

SYSTEMATIC REVIEW

Outcomes of Fenestrated and Branched Endografts for Partial and Total Endovascular Repair of the Aortic Arch — A Systematic Review and Meta-Analysis

Paolo Spath ^{a,b,*}, Federica Campana ^a, Nikolaos Tsilimparis ^c, Enrico Gallitto ^{a,d}, Rodolfo Pini ^{a,d}, Gianluca Faggioli ^{a,d}, Stefania Caputo ^a, Mauro Gargiulo ^{a,d}

^a Vascular Surgery, University of Bologna, DIMEC, Bologna, Italy

^b Department of Vascular Surgery, Hospital “Infermi” Rimini, AUSL Romagna, Rimini, Italy

^c Department of Vascular Surgery, Ludwig-Maximilian University Hospital, Munich, Germany

^d Bologna Metropolitan Vascular Surgery Unit, IRCCS Azienda Ospedaliero-Universitaria S. Orsola, Bologna, Italy

WHAT THIS PAPER ADDS

Endovascular treatment of the aortic arch is a ground gaining approach to treat high risk patients, and fenestrated and branched endografts have been proposed as a suitable solution. This systematic review updates and highlights the results of both manufactured, custom made, and off the shelf devices in the treatment of the aortic arch and specifically in both partial and total endovascular repair. Despite data from centres of excellence specialising in aortic pathologies and the lack of randomised control trials, endovascular treatment of the aortic arch seems to have satisfactory technical success and low early mortality rates.

Objective: Fenestrated and branched thoracic endovascular aortic repair (F/B-TEVAR) of the aortic arch is a viable approach in patients unsuitable for open repair. The aim was to summarise the published results of manufactured F/B-TEVAR devices for partial and total repair of the aortic arch, and to compare fenestrated with branched configurations.

Data Sources: PubMed, Scopus and The Cochrane Library were searched for articles (2018 – 2021) about patients with elective, urgent, or emergency aortic requiring a proximal landing zone in the aortic arch (zone 0 – 1 – 2) and treated by F/B-TEVAR.

Review Methods: The systematic review and meta-analysis were performed according to the PRISMA guidelines. Open repair, supra-aortic trunk (SAT) debranching + standard TEVAR, and *in situ* physician modified and parallel grafts were excluded. Primary outcomes were technical success and 30 day mortality rate. Secondary outcomes were 30 day major adverse events, and overall survival and procedure related endpoints during follow up.

Results: Of 458 articles screened, 18 articles involving 571 patients were selected. Indications for intervention were chronic dissections (50.1%), degenerative aneurysms (39.6%), penetrating aortic ulcers (7.4%), and pseudoaneurysms (2%). F-TEVAR, B-TEVAR, and F+B-TEVAR were used in 38.4%, 54.1%, and 7.5% of patients, respectively. Overall, technical success was 95.9% (95% confidence interval [CI] 0.93 – 0.97; $I^2 = 0\%$; p for heterogeneity (Het) = .77) and the 30 day mortality rate was 6.7% (95% CI 0.05 – 0.09; $I^2 = 0\%$; p Het = .66). No statistical differences were found comparing fenestrated with branched endografts, except for a higher rate of type I – III endoleaks in F-TEVAR (9.8% vs. 2.6%; $p = .034$). The overall survival rate and freedom from aortic related death at the one year follow up ranged between 82 – 96.4% and 94 – 94.7%, respectively. Thirteen and five studies were considered at moderate and high risk of bias, respectively.

Conclusion: F/B-TEVAR for the treatment of the aortic arch, according to experience in dedicated centres, now enjoys a satisfactory level of technical success together with a progressively reduced early mortality rate. There are several limitations, and further studies are needed to reach clearer conclusions.

Keywords: Aortic arch, Branched endografts, Endovascular repair, Fenestrated endografts, TEVAR, Total endovascular arch repair

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* Corresponding author. Department of Vascular Surgery, Vascular Surgery, University of Bologna, Policlinico S. Orsola-Malpighi, via Massarenti 9, 40138 Bologna, Italy.

E-mail address: paolo.spath@gmail.com; paolo.spath@auslromagna.it; paolo.spath2@unibo.it (Paolo Spath).

 @PaoloSpath

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INTRODUCTION

There is a variety of aortic arch pathologies that require treatment, ranging from aortic arch aneurysms and penetrating aortic ulcers (PAUs) to acute and chronic aortic dissections (ADs).¹ In addition, in the treatment of thoracic and thoraco-abdominal aortic aneurysms (TAAAs) with thoracic endovascular aortic repair (TEVAR), the aortic arch might be involved in some cases to ensure a healthy sealing zone in zones 0, 1, and 2 according to the Ishimaru classification.²

The recent consensus paper of the European Societies of Vascular Surgery and Cardio-Thoracic Surgery¹ proposed endovascular treatment of the aortic arch as a viable option for patients not suitable for open surgical repair with reasonable life expectancy and favourable anatomy. The advantages of endovascular repair in this population include minimising surgical trauma, avoiding cardiac arrest, and cardiopulmonary bypass, and thus reducing peri-operative risks even for hybrid procedures, consisting of standard TEVAR with proximal surgical transposition of supra-aortic trunks (SATs), that should be carefully evaluated for high risk surgical patients.³

Thus, fenestrated and branched thoracic endovascular aortic repair of the arch (F/B-TEVAR), potentially associated with surgical SAT debranching, should be considered, as already reported in previous systematic reviews.^{4–6} Other available options include parallel grafts,^{7,8} physician modified, or *in situ* fenestration of TEVAR;^{9,10} however, these techniques are not recommended for elective cases and are only appropriate for urgent treatment or as bailout options in the event of inadvertent coverage of supra-aortic trunks.¹

There are increasing technical innovations and more experience in endovascular repair of the aortic arch, and this systematic review aimed to update the current experience of manufactured, custom made, and off the shelf devices in total and partial endovascular repair of the aortic arch, reporting the early and follow up results of a new generation of endografts in the light of the latest recommendations,¹ and to highlight potential differences in the two endograft configurations.

MATERIALS AND METHODS

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA);¹¹ the review protocol was previously registered in the PROSPERO database [CRD42021290573]. This topic was defined using the PICO (Population, Intervention, Comparison, Outcome) strategy, with the population being patients with aortic arch pathologies or requiring endovascular aortic treatment with a proximal landing zone (PLZ) in the aortic arch; intervention, elective, urgent or emergency treatment with arch F/B-TEVAR; comparison, fenestrated vs. branched endografts; outcome, technical success and 30 day mortality rate.

Search strategy

Articles published in English were systematically reviewed between 1 January 2018 and 1 October 2021 to update the

results of early experience of endovascular treatment of the aortic arch previously published,^{4,5,12} focusing only on manufactured, custom made, and off the shelf F/B-TEVAR devices.

Two independent authors (P.S. and F.C.) performed an extensive search of the literature using three electronic medical databases (PubMed, Scopus, and Cochrane Library).

The full search strategy string is reported in [Supplementary Table S1](#). After removing duplicated records, two authors (P.S. and F.C.) independently performed title and abstract screening, followed by full text reading to select the final articles according to the inclusion and exclusion criteria. If any disagreement occurred, an additional author intervened (E.G.). Included papers were eventually reviewed by N.T. and M.G.

Inclusion and exclusion criteria

Studies were considered eligible if the following inclusion criteria were respected: (1) patients with aortic arch pathologies or requiring endovascular aortic treatment with PLZ in the aortic arch within Ishimaru zone 0 – 2, including degenerative aortic arch and descending thoracic aneurysms, chronic aortic dissections (e.g., progressive dilation of the aorta, post-dissection aneurysms), PAU, and pseudoaneurysms; (2) patients treated with manufactured, custom made, and off the shelf F/B-TEVAR devices. From a technical point of view, each stent graft had to report at least one modification (e.g., scallop, fenestration, branch) and not just a simple tube TEVAR, either requiring or not adjunctive SAT debranching (e.g., fenestrated or branched endograft for brachiocephalic trunk [BCT] and left common carotid artery (LCCA) + surgical carotid–subclavian bypass). Furthermore, the most proximal SAT had to have been revascularised directly by endovascular graft (scallop) or by stent grafting (branched or fenestrated).

Exclusion criteria considered were (1) patients treated with open surgical repair; (2) patients treated with debranching of proximal SAT followed by a standard tube TEVAR procedure; (3) patients treated with parallel graft (PG), *in situ* fenestration, or physician modified TEVAR; (4) case series including fewer than five patients; (5) technical success or 30 day mortality rate not reported. Repeated data published by the same group were also excluded, but papers published by the same authors were included after demonstrating different cases and approaches.

Outcomes and definitions

All outcomes were defined according to the reporting standards for endovascular aortic repair of aneurysms involving the renal or mesenteric arteries,² in the absence of dedicated aortic arch reporting standards. Total endovascular arch repair is defined as replacing the entire aortic arch, thus replacing or excluding from circulation aortic zones 0 – 2 (or beyond),¹ whereas all other procedures on the arch are known as partial arch.

The primary outcomes were (1) technical success, defined as successful delivery and deployment of the aortic

stent graft, successful side branch catheterisation and placement of bridging stents, patency of all aortic modular stent graft components and side branches, and absence of type I – III endoleaks on completion angiography, and (2) 30 day all cause death. Secondary outcomes were 30 day major adverse events (MAEs), and overall survival, freedom from aorta related death, supra-aortic trunk patency, and aneurysm sac remodelling during follow up. Thirty day MAEs included stroke, reported according to the definition reported by the authors; spinal cord ischaemia (SCI), defined as the presence of paraplegia or paraparesis, being temporary if there was complete resolution and expected return to baseline, and permanent if the injury had partial or no improvement compared with baseline examination; renal function worsening, defined as either the presence of post-operative acute kidney injury (defined with RIFLE or KDIGO classification) or a reduction > 30% of estimated glomerular filtration rate (eGFR); cardiac events, including myocardial infarction, congestive heart failure, and myocardial ischaemia requiring intervention; symptomatic or asymptomatic retrograde type A aortic dissection detected on post-operative computed tomography (CT) scans, and supra-aortic trunks patency detected on post-operative CT scans.

Data extraction and quality of the evidence

A standardised electronic database was used to extract data, including demographic information, the indication for surgical intervention, type of endograft used (and manufacturer), primary, secondary, and follow up outcomes. Risk of bias assessment was performed with the ROBINS-I tool.¹³ This tool is used to make judgements on the bias of confounding, selection of participants, classification of intervention, deviation from intended intervention, missing data, measurements of outcomes, and selection of reported results. Two independent authors (P.S. and F.C.) judged each domain for each included study as low, moderate, or serious risk of bias. Any discrepancy was resolved after consultation with other co-authors (E.G., N.T., and M.G.). The graphical representation of the risk of bias for each study was performed with the Robvis tool.¹⁴

Synthesis of the results

A proportion meta-analysis was performed for primary and secondary outcomes using ProMeta 3.0 software (Internovi, Italy, <https://www.meta-analisi.it/prometa-software/>). A random effects model was assessed *a priori* because of the heterogeneity of the observational studies. Binary outcomes were expressed as pooled rates and 95% confidence intervals (CIs). The pooled effect estimates were calculated as the back transformation of the weighted mean of the transformed proportions using Der Simonian–Laird weights of the random effects model and expressed as percentage proportions. Heterogeneity among the studies was estimated using the I^2 test and reported as percentages. An I^2 value < 30% was considered low heterogeneity, between 30% and 49% moderate, between 50% and 80% substantial,

and > 80% considerable heterogeneity. The Z test was used to assess the overall effect and data were graphed as a forest plot. Publication bias was assessed using the trim and fill method and analysed using a funnel plot. Subgroup analysis was planned to highlight the results of the studies having all patients treated with either fenestrated or branched endografts. Because of the small sample of patients treated with endografts, both fenestrated and branched endografts, this cohort was not included in the comparison.

A subgroup meta-analysis was also performed of studies reporting total endovascular arch repair with a PLZ in zone 0.

The analysis of variance random effect Q test was performed to compare the estimated pooled rate of the outcomes of fenestrated and branched endografts.

Regarding follow up outcomes, since the presentation of data was heterogeneous, follow up time and the presence of missing data, results were described through narrative synthesis.

Continuous data are reported as mean \pm standard deviation. Patient characteristics are reported as percentage or proportions. Statistical significance was set to $p < .05$.

RESULTS

Study Selection and analysis

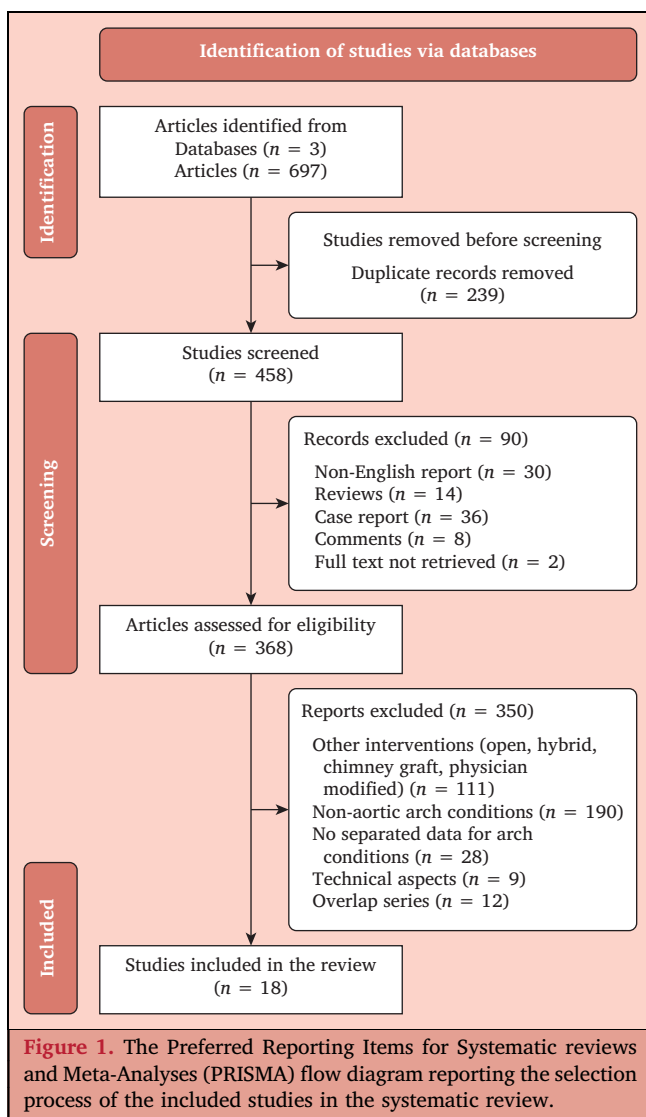
The selection process is shown in Figure 1. The initial study search after duplicate removal resulted in 458 studies; among these, 368 articles were assessed for eligibility after removing non-English reports, review articles, case reports, and commentaries. After reading the titles and abstracts, 88 articles were selected for full text reading, and ultimately, 18 articles were included after an accurate analysis accordingly to the inclusion and exclusion criteria. Sixteen retrospective^{15–30} and two prospective cohort studies were included;^{31,32} eight were multicentre studies^{15,18,21,23,25,26,31,32} (Table 1).

Overall, 571 patients (73.9% male, mean age 68.9 ± 2.5 years) were included. Only 30 (5.3%) patients were treated urgently. The most common comorbidities were hypertension (85.6%), dyslipidaemia (44.2%), diabetes (67.1%), and chronic kidney disease (19.3%). Previous aortic procedures had been performed in 223 patients (39.1%).

Indications for surgical intervention are presented in Supplementary Table S2. There were 277 (50.1%) chronic aortic dissections, 219 degenerative aneurysms (39.6%), 41 (7.4%) PAU, and 11 (2%) pseudoaneurysms. The specific reason for intervention was not reported in one study.³²

The characteristics of implanted devices are reported in Table 2. Custom made devices were implanted in 91% of cases. F-TEVAR endografts (46 single scallop, 83 scallop + fenestration, 90 only fenestrated) were used in 219 patients (38.4%) and B-TEVAR endografts (75 one branch; 189 two branches; 46 three branches) in 309 (54.1%) patients, and 43 (7.5%) patients were treated with an endograft with both fenestrations and branches (F + B-TEVAR).

Ishimaru's PLZ was zone 0 in 386 (67.6%) patients, zone 1 in 68 (11.9%), and zone 2 in 117 (20.5%) patients.



Additional surgical cervical debranching was performed in 295 (49.9%) cases.

Primary outcomes

Primary outcomes were reported in all included articles and were calculated for 571 patients (Fig. 2). Technical success was obtained in 558 patients, representing a pooled rate of 95.9% of the cohort (95% CI 0.93 – 0.97; $I^2 = 0\%$; p Het = .77). Thirty day death occurred in 25 patients, representing a pooled rate of 6.7% of patients (95% CI 0.05 – 0.09; $I^2 = 0\%$; p Het = .66).

Secondary Outcomes

Pooled rates of MAEs are presented in Table 3. Major or disabling strokes occurred in 6.2% of patients, and SCI in 4.5%. Specifically, 2.3% of patients had permanent paralysis. The definition adopted by the authors to define stroke and spinal cord ischaemia (SCI) is reported in Supplementary Table S3.

Mean follow up for each included study is shown in Table 1. Nine^{15,17–23,27} studies performed survival analysis during follow up; specifically, seven authors^{15,18,20–23,27} reported a survival rate at one year follow up that ranged from 82% to 96.4%, whereas the survival at three and five years ranged between 75 and 90.8%^{15,19,22,23} and 80.8 and 84.4%,^{15,22,23} respectively. Freedom from aortic related death at one year of follow up ranged from 94 to 94.7%:^{15,18} 94.7% at three years¹⁵ and 89.7 – 95.8% at five years of follow up.^{15,22} Furthermore, supra-aortic trunk patency ranged between 86.7% and 100%.^{16–18,31,32}

Ten studies also described aneurysm sac remodelling during follow up.^{15–17,19,20,22,23,26,29,31}

Eight studies^{15,17,19,22,23,26,29,31} reported either no change or a decrease in the aneurysm diameter in 71.3 – 100% of patients. Li *et al.*¹⁶ reported 81.3% of the cohort having complete thrombosis of the false lumen within the region covered by endografts. Zhang *et al.*²⁰ reported significant true lumen recovery and false lumen shrinkage; Law *et al.*²⁹ described a 100% rate of false lumen thrombosis.

Subgroup analysis

Subgroup analysis was performed to present primary and secondary outcomes of patients treated with fenestrated endografts. Only studies with 100% of patients treated with any fenestrated device (six studies^{15,17,23,24,28,30}) and any branched endograft (nine studies^{18,21,22,25–27,29,31,32}) were included. Three studies having patients treated with both fenestrated and branched endografts or fenestrated + branched endografts were excluded from this analysis.^{16,19,20}

Technical success was 96.8% (95% CI 0.92 – 0.99; $I^2 = 0\%$; p Het = .54) and 96% (95% CI 0.93 – 0.98; $I^2 = 0\%$; p Het = .93) for fenestrated and branched endografts, respectively ($p = .72$). The 30 day mortality rate was 6.4% (95% CI 0.04 – 0.11; $I^2 = 0\%$; p Het = .90) for F-TEVAR and 7.2% (95% CI 0.04 – 0.13; $I^2 = 24\%$; p Het = .23) for B-TEVAR, and did not reach statistical difference ($p = .76$).

Table 3 shows the results of fenestrated and branched endografts, with no statistical difference for any of the secondary outcomes except for a higher rate of type I – III endoleaks in fenestrated (9.8%; 95% CI 0.04 – 0.23) compared with branched (2.6%; 95% CI 0.01 – 0.06) ($p = .034$) endografts.

In 11 studies, 100% of patients were treated with total endovascular repair, having a PLZ 0,^{16,18,19,21,22,25–29,32} for a total of 285 patients (15 fenestrated, 255 branched, and 16 fenestrated + branched endografts). In these cases, technical success occurred in 94.8% (95% CI 0.91 – 0.97), and 30 day death in 7.8% (95% CI 0.05 – 0.12). Major or disabling strokes and SCI occurred in 7.2% (95% CI 0.04 – 0.12) and 5.2% (95% CI 0.03 – 0.10), respectively. Secondary outcome results and specifics are found in Table 4.

Risk of bias and publication bias

All the studies included were judged to be at moderate risk of bias except for five^{18,19,21,23,28} which were judged to be

Table 1. Characteristics of the included studies

Authors	Year	Study setting	Study design	Years of intervention	Patients – n	Mean follow up (range/SD)
Tsilimparis <i>et al.</i> ¹⁵	2021	Frankfurt, Birmingham, Malmö, Hamburg, Uppsala Munich	Retrospective, multicentre	Unknown –2020	108	12.8 (1–96)
Li <i>et al.</i> ¹⁶	2021	Shanghai, China	Retrospective	2009–2011	16	98 (0–119)
Hanna <i>et al.</i> ¹⁷	2021	London, UK	Retrospective	2009–2019	38	54 (0–126)
Dake <i>et al.</i> ³¹	2021	Tucson, Arizona; Palo Alto, Calif; Philadelphia and Pittsburgh, Pa; Rochester, Minnesota; Lebanon, NH; and Madison and Ann Arbor, Wis	Prospective, multicentre	2014–2016	31	25.2 (11)
Tenorio <i>et al.</i> ¹⁸	2021	Paris, Hamburg, Mayo Clinic, Malmö, Chapel Hill, Dallas, Munich, Warsaw	Retrospective, multicentre	2016–2019	39	3.2 (1–14)
Planer <i>et al.</i> ³²	2021	Zurich, Rome, Auckland, Toronto, Düsseldorf,	Prospective, multicentre	–	18	–
Kuzniar <i>et al.</i> ¹⁹	2021	Uppsala, Sweden	Retrospective	2010–2019	13	23 (1–118)
Zhang <i>et al.</i> ²⁰	2021	Shanghai, China	Retrospective	2009–2014	51	92 (62–114)
Verscheure <i>et al.</i> ²¹	2021	Lille, Hamburg, Malmö, Uppsala, Cleveland, Rio de Janeiro, Maastricht, London, Regensburg, Birmingham, Hong Kong, Nares, Warsaw	Retrospective, multicentre	2011–2018	70	10 (5–21)
Kudo <i>et al.</i> ²²	2020	Osaka, Japan	Retrospective	2012–2018	28	48 (24)
Sato <i>et al.</i> ²³	2020	Japan	Retrospective, multicentre	2009–2019	37	2.9 (3)
Fernández <i>et al.</i> ²⁴	2020	Pamplona, Spain	Retrospective	2014–2020	14	37.5 (3–72)
Van der Weijde <i>et al.</i> ²⁵	2020	The Netherlands, three centres	Retrospective, multicentre	2014–2018	11	17 (3–42)
Ferrer <i>et al.</i> ²⁶	2019	Rome, Turin, Bologna, and Cagliari	Retrospective, multicentre	2012–2018	24	8 (1–50)
Tsilimparis <i>et al.</i> ²⁷	2019	Hamburg, Germany	Retrospective	2012–2017	54	12 (9)
Toya <i>et al.</i> ²⁸	2018	Jikei, Japan	Retrospective	2015–2016	8	12 (7–29)
Law <i>et al.</i> ²⁹	2018	Hamburg, Germany	Retrospective	–	5	–
Tan <i>et al.</i> ³⁰	2018	Singapore	Retrospective	2015–2017	7	15 (5–23)
Total					571	

Studies are presented in chronological order, from the latest to the earliest included in the systematic review. Missing data are marked with –. Reported mean follow up time is considered in months. SD = standard deviation.

at high risk of bias. Details of the risk of bias for each study assessed with the ROBINS-I tool can be found in [Figure 3](#).

DISCUSSION

This systematic review presents the results of performance and outcomes of the fenestrated and branched platforms for the treatment of pathologies involving the aortic arch,³³ and aimed to perform an update since the publication of the latest international guidelines position papers¹ and since the latest innovative surgical solutions.^{18,34,35} The latest consensus document from the European Society of Vascular Surgery and the European Association for Cardiothoracic Surgery reported that patients unfit for open surgery and with suitable anatomy, requiring a zone 0 treatment, should be considered for endovascular aortic arch repair (Recommendation 30, Class IIa, Level B).¹

In recent years, several innovations have been proposed, such as the three internal branch configurations to reduce the risks of surgical exposure and bypass grafting,^{18,36} and some dedicated centres have reported encouraging rates of 0% for in hospital death,³⁷ with major roles for reaching a learning curve, accurate patient selection, and patient

centralisation (Recommendation 2, Class I, Level C¹), together with technological innovation.^{18,37,38}

For these reasons, a dedicated systematic review and meta-analysis was performed focusing only on manufactured, custom made, and off the shelf devices to standardise the indications, outcomes, and results.

Unlike previous systematic reviews,^{4,9,12} cases of open repair, standard tube TEVAR + surgical debranching, and physician modified or *in situ* and parallel graft techniques were excluded from the analysis, because they are considered appropriate for urgent treatment or as bailout options,¹ with worse early and long term results, as recently described in a review by Nana *et al.*⁶

It is well known that custom made endografts need a period of time to be available for intervention,³⁹ and in these cases treatment with a parallel graft as well as *in situ* or physician modified endograft should be considered⁴⁰ despite the higher rate of complications and need for additional procedures.⁴¹ Some recent studies have shown the possibility of available configurations of manufactured devices capable of covering up to 79% of arch anatomies, and will be proposed shortly as available grafts to treat urgent cases.^{42,43} In this specific analysis, urgent or

Table 2. Endografts and procedural details							
Authors	Year	Patients – n	Device type	Model	Manufacturer	Proximal landing zone	Adjunctive cervical bypass
Tsilimparis <i>et al.</i> ¹⁵	2021	108	CM	64 scallop + one fenestration 44 one fenestration	Cook Medical	21 LZ0 45 LZ1 42 LZ2	26 LCCA-LSA
Li <i>et al.</i> ¹⁶	2021	16	CM	16 one fenestration + one outer branch	MicroPort Medical	16 LZ0	2 LCCA-LSA 1 RCCA-LCCA
Hanna <i>et al.</i> ¹⁷	2021	38	CM	38 single scallops	Terumo Aortic	6 LZ0 6 LZ1 26 LZ2	7 LCCA-LSA 4 RCCA-LCCA-LSA
Dake <i>et al.</i> ³¹	2021	31	OTS	31 one outer branch (Gore TBE)	Gore	31 LZ2	0
Tenorio <i>et al.</i> ¹⁸	2021	39	CM	39 three inner branches	Cook Medical	39 LZ0	7 RCCA-RSA
Planer <i>et al.</i> ³²	2021	18	OTS	18 one outer branch for BCT	Nexus	18 LZ0	18 RCCA-LCCA-LSA
Kuzniar <i>et al.</i> ^{19,*}	2021	12	CM	3 single fenestrations for LSA or LCCA 4 single fenestrations + scallop Six two inner branches for BCT and LCCA	Cook Medical	12 LZ0	6 LCCA-LSA
Zhang <i>et al.</i> ²⁰	2021	51	CM	22 one outer branch 17 one outer branch + single proximal fenestration 10 one outer branch + double fenestration 2 two single branched	MicroPort Medical	18 LZ2 33 LZ0	5 RCCA-LCCA-LSA 3 RCCA-LCCA 3 LCCA-LSA
Verscheure <i>et al.</i> ²¹	2021	70	CM	63 two inner branches for BCT and LCCA 7 three inner branched	Cook Medical	70 LZ0	63 LCCA-LSA or transposition 7 RCCA-RSA or transposition
Kudo <i>et al.</i> ²²	2020	28	CM	4 one inner branch 24 two inner branch	Bolton Medical	28 LZ0	1 LCCA-LSA 24 RAA-LAA 3 RAA-LCCA-LAA
Sato <i>et al.</i> ²³	2020	37	CM	37 1–2 fenestrations	Najuta	31 LZ0 5 LZ1	16 NR
Fernandez <i>et al.</i> ²⁴	2020	14	CM	8 single scallops 1 scallop + fenestration 5 one fenestration	Terumo Aortic	6 LZ0 8 LZ1	8 LCCA-LSA
Van der Weijde <i>et al.</i> ²⁵	2020	11	CM	11 two inner branch (Customised Relay NBS Plus)	Terumo Aortic	11 LZ0	5 LCCA-LSA 3 LSA transpositions
Ferrer <i>et al.</i> ²⁶	2019	24	CM	24 two inner branch (RelayBranch)	Terumo Aortic	24 LZ0	21 LCCA-LSA 2 LSA transpositions
Tsilimparis <i>et al.</i> ²⁷	2019	54	CM	54 two inner branch	Cook Medical	54 LZ0	54 LCCA-LSA
Toya <i>et al.</i> ²⁸	2018	8	CM	6 scallops + one fenestration 2 scallops + two fenestrations	Najuta	8 LZ0	1 LCCA-LSA
Law <i>et al.</i> ²⁹	2018	5	CM	5 two inner branch (custom made Zenith Ascend)	Cook Medical	5 LZ0	5 LCCA-LSA
Tan <i>et al.</i> ³⁰	2018	7	CM	3 Scallops + one fenestration 2 one fenestration 1 two fenestrations 1 Scallop + two fenestration	Cook Medical	3 LZ0 4 LZ1	0
Total		571					295

Studies are presented in chronological order, from the latest to earliest included in the Systematic Review. CM = custom made devices; OTS = off the shelf devices; LCCA = left common carotid artery; LSA = left subclavian artery; RCCA = right common carotid artery; RSA = right subclavian artery; LAA = left axillary artery; RAA = right axillary artery. Proximal landing zone indicated according to Hishimaru's classification. LZ = landing zone.

* This study reports a total of 13 interventions performed on 12 patients.

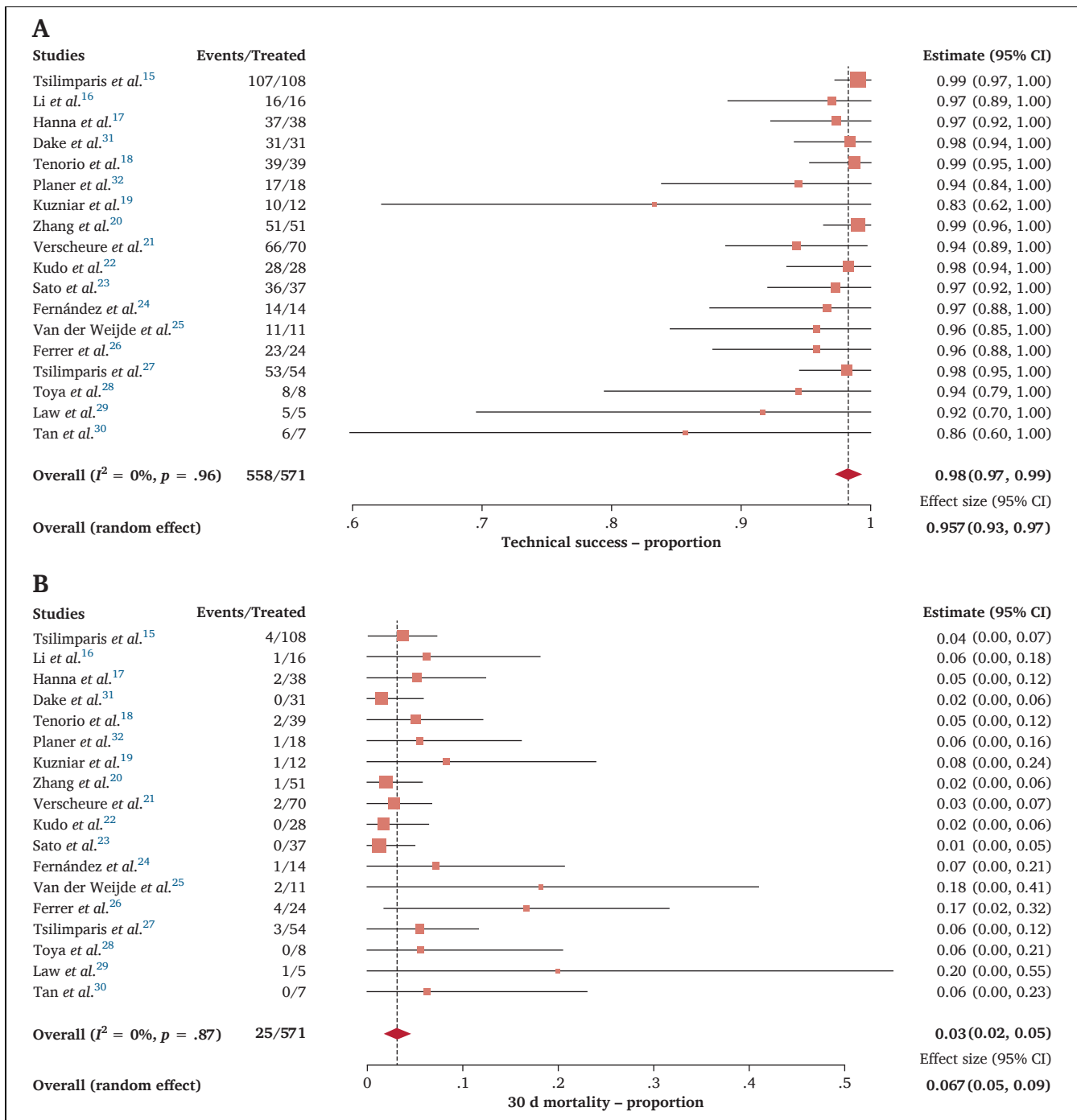


Figure 2. Forest plot presenting the meta-analysis of overall rate of technical success (A) and 30 day mortality rate (B). Event rates in the individual studies are presented as squares, with 95% confidence intervals (CIs) presented as extending lines. The pooled event rate with its 95% CI is depicted as a diamond. Studies are presented in chronological order, from the latest to the earliest in the systematic review.

emergency cases represented only 5% of patients, thus further specific analysis with the use of off the shelf devices should be undertaken.

An increasing trend in the rate of endovascular cases can be highlighted in this systematic review, showing a rate of 143 published patients per year in the last four years (571 patients treated from 2018 to 2021), whereas former systematic reviews^{5,12} with data collected between 1997 and

2019 reported a rate of published patients per year ranging from 49⁵ to 56.¹²

In this review the most frequent disease was chronic aortic dissections (50.1%), and post-dissection aortic dilation was the most common indication for treatment reported in the included articles; however, the exact number of post-dissection aneurysms was not extractable from the data.

Table 3. Secondary outcomes results								
Outcome	Studies – n	Patients – n	Events – n	Pooled outcome rate – %	95% CI	I ² – %	p Het	p value F vs. B
<i>Major or disabling stroke</i>								
Overall	13	447	22	6.2	0.04–0.09	0	.63	.54
Fenestrated endograft	4	167	7	5.3	0.03–0.10	0	.76	
Branched endograft	9	280	15	6.8	0.04–0.11	3.1	.41	
<i>Spinal cord ischaemia</i>								
Overall	15	540	15	4.5	0.03–0.07	0	.76	.83
Fenestrated endograft	4	197	7	3.9	0.02–0.08	0	.95	
Branched endograft	9	280	6	4.3	0.02–0.08	0	.79	
<i>Permanent spinal cord ischaemia</i>								
Overall	14	503	4	2.3	0.01–0.04	0	.98	.61
Fenestrated endograft	3	160	3	2.9	0.01–0.08	3.6	.35	
Branched endograft	9	280	1	2.0	0.01–0.05	0	.98	
<i>Renal function worsening</i>								
Overall	10	394	15	4.8	0.03–0.08	0	.94	.72
Fenestrated endograft	2	122	5	4.5	0.02–0.10	0	.82	
Branched endograft	7	221	10	5.4	0.03–0.09	0	.92	
<i>Cardiac events</i>								
Overall	14	484	24	6.7	0.04–0.10	8.1	.36	.98
Fenestrated endograft	4	167	9	6.3	0.03–0.11	0	.74	
Branched endograft	7	238	14	6.3	0.03–0.13	38.2	.14	
<i>Retrograde type A aortic dissection</i>								
Overall	11	381	6	3.2	0.02–0.06	0	.88	.47
Fenestrated endograft	4	197	3	2.4	0.01–0.06	0	.92	
Branched endograft	6	168	2	3.8	0.02–0.09	0	.60	
<i>Type I-III endoleaks</i>								
Overall	16	547	26	4.8	0.02–0.09	50.7	.011	.034
Fenestrated endograft	5	204	21	9.8	0.04–0.23	65.3	.021	
Branched endograft	9	280	4	2.6	0.01–0.06	0	.97	
<i>Supra-aortic trunks patency</i>								
Overall	13	461	454	96.2	0.94–0.98	0	.81	.080
Fenestrated endograft	3	164	146	94.2	0.89–0.97	0	.52	
Branched endograft	8	241	240	98	0.95–0.99	0	.95	

Each outcome result is reported as overall, for fenestrated endografts, and for branched endografts. The I² value for heterogeneity and its p value (p Het) is reported for each outcome. F = fenestrated endografts; B = branched endografts.

Off the shelf devices were used in only two studies (9%),^{31,32} highlighting that at this time experience with these devices is limited; therefore, it was not considered appropriate to perform a comparison between off the shelf and custom made devices.

The most used configuration was B-TEVAR (54.3%), with a proximal landing zone in zone 0 in 67.6%; double branched graft was the most frequent endograft used (33.1%). Among the F-TEVAR cases (219; 38.4%), roughly the same number of patients was treated with either only fenestrated or proximal scalloped and fenestrated grafts (15.8% and 14.5%, respectively). Also included in the review were 7.5% of cases treated with an endograft using both fenestrations and branches (F + B-TEVAR), but because of the small number of patients this cohort was not compared with other groups.

Concerning the primary outcomes, technical success was 95.9%. The overall 30 day mortality rate was 6.7%, with no statistical differences between F-TEVAR and B-TEVAR.

For neurological events, different definitions were adopted by authors to describe stroke, with the most

frequent being the clinical presentation of stroke, whereas a few articles described neurological consultations or imaging to confirm the condition. Moreover, a few articles included cases of minor stroke and transient ischaemic attack (TIA) in the reported number of strokes. Thus, only the pooled rate of strokes being defined as major or disabling (6.2%) were reported, although 16 patients were reported with minor strokes or TIAs. SCI impacted on 4.5% of patients and was defined mainly as the clinical presentation of paralysis. Among these, only four (2.3%) patients had permanent paralysis.

Subgroup analysis was performed to compare the results of F-TEVAR with B-TEVAR, and showed no statistical difference between the two techniques, except for a higher rate of type I – III endoleaks in fenestrated endografts (9.8% vs. 2.6%; $p = .034$). Recently, papers by Haulon *et al.*³⁸ and Lu *et al.*⁴⁴ have reported that branched endografts have a more stable landing zone for bridging stenting, and a more durable and stable configuration to face the rotational movements in four directions of the aortic arch during cardiac and respiratory cycles. Hence, this

Table 4. Total endovascular repair (zone 0 proximal landing zone)

Outcome	Studies – n	Patients – n	Events – n	Effect size – %	95% CI	I ² – %	p Het
Technical success	11	285	277	94.8	0.91–0.97	0	.81
Death	11	285	17	7.8	0.05–0.12	0	.50
Major or disabling stroke	8	249	14	7.2	0.04–0.12	8.0	.37
Spinal cord ischaemia	9	261	6	5.2	0.03–0.10	0	.46
Permanent spinal cord ischaemia	9	261	1	2.3	0.01–0.05	0	.98
Renal function worsening	7	221	10	5.4	0.03–0.09	0	.92
Cardiac events	9	266	15	6.7	0.04–0.12	21.3	.25
Retrograde type A aortic dissection	7	184	3	4.2	0.02–0.09	0	.69
Type I–III endoleaks	9	261	4	3.0	0.01–0.06	0	.51
Supra-aortic trunks patency	8	226	226	97.8	0.94–0.99	0	.90

The I² value for heterogeneity and its p value (p Het) are reported for each outcome.

configuration might be associated with a lower rate of type I – III endoleaks than fenestrated endografts. However, the lack of randomised control trials in this meta-analysis does not allow the drawing of conclusions on this topic or to confer superiority of one technique compared with another.

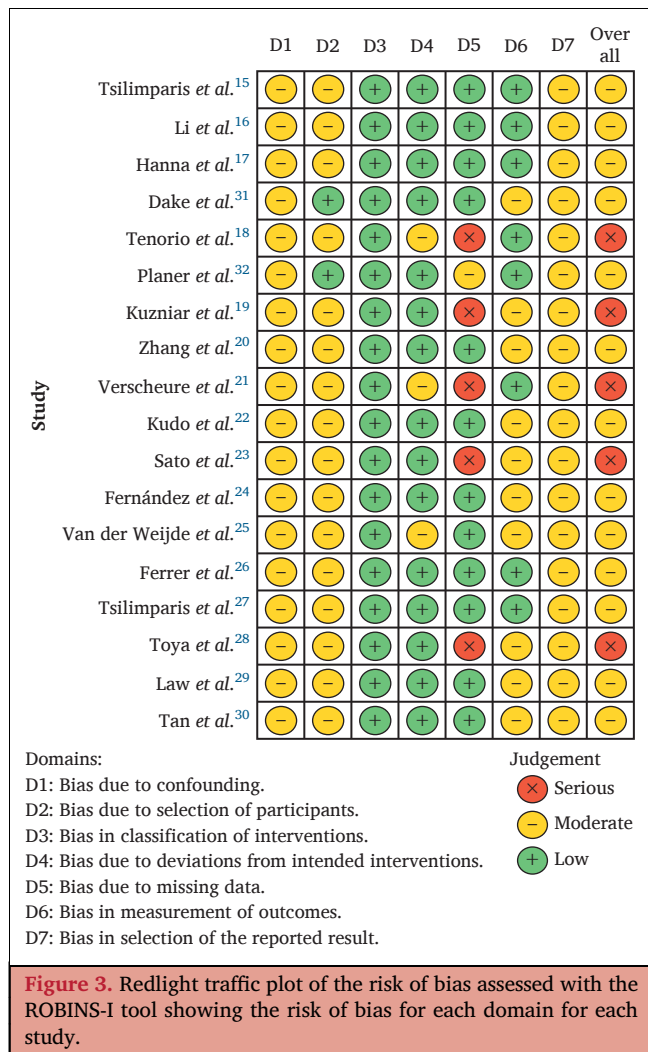
Articles with 100% of the cases with zone 0 F/B-TEVAR (11 articles, 285 cases) were also analysed. Most of these

patients were treated with branched endografts (89%, 255 cases), whereas only 15 (5%) and 16 (6%) cases were fenestrated and fenestrated + branched endografts, respectively. These papers reported for zone 0 endografts an overall technical success of 94.8%, and 30 day pooled mortality rate of 7.8%. Notwithstanding, these findings could not be compared since separated data of endografts with a PLZ in zones 1 and 2 could not be retrieved.

Supra-aortic trunk surgical debanching was performed in 295 cases. Only two studies^{30,31} did not perform any surgical debanching.

Overall, the risk of retrograde type A dissection was low, occurring in six cases (3.2%). Although limited data on total endovascular repair with proximal landing zone 0 are available, it can be speculated that the presence of a longer landing zone in the ascending thoracic aorta could play a role in stabilising the vessel intima and in reducing the occurrence of this complication.²¹

A consistent follow up period is necessary to assess the clinical stability and effectiveness of these demanding procedures. The reported mean follow up ranged between three and 98 months, representing one of the longest available. Only three studies had a mean follow up of less than one year,^{18,21,23} resulting in an increased risk of bias due to missing data. The major issue was that only a small number of studies performed a survival analysis, and the follow up data available in the included articles were reported as a narrative presentation of the present literature. The survival rate at one year ranged between 82% and 96%, suggesting acceptable patient life expectancy. At the same time, during follow up the overall primary and assisted patency of both surgical and stent graft revascularised vessels ranged from 86.7% to 100%, supporting a favourable trend already reported in other studies.^{4,5,12,6} Similar findings were confirmed by the absence of signs of sac enlargement reported by 10 studies, ranging from 71% to 100%, and testifying to the good midterm technical results of these procedures.



Limitations and future perspectives

Several limitations of this systematic review should be mentioned. First, the nature of this review is a proportion

meta-analysis without the presence of randomised controlled trials, which limits the quality of the evidence and makes it impossible to perform a comparison between different techniques. Among the included studies, there was heterogeneity in the number of cases reported and the total number of patients was restricted to draw strong conclusions. Strong heterogeneity can be also found in the reasons for intervention: different pathologies were included, but separated data on the outcomes were not available; hence, further analysis should be undertaken to better analyse different clinical entities. Moreover, urgent and emergency cases were included, suggesting the need of further studies specifically on these patients, potentially with the use of off the shelf devices.

Although fenestrated and branched repair were compared, the two endografts have different anatomical selection criteria, and for this reason they might be considered as two different entities, and additional analysis with randomised control trials should be undertaken. Results of patients with a proximal landing zone in zone 0 were also reported, but a comparison could not be made because separated data for zone 1 and 2 cases could not be retrieved, and dedicated studies for each landing zone could be performed. Different extensions of endovascular repair with variable aortic coverage⁴⁵ of the thoracic aorta were considered, with possible influence on clinical outcomes.

The presence of missing data might have also influenced the present results, especially regarding the follow up period.

It is also important to consider that the present encouraging data reflect the experience of centres of excellence for the treatment of aortic pathologies, supporting the indication to centralise patients with aortic arch pathologies to specialised centres, as reported by the European Society for Vascular Surgery.¹

Moreover, the results refer to the use of different brands and configurations of endografts, and endografts implanted in four of the included studies^{16,20,23,28} were selectively used in Asia; thus, the results coming from these studies should be considered in light of this specific background.

Last, from early experience of these techniques, reports might be limited to favourable outcomes and there might be indirect publication bias. However, by assessing publication bias with the trim and fill method, the aim was to minimise potential sources of publication bias.

Conclusions

Endovascular repair of the aortic arch using manufactured fenestrated and or branched devices seems to enjoy a satisfactory level of technical success in many cases together with a progressively reduced load in terms of early death. The evidence still represents the results of dedicated centres and is burdened by several limitations. Further studies with randomised controlled trials, longer term follow up, and homogeneous reporting of results are needed to reach clearer conclusions.

CONFLICT OF INTEREST

M.G. N.T. E.G. are consultants for Cook Medical for fenestrated and branched endovascular aneurysm repair. The

other authors declare that they have no competing interests.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2023.07.048>.

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