



Clinical Experience with “PeriBeam® Pericardial Membrane”, an Ion-Beam-Irradiated ePTFE Sheet

— Improving Safety During Re-Sternotomy in Pediatric Cardiac Surgery —

Hiroomi Murayama, MD

- General Manager, Aichi Children's Health and Medical Center
- Professor of Practice, Department of Cardiac Surgery, Nagoya University Graduate School of Medicine
- Visiting Professor, Department of Cardiovascular Surgery, Fujita Health University School of Medicine



Introduction

In pediatric cardiac surgery, definitive treatment often cannot be completed in a single operation and staged surgical procedures are frequently required. In this setting, cardiac or great vessel injury during re-sternotomy can result in life-threatening complications. Therefore, reconstruction of the pericardium at the time of the initial surgery is critically important to ensure safety during future reoperations.

Expanded polytetrafluoroethylene (ePTFE) pericardial membranes have long been widely used because of their biocompatibility and anti-adhesive properties. Recently, PeriBeam®, a Japan-manufactured ePTFE pericardial membrane with ion-beam surface modification and cleared in the United States under 510(k) (K240775), has become available for clinical use. It is expected to provide advantages in staged cardiac procedures.

Clinical Case

A female infant was prenatally diagnosed with a right-ventricular-type single ventricle and pulmonary atresia. At 1 month of age, she underwent pulmonary artery reconstruction using autologous pericardium combined with a B-T shunt*¹ (Fig. 1). At 5 months of age, as part of a staged surgical treatment, she underwent a bidirectional Glenn procedure (Fig. 2) with cardiopulmonary bypass. As re-sternotomy would be required for a planned TCPC*² conversion surgery in the future, the surgical team performed pericardial reconstruction using a PeriBeam® at the end of the procedure.

*¹ Blalock–Taussig shunt

*² Total Cavopulmonary Connection

Fig.1 Pulmonary artery plasty+ B-T shunt

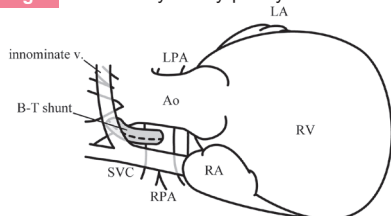


Fig.2 Bidirectional Glenn procedure

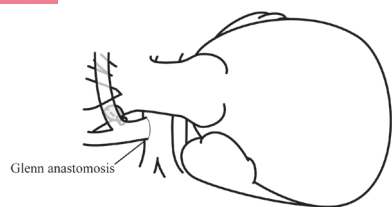


Fig.3 Fixing PeriBeam®

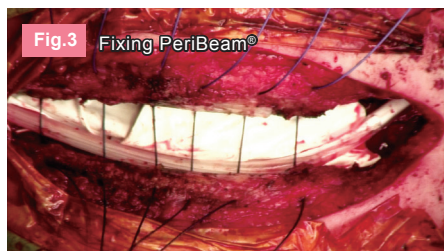
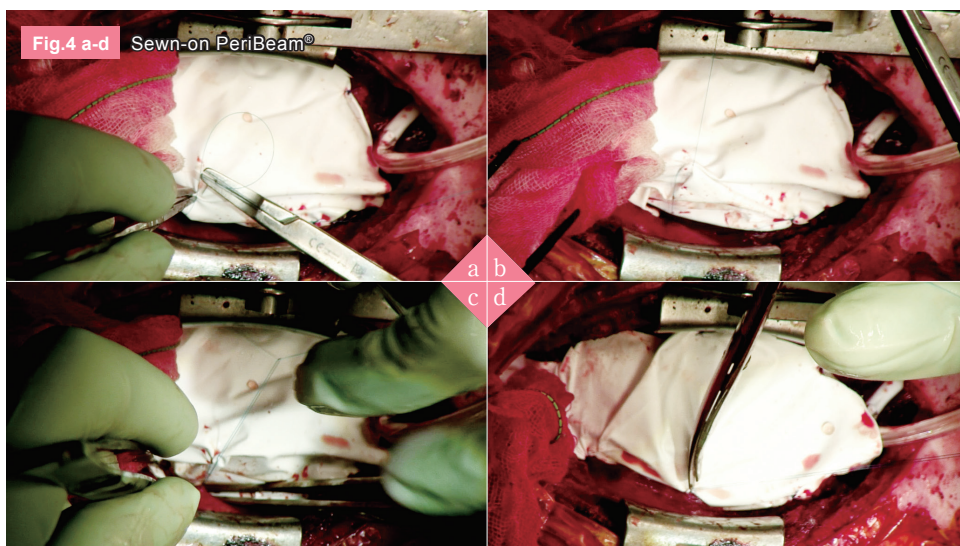


Fig.4 a-d Sewn-on PeriBeam®



Surgical Findings 1 (Bidirectional Glenn Procedure)

After completing of the Glenn anastomosis and separation from extracorporeal circulation, the ePTFE pericardial membrane “PeriBeam®” was applied to the pericardial defect. Similar to conventional ePTFE sheets, the device could be easily trimmed intraoperatively and shaped to fit the defect. PeriBeam® was used not only to reconstruct the pericardium but also to cover the innominate vein (brachiocephalic vein). It was secured with interrupted sutures, with the ion-irradiated surface faced the sternum side (Fig. 3). To facilitate future reoperation and allow safer exposure to the heart and great vessels from surrounding tissues, the sheet was fashioned slightly larger than the defect and sutured to extend over the lateral aspects of the heart (Fig. 4a-d). Suture handling was satisfactory. No impairment of cardiac contraction or relaxation was observed.

Postoperative Course (After Bidirectional Glenn Procedure)

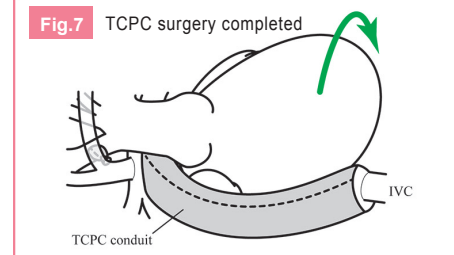
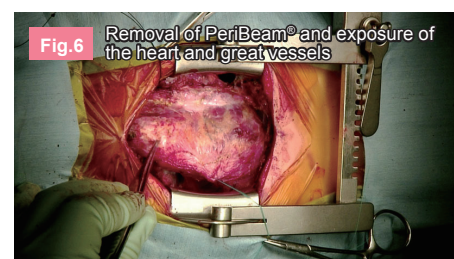
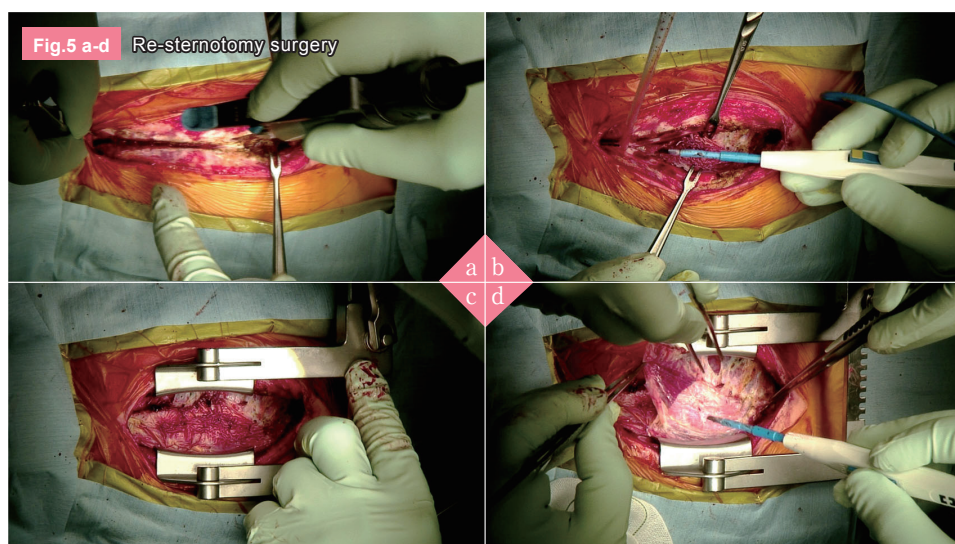
Postoperative hemodynamics were stable. No evidence of pericardial effusion or cardiac tamponade were observed. Inflammatory response improved over time, and no infectious complications, including wound infection or mediastinitis were noted.



Surgical Findings 2 (TCPC Surgery)

Approximately one year later, planned re-sternotomy was performed for TCPC surgery. Adhesion between the posterior sternum and the PeriBeam® was relatively mild. The risk of injury to the cardiac surface or great vessels during sternal re-entry was judged to be low.

After sternotomy, adhesion between the membrane and the heart and great vessels was also mild. The surgical field was safely developed with minimal dissection (Fig. 5a-d). In particular, in areas previously covered with PeriBeam®, removal of membrane itself functioned as part of the dissection plane, facilitating exposure of the heart and great vessels (Fig. 6). The membrane showed no significant thickening, hardening, or fragility, and largely maintained its original configuration. No fluid accumulation, excessive granulation tissue, or signs of infections were observed around the reconstructed pericardium. Re-sternotomy and TCPC completion proceeded smoothly without major complications (Fig. 7).



Conclusion

Pericardial reconstruction using the ePTFE pericardial membrane PeriBeam® was performed in a pediatric patient undergoing cardiac surgery. The device demonstrated satisfactory intraoperative handling, favorable postoperative course, and ease of management during reoperation. Based on this experience, PeriBeam® may represent a first-choice option for pericardial reconstruction in patients anticipating future reoperations.

(References)

- 1) Takahashi N, et al. Ion-beam Irradiated ePTFE for an Artificial Dura Mater. Neurological Surgery. 2003; 31(10): 1081–1088.
- 2) Takahashi N, et al. Biocompatibility of ePTFE Modified by Ion Beam Irradiation. Neurological Surgery. 2004; 32(4): 339-344.

Discussion

ePTFE is widely used in medical application for adhesion prevention and tissue reinforcement due to its chemical inertness and low tissue reactivity. In staged pediatric cardiac surgery, the primary objective of pericardial reconstruction is to ensure safety during re-sternotomy. In this case, reconstruction with PeriBeam® at the initial surgery contributed to safe sternal re-entry at reoperation and facilitated efficient exposure during reoperation. PeriBeam® incorporates surface modification through ion-beam irradiation¹⁾. This modification is thought to provide an appropriate level of tissue affinity, potentially reducing excessive fibrous adhesion while maintaining a stable interface between the prosthesis and surrounding tissues²⁾. Such properties may contribute to minimize microscopic dead space around the prosthesis and may potentially reduce the risk of postoperative complications.

Product Overview

- Device Name : PeriBeam® Pericardial Membrane
- 510(k) Number : K240775
- Regulation Number : 21 CFR 870.3470
- Product Code : DXZ
- Indications for use : The PeriBeam® Pericardial Membrane is indicated for the reconstruction or repair of the pericardium.
- Material: polytetrafluoroethylene (PTFE)
- Structure and Design : This product is an expanded polytetrafluoroethylene (ePTFE) sheet. One side of which has been irradiated with an ion beam. The thickness is 90µm (0.09mm). The irradiated surface is engraved with "ION" or "Ion" to distinguish between the ion beam irradiated and non-irradiated surfaces.

※Please read the Instructions for Use (IFU) prior to use.

Device Name	Product Number	Size (mm)	Thickness	Quantity
PeriBeam®	P-090-1010	100×100	0.09mm	1
	P-090-1212	120×120		

Manufacturer: TamaBio Company Limited
402 Gran Creste 2-2-18 Sakai Musashino-shi
Tokyo 180-0022 Japan
TEL : +81-422-53-5051
FAX : +81-422-38-5091
<https://tamabio.com/en/>