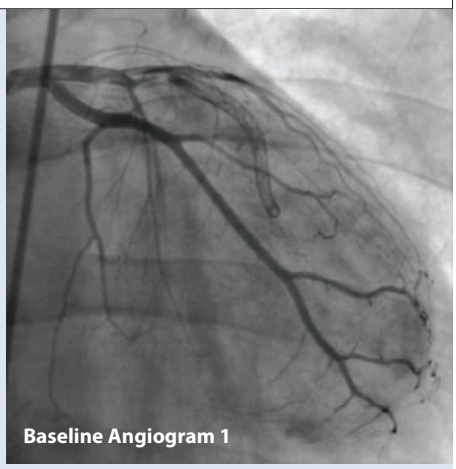
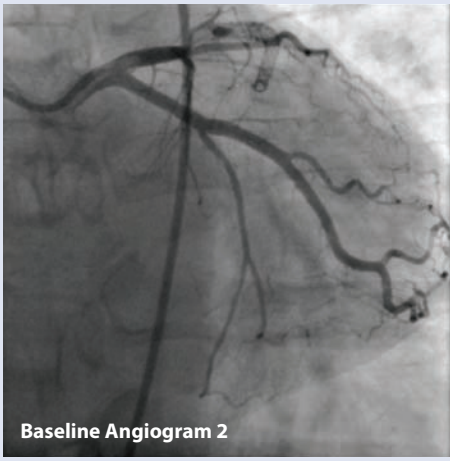
Case Study
Treatment for Chronic Ischemia

Roger Evans, MD, Cardiologist
Robert Fleming, MD, Cardiothoracic Surgeon
Kansas Medical Center, Andover, KS


Baseline Angiogram 1


Baseline Angiogram 2

Patient History

- 37 year old male
- Previous CABG: Single graft, LIMA to LAD, June 2007
- Previous PCI: 13 catheterizations, most recent – stent to LAD June 2008
- Cardiac medications: maximal calcium channel blockers, betablockers, and 60-90 nitro tablets per month
- Spent most of his waking time horizontal in bed or a recliner

Patient Presentation

- Stable Class IV angina
- NYHA Class III Heart Failure
- History of hypertension, hypercholesterolemia, previous smoker
- Summary: Patient experienced reoccurrence of exertional angina shortly after stent to LAD in June 2008. Despite maximum medical therapy, staying in good shape and smoking cessation, his fatigue worsened over the past year. Complains of angina all the time as well as feeling tired and cold. Unable to participate in activities with his 8 year old son, and feels "like an old man." Taking nitroglycerin tablets frequently for angina.
- Diagnostic cardiac catheterization showed:
  - LAD stents completely occluded
  - Left ventricular wall hypokinetic
  - LVEF 40%
- Thallium test showed anterior wall ischemia

TMR Procedure

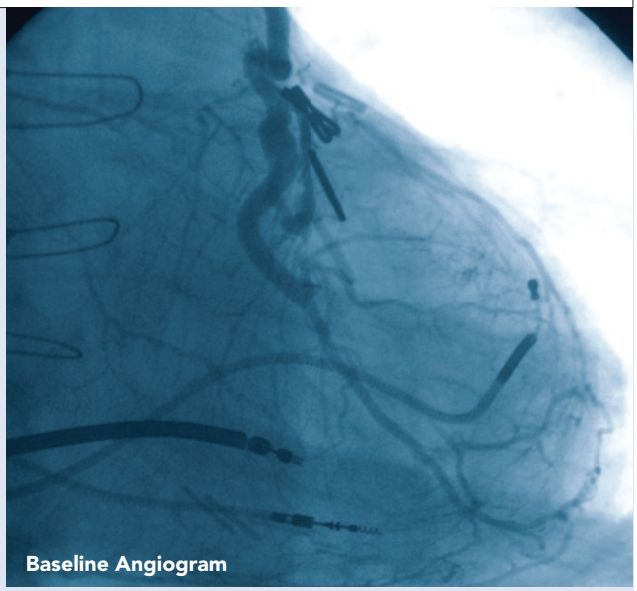
- Procedure performed June 2009
- Access to the left ventricle was achieved through a limited left anterior thoracotomy
- 36 Transmyocardial Revascularization (TMR) channels were placed in the anterior and anterolateral walls of the left ventricle
- Extubated in OR, CCU time was 24 hours, discharged on post-operative day #3

5-Month Follow-Up

Patient returned to work with increased energy and reduced angina. Nitro usage practically eliminated (one tablet a week). Return to normal activities including: playing catch with his son, doing household chores, going out to dinner, all without extreme fatigue and chest pain. A follow up Persantine stress test showed EF improved to 60%.

Case Study
Minimally Invasive Surgical TMR for Chronic Ischemia

Arthur Labovitz, MD, Cardiologist
Emily A. Farkas, MD, Cardiothoracic Surgeon
St. Louis University Hospital, St. Louis, MO


Baseline Angiogram

Patient History

- 75 year old male
- Previous CABG: 1981, 1994, 1995
- Previous PCI: 2008
- Cardiac medication: maximal calcium channel blockers, beta-blockers, nitrates

Patient Presentation

- Stable Class IV angina
- Diagnostic cardiac catheterization showed:
  - Patent left main stent
  - Patent LIMA to LAD bypass graft
  - 99% occlusion of proximal LAD
  - LVEF 39%

TMR Procedure

- Access to the left ventricle was achieved through a limited left anterior thoracotomy
- 40 Transmyocardial Revascularization (TMR) channels were placed in the free wall of the left ventricle (anterior, apical, lateral and posterior)
- Subject has a functioning ICD in place that did not discharge during the procedure
- Extubation was performed in the operating room
- CCU time was 24 hours and was discharged on post-operative day #3

5-Month Follow-Up

Patient angina free at 5-month follow-up and has completely discontinued all anti-anginal medications since taking the highest dose (120mg) of Imdur pre-TMR. No serious adverse events or rehospitalization during follow-up.

Indications for Use: Transmyocardial revascularization with the CardioGenesis TMR system is indicated for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization. Contraindications: None. Warnings and Precautions relevant to patient safety: TMR treatment should be limited to the lower 2/3 of the left ventricle to avoid the mitral valve and disruption of the conduction system near the AV groove. Do not treat the myocardium in the area of a left ventricular mural thrombus because of potential for the creation of emboli. The surgeon should have a defibrillator readily available throughout the surgical procedure. Refer to the CardioGenesis TMR System Instructions For Use for complete information. Please note: This Case Study is provided for your information and education only and is not a substitute for medical judgment.

CryoLife®
ML0477.001 (07/2015)
1655 Roberts Blvd., NW • Kennesaw, GA 30144 • Customer Care: 800.869.6334 • 24-Hour Technical Support: 800.741.7062 • www.cardiogenesis.com