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### Concomitant aortic root replacement during frozen elephant trunk 1 implantation does not increase perioperative risk 2 Tim Berger MD<sup>1</sup>; Salome Chikvatia, MD<sup>1</sup>; Matthias Siepe MD<sup>2</sup>, Stoyan Kondov, MD<sup>1</sup>; 3 Dominic Meissl, MS<sup>1</sup>; Roman Gottardi, MD, MBA<sup>1</sup>; Bartosz Rylski, MD<sup>1</sup>. 4 Martin Czerny, MD, MBA<sup>1</sup>; Maximilian Kreibich, MD, MHBA<sup>1</sup>; 5 <sup>1</sup>Department of Cardiovascular Surgery, Heart Centre Freiburg University, Faculty of Medicine, 6 University of Freiburg, Freiburg, Germany. 7 8 <sup>2</sup>Department of Cardiac Surgery, University Hospital Bern, University of Bern, Bern, Switzerland. 9 10 11 Word count of the entire manuscript: 3823 words. 12 Address for correspondence: 13 Maximilian Kreibich, MD MHBA 14 Heart Centre Freiburg University 15 Hugstetter Str. 55 16 79106 Freiburg 17 18 Germany Phone: +49 761 270 28180 19 Fax: +49 761 270 25500 20

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# 22 Glossary of Abbreviations

- 23 FET Frozen elephant trunk
- 24



### 25 Visual abstract

Key question. Is concomitant aortic root replacement during frozen elephant trunk total arch
replacement safe? (96/120 characters)

- 28
- 29 Key findings. Concomitant root replacement prolongs operative times, but does not influence
- 30 postoperative outcomes or operative risk. (119/120 characters)

CCF

- 31
- **Take-home message.** The FET procedure should not be a contraindication for concomitant root
- replacement, particularity in patients with borderline indications. (140/140 characters)
- 34

#### 35 Abstract

#### **36 Word count:** 218/250 words

Objectives. Our aim was to evaluate the risk of concomitant aortic root replacement during frozen
elephant trunk (FET) total arch replacement.

Methods. Between 03/2013 and 02/2021, 303 patients underwent aortic arch replacement using the FET technique. Patient characteristics, intra- and postoperative data were compared between patients with (n=50) and without (n=253) concomitant aortic root replacement (implantation of a valved conduit or using the reimplantation valve sparing technique) after propensity score matching.

**Results.** After propensity score matching there were no statistically significant differences in 44 preoperative characteristics including the underlying pathology. There was no statistically 45 significant difference regarding arterial inflow-cannulation or concomitant cardiac procedures, 46 while cardiopulmonary bypass (p<0.001) and aortic cross-clamp (p<0.001) times were 47 significantly longer in the root replacement group. Postoperative outcome was similar between the 48 groups and there were no proximal reoperations in the root replacement group during follow-up. 49 Root replacement was not predictive for mortality (p=0.133, odds ratio: 0.291) in our Cox 50 regression model. There was no statistically significant difference in overall survival (log rank: 51 p=0.062). 52

53 **Conclusions.** Concomitant FET implantation and aortic root replacement prolongs operative 54 times, but does not influence postoperative outcomes or increase operative risk in an experienced 55 high-volume centre. The FET procedure did not appear to be a contraindication for concomitant 56 aortic root replacement even in patients with borderline indications for aortic root replacement. 57 **Keywords**: frozen elephant trunk (FET); aortic root replacement; aortic root; aortic arch;

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## 58 Introduction

The frozen elephant trunk (FET) procedure has evolved as an effective and common treatment in 59 patients with thoracic aortic pathologies involving the aortic arch with good postoperative outcome 60 but a high incidence of planned and unplanned distal aortic reinterventions [1-7]. However, the 61 procedure remains complex and still carries a high risk for adverse events [4, 7, 8]. While FET 62 implantation in our high-volume centre is already performed as a training procedure and therefore 63 concomitant root replacement could be carried out more liberally, the addition of cardiac and aortic 64 root procedures still increases the complexity of the procedure further [9]. Hence, surgeons may 65 be hesitant to perform concomitant cardiac and/or aortic root procedures during FET total arch 66 replacement particularly in patients with borderline indications. Therefore, our aim was to evaluate 67 the risk of concomitant aortic root replacement during FET total arch replacement, i.e. the risk of 68 69 a complete proximal thoracic aortic fix rom the root beyond the aortic arch.

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#### 71 **Patients and Methods**

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Ethical statement. Our institutional review committee approved this retrospective study, and the
need for informed consent was waived (number: 20-1302; approval date: February 4, 2021).

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Patients and follow-up protocol. Between 03/2013 and 02/2021, 303 patients underwent FET
total arch replacement in one aortic centre currently performing over 60 total aortic arch procedures
per annum (as of 2021). Patients were followed-up for a total of 421 patient-years, with a median
follow-up of 8 [first quartile: 1; third quartile 29] months. All patients were routinely followed-up
after six months, twelve months and yearly thereafter in our dedicated aortic clinic. Computed
tomography angiography (CTA) scans were done preoperatively, before discharge, during every
follow-up visit, and when clinically warranted.

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Surgical approach and technique. Our standardised, integrated surgical management of the FET 84 technique has been reported [10-12]. In short, we carry out a full sternotomy and generally 85 cannulate the right axillary artery for arterial inflow for cardiopulmonary bypass. Any concomitant 86 procedures (valve, aortic root, coronary artery) take place while the patients are cooled down to a 87 target core body temperature of 25°C. We routinely apply cold-blood cardioplegia or the beating-88 heart technique (using 300 mL of normothermic myocardial perfusion) [12]. Bilateral cerebral 89 perfusion is normally used and we liberally perform trilateral antegrade cerebral perfusion 90 91 (additional cannulation of the left subclavian artery) when needed. For this reason, today, our preoperative work-up includes a CTA of the supra-aortic vessels including the Circle of Willis. 92

2008 Zone 2 is our standard anastomosis site for FET implantation, and today, we use the short version 2009 (100 mm) of the Thoraflex (Terumo Aortic, Inchinnan, UK) hybrid-graft exclusively. In case of 2019 classical aneurysm formation, we oversize the stent-graft component by 10% at the distal landing 2019 zone and in case of aortic dissections we avoid oversizing and choose the FET stent-graft size 2019 according to institutional standards. We do not routinely implant cerebrospinal fluid drainage 2019 before surgery.

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Indication for aortic root replacement. In the vast majority of patients root replacement was carried out according to the 2014 ESC guidelines [13]. In selected cases of young patients or/and patients with connective tissue disease especially if the wall of the aortic root appeared considerably thin intraoperatively, root replacement was done in root diameters lower than the guideline's threshold in an anticipative manner.

105

Data collection and definition of parameters. Data were collected retrospectively relying on our 106 prospectively-maintained aortic database. Acute aortic dissection was defined as a symptom onset 107 fewer than 14 days before hospital admission and was classified as chronic if symptoms had 108 occurred >14 days beforehand. The TEM classification was used to categorise aortic dissections 109 (Type A, Type B, Type non-A non-B) [14]. The modified Rankin Scale (mRS) was used to classify 110 the postoperative-stroke severity. Consulting neurologists evaluated all the strokes. Postoperative 111 strokes causing no clinical symptoms (mRS 0), no significant disability (mRS 1), or slight 112 disability (mRS 2) were classified as non-disabling postoperative strokes. 113

115 **Statistical Analysis.** Since the data has been collected during an observational study, we applied 116 propensity score matching. This mitigated the risk of confounding variables distorting the results. We achieved this by identifying pairs of observation that had the same propensity to experience 117 118 the treatment, but which differ in their actual treatment. To estimate propensity scores, we used the following variables: aneurysm, penetrating aortic ulcer, male, age, diabetes, history of stroke, 119 history of smoking, hyperlipidaemia, hypertension, history of renal failure, chronic obstructive 120 pulmonary disease, coronary artery disease, bicuspid aortic valve, and connective tissue disease. 121 We used a nearest neighbor method and a caliper of 10% of the standard deviation of the propensity 122 score logit. This approach lead to a total sample of 96 observations, with 48 patients with and 123 without concomitant aortic root replacement. To measure treatment effects, we employed standard 124 statistical techniques at a 5% signifiance level. A Student t tests or Wilcoxon signed-rank tests was 125 used to compare continuous variables as appropriate. McNemar tests was used for comparing 126 frequencies. Data are presented as absolute and relative frequency or as median [first quartile, third 127 quartile]. A Cox regression analyses was performed to investigate the influence of clinically 128 selected variables on overall mortality (selected variables: sex, age, concomitant root replacement, 129 redo case, acute pathology) and the Kaplan Meier method was used to analyse and compare overall 130 survival. No primary analysis was defined, therefore p-values may not be interpreted as 131 confirmatory but rather descriptive. The analysis was performed with the statistical software R 132 (version 4.1.1) and the library "MatchIt" (version 4.3.4), running on MacOS x86\_64-apple-133 darwin17.0. 134

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**Patient characteristics.** Concomitant aortic root replacement was performed in 50 (17%) patients 138 using a valved conduit (n=27, 54%) or the valve-sparring reimplantation technique (n=23, 46%). 139 These patients were significantly younger (p=0.002), predominantly male (p=0.051), commonly 140 presented with a bicuspid aortic valve (p=0.016), underwent prior aortic valve replacement 141 (p=0.024) and more commonly presented with a Type A aortic dissection (p=0.018). Patient 142 characteristics are summarised in Table 1. There were no statistically significant differences 143 between patients with and without concomitant aortic root replacement after propensity score 144 145 matching (Supplemental Table 1).

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Surgical details. As Table 2 shows, the right axillary artery was the preferred arterial inflow site in most patients and there were no statistically significant differences regarding the cannulation site or the incidence of additional cardiac procedures between the two matched groups. However, cardiopulmonary bypass (p<0.001), aortic cross-clamp (p<0.001) times were significantly longer in the root replacement group significantly prolonging the duration of the surgery (p=0.001). Unmatched data is presented in Supplemental Table 2. Indications for root replacement are summarized in Table 3.

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**155 Outcome characteristics.** Outcome characteristics are summarised in **Table 4** and **Supplemental 156 Table 3**. There was no difference between the two groups regarding postoperative outcomes. In 157 fact, in-hospital mortality tended to be lower in patients undergoing concomitant aortic root 158 replacement, but the difference did not reach statistical significance (p=0.111). In addition, overall survival tended to be higher in these patients as well but the difference did also not reach statistical
significance (log rank: p=0.062). No proximal reoperation was necessary in any patient in the root
replacement group during follow-up.

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163 Regression analysis. Concomitant root replacement was not identified as a significant variable in
164 our Cox regression model. The full model is shown in Table 5.

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#### 165 **Discussion**

Our study's most important findings can be summarised as: (i) Concomitant FET implantation and aortic root replacement is common particularly in patients with Type A aortic dissection and in redo scenarios. (ii) Concomitant aortic root replacement prolongs operative times, but does not impact postoperative outcomes or increases operative risk. (iii) The FET procedure should not be a contraindication for concomitant aortic root replacement by itself, particularity in patients with borderline indications for aortic root replacement.

There were statistically significant differences regarding the baseline characteristics between the 172 two unmatched groups, in particular, patients undergone concomitant aortic root replacement were 173 significantly younger and more commonly men in our cohort. Both difference may be associated 174 with the significantly higher incidence of patients with bicuspid aortic valves in this study. In fact, 175 a bicuspid aortic valve is generally more common in male patients and patients with bicuspid aortic 176 valve have a significantly higher risk for adverse aortic events at younger ages with lower 177 cardiovascular risk factors present [15, 16]. This fact may also explain the significantly higher 178 incidence of Type A aortic dissections (acute or residual after prior repair) in patients with 179 concomitant aortic root replacement. According to previous reports of patients with acute Type A 180 dissections, the need for concomitant root replacement has been reported to be higher in patients 181 with a bicuspid compared to patients with a tricuspid aortic valve [16, 17]. In residual aortic 182 183 dissection cases after previous repair for acute type A aortic dissection, it seems plausible that surgeons tend to aim for a complete aortic repair when performing the frozen elephant trunk 184 technique as a redo case in order to prevent any third step intervention for any residual root 185 186 pathology and because the frozen elephant trunk procedure has been shown to be safe in redo 187 scenarios [18, 19].

Intraoperative data reflect our standardized, integrated surgical approach to the FET procedure 188 189 with the right axillary artery as our routine choice for arterial inflow. The carotid artery remains a back-up option for arterial inflow in stable patients with compromised supraaortic perfusion due 190 191 to an acute dissection of the brachiocephalic trunk even though we usually also cannulate the right axillary artery, as we did not see a higher risk for cerebral malperfusion in these patients [20, 21]. 192 In selected scenarios (hemodynamically unstable patients, severe risk for spinal cord ischemia, re-193 do cases with retrosternal adhesions), the femoral artery may also be used. We generally switch to 194 central perfusion or establish concomitant axillary and femoral artery perfusion (e.g. in 195 atherosclerotic scenarios with risk for spinal cord ischemia, when iliac artery perfusion is 196 compromised preoperatively). 197

The beating heart technique is liberally performed in our centre and may simply be performed when an artificial graft is present in the ascending aorta [12, 22]. This may explain the numerically higher rate of beating heart procedures in patients with concomitant root replacement, since the procedure is usually carried out during cooling of the patient. Cardioplegia may then be stopped for the arch procedure and the FET can be implanted with a beating heart. The benefits of the beating heart technique during FET total arch repair have been shown by the Hannover group and by us previously [12, 22, 23].

The addition of a concomitant root replacement obviously caused longer operative times but did not affect postoperative outcomes. In fact, while there were not statistically significant difference in postoperative outcome, there was a numerically better outcome in patients with concomitant root replacement. Similar results have previously been reported in isolated Type A aortic dissection populations [23]. Hence, in patients with borderline indications for root replacement, this data suggests that the procedure can be performed safely. Limitations and strengths. Our study is limited by its small sample size and retrospective nature.
Of note, concomitant root replacement revealed favourable results in our and other high-volume
centres but these results may not be reproducible in less experienced centres. However, this

investigation contributes valuable knowledge on outcomes after concomitant aortic rootreplacement during FET total arch replacement.

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Concomitant FET implantation and aortic root replacement prolongs operative times, but does not
influence postoperative outcomes or increase operative risk in an experienced high-volume centre.
The FET procedure did not appear to be a contraindication for concomitant aortic root replacement
even in patients with borderline indications for aortic root replacement. Further prospective
multicentre studies or registry data are needed to confirm our results and their reproducibility.

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- 230 Disclosures. BR performs proctor activities for Terumo Aortic. MC is a consultant for Terumo
- Aortic, Medtronic and Cryolife, received speaking honoraria from Bentley and is a minority
- shareholder of TEVAR Ltd. BR and MC are shareholders of Ascense Medical. MK has received
- 233 speaking honoraria from Terumo Aortic.

#### 234 Data availability statement

- 235 The datasets presented in this article are not readily available because of the requirements of our
- institutional review board. Individual reasonable requests will be evaluated by the corresponding
- author.

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## Tables

Table 1. Patient characteristics (unmatched data)				
	No root replacement	Root replacement	p-value	
	(n=253)	(n=50)		
Age (years)	67 [59, 75]	62 [56, 70]	0.022	
Male	160 (63)	39 (78)	0.051	
Diabetes mellitus type 2	0 (0)	8 (16)	0.361	
Hyperlipidemia	85 (34)	15 (30)	0.627	
Hypertension	216 (85)	40 (80)	0.280	
Coronary artery disease	77 (30)	13 (26)	0.613	
History of smoking	113 (45)	20 (40)	0.538	
COPD	26 (10)	4 (8)	0.798	
History of stroke	33 (13)	6 (12)	1.000	
Renal impairment	34 (13)	7 (14)	1.000	
Bicuspid aortic valve	8 (3)	6 (12)	0.016	
Connective tissue disease	19 (8)	8 (16)	0.098	
Redo case	79 (31)	19 (38)	0.229	
CABG	7 (3)	1 (2)	1.000	
AVR	32 (13)	1 (2)	0.024	
MVR	2 (31)	0 (9)	1.000	
Ascending	78 (31)	19 (38)	0.407	
Hemi-arch	31 (12)	9 (18)	0.360	
Other	55 (22)	12 (24)	0.852	
Type A dissection *	90 (36)	27 (54)	0.018	
Acute	38 (15)	9 (18)	0.669	
Type B dissection	34 (13)	5 (10)	0.646	
Acute	22 (9)	2 (4)	0.391	
Type non-A-non-B dissection	34 (13)	3 (6)	0.163	
Acute	22 (9)	1 (2)	0.143	
Aneurysm	69 (27)	14 (28)	1.000	
PAU	23 (9)	1 (2)	0.147	
Other	3 (1)	2 (4)	0.192	

Values are n (%) or median [fist quartile, third quartile].

COPD; chronic, obstructive pulmonary disease; CABG, coronary artery bypass graft; AVR, aortic valve replacement; MVR, mitral valve reconstruction; PAU, penetrating aortic ulcer \*including chronic residual dissections

Table 2. Surgical details (propensity score matched population)				
	No root replacement	Root replacement	p-value	
	(n=48)	(n=48)		
Cannulation				
Aorta	0 (0)	1 (3)	1.000	
Femoral	3 (7)	0 (0)	0.242	
Axillary	47 (98)	45 (94)	0.612	
Carotid	1 (3)	4 (9)	0.362	
Valved conduit	-	26 (55)	- · · ·	
VSARR	-	22 (46)		
AVR	8 (17)	-		
CABG	6 (13)	8 (17)	0.772	
Beating heart	6 (13)	13 (28)	0.124	
CPB time (min)	208 [167, 253]	246 [218, 285]	< 0.001	
CX time (min)	106 [91, 156]	176 [124, 205]	< 0.001	
SACP time (min)	103 [81, 128]	113 [53, 169]	0.526	
Duration of surgery (min)	372 [325, 415]	422 [371, 501]	0.001	
Lowest body temperature (°C)	25 [24, 25]	25 [24, 25]	0.772	

Values are n (%) or median [fist quartile, third quartile]. VSARR, valve sparring aortic root replacement; CABG, coronary artery bypass graft; CPB, cardiopulmonary bypass; CX, aortic cross-clamp; SAP, selective antegrade cerebral perfusion

Table 3. Indications for root replacement	
Root aneurysm	33 (66)
Root dissection	15 (30)
Severe aortic regurgitation + Aneurysm	2 (4)
Values are n (%).	

<b>Table 4</b> . Outcome characteristics (propensity score matched population)				
	No root replacement	Root replacement	p-value	
	(n=48)	(n=48)		
Dialysis	5 (11)	1 (3)	0.204	
Tracheotomy	5 (11)	2 (5)	0.435	
Paraplegia	0 (0)	0 (0)		
Stroke	8 (17)	4 (9)	0.355	
Non-disabling	3 (7)	1 (3)	0.617	
In-hospital mortality	6 (13)	1 (3)	0.111	
Proximal reoperation*	1 (3)	0 (0)	1.000	
Values are n (%). *during follow-up		$\sim$		

Table 4. COX Regression: Overall mortality (propensity score matched population)			
Variable	р	OR	95% CI
Sex	0.975	1.026	0.206-5.116
Age	0.330	1.030	0.971-1.092
Root replacement	0.133	0.291	0.058-1.454
Redo case	0.422	1.703	0.464-6.248
Acute pathology	0.355	1.893	0.489-7.320
OR, odds ratio; CI, confidence interval			
		Sch	

## **Figure Legend**

## **Central Image.**

Kaplan-Meier curve of overall survival of patients following frozen elephant trunk total arch replacement with (turquois) or without (red) concomitant aortic root replacement. Log CEPTERMAN rank: p=0.062). Time in years.

