

# ARTICLE IN REVIEW:

## Matracell<sup>®</sup>-decellularized and non-decellularized pulmonary artery patches in pulmonary arterioplasty in infants

**PUBLICATION:** Seminars in Thoracic and Cardiovascular Surgery, 2022

**TITLE:** Decellularized vs Non-decellularized Allogeneic Pulmonary Artery Patches for Pulmonary Arterioplasty<sup>1</sup>

**AUTHORS:** Bonilla-Ramirez C, Aggarwal V, Atyam M, Qureshi AM, Heinle JS, McKenzie ED

**STUDY DESIGN:** Retrospective clinical study, 59 patients

**SUMMARY:** Fifty-nine pediatric patients (between 3.3 and 5.8 months) who underwent pulmonary arterioplasty during the bidirectional Glenn procedure were examined for pulmonary artery (PA) size, reinterventions, and panel-reactive antibodies (PRA). Patients received either decellularized (CardioGraft-MC<sup>®</sup>, DAPAP, n=28) or non-decellularized allogeneic pulmonary artery patches (CardioGraft<sup>®</sup>, non-DAPAP, n=31) provided by LifeNet Health. Although both groups had ranges consistent with a healthy population, the DAPAP group had higher pre-Fontan angiography Z-scores, a measure of PA size, compared to the non-DAPAP group for the right (median +1.2 [IQR +0.6, +1.5] vs +0.1 [IQR -0.4, +0.7], respectively; p=0.001) and left pulmonary arteries (median +0.2 [IQR -0.4, +1.1] vs -0.3 [IQR -1.8, +0.4], respectively; p=0.03). These results correlated with a linear regression model in which the DAPAP group was associated with higher Z-scores in both the right (estimate 0.17, p=0.0005) and left pulmonary arteries (estimate 0.12, p=0.01). Additionally, the DAPAP group had higher freedom from PA reinterventions compared to non-DAPAP patients (75% vs 42% at 7 years, respectively; p=0.014), suggesting longer durability with DAPAP. Although the data are limited to 8 patients (DAPAP n=5 and non-DAPAP n=3), the DAPAP group also had lower values of PRA than the non-DAPAP group (Class I 0% vs 23%; Class II 15% vs. 21%, respectively), suggesting a minimal immune response. Notably, both groups did not have any observed complications such as calcification, discrete coarctation, or pulmonary dilation. These results suggest that decellularized CardioGraft-MC patches may provide longer durability and higher freedom from reintervention compared to non-decellularized patches for pediatric patients. The authors therefore concluded that “since patch material is commonly used in growing children, the potential properties of decellularized patches have special relevance.” Consequently, “decellularized patches have become the standard material for pulmonary arterioplasty and arch repair [at our institution].”

### CardioGraft-MC<sup>®</sup> pulmonary artery (PA) patches were associated with higher pre-Fontan pulmonary artery Z-scores:

The patches were implanted during the Glenn procedure, and the subsequent pre-Fontan pulmonary artery angiography Z-scores for CardioGraft-MC were statistically higher for the right (p=0.001) and left (p=0.03) pulmonary arteries, although both groups had ranges close to zero, demonstrating the patch can maintain the repair at the desired diameter relative to body surface area.

### CardioGraft-MC PA patches offered higher freedom from reinterventions:

The present study showed statistically higher freedom from reintervention with the use of Matracell-decellularized CardioGraft-MC patches versus non-decellularized patches (75% vs 42% at 7 years, respectively; p=0.014), consistent with results from a prior related study.<sup>2</sup>

### While decellularized patches are pertinent for growing pediatric patients, there are also successful clinical outcomes with non-decellularized patches:

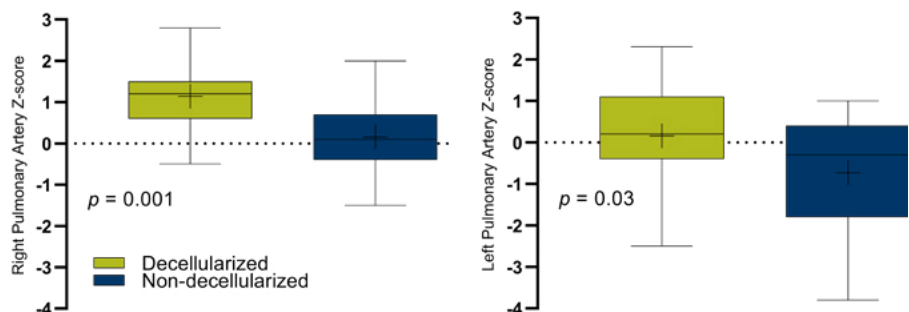
“Since patch material is commonly used in growing children, the potential properties of decellularized patches have special relevance [and]...have become the standard material for pulmonary arterioplasty and arch repair [at our institution].” Notably, both groups did not have any observed complications of calcification, discrete coarctation, or pulmonary dilation.

### References:

1. Bonilla-Ramirez C, Aggarwal V, Atyam M, Qureshi AM, Heinle JS, McKenzie ED. Decellularized Vs Non-decellularized Allogeneic Pulmonary Artery Patches for Pulmonary Arterioplasty. *Seminars in Thoracic and Cardiovascular Surgery*. 2022. <https://doi.org/10.1053/j.semtcvs.2022.07.005>.
2. Hopkins RA, Lofland GK, Marshall J, Connelly D, Acharya G, Dennis P, Stroup R, McFall C, O'Brien JE Jr. Pulmonary arterioplasty with decellularized allogeneic patches. *Ann Thorac Surg*. 2014 Apr;97(4):1407-12. doi: 10.1016/j.athoracsur.2013.12.005.

## Higher Pre-Fontan pulmonary artery Z-scores with CardioGraft-MC

**Figure 1.** CardioGraft-MC patches (n=28) had higher pre-Fontan pulmonary artery Z-scores compared to CardioGraft patches (n=31) for the right (median +1.2 [IQR +0.6, +1.5] vs. +0.1 [IQR -0.4, +0.7], respectively) and left pulmonary arteries (median +0.2 [IQR -0.4, +1.1] vs. -0.3 [IQR -1.8, +0.4], respectively). Figure recreated from data presented in Figure 3.<sup>1</sup>



68-20-389.01

LifeNet Health, the LifeNet Health logo, CardioGraft, CardioGraft-MC, and Matracell are registered trademarks of LifeNet Health. ©2022 LifeNet Health, Virginia Beach, VA. All rights reserved.

