

The Long Term Healing Response Following Implant of the HeartNet Ventricular Elastic Support System

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Introduction

Elastic restraint devices are being tested as investigational therapy for systolic HF. Concern has been raised that this therapy may cause constrictive pericarditis or, despite clinical evidence to the contrary, mitigate subsequent procedures. We present pathology evaluation addressing these concerns.

Methods

50 patients (age=52, 94% males, 80% nonischemic, NYHA II/III (35%/65%)) were implanted with the HeartNet Ventricular Elastic Support Therapy (HN VEST, Paracor Medical, Inc., Sunnyvale CA). Follow-up for the cohort has ranged up to 3 years. In 4 cases pathology evaluation was performed on explanted hearts transplanted for progressive HF. One patient was studied post-mortem. Two patients had a LVAD placed prior to transplant. Selected baseline and follow-up data are presented in Table 1.

Results

Duration of HN therapy ranged from 322 - 1324 days. Baseline EF ranged from 18-27% and LVEDV from 256-458 ml. All patients were considered to be NYHA II or III at the time of HN implant. Three patients with data available had peak VO₂ between 12 and 17 ml/kg/min. Gross images of explants at time of transplant or autopsy show HN partially encased in hyalinized fibrous epicardial exudate. In all cases histologic evaluation revealed mild epicardial fibrosis, neoangiogenesis and mild chronic inflammation around wire loops and moderate fibrosis around loop connectors with pericardial thickening (Figures 1-4). In no case was there evidence of coronary vessel compression. The fibrosis consisted of type III collagen which can be easily dissected.

Table 1. Baseline and follow-up data.

Pt	Baseline			Days to Event	
	EF (%)	LVEDV (ml)	PVO ₂ (ml/kg/min)	LVAD	Transplant (T) or Death (D)
#1	20	256	12	Not done	322 (T)
#2	18	348	12	120	554 (T)
#3	21	458	- ¹	252	335 (T)
#4	27	286	- ¹	Not done	799 (T)
#5	23	379	17	Not done	1324 (D)

¹ Not available.

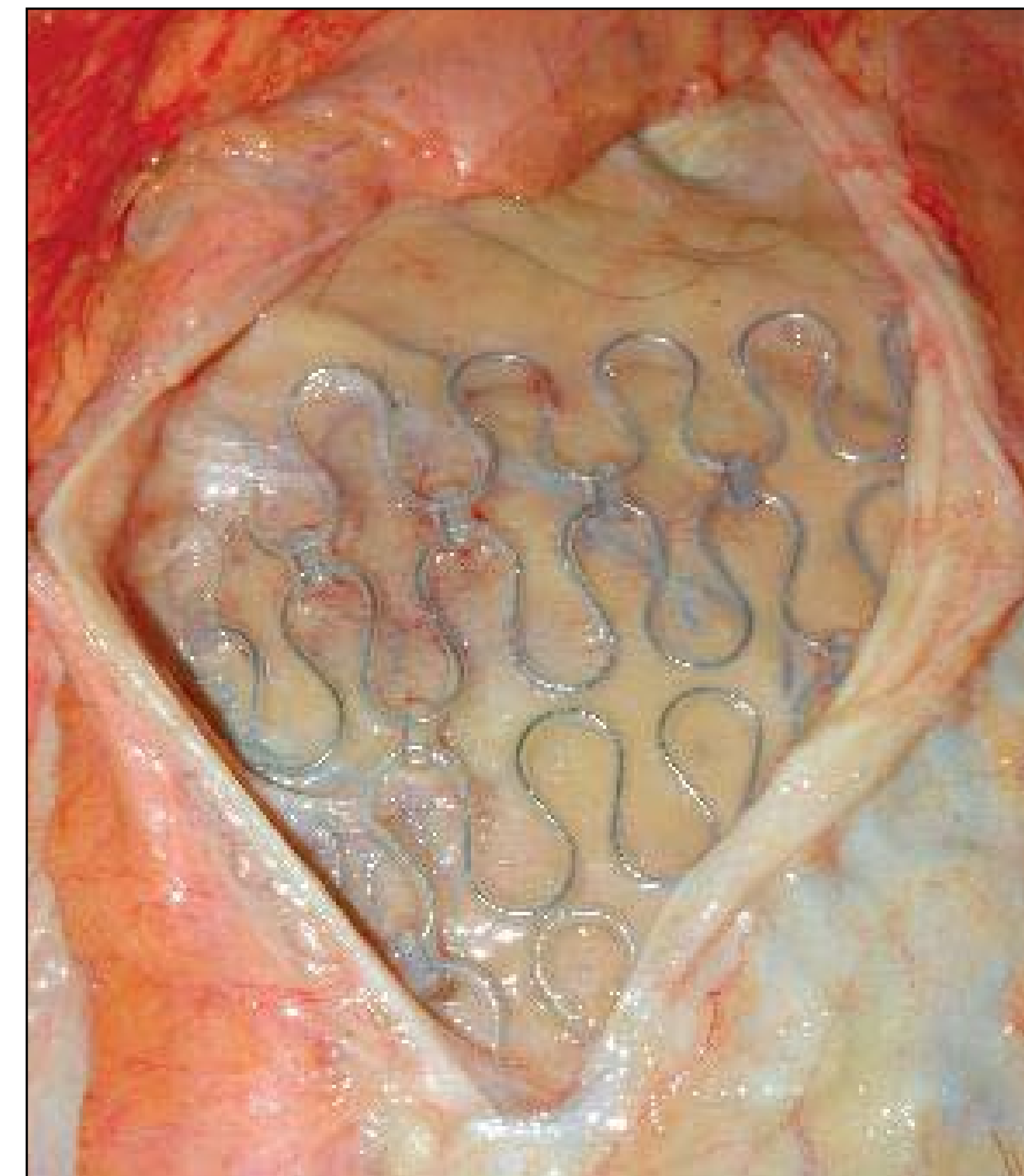


Figure 1. Note clean dissection plane between pericardium and HN. Also note mild degree of epicardial fibrosis in a post-mortem study 1324 days after HN implant procedure.

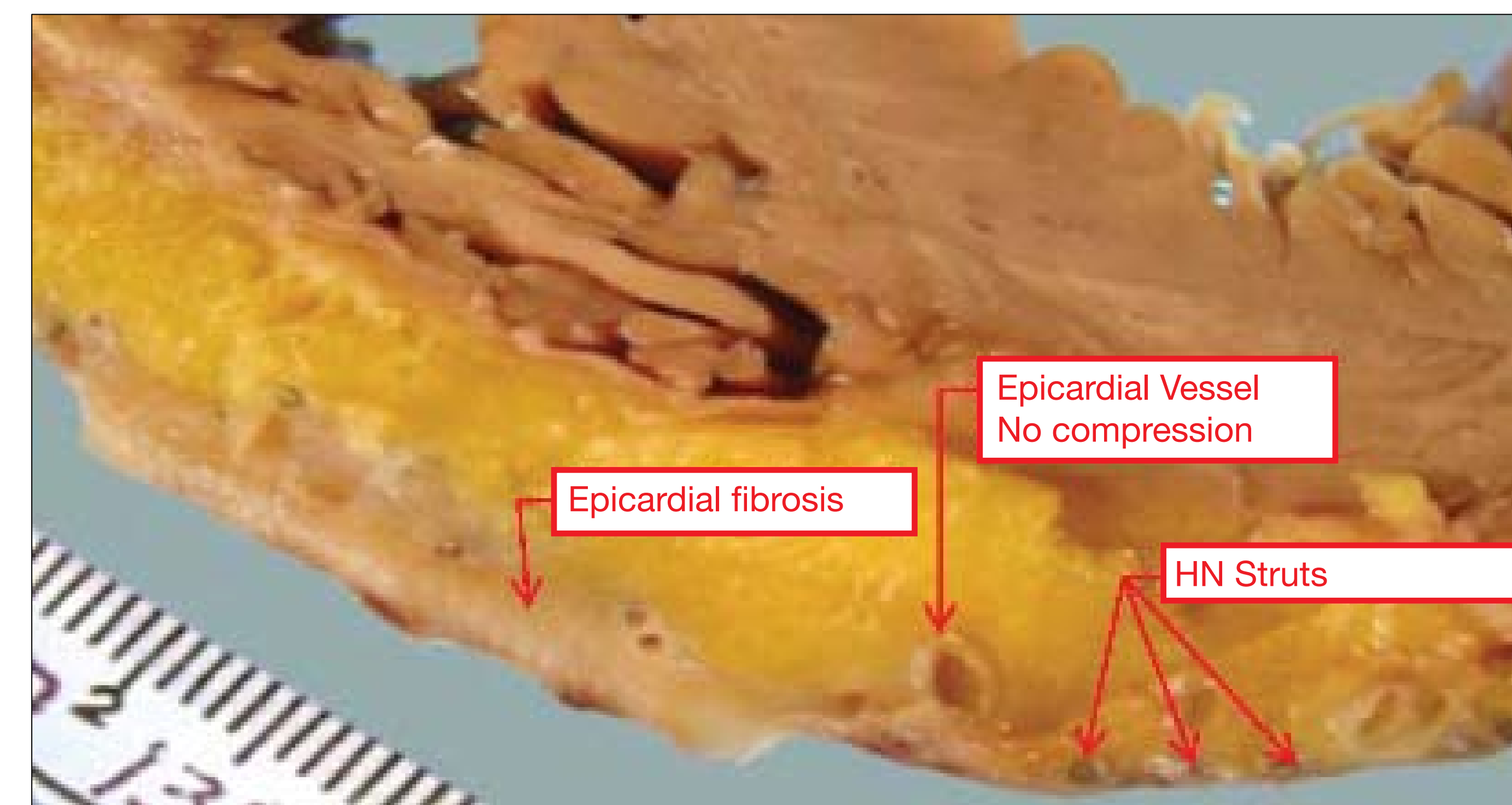


Figure 2. Gross image showing epicardial vessels, HN struts and mild epicardial fibrosis in a patient transplanted at 554 days after HN implant.

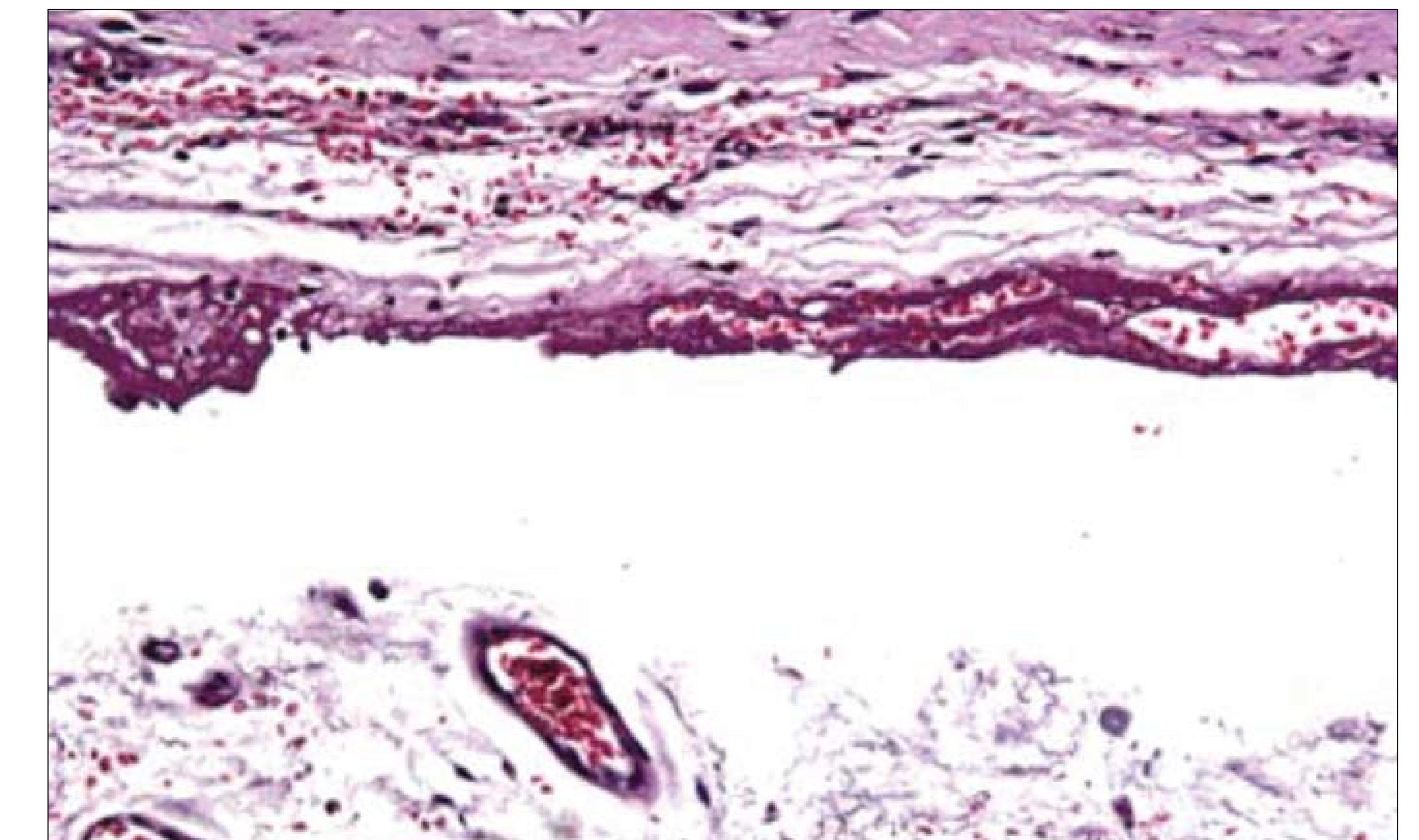


Figure 3. Note neoangiogenesis and mild epicardial fibrosis in a patient transplanted 322 days after HN implant procedure.

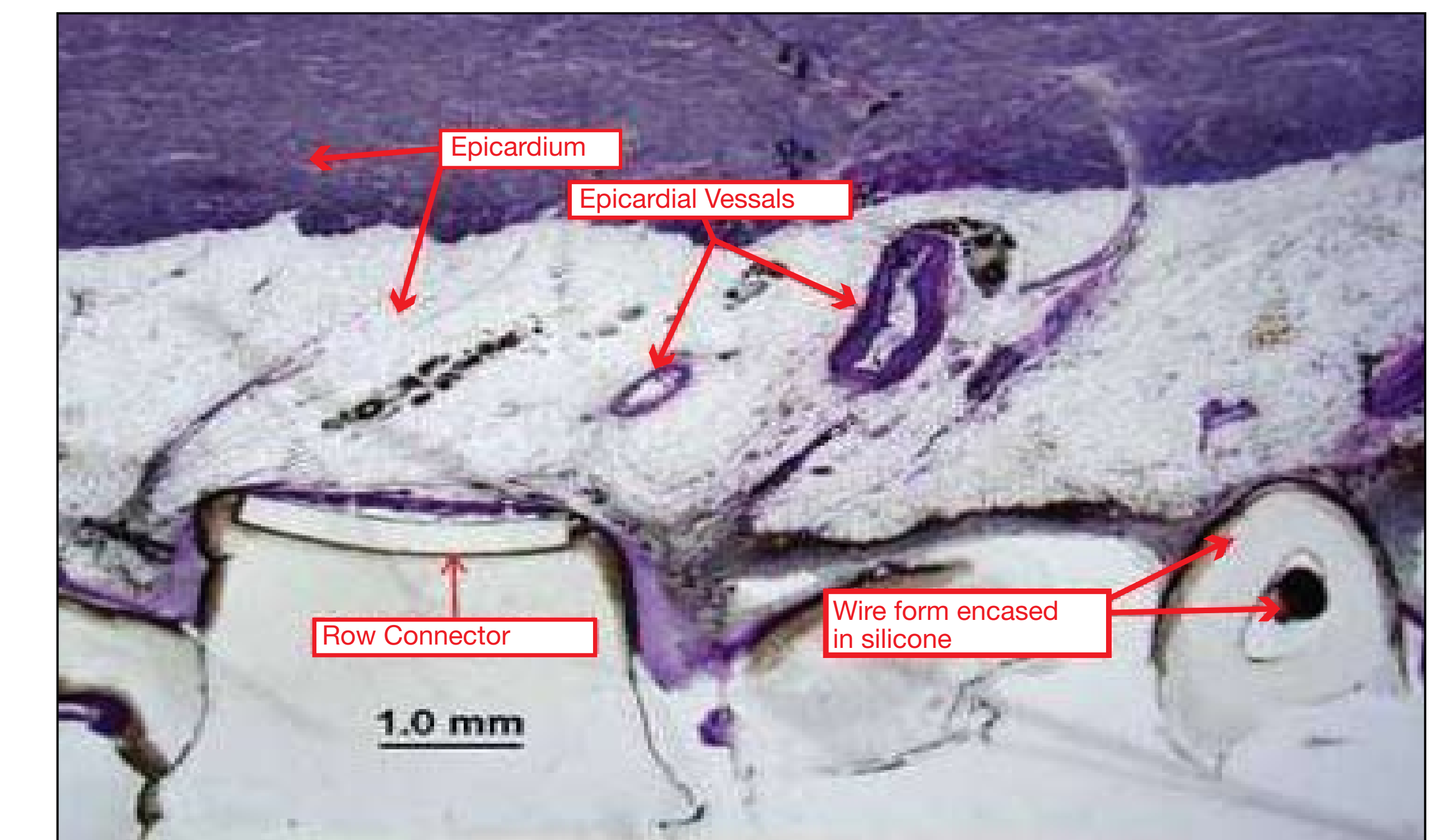


Figure 4. Mild epicardial fibrosis especially around row connector and wireform. No evidence of coronary artery compression in a patient transplanted 799 days after HN implant procedure.

Conclusions

In three patients studied in detail by an independent pathology service, a fourth studied at the transplant site, and a fifth at post-mortem (CV Path, Gaithersburg MD; University of Colorado Health Sciences Center, Denver CO; Otto-Von-Guericke-Universitat, Magdeburg Germany), there was evidence of a mild healing response. These findings suggest a low likelihood of pericardial constriction. Furthermore, based on these findings and the fact that these patients underwent orthotopic heart transplant, it appears that cardiac reoperations are feasible in patients receiving the HeartNet implant.

Caution: Investigational Device. Limited by Federal (or United States) law to investigational use. Investigational Device. To be used by Qualified Investigators only.