

Analysing debranching techniques in Frozen Elephant Trunk procedures: a narrative literature review

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Background and Objective: Since 2003, the Frozen Elephant Trunk (FET) technique has attained rising popularity for treating extensive aortic arch pathologies such as acute and chronic aortic dissection, as well as thoracic aortic aneurysm. Conventionally, the FET procedure included a complete resection of the aortic arch and, subsequently, a distal aortic anastomosis of the prosthetic part of the hybrid graft in arch zone 3. Simultaneous to the introduction of the FET technique, the traditional Elephant Trunk technique was simplified by adding debranching techniques which allows for proximalization of the distal aortic anastomosis in arch zone 2 or further proximal, achieved by using different debranching techniques. This review describes different debranching techniques to facilitate arch reconstruction, and aims to critically assess the outcomes and potential clinical advantages of proximalization using debranching in FET surgery.

Methods: We conducted a search using the PubMed and Google Scholar electronic databases to evaluate published outcomes of different debranching techniques. An overview of the data synthesis of 21 included studies is reported.

Key Content and Findings: Most studies report numeric, but not statistically significant improved outcomes after debranching in FET surgery for mortality, neurological complications, spinal cord injury, kidney failure, bowel ischemia and recurrent nerve palsy. Some studies report statistically significant improved results in isolated endpoints such as neurological, bowel ischemia, and recurrent nerve palsy. Most studies report debranching to be technically easier, but this is difficult to objectively assess and measure.

Conclusions: There is an improved numeric outcome of different debranching techniques with proximalization of the distal anastomosis, but without reaching statistical significance. This review shows marked heterogeneity across included studies and highlights the scarce use of existing guidelines in clinical research of open aortic arch surgery as proposed by the International Aortic Arch Surgery Study Group. Furthermore, this review demonstrates the urgent need for multicenter registries or studies to be able to compare the outcome of different surgical techniques for various aortic arch pathologies.

Keywords: Frozen Elephant Trunk (FET); aortic arch zone; aortic anastomosis; debranching; proximalization

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Brickwedel et al. Debranching in FET procedures: a literature review

Introduction

The introduction and development of the Frozen Elephant Trunk (FET) technique using a specialized hybrid vascular prosthesis by Karck *et al.*, revolutionized open surgical treatment combined with endovascular therapy for pathologies of the aortic arch and the proximal descending aorta in the early 2000's (1). The FET is a further development of the Elephant Trunk (ET) technique introduced by Borst *et al.* in the 1980's (2). This hybrid stent-graft prosthesis in FET procedures consists of two segments: a Dacron tube graft with or without side branches for the arch vessels, and an endovascular stent graft, which allows for the combined treatment of the ascending aorta, the aortic arch and endovascular therapy of the descending aorta.

Following the 2019 expert consensus document of the EACTS and ESVC, the FET technique is indicated for the following pathologies: acute type A aortic dissection (ATAAD) with a primary entry tear in the distal aortic arch or proximal descending aorta to prevent mid-term aneurysmal formation in the downstream aorta, complicated acute type B aortic dissection when endovascular interventions are contraindicated, and patients with concomitant distal thoracic and thoracoabdominal aortic disease (3).

Over the past two decades, there has been growing experience and improved clinical outcomes using the FET technique for the treatment of the above-mentioned pathologies (4). Despite these developments and improved outcomes, there is still a mortality reaching 21% in acute aortic dissections (5) and 17% in arteriosclerotic degenerative aneurysms (6). This data from the THORAFLEX French National and International E-vita Open registries (5,7) highlights the need for an ongoing surgical adaptation and simplification of the FET technique to improve early and long-term outcome (8).

Conventionally, the distal aortic anastomosis in FET procedures is performed in arch zone 3, distal to the origin of the left subclavian artery (LSA) to surgically exclude the arch pathology. This distal arch anastomosis in zone 3 and the one to the LSA are known to be technically demanding and time consuming for anatomical reasons (9). Thus, various modifications of this technique, with the goal of simplifying complex aortic arch surgery, have been reported to decrease the operative invasiveness, increase safety, and reduce circulatory arrest times (8,10,11). Many centers started implementing different debranching techniques with transposition of the supra-aortic vessels to create

an adequate landing zone for subsequent endovascular treatment, or for proximalization of the distal anastomosis from zone 3 to zone 2 or 1 using an ET or FET hybrid stent-graft prosthesis.

This review article describes different strategies and debranching techniques to facilitate total arch reconstruction and gives an overview of the outcomes and the potential clinical advantages of the different debranching techniques. We present this article in accordance with the Narrative Review reporting checklist (available at https:// cdt.amegroups.com/article/view/10.21037/cdt-22-502/rc).

Methods

Surgical techniques applied

Conventional FET technique: distal anastomosis in aortic arch zone 3

Using the conventional FET technique, the distal anastomosis is performed in aortic arch zone 3 and the supraaortic vessels are re-implanted as an island (island technique) using the E-vita open prosthesis (JOTEC GmbH, Hechingen, Germany) or, since the introduction of a branched hybrid graft, separately anastomosed to the supraaortic vessels (branched technique) using the Thoraflex[™] Hybrid Plexus prosthesis (Terumo Aortic, Vascutek Ltd., Inchinnan, UK). Initial results using the novel Thoraflex[™] hybrid four-branched arch graft were presented by the Hannover group in 2013 (12). Cerebral protection is usually performed using moderate hypothermic circulatory arrest (HCA) between 24 and 26 °C together with uni- or bilateral selective antegrade cerebral perfusion (SACP). Commonly, right subclavian artery (RSA) or direct aortic cannulation is performed (13). The cannulation of the RSA has the advantage that proximal clamping of the brachiocephalic trunk allows right-sided unilateral SACP. For bilateral SACP an additional cerebral perfusion catheter can easily be inserted into the left common carotid artery (LCCA) after transection of the aorta. In case of direct cannulation of the ascending aorta or the aortic arch, two catheters are directly inserted into the brachiocephalic trunk and LCCA for bilateral SACP. The aortic arch is resected in aortic arch zone 3, distally from the LSA origin and the stent-graft of the hybrid prosthesis is inserted into the descending aorta. The distal graft anastomosis is performed at the level of the proximal descending aortic. The reimplantation of the supra-aortic vessels to the hybrid graft is performed using the classical island or the branched technique (all three supraaortic vessels are anastomosed

to the selected branches of the hybrid prosthesis). Finally, ascending replacement is completed by the proximal anastomosis to the ascending aorta or to an aortic root graft, depending on the proximal aortic procedure.

Early debranching techniques

Spielvogel *et al.* presented results of aortic arch replacement using a trifurcated graft for debranching with HCA and SACP (11,14). Their technique commenced with an arterial cannulation of the RSA and a cooling to 15 °C. During deep HCA the arch vessels are transected and serially reimplanted into the trifurcated graft starting at the LSA, followed by the LCCA and brachiocephalic trunk. SACP is resumed through the trifurcated graft with the axillary perfusion providing perfusion to the head, spinal cord and upper extremities. The distal arch repair is performed proximal to the LSA in zone 2 using the ET technique for arch repair, followed by the proximal anastomosis. Finally, the trifurcated graft is re-implanted into the ascending graft and rewarming is commenced.

Galvin et al. (15) reported a similar technique to that described by Spielvogel et al. (11,14), called the "branchfirst" aortic arch reconstruction and debranching technique using a modified trifurcation arch graft with a side-arm perfusion port (TAPP graft, Vascutek Ltd., Inchinnan, UK), followed by a FET procedure or a secondstage endovascular intervention, if required. During cardiopulmonary bypass (CPB) the brachiocephalic trunk is clamped proximally and distally, and divided. The distal stump is anastomosed to the TAPP graft. The side-arm of the TAPP graft is connected to a separate cerebral head circuit for antegrade cerebral perfusion and the proximal brachiocephalic trunk stump is ligated while the right hemispheric cerebral perfusion is maintained through the LCCA and LCA. Thereafter, the LCCA and the LCA are anastomosed to the TAPP graft and all three arch branches are continuously perfused via the "ante flow" side arm of the graft. During moderate HCA, an open distal arch anastomosis is performed using an Anteflow graft (Vascutek Ltd.) or a FET hybrid stent graft (JOTEC E-vita or Thoraflex Hybrid) is introduced and deployed into the proximal descending aorta. Antegrade lower body perfusion is initiated by direct cannulation of the Dacron portion of the E-vita or using the perfusion side arm of the Thoraflex prosthesis. After the proximal root anastomosis is completed, the perfused TAPP graft is connected to the ascending graft. The remaining three side-arms of the Thoraflex graft are ligated and not used.

LSA debranching by aortoaxillary bypass

Tsagakis *et al.* previously introduced the proximalization of the distal aortic anastomosis to arch zone 2 using the Jotec E-vita open hybrid prosthesis and separating the LSA revascularization from open arch repair (16). Depending on the anatomy, they either transected and closed the LSA orifice and reimplanted the LSA into the aortic graft using an end-to-end anastomosis to an 8–12 mm vascular graft, or they performed an extra-anatomical bypass between the aortic graft and the left axillary artery in the left deltopectoral groove, introducing an 8-mm graft through the second intercostal space.

Using their recent technique, both axillary arteries are exposed for a T-anastomosis with an 8-mm graft prior to the sternotomy. The right axillary graft is connected to the main pump Y-line for CPB. The free end of the left axillary graft is ligated. After sternotomy and initiation of CPB, the left axillary graft is retrieved via the first intercostal space into the mediastinum and connected to a second arterial Y-line. After cardioplegic arrest, the brachiocephalic trunk is clamped initiating SACP. The aortic arch is resected in zone 2 and the LCCA is cannulated for bilateral SACP. Ligation of the origin of the LSA initiates the selective LSA perfusion via the left axillary graft. Completion of arch repair in zone 2 and proximal aortic repair are followed by end-to-site implantation of the left axillary graft in the proximal graft on the beating heart.

Debranching FET techniques using stent-bridging devices

Hybrid aortic techniques combining conventional aortic replacement with endovascular techniques are evolving and may enhance aortic arch repair techniques and improved patient safety.

Pichlmaier *et al.* (17) reported initial results of a novel stent-bridging technique for the anastomoses to the supraaortic vessels combining a Thoraflex Hybrid prosthesis with a self-expanding Viabahn covered stent (W.L. Gore & Assoc., Flagstaff, AZ, USA). The covered stent is introduced into the LCCA and LCA under direct vision after placing 2–4 aligning single sutures to bridge the anastomosis. The authors report an optimal alignment of the branches and target vessels resulting in fewer bleeding complications.

Roselli *et al.* (18) reported a modified FET procedure for patients with ATAAD combining hemiarch replacement with endovascular techniques as no commercial hybrid stent graft devices were available in the United States for a classical FET repair. The latest modification of their hybrid technique includes direct placement of branched stent grafts into the true lumen of the descending aorta covering the LSA. An approximately 8-mm hole is burned into the stent graft and a 2.5-cm long Viabahn branch vessel graft is deployed into the LSA. The proximal end of the aortic stent is then secured to the aortic wall using a running suture.

Simplified FET technique in arch zone 2 with an extraanatomic bypass to the distal LSA

In 2019, our group (9) reported a new vascular approach to the LSA-firstly, for arterial cannulation, and secondly, for debranching to perform the distal anastomosis in arch zone 2, what we call the "simplified FET technique". Here, instead of the RSA, the LSA is exposed via a leftsided supraclavicular approach. Arterial cannulation is achieved via an 8-mm Dacron graft sutured to the LSA in a T-graft fashion (LSA T-graft) for full body perfusion and blood supply to the left arm and left vertebral artery. The patient is cooled below 26 °C. During cooling, the mediastinum and the supraaortic vessel are prepared. During moderate HCA, two catheters are directly inserted into the innominate and LCCA for bilateral SACP. The aortic arch is transected between the LCCA artery and the LSA and the origin of the LSA is ligated. The compacted stent section of the ThoraflexTM Hybrid prosthesis is inserted into the distal arch and deployed in the descending aorta with over-stenting the origin of the LSA. The distal graft anastomosis is performed in arch zone 2 using the sewing collar of the Hybrid prosthesis. After completion of the distal anastomosis, the perfusion side branch of the prosthesis is cannulated and CPB is restarted to provide early antegrade lower body perfusion. During arch repair, limited flow is allowed to the LSA maintaining perfusion of the left vertebral artery and thereby establishing spinal cord protection. Subsequently, the 2nd and 1st branch of the Thoraflex[™] prosthesis are anastomosed to the supraaortic vessels and the proximal anastomosis is completed. During reperfusion and rewarming on the beating heart, the LSA Dacron-graft is directly pulled downwards below the left sternoclavicular joint into the upper intrathoracic aperture and anastomosed to the 3rd branch of the ThoraflexTM prosthesis in an end-to-end fashion.

"Zone 0 arch repair" strategy for type A acute dissection

Yamamoto *et al.* (19) recently described their zone 0 arch repair FET technique for acute type A aortic dissection in which the LSA is initially cannulated with a 9-mm vascular graft to establish CPB. If the brachiocephalic trunk is additionally dissected, the RSA is cannulated in the same way. After aortic cross-clamp and cardioplegic infusion, proximal aortic repair is performed during systemic cooling below 25 °C. During circulatory arrest, the origin of the LSA is ligated, LSA perfusion is resumed via the 9-mm graft, and SACP is subsequently performed to the LCCA

and the brachiocephalic trunk. The proximal ends of the LCCA and the brachiocephalic trunk are also ligated, whilst the ascending aorta is resected in zone 0 proximal to the brachiocephalic trunk. After preparing the distal anastomosis, the FET graft (J Graft FROZENIX, Japan Lifeline Co. Ltd., Tokyo, Japan) is deployed from the trimmed proximal aortic end in arch zone 0 toward the distal aortic arch. Proximally, the FET graft is anastomosed to a 4-branched arch graft. Distal perfusion is resumed using the perfusion branch of the arch graft and during rewarming the proximal anastomosis is performed. During cardiac reperfusion the third and second branches are anastomosed to the LCCA and the brachiocephalic trunk, respectively. Finally, the first branch of the arch prosthesis is anastomosed to the 9 mm graft of the LSA drawn into the mediastinum through the left thoracic cavity.

Literature search

A review of the literature was carried out by three independent reviewers (CD, TD and JB) following the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) guidelines. Each reviewer screened the titles and abstracts of the articles for eligibility and discussed any conflicts on study selection to reach consensus. An extensive electronic search of the PubMed database was undertaken in two separate searches with different search term algorithms: (I) ("frozen elephant trunk"[Title/Abstract]) AND ("zone" [All Fields]); (II) ((FET [Title/Abstract]) OR (Frozen Elephant Trunk[Title/Abstract])) AND (Mortality[Title/Abstract]) AND (Stroke[Title/Abstract]) AND ((Renal[Title/Abstract]) OR (Kidney[Title/Abstract])) AND ((Spinal[Title/Abstract]) OR (Paraplegia[Title/ Abstract])). Google Scholar was also searched applying similar search terms, and the first 150 results were screened to complement the library database search. The following filters were applied: Humans, English, German, period: 2000/1/1-2022/3/1. Additionally, a manual search of the reference lists of all included studies/reviews was done to identify all those studies that potentially met our inclusion criteria, as well as any studies missed by the database search.

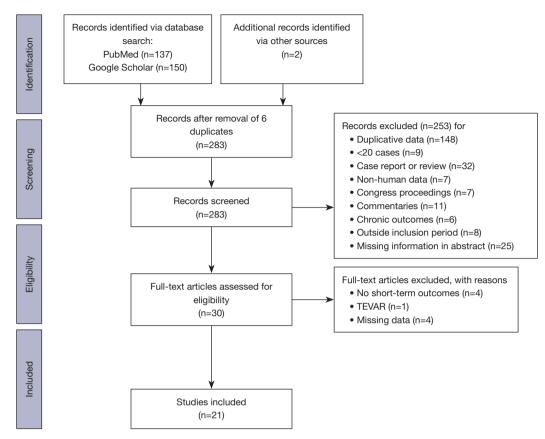


Figure 1 PRISMA 2009 flow diagram.

The process of article selection is depicted in *Figure 1*.

Eligibility criteria

Full text and review articles were included if they were published between January 2000–March 2022, written in English or German, and involved human participants. Case reports, commentaries, congress proceedings, and pediatric studies were excluded.

In the first PubMed search, studies comparing the shortterm results of debranching with proximalization of the distal anastomosis to zone 2, 1 or 0 with the results of the conventional zone 3 FET technique for ATAAD, chronic aortic dissection (CAD), and degenerative aneurysm (DA), were included in this review (*Tables 1,2*). For the second PubMed search, outcomes of FET studies were summarized in two separate tables (*Tables 3,4*) for the purpose of reference, and was based on the site of the distal anastomosis used for specific analysis [i.e., zone 2 and proximal combined (proximal reference group), and conventional FET technique in zone 3 (conventional reference group)]. Data on early mortality, stroke, spinal cord injury, kidney failure, bowel/hepatic ischemia and recurrent nerve palsy were extracted. Retrospective and prospective studies reporting at least 20 cases were included, and reviews were excluded. If a specific research group published more than one study with the same case load, only one of these studies was included. Studies were excluded if the publication was not openly accessible and the abstract did not include information on the site of the distal anastomosis.

Data extraction and statistical analysis

All data were extracted by three independent reviewers (CD, TD and JB). Results of selected studies were systematically reported using key clinical outcome parameters proposed by the consent statement from the International Aortic Arch Surgery Study Group (37). These outcomes were reduced to the following: mortality (30-day and in-hospital), global or focal neurological deficits, spinal cord injury (SCI), perioperative kidney injury, bowel ischemia, and recurrent nerve palsy. A study conclusion was added to the data of each reported comparative study (see *Table 2*).

| Author (reference) | Publication year | Study type | Arch zones & numbers | Indications & numbers | Patient numbers | Patient age*2 (years) | Male gender (%) |
|--------------------------|---------------------|-------------------------------|---|------------------------------|-----------------|-----------------------------------|-----------------|
| Detter (9) | 2019 | Retrospective, comparative | Zone 2 vs. 3; 30 vs. 62 | AAD, CAD, DA; 25, 32, 35 | 92 | 64±13 <i>v</i> s. 64±11 | 58.7 |
| Tsagakis (10) | 2021 | Retrospective, comparative | Zone 1+2* ¹ vs. Zone 3; 251 vs. 106 | AAD, CAD, DA; 192, 78, 87 | 357 | 60±11 <i>v</i> s. 60±12 | nd |
| Gottardi (20) | 2020 | Retrospective, comparative | Zone 1 <i>vs.</i> 3; 23 <i>vs.</i> 17 | AAD, CAD, DA; 30, 1, 9 | 40 | 59±13 vs. 60±10 | 65 |
| Panfilov (21) | 2021 | Retrospective, comparative | Zone 2 <i>vs.</i> 3; 17 <i>vs.</i> 27 | AAD, CAD; 29, 15 | 44 | 57 vs. 56.5 | 65 |
| Akbulut (22) | 2020 | Retrospective, comparative | Zone 0 <i>vs.</i> 3; 58 <i>vs.</i> 81 | AAD, CAD, DA; 71, 45, 23 | 139 | 54±9 vs. 55±12 | 79 |
| Leone* ³ (23) | 2019 | Retrospective, comparative | Zone 2 vs. 3; 69 vs. 213 | AAD, CAD, DA; 45, 164, 73 | 282 | 61 [18–81] <i>v</i> s. 63 [23–83] | 82.6 |
| Ma (24) | 2018 | Retrospective, comparative | Debranching vs. Zone 3; 36 vs. 132 | AAD; 168 | 168 | 50±9 vs. 46±8 | 81.5 |
| Together | | | | | 1,122 | | |

Table 1 Summary of study characteristics of comparative studies

*¹, together with other changes; *², either mean ± standard deviation or median and interquartile range; *³, incongruent data in the original paper. AAD, acute (including type A, B) aortic dissection; CAD, chronic aortic dissection; DA, degenerative aneurysm; nd, no data.

| Table 2 Summary of clinical outcomes of comparative studies, comparing aortic arch zone 2 (or proximal) vs. 3 including the conclusion of the |
|---|
| study |

| First author (reference) | Mortality (%) | | Neurology | Spinal cord | Kidney injury | Bowel ischemia | Recurrent nerve | | |
|-----------------------------|----------------------------------|----------------------------------|---------------------------------|----------------------------------|-----------------------------------|---------------------------------|----------------------------------|--|--|
| | 30-day | In-hospital | global/focal (%) | injury (%) | perioperative*2 (%) | (%) | palsy (%) | Study conclusion | |
| Detter (9) | 3.3 vs. 17.7 (P=0.75) | nd | 0 <i>vs.</i> 17.7 (P=0.046) | 0 vs. 1.6 (nd) | 13.3 <i>vs.</i> 17.7 (P=0.78) | nd | 3.3 <i>vs.</i> 22.6 (P=0.020) | Proximalization leads to improved outcome | |
| Tsagakis ^{*1} (10) | 11 <i>vs.</i> 15 (P=0.27) | 11 <i>vs.</i> 17 (P=0.17) | 4 vs. 8 (P=0.18) | 3 <i>vs.</i> 6 (P=0.29) | 1 <i>vs.</i> 2 (P=0.68) | 2 vs. 7 (P=0.044) | nd | Debranching and proximalization improves results | |
| Gottardi (20) | 13 <i>vs.</i> 5.9 (P=0.61) | nd | 13 <i>vs.</i> 5.9 (P=0.61) | 4.3 <i>vs</i> . 11.8 (P=0.57) | nd | 4.4 vs. 5.8 (nd) | 0 <i>vs</i> . 0 | Technically easier | |
| Panfilov (21) | 0 <i>vs.</i> 14.8 (P=0.167) | nd | 5.9 <i>vs.</i> 3.7 (P=0.533) | 5.9 <i>vs.</i> 0 (P=0.533) | 29.4 <i>vs.</i> 25.9 (P=0.833) | nd | nd | No short term differences | |
| Akbulut (22) | nd | 13.8 <i>vs.</i> 14.8 (P=0.53) | 6.9 <i>vs.</i> 3.7 (P=0.32) | 3.4 <i>vs.</i> 3.7 (P=0.334) | 1.7 <i>vs.</i> 1.2 (P=0.66) | nd | nd | Personalized treatment should be applied | |
| Leone (23) | nd | 20 <i>vs.</i> 16 (P=0.518) | 5.8 <i>vs.</i> 9.9 (P=0.431) | 1.4 <i>vs.</i> 7.5 (nd) | 14.5 <i>vs.</i> 20.7 (P=0.343) | 2.9 <i>vs.</i> 7.5 (P=0.281) | 2.8 <i>vs.</i> 5.2 (P=0.526) | Zone 2 smaller and more acute cases | |
| Ma (24) | 5.6 <i>vs.</i> 14.4 (P=0.254) | nd | 5.6 <i>vs.</i> 5.3 (P>0.999) | nd | 8.3 <i>vs.</i> 15.5 (P=0.414) | nd | nd | Debranching is promising but more expensive | |

*¹, together with other changes; *², either temporary renal replacement therapy or permanent. nd, no data.

Due to the strong heterogeneity in designs of the selected studies, a meta-analysis was not performed. The data of included studies was synthesized to report the effect of proximalization on the outcome using alternative synthesis methods following "The Synthesis Without Metaanalysis (SWiM) guidelines. All publications reporting clinical outcome parameters were documented as counts and percentages.

| Table 3 Frozen Elephant Trunk indications and outcome of the non-comparative reference group in arch zo | zone 2 and 1 | proximal |
|---|--------------|----------|
|---|--------------|----------|

| Author, year published, arch | Indications & numbers | Mortality (%) | | Neurology/ | Spinal cord | Kidney injury | Bowel/hepatic | Recurrent nerve |
|--------------------------------|--------------------------|---------------|------------|------------|-------------|---------------------|---------------|-----------------|
| zone (Ref.) | | 30-day | In-hospita | stroke (%) | injury (%) | perioperative*1 (%) | ischemia (%) | palsy (%) |
| Roselli in 2018 zone 2 (18) | AAD 72 | nd | 3 (4.2%) | 3 (4.2%) | 1 (1.4%) | 2 (2.8%) | nd | nd |
| Yamamoto in 2019 zone 0 (19) | AAD 108 | 3 (2.8%) | 7 (6.5%) | 4 (3.7%) | 0 (0.0%) | 6 (5.6%) | 4 (3.7%) | 1 (0.9%) |
| Zhong in 2018 zone 2 (25) | CAD 35 | nd | 2 (5.7%) | 0 (0.0%) | 0 (0.0%) | 2 (5.7%) | nd | nd |
| Liu in 2020 zone 2 (26) | AAD 268 | 15 (5.6% |) nd | 9 (3.4%) | 13 (4.9%) | 30 (11.2%) | 19 (7.1%) | nd |
| Zou in 2021 zone 2 (27) | AAD 109 | nd | 10 (9.2%) | 7 (6.4%) | 5 (4.6%) | 13 (11.9%) | nd | nd |
| | | | | | | | | |
| Luo in 2021 zone 2 (28) | CAD 79 | nd | 4 (5.1%) | 2 (2.5%) | 3 (3.8%) | 4 (5.1%) | nd | 0 (0.0%) |
| Xie in 2021 zone 2/zone 0 (29) | AAD 511 | 23 (4.5% |) nd | 14 (2.7%) | 12 (2.3%) | 33 (6.5%) | nd | nd |
| Range | | 2.8- | -9.2% | 0.0-6.4% | 0.0–4.9% | 2.8–11.9% | 3.7–7.1% | 0.0-0.9% |
| Total | 1,182 | 64 (5 | 5.41%) | 39 (3.30%) | 34 (2.88%) | 90 (7.61%) | 23 (1.95%) | 1 (0.08%) |

*¹, either temporary renal replacement therapy or permanent. AAD, acute (including type A, B) aortic dissection; CAD, chronic aortic dissection; nd, no data.

Results

Literature search and study characteristics

The PRISMA flow diagram reporting study inclusion is shown in *Figure 1*. A total of 287 citations were identified in two databases. A manual search of the reference lists found 2 additional articles which met our inclusion criteria. After 6 duplicates were removed, and 283 screened by title and abstract, 30 full text articles were assessed for eligibility. Finally, a total of 21 articles with 3,849 patients were selected for inclusion.

All 21 publications were of retrospective nature. The study characteristics of the 7 comparative studies are summarized in *Table 1*, and the results are presented in *Table 2*. The 7 studies as reference for zone 2 and proximal are depicted in *Table 3*, and the 7 referencing studies for conventional zone 3 are shown in *Table 4*.

In the comparative studies, a total of 560 patients were treated for ATAAD, 335 CAD, and 227 DA. Reported study size varied from 40 to 357 patients. The FET was implanted in arch zone 2 or further proximal in 484 patients and in arch zone 3 in 638 patients. The majority of the 7 comparative studies reported clinical outcomes in the proximal versus the zone 3 approach for all aortic pathologies (5 out of 7), whereas Ma *et al.* (24) selectively reported about ATAAD patients. Paniflov *et al.* (21) exclusively included ATAAD and CAD (*Table 1*).

In the non-comparative reference studies for isolated

zone 2 and proximal FET replacement, a total of 1,068 patients were treated for ATAAD and 114 for CAD (*Table 3*), whilst 1,340 patients were treated for ATAAD, 99 for CAD, and 97 for DA in the non-comparative reference studies reporting outcomes for conventional arch zone 3 surgery (*Table 4*).

Clinical outcomes

Mortality

Only one of the 7 comparative studies reported both 30-day and in-hospital mortality (10), all other studies reported either one, or the other. Overall mortality rate for the debranching with proximalization and the conventional FETs ranged from 0–20% and from 5.9–17.7%, respectively (*Table 2*). All, but two (20,23) of the comparative studies showed a numeric, but not statistically significant improved outcome.

In the 7 non-comparative arch zone 2 and proximal studies, one reported both 30-day and in-hospital mortality (19), four in-hospital (18,25,27,28) and only two 30-day mortality (26,29). Here, the overall mortality rate ranged from 2.8–9.2% with an average rate of 5.4% (*Table 3*). Of the 7 non-comparative conventional arch zone 3 studies, only one reported 30-day mortality (36), and six in-hospital mortality (30-35), with an overall mortality rate range of 5.9-16.1% and a mean of 8.3% (*Table 4*).

Table 4 Frozen elephant trunk indications and outcome of the non-comparative reference group in conventional arch zone 3

| Author, year | Indications & | Mortality (%) | | Neurology/ | Spinal cord | Kidney injury | Bowel/hepatic | Recurrent |
|--------------------------------|-----------------------------|---------------|-------------|------------|-------------|------------------------|---------------|-----------------|
| published, arch zone (Ref.) | numbers | 30-day | In-hospital | stroke (%) | injury (%) | perioperative*1 (%) | ischemia (%) | nerve palsy (%) |
| Di Bartolomeo in 2009 (30) | AAD, CAD, DA; 2, 25, 7 | nd | 2 (5.9%) | 0 (0.0%) | 3 (8.8%) | 5 (14.7%) | nd | nd |
| Dias in 2015 (31) | AAD, CAD, DA; 2, 15, 4 | nd | 3 (14.2%) | 1 (4.7%) | 2 (9.5%) | 1 (4.7%) | nd | nd |
| Martens in 2016 (32) | AAD, CAD, DA; 88, 44, 67 | nd | 32 (16.1%) | 20 (10.1%) | 9 (4.5%) | 68 (34.2%) | nd | 27 (14.0%) |
| Ma in 2016 (33) | AAD; 104 | nd | 9 (8.6%) | 2 (1.9%) | 3 (2.9%) | 4 (3.8%) | nd | 1 (1.0%) |
| Soknes in 2021 (34) | CAD, DA; 15, 19 | nd | 3 (8.8%) | 4 (11.7%) | 3 (8.8%) | 4 (11.7%) | nd | nd |
| Chang in 2022 (35) | AAD; 929 | nd | 57 (6.1%) | 57 (6.1%) | 49 (5.3%) | 111 (11.9%) | 12 (1.3%) | nd |
| Shen in 2022 (36) | AAD; 215 | 21 (9.8%) | nd | 9 (4.2%) | 1 (0.5%) | 21 (9.8%) | nd | nd |
| Range | | 5.9- | 16.1% | 0.0–11.7% | 0.5–9.5% | 3.8-34.2% | nd | 1.0–14.0% |
| Total | 1,536 | 127 | (8.3%) | 93 (6.1%) | 70 (4.6%) | 214 (13.9%) | nd | 28 (9.24%) |

*¹, either temporary renal replacement therapy or permanent. AAD, acute (including type A, B) aortic dissection; CAD, chronic aortic dissection; DA, degenerative aneurysm; nd, no data.

Global or focal neurological deficit

All included publications reported permanent global or focal neurological deficit. The mean rate of permanent neurological deficit (PND) was 3.3% for the proximal reference group (Table 3). The conventional zone 3 reference group showed an overall rate of PND of 6.1% (Table 4). As presented in Table 2, the comparative studies reported numerically less new PND in patients undergoing debranching with proximalization when compared to patients undergoing conventional FET (0-13% vs. 3.7-17.7%). Three studies showed an impaired neurological outcome after debranching (20-22), one study did not show any differences (24), and the remaining three studies (9,10,23) demonstrated an improved neurological outcome by number, which was statistically significant in one (9) of the comparative study groups [improvement from 17.7% (conventional) to 0% (debranching and zone 2), P=0.046].

Spinal cord injury

The prevalence of SCI ranged from 0–11.8% across all studies. Reported SCI for the proximal reference studies showed a range from 0.0–4.9%, with a mean of 2.8% (*Table 3*), whereas the conventional reference studies showed an overall prevalence of 4.6% ranging from 0.5–9.5% (*Table 4*). One of the comparative studies did not report about SCI (24). In 5 of the remaining 6 comparative studies,

proximalization showed numerically improved results, ranging between 0 to 5.9% for the debranching cohort, and 0 to 11.8% for the conventional cohort, but the comparison did not reach statistical significance (9,10,20,22,23). One study reported an impaired outcome for the debranching technique (21).

Perioperative kidney injury

All, but one study reported perioperative kidney injury, but didn't clarify whether it was pre-existing, or a new onset after surgery (20). Only two of the comparative studies reported permanent loss of kidney function (10,22). All other studies did not provide a clear definition of the kidney failure outcome parameter. There was no statistically significant difference concerning kidney injury between the conventional and the debranching group of the comparative studies (*Table 2*). The mean rate of postoperative kidney failure in the proximal reference group showed was 7.6%, whereas the conventional reference group documented a mean kidney failure rate of 13.9% (*Tables 3,4*). Additionally, there was a lack in reporting the stage of kidney failure in both reference groups.

Bowel & hepatic ischemia

Only 3 of the 7 comparative studies reported bowel ischemia (*Table 2*). Tsagakis *et al.* (2% *vs.* 7%, (P=0.044), Gottardi *et al.* (4.4% *vs.* 5.8%, P value was not calculated),

and Leone *et al.* (2.9% *vs.* 7.5%, P=0.281) reported a numerically improved visceral outcome after debranching with proximalization, but without any statistical significance (10,20,23). The incidence of bowel ischemia in the proximal reference group was only documented by two authors (19,26) and varied from 3.7–7.1% (*Table 3*). Only 1 of the 7 studies of the conventional reference group (*Table 4*) documented visceral complications with a rate of 1.3% (35).

Recurrent nerve palsy

Recurrent nerve palsy was reported in 3 of the 7 comparative studies with a range between 0 and 22.6% (9,20,23). Two of these studies reported a numerically improved outcome in patients undergoing the debranching with proximalization versus the conventional approach (0% to 3.3%. vs. 0% to 22.6%) (9,23). Only one of the comparative studies reached statistical significance (3.3% vs. 22.6%, P=0.020) (9).

In the proximal reference group, only 2 studies reported recurrent nerve palsy as outcome parameters (19,28). Yamamoto *et al.* reported a rate of 0.9% (19), and Luo *et al.* a rate of 0% (28). Similarly, in the conventional reference group only 2 studies reported the outcome for recurrent nerve palsy: Martens *et al.* with 14.0% and Ma *et al.* with 1.0% (32,33).

Discussion

Overall, this review demonstrates marked heterogeneity of aortic pathologies, patient characteristics, surgical techniques, reported outcomes from various countries, and the experience of the surgeon and centers (explained by the variance and dates of the reported cases, see Tables 1,3,4) in the included studies. A meta-analysis was not performed due to the high heterogeneity across the selected comparative and non-comparative studies. Instead, this review synthesized the data of 7 comparative studies using alternative synthesis methods in order to determine the possible advantage of different debranching techniques with proximalization of the distal anastomosis as compared to the conventional FET technique with the distal anastomosis in arch zone 3. Due to low patient numbers in the 7 selected publications with comparative studies, two additional reference groups (i.e., proximal and conventional) were included for the purposes of a broader comparison of FET outcomes (Tables 3,4).

Comparison of the outcomes was challenging due to the heterogeneity in study design, study cohorts, and outcome parameter definitions. This, together with the lack of statistical significance, despite most comparative studies reporting an improved numeric outcome, hampers the ability to clearly recommend debranching techniques with proximalization as the preferred surgical approach in FET procedures.

Other reviews also evaluated the safety and efficacy of the FET technique focusing on the proximalization of the distal anastomosis (38,39). Only Rezaei et al. made a statistical statement about the effect of the proximalization on postoperative cerebrovascular events, paraplegia, renal failure, and 30-day mortality, with a preference of proximalization as the safer technique, even in reoperations (38,40). However, it must be critically noted that all included publications compared outcomes of early FET procedures performed by less experienced surgeons (usually zone 3) with recent procedures done by more experienced surgeons (usually zone 2 or further proximal). This, together with an incongruent allocation and comparison of the 3 main pathologies ATAAD, CAD, and DA, lead to non-comparable outcomes, especially since every aortic arch pathology is associated with its own characteristic risk for complications. For example, involvement of the aortic valve as well as the diameters of the true and false lumen of the ascending aorta following ATAAD causes different neuropathologies (41,42). In DA, age and aortic arch atheroma may lead to an impaired outcome (43,44).

The above findings and the lack of using defined endpoints, as suggested by the International Aortic Arch Surgery Study Group (37), was ultimately responsible for the inability to conduct a meta-analysis and make any conclusive deductions. There is clearly an urgent need in cardiac surgery to report results for complex procedures involving many other organ systems, such as FET procedures, using established, pre-defined endpoints (37) to ensure comparability across different centers, different procedures and different pathologies (5,7,45). In other fields, pre-defined endpoints have successfully been implemented into clinical research [e.g., the updated endpoint definitions for aortic valve clinical research by the Valve Academic Research Consortium 3 (VARC-3)] (46,47).

In addition, it must be taken into consideration that some of the included studies reported surgical modifications along with proximalization of the distal anastomosis from zone 3 towards zone 2, or even further proximal which could also have contributed to improved outcomes such as reduced visceral ischemia or kidney injury. The "Essen group", for example, added a selective distal aortic perfusion (10), the

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"Istanbul group" changed the implantation technique of the supraaortic vessels (22), the "Hannover group" added the socalled beating heart technique to reduce cardiac ischemia time during aortic arch replacement (6), the "Bologna group" used hybrid vascular grafts to simplify the anastomosis to the LSA in complex anatomic conditions (23), and our group changed the technique of arterial cannulation and simplified the debranching technique to the LSA (9).

Over the past two decades the FET technique has evolved as one of the preferred surgical techniques which permits the treatment of extensive aortic arch pathologies including the proximal descending aorta (3,6-24,37,48-51). Further advancements of this technique were already reported in 2012 when the first cases of debranching techniques with proximalization were described (49). Over the past few years such proximalization techniques gained popularity when compared to the conventional approach, especially for the treatment of ATAAD (9,10,20-24). One key for successful aortic arch surgery seems to be the management of the LSA, to facilitate the proximalization and or debranching, and therefore simplify the distal anastomosis of the FET procedure (50,51).

Conclusions

Overall, most studies reported improved numeric outcome of different debranching techniques with proximalization of the distal anastomosis as compared to FET using a conventional zone 3 aortic anastomosis. Due to the low case load, statistical significance was rarely reached. Proximalization is described by several authors to be technically easier, but this "parameter" is difficult to measure objectively. Due to inconsistent reporting of outcome parameters and numbers not reaching statistical significance, debranching cannot be categorically recommended as the preferred surgical approach in FET procedures.

This review highlights the scarce use of existing guidelines for pathology and endpoint definitions in clinical research of open aortic arch surgery as proposed by the International Aortic Arch Surgery Study Group. Our findings demonstrate the need for these established guidelines to be implemented as a standard practice in all studies on aortic arch surgery to ensure consistency, comparability and hence, allow for investigation in a metaanalysis. Rylski *et al.* also highlighted the importance of using standards of reporting in open and endovascular aortic surgery (STORAGE guidelines), to ensure transparency in clinical research (45). Reporting of comparable outcome parameters should be consistent and appears of utmost importance to guide future surgical decision-making.

Furthermore, the consistent numerically lower complication rates in debranching studies that did not reach statistical significance in comparison to the conventional technique demand for studies with larger case load. Establishing registries with high case numbers for FET surgery is the key to provide the necessary data to assist surgeons in surgical planning and may be of particular interest for low-volume centers. In addition, evidence based on profound clinical judgement and the results from surgical experience, specifically in high volume centers, could also be used as a guide in inexperienced centers when planning FET procedures (6,9,11,23).

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