

# Case Study of Extended Extra-aortic Counterpulsation Support with C-Pulse® Device Does Not Alter Aortic Wall Structure

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## INTRODUCTION

Counterpulsation devices, such as the C-Pulse Heart Assist System have been developed with comparable hemodynamic benefit to Intra-aortic balloon pump [1] and fewer limitations. The C-Pulse System is an implantable, extra-aortic counterpulsation, non-blood contacting, heart assist device for the treatment of heart failure (NYHA Class III-ambulatory IV) in patients who did not respond to biventricular pacing or medical therapy. A U.S. prospective randomized controlled multi-center trial is underway. Long-term effects of the extra-aortic device on aortic wall structure are not well established.

## OBJECTIVE

To assess the impact of long term (21 months) extra-aortic counterpulsation C-Pulse implantation on aortic wall structures.

## CLINICAL SUMMARY

A 58-year-old female presented with shortness of breath, orthopnea, paroxysmal nocturnal dyspnea, and an ejection fraction of 15% (NYHA class III). She was diagnosed with non-ischemic cardiomyopathy and treated with medical management and a dual chamber pacemaker. Her condition did not improve despite optimal medical therapy and she was listed for heart transplant.

A C-Pulse Heart Assist System was implanted 7 months after her first diagnosis as a bridge-to-transplant. One month after implantation, her symptoms improved from NYHA class III to class I and her cardiac output increased from 3.5 to 5.5 L/min. Echocardiography showed a decrease of her baseline mitral regurgitation from moderate to mild. Her MLWHF questionnaire score decreased from 77 to 13. At 12 months, her 6MWT had increased from 305m at baseline to 457m. Her later course was complicated by persistent *S. aureus* driveline infection. She was upgraded to UNOS status 1A and received a heart transplant 21 months post device implantation.

Figure 1. Intra-operative photo of the C-Pulse in-situ before heart transplantation.

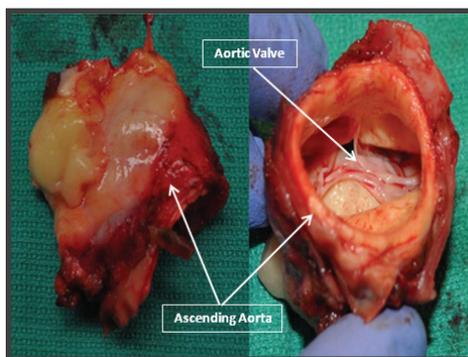
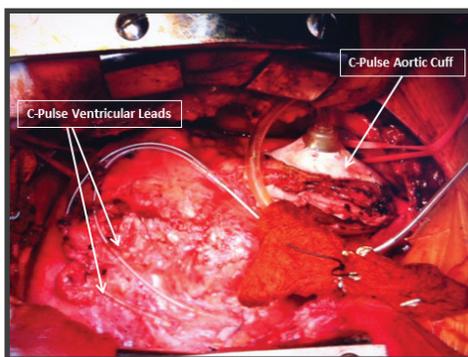


Figure 2. Photo of the ascending aorta and aortic valve with C-Pulse explanted during heart transplantation. Labels point to C-Pulse Ventricular Leads and C-Pulse Aortic Cuff.

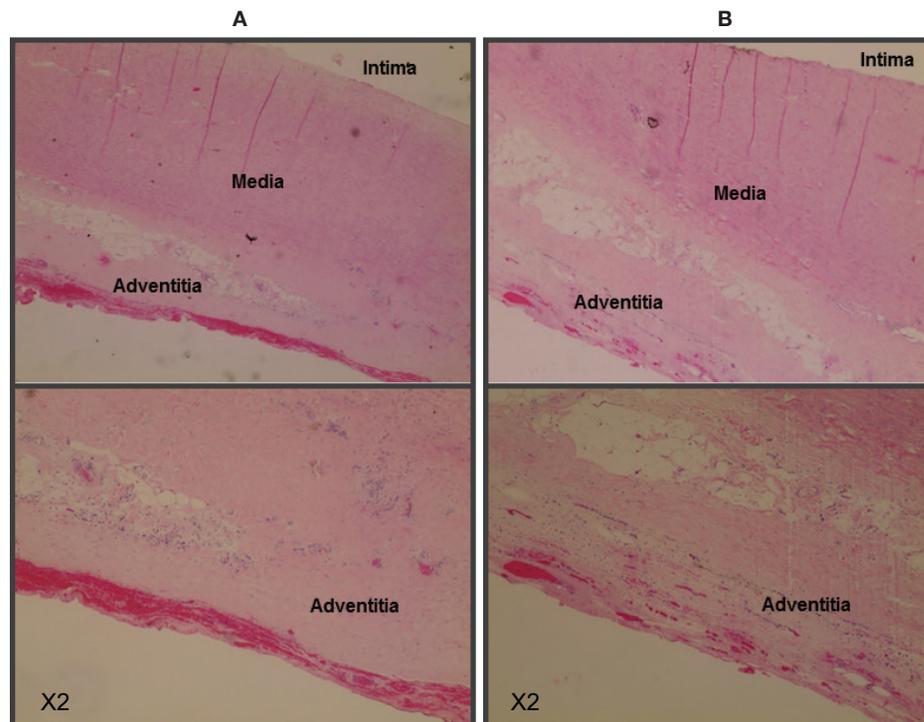


## HISTOPATHOLOGY ANALYSIS

Tissue samples from her ascending aorta within and proximal to the C-Pulse cuff were obtained during transplantation. Macroscopically, the aortic samples appeared grossly normal with no intimal disruption, tear, or dissection (Figure 2).

Aortic samples were stained with hematoxylin and eosin (Figure 3). The intima and media of the ascending aortic wall within the C-Pulse cuff remained intact, with no evidence of disruption compared to wall structure proximal to the cuff. No significant inflammation was noted except mild neutrophilic infiltration in the adventitial surface. Fibrinoid degeneration on the adventitia was noted on both ascending aorta samples.

Figure 3. Hematoxylin and eosin staining of a section of the ascending aorta proximal to the C-Pulse cuff (Column A) and a section of the aorta from within the C-Pulse cuff (Column B).



## CONCLUSIONS

Long-term implantation of an extra-aortic counterpulsation device provided substantial hemodynamics and symptoms improvement in a Class III heart failure patient and does not appear to significantly alter the aortic wall structures.

An ongoing randomized clinical trial is needed to clarify the safety, effectiveness, reliability, and reproducibility of the C-Pulse device in a larger sample of heart failure patients.

## REFERENCE

1. Davies, A.N., Peters, W.S., Su, T., et al., Extra-ascending aortic versus intra-descending aortic balloon counterpulsation-effect on coronary artery blood flow. *Heart Lung Circ*, 2005. 14(3): p. 178-86.