years)	22 months (3-72 months)
Ramaiah 2003[32]	Case series	46	NR	NR	70 years (NR)	9 months (1-15 months)
Schoder 2003[33]	Case series	28	28	0	71.6 years (53-82 years)	NR
Taylor 2001[34]	Case series	37	19	18	NR (17-90 years years)	17.5 months (6-45 months)
Temudom 2000[35]	Case series	14	NR	NR	62 years (35-84 years)	5.5 months (1-15 months)
Totaro 2002[36]	Case series	32	NR	NR	62 years (48-82 years)	12 months (6-18 months)

[a]median; [b]1 patient included in Czermak 2002[15] (excluded from total count); [c] 3 patients included in Alric 2002[10] (excluded from total count); NR – not reported, F – female; M – male; TAA – thoracic aortic aneurysm; AD – dissecting aneurysm

4.1.4 Quality of the available evidence

a) Comparative observational studies

Two comparative observational studies were identified. Doss 2003a[17] included patients who were managed surgically using cardiopulmonary bypass and patients who were treated acutely with endovascular stent graft. Allocation to the two groups was non-randomised and based on a patient's suitability for surgery. Najibi 2002[30] compared patients treated with endovascular stent grafts with a historic nonrandomised cohort of patients who had undergone open repair but who were considered, retrospectively, to have been candidates for stent-graft treatment. The results of the quality assessment for the two studies are shown in Table 3.

In both studies, the groups undergoing ESG placement and open surgical repair were not comparable in terms of their demographic and clinical characteristics. Patients treated with stent grafts suffered from a greater number of concomitant diseases such as hypertension, cardiac disease and chronic obstructive pulmonary disorder (COPD), in both studies. In addition, the sexes were distributed unequally between the intervention and control group in the study by Najibi 2002.[30] Confounding factors were not accounted for in either study.

Given that the patients treated with ESGs and open surgical repair were not similar, and because of the lack of case-mix adjustment, it was felt that it would not be valid to compare the two groups. Therefore, only the results for ESG patients are reported for these studies in the main body of the report. Full details of the study findings in both groups are presented in the data extraction tables in Appendix 2.

Table 3. Results of quality assessment for comparative observational studies

Criteria	Study ID	
	Doss 2003a[17]	Najibi 2002[30]
1. Were participants a representative sample selected from a relevant patient population?	?	?
2. Were the inclusion/exclusion criteria of participants clearly described?	Y	Y
3. Were participants entering the study at a similar point in their disease progression?	?	?
4. Were the groups comparable on demographic characteristics and clinical features?	N	N
5. Was the recruitment period clearly stated?	Y	Y
6. Was the intervention (and comparison) that which is being considered in the review? (or was it a significant modification?)	Y	Y
7. Was an attempt made to blind study participants to the intervention they received?	N	N
8. Was an attempt made to blind outcomes assessors?	N	N
9. Was the operation undertaken by someone experienced in performing the procedure?	Y	Y
10. Did the staff, place, and facilities where the patients were treated provide an appropriate environment for performing the procedure?	Y	Y
11. Were objective (valid and reliable) outcome measures used?	N	Y
12. Were all the important outcomes considered?	N	Y
13. Was follow-up long enough to detect important effects on outcomes of interest?	?	?
14. Was information provided on non-respondents, dropouts?	N	N
15. Were participants lost to follow-up likely to introduce bias?	?	?
16. Were all important confounding factors identified?	N	N
17. Were confounding factors taken into account in the analyses?	N	N

18. Were the main findings clearly described? (to allow replication)	Y	Y
Y Yes; N No; ? Unclear		

b) Case series

The majority of the studies identified were case series (n=27). The evaluation of the included case series in relation to study quality is shown in Table 4. The reporting quality of the included studies varied and it was not clear in any of the included studies whether the participants were a representative sample from a relevant population. In addition, the majority of studies included heterogeneous groups of patients with aortic aneurysms of varying aetiologies, at differing points in their disease progression. It was also unclear in the majority of studies whether participants were selected consecutively and whether data collection was undertaken prospectively. On the whole, most studies reported some objective outcome measures but very few reported all of the outcome measures of importance. The description of participants lost to follow up was not well reported, and in most studies it was unclear whether this was likely to introduce bias.

Table 4. Results of quality assessment for case series

Criteria		Yes	No	Unclear
1.	Were participants a representative sample selected from a relevant population?	0	0	27
2.	Are the inclusion/exclusion criteria of the patients in the study clearly described?	6	21	0
3.	Were participants entering the study at a similar point in their disease progression?	0	0	27
4.	Was selection of patients consecutive?	2	0	25
5.	Were all important prognostic factors identified?	19	6	2
6.	Was data collection undertaken prospectively?	2	1	24
7.	Was the recruitment period clearly stated?	26	1	0
8.	Was the intervention that which is being considered in the review?	26	0	1
9.	Was the procedure undertaken by someone experienced in performing it?	2	0	25
10.	Did the staff, place, and the facilities where the patients were treated provide an appropriate environment for performing the procedure?	21	0	6
11.	Were objective (valid and reliable) outcome measures used?	18	7	2
12.	Were all important outcomes considered?	2	25	0
13.	Was the follow-up long enough to detect important effects on outcomes of interest?	0	0	27
14.	Was information provided on non-respondents and dropouts?	2	24	1
15.	Were participants lost to follow up likely to introduce bias?	0	3	24
16.	Were the main findings clearly described?	27	0	0

4.2 Overview of the efficacy findings

4.2.1 Technical success rate

The technical success rate was reported in 18 studies and ranged from 76% to 100%. The overall technical success rate across the 18 studies was 93%. Technical success rates are reported in Table 5.

Three studies[19, 27, 30] reported a definition for technical success. Gerber 2003[19] defined technical success as "perfect stent graft delivery and no primary endoleak". The definition used by Marin 2003[27] was "successful insertion and deployment of the ESG without the need for surgical conversion, no perioperative mortality, and absence of type I or type III endoleak, up to 24 hours post-operatively". Najibi 2002[30] reported

the 30-day technical success rate as defined by the Society for Vascular Surgery/International Society for Cardiovascular reporting standards. The technical success rate in the three studies that provided a definition were 76%, 85% and 89%, respectively, with an overall rate of 84%.

Table 5. Technical success rate (%)

Study ID	Number of participants			Technical success rate
	Total	Elective	Emergency	(%)
Bell 2003[11]	67	42	25	100%
Bortone 2001[13]	16	NR	NR	94%
Criado 2002[14]	47	NR	NR	98%
Czermak 2000[4]	7[a]	NR	NR	86%
Czermak 2002[15]	18	NR	18	78%
Doss 2003a[17]	26	NR	NR	77%[b]
Fattori 2003[18]	70	NR	NR	97%
Gerber 2003[19]	17	NR	NR	76%[c]
Grabenwoger 2003[20]	19	18	1	100%
Haulon 2002[21]	14	10	4	100%
Heijmen 2002[22]	27	27	0	96%
Marin 2003[27]	94	NR	NR	85%[c]
Morgan 2002[29]	4	NR	NR	100%
Najibi 2002[30]	19	NR	NR	89%[c]
Ramaiah 2003[32]	46	NR	NR	100%
Taylor 2001[34]	37	19	18	97%
Temudom 2000[35]	14	NR	NR	78%
Totaro 2002[36]	32	NR	NR	100%
Total	**573**	**-**	**-**	**93%**

[a] 1 patient included in Czermak 2002[15] (excluded from total count)
[b] Data extracted from Balzer 2002[38]
[c] Definition reported

4.2.2 Blood loss (ml)

Details about blood loss were reported in 7 studies. Five studies[26, 29-31, 35] (n=154) reported the mean blood loss with an average blood loss of 339 ml (range, 135 ml to 670 ml). Two studies[11, 22] reported a median blood loss of 200 ml and 300 ml, respectively. Details of blood loss are reported in Table 6.

Table 6. Blood loss

Study ID	Number of participants			Mean blood loss (range)
	Total	Elective	Emergency	
Bell 2003[11]	67	42	25	300 ml (50-3000 ml) [a]
Heijmen 2002[22]	27	27	0	200 ml (50-1500 ml) [a]
Lepore 2002[26]	43	20	23	670 ml (100-5800 ml)
Morgan 2002[29]	4	NR	NR	135 ml (NR)
Najibi 2002[30]	19	NR	NR	325 ml (± 353 ml)
Orend 2003[31]	74	48	26	150 ml (100-3000 ml)
Temudom 2000[35]	14	NR	NR	400 ml (200-800 ml)
Total	**248**	**-**	**-**	**339 ml**

[a] Median

4.2.3 Rate of conversion to open repair

Ten studies reported the rate of conversion to open repair. The rate ranged from 0% to 7% in the included studies and the overall rate of conversion to open repair was 3%. Details about the rate of conversion to open repair during and after surgery are shown in Table 7.

Table 7. Rate of conversion to open repair

Study ID	Number of participants			Rate of conversion to open repair
	Total	Elective	Emergency	
Doss 2003a[17]	26	NR	NR	0%
Fattori 2003[18]	70	NR	NR	6%
Gerber 2003[19]	17	NR	NR	6%
Haulon 2002[21]	14	10	4	0%
Heijmen 2002[22]	27	27	0	4%[a]
Lamme 2003[25]	21	NR	NR	5%
Lepore 2002[26]	43	20	23	0%
Marin 2003[27]	94	NR	NR	3%[b]
Najibi 2002[30]	19	NR	NR	0%
Temudon 2000[35]	14	NR	NR	7%
Total	**345**	**-**	**-**	**3%**

[a] occurred as a separate procedure 2 weeks after stent-graft placement
[b] includes one late conversion

4.2.4 Changes in aneurysm size

Seven studies reported numbers of patients who had changes in aneurysm size following stent-graft placement. Patients experiencing an increase in aneurysm size over follow-up, where reported and excluding Schoder 2003,[33] ranged from 0 to 7%. In the study that included the largest number of patients,[27] 5% of patients had an increase in aneurysm size. Changes in aneurysm size are shown in Table 8.

Table 8. Changes in aneurysm size

Study ID	Number of participants	Changes in aneurysm size		
		Increase	No change	Decrease
Bell 2003[11]	29[a]	2 (7%)	20 (69%)	5 (17%)
Czermak 2002[15]	18	0	0	18 (100%)
Fattori 2003[18]	70	NR	10 (14%)	51 (73%)
Heijmen 2002[22]	27	1 (4%)	NR	NR
Marin 2003[27]	84[b]	4 (5%)[c]	NR	NR
Najibi 2002[30]	19	0[d]	NR	NR
Schoder 2003[33]	1-year (n=18):	2 (11%)	4 (22%)	12 (67%)
	2-year (n=9):	1 (11%)	8 (89%)	0
	3-year (n=5):	1 (20%)	3 (60%)	1 (20%)

[a] patients with degenerative aneurysm (2 patients were lost to follow-up)
[b] data extracted from Ellozy 2003[5]
[c] enlargement ≥5 mm
[d] at short-term follow-up

Three studies reported changes in the diameter of the aneurysm or false lumen. These findings are shown in Table 9.

Table 9. Mean changes in aneurysm diameter

Study ID	Number of participants	Mean diameter mm (range)		Mean reduction in diameter mm
		Before procedure	After procedure	
Fattori 2003[18]	NR[a]	52.27 (NR)	41.38 (1.00 to 45.00)	11.06 (± SD 10.2)
Grabenwoger 2003[20]	19	23.00 (± 5.80)	7.00 (± 4.40)	NR
Schoder 2003[33]	18[b]	NR	NR	6.6 (± SD 6.4) at 1-year (-10.4%, p=0.001)

[a] patient with >6 months follow-up and aneurysm or false lumen shrinkage
[b] patients without evidence of endoleak

4.2.5 Length of hospital stay (days)

Seventeen studies reported details about length of hospital stay. The mean length of hospital stay across 12 studies[4, 7, 18, 20, 21, 23, 30-33, 35, 36] (n=382) was 6.3 days (range 3 to 10 days). Median length of hospital stay was reported in 2 studies[11, 25] and was 4 and 6 days, respectively. Details about length of hospital stay are shown in Table 10.

Table 10. Length of hospital stay

Study ID	Number of participants			Mean length of hospital stay (range)
	Total	Elective	Emergency	
Alric 2002[10]	7[a]	NR	NR	NR (5-13 days)
Bell 2003[11]	67	42	25	4 days (range 1-41 days) [b]
Czermak 2000[4]	7	NR	NR	5 days (range 4 -11 days)
Fattori 2003[18]	70	NR	NR	5 days (± 9 days)
Grabenwoger 2003[20]	19	18	1	8 days (NR)
Haulon 2002[21]	14	10	4	6 days (range 5-9 days)
Heijmen 2002[22]	25[c]	25	0	NR (3-36 days)
Herold 2002[23]	34	30	4	3 days (NR)
Lambrechts 2003[7]	26	NR	NR	6 days (3-20 days)
Lamme 2003[25]	21	NR	NR	6 days (3-63 days) [b]
Marty-Ane 2003[28]	9	0	9	NR (7 days to 3 months)
Najibi 2002[30]	19	NR	NR	6 days (± 5.8 days)
Orend 2003[31]	74	48	26	8 days (4 -35 days)
Ramaiah 2003[32]	46	NR	NR	6 days (NR)
Schoder 2003[33]	28	28	0	9 days (4 -20 days)
Temudom 2000[35]	13[d]	NR	NR	3 days (1-4 days)
Totaro 2002[36]	32	NR	NR	10 days (NR)
Total	**511**	**-**	**-**	**6.3 days**

[a] Patients with non-traumatic rupture only
[b] Median
[c] Data reported for 25 out of 27 patients;
[d] Excludes 1 patient who had an extended hospital stay

4.3 Overview of the safety findings

4.3.1 Mortality

a) 30-day mortality rate

The 30-day mortality rate was reported in 17 studies and ranged from 0% to 14%. Across the studies the overall 30-day mortality rate was 5%. Thirty-day mortality rates are summarised in Table 11.

Table 11. 30-day mortality rate (%)

Study ID	Number of participants			30-day mortality (%)
	Total	Elective	Emergency	Total
Alric 2002[10]	10	NR	NR	10%
Bell 2003[11]	67	42	25	8%
Criado 2002[14]	47	NR	NR	2%
Czermak 2000[4]	7[a]	NR	NR	0%
Czermak 2002[15]	18	0	18	6%
Haulon 2002[21]	14	9	5	14%
Heijmen 2002[22]	27	27	0	0%
Herold 2002[23]	34	30	4	3%
Lambrechts 2003[7]	26	NR	NR	0%
Lamme 2003[25]	21	NR	NR	0%
Lepore 2002[26]	43	20	23	7%
Marty-Ane 2003[28]	9[b]	0	9	0%

Morgan 2002[29]	4	NR	NR	0%
Orend 2003[31]	74	48	26	10%
Schoder 2003[33]	28	28	0	0%
Taylor 2001[34]	37	19	18	8%
Totaro 2002[36]	32	NR	NR	0%
Total	**494**	**223**	**128**	**5%**

[a] 1 patients also included in Czermak 2002[15] (excluded from total count)
[b] 3 patients also included in Alric 2002[10] (excluded from total count)

Data on 30-day mortality following aortic transaction was available in two studies, Marty-Ane et al.[28] included 9 patients with traumatic aortic transection and Orend et al.[31] included 12 patients with 'acute traumatic transection of the descending thoracic aorta' in their study of 74 patients. The reported 30-day mortality in these studies were 0% and 16.7%, respectively (overall rate, 9.5%). Other studies included patients with aortic transaction but did not present the results separately.

b) Overall mortality

The overall mortality rate was reported (or was calculable) in 17 studies and ranged from 3% to 23%. The overall mortality rate across the studies was 12% over a mean follow-up period of 14 months. Overall mortality rates are summarised in Table 12.

Table 12. Overall mortality

Study ID	Number of participants	Mean months of follow-up (range)	Overall mortality
Alric 2002[10]	10	7.9 (4-22)	2 (20%)
Bortone 2001[13]	16	6.2 (NR)	1 (6%)
Criado 2002[14]	47	18 (1-44)	5 (11%)
Czermak 2000[4]	7[a]	14 (1-25)	1 (14%)
Czermak 2002[15]	18	17.4 (0-38)	2 (11%)
Fattori 2003[18]	70	25 (1-60)	3 (4%)
Haulon 2002[21]	14	7.25 (2-12)	2 (14%)
Heijmen 2002[22]	27	NR	1 (4%)
Krohg-Sørensen 2003[24]	20	8[b] (1-24)	2 (10%)
Lepore 2002[26]	43	19 (0-34)	8 (19%)
Marin 2003[27]	84[c]	15 (0-52)	9 (11%)
Najibi 2002[30]	19	12 (3-22)	2 (11%)
Orend 2003[31]	74	22 (3-72)	11 (15%)
Ramaiah 2003[32]	46	9 (1-15)	11 (24%)
Schoder 2003[33]	28	NR	3 (11%)
Taylor 2001[34]	37	17.5 (6-45)	1 (3%)
Temudom 2000[35]	14	5.5 (1-15)	2 (14%)
Total	**573**	**14**	**66 (12%)**

[a] 1 patients also included in Czermak 2002[15] (excluded from total count)
[b] median follow-up
[c] extracted from Ellozy 2003[5]

c) Elective versus emergency surgery

Patients who receive stent-graft placement as an emergency procedure differ from those who undergo elective surgery, because without treatment they inevitably will die.[ii] They also have a very high risk of operative mortality if they are treated with open repair. Eight studies[11, 15, 22, 26, 28, 31, 33, 34] reported separate mortality data for patients who had undergone emergency procedures. Only one study, Bell 2003,[11] reported criteria for emergency patients which included patients receiving treatment

[ii] Personal communication, Professor Jonathan Michaels

within 48 hours of admission, leaking or symptomatic aneurysms, complicated type B aortic dissection and aortic transection.

Eight studies reported 30-day mortality rates according to whether patients had undergone stent-graft treatment as an elective or emergency procedure. The 30-day mortality rate for patients who underwent elective treatment ranged from 0% to 10% (overall rate, 3%). For procedures performed as an emergency the rate ranged from 0% to 17% (overall rate, 11%). These rates are summarised in Table 13.

Table 13. 30-day mortality rate: Elective vs. emergency surgery

Study ID	Number of participants		30-day mortality (%)	
	Elective	Emergency	Elective	Emergency
Bell 2003[11]	42	25	2%	16%
Czermak 2002[15]	0	18	-	6%
Heijmen 2002[22]	27	0	0%	-
Lepore 2002[26]	20	23	10%	4%
Marty-Ane 2003[28]	0	9	-	0%
Orend 2003[31]	48	26	6%	15%
Schoder 2003[33]	28	0	0%	-
Taylor 2001[34]	19	18	0%	17%
Total	**184**	**119**	**3%**	**11%**

Four studies reported overall mortality according to whether patients had undergone stent-graft treatment as an elective or emergency procedure. The average follow-up was 18 months and overall mortality rates ranged from 4% to 20% (overall rate, 11%) in the elective treatment groups and from 11% to 17% (overall rate, 15%) in the emergency treatment group. Overall mortality rates are summarised in Table 14.

Table 14. Overall mortality: Elective vs. emergency surgery

Study ID	Number of participants		Mean months of follow-up (range)	Overall mortality	
	Elective	Emergency		Elective	Emergency
Czermak 2002[15]	0	18	17.4 (0-38)	-	2 (11%)
Heijmen 2002[22]	27	0	NR	1 (4%)	-
Lepore 2002[26]	20	23	19 (0-34)	4 (20%)	4 (17%)
Schoder 2003[33]	28	0	NR	3 (11%)	-
Total	**75**	**41**	**18**	**8 (11%)**	**6 (15%)**

4.3.2 Endoleaks

Endoleaks are a complication following aneurysm repair that are specific to ESG repair. The classification of endoleaks used in this review is that developed by White 1998[52] for AAA repair (see Appendix 5).

Five studies reported that there were no cases of endoleak during a mean follow-up period of 12 months (range, 7 to 24 months). Nineteen studies reported at least 1 case of endoleak. There were 96 (13%) cases of endoleak reported over a mean follow-up period of 12 months (range, 3 to 25 months). Where reported, there were 37 cases of type I endoleaks, 19 cases of type II endoleaks, and 1 type IV endoleak.

Five studies[14, 18, 22, 33, 34] reported cases of endoleak at 30-days. Overall, there were 22 (10.5%) cases of endoleak; 8 type I, 7 type II and 7 of an unknown type.

The incidence of endoleak is shown in Table 15.

Table 15. Incidence of endoleak

Type of endoleak	Study ID	Number of	Cases of	Mean follow-up

		participants	endoleak	(months)
No cases	Alric 2002[10]	10	0	8
	Bergeron 2003[12]	33	0	24
	Daenen 2003[16]	7	0	9
	Haulon 2002[21]	14	0	7
	Najibi 2002[30]	19	0	12
Type I (n=35)	Bell 2003[11]	67	3 (5%)	3
	Czermak 2002[15]	18	3 (17%)	17
	Doss 2003a[17]	26	2 (8%)	Not reported
	Gerber 2003[19]	17	4 (24%)	Not reported
	Lamme 2003[25]	21	1 (5%)	24
	Lepore 2002[26]	43	7 (16%)	19
	Marin 2003[27]	94	14 (15%)	Not reported
	Marty-Ane 2003[28]	9[a]	1 (11%)	Not reported
	Schoder 2003[33]	28	2 (7%)	
Type II (n=16)	Gerber 2003[19]	17	1 (6%)	Not reported
	Heijmen 2002[22]	27	2 (7%)	3
	Lambrechts 2003[7]	26	3 (12%)	8
	Lamme 2003[25]	21	1 (5%)	0
	Marin 2003[27]	94	9 (10%)	Not reported
	Schoder 2003[33]	28	3 (11%)	Not reported
Type IV (n=1)	Gerber 2003[19]	17	1 (6%)	Not reported
Type not reported (n=39)	Fattori 2003[18]	70	5 (7%)	25
	Grabenwoger 2003[20]	19	1 (5%)	17.2
	Heijmen 2002[22]	27	1 (4%)	12
	Morgan 2002[29]	4	1 (25%)	6
	Orend 2003[31]	74	15 (20%)	22
	Ramaiah 2003[32]	46	2 (4%)	9
	Taylor 2001[34]	37	2 (5%)	3
	Temudom 2000[35]	14	2 (14%)	6
	Totaro 2002[36]	32	10 (31%)	12
	Total	***752***	***96 (13%)***	***12.3***

[a] 3 patients included in Alric 2002[10] (excluded from total count)

4.3.3 Other technical complications

The incidence of technical complications is shown in Table 16.

Injury to access artery (9 studies, n=339): Nine studies reported cases of injury to the access arteries during stent-graft placement. The rate of injury ranged from 4% to 14%. Types of injury, where reported, included iliac artery dissection,[17] perforation of the common iliac artery,[22] dissection/rupture of the femoral artery,[4, 23] dissection of the access vessels[4] and rupture of the iliac artery.[7] Overall, in the included studies that reported this outcome there were 21 (6%) cases of injury to the access arteries.

Stent fracture (4 studies, n=185): Three studies[16, 24, 31] reported that there were no cases of stent fracture during follow-up periods that ranged from a median 8 months to a mean 22 months. One study,[27] (n=84) with an average of 15 months follow-up, reported 11 (13%) cases of stent fracture.

Stent migration (15 studies, n=328): Ten studies[10, 13, 14, 16, 23, 24, 28, 30-32] reported that there were no cases of stent migration observed during a mean follow-up period of 11 months (range, 6 to 18 months). Five studies[5, 15, 22, 25, 34, 35] reported 6 cases of stent migration during a mean follow-up period of 13 months (range, 6 to 24 months). Overall, in the included studies that reported this outcome, there were 6 (2%) cases of stent migration.

Table 16. Incidence of technical complications

Complication	Study ID	Number of participants	Number of cases	Mean follow-up (months)
Injury to the access artery	Bell 2003[11]	67	6 (9%)	-
	Criado 2002[14]	47	2 (4%)	-
	Czermak 2000[31]	7	1 (14%)	-
	Doss 2003a[17]	26	1 (4%)	-
	Heijmen 2002[22]	27	1 (4%)	-
	Herold 2002[23]	34	2 (6%)	-
	Lambrechts 2003[7]	26	2 (8%)	-
	Lamme 2003[25]	21	1 (5%)	-
	Marin 2003[27]	84 [a]	4 (5%)	-
	Total	***339***	***21 (6%)***	**-**
Stent fracture	Daenen 2003[16]	7	0	9
	Krohg-Sørensen 2003[24]	20	0	8[b]
	Marin 2003[27]	84[a]	11 (13%)	15
	Orend 2003[31]	74	0	22
	Total	***185***	***11 (6%)***	***15***
Stent migration	Alric 2002[10]	10	0	7.9
	Bortone 2001[13]	16	0	6.2
	Criado 2002[14]	47	0	18
	Czermak 2000[31]	7	0	14
	Czermak 2002[15]	18	1 (6%)	17.4
	Daenen 2003[16]	7	0	9
	Heijmen 2002[22]	27	2 (7%)	3
	Herold 2002[23]	34	0	Not reported
	Krohg-Sørensen 2003[24]	20	0	8[b]
	Lamme 2003[25]	21	1 (5%)	24
	Marty-Ane 2003[28]	9[d]	0	Not reported
	Najibi 2002[30]	19	0	12
	Ramaiah 2003[32]	46	0	9
	Taylor 2001[34]	37	1 (3%)	17.5
	Temudom 2000[35]	14	1 (7%)	5.5
	Total	***328***	***6 (2%)***	***12***

[a] Data extracted from Ellozy 2003[5]
[b] Median
[c] 1 patient included in Czermak 2002[15] (excluded from total count)
[d] 3 patients included im Alric 2002[10] (excluded from total count)

4.3.4 Non-technical complications

Non-technical complications reported in more then one study are shown in Table 17.

Paraplegia (15 studies, n=408): Twelve studies[7, 10, 12, 16, 17, 22-24, 28, 29, 32, 34] reported that there were no cases of paraplegia observed. Three studies[11, 20, 26] reported cases of paraplegia. In the remaining studies it was not clear whether there were no cases of paraplegia, or whether this outcome had not been reported. Overall, in the included studies that reported this outcome there were 7 (2%) cases of paraplegia. One study[11] reported the number of cases of paraplegia according to whether treatment was elective or emergency (5% and 4%, respectively).

Stroke (9 studies, n=289): Two studies[17, 28] reported that were no cases of stroke. Seven studies[11, 12, 22, 26, 30, 33, 34] reported 17 (6%) cases of stroke.

Renal failure requiring dialysis (8 studies, n=198): The incidence of renal failure was reported in 8 studies. Overall, there were 6 (3%) cases of renal failure that required dialysis during a mean follow-up period of 12.6 months (range, 8 to 19 months). Within the individual studies the rate of renal failure ranged from 0% to 11%.

Mechanical ventilation (3 studies, n=143): The number of patients requiring mechanical ventilation for more than 24 hours and for more than 48 hours was reported in 1 study[31] and 2 studies,[17, 26] respectively. Orend 2003[31] reported that 4 patients (5%) required mechanical ventilation for more than 24 hours. Doss 2003a[17] and Lepore 2002[26] reported that 2 (8%) and 6 (14%) patients, respectively, required mechanical ventilation for more than 48 hours.

Wound complications (9 studies, n=281): Nine studies reported 22 (8%) cases of wound complications over a mean follow-up period of 9 months (range, 1 to 24 months). Complications, where reported, included groin haematoma,[11] femoral wound haematoma and access-site femoral artery thrombosis,[14] groin infection,[40] groin haematoma or superficial infection,[22] groin pseudoaneurysm,[7] suture granuloma,[25] inguinal lymphocele,[30] prolonged duration of healing at access site,[33] lymph fistula in the groin and haematoma of the arm,[35] and infection at the site of access.[5]

Other neurological complications (9 studies, n=334): Nine studies reported 11 (3%) cases of neurological complications following treatment. Complications, where reported, included transient monoparesis,[18] ischaemia of the left arm,[20] transient blindness,[21] transient aphasia,[7] spinal cord ischaemia,[25] and transient paraparesis.[19, 31]

Pneumonia (3 studies, n=114): Three studies reported 5 (4%) cases of pneumonia over a mean follow-up period of 11 months (range, 1 to 24 months).

Myocardial infarction (MI) (2 studies, n=121): Two studies[14, 31] reported individual cases of myocardial infarction occurring at 1 month and 22 months, respectively (approximately 2% of cases). Both cases were nontransmural.

Post-implantation syndrome (2 studies, n=115): Two studies[14, 18] reported 56 cases of post-transplant/post-implantation syndrome. In the study by Fattori 2003,[18] 81% of 68 patients suffered from transient post-implantation syndrome (characterised by mild leucocytosis, elevated levels of C reactive protein and moderately elevated body temperature) over a mean follow-up period of 25 months.

There were a number of individual and multiple cases of complications reported in single studies. These are shown in Table 18. Aneurysm rupture was reported in one study only (Marin 2003[27]) and occurred in 5 of 94 patients (5%).

Table 17. Incidence of common non-technical complications

Complication	Study ID	Number of participants	Number of cases	Mean follow-up (months)
Paraplegia	Alric 2002[10]	10	0	7.9
	Bell 2003[11]	67	3 (4%)[a]	1
	Bergeron 2003[12]	33	0	24
	Daenen 2003[16]	7	0	9
	Doss 2003a[17]	26	0	Not reported
	Grabenwoger 2003[20]	19	1 (5%)	17.2
	Heijmen 2002[22]	27	0	Not reported
	Herold 2002[23]	34	0	Not reported
	Krohg-Sørensen 2003[24]	20	0	8[b]
	Lambrechts 2003[7]	26	0	8
	Lepore 2002[26]	43	3 (7%)	19
	Marty-Ane 2003[28]	9	0	Not reported
	Morgan 2002[29]	4	0	6.3
	Ramaiah 2003[32]	46	0	9
	Taylor 2001[34]	37	0	17.5
	Total	***408***	***7 (2%)***	**12**
Stroke	Bell 2003[11]	67	3 (4%)	1

	Bergeron 2003[12]	33	2 (6%)	24
	Doss 2003a[17]	26	0	Not reported
	Heijmen 2002[22]	27	1 (4%)	18
	Lepore 2002[26]	43	8 (19%)	19
	Marty-Ane 2003[28]	9	0	Not reported
	Najibi 2002[30]	19	1 (5%)	12
	Schoder 2003[33]	28	1 (4%)	Not reported
	Taylor 2001[34]	37	1 (3%)	17.5
	Total	***289***	***17 (6%)***	**15**
Renal failure requiring dialysis	Doss 2003a[17]	26	1 (4%)	Not reported
	Herold 2002[23]	34	1 (3%)	Not reported
	Lambrechts 2003[7]	26	1 (4%)	8
	Lepore 2002[26]	43	1 (2%)	19
	Marty-Ane 2003[28]	9	0	Not reported
	Morgan 2002[29]	4	0	6.3
	Najibi 2002[30]	19	2 (11%)	12
	Taylor 2001[34]	37	0	17.5
	Total	***198***	***6 (3%)***	**13**
Mechanical ventilation >48 hours	Doss 2003a[17]	26	2 (8%)	Not reported
	Lepore 2002[26]	43	6 (14%)	19
	Orend 2003[31]	74	4 (5%)[c]	22
	Total	***143***	***12 (8%)***	**21**
Wound complications	Bell 2003[11]	67	1 (2%)	1
	Criado 2002[14]	47	2 (4%)	1
	Heijmen 2002[22]	27	4 (14%)	Not reported
	Lambrechts 2003[7]	26	1 (4%)	8
	Lamme 2003[25]	21	1 (5%)	24
	Najibi 2002[30]	19	1 (5%)	12
	Schoder 2003[33]	28	2 (7%)	Not reported
	Temudom 2000[35]	14	2 (14%)	5.5
	Totaro 2002[36]	32	8 (25%)	12
	Total	***281***	***22 (8%)***	**9**
Neurological complications	Fattori 2003[18]	70	1 (1%)	25
	Gerber 2003[19]	17	1 (6%)	Not reported
	Grabenwoger 2003[20]	19	1 (6%)	17.2
	Haulon 2002[21]	14	1 (7%)	7.25
	Lambrechts 2003[7]	26	1 (4%)	8
	Lamme 2003[25]	21	1 (5%)	24
	Marin 2003[27]	84[d]	3 (4%)	1
	Marty-Ane 2003[28]	9	0	Not reported
	Orend 2003[31]	74	2 (3%)	22
	Total	***334***	***11 (3%)***	**15**
Pneumonia	Bell 2003[11]	67	2 (3%)	1
	Lambrechts 2003[7]	26	1 (4%)	8
	Lamme 2003[25]	21	2 (10%)	24
	Total	***114***	***5 (4%)***	**11**
Myocardial infarction	Criado 2002[14]	47	1 (2%)[e]	1
	Orend 2003[31]	74	1 (1%)[f]	22
	Total	***121***	***2 (2%)***	**12**
Post-implantation syndrome	Criado 2002[14]	47	1 (2%)	1
	Fattori 2003[18]	68[g]	55 (81%)[h]	25
	Total	***115***	***56 (49%)***	**13**
Lower extremity ischaemia	Czermak 2000[31]	7	1 (14%)	14
	Marin 2003[27]	84[d]	2 (2%)	15
	Total	***91***	***3 (3%)***	**14.5**

[a] 30-day outcomes
[b] Median
[c] >24 hours data
[d] Extracted from Ellozy 2003[5]
[e] Non-Q wave

[f] Non-transmural
[h] n=68 with a technically successful stent-graft placement
[g] Transient

Table 18. Incidence of complications reported in single studies

Complication	Study ID	Number of participants	Number of cases
Endocarditis	Bell 2003[11]	67	1 (1%)
Pulmonary embolus	Bell 2003[11]	67	1 (1%)
Perforated duodenal ulcer	Bell 2003[11]	67	1 (1%)
Respiratory complications	Criado 2002[14]	47	3 (6%)
Lymph leakage	Criado 2002[14]	47	1 (2%)
Antibiotics required for pulmonary infection	Heijmen 2002[22]	27	2 (7%)
Acute cholecystitis	Lambrechts 2003[7]	26	1 (4%)
Peripheral emboli	Lambrechts 2003[7]	26	1 (4%)
Surgical drainage of aneurysm sac hygroma	Lamme 2003[25]	21	1 (5%)
Cardiac arrhythmia	Lamme 2003[25]	21	1 (5%)
Aneurysm rupture	Marin 2003[27]	94	5 (5%)
Additional operative procedures	Orend 2003[31]	74	11 (15%)
Postoperative bleeding requiring blood transfusion	Schoder 2003[33]	28	1 (4%)

[a] n=68 with a technically successful stent-graft placement

5 DISCUSSION

A total of 29 studies were identified for inclusion in the review. The majority of the included studies were case series. Two comparative observational studies were identified that compared open surgical repair and endovascular stent grafting, but patients were not comparable in terms of their demographics and clinical characteristics. Therefore, only the results for ESG patients were reported for these two studies.

5.1 Efficacy

Data from the included studies indicated that technical success was achieved in around 93% of cases. In 3 studies that provided a definition, which included freedom from endoleak, the technical success rate was around 84%. The overall rate of conversion to open repair during or after ESG was around 3%.

Length of hospital stay ranged from 3 to 10 days in the included studies and overall, patients spent an average of 6.3 days in hospital. Changes in aneurysm size were not well documented by the included studies. Patients experiencing an increase in aneurysm size ranged from 0% to 7%. In one large study[27] with over 12 months follow-up, the rate of patients experiencing an increase in aneurysm size was 5%. The rate of aneurysm rupture was also reported in this study and was 5%.

5.2 Safety

The overall 30-day mortality rate after ESG placement was 5% across the included studies. Where reported, overall 30-day mortality rates for elective and emergency patients were 3% and 11%, respectively.

The most commonly occurring technical complications related to the stent-graft device were endoleaks (13%), injury to the access site (6%), and stent fracture (6%). Where reported, type I endoleaks (defined as perigraft leak at the graft attachment site) were the most frequent type occurring. Stent fracture and stent migration occurred in 6% and 2% of patients in the included studies, respectively.

The most commonly occurring non-technical complications experienced by patients undergoing ESG placement were wound complications associated with the access site (8%) and the need for mechanical ventilation for at least 24 hours (8%). The incidence of 'post-implantation syndrome' was particularly high in one study[18] (81% of 68 patients) with 44% experiencing slight/moderate back pain. The incidence of stroke and paraplegia were 6% and 2%, respectively. The majority of cases of paraplegia were reported to be transient and to have resolved during follow-up.

5.3 Assumptions, limitations and uncertainties

Methodological quality of the included studies

This review is limited by the poor quality of the available evidence. The majority of the available data came from case series. In two studies that did include an open repair group, the patients were too heterogeneous in terms of disease severity and other characteristics to enable a valid comparison with patients receiving ESG placement. The assessment of quality showed that the selection of patients into the studies was unclear in the majority of the include studies. In addition, a number of studies reported on heterogeneous groups of patients with aortic disease of varying aetiologies, without reporting outcomes separately. Reporting of outcomes was

incomplete in some studies and the description of drop-outs and losses to follow-up was poor.

Patients

Most studies included patients with various diseases of the thoracic aorta, but results were rarely presented separately, and it was often unclear whether the included patients had the same degree of disease severity. Patients with acute and chronic aneurysms and/or dissections were grouped together and few results were presented separately for patients undergoing emergency treatment. Patients requiring emergency treatment have a high mortality risk if they do not receive surgery, compared to patients treated electively for whom the prognosis without treatment may be variable.

Outcomes

In some studies, very few outcomes were reported and no study reported *a priori* outcomes of interest. Definitions of outcomes were rarely given, such as in the case of technical success. Only 3 out of the 18 studies that reported this outcome provided a definition. In addition, there was little data on the long-term outcomes following ESG. Only 3 studies had a mean follow-up period exceeding 24 months and therefore the long-term durability of the devices is not clear.

5.4 Need for further research

Well-designed prospective studies are needed to more adequately assess the safety and efficacy of ESG placement for the treatment of thoracic aortic aneurysms. Studies comparing alternative treatments to ESG placement should use appropriately matched and concurrent controls. In addition, long-term studies are required to assess the durability of ESGs over a number of years.

6 CONCLUSIONS

The evidence base for the assessment of the safety and efficacy of ESG placement for the treatment of thoracic aortic aneurysms is poor. The majority of the studies identified for inclusion in this systematic review were case series. In two studies that did compare endovascular stent grafting with open surgical repair, patients were not comparable in terms of their demographic and clinical characteristics. The results of the quality assessment showed that studies included heterogeneous groups of patients and that reporting of outcomes was incomplete. However, despite the quality of the evidence, the safety of ESG placement needs to be assessed in light of the fact that mortality and morbidity are likely to be very high if patients presenting with the various diseases of the thoracic aorta are untreated, and in view of the safety and efficacy of the alternative, open surgical repair, which carries a significant mortality and morbidity risk in itself. However, there was insufficient evidence to enable a comparison of the safety and efficacy of ESG placement with open surgical repair.

Data from the included case series indicated that ESG placement was technically successful in the majority of cases (approximately 84%) and had a 30-day mortality rate of 5%. Patients treated as emergency cases in the included studies experienced a greater 30-day mortality rate compared to patients treated electively (11% versus 3%, respectively). Conversion to open repair was performed in around 3% of patients and the length of stay in hospital averaged 6.3 days. The rate of aneurysm rupture at follow up was reported in only one study and was 5%. The most common complication experienced by patients related to the stent-graft device was endoleak, (particularly type I endoleaks) and the most common non-technical complication was wound complications. Rates of stroke and paraplegia were 6% and 2%, respectively.

Well-designed, prospective studies are needed to more adequately assess the safety and efficacy of ESG placement for the treatment of thoracic aortic aneurysms. The types of patients selected for inclusion needs to be carefully considered to enable subgroup analyses of homogenous groups to be undertaken. Studies should also aim to include appropriately matched controls, as up-to-date studies comparing ESG placement to alternative treatments are currently lacking. In addition, long-term data are required to assess the durability of ESG devices over a number of years.

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8 ADDENDUM: DATA FROM THE REGISTRY FOR ENDOVASCULAR TREATMENT OF THORACIC ANEURYSMS AND DISSECTIONS

Data was provided by Dr SM Thomas, Database Co-ordinator and Mr S Ayers, Data Administrator, Sheffield Vascular Institute.

8.1 Summary of the registry

The registry for endovascular treatment of thoracic aneurysms and dissections has been collecting cases since the beginning of 2000 and, currently, 21 centres across the UK have contributed cases. Submission of data to the registry is voluntary.

8.2 Thoracic aortic aneurysms

8.2.1 Patient characteristics

A total of 244 cases of thoracic aortic aneurysms (TAA) have been entered into the registry; 159 (69%) were men (data is missing for 14 patients). Indications for treatment are summarised in Table 19. In addition, details of disease aetiology and type of endoprosthesis used are shown in Tables 20 and 21, respectively.

Table 19. Indication for treatment

	n	%
Elective Asymptomatic TAA	123	50.4
Elective Symptomatic TAA	49	20.1
Ruptured TAA	24	9.8
Infective	8	3.3
Other	31	12.7
Missing data	9	0.9

Table 20. Aetiology

	n	%
Degenerative	128	52.5
Chronic dissection	24	9.8
Marfan Syndrome	1	0.4
Traumatic	32	13.1
Known collagen or inflammatory disease	3	1.2
Anastomic false aneurysm	4	1.6
Other	30	12.3
Missing data	22	9

Table 21. Type of endoprosthesis

	n	%
Aneurx	8	3.2
Cook Zenith	16	6.5
Endofit	10	4.0
Endomed	1	0.4
Gore Excluder	79	32.4
Gore Excluder + Talent	1	0.4
Medtronic Talent	110	45
Stenford	1	0.4
Vsci Debakey	1	0.4
Vanguard	1	0.4
Vascutek Gelsoft Knitted stent graft	1	0.4

The most common indication for treatment was an asymptomatic TAA (50%) and 53% of patients had a degenerative (atherosclerotic) aneurysm. The most commonly used stent-graft was the Medtronic Talent (45%).

8.2.2 Safety and efficacy outcomes

Short term safety and efficacy outcomes were available and are reported in Tables 22-26 below. Technical success (excluded aneurysm) was achieved in 184 patients (75%) and 1 (0.4%) patients required conversion to open surgical repair. Around 1% of procedures were abandoned.

Table 22. Efficacy

Outcome	n	%
Technical success	184	75.0
Conversion to open repair	1	0.4
Procedures abandoned	3	1.2
Endoleak	38	15.6
Missing data	20	7.7

Thirty day outcomes

A total of 18 patients with TAA died within 30 days of treatment (7%). The aneurysm was fully excluded in 177 patients (72%) and 32 had an endoleak (13%).

Table 23. 30 day outcomes

Outcome	n	%
Death	18	7.4
Aneurysm Excluded	177	72.5
Endoleak	32	13.1
Missing data	17	7

Complications

Technical complications are shown in Table 29. The most commonly reported technical complication was stent graft migration (4%). Endoleaks either immediately post procedure or at 30 day follow up occurred in 38 patients (15.6%); type I proximal endoleaks were the most common type. The number and types of endoleaks reported to the registry are shown in Table 30.

Table 24. Technical complications

	n	%
Unable to advance stent graft	7	2.9
Unable to deploy stent graft	1	0.4
Stent graft migration	10	4.1
Inadvertent branch occlusion	3	1.2
Aneurysm Rupture	1	0.4
Arterial perforation	5	2
Distal embolisation	6	2.5
Other	22	9

Table 25. Endoleaks

	n	%
Total	38	15.6
Type		
Proximal (Type Ia)	13	5.3
Distal (Type Ib)	5	2
Junctional	8	3.3

Collateral (Type II)	7	2.9
Graft Tear (Type III)	0	0
Other	5	2

Non-technical complications are shown in Table 31. Pulmonary and cardiac complications were the most commonly reported non-technical complication, occurring in 13% and 9% of patients in the registry, respectively. Neurological complications were relatively rare, 2% of patients experienced a stroke or TIA and paraplegia/ paraparesis was reported in 3%.

Table 26. Non-technical complications

	n	%
*Neurological complications**		
TIA	1	0.4
Recovered stroke	1	0.4
Non-disabling stroke	4	1.6
Disabling major stroke	0	0
Paraplegia	3	1.2
Paraparesis	5	2
Other	13	5.3
Mising data	31	12.7
Other medical complications		
Cardiac	22	9
Pulmonary	33	13.5
Renal	8	3.3
Other	37	15.2

8.3 Acute thoracic aortic dissections

8.3.1 Patient characteristics

There are currently 56 cases of acute thoracic aortic dissections entered into the registry, 37 (66%) are male (data was missing data for 7 patients. Data on aetiology of the dissections, complications of the dissection and the type of endoprosthesis used are shown in Tables 27-29, respectively. All of the cases treated had complications following dissection and so intervention was required. The most common underlying condition was hypertension (36%). In some cases, patients had more than one complication.

Table 27. Aetiology of Dissection

	n	%
Spontaneous(no known cause)	8	14.3
Hypertension	20	35.7
Marfan syndrome	1	1.8
Penetrating ulcer	9	16.1
Other	4	7.1
Missing data	14	25.0
Stanford Classification of dissection		
Type a	0	0.0
Type b	42	75
Missing data	14	25

Table 28. Complications of dissection

	n	%
Uncomplicated	0	0.0

Aneurysm formation	9	16.1
Branch vessel ischaemia	10	17.9
Rupture	19	33.9
Persistent pain	27	48.2
Other	5	8.9

Table 29. Type of endoprosthesis

	n	%
Cook Zenith	1	1.7
Endofit	5	8.6
Endomed	1	1.7
Gore Excluder	20	35.7
Medtronic Talent	16	28.6
Missing data	13	23.2

8.3.2 Safety and efficacy outcomes

Safety and efficacy outcomes are reported in Tables 30-32 below. Immediate technical complications reported to the database included stent graft migration in 4% of patients and inadvertent branch occlusion in 9%. Persistent true lumen collapse was reported in 1 patient (2%). No problems were reported in stent graft deployment. Two patients died within 30 days of ESG placement (4%). The most common non-technical complications were pulmonary (11%).

Table 30. Initial Outcome

	n	%
Stent graft deployed to tear	42	75
Restored flow to target vessel	14	25
Relief of true lumen collapse	22	39

Table 31. Technical complications

	n	%
Unable to advance stent graft	0	0
Unable to deploy stent graft	0	0
Stent graft migration	3	5.4
Inadvertent branch occlusion	3	5.4
Persistent true lumen collapse	3	5.4
Other	3	5.4

Table 32. Mortality and Morbidity

	n	%
Mortality at 30 days	3	5.4
Neurological complications		
TIA	0	0
Recovered stroke	0	0
Non-disabling stroke	1	1.8
Disabling major stroke	0	0
Paraplegia	0	0
Paraparesis	1	1.8
Other	1	1.8
Other Medical Complications		
Cardiac	3	5.4
Pulmonary	7	12.5
Renal	3	5.4

Other	5	8.9

8.4 Comparison with systematic review

The data outputs from the registry are consistent with the findings presented in the systematic review of the recent literature. The rate of technical success was within the range identified in the literature, and 30 day mortality and complication rates were similar to those reported.

There are, however, a few limitations to the registry data:

- Data has not been subject to the peer-review process.
- Relatively low numbers of patients have been submitted to the registry since its initiation in 2000.
- Submission of cases to the registry is voluntary and therefore selection bias could be significant.
- Some of the cases in the registry precede the date limits set for the systematic review and, therefore, efficacy and safety outcomes may be affected by clinicians' experience with the technique.

9 APPENDICES

Appendix 1. Search strategies

Search strategies used in the major electronic bibliographic databases:

Biological Abstracts
2000-2003
SilverPlatter WebSPIRS
Search undertaken December 2003

#1	thora*
#2	aneurysm*
#3	#1 and #2
#4	endo* near5 stent*
#5	endo* near5 graft*
#6	intravascular near5 stent*
#7	intravascular near5 graft*
#8	endovascular aneurysm repair*
#9	evar
#10	#4 or #5 or #6 or #7 or #8 or #9
#11	#3 and #10

Central, CDSR, HTA, NHS EED
2003 Issue 4
The Cochrane Library, Update Software (CD ROM version)
Search undertaken December 2003

#1	Thora*
#2	ANEURYSM explode tree 1 (MeSH)
#3	Aneurysm*
#4	(#2 or #3)
#5	(#1 and #4)
#6	STENTS single term (MeSH)
#7	(endo* next stent*)
#8	(endo* next graft*)
#9	(intravascular next stent*)
#10	(intravascular next graft*)
#11	(endovascular next aneurysm next repair*)
#12	evar
#13	(#6 or #7 or #8 or #9 or #10 or #11 or #12)
#14	(#5 and #13)

Cinahl
2000-2003
Ovid Online
Search undertaken December 2003

#1	Aortic Aneurysm, Thoracic/
#2	thora$.tw.
#3	Aneurysm/
#4	aneurysm$.tw.
#5	#3 or #4
#6	#2 and #5

#7 #1 or #6
#8 Stents/
#9 endo$ stent$.tw.
#10 endo$ graft$.tw.
#11 intravascular stent$.tw.
#12 intravascular graft$.tw.
#13 endovascular aneuysm repair$.tw
#14 evar.tw.
#15 or/#8-#14
#16 #7 and #15

CRD Databases (NHS DARE, EED, HTA)
CRD Web site - complete databases
Search undertaken December 2003
thoracic aneurysm and (endovascular graft or endovascular stent or intravascular graft or intravascular stent or endovascular aneurysm repair or evar)

Embase
2000-2003
SilverPlatter WebSPIRS
Search undertaken December 2003
#1 explode 'thoracic-aorta-aneurysm' / all subheadings
#2 thora*
#3 explode 'aneurysm-' / all subheadings
#4 aneurysm*
#5 #3 or #4
#6 #2 and #5
#7 #1 or #6
#8 explode 'stent-' / all subheadings
#9 endo* near5 stent*
#10 endo* near5 graft*
#11 intravascular near5 stent*
#12 intravascular near5 graft*
#13 evar
#14 endovascular aneurysm repair*
#15 #8 or #9 or #10 or #11 or #12 or #13 or #14
#16 #7 and #15

Medline
2000-2003
Ovid Online
Search undertaken December 2003
#1 Aortic Aneurysm, Thoracic/
#2 thora$.tw
#3 exp ANEURYSM/
#4 aneurysm$.tw
#5 #3 or #4
#6 #2 and #5
#7 #1 or #6
#8 Stents/

#9 endo$ stent$.tw
#10 endo$ graft$.tw
#11 intravascular stent$.tw
#12 intravascular graft$.tw
#13 endovascular aneurysm repair$.tw
#14 evar.tw
#15 or/#8 – #14
#16 #7 and #15

Medline in Process
December 10th 2003
Ovid Online
Search undertaken December 2003
#1 thora$.tw.
#2 aneurysm$.tw.
#3 #1 and #2
#4 endo$ stent$.tw.
#5 endo$ graft$.tw.
#6 intravascular stent$.tw.
#7 intravascular graft$.tw.
#8 endovascular aneurysm repair$.tw.
#9 evar.tw.
#10 or/#4-#9
#11 #3 and #10

Science and Social Sciences Citation Index
2000-2003
Web of Knowledge
Search undertaken December 2003
(thora* same aneurysm*) and (endo* or stent* or endo* graft* or intravascular stent* or intravascular graft* or endovascular aneurysm repair* or evar)

Appendix 2. Details of data extraction

Author(s)	Design/Patients	Participant characteristics	Results
Alric 2002[10] **Recruitment period:** November 1999 to April 2001 **Country:** France (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) Excluder Thoracic Endoprothesis (W.L. Gore & Associates, AZ, USA) (n=9) **Funding:** Not reported	**Design:** Case series **Inclusion**: None reported **Exclusion**: None reported **Patients:** 10 **Follow-up**: Mean 7.9 months (4 to 22)	**Diagnosis**: 3 traumatic and 7 non-traumatic ruptures (6 aneurysms and a penetrating ulcer) of the descending thoracic aorta. Aortic rupture was defined as disruption of the aortic wall with fresh blood outside the adventitia and mediastinal haematoma (contained rupture), haemothorax or aortobronchial fistula documented by CT within 7 days of symptom onset. **Mean age (range)**: 75 years (49-85) **Gender**: male 7; female 3 **Co-morbidities**: COPD, cardiac failure, arterial hypertension, atrial fibrillation, respiratory insufficiency, CAD, stroke, tumours.	**Efficacy**: **30-day mortality**: 10% (female patient died from MI, and a second patient died 4 months later from unrelated acute adrenal failure secondary to pneumonia with septicaemia) **Length of hospital stay (days)**: 5 to 13 (non-traumatic); weeks (traumatic) **Adverse events**: Mortality: 20% Paraplegia: None reported Endoleaks: None reported Stent migration: None reported

Author(s)	Design/Patients	Participant characteristics	Results
Bell 2003[11] **Recruitment period:** July 1997 to October 2002 **Country:** UK (single centre) **Intervention details**: Thoracic excluder (Gore & Associates); Talent; AneuRx; Endofit; Cook; Stentor; and Vanguard. **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** total 67 Elective: 42 Emergency: 25 **Follow-up**: 17 months (range 2-64)	**Diagnosis**: *Elective* / *Emergency* / *Total* Total: 42 / 25 / 67 Degenerative aneurysm: 28 / 8 / 36 'Infected' aneurysm: 0 / 8 / 8 Chronic dissection: 7 / 1 / 8 Acute dissection: 2 / 4 / 6 Coarctation: 5 / 0 / 5 Transection: 0 / 3 / 3 Vasculitis: 0 / 1 / 1 **Mean age (range)**: median 72 years (17-90) **Gender**: male 40; female 27 **Co-morbidities**: Not reported.	**Efficacy**: **Technical success rate**: 100% **30-day mortality**: 5 (8%) Elective: 1 (2%); Emergency: 4 (16%); **Late mortality**: 6 (2 stent-related, 1 patient died at 28 months from aortic rupture secondary to graft migration, other patient died at 5 months of rupture. There was no evidence of aortic rupture in 2 of the 4 other patients). **Blood loss**: median 300 (range 50-3000); **Length of hospital stay (days)**: median 4 (range 1-41); **Adverse events**: Injury to access artery (30-day): total 6 (9%) Elective: 4 Emergency: 2 Paraplegia (30-day): total 3 (4%) Elective: 2 Emergency: 1 Endoleaks (at 3-months): 3 (no type II or II detected) Other 30-day: *Total* / *Elective* / *Emergency* Stroke: 3 (4%) / 2 / 1 Bronchopneumonia: 2 (3%) / 2 / 0 Groin haematoma: 2 (3%) / 2 / 0 Endocarditis: 1 (1%) / 1 / 0 Pulmonary embolus: 1 (1%) / 0 / 1 Perforated duodenal ulcer: 1 (1%) / 1 / 0 **Changes in aneurysm size:** In patients with degenerative aneurysms (n=29), 20 remained the same, 5 shrunk and 2 increased in size. (2 patients lost to follow-up). Complete thrombosis of the lumen occurred in 12/14 patients with acute or chronic type B dissection. 1/8 patients treated for chronic dissection had a decrease in maximum aortic diameter; all others remained the same.

Author(s)	Design/Patients	Participant characteristics	Results
Bergeron 2003[12] **Recruitment period:** October 1999 to February 2003 **Country:** France (single centre) **Intervention details**: Gore (n=11); Talent (n=21). **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 33 **Follow-up**: Mean 2 years (1-40 months)	**Diagnosis**: 33 were suffering from thoracic aortic aneurysms or chronic thoracic aortic dissection. 3 patients presented associated abdominal aortic aneurysms. **Mean age (range)**: 70 (range 35-88) years **Gender**: ratio of male to female was 5.3 **Co-morbidities**: Not reported	**Efficacy**: Overall mortality: 2 patients (6.2%) died at 2 and 3 days, respectively. In-hospital mortality: 3 patients (9%). Mortality at <6 months: 2 Late mortality: 3/30 (10%) **Adverse events**: Paraplegia: No cases. Endoleaks: No cases. Stroke: 1 patient (3.1%) at 4 days. 1 patient had major fatal stroke at 15 months.

Author(s)	Design/Patients	Participant characteristics	Results
Bortone 2001[13] **Recruitment period:** March 1999 to August 2000 **Country:** Italy (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) also Excluder **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 16 **Follow-up**: mean 6.2 months	**Diagnosis**: 5 patients with atherosclerotic aneurysm, 3 patients with chronic post-traumatic pseudoaneurysm, 3 patients with acute post-traumatic pseudoaneurysm and 5 patients with type B aortic dissection. **Mean age (range)**: range 21-77 **Gender**: male 15; female 1 **Co-morbidities**: 2 patients had left carotid-subclavian by-pass graft	**Efficacy**: **Technical success rate**: 15 (94%); **Mortality**: 1 patient died due to multiorgan failure. No other patients died during follow-up. Overall operative mortality: 1 (6.2%) **Adverse events**: Stent migration: No changes in the position or configuration of the grafts were observed.

Author(s)	Design/Patients	Participant characteristics	Results
Criado 2002[14] **Recruitment period:** 4 yr period ending March 2002 **Country:** USA (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Patients with small or diseased arteries or extensive aneurysmal disease without "landing zones" for endograft attachment and seal were excluded. **Patients:** 47 **Follow-up**: mean 18 months (1 to 44 months).	**Diagnosis**: Thoracic aortic aneurysms (TAA) (n=31); Type B aortic dissection (AD) (n=16). **Mean age (range)**: TAA 74 years (37-88) years; AD 56 years (33-68) **Gender**: TAA: male 19; female 12 AD: male 14; female 2 **Co-morbidities**: TAA 61%; AD not reported **Risk stratification**[a] 0-I: 7 II-III: 40	**Efficacy**: **Technical success rate**: 97.9% (One procedure was aborted because of access failure) **30-day mortality**: 2.1% **Mortality**: 1 patient died at 60 days from a ruptured and infected thoracoabdominal aneurysm due to endoleak. 4 additional death noted during follow-up (unrelated n=3; unknown n=1). **Adverse events**: Injury to access artery: 4.3% (1 patient died) Endoleak at 30-days: n=5 (type I n=3 with secondary endovascular repair) other under observation. Stent migration: No cases. Other outcomes at 30-days: femoral wound haematoma (n=1); access-site femoral artery thrombosis (n=1); respiratory complications (n=3); non-Q wave MI (n=1); "post-transplant syndrome" (n=1); and lymph leakage (n=1). Of 16 cases of aortic dissection, 10/14 false lumen completely thrombosed, and 4 partially thrombosed.
[a] Based on the Society for Vascular Surgery/International Society for Cardiovascular Surgery scoring			

Author(s)	Design/Patients	Participant characteristics	Results
Czermak 2000[4] **Recruitment period:** **Setting:** Austria (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) and Vanguard **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** 7 **Follow-up**: 14 months (range 1-25 months)	**Diagnosis**: All patients had Stanford type B aortic dissection. Five patients had acute dissections and two patients had chronic dissections. **Mean age (range)**: 67 years (43-80 years) **Gender**: male 6; female 1 **Co-morbidities**: Not reported	**Efficacy**: **Technical success rate**: 6/7 (86%) **30-day mortality**: 0%; **Length of hospital stay (days)**: mean 5 (range 4 to 11) **Adverse events**: Injury to access artery: 1 (dissection of the access vessels) Mortality: 1 pt at 6 weeks. Paraplegia: No neurological complications observed. Stent migration: None reported. Aneurysm expansion: Left lower extremity ischaemia: n=1 Additional comments: In 5 patients with chronic dissection: immediately after therapy 0-40% (mean 20%), at 3 months mean 55%, and 6 months mean 90%.

Author(s)	Design/Patients	Participant characteristics	Results
Czermak 2002[15] **Recruitment period:** January 1996 to November 2001 **Country:** Austria (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) also Vanguard (Boston Scientific) and Excluder. **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** total 54 Elective: 36 Emergency: 18[a] **Follow-up**: 17.4 months (0-38 months)	**Diagnosis**: Emergency patients: Trauma (n=6); acute dissection (n=5); penetrating ulcer (n=2); and ruptured thoracic aortic aneurysm (n=5). **Mean age (range)**: 62 years (19-80 years) **Gender**: male 46; female 8 **Co-morbidities**: COPD, symptomatic CAD, hypertension, diabetes, severe obesity, and multiple trauma.	**Efficacy**: **Technical success rate** Emergency: 78% (secondary 83%) **30-day mortality** Emergency: 1/18 (5.6%) **Adverse events**: Mortality: 2 patients (at day 1 and 7 months) Endoleaks: type I n=3 Stent migration: n=1 (patient received 2 grafts) None of the patients treated for traumatic rupture developed complications. Progression of disease n=2 patients (penetrating ulcer) All patients showed signs of shrinkage of the false lumen and increase of the true lumen.
[a] All patients were classified with ASA physical status III (n=9) or IV (n=9).			

Author(s)	Design/Patients	Participant characteristics	Results
Daenen 2003[16] **Recruitment period:** December 1998 to May 2001 **Country:** Belgium (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) (n=3) and Excluder (W.L. Gore and Associates) (n=4) **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 7 **Follow-up**: 9 months (1-18 months)	**Diagnosis**: Thoracic aortic rupture (TAR). Two patients had symptomatic TAR (i.e. severe back pain). **Mean age (range)**: Not reported. **Gender**: Not reported **Co-morbidities**: severe multiple organ failure (n=2)	**Efficacy**: No efficacy outcomes reported. The authors note that complete thrombosis of the pseudoaneurysm and ultimately complete healing of the rupture was seen in all cases. **Adverse events**: Paraplegia: None reported. Endoleaks: None reported. Stent fracture: None reported. Stent migration: None reported.

Author(s)	Design/Patients	Participant characteristics	Results
Doss 2003a[17] **Recruitment period:** Nov 1999 to Feb 2002 **Country:** Germany (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) and Excluder (W.L. Gore and Associates). **Funding:** Not reported	**Design:** Case series **Inclusion**: All patients presenting with an acute lesion of the descending thoracic aorta were considered as potential candidates for stent grafting. **Exclusion**: Endovascular stent-grafting ESG): Landing zone diameters >44 mm; landing zone lengths <1.5 cm to the celiac axis and the left common carotid artery; patients with lesions originating from the ascending aorta; a heavy tortuous course of the abdominal aorta or extreme kinking (>60 degrees) of the thoracic aorta; diameter of the common iliac arteries <7 mm. **Patients:** total 54 ESG: 26 Open surgery: 28 **Follow-up**: Not reported	**Diagnosis** Open surgery: traumatic aortic ruptures (n=12); ruptured thoracic aortic aneurysms (n=11); type B dissection (n=5). ESG: traumatic aortic ruptures (n=4); ruptured thoracic aortic aneurysms (n=13); type B dissection (n=9). An acute thoracic aortic rupture or perforation was defined as follows: evidence of leakage from the aorta, periaortic haematoma and the presence of left-sided haemothorax; recent onset of thoracic pain. **Mean age (range)** ESG [a]: 61.1 years (S.D. 18.3) **Gender** ESG[a]: male 14; female 12 **Co-morbidities**: **Open surgery** / **Stent** COPD 2 / 8 Stroke 0 / 2 Cardiac disease 2 / 7 Renal failure 1 / 1 Hepatic disease 1 / 2 Marfan's disease 0 / 1 Hypertension 10 / 12 Previous thoracic surgery 1 / 5	**Efficacy**: **Technical success:** 20/26 (76.9%)[a] **Perioperative mortality**: total 6/54 (11.1%) Open surgery: 5/28 (17.8%) ESG: 1/26 (3.8%) **Mortality by diagnosis**: Ruptured aortic aneurysm: open surgery 2; ESG 1 Perforated type B dissection: open surgery 1; ESG 0 Traumatic aortic rupture: open surgery 2; ESG 0. **Rate of conversion to open repair**: None **Adverse events**: Injury to access artery: 1 (3.8%) iliac artery dissection Paraplegia: Open surgery: 1/28 (1.9%) ESG: 0 (no cases of stroke in either group) Endoleaks: Distal type I: 2/26 (7.7%) (both sealed spontaneously) Mechanical ventilation (>48 hrs): Open surgery: 8/28 (28.6%) ESG: 2/26 (7.7%) Renal failure requiring dialysis: Open surgery: 4/28 (14.3%); ESG: 1/26 (3.8%) Surgical re-exploration for bleeding: Open surgery: 3/28 (10.7%) ESG: 0 Access failure: stent 2/26 (7.7%)

[a] Extracted from Balzer 2003[38]

Author(s)	Design/Patients	Participant characteristics	Results
Fattori 2003[18] **Recruitment period:** July 1997 to July 2002 **Country:** Italy (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) (n=67). In 56 cases the stent was custom-made. In other cases the Thoracic excluder (Gore) was used. **Funding:** Not reported	**Design:** Case series **Inclusion**: 1 cm or more of normal aortic wall at the aneurysm neck that did not involve the left subclavian artery or the celiac axis or a 1 cm or more distance of the entry site from the left subclavian artery in the aortic dissection; 42 mm or smaller diameter of the proximal and distal neck; 9 mm or larger diameter of the femoral or the iliac arteries; and no severe aortoiliac tortuosity. **Exclusion**: Not reported. **Patients:** 70 **Follow-up**: mean 25 months (1-60 months)	**Diagnosis**: Degenerative aneurysm n=18; trauma n=21; descending thoracic aortic dissection n=22 (acute type B n=4, chronic type B n=12; residual dissection after repair of the ascending aorta for type A dissection n=6); penetrating ulcer (with or without intramural haematoma) n=6; suture dehiscence and pseudoaneurysm after surgical replacement of the descending aorta n=3. **Mean age (range)**: female 58.7 years (range, 30-77 years); male 55.3 years (19-80 years) **Gender**: male 57; female 13 **Co-morbidities**: pulmonary dysfunction (51%), including CAD, renal insufficiency, carotid arterial occlusion disease, and previous aortic or cardiac surgery (27%)	**Efficacy**: **Technical success rate**: 68/70 (97%) (n=2 (3%) tortuosity of the aortic arch and complication due to iliac transection) By cause: atherosclerosis 17/18; dissection 22/22; trauma 20/21; penetrating atherosclerotic ulcer 6/6; suture detachment 2/2; and pseudoaneurysm 1/1 **Length of hospital stay (days)**: mean 5 days (+/- 9) **Rate of conversion to open repair**: 4/68 (6%) **Mortality:** No hospital deaths. Post-treatment mortality included 1 respiratory insufficiency at 18 months and 2 aortic rupture at days 20 & 40, respectively. **Adverse events**: Paraplegia: None observed. One case of transient left monoparesis. Endoleaks: 2 (3%) proximal type I leaks detected at end of procedure. Late endoleak (1-60 months) n=5 (7%) Aneurysm expansion: 10 patients with thrombosed aneurysms (no endoleak) showed no reduction in size. Transient post-implantation syndrome (mild leukocytosis, elevated levels of C reactive protein, moderately elevated body temp): n=55/68 (81%). Non-specific slight to moderate back pain: n= 30/68 (44%) Long term (1-60 month) complications: 1 patient had persisting post-inflammatory syndrome **Changes in aneurysm size:** Progressive reduction in the size of the thrombosed aneurysm and the thoracic false lumen was observed during follow-up in 51 patients. In patients with >6-months follow-up and aneurysm or false lumen shrinkage, the mean diameter of the descending aorta decreased from 52.27 mm (before procedure) to 41.38 mm (range, 1.00 to 45.00 mm). The mean reduction in dimension of aneurysms was 11.06 mm (+/- 10.2 mm).

Author(s)	Design/Patients	Participant characteristics	Results
Grabenwoger 2003[20] **Recruitment period:** June 1997 to Feb 2002 **Country:** Austria (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) (n=4, 21%) and Gore Thoracic Excluder (n=15, 79%) **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 19 Elective: 18 Emergency: 1 **Follow-up**: mean 17.2 months (range 3 to 63 months)	**Diagnosis**: Acute type B dissection (n=11, 16.6%), penetrating ulcer (n=6, 9%), traumatic aneurysm (n=2, 3%). Symptoms present included chest or back pain (all patients), dyspnoea (n=2), low output syndrome (n=1) and penetrating ulcer exhibiting haemoptysis (n=3). **Mean age (range)**: 61 years (20-85 years) **Gender**: male 16 (84.2%); female 3 (15.8%) **Co-morbidities**: Hypertension (n=17, 89.4%), CAD with previous MI (n=3, 15.5%) and COPD (n=8, 42.1%). Previous cardiac surgery (n=3, 2 CABG and 1 aortic valve replacement).	**Efficacy**: **Technical success rate**: 19/19 (100%) **Length of hospital stay (days)**: mean 8.4 days **Late mortality**: 1/19 (5.3%) (due to MI) **Adverse events**: Paraplegia: 1 patient (within 14 h post-operatively) and 1 case of ischaemia of the left arm. Endoleaks: 1/19 (1 patient had be operated on again due to contained rupture of the thoracic aorta caused by endoleak). **Size of the aortic lumen**: The mean diameter of the false lumen of the dissected aorta decreased from 2.3 cm (+/- 0.58) to 0.7 cm (+/- 0.44), and the true lumen increased from 1.56 cm (+/- 0.5) to 4.10 cm (+/- 0.60) in the thoracic region.

Author(s)	Design/Patients	Participant characteristics	Results
Gerber 2003[19] **Recruitment period:** Jan 97 to Dec 01 **Country:** Switzerland (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) and Vanguard, Thoracic Excluder (Gore) **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 17 **Follow-up**: Not reported	**Diagnosis**: atherosclerotic aneurysm verum (n=5), type B dissection with contained rupture (n=3), intramural haematoma with contained rupture (n=1), false aneurysm of unknown origin (n=1), Marfan's syndrome (n=1) and traumatic rupture of the descending aorta (n=6). **Mean age (range)**: range 26-80 years **Gender**: male 13; female 4 **Co-morbidities**: arterial hypertension (n=8), smokers (n=4), elevated blood cholesterol (n=3) and coronary heart disease (n=1).	**Efficacy**: **Technical success rate**: 13/17 (76%) (defined as perfect stent graft delivery and no primary endoleak) **Rate of conversion to open repair**: 1/17 (5.8%) **Early mortality**: 1/17 (5.8%) **Adverse events**: Paraplegia: 1/17 (5.8%) patients suffered transient paresis of the left leg (after conversion to open surgery). Endoleaks: 6 (4 type I, 1 type II, 1 type IV)

Author(s)	Design/Patients	Participant characteristics	Results
Haulon 2002[21] **Recruitment period:** Dec 1999 to Jan 2001 **Country:** France (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) (n=13) (12 standard and 1 customised) and (n=1) Gore Thoracic excluder. **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 14 Elective: 9 Emergency: 5 **Follow-up**: 7.25 months (range 2 to 12 months)	**Diagnosis**: type B dissection (n=4), rupture of isthmus (n=4); aneurysm (n=3); penetrating ulcer (n=2), iatrogenic injury (n=1). **Mean age (range)**: 45.8 years (20-78 years) **Gender**: male 10; female 4 **Co-morbidities**: COPD (n=6); stroke (n=1), multiple trauma (n=3), liver cirrhoses (n=1), MI (n=1), recent thoracic surgery (n=1).	**Efficacy**: **Technical success rate**: 14 (100%); **30-day mortality**: 2/14 (14%) (extensive anterior infarction and haemorrhagic stroke, respectively). There were no late deaths. **Length of hospital stay (days)**: mean 6.25 (range 5-9 days); **Rate of conversion to open repair**: 0% **Adverse events**: Paraplegia: 1 patient experienced transient blindness. Endoleaks: Unclear. Narrowing of the thoracic aorta (>2 mm) was observed in 3 patients treated for TAA. The diameter of the false periaortic aneurysm decreased (>2 mm) in 3 patients treated for penetrating atherosclerotic ulcer.

Author(s)	Design/Patients	Participant characteristics	Results
Heijmen 2002[22] **Recruitment period:** July 1997 to June 2001 **Country:** The Netherlands (single centre) **Intervention details**: AneuRx (Medtronic AVE, CA, USA) (n=6, 21%), Talent LPS (Medtronic) (n=9, 32%) and Excluder (WL Gore & Associates) (n=13, 46%). **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** 27 (all elective) **Follow-up**: Not reported.	**Diagnosis**: chronic aortic dissection (n=4, 14%), penetrating aortic ulcer (n=2, 7%), para-anastomotic pseudoaneurysm 5 years post-surgery (n=1, 4%), atherosclerosis (n=20, 71%). **Mean age (range)**: 70 years (50-82) **Gender**: male 17; female 10 **Co-morbidities**: COPD (n=8, 30%), renal insufficiency (n=6, 22%), CAD including previous CABG (n=9, 33%) and carotid occlusive disease (n=5, 19%). 14 patients had history of previous thoracic or abdominal aortic surgery. PAD was present in 4 patients (15%).	**Efficacy**: **Technical success rate**: 26/27 (96%); **30-day mortality**: 0%; **Blood loss**: median 200 (50-1500) ml; **Length of hospital stay (days)**: range 3-36 days (25/28 patients); **Rate of conversion to open repair**: unclear **Adverse events**: Injury to access artery: 1 perforation of the common iliac artery. Mortality: No operative mortality. One non-related late death due to stroke (18 months). Paraplegia: None reported. Endoleaks: 4 (14%) intraoperative (all type II), 4 prior to discharge, 2 (7%) at 3-months (both type II), and 1 (6%) at 12-months Stent migration: 1 intraoperative (patient required open surgical repair) and 1 at 3-months Stroke: 1 (4%) Antibiotics required for pulmonary infection: 2 (7%) Groin haematoma or superficial infection: 4 (14%) **Changes in aneurysm size:** Maximal aneurysmal diameter either remained stable or decreased slightly over time in all but one patient with evidence of endoleak.

Author(s)	Design/Patients	Participant characteristics	Results
Herold 2002[23] **Recruitment period:** Aug 1999 to Aug 2001 **Country:** Germany (single centre) **Intervention details:** Talent (Medtronic AVE, California, USA) **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported **Patients:** 34 Elective: 30 (88.3%) Emergency: 4 (11.7%) **Follow-up**: Not reported	**Diagnosis**: Acute, complicated type B aortic dissection (n=6, 18%), symptomatic chronic type B dissection (n=12, 35%), true aneurysm of the descending aorta (n=7, 21%) and atherosclerotic contained rupture of the descending aorta (n=9, 26%). **Mean age (range)**: 68.6 (range 58-84) years **Gender**: male 27; female 7 **Co-morbidities**: CAD 11 (32.3%); hypertension 30 (88.2%); COPD 14 (41.1%); diabetes 4 (11.7%)	**Efficacy**: **30-day mortality**: 1 (2.9%) (chronic B dissection. Patient died 6 days after stenting of an acute MI.) **Late mortality (>3 months)**: 3 (8.8%) **Length of hospital stay (days)**: mean 2.8 days **Adverse events**: Injury to access artery: 2 (5.8%) dissection of the femoral artery Paraplegia: None reported. Stent migration: None reported. Renal failure: moderate 9 (26.4%); severe (no dialysis) 3 (8.8%); severe (dialysis) 1 (2.9%) Preoperative organ ischaemia: renal 6 (17.6%); leg 2 (5.8%); gut 2 (5.8%) Previous cardiac surgery: 7 (20.5%) New York Heart Association classification: NYHA III 15 (44.1%); NYHA IV 19 (55.9%)

Author(s)	Design/Patients	Participant characteristics	Results
Krohg-Sørensen 2003[24] **Recruitment period:** July 2000 to Dec 2002 **Country:** Norway (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) and Gore excluder (n=9 and n=11, respectively) **Funding:** None reported.	**Design:** Case series **Inclusion**: All patients considered high-risk for surgery. **Exclusion**: Not reported. **Patients:** 20 **Follow-up**: median 8 months (range 1-24 months)	**Diagnosis**: Degenerative aneurysm (n=9, 4 elective, 3 symptomatic, 2 ruptured); mycotic aneurysm (n=3); false aneurysm after previous surgery (n=2); aortic dissection (n=3, 1 chronic and 1 acute type B dissection, 1 type A with cardiac tamponade and rupture); penetrating atherosclerotic ulcers with rupture (n=1); and Takayasu's aortitis with rupture (n=1). **Mean age (range)**: (22-81 years) **Gender**: male 10; female 10 **Co-morbidities**: COPD 2; CAD 8; hypertension 3; dialysis 2; cardiac failure 1; sepsis 2; history of thoracotomy 1.	**Efficacy**: **Mortality**: 2 patients died at 3.5 months and 11 days respectively. **Adverse events**: Paraplegia: None reported. Endoleaks: None reported. Stent fracture: None reported. Stent migration: None reported.

Author(s)	Design/Patients	Participant characteristics	Results
Lambrechts 2003[7] **Recruitment period:** Feb 200 and Jan 2002 **Country:** Belgium (single centre) **Intervention details**: AneuRx (Peripheral Technologies, CA, USA) (n=1); Talent (world Medical Corp. FL, USA) (n=13); Excluder (WL Gore & Associates, AZ USA) (n=12). **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 26 **Follow-up**: 8 months (range, 1-18 months)	**Diagnosis**: Traumatic aortic isthmus rupture (n=3); complicated type B dissection (n=11); thoracic atherosclerotic aneurysm (n=12). **Mean age (range)**: 64 years (30-84) **Gender**: male 8; female 18 **Co-morbidities**: Cigarette smoking 13 (50%); arterial hypertension 18 (69%); CAD 5 (19%); congestive heart failure 4 (15%); PVD 11 (42%); COPD 5 (19%); NIDDM 1 (4%); hypercholesterolemia 7 (27%) **Other baseline details:** Renal failure: Mild: 6 (23%) Severe (no dialysis): 1 (4%) Severe (with dialysis): 1 (4%) History of cerebrovascular disease: 3 (12%) Systemic disorders: 5 (19%)	**Efficacy**: **30-day mortality**: 0%; **Length of hospital stay (days)**: 6 days (range, 3-20 days); **Adverse events**: Injury to access artery: rupture of iliac artery: n=2 Mortality: Late (>30 days): 4 (15%) Paraplegia: None reported. Endoleaks: n= 3 (all type II) Procedure-related peripheral emboli: 1 Acute cholecystitis: 1 Pneumonia: 1 Groin pseudoaneurysm: 1 Transient renal failure: 1 Transient aphasia: 1 **Thrombosis of the aneurysm:** Atherosclerotic aneurysm: complete thrombosis of the aneurysm sac (with disappearance of endoleak) occurred in 2 patients at 6-months. Type B dissection: The mean value of the maximal diameter of the descending thoracic aorta and false lumen decreased significantly in 11 patients. 1 patient with chronic and 2 patients with acute type B dissection had complete disappearance of the thoracic false lumen after 3, 6 and 12 months, respectively. Traumatic aortic isthmus rupture: retraction of the thrombus occurred in 2 chronic patients, complete resolution of the periaortic haematoma occurred at 6-months in 1 patient treated for acute isthmus rupture. The decrease of the mean aortic isthmus diameter after stenting was not significant (n=3, p=0.1).

Author(s)	Design/Patients	Participant characteristics	Results
Lamme 2003[25] **Recruitment period:** Oct 1998 to Feb 2002 **Country:** The Netherlands (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) (n=3), Gore (WL Gore and Associates) (n=17) and AneuRx (Medtronic AVE) (n=1). **Funding:** Not reported	**Design:** Case series **Inclusion**: Patients selected based on spiral CT angiography. Patients were considered suitable if there was a proper anchoring site for the stent-graft both proximal and distal to the lesion (max diameter 36 mm and min length 10 mm), with distal anchoring site cranial to the visceral arteries. Access through the abdominal aorta should be feasible. **Exclusion**: None reported. **Patients:** 21 Elective: Emergency: **Follow-up**: mean 24 months (range, 5-44 months)	**Diagnosis**: Descending aorta (n=18), aortic arch (n=2), ascending aorta (n=1). Pathology: false (n=6), descending thoracic aortic aneurysm (TAA) (n=8), mycotic TAA (n=2), ruptured TAA (n=1), traumatic rupture (n=4). **Mean age (range)**: 55.6 years (range, 19-86 years) **Gender**: male 12; female 9 **Co-morbidities**: Not reported.	**Efficacy**: **Length of hospital stay (days)**: median 6 days (range, 3-63 days); **Rate of conversion to open repair**: 1 **Late mortality**: 1 patient died at 9 months (not aneurysm/rupture related). **Adverse events**: Injury to access artery: 1 acute dissection. Paraplegia: spinal cord ischaemia in 1 patient. Endoleaks: 2 (1 type I (treated successfully)and 1 type II (persistent)) Stent migration: 1 PTA of origin of subclavian artery: 1 Surgical drainage of aneurysm sac hygroma: 1 Open surgical repair: 1 (mid-term results) Pneumonia: 2 Suture granuloma: 1 Cardiac arrhythmia: 1

Author(s)	Design/Patients	Participant characteristics	Results
Lepore 2002[26] **Recruitment period:** June 1999 to July 2001 **Country:** Sweden (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) Excluder (Gore), AneuRx and Hemobahn (WL Gore and Associates). **Funding:** Not reported	**Design:** Case series **Inclusion**: Adequate vascular access through the illiac arteries or the lower abdominal aorta; an adequate landing zone with minimal calcification or thrombus; aortic neck diameter <44 mm and length at least 10 to 15 mm; adequate normal segments adjacent to vital arteries; <90 degree angle between the arch and descending thoracic aorta. **Exclusion**: Not reported. **Patients:** 43 Elective: 20 Emergency: 23 **Follow-up**: mean 19 months (range, 0-34 months)	**Diagnosis**: Descending thoracic aortic dissections [n=16, 14 type B (11 acute, 3 chronic) and 2 type A], aneurysms (n=14), contained ruptures (n=7), mycotic aneurysms (n=3), posttraumatic pseudoaneurysms (n=2), and an aneurysm of an anomalous right subclavian artery (n=1). **Mean age (range)**: 67 years (range, 17-82 years) **Gender**: male 28; female 15 **Co-morbidities**: hypertension 11; sepsis 4; angina 3; cerebrovascular injury 3; chronic atrial fibrillation 3; COPD 3; MI 2; abdominal aneurysm 2; deep venous thrombosis 2; tuberculosis 2; malignancy 1; previous CV operations 15.	**Efficacy**: **30-day mortality**: 3 (7%); **Blood loss**: mean 670 ml (range, 100-5800 ml); **Rate of conversion to open repair**: 0% **Overall mortality:** 8 (19%) **Mortality >30 days:** 5 (12%) **Overall survival at 18-months:** 80% **Adverse events**: Paraplegia: 3 (7%) Endoleaks: 7 (16%) - all type I Cerebrovascular accident: 8 (19%) Respiratory insufficiency (ventilation >48 hrs): 6 (14%) Renal failure requiring hemodialysis: 1 (2%) Repeat stent-graft: 3 (7%)

Author(s)	Design/Patients	Participant characteristics[a]	Results
Marin 2003[27] **Recruitment period:** Nov 1992 to Dec 2002. **Country:** USA (two centres) **Intervention details**: Second-generation systems employed in latter 5 years. Talent, Gore and AneuRx. **Funding:** Investigator and manufacture sponsored studies.	**Design:** Case series **Inclusion**: Patients were eligible for selection into 5 separate protocols (see table below). **Exclusion**: Proximal extent (ascending arch, <2 cm from subclavian); thrombus in neck; acute or chronic dissection (Gore trials); ruptured aneurysm (Gore trials); connective tissue disorder; dominant intercostal supplying blood to spinal cord; systemic infection; bleeding diathesis or hypercoagulable state; contrast contraindicated; anticoagulation contraindicated; recent MI, CVA or surgical intervention; renal insufficiency (end-stage renal disease or creatinine >3.5 / creatinine > 1.7). **Patients:** 94 **Follow-up**: Not reported.	**Diagnosis**: Fusiform aneurysm: 51 (61%); Pseudoaneurysm: traumatic 5 (6%); para-anastomotic 13 (15%); aortic dissection 9 (11%); mycotic aneurysm 2 (2%); penetrating ulcer 4 (5%). **Mean age (range)**: 71 years (+/- 12 years) **Gender**: male 54; female 30 **Co-morbidities**: 74 patients (88%) had more than 3 co-morbid diseases. Hypertension 58 (69%); CAD 41 (48%); previous CABG/PTCA 12 (14%); COPD 37 (44%); diabetes 6 (7%); PVD 12 (14%); chronic renal insufficiency 12 (14%); End-stage renal disease 3 (4%); hypercholesterolemia 18 (21%)	**Efficacy**: **Technical success rate[b]**: 85.1%; **Rate of conversion to open repair** Immediate: 2 (2.9%) Late: 1 **Adverse events**: Endoleaks: 14 (15%) type I or type II; 9 (10%) type II Stent fracture: (n=817, AAA and TAA) device fatigue in 64 implants (7.8%). Most common form was longitudinal metal bar fractures. Aneurysm rupture with ESG: 5 **Major adverse event (AAA and TAA n=817):** Haematoma 22 (2%); pulmonary complication 9 (1.1%); cardiac complication 29 (3.6%); renal function complication 14 (1.7%); wound complication 17 (2.1%); bowel complication 3 (0.4%); neurological complication 6 (0.7); genitourinary complications 19 (2.3%). Freedom from abdominal or thoracic aortic aneurysm rupture: 98% (+/- 1%) at 9 years. Successful aneurysm exclusion free from major complication (defined as limb occlusion, graft infection, or rupture) or major re-intervention (defined as graft explant, distal revascularisation, or conversion to open repair): 85% (+/- 2%) at 9 years. **Adverse events reported in Ellozy 2003[5]** Injury to access artery: 4/84 (5%) bleeding complications associated with access vessels. Paraplegia: Neurologic complications in 1st month: 3/84 (4%) (1 died) Endoleaks: persistent: proximal type 1 n=1/84; proximal type I at 3 months n=3/84 (4%). Late type III at 32 months (n=1). Late distal type I (n=2) Stent fracture: 11/84 (13%) (mean 20 months follow-up (1-38)) (2 associated with endoleak) Stent migration: 1/84 (intraoperatively) Aneurysm expansion: enlargement 5 mm or more n=4/84 (5%) (all patients had type I or II endoleak) Lower extremity ischaemic complication requiring revascularisation: 2/84 (2%) Inguinal lymphocele: 1/84 Freedom from adverse device-related events (i.e. aneurysm rupture or type I or type III endoleak) at 40-months: 74% +/-10%

[a] Extracted from Ellozy 2003[5]; [b] Defined as: successful insertion and deployment of the ESG without the need for surgical conversion; no perioperative mortality; absence of type I or type III endoleak; and freedom from limb obstruction or occlusion, up to 24 hrs post-operatively.

Five protocols:

	Investigational device exemption	**Talent Phase I trial**	**Talent Phase II trial**	**Gore Phase I trial**	**Gore Phase II trial**
Indication	Atherosclerotic aneurysm, pseudoaneurysm, aortic dissection, penetrating ulcer	Atherosclerotic aneurysm, pseudoaneurysm, aortic dissection, penetrating ulcer + ruptured TAA	Atherosclerotic aneurysm, pseudoaneurysm, aortic dissection, penetrating ulcer	Atherosclerotic aneurysm, pseudoaneurysm, aortic dissection, penetrating ulcer	Atherosclerotic aneurysm, pseudoaneurysm, aortic dissection, penetrating ulcer
Candidate for open repair?	No	No	Yes	No	Yes
Proximal neck length (mm):	>/=15	>/=10	>/=10	>/=20	>/= 20
Proximal neck diameter (mm):	22 </= ND </= 40	18 </= ND </= 40	18 </= ND </= 40	23 </= ND </= 37	23 </= ND </= 37
Aneurysm diameter (cm):	>/= 6 saccular or symptomatic aneurysm	>/= 5, or 1.5X adjacent normal aorta	>/= 5, or 1.5X adjacent normal aorta	>/= 4, or 1.5X adjacent normal aorta	2X adjacent normal aorta or saccular aneurysm
Access vessel (mm):	>/= 8	>/= 8	>/= 8	>/= 6	>/= 6
Life expectancy ≥12 months?:	Yes	Yes	Yes	Yes	Yes
Signed inform consent?:	Yes	Yes	Yes	Yes	Yes
Accept open repair if stent graft fails?:	Yes	Yes	Yes	Yes	Yes

Author(s)	Design/Patients	Participant characteristics	Results
Marty-Ane 2003[28] **Recruitment period:** Jan 2001 to July 2002 **Country:** France (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) in 4 cases and Excluder (Gore) in 5 cases. **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** 9 (all emergency) **Follow-up**: 4 to 20 months.	**Diagnosis**: Acute traumatic rupture of the descending thoracic aorta. All patients had polytrauma with blunt thoracic trauma. **Mean age (range)**: 52.3 years (range, 23-78 years) **Gender**: male 6; female 3 **Co-morbidities**: Not reported.	**Efficacy**: **30-day mortality**: 0% **Length of hospital stay (days)**: ranged from 7 days to 3 months **Adverse events**: Mortality: No perioperative deaths. Endoleaks: 1 (proximal type I) No cases of renal failure, neurologic complication (paraplegia or stroke), embolisation, or stent-graft migration were reported.

Author(s)	Design/Patients	Participant characteristics	Results
Morgan 2002[29] **Recruitment period:** Nov 1996 to May 2001 **Country:** UK (single centre) **Intervention details**: Gore Excluder (WL Gore and Associates) **Funding:** Not reported	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 4 **Follow-up**: mean 6.3 months (range, 44 days to 16 months)	**Diagnosis**: 4 patients with acute contained ruptures of the thoracic aorta (1 atheromatous aneurysm, 1 aortic ulcer, 1 saccular aneurysm, 1 type B dissection). **Mean age (range)**: Not reported **Gender**: Not reported **Co-morbidities**: Not reported.	**Efficacy**: **Technical success rate**: 4/4 (100%) **30-day mortality**: 0% **Blood loss**: mean 135 ml **Adverse events**: Endoleaks: n=1 (type not reported) No procedural morbidity or mortality. No significant deterioration in renal function or cases of paraplegia. Patients were discharged home after 6 days, 9 days, 11 days and 12 days, respectively.

Author(s)	Design/Patients	Participant characteristics	Results
Najibi 2002[30] **Recruitment period:** March 1999 and Jan 200 **Country:** USA (single centre) **Intervention details**: Talent (Medtronic AVE, California, USA) (n=5) and Excluder (Gore) (n=14). **Funding:** Manufacturer-sponsored (WL Gore and Associates).	**Design:** Case series **Inclusion**: Descending TAA of more than 2 times the diameter of the adjacent aorta or a saccular aneurysm with a thrombus-free non-aneurysmal proximal aortic landing zone >20 mm in length and with angulation of the aortic segment of <60 degrees. The iliofemoral system had to be able to accommodate the 22F-27F introducer sheath. **Exclusion**: Recent MI or stroke (<6 weeks), pulmonary insufficiency necessitating chronic home oxygen therapy, or renal insufficiency (creatinine level >/= 2.0 mg/dL). No other surgical procedures could take place at the same time or within 30 days before endograft placement, except left carotid to subclavian bypass. **Patients:** 19 7 patients underwent stenting on a compassionate basis and did not meet the inclusion/exclusion criteria. **Follow-up**: 12 months (range, 3 to 22 months)	**Diagnosis**: Descending TAA. **Mean age (range)**: 70.6 years (range, 59 -78 years) **Gender**: male 15; female 4 **Co-morbidities**: Not reported. **Historic cohort:** (mean age 70.1 ranges, 67-75 years). Patients with descending TAA (including 1 contained rupture and 2 symptomatic pseudoaneurysms). Had undergone operative repairs for aneurysms that were symptomatic, >two times the diameter of the adjacent normal aorta, or >6 cm in diameter. Open surgical repair was performed with standard tube graft interposition electively in 7 patients and emergently in 3 patients.	**Efficacy**: **Technical success rate (30-day)**[a]: 17/19 (89%) **Mortality**: Endovascular stent-grafting: 2 (2 days and 5 months respectively) Open surgery (perioperative): 1 (10%) Open surgery (1-year follow-up): 3 **Blood loss** Endovascular stent-grafting: 325 ml (+/- 353 ml) Open surgery: 1205 ml (+/- 1493 ml) **Length of hospital stay (days)** Endovascular stent-grafting: 6.2 days (+/- 5.8 days) Open surgery: 16.3 days (+/- 6.7 days) **Rate of conversion to open repair**: 0% **Adverse events**: Endoleaks: None reported. Stent migration: None reported. Aneurysm expansion: None reported at short-term follow-up. **Clinical success rate (12-months)[b]:** 84% (n=16) **Total morbidity rate** Endovascular stent-grafting: 26%, major 4 (21%, 1 retroperitoneal haematoma and external iliac artery dissection, 1 common femoral artery pseudoaneurysm, 2 renal insufficiency (creatinine levels >2.3 mg/dL)), minor 1 (5%, inguinal lymphocele) Open surgery: 50%, major 4 (2 severe renal insufficiency, 1 stroke with residual hemiparesis, 1 ischaemic colitis), minor 1 (wound infection). **Size of the aneurysm:** At 1-month of follow-up, size of the aneurysm increased in 2 patients, decreased in 15 patients, and remained the same in 1 patient. Aneurysm size, on average, decreased from 68 mm (+/- 22 mm) to 58 mm (+/- 13 mm) at 1-month, to 51 mm (+/- 14 mm) at 6-months ($p<0.05$) and to 49 mm (+/- 12 mm) at 12-months ($p<0.01$).

[a] Defined as: successful endograft deployment without death, need for standard open aortic reconstruction for 30 days, or evidence of persistent (>48 hours) endoleak; [b] Inclusive of those patients at 6-months after implantation who had spontaneous seal of a persistent endoleak and showed no evidence of aneurysm enlargement.

Author(s)	Design/Patients	Participant characteristics	Results
Orend 2003[31] **Recruitment period:** 1995 to 2001 **Country:** Germany (single centre) **Intervention details**: Gore (n=51); Talent (n=19); Corvita (n=2); Vanguard (n=1); Stenford (n=1); AneuRx (n=1). **Funding:** Not reported.	**Design:** Case series **Inclusion**: Proximal neck length, >10 mm, <38 mm; proximal neck distal to the left common artery; existence of a distal neck length proximal to the celiac artery >10 mm. Diameter of the aneurysm or of the aortic segment with dissection had to be >55 mm. Type B dissection: presence of ischaemic complications, intractable hypertension or uncontrollable pain, an expanding false lumen and a patent primary entry site. **Exclusion**: Patients with aortic tortuosity. **Patients:** 74 Elective: 48 Emergency: 26 **Follow-up**: mean 22 months (range, 3 to 72 months)	**Diagnosis**: Aneurysm of the descending aorta (n=34); acute traumatic transection of the descending thoracic aorta (n=12); type B dissection (n=12); posttraumatic aneurysm of descending thoracic aorta (n=6); aortobronchial fistula descending thoracic aorta (n=1); thoracoabdominal aneurysm (n=5); aortic coarctation (n=2). **Mean age (range)**: 65 years (range, 12-87 years) **Gender**: male 60; female 14 **Co-morbidities**: Not reported.	**Efficacy**: **30-day mortality**: 7 (9.5%) Elective: 3 Emergency: 4 **Blood loss**: 150 ml (range 100 - 3000 ml) **Length of hospital stay (days)**: 8 days (range, 4 -35 days); **Adverse events**: Mortality: Hospital: 8.1%. 5 patients died during the follow-up period, cardiopulmonary events were responsible in 3 patients. Endoleaks: 15 (20.3%) Stent fracture: No graft or wire fractures were identified. No permanent neurologic deficit was postoperatively diagnosed in any patient. 2 patients had transient postoperative paraparesis. Mechanical ventilation (>24 hours): 4 Non-transmural MI (during hospitalisation): 1 Additional operative procedures: 11/74 (14.8%) **Results by diagnosis:** ***Atherosclerotic and posttraumatic aneurysm of the descending thoracic aorta (n=40)*** 30-day mortality rate: 3/40 (7.5%) Hospital mortality rate: 1/40 (2.5%) Endoleaks: 9 type I ***Acute traumatic dissection (n=12)*** 30-day mortality rate: 2/12 (16.6%) Endoleaks: 2 type I ***Dissection type B with aneurysmal dilatation (n=14)*** Hospital mortality: 1/14 (7%) Endoleaks: 4 type I, 2 secondary Other complications: 2 type A dissections, 1 false lumen rupture

Author(s)	Design/Patients	Participant characteristics	Results
Ramaiah 2003[32] **Recruitment period:** February 2000 to February 2001 **Country:** USA (single centre) **Intervention details**: Gore excluder (WL Gore, Flagstaff AZ) **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** 46 **Follow-up**: mean 9 months (range, 1 - 15 months)	**Diagnosis**: 23 patients (50%) had atherosclerotic aneurysms, 14 patients (30%) had dissections, 3 patients (7%) had aortobronchial fistulas, 3 patients (7%) had pseudoaneurysms, 2 patients (4%) had traumatic ruptures and 1 patient (2%) had a ruptured aortic ulcer. **Mean age (range)**: 70 **Gender**: male 29; female 17 **Co-morbidities**: Not reported.	**Efficacy**: **Technical success rate**: 100% **Length of hospital stay (days)**: average 6 days; **Mortality**: overall 23%. 2 patients died in the immediate post-operative period. **Adverse events**: Paraplegia: No cases reported. Endoleaks: 2 (4%) Stent migration: No cases reported.

Author(s)	Design/Patients	Participant characteristics	Results
Schoder 2003[33] **Recruitment period:** April 1998 to November 2001 **Country:** Austria (single centre) **Intervention details**: Excluder (WL Gore) **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** 28 (all elective) **Follow-up**: 22 patients at 1 year, 12 patients at 2 years, 5 patients at 3 years.	**Diagnosis**: Atherosclerotic thoracic aortic aneurysms. 20 patients (71%) were unsuitable for open repair based on serious co-morbidities or previous thoracic surgery. **Mean age (range)**: mean 71.6 years (53-82 years) **Gender**: male 17; female 11 **Co-morbidities**: Hypertension 18 (90%); CAD 8 (40%); cerebral vascular disease 7 (35%); renal impairment 5 (25%) and poor pulmonary reserve 10 (50%). Previous thoracic surgery 5 (25%).	**Efficacy**: **30-day mortality**: 0% **Mortality**: 3 patients died during the follow-up period (hepatic failure, cardiac failure and metastatic carcinoma). **Length of hospital stay (days)**: mean 9 (range, 4 -20 days) **Adverse events**: Endoleaks: intraoperative: 3 (type I); postoperative 5 (2 type I, 3 type II) Aneurysm expansion: 1 and constant size in 3 patients with endoleak. Other complications: Fever (>38 degrees C): 10/28 (36%) Elevation of C-reactive protein (>1 mg/dL): 24/26 (92%) Minor complications occurred in 3/28 (11%) patients. Temporary increase in serum creatinine: 1 Prolonged duration of healing at access site: 2 2 patients had major complications, 1 sustained a stroke and 1 patient experienced postoperative bleeding requiring blood transfusion.
Further results			
Cumulative survival at 1 year: 96.1% (+/- 3.8%), at 2-years: 90.9% (+/- 6.2%), at 3-years: 80.2% (+/- 11.5%) **Change in aneurysm size**: In patients without endoleak, mean decrease in aneurysm size was 6.6 mm (+/- 6.4) (-10.4%, p=0.001) at 1-year follow-up. During the first year the aneurysm decreased in 12/18 (67%) patients, was unchanged in 4 (22%) and increased in 2 (11%). There was no significant interval decrease between the 1- and 2-year follow-ups (mean 0.1 +/- 3 mm, p=0.7) and the 2- and 3-year follow-ups (mean -0.8 +/- 3.7 mm, p=0.91). During the second year the size of the aneurysm was constant in 8/9 patients (89%) and increased in 1 (11%). At 3-years, in 3/5 (60%) patients the diameter remained constant, decreased in 1 (20%) and increased in 1 (20%). **Volume measurements:** In 4 patients with endoleak, the volume of the aneurysm sac was unchanged in 2 and increased in 2. In 18 patients with endoleak, the mean decrease in thrombus volume was 53.2 +/- 56.8 ml (-40%, p=0.001) at 1-year follow-up. During the first year, the volume decreased in 13/18 (72%) patients, was unchanged in 4 (22%), and increased in 1 (6%). There was no significant interval decrease in the volume between the 1- and 2-year follow-up and the 2- and 3-year follow-up. During the second year, the volume decreased in 2/9 (22%) patients, was constant in 6 (67%) and increased in 1 (11%).		

Author(s)	Design/Patients	Participant characteristics	Results
Taylor 2001[34] **Recruitment period:** July 1997 to October 2000 **Country:** UK (two centres) **Intervention details**: 26 Excluder (Gore), 9 AneuRx (Medtronic), 1 Vanguard (Boston Scientific) and 1 Stenford. **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** total 37 Elective: 19 Emergency: 18 **Follow-up**: 17.5 months (range, 6-45 months)	**Diagnosis**: All patients had pathological lesions of the distal arch or descending thoracic aorta. 18 patients had degenerative aneurysms (min 6 cm diameter); 5 patients had injuries to the proximal descending thoracic aorta following trauma; 4 patients had symptomatic acute type B dissections of the descending thoracic aorta and 2 patients had chronic dissection; 3 patients had aneurysms related to surgery for coarctation; and 5 patients had an infected false aneurysm. All patients had been turned for open repair either because of serious co-morbidity or because the patient had previously undergone surgery. **Mean age (range)**: range 17-90 **Gender**: male 25; female 12 **Co-morbidities**: Not reported	**Efficacy**: **Technical success rate**: 36/37 (97%) **30-day mortality**: 3/37 (8%) (all urgent) Elective: 0%; Emergency: 3/18 (17%); **Adverse events**: Mortality: 1 patient died at 28 months of aortic rupture. Paraplegia: None reported. Endoleaks: 1 (proximal type I) resulting in open repair and removal of stent graft at 6 weeks; 2 patients at 3 months treated with distal extension cuffs. Stent migration: 1 (patient with Stenford graft died due to aortic rupture) 1 patient suffered a stroke with spontaneous full recovery. 2 patients had persistent flow into the sac at 24 hours both had resolved at 3-month follow-up. No cases of renal failure were reported.

Author(s)	Design/Patients	Participant characteristics	Results
Temudom 2000[35] **Recruitment period:** Feb 1997 to June 1998 **Country:** USA (single centre) **Intervention details**: Four devices: two custom-made stents (n=3) and two commercially-available (n=11), Vanguard and Excluder. **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported. **Exclusion**: Not reported. **Patients:** 14 **Follow-up**: mean 5.5 months (range, 1 to 15 months)	**Diagnosis**: 9 patients had atherosclerotic aneurysm (6 had fusiform aneurysms and 3 patients had penetrating aortic ulcers) and 5 patients had pseudoaneurysms (3 caused by penetrating trauma and 2 paraanastomotic aneurysms). **Mean age (range)**: 62 years (range, 35 to 84 years) **Gender**: male 5; female 9 **Co-morbidities**: COPD (64%); previous thoracotomy (36%); hypertension (36%); malignancy (7%); diabetes mellitus (7%); renal insufficiency (7%); carotid occlusive disease (7%) and paraplegia secondary to traumatic spinal cord injury (7%).	**Efficacy** **Mortality**: 2 (1 due to stent migration and 1 due to progression of severe pulmonary hypertension) **Technical success rate**: 11/14 (78%) **Blood loss**: mean 400 ml (range, 200 to 800 ml) **Length of hospital stay (days)**: mean 2.9 days (range, 1 to 4 days) (n=13, excluding 1 patient who had an extended stay due to pulmonary failure) **Adverse events**: Paraplegia: None reported and no cases of stroke. Endoleaks: 2 patients. Stent migration: 1 patient, requiring immediate conversion to open repair (patient died). Wound complications: 1 lymph fistula in the groin and 1 haematoma of the arm. Transient neurological deficit: 1 (at 2 weeks)

Author(s)	Design/Patients	Participant characteristics	Results
Totaro 2002[36] **Recruitment period:** Jan 2000 to Feb 2001 **Country:** Italy (single centre) **Intervention details**: Excluder **Funding:** Not reported.	**Design:** Case series **Inclusion**: Not reported **Exclusion**: Not reported **Patients:** 32 **Follow-up**: 12 months (range, 6-18 months)	**Diagnosis**: 7 patients had thoracic aortic aneurysm > 6cm in diameter, and 25 had type B dissection (5 acute and 20 subacute). **Mean age (range)**: 62 years (range, 48 - 82 years) **Gender**: male 22; female 10 **Co-morbidities**: All patients had a history of chronic hypertension and 25 (84%) were obese.	**Efficacy** **Technical success rate**: 100% **30-day mortality**: 0% **Length of hospital stay (days)**: mean 10 days **Adverse events** Endoleaks: 10 patients had primary endoleak. Infection of the site of access: 8 (6 superficial, 2 deep)

Appendix 3. Details of related study publications

Alric 2002b (Alric P, Marty-Ane CH. Endovascular treatment of ruptured thoracic aortic aneurysms. Journal of Thoracic & Cardiovascular Surgery 2002; 124(1):180-182.)

Includes the same group of patients as reported in Alric 2002a[10]

Balzer 2002 (Balzer JOD. Urgent thoracic aortal dissection and aneurysm: treatment with stent-graft implantation in an angiographic suite. European Radiology 2003; 13(10):2249-2258.)

Includes same group of patients as Doss 2003a[17]

Bell 2003 (Bell RE, Taylor PR, Aukett M, Sabharwal T, Reidy JF. Results of urgent and emergency thoracic procedures treated by endoluminal repair. European Journal of Vascular and Endovascular Surgery 2003; 25(6):527-531.)

Includes same patients as Bell 2003[11]

Doss 2003b (Doss M, Balzer J, Martens S, Wood JP, Wimmer-Greinecker G, Moritz A et al. Emergent endovascular stent grafting for perforated acute type B dissections and ruptured thoracic aortic aneurysms. Annals of Thoracic Surgery 2003; 76(2):493-497.)

Patients included in series by Doss 2003a[17]

Ellozy 2003 (Ellozy SH, Carroccio A, Minor M, Jacobs T, Chae K, Cha A et al. Challenges of endovascular tube graft repair of thoracic aortic aneurysm: midterm follow-up and lessons learned. Journal of Vascular Surgery 2003; 38(4):676-683.)

Subset of patients included in Marin 2003[27]

Hutschala 2002 (Hutschala D, Fleck T, Czerny M, Ehrlich M, Schoder M, Lammer J et al. Endoluminal stent-graft placement in patients with acute aortic dissection type B. European Journal of Cardio-Thoracic Surgery 2002; 21(6):964-969.)

Patients included in the study by Grabenwoger 2003[20]

Lepore 2003 (Lepore VLn. Treatment of descending thoracic aneurysms by endovascular stent grafting. Journal of Cardiac Surgery 2003; 18(5):436-443.)

Patients are the same as those reported in Lepore 2002[26]

Orend 2002a (Orend KH, Pamler R, Kapfer X, Liewald F, Gorich J, Sunder-Plassmann L. Endovascular repair of traumatic descending aortic transection. J Endovasc Ther 2002; 9(5):573-578.)

Subset of patients reported in Orend 2003[31]

Pamler 2002 (Pamler RS, Kotsis T, Gorich J, Kapfer X, Orend KH, Sunder-Plassmann L. Complications after endovascular repair of type B aortic dissection. J Endovasc Ther 2002; 9(6):822-828.)

Patients included in Orend 2003[31]

Appendix 4. Excluded studies

Study ID	Reason for exclusion
Ahn 2001[53]	Case report
Bell 2003[1]	Editorial, not a primary study.
Bell 2003[54]	Small case series (n=5) investigating stent-graft placement in patients with aneurysms associated with coarctation.
Brunkwall 2003[55]	Majority of patients received a "home-made" stent device
Buffolo 2002[56]	Patients received a custom-made stent.
Cambria 2002[57]	Majority of patients received custom-made device.
Carroccio 2003[58]	Overview. Not a primary study.
Doss 2002[59]	Study also included patients with abdominal stents; results were not presented separately.
Gaines 2002[60]	Not a primary study.
Gan 2002[61]	Case report
Gawenda 2002[62]	Case report
Gowda 2003[63]	Case report
Greenburg 2000[64]	Patients received custom-made stent.
Hoffer 2002[65]	Case report
Kasirajan 2002[66]	Case report.
Kato 2001[67]	Patients received custom-made stent-graft.
Kato 2001[68]	Patients received custom-made stent-graft.
Kato 2003[69]	Home-made stent grafts were used in all patients.
Kilaru 2002[70]	Case report
Lopera[71]	Patients received custom-made stents.
Lundbom 2001[72]	Majority of patients received 'home-made' stent-graft.
Maruyama 2000[73]	Case reports.
Orend 2002b[74]	The type of stent-graft used was not reported.
Palombi 2000[75]	Case report
Rachel 2002[76]	Case report
Saccani 2002[77]	Case reports
Sam 2003[78]	Case reports
Sanada 2003[79]	Not a stent-graft which is commercially-available in the UK.
Shim 2000[80]	Abstract.
Shim 2001[81]	Abstract.
Shim 2001[82]	Abstract.
Shim 2002[83]	Patients received custom-made stents.
Shimono 2002[84]	Not a commercially-available stent-graft.
Stanley 2003[85]	Case report
Stoica 2003[86]	Case report
Thompson 2002[87]	Majority of patients were treated with custom-made stents.
Thurnher 2002[88]	Not a primary study or a systematic review (review article)
Umana 2002[89]	Patients receiving stent-grafting were grouped with patients receiving surgical treatment.
Won 2001[90]	Patients received custom-made stents.
Won 2001[91]	Duplicate article[90]
Yamazaki 2001[92]	Patients received custom-made stents.
Zanchetta 2003[93]	Report of a centre's experience using an intracardiac echocardiography (ICE) probe to guide endovascular aortic procedures. Not relevant to this review.

Appendix 5. Classification of endoleaks

Classification based on White 1998.[52]

Type I	Perigraft leak from poor proximal or distal attachment or seal
Type II	Collateral backflow / retrograde endoleak
Type III	Mid-graft fabric tear / modular disconnection or poor seal
Type IV	Porosity – graft-wall fabric porosity or suture holes