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2	Procedure?
3	Running head: Recoarctation of the Aorta after Norwood
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### 17 Abstract

- **Background:** This study aimed to evaluate whether pre- and post-operative anatomic factors affect
- 19 the incidence of recoarctation of the aorta (reCoA) after the Norwood procedure for hypoplastic left
- 20 heart syndrome.
- 21 Methods: This retrospective study included 46 patients who underwent Norwood procedure with right
- ventricle-to-pulmonary artery conduit between 2009 and 2017. Anatomical factors such as
- preoperative length, diameter of the main pulmonary artery (MPA), and postoperative neo-aortic arch
- angle stratified by arch reconstruction technique were analyzed using the receiver operating
- 25 characteristic analysis.
- **Results:** Eleven patients needed surgical intervention for reCoA at stage 2. Out of the 29 patients who
- 27 underwent direct anastomosis during arch reconstruction, seven developed reCoA. Six patients
- received the bridge technique (patch augmentation for both lesser and greater curvatures) and were all
- spared from reCoA. Among the patients who had direct anastomosis, the preoperative MPA length
- 30 was linearly correlated with the postoperative arch angle (P=0.028) and was associated with the
- 31 occurrence of reCoA (P=0.003), and the best cutoff value for MPA length was 9.5 mm. The
- 32 postoperative arch angle was also correlated with the incidence of reCoA (P<0.001) and was larger in

- patients who underwent the bridge technique than in patients who had direct anastomosis (128° vs.
- 34 112°, *P*=0.004) despite comparable MPA length.
- **Conclusions:** The Norwood procedure with direct anastomosis can be performed in patients with a
- 36 longer preoperative MPA since a shorter MPA poses a potential risk for reCoA. In this case, the bridge
- 37 technique should be considered to attain a large and smooth neo-aortic arch.

# **Abbreviations**

MPA	main pulmonary artery
ROC	receiver operating characteristic
reCoA	recoarctation of the aorta
RV-PA	right ventricle-to-pulmonary artery
MDCTA	multidetector computed tomographic angiography
AUC	area under the ROC curve
HLHS	hypoplastic left heart syndrome
CI	confidence interval

### Introduction

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Recoarctation of the aorta (reCoA) after the Norwood procedure for hypoplastic left heart syndrome (HLHS) has been reported in 11–37% of the patients<sup>1,2</sup>. Aortic arch obstruction increases afterload in the systemic ventricle, resulting in ventricular dysfunction, tricuspid regurgitation, and an imbalance in the ratio of the systemic-to-pulmonary blood flow<sup>3</sup>. A number of theories have been proposed to explain the underlying cause of reCoA, namely caliber changes through the arch, remaining ductal tissue and coarctaion shelf, and tensed anastomosis of a native tissue-to-tissue connection<sup>3,4</sup>. Recent studies investigated the relationship between aortic geometry and the incidence of reCoA, and concluded that arch angle augmentation with pericardium creates a smoother arch angle and a lower frequency of reCoA<sup>4,5</sup>. Herein, we aimed to describe the incidence of reCoA after the Norwood procedure for HLHS in the last 10 years at Okayama University Hospital and evaluate whether preoperative anatomic factors, such as the main pulmonary artery (MPA) geometry, affect the postoperative neo-aortic arch angle and occurrence of reCoA.

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### **Patients and Methods**

Fifty-nine consecutive patients with HLHS underwent the Norwood procedure with right ventricle-topulmonary artery (RV-PA) conduit at Okayama University Hospital between January 2009 and

October 2017. Three patients passed away in the hospital after stage 1 Norwood procedure, and another three patients passed away after discharge. reCoA was defined by the need for surgical intervention, either with an indication of > 10 mmHg at the narrowing point measured by a catheter or a discrete narrowing seen by multidetector computed tomographic angiography (MDCTA) before stage 2. Thirteen (24.5%) of the surviving 53 patients developed reCoA. We retrospectively reviewed 53 patients who underwent the bidirectional Glenn procedure. Seven patients were excluded (echo data were not available, n=5; not followed up, n=1; double patent ductus arteriosus, n=1). Data were analyzed in 46 patients who were divided into two groups: group R (reCoA group, n=11) and group N (non-reCoA group, n=35). The exclusion criteria are outlined in a flow diagram (Figure 1). This study was approved by the Institutional Review Board of the hospital, and the requirement of informed consent was waived due to the observational nature of the study. A thorough review of medical records was conducted, and preoperative, intraoperative, postoperative, and follow-up data were collected.

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71 Surgical Technique

The Norwood procedure with RV-PA conduit was performed as previously described<sup>6,7</sup>. Further detailed updated operative procedures, especially for the reconstruction of the neo-aortic arch without

patch material, were recently reported<sup>8</sup> (Figure 2A). Because homografts are not commercially available in Japan, arch reconstruction without patch supplementation is always the first choice. Briefly, we describe several key points of the surgical techniques for arch reconstruction. First, the MPA was transected just proximal to the bifurcation in a triangular shape using a "fish mouth" incision, to create longer anterior and posterior flaps of tissue to keep the proximal MPA as much as possible. This incision technique makes the MPA 4–5 mm longer than the conventional straight incision. Second, we used a novel "proximal arch plication" technique to lower the reconstructed arch height, whereby the proximal aortic arch just opposite the site of the innominate artery was sutured anteriorly and posteriorly with interrupted sutures. These imbricating sutures enabled the reconstructed arch to be close to the MPA. Since 2011, a small piece of glutaraldehyde-treated pericardial patch is being used if the MPA tissue is of insufficient length to reconstruct the aortic arch without patch materials. The patch augmentation was classified as either "anterior patch" when applied to only the greater curvature (Figure 2B) or "bridge technique" when applied to both the lesser and greater curvatures like a bridge connecting the MPA and the descending aorta (Figure 2C). The ductus arteriosus tissue was completely excised in all the patients. The descending aorta and distal arch were directly anastomosed without the interdigitating technique.

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Geometry analysis of the MPA and aortic arch was performed by preoperative echocardiography or MDCTA before the Norwood procedure, and postoperative MDCTA before stage 2. Preoperative data of the following parameters were collected: (1) MPA length: length of the lesser curvature of the MPA between the pulmonary valve annulus and pulmonary artery bifurcation, the origin of the right pulmonary artery; (2) MPA diameter, diameter just below the bifurcation level; and (3) Des.Ao. diameter: diameter of the descending aorta at the level of the left bronchus (Figure 3A), measured by an echocardiographic investigator who was blinded to the clinical outcomes. Postoperative data of the following parameter were collected by left lateral oblique view of MDCTA: (4) Arch angle: an angulation between the two tangent lines from the highest points of the aortic arch to the centerline of the descending aorta (Figure 3B), measured by a radiologic technologist who was blinded to the clinical outcomes.

Statistical Analysis

Continuous variables are reported as median and interquartile range, while categorical variables are reported as absolute frequency and percentage. Continuous variables were compared using a Student's *t*-test or Mann-Whitney U test based on the normality of the data. Categorical variables were

compared using Fisher's exact tests or the chi-square test. Postoperative arch angle stratified by arch reconstruction technique was compared using the analysis of variance. Receiver operating characteristic (ROC) curves were calculated to determine the best cutoff value of preoperative and postoperative factors for reCoA. The accuracy of the tests was assessed by measuring the area under the ROC curve (AUC). Pearson's correlation coefficient was computed to investigate the association between each arch reconstruction technique and postoperative arch angle. The level of statistical significance was set at  $P \le 0.05$ . All statistical analyses were performed using SPSS version 22 (Chicago, IL, USA).

#### **Results**

The patient characteristics are outlined in Table 1. Eleven of the patients required surgical reintervention for reconstructed neo-aortic arch (group R), while the other 35 did not (group N). Age and body weight did not significantly differ between the two groups. The follow-up period was also comparable (group R: 89±27 months; group N: 73±30 months, P=0.393). More than half of the patients in both groups had direct anastomosis without using any materials (direct anastomosis group) (Figure 2A) (group R: 64%; group N: 63%, P=0.963) (Table 1). Patch augmentation for only the greater curvature (anterior patch group) (Figure 2B) was performed in four patients (36%) in group R

and seven patients (20%) in group N. All the patients who received the bridge technique (Figure 2C)

were spared from reCoA (group R: 0%; group N: 17%, *P*=0.141).

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128 Aortic Arch and Pulmonary Artery Geometry

The geometric data are summarized in Table 2. The preoperative MPA diameter did not differ

between the two groups (group R: 11.0 [9.7-11.4]; group N: 11.2 [10.0-13.0] mm, P=0.141). The

MPA length was significantly shorter in group R than in group N (group R: 8.5 [8.0–9.2]; group N:

9.8 [8.3–11.0] mm, P=0.009). The Des. Ao. diameter did not differ between the two groups (group R:

6.4 [5.7–7.0]; group N: 6.6 [6.0–7.1] mm, P=0.460). The postoperative arch angle was significantly

larger in group N than in group R (group R: 104 [98–105]°; group N: 117 [105–122]°, P<0.001).

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Impact of Preoperative Anatomical Factor on Reconstructed Neo-Aortic Arch

The pre- and post-operative measurements stratified by the arch reconstruction technique are

described in Table 3. Within the direct anastomosis group, the MPA length was significantly shorter in

group R than in group N (group R: 8.4 mm; group N: 10.5 mm, P=0.011), and the postoperative arch

angle was significantly larger in group N than in group R (group R: 100°; group N: 117°, P=0.002).

141 The MPA length (group R: 9.0 mm; group N: 10.3 mm, *P*=0.272) and postoperative arch angle (group

R: 105°; group N: 122°, *P*=0.159) did not differ between the two groups within the anterior patch
group. The postoperative arch angle in the bridge technique group was significantly larger than that in
the other groups (direct anastomosis group: 112°; anterior patch group: 119°; bridge technique group:
128°, *P* = 0.010). ROC curve analyses, performed in the direct anastomosis group with preoperative
factors to predict reCoA, revealed that only preoperative MPA length could predict reCoA with
statistical significance (AUC: 0.880; 95% confidence interval [CI]: 0.755–1.000; *P*=0.003) with the
best cutoff at 9.5 mm (sensitivity: 77.27%; specificity: 100.0%) (Figure 4).

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- 150 Relationship Between Postoperative Arch angle and Recoarctation of the Aorta
- 151 The ROC curve analysis demonstrated that postoperative arch angle was strongly associated with
- 152 reCoA (AUC: 0.905; 95% CI: 0.817–0.993; *P*<0.001) (Figure 5).

- 154 Impact of Arch Reconstruction Technique on Recoarctation of the Aorta
- Postoperative results were compared among the different arch reconstruction techniques (Table 4);
- none of the preoperative anatomical factors differed among them. The postoperative arch angle did not
- differ between the direct anastomosis and anterior patch groups (112° vs. 119°, *P*=0.817); however, it
- was significantly larger in the bridge technique group than in the direct anastomosis group (112° vs.

128°, P=0.004). The reCoA occurrence was more frequent in the direct anastomosis group than in the bridge technique group (7 vs. 0, P=0.178).

Figure 6 shows the correlations between preoperative MPA length and postoperative arch angle stratified by arch reconstruction technique. The MPA length was correlated with the arch angle in both the direct anastomosis ( $R^2$ =0.171, P=0.028) and anterior patch ( $R^2$ =0.385, P=0.041) groups; however, there was no correlation between them in the bridge technique group ( $R^2$ =0.392, P=0.184).

## **Comment**

In addition to achieving a smooth neo-aortic arch without any residual stenosis, we believe that arch reconstruction using only native tissue can minimize the potential disadvantage of inelastic patch material. More than half of the patients had direct anastomosis without using any materials; however, our strategy was shifted to use a patch augmentation only for the greater curvature, then for both the greater and lesser curvatures (bridge technique) during the last five years in cases where the MPA length seemed insufficient to reconstruct the neo-aortic arch directly. The key finding from our study was that only the preoperative MPA length was associated with the postoperative arch angle and occurrence of reCoA remarkably, and that the best cutoff value was 9.5 mm if the arch was reconstructed directly. In cases where the preoperative MPA length is shorter, other techniques should

be considered instead. Another important finding was that the bridge technique contributed to the attainment of a large and smooth neo-aortic arch. As a result, none of the patients in the bridge technique group suffered from reCoA.

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Impact of Main Pulmonary Artery on Direct Anastomosis

A tension free neo-aortic arch has been considered technically possible in all HLHS without the use of patch augmentation, even in the interrupted aortic arch, by extensively mobilizing the descending aorta, arch, and brachiocephalic artery<sup>9</sup>. Griselli and colleagues (2006) described that the management of arch reconstruction has changed from the original direct anastomosis to patch supplementation because direct anastomosis is technically demanding and surgeon-specific, requiring several technical adjustments for each individual patient<sup>10</sup>. Consequently, a number of modifications of arch reconstruction were introduced, namely, the full length of the small ascending aorta anastomosed endto-side to the anterior and rightward aspect of the MPA at the level of the sinotubular junction, along the longitudinal split of the medial descending aorta<sup>9</sup>. Lamers et al. (2012) reported excellent results with patch augmentation for both the greater and lesser curvatures together with an interdigitating technique<sup>11</sup>. In their study, the incidence of reCoA in all cohorts was 16% (23/142); the incidence decreased to 2% (1/63) with their combined technique. Due to the combined procedure, however, the

technique that contributed to the lower reCoA incidence was unknown. Asada and others (2017) reported an innovative "Chimney reconstruction" technique for direct anastomosis that divides the MPA very distally for the anterior 240°, extending the division line proximally into the posterior pulmonary sinus to create a U-shaped cuff<sup>12</sup>. Even with these techniques, including our technical modifications, arch reconstruction with direct anastomosis is still unfeasible in some cases. A recent study demonstrated that limited availability of native tissues in hypoplastic aorta led to a direct anastomosis of the neo-aortic arch, resulting in the distortion and narrowing of the neoaorta<sup>10</sup>. During arch reconstruction, the MPA has to be pulled up to the descending aorta. As the MPA plays a key role in connecting other structures, an insufficient length will result in excessive tension at the anastomosis site. Our study showed that MPA length < 9.5 mm was associated with postoperative reCoA; hence, the bridge technique, which extends the lesser curvature of the neo-aortic arch with patch material, is recommended in order to create a smooth arch angle and release the excessive tension.

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Neo-Aortic Arch Morphology and Recoarctation of the Aorta

Neo-aortic arch geometry has only been studied recently. Ou and colleagues (2008) classified the reconstructed aortic arch with simple coarctation of aorta patients by magnetic resonance angiography and performed flow mapping<sup>13</sup>. In comparison to the smooth Romanesque arch, angulated Gothic arch was more closely associated with an increased systolic central aortic stiffness and left ventricular mass

index, despite the absence of clinical evidence of reCoA. Itatani et al. (2012) reported a computational hemodynamic analysis of the reconstructed aorta of patients who underwent various types of aortic arch reconstruction in the Norwood procedure<sup>5</sup>. They showed that those who underwent arch reconstruction with a patch in the lesser curvature had a larger arch space, smoother curved reconstructed arch with no flow acceleration, lower energy loss, and lower wall share stress, compared to those who underwent arch reconstruction without patch material. Hasegawa and others (2015) demonstrated that the neo-aortic arch angle was larger in patients who underwent patch augmentation for the lesser curvature than in those who underwent direct anastomosis<sup>4</sup>. In the present study, the patients who underwent patch augmentation for both the greater and lesser curvatures had smooth arch angles and were entirely spared from reCoA as well as compression of the bronchus and branch PA due to narrow retroaortic space. Patch augmentation for only the greater curvature (anterior patch) did not contribute to preventing reCoA because the postoperative arch angle was already determined when the posterior wall of the MPA was anastomosed with the neo-aortic arch; it only increases the risk of utilizing artificial material. Additionally, the postoperative arch angle was correlated with the preoperative MPA length despite the use of an anterior patch, while a large postoperative arch angle was obtained using the bridge technique regardless of the preoperative MPA length.

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Arch Reconstruction with or without Patch

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Various materials have been used as patches for arch reconstruction, including cryopreserved homografts, autologous pericardium, and bovine pericardium. In North America and Europe, homograft patches have been used for neo-aorta augmentation. Due to its limited supply and exclusion by the national health insurance in Japan, glutaraldehyde-treated autologous pericardium patches are mostly used to prevent secondary shrinkage and aneurysmal formation instead. Our policy to reconstruct the neo-aortic arch with direct anastomosis as much as possible is based on a number of major concerns for patch materials. First, exogenous patch materials often introduce a risk for reCoA, owing to a lack of growth, calcification, and immune response<sup>14</sup>. Second, artificial materials increase aortic wall stiffness and decrease distensibility in the reconstructed arch<sup>15</sup>. The elastic properties of the arterial tree are known to have profound influence on ventricular function<sup>15</sup>. Furthermore, ventriculoarterial coupling in operated HLHS was reported to be affected by aortic arch size mismatch owing to surgical enlargement of the hypoplastic aorta<sup>16</sup>. Therefore, arch reconstruction with direct anastomosis should always be considered first, but if any patch material is to be utilized, a piece of autologous pericardium fixed with glutaraldehyde is recommended as some studies have already advocated<sup>17,18</sup>. The key here is to use as little patch as possible to bridge the tiny gap between the

pulmonary trunk and aorta, since an excessive use will pose a risk of compression of the bronchus and left pulmonary artery and obstruction of the neo-aortic arch<sup>4</sup>.

Limitations

The limitations of the present study need to be acknowledged. This study was retrospective and nonrandomized, and included data from a single center. In addition, biases could have been caused by patient selection and surgical judgment. Using only a small number of patients limits the statistical power behind any conclusion. The aortic arch geometric measurements in this study could be biased according to this method. Three-dimensional aortic arches are being evaluated with 2-dimensional lateral measurements. The use of 3-dimensional aortic data from computed tomography or magnetic resonance imaging could provide further clinical insights, and multicenter outcome studies on large populations in a prospective design are needed to verify the findings derived from the present study.

Conclusion

The Norwood procedure with direct anastomosis can be performed in patients with a longer preoperative MPA length, as a shorter MPA length poses a potential risk for reCoA. In this case, the bridge technique should be considered to attain a large and smooth neo-aortic arch.

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- 264 Conflicts of Interest: The authors declare no conflicts of interest.

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315 <u>Tables</u>

# 316 Table 1. Patient Characteristics

Characteristics*	Group l	R (n=11)	Group 1	N (n=35)	P value
Male	6	(55%)	19	(54%)	0.709
Preceding Bil.PAB	5	(45%)	17	(49%)	0.857
Age at Norwood (days)	5	(3-50)	4	(10-56)	0.958
Weight at Norwood (kg)	3.1	±0.6	3.1	±0.7	0.980
Diagnosis					
MA/AA	5	(45%)	19	(54%)	0.609
MA/AS	3	(27%)	2	(6%)	0.045
MS/AA	3	(27%)	9	(26%)	0.918
MS/AS	0	(0%)	5	(14%)	0.184
Follow-up period (months)	89	±27	73	±30	0.393
Arch reconstruction					
Direct anastomosis	7	(64%)	22	(63%)	0.963
Patch (anterior patch)	4	(36%)	7	(20%)	0.267
Patch (bridge technique)	0	(0%)	6	(17%)	0.141

AA, aortic atresia; AS, aortic stenosis; Bil.PAB, bilateral pulmonary artery banding; MA, mitral atresia; MS, mitral stenosis. \*Continuous variables are presented as median (IQR) or mean (± SD), and categorical data are presented as absolute counts (%).

Table 2. Aortic Arch and Pulmonary Artery Geometry

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Variables	Group	R (n=11)	Group	Group N (n=35)		
Preoperative						
MPA diameter (mm)	11.0	(9.7–11.4)	11.2	(10.0–13.0)	0.141	
MPA length (mm)	8.5	(8.0–9.2)	9.8	(8.3–11.0)	0.009	
Descending Ao. diameter (mm)	6.4	(5.7–7.0)	6.6	(6.0–7.1)	0.460	
Postoperative  Arch angle (°)	104	(98–105)	117	(105–122)	<0.001	

322 Ao., aorta; MPA, main pulmonary artery. \*Continuous variables are presented as median (IQR).

	Dire	ct anastomosis	A	Bridge technique				
Variables	Group R (n=7)	Group N (n=22)	P value	Group R (n=4)	Group N (n=7)	P value	Group N (n=6)	
Preoperative								
MPA diameter (mm)	11.3 (10.1–11.5)	12.0 (9.9–14.1)	0.269	10.4 (9.9–10.9)	11.2 (10.6–11.5)	0.161	10.5 (9.8–12.1)	
MPA length (mm)	8.4 (7.4–8.8)	10.5 (9.5–11.6)	0.011	9.0 (8.3–9.6)	10.3 (9.1–12.5)	0.272	9.2 (7.9–9.8)	
Descending Ao. Diameter (mm)	6.6 (5.5–7.5)	6.7 (6.3–7.1)	0.882	6.1 (5.8–6.6)	6.9 (6.6–7.6)	0.192	6.6 (6.0–7.1)	
Postoperative								
Arch angle (°)	100 (95–104)	117 (110–122)	0.002	105 (103–109)	122 (113–124)	0.159	128 (122–143)	

Ao., aorta; MPA, main pulmonary artery. \*Continuous variables are presented as median.

Direct anastomosis versus anterior patch						Direct anastomosis versus bridge technique					
Variables	Direct anastomosis		Anterior patch  P value		Direct anastomosis		Bridge technique		P value		
variables	(n=29)		(n=11)		1 value	(n=29)		(n=6)		P value	
Preoperative											
MPA diameter (mm)	11.3	(9.8–13.8)	10.7	(10.4–11.5)	0.138	11.3	(9.8–13.8)	10.5	(9.8–12.1)	0.427	
MPA length (mm)	9.8	(8.3–11.0)	9.7	(8.5–11.3)	0.971	9.8	(8.3–11.0)	9.2	(7.9–9.8)	0.362	
Descending Ao. Diameter (mm)	6.6	(6.0–7.1)	6.8	(6.1–7.3)	0.849	6.6	(6.0–7.1)	6.6	(6.0–6.8)	0.442	
Postoperative											
Arch angle (°)	112	(105–120)	119	(105–122)	0.817	112	(105–120)	128	(122–143)	0.004	
Recoarctation of the aorta	7	(24%)	4	(36%)	0.439	7	(24%)	0	(0%)	0.178	

Ao., aorta; MPA, main pulmonary artery. \*Continuous variables are presented as median (IQR), and categorical data are presented as absolute counts (%).

#### Figure Legends

328

344

postoperative reCoA.

329 Figure 1. Flow diagram depicting the exclusion criteria. BDG, bidirectional Glenn procedure; CoA, 330 coarctation of the aorta; HLHS, hypoplastic left heart syndrome; PDA, patent ductus arteriosus. 331 Figure 2. Operative schema depicting the different methods of neo-aortic arch reconstruction. A. 332 Direct anastomosis without using any materials. **B**. Patch augmentation for only greater curvature 333 (anterior patch). C. Patch augmentation for lesser curvature in addition to greater curvature (bridge 334 technique). 335 Figure 3. Geometry analysis of the main pulmonary artery (MPA) and aortic arch. A. Preoperative 336 computed tomography in the left lateral oblique view. a = MPA length (length of the lesser curvature 337 of the MPA between the pulmonary valve annulus and pulmonary artery bifurcation, usually at the 338 root of the right pulmonary artery); b = MPA diameter (diameter just below the bifurcation level); c =339 Des. Ao. diameter (diameter of the descending agrta at the level of the left bronchus). B. Postoperative 340 computed tomography in the left lateral oblique view. d = arch angle (angulation between the two 341 tangent lines from the highest points of the aortic arch to the centerline of the descending aorta). 342 Des.Ao., descending aorta; MPA, main pulmonary artery. 343 Figure 4. ROC curve analyses stratified by preoperative factors to predict the occurrence of

- **Figure 5.** ROC curve analysis for postoperative reCoA: postoperative arch angle.
- **Figure 6.** Linear regression analyses, stratified by the various arch reconstruction techniques, between
- 347 the MPA length and postoperative arch angle.



















