

**Table 2**

Correlation Statistics for Cardiopulmonary Bypass and Clamp Times With Variables of Antioxidant Defense and Lipid Peroxidation (Pearson Correlation Coefficient [R] and Statistical Significance [P])

	CPB Time	Clamp Time
<i>GST_p1</i>		
R	−0.398*	−0.389*
P	.036	.041
<i>GST_p2</i>		
R	0.048	0.011
P	.808	.955
<i>GST_p3</i>		
R	−0.464*	−0.427*
P	.013	.023
<i>GSSG_p1</i>		
R	0.287	0.130
P	.138	.510
<i>GSSG_p2</i>		
R	−0.079	0.001
P	.688	.995
<i>GSSG_p3</i>		
R	−0.071	−0.011
P	.720	.955
<i>MDA_p1</i>		
R	−0.218	−0.114
P	.265	.565
<i>MDA_p2</i>		
R	0.000	−0.037
P	1.000	.852
<i>MDA_p3</i>		
R	−0.159	−0.104
P	.418	.599

CPB, cardiopulmonary bypass; GSSG, oxidized glutathione; GST, total glutathione; MDA, malondialdehyde.

\* Correlation is significant with  $P < .05$  (2-tail test).

given that knowledge to date has been derived from animal models. Such information may have important therapeutic implications, because preventing this phenomenon would afford

greater myocardial protection and improve postoperative outcome.

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## Ventricular Restoration: New Therapeutic Approaches



### Restauración ventricular: nuevos enfoques terapéuticos

#### To the Editor,

Ischemic heart disease is the leading cause of heart failure (HF).<sup>1</sup> Ventricular aneurysms are more common in persons with a prior myocardial infarction, resulting in progressive ventricular remodeling and HF.<sup>1</sup>

Our aim is to describe 2 new techniques for ventricular restoration using the Parachute<sup>®</sup> percutaneous device (CardioKinetix; Menlo Park, United States) and the PliCath HF<sup>®</sup> epicardial device (BioVentrix; San Ramon, United States) in patients with HF

and a previous ventricular aneurysm secondary to extensive myocardial infarction. We also discuss the clinical outcomes of 4 patients treated with this new technology.

The Parachute<sup>®</sup> percutaneous device (Figure A) has a self-expanding nitinol structure with anchor-shaped filaments at its distal end, which allow apposition to the ventricular wall and anchoring in the endomyocardium. The metal structure is covered by an impermeable polytetrafluoroethylene membrane, enabling occlusion of the aneurysm cavity, excluding the ventricular aneurysm.<sup>2,3</sup> A large gauge introducer (16 Fr) is inserted via an arteriofemoral access point, facilitating advancement of the device's delivery system. For the retrograde arterial approach, the left ventricular apex is reached via the aortic valve. Once optimal positioning is achieved, the release and apposition of the device against the ventricular wall is completed by inflating a balloon.

The PliCath HF® epicardial device (Figure B) is implanted using median sternotomy and fluoroscopic guidance. The right ventricle is accessed by inserting a specially-designed curved needle through the anterior ventricular wall and crossing the left ventricular cavity and the septum. To insert this needle, a guide composed of a high-strength biocompatible material (polyetheretherketone) is advanced to the pulmonary artery, and is then used to insert a catheter. A fastening anchor is introduced through this catheter and is then retracted until it comes into contact with the right ventricular face of the septum. The catheter is then removed and another fixing anchor is placed on the outer face of the ventricular wall via the point of needle insertion. Several pairs of anchors are implanted in a similar way until optimal plication of the ventricular aneurysm is achieved. The anchors are composed of a highly resistant material (titanium) and are coated with polyester to facilitate endothelialization.

The 4 patients had extensive anterior myocardial infarction and signs and symptoms of HF. All underwent imaging tests, showing ventricular aneurysms and lack of viability in the left anterior ventricular wall. The first 2 were successfully treated using the Parachute® device, and the others using the PliCath® device. The baseline characteristics of the procedure and follow-up are summarized in the Table.

The anteroapical region is particularly vulnerable to swelling due to its greater curvature and thinner structure. Expansion and thinning of this region, as in the case of ventricular aneurysm following extensive myocardial infarction, increases the ventricular radius and thus wall tension. This eventually degenerates into inefficient ventricular contractility and finally HF.<sup>3,4</sup>

Classical surgical ventricular restoration procedures using ventricular aneurysm resection were developed to reduce volume and obtain an elliptical ventricular shape, thus halting progressive ventricular remodeling. However, these procedures had a high complications rate related to cannulation, cardiopulmonary bypass, and left ventriculotomy. They were therefore abandoned in routine clinical practice because of their high surgical risk.<sup>4</sup>

New approaches have recently emerged for ventricular restoration, which are less invasive and provide the benefits of restoration therapy without exposing the patient to the greater risk of classical surgical techniques.

The PARACHUTE IV study<sup>2,3</sup> (NCT00573560, United States and NCT01286116, Europe) evaluated the Parachute® device. Thirty-nine patients with ventricular aneurysms, HF (functional class II-IV), and left ventricular ejection fraction between 15% and 40% were recruited in the US and Europe. The procedure was attempted in 34 patients and was successful in 31. In patients who were successfully treated, diastolic volume was significantly reduced, and 85% of them showed improved functional class. Of the 31 patients, 2 (6.5%) died of cardiac causes in the first 6 months, and no other cardiac deaths occurred during the 3-year follow-up.

CONFIGURE-HF (NCT01568138) is a safety study that is evaluating the PliCath HF® device. This is a multicenter, multinational safety study in patients with previous ventricular aneurysms, ventricular dilation (indexed telesystolic volume  $\geq 60$  mL / m<sup>2</sup>) and a left ventricular ejection fraction of 15% to 40%. The primary objective of this study is to assess the overall rate of serious adverse events related to the device.

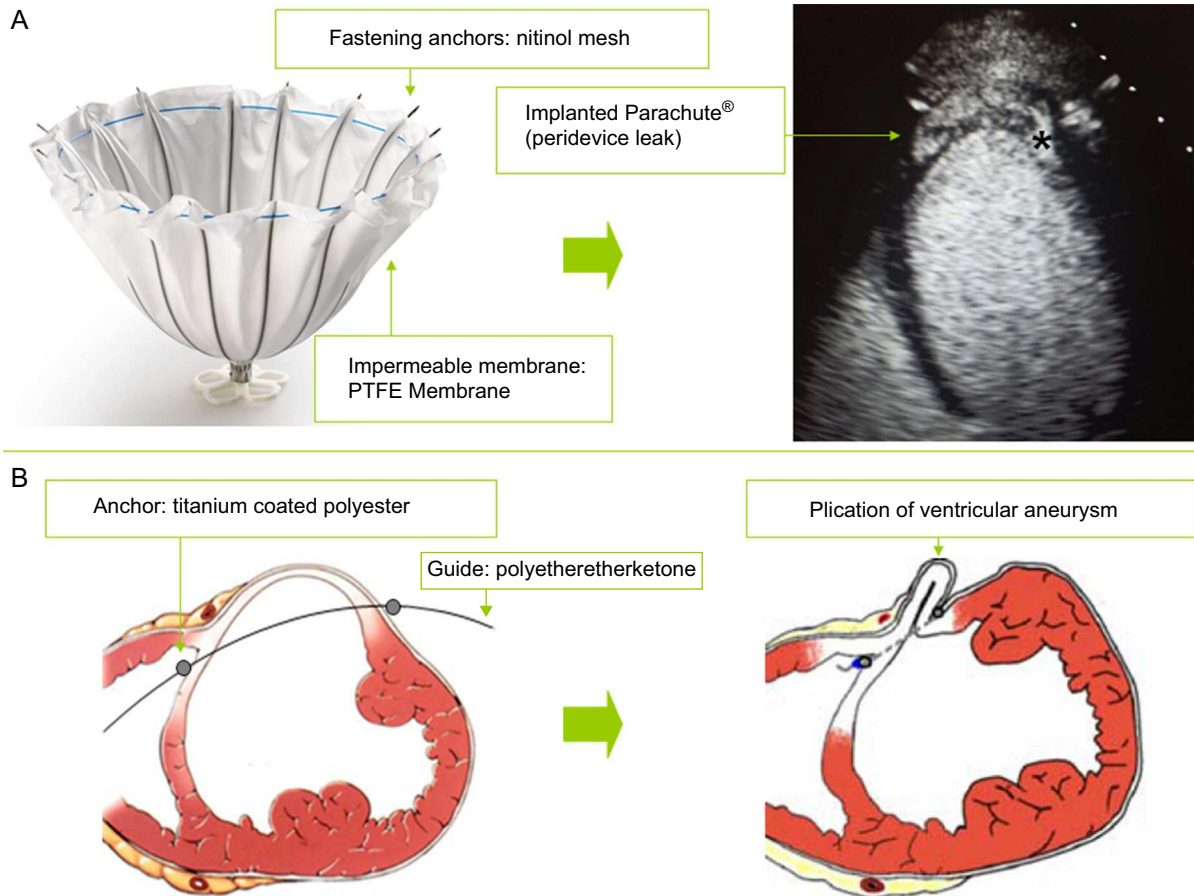
These initial studies will report the feasibility and safety of these new techniques. We are still at an early stage in the development of this technology, but if further clinical trials confirm that if these techniques are safe and able to halt ventricular remodeling, they may be a therapeutic alternative for these patients.

**Table**  
Baseline Characteristics of the Intervention and Follow-up

Case	Device	Sex	Age, years	Intervention specialists	Anesthesia	Access	Admission, days	Admission complications	LVEDV pre, mL	LVEDV post, mL	LVEF pre, %	LVEF post, %	FC pre	FC post	Follow-up, months
1	Parachute®	Male	64	Interventional cardiologist, cardiac surgeon, anesthesiologist	Sedation + local anesthesia	Femoral surgical dissection	4	No	136	124	25	32	III	II	15
2	Parachute®	Male	67	Interventional cardiologist, cardiac surgeon, anesthesiologist	Sedation + local anesthesia	Femoral surgical dissection	3	No	126	124	30	30	III	I	12
3	PliCath HF®	Male	53	Cardiac surgeon, anesthesiologist	General anesthesia	Medial sternotomy	10	Light post-operative bleeding	103	84	40	48	III	I	6
4	PliCath HF®	Male	49	Cardiac surgeon, anesthesiologist	General anesthesia	Medial sternotomy	13	No	99	101	38	38	III	I	6

FC, New York Heart Association functional class; LVEF, left ventricular ejection fraction; LVEDV, left ventricular end-diastolic volume.

with the Heart Failure Association (HFA) of the ESC. ESC Guidelines for the



**Figure.** Diagram of the Parachute® and PliCath HF® devices. PTFE, expanded polytetrafluoroethylene.

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## Percutaneous Mitral Valve Repair With Mitraclip® System in a Patient With Acute Mitral Regurgitation After Myocardial Infarction



### Reparación valvular mitral con dispositivo MitraClip® en paciente con insuficiencia mitral aguda tras infarto de miocardio

#### To the Editor,

We present the case of a 76-year-old male patient who was seen at our center for anginal chest pain that had started

24 hours earlier. The electrocardiogram at admission showed pathological inferolateral Q-waves with ST segment elevation in the inferolateral leads. An emergency coronary angiography was performed, which showed occlusion of the proximal circumflex artery and insignificant abnormalities in the other arteries (Figures 1A and B). In this situation, we decided to treat the artery that was causing the infarction, implanting a Multilink 8 3/23 mm stent (Abbott Vascular; Santa Clara, California, United States), with optimal angiographic result (Figure 1C). In the following 24 hours the patient suffered two episodes of acute pulmonary edema, which were controlled with diuretic and