BioVentrix

QUARTERLY NEWSLETTER
OCTOBER - DECEMBER 2015

## In this Issue



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## Introduction

Welcome to the inaugural issue of the BioVentrix Quarterly Newsletter! As we enter the fourth quarter of 2015, BioVentrix is making great strides and experiencing tremendous clinical momentum. We now have 10 implanting centers in 5 countries – Italy, France, Czech Republic, Spain, and Germany. Just last month we completed our 30th hybrid transcatheter procedure with the Revivent-TC™ system. Importantly, the data continues to show the same volume reduction efficacy with this hybrid approach as was demonstrated with the surgical technique. August also marked the 5th anniversary of the first Revivent™ human implant and the long term durability continues to impress. We are clearly helping many ischemic heart failure patients who have few remaining therapeutic options.

In this edition of the newsletter we're featuring:

- Case Spotlight – Asklepios Kilink St. Georg, Hamburg, Germany
- Updated Clinical Results
- European Society of Cardiology (ESC) - Investigators Meeting and 'Hot Topic'
- FAQ's

Our hope is that you will find this newsletter to be informational and educational. We welcome your input on what content you might find interesting or topics which you would like to discuss. Also, we hope to feature your own unique patient testimonies and success stories in the 'Case Spotlight' in upcoming issues. Our goal of providing innovative solutions for ischemic heart failure can only be realized in partnership with you, our supportive clinical partners.

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## Case Spotlight

### Asklepios Klinik St. Georg, Hamburg, Germany

We recently completed the 30th less-invasive, hybrid procedure. Dr. Christian Frerker and Dr. Tobias Schmidt (interventional cardiologists) and Dr. Ralf Bader (surgeon) implanted 4 micro-anchors pairs into a 77 yr. old patient at Asklepios Klinik St. Georg in Hamburg, Germany.

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## Updated Clinical Results

Updated clinical data on 79 patients is presented in Tables 1-4. The first 51 patients were treated with the surgical delivery method and the subsequent 28 patients were treated with the transcatheter method. The implanted anchor pairs were exactly identical for both groups. Patients in both groups are indistinguishable clinically and statistically from the entire group.

Continued on page 2

## Updated Clinical Results (Continued from page 1)

### Table 1. Hemodynamic Data

| Statistics | Baseline | 6-Month | 12-Month | 24-Month |
|---|---|---|---|---|
| **LV End-Diastolic Volume Index (ml/sqm)** | | | | |
| N | 79 | 63 | 47 | 27 |
| Mean (SD) | 105.24 (32.54) | 81.07 (26.72) | 75.02 (20.91) | 83.85 (29.33) |
| P< vs. baseline | | 0.001 | 0.001 | 0.007 |
| **LV End-Systolic Volume Index (ml/sqm)** | | | | |
| N | 79 | 63 | 47 | 27 |
| Mean (SD) | 73.80 (26.62) | 54.33 (24.26) | 50.29 (18.70) | 57.70 (25.98) |
| P< vs. baseline | | 0.001 | 0.001 | 0.02 |
| **Ejection Fraction (%)** | | | | |
| N | 79 | 64 | 47 | 27 |
| Mean (SD) | 29.75 (7.49) | 34.68 (9.87) | 34.05 (8.09) | 33.41 (9.70) |
| P< vs. baseline | | 0.004 | 0.006 | 0.11 (NS) |

### Table 2. Heart Failure Symptom Assessment

| Statistics | Baseline | 6-Month | 12-Month | 24-Month |
|---|---|---|---|---|
| N | 78 | 68 | 55 | 27 |
| Mild/Moderate HF (NYHA Class I and II) | 43.60% | 72.00% | 78.20% | 85.20% |
| Advanced HF (NYHA Class III and IV) | 56.40% | 28.00% | 21.80% | 14.80% |

### Table 3. Exercise Capacity

| Statistics | Baseline | 6-Month | 12-Month | 24-Month |
|---|---|---|---|---|
| **Total Distance Walked (metres)** | | | | |
| N | 75 | 62 | 50 | 24 |
| Mean (SD) | 345.12 (110.07) | 401.77 (105.03) | 420.71 (106.18) | 379.82 (111.45) |
| P< vs. baseline | | 0.001 | 0.001 | 0.16 (NS) |
| Median | 350 | 410 | 420 | 381.50 |

### Table 4. Quality of Life Evaluation

| Statistics | Baseline | 6-Month | 12-Month | 24-Month |
|---|---|---|---|---|
| **Overall MLHF Score** | | | | |
| N | 72 | 65 | 53 | 25 |
| Mean (SD) | 42.68 (23.13) | 23.29 (18.50) | 26.43 (18.81) | 25.48 (21.75) |
| P< vs. baseline | | 0.001 | 0.001 | 0.001 |
| Median | 44 | 18 | 23 | 19 |

## Case Spotlight (Continued from page 1)

### Patient Characteristics

- 77 yrs. old
- NYHA class II
- Chronic Renal Failure
- Single-Lead ICD implantation in 2014
- Persistent AF
- MitraClip in 2014
  - MR Type I
- 3 vessel CAD
  - Previous MI in 2000
  - Anterior aneurysm
  - LVESV=545 ml
  - LVEF= 8%
  - LVEDV=593 ml

**Fig. 1 Fluoroscopy View, Post-Procedure**

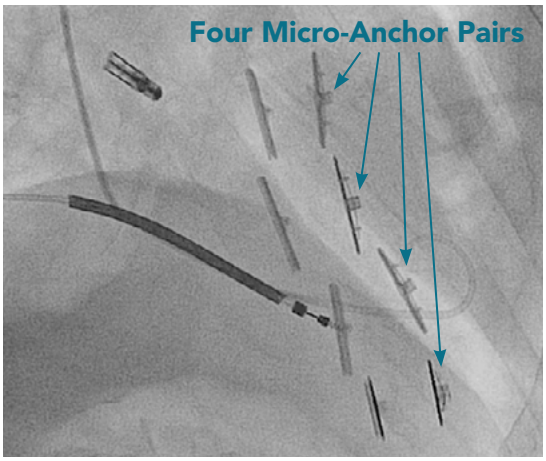



**Fig. 2 Pre- and Post-Procedure Comparison**

| Pre-Procedure | Post-Procedure | Change |
|---|---|---|
| • LVESV=545 ml | • LVESV=377 ml | • LVESV Reduction=31% |
| • LVEF=8% | • LVEF=15% | • LVEF Improvement=88% |
| • LVEDV=593 ml | • LVEDV=442 ml | • LVEDV Reduction =25% |
| • SV=48 ml | • SV=65 ml | • SV Improvement =35% |

## Case Spotlight *(Continued from page 2)*

"The Revivent-TC hybrid system allows for treatment of worsening heart failure patients and those that are already very ill without opening the chest," said Dr. Frerker. "This may be the medical breakthrough needed to treat heart failure patients. We are very pleased with the outcome of the procedure," added Dr. Schmidt. "The procedure reduces wall stress and reshapes the left ventricle to improve its pumping efficiency. That is important for treating the underlying cause of heart failure," according to Dr. Bader.

**Fig. 3 TEE, Pre-Procedure**

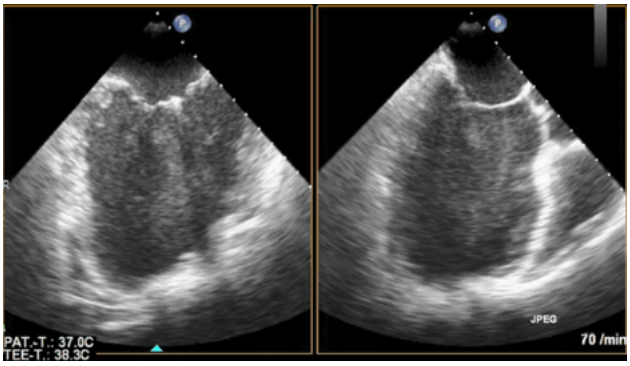



**Fig. 4 TEE, Post-Procedure**

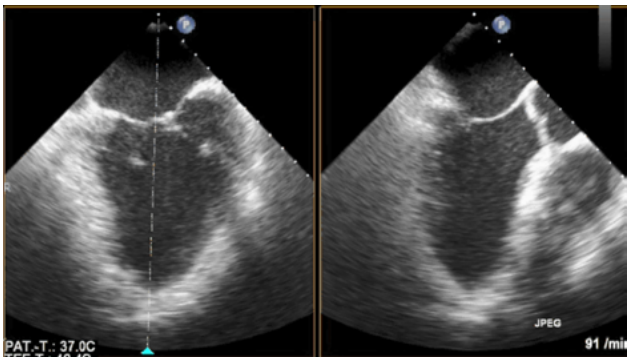
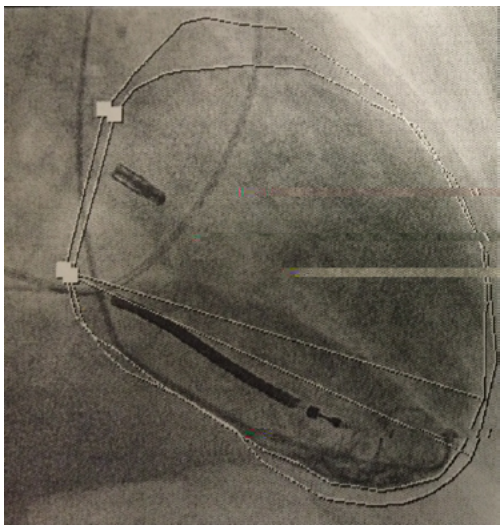
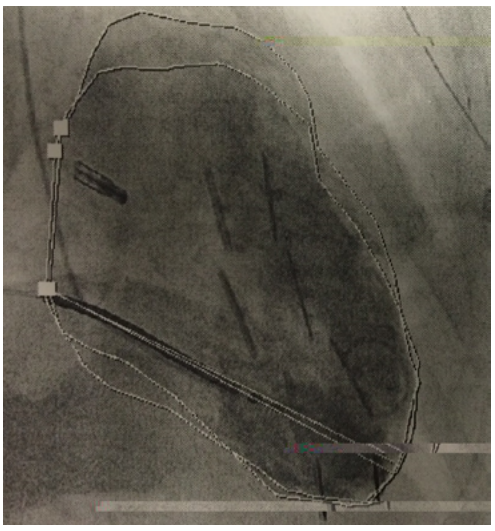



**Fig. 5 Fluoroscopy View, Pre- and Post-Procedure Volume Reduction**



**Pre-Procedure**



**Post-Procedure**

**The procedure was a great success with a volume reduction of 31% (LVESV), 25% (LVEDV) and LVEF was improved by 88%.**

## Case Spotlight: Physicians

**Dr. Christian Frerker**
Interventional Cardiologist
Asklepios Klinik St. Georg
Hamburg, Germany

**Dr. Tobias Schmidt**
Interventional Cardiologist
Asklepios Klinik St. Georg
Hamburg, Germany

**Dr. Ralf Bader**
Cardiothoracic Surgeon
Asklepios Klinik St. Georg
Hamburg, Germany

## European Society of Cardiology (ESC) - Investigators Meeting

On Monday, August 31st, BioVentrix hosted an 'Investigators Meeting' in conjunction with the ESC in London. This interactive meeting was attended by 17 current and future investigators. The agenda ranged from a compelling analysis of the updated clinical data set by Dr. Christoph Schmitz (Potsdam), to a review of the promising Revivent impact on Ischemic Mitral Regurgitation (IMR) by Dr. Nina Wunderlich (Darmstadt). Case reports were presented by Dr. Michele Senni (Bergamo), Dr. Salvatore Brugaletta (Barcelona) and Dr. Tobias Schmidt (Hamburg). The final topic was a presentation on progress towards a fully percutaneous system by BioVentrix Chief Medical Office, Dr. Lon Annest. This was a very productive event that will be convened again in early 2016. All the great feedback was very much appreciated.

## Frequently Asked Questions (FAQ's)

**Can a BioVentrix patient be found in the Electrophysiology (EP) lab?**

The typical BioVentrix patient presents with LV anteroseptal scar, dilated LV, post-MI ischemic cardiomyopathy, and low LVEF (> 15%). Strauss et al. studied 233 patients[1]. The patients had LVEF < 35% and those with RBBB (Right Bundle Branch Block) were more likely to have ischemic heart disease and significantly larger scar size than patients with LBBB (Left Bundle Branch Block). According to the authors, "Our study supports the premise that RBBB has a strong association with large anteroseptal scar in cardiomyopathy patients, and occlusion of a proximal LAD septal perforator cause RBBB."

BioVentrix patients may be found in the EP lab. Further investigation is warranted to determine that the patients meet the BioVentrix inclusion criteria.

[1]'Right, But Not Left, Bundle Branch Block Is Associated With Large Anteroseptal Scar', Strauss et al.

## Hot Topic - IMR Study

**Dr. Nina Wunderlich**
Director,
Non-Invasive Cardiology
Cardiovascular Center
Darmstadt, Germany

We are pleased to announce the addition of Dr. Nina Wunderlich to our team as a clinical consultant to spearhead the execution of our IMR analysis and study. Dr. Wunderlich is a recognized expert in the field of echocardiography, innovative percutaneous technologies, and catheter-based treatment of MR. She is a frequent lecturer, proctor and author who has published numerous peer reviewed articles on these various topics. She is board certified in both internal medicine and cardiology and is currently employed at the Cardiovascular Center in Darmstadt, Germany. With BioVentrix, she will be responsible for designing and implementing the study protocol which is intended to definitively determine the impact of the Revivent therapy on IMR.

### Meet the BioVentrix Team at:

***European Association for Cardio-Thoracic Surgery (EACTS)***
Oct. 3-7, Amsterdam, The Netherlands

***German Cardiac Society, Autumn Meeting***
Oct. 8-10, Berlin, Germany

***Transcatheter Cardiovascular Therapeutics (TCT)***
Oct. 11-15, San Francisco, CA