Percutaneous Ventricular Restoration (PVR) therapy using the Parachute Device in Patients with Ischemic Dilated Heart Failure

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Einstein Medical Center
Philadelphia, PA
Heart Failure at the Center of Healthcare Cost & Reform

Heart Failure: A Growing Problem

US Population with HF

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2015</th>
<th>2020</th>
<th>2025</th>
<th>2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>9,000,000</td>
<td>9,000,000</td>
<td>9,000,000</td>
<td>9,000,000</td>
<td>9,000,000</td>
</tr>
</tbody>
</table>

Hospitalization & Mortality

- 1.1M hospitalizations annually
- 3M physician visits annually
- 250,000 deaths annually
- 5 year mortality rate of ~ 50%

Health Care Costs & Reform

- HF Costs $31B now….$70B by 2030
- HF Hospitalization ~2/3 of HF costs
- HF included in Quality Metrics
- Hospital Readmission Reduction Program

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Parachute System

Parachute Implant

Anchor (Laser Cut)
Engages LV Wall (2mm)

Suture (Polypropylene)
Collapses Device. Supports ePTFE at the Edge

Membrane (ePTFE)
Dual layer occlusive membrane. Allows tissue growth.

Frame (Nitinol)
16 Arms Laser Cut from a Single Tube

Foot (Urethane)
Radiopaque. Shock Absorber

Guide Catheter
3 shapes (14 or 16Fr)

Delivery System
20cc balloon is inflated to anchor device

<table>
<thead>
<tr>
<th>Size</th>
<th>65mm</th>
<th>75mm</th>
<th>85mm</th>
<th>95mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard (+3mm)</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Short</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>
The cause of LV remodeling is the eccentric wall motion caused by the myocardial infarct.

The initial LV dilatation stretches the muscle fibers causing them to contract more forcefully in order to maintain stroke volume.

As the LV enlarges the increased wall tension is detrimental to the surviving myocardium's ability to contract.

To relieve symptoms we must cause the LV to contract more effectively and require less pressure to fill for the next contraction.

The filling pressure increases due to the resistance caused by the less compliant LV. As a result, this backs up blood into the lungs, impeding oxygen exchange causing shortness of breath and decreased exercise ability. Thus the cascade of events from the scar as a result of an MI impairs both systolic and diastolic function of the heart.

The LV's ability to stretch and accommodate filling from the left atrium through the mitral valve is compromised by the presence of the scar.
Parachute Reduces LV Volume, Reshapes LV, and Restores Cardiac Function

(1) “RESTORING EFFECT”

Reduces wall stress in the upper chamber by changing LV geometry and reducing volume

(2) “TRAMPOLINE EFFECT”

Replaces the stiff/rigid scar with a more compliant Parachute that provides outward force by the anchors to aid in diastolic filling

Improves diastolic compliance that reduces end diastolic filling pressures
Analysis Population

- 111 Consecutive Intent-to-Treat patients included in this presentation.

- All enrolled on or before December 31, 2012 in the following trials: Europe Cohort A (16), US Feasibility (18), Europe Cohort B (54), and Parachute III (23)
# Patient Baseline Characteristics, N=111

## Demographics

<table>
<thead>
<tr>
<th>Age, years</th>
<th>60.7 ± 10.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>93/111 (83.8%)</td>
</tr>
<tr>
<td>BMI</td>
<td>28.5 ± 5.1</td>
</tr>
</tbody>
</table>

## Underlying Heart Disease

| Ischemic         | 111/111 (100%) |

## NYHA Class

| NYHA I*          | 1/111 (0.9%) |
| NYHA II*         | 45/111 (40.6%) |
| NYHA III         | 65/111 (58.5%) |

## Medical History

| Smoking History, % | 78/105 (74.3%) |
| History of Hypertension, % | 76/111 (68.5%) |
| History of Diabetes, % | 39/111 (35.1%) |
| Prior ICD, %       | 42/111 (37.8%) |
| Prior CRT, %       | 20/111 (18.0%) |
| Prior PCI, %       | 84/111 (75.7%) |
| Prior CABG, %      | 19/111 (17.1%) |
| HF Hosp. 12M Before Enrlmt, % | 30/95 (31.6%) |

## Cardiac Medications

| Aspirin, %      | 86/98 (87.8%) |
| Anticoagulant, %| 39/100 (39.0%) |
| ACE Inhibitor, %| 82/111 (73.9%) |
| ARB, %          | 21/111 (18.9%) |
| Beta Blocker, % | 108/111 (97.3%) |
| Diuretic, %     | 94/111 (84.7%) |
| Optimal Medical Therapy¹, % | 87/111 (78.4%) |

¹defined as beta blocker + diuretic + (ACE or ARB)

*NYHA III or IV in the last 3 months
Left Ventricle Baseline Characteristics, N = 111

- **Cardiac Output**: $4.6 \pm 2.2$ L/min
- **Left Atrial Volume**: $84.4 \pm 28.2$ ml
- **EDVi**: $122.4 \pm 27.4$
- **COi**: $2.3 \pm 1.1$
- **LAVi**: $43.3 \pm 14.5$
- **EDV**: $240.4 \pm 61.0$ ml
- **EF**: $27.9 \pm 7.8$
- **EDP**: $21.3 \pm 19.6$ mmHg
- **LVDD**: $6.0 \pm 0.9$ cm
- **MR**: $79\%$
- **AR**: $33\%$
- **Long Axis**: $9.6 \pm 1.0$ cm

Sample size may differ for each variable due to echo quality and availability.
## Procedure Data, N=111

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Success, %</strong></td>
<td>106/111 (95.5%)</td>
</tr>
<tr>
<td><strong>Device Size</strong></td>
<td></td>
</tr>
<tr>
<td>65mm, %</td>
<td>3/111 (2.7%)</td>
</tr>
<tr>
<td>75mm, %</td>
<td>49/111 (44.1%)</td>
</tr>
<tr>
<td>85mm, %</td>
<td>42/111 (37.8%)</td>
</tr>
<tr>
<td>95mm, %</td>
<td>17/111 (15.3%)</td>
</tr>
<tr>
<td><strong>Duration, minutes</strong></td>
<td>86.0 ± 41.4</td>
</tr>
<tr>
<td><strong>Fluoroscopy Time, minutes</strong></td>
<td>20.7 ± 25.8</td>
</tr>
<tr>
<td><strong>Days in Hosp. Prior to Discharge</strong></td>
<td></td>
</tr>
<tr>
<td>US</td>
<td>2.9 ± 1.9</td>
</tr>
<tr>
<td>EU</td>
<td>5.9 ± 3.0</td>
</tr>
<tr>
<td><strong>Procedure Complications by VARC</strong></td>
<td>16/111 (14.4%)</td>
</tr>
<tr>
<td>Major, %</td>
<td>8/111 (7.2%)</td>
</tr>
<tr>
<td>Minor, %</td>
<td>9/111 (8.2%)</td>
</tr>
</tbody>
</table>


Angiographic sequence of a Parachute implantation in the left ventricle (LV). Pigtail in the LV cavity to perform LV angiography (A), Device placement with foot exposed and in contact with the antero-apical wall (B), Balloon inflation to facilitate self-expansion of the device (C), Device fully expanded but still attached to the delivery system (D) Final positioning after release of the device (E).
<table>
<thead>
<tr>
<th>Variable</th>
<th>N*</th>
<th>Baseline</th>
<th>12M</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Rate</td>
<td>95</td>
<td>67.5 ± 13.1</td>
<td>67.9 ± 10.5</td>
<td>NS</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic, mmHg</td>
<td>95</td>
<td>118.6 ± 17.2</td>
<td>117.3 ± 14.6</td>
<td>NS</td>
</tr>
<tr>
<td>Diastolic, mmHg</td>
<td>95</td>
<td>71.7 ± 10.0</td>
<td>71.6 ± 10.1</td>
<td>NS</td>
</tr>
<tr>
<td>LV Volume</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ESVi, ml/m²</td>
<td>81</td>
<td>87.6 ± 24.6</td>
<td>73.2 ± 22.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>EDVi, ml/m²</td>
<td>81</td>
<td>120.8 ± 26.2</td>
<td>103.8 ± 25.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Systolic Improvement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ejection Fraction, %</td>
<td>81</td>
<td>28.4 ± 8.0</td>
<td>30.4 ± 8.1</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Fractional Shortening, %</td>
<td>72</td>
<td>18.5 ± 9.8</td>
<td>20.3 ± 8.6</td>
<td>0.14</td>
</tr>
<tr>
<td>Contractility Index (Ees), mmHg-m²/ml</td>
<td>81</td>
<td>1.3 ± 0.5</td>
<td>1.6 ± 0.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Stroke Work / EDVi, mmHg</td>
<td>81</td>
<td>26.8 ± 8.7</td>
<td>29.0 ± 8.2</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Diastolic Improvement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAVi, ml/m²</td>
<td>43</td>
<td>43.6 ± 15.1</td>
<td>37.8 ± 10.9</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

*Paired analysis on available data thus the different Ns
NYHA, N=106

N=106 is the number of patients discharged with the Parachute device

*NYHA II at baseline had to be NYHA III or IV in the last 3 months
NYHA, N=106

- Baseline, All: 32% Maintain, 54% Improve
- 12M: 35% Maintain
- Baseline, NYHA II*: N=43
- 12M: 51% +1 NYHA

- N=106 is the number of patients discharged with the Parachute device
- *NYHA II at baseline had to be NYHA III or IV in the last 3 months
NYHA, N=106

N=106 is the number of patients discharged with the Parachute device
*NYHA II at baseline had to be NYHA III or IV in the last 3 months
6 Minute Walk Data, N=89

N=89 is the number of patients completing both a baseline and 12M 6MWT
Stroke Rate

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>BL</th>
<th>180 days</th>
<th>360 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL</td>
<td>106</td>
<td>96</td>
<td>82</td>
</tr>
</tbody>
</table>
Mortality (all-cause) Rate

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>180 days</th>
<th>360 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>BL</td>
<td>106</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td></td>
<td>84</td>
</tr>
</tbody>
</table>

5.7%
Mortality + HFH Rate

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>BL</th>
<th>180 days</th>
<th>360 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>106</td>
<td>86</td>
<td>73</td>
</tr>
</tbody>
</table>
Conclusions

• Device efficacy as measured by hard clinical endpoints of death and repeat hospitalization for worsening HF are favorable when compared to published literature and support the design of the current US randomized trial, PARACHUTE IV (actively enrolling).

• Hemodynamic improvements are seen in both the systolic and diastolic phases of the cardiac cycle.

• Functional improvement is shown by an increase in the 6MWT and reduction in NYHA class.

• High procedural success rate of 96% with a low Major VARC rate of 7.2%.
VENTRICULAR ASSIST DEVICE

Definition:

- Mechanical Device which is used to replace or reproduce the pump function of the left and/or right ventricle.

Basic Principle:
- Improve arterial flow (end-organ perfusion)
- Improve ventricular unloading

Price:
- Blood element destruction
- Thomboembolism
- Infection
- Cost
Percutaneous VAD in the Cath Lab

- Hemodynamic support for cardiogenic shock
- Hemodynamically assisted high-risk PCI
- Assisted percutaneous valve therapies
- Assisted left-sided arrhythmia ablation
Clinical Goals in Emergent Patients

• Restore Stable Hemodynamics
  – *reversing decline of end-organ perfusion, reducing risk of end-organ failure, breaking cycle of cardiogenic shock*

• Minimize Infarct Size
  – *reducing myocardial ischemia, halting cell damage, maximizing residual cardiac function*

• Ease-of-Use & Safety
  – *consistent with critical treatment time scenarios and risk-benefit considerations of emergency care*
Clinical Goals in Complex Interventions

• Maintain Hemodynamics
  – avoiding disruptions in cardiac output, clinical challenges to end-organ function and neurological instabilities

• More Time for Balloon Inflation & Stent Placement
  – by raising the patient’s ischemic threshold to minimize cell damage from balloon inflation or coronary dissection

• Prophylactic Safety Profile & Ease-of-Use
  – reduce complications such as bleeding or embolization to end organs such as stroke or limb ischemia
Heart muscle can recover with support

High Potential of heart muscle recovery, Gain in Ejection Fraction

Low Potential of heart muscle recovery, Loss in Ejection Fraction

A  Ventricular remodeling after acute infarction

Initial infarct  Expansion of infarct (hours to days)  Global remodeling (days to months)

Evolution of Cardiac Support in Cath lab

- ECMO
- IABP
- CPS
- Hemopump
- TandemHeart
- Impella

Time Periods:
- 70’s
- 80’s
- 90’s
- 00’s
PERCUTANEOUS LEFT VENTRICULAR ASSIST DEVICES

- Cardiogenic Shock Accompanying MI^{1,2}
  - 7-10% of AMI^{3,4}
    - 7% STEMI
    - 2.5% non-STEMI
  - Improved Survival with Rapid Culprit Revascularization^{5,6}
  - 50-70% Mortality^{4-7}

- Percutaneous Ventricular Assist
  - IABP – NO IMPROVEMENT IN SURVIVAL^{4-7}
  - pVAD
    - TandemHeart
    - Impella

---

## Hemodynamic Advantage of pVAD vs. IABP

<table>
<thead>
<tr>
<th>Advantage</th>
<th>pVAD</th>
<th>IABP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directly unload the left ventricle</td>
<td>++++</td>
<td>-</td>
</tr>
<tr>
<td>Reduce myocardial workload and oxygen consumption</td>
<td>++++</td>
<td>++</td>
</tr>
<tr>
<td>Increase cardiac output and coronary and end-organ perfusion</td>
<td>++++</td>
<td>+</td>
</tr>
</tbody>
</table>
PERCUTANEOUS LEFT VENTRICULAR ASSISTANCE

**Tandem Heart:**
- Trans-septal LA inflow (21 F)
- Femoral arterial outflow (15-17 F)
- 3.5-4 L/min at 7500 rpm
- Systemic anticoagulation
- Approved for short-term support
PRT TandemHeart vs. IABP

- University of Leipzig (2005)
- CS p AMI with intention for PCI
- PRT: TandemHeart (21) vs. IABP (20)
- Improved Hemodynamic parameters
  - Cardiac Power Index
    - TandemHeart 0.22 → 0.37
    - IABP 0.22 → 0.28
    - p<0.004
- Improved Metabolic Parameters
  - Serum Lactate (6 hours)
- Complications
  - Increased Complications in TH vs. IABP
- Mortality (30 day)
  - TandemHeart 45%
  - IABP 43%
  - (P=0.86)
TandemHeart vs. IABP

► PRT Multi-Center (2006)
► Cardiogenic Shock (70% AMI)
► TandemHeart (n=19) vs. IABP (n=14); “roll-in” (n=9)

A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock

Daniel Burkhoff, MD, PhD,* Howard Cohen, MD,* Corinna Brunckhorst, MD,* and William W. O’Neill, MD,* for the TandemHeart Investigators Group† Orangeburg and New York City, NY; Zurich, Switzerland; and Royal Oak, MI

Background and Aim Despite major advances in the treatment of heart failure, cardiogenic shock (CGS) remains associated with substantial mortality. Recent data suggest that the TandemHeart percutaneous ventricular assist device (pVAD) may be useful in the management of CGS. The aim of this prospective randomized study was to test the hypothesis that the TandemHeart (pVAD) provides superior hemodynamic support compared with intraaortic balloon pumping (IABP).

Methods Forty-two patients from 12 centers presenting within 24 hours of developing CGS were included in the study and treated in an initial roll-in phase (n = 9) or randomized to treatment with IABP (n = 14) or TandemHeart pVAD (n = 19). Thirty patients (71%) had persistent CGS despite having an IABP in place at the time of study enrollment.

Results Cardiogenic shock was due to myocardial infarction in 70% of the patients and decompensated heart failure in most of the remaining patients. The median duration of support was 2.5 days. Compared with IABP, the TandemHeart pVAD achieved significantly greater increases in cardiac index and mean arterial blood pressure and significantly greater decreases in pulmonary capillary wedge pressure. Overall 30-day survival and severe adverse events were not significantly different between the 2 groups.

Conclusion In patients presenting within 24 hours of the development of CGS, TandemHeart significantly improves hemodynamic parameters, even in patients failing IABP. Larger scale studies are required to assess the influence of improved hemodynamics on survival. [Am Heart J 2006;152:469.e1–469.e8.]

Despite major advances in the treatment of heart failure for patients with mild, moderate, or severe symptoms, cardiogenic shock (CGS) is an area of relatively little progress. Cardiogenic shock occurs in a variety of settings such as myocardial infarction, post-cardiotomy shock, decompensated chronic heart failure, acute valve failure, and myocarditis. Depending on the clinical circumstances, inhospital mortality rates are reported in the range between 40% and 80%.1 No study has yet shown a strategy to improve short-term (30 day) survival, although emergency revascularization enhances survival at 6 and 12 months compared with conservative medical treatment.2,3 Insertion of an intraaortic balloon is considered to be standard of care in patients with medically refractory CGS,6 despite the fact that there are no randomized studies proving its efficacy.7

Accordingly, there have been multiple efforts to develop devices to provide more effective hemodynamic support while maintaining the clinically acceptable degree of invasiveness of the intraaortic balloon pumping (IABP).8,9 One such device, the TandemHeart percutaneous ventricular assist device (pVAD), has recently been studied in the setting of CGS and was shown to improve all hemodynamic parameters and reduce serum lactate, indicating improved tissue oxygenation and reversal of the CGS state.10

The purpose of this study was to test the hypothesis that the TandemHeart pVAD would provide superior hemodynamic support compared with IABP. Correlation

From the "Cardiovascular Research Foundation, Orangeburg, NY; Lenox Hill Hospital, New York City, NY; University Hospital Zurich, Zurich, Switzerland; and St William Beneficent Hospital, Royal Oak, MI. This study was supported by CardioJect, Inc, Pittsburgh, PA.


Reprint requests: Corinna Brunckhorst, MD, University Hospital Zurich, Zurich, Switzerland.

See Appendix.

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Impella 2.5 Cannula

- **Impella 2.5**
  - Pigtail: 6F
  - Catheter: 9F
  - Cannula: 12F
  - Sheath: 13F

- **Blood Inlet**
- **Blood Outlet**
- **Motor**
- **Pressure Lumen**
Impella

- Impella LP 2.5
  - 13 F sheath (percutaneous)
  - 9 F cannula
  - 2.5 L maximal flow
  - 510K FDA approved for LV support for up to 6 hours
  - Sold by AbioMed

- Impella LP 5.0
  - 21 F
  - Requires surgical implantation
  - 5.0 max flow
Comparison of IABP to Impella Pump

IABP

LV Pressure

LV Volume

Impella

LV Pressure

LV Volume

LV Pressure
Impella pVAD

- PRT; November 2008
- 26 patients
  - 13 IABP
  - 12 Impella LP2.5
- Hemodynamics
  - IABP ΔCI 0.11
  - Impella ΔCI 0.49
- 30 day survival:
  - 46% in both groups

A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

Melchor Seyerith, MD,* Dirk Sibbing, MD,* Ira Bauer, MS,* Georg Fichtlscherer, MD,* Lorenz Bott-Fügels, MD,* Robert Byrne, MRCP,* Josef Dinglinger, MD,* Adnan Kastrati, MD,* Albert Schömig, MD,*

Munich, Germany

Objectives
The aim of this study was to test whether the left ventricular assist device (LVAD)-Impella LP2.5 (Alphamed Europe GmbH, Aachen, Germany) provides superior hemodynamic support compared with the intra-aortic balloon pump (IABP).

Background
Cardiogenic shock caused by left ventricular failure is associated with high mortality in patients with acute myocardial infarction (AMI). Thus, LVAD may help to bridge patients to recovery from left ventricular failure.

Methods
In a prospective, randomized study, 20 patients with cardiogenic shock were studied. The primary endpoint was defined as the change in the cardiac index (CI) from baseline to 30 min after implantation. Secondary endpoints included lactate, hemodynamics, and mortality after 30 days.

Results
In 20 patients the allocated device (n = 13 IABP, n = 7 Impella LP2.5) could be safely placed. One patient died before implantation. CI increased from 3.4 l/min/m² to 4.9 l/min/m² after 30 min (p = 0.02). Overall 30-day mortality was 40% in both groups.

Conclusions
In patients presenting with cardiogenic shock caused by AMI, the use of a percutaneously placed LVAD (Impella LP2.5) is feasible and safe, and provides superior hemodynamic support compared with standard treatment using an intra-aortic balloon pump.
Pulse pressure prior to stent deployment

Depressed systolic arterial pressure during stent deployment. Patient supported with Impella maintaining diastolic arterial pressure ~90mmHg
## Procedural Characteristics (N=324)

**Significant Imbalance Between Two Arms**

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Impella (Mean±SD or %)</th>
<th>IABP (Mean±SD or %)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of SVG lesions</td>
<td>16.1%</td>
<td>8.7%</td>
<td>0.04</td>
</tr>
<tr>
<td>Rotational Atherectomy</td>
<td>15.3%</td>
<td>8.1%</td>
<td>0.04</td>
</tr>
<tr>
<td>Total Contrast Media (cc)</td>
<td>265±149</td>
<td>231±107</td>
<td>0.02</td>
</tr>
<tr>
<td>Total PCI time (hour)</td>
<td>1.1±0.7</td>
<td>1.0±0.7</td>
<td>0.16</td>
</tr>
<tr>
<td>Total Support Time (hour)</td>
<td>1.8±2.7</td>
<td>8.7±24.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Discharge from Cathlab on device support</td>
<td>5.7%</td>
<td>31.8%</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
### How Atherectomy Was Used

**More Aggressive Use in Impella Arm**

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Impella (Mean±SD)</th>
<th>IABP (Mean±SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # of passes per patient</td>
<td>6.3±1.1</td>
<td>3.8±1.1</td>
<td>0.14</td>
</tr>
<tr>
<td>Average # of passes per lesion</td>
<td>3.9±1.9</td>
<td>1.7±1.1</td>
<td>0.003</td>
</tr>
<tr>
<td>Total duration (sec)</td>
<td>119.1±83</td>
<td>103.4±104</td>
<td>0.69</td>
</tr>
<tr>
<td>Maximum burr size</td>
<td>1.62±0.27</td>
<td>1.57±0.24</td>
<td>0.60</td>
</tr>
</tbody>
</table>
"When I yell 'CLEAR' that doesn't mean you."