



# Evidence-based frozen elephant trunk practice: a narrative review

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**Background and Objective:** The frozen elephant trunk (FET) allows a single-stage repair of complex arch pathologies due to its stented and non-stented hybrid prosthesis (HP) features. FET inherently has its own related complications including distal stent graft-induced new entry (dSINE), failure of aortic remodelling, endoleak, reintervention, and kinking of the stent. The aim of this narrative review is to discuss the latest evidence regarding the postoperative clinical outcomes of the FET procedure. Another aim is to provide an overview of results achieved using different FET devices on the global arch prostheses market.

**Methods:** A comprehensive literature search was conducted using multiple electronic databases to identify and extract the relevant data and information.

**Key Content and Findings:** This review found that the literature reported a 5–12% mortality rate post-FET, with varying figures depending on the prosthesis type. Between 0–18.2% of patients developed dSINE, while 0.1–28% developed endoleak. Reintervention occurred in 0–28% of patients and the incidence of kinking has been quoted between 0–8% in the literature. Reporting aortic remodelling rates was challenging due to the lack of standardisation and various measurements reported; however, all studies included in this review reported relative increase in true lumen diameter, reduction in the false lumen diameter, and/or false lumen thrombosis.

**Conclusions:** In conclusion, FET can achieve a favourable postoperative profile in terms of survival, complications and aortic remodelling, and remains the gold-standard treatment for thoracic aortic pathologies implicating the arch and descending thoracic aorta.

**Keywords:** Frozen elephant trunk (FET); total arch replacement (TAR); type A aortic dissection (TAAD); hybrid prosthesis (HP)

Submitted Jul 15, 2023. Accepted for publication Oct 30, 2023. Published online Dec 04, 2023.

doi: 10.21037/cdt-23-300

View this article at: <https://dx.doi.org/10.21037/cdt-23-300>

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## Introduction

Over the past three decades, there have been significant advancements in the management of complex aortic pathologies involving the aortic arch and proximal descending thoracic aorta (DTA), including type A aortic dissection (TAAD) and arch aneurysms. Borst and colleagues pioneered the two-stage classic elephant trunk procedure which entailed replacing the aortic arch with a Dacron graft via a median sternotomy, followed by utilisation of the elephant trunk technique to facilitate the second stage of intervention, which involves retrograde stenting of the DTA (1-3). In 1996, the frozen elephant trunk (FET) technique was introduced, which revolutionized aortic arch repair.

FET employs an aortic hybrid prosthesis (HP) that allows for a single-stage total arch replacement (TAR) with antegrade DTA stenting in a hybrid fashion (4,5). This approach combines the benefits of the traditional elephant trunk procedure with current advanced stenting technology (6). However, as with any complex surgical procedure, FET is not devoid of complications. Distal stent graft-induced new entry (dSINE), inadequate deployment or kinking of the distal stent graft, neurological sequelae in the form of cerebrovascular accidents and spinal cord ischemia (SCI), and postoperative endoleak are some major intraoperative problems that must be addressed, as these may require secondary intervention and, hence, negating its single-stage advantage (7-9). Several FET HPs currently exist commercially with varying designs and features, which has translated to variability in the clinical outcomes achieved.

The rapid advancements in HP designs and surgical strategies for distal arch and proximal DTA pathologies necessitate a contemporary appraisal. The main scope of this narrative review is to collate and evaluate the latest evidence regarding the postoperative clinical outcomes of FET. Another aim is to provide an overview of results achieved using different FET HPs on the global arch prostheses market. We present this article in accordance with the Narrative Review reporting checklist (available at <https://cdt.amegroups.com/article/view/10.21037/cdt-23-300/rc>).

## Methods

A literature review was performed using major electronic databases including PubMed, Google Scholar, EMBASE and Scopus to search all scientific articles published through to April 2023. The search terms used included: “Frozen

elephant trunk”, “FET”, “Hybrid prosthesis”, “Stent-graft”, “Mortality”, “Survival”, “Distal stent-induced new entry”, “dSINE”, “Aortic remodelling”, “Endoleak”, “Reintervention”, “Kinking” and “Coagulopathy”. Additional sources were identified by reviewing reference lists of relevant publications. Publications with low reliability as well as non-English publications were excluded. Data were extracted based on their relevance to the topic instead of implementing a systematic approach to paper selection. A summary of our search strategy can be found in *Table 1*.

## Mortality and survival

Aortic dissection (AD) is a life-threatening surgical emergency calling for immediate surgical intervention. Despite this, FET has been associated with favourable survival (10-13). The causes of death after TAR with FET are multifaceted and include neurological injury, disease progression, end-organ damage due to malperfusion, and intraoperative haemorrhage. Thirty-day mortality ranges from 5% to 12% across the published literature (6,10-13) (*Table 2*).

A recent study by Panfilov *et al.* (16) evaluated the clinical outcomes of 44 patients who had type A or type B AD and were treated with FET using the E-vita HP. The authors reported a 9.1% 30-day mortality rate, with the causes put down to uncontrollable bleeding (n=2), abdominal aortic rupture (n=1), and intestinal malperfusion (n=1) (16). In a systematic review and meta-analysis, Moulakakis *et al.* (22) assessed the effectiveness of aortic arch surgeries across 46 studies that included 2,272 patients. Out of the 20 studies (n=1,316) that utilised the FET technique, the pooled estimate for the 30-day mortality was 9.5% (95% CI: 7.8–11.4%). In another recent meta-analysis by Preventza *et al.* of more than 3,000 FET procedures across 35 studies, the total pooled operative mortality was 8.8% (95% CI: 7.0–10.9%) (17). Other studies have shown similar trends in mortality post-FET [Hanif *et al.* (19): 7.7%; Tian *et al.* (21): 8.3%]. Upon exploring further meta-analyses, across 85 studies encompassing 10,960 patients, Mousavizadeh *et al.* found that the pooled estimate of in-hospital mortality (in 5,569 patients), 30-day mortality (in 6,614 patients), and 1-year mortality (in 1,006 patients) was 7% (95% CI: 5–9%;  $I^2=76\%$ ), 8% (95% CI: 6–10%;  $I^2=76\%$ ) and 9% (95% CI: 4–17%;  $I^2=90\%$ ), respectively (23). Lastly, a meta-analysis by Nakhaei *et al.* of 5,068 FET patients, reported a relatively lower 5% pooled estimate of in-hospital mortality

**Table 1** The search strategy summary

| Items                                | Specification   |
|--------------------------------------|---|
| Date of search                       | 19/03/2023 and 20/03/2023   |
| Databases and other sources searched | PubMed (main database searched), Google Scholar, EMBASE, Scopus   |
| Search terms used                    | “Frozen elephant trunk”, “FET”, “Hybrid prosthesis”, “Stent-graft”, “Mortality”, “Survival”, “Distal stent-induced new entry”, “dSINE”, “Aortic remodelling”, “Endoleak”, “Reintervention”, “Kinking” and “Coagulopathy”  |
| Timeframe                            | All published studies in the literature were considered with a focus on more recent original/observational studies (no time limit)  |
| Inclusion and exclusion criteria     | Inclusion: published original/observational papers and reviews in English that specifically investigated the frozen elephant technique for total arch replacement in aortic dissections and aneurysms<br><br>Exclusion: not relevant for the scope of the paper, or that included other techniques for total arch replacement in their main data analysis; non-English publications |
| Selection process                    | The search was conducted independently by F.K., R.C., T.A., M.J.; data selection is the intersection of the search of these four authors  |

**Table 2** Overall summary of the findings in ‘Mortality and survival’ section

| Study                         | Year | Study type                        | Prosthesis type                  | N of patients | Mortality, % |
|-------------------------------|------|-----------------------------------|----------------------------------|---------------|--------------|
| Tan <i>et al.</i> (14)        | 2022 | International analysis            | THP                              | 931           | 1.5          |
| Nakhaei <i>et al.</i> (15)    | 2022 | Systematic review & meta-analysis | THP + E-vita + frozenix + cronus | 5,068         | 5            |
| Panfilov <i>et al.</i> (16)   | 2021 | Observational                     | E-vita open                      | 44            | 9.1          |
| Preventza <i>et al.</i> (17)  | 2020 | Systematic review & meta-analysis | –                                | 3,154         | 8.8          |
| Chu <i>et al.</i> (18)        | 2019 | Observational                     | THP                              | 40            | 5            |
| Hanif <i>et al.</i> (19)      | 2018 | Systematic review & meta-analysis | THP + E-vita                     | 897           | 7.7          |
| Berger <i>et al.</i> (20)     | 2019 | Observational                     | THP                              | 55            | 11           |
|                               |      |                                   | E-vita                           | 33            | 12           |
| Shrestha <i>et al.</i> (13)   | 2017 | Observational                     | THP                              | 50            | 6            |
| Tian <i>et al.</i> (21)       | 2013 | Systematic review & meta-analysis | THP + E-vita                     | 1,675         | 8.3          |
| Moulakakis <i>et al.</i> (22) | 2013 | Systematic review & meta-analysis | –                                | 1,316         | 9.5          |
| Pacini <i>et al.</i> (11)     | 2011 | Observational                     | E-vita                           | 240           | 12           |

THP, Thoraflex Hybrid Plexus.

(95% CI: 4–7%,  $I^2=52\%$ ) (15).

Tan *et al.* recently analysed original data from 931 FET patients who received the Thoraflex Hybrid Plexus (THP) graft and were followed up for 84 months postoperatively. Their results showed 30-day mortality was 0.6% (n=6), while overall mortality was 1.5% (n=14) (14). It is important to note that only 3 deaths were attributed to the device itself, meanwhile, the remaining 11 were classed as being

procedure-related. This notion that FET is effective in the long term is supported by Yoshitake *et al.* in addition to the aforementioned Tan *et al.* (14), as this was found to be significantly better in the FET group than in the group of patients who did not undergo FET ( $P=0.008$ ) (24). Survival rates were  $95.0\% \pm 5.1\%$  and  $93.0\% \pm 7.0\%$  in the FET group at 3 and 5 years postoperatively, compared to  $85.3\% \pm 14.8\%$  and  $80.8\% \pm 19.2\%$  in the non-FET group (16,23,24).

The causes of death in this study were pulmonary-related (n=2), stroke (n=2), multiple organ failure (n=2), low output syndrome (n=3), hepatic failure (n=1), bleeding (n=1), and pancreatitis (n=1). *Table 2* summarises the findings in this section.

## dSINE

The development of dSINE following FET is well-established within the literature as a substantial complication of FET in the treatment of TAAO (25). The underlying pathology is an injury to the aortic intima caused by the stent-graft at its distal end, resulting in a new entry tear distally. As discussed by Dong *et al.*, the increased radial stress on the aortic wall by the FET graft can be limited by the graft's ability to self-expand (25). The stress in the aortic wall increases, when there is higher segment curvature, with the highest tension concentrated on the outer edge of the graft (25), and graft oversizing considerably, predicts a larger likelihood of dSINE tears forming (26,27). In addition, the design of the FET HP could also play an important role in regards to the distribution of radial force (20).

Vessel walls in chronic AD (CAD) tend to be more fragile than those in acute AD (AAD) (14,15). The changes in the aorta's morphology are possible consequences of increased calcifications within the wall with a thicker and less flexible membrane, which causes the aorta to become less elastic and subsequently impedes remodelling (28). Several studies have found that dSINE was more common in CAD than in AAD and that aortic fragility is a risk factor (26,28,29). The 'spring back force' is the force generated when the graft tries to straighten itself to its natural configuration, which acts upon the aortic wall, causing it to develop dSINE (30). On the contrary, Berger *et al.* found that AAD is a significant risk factor for distal aortic failure after the FET procedure compared to CAD, likely due to vulnerability of the dissection membrane in the acute phase which increases the likelihood of developing dSINE (31). Furutachi *et al.* noted that the Frozenix graft had a strong spring back force, whereas the THP design has been found to reduce the shear stress on the intima which can explain its more favourable results in other studies (30,32).

The incidence of dSINE differed when various devices were investigated across multiple studies. A retrospective multicentre 7-year Japanese study of 177 AAD and CAD patients reported an overall dSINE incidence of 14.1% (n=25), with a cumulative incidence of 7.1%, 12.4% and 21.4% after 12, 36 and 60 months, respectively.

Interestingly, the authors found no association between dSINE and mid-term survival (9). A Nakhaei *et al.* meta-analysis (15) of 5,068 patients found a 2% pooled estimate of dSINE (95% CI: 1–6%,  $I^2=78\%$ ), and there was no heterogeneity ( $I^2=0\%$ ) amongst European studies, including those utilising THP and E-Vita stent-grafts. However, the reported incidence across the literature was found to be up to 28%. For THP, the incidence of dSINE in the literature ranged from 0–16%, whereas it was 0–18.2% for E-vita and 0–15.8% for Frozenix. Compared to other devices, many studies reported a significantly low incidence of dSINE in patients with the THP prosthesis, one of which was Kreibich *et al.* (27). Out of 70 patients, 9 (12.9%) developed dSINE at 27 months with a median time frame of  $17.7 \pm 11.7$  months post-FET (27). In comparison, a multicentre study investigated the incidence of dSINE with THP and E-vita Open, and found a lower rate of dSINE favouring THP over E-vita [16% (n=55) vs. 18.2% (n=33)] but not reaching statistical significance ( $P=0.19$ ) (20).

Notably, none of the 50 patients experienced dSINE following the FET procedure in a trial conducted by Iino *et al.* (33) using the Frozenix graft combined with the Gelweave graft. Using the Frozenix graft independently, Hirano *et al.* (34) and Yoshitake *et al.* (24) found that dSINE occurred in 4% (n=13) and 0.72% (n=1) of patients who underwent the J graft open stent graft procedure. Conversely, the aforementioned Furutachi *et al.* used Frozenix in 19 patients and observed a postoperative dSINE rate of 15.8% (30).

The prognosis of untreated dSINE is severe, with a 25% mortality rate for those who opted not to have treatment up to 3 years post-FET, and dSINE may develop at any time after graft implantation (35). This emphasises the need for follow-up and computed tomography (CT) surveillance, especially as most patients with dSINE are asymptomatic (29). If detected, there are two possible treatment options for dSINE. The initial treatment involves medical management aimed at optimising blood pressure, as was the case in Dong *et al.* (25) and Pantaleo *et al.* (26) where 3/8 and 12/30 dSINE patients with a stable FL were managed conservatively. However, if the FL continues to expand, endovascular reintervention using thoracic endovascular aortic repair (TEVAR) is required (26,36). Alongside the degree of expansion of the lumen, other factors are considered when choosing the optimum treatment option, such as the degree of malperfusion, the likelihood of rupture of the FL, the formation of a pseudoaneurysm, or if the patient becomes symptomatic (37). It is reported that TEVAR secondary

**Table 3** Overall summary of the findings in 'dSINE' section

| Study                        | Year | Study type    | Prosthesis type     | N of patients | dSINE, % |
|------------------------------|------|---------------|---------------------|---------------|----------|
| Berger <i>et al.</i> (31)    | 2022 | Observational | THP                 | 186           | 11.8     |
| Nomura <i>et al.</i> (28)    | 2021 | Observational | Frozenix            | 19            | 12.9     |
| Iino <i>et al.</i> (33)      | 2022 | Observational | Frozenix + Gelweave | 50            | 0        |
| Yoshitake <i>et al.</i> (24) | 2020 | Observational | Frozenix            | 139           | 0.72     |
| Kreibich <i>et al.</i> (5)   | 2020 | Observational | THP                 | 35            | 11       |
| Kreibich <i>et al.</i> (27)  | 2020 | Observational | THP + E-vita        | 70            | 12.9     |
| Hirano <i>et al.</i> (34)    | 2020 | Observational | Frozenix            | 76            | 4        |
| Furutachi <i>et al.</i> (30) | 2019 | Observational | Frozenix            | 19            | 15.8     |
| Berger <i>et al.</i> (20)    | 2019 | Observational | THP                 | 55            | 16       |
|                              |      |               | E-vita              | 33            | 18.2     |

dSINE, distal stent graft-induced new entry; THP, Thoraflex Hybrid Plexus.

reintervention for dSINE has been found to have outstanding outcomes (28). A summary of the above results can be found in *Table 3*.

A recent comprehensive review of the literature by Jubouri *et al.* (38) investigated the incidence of dSINE post-FET as well as the relationship between dSINE and aortic remodelling. The authors stressed the importance of careful sizing of the FET HP as the literature evidently shows a strong link between graft oversizing and increased dSINE rates. Hence, choosing an appropriate diameter and length of stent-graft can be considered a protective factor against dSINE (38).

### Aortic remodelling in aortic dissection

Aortic remodelling is another established outcome that can be considered an important prognostic factor following FET. Unresolved AD poses a significant risk of aortic rupture, aneurysmal degeneration, distal organ malperfusion, and reintervention, and hence positive aortic remodelling is deemed favourable for survival (39). Volumetric changes of the false lumen (FL) and true lumen (TL) are directly correlated to the long-term sequelae of AD (38). This section will aim to outline aortic remodelling rates post-FET in the literature and evaluate any differences reported.

At the level of the distal thoracic aorta, complete or partial false lumen thrombosis (FLT) occurs on average in 88.9% of patients following FET, which is superior to conservative management rates of 33.3–77.8% in the

literature (39). Although FET is overall associated with more favourable remodelling outcomes, this is dependent on multiple factors. Additionally, the way aortic remodelling is defined in the literature is ambiguous and often variable. In a three-year comprehensive review by Iida *et al.* (40), authors assessed aortic remodelling in 26 TAAD patients post-FET using CT scans. Authors defined three patterns by which remodelling occurred: there was either no communication between the lumens, the proximal tear was located in the DTA, or communication did occur but at the level of the abdominal aorta. In the first pattern, where the dissections were thrombosed, complete aortic remodelling was achieved in all patients (n=12), as expected. However, in patients (n=9) where the DTA was affected, aortic remodelling did not occur, regardless of the location of the tear. In fact, 3 patients from this subgroup exhibited negative remodelling and required further interventions for aortic dilatation. In the remaining 5 out of 26 patients, remodelling occurred only up to abdominal aorta branches or infrarenal arteries, but not any further distally, unless the entries were visualised as 'ulcer-like projections' (n=2). Unlike the studies reporting on aortic remodelling, this retrospective analysis highlighted the number of communications between the lumens, in addition to the proximal entry tear site. However, this was limited by not linking this data to the aortic remodelling outcomes in detail. More quantitative measures at which levels negative remodelling occurred could have created a more standard overview of the results. Additionally, this study was limited by the short-term measure of aortic remodelling, with the

average CT occurring  $21.6 \pm 10.2$  days postoperatively (40).

Similarly, in a review of 16 patients with TAAD, Song *et al.* (41) noted that changes in aorta diameter were most significant at the level of the aortic arch ( $P=0.07$ ), reducing from  $43.0 \pm 3.5$  mm preoperatively to  $28.4 \pm 2.7$  mm at 3 months post-discharge. In concurrence with the previous literature, the distal aorta showed worsening remodelling rates, with lumen diameter increasing from  $29.1 \pm 0.4$  to  $31.2 \pm 1.2$  mm ( $P=0.42$ ) and from  $18.5 \pm 0.3$  to  $20.1 \pm 0.3$  mm ( $P=0.66$ ) at the level of the diaphragm and common iliac artery bifurcation, respectively.

It is important to note that standardised definitions of aortic remodelling may allow for a better comparison of this outcome following FET. For instance, Dohle *et al.* (42) defined positive remodelling as an increase in TL diameter by 10% with a static overall aortic lumen, or vice versa. Whilst diameter change between 0–10% was deemed stable, rates below this limit were defined as negative remodelling (42). Additionally, the authors expanded their study population to include both aortic remodelling outcomes in CAD ( $n=22$ ) with AAD ( $n=48$ ). Three segments of the aorta were observed for volumetric changes: the stent-graft segment (A), downstream the coeliac artery (B) and distal to the bifurcation (C). *Table 4* summarises the volumetric changes at each level, in both CAD and AAD. Firstly, in segment A, within the first year of follow-up, TL volume increased by 13% ( $P<0.0001$ ) in AAD and by 11% in CAD ( $P=0.0055$ ). Similarly, FL decreased by 44% ( $P<0.0001$ ) and 39% ( $P<0.0001$ ), respectively. Next, both AAD and CAD exhibited a 16% TL diameter increase in segment B ( $P<0.0001$ ) within 1 year. The FL continued to decrease at this level in AAD ( $-12\%$ ,  $P=0.0653$ ) but remained unchanged in CAD. Finally, there was an 11% increase in TL diameter in AAD at segment C ( $P=0.092$ ) but only 4% in CAD patients ( $P=0.1214$ ). FL diameter had in fact increased by 8% ( $P=0.18$ ) in AAD and 6% in CAD ( $P=0.0474$ ). Although CAD exhibited better rates of positive or stable remodelling within the first year (A: 100%, B: 82%, C: 77% *vs.* A: 90%, B: 65%, C: 62%), AAD showed superior remodelling in the long-term. After the first year of follow-up, positive or stable aortic remodelling was present in 92%, 65%, and 62%, in contrast to 75%, 44%, and 38% in segments A, B and C accordingly. Furthermore, in AAD, at the level of the aortic stent-graft, FLT occurred in 88% of patients and increased up to 92% at the 1-year follow-up. Additionally, full obliteration of the FL in segment B was significantly correlated with complete thrombosis distally in segment C ( $r_{sp}=0.63$ ;  $P<0.0001$ ). This is comparable to

the CAD FLT rates; segment A exhibited 82% thrombosis which remained unchanged at follow-up. Additionally, segment B included 23% thrombosis, notably increasing to 41% after the first year, however, no patients with chronic segment C dissections showed any evidence of FLT (42).

Berger *et al.* (44) discuss the impact of the number of communications between the lumens on aortic remodelling. FET allows for the closure of these channels, in addition to reducing the significant pressure exhibited on the aortic walls. This 2018 analysis, however, highlights that this benefit is achieved likewise in both CAD and AAD, in contradiction to the aforementioned literature. This is supported by Iafrancesco *et al.* (45). The authors here report an international multicentre study on 137 patients, where the rate of FLT at the level of the mid-DTA and the distal abdominal aorta was measured. At the former site, 99.3% exhibited FLT, in comparison to 13.9% distally. Although these rates were similar between acute and chronic proximally, at the level of the DTA, CAD showed increased negative remodelling (33% *vs.* 17.5%,  $P=0.040$ ). Hence, it is clear that the extent of remodelling decreases distally.

Another limitation of the literature is the long-term evaluation of aortic remodelling. A 2022 study followed up 57 patients with AD at 2 years and compared remodelling between AAD and CAD using CT angiography (43). TL diameters, total aorta diameters and FLT rates were not significantly different among the two groups. It was found that  $62.2\% \pm 26\%$  of the AAD group showed freedom from negative remodelling, whilst this was  $76.2\% \pm 11\%$  in the CAD group ( $P=0.853$ ). This difference could be attributed to the sample size including both type A and B ADs with no clear divide between each indication. Despite the lack of long-term data, Song *et al.* (41) highlighted the insignificant difference of aorta diameter change on discharge, in comparison to the 3-month follow-up. At the level of the aortic arch, diaphragm, and common iliac bifurcation, on average, the aorta increased by 0.1, 0.3, and 0 mm respectively. However, little is known about the pathophysiology of aortic remodelling and further high-quality trials are needed.

Negative aortic remodelling often necessitates further reintervention; this is usually a second-stage TEVAR, like Iida *et al.* reported in the 3 patients that exhibited aortic dilatation 3 weeks postoperatively (40). *Table 5* summarises further management planned by the authors depending on the aortic remodelling status. Factors that Di Bartolomeo *et al.* (39) have recommended assessing prior to surgery to predict positive remodelling include a preoperative

**Table 4** Overall summary of the findings in 'Aortic remodelling in aortic dissection' section

| Study                          | Year | Prosthesis type  | N of patients | Aortic remodelling  |
|--------------------------------|------|------------------|---------------|---|
| Kozlov and Panfilov (43)       | 2022 | –                | 57            | Average freedom from negative remodelling at 2-year follow-up:<br><i>Acute</i> : 62.2%<br><i>Chronic</i> : 76.2%  |
| Song <i>et al.</i> (41)        | 2020 | Wei Chuang       | 16            | Average change in aorta diameter (mm) preoperatively to 3-month follow-up:<br><i>Ascending aorta</i> : –14.6<br><i>Aortic arch</i> : –3.2<br><i>Bifurcation of pulmonary arteries</i> : +5.1<br><i>Diaphragm</i> : +2.1<br><i>Common iliac bifurcation</i> : +1.6 |
| Iida <i>et al.</i> (40)        | 2019 | J-Graft Frozenix | 26            | Achieved 53.8% (n=14)<br>Not achieved 34.6% (n=9)<br>Partially 11.5% (n=3)  |
| Berger <i>et al.</i> (44)      | 2018 | THP              | 65            | Average diameters (mm):<br><i>TL diameter</i> : + 13 (at 24 months)<br><i>FL diameter</i> : –16 (at 36 months)  |
| lafrancesco <i>et al.</i> (45) | 2017 | E-vita Open      | 137           | FL thrombosis:<br><i>Mid-descending thoracic aorta</i> : 99.3%<br><i>Distal abdominal aorta</i> : 13.9%   |
| Dohle <i>et al.</i> (42)       | 2016 | E-vita Open      | 70            | FL thrombosis (acute, chronic)<br>(A) 92%, 82%<br>(B) 29%, 41%<br>(C) 15%, 0%<br>TL changes (acute, chronic)<br>(A) +13%, 11%<br>(B) +16%, +16%<br>(C) +11%, +4%<br>FL changes (acute, chronic)<br>(A) –44%, –39%<br>(B) –12%, unchanged<br>(C) +8%, +6%          |

THP, Thoraflex Hybrid Plexus; TL, true lumen; FL, false lumen.

visualisation of the aortic anatomy (using CT angiography) and dissection extent, in addition to the affected vasculature between the TL and FL, and baseline diameters of the aorta on presentation, if appropriate (38). In the presence

of this information, the choice of FET prosthesis and its length can also be more appropriately made. The most popular products on the European market remain the E-vita and THP prostheses, with some evidence favouring aortic

**Table 5** Summary of further management planned by Di Bartolomeo *et al.* (39) depending on the aortic remodelling status

| Aortic remodelling   | Management            |
|--|-----------------------|
| <b>Present</b>   |                       |
| Complete remodelling (n=12)  | No further management |
| Complete remodelling with only ulcer-like projections below the diaphragm (n=2)        |                       |
| Remodelling is present at the level of the proximal entry tear, but not distally (n=3) |                       |
| <b>Absent</b>  |                       |
| No remodelling but no aortic dilatation (n=5)  | Further observation   |
| No remodelling with aortic dilatation (n=3)  | TEVAR                 |
| No remodelling with FET retraction (n=1)   | TEVAR                 |

TEVAR, thoracic endovascular aortic repair; FET, frozen elephant trunk.

remodelling outcomes in the latter device (46). Moreover, additional length to the prosthesis offers support to the dissecting membranes, reduces pressure on the friable walls, and encourages TL expansion distally; however, this must be balanced with the increased risk of SCI and other neurological sequelae (41). Roselli *et al.* (47) have suggested that devices around 15 cm in length are most suitable.

### Endoleak

Post-FET endoleak is the persistent leakage of blood outside the stent graft and within the dissection flap or aneurysm sac, hindering the resolution of the dissection. Endoleak counteracts the protective forces that the FET stent graft imposes to promote aortic remodelling. Without this, patients are at risk of a multitude of complications associated with unresolved or worsening dissections/aneurysms. The estimated incidence of endoleak post-FET in the literature is 3%, with type Ib being the most common subtype (15).

In a retrospective study by Kandola *et al.*, the sizing and sealing of FET stents for thoracic aortic aneurysm (TAA) was analysed. The 36 patients included were followed up with CT angiography after 25.8±5.7 months on average. Notably, the incidence of endoleak was 28% in this study (n=10) and 8% developed sac expansion (n=3). Out of this group (n=13), 38% (n=5) required further reintervention with TEVAR. The remaining 23 patients who did not develop these complications were found to have more than a 10% oversized stents or more than 30 mm seal (n=11, P=0.0031). Expectedly, 31% (n=11) of those with appropriately oversized and sealed stents exhibited a significantly lower incidence of endoleak, in contrast to

those without (0 *vs.* 71.4%, P<0.0004). Kandola *et al.* (48) highlighted the significance of pre-planned stent proximal landing zones, weighing both the benefit of appropriate oversizing and sealing with the risk of interrupting intercostal artery supply and subsequent SCI. In addition to the length of the prosthesis, appropriate angulation of the prosthesis is essential at the landing zone to prevent further aneurysmal formation (46,49).

In their 2021 study, Phung *et al.* (50) reported the short-term outcomes following FET in 25 patients. Amongst other complications, 2 out of 25 patients (8%) were found to have type I endoleak on postoperative CT. This relatively high rate could be attributed to the authors' choice to not oversize the stent grafts and use multi-slice CT images to size the HP preoperatively. Because both cases of endoleak originated from the brachiocephalic arteries, the authors modified their surgical technique to press the stent-graft to the aorta using sutures and felt in the left half of the perimeter of the brachiocephalic trunk (50). Importantly, it is unclear what the long-term pattern of endoleak incidence post-FET is.

Berger *et al.* (20) investigated the incidence of this complication at 1-year follow-up. Out of 88 patients, of which 55 received THP and 33 E-vita, only 1 developed an endoleak (1%). This single case reported occurred in the E-vita group (P=0.38). The result is further supported by Tan *et al.*, where endoleak rates using THP were evaluated in 931 patients across 84 months postoperatively. Only one patient (0.1%) had developed type Ib endoleak at day 150 postoperatively (14). This further emphasises the importance of careful HP choice preoperatively on the rates of this detrimental outcome. In addition, as discussed earlier, there is clear evidence supporting the relationship

**Table 6** Overall summary of the findings in 'Endoleak' section

| Study                      | Year | Study type             | Prosthesis type   | N of patients | Endoleak incidence |
|----------------------------|------|------------------------|-------------------|---------------|--------------------|
| Tan <i>et al.</i> (14)     | 2022 | International analysis | THP               | 931           | 1 (0.1%)           |
| Phung <i>et al.</i> (50)   | 2021 | Observational          | –                 | 25            | 2 (8%)             |
| Kandola <i>et al.</i> (48) | 2020 | Observational          | THP + E-vita Open | 63            | 10 (28%)           |
| Berger <i>et al.</i> (20)  | 2019 | Observational          | THP + E-vita Open | 88            | 1 (1%)             |

THP, Thoraflex Hybrid Plexus.

between stent graft size and the occurrence of endoleak, with oversizing by 10–25% being recommended. Hence, an appropriate diameter and length of stent graft must be chosen to balance out the risk of endoleak, dSINE and SCI whilst optimising aortic remodelling and minimising the need for reintervention (14,39,48). *Table 6* provides an overview of the findings in this section.

## Reintervention

Although FET yields favourable outcomes, secondary interventions are often necessary, with the majority of cases being due to dSINE, negative aortic remodelling or endoleak. In rarer cases, reintervention can also include aorto-oesophageal fistulae and graft kinking (5,51,52). Reasons for particularly early reinterventions fall to either a rapid increase in the diameter of the proximal DTA or an ineffective seal of the primary entry tear that indicated the FET procedure (44). It is important to consider if there are any identifiable predictors of this, analysing whether there are variable reintervention rates between devices or between underlying pathologies (53).

Wada *et al.* (54) found that when utilising FET in AAD, the reintervention rate 1-year post-operation was 5.4%, and overall 8.2% (16/196) of patients required TEVAR reintervention. The large sample size of this study increases its external validity and confidence that the conclusions drawn are representative of reality. Other studies, such as those conducted by Kreibich and colleagues (5) showed a higher rate of reintervention at 32% (n=10/31). However, there is some evidence that shows a reduced indication for reintervention after FET in AAD. In a retrospective case study where 31 patients were treated for AAD and 34 for CAD, a Kaplan-Meier estimate for freedom from aortic reintervention showed CAD having increased freedom from reintervention in comparison to AAD (44). At 12 months, there was an estimated 84% freedom from reintervention for CAD, but 80% for AAD. These values and conclusions

are consistent with the studies discussed earlier. However, there is also consistent evidence showing no difference in the underlying pathology between those with and without aortic reinterventions (5), with a similar incidence of dSINE after FET for both AAD and CAD (7). For patients with a high risk of retrograde TAAD (RTAD), FET has been deemed an effective method for treating chronic type B aortic dissection (TBAD).

A recent systematic review and meta-analysis of outcomes of patients using FET in TAA concluded that while direct statistical comparison between E-vita and THP could not be made due to the heterogeneity of studies, reintervention was lower for the E-vita device than for the THP (55). Elsewhere, Geragotellis *et al.* conducted a scoping review of the literature looking specifically at endovascular reintervention post-FET. The authors reported reintervention rates ranging from 0–12.9% for dSINE, 1.6–29.9% for negative aortic remodelling, and 0–4.55% for endoleak, with THP demonstrating a more favourable outcome relative to its market competitors (52).

More meaningfully, reintervention post-FET has been associated with the sizing of the graft, not aortic pathologies (49). A retrospective analysis of 63 cases, of which 36 cases were intended to be single-stage procedures, saw that 5 (14%) patients required reintervention, and this was attributed to the wrong sizing of the FET distal stent. In 11 patients with appropriately sized stents, no endoleak or sac expansion occurred, but in the 14 with inadequate sizing, 7 (50%) developed endoleak and 3 (21%) developed sac expansion. Only 4 (29%) did not develop a complication requiring further endovascular reinterventions. It seems that identifiable predictors of reintervention lie more closely with appropriate sizing being conducted as opposed to underlying pathologies (56).

Kozlov and colleagues (57) further the concept of the reintervention rate post-FET being more heavily associated with the device itself as opposed to pathology. In their study, it was concluded that standard FET is decent but

**Table 7** Summary of studies reporting on 12-month postoperative reintervention rates

| Author                      | Year | Study type                        | Prosthesis type  | N of patients | Reintervention |
|-----------------------------|------|-----------------------------------|--|---------------|----------------|
| Masiello <i>et al.</i> (60) | 2022 | Observational                     | THP  | 70            | 0 (0%)         |
| Wada <i>et al.</i> (54)     | 2022 | Observational                     | J Graft Frozenix   | 196           | 11 (5.6%)      |
| Tian <i>et al.</i> (6)      | 2020 | Systematic review & meta-analysis | E-vita, THP, Chavan-Haverich, Cronus, GoreTAG, Talent, Valient, J Graft, and Gianturco | 4,178         | 255 (6.1%)     |
| Kandola <i>et al.</i> (48)  | 2020 | Observational                     | E-vita or THP  | 36            | 5 (14%)        |
| Kreibich <i>et al.</i> (5)  | 2020 | Observational                     | THP  | 107           | 35 (33%)       |
| Kozlov <i>et al.</i> (57)   | 2019 | Observational                     | Elongated FET technique (E-vita Open + E-vita Thoracic)                                | 11            | 0 (0%)         |
|                             |      |                                   | E-vita Open  | 15            | 1 (6.7%)       |
| Goebel <i>et al.</i> (59)   | 2018 | Observational                     | E-vita Open  | 72            | 0 (0%)         |
| Berger <i>et al.</i> (23)   | 2018 | Observational                     | THP  | 65            | 18 (28%)       |
| Koizumi <i>et al.</i> (56)  | 2018 | Observational                     | J Graft Frozenix   | 30            | 4 (13%)        |

THP, Thoraflex Hybrid Plexus; FET, frozen elephant trunk.

elongated FET seems to be superior, as it had a reduced reintervention rate of 0% (n=0) in comparison to 6.7% (n=1; endovascular). This conclusion must be contextualised, however, due to the small sample size. Apart from the reintervention rate, cardiopulmonary bypass time and overall procedure duration were also significantly longer in patients with standard FET (57).

A systematic review to show long-term outcomes following the FET procedure showed freedom from reintervention at 1, 2, 3, and 5 years were 93.9%, 91.6%, 89.3%, and 86.8% respectively (6). On discussion, after factoring in the presence of confounding factors such as an assortment of surgical approach management, neuroprotective strategies, and the type and length of FET used, it was summarised that while the need for reintervention after FET is not negligible, FET simplifies the necessary second stage procedures required. The successful use of TEVAR to successfully treat reinterventions is commented on numerously throughout the literature (54,56), with Meisenbacher and colleagues further commenting that following FET, TEVAR was the preferred method for reintervention with a reported 100% technical success rate and a 95% survival rate (58). Goebel *et al.* (59) analysed the efficacy of hybrid aortic repair and after 12 months found a reintervention rate of 0, and that a 2.7% (n=2) reintervention rate was only found at 36 months follow-up. Both patients underwent open thoraco-abdominal surgery due to progressive aneurysm growth. Another study that reported 0% reintervention is

that by Masiello *et al.* (60) who used THP in 70 patients, of which 41 (58.6%) were emergent cases.

Overall, when looking at reinterventions post-FET procedures, more long-term data is needed to confirm the encouraging results reported. The aforementioned Tan *et al.* followed up patients for 84 months post-FET using THP and reported a 95% (n=869) freedom from adverse events (14). An overall summary of the findings in this section can be found in *Table 7*.

### Kinking and coagulopathy

Kinking of the FET HP is an uncommon yet life-threatening complication of FET. It is thought that sufficient retrograde blood flow, longer prosthesis and the positioning of the stent graft at the level of the aorta all contribute to its incidence (61). As a result of the turbulence of blood, this can result in fatal outcomes, such as dislodging septic emboli and end-organ ischaemia. Kinking has been reported to occur at a rate ranging from 0% to 8% in the literature. Kreibich *et al.* (5) reported that 2 out of 35 patients developed kinking post-FET using THP. Other devices quoted in the literature that were associated with kinking involve 3 out of 38 patients (8%) with the branched 1-piece graft from Yuhengjia Sci-Tech Co. and 1 out of 60 patients (2%) with the Frozenix graft (61).

In a systematic review and meta-analysis of 6,313 FET patients, 7% were found to have postoperative bleeding, with THP showing superior results (62). Meanwhile,

the incidence of thromboembolic events post-FET remains unclear. However, reporting studies have quoted low figures. For example, Ibrahim *et al.* encountered an 11.7% incidence of thrombotic complications in their study of 128 THP patients. Nevertheless, all 15 patients received anticoagulation therapy and of these, 7 required further intervention (5 open surgery and 2 endovascular). Importantly, an 86.7% (n=13) resolution rate was recorded. Interestingly, the authors suggested an association between the incidence of thromboembolic complications and a patient history of autoimmune disease (P=0.01) (63).

## Conclusions

The FET procedure can achieve a favourable postoperative profile in terms of survival, complications and aortic remodelling, and remains the gold-standard treatment for thoracic aortic pathologies implicating the arch and DTA. However, long-term follow-up is still required to maximise clinical efficacy. Further prospective evaluation of the various commercially available HPs in relation to selected indications is needed.

## Acknowledgments

*Funding:* None.

## Footnote

*Provenance and Peer Review:* This article was commissioned by the editorial office, *Cardiovascular Diagnosis and Therapy* for the series “Frozen Elephant Trunk”. The article has undergone external peer review.

*Reporting Checklist:* The authors have completed the Narrative Review reporting checklist. Available at <https://cdt.amegroups.com/article/view/10.21037/cdt-23-300/rc>

*Peer Review File:* Available at <https://cdt.amegroups.com/article/view/10.21037/cdt-23-300/prf>

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <https://cdt.amegroups.com/article/view/10.21037/cdt-23-300/coif>). The series “Frozen Elephant Trunk” was commissioned by the editorial office without any funding or sponsorship. E.P.C., I.M. and M.B. served as the unpaid Guest Editors of this series. The authors have no other conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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**Cite this article as:** Kayali F, Chikhal R, Agbobu T, Jubouri M, Patel R, Chen EP, Mohammed I, Bashir M. Evidence-based frozen elephant trunk practice: a narrative review. *Cardiovasc Diagn Ther* 2023;13(6):1104-1117. doi: 10.21037/cdt-23-300