Perspective

Zone zero hybrid arch exclusion versus open total arch replacement

Ourania Preventza[1,2], Corinne W. Tan[2], Vicente Orozco-Sevilla[2], Caleb J. Euhus[2], Joseph S. Coselli[1,2]

[1]Department of Cardiovascular Surgery, Texas Heart Institute, Houston, TX, USA; [2]Division of Cardiothoracic Surgery, Baylor College of Medicine, Houston, TX, USA

Correspondence to: Ourania Preventza. Division of Cardiothoracic Surgery, Baylor College of Medicine, Houston, TX, USA; Department of Cardiovascular Surgery, Texas Heart Institute, 6770 Bertner Avenue, Houston, TX 77030, USA. Email: opsmile01@aol.com.

Open total aortic arch replacement is one of the most technically demanding operations in cardiothoracic surgery, requiring operator expertise and intraoperative and postoperative teamwork. Despite current advancements in the field of open aortic surgery with regard to intraoperative brain protection and postoperative care, the morbidity and mortality associated with open total arch operations varies. Endovascular and hybrid procedures involving the use of zone 0 as a landing zone allow fair comparison between open total arch and hybrid operations. Hybrid procedures involving all of the other landing zones [1–4] should not be compared with open total arch replacement, as the extent of the pathology is different.

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Introduction

Because of their complexity, open total arch operations are limited to specialized aortic centers. In a recent large (N=3,265) retrospective study of open total arch replacement cases in the ARCH international aortic database, in-hospital mortality at specialized centers was more than 10%, and the permanent neurologic deficit rate was more than 6.7% (1). In an effort to minimize the morbidity and mortality associated with these procedures, various catheter-based repair techniques called hybrid procedures have been developed to perform arch replacement by using commercially available endovascular technology or custom-made devices.

Open total arch replacement

Cooley and colleagues in 1955 reported the first aortic arch replacement (2), and Griepp and colleagues in 1975 introduced the application of hypothermia in aortic surgery by describing four cases of arch replacement involving hypothermic cardiac arrest (3). Newer open techniques and adjuncts have been developed to facilitate the conduct of the operation and to decrease associated morbidity and mortality (4-10). Our technique has evolved over the years with regards to brain protection, target temperature, cannulation strategy and cerebral perfusion. The following are some of the technical aspects of the open approach.

Depending on the individual case, different cannulation sites for cardiopulmonary bypass (CPB) have been used, such as the right axillary, innominate, right common carotid, and femoral arteries, usually either through a Dacron graft or by direct aortic cannulation for arterial inflow. Our most recent cannulation strategy has just been published (11). In cases of redo sternotomy with proximity of the ascending aorta and aortic arch to the sternum, right axillary artery cannulation with a side graft is our first choice. The target nasopharyngeal temperature is approximately 21 to 25 ℃, and the near-infrared spectroscopy signals are monitored during the procedure. The different reconstruction techniques include island patch configuration with two or all three head vessels implanted and the Y-graft aortic arch repair with a prefabricated or custom-made bifurcated

(Y), trifurcated (double-Y), or single graft (Vascutek Ltd., a subsidiary of Terumo Corporation, Renfrewshire, Scotland), or a combination of these techniques.

We perform the elephant trunk (ET) procedure if the extent of aortic pathology warrants it. We use the side arm of the skirted ET Gelweave graft (Vascutek Ltd., Ann Arbor, Michigan, USA) for the purpose of maintaining full flow and perfusing the lower body distally during the aortic reconstruction after the distal anastomosis is completed. The length of the ET is approximately 8 cm and is limited to no more than 10 cm in an effort to prevent spinal cord ischemia. Even in cases when we use the frozen elephant trunk technique (FET), we do not cover more than 10–15 cm of the descending thoracic aorta, which others also have recommended to avoid spinal cord injury.

Regardless of the repair, antegrade cerebral perfusion (ACP) is our current and sole choice for cerebral perfusion during circulatory arrest. In all total arch operations, ACP is administered bilaterally via the right and left common carotid artery (LCCA) at a flow rate of 10 mL/kg/min. In cases where the regional cerebral oxygen saturation reading from near-infrared spectroscopy decreases to less than 10% of the patient's baseline measurement, we increase the flow to 13 mL/kg/min. Bilateral ACP is easily administered via a 9F Pruitt balloon-tip catheter inserted into the branches of the Y graft or, in cases of island arch repair, directly into the LCCA (LeMaitre Vascular, Burlington, Massachusetts, USA). The hybrid type III approach (12) is an open total arch operation used to treat the entire "mega-aorta" in one or two stages; the endovascular repair is performed on the descending thoracic aorta, and the "stented" landing zone facilitates the subsequent endovascular operations in the second stage (13,14). Type III arch repair, although it is described as "hybrid arch repair", should not be included and mixed with the hybrid techniques involving zone 0, because the patients and the stented area are different. As others have advocated (15), we limit the use of single-stage repair because of the associated risk of spinal cord ischemia. A specific device designed for this approach has been embraced widely in Europe; it involves the use of the Thoraflex hybrid prosthesis (Vascutek Ltd., Inchinnan, Glasgow, UK) (16) and the E-vita open stent-graft (JOTEC GmbH, Hechingen, Germany) (17). A national clinical trial of the Thoraflex hybrid prosthesis is currently underway in the United States (https://clinicaltrials.gov/ct2/show/NCT02724072).

Zone 0 landing zone and hybrid arch exclusion

Nikolay Volodos' team performed the first hybrid aortic arch repair in 1991 (18); in 2013, Volodos reported that the patient was still alive and the stent graft was stable (19). Since then, great strides have been made in endovascular technology for treating aortic pathology. A totally endovascular approach is being developed that uses custom-made devices (20), which raises the question of device durability. When we discuss hybrid arch operations that are comparable to open total arch repair, the hybrid procedure should involve debranching the supra-aortic arch vessels: if not all of them, then at least the innominate artery, the LCCA, or both (12,21,22). This approach avoids hypothermic circulatory arrest, CPB and aortic cross-clamping. In hybrid type II arch repair, CPB is required, the ascending aorta is replaced with a Dacron graft and the Dacron graft in the ascending aorta is considered zone 0. The hybrid procedure can be performed via median sternotomy or left thoracotomy, using the descending thoracic aorta for arterial inflow, if the median sternotomy is prohibitive (22). A series of extra-anatomic bypasses with arterial inflow to the iliac arteries have also been reported (23). The different landing zones have been described (24) as follows: zone 0 is in the ascending aorta, proximal to the brachiocephalic artery; zone 1 covers the aortic arch between the brachiocephalic artery and the LCCA; zone 2 covers the part of the arch between the LCCA and the left subclavian artery (SCA); zone 3 covers the proximal descending thoracic aorta distal to the left SCA; and zone 4 covers the mid-descending thoracic aorta.

Patel and colleagues (25,26), in an analysis of 721 cases performed over 17 years at the University of Michigan, echo concerns from the Stanford group, that the majority of patients with proximal disease have aneurysm of the root and proximal ascending aorta with a "complex anatomy of the sinuses, sinotubular junction (STJ) and coronary ostia", making zone 0 hybrid debranching procedures challenging. In the classic zone 0 hybrid debranching procedure, classification described by Bavaria and colleagues (27), type IA involves the end-to-side anastomosis of a 4-branched graft to the ascending aorta, which is usually performed off bypass with a side-biting clamp on the ascending aorta. In contrast, type IB is done when there is limited amount of aorta between the STJ and the ascending aorta; full CPB and cross-clamping are required. The type II aortic arch repair is done when the native proximal aorta is unsuitable for grafting. This operation requires constructing the

Table 1 Contemporary series of open total arch procedures (frozen elephant trunk series not included)

First author, year	Study period	N	In-hospital mortality	Permanent stroke	Permanent SCI/ paraplegia	Permanent renal failure	Follow-up time
Kazui, 2007 (5)	1986–2006	420 TAR, 472 total	9.3%*	3.2%*	NA	NA	NA
Sundt, 2008 (28)	1993–2007	95 TAR, 347 total	16.8%	9.5%*	NA	8%*	NA
Bischoff, 2010 (4)	1999–2009	206	6.8%	3.4%	NA	1%	3.7 years (median)
Kulik, 2011 (29)	2002–2010	88	5.7%	3.4%	3.4%	3.4%	2.9±2.3 years
LeMaire, 2011 (6)	2006–2009	55	2%	5%	NA	5%	483±221 days
Patel, 2011 (26)	1993–2009	587 TAR†, 721 total	5%*	4.7%*	NA	1.9%*	52.6±39.9 months
Misfeld, 2012 (30)	2003–2009	182 TAR, 636 total	11.3%*	11.3%*	NA	14.6%	4.9±0.1 years
Thomas, 2012 (31)	2001–2010	65 TAR, 209 total	6%‡	6%§	NA	3%	NA
Zierer, 2012 (32)	2000–2011	318 TAR, 1,002 total	5%*	2.5%*	0.3%	4%*	NA
Okita, 2013 (8)	2002–2012	423	4.5%	3.3%	0.6%	3.1%§	2.3±2.3 years
Hiraoka, 2014 (33)	2008–2012	158	7%	8.2%	NA	NA	NA
Leshnower, 2014 (7)	2004–2012	145	9.7%	2.8%	0	2.8%	33 months
Preventza, 2015 (9)	2005–2013	274	10.2%	5.5%	0.7%	1.1%	4.5 years (median)

All Ns and percentages refer to total arch replacement patients only unless otherwise specified. Follow-up times are reported as means unless otherwise noted. *, refers to the entire cohort and not only the total arch replacement patients; †, it is unclear how many of these procedures were total arch replacements. We infer that 587 of them were because they involved bypass to the innominate (n=296), left common carotid (n=216), or subclavian artery (n=75); ‡, the in-hospital mortality rate was 5.5% for patients who underwent elective procedures and 10% for those who underwent emergency procedures; §, not specified as temporary or permanent. NA, not available in published article; SCI, spinal cord injury; TAR, total arch replacement.

landing site, zone 0, with a Dacron graft in the ascending aorta. The type III "hybrid" operation, as mentioned previously, is really an open total arch procedure in which the descending thoracic aorta is the stented segment.

Our hybrid approach involves median sternotomy and mobilizing the brachiocephalic vessels. Near-infrared spectroscopy is used during the supra-aortic vessel debranching, and the systemic mean aortic pressure is kept at 80 to 100 mmHg during the head-vessel reconstruction. This reconstruction involves the use of a prefabricated Y graft (Vascutek) or a custom-made version prepared at the operating table. We begin the reconstruction by attaching the main body of the graft to the right anterolateral aspect of the ascending aorta. During this anastomosis, we keep the mean arterial pressure (MAP) low (50–60 mmHg). The head-vessel debranching is performed distally to proximally by revascularizing the left SCA first (end-to-end anastomosis) and then the LCCA and innominate artery. During these anastomoses, the MAP is kept between 80 and 100 mmHg. If the left SCA is not accessible through the median sternotomy, a left carotid-to-subclavian bypass is done via a left supraclavicular incision during the same operation or a subsequent one. If the left vertebral artery originates from the arch, it is directly reattached to the side of the Y graft, the LCCA, or the left SCA. The endovascular exclusion of the arch is performed by delivering a stent antegrade or retrograde, according to the surgeon's preference and the quality and size of the iliofemoral vessels. If the ascending aorta is more than 4 to 4.5 cm in diameter and we believe that the patient can tolerate CPB, we tend to replace the ascending aorta under CPB to prevent ascending aortic dissection. When more than 15 cm of the descending aorta is covered, a cerebrospinal fluid (CSF) catheter is inserted, and CSF is drained intraoperatively and postoperatively. In addition, we protect the spinal cord by increasing the MAP to 90 to 100 mm Hg after stent deployment.

Contemporary results

Tables 1,2 show open total arch replacement results from

Table 2 Contemporary series of hybrid arch procedures exclusively with zone 0 as proximal landing zone

First author, year	Study period	No. zone 0 hybrid/ debranching procedures	In-hospital mortality	Permanent stroke	Permanent SCI/ paraplegia	Permanent renal failure	Follow-up time	RAAD	Endoleak
Gottardi, 2008 (34)	1996–2007	13 zone 0, 73 all zones	23.1%	0	NA	NA	37 months	NA	24.6% early, 13.6% late
Weigang, 2009 (35)	NA	26 zone 0	15.4%	0	0	NA	NA	NA	3.8%
Geisbusch, 2011 (36)	1997–2009	15 zone 0, 47 all zones	27%	0	0	13.3%	21.4 months	6.7%	0
Czerny, 2012 (37)	2003–2011	66 zone 0 (5 centers)	9%	5%	3%	NA	25 months	7.6%	22.6% early, 9.1% late
Ferrero, 2012 (38)	2005–2010	11 zone 0, 27 all zones	9.1%	0	0	NA	11.8±9.7 months	NA	3.7% late*
Melissano, 2012 (39)	1999–2011	32 zone 0, 143 all zones	9.4%	9.4%†	0	0	5 years	NA	6.2% early, 3.1% late
Vallejo, 2012 (23)	2002–2012	27 zone 0, 38 all zones	29.6%	7.4%†	3.7%	7.4%	28.1 months	3.7%	3.7% early, 7.4% late
Andersen, 2013 (40)	2005–2012	48 zone 0, 87 all zones	20.8%	4.2%†	0	4.2%	28.4±21.5 months	11.1%‡	17%§
Bavaria, 2013 (12)	2005–2012	36 zone 0, 47 all zones	8%	8%†	6%	3%	30±21 months	2.8%	0
Cochennec, 2013 (41)	2004–2011	7 zone 0, 17 all zones	14%	14%	0	NA	13 months	14.3%	28.6%
Kent, 2014 (42)	2007–2012	20 zone 0 (2 centers)	5%	5%	0	0	18.5±15.3 months‖	NA	15% early
Preventza, 2015 (9)	2005–2013	45 zone 0	11.1%	8.9%	0	0	4.5 years	0	NA
Faure, 2016 (43)	2005–2015	11 zone 0, 33 all zones	9%	18%†	9%†	NA for zone 0	24.3 months	0	9% late
He, 2016 (44)	2012–2015	16 zone 0, 43 all zones	6.25%	0	0	6.25%*	15 months	0	2.3% early*, 4.8% late*
Aalaei-Andabili, 2017 (45)	2010–2015	48 zone 0	17%	6%†	2%	10.4%	17 months	NA¶	5% late

All Ns and percentages refer only to patients who underwent zone 0 procedures unless otherwise specified. Follow-up times are reported as means unless otherwise noted. *, refers to entire cohort (not just to patients who underwent zone 0 procedures); †, not specified as permanent or temporary; ‡, percentage represents 3 out of 27 patients who were at risk because their landing zone was in the native ascending aorta; §, not specified as early or late; ‖, 17.5 months is reported in the text, whereas the abstract says 18.5 months; ¶, type II repair only; not at risk for RAAD. NA, not available in published article; RAAD, retrograde ascending aortic dissection; SCI, spinal cord injury.

various well-known aortic centers and results on zone 0 procedures in which the stent graft is landed in the ascending aorta and debranching of the supra-aortic vessels has occurred. Although there are no randomized controlled trial data to support any particular approach for treating aortic arch pathology, a few comparative studies (*Table 3*) have examined the outcomes of traditional arch repair versus zone 0 hybrid repair. Benedetto and colleagues (52) identified four comparative observational studies of open total arch replacement versus hybrid thoracic endovascular aortic repair that included a total of 378 cases (269 open, 109 hybrid). Their pooled analysis did not show any

Table 3 Comparative series with zone 0 as proximal landing zone (hybrid debranching) versus open total arch procedures

First author, year	Study period	No. zone 0 hybrid procedures	No. open procedures	Outcomes of hybrid *vs.* open repairs				Follow-up time	RAAD	Endoleak
				Death	Permanent stroke	Permanent SCI/ paraplegia	Permanent renal failure			
Milewski, 2010 (21)	2000–2009	19 zone 0*, 66 all zones	52 total arch (45 elective), 1,196 all open arch	11% *vs.* 16%[†] (P=0.7)	4% *vs.* 9%[†] (P=0.644)	7% *vs.* 0%[†] (P=0.137)	11% *vs.* 7%[†] (P=0.66)	13.3 months (hybrid), 22.7 months (open)[†]	NA	NA
Murashita, 2012 (46)	2007–2010	4 zone 0, 27 all zones	191[‡]	3.7%[§] *vs.* 7.8%	7.4%[§‖] *vs.* 4.7%[‖]	7.4%[§] *vs.* 0%	3.7%[§‖] *vs.* 1.6%[‖]	7 months (median)	NA	7.4%[§]
Iba, 2014 (47)	2008–2013	14 zone 0, 50 all zones	143	2%[§] *vs.* 3% (P=0.76)	6%[§] *vs.* 2% (P=0.17)	0% *vs.* 0%	0% *vs.* 1%[‖] (P=0.40)	25±16 months	NA	0% *vs.* 0%
Sood, 2014 (48)	1993–2013	11 zone 0, 44 all zones	93	7%[§] *vs.* 8% (P=0.936)	5%[§] *vs.* 8% (P=0.511)	0%	2.3% *vs.* 4.3% (P=0.554)	66 months	NA	4.5%[§]
De Rango, 2015 (49)	2007–2013	23 zone 0, 71 all zones (0 and 1)	29	8.6%[§] *vs.* 13.8% (P=0.4)	5.6%[§] *vs.* 3.4% (P=1)	2.8%[§] *vs.* 0% (P=0.5)	NA	26.2 months	4.2%[§]	4.2%[§]
Preventza, 2015 (9)	2007–2015	45	274	11.1% *vs.* 10.2% (P=0.79)	8.9% *vs.* 5.5% (P=0.32)	0% *vs.* 0.7% (P=1.0)	0% *vs.* 1.1% (P=1.0)	4.5 years	0%	NA
Tokuda, 2016 (50)	2002–2014	33 zone 0, 58 all zones	124	3.4%[§] *vs.* 0% (P=0.1)	17%[§‖] *vs.* 12%[‖] (P=0.36)	1.7% *vs.* 0.8% (P=0.54)	3.4%[§] *vs.* 0.8% (P=0.24)	52.5 months	NA	NA
Narita, 2016 (51)	2008–2014	35	26 (ET + TEVAR)	5.7% *vs.* 0% (P=NS)	11.4% *vs.* 7.7% (P=NS)	2.9% *vs.* 3.8% (P=NS)	5.7% *vs.* 0%[‖] (P=NS)	309 days	5.7% *vs.* 0% (P=NS)	2.9% *vs.* 27% (late) (P=NS)

*, type I, n=17; type II arch, n=2 (stent landed in zone 0 for all 19 type I and II procedures); type III arch, n=8; †, these numbers refer to the 27 hybrid procedures and the 45 elective open total arch procedures; ‡, death, paraplegia, stroke, and renal failure rates are not reported for the open procedures; §, for all zones (rather than just zone 0); ‖, not specified as permanent or transient. ET, elephant trunk; NA, not available in published article; RAAD, retrograde ascending aortic dissection; SCI, spinal cord injury; TEVAR, thoracic endovascular aortic repair; NS, not significant.

significant reduction in mortality in the hybrid group. Our study (9) echoes these findings: survival during the 4.5-year follow-up period was similar between the hybrid and traditional cohorts. The two propensity-matched subgroups did not differ with regard to survival (85.7% for the hybrid and 69.6% for the traditional group, P=0.29). Numerous studies in the literature are confusing, using the terms "hybrid" and "debranching" interchangeably and often not distinguishing among the different landing zones (Z0–Z3) and hybrid procedures (I, II, and III). Given the multiple partial and complete revascularization approaches and the heterogeneity of the patient population, it is challenging to compare apples to apples.

Conclusions

In the treatment of total aortic arch pathology, the traditional open repair remains the gold standard. The expansion of hybrid zone 0 repair promises a new treatment avenue for high-risk patients who may not be able to tolerate a prolonged standard open repair with CPB and circulatory arrest. However, definitive conclusions cannot yet be drawn about the superiority of one treatment versus the other. Rather, the choice of repair technique is influenced by patients' comorbidities and age. A better definition of the "high-risk patient" is required, and careful review of the literature is imperative.

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Footnote

Conflicts of Interest: Dr. O Preventza is a consultant for W.L. Gore and Associates, is a former Medtronic consultant, and participates in clinical studies for Medtronic, Gore, and Vascutek Terumo. Dr. JS Coselli is a consultant for Vascutek Terumo, Gore, and Medtronic; receives royalties from Vascutek Terumo; and participates in trials for Vascutek Terumo, Gore, Medtronic, Bolton Medical, Abbott, and Edwards Lifesciences. The other authors have no conflicts of interest to declare.

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