# Outcome of Frozen Elephant Trunk Technique for Acute Type A Aortic Dissection

As Systematic Review and Meta-Analysis

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**Abstract:** Acute aortic dissections of Stanford type A require emergency surgery repair and present challenges to surgeons. The frozen elephant technique is one of several approaches used to treat aortic arch dissection. The purpose of this meta-analysis was to investigate the clinical effectiveness of the frozen elephant technique for treating acute type A aortic dissection.

Medline, Cochrane, Google Scholar, and ClinicalTrials.gov databases were searched up to March 31, 2014, for studies that assessed the use of frozen elephant trunk technique for treating acute type A aortic dissection. The primary outcome was in-hospital mortality. Secondary outcomes included rate of stroke, spinal cord injury, renal failure, and reoperations for bleeding.

Eleven studies were included in the analysis that encompassed 881 patients. The mean age ranged from 45.4 to 66.8 years, and the proportion of the population that was male ranged from 45 to 85%. The overall in-hospital mortality rate was 8%. The rate of stroke, spinal cord injury, renal failure, and frequency of reoperations for bleeding were 3, 4, 5, and 5, respectively. Sensitivity analysis indicates that the findings are robust and there was no publication bias.

These findings indicate that the frozen elephant techniques does not bring unacceptable mortality or morbidity risk for treating acute type A aortic dissection.

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Abbreviations: XX = xxx, XX = xxx.

# INTRODUCTION

A ortic dissection is the most common catastrophe of the aorta, with about 50% of patients dying within 48 hours, if left untreated.<sup>1</sup> The 2-week mortality rate approaches 75% in patients with undiagnosed ascending aortic dissection.<sup>1</sup> Acute aortic dissections of Stanford type A that affects the ascending aorta, the arch, and more distal aorta require emergency surgery repair and present challenges to surgeons.<sup>2</sup>

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A number of techniques have evolved to treat arch pathologies, which involve arch debranching followed by stenting over the aortic arch. The frozen elephant technique is one hybrid approach that was adapted from the classic elephant trunk technique first described by Borst et al.<sup>3-5</sup> The elephant trunk technique involves 2 steps. In the first step, the ascending aorta and arch are repaired by a median sternotomy, and in the second step, a free-floating extension of the arch prosthesis (ie, the elephant trunk) is left behind in the proximal descending aorto.<sup>3-5</sup> In the frozen elephant technique, the endovascular component is performed either simultaneously or in stages. A "hybrid" vascular graft made up of a conventional tube graft with an endovascular stented graft at the distal end is used to achieve a blood-tight seal in the descending aorta.<sup>6-8</sup> This allows for the treatment of the aortic arch and proximal descending pathologies in a single operation, which helps to minimize complications and reduce high mortality associated with the classical elephant technique.6-

Prior meta-analyses have assessed the efficacy and safety of different hybrid techniques including the frozen elephant technique in treating aortic arch dissection.<sup>9–11</sup> However, they either included type B aortic dissection or other aortic diseases. Our meta-analysis investigated the clinical effectiveness of the frozen elephant technique for specifically treating acute type A aortic dissection.

#### **METHODS**

#### Study Search

Meta-analyses do not involve humans and do not require Institutional Review Board review. The systematic review and meta-analysis was performed in accordance with the PRISMA guidelines.<sup>12</sup> Medline, Cochrane, Google Scholar, and ClinicalTrials.gov databases were searched up to March 31, 2014, for studies that assessed the use of frozen elephant technique for treating acute type A aortic dissection. The search terms included frozen elephant trunk, stent grafting technique, hybrid technique, and aortic dissection. All identified studies were reviewed by 2 independent reviewers, and where there was a discrepancy, a third reviewer was consulted. Studies were included if patients were >18 years of age, had been diagnosed with acute Stanford type A aortic dissection, or acute DeBakey type I or type II aortic dissection. Included studies involved the hybrid technique that combined open arch surgery and aortic endovascular treatment (ie, frozen elephant trunk method). Studies were excluded if they did not report separate outcomes for patients with acute type A aortic dissection, or include only patients with chronic aortic dissections or with thoracic aortic aneurysms. Non-English or non-Chinese publications, letters, comments, editorials, and case reports were also excluded.

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# **Data Extraction**

Data was extracted by 2 independent reviewers, and if necessary, a third was consulted to resolve disagreements. The following information was extracted from studies that met the inclusion criteria: the name of the first author, year of publication, study design, patient demographics, diagnosis, type of intervention, length of follow-up, and postoperative outcomes.

# **Quality Assessment**

The modified 18-item Delphi checklist was used to assess the quality of the included studies, which is designed for assessing the quality of single-arm clinical study.<sup>13</sup> Similar to study selection and data extraction, 2 independent reviewers performed the quality assessment and a third reviewer was consulted to resolve any disagreements.

# **Statistical Analysis**

The primary outcome was in-hospital mortality. Secondary outcomes included rate of stroke, spinal cord injury, renal failure, and reoperations for bleeding.

Event rates with 95% confidence intervals (CIs) were calculated for binary outcomes for each individual study and for those studies combined. A  $\chi^2$ -based test of homogeneity was performed and the inconsistency index ( $I^2$ ) and Q statistics were

determined. If  $I^2$  was >50% or >75%, the trials were considered to be heterogeneous or highly heterogeneous, respectively. If  $I^2$  was <25%, the studies were considered to be homogeneous. If the  $I^2$  statistic were >50%, a random-effects model (DerSimonian-Laird method) was used. Otherwise, fixed-effects models (Mantel-Haenszel method) were employed. Combined effects were calculated and a 2-sided P value <0.05 was considered to indicate statistical significance. Sensitivity analysis was carried out for the primary outcome using the leave-one-out approach. Publication bias was assessed by constructing funnel plots for primary outcome by Egger test. The absence of publication bias was indicated by the data points forming a symmetric funnel-shaped distribution and 1-tailed significance level P > 0.05 (Egger test). All analyses were performed using Comprehensive Meta-Analysis statistical software, version 2.0 (Biostat, Englewood, NJ).

# RESULTS

The initial search identified 224 studies, 196 of which were excluded, following screening of the titles and abstracts, because of not being relevant for the analysis (Figure 1). Twenty-eight studies were reviewed in depth and 17 were excluded for not investigating acute type A aortic dissection (n = 5) and not reporting findings for type A aortic dissection



FIGURE 1. Flowchart of study selection.

TABLE	1. Summary of Stu	idy and Operati	ve Characteristics on Aortic	Arch Surgeries Utilizing the Frozen	Elephant Trunk Techr	nique			
Paper No.	First Author (Year)	Study Design	Type of Patients	Prosthesis	Circulatory Arrest Temperature, $^{\circ}C^*$	Number of Patients	Age, y	Male (%)	Follow-Up, mo*
1	Xiao (2014) <sup>23</sup>	Prospective	Acute Stanford type A aortic dissection	Stent graft (Shanghai MicroPort Medical Co, Ltd, Shanghai, China)	18.9 (2.7)	33	48.0	73%	27.2 (15.3)
5	Hoffman (2013) <sup>15</sup>	Retrospective	Acute Stanford type A aortic dissection	E-Vita open plus hybrid prosthesis (Jotec. Hechingen. Germany)	20 (core)	32	58	81%	17 (4)
ŝ	Ma (2013) <sup>22</sup>	Retrospective	Acute Stanford type A aortic dissection	4-branched vascular graft	25	398	46	82%	NA
4	Roselli (2013) <sup>14</sup>	Prospective	DeBakey type I acute aortic dissections	Dacron graft with GoreTAG stent (Gore Medical, Flagstaff, AZ, USA)	18	17	61.4	82%	NA
5	Tamura (2014) <sup>17</sup>	Retrospective	Acute Stanford type A aortic dissection	Gianturco Z-stents (Cook Inc, Bloomington, IN, USA)	28	25	64	64%	Median 58 (range 12–169)
9	Shen (2012) <sup>21</sup>	Prospective	Acute Stanford type A aortic dissection	4-branch graft with self-expanding stent	22 (rectal)	38	45.4	74%	12 (3)
7	Shi (2011) <sup>20</sup>	Retrospective	Stanford type A aortic dis section	Self-expandable stent vessel prosthesis	23.7 (3.7) (rectal)	46	52.7	76%	13.7 (7.4)
8	Sun (2011) <sup>3</sup>	Retrospective	Stanford Type A acute aor ticdissection	4-branch prosthetic graft with stent graft	18-22	148	45	85%	42 (18)
6	Uchida (2011) <sup>16</sup>	Retrospective	DeBakey type I acute aortic dissection	UBE graft (UBE Industries Ltd., Tokvo. Japan)	28 (rectal)	80	66.8	45%	74.3 (48.0)
10	Chen (2010) <sup>19</sup>	Retrospective	Debakey I aortic dissection	Woven Dacron graft with Gian turco-type self-expandable metallic stent (Microport Medical Corp., Shanghai, China)	22-25 (rectal)	28	51.2	79%	30.1 (19.3)
Ξ	Pochettino (2009) <sup>18</sup>	Prospective	Acute Stanford type A aortic dissection	Dacron graft (Vascutec Ltd, Renfrewshire, Scotland) with Gore TAG stent (W. L. Gore & Associates, Flagstaff, AZ, USA)	NA	36	59	NA	15.9
* Dat:	a presented in mean (st	tandard deviation)							

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(n=11), and were duplicate studies (n=1). Eleven studies were included in the systematic review and meta-analysis (Table 1).<sup>3,14-23</sup>

# **Study Characteristics**

Of the 11 studies included in the final analysis, all were observational in design, and 3 were prospective and 8 were retrospective studies. A total of 881 patients were encompassed by all 11 studies (range 25–398 patients) (Table 1). The mean age ranged from 45.4 to 66.8 years, and the proportion of the population that was male ranged from 45% to 85%. Follow-up ranged from about 13 to 74 months. A variety of prostheses were utilized across the studies.

# **In-Hospital Mortality**

All of the included studies in the meta-analysis reported the in-hospital mortality after utilizing the frozen elephant trunk technique (Table 2). Ten studies<sup>14–18,19–21,23</sup> reported in-hospital mortality, whereas only one<sup>22</sup> reported early mortality.  $\chi^2$ -based test of homogeneity indicated that there was heterogeneity among the 11 studies (*Q* statistic = 17.42,  $I^2$  = 45.58%, P = 0.0666); hence, a fixed-effects analysis was used. The overall in-hospital mortality was 8% (95% CI = 0.06 to 0.10, P < 0.001, Figure 2A).

# **Stoke Rate**

All 11 studies reported the events of stroke following surgery (Table 2).  $\chi^2$ -based test of homogeneity indicated that there was no heterogeneity among the 11 studies (*Q* statistic = 10.44,  $I^2$  = 4.24%, P = 0.408); consequently, a fixed-effects analysis was used. The overall stroke rate was 3% (95% CI = 0.02 to 0.05, P < 0.001, Figure 2B).

# Rate of Spinal Cord Injury

Nine of the studies<sup>3,14–18,20–22</sup> reported the frequency of spinal cord injury after surgery (Table 2). A fixed-effects analysis was used because of the homogeneity among the studies (Q statistic = 6.86,  $I^2 = 0\%$ , P = 0.552). The overall rate of spinal cord injury was 4% (95% CI = 0.03 to 0.06, P < 0.001, Figure 2C).

#### **Rate of Renal Failure**

Eight of the 11 studies<sup>3,14,16–19,22,23</sup> reported postsurgery events of renal failure (Table 2). A random-effects analysis was used because of the heterogeneity among the studies (Q statistic = 21.25,  $I^2 = 67.06\%$ , P = 0.003). The overall rate of renal failure was 5% (95% CI = 0.02 to 0.10, P < 0.001, Figure 2D).

# **Rate of Reoperations for Bleeding**

Seven studies<sup>3,15–17,19–21</sup> reported the events of reoperations to treat bleeding (Table 2). Analysis of the pooled data indicated that there was homogeneity among the studies (Q statistic = 5.48,  $I^2 = 0\%$ , P = 0.484); therefore, a fixedeffects analysis was used. The overall rate of reoperation for bleeding was 5% (95% CI = 0.03 to 0.08, P < 0.001, Figure 2E).

## Sensitivity Analysis and Publication Bias

Sensitivity analysis was performed using the leave-one-out approach for in-hospital mortality with each study removed in turn (Figure 3). The direction and magnitude of combined

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Paper No.	First Author (Year)	Cardiopulmonary Bypass Time, min	Cross-Clamp Time, min	Circulatory Arrest Time, min	Cerebral Perfusion Time, min	In-Hospital Mortality (%)	Stroke (%)	Spinal Cord Injury (%)	Renal Failure (%)	Reoperation for Bleeding (%)
-	Xiao (2014) <sup>23</sup>	296.9 (54.3)	174.2 (39.3)	52.2 (33.2)	NA	6 (18%)	0	NA	1 (3%)	NA
2	Hoffman $(2013)^{15}$	219 (39.2)	152 (38.7)	57 (6.7)	43 (4)	0	0	0	NA	4 (13%)
~	Ma (2013) <sup>22</sup>	201 (51)	111 (31)	NA	24 (8)	$31(9\%)^*$	10 (3%)	17 (4%)	10 (3%)	NA
4	Roselli (2013) <sup>14</sup>	NA	NA	28 (4)	NA	0	2 (12%)	0	1(6%)	NA
5	Tamura $(2014)^{17}$	$163^{*}$	NA	34*	$69^*$	0	1 (4)	0	3 (12%)	1 (4)
5	Shen $(2012)^{21}$	159(60.1)	116.3 (39.9)	38 (16.9)	40.1 (21.2)	3 (8%)	0	2(5%)	NA	0
7	Shi $(2011)^{20}$	107.9 (17.7)	79.7 (15.8)	35.5 (7.1)	35.5 (7.1)	1(2%)	0	0	NA	2 (4%)
~	Sun $(2011)^3$	197 (47)	107 (27)	NA	24 (9)	7 (5%)	4 (3%)	3 (2%)	1(1%)	5(3%)
6	Uchida (2011) <sup>16</sup>	178 (48)	NA	NA	78 (18)	2(3%)	2 (3%)	0	3 (4%)	4 (5%)
10	Chen $(2010)^{19}$	213.2 (47.2)	141.9 (32.5)	27.2 (6.8)	38.8 (9.7)	4 (14%)	3(11%)	NA	2(7%)	1 (4%)
11	Pochettino (2009) <sup>18</sup>	245 (39)	NA	60 (13)	NA	5 (14%)	1 (3%)	3 (8%)	6 (17%)	NA
* Early	mortality.									

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FIGURE 2. Meta-analysis for (A) in-hospital mortality, (B) stroke, (C) spinal cord injury, (D) renal failure, and (E) reoperation for bleeding.

Event rate and 95% CI

Study name	Event rates	Lower limit	Upper limit	Z-Value	<b>P-Value</b>	
Xiao (2014)	0.07	0.06	0.09	-18.08	0.000	1
Hoffman (2013)	0.08	0.06	0.10	-18.05	0.000	
Ma (2013)	0.08	0.06	0.11	-12.59	0.000	
Roselli (2013)	0.08	0.06	0.10	-18.10	0.000	
Tamura (2013)	0.08	0.06	0.10	-18.07	0.000	
Shen (2012)	0.08	0.06	0.10	-17.79	0.000	
Shi (2011)	0.08	0.06	0.10	-17.91	0.000	
Sun (2011)	0.08	0.06	0.11	-16.59	0.000	
Uchida (2011)	0.08	0.06	0.10	-17.60	0.000	
Chen (2010)	0.08	0.06	0.10	-17.99	0.000	
Pochettino (2009)	0.07	0.06	0.10	-17.91	0.000	
Combined effect	0.08	0.06	0.10	-18.25	0.000	
						-0

#### Statistics with study removed

FIGURE 3. Sensitivity analysis for in-hospital mortality.

estimates did not vary markedly with the removal of the studies, indicating that the meta-analysis had good reliability and the data was not overly influenced by each study. The results via Egger test showed that there was no publication bias for the findings with regard to in-hospital mortality (t = 1.139, 1-tailed, P = 0.142, Figure 4).

#### Quality Assessment

The modified 18-item Delphi checklist was used to assess the quality of the included studies (Table 3). In general, the quality across the reported studies was high. However, the lack of reporting of several important experimental characteristics may have affected overall quality of several of the included studies. All of the studies were single-site studies. Six<sup>3,14,15,18,20,21</sup> of the 11 studies did not report if the patients were recruited consecutively. Four did not report the length of follow-up postsurgery,<sup>3,14,18,22</sup> and none reported the percentage of patients who were lost to follow-up. Two studies<sup>19,21</sup> did not report adverse events.

# DISCUSSION

Our meta-analysis investigated the efficacy and safety of the frozen elephant technique when applied for the treatment of acute type A aortic dissection. We found that, overall, the inhospital rate was 8%, and the rate of stroke, spinal cord injury,



**FIGURE 4.** Funnel plot for publication bias for in-hospital mortality.

renal failure, and frequency of reoperations resulting from bleeding was  $\leq$ 5%. Sensitivity and publication bias analyses indicated that the findings are robust; none of the study overly influenced the findings and there was no publication bias. Overall, the included studies were of high quality. These findings indicate that the frozen elephant techniques does not bring unacceptable mortality or morbidity risk for treating acute type A aortic dissection.

0.00

0.25

0.50

-0.25

Our findings are consistent with several prior metaanalyses that assessed the safety and efficacy of hybrid aortic arch replacement for treating aortic arch pathologies. Cao et al<sup>10</sup> performed a systematic review of periprocedural mortality and neurologic outcomes of hybrid procedures to treat aortic arch dissection and other aortic diseases. The pooled data came from 50 studies that included 1886 patients. Perioperative mortality across all hybrid techniques and aortic pathologies had a pooled event ratio of about 11%, and perioperative stroke and spinal cord ischemia had pooled ratios of 6.9% and 6.8%, respectively. For dissected aorta, the pooled rate was 9.8% for mortality rate, 4.3% for stroke, and 5.8% for spinal cord ischemia. The authors conclude that hybrid repair carries minimal risk of perioperative mortality and neurologic morbidity.

Moulakakis et al11 performed a systematic review and meta-analysis that evaluated the efficacy of hybrid techniques in patients with aortic arch pathologies. They included 46 studies in the analysis that consist of 2272 patients. Of the included studies, 26 studies (n = 956 patients) reported aortic debranching procedures and 20 studies (n = 1316 patients) performed either stented or frozen elephant trunk technique. The pooled estimate for the 30-day/in-hospital stay mortality for elephant trunk technique was 9.5% and for the arch debranching was 9.5%. Irreversible spinal cord injury symptoms were 5.0% and 3.6%, respectively. Cerebrovascular events were low, 6.2% for elephant trunk technique and 7.6% for arch debranching. Similar to Cao et al,<sup>10</sup> the authors conclude that hybrid repair, including elephant trunk technique, provides a safe alternative to open repair. Although the authors do note that stroke and mortality rates are still a concern.

Only 1 prior meta-analysis by Tian et al<sup>9</sup> focused on the safety and efficacy of the frozen elephant trunk technique. However, in contrast to our study, they assessed the use of this technique to treat multiple aortic pathologies. Their analysis included 17 observational studies. The pooled mortality was

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TAL	<b>3LE 3.</b> Summary of Quality Assessment											
	First Author (Year)	Xiao (2014) <sup>23</sup>	Hoffman (2013) <sup>15</sup>	Ma (2013) <sup>22</sup>	Roselli (2013) <sup>14</sup>	Tamura (2014) <sup>17</sup>	Shen (2012) <sup>21</sup>	Shi (2011) <sup>20</sup>	Sun (2011) <sup>3</sup>	Uchida (2011) <sup>16</sup>	Chen (2010) <sup>19</sup>	Pochettino (2009) <sup>18</sup>
-	Is the hypothesis/aim/objective of the study clearly stated in the abstract, introduction or methods socion9	Y	Y	Y	Υ	Υ	Υ	Y	Y	Ч	Υ	Y
7	Are the characteristics of the partici- pants included in the study described?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Υ	Υ
ω4	Were the cases collected in >1 center? Are the eligibility criteria (inclusion and exclusion criteria) to entry the	ΥX	ZΥ	ΥX	Ζ≻	Ζ≻	ΧΥ	ХY	ХY	ЧX	ZΥ	ΥX
2	where participants recruited consecutives to the sector to the sector of the sector to the sector of	Y	Z	Y	Z	Υ	Z	Z	Z	Υ	Υ	z
9	Did participants enter the study at a	Y	Υ	Υ	Y	Y	Y	Υ	Υ	Υ	Υ	Υ
Г	Was the intervention clearly described in the study?	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Y
$\infty$	Were additional interventions (cointer- ventions) clearly reported in the shidy?	Z	Z	Z	Z	Z	Z	Z	Z	Z	Z	Z
6	Are the outcome measures clearly defined in the introduction or methods section?	Y	Y	¥	Y	Y	¥	Y	Y	Y	Υ	Y
10	Were relevant outcomes appropriately measured with objective and/or sub- iective methods?	Y	Y	¥	¥	¥	Υ	Y	Y	Y	Υ	Y
11	Were outcomes measured before and after intervention?	Z	Z	Z	Z	Z	Z	Z	Z	Z	Z	Z
12	Were the statistical tests used to assess the relevant outcomes annronriate?	Υ	Y	Υ	Y	Y	Υ	Υ	Υ	Υ	Υ	Y
13	Was the length of follow-up reported?	Υ	Υ	Z	Z	Υ	Υ	Υ	Z	Υ	Υ	Z
14 15	Was the loss to follow-up reported? Does the study provide estimates of the	zz	ΖZ	zz	ΖZ	ΖZ	zz	ΖZ	zz	ΖZ	ΖZ	ΖZ
	random variability in the data analysis of relevant outcomes?											
16 17	Are adverse events reported? Are the conclusions of the study sup	ХX	ΥΥ	ΥY	ХX	ХX	zγ	ΥΥ	ЧY	YY	ХY	YY
18	ported by results? Are both competing interest and source of support for the study reported?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Z	= No, Y = Yes.											

8.3%, stroke was 4.9%, and spinal cord injuries were 5.1%. Five of the studies reported the 5-year survival to be between 63% and 88%. They found a strong linear correlation of length of time for cardiopulmonary bypass, myocardial ischemia, and circulatory arrest with perioperative mortality.

The elephant trunk technique requires 2 stages of the operation. Across different studies that evaluated the use of this technique, each stage of the operation is associated with a certain degree of mortality: first-stage mortality rate ranged from 0% to 32.1%, and second stage ranged from 0% to 33.3%.<sup>24</sup> The mortality at each stage indicates a limitation of the staged approach.<sup>24</sup> The frozen elephant technique involves a 1-stage repair. Several studies indicate that the mortality associated with the single-stage frozen elephant trunk technique ranges from 0% to 12.8%.<sup>24</sup> In 2 studies that compared conventional and frozen elephant trunk technique, the rate of inhospital deaths was similar between the techniques; the mean in-hospital mortalities for elephant trunk technique were 21.6%<sup>25</sup> and 13.9%,<sup>26</sup> and for frozen elephant trunk technique were  $8.7\%^{25}$  and  $4.8\%^{26}$  ( $P \ge 0.100$ ). In one of the studies,<sup>25</sup> but not the other, the frozen elephant trunk technique was associated with new-onset paraplegia (P < 0.001). In both the studies, permanent neurologic dysfunction was similar between treatments (P > 0.05). These findings support the finding that the frozen elephant technique is associated with an acceptable mortality rate.

There are several limitations to our analysis that should be considered when interpreting the results. The number of comparative studies included in our analysis was too small to perform a comparison of the frozen elephant technique with other techniques to treat type A aortic arch dissection. Most of the included studies were retrospective in design and differences in surgical parameters and patient baseline characteristics may partially explain the heterogeneity seen across the studies and possibly affect our results. There was little information in the included studies regarding long-term survival, indicating the need for well-designed long-term studies to investigate this question.

In conclusion, our analysis found that frozen elephant trunk technique for aortic arch dissection did not result in unacceptable rates of mortality and morbidity risks. Although this analysis did not compare elephant trunk technique to another method(s), it still gives insight into the use of this technique and highlights the need for prospective studies that compare different open conventional or other hybrid techniques with the frozen elephant technique.

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