Heart-FID

- **CONDITION:** Heart failure with iron deficiency anemia
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**DESCRIPTION:** This is a randomized, double blind, placebo-controlled study to investigate the efficacy and safety of Injectafer® (ferric carboxymaltose) as treatment for heart failure with iron deficiency. Study drug administration will occur as two intravenous doses every six months for duration of study.

**CRITERIA LIST/QUALIFICATIONS:**

- **Inclusion:**
  - Ejection fraction ≤35%
  - Stable heart failure (NYHA II-IV) on maximally tolerated background therapy
  - Hemoglobin 9.0-13.5 g/dL (females) or <15.0 g/dL (males), serum ferritin <100 ng/mL or 100-300 ng/mL with TSAT <20%

- **Exclusion:**
  - Current or planned LVAD or heart transplantation, history of recent cardiovascular events, and significant co-morbidities

**SPONSOR:** Luitpold Pharmaceuticals, Inc.
UNIQUE CASES AND OUT OF THE BOX APPROACHES

Benjamin Sun, MD
Minneapolis Heart Institute

Case 1

- 29 y.o. male hx of substance abuse
- 2014 TVR with tissue valve for MSSA endocarditis
- 2016 January, recurrent MSSA and TV prosthetic valve endocarditis
  - Did not want surgery and wanted conservative management
- 2016 July, came in in profound shock with bacteremia. Shock liver, renal failure and blue lips.
Surgical Candidate?

- Shock liver
- Acute renal failure
- Extremely difficult patient to deal with
- No (%%$@#%) way.

- Of course we have ECMO!
Few days later

- **The Good**
  - Shock liver resolving
  - Starting to trickle urine
  - Acidosis corrected
- **The Bad**
  - No flow through his tricuspid valve
  - Still bacteremic
- **The Ugly**
  - Arms and legs are black and ischemic
  - Will need bilateral forearm amputations
  - Will need BKA and or AKA on legs.

Met with Family

- **Futility**
  - How would he handle 4 amputations?
    - Best friend was in the Gulf War and had 3 amputations
    - He went to Texas (Ft Bragg) to help him rehab
  - Family begged us to help
  - Swore he had been clean for 6 months. (Family and girl friend)
  - Oh (*&%$#@!!) crap.
Valve

What did I do?
In vivo remodeling potential of a novel bioprosthetic tricuspid valve in an ovine model

Anna M. Fallon, PhD, Traci T. Goodchild, PhD, James L. Cox, MD, and Robert G. Matheny, MD

Objectives: A novel bioprosthetic tricuspid valve was constructed from an acellular extracellular matrix (ECM) bioscaffold. The valve’s mechanical functionality and potential for histologic regeneration was evaluated in an ovine model.

Methods: The native tricuspid valves of 4 domestic sheep were excised and replaced with bioprosthetic valves constructed from the ECM bioscaffold material shaped into the form of a tube. In vivo function was assessed over time by transthoracic echocardiography. Animals were euthanized at 3, 5, 8, and 12 months after valve implantation, and explanted valves were examined for gross morphology and by qualitative histopathologic analysis.

Results: All 4 sheep survived until the specified date. Forward flow by echocardiography was normal with trivial to mild regurgitation. Annular morphology and mobility of the leaflets appeared normal with excellent leaflet coaptation. Explanted valves were grossly normal at all time points and showed evidence of progressive tissue remodeling and integration at the host-tissue interface. Histopathologic analysis demonstrated massive host-cell infiltration, structural reorganization of the ECM bioscaffold, elastin generation at the annulus by 3 months, and increased collagen organization and glycosaminoglycan presence in the leaflets by 5 months, with no evidence of foreign body response.

Conclusions: When implanted in the form of a tubular valve, the acellular ECM bioscaffold demonstrates feasibility as a biomechanically sound bioprosthetic tricuspid valve replacement with evidence of progressive endothelialization and constructive tissue remodeling. (J Thorac Cardiovasc Surg 2014;148:333-40)
**Technique**

**FIGURE 1.** Procedural photographs of the tricuspid valve implantation. A. View from the atrial side shows initial placement of the 3 papillary muscle attachments (valve body and attachment denoted by white arrows). B. View from the ventricular side shows all 3 papillary muscle attachments (denoted by white circles). C. View from the atrial side showing the implanted valve annulus.

**3 and 8 months animals**

[Images of tricuspid valve implantation in 3 and 8 months animals]
CorMatrix Scaffold

New Tricuspid Valve
Early experience treating tricuspid valve endocarditis with a novel extracellular matrix cylinder reconstruction

Marc W. Gendrisch, MD, W. Douglas Boyd, MD, John L. Harlan, MD, John B. Richardson, Jr, MD, Joseph E. Flack III, MD, Brian A. Palafox, MD, William E. Johnson III, MD, Benjamin Sun, MD, Richard Lee, MD, T. Sloane Guy, MD, Gyu I. Gang, MD, James L. Cox, MD, and Vivek Rao, MD, PhD

Objective: The short-term outcomes were evaluated in patients treated for tricuspid valve endocarditis using a novel extracellular matrix (ECM) cylinder reconstruction technique.

Methods: Patients with clinically significant tricuspid regurgitation whose valves were not repairable by conventional techniques underwent valve replacement with a cylindrical construct sewn out of CorMatrix ECM (CorMatrix Cardiovascular, Roswell, Ga). The cylinders were sized to the native valve dimensions and attached distally to the papillary muscles using polypropylene sutures and ECM pledgets, and proximally to the annulus using a running suture. Patient data were collected retrospectively.

Results: From November 2011 to October 2013, 12 surgeons performed 19 tricuspid valve cylinder reconstructions in 8 men and 10 women (age range, 19-55 years). Of the 19 patients, 11 had active and 5 had treated endocarditis. One case was robotic-assisted. No deaths occurred, and no new cases of heart block developed. The papillary attachments were disrupted intraoperatively in 1 patient and after 7 days in another; both were successfully revised. A third patient experienced recurrent disruption of the implant at 13 and 22 months and ultimately received a pericardial valve. Fungal infection occurred in 1 cylinder at 6 months; a second ECM cylinder was implanted. Follow-up data were available for 13 patients at 1 to 2 months, 8 at 6 months, and 3 at 12 and 18 months. Other than patients undergoing reoperation, all showed well-functioning tricuspid valves with no mild regurgitation.

Conclusions: Cylinder reconstruction with ECM could be a suitable technique for replacing the tricuspid valve while preserving annuloventricular continuity in patients with infective endocarditis not repairable by conventional techniques. (J Thorac Cardiovasc Surg 2014;:1-7)

August 2017 (1 year follow up)
History

- 30 y.o. black male with complex cyanotic congenital heart disease
  - dextroposition
  - single right ventricle
  - both great vessels arising from this single ventricle
    - Double outlet R ventricle
    - aorta is anterior and leftward
  - pulmonary stenosis
  - common atrioventricular valve (tricuspid)
  - S/p atrioventricular valve replacement-33 mm St. Jude
  - S/p R thoracotomy for BiV pacemaker
  - IVC interruption with azygous continuation to left-sided superior vena cava
  - ipsilateral pulmonary venous return to a common atrium

Anatomy
Decompensation

- Admitted for class IV Heart failure
- IV inotropes, nesiritide
- Remained class IV
  - Renal insufficiency
  - Hepatic congestion
    - Ascites
  - Severe peripheral edema
  - CVP 34

Options

- Single VAD (technically RVAD)
  - Common atrium or ventricle to aorta
  - central shunt
- BIVAD
  - Common atrium to PA
  - Common atrium or common ventricle to aorta
  - Control shunt with individual VAD flows
- BIVAD
  - Baffle common atrium to separate systemic venous and pulmonary artery returns
  - RVAD from system venous return
  - LVAD from common ventricle to aorta
- TAH
- Run Away
What We Did

- Cannulated
  - L femoral artery/vein
  - R SVC, L SVC
- Opened common atrium
  - Identified all connections
- Baffled pulmonary veins though mechanical A-V valve into common ventricle
- Oversew pulmonary valve
- Closed ASD
What We Did

Anatomy
Atrial Baffle
Cannulation

- R sided inflow from blind pouch atrium
- Outflow to PA (oversewn PV)
- L sided inflow (common) ventricle apex
- Outflow to aorta
- 13 hours in OR
- Bypass time 400 min
- No crossclamp
## IVC injection

![Image of IVC injection]

## Post Operative

- RVAD 5.0 L/min
- LVAD 6-6.5 L/min
- Long postop recovery
  - Pulmonary toilet
  - Malnutrition
  - Hepatic recovery
- Rehabilitation
  - >15 min on treadmill
- Discharged 3/2/2004
Rehabilitation

Complication

- Admitted electively for status 1a listing
- Converted from coumadin to heparin
- Everything clinically perfect
  - PTT 65 sec
  - BIVAD flows stable
  - Vitals normal
- Mental status changed 3 am
- Massive hemorrhagic CVA
CT Scan

0400 0700

Postmortem

Autopsy Report
Patient Name: XXXXX, XXXXX X
Accession #: U04-71
Med. Rec. #: 907201302
Physician(s): DANIELS, CURT JOHN Benjamin Sun, M.D.

*****Pathologic Diagnoses*****

SUBARACHNOID HEMORRHAGE, RIGHT HEMISPHERE, BRAIN
Secondary to ruptured berry aneurysm at junction of right middle cerebral artery and right posterior communicating artery Edema, brain

Complex congenital heart disease Dextrocardia Malpositioned ventricles (right ventricle: more leftward and anterior; left ventricle: more rightward and posterior) L-transposition of the great arteries Double outlet right ventricle Hypoplastic left ventricle Hypoplastic mitral valve Ventricular septal defect, high in the ventricular septum Pulmonary valve stenosis Anomalous pulmonary and systemic venous return, by clinical history Massive dilatation, atria and right ventricle Severe ventricular hypertrophy Common atrium (status/post insertion of intra-atrial pericardial baffle) Status/post placement of biventricular assistive devices Status/post tricuspid valve replacement
CONCLUSION: Individuals with a variety of congenital heart disorders may be at an increased risk of intracranial aneurysm development and cervicocephalic arterial dissection, particularly in adolescence. The muscular arteries of the head and neck are derived from neural crest cells and the neural crest is also of major importance in early cardiac development, suggesting that an abnormality of the neural crest may be the common pathogenetic factor explaining this association.

My Most Painful Case

- Wonderful patient and family
- Touched everyone
- Extraordinarily compliant
- Dealt a short hand from birth
- Could not get a break