CONFERENCE PROCEEDINGS

Volume 12, May 2016

The Proceedings of the Twelfth International Conference on

Pediatric Mechanical Circulatory Support Systems & Pediatric Cardiopulmonary Perfusion

Emile A. Bacha, MD, Paul J. Chai, MD & Akif Ündar, PhD, *Editors*

May 18-21, 2016, New York, NY, USA

PennState Health
Milton S. Hershey Medical Center

NewYork-Presbyterian
Morgan Stanley Children's Hospital

Columbia University
College of Physicians and Surgeons

Table of Contents

Welcome to the Twelfth International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion

Emile A. Bacha, MD[1], Paul J. Chai, MD[2], and Akif Ündar, PhD[3]

[1]Pediatric and Congenital Cardiac Surgery, NewYork-Presbyterian/Morgan Stanley Children's Hospital, New York, NY, USA; [2]Pediatric Cardiac Transplantation and Mechanical Assistance Programs, NewYork-Presbyterian/Morgan Stanley Children's Hospital, Assistant Attending Surgeon, NewYork-Presbyterian/ Columbia University Medical Center, New York, NY, USA; [3]Department of Pediatrics, Surgery, and Bioengineering, Penn State College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA.

We are honored to welcome you to the 12th International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion at the Vivian and Seymour Milstein Family Heart Center, New York-Presbyterian / Columbia University Medical Center, New York, NY, May 18-21, 2016.

The main objective of this event will be to have a multidisciplinary team approach for suggesting solutions for current problems with pediatric cardiac patients whom may need acute or chronic mechanical circulatory support. We will bring clinicians, scientists and biomedical engineers into the same room to discuss the latest clinical and translational research results for the improvement of the outcomes of this fragile patient population.

The Congenital Heart Center at Columbia is one the largest heart failure and heart transplant programs in the United States. We will aim to share the expertise that has been built around this experience, as well as also sharing knowledge accumulated through a very large perioperative mechanical support and ECMO program, with the attendees. We look forward to exchanging ideas, protocols and research data in an open and collaborative manner.

Acknowledgements

Special thanks go to Deborah Schwarz, RPA, CIBE, Annmarie Tarleton, and Christine Rein from the New York-Presbyterian/Columbia University Medical Center, for their assistance in the coordination of this event. We would specifically like to thank Dr. Shigang Wang, of the Pediatric Cardiovascular Research Center at Penn State Hershey, for preparing the Conference Proceedings from start to finish.

Artificial Organs

More than 435 peer-reviewed publications, including original articles, editorials, special reports, letters and case reports have been published in Artificial Organs by the participants of the international conference during the past 11 years (1).

Special thanks to Carol Malchesky, Editorial Assistant, Angela T. Hadsell, Executive Editor, and Paul Malchesky, D. Eng, Editor-in-Chief, for making this issue possible and for their continued support year after year. Parts of this Welcome Letter were extracted from Drs. Bacha, Chai and Ündar's earlier publication (2).

Once again, we are honored to welcome each of you to this unique event.

References

1. Luciani GB, Ündar A. Outcomes of the Eleventh International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion [Guest Editorial]. Artif Organs 2016; 40(1) 7-11.
2. Ündar A, Chai P, Bacha E. Welcome to the Twelfth International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion [Invited Editorial]. Artificial Organs 2016 (in-press).

Planning & Scientific Committee

Emile A. Bacha, MD, *New York, NY, USA (Local Scientific Chair)*

Paul J. Chai, MD, *New York, NY, USA (Co-Chair)*

Akif Ündar, PhD, *Hershey, PA, USA (Co-Chair)*

Keynote Lecturers

Giles J. Peek, MD, *Bronx, NY, USA*

Francis Fynn-Thompson, MD, *Boston, MA, USA*

Emile Bacha, MD, FACS, *New York, NY, USA*

J. William Gaynor, MD, *Philadelphia, PA, USA*

Invited Lecturers

Antonio Amodeo, MD, *Rome, Italy*

Matthew Bacchetta, MD, MBA, MA, *New York, NY, USA*

Michael Brewer, MS, CCP, *New York, NY, USA*

Luiz Fernando Caneo, MD, PhD, *Sao Paulo, Brazil*

Paul Chai, MD, *New York, NY, USA*

Eva Cheung, MD, *New York, NY, USA*

John M. Costello, MD, *Chicago, IL, USA*

William M. DeCampli, MD, PhD, *Toronto, ON, Canada*

Edward Hickey, MD, *Toronto, ON, Canada*

Viktor Hraska, MD, PhD, *Sankt Augustin, Germany*

Michael Hubler, MD, PhD, *Zürich, Switzerland*

Hanneke Ijsselstijn, MD, PhD, *Rotterdam, Netherlands*

Robert D.B. (Jake) Jaquiss, MD, *Durham, NC, USA*

Robert Jarvik, MD, *New York, NY, USA*

Ganga Krishnamurthy, MD, *New York, NY, USA*

Giovanni Battista Luciani, MD, *Verona, Italy*

William S. Pierce, MD, *Hershey, PA, USA*

Marc E. Richmond, MD, MS, *New York, NY, USA*

Kellie Schiavo, CCP, *Philadelphia, PA, USA*

Brigitte Stiller, MD, *Freiburg, Germany*

Hiroo Takayama, MD, PhD, *New York, NY, USA*

Ravi Thiagarajan, MD, MPH, *Boston, MA, USA*

Akif Ündar, PhD, *Hershey, PA, USA*

Ross M. Ungerleider, MD, MBA, *Winston-Salem, NC, USA*

Educational Credits

The 12th International Conference has been approved for the following credits:

- **Physicians:** **16.00 *AMA PRA Category 1 Credit(s)™***
- **Perfusionists:** **25.30 Category 1 CEU's**
- **Nurses:** **18.10 Category 1 CEU's**

Educational Supporters

- ***Division of Cardiac, Thoracic & Vascular Surgery, Columbia University Medical Center, New York, NY, USA***
- ***Pediatric Cardiac Surgery at Morgan Stanley Children's Hospital and New York-Presbyterian Hospital, New York, NY, USA***
- ***Penn State Hershey Pediatric Cardiovascular Research Center, Hershey, PA, USA***
- ***Penn State Hershey Children's Hospital, Hershey, PA, USA***
- ***Department of Pediatrics, Penn State College of Medicine, Hershey, PA, USA***
- ***International Society For Pediatric Mechanical Cardiopulmonary Support***

Scientific Program

Wednesday, May 18, 2016

1:00pm – 5:00pm	**On-Site Registration (only if space is available) Exhibit/Wet-Lab Setup**

Thursday, May 19, 2016

7:00am – 8:00am	**Registration, Breakfast & Vendor Exhibits**
8:00am – 8:10am	**Welcome Remarks** *Emile A. Bacha, MD*
8:10am – 10:30am	**PLENARY SESSION 1:** **Pediatric Mechanical Circulatory Support Systems: 2016 Update** **Moderators:** *Emile A. Bacha, MD, Robert D.B. (Jake) Jaquiss, MD and William S. Pierce, MD*
8:10am – 8:30am	**Current Pediatric Mechanical Support: Berlin Heart/Centrimag-2015** *Antonio Amodeo, MD*
8:30am – 8:50am	**Use of Adult VADs in Pediatric Patients** *Michael Hubler, MD, PhD*
8:50am – 9:10am	**Use of VAD/Mechanical Support in Single Ventricle Patients** *Paul Chai, MD*
9:10am – 9:30am	**Use of the Syncardia TAH** *Robert D.B. (Jake) Jaquiss, MD*
9:30am – 9:50am	**Anticoagulation During VAD Therapy** *Ravi Thiagarajan, MD, MPH*
9:50am – 10:10am	**Pediatric Cardiac Transplantation Following VAD Therapy** *Marc E. Richmond, MD, MS*
10:am – 10:30am	**Panel Discussion**
10:30am - 11:15am	**Coffee Break, Vendor Exhibits & Posters**
11:15am - 11:45am	**Keynote Lecture #1** **ECMO for CHD** *Giles J. Peek, MD*
11:45am - 12:15pm	**Key Note Lecture #2** **Surgical Management of Pediatric Heart Failure - The Boston Approach** *Francis Fynn-Thompson, MD*

12:15pm - 12:30pm	**Presentation of Young Investigator's Awards**
12:30pm - 1:30pm	**Lunch Break & Vendor Exhibits**
1:30pm – 3:30pm	**PLENARY SESSION 2:** **Minimizing Adverse Effects of CPB in Neonates and Infants** **Moderators:** *Giovanni Battista Luciani, MD and Edward Hickey, MD*
1:30pm – 1:50pm	**History of CPB** *Viktor Hraska, MD, PhD*
1:50pm - 2:10pm	**Attenuating the Systemic Inflammatory Response and Blood Conservation Techniques for a Diverse Patient Population – The Columbia Experience** *Michael Brewer, MS, CCP*
2:10pm – 2:30pm	**Inflammation in CPB/MUF: Is This Still an Issue?** *Ross M. Ungerleider, MD, MBA*
2:30pm – 2:50pm	**Use of NIRS/Other Monitoring Techniques in CPB/Cerebral Protection Techniques During CPB** *Giovanni Battista Luciani, MD*
2:50pm – 3:10pm	**Temperature Management in CPB: Is it Still Relevant/ Myocardial Protection** *Edward Hickey, MD*
3:10pm – 3:30pm	**Impact of Translational Research on Optimization of the Neonatal CPB Circuits and Techniques – The Penn State Hershey Approach** *Akif Ündar, PhD*
3:30pm – 4:15pm	**Coffee Break & Vendor Exhibits/Wet-Labs**
4:15pm – 5:30pm	**Regular Slide Presentations #1:** **Moderators:** *Ross M. Ungerleider, MD, MBA and Francis Fynn-Thompson, MD* 5 slide presentations – 15 minutes each (selected from submitted abstracts)

S1. Development of a Pediatric Cardiac Mechanical Support Program
Abhishek Kashyap, MD[1], Joseph W. Turek MD PhD[1], Samantha J. Wagner[1], Laura Felderman RN BSN CCTC[1], Elizabeth A. Jaggers MBA CPA[1], R. Erik Edens MD PhD[2], and Peter J. Gruber MD PhD[1]
Department of Cardiothoracic Surgery, Division of Pediatric Cardiac Surgery[1], Stead Family Department of Pediatrics[2], University of Iowa Hospitals and Clinics, Iowa City, IA, USA

S2. Successful Bridge-to-Transplant of Functionally Univentricular Patients with a Modified Continuous-Flow Ventricular Assist Device

Michael C. Monge MD[1,3], Bradley T. Ku/at, CCP[1], Osama El tayeb, MD[1,3], Neale R. Zingle, CCP[1], Steven T. Moss, CCP[1], Jeffrey G. Gossett, MD[2,4], Elfriede Pahl, MD[2,4], John M.Costello, MD[2,4], Carl L Backer, MD[1,3]
Divisions of Cardiovascular-Thoracic Surgery[1] and Cardiology[2], Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Jllinois Departments of Surgery[3] and Pediatrics[4], Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

S3. Evolution of Mitral Regurgitation in Berlin Heart EXCOR LVAD Patients Less Than 10kg

A. Di Molfetta, S. Filippelli*, G. Ferrari°, R. Iacobelli*,R. Adorisio*, M. Pilati*, A.Toscano*, S. Morelli*, A. Amodeo**
*Department of Pediatric Cardiology and Cardiac Surgery- Pediatric Hospital Bambino Gesù- Rome, Italy °Cardiovascular Engineering Laboratory- Institute of Clinical Physiology-Rome, Italy^KU-Leuven-Department of Cardiac Surgery, Belgium

S4. Hybrid Continuous-Flow Total Artificial Heart for Pediatric Patients

Carson Fox, MS[1], Nohra Murad1, Paul Allaire, PhD[2], Tim Dimond, PhD[2], Robert Mentzer, Jr, MD[3], Francisco Arabia, MD[3], Joseph Rossano, MD[4], and Amy Throckmorton, PhD[1]
[1]School of Biomedical Engineering, Science, and Health Systems, Drexel University, Philadelphia, PA USA; [2]Rotor Bearing Solutions International, Charlottesville, VA, USA; [3]Cedars-Sinai Heart Institute, Los Angeles, CA, USA; [4]Pediatric Cardiology, The Children's Hospital of Philadelphia, Philadelphia, PA, USA

S5. A Computer Controlled Hydraulic Simulator of the Pediatric Circulation

Daniel S. Torres[1],, Idágene A. Cestari, PhD[1,2]*
Biomedical Engineering Program of the Polytechnic School of Engineering[1], Bioengineering Division of the Heart Institute (InCor)[2], University of São Paulo, SP, Brazil. *Scholarship granted by FAPESP (São Paulo Research Foundation)

Friday, May 20, 2016

7:00am – 8:00am	**Registration, Breakfast & Vendor Exhibits**
8:00am – 10:00am	**PLENARY SESSION 3:**
	ECLS: Utilization, Management and Outcomes **Moderators:** *Paul J. Chai, MD and J. William Gaynor, MD*
8:00am – 8:20am	**Setting Up a New ECMO Program** *Eva Cheung, MD*
8:20am – 8:40am	**ECMO in the Field/Transport** *Matthew Bacchetta, MD, MBA, MA*
8:40am – 9:00am	**E-CPR** *Ganga Krishnamurthy, MD*
9:00am – 9:20am	**Long-term Follow-up with E-CPR** *John M. Costello, MD*
9:20am – 9:40am	**Long-term Outcome after Neonatal ECMO Treatment for Respiratory Failure** *Hanneke Ijsselstijn, MD, PhD*
9:40am – 10:00am	**Outcomes of the Multi-Center European Trial on a New ECLS System for Neonates and Infants** *Brigitte Stiller, MD*
10:00am – 10:45am	**Coffee Break, Vendor Exhibits & Posters**
10:45am-11:15am	**Key Note Lecture #3**
	Complex Cardiac Repairs: Are they justified? *Emile A. Bacha, MD*
11:15am-11:45am	**Key Note Lecture #4**
	Surgical Risk Stratification *J. William Gaynor, MD*
11:45am-12:00pm	**Panel Discussion**
12:00pm-1:00pm	**Lunch Break & Vendor Exhibits**
1:00pm – 3:00pm	**Regular Slide Presentations #2**
	Moderators: *John M. Costello, MD, MPH and Brigitte Stiller, MD* 8 slide presentations – 15 minutes each (selected from submitted abstracts)

S6. Routine Use of Distal Arterial Perfusion in Pediatric Femoral Veno-arterial Extracorporeal Membrane Oxygenation

Christine A. Schad, MD[1], Brian P. Fallon, BA[2], Julie Monteagudo, MD[1], Shunpei Okochi, MD[1], Eva W. Cheung, MD[3], Nicholas J. Morrissey, MD[4], Angela V. Kadenhe-Chiweshe, MD[1], Gudrun Aspelund, MD[1], Steven Stylianos, MD[1] and William Middlesworth, MD[1]

[1]Department of Surgery, Division of Pediatric Surgery, [2]Columbia University College of Physicians and Surgeons, [3]Division of Pediatric Cardiology, Pediatric Critical Care Medicine, Department of Surgery, [4]Division of Vascular Surgery, New York-Presbyterian, Columbia University Medical Center, New York, NY, USA

S7. ECMO Outcomes After the Comprehensive Stage II Procedure in Patients with Single Ventricles

Daniel Gomez, CCP, Vicky Duffy, RRT, Diane Hersey, RN Carl Backes, MD, Peter Rycus, MPH, Patrick McConnell, MD, Jordan Voss, CCP, Mark Galantowicz, MD, Clifford L Cua, MD

The Heart Center, Nationwide Children's Hospital, Columbus, OH, USA

S8. Selective Cerebro-Myocardial Perfusion in Complex Neonatal Aortic Arch Pathology: The Midterm Results

Stiljan Hoxha, MD, Riccardo Giuseppe Abbasciano, MD, Salvatore Torre, MD, Daniele Ferrarini, CCP, Tiziano Menon, CCP, Luca Barozzi, MD, Giuseppe Faggian, MD, and Giovanni Battista Luciani, MD

Division of Cardiac Surgery, Department of Surgery, University of Verona School of Medicine, Verona, Italy

S9. Myocardial Protective Effect of Cardioplegic Cardiac Arrest Versus Ventricular Fibrillation During Cardiopulmonary Bypass on Immediate Post-Operative and Mid-Term Left Ventricular Function

Sang Yoon Kim, MD[1], Sungkyu Cho, MD[1], Ji-Hyun Lee, MD[2], Jin-Tae Kim, PhD[2], Woong-Han Kim, PhD[1]

[1]Department of Thoracic and Cardiovascular Surgery, College of medicine, Seoul National University Hospital, Seoul, Korea, [2]Department of Anesthesiology and Pain Medicine, Seoul National University Hospital, Seoul, Korea

S10. A Hybrid Pediatric Cardiopulmonary Bypass Circuit for Complex Suprahepatic Inferior Vena Cava Reconstruction

Daniel R Duncan, CCP FPP, and Paul J Kerins, CCP

The Nemours Cardiac Center, A.I. duPont Hospital for Children, Wilmington, DE, USA

S11. Development of a Droplet Based Microfluidic Immunoassay for Biomarker Measurement during Cardiopulmonary Bypass

Andrew Pskowski and Jeffrey D. Zahn

Department of Biomedical Engineering, Rutgers University, Piscataway, New Jersey, USA

S12. HeartWare Ventricular Assist Device Implantation for Failing Fontan Physiology

Bartlomiej Imielski, MD[1], Robert Niebler, MD[2], Steven Kindel, MD[3], Ronald Woods, MD PhD[1]

Department of Cardiothoracic Surgery, Medical College of Wisconsin, Milwaukee, WI[1]; Department of Pediatrics, Section of Critical Care[2]; Section of Cardiology[3], Medical College of Wisconsin, Milwaukee, WI

S13. Ventricular Energetics in Pediatric LVAD Patients: A Retrospective Clinical Study

A. Di Molfetta, G. Ferrari°, R. Iacobelli*,R. Adorisio*, M. Pilati*, A.Toscano*, S. Filippelli*, S. Morelli*, A. Amodeo**

*Department of Pediatric Cardiology and Cardiac Surgery- Pediatric Hospital Bambino Gesù- Rome°Cardiovascular Engineering Laboratory- Institute of Clinical Physiology-Rome^KU-Leuven- Department of Cardiac Surgery

3:00pm – 3:45pm	**Coffee Break, Vendor Exhibits, Posters & Wet-Labs**
3:45pm – 5:45pm	**Parallel Sessions**

Session I: Wet-Labs by Exhibitors (4 sessions, 30 minutes each)
Session II: Hospital tours

Saturday, May 21, 2016

7:00am – 8:00am	**Registration, Breakfast & Vendor Exhibits**
8:00am – 10:00am	**PLENARY SESSION 4:**

Engineering Approach to Pediatric Cardiovascular Medicine: New Devices
Moderators: *William M. DeCampli, MD, PhD and Akif Ündar, PhD*

8:00am – 8:20am **Completing the Development of the Infant Jarvik 2015 Ventricular Assist Device**
Robert Jarvik, MD

8:20am – 8:40am **Flow Dynamics during Ventricular Assist: Lowering the Cerebral Embolic Risk**
William M. DeCampli, MD, PhD

8:40am – 9:00am **Transplant Following Long-term Non-pulsatile LVAD Support**
Hiroo Takayama, MD, PhD

9:00am – 9:20am **Pulsatile Versus Non-pulsatile Flow During ECLS**
Akif Ündar, PhD

9:20am – 9:40am **Clinical Evaluation of Medos Hilite LT Oxygenators in ECLS**
Kellie Schiavo, CCP

9:40am – 10:00am **Pediatric Mechanical Circulatory Support Systems in Latin America**
Luiz Fernando Caneo, MD, PhD, Sao Paulo, Brazil

10:00am – 10:45am	**Coffee Break, Vendor Exhibits & Posters**
10:45pm – 1:00pm	**Regular Slide Presentations #3**

Moderators: *Emile A. Bacha, MD and Viktor Hraska, MD, PhD*
8 slide presentations – 15 minutes each (selected from submitted abstracts)

S14. Tapered Hypothermic Cardiopulmonary Bypass Allows Reduction of Air Microembolism in Infants.
Abbasciano RG, MD, Torre S, MD, Hoxha S, MD, Biondani E, CCP, Barozzi L, MD, Menon T, CCP, Faggian G, MD, Luciani GB, MD
Division of Cardiac Surgery, Department of Surgery, University of Verona School of Medicine, Verona, Italy

S15. Continuous Hemofiltration Balance as a Predictor of Outcomes in Congenital Cardiac Surgery
Ragab S. Debis[1], Mazen S. Faden[1], Mahmoud A. Abdulaziz[1], Ahmed A. Elassal [1,2], and Osman O. Al-Radi[1]
[1]Abdulla Bakhsh Children's Heart Center, King Abdulaziz University, Jeddah, Saudi Arabia; [2]Cardiothoracic Surgery Department, Zagazig

University, Egypt

S16. Externally Applied Compression Therapy for Fontan Patients

Joe Hernandez, MS[1], Sam Lee, MD[2], William Moskowitz, MD[2], Steven Chopski, PhD[3], and Amy Throckmorton, PhD[3]

[1]Biomedical Engineering, Virginia Commonwealth University, Richmond, VA USA; [2]Pediatric Cardiology, Children's Hospital of Richmond, Virginia Commonwealth University, Richmond, VA USA; [3]School of Biomedical Engineering, Science, and Health Systems, Drexel University, Philadelphia, PA USA

S17. Effects of Prime Volume on Serum Ionized Calcium in Children on Veno-Arterial ECMO

Shunpei Okochi, MD[1], Christine A. Schad, MD[1], Michael P. Brewer, MS CCP[2], Angela V. Kadenhe-Chiweshe, MD[1], William Middlesworth, MD[1], Eva W. Cheung, MD[3]

[1]Department of Surgery, Division of Pediatric Surgery, [2]Cardiovascular Perfusion, [3]Department of Pediatrics, Division of Pediatric Cardiology and Critical Care Medicine, Morgan Stanley Children's Hospital of New York - Presbyterian, Columbia University Medical Center, New York, NY, USA

S18. An In-Vitro study for Comparison of Artificial Heart Valve Prostheses Using Hemodynamic Energy

Duck Hee Lee, MS[1,2], Jong Tae Lee, BS[2], ChiBum Ahn, , PhD[4] , YeonSoo Shin, BS2, Jaesoon Choi, PhD[1], Jae Seung Jung, MD[2,3], Ho Sung Son, MD[2,3] and Kyun Sun, MD[2,3]

Biomedical Engineering R&D Center, Asan Institute for Life Science, Asan Medical Center, Seoul, Korea[1], Korea Artificial Organ Center, College of Medicine, Korea University, Seoul, Korea[2], Department of Thoracic and Cardiovascular Surgery, College of Medicine, Korea University, Seoul, Korea[3], Department of Molecular Medicine, Graduate School of Medicine, Gachon University, Incheoh, Korea[4]

S19. A Novel Method for Evaluation of Intracellular Calcium during Electrical Stimulation inside a Plate Reader

Douglas M. Veronez[1,], Ismar N. Cestari, PhD[2]; Idágene A. Cestari, PhD[1,2]*

Biomedical Engineering Program of the Polytechnic School of Engineering[1], Bioengineering Division, Heart Institute (Incor)[2], University of São Paulo, São Paulo, SP, Brazil. * Scholarship granted by FAPESP (São Paulo State Research Foundation)

S20. Acute Biventricular Interaction in Pediatric Patients Implanted With Continuous Flow and Pulsatile Flow LVAD: A Simulation Study

A. Di Molfetta, G. Ferrari°, R. Iacobelli*, L. Fresiello^, M. Pilati*, A.Toscano*, S. Filippelli*, S. Morelli*, A. Amodeo**

*Department of Pediatric Cardiology and Cardiac Surgery- Pediatric Hospital Bambino Gesù- Rome°Cardiovascular Engineering Laboratory-

Institute of Clinical Physiology-Rome^KU-Leuven- Department of Cardiac Surgery

S21. Building a Better Neonatal ECLS Circuit: Comparison of Hemodynamic Performance and Gaseous Microemboli Handling in Different Pump and Oxygenator Technologies

Payal Trivedi, DO[1,2], Shigang Wang, MD[1], Karl Woitas CCP[1], Allen R. Kunselman, MA[3], Akif Ündar, PhD[1, 4], and Kristen Glass, MD[1,2]

Penn State Hershey Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Division of Newborn Medicine[2], Public Health and Sciences[3], Surgery and Bioengineering[4]. Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

Digital Poster Presentations – May 19-21, 2016

P1. In-vitro Evaluation of an Alternative Neonatal ECLS Circuit on Hemodynamic Performance and Bubble Trap

Shannon B. Spencer, BSc[1], Shigang Wang, MD[1], Karl Woitas, CCP[1], Kristen Glass, MD[1], Allen R. Kunselman, MA[2], and Akif Ündar, PhD[1, 3]

Penn State Hershey Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Public Health and Sciences[2], Surgery and Bioengineering[3]. Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P2. Mechanical Circulatory Support for Pediatric Patients with Fulminant Myocarditis

Shu-Chien Huang, Yih-Sharng Chen, Heng-Wen Chou, Nai-Hsin Chi, Chih-Hsien Wang, Shoei-Shen Wang

Cardiac Surgical Division, Surgical Department, National Taiwan University Hospital, Taipei, Taiwan

P3. Trend of Echocardiographic Parameters in Pediatric Patients with Berlin Heart EXCOR LVAD: A Prospective Observational Study

R. Iacobelli[1], A. Di Molfetta[1], S. Filippelli[1], A. Toscano[1], S. Morelli[1], G. Ferrari[2], MG. Trivella[2], A. Amodeo[1]

[1]Department of Pediatric Cardiology and Cardiac Surgery- Pediatric Hospital Bambino Gesù- Rome; [2]Cardiovascular Engineering Laboratory- Institute of Clinical Physiology-Rome^KU-Leuven- Department of Cardiac Surgery

P4. Continuous Metabolic Monitoring Allows Tapering of Hypothermic Cardiopulmonary Bypass During Open-Heart Repair in Infancy

Salvatore Torre, MD, Riccardo Giuseppe Abbasciano, MD, Stiljan Hoxha, MD, Elisa Biondani, CCP, Luca Barozzi, MD, Tiziano Menon, CCP, Giuseppe Faggian, MD, Giovanni Battista Luciani, MD

Division of Cardiac Surgery, Department of Surgery, University of

Verona School of Medicine, Verona, Italy

P5. Validation of a new model of cardiopulmonary bypass in rat with Circulatory Arrest and Selective Antegrade Cerebral Perfusion
Daniele Linardi[1], Elisabetta Milani[1], Tiziano Menon[1], Maddalena Tessari[1], Grygory Tsenov[2], Andrea del Pilar Rodriguez[2], Giang Tong[3], Katharina Schmitt[3], Giovanni Battista Luciani[1], Giuseppe Faggian[1], Alessio Rungatscher[1]
University of Verona, Verona, Italy, Department of Cardiac Surgery[1] University of Verona, Verona, Italy, Department of Anatomy and Histology[2] University of Berlin, Berlin, Germany, Klinik für angeborene Herzfehler und Kinderkardiologie Deutsches Herzzentrum Berlin[3]

P6. Does Flexible Arterial Tubing Retain More Hemodynamic Energy During Pediatric Pulsatile ECLS?
Shigang Wang, MD[1], Allen R. Kunselman, MD[2], Akif Ündar, PhD[1,3]
Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Department of Public Health Sciences[2], Surgery and Bioengineering[3], Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P7. Contemporaneous Use of Continuous and Pulsatile Flow VAD on A Fontan Patient: A Simulation Study
A. Di Molfetta, G. Ferrari°, R. Iacobelli*, L. Fresiello^, M. Pilati*, A.Toscano*, S. Filippelli*, S. Morelli*, A. Amodeo**
*Department of Pediatric Cardiology and Cardiac Surgery- Pediatric Hospital Bambino Gesù- Rome; °Cardiovascular Engineering Laboratory- Institute of Clinical Physiology-Rome^KU-Leuven- Department of Cardiac Surgery

P8. Biventricular Assistance Using Both Continuous and Pulsatile Flow VAD: A Simulation Study on Pediatric Patients
A. Di Molfetta, G. Ferrari°, R. Iacobelli*, L. Fresiello^, M. Pilati*, A.Toscano*, S. Filippelli*, S. Morelli*, A. Amodeo**
*Department of Pediatric Cardiology and Cardiac Surgery- Pediatric Hospital Bambino Gesù- Rome°Cardiovascular Engineering Laboratory- Institute of Clinical Physiology-Rome^KU-Leuven- Department of Cardiac Surgery

P9. Does an Open Recirculation Line Affect The Flow Rate and Pressure in A Neonatal ECLS Circuit with A Centrifugal or Roller Pump?
Shigang Wang, MD[1], Shannon B. Spencer, BSc[1], Karl Woitas, CCP[1], Kristen Glass, MD[1], Allen R. Kunselman, MA[2], and Akif Ündar, PhD[1, 3]
Penn State Hershey Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Public Health and Sciences[2], Surgery and Bioengineering[3]. Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P10. Can Pulsatile Flow be Synchronized with Various Heart Rates and Cardiac Arrhythmias During ECLS? An In-Vitro Study

Shigang Wang, MD[1], Shannon B. Spencer, BSc[1], Allen R. Kunselman, MD[2], Akif Ündar, PhD[1,3]

Pediatric Cardiovascular Research Center, Department of Pediatrics[1], Department of Public Health Sciences[2], Surgery and Bioengineering[3], Penn State Milton S. Hershey Medical Center, Penn State Hershey College of Medicine, Penn State Hershey Children's Hospital, Hershey, PA, USA

P11. Successful Use of the Heartware HVAD as Bridge to Transplantation after Previous Implantation of Bilateral Berlin Heart EXCOR Devices in an 8 Year Old Boy

Raj Sahulee, DO and Hari Rajagopal MD

Department of Pediatrics, Division of Pediatric Cardiology, Icahn School of Medicine at Mount Sinai. New York, NY, USA

1:00pm **Closing Remarks**

KL1. ECMO for CHD

Giles J Peek , MD, FRCS, CTh, FFICM, Chief of Pediatric Cardiothoracic Surgery, ECMO Director,
Children's Hospital at Montefiore, Bronx, NY

It is a little known fact that the first successful use of ECMO children was in 1972 for a baby with cardiac failure following a mustard procedure. This predated the first successful use for neonatal respiratory failure which did not occur until 1975. Since then ECMO has become one of the cornerstones of any successful congenital heart surgery program. The evolution in technology with replacement of silicone lungs and roller pumps with poly-methyl pentene lungs and Mendler concept centrifugal pumps has made ECMO more accessible for surgical patients as the modern circuits have become much easier to manage with less anticoagulation as well as requiring less supervision that the classical circuit of yesteryear.

Congenital heart surgeons now routinely use ECMO for pre-operative stabilization, post-operative support of low cardiac output states or cardiac arrest (ECPR), for support during difficult Cath lab or airway procedures and for perioperative support during lung transplantation. In addition ECMO is an important tool in bridging patients with heart failure to decision, device or even transplant.

Without ECMO our surgical programs would not enjoy such good overall outcomes, it is an essential tool for all congenital heart surgeons.

KL2. Surgical Management of Pediatric Heart Failure - The Boston Approach

Francis Fynn-Thompson, MD

KL3. Complex Cardiac Repairs: Are they justified?

Emile A. Bacha, MD

KL4. Surgical Risk Stratification

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Assessment of surgical outcomes is important for multiple reasons including benchmarking, quality improvement, and public reporting of outcomes. However, there is tremendous heterogeneity between providers and institutions in terms of patient population and the types of procedures (case-mix) which are performed each year. In addition, case volume for cardiac surgical procedures is relatively small, limiting the statistical power for comparisons.

Ideally, assessment of outcomes would involve homogeneous groups of patients with similar characteristics undergoing the same operation. However, given the reality of congenital heart surgery, this is not possible. Therefore, it is necessary to develop ways to adjust for differences in case-mix. This usually involves grouping procedures of similar risk in order to increase the numbers and statistical power for comparison. This grouping can be based on expert opinion, empiric data, or both. In addition, patient characteristics such as neonatal status, prematurity, severity of disease, and genetic anomalies may vary significantly between institutions. These factors may independently modify the risk of a procedure. If these factors are not taken into account in risk adjustment, inappropriate conclusions may be drawn concerning the relative performance of surgeons and institutions.

This presentation will discuss some of the difficulties underlying surgical risk adjustment from congenital heart surgery, as well as ongoing efforts to develop robust methods for surgical risk stratification.

IL1. Current Pediatric Mechanical Support: Berlin Heart/CentriMag-2015

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Mechanical circulatory support with the EXCOR pediatric device has emerged as a gold-standard to treat advanced heart failure in children as bridge to transplantation or recovery. It is the only system which is available for all patient sizes and allows for uni- and biventricular support. Actually are recorded over 1700 EXCOR pediatric implantation in 159 centers worldwide. Moreover, several studies have highlighted that patient status at time of VAD implantation is crucial for overall therapy success.

Inotrope-dependency and failure of one organ system with need for mechanical ventilation or beginning renal or liver failure are regarded as indication criteria for VAD therapy. Most children can be treated with LVAD alone reaching survival rates of more than 75%% in selected patients, however more than 35% need primary BVAD support. In recent years the LVAD seems to be the first choice while the BIVAD is used only in selected patients. The latter one was identified as a predictor for higher mortality reflecting the more profound patient sickness. The neurological events (majority ischemic strokes) occur in more than 25% of patients and are the main cause of death. The weaning is present in 5% of patients with most of them represented by myocarditis or post-cardiotomy During VAD support regular pump inspection, optimal anticoagulation and meticulous wound-care are important factors to minimize the risk for complications such as bleeding, thromboembolism and infection. In addition rehabilitation, psychosocial support and education must be provided for children on VAD to thrive and get them prepared for heart transplantation.

The use of CentriMag seems to have the best indication in post-cardiotomy failing ventricle. In acute phase of single ventricle failure initial connection of CentriMag pump to the BH EXCOR cannulas is recommended in case of transition from ECMO support, allowing the option of adding an oxygenator in the VAD circuit in case of persistent poor lung function. In the acute phase, continuous flow is preferable as can also allow a better unloading of the systemic ventricle throughout the entire cardiac cycle and consequently provide higher flow than pulsatile pumps at same filling pressure. Furthermore, it can reduce pulmonary venous congestion avoiding pulmonary veins blood flow reversal that occurs with a pulsatile device in absence of a compliant pulmonary venous atrium. The temporary use of CentriMag, using BH cannula in small kids, to better deal the anticoagulation management is not supported by clinical evidence.

IL2. Use of Adult VADs in Pediatric Patients

Michael Hubler, MD, PhD

IL3. Use of VAD/Mechanical Support in Single Ventricle Patients

Paul Chai, MD

IL4. Use of the Syncardia TAH

Robert D.B. (Jake) Jaquiss, MD

IL5. Anticoagulation during VAD Therapy

Ravi Thiagarajan, MD, MPH

IL6. Pediatric Cardiac Transplantation Following VAD Therapy

Marc E. Richmond, MD, MS

IL7. History of CPB

Viktor Hraska, MD, PhD
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Cardiac surgery had begun slowly in the 1940s with just a handful of operations that could be done without the use of cardiopulmonary bypass: closure of a patent ductus coarctation repair, the Blalock-Taussig shunt, mitral commisurotomy, and in the early 1950s closure of atrial septal defects with the use of hypothermia or the Gross well.

However, by 1950 it became obvious that a heart-lung machine would be required to deal with the majority of congenital cardiac malformations and valvular heart disease. Such a machine would first require a safe method of anticoagulation that could be reversed at the end of the operation; second, it would require a method of pumping blood without destruction of red blood cells; and third, there would have to be a method to oxygenate blood and dissipate carbon dioxide during the time that the heart and lungs were temporarily at rest. The first two requirements were easily met. Heparin and protamine were readily available, and there were several pumps being used in the dairy and food industry that could be adapted. The real problem was to develop an artificial oxygenator (1).

In the meantime the concept of "cross circulation" using autologous lung as the oxygenator for cardiopulmonary bypass was developed by C. Walton Lillehei, at the University of Minnesota. This technique received a great deal of attention in both the profession and in the media, some positive and some critical. It was pointed out that the operation had obvious risks for both the recipient and the donor. Lillehei was the first surgeon to successfully close a ventricular septal defect, the first to do a total repair of tetralogy of Fallot, and the first to repair a persistent common atrioventricular canal. He did 45 operations using cross circulation and had 28 survivors (1).

At the same time frame John H. Gibbon, at Thomas Jefferson Medical College in cooperation with IBM developed the Gibbon-IBM heart-lung machine with the "screens" oxygenator. From 1952 to 1953 John Gibbon did 4 open heart operations using the heart-lung machine. Three of the 4 patients died in the operating room, and the fourth was a success but came close to being a disaster because of premature clotting in the oxygenator (1).

The first attempts at cardiopulmonary bypass during those years were a series of disasters with an appalling mortality rate due to the lack of reliable oxygenator. The concept of oxygenator was first elaborated by the English scientist Robert Hooke and developed into practical extracorporeal oxygenators by French and German experimental physiologists in the 19th century. Indeed, most of the extracorporeal oxygenators used until the late 1970s were derived from von Schroder's 1882 bubble oxygenator and Frey and Gruber's 1885 film oxygenator. As there is no intervening barrier between blood and oxygen, these are called 'direct contact' oxygenators. The true game changer was development of disposable bubble oxygenator by De Wall at University of Minnesota in the late fifties. As Denton Cooley stated, "Walt Lillehei brought the can opener to the cardiac surgery picnic." The can opener was, of course, the disposable DeWall bubble oxygenator.

These oxygenators contributed significantly to the development and practice of cardiac surgery till the 1980s (2).

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IL8. Attenuating the Systemic Inflammatory Response and Blood Conservation Techniques for a Diverse Patient Population – The Columbia Experience

MP Brewer, E Bacha, P Chai, J Quaegebeur, D Kalfa

Pediatric Cardiac Surgery, Morgan Stanley Children's Hospital of New York-Presbyterian Columbia University Medical Center

The initiation of cardiopulmonary bypass incites an assault on the body's immune system for all patients being treated but at different rates based on size and blood usage. This inflammatory response affects every component with in the body leading to edema, lung injury, SIRS syndrome, coagulation disorder, and poor post-operative outcomes. For decades programs have worked tirelessly to lower the prime volumes of their CPB circuits while also lowering surface areas to minimize the effect on the body's inflammatory system. Here we will summarize where we started, our present practice, and where we are headed in this ever changing cardiac landscape to deliver the best care possible to our patients.

IL9. Inflammation in CPB/MUF: Is This Still an Issue?

Ross M. Ungerleider, MD, MBA

IL10. Use of NIRS/Other Monitoring Techniques in CPB/Cerebral Protection Techniques During CPB

Giovanni Battista Luciani, MD

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Continuous monitoring techniques have become standard of care to assess safety and efficacy of pediatric cardiopulmonary bypass (CPB) in ensuring end-organ protection. Among these, online direct systemic and indirect regional metabolic monitoring (i. e. cerebral) are the ones most commonly used in neonatal and infant surgery, where morbidity, particularly cerebral and cardiac, associated with open-heart repair remains substantial. The advantages and limitations inherent with systemic metabolic monitoring using CDI and with regional cerebral monitoring using near infrared spectroscopy (NIRS) will be discussed. Thereby, the feasibility of tapering neonatal and infant CPB to individual patient needs exclusively using MVO2 and cerebral rSO2 (metabolically-monitored CPB) will also be analyzed in light of the constant strive to improve circuit miniaturization and control bypass-related morbidity.

IL11. Temperature Management in CPB: Is it Still Relevant/ Myocardial Protection

Edward Hickey, MD

IL12. Impact of Translational Research on Optimization of the Neonatal CPB Circuits and Techniques – The Penn State Hershey Approach

Akif Ündar, PhD[1,2,3], Shigang Wang, MD[1], David A. Palanzo, CCP[4], Robert Wise, CCP[4], Karl Woitas, CCP[4], Larry D. Baer, CCP[4], Allen R. Kunselman, MA[5], Joseph B. Clark, MD[2], John L. Myers, MD[2]

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Over the past 12 years at Penn State Hershey, our multi-disciplinary research team has established the pediatric cardiovascular research center with the goal to improve the outcomes for children undergoing cardiac surgery with cardiopulmonary bypass (CPB) procedures. Currently, every CPB component being used in our clinical settings at Penn State Hershey has been selected based on the results of the following translational research projects.

- Evaluation of different diameter arterial tubing and arterial cannulae in simulated neonatal/pediatric CPB circuits;
- Handling ability of gaseous microemboli of two pediatric arterial filters in a simulated CPB model;
- Evaluation of hollow-fiber membrane oxygenators with or without integrated arterial filters for neonatal cardiopulmonary bypass;
- Microemboli generation, detection and characterization during CPB procedures in neonates, infants, and small children;
- Using a secondary reservoir for pump suckers to avoid the generation of foam during CPB procedures in neonatal patients.
- Cerebral oxygen saturation and blood flow pulsatility with pulsatile perfusion during pediatric cardiopulmonary bypass

The objective of this presentation is to summarize the above translational research projects for neonatal CPB patients in Penn State Hershey Pediatric Cardiovascular Research Center, and to share the latest results with all interested centers.

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IL13. Setting Up a New ECMO Program

Eva Cheung, MD

IL14. ECMO in the Field/Transport

Matthew Bacchetta, MD, MBA, MA

IL15. E-CPR

Ganga Krishnamurthy, MD

IL16. Long-term Follow-up with E-CPR

***John M. Costello, MD MPH*[1,2]**

Divisions of Cardiology & Critical Care Medicine, Ann & Robert H. Lurie Children's Hospital of Chicago[1]; Department of Pediatrics, Northwestern University Feinberg School of Medicine[2], Chicago, IL, USA

The acute morbidity and mortality associated with extracorporeal cardiopulmonary resuscitation (E-CPR) in children have been well described.[1,2] Less is known about the long-term outcomes of this high-risk patient population.[3] Although exposure to E-CPR has the potential to influence these outcomes, many other factors are likely contributory, and thus assigning causality between E-CPR and specific outcomes is difficult.

Mortality is relatively uncommon following hospital discharge in children who received E-CPR. In a multicenter study, Garcia-Guerra and colleagues reported that of 25 pediatric E-CPR patients who survived to hospital discharge, only 3 (12%) died during short term follow-up.[4] In a study from Boston Children's Hospital that included E-CPR and well as regular cardiac ECMO patients, 24 of 196 patients (12%) died during intermediate term follow-up.[5] These data suggest that survival following hospital discharge for pediatric cardiac patients who received E-CPR is fairly good.

Given the frequent presence of complex congenital heart disease and the acute neurological injuries experienced by some patients who received E-CPR, it is not surprising that neurodevelopmental disabilities will exist in a subset of patients at intermediate term follow-up. Investigators from the Western Canadian Complex Pediatric Therapies Follow-up Group reported intermediate-term neurodevelopmental outcomes for a series of children who received E-CPR when less than five years of age.[4] Of 55 treated patients, 43% were alive at age 5 years. The mean full-scale intelligence quotient (FSIQ) was 76.5 (±15.9), and 4 patients (24%) and a FSIQ more than two standard deviations below the population mean. Chrysostomou et al reported neurodevelopmental outcomes for a series of 69 pediatric cardiac ECMO survivors, 43 percent of whom received E-CPR.[6] At two years of follow-up, 81% of patients had at most mild disability. These data indicate that the majority of pediatric E -CPR survivors have reasonable neurodevelopmental outcomes.

Quality of life experienced by pediatric E-CPR survivors has not been specifically reported. In 41 pediatric cardiac ECMO survivors, half of whom received E-CPR, the physical component of health-related quality of life was lower than that of the general population but similar to that of patients with complex cardiac disease, whereas psychosocial quality of life was similar to that of the general population and of other pediatric cardiac populations.[5] E-CPR was not found to be a risk factor for lower quality of life.

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IL17. Long-term Outcome after Neonatal ECMO Treatment for Respiratory Failure

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In this presentation we provide an overview of long-term outcome studies in neonatal ECMO survivors who joined a nationwide longitudinal follow-up program in the Netherlands.

Since 1998 (Nijmegen) and 2001 (Rotterdam), a longitudinal structured follow-up program has been established for all neonatal and pediatric ECMO survivors. This program includes standardized assessments on growth, neurodevelopment, lung function, and exercise capacity from 6 months to 8 (Nijmegen) or 17 (Rotterdam) years.

Neonatal ECMO survivors without intracranial abnormalities and without severe neurologic morbidity had problems with gross motor function, school performance, sustained attention, and working memory despite average intelligence. It seemed that these problems got worse when the children got older. Moreover, their maximal exercise capacity was significantly below the norm and deteriorated between 5 and 12 years. Most problems were encountered in children with congenital diaphragmatic hernia. Interestingly, their feelings of competence and self-esteem were comparable to or even better than that of the reference population. At least one sign of chronic kidney disease and/or hypertension was observed in 32% of 169 participants at a median age of 8 years.

In conclusion, in a nationwide cohort of neonatal ECMO survivors we showed that these patients have long-term problems with neurodevelopment, school performance, exercise capacity and chronic kidney disease. Deterioration of problems when the children get older suggests that they grow into their deficits. Early recognition of morbidity and timely intervention is important.

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IL18. Outcomes of the Multi-Center European Trial on a New ECLS System for Neonates and Infants

Brigitte Stiller, MD

IL19. Completing the Development of the Infant Jarvik 2015 Ventricular Assist Device

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Background and Objective:

The Infant Jarvik VAD has been under development for more than a decade, as one of six devices originally funded by the National Heart, Lung, and Blood Institute's Pediatric Circulatory Support and PumpKIN programs. We now report the major evolutionary design modifications in the device, which have yielded a successful implantable infant-size VAD. This has been an especially challenging task since an infant pump must meet all of the essential criteria required for adult VADs, and do it without increased blood damage, using tiny blood flow channels, a very thin motor, precise welding of paper thin titanium components, and optimized hydrodynamic pump blade shapes.

Methods:

The initial approach was to scale down the adult Jarvik 2000, but although prototypes as small as an AAA battery were successfully developed, they failed in animal implants because the pin bearings thrombosed and caused the rotor to seize up and stop. Five different pin bearing designs all failed, and it was not until the new cone bearings were developed that the infant pumps would run long term. The 11mm OD infant Jarvik 2000 fit well in 7-8 Kg piglets and pumped up to 1.5 L/min. In 25 Kg lambs, using 8mm ring reinforced GoreTex grafts. The pumps stayed free of thrombus for over 60 days, and there were no pump stop events. However, hemolysis was high and the animals were in poor condition. In Vitro, Normalized Index of Hemolysis (NIH) was over 1.00 g/100L.

Following these results, we initiated a pump optimization effort, using CFD analysis of the design, actual pump modifications, and bench hemolysis tests. This effort helped us lower the NIH from ~1.00 down to 0.4 g/100L but that still was considered too elevated. We identified the cone bearing contact points as the source of hemolysis at pump speeds over 20,000 rpm, but also showed minimal hemolysis below 20,000 rpm. Unfortunately, at speeds below 20,000 rpm, the 8mm OD Jarvik 2000 produced insufficient flow and pressure. After increasing the pump diameter to 15mm OD and redesigning the blades, the new version of the pump was renamed the Infant Jarvik 2015.

Results:

The 15mm OD pump is about the size of an AA battery. With its larger flow channels, flow up to 3 L/min. at 18,000 rpm is obtained. In Vitro hemolysis was reduced below 0.05 g/100L. Six 25 kg sheep have been maintained for 30-60 days with low plasma free hemoglobin (generally below 5 mg/dl), no pump or graft thrombosis, excellent long term condition and practically no abnormal pathology at necropsy.

Conclusions:

Following redesign efforts, the pre-clinical test results on the resulting device, the Infant Jarvik 2015 VAD, indicate that the hemolysis issue has been sufficiently addressed. Based on the performance of the device, it appears to be well-positioned for a clinical trial in the near future.

IL20. Flow Dynamics during Ventricular Assist: Lowering the Cerebral Embolic Risk

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Stroke remains the most significant morbidity in patients with ventricular assist device (VAD). The average hazard rate of stroke or other thromboembolic event is 1-3% per month. Approaches to reducing this incidence include (1) anticoagulation, (2) early detection of pump thrombosis, and (3) device design aimed at optimizing both the fluid dynamics and surface composition to minimize activation of clotting and coagulation. An acceptable solution to the problem has not been found.

Our laboratory has centered on another approach to the problem. Assuming there is always some chance that thrombus will develop; we have used a combination of computational fluid dynamics (CFD) and bench top modelling to show that there is a patient-specific optimal VAD implantation geometry that minimizes the probability of thrombus embolizing from the VAD to the brain.

Our principal findings are as follows: In a typical anatomic configuration and model, the probability of embolization to either carotid or vertebral artery varies from 7.9% to 27.1% depending on the orientation of the VAD outflow cannula/aortic anastomosis. In one representative anatomic configuration, the minimum probability corresponds to an outflow graft anastomosed to the ascending aorta laterally, two centimeters from the innominate artery origin, and at an angle of 30 degrees measured relative to the local perpendicular direction to the right lateral wall of the ascending aorta taken at the anastomosis centerline. The exact optimal configuration varies with the aortic anatomy, so it is "patient-specific". Pulsatile flow affects the results, but an optimal configuration still exists. Pediatric, especially infant results differ from those of adult patients because particle path-lines do not scale simply with anatomic dimensions. We have validated these results using an independent methodology, namely bench top modelling that simulates both VAD flow characteristics as well as multiple compartments of the human circulation. Averaged across all measurements, the difference between the two methodologies is < 3%.

Our current work is centered on (1) investigating trajectories of thrombi originating at the aortic root (with and without LV ejection), (2) incorporating fluid-structure, thrombus-thrombus, and thrombus-wall interaction, and (3) initiating a translational study correlating VAD implantation geometry with stroke incidence using the INTERMACS registry. Results to date suggest a patient-specific, plausible surgical plan to reduce stroke probability in the VAD population.

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IL21. Transplant Following Long-term Non-pulsatile LVAD Support

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Continuous-flow durable LVAD is now considered as a standard of care in patients with end stage heart failure in particular in adult patient population. The heart transplant (HTx) therapy is facing with new challenges because of the excellent survival by the LVAD technology as well as the stagnant number of the annual HTx: the HTx wait time has been increasing; and more HTx are performed in the LVAD patients. Current evidence suggests that the mid-term survival with LVAD therapy be satisfactory, the wait list mortality be decreasing, and bridging with a continuous flow LVAD may or may not be related to worse outcomes after the HTx. Based on this new information, there is a suggestion to modify the current donor allocation system in order to further improve the wait list mortality. Also important, prolonged support with continuous flow LVAD might result in more incidence of primary graft failure after HTx.

IL22. Pulsatile Versus Non-pulsatile Flow during ECLS

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Despite the advances in medical therapy and development of new devices, the mortality rates for neonatal, pediatric, and adult patients receiving extracorporeal life support (ECLS) remain extremely high. Based on the Extracorporeal Life Support Organization (ELSO) registry report released in January 2016, which includes data on 73,596 patients, mortality rates for neonatal, pediatric, and adult patients receiving ECLS due to cardiac deficits are 59%, 49%, and 59%, respectively. The same report indicates mortality rates for neonatal, pediatric, and adult patients receiving ELCS for respiratory complications are 26%, 42%, and 42%, respectively. In addition to mortality, patients receiving ECLS are susceptible to the following morbidities: hemorrhage; neurologic, renal, cardiovascular, and pulmonary complications; infection; metabolic imbalance; and mechanical complications in the ECLS circuit components. These statistics demonstrate the existence of an unmet clinical need to improve not only mortality rates, but also morbidity that can cause vital organ injury. In the ELSO database, most, if not all of the patients, were subjected to the non-pulsatile flow.

Since 2013, we have completed several in-vitro and in-vivo experiments using novel pulsatile ECLS circuits that may be the alternative to conventional non-pulsatile flow. Each component of the ECLS circuit is equally important to generate physiologic quality of pulsatility. There is no question of the importance of the pump for generating physiologic quality of pulsatile flow, but we have also found that delivering the hemodynamic energy generated from the pump to the patient is best accomplished by using a pmp oxygenator and arterial cannula, as well as the proper length of the arterial tubing. We have already completed dozens of translational projects to determine the best components for pulsatile and non-pulsatile ECLS systems. We have documented that using a novel diagonal pump can generate both non-pulsatile and pulsatile flow, but more importantly, we have also demonstrated the ability of this novel circuitry to deliver physiological quality of pulsatility in neonatal, pediatric and adult ECLS models, as demonstrated in our earlier experiments. The objective of this lecture is to share the latest results with other investigators.

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IL23. Clinical Evaluation of Medos Hilite LT Oxygenators in ECLS

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Objective:

The objective of this study was to evaluate the Medos Hilite 2400LT and 7000LT oxygenators for routine use in neonatal, infant, and pediatric patients requiring ECMO support.

Methods:

From May 2015 to April 2016, ten patients received ECMO support with the use of Medos Hilite oxygenators. The Medos Hilite 7000LT was utilized with a standard 3/8" ECMO circuit for patients who weighed greater than 12kg (n=3), while the Medos Hilite 2400LT was incorporated into a ¼" ECMO circuit for patients weighing less than 12kg (n=7). Data was collected daily and included: pre-oxygenator and post-oxygenator blood gas samples, ECMO circuit parameters (flow, pre- and post-membrane pressures, gas flow settings, and temperature settings) and patient blood gas and coagulation studies.

Results:

Of the ten patients receiving ECMO support with the use of a Medos Hilite oxygenator, nine were on veno-arterial ECMO support for cardiac failure and one was on veno-venous ECMO support for respiratory failure. The length of time each patient was supported with the Medos oxygenator ranged from one day to five days, with this variability being based on the patient's condition and the integrity of the ECMO circuit. While five of the Medos oxygenators were changed out due to increasing pressure gradients and concern for clot, none were removed due to poor oxygenator function (CO2 clearance, oxygenation).

Conclusions:

A successful evaluation of 10 patients on Medos Hilite oxygenators led to an increased comfort level of the ECMO team. The staff became familiar with the setup, priming, and use of the oxygenator. The results demonstrated the Medos Hilite 2400LT and 7000LT oxygenators provided adequate support for patients requiring ECMO with respect to pressure gradient, gas exchange and heat efficiency. Concerns with the Medos included the lack of a coating on the oxygenator and the inability to visualize clots that may be forming within the membrane. The coated Medos oxygenators are not available for sale in the United States.

IL24. Pediatric Mechanical Circulatory Support Systems in Latin America

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In spite of reduced availability of technical and economic resources, a Mechanical Circulatory Support (MCS) program can be implemented successfully in a developing country. The adoption of new technologies should be followed by good results and cost-effectiveness, therefore the health priorities in developing countries, and the status of their health systems are likely to be the limiting factors in accomplishing a widely available care. MCS devices can be used for short and long-term support. In the short-term group, the most commonly used devices in the pediatric population are ECMO and centrifugal pumps. Considering ECMO as the first step to start a MCS program is possible to understand the difficulties to have a well-established MCS program in Latin America. Since the first successful utilization of ECMO in 1975 more than 69.000 patients have been supported worldwide, but less than 1% of the extracorporeal life support organization (ELSO) registry patients are from Latin American (LA) countries. This is most probably due to the financial cost and the poor technical and human resources. In 2012, the Latin-American ELSO's chapter was founded in order to enhance the use of ECMO and the credibility in the region, through the helpful guidelines and expertise of the organization. Following ELSO guidelines for training, centers from Chile, Colombia and Brazil started a standard education process, with the support of experts from USA, Europe and Canada. From 2012 to nowadays, the number of registered centers reporting their data to ELSO in LA increased from 4 to 33, and the number of scientific publications by LA authors augmented almost 10 times. Recently, we published the positive impact of team training and new technology incorporation on the short-term results of patients undergoing post-cardiotomy ECMO in pediatric patients and patients with congenital heart disease in our center. Colombia also reported a successful cost-effective model of care with nurses as ECMO specialists supported by a multidisciplinary team. The uses of long-term devices (para corporeal VADs, implantable pumps and Total Artificial Heart) are currently limited to a few centers in LA. The scarcity of donors, particularly for the pediatrics population, and the advanced heart failure presentation of these patients in heart transplantation centers, make mandatory the implementation of MCS in these places. Our Institute, the Heart Institute of University of Sao Paulo Medical School, has one of largest transplantation program in Brazil. Our program began in 1992, and since then, we have performed an average of six HTX per year. Due to improvements in the state funding system and greater availability of air transport for long-distance organ procurement, we have averaged 17 transplants annually in the last three years. Although cardiac transplantation (HTX) is considered the best treatment for terminal heart failure, the scarcity of donors, particularly in pediatrics, is limiting its use. Waiting list time for transplantation in a 5 Kg baby is greater than 8 months, demanding a circulatory support with a long-term MCS in almost 50% of these cases. The clinical protocol for using a para corporeal pump of 15, 25 e 60 mL and a complete set of cannulas developed by our bioengineering department was recently approved and we are ready to start the clinical application. New challenges remain regarding the incorporation of MCS by the public health service, and the education and training required to use these devices with the same safety and results that the centers of excellence abroad have been able to accomplish. In this direction, an international partnership is important to train people and to improve the results with MCS. On the other hand, what concerns us most is that there is still a lot more to come, demanding major changes in the society, the economy and the health care.

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S1. Development of a Pediatric Cardiac Mechanical Support Program

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Objective: The development of a pediatric cardiac support program is a complex, multidisciplinary project. Despite relatively low volumes, the University of Iowa Congenital Heart Program has had considerable success in its mechanical support program. This study aims to describe the Iowa experience from its inception to the present, in particular examining those specific factors that have led to substantial improvements in the program, additionally identifying where further gains can be made.

Methods: We retrospectively reviewed all pediatric patients who received mechanical cardiac support at the University of Iowa from the inception of program in 1991. In total, 29 patients received mechanical support between December 1991 and December 2015 and are included in the study. Median age at implant was 12.8 ± 6.2 years. Factors examined included: OR time, ICU and hospital length of stay, intubation days, blood product usage, pre and post-operative bilirubin, creatinine and BNP and device implanted. Categorical and continuous variables were compared using Chi-squared and Wilcoxon rank-sum tests, respectively.

Results: Of the 29 patients who received mechanical support, 17 (58.6%) were discharged home, 11 (37.9%) died during their hospitalization and 1 (3.4%) remains hospitalized. Between December 1991 and December 2011, in-hospital mortality was 64.3%. Following this period, significant changes were made to patient management with in-hospital mortality decreasing to 20% between December 2011 and December 2015. Comparison between deceased and living patients revealed several significant factors including: median number of PRBCs transfused, 8 vs 4 units (p =0.048), median OR time, 396 vs 299 minutes (p=0.003) and device implanted (**Table 1**).

Table 1. Comparison of mechanical support devices.

Device	Deceased (n=11)	Home (n=17)	P value
Heartware	0 (0%)	10 (59%)	p=0.008
Thoratec	6 (55%)	3 (17%)	
Berlin	5 (45%)	2 (12%)	
Other	0 (0%)	2 (12%)	

Conclusions: During the early stages of the mechanical support program, higher than expected mortality rates prompted changes in the management of pediatric cardiac patients, specifically, the development of a dedicated management team. These changes significantly improved outcomes and can be used as a model for similar cardiac support programs, especially in smaller volume programs.

S2. Successful Bridge-to-Transplant of Functionally Univentricular Patients with a Modified Continuous-Flow Ventricular Assist Device

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Objective: A continuous flow extracorporeal ventricular assist device (VAD) was modified to support functionally univentricular infants and children awaiting heart transplantation.

Method: A centrifugal VAD, designed to flow from 1.5 to 8 L/min, was used as a bridge-to-transplant in 4 patients with functionally univentricular circulation. A variable restrictive recirculation shunt permitted lower flow ranges in small patients. In hypoxic patients, an oxygenator was incorporated into the circuit.

Results: From 2012 to 2015, the modified VAD was placed in 4 patients with Glenn physiology. Age ranged from 0.97 to 6.98 (median= 2.2yrs). Body surface area (BSA) ranged from 0.41 to 0.84 m^2 (median = 0.54 m^2). One patient was on ECMO prior to VAD. A recirculation shunt was used in three patients. Three patients required temporary use of an oxygenator for 4, 10, and 27 days. Median time on the VAD was 24.5 days (range= 20 - 47 days), with one patient still supported. Three patients survived transplant and were discharged at 28 - 82 days post-transplantation. Two patients experienced major bleeding events. One patient experienced a minor cerebrovascular accident.

Conclusions: The centrifugal VAD successfully supported palliated functionally univentricular patients awaiting heart transplantation. The modified recirculation shunt facilitated the successful support of patients in whom optimal flows were substantially lower than that recommended by the manufacturer. The design allowed placement of an in-line oxygenator in hypoxic patients.

S3. Evolution of Mitral Regurgitation in Berlin Heart EXCOR LVAD Patients Less Than 10kg

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Introduction: Left ventricular assist device (LVAD) is an important treatment option for bridging pediatric patients to heart transplant. LVAD implantation allows left ventricular (LV) unloading with an improvement in mitral regurgitation (MR). However, a significant MR may persist in some patients with LVAD.

Methods: Echocardiographic data of 15 pediatric patients less than 10Kg undergoing Berlin Heart EXCOR LVAD implantation were retrospectively collected before implantation and at one, three and six months after LVAD to asses LV unloading and MR evolution.

Results: The etiology of HF was idiopathic dilated cardiomyopathy (79%) and non-compacted LV myocardium (21%). Mean time of LVAD staying was 115.45±84.33 days. The incidence of MR was in 8 patients at the baseline and 4 patients at the three and six months follow up. At the univariate analysis of patients with and without significant MR at the implantation, age, mitral valve annulus, left atrial size and vena contracta were predictive for residual significant MR after LVAD implantation. LV unloading provided by the LVAD was more evident till the first month follow up and decreased at the three and six months follow up. Nine patients (60%) were successfully transplanted, two patients (13%) are still on LVAD support and four patients (26%) died for major complication.

Parameters	Baseline	1 month	3 months	6 months
Weight (Kg)	6.0±1.9	6.5±1.9	7.4±2.0	7.9±1.9
Left Atrium (mm)	25.4±8.9	16.8±3.7	19.4±6.2	19.3±5.8
Left Ventricular End Systolic Volume (ml)	46.5±22.4	12.7±10.4	24.3±14.6	28.3±17.3
Left Ventricular End Diastolic Volume (ml)	55.1±23.2	18.9±11.1	34.4±17.6	40.6±23.6
Mitral Valve Anulus (mm)	18.1±6	15.3±2.6	17.4±5.4	18.6±5.2
Vena Contacta (mm)	2.2±0.9	1.9±0.8	2.4±1.0	3.0±1.6
Right Ventricular Fractional Area Change (%)	34.1±9.7	34.1±9.7	41.2±13.6	36.0±18.3

Conclusion: The MR persistence is a possible complication also in pediatric LVAD recipient. The possibility of concomitant valve surgery is controversial, especially in low weight children and patients should be carefully selected for this option. A patient-tailored and frequent LVAD conduction optimization could potentially improve the hemodynamic benefits of LVAD and, in particular, LV unloading and MR.

S4. Hybrid Continuous-Flow Total Artificial Heart for Pediatric Patients

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Purpose: Clinical trials of mechanical circulatory support devices have demonstrated that pediatric patients derive substantial survival and quality of life benefits. Only two total artificial hearts (TAHs) are approved for clinical implantation in the US, and the implementation of TAHs in the treatment of patients with CHF has increased more than 3 fold. These devices and other TAHs under development, however, have several design challenges and limitations, including thromboembolic events, neurologic impairment, risk of infection due to large size, infection at the abdominal site of the percutaneous driveline, lack of ambulation due to a heavy portable unit, non-pulsatile blood flow conditions, and the use of polyurethane membranes and valves which risks rupture or failure after repetitive flexions.

To address these limitations and to provide a new therapeutic solution, we are developing an innovative therapeutic alternative: a unique hybrid-design, continuous flow, implantable or extracorporeal, magnetically levitated, TAH (Dragon Heart). The Dragon Heart is designed to support pediatric patients (BSA > 0.85 m2) with CHF. This TAH has only 2 moving parts - an axial impeller for the pulmonary circulation and a centrifugal impeller for the systemic circulation. This device utilizes the latest generation of magnetic bearing (i.e. valveless) technology. The compact Dragon TAH, which has a target diameter and height of 60 mm by 50 mm, will produce the physiologic pressures and flows necessary to support CHF patients.

Methods: The pump geometries (axial and centrifugal) were established using standard pump design equations and available literature on similar pumps. Computational modeling using ANSYS CFX 15.0 was completed to gain insight into the performance of the pump geometries. The designs were the basis for prototype manufacturing and subsequent hydraulic testing. Two hydraulic test rigs were constructed to evaluate the performance of the prototypes. A blood analog solution of water and glycerin was utilized for the experiments.

Results: The results of the computational studies and prototype testing demonstrate that the Dragon Heart is capable of delivering the target blood flow rates of 1-6.5 L/min with pressure rises of 15-25 mmHg for the pulmonary circulation and 80-140 mmHg for the systemic circulation at 1,500-12,000 RPM.

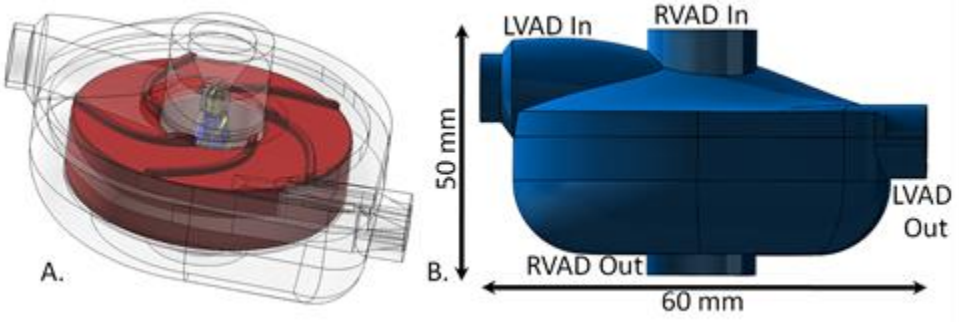

Fig. 1: Dragon Heart Pediatric TAH. A. Hybrid Design, B. Dimensioned Geometry, Side View.

Conclusions: This initial design of the Dragon Heart was successful and serves as the foundation to continue development. The long-term goal of this research is to commercialize a novel, less expensive, more compact, low thrombus, and effective therapeutic alternative for pediatric patients with CHF.

S5. A Computer Controlled Hydraulic Simulator of the Pediatric Circulation

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Objective: The aim of this work is to develop a simulator of the left branch of the pediatric circulation based on a physical hydraulic model equipped with electronic components and a computer controlled interface to allow precise and easy adjustments of flow and pressure, important in studying the performance of mechanical circulatory assist devices.
Methods: Left ventricle mechanics, atrial filling and aortic compliance were mimicked by a pneumatically driven pulsatile VAD (15 ml ejection volume), a fluid filled reservoir and an aortic compliance air and fluid chamber. A brushless DC motorized clamp and a diaphragm air pump were used to vary the loop resistance and compliance, respectively. Ventricular, aortic and atrial pressures and systemic flow are A/D converted by a microcontroller which is programmed to control compliance and resistance. A friendly user interface, where the user sets the simulation parameters and monitors the real-time signals was created for Windows OS.
Results: The table below shows atrial and aortic pressures and systemic flow in normal and HF simulated conditions. The values are consistent with the range of target values for patients up to 1 year of age. The figure depicts an image of the computer screen interface for normal and HF conditions (120 bpm HR, 50% systolic interval). The simulator takes less than 30 sec for adjusting the parameters.

Table. Physiological ranges and resulted data for hemodynamic parameter in normal and HF conditions.

Parameter, Units	Normal			HF		
	Range	Target	Measured	Range	Target	Measured
Mean AoP, mmHg	70 - 75	75	75	50 - 55	52	52
AoP sys/dia, mmHg	-	90/60	90/60	-	75/30	75/30
Mean LAP, mmHg	10 - 12	11	11	18 - 25	19	19
Mean Aortic flow, L/min	0.80 - 1.00	0.90	0.91	0.60 - 0.70	0.65	0.68
SVR, mmHg.s/mL	3.5 - 4.9	4.5	4.6	2.1 - 3.7	3.1	2.9

AoP, aortic pressure; LAP, left atrium pressure; SVR, systemic vascular (loop) resistance.

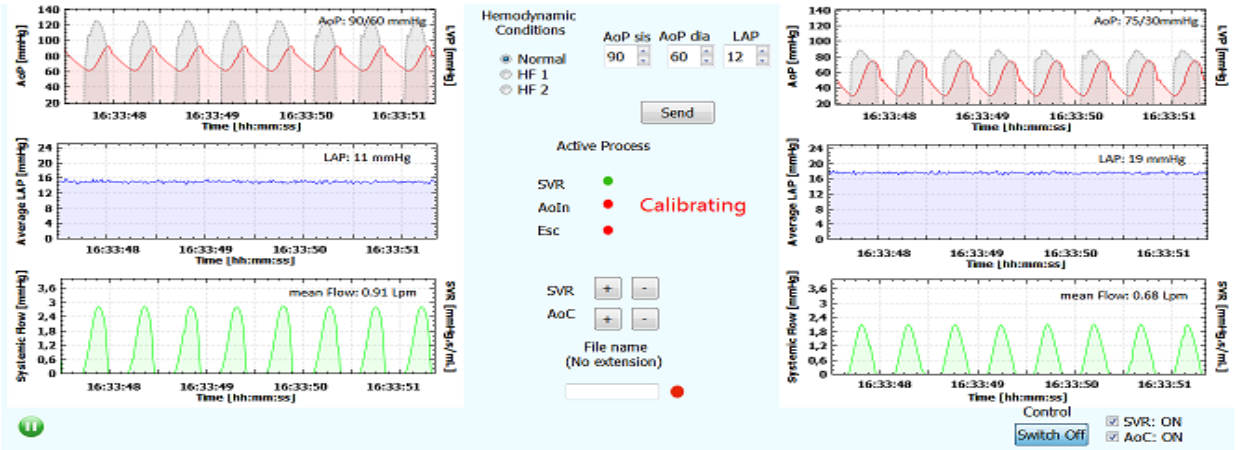

Fig. User interface screen with waveforms for normal (real-time, left) and for HF (recorded, right). Also seen the waveforms of AoP (top, red), left ventricular pressure (top, grey), LAP (middle) and flow (bottom) and the keys for calibration and settings of desired values of variables.

Conclusions: Our equipment allows an accurate control of flow and pressure simulating the pediatric circulation in physiological or pathological conditions. This simulator is a useful tool for teaching and research on mechanical circulatory assistance. Studies are under way to expand the simulator to include the pulmonary circulation and the assessment of the PV-Loop.

S6. Routine Use of Distal Arterial Perfusion in Pediatric Femoral Veno-arterial Extracorporeal Membrane Oxygenation

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Objective: Lower-extremity ischemia is a significant complication in children on femoral veno-arterial extracorporeal membrane oxygenation (VA ECMO). We routinely use distal perfusion catheters (DPCs) in all femoral arterial cannulations in attempts to reduce ischemia. We report the outcomes of prophylactic DPC placement, and compare it to a historical population for whom DPC placement was performed only in response to clinically evident lower-extremity ischemia.

Methods: We performed a single-center, retrospective review of pediatric patients supported with femoral VA ECMO from January 2005 to May 2015. Patients with prophylactic DPC placement at cannulation (prophylactic DPC) were compared to a historical group with DPCs placed in response to ischemic changes (reactive DPC). Ischemic complication requiring invasive intervention (fasciotomy or amputation) was the primary outcome.

Results: Twenty-nine patients underwent a total of 31 CFA cannulations, 17 with prophylactic DPC and 14 with reactive DPC. Ischemic complications requiring invasive intervention developed in 2 of 17(12%) prophylactic DPC patients versus 4 of 14(29%) reactive DPC. In the reactive DPC group, 7 of 14 (50%) had ischemic changes post-cannulation, 6 underwent DPC placement, and 3 out of 6 of these patients still required invasive intervention. One of the seven patients had ischemic changes, did not undergo DPC and required amputation. While a greater percentage of patients in the prophylactic group was cannulated during ECPR, statistical significance was not otherwise demonstrated.

Table 1. Patient and ECMO-related variables in patients with and without routine DPC placement.

	Prophylactic DPC (n= 17)	Reactive DPC (n=14)	p value[♯]
Age, y	13.2 (6-20)	14.0 (4-22)	0.647
BSA, m^2	1.3 (0.73-1.69)	1.4 (0.68-2.03)	0.662
Arterial cannula size, F	15.3 (14-19)	16.2 (12-18)	0.157
Arterial cannula size (F) to BSA m^2 ratio (F/m^2)	12.4 (9.3-19.2)	12.6 (8.9-15.9)	0.812
Contralateral cannulas	11 (65%)	13 (93%)	0.094
Hours on ECMO, h	257.8 (22-749)	167.7 (12-291)	0.284
ECPR	9 (53%)	2 (14%)	0.057
DPC placed	17 (100%)	6 (43%)	
Percutaneous access of SFA for DPC*	16/17 (94%)	2/6 (33%)	
Time to DPC placement, h	2.35 (0-10.5)	16 (4-29)	
Ischemia requiring surgical intervention	2 (12%)	4 (29%)	0.370
Survival to decannulation	13 (76%)	8 (57%)	0.441
Survival to discharge	7 (41%)	7 (50%)	0.623

 Continuous variables are compared using Mann-Whitney U Test; categorical variables are compared using Chi-Square, Fisher's Exact.
Abbreviations: Year (y), centimeters (cm), kilograms (kg), meters-squared (m^2), French (F), Extracorporeal Cardiopulmonary Resuscitation (ECPR), hours (h) *Percentage refers to successful percutaneous access, SFA cutdown performed only if ultrasound-guided percutaneous attempts failed.

Conclusions: We demonstrate feasibility of SFA access in pediatric patients. We note a trend toward fewer ischemic complications with prophylactic DPC placement, and observe that salvaging a limb with a reactive DPC was only successful 50% of the time. Although there was no statistical difference in the primary outcome between the two groups, limitations and confounding factors include small sample size and a greater percentage of patients in the prophylactic DPC group cannulated with CPR in progress.

S7. ECMO Outcomes after the Comprehensive Stage II Procedure in Patients with Single Ventricles

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Introduction: Outcomes for extracorporeal membrane oxygenation (ECMO) have been described for patients with single ventricle physiology undergoing cavopulmonary connection (Glenn procedure). An alternative surgical pathway for patients with single ventricle physiology consists of an initial hybrid procedure followed by a comprehensive Stage II procedure. No data exist describing the outcomes of patients requiring ECMO after the comprehensive Stage II procedure. Goal of this study is to describe the outcomes for patients who required ECMO after the comprehensive Stage II procedure.

Methods: Data from the Extracorporeal Life Support Organization (ELSO) registry from 2001 to 2015 for children undergoing the comprehensive Stage II procedure older than 3 months of age were retrospectively analyzed. Demographics and ECMO characteristics were recorded.

Results: Total of 6 children required ECMO support after the comprehensive Stage II procedure (2 males: 4 females). Four patients had the diagnosis of hypoplastic left heart syndrome and 2 patients had the diagnosis of an unbalanced atrioventricular septal defect. Bypass time was 242.8 $\pm$ 110.9 minutes and cross clamp time was 91.2 $\pm$ 46.2 minutes for the surgical procedure. Weight was 5.8 $\pm$ 1.3 kg and age was 150.2 $\pm$ 37.9 days at time of ECMO. ECMO duration was 276.0 $\pm$ 218.1 hours. Complications during the ECMO run included hemorrhage in 4 patients (67%), renal dysfunction in 2 patients (33%), and neurologic injury in 2 patients (33%). Four patients (67%) were discharged alive after ECMO decannulation.

Conclusions: Despite being a much more extensive surgical procedure, the morbidity and mortality after ECMO in patients undergoing the comprehensive Stage II procedure is similar to those in patients undergoing the Glenn procedure. If needed, ECMO support is reasonable for patients after the comprehensive Stage II procedure.

S8. Selective Cerebro-Myocardial Perfusion in Complex Neonatal Aortic Arch Pathology: The Midterm Results

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Background: Management of aortic arch surgery in pediatric patients is challenging, thus repair is traditionally accomplished using a period of deep hypothermic circulatory arrest (DHCA). In order to reduce neurologic morbidity related to DHCA, cardiac morbidity and mortality of complex aortic arch surgery, various strategies of beating brain and heart were developed. More recently, an alternative and novel strategy for cerebro-myocardial protection was developed by our group, where regional low-flow perfusion is combined with controlled and independent coronary perfusion.

Objective: This retrospective study aims to assess the safety, efficacy and to report the midterm results of selective and independent cerebro-myocardial perfusion in complex congenital aortic arch surgery.

Methods: From April 2008 to August 2015, 28 consecutive neonates underwent aortic arch surgery under cerebro-myocardial perfusion. There were 17 male and 11 female, with median age of 23 days (3-30 days) and a median body weight of 3.3 kg (1.6-4.2kg). The spectrum of pathologies treated was extremely heterogeneous and included 13 neonates having single stage-two ventricle repair (46%), 7 staged two-ventricle repair (25%) and 8 single ventricle repair (29%). All operations were conducted via midline sternotomy, under moderate hypothermia and with a "beating heart and brain". Arch repair was achieved with different techniques, end-to-side anastomosis in 19 (68%), patch augmentation in 9 (32%).

Results: Average cardiopulmonary bypass time was 131 ± 64 min (42-310min). A period of cardiac arrest to complete intracardiac repair was required in 9 patients (32%), and DHCA in 1(3.6%) for correction of total anomalous pulmonary venous drainage. Average time of splanchnic ischemia during cerebro-myocardial perfusion was 30 ± 11 min (15-69min). Three patients (11%) required veno-arterial extracorporeal membrane oxygenation. Renal function proved satisfactory in all but a period of peritoneal dialysis was required in 10 (36%), while liver dysfunction was noted only in 3 (11%). There were 3 (11%) early and 2 deaths during a median follow-up of 2.9 years (range 6 months-7.7 years), with an actuarial survival of 82% at 7 years. At last follow-up no one of the patients showed signs of neurologic dysfunction.

Conclusions: The present experience shows that a strategy of selective and independent cerebro-myocardial perfusion is safe, versatile and feasible in neonates with complex congenital arch pathology. Favorable outcomes were noted in terms of neurological injuries, organ perfusion and cardiac morbidity.

S9. Myocardial Protective Effect of Cardioplegic Cardiac Arrest Versus Ventricular Fibrillation During Cardiopulmonary Bypass on Immediate Post-Operative and Mid-Term Left Ventricular Function

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Objective: The objective of this study is to compare the myocardial protective effect of cardioplegic cardiac arrest (CCA) to that of ventricular fibrillation (VF) on short-term and mid-term left ventricular (LV) function in right ventricular outflow tract (RVOT) surgery.

Methods: RVOT operations from January 2006 to December 2015 were reviewed. The number of cases using CCA only was 71 and that of cases using VF only was 49. Post-operative mortality and morbidity were compared between the two groups. With available echocardiographic data, left ventricular ejection fraction (LVEF) and left ventricular internal dimension (LVID) were compared in 64 cases of CCA group and 39 cases of VF group. Mid-term echocardiographic follow up data between post-operative 6 month and 24 month were analyzed

Results: There was no peri-operative mortality, post-operative mechanical circulatory support or cerebrovascular accident. There was no statistically significant difference of ventricular and atrial arrhythmia. Decrease of LVEF was 0.47 ± 10.10% in CCA group and was 3.29 ± 10.20% in VF group (*p*-value = 0.174). The systolic LVID was decreased by 0.39 ± 3.54 mm in CCA group, while that was increased by 1.60 ± 4.82 mm in VF group (*p*-value = 0.020). Multiple linear regression was performed for risk factor of immediate post-operative increase of systolic LVID. Procedure under VF, not using LV vent catheter, young age and higher pre-operative LVEF were risk factor for increasing immediate post-operative systolic LVID. Mid-term follow up LVEF was increased by 0.96 ± 10.49% in CCA group, and was decreased by 2.94 ± 9.41% in VF group (*p*-value = 0.085). Mid-term increase of systolic LVID was 1.17 ± 3.79 mm in CCA group and 3.00 ± 4.46 mm in VF group (*p*-value = 0.049) .

Conclusions: Myocardial protection using CCA is safe and more effective in LV function preservation for immediate post-operative and mid-term follow up.

S10. A Hybrid Pediatric Cardiopulmonary Bypass Circuit for Complex Suprahepatic Inferior Vena Cava Reconstruction

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Complex vascular repairs involving a multidisciplinary team frequently demand a rapidly evolving preoperative strategy. When the procedure requires circulatory support, lack of firm consensus regarding the mode of bypass creates a unique challenge for the perfusionist, who must choose the most appropriate components and circuit configuration to provide safe and effective treatment. We present the case of an eight year old child who required reconstruction of the suprahepatic inferior vena cava following liver transplantation for stage three hepatoblastoma. Proposed modes of circulatory support included centrifugal veno-venous bypass, partial cardiopulmonary bypass with venous cardiotomy reservoir, and full cardiopulmonary bypass with cardioplegia and deep hypothermic circulatory arrest capability. Due to fluid overload secondary to renal insufficiency, there was also concern that post-operative ECMO may be required if the procedure was poorly tolerated. We modified our conventional pediatric roller pump and circuit to include a centrifugal pump and bypass loops around both the venous reservoir and oxygenator, enabling intraoperative conversion from veno-venous bypass to full cardiopulmonary bypass without interruption of flow. Additionally, in the event of failure to wean from bypass, a primed diffusion membrane could be placed in line and ECMO commenced on the same system without cessation of flow or gas exchange. The patient tolerated the procedure well and was subsequently discharged to home. Use of this multi-modal hybrid cardiopulmonary bypass circuit allowed us to offer a wide array of extracorporeal therapies in a single, safe, and cost effective package.

S11. Development of a Droplet Based Microfluidic Immunoassay for Biomarker Measurement during Cardiopulmonary Bypass

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Objective: The objective of this study is to develop a point of care microdevice for monitoring multiple biomarkers during and after pediatric heart surgery. Such a system is expected to enable high frequency monitoring of biomarkers as potential surrogate markers of clinical outcome. We seek to perform multiplex assays capable of simultaneously measuring multiple analytes, especially inflammation markers, in a single sample.

Methods: We are developing a diagnostic device based on performing a magnetic bead based immunoassay within aqueous droplets. Each droplet acts as an incubation vessel with bead concentrated via a magnetic field split away from a carrier droplet and resuspended in a receiving droplet. In this manner, the serial incubation steps for performing an immunoassay may be automated and each individual measurement can be staggered to allow high frequency measurements

Results: A microfluidic device for performing parallel, low-volume multiplex immunoassays was designed, fabricated, and tested. The immunoassays can have a large dynamic range while retaining high sensitivity. We have demonstrated the ability to track analyte concentrations within a microdevice. We expect this approach can be expanded to high frequency sampling to detect temporally varying biomarker concentrations in blood.

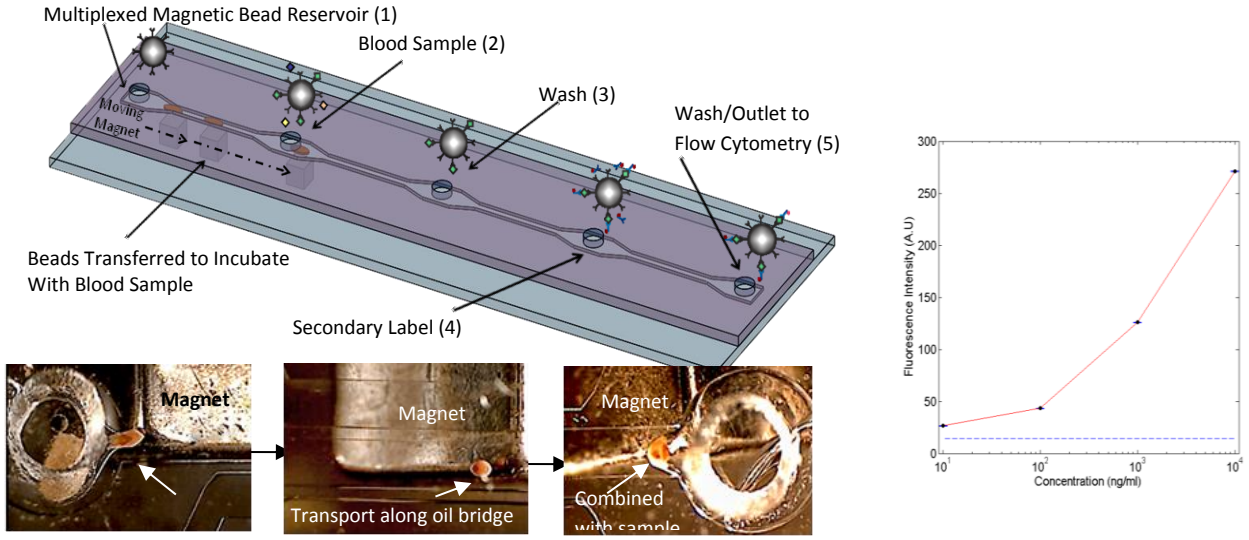

Figure 1: (Left) Schematic of immunoassay device. Each reservoir is separated by an inert 'oil bridge' with beads pulled from one reservoir to the next by magnetic actuation. The bead state is shown at each stage: (1) Microbeads conjugated with antigen-specific antibody are introduced into device (2) Microbeads are incubated in blood sample where they capture their antigen of interest (3) The beads are washed (4) The beads are incu-bated with their secondary fluorescence (PE) label. (5) Beads are washed and extracted from the device for flu-orescence quantification via flow cytometry. Photographs show magnetic actuation ejecting beads from the bead reservior, transporting them across the oil bridge and combing droplets in the sample reservior. (Right) Biotinylated bead flourescence intensity as a function of PE-streptavidin label concentration analyzed with 488 nm excitation in a BD FACSCaliber flow cytometer.

Conclusions: A fully integrated assay will allow high frequency measurements of inflammatory biomarkers during mechanical circulatory support procedures such as CPB and ECMO. Serial determination of biomarker levels during the early post-operative period promises to be a valuable tool for the evaluation of peri-operative morbidity in pediatric patients, especially myocardial and cerebral damage.

S12. HeartWare Ventricular Assist Device Implantation for Failing Fontan Physiology

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Objective: To describe the clinical course of a series of patients with hypoplastic left heart syndrome (HLHS) and refractory heart failure supported with a HeartWare ventricular assist device (HVAD) following Fontan palliation.

Methods: This is a retrospective review of three consecutive patients supported with a HVAD for HLHS with failing Fontan physiology through October 2015. Data includes patient characteristics, operative variables, post-implantation hemodynamic/device parameters, event outcomes, and duration of VAD support.

Results: All patients were male; none required pre-VAD implantation mechanical circulatory support. Patient 1 required delayed sternal closure and developed chemical pancreatitis. The second developed first-degree AV block and ascites requiring paracentesis. The third required an exploratory laparotomy with conversion to mediastinal exploration for chest wall hemorrhage causing tamponade on post-operative day 21 and a gastric ulcer resulting in hemoptysis requiring re-hospitalization, surgical intervention and blood transfusion on post-operative day 108.

Items	Patient 1	Patient 2	Patient 3
Age at implant (years)	11.7	13.5	17.5
Weight (kg)	33	36	68
Fontan Pressure Pre-Implant (mmHg)	27	25	32
Duration of mechanical ventilation	3 days	2 days	2 days
Estimated CI (L/min/m2) on POD30	4.1	3.7	3.3
RPM setting on POD 30	3120	2980	3200
Duration of Support (days)	148	272	154
Days as an outpatient days (%)	86(58%)	222(82%)	102(66%)
Fontan pressure (mmHg) at Transplant	22	25	N/A

Conclusions: We present two patients bridged to transplantation using the HeartWare VAD, and one on continued VAD support for failing Fontan circulation. We demonstrate durable support with transition to outpatient care while awaiting heart transplantation.

S13. Ventricular Energetics in Pediatric LVAD Patients: A Retrospective Clinical Study

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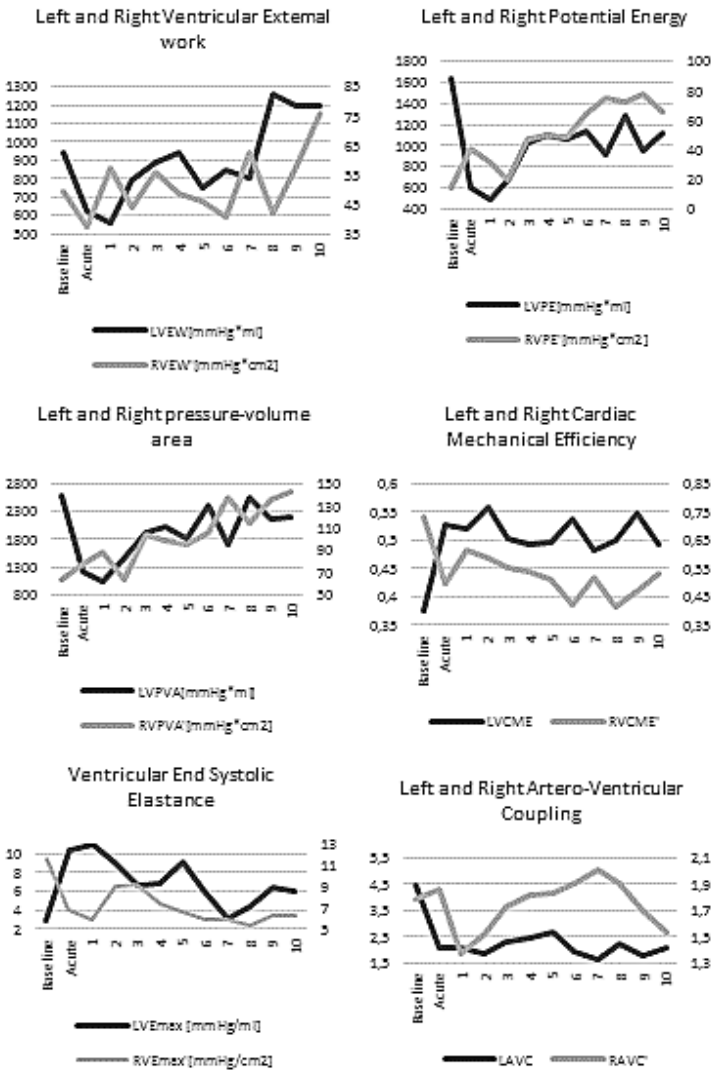
Introduction: The continued decline in donor hearts' availability prolonged the LVAD support duration and leads to an increased interest in the use of LVAD as a bridge to heart recovery. To evaluate ventricular unloading and recovery, left and right ventricular energetic parameters were proposed in literature. The aim of this study is to estimate the trend of right and left energetic parameters in pediatric patients implanted with LVAD.

Methods: Echocardiographic data of 12 pediatric LVAD patients were retrospectively collected at the baseline, in the acute phase after the LVAD implantation and at the monthly follow ups till the LVAD explantation. Data were used to estimate left and right ventricular energetic parameters.

Results: we found a significant relationship between the left and right ventricular energetic parameter trends along all the study period. Left ventricular end systolic pressure-volume relationship showed a statistically significant improvement till the follow-up of two months (p= 0.002) and then it progressively decreases. Left atero-ventricular coupling significantly decreases after the LVAD (p=0.04) and right atero-ventricular coupling decreases in the short term follow up. Left ventricular external work, potential energy and pressure-volume area decrease at the short term follow up and then increase progressively. The right ventricular external work, potential energy and pressure-volume area increase after the LVAD implantation. Finally the left (right) cardiac mechanical efficiency is improved (decreased, p=0.02) by the LVAD.



Conclusion: The trend of energetic variables shows that the benefits provided by the LVAD could decrease over time. A continuous and patient tailored LVAD parameter programming could contribute to prolongue LVAD benefits. The introduction of energetic parameters could lead to a more complete evaluation of LVAD patient's outcome which is, typically, a multiparametric process.

S14. Tapered Hypothermic Cardiopulmonary Bypass Allows Reduction of Air Microembolism in Infants

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Objective: Gaseous microemboli (GME) production is associated with neurological and psychological deficits in patients, both adults and infants, undergoing cardiopulmonary bypass (CPB). Numerous factors influence the generation of GME in the CPB circuit, such as perfusion temperature, hemodilution, circuit length and biocompatibility. Nowadays CPB is usually conducted applying nominal flows but the monitoring of hemodynamic (MVO2) and metabolic (NIRS and continuous blood gas monitoring) parameters suggest that it is possible to maintain adequate values of perfusion using lower flows. The aim of our study was to investigate if a CPB strategy that implemented the use of continuous metabolic and hemodynamic monitoring could reduce the GME production, both in normothermic and hypothermic (with a reduction of flows up to 30%) patients.

Methods: Twenty consecutive infants and young children undergoing surgery requiring CPB were included: In Group A, there were 10 patients undergoing normothermic CPB; in Group B, 10 patients that necessitated moderate hypothermic (28-30° C) CPB. In both groups we conducted a validation test for continuous metabolic and hemodynamic monitoring guided CPB, for a variable period of 20 minutes, aiming for the minimal flow that could maintain values of MVO2 > 70% and NIRS > 45%. The patients enrolled in group A were significantly different from group B as for age (600 days vs 36 days), weight (9.4 kg vs 3.2 kg), BSA (0.43 m2 vs 0.21 m2) and physio-pathological characteristics (complex congenital heart defects were more frequent in group B). Nonetheless, these differences had no impact on the results as each patient served as his/her own control. We collected data in four different periods: T1 (beginning of CPB), T2 (aortic cross clamping), T3 (during the test) and T4 (clamp removal).

Results: Patients in group A showed a significant reduction in terms of GME production both in the arterial and venous line. Specifically, during the metabolic and hemodynamic monitoring it was possible to reduce the flow up to 85% of the nominal value, obtaining a reduction of 70% of GME on the arterial line ($p<0.05$). In group B (moderate hypothermia), the individualized flow was reduced down to 75% of the nominal value, maintaining stable values of MVO2 and NIRS. This corresponded to an 85% reduction of GME in the arterial line ($p<0.05$). We recorded the perioperative clinical outcome in all 20 patients enrolled to verify the safety of our study: there was no mortality in both groups, 4 patients from group B necessitated a prolonged (> 4 days) invasive ventilator assistance, 3 patients needed inotropic support (1 patient from group A). No renal failure, sepsis or neurological morbidity was recorded.

Conclusions: Neurological deficits secondary to cardiac surgery are associated with mortality and morbidity, influencing hospitalization costs, home care and affecting the quality of life of paediatric patients and their families. Our study shows that a reduction in GME production is possible when applying a safe individualized strategy of conduction of CPB, which allows significant flow reduction, maintaining normal haemodynamic and metabolic parameters, both in normothermia and moderate hypothermia. These progresses, along with circuit miniaturization and better filters and oxygenators will lead to an improvement of neurological protection during cardiopulmonary bypass.

S15. Continuous Hemofiltration Balance as a Predictor of Outcomes in Congenital Cardiac Surgery

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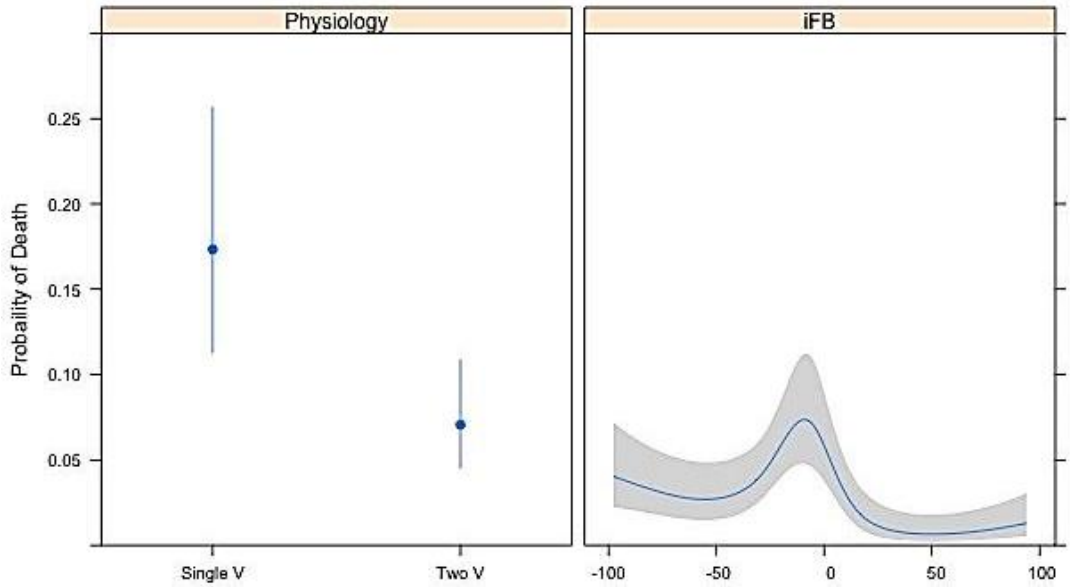
Objective: Hypothermic cardiopulmonary bypass (CPB) results in hemodilution and increased interstitial fluid. This is most marked in small children and neonates. CPB induced inflammatory response contributes to capillary leak, pulmonary and myocardial edema. Continuous Hemofiltration (CH) is effective at mitigating the effects of hemodilution and interstitial edema. The objective of this study to investigate the predictive ability of the achieved balance indexed to body weight on the short term outcomes of congenital cardiac surgery.

Methods: All patients who underwent surgery with the use of CPB at a single institution were included. CH was applied to all patients regardless of their preoperative clinical state or urgency. The goal of CH was to achieve a hemoglobin concentration of 10 to 12 gm/dl in 2 ventricle patients and 12 to 14 gm/dl in single ventricle patients. The Fluid Balance was calculated by subtracting the filtered fluid plus urine output from the total CPB prime volume. This was then indexed to body weight in kilograms. Logistic regression with in-hospital death as the primary outcome was used to study the relationship of indexed Fluid Balance (iFB) and probability of death. Risk Adjustment in Congenital Heart Surgery-1 (RACHS-1) categories was used to adjust for complexity. The R package was used for analysis.

Results: Three hundred and five patients were included. The relationship between iFB and the probability of death was non-linear (p-value=0.048), see figure. Patients with near zero or positive iFB had significantly lower probability of death. This was true for both single and two ventricle patients.



Conclusions: Highly negative iFB may be an indicator of the preoperative fluid state of patients who undergo surgery with CPB and CH. Patients who present in severe congestive heart failure or in a decompensated state have worse outcomes.

S16. Externally Applied Compression Therapy for Fontan Patients

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Purpose: Limited therapeutic options are available for Fontan patients with dysfunctional or failing single ventricle physiology. This study describes the evaluation of an alternative, non-invasive, at-home therapeutic option for Fontan patients. Our hypothesis is that routinely administered, externally applied compression treatments to the lower extremities will augment systemic venous return, improve ventricular preload, and thus enhance cardiac output in Fontan patients.

Methods: In a pilot clinical study (n=2), we employed the NormaTec Pneumatic Compression Device (PCD), which has received FDA 510(k) premarket clearance for use to treat patients with venous insufficiency. This device is composed of trousers with inflatable compartments that facilitate circumferentially and uniformly applied pressure to the patient's lower extremities. A programmable controller is used to set the applied pressure level and sequential intervals of inflation and deflation. Following an initial health screening, test subjects were pre-evaluated with a modified-Bruce, treadmill exercise stress test, and baseline data on cardiorespiratory health was collected. The patients were fitted and trained on how to use the PCD. Test subjects then conducted 6 days of external compression therapy at-home. During compression therapy, the applied pressure was determined based on the patient's diastolic pressure, plus an incremental adjustment. Full compression cycle time was 30 minutes with a rest period of 5 minutes between each set. Four sets were completed to constitute a day of treatment. After 1 week, patients were re-evaluated with a final treadmill stress test and data acquisition of new cardiorespiratory parameters.

Results: The data from this evaluation are displayed in Table 1. The patients showed an improvement in exercise duration time, peak oxygen volume, and ventilator threshold, as compared to the baseline evaluation. The findings are promising and provide the foundation for future studies that will focus on increasing study participation (sample size) to better assess the clinical benefit of compression therapy for Fontan patients.

Table 1: Cardiopulmonary Exercise Test Results (n=2) - At-Home External Compression Therapy for Fontan Patients

Measured Parameter	Subject #1			Subject #2		
	Pre-	Post-	% Change	Pre-	Post-	% Change
Exercise Duration (Sec)	690	760	10.1%	670	730	9.0%
Heart Rate (bpm)	70	71	1.4%	60	67	11.7%
MAP (mmHg)	112.0	96.0	(14.3%)	90.3	94.7	4.8%
VO_2 Peak (ml/Kg/min)	24.93	36.75	47.4%	27.35	31.15	13.9%
RER Peak	0.99	1.01	2.6%	1.20	1.29	7.4%
VO_2 at VT (ml/Kg/min)	17.87	30.5	-	22.6	26.38	-
% $VT/V0_2$ Peak	71.7%	83.0%	-	82.6%	84.7%	-
VE/VCO_2 Slope	27.838	25.099	(9.8%)	27.36	31.763	16.1%
O_2 Uptake Efficiency Slope (OUES)	1,850.1	2,442.9	32.0%	1,903.4	2,039.8	7.2%

Conclusions: These results support the continued investigation of this alternative therapeutic option to provide cardiovascular benefit to thousands of Fontan patients with dysfunctional single ventricle physiology.

S17. Effects of Prime Volume on Serum Ionized Calcium in Children on Veno-Arterial ECMO

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Objective: The objective of this study was to analyze serum ionized calcium (iCa) in children peri-cannulation for venoarterial extracorporeal membrane oxygenation (VA-ECMO).

Methods: We performed a single-center, retrospective review of children under 10kg cannulated for VA ECMO from January 2012 to December 2015. Patients without measured iCa within sixty minutes of cannulation or who received calcium peri- cannulation prior to next measured iCa were excluded. Patients were divided into two groups: patients with an adult oxygenator (AOx) (prime volume = 407mL) or patients with a pediatric oxygenator (POx) (prime volume = 220mL). POxs were primed with 200mg of calcium and AOxs were primed with 400mg. Serum iCa values before and immediately after cannulation were analyzed.

Results: ECMO cannulation was universally associated with a decrease in iCa (n=23, 100%) and all patients received calcium within 12 hours of ECMO cannulation. Average decrease in iCa was 18.8% (range: 7-62%). Children with the AOx (n=13) received 54% greater prime volume than patients with the POx (n=10). ICa decrease correlated with greater prime volume (22.8% vs 13.6%, p=0.03, Table 1). There was no difference between the prime concentration of calcium delivered between POx and AOx (p=0.42). There was no correlation between the change in iCa and the pre-cannulation iCa (r^2=0.16), the total calcium (r^2=0.19), serum albumin (r^2=0.05), serum magnesium (r^2=0.002), and change in pH (r^2=0.02). Serum pH was significantly higher (p=0.01) after ECMO cannulation.

Table 1: Decrease in serum calcium (%) before and after ECMO cannulation

Prime Volume	220mL	407mL
% Change	17	24
	38	18
	14	14
	11	62
	14	14
	8	10
	10	14
	7	25
	9	28
	8	31
		26
		19
		11
Total:	**n=10**	**n=13**
Mean:	**13.6%**	**22.8%**

Conclusions: ECMO cannulation was universally associated with a decrease in iCa in this study population. The magnitude of this change was related to the prime volume. Because hypocalcemia can have major physiological effects, further investigation into calcium dosing in the ECMO prime is warranted.

S18. An In-Vitro Study for Comparison of Artificial Heart Valve Prostheses Using Hemodynamic Energy

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Objective: Hemodynamic energy (HE), comprised of kinetic energy (KE) and pressure energy (PE), determines the direction of the blood flow in the circulatory system. Hence the objective of this study is artificial heart valve prostheses with the same orifice size may generate different HE due to the differences in valve opening mechanism, materials, and so on. The goal of this study was to compare HE differences between a mechanical vs. tissue heart valve by using in vitro mock system.

Methods: Two artificial heart valve prostheses were compared in terms of HE: a mechanical valve (BiCarbon 21 mm, Sorin Group, Milano) and a tissue valve (Edwards 3000 Perimount Magna 21 mm, Edwards Lifesciences, Irvine). Pulsatile flow was generated by a Korean external ventricular assist device (KH-VAD, KAOC, Seoul), and the mock system was primed with 40/60 glycerin/water solution. Real-time flow rates and pressures were recorded at 50, 60, 70, 80, and 90 pulse rates per minute for five minutes. HE markers were surplus hemodynamic energy (SHE) and energy equivalent pressure. Under the same diameter, the mechanical vs. tissue valve was found to have different impact on HE. The tissue valve showed higher hemodynamic energy performance (SHE, SHE retention, %EEP, %EEP retention) overall It suggests that a tissue valve is likely to retain more hemodynamic energy and flow pulsatility generated by the heart, which in turn leads to higher tissue perfusion.

Results: The biological valve generally had higher proximal MAP. And biological valve showed higher proximal EEP in 50, 60, 70, and 90 BPM. The biological valve also showed higher distal EEP and SHE than mechanical valves in all pulse rate settings. The biological valve showed higher proximal %EEP in the lower pulse rate settings (50, 60 BPM). The mechanical valve showed higher proximal %EEP in the 80 BPM setting. No statistically significant differences in %EEP were seen at 70 and 90 BPM settings.

Table 1. P-value by two way ANOVA adjusting for pump rate.

	BIO			MEC			P-value
	LS-Mean	95% CI		LS-Mean	95% CI		
MAP % change	-74.55	-76.46	-72.64	-78.42	-80.33	-76.51	0.0060
EEP % change	20.12	19.26	20.99	17.65	16.78	18.51	0.0002
SHE % change	85.52	85.42	85.61	86.45	86.36	86.55	<.0001
%EEP % change	91.71	91.63	91.79	92.36	92.28	92.44	<.0001

Conclusions: This research compared hemodynamic energy parameters between mechanical and biological aortic valve prostheses under pulsatile flow. The biological valve showed higher HER, % EEP, SHE retention, and % EEP retention, suggesting that it better preserves the hemodynamic energy generated by the heart. Higher preservation of the hemodynamic energy can be interpreted as higher preservation of pulsatility. Thus, biological valves may preserve pulsatility and the benefits of pulsatile perfusion more than the mechanical valves.

Acknowledgement: This research was supported by a grant of the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: A121157) and Supported by a Korea University Grant (K1325201).

S19. A Novel Method for Evaluation of Intracellular Calcium during Electrical Stimulation inside a Plate Reader

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Objective: In this work we describe a method developed to study intracellular calcium concentration in cultured myoblasts during electrical stimulation using fluorescence measurements.

Methods: H9c2 cells (ATCC CRL-1446) were cultured until 80% confluence and plated in a custom 96 well microplate with a custom made embedded electric stimulator. Cells were plated in regular wells (controls) and wells where electrodes were inserted (stimulated group – S). In the following day cells were loaded in PBS (phosphate buffered saline) containing 5µM of cytoplasmic Ca^{2+} indicator Fluo-4AM, 0.02% of pluronic F-127, 2.5 mM of probenecid (Life Technologies) and 45 min after cells were washed and incubated in PBS containing 2,5 mM of probenecid for 30 min at 37ºC, 5% CO_2 .

The fluorescence intensity was measured once per minute over 70 minutes with FluoStar Omega plate reader (BMG Labtech) using 485/520 nm as excitation/emission filters. A square monophasic pulse stimulus (1 Hz, 8 V/cm, 5 ms) was applied 10 min after the starting of recording during 20 min. Statistical analysis was performed by Mann–Whitney U test and Wilcoxon signed-rank test (*p<0.05).

Results: Fig.1 shows the cytoplasmic calcium measurements (n = 6). Electrical stimulation resulted in decreased intensity of fluorescence signals from 0.85±0.09 to 0.66±0.06. Reduced fluorescence was not observed in control wells. Fig.2 shows the values of fluorescence considering the phase of stimulation. At 10 min and 30 min there are artifacts due to ambient light exposure.

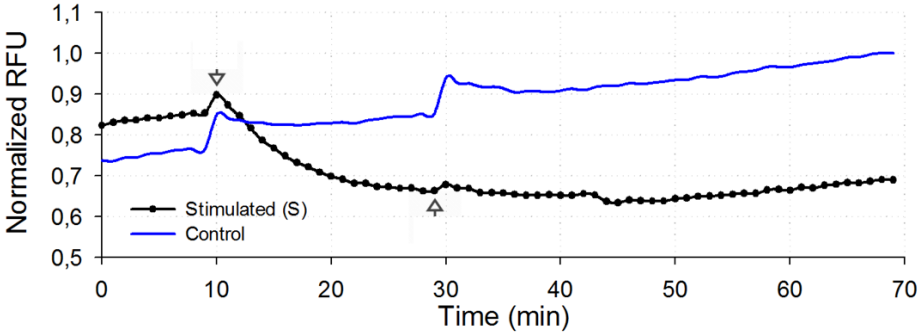

Fig.1: Calcium Fluorescence in Normalized Relative Fluorescence Units (RFU), the arrows indicates the beginning and end of stimulation.

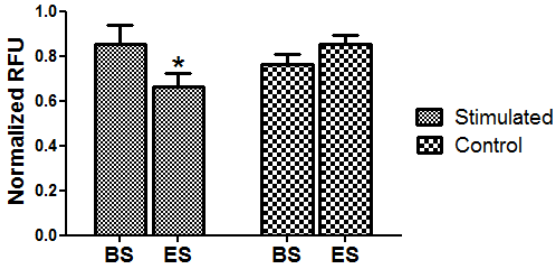

Fig.2: Values of fluorescence for stimulated cells compared with control group before stimulation (BS) and at the end of stimulation (ES).

Conclusions: We developed a method to measure intracellular calcium concentration during stimulation on a plate reader. This methodology allows for automated assessment of intracellular calcium concentration during electrical stimulation.

S20. Acute Biventricular Interaction in Pediatric Patients Implanted With Continuous Flow and Pulsatile Flow LVAD: A Simulation Study

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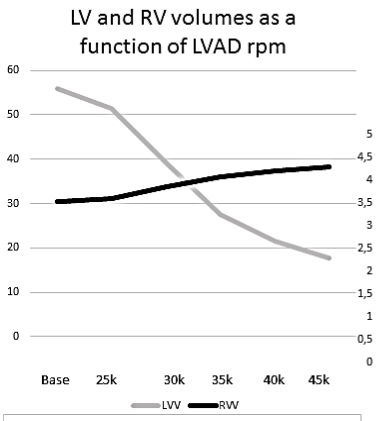
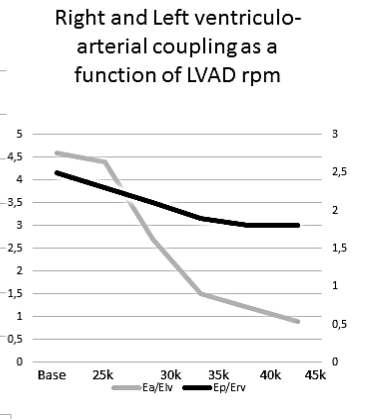
Objective: LVADs are used to bridge pediatric patients till transplantation. LVAD unloads the LV, but the LVADs effects on right ventricular (RV) function are controversial. This work aims at studying the ventricular interdependency in the presence of continuous (c-) and pulsatile (p-) flow LVAD in pediatric patients using a lumped parameter model including the representation of the septum.

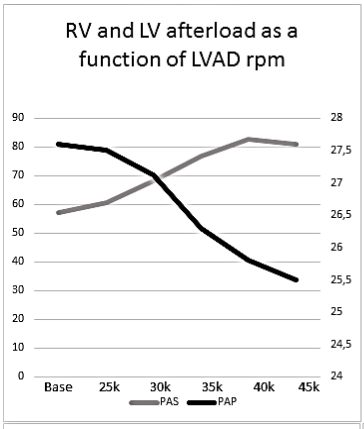
Methods: 5 pediatric patients' data were used to simulate patient's baseline. The effects on LV and RV functions, energetics, preloads and afterloads of different c-LVAD speeds, p-LVAD rate, p-LVAD systole duration, p-LVAD filling and ejection pressures were simulated.

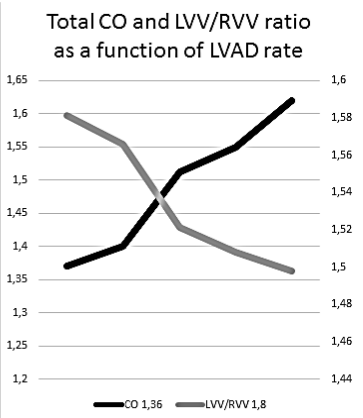
Results: c-LVAD and p-LVAD unload the LV decreasing the LV external work and improving the LV ventriculo-arterial coupling and these effects are more evident increasing the c-LVAD speed, the p-LVAD rate and the p-LVAD systole duration. c-LVAD and p-LVAD decrease the RV afterload, increase the RV ejection fraction and improve the RV ventriculo-arterial coupling. The LVAD presence increases RV volumes and RV external work, proportional to the leftward shift of the septum that is more evident increasing the c-LVAD speed, the p-LVAD rate and the p-LVAD systole duration.

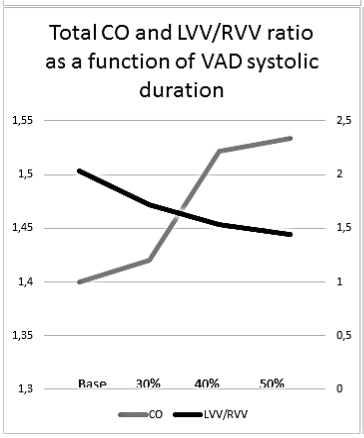
Conclusion: The study of the interventricular interaction could lead to the development of a dedicated algorithm to optimize LVAD setting in pediatric population.

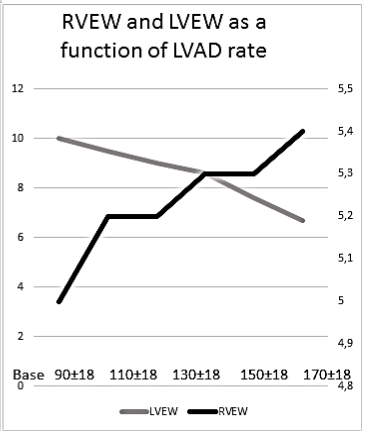












S21. Building a Better Neonatal ECLS Circuit: Comparison of Hemodynamic Performance and Gaseous Microemboli Handling in Different Pump and Oxygenator Technologies

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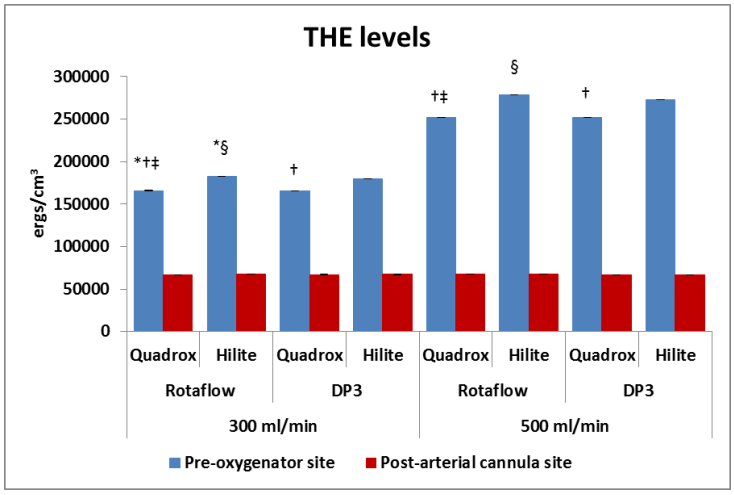
Background: Neurologic complications secondary to neonatal ECLS are associated with significant morbidity and mortality. While these complications are likely multifactorial, gaseous microemboli (GME) in the ECLS circuit may be a possible cause. Advances in neonatal circuitry may improve hemodynamic performance and GME handling leading to reduction in patient complications.

Objective: In this study we compared two different centrifugal pumps (Maquet RotaFlow and Medos DeltaStream DP3) and oxygenators (Maquet Quadrox-iD and Medos Hilite LT) on hemodynamic performance, specifically pressure drops and total hemodynamic energy (THE) levels and GME handling in a neonatal ECLS circuit model.

Methods: The experimental circuit consisted of the Maquet RotaFlow pump, Quadrox-iD Pediatric oxygenator, Medos DeltaStream DP3 pump, Hilite 800 LT oxygenator, and the Better-Bladder arranged in parallel using a "Y" connector. The circuit was primed with lactated Ringer's solution and packed human red blood cells with hematocrit 40%. Hemodynamic trials collecting real-time pressure and flow data were conducted at flow rates of 300 and 500 ml/min at 36°C. To evaluate GME handling, 0.5cc of air was injected into the venous line testing 8 unique combinations of pump and oxygenator with or without the Better Bladder at both flow rates. The Emboli Detection and Classification Quantifier (EDAC) System was used for GME detection and size characterization.

Results: THE levels at pre-oxygenator and post-arterial cannula sites and GME handling results are displayed below in Figure 1 and Table 1 respectively.

Conclusions: The RotaFlow centrifugal pump and Quadrox iD oxygenator circuit arrangement had the best hemodynamic performance with significantly lower pressure drops and THE loss. Conversely, the Medos DeltaStream DP3 pump and Hilite LT oxygenator with the Better-Bladder had better GME handling except at the slower flow rate of 300 ml/min. The Better-Bladder significantly decreased GME at all stages of the experiment. Further in vivo studies are necessary to validate these findings.



* p<0.01 RotaFlow vs. DP3; ‡ p<0.01 RotaFlow and Quadrox vs. DP3 and Hilite;
† p<0.01 Quadrox vs. Hilite; § p<0.01 RotaFlow and Hilite vs. DP3 and Quadrox.

Table 1. Total GME counts.

Flow Rate	Pump	Oxygenator	Bladder	GME total count	
				Pre-oxygenator	Post-oxygenator
300ml/min	RotaFlow	Quadrox	With	99±50 *	20±17 *
			Without	6100±1818	6519±3596
		Hilite	With	54±37 *	6±7 *
			Without	6124±215	8344±651
	DP3	Quadrox	With	7±8 *	1±2 *
			Without	4030±674	5550±875
		Hilite	With	5±4 *	41±17 *
			Without	4654±425	4303±328
500ml/min	RotaFlow	Quadrox	With	23±16 *	4±4 *
			Without	11262±1024	7410±356
		Hilite	With	10±6 *	3±1 *
			Without	11764±385	8845±1097
	DP3	Quadrox	With	13±17 *	1±2 *
			Without	10904±307	7985±409†
		Hilite	With	3±3 *	6±9 *
			Without	6928±1885	7164±666

* p<0.01 All groups with Better-Bladder vs. without Better-Bladder DP3.

P1. In-vitro Evaluation of an Alternative Neonatal ECLS Circuit on Hemodynamic Performance and Bubble Trap

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Objective: The objective of this study was to evaluate an alternative neonatal extracorporeal life support (ECLS) circuit with a RotaFlow centrifugal pump and Better-Bladder for hemodynamic performance and gaseous microemboli (GME) capture in a simulated neonatal ECLS system.

Methods: The circuit consisted of a Maquet RotaFlow centrifugal pump, a Quadrox-iD Pediatric diffusion membrane oxygenator, 8Fr arterial cannula, and 10Fr venous cannula. A "Y" connector was inserted into the venous line to allow for comparison between Better-Bladder (BB) and no BB. The circuit and pseudo patient were primed with lactated ringer's solution and packed human red blood cells (hematocrit 35%). All hemodynamic trials were conducted at flow rates ranging from 100 ml/min to 600 ml/min at 36°C. Real-time pressure and flow data were recorded using a data acquisition system. For GME testing, 0.5cc of air was injected via syringe into the venous line. GME were detected and characterized with or without the Better Bladder using the Emboli Detection and Classification Quantifier (EDAC) System. Trials were conducted at flow rates ranging from 200 ml/min to 500 ml/min.

Results: Figure 1 present mean circuit pressures at flow rates of 100ml/min – 600ml/min. The hemodynamic energy data showed that up to 75.2% of the total hemodynamic energy was lost from the circuit. The greatest pressure drops occurred across the arterial cannula and increased with increasing flow rate from 10.1 mmHg at 100 ml/min to 114.3 mmHg at 600 ml/min. The EDAC results showed that the Better-Bladder trapped a significant amount of the GME in the circuit (Table 1, * $p<0.01$, with BB vs. without BB; † $p<0.01$, pre-oxy site vs. post-oxy site.). When the bladder was removed, GME passed through the pump head and the oxygenator to the arterial line.

Conclusions: This study showed that a RotaFlow centrifugal pump combined with a Better-Bladder can help to significantly decrease the number of GME in a neonatal ECLS circuit. Even with this optimized alternative circuit, a large percentage of THE was lost. The arterial cannula was the main source of resistance in the circuit. Further animal studies are needed to verify our findings.

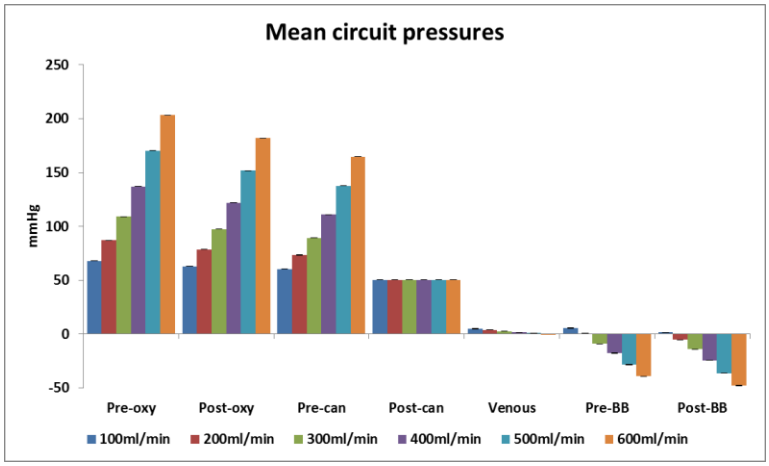

Figure 1. Mean circuit pressures. Venous: pre-venous cannula site.

Table 1. Total GME counts.

Flow rate	Bladder	Pre-oxygenator	Post-oxygenator
200 ml/min	With	0.2±0.4	0.0±0.0
	Without	3.2±4.2	16.5±016.3
300 ml/min	With	1.8±1.7 *	1.3±1.6
	Without	1516.3±347.2 †	81.3±62.9
400 ml/min	With	0.3±0.8 *	0.0±0.0 *
	Without	1591.8±278.6 †	648.3±324.7
500 ml/min	With	0.0±0.0 *	0.0±0.0 *
	Without	2810.5±124.3 †	1339.8±70.2

P2. Mechanical Circulatory Support for Pediatric Patients with Fulminant Myocarditis

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Objective: Acute/ Fulminant myocarditis is an emergency for pediatric patients. The initial presentation might be subtle, and quickly deteriorate to cardiac arrest. The patients with severe cardiogenic shock require mechanical support, mainly extracorporeal membrane oxygenation (ECMO). We review out 20 years' experience for pediatric patients require ECMO support.

Methods: The patients received ECMO support was prospectively recorded. The pediatric patients (age<18year old) received ECMO support for acute/fulminant myocarditis were retrieved from the database.

Results: There were 51 patients included in the study. There were four neonate (< 30 days), three infants (1 month to one year) and 44 patients older than one year. Cannulation site included femoral route for 28(63%) and neck or cardiac route for the other patients. Twenty-two (23%) of them were transferred from other hospital with ECMO support. Two patients were bridged to heart transplant, with one mortality. Another 6 patients were bridged to ventricular assist device (VAD), and two of them received transplantation, two died on support, and the other two successfully weaned off from VAD. The overall survival rate was 76% (39/51). The major cause of mortality was multi-organ failure or neurologic complication due to prolonged shock or ECMO complication.

Conclusions: Pediatric patients with cardiogenic shock due to myocarditis could be successfully rescued by ECMO and VAD in about 80% of them, and some required heart transplantation. Avoiding the catastrophic cardiac arrest might further improve the outcome. The lacking of heart transplant and long-term pediatric VAD are still of concern.

P3. Trend of Echocardiographic Parameters in Pediatric Patients with Berlin Heart EXCOR LVAD: A Prospective Observational Study

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Background: LVAD is an effective strategy for bridging children to heart transplant or to heart recovery. We sought to evaluate the changes in echocardiographic parameters in Berlin Heart EXCOR LVAD pediatric patients.

Methods: Clinical and Echocardiographic data of children implanted from 2013 to 2015 were prospectively collected before LVAD implantation and monthly follow-up until LVAD explantation. Standard Echo measurements included : M-Mode left ventricular end-diastolic and end-systolic diameters (LVEDD, LVESD), 2D volumes (LVESV,LVEDV) and ejection fraction evaluated by modified Simpson Method, grade of mitral regurgitation, left atrial size, right ventricular fractional area change (RVFAC), tricuspid valve diameter and peak systolic pulmonary pressure (Paps)

Results: 12 patients were enrolled in the analysis. 9 patients (75%) were affected by idiopathic dilated cardiomyopathy, 2 patients (17%) by non-compacted left myocardium and 1 patient (8%) by restrictive cardiomyopathy. At the implantation, average patient's age and weight were 13.1±11.1 months and 7.2±3.7Kg, respectively. Average LVAD support was 226±104 days. Six patients (50%) were successfully transplanted, with 1 weaning (8%), 3 deaths (25%) for major neurological complication and 2 (17%) still on LVAD. Left ventricle was significantly unloaded with a statistically significant reduction in LVEDV (p_acute=0.0001, P_fup1=0.0004, p_fup2=0.0006, p_fup3=0.02, p_fup4=0.03, p_fup5=0.05), LVESV (p_acute=0.0003, P_fup1=0.0003, p_fup2=0.0003, p_fup3=0.03, p_fup4=0.04) and a statistically significant improvement of left ventricular ejection fraction (EF) (p_acute=0.01, P_fup1=0.02, p_fup2=0.02). Despite an initial decrease in LVESV and LVEDV, EF showed a trend in worsening at long-term follow-up (4mths). A similar trend was observed in left atrial size, mitral valve annulus and mitral regurgitation. Right ventricular function showed an initial improvement with a trend in worsening during long-term assistance

Conclusion: In prolonged duration of LVAD support, the benefic effects of LV unloading seems to be decreased over time resulting in both left and right ventricular dilatation.

P4. Continuous Metabolic Monitoring Allows Tapering of Hypothermic Cardiopulmonary Bypass during Open-Heart Repair in Infancy

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Background: Cardiopulmonary bypass (CPB) in neonates and children carries distinct burden in terms of morbidity due to systemic inflammatory response (SIRS). Different strategies have been adopted to mitigate SIRS. Prior work using intraoperative monitoring of systemic and cerebral metabolic parameters has shown that nominal CPB flows may be overestimated by at least 10% under normothermic conditions. Definition of ideal CPB flow under moderate hypothermic conditions is lacking.

Objective: The present study was undertaken to evaluate safety and efficacy of metabolic CPB management during moderately hypothermic CPB in neonates and infants requiring open heart repair.

Methods: Twenty-three consecutive infants and young children undergoing surgical repair for congenital heart disease using hypothermic CPB were enrolled in the study. There were 11 male and 12 female, aged 0.78 ± 2 years, with a mean body weight of 4.8 ± 3.5 Kg and BSA of 0.26 ± 0.14 m2. All patients were managed according to a standardized protocol. After CPB start, body temperature was lowered to 25 °C (rectal). Hemodynamic (CI, MVO2, DO2) and metabolic (cerebral NIRS, pH, paO2, paCO2, base excess, lactate, Hb) data were collected at 5 time points: T0 at CDI calibration, T1 5 minutes after aortic clamp, T2 after 5 minutes of hypothermic CPB, T3 at the end of the 20 minutes test and T4 after aortic clamp removal. This means that data collected at T0, T1 and T4 correlate with normal CPB conduction, while T2 and T3 correlate with metabolic hypothermic CPB conduction. During the test phase, CPB was managed maintaining an MVO2 >70% and cerebral NIRS >45. Hospital clinical outcome was also recorded and evaluated.

Results: Surgical procedures included 9 patients with left to right shunt lesions, 2 patients with right to left shunt lesions, 9 patients with complex lesions, requiring complex repairs and 3 patients with obstructive lesions. The 20 minute test allowed reduction of CPB flows greater than 20% ($p<0.05$), with no impact on pH, blood gas exchange and lactate. Morbidity included: need for inotropic support in 4 patients (17.4%), prolonged ventilation in 8 cases (34.8%), renal failure requiring dialysis in 3 patients (13%), need for re-exploration in 3 cases (13%) and sepsis in 2 patients (11.5%). There was 1 (4.3%) in-hospital mortality, no neurological morbidity and no need for ECMO support.

Conclusions: The present study shows that moderately hypothermic CPB in neonates and infants can be safely managed exclusively by systemic and cerebral metabolic monitoring. This strategy allows reduction of over 20% of predicted CPB flows under hypothermia and may allow tapering of transfusion requirements during complex open-heart repair and control of attendant morbidity.

P5. Validation of a New Model of Cardiopulmonary Bypass in Rat with Circulatory Arrest and Selective Antegrade Cerebral Perfusion

Daniele Linardi[1], Elisabetta Milani[1], Tiziano Menon[1], Maddalena Tessari[1], Grygory Tsenov[2], Andrea del Pilar Rodriguez[2], Giang Tong[3], Katharina Schmitt[3], Giovanni Battista Luciani[1], Giuseppe Faggian[1], Alessio Rungatscher[1]

University of Verona, Verona, Italy, Department of Cardiac Surgery[1], University of Verona, Verona, Italy, Department of Anatomy and Histology[2], University of Berlin, Berlin, Germany, Klinik für angeborene Herzfehler und Kinderkardiologie Deutsches Herzzentrum Berlin[3]

Objective: Selective antegrade cerebral perfusion (SACP) is adopted by many surgical groups as an alternative to deep hypothermic circulatory arrest (DHCA) during aortic arch surgery in adult and pediatric patients. However there are still no preclinical evidences to support use of SACP associated to moderate hypothermia (28-30°C) instead of DHCA (18-20°C). Therefore, in this contest, a new reliable, repeatable and low-cost animal model of circulatory arrest and SACP during cardiopulmonary bypass (CPB) is needed.

Methods: CPB with central cannulation, through right jugular vein and left carotid artery, was instituted in adult male Wistar rats. Animals were randomized to normothermic circulatory arrest without cerebral perfusion (NCA) or SACP (upper left carotid artery cannulation; 10 ml/kg/min) in normothermia (35-36°C). After 20 min of circulatory arrest, rats underwent 60 min of reperfusion. EEG activity was recorded during all experiments. Thereafter animals were sacrificed and brains were collected for histology and molecular biology analysis.

Results: EEG activity 2-40 Hz (Power Spectrum Analysis) decreased in all rats during circulatory arrest. However, SACP determined fast recovery of brain activity and higher EEG power spectral density compared to NCA ($p < 0.05$). Histological damage scores, brain TNF-α, caspase-3, TUNEL and GSH/GSSG ratio were attenuated in SACP compared to NCA (all $p<0.05$).

Conclusions: Cannulation of upper left carotid artery guarantees good perfusion of the whole brain in this animal model of CPB and circulatory arrest. With these experiments we manage to validate a model of SACP, reliable, repeatable and not expensive. In the near future we will use this model to compare DHCA and SACP in moderate hypothermia, and to assess the ideal temperature to guarantee best cerebral protection. Furthermore it will be possible to study effects of infusion of specific neuro-protective drugs directly into cerebral circulation.

P6. Does Flexible Arterial Tubing Retain More Hemodynamic Energy During Pediatric Pulsatile ECLS?

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Objective: The objective of this study was to evaluate the hemodynamic performance and energy transmission of flexible arterial tubing as the arterial line in a simulated pediatric pulsatile ECLS system.

Methods: The ECLS circuit consisted of a Medos DeltaStream DP3 diagonal pump head, Medos Hilite 2400 LT oxygenator, Biomedicus arterial/venous cannula (10Fr/14Fr), 3 feet of polyvinyl chloride (PVC) arterial tubing or latex rubber arterial tubing, primed with lactated ringer's solution and packed red blood cells (hematocrit 40%). Trials were conducted at flow rates of 300 to 1200 ml/min (300ml/min increments) under non-pulsatile and pulsatile modes at 36°C using either PVC arterial tubing (PVC group) or latex rubber tubing (Latex group). Real-time pressure and flow data were recorded using a custom-based data acquisition system.

Results: Mean pressures and energy equivalent pressures (EEP) were the same under non-pulsatile mode between two groups. Under pulsatile mode, EEPs were significantly great than mean pressure, especially in the Latex group ($p<0.05$). There was no difference between the two groups with regards to pressure drops across ECLS circuit, but pulsatile flow created more pressure drops than non-pulsatile flow ($p<0.05$). Surplus hemodynamic energy (SHE) levels were always higher in the Latex group than in the PVC group at all sites. Although total hemodynamic energy (THE) losses were higher under pulsatile mode compared to non-pulsatile mode, more THEs were delivered to the pseudo patient, particularly in the Latex group ($p<0.05$) (**Figure 1**).

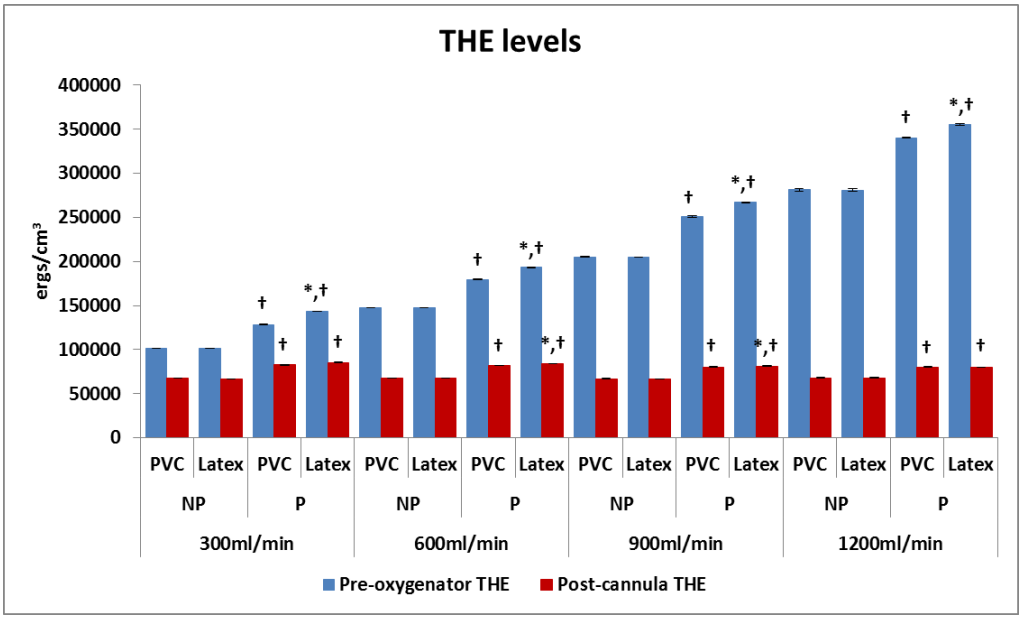

Figure 1. THE levels under non-pulsatile (NP) and pulsatile (P) modes. * p<0.05, PVC vs. Latex tubing; † p<0.05, NP vs. P mode.

Conclusions: The results showed that the flexible arterial tubing retained more hemodynamic energy passing through it under pulsatile mode while mean pressures and pressure drops across the ECLS circuit were similar between PVC and latex rubber arterial tubing. Further studies are warranted to verify our findings.

P7. Contemporaneous Use of Continuous and Pulsatile Flow VAD on A Fontan Patient: A Simulation Study

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Objective: The aim of this work is to develop and test a lumped parameter model of the cardiovascular system to simulate the contemporaneous use of pulsatile (PF) and continuous flow (CF) VAD on Fontan patient.

Methods: Echocardiographic and hemodynamic data of 5 Fontan patients were retrospectively collected and used to simulate the patient's baseline hemodynamics. Then, for each patient, the following assistance modality was simulated: (a) CF VAD for the cavo-pulmonary assistance and PF VAD assisting the single ventricle (RCF+LPF), (b) CF VAD assisting the single ventricle and PF VAD for the cavo-pulmonary assistance (LCF+RPF).

Results: The numerical model can well reproduce patient's baseline. The cardiac output increases more importantly in the LCF+RPF configuration (35% vs 8%). Ventricular volumes decrease more evidently in the configuration LCF+RPF (28% vs 6%), atrial pressure decreases in the LCF+RPF modality (10%), while it slightly increases in the RCF+LPF modality. The pulmonary arterial pressure slightly decreases (increases) in the configuration RCF+LPF (LCF+RPF). Ventricular External work increases in both configurations because of the total increment of the cardiac output. However artero-ventricular coupling improves in both configurations: RCF+LPF -14%, LCF+RPF -41%. The pulsatility index decrease (increase) by 8% (13.8%) in the configuration LCF+RPF (RCF+LPF)

Conclusion: A model could permit to simulate extreme physiological condition as the implantation of both CF and PF VAD on the Fontan patient and could permit to choose the proper VAD on the base of patient's condition. The configuration LCF+RPF seems to maximize the hemodynamic benefits.

P8. Biventricular Assistance Using both Continuous and Pulsatile Flow VAD: A Simulation Study on Pediatric Patients

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Introduction: The aim of this work is to develop and test a lumped parameter model of the cardiovascular system to simulate the contemporaneous use of pulsatile (PF) and continuous flow (CF) VAD on the same patient.

Methods: Echocardiographic and hemodynamic data of 5 pediatric patients undergoing VAD implantation were retrospectively collected and used to simulate the patient's baseline condition with the numerical model. Once the baseline hemodynamic was reproduced for each patient, the following assistance modality was simulated: (a) CF VAD assisting the right ventricle and PF VAD assisting the left ventricle (RCF+LPF), (b) CF VAD assisting the left ventricle and PF VAD assisting the right ventricle (LCF+RPF).

Results: The numerical model can well reproduce patient's baseline. The cardiac output increases in both assisted configuration (RCF+LPF: +17%, LCF+RPF: +21%), Left (Right) ventricular volumes decreases more evidently in the configuration LCF+RPF (RCF+LPF), Left (right) atrial pressure decreases in the LCF+RPF (RCF+LPF) modality. The pulmonary arterial pressure slightly decreases in the configuration LCF+RPF and it increases with RCF+LPF. Left and Right Ventricular External work increases in both configurations because of the total increment of the cardiac output. However left and right artero-ventricular coupling improve and the improvement is more evident in the LCF+RPF (-36% for the left ventricle and -21% for the right ventricle). The pulsatility index decrease by 8.5% in the configuration LCF+RPF and increase by 6.4% with RCF+LPF.

Conclusion: A numerical model could be useful to personalize on patients the choice of the VAD that could be implanted to maximize the hemodynamic benefits. Moreover, a model could permit to simulate extreme physiological condition as the implantation of both CF and PF VAD on the same patient.

P9. Does an Open Recirculation Line Affect The Flow Rate and Pressure in A Neonatal ECLS Circuit with A Centrifugal or Roller Pump?

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Objective: The objective of this study is to evaluate the impact of an open or closed recirculation line on flow rate, circuit pressure, and hemodynamic energy transmission in simulated neonatal ECLS systems.

Methods: The two neonatal ECLS circuits consisted of a Maquet HL20 roller pump (RP group) or a RotaFlow centrifugal pump (CP group), Quadrox-iD Pediatric oxygenator, and Biomedicus arterial and venous cannulae (8Fr and 10 Fr) primed with lactated ringer's solution and packed red blood cells (hematocrit 35%). Trials were conducted at flow rates ranging from 200 to 600 ml/min (200 ml/min increments) with a closed or open recirculation line at 36°C. Real-time pressure and flow data were recorded using a custom-based data acquisition system.

Results: In the RP group, the pre-oxygenator flow did not change when the recirculation line was open while the pre-arterial cannula flow decreased by 15.7% - 20.0% ($p<0.01$) (**Table 1**). Circuit pressure, total circuit pressure drop, and hemodynamic energy delivered to patients also decreased ($p<0.01$). In the CP group, the pre-arterial cannula flow did not change while pre-oxygenator flow increased by 13.6% - 18.8% ($p<0.01$) (**Table 1**). Circuit pressure drop and hemodynamic energy transmission remained the same.

Table 1. Shunt flow from the open recirculation line.

Group	Recirculation line	Roller pump			Centrifugal pump		
		Pre-oxy flow (ml/min)	Pre-can flow (ml/min)	Shunt flow (ml/min)	Pre-oxy flow (ml/min)	Pre-can flow (ml/min)	Shunt flow (ml/min)
200 ml/min	Closed	218.5±1.7	214.2±1.2*	-	215.6±0.1*	215.9±0.1	-
	Open	219.0±1.2	175.1±1.1	43.9±0.8 (20.0%)	253.1±0.1	213.2±0.1	40.0±0.1 (18.8%)
400 ml/min	Closed	413.5±1.1	413.6±1.2*	-	408.7±0.1*	406.6±0.1	-
	Open	414.5±0.2	351.7±0.4	62.8±0.3† (17.9%)	462.7±0.1	402.0±0.1	60.7±0.1† (15.1%)
600 ml/min	Closed	611.2±1.0	616.2±1.4*	-	613.5±0.3*	613.3±0.2	-
	Open	613.3±1.6	530.1±1.3	83.2±1.1† (15.7%)	690.5±0.1	608.0±0.1	82.5±0.1† (13.6%)

* $P<0.01$, Closed vs. open recirculation line; † $p<0.01$, 200ml/min vs. other flow rates.

Conclusions: The results showed that the shunt of an open recirculation line could decrease perfusion flow in patients in the ECLS circuit using a roller pump, but did not change perfusion flow in the circuit using a centrifugal pump. An additional flow sensor is needed to monitor perfusion flow in patients if any shunts exist in the ECLS circuit.

P10. Can Pulsatile Flow be Synchronized with Various Heart Rates and Cardiac Arrhythmias During ECLS? An In-Vitro Study

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Objective: The objective of this study is to evaluate ECG-synchronized pulsatile flow under varying heart rates and different atrial and ventricular arrhythmias in a simulated ECLS system.

Methods: The ECLS circuit consisted of an i-cor diagonal pump and console, an iLA membrane ventilator, and an 18 Fr arterial cannula. A hardshell venous reservoir served as a pseudopatient. The circuit was primed with lactated Ringer's solution and packed red blood cells (hematocrit 35%). An ECG simulator was used to trigger pulsatile flow and generate selected cardiac rhythms. All trials were conducted at a flow rate of 2.5 L/min at room temperature for the normal sinus rhythm at 45 bpm – 180 bpm under non-pulsatile and pulsatile mode. Various atrial and ventricular arrhythmias were also tested. Real-time pressure and flow data were recorded using a custom-based data acquisition system.

Results: Energy equivalent pressure (EEP) generated by pulsatile flow was always higher than mean pressure. No surplus hemodynamic energy (SHE) was recorded under non-pulsatile mode. Under pulsatile mode, SHE levels increased with increasing heart rates (45 bpm - 120 bpm). SHE levels under a 1:2 assist ratio were higher than the 1:1 and 1:3 assist ratios with a heart rate of 180 bpm. A similar trend was recorded for total hemodynamic energy (THE) levels. There was no statistical difference between the two perfusion modes with regards to pressure drops across the ECLS circuit. The main resistance and energy loss came from the arterial cannula. The i-cor console can follow ECG changes of common atrial and ventricular arrhythmias to trigger ECG-synchronized pulsatile flow (**Figure 1**).

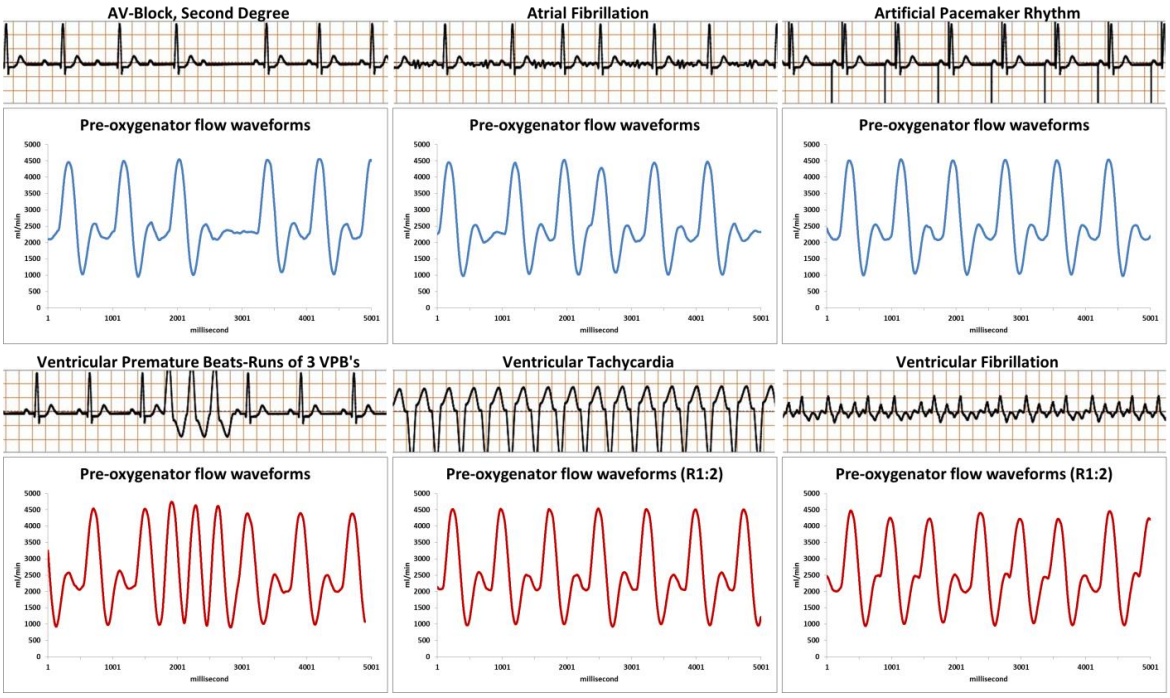

Figure 1. Pulsatile flow under atrial fibrillation and ventricular premature beats.

Conclusions: Our results demonstrated that the i-cor ECLS system can provide physiological pulsatile flow, and can synchronize well with normal heart rate and various atrial/ventricular arrhythmias. Further studies are warranted to confirm our findings.

P11. Successful Use of the Heartware HVAD as Bridge to Transplantation after Previous Implantation of Bilateral Berlin Heart EXCOR Devices in an 8 Year Old Boy

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Introduction: Continuous-flow ventricular assist devices are being implanted with increased frequency in the United States in children with end-stage heart failure. We report the first reported use of the HeartWare HVAD in an 8 year old boy who had been previously supported with bilateral Berlin Heart EXCOR devices.

Case: A 4 year old Hispanic male with dilated cardiomyopathy and end stage heart failure secondary to fulminant myocarditis underwent successful implantation of bilateral Berlin Heart EXCOR VADs after a 14 day stabilization period on extra-corporeal membrane oxygenation (ECMO). The patient was maintained on bilateral VADs with eventual significant recovery of biventricular function and explantation of the devices on post-operative day (POD) 15. In May of 2014, at the age of 8 (23 Kg, BSA 0.86 m2), he presented with worsening of LV function and repeated episodes of symptomatic SVT. He was hospitalized and started on intravenous milrinone therapy without significant symptomatic improvement after 12 days. With informed consent from the family a Heart Ware HVAD was implanted. During his post-operative course, complications included prolonged respiratory failure requiring tracheostomy, and poor oral nutrition requiring nasogastric nutritional supplementation. On POD 198, a suitable donor heart became available and the patient underwent orthotropic heart transplantation. The patient's post-transplant course was uneventful. He was eventually discharged home with in-home rehabilitation on POD 17 after his transplant.

Conclusion: The Heart Ware device was utilized in our 8 year old patient with only a BSA of 0.86 m2. Currently the HeartWare HVAD is only recommended for patients with BSA of 1.5 m2 and greater (HeartWare, Inc), however it has been reportedly been successfully implanted in patients as small as a BSA of 0.70 m2 . There are no reports of it being used in a previously scarred myocardium. Furthermore, at the time of this report, the longest reported case of HeartWare device support to successful transplantation in children in the US was 148 days. Our patient was supported for 198 days without any significant thrombotic or hemorrhagic neurologic injury. Continuous flow devices like the HeartWare HVAD are being used in smaller and smaller children and to date this report is one of few that have been successful in bridging such a small child to transplantation after > 6 months of VAD therapy. Thus implantable Heart Ware HVAD can be used to provide circulatory support for those who have had previous para-corporeal mechanical circulatory support.

The List of Publications during the Past Eleven International Conferences (September 2005 – March 2016)

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2013

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Index of Authors

G

H

I

J

K

L

M

N

O

P

Q

R

S

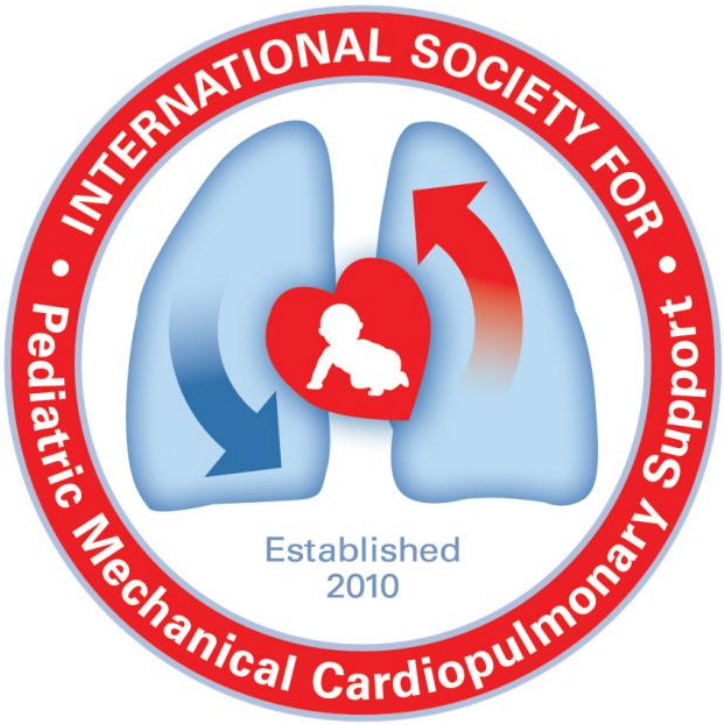
T

U

V

W

Z



The mission of this society is to focus on the current problems associated with pediatric cardiac patients during and after acute or chronic cardiac support. The society will bring together as many distinguished clinicians, bioengineers, and basic scientists as possible to precisely define current problems and suggest novel approaches and solutions.

Our motto continues to be:

IF THE COURSE OF JUST ONE CHILD'S LIFE IS IMPROVED AS A RESULT OF THIS SOCIETY, WE HAVE REACHED OUR GOAL.

Akif Ündar, PhD, Founder and President

International Society Web Site: http://www.cvent.com/d/7cqc1m