

# CONFERENCE PROCEEDINGS

Volume 4, May 2008

**The Proceedings of the  
Fourth International Conference on  
PEDIATRIC MECHANICAL  
CIRCULATORY SUPPORT SYSTEMS  
& PEDIATRIC  
CARDIOPULMONARY PERFUSION**



photo by Larry Mayer

• **May 21-24, 2008** •

**Hilton Portland &  
Executive Tower**

**Portland, Oregon, USA**

**Editor: Akif Ündar, PhD**

**HONORARY CHAIRS**

**William S. Pierce, MD • John A. Waldhausen, MD**

**PROGRAM CO-CHAIRS**

**Brian W. Duncan, MD • John L. Myers, MD • Gerson Rosenberg, PhD  
Carmen Giacomuzzi, BSN, CCP • Akif Ündar, PhD • Ross M. Ungerleider, MD, MBA**



**A continuing education service of Oregon Health & Science University  
and Penn State College of Medicine**

Fourth International Conference on **Pediatric Mechanical**  
Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion

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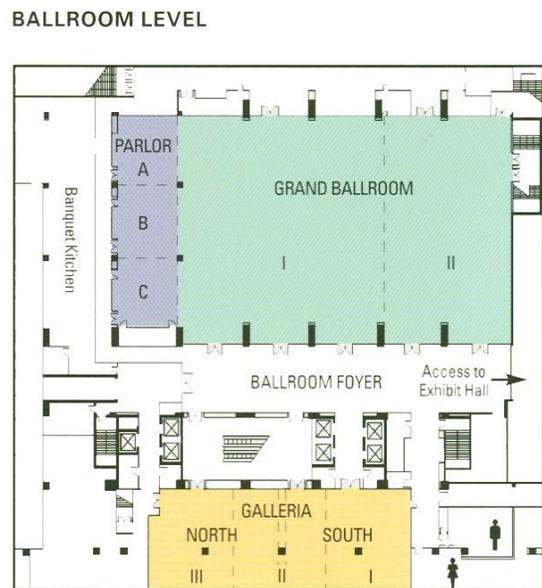
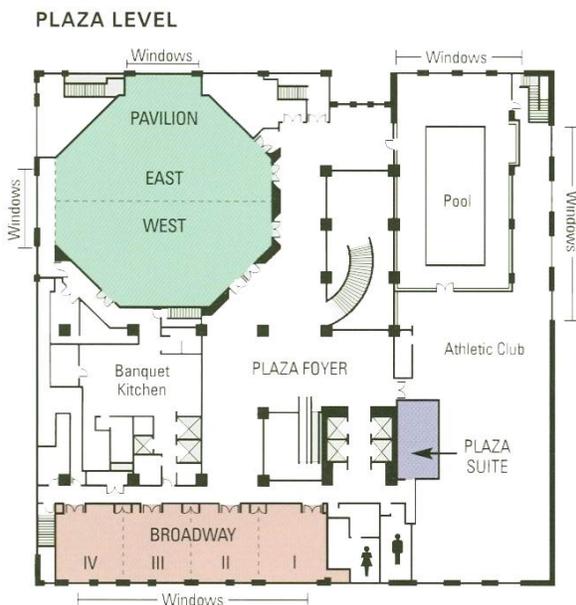
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## The Hilton Portland & Executive Tower

May 21	Congruent Communication Workshop	Galleria III
	Perfusion Hands-on Workshop	Gallerias I and II
	Surgical Videos	Parlors
May 22-24	Speaker Ready Room	Galleria III
	Scientific Meeting	Grand Ballroom I
	Lunches and Awards Dinner	Pavilion Ballroom
May 22-23	Moderated Poster Sessions	Parlors
	Exhibits	Gallerias I and II



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## Welcome to Portland!

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Ross M. Ungerleider, MD, MBA  
Department of Cardiothoracic Surgery  
Doernbecher Children's Hospital, Oregon Health & Science University  
Portland, Oregon, USA

On behalf of the organizing committee for the Fourth International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion, welcome to Portland, Oregon. For some, we understand that this is your first visit to Portland. For those who have been here before, we know you have been eagerly looking forward to your return. We hope that the experience meets your expectations.

A lot of people have worked hard to ensure that your visit succeeds—at both a scientific level as well as at the level of connecting with colleagues who share your passion for pediatric heart care. During meeting hours we will have members of the OHSU CME division, as well as staff from our cardiothoracic surgery program, at the Hilton to help you with your needs.

We have created an ambitious program that will address numerous and timely topics. To accommodate such a large number of invited speakers, we will keep the talks on time. They will move along in a concise fashion (the moderators will see to that!) and we hope each session will provide you with substantial new information that will be useful to you. The break and evening time will give you an opportunity to explore with individual speakers more details if you are interested in their material.

If you have any needs, please don't hesitate to contact Irene Reskin or myself and we will direct you to the people most likely to help. In addition to the meeting, some of you may wish to spend some time

exploring Portland. You should! That is why we had the meeting here.

I would make the following suggestions:

- 1) If you wish to visit the OHSU medical center, or Doernbecher Children's Hospital, talk with one of your numerous faculty colleagues who are from OHSU. They will find a way to show you where we work. We are hoping to decrease our clinical volume during the week of the conference so that we can show you the facilities. If we are doing clinical work, your colleagues may arrange to take you along.
- 2) Portland is loaded with eclectic and outstanding restaurants. The hotel concierge can help you make dinner reservations, and our staff will be glad to provide you with suggestions.
- 3) There is wonderful shopping near the hotel. There will be suggestions in your registration materials.
- 4) Please ask us if you have other questions.

Finally, it is important to acknowledge the impact that this meeting has had on our field. Over the past four years, since this conference was created by the group at Hershey Medical Center, important advances have been reported in the conference sessions that have clearly changed our field. Please join me in thanking the extraordinary group from Hershey, Drs. Ündar, Myers, Pierce, Rosenberg, Waldhausen and others who have committed their careers to the advancement of pediatric CPB and mechanical assist.

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## Welcome to the Fourth Annual Event

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Akif Ündar, PhD, Conference Founder  
Pediatric Cardiac Research Laboratories  
Departments of Pediatrics, Surgery, and Bioengineering  
Penn State College of Medicine, Penn State Children's Hospital  
Hershey, Pennsylvania, USA

On behalf of the organizers of the *Fourth International Conference on Pediatric Mechanical Circulatory Support Systems and Pediatric Cardiopulmonary Perfusion*, I am honored to welcome each of you to this unique event.

The overall objective of the proposed meeting is to bring together internationally known clinicians, bioengineers, and basic scientists involved in research on pediatric mechanical cardiac support systems and pediatric cardiopulmonary bypass procedures. The primary focus is to *explicitly describe the problems with current pediatric mechanical circulatory support systems, methods, and techniques during acute and chronic support and to suggest appropriate solutions.*

This international event is unique since it is the only conference solely dedicated to pediatric cardiac devices during acute and chronic mechanical circulatory support. To date, no other national or international conference has precisely defined the problems with pediatric cardiac patients, or suggested solutions with new methodologies and devices for pediatric patients, more specifically for neonates and infants.

### *Past Three Conferences*

Research findings reported during the past three conferences have already made a significant impact on the treatment of pediatric cardiac patients worldwide. More than 800 leading international scholars from 27 countries, including Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Finland, France, Germany, Greece, Ireland, Italy, Japan, Kuwait, Netherlands, New Zealand, Poland, Saudi Arabia, Scotland, South Korea, Spain, Switzerland, Taiwan, Turkey, the United Kingdom,

and the United States, have participated in the 2005, 2006, and 2007 events.

### *Special Issues of the ASAIO Journal*

The American Society for Artificial Internal Organs (ASAIO) has endorsed this event since its initiation, dedicating an issue of the *ASAIO Journal* to manuscripts developed each year from the Conferences.

All regular slide and poster abstract presenters are required to submit full manuscripts before their presentations for possible publication in the *ASAIO Journal*. Although it is not required, we also request that invited speakers also submit full manuscripts. The Nov-Dec 2008 issue of the *ASAIO Journal* will feature the manuscripts submitted at this fourth conference.

*ASAIO Journal* issues Sept-Oct 2005, Sept-Oct 2006, and Nov-Dec 2007 were dedicated to the manuscripts submitted at the First, Second, and Third Conferences, respectively. All manuscripts undergo the usual rigorous peer-review process for publication acceptance in the *ASAIO Journal*. To date, 141 manuscripts, including cutting-edge original articles, case reports, editorials, and special reports, have been published in the past three special issues of the *ASAIO Journal* [1]. Organizers of this event greatly appreciate the hard work of the Editorial Office including Betty L. Littleton, BA, Managing Editor, and Joseph B. Zwischenberger, MD, Editor of the *Journal*.

### *Financial Support*

During the past three years, we were able to organize this event using significant funds from the Penn State

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Hershey Children's Hospital. For the Fourth Conference, we have received educational grants from *Bayer Healthcare*, the *National Heart, Lung, and Blood Institute* and the *Office of Rare Diseases at the National Institutes of Health*. In addition, major financial support was received from companies including Baxter Healthcare, Berlin Heart, CorMatrix Cardiovascular, CryoLife, Levitronix, Lippincott Williams & Wilkins, Luna Innovations, MAQUET, MEDOS Medizintechnik AG, MicroMed Cardiovascular, Medtronic Cardiac Surgery, Somanetics Corporation, Sorin Group USA, St. Jude Medical, and SynCardia Systems.

### *Special Thanks to Local Organizing Committee*

Every single detail of this fourth event from A to Z was organized under the leadership of Prof. Ross Ungerleider. Dr. Ungerleider not only organized the scientific sessions and invited speakers, but also arranged an outstanding social program. A new feature this year, put together by Carmen Giacomuzzi, CCP and Brian Mejak, CCP, is an excellent wet lab offering hands-on experience for perfusionists. I sincerely appreciate all the support we received from Dr. Ungerleider's staff including Lisa Frankovich and Johann Kuball. In particular, my special thanks go to Irene Reskin for applying her spectacular skills in the coordination and organization of this event.

### *Future Conferences*

The Board of Trustees of the *American Society for Artificial Internal Organs (ASAIO)* has invited us to combine our unique international event with the annual event of the ASAIO. After careful review, we have accepted this invitation. Starting in 2009, the fifth international conference will be held at the same time and place as the annual ASAIO Meeting. All administrative issues including conference registration will be handled by the Executive Office of the Society. This merger will not impact our scientific program. We will have parallel scientific sessions in the same exhibit hall, so participants of both events can see pediatric as well as adult devices.

The following is a list of locations and dates for the future conferences:

*Fifth International Conference* – The Hilton Anatole Hotel, Dallas, TX, May 28-30, 2009 (Confirmed)

*Sixth International Conference* – The Hilton Hotel, Baltimore, May 27-29, 2010 (Confirmed)

Once again, I am honored to welcome each of you to this unique event. Our motto continues to be: *If the course of just one child's life is improved as a result of this event, we have reached our goal.*

### References

1. **Ündar A.** International conference on pediatric mechanical circulatory support systems and pediatric cardiopulmonary perfusion: Outcomes and future directions [Invited Editorial]. *ASAIO Journal* 2008; 54: 141-146.
2. **Ündar A.** *Design and performance of physiologic pulsatile flow cardiopulmonary bypass systems for neonates and infants. Ph.D. Dissertation, The University of Texas at Austin, May 1996.*

### *Personal Note*

No matter how much one achieves, or how much one has done, there are always some special people who have directly or indirectly helped in his/her success. While I was in graduate school and pursuing my PhD in Biomedical Engineering at the University of Texas at Austin, I needed to complete my experiments using a neonatal piglet cardiopulmonary bypass model. Through Dr. John Calhoun, who is currently the Chief of Surgery at the UTHSC at San Antonio and was co-supervisor of my dissertation along with thesis advisor Dr. Thomas Runge, I met with Dr. Ross Ungerleider (who was the Chief of Pediatric Cardiac Surgery at Duke University). During the summer of 1995 (less than 6 weeks) with Dr. Ungerleider's surgery residents, Andrew J. Lodge and Casey W. Daggett, we were able to complete all of the necessary experiments for my PhD project [2] (39 CPB experiments in piglets) at Dr. Ungerleider's laboratory at Duke University Medical Center. Without Dr. Ungerleider's support, it could have taken a couple of more years to complete the necessary experiments.

Since then, Ross has not only become my true mentor, but also a friend whose advice I always trust. I feel so fortunate to know Ross and am especially honored to co-chair this international event with such an exceptional person.

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## Scientific Committee

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### Honorary Chairs

William S. Pierce, MD  
Professor Emeritus  
Evan Pugh Professor of Surgery  
Penn State College of Medicine  
Hershey PA, USA

John A. Waldhausen, MD  
Professor Emeritus  
Founding Chairman of Surgery  
Penn State College of Medicine  
Hershey PA, USA

### Program Co-Chairs

Brian W. Duncan, MD  
Department of Cardiac Surgery  
Children's Hospital  
Cleveland Clinic Foundation  
Cleveland OH, USA

Carmen Giacomuzzi, BSN, CCP  
Department of Perfusion Services  
Oregon Health & Science University  
Doernbecher Children's Hospital  
Portland OR, USA

John L. Myers, MD  
Departments of Surgery and Pediatrics  
Penn State College of Medicine  
Hershey PA, USA

Akif Ündar, PhD  
Department of Pediatrics, Surgery and  
Bioengineering  
Penn State College of Medicine  
Penn State Children's Hospital  
Hershey PA, USA

Gerson Rosenberg, PhD  
Departments of Surgery and Bioengineering  
Penn State College of Medicine  
Hershey PA, USA

Ross M. Ungerleider, MD, MBA  
Department of Cardiothoracic Surgery  
Oregon Health & Science University  
Doernbecher Children's Hospital  
Portland OR, USA

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## **Educational Grants**

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**Bayer Healthcare**  
**National Heart, Lung, and Blood Institute**  
**Office of Rare Diseases at the National Institutes of Health**

## **Conference Exhibitors**

**Baxter Healthcare Corp.**

**Berlin Heart**

**CorMatrix Cardiovascular, Inc.**

**CryoLife, Inc.**

**Levitronix, LLC**

**Lippincott Williams & Wilkins**

**Luna Innovations, Inc.**

**MAQUET**

**MEDOS Medizintechnik AG**

**Medtronic Cardiac Surgery**

**MicroMed Cardiovascular, Inc.**

**Somanetics Corporation**

**Sorin Group USA, Inc.**

**St. Jude Medical**

**SynCardia Systems, Inc.**

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## Final Scientific Program

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**WEDNESDAY, MAY 21, 2008**

2 p.m.

### **PERFUSION HANDS-ON WORKSHOP**

Chair: Carmen Giacomuzzi, CCP (Portland, OR)

Instructors/Facilitators: Chris Brabant, CCP (Milwaukee, WI),  
Carmen Giacomuzzi, CCP (Portland, OR), Brian Mejak, CCP (Portland, OR),  
Steve Moss, CCP (Chicago, IL), Stuart Sheppard, PhD (Southampton, UK),  
Shigang Wang, MD (Hershey, PA), Karl Woitas, CCP (Hershey, PA)

Perfusionists representing four different institutions will be demonstrating various extra-corporeal systems. Participants will rotate through workstations followed by an open discussion forum. Stations will include devices such as the MAQUET MECC™ System, neonatal circuit utilizing the Terumo System 1, a hybrid ECMO/VAD circuit, and the MEDOS Delta Stream Blood Pump DPI and Console. In addition, participants will experiment with pulsatile perfusion and learn how the EDAC™ Quantifier can impact your perfusion practice.

5 p.m.

### **VIEWING OF SELECTED SURGICAL VIDEOS**

#### **TOF with Limited Ventriculotomy**

Paul Chai, MD (Tampa, FL)

#### **Anomalous Coronary Artery**

James Jagers, MD (Durham, NC)

#### **Truncus Arteriosus with IAA**

James Tweddell, MD (Milwaukee, WI)

#### **Modified Ross Procedure**

Ross Ungerleider, MD (Portland, OR)

#### **Arch Reconstruction**

Kristine Guleserian, MD (Dallas, TX)

#### **Insertion of the Berlin Heart Followed by Transplant**

Robert Jaquiss, MD (Little Rock, AR)

#### **Nikaidoh on a 3.5-Month-Old**

Christian Pizarro, MD (Wilmington, DE.)

**THURSDAY, MAY 22, 2008**

### **Opening Session**

7 a.m.

Registration/Speaker Ready Room Open

7:50 a.m.

Welcome

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- 8 a.m.                    **PLENARY SESSION #1: Advances in CPB that Benefit the Patient**  
Moderators: Ross Ungerleider, MD (Portland, OR); John L. Myers, MD  
(Hershey, PA)  
**Circuit Miniaturization—Advantages of Asanguineous Prime**  
Ed Hickey, MD (Toronto, Canada)  
**MECC May Create Useable Miniaturized Circuitry**  
Steve Langley, MD (Portland, OR)  
**Cardioplegia to Minimize Blood Prime**  
Kristine Guleserian, MD (Dallas, TX)  
**Microdevices for Measuring Systemic Inflammation**  
Jeffrey D. Zahn, MD (Piscataway, NJ)  
**Plasma Proteomics in Infants Undergoing Cardiopulmonary Bypass  
Procedure**  
David S. Phelps, PhD (Hershey, PA)  
**Intraoperative Techniques to Assess Cardiac Function**  
Linda Pauliks, MD (Hershey, PA)  
**What We Know and Don't Know About NIRS**  
Jennifer Hirsch, MD (Ann Arbor, MI)  
**Cardiac Cath for Patients on Mechanical Assist**  
Laurie Armsby, MD (Portland, OR)
- 10 a.m.                    Break/Exhibits/Posters
- Invited Lectures**
- 10:40 a.m.                **Novel Micromachined Ultrasound Transducers for Cardiac Imaging**  
David Sahn, MD (Portland, OR)
- 11 a.m.                    **How Do We Normalize Outcome Measures So That We Can Comprehend  
Results?**  
Karl Welke, MD (Portland, OR)
- 11:20 a.m.                **From Experimentation to Innovation to Standard of Care: How Do We  
Demystify Dogma and Create Progress?**  
Ross Ungerleider, MD (Portland, OR)
- 12 p.m.                    LUNCH
- 1 p.m.                    **PLENARY SESSION #2: CONQUERING COAGULATION**  
Moderators: Aubyn Marath, MD (Portland, OR); James Jagers, MD (Durham,  
NC)  
**Aprotinin Has a Role in Pediatric Cardiac Surgery**  
James Tweddell, MD (Milwaukee, WI)  
**HIT Happens**

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Lynn Boshkov, MD (Portland, OR)

**New Anticoagulation Strategies**

Andras Gruber, MD, PhD (Portland, OR)

**CPB as a Procoagulant State**

James Jagers, MD (Durham, NC)

**Outcomes for Children with Congenital Heart Disease Requiring ECMO**

Ravi Thiagarajan, MD (Boston, MA)

**Coagulation Issues in the Fontan Circulation**

Kirsten Odegard, MD (Boston, MA)

**Aprotinin and the Brain**

Nobu Ishibashi, MD (Washington, DC)

3 p.m.

**INVITED GUEST LECTURER**

**New Strategies for Preservation of Small Diameter Grafts**

Steve Hanson, PhD (Portland, OR)

3:20 p.m.

Break/Exhibits/Posters

3:45 p.m.

**REGULAR SLIDE PRESENTATIONS: SESSION #1**

Moderator: Akif Ündar, PhD (Hershey, PA)

S.1. **Current Status of Blood Transfusion-Free Open Heart Surgery in Infants and Small Children**

Yasuhiro Kotani, MD, Osami Honjo, MD, Mahito Nakakura, CE, Yasuhiro Fujii, MD, Shinya Ugaki, MD, Yu Oshima, MD, Ko Yoshizumi, MD, Shingo Kasahara, MD, Shunji Sano, MD

Department of Cardiovascular Surgery, Okayama University Hospital, Japan

S.2. **Efficiency of Miniaturized Circuit and Vacuum-Assisted Venous Drainage in Decreasing Blood Transfusion**

Yves Durandy MD. Institut Jacques Cartier, Massy- France

S.3. **Why Do We Cool to 18° C?**

Jamie You, CCP. Brian Mejak, CCP. Carmen Giacomuzzi, CCP. Eileen Heller, CCP. Ross Ungerleider, MD. Karl Welke, MD

Division of Pediatric Surgery, Doernbecher Children's Hospital, Oregon Health & Science University Portland, Oregon

S.4. **Results with All Blood Retrograde Microplegia as a Myocardial Protection Strategy for Complex Neonatal Arch Reconstruction**

Richard N Gates, MD, Brian A Palafox, MD, Beth Parker, CCP

Division of Cardiothoracic Surgery, Children's Hospital of Orange County, Orange, California, USA

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- S.5. **Pulsatile Perfusion on Vital Organ Recovery During and After Pediatric Open-Heart Surgery in Ventricular Septal Defects**  
Alkan-Bozkaya T., Akcevin A., Ündar A\*, Türkoğlu H., Paker T, Aytaç A.  
V.K.V. American Hospital, Dept. of Cardiovascular Surgery, Istanbul, Turkey  
and \*Penn State University, Children's Hospital, Hershey, PA, USA
- S.6. **Operative Risk and Outcome of Surgery in Adults with Congenital Valve Disease**  
Giovanni Battista Luciani, MD, Francesca Viscardi, MD, Mara Pilati, MD, Luca Barozzi, MD, Giuseppe Faggian, MD, Alessandro Mazzucco, MD.  
Divisions of Cardiac Surgery and Cardiology, University of Verona, Verona, Italy
- S.7. **“Stolen” Blood Flow: The Effect of an Open Arterial Filter Purge Line in a Simulated Neonatal CPB Model**  
Shigang Wang, MD, Akemi Miller, BA, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, and Bioengineering  
Penn State College of Medicine, Penn State Children's Hospital, Hershey,  
Pennsylvania, USA
- S.8. **Development of a Miniaturized Heart-Lung Machine for Neonates with Congenital Heart Defect**  
Jutta Arens<sup>1</sup>, MSc; Heike Schnöring<sup>2</sup>, MD; Jaime Vázquez-Jiménez<sup>2</sup>, MD;  
Thomas Schmitz-Rode<sup>1</sup>, MD; Ulrich Steinseifer<sup>1</sup>, PhD  
<sup>1</sup> Applied Medical Engineering, Helmholtz Institute, RWTH Aachen, Germany  
<sup>2</sup> Pediatric Cardiac Surgery, University Clinic Aachen, Germany
- S.9. **Extracorporeal Circulation (ECC) in the Rat Model Using a New Miniaturized Hollow Fiber Oxygenator**  
Rungatscher A<sup>1</sup>, Cresce GD<sup>2</sup>, Tessari M<sup>1</sup>, Walpoth BH<sup>2</sup>, Faggian G<sup>1</sup>  
<sup>1</sup> Cardiovascular Surgery, University of Verona Medical School, Italy  
<sup>2</sup> Cardiovascular Research, University Hospital of Geneva, Geneva, Switzerland
- S.10. **Feasibility of Ultrafiltration of Blood for Priming Before Cardiopulmonary Bypass in Neonatal Piglets**  
Shinya Ugaki, Shingo Kasahara, Osami Honjo, Yasuhiro Kotani, Yu Oshima, Ko Yoshizumi and Shunji Sano  
Department of Cardiovascular Surgery, Okayama University, Okayama, Japan
- S.11. **The Effects of Vasopressor and Vasodilator on Hemodynamic Energy in Terms of Surplus Hemodynamic Energy**  
Choon Hak Lim MD, Jae Soon Choi PhD, Ho Sung Son MD, Jung Joo Lee PhD,  
Hye Won Lee MD, Kyung Sun MD, PhD  
Department of Anesthesiology and Pain Medicine, Thoracic and Cardiovascular  
Surgery, Korea Artificial Organ Center, Korea University, Seoul, Korea

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- S.12. **Detection and Classification of Gaseous Microemboli in a Simulated Pediatric CPB Circuit: Effect of Flow Rate and Perfusion Mode on Microemboli Delivery**  
Akemi Miller, Shigang Wang, MD, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, and Bioengineering, Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA
- S.13. **Computational Fluid Dynamics for Pediatric Surgical Planning and Fetal Hemodynamics**  
Kerem Pekkan, PhD  
Department of Biomedical Engineering, Carnegie Mellon University, Pittsburgh, Pennsylvania, USA

6 p.m.

**MODERATED POSTER PRESENTATIONS: SESSION #1**

Moderators: Pirooz Eghtesady, MD (Cincinnati, Ohio); Carmen Giacomuzzi, CCP, Portland, Oregon

- P.1. **The Influence of Neurologic Monitoring on the Management of Pediatric Cardiopulmonary Bypass**  
S. Kimatian MD, FAAP, K Saliba DO, X. Soler MD, E. Valentine MD, M. Coleman, A. Kunselman, G. Schuler, MSc, CCRC, J. Myers MD  
Departments of Anesthesiology, Surgery, and Public Evaluation Sciences, Penn State College of Medicine, Hershey, Pennsylvania, USA
- P.2. **The Myocardial Protection of Histidine-Ketoglutarate-Tryptophan (HTK) Cardioplegic Solution on the Long-Term Ischemic Period in Pediatric Heart Surgery**  
Jinping Liu, M.D, Zhengyi Feng, M,D, Ju Zhao, M.D, Bo Li, Cun Long, M.D  
Department of Cardiopulmonary Bypass, Fuwai Hospital, CAMD & PUMS, Beijing, China
- P.3. **Surgical Repair of Tetralogy of Fallot with Absent Pulmonary Valve in an Infant with Sickle Cell Anemia**  
Joanne P. Starr\* MD, Meena Nathan\* MD, Joel Hardin\* MD, Peri Kamalakar# MD, Wondwessen Bekele# MD, Moshe Bell# MD, Srikanth Patankar\* MD, Elizabeth Cortez\* CCP, Stacey Rifkin# DO  
\*Children's Heart Center, #Pediatric Hematology and Oncology, Children's Hospital of New Jersey at Newark Beth Israel Medical Center, Newark, NJ
- P.4. **Thyroid Hormones Homeostasis in Pediatric Patients During and After Cardiopulmonary Bypass: Is There a Difference Between the Pulsatile and Nonpulsatile Perfusion Modes?**  
Alkan-Bozkaya T., Akcevin A., Ündar A., Türkoğlu H., Paker T, Aytaç A. V.K.V. American Hospital, Dept. of Cardiovascular Surgery, Istanbul, Turkey and Penn State University, Children's Hospital, Hershey, PA, USA

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- P.5. **Routine Mechanical Ventricular Assist Following the Norwood Procedure Improved Cerebral Perfusion**  
Jamie You, CCP. Brian Mejak, CCP. Carmen Giacomuzzi, CCP, Eileen Heller, CCP, Ross Ungerleider, MD, Karl Welke, MD  
Division of Pediatric Surgery, Doernbecher Children's Hospital, Oregon Health & Science University Portland, Oregon
- P.6. **Development of an Ultra-Durable Heparin-Free Pediatric ECMO System at the National Cardiovascular Center of Japan**  
Eisuke Tatsumi, MD, Nobumasa Katagiri, MS, Toshihide Mizuno, DVM, Yoshiaki Takewa, MD, Tomohiro Tsukiya, PhD, Akihiko Homma, PhD, Yoshiyuki Taenaka, MD, Teruyuki Hayashi, CCP, Toshikatsu Yagihara, MD  
Departments of Artificial Organs, Department of Surgery, National Cardiovascular Center, Suita, Osaka, Japan
- P.7 **Coagulation Times and Heparin Management for Pediatric Patients Requiring Extracorporeal Membrane Oxygenator Support**  
Timothy M. Maul, PhD<sup>1,2,3</sup>, Erin L. Wacker, BS<sup>1,2,3</sup>, Kent, Kelly, CCP<sup>1</sup>, Victor O. Morell, MD<sup>1</sup>, Peter D. Wearden, MD, PhD<sup>1,3</sup>  
Departments of Cardiac Surgery, Children's Hospital of UPMC<sup>1</sup>, Bioengineering, University of Pittsburgh<sup>2</sup>, and the McGowan Institute for Regenerative Medicine<sup>3</sup>, Pittsburgh, Pennsylvania, USA
- P.8. **Different Albumin Concentration in Extracorporeal Circuit Prime on Perioperative Fluid Status in Young Children**  
Kun Yu, Yinglong Liu, Feilong Hei, Jingping Liu, Zhengyi Feng, Jingwen Li, Cun Long  
Division of Cardiothoracic Surgery, Extracorporeal Circulation, Cardiovascular Institute and Fuwai Hospital CAMS and PUMS Beijing, China
- P.9. **A Performance Evaluation of Eight Geometrically Different 10 FR Pediatric Arterial Cannulae Under Pulsatile vs. Non-Pulsatile Perfusion in an Infant CPB Model**  
Alan R. Rider, Bingyang Ji, MD, Allen Kunselman, MA, William J. Weiss, PhD, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, Bioengineering, and Health Evaluation Sciences, Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA
- P.10. **Postoperative Hemodynamics After Cardiopulmonary Bypass in Newborn Piglets**  
Theodor Tirilomis, PhD, Lars Nolte, Oliver J. Liakopoulos, PhD, Carola Ballat, Katja Steinke, MD, Marc Bensch, PhD, Friedrich A. Schoendube, PhD  
Department for Thoracic, Cardiac, and Vascular Surgery, University of Goettingen, Goettingen, Germany

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- P.11. **Reducing Gaseous Microemboli During Pediatric Perfusion: Case Studies with the EDAC™ QUANTIFIER**  
Ted Lynch, PhD  
Luna Innovations Incorporated, Hampton, Virginia, USA
- P.12. **Comparison of Two Different Blood Pumps on Delivery of Gaseous Microemboli During Pulsatile and Non-Pulsatile Perfusion in a Simulated Infant CPB Model**  
Shigang Wang, MD, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, and Bioengineering, Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA
- P.13. **The Capability of Trapping Gaseous Microemboli of Two Pediatric Arterial Filters with Pulsatile and Non-pulsatile Flow in Simulated Infant CPB Model**  
Shigang Wang, MD, Khin N. Win, BS, Woitas, K., CCP, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, and Bioengineering, Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA
- P.14. **Fetal Surgical Management of Congenital Heart Block in a Hydropic Fetus: Lessons Learned from a Clinical Experience**  
Pirooz Eghtesady, MD, PhD, Erik Michelfelder, MD, Timothy K. Knilans, MD, Jeffrey Livingston, MD Peter B. Manning, MD, and Timothy Crombleholme, MD, PhD  
Pediatric Cardiac Surgery, Pediatric Cardiology and The Fetal Care Center of Cincinnati, Cincinnati Children's Hospital, Cincinnati, OH
- P.15. **Enteroviral Sepsis and Ischemic Cardiomyopathy in a Neonate**  
Meena Nathan MD, Rowan Walsh MD, Joel Hardin MD, Stanley Einzig MD, Brian O Connor MD, Duraisamy Balaguru MD, Rajiv Verma MD, Joanne Starr MD  
Division of Pediatric Cardiac Surgery, Division of Pediatric Cardiology, Children's Hospital of New Jersey at Newark Beth Israel Medical Center, Newark, NJ
- P.16. **An Implementation of Sensor-Based Force-Feedback in a Compact Laparoscopic Surgery Robot**  
<sup>1</sup>Jaesoon Choi, PhD, <sup>2</sup>Duk H. Lee, MA, <sup>2</sup>Jun W. Park, PhD, <sup>2</sup>Doo J. Bach, MA, <sup>1</sup>Seung J. Song, MA, <sup>1</sup>Yoon H. Kim, MA, <sup>2</sup>Yungho Jo, PhD, <sup>1</sup>Kyung Sun, MD, PhD, MBA  
<sup>1</sup>Korea Artificial Organ Center, College of Medicine, Korea University, Seoul, Korea  
<sup>2</sup>Biomedical Engineering Branch, Research Institute, National Cancer Center, Gyeonggi, Korea

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P.17. **Delivery of Gaseous Microemboli with Vacuum-Assisted Venous Drainage During Pulsatile and Non-Pulsatile Perfusion in a Simulated Infant CPB Model**

Shigang Wang, MD, Larry Baer, CCP, Allen R. Kunselman, MA, John L. Myers, MD, Akif Ündar, PhD

Departments of Pediatrics, Surgery, Bioengineering, and Health Evaluation Sciences, Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

P.18. **Microemboli Detection and Classification by Innovative Ultrasound Technology During Simulated Neonatal CPB at Different Flow Rates, Perfusion Modes and Perfusate Temperatures**

Robert S. Schreiner, Alan R. Rider, John W. Myers, Bingyang Ji, MD, Allen R. Kunselman, MA, John L. Myers, MD, Akif Ündar, PhD

Departments of Pediatrics, Surgery, Bioengineering, and Health Evaluation Sciences, Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

7:30 p.m.

**ALL-ATTENDEE DINNER**

Awards Recognition—Moderators: John L. Myers, MD, Akif Ündar, PhD, Ross Ungerleider, MD

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**FRIDAY, MAY 23, 2008**

- 7 a.m. Breakfast/Speaker Ready Room Open
- 8 a.m. **PLENARY SESSION #3: MECHANICAL DEVICES**  
Moderators: Shunji Sano, MD (Okayama, Japan); William S. Pierce, MD (Hershey, PA); Gerson Rosenberg, PhD (Hershey, PA)  
**Impella Device in Pediatric Patients**  
Thorsten Siess, PhD (Aachen, Germany)  
**Levitronix Centrifugal Pumps in Pediatric Patients**  
Kurt A. Dasse, PhD (Waltham, MA)  
**Emboli—Strategies to Reduce Incidence and Impact**  
Timothy Jones, MD, FRCS (Birmingham, UK)  
**Ventricular Assist Device Implementation in the Pediatric Population: Does Pump Size Selection and Associated Hemodynamics Impact Outcomes?**  
S. Adil Husain, MD (Gainesville, FL)
- NATIONAL HEART, LUNG, AND BLOOD INSTITUTE PEDIATRIC GRANT AWARDEES:**  
**PediPump**  
Brian Duncan, MD (Cleveland, OH)  
**Penn State Pulsatile VAD**  
William Weiss, PhD (Hershey, PA)  
**Pediaflow VAD**  
Peter Wearden, MD (Pittsburgh, PA)
- 10 a.m. Break/Exhibits/Posters
- Invited Lectures**
- 10:40 a.m. **Interagency Registry for Mechanical Circulatory Support**  
Christopher Almond, MD (Boston, MA)
- 11 a.m. **Single Ventricle – What Does the Future Hold?**  
Tom Spray, MD (Philadelphia, PA)
- 11:30 a.m. **Hypoplastic Left Heart Syndrome with Post-Op Support**  
Shunji Sano, MD (Okayama, Japan)
- 12 p.m. LUNCH

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1 p.m.

**PLENARY SESSION #4: OPTIMIZING CONGENITAL HEART SURGERY**

Moderators: Tara Karamlou, MD (Portland, OR); Gordon Cohen, MD (Seattle, WA)

**Novel Approaches to ECMO Following Cardiac Surgery**

Gordon Cohen, MD (Seattle, WA)

**Mechanical Assist Following Stage I Palliation**

Mark Rodefeld, MD (Indianapolis, IN)

**Mobile ECMO**

Robert Jaquiss, MD (Little Rock, AR)

**Adult Congenital Heart Surgery is Best Performed by Congenital Heart Surgeons**

Tara Karamlou, MD (Portland, OR)

**Fetal Cardiac Surgery: Mission Impossible?**

Pirooz Eghtesady, MD, PhD (Cincinnati, OH)

**ECMO for Single Ventricle**

Chitra Ravishankar, MD (Philadelphia, PA)

2:30 p.m.

**REGULAR SLIDE PRESENTATIONS: SESSION #2**

Moderators: Akif Ündar, PhD (Hershey, PA); Brian Duncan, MD (Cleveland, OH)

S.14 **Preliminary Single Center North American Experience with the Berlin Heart Pediatric EXCOR Device**

S.R. Rockett, J.C. Bryant, W.A. McKamie, C.E. Johnson, C.W. Chipman, M. Imamura, R.D.B. Jaquiss

Division of Pediatric Cardiothoracic Surgery, University of Arkansas for Health Sciences and Arkansas Children's Hospital, Little Rock, Arkansas, USA

S.15. **Initial Experience with the TandemHeart Circulatory Support System in Pediatric Patients**

Marco Ricci, MD, Colleen B. Gaughan, MD, Courtney Novello, CCP, Michael Rossi, DO, Fotios M. Andreopoulos, PhD, Tomas A. Salerno, MD, Anthony L. Panos, MD

From the Division of Cardiothoracic Surgery, Holtz Children's Hospital/Jackson Memorial Hospital, University of Miami Miller School of Medicine, Miami, FL

S.16. **Evolving Practice with the Use of Mechanical Support for End-Stage Dilated Cardiomyopathy in Children: A Three-Year Experience from a Large Pediatric Transplant Centre**

Jef Willems, Carin van Doorn, Aparna Hoskote, Allan Goldman, Liz Smith, Nigel Cross, Ann Karimova

Cardiac Critical Care Unit, Cardiothoracic Surgery, Perfusion Dept, Great Ormond Street Hospital London, UK

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- S.17. **Antithrombotic Therapy During Mechanical Circulatory Support in Pediatric Patients**  
Ulrich Schweigmann and Werner Streif  
Department Pediatrics, Innsbruck Medical University, Austria
- S.18. **ECMO vs. Berlin Heart: Support Mode Affects Cerebral and Somatic NIRS Saturation During Bridge to Transplantation for Cardiac Failure in Children**  
Michael E. Mitchell, MD, James S. Tweddell, MD, Nancy S. Ghanayem, MD, Ndidi Musa, MD, Richard J. Berens, MD, Kimberly L. Gandy, MD, Kathleen Mussatto, RN, and George M. Hoffman, MD  
Departments of Pediatrics, Surgery, Cardiothoracic Surgery, Medical College of Wisconsin, Children's Hospital of Wisconsin, Milwaukee, Wisconsin, USA
- S.19. **Use of Pulsatile Ventricular Assist Device (Berlin Heart EXCOR<sup>®</sup>) and Interventional Lung Assist Device (NovaLung<sup>®</sup>) in an Animal Model**  
Tilman Humpl, MD, PhD; Julius Z. Wermelt, MD; Osami Honjo, MD; Glen van Arsdell, MD; Coleen Gruenwald, RRT; Johannes Müller, MD; Ali Kilic BioMed Engineer  
Department of Critical Care Medicine, Department of Cardiovascular Surgery, The Hospital for Sick Children, 555 University Avenue, Toronto, ON, M5G 1X8, Canada; Berlin Heart GmbH, Wiesenweg 10, 12247 Berlin, Germany
- S.20. **In Vitro Performance Evaluation of the Integrated Pediatric Cardiopulmonary Support System (pCAS)**  
George M. Pantalos, Ph.D., Tracy Merkley, M.S., Jeffrey Speakman, Gregory Johnson, Ph.D., Mark J. Gartner, Ph.D.  
University of Louisville, Cardiovascular Innovation Institute, Louisville, KY & Ension, Inc., Pittsburgh, PA
- 3:45 p.m. Break
- 4:15 p.m. **DEBATE: "PULSATILE VS. NON-PULSATILE FLOW"**  
Moderator: Peer M. Portner, PhD (Palo Alto, CA)  
Pro: Akif Ündar, PhD (Hershey, PA)  
Con: Yukihiko Nose, MD (Houston, TX)
- 4:50 p.m. Break
- 5 p.m. **AUDIENCE RESPONSE—All Participants**  
Moderator: Ross Ungerleider, MD (Portland, OR)
- 6:30 p.m. **MODERATED POSTER PRESENTATIONS: SESSION #2**  
Moderators: Akif Ündar, PhD (Hershey, PA); J. Brian Clark, MD (Hershey, PA)

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- P.19. **An Axial Flow Turbo Pump with Hydrodynamic Bearings as a Ventricular Assist Device Applicable to Pediatric Patients**  
Y.Taenaka<sup>1</sup>, T.Tsukiya<sup>1</sup>, T.Mizuno<sup>1</sup>, H.Tanaka<sup>1</sup>, E.Tatsumi<sup>1</sup>  
Y.Kakiuchi<sup>2</sup>, T.Hidaka<sup>2</sup>, T.Okubo<sup>2</sup>, T.Osada<sup>2</sup>, R.Kosaka<sup>3</sup>, O.Maruyama<sup>3</sup>,  
M.Nishida<sup>3</sup>, T.Yamane<sup>3</sup>,  
National Cardiovascular Center, Osaka, Japan<sup>1</sup>, Mitsubishi Heavy Industries  
Ltd., Hyogo, Japan<sup>2</sup>, National Institute of Advanced Industrial Science and  
Technology (AIST), Ibaraki, Japan<sup>3</sup>
- P.20. **In Vivo Performance of the Percutaneous Transhepatic Transseptal TandemHeart® Circulatory Support System**  
D. Scott Lim<sup>†</sup>, MD, Cory J. Cortese<sup>‡</sup>, BS, Amber N. Loree<sup>‡</sup>, BS, David A.  
Dean<sup>§</sup>, MD, Robert G. Svitek<sup>‡</sup>, PhD  
<sup>†</sup>Department of Pediatrics, Division of Pediatric Cardiology, University of  
Virginia, Charlottesville, Va.  
<sup>‡</sup>R&D and Engineering Department, CardiacAssist, Inc., Pittsburgh, Pa.  
<sup>§</sup>Allegheny-Singer Research Institute, Pittsburgh, Pa.
- P.21. **A Novel, Low Cost, Disposable Pediatric Pulsatile Rotary Ventricular Pump (PRVP) for Cardiac Surgery that Provides a Physiological Flow Pattern**  
Daniel E. Mazur, Kathryn Osterholzer, PhD, Scott I. Merz, PhD  
MC3 Corp., Ann Arbor, Michigan, USA
- P.22. **Management of a Pediatric Patient on the Berlin EXCOR® Ventricular Assist Device with Argatroban After Heparin-Induced Thrombocytopenia**  
Michael L. Schmitz, MD, Sherry C. Faulkner, CCP., Adnan T. Bhutta, MD, Paul  
M. Seib, MD, Elizabeth A. Frazier, MD, Michiaki Imamura, MD, PhD, Robert  
D. B. Jaquiss, MD, The University of Arkansas for Medical Sciences, College of  
Medicine, and Arkansas Children's Hospital
- P.23. **Berlin Heart in Congenital Heart Disease: Crossing the Border of Septated Hearts**  
Davide F. Calvaruso, MD, Antonio Rubino, MD, Salvatore Ocello, MD, David  
F. Petruccelli, MD, Diego Guardi, MD, Nicoletta Salviato, MD, Salvo Colletto,  
CCP, Adriano Cipriani, MD, Carlo F. Marcelletti, MD  
Department of Pediatric Cardiac Surgery, ARNAS Ospedale Civico, Palermo,  
Italy
- P.24. **A New Dressing Technique to Prevent Cannula Infection After Berlin Heart EXCOR® Pediatric Implantation**  
Jodi Conway, BScN, Holger Buchholz, MD, Laurence Lequier, MD, David Ross  
MD, Bev Wiwchar BCcN, Patti Massicotte, MD, Mary Bauman, MScN NP,  
David Darlington, CPC CCP, Ivan Rebeyka, MD  
Pediatric Ventricular Assist Device Program and the Departments of Pediatrics  
and Surgery, Stollery Children's Hospital and the University of Alberta,  
Edmonton, Alberta, Canada

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- P.25. **Development of an Interprofessional Pediatric Ventricular Assist Device Support Team**  
Sarah Furness RN, Cecilia Hyslop-St. George, RN Med., Barbara Pound RN, Misty Earle, RN, Andrea Maurich RN, Danika Rice RN, Tilman Humpl MD, PhD
- P.26. **Prolonged But Successful Weaning from LVAD After Cardiac Decompensation Due to Late-Recognized Coarctation of the Aorta in a Toddler**  
Christian Meierhofer, MD<sup>1</sup>, Ludwig Mueller, MD<sup>2</sup>, Herwig Antretter, MD<sup>2</sup>, Guenther Laufer, MD<sup>2</sup>, Peter Mair, MD<sup>3</sup>, Corinna Velik-Salchner, MD<sup>3</sup>, Martin Fruehwirth, MD<sup>4</sup>, Nikolaus Neu, MD<sup>4</sup>, Elisabeth Schermer, MD<sup>1</sup>, Jorrit Brunnemann, MD<sup>1</sup>, Ralf Geiger, MD<sup>1</sup>, Joerg-Ingolf Stein, MD<sup>1</sup>, Ulrich Schweigmann, MD<sup>1</sup>  
<sup>1</sup>. Department of Pediatrics, Division of Pediatric Cardiology, Pneumology, Allergology and Cystic Fibrosis  
<sup>2</sup>. Department of Cardiac Surgery  
<sup>3</sup>. Department Anaesthesia and Intensive Care Medicine  
<sup>4</sup>. Department of Pediatrics, Pediatric Intensive Care Unit  
Medical University Innsbruck, Austria
- P.27. **Rapidly Deployed ECMO as an Extension of CPR: Sigle Center Results**  
Peter Wearden MD, Ana Manrique, MD, Margarita Arroyo, MD, Kent Kelly CCP, Ricardo Munoz MD, Victor Morell MD  
Departments of Pediatrics, Heart Center - Cardiothoracic Surgery, University of Pittsburgh, Children's Hospital of Pittsburgh-UPMC, Pittsburgh, Pennsylvania, USA
- P.28. **Mock Circulation Simulation of Pediatric Extracorporeal Membrane Oxygenation (ECMO) in the Presence of a Congenital Heart Defect**  
George M. Pantalos, PhD, Tracy Merkley, MS, Erle H. Austin, III, MD, Christopher Mascio, MD  
University of Louisville, Department of Surgery and the Cardiovascular Innovation Institute, Louisville, Kentucky
- P.29. **Extracorporeal Membrane Oxygenation Circulatory Support After Congenital Cardiac Surgery**  
Yasuyuki Suzuki, MD, Sanae Yamauchi, MD, Kazuyuki Daitoku, MD, Kozo Fukui, MD, Ikou Fukuda, MD  
Department of Thoracic and Cardiovascular Surgery, Hirosaki University School of Medicine, 5 Zaifucho, Hirosaki, Aomori, 036-8562, Japan

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- P.30. **Acute Lung Failure During Mechanical Circulatory Support**  
Ulrich Schweigmann<sup>1)</sup>, Birgit Schwarz<sup>3)</sup>, Corinna Velik-Salchner<sup>3)</sup>, Herbert Hangler<sup>4)</sup>, Jorrit Brunnemann<sup>1)</sup>, Ralf Geiger<sup>1)</sup>, Jörg-Ingolf Stein<sup>1)</sup>, Martin Frühwirth<sup>2)</sup>, Nikolaus Neu<sup>2)</sup>, Elisabeth Schermer<sup>1)</sup>  
1) Dept. Pediatrics, Pediatric Cardiology  
2) Dept. Pediatrics, Pediatric Intensive Care  
3) Dept. Anaesthesia and Intensive Care Medicine  
4) Dept. Cardiac Surgery  
Innsbruck Medical University, Austria
- P.31. **Hematological Testing in Animal Implant Studies**  
Kathryn E Richards<sup>1)</sup>, Thomas P Nifong<sup>3)</sup>, Tigran Khalapyan<sup>2)</sup>, William J Weiss<sup>2)</sup>, Gerson Rosenberg<sup>2)</sup>, Christopher A Siedlecki<sup>2)</sup>  
<sup>1)</sup>Department of Bioengineering, The Pennsylvania State University, Hershey, PA, USA, <sup>2)</sup>Department of Surgery, Penn State College of Medicine, Hershey, PA, USA, <sup>3)</sup>Department of Pathology, Penn State College of Medicine, Hershey, PA, USA
- P.32. **Treatment with ECMO in a Newborn with Malignant Arrhythmias After Resection of Cardiac Tumor Resulting in Low Cardiac Output Syndrome**  
Theodor Tirilomis, PhD, Oguz Coskun, MD, Heike Schneider, PhD, Wolfgang Ruschewski, PhD  
Department for Thoracic, Cardiac, and Vascular Surgery, and Department for Pediatric Cardiology, University of Goettingen, Goettingen, Germany
- P.33. **Reoperations in Adults After Correction of Tetralogy of Fallot**  
S.Tolga Coskun<sup>1)</sup>, MD, K.Oguz Coskun<sup>2)</sup>, MD, Aron Popov<sup>2)</sup>, MD, Kerstin Bockhorst<sup>3)</sup>, BSc, Ute Blanz<sup>1)</sup>, MD, Andreas Bairaktaris<sup>1)</sup>, MD, Reiner Koerfe<sup>1)</sup>, PhD  
<sup>1)</sup>Department of Cardiac Surgery, Heart Center North Rhein Westphalia, Bad Oeynhausen, Germany  
<sup>2)</sup>Department of Thorax and Cardiovascular Surgery, Göttingen University, Germany  
<sup>3)</sup>Department of Health Sciences Research, University Bielefeld, Germany

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**SATURDAY, MAY 24, 2008**

- 7 a.m. Breakfast/Speaker Ready Room Open
- 8 a.m. **PLENARY SESSION #5: PERFUSION**  
Moderators: Carmen Giacomuzzi, CCP (Portland, OR); Brian Mejak, CCP (Portland, OR)  
**Should ACTs Still Be Used During Heart Surgery?**  
Colleen Gruenwald, CCP (Toronto, Canada)  
**Vacuum-Assisted Venous Drainage**  
Chris Brabant, CCP (Milwaukee, WI)  
**Experience with the Levitronix Pump**  
Ron Angona, CCP (Rochester, NY)  
**Berlin Heart in Neonates and Infants**  
Johannes Müller, MD (Berlin, Germany)  
**Experience with Intermittent Perfusion for Neonatal Heart Surgery**  
Christian Pizarro, MD (Wilmington, DE)  
**MECC from the Perfusion Perspective**  
Stuart Sheppard, PhD (Southampton, UK)  
**DEBATE: "CIRCUIT MINIATURIZATION WILL ADD RISK FOR THE PATIENT"**  
Moderator: Brian Mejak, CCP (Portland, OR)  
Pro: Rich Ginther, CCP (Dallas, TX)  
Con: Ed Darling, CCP (Syracuse, NY)
- 10 a.m. Break
- Invited Lectures**
- 10:30 a.m. **Tell Me What You Need and I Will Tell You How to Get By Without It: CPB in Underdeveloped Countries**  
Aubyn Marath, MD (Portland, OR)
- 10:50 a.m. **How Do We Help When Our Help No Longer Works?**  
Carmen Giacomuzzi, CCP (Portland, OR)
- 11:15 a.m. **Human Factors and CPB**  
Thor Sundt, MD (Rochester, NY)

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Chitra Ravishankar, MD, USA  
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Marco Ricci, MD, USA  
Kathryn Richards, BS, USA  
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Gerson Rosenberg, PhD, USA  
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Yoshiyuki Taenaka, MD, Japan  
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Shinya Ugaki, MD, Japan  
Akif Ündar, PhD, USA  
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Kent E. Vrana, PhD, USA  
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Shigang Wang, MD, USA  
Wei Wang, MD, PhD, China  
Peter Wearden, MD, USA  
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Jef Willems, MD, UK  
William G. Williams, MD, Canada  
Karl R. Woitas, CCP, USA  
Jamie You, CCP, USA  
Kun Yu, MD, China  
Jeffrey D. Zahn, MD, USA  
Deming Zhu, MD, China  
Joseph B. Zwischenberger, MD, USA

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**Circuit Miniaturization – Advantages of an Asanguinous Prime**

Edward J Hickey, MD  
John Kirklin Fellow, Congenital Heart Surgeons' Society  
The Hospital for Sick Children, Toronto, Canada

**Purpose:**

Reducing allogeneic blood usage is associated with improved clinical outcome in trauma and non-cardiac surgery. Progressive reductions in commercially available circuit components have now made routine infant cardiopulmonary bypass with asanguinous prime a possibility. Challenges include hemodilution and safety concerns surrounding small reservoir volumes. We critically appraise the experimental and clinical literature supporting the pursuit of asanguinous prime in cardiopulmonary bypass. We make particular reference to our program of experimental asanguinous prime CPB in neonatal swine.

**Methods:**

After initial studies at Duke, North Carolina we subsequently introduced an experimental model of asanguinous prime CPB in 2-5kg piglets at OHSU, Oregon. Progressively smaller circuits were constructed using commercially available clinical components. The latest circuit (total prime ≈70 ml)

uses Capiox Baby RX™ oxygenator (49 ml prime), 3/8" arterial line, 1/4" venous line and a 45 cm raceway. Venous return is vacuum-assisted and neither filters nor cardioplegia circuits are employed. We have examined endpoints including right ventricular and lung function recovery, systemic inflammation (Karamlou et al 2005), cerebral no-reflow and intra-cerebral TNF-α between conventional circuits and miniaturized circuits with asanguinous prime.

**Results:**

Our investigations have demonstrated that asanguinous prime neonatal CPB is associated with: 1) improved post operative lung compliance, pulmonary vascular resistance, RV work index and reduced pulmonary oedema; 2) reduced systemic TNF-α load; 3) reduced cerebral no-reflow post-DHCA and 4) reduced *de novo* intra-cerebral production of TNF-α.

Endpoint	Conventional CPB	Asanguinous CPB	<i>P</i> value
% Body weight gain	7.5±1	4.4±0.6	.04
% Fall in lung compliance	38±4	18±6	<.01
RV cardiac index (ml/kg/min)	19±5	81±11	<.001
Cerebral fraction of CO post-DHCA %	17±11	32±6	.04
Serum TNF-α pg/ml	3166±1877	439±429	.02
Quantitative ratio of intra-cerebral TNF-α production	4.5 : 1		.04

**Conclusions:**

Circuit miniaturization will allow asanguinous prime CPB to become a routine clinical reality. Eliminating intra-operative allogeneic blood usage will offer pulmonary, cerebral and systemic inflammatory advantages over conventional CPB which will translate into reduced post-operative morbidity and mortality. We should work with industry to pursue safe strategies for the implementation of miniaturized CPB.

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### **MECC May Create Useable Miniaturized Circuitry**

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Stephen Langley MD FRCS(CTh)  
Portland, Oregon, USA

Minimal extracorporeal circulation (MECC) has been gaining popularity with cardiac surgeons undertaking coronary artery bypass grafting since its first description in 2002. More recently it has been used during aortic valve replacement in adult patients too [1]. MECC differs from standard cardiopulmonary bypass (CPB) in two important ways; firstly there is no venous reservoir with the perfusion being volume constant and the patient acting as his/her own reservoir. Secondly there are no cardiotomy suckers, with all suction going to a cell saver.

Various features that characterize standard CPB have been shown to have deleterious effects on patients undergoing cardiac surgery. These features include hemodilution, a large foreign surface, a blood gas interface, and the use of a roller-pump and cardiotomy suckers. The MECC circuit avoids these features and in its simplest form consists of a centrifugal pump and an oxygenator with an optional arterial filter. In addition, a venous bubble trap (VBT) can be placed between the right atrium and the centrifugal pump. The VBT removes air entrained into the circuit and is efficient at removing bubbles over 175µm in size. The MECC circuit is primed by

retrograde autologous priming. Various modifications of the basic circuit can allow for cardiac venting and delivery of cardioplegia.

In adult patients the use of MECC is associated with improved outcome compared to standard CPB in terms of both reduced inflammation [2] and better organ function postoperatively. From a cardiac standpoint there is a smaller rise in troponin [1,2] and cardiac index is better preserved. In the lungs alveolar damage has been shown to be less and time to extubation is reduced. There is evidence of better preservation of both renal function and coagulation, with less red cell damage, less bleeding and a reduced incidence of blood and platelet transfusion [1]. A lower cerebral embolic count has been demonstrated, together with better cerebral oxygenation on bypass. In addition, a shorter time on ICU and reduced hospital length of stay has resulted in cost savings.

The practical challenges and feasibility of undertaking infant cardiac surgery with the use of MECC will be discussed together with our experimental approach to this in an infant model.

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**Cardioplegia to Minimize Cardiopulmonary**

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Kristine J. Guleserian, MD  
UT Southwestern Medical Center/Children's Medical Center  
Dallas, Texas, USA

It is well known that the benefits associated with reduced circuit/cardiopulmonary bypass prime include reduction in hemodilution, reduction in utilization of blood products for transfusion as well as attenuation of the systemic inflammatory response. Conventional circuit miniaturization typically entails downsizing of circuit tubing diameter and length as well as reducing oxygenator and/or hemoconcentrator surface area. Additional means of reducing circuit prime, although not widely supported, may include the elimination of circuit components such as arterial line filters and/or bubble traps. A less utilized technique employed to reduce cardiopulmonary

bypass prime includes customization of the cardioplegia circuit. Currently available cardioplegia systems for the pediatric patient population may have priming volumes of up to 200mL---a volume that is greater than total priming volumes of the most miniaturized circuits. Lack of suitable cardioplegia systems in the neonatal patient population have warranted customization and circuit modification to allow for minimal additional priming volume to the entire circuit. Our current static priming strategy allows for a total cardiopulmonary bypass circuit prime of 185 milliliters and our customized circuit will be described.

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## Development of a Real Time Immunoassay for Systemic Inflammation Monitoring During Cardiac Surgery

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Lawrence Sasso<sup>1)</sup>, Akif Ündar<sup>2)</sup> and Jeffery D. Zahn<sup>1)</sup>

1) Department of Biomedical Engineering, Rutgers University, Piscataway, NJ, 08854

2) Department of Pediatrics, Pennsylvania State University, Milton S, Hershey Medical Center, Hershey, PA, 17033

Several studies have clearly shown that cardiac surgery induces systemic inflammatory responses, particularly when cardiopulmonary bypass (CPB) is used. CPB induces complex inflammatory responses characterized by complement, neutrophil, and platelet activation, and the release of pro-inflammatory cytokines. These systemic responses are attributed to several factors, including exposure of blood to nonphysiologic surfaces of the heart-lung circuit, ischemia-reperfusion of the involved tissues, surgical trauma and hypothermia. The ability to clinically intervene in inflammation, or even study the inflammatory response to CPB, is limited by the lack of timely measurements of inflammatory responses (complement, neutrophil, monocyte, platelet activation, and the release of pro-inflammatory cytokines). Current technology provides measurements of the effects of cardiopulmonary bypass on activation of complements, neutrophils, platelets, and cytokines hours or days post-surgery. The objective of this project is to develop and test a microanalytical system for online monitoring of inflammatory responses during the CPB procedure. A novel approach towards real time detection of pro-inflammatory proteins is described. The system is based on serial processing of paramagnetic core cytometric beads.

The microimmunoassay device has been designed and tested with streptavidin coated paramagnetic microbeads and fluorescent dye conjugated biotin (Biotin FITC). The device consists of inlets for beads, biotin dye sample and wash fluid, and corresponding outputs, as well as two magnets on opposite sides of the device. Three fluid streams run adjacent in a common channel. Each bead is introduced in a carrier fluid, and is immediately pulled into the biotin FITC stream by the first magnet. The bead then rolls along the wall of the microchannel while avidin-biotin binding occurs. At a prescribed location downstream the bead is attracted to the second magnet on the opposite wall of the channel and is pulled from the biotin FITC solution, across the original carrier fluid and into a wash solution. The bead is then transported to an outlet channel where the

bead fluorescence can be detected. The detection occurs on an epi-fluorescence microscope platform with an integrated argon ion laser which excites the fluorophore at 488 nm, and detects the FITC emission via a photomultiplier tube (PMT).

To determine the optimal conditions for the avidin-biotin binding, beads were first incubated with the biotin FITC solution at varying concentrations in an eppendorf tube for 30 seconds. The beads were then washed with PBS and resuspended in a buffer. The bead fluorescence was then determined using the argon laser and PMT detection. This test demonstrated fluorescence saturation due to complete biotin binding on the bead surface for concentrations greater than 300ng/mL. The beads were then reacted in the device as described above. By tailoring the fluid flow rates to 0.3uL/min, the beads had a residence time in the biotin FITC solution of 18 seconds. The data from this test showed a linear fluorescence dependence on biotin FITC concentration. Thus, the device can be calibrated based on traditional ELISA so that it can continuously measure sample concentrations.

Future studies will focus on conducting binding studies on clinically relevant complements such as the anaphylatoxins C3a, C4a and C5a with antibody bound cytometric beads. Currently, this design is being adapted for realtime immunological measurements of complements by conjugating a biotinylated human anti-C3a antibody with the streptavidin coated beads. Following antibody incubation, the device will be tested for C3a detection. The beads will first go through 2 cycles of incubation to allow antibody-antigen binding followed by the binding of a fluorescently labeled secondary antibody. The first cycle as described above where they would bind the antigen of interest (e.g., C3a). The outlet of the first cycle would transfer the beads into a second cycle which would contain the PE fluorescently labeled secondary antibody followed by fluorescence detection as described.

Keywords: Immunosensing, blood separation, real time monitoring, microfluidics

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## **Plasma Proteomics in Infants Undergoing Cardiopulmonary Bypass Procedure**

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<sup>1,2</sup>Todd M. Umstead, BS, <sup>1,2</sup>Akif Ündar, PhD, <sup>3</sup>Willard M. Freeman, PhD, <sup>3</sup>Kent Vrana, PhD, <sup>2</sup>John L. Myers, MD, <sup>1,2</sup>David S. Phelps, PhD

<sup>1</sup>Penn State Center for Host defense, Inflammation, and Lung Disease (CHILD) Research, <sup>2</sup>Department of Pediatrics, and <sup>3</sup>Department of Pharmacology, Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

### **Purpose:**

We employed a discovery proteomics approach employing the 2-dimensional difference gel electrophoresis (2D-DIGE) experimental design to quantify changes in plasma proteins before, during, and after CPB. 2D-DIGE employs an internal standard for normalization between gels, facilitating their comparison and permitting rigorous quantitation of protein spots. This allows a simultaneous assessment of the levels of hundreds of proteins and may allow us to gain a more comprehensive understanding of the events leading up to CPB-related organ injury and to identify biomarkers.

Our goal was to identify changes in plasma proteins that could be related to the development of samples to identify changes in protein expression and inflammatory biomarkers during or shortly after CPB.

### **Methods:**

To accomplish this we selected 4 patients diagnosed with congenital defects undergoing CPB. The patients were approximately 5 months of age and had similar pump, CPB, and cross-clamp times. Plasma

### **Conclusions:**

The significance of these changes remains to be determined, but this pilot study has shown that the 2D-DIGE approach has the potential to identify changes in the levels of expression of specific serum proteins during and after CPB and may allow us to find biomarkers that predict complications following CPB. This knowledge may provide us with insight into the mechanism(s) responsible for, and strategies to prevent, CPB-related complications.

samples were taken at five time points: 1) 30 minutes before surgery; 2) 5 minutes after initiation of CPB; 3) at the end of CPB; 4) 1 hour after weaning from CPB; and 5) 24 hours after weaning from CPB. To compare the plasma proteins at each of these time points we used 2D-DIGE. Prior to electrophoresis all plasma samples were subject to immunodepletion of the 14 most abundant plasma proteins. This procedure allowed us to increase the relative amounts of lower abundance proteins applied to the gels.

### **Results:**

We were able to resolve 500 protein spots in all samples. Among these we have tentatively identified 189 spots that make up 32 individual proteins and account for 88% of the total protein detected on the gels. Significant changes occur in half of these proteins during the course of the study. Of particular interest is the comparison of the preoperative sample (#1) with the 24h post-operative sample (#5). This analysis found significant increases in several proteins, including alpha-1-antichymotrypsin and lipopolysaccharide binding protein, among others, and significant decreases in apolipoprotein A-IV and hemopexin.

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**Intraoperative Techniques to Assess Cardiac Function**

Linda B Pauliks, MD, Akif Ündar, PhD, J. Brian Clark, MD, John L Myers, MD  
Departments of Pediatrics, Surgery and Bioengineering  
Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

**Purpose:**

The noninvasive assessment of cardiac function during mechanical circulatory support is challenging: Conventional markers such as ejection fraction are significantly load-dependent. Yet loading conditions can be very abnormal and may also vary widely during support. For this reason, it may be difficult to interpret ejection phase markers (like fractional shortening or ejection fraction), particularly during the weaning process.

The lack of a quantitative marker for right ventricular (RV) systolic function is another short fall of conventional markers. Volume based markers (such as ejection fraction) are less reliable in the RV due to its complex three-dimensional shape. It is further complicated by the inhomogeneous work-load distribution in this chamber.

Tissue Doppler imaging is an echocardiographic technique that permits quantitation of regional wall motion in the heart, including in the right ventricle. Tissue Doppler derived peak systolic strain rate (SR) is a relatively load-independent marker of LV systolic function in experimental validation studies. We hypothesized that SR changes would improve assessment of right and left ventricular function during mechanical circulatory support.

**Methods:**

Color tissue Doppler images were acquired in the OR in 17 patients while the child was already intubated and sedated. Follow up was obtained 8 and 24 h post-operatively in the critical care unit. Peak SR was measured in the mid LV and RV free wall (long axis) and posterior wall (LV short axis, radial). Velocities were measured near the mitral and tricuspid ring (long axis) and in the posterior wall (short axis). Patients were on inotropic support as clinically indicated.

**Results:**

Mean CPB and cross clamp time were 120±41min and 61±30min. Children were between 6 days and 7.8 years old (median 6 months). The mean weight was 9.7±5.4 kg with a BSA of 0.46±0.19 m<sup>2</sup>. From a clinical perspective, all patients were hemodynamically stable and on low doses of inotropic support including dopamine, milrinone or nitroprusside with no child on >2 agents. There were no death or resuscitation events. Peak systolic SR and strain rate decreased markedly postoperatively (Table, compared to baseline \* p<0.01, # p<0.05, NS p>0.05). The LV radial parameters normalized most rapidly. Longitudinal parameters lagged behind, particularly in the RV. SR appeared to be more sensitive to changes than velocities.

Table: Perioperative changes of LV and RV wall motion in children undergoing open heart surgery

Tissue Doppler Imaging Parameter	OR PREOP	POST	NEXT DAY
<b>SYSTOLIC STRAIN RATE</b>			
LV radial SR (1/s)	3.6±0.4	2.2±0.6 *	2.8±0.7 *
LV longitudinal SR (1/s)	-2.3±0.7	-1.4±0.4 *	-1.8±0.5 *
RV longitudinal SR (1/s)	-2.9±0.8	-1.7±0.5 *	-1.8±0.6 *
<b>SYSTOLIC VELOCITIES</b>			
LV radial systolic velocity (cm/s)	4.6±1.2	3.4±0.9 *	4.1±1.3 NS
LV longitudinal systolic velocity (cm/s)	4.9±1.5	3.6±1.2 *	4.1±1.1 #
RV longitudinal systolic velocity (cm/s)	7.2±2.0	3.6±1.3 *	4.1±1.6 *

**Conclusions:** Tissue Doppler peak systolic SR is a sensitive marker of left ventricular mechanics in children and may improve perioperative monitoring. It offers a method to quantitatively assess right ventricular function and may help to compare different cardioprotective strategies.

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**Near Infrared Spectroscopy (NIRS) – What We Know and What We Need to Know: A Systemic Review of the Congenital Heart Disease Literature**

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Jennifer C. Hirsch, MD; John R. Charpie, MD, PhD; Richard G. Ohye, MD; James G. Gurney, PhD  
Departments of Surgery and Pediatrics  
University of Michigan, Michigan Congenital Heart Center, Ann Arbor, Michigan, USA

**Background:**

Neurological dysfunction is a significant problem in patients with congenital heart disease (CHD). Near infrared spectroscopy (NIRS) has the potential to provide a real-time window into regional oxygenation of the cerebral tissues. Enthusiasm has increased for the use of NIRS in the peri-operative period in hopes of reducing neurological dysfunction. As with any new technology, the potential clinical gains need to be critically evaluated prior to incorporation into routine patient care. Each monitoring device comes with cost. In addition, responding to data in ways that seem intuitively beneficial can be risking when the long- or even intermediate-term impact on outcomes is unknown. In order to examine the available evidence for the use of NIRS in the care of CHD patients, a systematic review of the literature was performed.

**Methods:**

A search was performed for the use of NIRS in CHD patients from 1950 to April 2007 with MEDLINE, Pre-MEDLINE, EMBASE, and Cochrane databases. All primary clinical studies evaluating the use of NIRS

in the care of CHD patients were included. A total of 54 manuscripts were identified that met the search criteria. An additional 13 review articles were evaluated for comparative purposes.

**Results:**

Of the 54 manuscripts, there were 50 case series, 4 randomized trials, and 3 retrospective studies. Few manuscripts involved any post-discharge endpoints. Of all the manuscripts analyzed, only two studies utilizing NIRS alone had follow up after hospital discharge, to a maximum of 3 months, one of which incorporated formal neurological testing. Neither of these studies was able to demonstrate a benefit with the use of NIRS. One retrospective study correlated neurological outcomes with an interventional algorithm, which included NIRS and other intra-operative measures of cerebral perfusion. This study demonstrated a decrease in neurological dysfunction when alterations in cerebral perfusion measures were intervened upon. Three small studies were able to correlate NIRS with other clinical outcomes, including MRI findings and mortality.

**Conclusions:**

Many centers, and even entire countries, have adopted NIRS as standard of care. Yet, there exists essentially no level I evidence-based medical research to support this policy or to indicate that clinical decisions made upon NIRS data are beneficial to the patient. The ability to determine the role of NIRS in preventing clinical neurological dysfunction in CHD patients is difficult based upon the current literature. The majority of studies from this systematic review are limited by the fact that they are case series with small sample size. The available data may suggest that multimodality monitoring of cerebral perfusion, including NIRS, may be a useful adjunct for the prevention of neurological injury. However, the current literature on the use of NIRS alone for CHD patients does not demonstrate a clinical improvement in short-term neurological outcome. The data correlating NIRS findings with indirect measures of clinical neurological outcome, such as MRI, and even mortality are also limited. While NIRS appears to have the promise of the ability to measure regional tissue oxygen saturation, before universal implementation of this technology, it is essential that rigorous clinical trials be performed to demonstrate improved outcomes with NIRS.

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**Cardiac Catheterization in Post-operative Patients on Mechanical Assist**

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Laurie Armsby MD, Grant Burch MD, Stephen Langley MD FRCS(CTh), Ross Ungerleider MD  
Oregon Health & Science University, Portland, Oregon, USA

With increased use of mechanical assist as both emergent and elective strategies of circulatory support in the post-operative cardiac patient, catheterization in patients on ECMO/VAD has become an increasingly important method of providing information to guide treatment and potential interventions. Less invasive means of acquiring information, such as transthoracic echocardiographic imaging, are frequently suboptimal in the patient with an open chest; and transesophageal echocardiography is not commonly used due to concerns regarding patient size and risk of upper gastrointestinal hemorrhage in anticoagulated patients.

There are both diagnostic and therapeutic indications for cardiac catheterization in patients on mechanical support, in particular, the ability to identify residual lesions which may facilitate critical therapeutic interventions. However, the potential complications of these procedures often limit or delay their use. These include transportation issues, vascular access, accurate hemodynamic measurements, acceleration of renal failure through exposure to contrast agents, and retroperitoneal or intra-thoracic hemorrhage following transcatheter interventions.

I will discuss these issues and provide an algorithm for managing this difficult group of patients.

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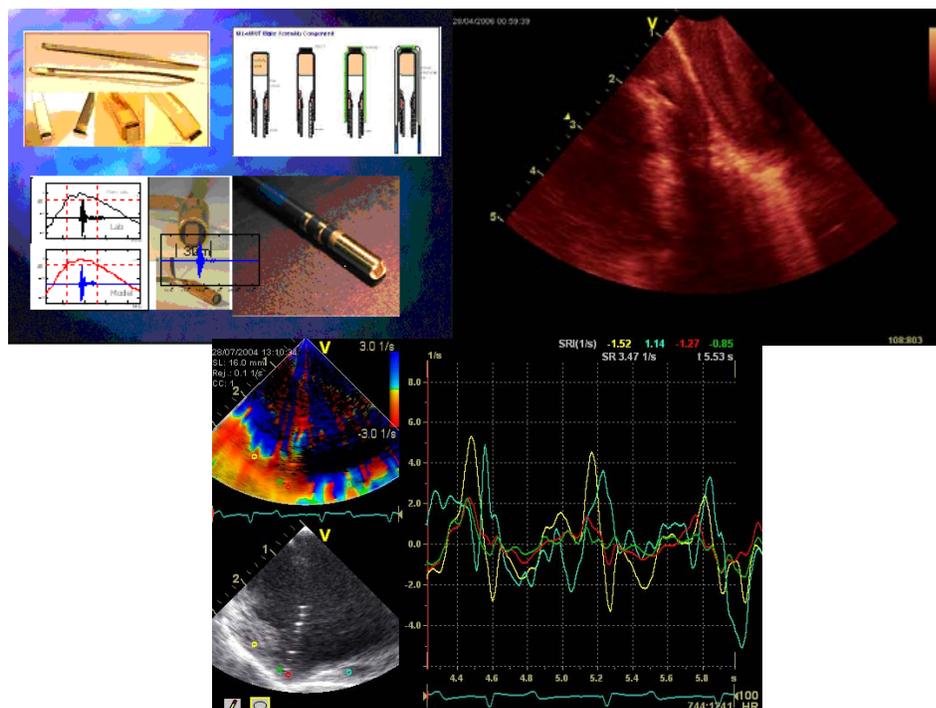
## Experimental Studies with a 9 French Forward-Looking Intracardiac Imaging and Ablation Catheter

<sup>1</sup>Douglas N. Stephens, MS; <sup>2</sup>David J. Sahn, MD; <sup>3</sup>Matthew O'Donnell, PhD; <sup>4</sup>Kai Thomenius, PhD; <sup>4</sup>Aaron Dentinger, PhD; <sup>5</sup>Peter Chen, PhD; <sup>6</sup>K. Kirk Shung, PhD; <sup>6</sup>Jonathan Cannata, PhD; <sup>7</sup>Pierre Khuri-Yakub, PhD; <sup>7</sup>Omer Oralkin, PhD; <sup>8</sup>Aman Mahajan, MD; <sup>8</sup>Kalyanam Shivkumar, MD, PhD

<sup>1</sup>University of California, Davis, CA; <sup>2</sup>Oregon Health & Science University, Portland, OR; <sup>3</sup>University of Washington, Seattle, WA; <sup>4</sup>GE Global Research, Schenectady, NY; <sup>5</sup>Irvine Biomedical Inc/St. Jude's, Irvine, CA; <sup>6</sup>University of Southern California, Los Angeles, CA; <sup>7</sup>Stanford University, Palo Alto, CA; <sup>8</sup>University of California, Los Angeles, CA  
Supported by NHLBI Bioengineering Research Partnership grant R01 HL067647.

Intracardiac ultrasound imaging catheters to date have been side-looking because of the limited available space on the tip of a catheter for forward-looking arrays. A forward-looking miniaturized phased array could be of importance for monitoring electrophysiology (EP) interventions or for anatomic intracardiac imaging during heart surgery. We have integrated a high frequency, high resolution, near field optimized 28-element 13 MHz broad bandwidth forward-looking array on a 9 French (Fr) EP-style highly steerable catheter. The scanning catheter also has a custom tip with an ablation electrode face and two ports, one for a thermocouple and one for an anchoring guidewire. This device was tested in 4 acute pig studies for image quality, anatomic identification, visualization of other catheter devices and a mechanism for stabilization

when imaging ablation. Proximal and distal electrodes allowed 3D spatial registration of catheter location with NavX mapping. In all animals, microlinear forward-looking array catheters were positioned in the right atrium and ventricle, and in 3 pigs successfully imaged and localized ablation was verified on post-mortem photography on the right side of the septum. In the fourth animal, imaging was performed in the right ventricular apex in two locations. The device has adequate shielding to avoid radiofrequency interference during ablation and was capable of resolving both bubbling of tissue and intensity changes during ablation out to 2 cm from the transducer face. The performance of this device in terms of penetration and resolution exceeded specifications and as a forward looking device; it is very easy to use.



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## How Do We Normalize Outcome Measures So That We Can Comprehend Results?

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Karl Welke, MD  
Department of Cardiothoracic Surgery  
Oregon Health & Science University, Portland, Oregon, USA

Payers, providers, and patients and their families are increasingly using health care outcomes in the evaluation and choice of medical treatment. While adult cardiac surgery was the initial focus of public reporting efforts, pediatric cardiac surgery is increasingly being included. All parties are searching for metrics that can be used to evaluate the quality of health care and sources for these metrics. The initiation of pay for participation and the expected move to pay for performance has increased the stakes and amplified the importance of valid quality measures.

Mortality is the most frequently cited measure of quality for pediatric cardiac surgery programs. However, there are important characteristics of this specialty that make comparisons of mortality rates problematic. In order to detect statistically relevant differences, it is essential to have adequate sample sizes and event rates. Pediatric cardiac surgery operations are performed relatively infrequently at individual hospitals and in general the mortality rates are low. The combination of small sample sizes and low event rates limits the statistical power of a comparison of both individual hospital mortality rates to a mean or benchmark and between two hospitals. As a result important differences between hospitals may not be identified, a type II error.

Volume is the most frequently cited structural measure associated with outcomes. The Leapfrog group and some states have set hospital case volume standards for various operations. Overall surgical

volumes and raw mortality rates are frequently used to compare the performance of pediatric cardiac surgical programs. However, in pediatric cardiac surgery, volume alone is an unreliable discriminator of mortality. Patient and surgical case mix adjusted data are essential for identifying better performing, higher quality hospitals. Volume is not a measure of quality, but rather an easily obtained structural attribute associated with quality. It is likely a surrogate for process measures and characteristics of systems of care that lead to better outcomes, but are not currently captured in administrative or most clinical databases. As a result, institution specific risk adjusted outcomes are likely to be more informative than a volume threshold.

Many factors contribute to the mortality risk of a patient undergoing pediatric cardiac surgery. Identification the structural measures and process measures that account for the apparent contribution of volume to outcome and are the real drivers of quality may not come from analyzing large administrative or even clinical databases. Instead it may require multidisciplinary, multicenter quality improvement initiatives such as the Northern New England Cardiovascular Disease Study Group. Site visits to well-performing hospitals, regardless of size, may elucidate common factors that can be implemented at lower-performing hospitals. Although this approach is costly and time consuming, it may be the necessary step to understanding the important characteristics of a system that achieves superior outcomes.

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**From Experimentation to Innovation to Standard of Care: How Do We  
Demystify Dogma and Create Progress?**

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Ross M. Ungerleider, MD, MBA  
Department of Cardiothoracic Surgery  
Doernbecher Children's Hospital, Oregon Health & Science University, Portland, Oregon, USA

We cling to erroneous beliefs because life presents us with incomplete and ambiguous data. Statements are particularly at risk for creating dogmatic beliefs if they are based on "plausible" (albeit wrong) scientific reasoning. Since defiance of such reasoning can be career threatening, especially for young investigators, we are more likely to propagate erroneous concepts than to perform the studies required to refute them.

This talk will evaluate how group pressure to conform to commonly held beliefs can prevent us from making the types of scientific leaps that can create important progress. The audience will be given several examples of dogmatic thinking that has subsequently been shown to be wrong and will be given tools for embarking on a true learning quest whereby they can "let go" of conventional answers

and by engaging in a process of exploring with suspended judgment. Every problem has a solution that no one has thought of yet.

The audience will learn about complex adaptive systems and how they differ from mechanical systems. They will be introduced to the concept of explore to understand as opposed to interrogate, judge, tell and coerce.

Examples of some significant advances that have occurred in neonatal CPB will be traced to show how they contradicted commonly held beliefs. Building on this will be suggestions of ideas for future innovations. The talk will expose ways that we get stuck in our thinking and how to get unstuck.

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### **Aprotinin Has a Role in Pediatric Cardiac Surgery**

James S. Tweddell, MD, Children's Hospital of Wisconsin and the Medical College of Wisconsin

Excessive postoperative bleeding during pediatric cardiac surgery calls for transfusion of blood products, early reoperation especially for those undergoing complex neonatal surgery is common. Bleeding and reoperation for bleeding increases hospital mortality and morbidity. In addition, smaller and younger patients are more susceptible to the inflammatory response to bypass that results in increased capillary permeability, fluid accumulation and multi-organ dysfunction.

Neonates and young infants have immature coagulation systems including; reduced concentrations of vitamin K dependent factors, II, VII, IX and X, reduced contact factors, XI and XII and others including ATIII, Protein C, Protein S, C1 esterase inhibitor and plasminogen. Hemodilution also results in coagulopathy and occurs due to the large volume of the cardiopulmonary bypass (CPB) circuit compared with the blood volume of an infant or neonate. Consumption of limited clotting factors and platelets by the CPB circuit also contributes to coagulopathy.<sup>1</sup>

Aprotinin, a serine protease inhibitor, has been shown in randomized controlled trials involving thousands of patients to be the most effective agent to reduce bleeding associated with CPB.<sup>2</sup> Aprotinin is commonly classified as an antifibrinolytic. In contrast to lysine analogs such as  $\epsilon$ -aminocaproic acid and tranexamic acid, aprotinin limits fibrinolysis by directly inhibiting plasmin, a serine protease. In addition, aprotinin blocks PAR-1 activation of platelets by thrombin (also a serine protease), thereby preserving platelet function including the ability of platelets to respond to exposed collagen.

Limited numbers of studies in children including neonates and infants suggest that aprotinin is both safe and efficacious in this age range.<sup>3,4,5</sup>

Aprotinin has broad, dose dependent, anti-inflammatory activity. Aprotinin inhibits; Kallikrein, plasmin, complement, leukocyte activation and degranulation and limits pro-inflammatory cytokine production including TNF- $\alpha$ , IL-6 and IL-8.<sup>6</sup> Aprotinin limits formation of bradykinin. Bradykinin is a mediator of cerebral injury. Randomized controlled trials have shown that aprotinin significantly reduces the risk of stroke in adults undergoing cardiac surgery.<sup>7</sup> The mechanism of stroke reduction is unknown but animal models have shown more rapid recovery of high-energy phosphates and intracellular pH following circulatory arrest.<sup>8</sup> In addition following middle cerebral artery occlusion aprotinin results in lower bradykinin tissue levels, decreased water content, preserved ATP and lower lactate level.<sup>9</sup> Reduction in bradykinin production occurs at levels commonly achieved with doses of aprotinin used to reduce bleeding and can reasonably be assumed to be neuroprotective in neonates, infants and children.

Aprotinin is safe and efficacious in children and limits bleeding and transfusion in pediatric patients undergoing complex heart surgery. The broad anti-inflammatory impact of aprotinin may limit multi-organ dysfunction and in particular may be neuroprotective.

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### **HIT Happens**

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Lynn K Boshkov, MD, Aileen Kirby, MD, Laura Ibsen, MD and Ross Ungerleider, MD  
Departments of Pathology, Medicine & Pediatrics  
Oregon Health & Science University, Portland, Oregon, USA

Heparin-induced thrombocytopenia (HIT) occurs in 1-3% of adult cardiac surgeries with a thrombotic morbidity of 38-81% and thrombotic mortality of ~28%. Although HIT is infrequently recognized in pediatrics, experience at OHSU and elsewhere suggests neonates and young children < 4 years old undergoing cardiopulmonary bypass (CPB) may have a 1-2% incidence of HIT with HIT-related morbidity and mortality similar to adults. Diagnostic and therapeutic challenges in such cases include frequent thrombocytopenia after CPB, imperfect laboratory testing, lack of established dosing of direct thrombin inhibitors (DTIs) in pediatric patients and increased anticoagulant-related bleeding in young children.

HIT associated thrombosis in pediatric CPB patients can be arterial or venous and includes shunt thrombosis, catheter-related thrombosis, and pulmonary embolism. Diagnosis should ideally be made by washed platelet functional assay (used at OHSU), as the PF4 ELISAs may be falsely positive in up to 50% of reoperative cardiac patients (similar

to adult data). A retrospective cohort chart review of 219 infants and children < 2 years undergoing CPB at Doernbecher Children's Hospital over a 2 ½ year period identified 6 HIT positive patients, 33 HIT negative patients and 53 HIT untested patients. HIT pos patients had a higher thrombotic rate (66.7%) vs HIT neg (18.2%,  $p = 0.028$ ) and HIT untested (5.7%,  $p = 0.001$ ) patients.

HIT appears to have an unfavorable natural history in neonates and young children, and accumulating evidence suggests that, as in adults, alternative anticoagulation with a DTI may be best. We have previously reported our experience with the DTI argatroban in 10 pediatric HIT patients with congenital heart disease and current or previous HIT in which argatroban was used for prophylactic and therapeutic infusion, catheterization, ECMO and CPB. A prospective multicenter study of argatroban in 18 pediatric patients ( $n=8 < 6$  mos,  $n=6$  6mo-8yr) has recently been concluded. Preliminary data/dosing from this trial will also be presented.

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## New Anticoagulation Strategies

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Andras Gruber, MD<sup>1</sup>, Erik I Tucker, BS, Michelle Berny, BS, Tara C. White, BS, Sawan Hurst, BS, Ulla M Marzec, MS, Owen JT McCarty, PhD, David Gailani, MD, Enrico Di Cera, MD, Stephen R. Hanson, PhD

<sup>1</sup>Departments of Bioomedical Engineering and Medicine  
School of Medicine, Oregon Health and Science University, Portland, Oregon, USA

### Purpose:

To identify and test fundamentally new antithrombotic strategies that are specific for thrombosis, and thus prevent or treat thrombotic diseases without detrimental effects on hemostasis. Two new strategies have been tested and validated in a primate model of high flow vascular graft thrombosis.

### Methods:

Two novel antithrombotic compounds were designed and generated. The first compound is a monoclonal antibody (aXIMab) that neutralizes coagulation factor XI (FXI) activity. Since the extrinsic pathway activity overrides FXI inhibition outside of blood vessels but tissue factor is not present in mid-blood stream, anticoagulation by inhibition of FXI is more specific for thrombosis than hemostasis. The second one is a thrombin analog, WE-thrombin, that is anticoagulant (antithrombotic) via protein C activation inside blood vessels and moderately procoagulant (hemostatic) outside blood vessels. The experimental set-up is an established model of acute vascular graft thrombosis in a high flow permanent

AV shunt in large primates (baboons). Thrombus formation was quantified in real-time using radioimaging; hemostasis was monitored using template bleeding times. The effects of WE-thrombin and aXIMab administration on thrombosis and hemostasis were compared to negative (vehicle treatment) and positive (low-molecular-weight heparin, aspirin) controls.

### Results:

aXIMab treatment decreased total graft associated platelet deposition by 63% and fibrin accumulation by 81% compared with vehicle treated control animals, while not affecting bleeding times. aXIMab also prevented vascular graft occlusion more effectively than high dose aspirin, which increased bleeding times by 88%. Treatment with WE-thrombin decreased thrombus associated platelet and fibrin accumulation, similar to high dose low-molecular-weight heparin. Heparin increased bleeding by 46% compared with controls, while WE-thrombin had no impact on bleeding times.

### Conclusions:

The results suggest that utilizing the body's endogenous antithrombotic system by enhancement of the protein C pathway and inhibiting contact system complex activation by blocking FXI both deliver powerful antithrombotic effects without impairment of hemostasis. These novel antithrombotic treatment strategies offer fundamentally new and safe approaches to therapeutic anticoagulation, potentially leading to the development of new drugs.

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## Cardiopulmonary Bypass: A Procoagulant State

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James Jagers, MD

Chief Pediatric Cardiothoracic Surgery, Duke University Medical Center, Durham, North Carolina, USA

Open cardiac surgery has enjoyed significant improvement in outcome over the last several years. Complex heart defects once considered fatal are now readily addressed with low mortality. However, repair of these defects requires the use of cardiopulmonary bypass (CPB) which results in significant alteration of normal homeostatic mechanisms. Normal hemostasis reflects a highly complex interaction between endothelial cells, platelets, local and systemic inflammatory mediators and coagulation factors.<sup>iii</sup> The inflammatory and coagulopathic complications are manifest as diffuse capillary leak syndrome, coagulopathy, respiratory failure, myocardial dysfunction, renal insufficiency, and neuro-cognitive defects. <sup>iii</sup> Clinical experience reinforces that these adverse effects seem to be more pronounced in neonates and young infants as compared to older children or adults.

Coagulation is a physiologic defense mechanism that maintains the integrity of the circulatory system in response to injury or inflammation. It is a dynamic balance between coagulation and fibrinolysis to prevent hemorrhage or thrombosis. Surgical trauma results in disruption of this normal anticoagulant surface of endothelial cells, exposing sub-endothelial cell matrix. Inflammatory stimuli and tissue trauma result in the

expression and activation of Tissue Factor on endothelial cells and on circulating monocytes. Tissue factor in turn binds factor and activates Factor VII. Activated Factor VII converts factor IX and X to their active enzyme forms. Activated Factor X then converts prothrombin to thrombin which in turn converts fibrinogen to fibrin and clot is formed. The delicate balance of pro and anticoagulant mechanisms are disrupted by the noxious stimuli of cardiopulmonary bypass and these inflammatory cascades and coagulation cascades that are activated by CPB are interrelated and interdependent.<sup>iv</sup> Thrombin levels increase within minutes of the onset of CPB.<sup>vvi</sup> Levels of tissue plasminogen activator are elevated in neonates during CPB and levels of Plasminogen activator inhibitor have been found to be elevated after CPB.<sup>vii</sup><sup>viii</sup> Tissue factor activity has also been shown to be elevated four hours after cardiopulmonary bypass and again at 24 hours after CPB. <sup>ix</sup> The findings of increased extrinsic pathway activity and increased PAI levels post CPB may result in a procoagulant phenotype in neonates and young infants for several hours after surgery.

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**Outcomes for Children with Congenital Heart Disease Requiring ECMO**

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Ravi R. Thiagarajan MBBS, MPH  
Cardiac Intensive Care Unit, Children's Hospital Boston  
Boston, Massachusetts, USA

Extracorporeal Membrane Oxygenation (ECMO) has become an important adjunct in the treatment of infants and children with Congenital Heart Disease. ECMO support is sometimes required to manage cardiac, respiratory failure or both in infants and children with Congenital Heart Disease after all other conventional therapies have failed to improve the patient's condition. ECMO has been used for these purposes for pre-operative stabilization, in the post-operative period to manage low cardiac output or respiratory failure after cardiac surgery, or to provide cardio-respiratory support for critically ill patients who need an intervention in the cardiac catheterization laboratory to correct residual cardiac lesions. Survival outcomes following the use of ECMO to support cardiopulmonary function in children is variable. The Extracorporeal Life Support Organization Registry which collects ECMO support and patient outcome details reports a survival rate of 43% in 2003. Other single centers report higher survival rates of higher survival rates are also available. Factors that determine survival include 2 ventricle type anatomy, the timing of initiation of ECMO support, and the presence of ECMO complications such as CNS injury and renal failure.

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A growing role for the use of ECMO is its use to support patients with congenital heart disease who have a cardiac arrest. ECMO used to support cardiopulmonary resuscitation (E-CPR) is a growing indication for ECMO use (10% of all ECMO uses in 2005), and is largely used in children with cardiac disease. Survival outcomes for children with heart disease using E-CPR are better than other indications. Survival for patients using E-CPR depends on providing good quality CPR prior to ECMO support.

Long-term outcomes following ECMO support of children with heart disease needing cardiac support is not clearly known. However, because of increased use of anticoagulation and critical illness prior to institution of Mechanical Support in ECMO patients compared to patients using a ventricular assist device the rate of complications in the ECMO group is esp. Neurological Complications were noted to be higher in the ECMO group. Long term follow-up including neuro-developmental evaluation will be critical in the future of ECMO use in children with heart disease. This presentation will evaluate the current indications and survival outcomes for children with heart disease placed on ECMO.

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## Coagulation Issues in the Fontan Circulation

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Kirsten C. Odegard, MD  
Assistant Professor of Anesthesia  
Children's Hospital Boston, MA

Thromboembolic complications, reported in as many as 15-33% of patients who have undergone the Fontan operation are an important cause of morbidity and mortality following the Fontan procedure. Thromboembolic events may occur in the immediate post-operative period when patients are in low output state with increased pulmonary vascular resistance related to cardiopulmonary bypass resulting in decreased flow through the Fontan pathway or may be a late complication. Factors that may predispose to thrombus formation include stasis of blood flow through the Fontan pathway and pulmonary circulation, presence of atrial suture lines and distention, increased venous pressure, atrial arrhythmias, ventricular dysfunction and a hypercoagulable state secondary to low levels of the naturally occurring anticoagulants protein C, protein S and AT III has been postulated and more recently we have described elevation of factor VIII levels as a possible predisposing factor to thrombus formation. However, we have also previously demonstrated that both pro- and anticoagulant factor level abnormalities occur earlier in the course of staged surgical palliation for patients with single ventricle CHD, i.e., preceding the Fontan operation and physiology and have speculated that a "functional balance" exists also in these patients that prevent thrombophilia. We have just finished a prospective, longitudinal study evaluating changes in coagulation and hemodynamic profiles in patients with hypoplastic left heart syndrome from Stage I palliation through completion of the Fontan operation. Significantly lower levels of both pro- and anti-coagulation factors were demonstrated through to completion of the Fontan procedure.

When comparing post Fontan coagulation factors with pre Fontan values, factor VIII was significantly higher; 44% had a factor VIII value >160% but there were no specific hemodynamic variables predictive of coagulation abnormalities.

The large increase in factor VIII post Fontan procedure appears to be an acquired defect, the cause of which remains to be determined. The importance of an elevated factor VIII level as an independent risk factor for both primary and recurrent venous thrombosis in adult patients without cardiac defects has been reported. Studies have also shown that children with increased factor VIII levels are at increased risk for thrombosis. Elevated factor VIII, D-dimer or both at diagnosis of thrombosis, and a persistent elevation in children with thrombosis after standard-duration anticoagulant therapy, predicted a poor outcome.

Current practices for anticoagulation of Fontan patients are strictly empiric, vary widely, and are of unknown efficacy, and based upon small and retrospective analyses. Because of the difficulty and potential morbidity of long-term anticoagulation, particularly in young children, following the Fontan procedure, identifying patients who are at increased risk for thrombosis would allow for targeted therapy with improved outcome. Monitoring factor VIII levels may define a group of at-risk Fontan patients who may benefit from long term anticoagulation prophylaxis. Further work is necessary to determine whether there may be a critical factor VIII plasma concentration associated with thromboembolic risk in these patients.

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## **Optimal Dose of Aprotinin for Neuroprotection and Renal Function in a Piglet Model**

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Nobu Ishibashi, MD, Yusuke Iwata, MD, Toru Okamura, MD, Richard A. Jonas, M.D.  
Children's National Medical Center, Washington, DC, USA

### **Background:**

The efficacy of aprotinin in reducing blood loss after CPB is well established, however its neuroprotective potential is less well known. Furthermore, there is controversy regarding optimal dosing and possible renal complications.

### **Methods:**

54 piglets were randomly assigned to three CPB groups at risk for post-op cerebral and renal dysfunction: circulatory arrest at 25°C, ultra-low flow (10 ml/kg/min) at 25°C or 34°C. Animals were randomized to: control (no aprotinin), low dose (30,000 KIU/kg into prime only), full dose (30,000 KIU/kg bolus IV into prime plus 10,000 KIU/kg infusion), and double full dose. Tissue oxygenation index (TOI) was monitored by near-infrared

spectroscopy. Neurologic functional and histological scores, creatinine and blood urea nitrogen (BUN) were outcomes of interest.

### **Results:**

Aprotinin significantly improved neurological scores on postoperative day 1 after ultra-low flow bypass at 25°C or 34°C ( $P < .01$ ), but not after HCA ( $P = .57$ ). Linear regression indicated a strong dose-response relationship with higher aprotinin doses having the best neurological scores. During LF, a higher TOI was correlated with a higher aprotinin dose ( $P < .05$ ). Use of aprotinin and dose had no significant effect on creatinine, BUN, or BUN-to-creatinine ratio on day 1. Low body weight was the only predictor of high BUN ( $r = -0.39$ ,  $P < .01$ ).

### **Conclusions:**

Aprotinin significantly improves neurologic recovery without impairing renal function. Future studies are needed to examine the safety and efficacy of a double usual full dose strategy.

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**New Strategies for Preservation of Small Diameter Vascular Grafts**

Stephen R. Hanson, PhD  
Department of Biomedical Engineering  
Oregon Health & Sciences University, Portland, Oregon, USA

**Purpose:**

The purpose of these investigations was to evaluate local drug delivery approaches for prevention of thrombosis and intimal hyperplasia within small diameter synthetic vascular grafts (e.g., 3-4 mm i.d. ePTFE) that are used for peripheral arterial reconstruction, arteriovenous shunts, and neonatal cardiac applications (e.g., Norwood procedure).

**Methods:**

The method is based on delivery of drug directly and circumferentially through the wall of conventional ePTFE grafts (e.g., 30 $\mu$  porosity) using an implantable mini-pump. Drugs thus enter the blood flow-field at the graft-blood interface, thereby achieving very high drug concentrations along the graft wall and at distal anastomoses. Two models were studied. First, to prevent acute thrombotic graft occlusion, heparin (6 units/kg/hr; 2 ml/month volume infusion) was infused into 4.0 mm i.d. ePTFE that was used to replace the IVC in 6 rabbits<sup>1</sup>. Six other animals infused with saline served as controls. All grafts were harvested at

2 weeks. In a second series of studies designed to assess anastomotic intimal hyperplasia and its prevention, 4.0 mm i.d. ePTFE grafts were placed as bilateral aorto-iliac implants in baboons. Nine grafts were infused with sirolimus (2 mg/month; 2 ml/month volume infusion) while 9 other grafts infused with saline served as controls. All grafts were harvested at 1 month.

**Results:**

Results are shown in the following table. In the rabbit model, heparin infusion perfectly preserved graft patency (100%) vs. the control grafts (0% patent) without affecting systemic clotting times (APTT). Comparing the proximal (untreated) vs. distal (heparin-treated) anastomoses, local heparin infusion reduced neointimal thickening, neointimal area, and SMC proliferation (BrdU index) by 72-85%. In the baboon studies, 8 of 9 grafts were patent in both the control and treated groups. Local infusion of sirolimus at treated distal anastomoses reduced the total area and average thickness of neointima by 79%-88%.

**Rabbit IVC Replacement with Heparin Infusion<sup>1</sup>**

Measurement	Proximal	Distal
Intimal thickness (mm)	0.66 $\pm$ 0.19	0.14 $\pm$ 0.07
Intimal area (mm <sup>2</sup> )	2.78 $\pm$ 0.24	0.42 $\pm$ 0.21
SMC proliferation	25% $\pm$ 6%	7% $\pm$ 2%

**Baboon Aorto-Iliac Graft Model<sup>2</sup> – Sirolimus Infusion**

Measurement	Control	Treated
Graft patency	8/9	8/9
Intimal area (mm <sup>2</sup> )	1.11 $\pm$ 0.19	0.13 $\pm$ 0.08
Intimal thickness (mm)	0.92 $\pm$ 0.21	0.19 $\pm$ 0.06

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**Conclusions:**

Local drug delivery directly through the wall of small diameter synthetic grafts has been shown to preserve graft patency and limit intimal thickening. Heparin infusion, at very low doses, may prevent thrombotic graft occlusion even in a challenging low blood flow environment (IVC grafting), while the local infusion of very low dose antiproliferative agents (e.g., sirolimus) may effectively prevent intimal hyperplasia at arterial graft anastomoses (aorto-iliac grafts). These benefits are achieved with minimal systemic side-effects. The method also has advantages that: 1) dose and dose-duration effects can be established experimentally, and 2) agents can be then be administered as necessary, at constant, effective concentrations for extended periods of time. This method may prove advantageous in situations where the usefulness of small caliber synthetic grafts remains limited by thrombosis and anastomotic intimal hyperplasia.

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**Current Status of Blood Transfusion-Free Open-Heart Surgery in Infants and Small Children**

Yasuhiro Kotani, MD, Osami Honjo, MD, Mahito Nakakura, CE, Yasuhiro Fujii, MD, Shinya Ugaki, MD, Yu Oshima, MD, Ko Yoshizumi, MD, Shingo Kasahara, MD, Shunji Sano, MD  
Department of Cardiovascular Surgery, Okayama University Hospital, Japan

**Purpose:**

Reduction in cardiopulmonary bypass (CPB) circuit volume and/or refinement of perfusion strategy allows open-heart surgery in infant and small children without blood transfusion. We sought to analyze our current practice of blood transfusion-free open-heart surgery in children less than 20 kg.

**Methods:**

This study included 407 children weighing 5-20kg undergoing open-heart surgery between 2004 and 2007. A miniaturized CPB circuit was used and CPB flow was maintained at 150ml/kg/min with mild to moderate hypothermia. Modified ultrafiltration was performed after cessation of CPB. Criteria for blood transfusion during CPB included a hematocrit of less than 15% or systemic venous oxygen saturation of less than 65%. Patients were divided into three

groups based on body weight: 5-10kg (Group 1), 11-15kg (Group 2), and 16-20kg (Group 3).

**Results:**

Blood transfusion-free open-heart surgery was achieved in 197 of the 407 patients (48.4%). There were no hemodynamic instability and neurological complication related to hemodilution. Pre-, lowest, and post-operative hematocrit were 37.5±7.4%, 22.3±5.0%, 40.5±8.6%, respectively. Blood transfusion could be avoidable in 72 of 236 (30.5%) patients in Group 1, 90 of 132 (68.2%) patients in Group 2, and 35 of 39 (89.7%) patients in Group 3. Achievement of blood transfusion-free open-heart surgery also depends on complexity of diagnosis and procedure required (Table 1).

	ASD (n=36)	VSD (n=87)	TOF (n=61)	PA/VSD (n=23)	AVSD (n=28)	BDG (n=69)	Fontan (n=104)
Mean body weight (kg)	13.7±4.2	10.2±4.0	8.6±1.6	10.6±1.9	8.4±3.4	7.8±2.1	13.0±2.5
Rate of blood transfusion-free surgery (%)	94.4	57.5	21.3	43.5	25.0	40.6	59.6

**Conclusions:**

Blood transfusion-free open-heart surgery can be achieved in the half of the patients less than 20 kg. Transfusion-free open-heart surgery is still a challenge for patients less than 10 kg, and further miniaturization of CPB circuit and refinement of perfusion strategy would be warranted.

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**Efficiency of Miniaturized Circuit and Vacuum-Assisted Venous Drainage  
in Decreasing Blood Transfusion**

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Yves Durandy, MD  
Institut Jacques Cartier, Massy- France

Though essential in pediatric cardiac surgery, blood transfusion is associated with increased morbidity and cost and remains poorly accepted by parents.

The goal of this study was to assess efficiency of downsized bypass circuit and vacuum-assisted venous return in decreasing blood transfusion. The study included 150 patients (2.3 to 10 kg). Bypass circuit was composed of a KidsD100 oxygenator connected to 3/16 inch lines. The prime volume was 125 ml and the primary outcome defined as an 8g/dl minimal haemoglobin level during the procedure.

Vacuum-assisted venous drainage (-10 to -30 mmHg) was added, when necessary, to 30 cm gravity venous drainage.

The study assessed:

- 1- Feasibility of venous drainage
- 2- Haemoglobin level and donor exposure
- 3- Serum lactate level and time to extubation.

Venous drainage was achieved through gravity until 600-700 ml/min, for flow up to 1200 ml/min vacuum-assisted drainage was needed and efficient.

While all patients less than 6.4 kg were transfused, only 45% of patients weighing 6.4 to 11 kg needed homologous blood transfusion. In the transfused group, one unit each of PRBC and FFP (donor exposure=2) were adequate, including surgery and intensive care requirement. No patient had platelet infusion.

	Transfused patients	Bloodless surgery
Haemoglobin before surgery	10.2 g/dl (6.7-15.9)	11.4 g/dl (9.7-16.8)
Haemoglobin during surgery	11.5 g/dl (7.8-15.8)	8.7 g/dl (7.5-12.9)
Haemoglobin after surgery	15 g/dl (11.2-16.8)	10.6 g/dl (8.5-14.9)
Lactate before surgery	1.3 mmol/l (0.7-4.6)	1.1 mmol/l (0.7-1.7)
Lactate during surgery	2.4 mmol/l (1.2-5.3)	1.8 mmol/l (1-3.2)
Lactate after surgery	2.5 mmol/l (1.1-7.9)	1.5 mmol/l (0.9-3.1)
Lactate extubation time	1.5 mmol/l (0.9-3.5)	1.6 mmol/l (0.9-2.5)
Time to extubation	12 hrs (2-290)	3 hrs (1-12)

(Data shown are median and (minimal-maximal) values)

In our experience, miniaturized bypass circuit and vacuum-assisted venous return are efficient in decreasing blood transfusion without adverse clinical events.

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### Why Do We Cool to 18 °C?

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Jamie You, CCP. Brian Mejak, CCP. Carmen Giacomuzzi, CCP. Eileen Heller, CCP. Ross Ungerleider, MD. Karl Welke, MD  
Division of Pediatric Surgery, Doernbecher Children's Hospital, Oregon Health & Science University Portland, Oregon

#### **Background:**

Conventional strategies for neonatal heart repair frequently involve cooling to 18° C. Although this might have been warranted in an era where exposure to uninterrupted circulatory arrest was long, operative strategies regarding cerebral protection have changed. Profound hypothermia may not be necessary, and may in fact increase morbidity from inflammation, when coupled with a strategy of more continuous perfusion during CPB.

#### **Methods:**

We conducted a retrospective review of twenty-nine consecutive infants, with an average age of 14.3±21.6 days and average weight of 3.3±0.6 kg, the Norwood operation. Patients were divided into two groups based on target temperature achieved. In Group A (n=18, 3.2±0.6kg, 11.1±15.4 days of age), infants were cooled to 18 °C. and underwent deep hypothermic circulatory arrest (DHCA) with intermittent perfusion (2 minutes every 15 minutes). In Group B (n=11, 3.5±0.4kg, 19.5±29.2 days of age), neonates were cooled to 25 °C and underwent intermittent hypothermic circulatory arrest (IHCA), when needed at an average duration of 6.8 minutes per exposure (1-16 minutes). All patients were routinely placed on a ventricular assist device (VAD) following modified ultrafiltration (MUF) VAD flows

were maintained at approximately 146.9±31.1 mL/kg/min. The duration of ventricular assist averaged 50.5 ± 40.7 hours. ScO<sub>2</sub>, SsO<sub>2</sub>, MAP and lactic acid were continuously monitored from time of intubation to withdrawal of VAD support. Data from the post-induction period to 24 hours postoperatively were analyzed and included ten minutes prior to CPB, ten minutes prior to termination of CPB, MUF, time before VAD initiation, and hourly measurements on VAD.

#### **Results:**

The average circulatory arrest time in Group A was significantly longer than Group B (54.0±12.8 vs 22.8±17.6 minutes, p<0.01). There were no differences between groups in baseline MAP or ScO<sub>2</sub>. ScO<sub>2</sub> following MUF were 44.0±12.3% in Group A and 51.7±13.3 % in Group B (p=0.17). SsO<sub>2</sub> values were higher in Group B at all time points, although this did not reach statistical significance. Lactic acid levels in both groups peaked following MUF (6.8±1.6 mmol/L in Group A and 6.5±2.7 mmol/L in Group B) but dropped significantly (P<0.01) by hour 18 of VAD support (3.8±1.8 mmol/L in Group A and 2.5±1.2 mmol/L in Group B). All patients were successfully weaned off VAD. Hospital survival rates were 14/18 in Group A and 10/11 in Group B, respectively.

#### **Conclusions:**

Hypothermia is important technique for protecting the brain and other major organs during CPB. However, negative effects of hypothermia related to inflammation have been described. The results of this retrospective review are interesting in that when comparing both groups, one strategy did not confer any advantage over the other. This would suggest the strategy of cooling to 25 °C and employing short periods of IHCA is a safe alternative to DHCA. Although the numbers of patients in either group were too small to indicate a statistical difference, infants who were cooled to 25 °C with IHCA did show a trend towards higher ScO<sub>2</sub> values at all time points.

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## **Results with All Blood Retrograde Microplegia as a Myocardial Protection Strategy for Complex Neonatal Arch Reconstruction**

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Richard N Gates, MD, Brian A Palafox, MD, Beth Parker, CCP  
Division of Cardiothoracic Surgery, Children's Hospital of Orange County, Orange, California, USA

### **Purpose:**

Neonatal arch reconstructions present a challenge for myocardial protection. We report our results for 8 patients treated with intermittent cold all blood retrograde cardioplegia during arch reconstruction using continuous selective normothermic cerebral perfusion.

### **Methods:**

Over a 10 month period 8 consecutive neonates underwent complex arch reconstruction. Mean age

was 8.4 days (range 2-23); weight 3.1 Kgs (range 2.7-3.8). Diagnosis was HLHS (5), IAA/VSD (2), and complex AP window (1).

### **Results:**

Mean CPB time was 149 minutes (range 80-201), mean cross-clamp time was 74 (range 51-101). All patients had primary chest closure and none required ECMO. One patient (12%) had a period of low cardiac output syndrome which resolved with high dose inotropes. All patients were discharged alive and well.

### **Conclusions:**

Intermittent all blood retrograde microplegia is an effective myocardial protection strategy for complex neonatal arch reconstruction. Post-operative myocardial function is very good. This protection approach facilitates continuous selective normothermic cerebral perfusion.

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**Pulsatile Perfusion on Vital Organ Recovery During and After Pediatric  
Open-Heart Surgery in Ventricular Septal Defects**

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Alkan-Bozkaya T., Akcevin A., Ündar A\*, Türkoğlu H., Paker T., Aytaç A.  
V.K.V. American Hospital, Dept. of Cardiovascular Surgery, Istanbul, TURKEY and \*Penn State University,  
Children's Hospital, Hershey, PA, USA

**Purpose:**

The controversy over the benefits of pulsatile flow compared to the nonpulsatile flow during and after cardiopulmonary bypass (CPB) in pediatric patients still remains. The aim of the present study was to evaluate pulsatile perfusion in pediatric patients who had ventricular septal defects undergoing CPB in a clinical setting.

**Methods:**

70 consecutive pediatric patients undergoing open heart surgery for repair of ventricular septal defects were prospectively entered into the study and were randomly assigned to either the pulsatile perfusion group (Group P, n = 35) or the nonpulsatile perfusion group (Group NP, n = 35). All patients received identical surgical, perfusional, and postoperative care. Study parameters included intubation time, duration of ICU and hospital stay, the need for inotropic support, pre- and postoperative enzymes (ALT, AST), creatinin, CRP, lactate, albumine (mg/dL), blood count (leukocytes, hematocrit, platelets), mean urine output (ml/day) and total drainage (ml). Major complications and clinical outcome were documented.

**Conclusions:**

We found statistically meaningful results regarding outcomes (shorter ICU and hospital stay period) for CPB in pediatric patients compared to pulsatile and nonpulsatile type perfusion systems. We conclude that the use of pulsatile flow indicated that improved patient outcome in preserving cardiac function and maintaining better renal and pulmonic function in the early post-bypass period.

**Results:**

There were no statistically significant differences seen in either preoperative or operative parameters between the two groups (age, BSA, weight, X-Clamp and CPB time, base flow, flow rates and hemofiltration).

The Group P, compared to Group NP, had significantly less inotropic support (number of agents  $1.3 \pm 0.1$  vs  $1.83 \pm 0.14$ ,  $p = 0.0034$ ; dopamine  $7.02 \pm 0.57$  vs  $8.48 \pm 0.59$   $\mu\text{g}/\text{kg}/\text{min}$ ,  $p = 0.046$ ; adrenalin  $0.018 \pm 0.004$  vs  $0.035 \pm 0.004$   $\mu\text{g}/\text{kg}/\text{min}$ ,  $p = 0.021$ ), less intubation period ( $6.45 \pm 1.37$  vs  $11.51 \pm 1.99$  hours,  $p = 0.0024$ ), less duration of ICU ( $1.25 \pm 0.09$  vs  $2.31 \pm 0.11$  days,  $p = 0.015$ ) and hospital stay ( $5.71 \pm 0.2$  vs  $10.12 \pm 0.21$  days,  $p = 0.0034$ ).

Although there were no significant differences in either creatinin, enzyme levels and drainage amounts between two groups, lower lactate levels  $19.23 \pm 2.62$  vs  $34.76 \pm 3.09$  mg/dL,  $p = 0.00031$ ), higher albumine levels  $3.26 \pm 0.047$  vs  $2.98 \pm 0.06$  mg/dL,  $p = 0.048$ ) and higher urine output ( $644.2 \pm 42.5$  vs  $521.56 \pm 43.2$  ml/day,  $p = 0.021$ ) during ICU period was observed in Group P.

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**Operative Risk and Outcome of Surgery in Adults with Congenital Valve Disease**

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Giovanni Battista Luciani, MD, Francesca Viscardi, MD, Mara Pilati, MD, Luca Barozzi, MD, Giuseppe Faggian, MD, Alessandro Mazzucco, MD.

Divisions of Cardiac Surgery and Cardiology, University of Verona, Verona, Italy.

**Purpose:**

Adults with congenital valve disease (CVD) pose critical challenges due to need for complex, often multiple, surgical procedures, while accommodating satisfactory long-term quality life. To define operative risk and outcome of surgery in adults with CVD, experience in a large congenital heart surgery center was reviewed.

**Methods:**

Between 2002-2007, 371 operations in adults (>18 years) with CVD out of 2473 overall valve procedures (15%) were performed. There were 288 males (77.6%), aged  $56 \pm 9$  years (vs.  $69 \pm 22$  years in overall valve,  $p=0.02$ ). Diagnosis was bicuspid aortic valve (BAV) in 343 (92%), s/p ToF repair in 11, atrio-ventricular valve dysfunction in 10, other in 7. One or more associated lesions requiring repair were present in 259 patients (70% vs. 17%,  $p=0.001$ ), consisting of ascending aortic pathology in 205 (55%), RVOT lesion in 40, coronary disease in 34, mitral/tricuspid disease in 27, septal defect in 17,

subaortic stenosis in 4, arch lesion in 4, other in 3. Fifty-two patients (14% vs. 2.5% overall,  $p=0.001$ ) had undergone 75 prior operative procedures (1.4/patient), and 14 (3.8% vs. 1.9% overall,  $p=0.04$ ) required emergent surgery due to endocarditis or dissection. Surgery consisted of valve repair in 36 (10% vs. 3% overall,  $p=0.02$ ) and replacement in 335: a stentless solution (native valve, autograft, xenograft) was offered to 101 (29%) patients. In BAV patients, partial root replacement was associated in 63 (31%), complete in 77 (38%) and ascending aorta in 92 (45%).

**Results:**

There were 2 (0.5%) hospital deaths (vs. 1.6% overall,  $p=0.02$ ), both due to relapse endocarditis. Hospital complications occurred in 26 patients (7.0% vs. 10.8% overall,  $p=0.04$ ), due to cardiac cause in 10, neurologic in 6, hemorrhage 4, sepsis in 3, MOF in 3. During a 5-year follow-up (average  $2.6 \pm 1.8$  years), there was 1 late cardiac death and 3 reoperations (99% free).

**Conclusions:**

In spite of higher prevalence of associated procedures, reoperation and emergent indication, operative risk in CVD is lower than in acquired, possibly due to younger age. Stentless valve surgery allowing normal life-style (exercise, pregnancy), at the expense of greater risk of late reoperation, is increasingly preferred.

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**“Stolen” Blood Flow: The Effect of an Open Arterial Filter Purge Line in a Simulated Neonatal CPB Model**

Shigang Wang, MD, Akemi Miller, BA, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, and Bioengineering  
Penn State College of Medicine, Penn State Children’s Hospital, Hershey, Pennsylvania, USA

**Purpose:**

The purpose of this study was to evaluate the effect of different flow rates and pressures on the degree of shunting of blood flow by the arterial filter purge line in a simulated neonatal CPB circuit.

**Methods:**

The circuit was primed with heparinized bovine blood (hematocrit 24%) and post-filter pressure was varied from 60-180 mmHg (20 mmHg increments) using a Hoffman clamp. Trials were conducted at flow rates ranging from 200-600 ml/min (100 ml/min increments). The purge line of the arterial filter was kept open and blood temperature maintained 35°C during all trials. A calibrated two-channel TS410 Transit Time Tubing Flowmeter (Transonic Systems Inc., Ithaca, NY, USA) was used to measure flow rates on either side of the arterial filter.

**Results:**

The open arterial purge line shunted approximately 80 ml/min of blood flow during trials conducted at post-filter pressure 60 mmHg, while an average more than 160 ml/min of blood flow was diverted during trials at 180 mmHg. During trials conducted at a post-filter pressure of 60 mmHg, 42.6% of blood flow was shunted through the purge line at a flow rate of 200 ml/min, while only 12.8% of flow was diverted at a flow rate 600 ml/min. During trials conducted at a post-filter pressure of 180 mmHg, 82.8% of blood flow at 200ml/min and 25.9% of blood flow at 600ml/min was diverted through the open arterial purge line. At the post-filter pressure 60 mmHg, the purge line pressure was equal to 1/2 of the post-filter pressure. At 180 mmHg, the purge line pressure was equal to 2/3 of the post-filter pressure. The following table provides the rate of purge line flow shunting at different post-filter pressures and pump flow rate settings.

The purge line shunting flow rates (ml/min, % shunted) at different post-filter pressures and pump flow rate settings.

Pump flow (ml/min)	Post-Filter Pressure (mmHg)						
	60	80	100	120	140	160	180
200	87.7±2.7 (42.6±1.1%)	102.8±2.6 (49.8±1.1%)	118.2±2.2 (57.3±1.0%)	133.5±2.2 (64.8±1.2%)	145.0±3.9 (70.2±1.9%)	158.8±2.9 (76.8±1.3%)	169.7±1.9 (82.2±1.1%)
300	87.0±2.8 *(28.5±0.7%)	101.8±2.6 *(33.3±0.6%)	117.5±1.6 *(38.5±0.3%)	130.3±2.9 *(42.7±0.8%)	143.3±2.4 *(46.9±0.6%)	154.0±2.4 *(50.4±0.8%)	167.3±2.4 *(54.8±0.6%)
400	83.3±2.3 *(20.8±0.6%)	98.3±2.3 *(24.5±0.6%)	112.3±2.7 *(28.0±0.7%)	127.0±2.4 *(31.6±0.7%)	140.8±2.9 *(35.1±0.8%)	152.5±2.4 *(38.0±0.7%)	163.7±1.4 *(40.8±0.4%)
500	79.0±2.3 *(15.8±0.5%)	94.5±3.4 *(19±0.7%)	108.8±3.5 *(21.8±0.7%)	123.3±3.0 *(24.7±0.6%)	135.0±2.1 *(27.1±0.4%)	147.0±2.8 *(29.5±0.5%)	159.0±3.1 *(31.9±0.6%)
600	76.3±4.8 *(12.8±0.7%)	91.2±5.0 *(15.3±0.7%)	105.5±4.1 *(17.7±0.6%)	118.8±3.3 *(19.9±0.4%)	131.8±3.7 *(22.1±0.5%)	144.2±4.9 *(24.2±0.7%)	154.5±2.9 *(25.9±0.3%)

\* p<0.01 All other pump flow rates vs. 200ml/min.

**Conclusions:**

The results of this study confirm that a significant amount of flow is diverted away from the patient when the arterial purge line is open. Shunting of blood flow through the arterial purge line could result in less effective tissue perfusion, particularly at low flow rates and high post-filter pressures. To minimize hypoperfusion injury, a flow probe (distal to the arterial filter) may be used to monitor real-time arterial flow in the setting of an open arterial filter purge line.

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## Development of a Miniaturized Heart-Lung Machine for Neonates with Congenital Heart Defect

Jutta Arens<sup>1</sup>, MSc; Heike Schnöring<sup>2</sup>, MD; Jaime Vázquez-Jiménez<sup>2</sup>, MD; Thomas Schmitz-Rode<sup>1</sup>, MD; Ulrich Steinseifer<sup>1</sup>, PhD

<sup>1</sup> Applied Medical Engineering, Helmholtz Institute, RWTH Aachen, Germany

<sup>2</sup> Pediatric Cardiac Surgery, University Clinic Aachen, Germany

### Purpose:

Predominantly standard adult Heart Lung Machines (HLMs) are used for paediatric cardiac surgery, only with individually downsized components. Downsizing is limited, e.g. by the required gas exchange surface, the tubing between the components, etc. In order to diminish known complications related to cardiopulmonary bypass (e.g. inflammatory reaction and capillary leak syndrome) we developed a new miniaturized heart lung machine (MiniHLM) for neonates, with significantly reduced priming volume and blood contact surface by integration of all major system components in one single device.

### Methods:

In particular, a rotary blood pump with reusable drive unit is centrally integrated into an oxygenator with 0.36 m<sup>2</sup> gas exchange surface. The cardiotomy reservoir with integrated heat exchanger is directly

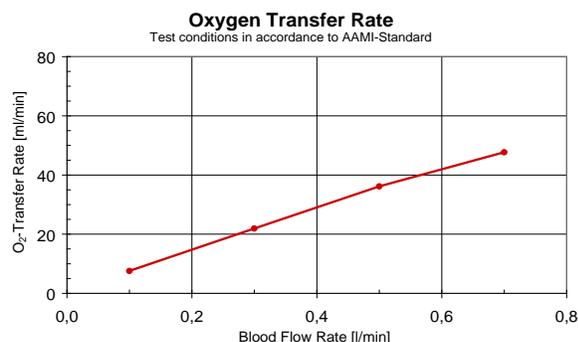
connected to the pump inlet. Thus, tubing is only necessary between patient and MiniHLM (venous and arterial). This tubing is kept to a minimum length by placement of the MiniHLM directly at the operation table.

### Results:

A total priming volume of 100 ml could be achieved for the entire extracorporeal circuit (incl. a/v line), in contrast to the currently smallest commercially available device with 223 ml.

Clinically demanded blood flow rates of up to 700 ml/min at pressure drops of up to 250 mmHg could be easily achieved by the pump in an in-vitro setup simulating the clinical application.

In-vitro oxygenation tests proved a sufficient gas exchange rate for CO<sub>2</sub> and Oxygen.



In animal experiments with female New Zealand white rabbits (n = 13; 4.1 ± 1 kg) the MiniHLM guaranteed both a sufficient gas exchange and an adequate blood flow. 12 rabbits could successfully be weaned off after 1 hour of aortic clamp time.

### Conclusions:

The first in-vitro and in-vivo-tests fully validate the concept of the MiniHLM. Its low priming volume and blood contact surface may significantly reduce complications during heart surgery in neonates.

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## **Extracorporeal Circulation (ECC) in the Rat Model Using a New Miniaturized Hollow Fiber Oxygenator**

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Rungatscher A1, Cresce GD2, Tessari M1, Walpoth BH2, Faggian G1  
1 Cardiovascular Surgery, University of Verona Medical School, Italy  
2 Cardiovascular Research, University Hospital of Geneva, Geneva, Switzerland

### **Aims:**

CPB is an essential component of cardiac surgery, with still unknown device/patient interactions. In order to evaluate the response of CPB to hemodynamic, biochemical, inflammatory, as well as thermo- pharmacodynamic interactions, a novel miniaturized oxygenator with controlled and standardized specifications has been developed together with an improved surgical central cannulation technique.

### **Methods:**

A hollow-fibre small priming volume (6.3ml) oxygenator was manufactured according to specifications resulting from engineering, heart surgery and perfusionist expertise (Dideco-Sorin Group, Italy) with the following characteristics: Gas Exchange Surface-450cm<sup>2</sup>, Heat Exchange Surface-

16cm<sup>2</sup>. The oxygenator was tested *in vitro* and *in vivo* in 5 anaesthetised, ventilated, open-chest rats using a miniaturized roller pump and heat exchanger. Pressures were monitored in the animal, before and after the oxygenator. Central venous cannulation through the right atrium, and aortic cannulation, through the carotid artery, were used.

### **Results:**

*In vitro*: blood oxygenation increased 10-fold (from room air to 100% FIO<sub>2</sub>) and PCO<sub>2</sub> removal was 2.5-fold. *In vivo*: CPB was performed without blood prime for 60mins (no ventilation) maintaining stable haemodynamics. A maximal blood flow rate of 124ml/min/kg was obtained. Arterio-venous PO<sub>2</sub> gradients were 10-fold (FIO<sub>2</sub>@100%) with only small variations when changing blood flow rates.

### **Conclusion(s):**

The results obtained with this new, standardized and miniaturized hollow fibre oxygenator, new cannulation technique and CPB circuit, achieves optimal gas transfer with small asanguinous priming volumes. This study opens new potentials for various CPB-related study protocols in the small animal.

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**Feasibility of Ultrafiltration of Blood for Priming Before Cardiopulmonary Bypass in Neonatal Piglets**

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Shinya Ugaki, Shingo Kasahara, Osami Honjo, Yasuhiro Kotani, Yu Oshima, Ko Yoshizumi and Shunji Sano  
Department of Cardiovascular Surgery, Okayama University, Okayama, Japan

**Purpose:**

Blood priming is necessary for CPB in neonates to avoid excessive hemodilution, however use of blood could have detrimental effects on post-CPB outcomes in neonatal open heart surgery. We evaluated whether ultrafiltration of priming blood prior to CPB could reduce inflammatory mediators in priming blood as well as hemodynamic worsening and inflammatory responses after CPB in neonatal piglets.

**Methods:**

Twelve piglets aged 1-week-old ( $3.5 \pm 0.2$  kg) were divided into two groups. Group U ( $n=6$ ) employed the priming blood ultrafiltered before CPB, but group N ( $n=6$ ) used the non-ultrafiltered blood for priming. CPB was performed under moderate hypothermia for two hours including one hour's cardiac arrest and

then modified ultrafiltration (MUF) was performed. Hemodynamics, the values of thrombin-antithrombin complex and IL-8 levels in serum and airway were assessed before CPB and after the end of MUF.

**Results:**

The values of IL-8 and serotonin in priming blood significantly decreased following ultrafiltration. Although serum IL-8 levels after MUF were not different between the two groups, group U after MUF had lower thrombin-antithrombin complex levels ( $23.9 \pm 5.1$  vs.  $33.7 \pm 4.6$  ng/ml,  $p < 0.05$ ) and lower IL-8 levels in airway ( $925 \pm 710$  vs.  $2495 \pm 1207$  pg/ml,  $p < 0.05$ ) than group N. Cardiac index and pulmonary vascular index after MUF in group U were also better than group N ( $0.32 \pm 0.06$  vs.  $0.19 \pm 0.05$  l/min/kg,  $p < 0.05$  and  $6304 \pm 1477$  vs.  $9715 \pm 3289$  dynes/cm<sup>5</sup>/kg,  $p < 0.05$ ).

**Conclusions:**

The ultrafiltration of blood priming before CPB could attenuate not only hemodynamic deterioration but also activation of the coagulation pathway and inflammatory responses in neonatal piglets. This procedure may be helpful to improve post-operative outcomes in neonatal open-heart surgery.

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## **The Effects of Vasopressor and Vasodilator on Hemodynamic Energy in Terms of Surplus Hemodynamic Energy**

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Choon Hak Lim MD, Jae Soon Choi PhD, Ho Sung Son MD, Jung Joo Lee PhD, Hye Won Lee MD, Kyung Sun MD, PhD

Department of Anesthesiology and Pain Medicine, Thoracic and Cardiovascular Surgery, Korea Artificial Organ Center, Korea University, Seoul, Korea

### **Introduction:**

In a previous study, we reported that inotropic agents affect the hemodynamic energy, which can be measured using the energy equivalent pressure (EEP) and surplus hemodynamic energy (SHE). However, there has been no study about the effect of vasopressors and vasodilators on EEP and SHE. Thus, we investigated the change in the hemodynamic energy induced by phenylephrine, nitroprusside, norepinephrine, and milrinone in terms of the EEP and SHE.

### **Methods:**

Phenylephrine (1, 3  $\mu\text{g}/\text{kg}/\text{min}$ ), nitroprusside (0.5, 1  $\mu\text{g}/\text{kg}/\text{min}$ ), norepinephrine (0.1, 0.25  $\mu\text{g}/\text{kg}/\text{min}$ ), and milrinone (bolus 50  $\mu\text{g}/\text{kg}$ , followed by 0.5, 0.7

$\mu\text{g}/\text{kg}/\text{min}$ ) were infused into 13 anesthetized dogs. The hemodynamic parameters, mean arterial pressure (MAP), and flow were recorded in the descending thoracic aorta, and EEP and SHE were calculated.

### **Results:**

MAP, EEP, and SHE increased significantly with phenylephrine administration. However, the flow in the descending aorta decreased significantly ( $P < 0.05$ ). Norepinephrine also significantly increased MAP, EEP, and SHE ( $P < 0.05$  in all cases). The MAP, EEP, and SHE significantly decreased after nitroprusside infusion ( $P < 0.05$ ), while milrinone did not have an effect on MAP, EEP, or SHE.

### **Conclusions:**

Vasopressors were found to increase EEP and SHE, while a vasodilator decreased EEP and SHE.

Corresponding Author: Ho Sung Son MD

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**Detection and Classification of Gaseous Microemboli in a Simulated Pediatric CPB Circuit: Effect of Flow Rate and Perfusion Mode on Microemboli Delivery**

Akemi Miller, Shigang Wang, MD, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, and Bioengineering  
Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

**Purpose:**

The purpose of this investigation was to evaluate the effect of flow rate and perfusion mode on the delivery of gaseous microemboli (>10µm) in a simulated pediatric cardiopulmonary bypass (CPB) circuit with an open arterial filter purge line.

**Methods:**

The simulated pediatric CPB circuit used in this study is identical to the CPB circuit used in our operating rooms. The circuit was primed with 450ml fresh, heparinized bovine blood plus 200 ml Lactated Ringer's solution (total volume 650ml, corrected Hct 25%). Following the injection of 5cc air into the venous line, an EDAC<sup>TM</sup> Quantifier (Luna Innovations, Inc., Roanoke, VA) was used to simultaneously record microemboli counts at post-pump, post-oxygenator, and post-arterial filter sites.

Trials were conducted at 4 different flow rates (500, 750, 1000, 1250ml/min) and 2 perfusion modes (pulsatile, non-pulsatile).

**Results:**

Microemboli counts uniformly increased with increasing pump flow rates (see Table). In general, pulsatile flow delivered more gaseous microemboli to the circuit than non-pulsatile flow. In all trials, the majority of gaseous microemboli detected in the simulated pediatric CPB circuit were less than 20µm in diameter. At the lowest flow rate tested (500ml/min), all microemboli (>10µm) were cleared from the circuit by the oxygenator and arterial filter. Clearance efficiency was decreased at higher flow rates (750-1250ml/min). Over 98% of microemboli detected at the post-oxygenator site were less than 40µm in diameter.

Flow Rate (ml/min)	Post-pump		Post-oxygenator		Post-arterial filter	
	NP	P	NP	P	NP	P
500	38.7±15.2 92%	87.2±51.4 90%	3.3±2.7 100%	7.8±4.4 100%	0±0 100%	0±0 100%
750	1054.7±220.2 89.8%	945±39.5 90.3%	199.8±33.7 98.9%	201.3±31.3 99.2%	7.8±3.1 100%	5.2±3.1 100%
1000	2485.5±283.3 89.6%	2812.7±285.4 90.3%	860.2±126.7 98.8%	992.8±168 98.6%	80.8±16.3 100%	81.5±14.8 100%
1250	4965.2±367.7 89.2%	5619.5±303.3 90.3%	2450.2±314 98.4%	2474.5±208.8 98.3%	316.3±43.4 100%	312.2±37.3 100%

Microemboli counts at post-pump, post-oxygenator and post-arterial filters sites for all flow rates and perfusion modes. (Percentages indicate the fraction of detected microemboli with diameters 0-40µm. NP = non-pulsatile, P = pulsatile)

**Conclusions:** All microemboli detected by the EDAC<sup>TM</sup> Quantifier (except two) were less than 40µm in diameter and would not have been detected by conventional Transcranial Doppler. The EDAC<sup>TM</sup> Quantifier could provide more accurate reporting of gaseous microemboli during CPB procedures, allowing surgeons and perfusionists to more rigorously localize and correct potential sources of air leak within the circuit and operative field. This increased vigilance could result in significant reductions in the systemic entry of gaseous microemboli and may decrease the incidence of post-operative NP dysfunction in microischemia-sensitive patients. Although the EDAC<sup>TM</sup> Quantifier has a higher sensitivity than conventional TCD, its use is limited to the detection of circuit microemboli and can not be used for systemic microemboli detection.

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**Computational Fluid Dynamics for Pediatric Surgical Planning and Fetal Hemodynamics**

Kerem Pekkan, PhD

Department of Biomedical Engineering, Carnegie Mellon University, Pittsburgh, Pennsylvania, USA

**Purpose:**

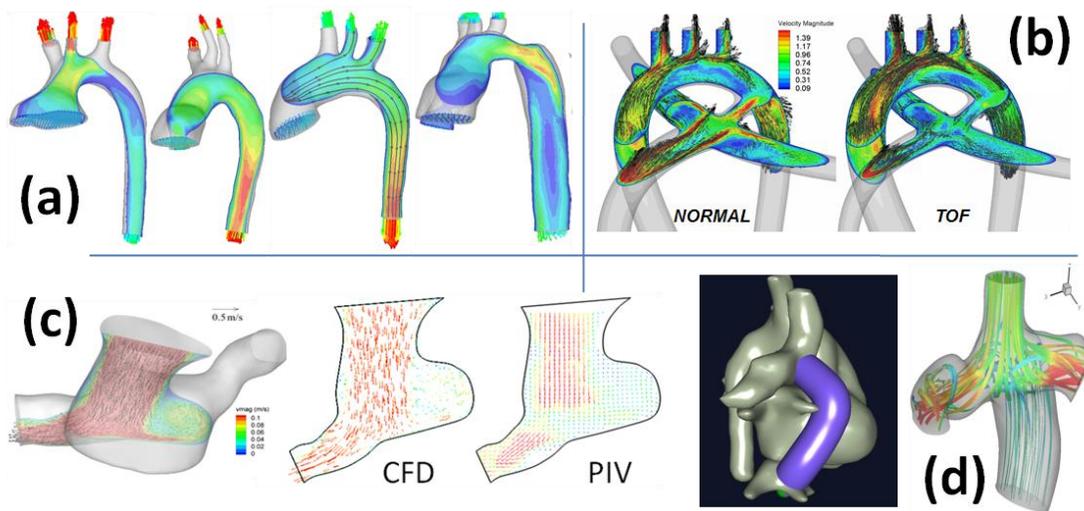
Each year, 8 out of 1000 babies born with a congenital cardiac defect (CHD). Neonatal survivors require three open heart surgeries by the age of two to palliate the otherwise fatal hypoxia and have to adapt to a less than optimal single-ventricle circulation. Although early post-surgery survival is improved considerably, morbidity in adult patients is frustrating. Bioengineering modeling of three-dimensional (3D) blood flow has played a significant role in the evolution of surgical designs and enabled recent improvements in pediatric devices. In this talk the state-of-the-art bioengineering computational fluid dynamics (CFD) models as applied to the surgical planning of pediatric congenital reconstructive surgeries (Fig a and d) and fetal hemodynamics (Fig b) will be reviewed. Specific challenges, *in vitro* experimental validation, *in vivo* prediction capability, as well as model verification requirements will be emphasized.

**Methods:**

Patient-specific image based modeling protocols, in-house and commercial solver capabilities, mesh generation, boundary conditions and computer aided design strategies will be presented through several case/research studies. Interactive complex 3D anatomical editing tools (Fig d) that are coupled to CFD analysis will be introduced.

**Results:**

The recent CFD studies, as applied to 2<sup>nd</sup> and 3<sup>rd</sup> stage repair, that investigated the hydrodynamic performance of common surgical templates will be presented (Fig c). More challenging applications from our current research include patient-specific modeling of neonatal cardiopulmonary bypass, embryonic aortic arch development and hepatic vein flow fields. In these applications, lumped-parameter-CFD coupled models are found to be useful in simulating the complex congenital circuits.



**Conclusions:**

Bioengineering CFD modeling once verified and experimentally validated provides quantitative temporal and spatial hemodynamic understanding of the reconstructed surgical pathway or the complex pediatric vascular morphology. Through patient-specific CFD analysis hemodynamic performance of different surgical templates could be compared. In addition, prediction of the post-op physiological state or off-design conditions; like exercise and respiration is possible using the baseline patient data. CFD analysis is also useful, in the fetal stages of the congenital heart defects, providing quantitative data on mechanical loading due to blood flow, and to quantify its impact on great vessel morphology. The future trend is towards CFD modeling in larger patient data-sets provided through multi-institute 3D anatomical reconstruction databases.

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**The Influence of Neurologic Monitoring on the Management of Pediatric  
Cardiopulmonary Bypass**

S. Kimatian MD, FAAP, K Saliba DO, X. Soler MD, E. Valentine MD, M. Coleman, A. Kunselman, G. Schuler, MSc, CCRC, J. Myers MD

Departments of Anesthesiology, Surgery, and Public Evaluation Sciences, Penn State College of Medicine, Hershey, Pennsylvania, USA

**Purpose:**

The objective of this study was to determine how the addition of neurologic monitoring impacted the optimization of hematocrit while on Cardiopulmonary Bypass (CPB) during pediatric cardiac surgery.

**Methods:**

During the period of 2002 to 2004, intra operative neurologic monitoring was integrated into the standard management of pediatric cardiac patients requiring CPB. Intra operative neurologic monitoring was modeled on the process described by Austin et al (Austin et al, Journal of Thoracic and Cardiovascular Surgery, Vol 114, No 5, 1997, pp707-715) and consisted of Near Infrared Spectroscopy (NIRS), Trans Cranial Doppler (TCD), and eight channel electroencephalography (EEG). During the period of time spanning 2001 to 2006 there were no other significant changes made to either the standard management of patients or the members of the surgical team (surgery, anesthesiology, nursing, or perfusion).

The data was collected by retrospective chart review of pediatric patients presenting for cardiac surgery requiring CPB in the years 2001 and 2006. Patient data from the 2001 group represented patient management prior to the implementation of intra operative neurologic monitoring; whereas the data from the 2006 group represented patient management after intra operative neurologic monitoring had been established as part of the protocol for managing pediatric patients on CPB.

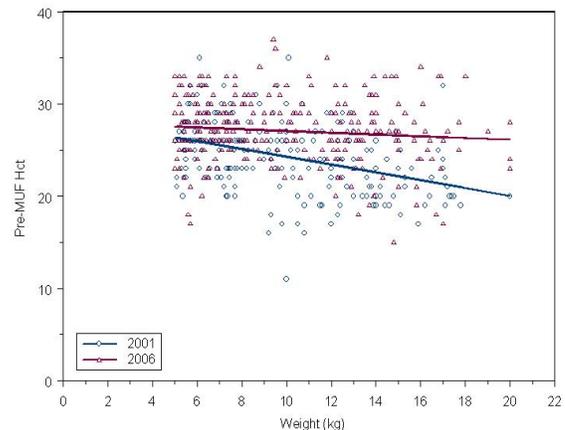
**Conclusions:**

The addition of intra operative neurologic monitoring was associated with a significant change in the management of pediatric patients on CPB. This is demonstrated by an increased use of donor blood in the CPB circuit prime and the maintenance of a higher hematocrit during the bypass period.

The benefits of a higher hematocrit during bypass have been suggested by examination of post operative neurologic function (Wypij et. al, The Journal of Thoracic and Cardiovascular Surgery, Volume 135, Number 2 2008, pp 355 - 360), and our study reinforces those findings in that the addition of intra operative neurologic monitoring resulted in a similar change in the management of CPB hematocrit.

**Results:**

Demographic comparison showed no significant difference in patient age, height, weight, or Jenkins classification at the time of surgery. Analysis of CPB management revealed a significant increase in the use of donor blood added to the CPB circuit prime, as well as in the maintenance of a higher hematocrit during the bypass period after the implementation of intra operative neurologic monitoring. A graphic representation (below) of the regression analysis of pre -modified ultrafiltration (MUF) Hct versus weight presents an example of the change in clinical management of the CPB hematocrit between the two groups.



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## **The Myocardial Protection of Histidine-Ketoglutarate-Tryptophan (HTK) Cardioplegic Solution on the Long-Term Ischemic Period in Pediatric Heart Surgery**

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Jinping Liu, M.D, Zhengyi Feng, M.D, Ju Zhao, M.D, Bo Li, Cun Long, M.D  
Department of Cardiopulmonary Bypass, Fuwai Hospital, CAMD & PUMS, Beijing, China, 100037;  
Email: [jinpingfw@hotmail.com](mailto:jinpingfw@hotmail.com)

### **Purpose:**

Myocardial protection plays a very important role during ischemic arrest for open heart surgery. Ischemia-reperfusion injury related to long term myocardial ischemia in complicated open heart surgery for infants may increase morbidity or mortality. Cardioplegic reperfusion during the long term ischemic period also will disturb cardiac surgeons. We reviewed the clinical experiences on myocardial protection of one single perfusion with a cardioplegic solution based on intracellular components added with histidine-ketoglutarate-tryptophan (HTK) for infants.

### **Methods:**

This retrospective study includes 118 infants who suffered from severe congenital heart disease undergoing open-heart surgery between January 2004 and December 2007. We divided the entire cohort into two groups: In group A (n=63), myocardial

protection was carried out with one single perfusion with HTK solution, and in group B (n=55) with conventional St.Thomas crystalloid cardioplegia. The duration of aortic cross-clamping time, cardiopulmonary bypass (CPB) time, the incidence of arrhythmias, the doses of inotropic agent, Creatine kinase values (units) on day 1, length-of-stay in the intensive care unit and mortality were evaluated.

### **Results:**

The duration of CPB did not differ between the group A and the group B, but the duration of aortic cross-clamping time in the group A was significantly shorter than that of in the group B ( $P<0.05$ ). During reperfusion, the spontaneous re-beating rate was higher in group A ( $P<0.05$ ). There was no difference on the doses of inotropic agent and Creatine kinase values between these two groups. The mortality in group A was lower than that of in group B ( $P<0.01$ ).

### **Conclusions:**

It was concluded that during long term myocardial ischemia in complex pediatric open-heart surgery, one single perfusion with HTK solution can effectively shorten aortic cross-clamping time and CPB time, and also can decrease incidence of arrhythmias and length-of-stay in the intensive care unit.

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## Surgical Repair of Tetralogy of Fallot with Absent Pulmonary Valve in an Infant with Sickle Cell Anemia

Joanne P. Starr\* MD, Meena Nathan\* MD, Joel Hardin\* MD, Peri Kamalakar# MD, Wondwessen Bekele #MD, Moshe Bell# MD, Srikanth Patankar\* MD, Elizabeth Cortez\* CCP, Stacey Rifkin# DO.

\*Children's Heart Center, #Pediatric Hematology and Oncology  
Children's Hospital of New Jersey at Newark Beth Israel Medical Center, Newark, NJ

### Introduction:

The association of congenital heart disease in infants with sickle cell anemia is rare. There are few reports in the literature describing the perioperative management of these infants. We present a case of a 13 month old male with Tetralogy of Fallot - absent pulmonary valve and sickle cell anemia who underwent surgical repair.

### Case Report:

A 13 month old, 9kg male diagnosed prenatally with Tetralogy of Fallot, absent pulmonary valve and sickle cell disease underwent surgery at our institution. He was born at 40 weeks and had no respiratory symptoms at birth, despite marked dilatation of pulmonary arteries. He remained asymptomatic from both a respiratory and cardiac standpoint. However, he required several hospital admissions for vaso-occlusive crises.

Based on a consensus opinion at a multidisciplinary meeting on the perioperative management of this patient, he was admitted two days prior to surgery for intravenous hydration. Transfusion was not necessary at this admission because he had received a transfusion a week prior to the surgical date.

In the operating suite, the cardiopulmonary bypass circuit was primed with 2 units of fresh frozen plasma, 3 units of packed red blood cells, 2000 units of heparin, 4.5 mg of furosemide, 270 mg solumedrol, 40 milliequivalents of sodium bicarbonate, 400 mg of calcium chloride, 25cc of 25% albumin and 1000 mg of Amicar. The patient was systemically heparinized with 300 IU/kg of heparin and was cannulated via the ascending aorta, inferior and superior cavae. Upon commencement of bypass an exchange transfusion approximately equal to one blood

volume (700-750cc) was performed. He was cooled to 34°C once on bypass. During bypass, high flow rates were maintained, arterial saturation were 100% and venous saturations were kept as close to 90% as possible. The serum pH was maintained between 7.32 to 7.45. The mean hematocrit was 28% (range 26-34%). Cardioplegia (4:1 crystalloid to blood) was administered via the aortic root starting out at 34°C and cooling slowly to 18° C. Two additional doses were administered during the cross clamp period. A complete repair of the cardiac defect was performed. Post bypass the patient received platelets, fresh frozen plasma, and cryoprecipitate for hemostasis. Hemoglobin electrophoresis was sent prior to bypass, directly after exchange and after bypass.

Postoperatively, the hematocrit was maintained between 28-32%. He had an uneventful postoperative course and was discharged on the 8<sup>th</sup> postoperative day. On last follow up 1 month post discharge, the patient was doing well.

### Discussion:

Patients with sickle cell anemia and congenital heart defects that require surgical correction are at greater risk for perioperative complications, specifically acute chest syndrome and stroke. In order to avoid a sickling crisis a reduction of HbS to <30% is required. This can be achieved either pre or intraoperatively by exchange transfusion. Because of the patient's size, an exchange transfusion was performed at the commencement of bypass. We achieved a more than adequate reduction in HbS that lasted well into the postoperative period. In addition to exchange transfusion, high flow rates, avoidance of significant hypothermia/acidosis/hypoxemia are essential.

	1 month Preop	Pre exchange	Post exchange	Post CBP	Postoperative day 1	Postoperative day 9
HbS	49.6%	42.7%	5.3%	5.5%	4.2%	22.5%
Hematocrit	28.2%	27%	26%	33%	30.3%	32.1%

### Conclusions:

Exchange transfusion performed on commencement of bypass allows safe conduct of complex congenital heart surgery in infants with sickle cell anemia and mitigates the occurrence of postoperative complications.

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## Thyroid Hormones Homeostasis in Pediatric Patients During and After Cardiopulmonary Bypass: Is There a Difference Between the Pulsatile and Nonpulsatile Perfusion Modes?

Alkan-Bozkaya T., Akcevin A., Ündar A., Türkoğlu H., Paker T., Aytaç A.  
V.K.V. American Hospital, Dept. of Cardiovascular Surgery, Istanbul, TURKEY and Penn State University,  
Children's Hospital, Hershey, PA, USA

### Purpose:

This study was undertaken to evaluate the effects of cardiopulmonary bypass (CPB) on the thyroid hormones of neonates undergoing open heart surgery according to two different -pulsatile and nonpulsatile - perfusion modes.

### Methods:

100 consecutive pediatric patients undergoing open heart surgery for repair of congenital heart disease were prospectively entered into the study and were randomly assigned to either the pulsatile perfusion group (Group P, n = 50) or the nonpulsatile perfusion group (Group NP, n = 50). All patients received identical surgical, perfusional, and postoperative care. Thyroid-stimulating hormone (TSH) and thyroid hormones (TotalT3-T4, FT3, FT4) were measured by radioimmunoassay. Blood samples were obtained from 100 neonates before, during and after CPB (postoperative 24-72 hours and 1<sup>st</sup> week).

Study parameters included thyroid hormones changes, intubation time, duration of ICU and hospital stay, the need for inotropic support. Major complications and clinical outcome were documented.

### Conclusions:

We conclude that pediatric patients undergoing CPB significant changes in thyroid hormone metabolism similar to adult patients. The exact mechanism responsible for causing the changes of thyroid homeostasis is not clear. We compared to our results according to pulsatile and nonpulsatile perfusion modes of CPB. These results indicate that the normal thyroid hormones homeostasis and improved patient outcome may be provided by the use of pulsatile perfusion mode.

### Results:

Mean preoperative thyroid hormones levels were similar for two groups. TSH, Total T3-T4 and FT3-FT4 levels were markedly reduced versus their preoperative values in both groups. FT3 and FT4 levels were less reduced in pulsatile group significantly during CPB and postoperative 72 hours. Thyroid hormones changes after CPB were as follows in the pulsatile (Group P) and nonpulsatile perfusion group (Group NP) respectively:

FT3, during CPB  $2.27 \pm 0.6$  pg/mL vs  $1.33 \pm 0.2$  pg/mL ( $p < 0.00017$ ), postoperative 72 h  $2.35 \pm 1.21$  pg/mL vs  $1.98 \pm 1.34$  pg/mL ( $p < 0.0041$ ), FT4, during CPB  $1.72 \pm 0.19$  ng/dL vs  $0.62 \pm 0.14$  ng/dL ( $p < 0.0023$ ), postoperative 72 h  $1.86 \pm 0.8$  ng/dL vs  $1.71 \pm 0.6$  ng/dL ( $p < 0.0038$ ).

There were no significant differences in other hormones levels between 2 groups early postoperative period.

The Group P, compared to Group NP, had significantly less inotropic support (number of agents  $1.53 \pm 1.02$  vs  $2.56 \pm 1.03$ ,  $p = 0.0015$ ; dopamine  $7.23 \pm 3.27$  vs  $11.3 \pm 4.2$   $\mu\text{g/kg/min}$ ,  $p = 0.0018$ ; dobutamine  $5.45 \pm 4.55$  vs  $7.03 \pm 6.1$   $\mu\text{g/kg/min}$ ,  $p = 0.035$ ), less intubation period ( $15.26 \pm 10.21$  vs  $19.41 \pm 14.56$  hours,  $p = 0.045$ ), less duration of ICU ( $2.12 \pm 1.02$  vs  $3.34 \pm 1.26$  days,  $p = 0.043$ ) and hospital stay ( $7.34 \pm 2.12$  vs  $9.41 \pm 3.18$  days,  $p = 0.005$ ).

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## **Routine Mechanical Ventricular Assist Following the Norwood Procedure Improved Cerebral Perfusion**

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Jamie You, CCP. Brian Mejak, CCP. Carmen Giacomuzzi, CCP. Eileen Heller, CCP. Ross Ungerleider, MD. Karl Welke, MD  
Division of Pediatric Surgery, Doernbecher Children's Hospital, Oregon Health & Science University Portland, Oregon, 97239

### **Background:**

Previous studies have demonstrated excellent survival following the Norwood procedure for palliation of hypoplastic left heart syndrome (HLHS) by the routine use of a ventricular assist device. However, assessment of adequate cerebral perfusion remains a challenge after surgery. The present study used near infrared pectroscopy (NIRS) to measure the cerebral oxygen saturation (ScO<sub>2</sub>) peri-operatively. Other parameters including the somatic NIRS oxygen saturation (SsO<sub>2</sub>), lactic acid, and mean arterial pressure (MAP) were also assessed during the period ventricular assist device (VAD) support.

### **Methods:**

Twenty-nine consecutive infants, with an average age of 14.3±21.6 days and an average weight of 3.3±0.6 kg, undergoing Norwood operation for HLHS were routinely placed on a ventricular assist device (VAD) immediately following modified ultrafiltration. We used the pre-existing cannulas from cardiopulmonary bypass (CPB) that were in the right atrium and the neo-aorta to support the patients on ventricular assist. VAD flows were maintained at approximately 146.9±31.1 mL /kg/min. The duration of VAD averaged 50.5 ± 40.7 hours. ScO<sub>2</sub>, SsO<sub>2</sub>, MAP and lactic acid were continuously monitored from time of intubation to withdrawal of VAD support. Data from

the post-induction period to 24-hour postoperatively were analyzed. Data points collected included ten minutes prior to CPB, ten minutes prior to termination of CPB, MUF, time before VAD initiation, and hourly measurements on VAD.

### **Results:**

Average MAPs for the study were 35.0±6.9 mmHg (pre-CPB), 46.0±9.8 mmHg (prior to VAD initiation), 64.4±8.5 mmHg (two hours post-VAD), and 51-54mmHg for the duration of the first twenty four hours on VAD support. Baseline ScO<sub>2</sub> values were 60.5±12.4 % and rose to an average of 72.0±13.1 % on CPB. ScO<sub>2</sub> prior to VAD initiation was 47.0±13.0 % and increased to 49.9±12.1 % upon initiation. ScO<sub>2</sub> values dropped to its lowest point (45.6±13.3 %) after two hours of ventricular assist but were significantly higher (P<0.01) at hour 12 of support (45.6±13.3% vs. 55.1±9.3%). SsO<sub>2</sub> values ranged from 65.7 ±9.2 to 75.4±7.1 % during the twenty four hour study period. Lactic acid levels peaked following modified ultrafiltration at 6.8±2.2 mmol/L, but dropped significantly (P<0.01) to pre-operative levels (1.9±0.8 mmol/L) by hour 18 of VAD support (2.1±0.7 mmol/L). All patients were successfully weaned off VAD. The hospital survival rate was 82%.

### **Conclusion:**

ScO<sub>2</sub> continually increased during the first twenty-four hours of routine postoperative VAD following the Norwood operation. In addition to increased ScO<sub>2</sub>, tissue perfusion was improved during VAD support reflected by decreasing lactate levels and stabilized SsO<sub>2</sub> levels. It could simplify postoperative management, lead to excellent hospital survival, and augment cerebral oxygen delivery, resulting in improved neurologic outcomes for this challenging group of patients.

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**Development of an Ultra-Durable Heparin-Free Pediatric ECMO System at the National Cardiovascular Center of Japan**

Eisuke Tatsumi, MD, Nobumasa Katagiri, MS, Toshihide Mizuno, DVM, Yoshiaki Takewa, MD, Tomohiro Tsukiya, PhD, Akihiko Homma, PhD, Yoshiyuki Taenaka, MD, Teruyuki Hayashi, CCP, Toshikatsu Yagihara, MD  
Departments of Artificial Organs, Department of Surgery, National Cardiovascular Center, Suita, Osaka, JAPAN

**Background:** Extracorporeal membrane oxygenation (ECMO) is a potent therapeutic option in treating the patients with life threatening severe respiratory and/or circulatory failure. This modality is extremely important especially in pediatric cases. The current system, however, has inherent limiting barriers to its extensive use: 1) poor durability due to plasma leak in long-term use, and 2) poor antithrombo-genicity that necessitates systemic heparinization. At the National Cardiovascular Center of Japan, an ultra-durable heparin-free ECMO system has been under development.

**Methods:** Our ECMO system consists of a compact leakless oxygenator, and a sealless durable centrifugal pump. The oxygenator is made of special hollow fiber membrane in which micropores are blind-ended at the blood contacting surface to prevent plasma leak. There are three different sizes of oxygenators: maximum blood flow for S-size (infant size), M-size (child size) and L-size (adult size) are 2, 4 and 6 L/min, respectively. Total priming volume of the S-size circuit is only 147 ml. The entire

blood-contacting surface is coated with a novel heparin-bonding material (T-NCVC coating) to impart extremely potent antithrombo-genicity for long-term. Heparin-free veno-arterial bypass ECMO was carried out in chronic animal experiments using 19 goats weighing from 20–64 kg. Systemic anticoagulation was not conducted at all, except for one-shot heparin injection at cannulae insertion.

**Results:** Over one month (34-92 days) heparin-free ECMO could run in 18 out of 19 animals until elective termination. In these animals gas-exchange function was kept stable at sufficient level throughout the experiments. Plasma leak was not observed in any case. Platelet count, ACT, APTT, and fibrinogen were kept normal, and the blood heparin level was always less than measurable level. In postmortem examination, some clots were seen at the inlet and outlet of oxygenator where the blood tended to be relatively stagnant, but the fiber bundle was always surprisingly clean. The other parts of the circuit were free of thrombus formation.

No.	Body weight (kg)	Oxygenator size	Bypass Flow (L/min)	Systemic anticoagulation	Device failure/ Plasma leak	Condition	Duration (days)
1	30	S	1.5 – 1.6	no	no	good	67
2	20	S	1.4 – 1.6	no	no	good	50
3	41	M	2.0 – 2.9	no	no	good	42
4	45	M	1.7 – 3.2	no	no	good	65
5	60	M	2.9 – 3.3	no	no	good	43
6	58	L	2.0 – 2.2	no	no	good	36
7	60	L	2.0 – 2.5	no	no	good	60
8	41	L	1.7 – 2.4	no	no	good	71
9	59	L	1.8 – 2.8	no	no	good	34
10	60	L	2.0 – 2.5	no	no	good	39
11	50	L	2.0 – 2.8	no	no	good	36
12	54	L	1.9 – 2.3	no	no	good	40
13	53	L	1.9 – 2.3	no	no	good	35
14	56	L	2.4 – 2.6	no	no	good	66
15	64	L	2.4 – 2.7	no	no	good	92
16	56	L	2.4 – 2.6	no	no	good	37
17	56	L	2.4 – 2.6	no	no	good	36
18	50	L	2.3 – 2.6	no	no	infection	14
19	52	L	2.2 – 2.6	no	no	good	37

**Conclusions:** In Japan, the adult size system has been already applied to the patients with bleeding complications as heparin-free prolonged ECMO, and demonstrating excellent clinical outcomes. We conclude that our ECMO system has an ability to be used for over-a-month cardiopulmonary support with minimum or without systemic heparinization.

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**Coagulation Times and Heparin Management for Pediatric Patients  
Requiring Extracorporeal Membrane Oxygenator Support**

Timothy M. Maul, PhD<sup>1,2,3</sup>, Erin L. Wacker, BS<sup>1,2,3</sup>, Kent, Kelly, CCP<sup>1</sup>, Victor O. Morell, MD<sup>1</sup>, Peter D. Wearden, MD, PhD<sup>1,3</sup>

Departments of Cardiac Surgery, Children's Hospital of UPMC<sup>1</sup>, Bioengineering, University of Pittsburgh<sup>2</sup>, and the McGowan Institute for Regenerative Medicine<sup>3</sup>, Pittsburgh, Pennsylvania, USA

**Purpose:**

Extracorporeal membrane oxygenator (ECMO) support for pediatric cardiac surgery patients both pre- and post-operatively has provided adequate survival for congenital defects. However, comorbidities, including bleeding and thromboembolism, remain significant clinical challenges. Traditionally, heparin management has been monitored with activated clotting times (ACTs). However, for low clotting times, partial thromboplastin times (PTTs) may be more accurate. The purpose of this study was to analyze the relationships between heparin dosing for seventeen pediatric patients on ECMO and point of care (POC) ACT and PTT values, as well as laboratory PTT values.

**Methods:**

POC ACTs and PTTs (Hemochron Jr.), laboratory PTTs and heparin dosing were recorded for seventeen

pediatric patients during ECMO support. Values for the first three hours of support were eliminated because they were artificially elevated from pre-operative heparin administration. Spearman's ranked correlations were performed for each coagulation test compared to heparin dosage. The ECMO circuit for all patients consisted of 8 feet of either 3/8" or 1/4" diameter Carmeda™ coated tubing and hollow fiber oxygenator (Medtronic). Each 1/4" circuit was primed with 700mL PlasmaLyte containing 1 unit of packed RBCs, 30mL Tham and 10mL NaHCO<sub>3</sub> (volumes doubled for 3/8" circuits).

**Results:**

The average ECMO support time was 147.9 ±45.0 hours for patients with an average age and weight of 3.7±1.6yrs and 13.0±4.3kg, respectively. The following table represents the correlation results.

Coagulation Test	Average	Standard Deviation	Samples	Correlation to heparin dose (units/kg/hr)	Significance
POC ACT	145 sec	41 sec	827	$\rho=0.129$	$p<0.0001$
POC PTT	121 sec	95 sec	519	$\rho=0.653$	$p<0.0001$
Lab PTT	101 sec	36 sec	623	$\rho=0.429$	$p<0.0001$

**Conclusions:**

Although each coagulation test showed significant correlation with the heparin dose, only the PTT showed a minor linear correlation. Furthermore, there was little correlation between ACT and PTT ( $\rho=0.339$ ). Seemingly contrary to historical data, our results may be reflective of the current clinical trend of maintaining low clotting times to minimize bleeding complications through the use of heparin-bonded surfaces. Future studies will attempt to better model patient coagulation status through a multi-parameter statistical model.

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## **Different Albumin Concentration in Extracorporeal Circuit Prime on Perioperative Fluid Status in Young Children**

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Kun Yu, Yinglong Liu, Feilong Hei, Jingping Liu, Zhengyi Feng, Jingwen Li, Cun Long  
Division of Cardiothoracic Surgery, Extracorporeal Circulation, Cardiovascular Institute and Fuwai Hospital CAMS  
and PUMS Beijing 100037, PRC

### **Objective:**

To determine the effects of different dosage of albumin priming for extracorporeal circuit on perioperative fluid status and fluid management in young children.

### **Method:**

151 consecutive cases pediatric patients of 2 months to 36 months years old scheduled for open heart surgery were studied, divided into 2 groups randomly, accepted albumin for acute hemodilution, priming of the heart lung machine, the final albumin concentration were adjusted to 5% (H group, n=83) and 3% (L group, n=68) respectively. Perioperative fluid intake, output, blood loss, diuretic dosage, the use of allogeneic blood products, ultrafiltration, and daily balance were recorded until post operation day 2. Serial hematocrits, colloid osmotic pressure were

measured. Outcomes and complications were documented.

### **Results:**

Patients in both groups had a net positive fluid balance at the end of operation, and a net negative fluid balance post operation. There were no significant differences in hemodynamic parameters, blood loss, the amount of allogeneic blood products and albumin infused after operation between two groups. Patients in H group had significantly higher colloid osmotic pressures, lower hematocrits, less fluid intake, less urine output and during operation and postoperatively ( $P < 0.05$ ), by 6hrs postoperatively, there were no differences between two groups. The amount diuretic agent after operation in group H was more ( $P < 0.05$ ). No significant differences were found in length of mechanical ventilation, intensive care unit or hospital stay, complications, or mortality.

### **Conclusions:**

Higher concentration of albumin prime in extracorporeal circuit may have an effect of attenuate the extravasation of fluid out of the vascular space, but no significant clinical benefit.

### **Key Words:**

pediatrics; extracorporeal circuit; colloids; cardiac surgery; postoperative

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## A Performance Evaluation of Eight Geometrically Different 10 FR Pediatric Arterial Cannulae Under Pulsatile vs. Non-Pulsatile Perfusion in an Infant CPB Model

Alan R. Rider, Bingyang Ji, MD, Allen Kunselman, MA, William J. Weiss, PhD, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, Bioengineering, and Health Evaluation Sciences,  
Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

### Purpose:

The purpose of this investigation is to compare eight commercially available pediatric aortic cannulae with different geometry during pulsatile vs. non-pulsatile perfusion in terms of pressure drops and surplus hemodynamic energy (SHE) level in an in vitro infant CPB model.

### Methods:

The experimental set-up is composed of two parts. The first part is the CPB circuit, which is identical with our clinical set-up in the operating room. The second part is the simulated Penn State neonatal patient. One of eight cannulae is attached at the distal end of the arterial line, while the insertion tip of the cannula is fixed to the "aorta" of the simulated patient. The pseudo patient was subjected to seven different pump flow rates at 100 ml/min

increments in the 400 to 1000 ml/min range and the mean arterial pressure (MAP) is set at a constant 40 mmHg via Hoffman clamp. A 20 second segment of the pressure and flow waveforms with non-pulsatile flow are then recorded at the pre-cannula and post-cannula sites. The perfusion mode is then switched to pulsatile flow. The following formula is used to calculate the SHE levels.

$$SHE \text{ (ergs/cm}^3\text{)} = 1332 [((\int p dt) / (\int f dt)) - MAP]$$

(*f* = flow, *p* = pressure)

### Results:

The following table represents pressure drops and SHE level results of these eight arterial cannulae (Mean ± SD) at the pre-cannula and post-cannula sites with a pump flow rate of 600 ml/min. The others flow rates have similar patterns.

Type of Cannula	Cannula pressure drop (mmHg)		SHE (Pre-Cannula) (ergs/cm <sup>3</sup> )		SHE (Post-Cannula) (ergs/cm <sup>3</sup> )	
	NP	P	NP	P	NP	P
RMI (Long Tip)	21.2±1.0	27.6±1.2	2,759±158	*20,250±791	111±57	*871±368
Terumo	22.6±0.4	29.0±0.4	2,889±61	*18,955±536	117±55	*751±332
DLP (Long Tip)	22.8±0.8	28.0±1.3	2,961±79	*19,338±1613	88±34	*623±188
DLP (Short Tip)	22.3±0.2	29.3±0.2	2,924±24	*20,449±265	92±19	*717±145
Jostra	27.6±1.2	33.6±1.0	2,877±74	*18,450±258	74±44	*501±269
Polystan	32.6±0.3	38.5±0.5	2,847±37	*17,789±479	82±31	*571±197
THI	42.8±1.3	48.3±1.4	2,748±41	*16,641±600	48±32	*271±185
Surgimedics (Short Tip)	43.3±0.5	48.8±0.3	2,796±46	*17,143±625	35±8	*218±44

\* *p*<0.001, P vs. NP

### Conclusions:

The results suggest that the different geometries of the aortic cannulae have a significant impact on the pressure drops of the cannulae as well as hemodynamic energy generation and delivery. Pulsatile perfusion produces more "extra" hemodynamic energy compared to the non-pulsatile perfusion mode with all eight cannulae used in this study. This model allows objective assessment of new cannulae as they are designed so that the surgeon can choose cannulae with the "best" hemodynamic profile.

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**Postoperative Hemodynamics After Cardiopulmonary Bypass in Newborn Piglets**

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Theodor Tirilomis, PhD, Lars Nolte, Oliver J. Liakopoulos, PhD, Carola Ballat, Katja Steinke, MD, Marc Bensch, PhD, Friedrich A. Schoendube, PhD

Department for Thoracic, Cardiac, and Vascular Surgery, University of Goettingen, Goettingen, Germany

**Purpose:**

Depression of cardiac function is frequently observed during the first hours after heart surgery resulting in inotropic support for treatment and prevention of further hemodynamic deterioration. The aim of this study was analysis of hemodynamics early after cardiopulmonary bypass in a neonatal animal model without use of inotropic drugs.

**Methods:**

Ten newborn piglets (younger than 7 days) were placed on mild hypothermic CPB (32°C) for 180 minutes, including 90 minutes of cardioplegic arrest. Hemodynamics were examined after termination of CPB and according to the protocol none of the

animals received any inotropic support. After 6 hours survived animals were euthanized (CPB group, n=4). For control, neonatal piglets were examined for the same time interval after surgery without CPB (control group, n=3).

**Results:**

Systolic left-ventricular pressure ( $LVP_{syst}$ ) increased after CPB and was higher in CPB group vs. control group ( $p<0.05$ ). In both groups there was a trend of decreased mean arterial blood pressure (MAP) and regional myocardial contractility (amplitude of wall thickness) after surgery, but differences did not reach statistical significance.

**Conclusions:**

Present data suggest that hemodynamic depression early after heart surgery is more attributed to the surgical trauma than to CPB. Effects may be potentiated by CPB use.

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**Reducing Gaseous Microemboli During Pediatric Perfusion: Case Studies  
with the EDAC™ QUANTIFIER**

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Ted Lynch, PhD  
Luna Innovations Incorporated, Hampton, Virginia, USA

**Purpose:**

To show that real-time monitoring for gaseous microemboli (GME) with the EDAC QUANTIFIER™ may reduce the number of GME that pass the arterial line filter during bypass.

**Methods:**

A review of the literature was performed to showing that choice of circuit components, priming technique, methods of venous drainage and other surgical events, perfusionist interventions such as drug injections and blood sampling, and errors in circuit setup have all been associated with the generation of GME during bypass. Moreover, this search revealed that higher emboli counts during bypass surgery are associated with poor patient outcomes. In one study patients in which greater than 500 emboli were detected during bypass surgery had an average length of stay of 55.8 days while patients with less than 100 emboli detected had an average length of stay of 8.6 days. Stroke rate, cardiac complications were also

associated with higher emboli counts, while other studies have shown the emboli counts are associated with higher rates neurological deficits as measured by neuropsychological testing. Next, events associated with increased GME were simulated during closed loop and animal model tests using the EDAC™ QUANTIFIER to monitor the bypass circuit at three locations. Additional observations from recent clinical tests of the EDAC™ QUANTIFIER on pediatric cases will also be presented.

**Results:**

Laboratory tests shown in the presentation clearly illustrate the impact the EDAC™ QUANTIFIER can have in reducing embolic counts and volume during circuit priming and during perfusionist interventions such as drug injection or blood sampling. Examples of venous line air introduced during surgery will be provided from three pediatric cases.

**Conclusions:**

Simulations of GME introduction into the bypass circuit provide case studies showing how data from the EDAC™ QUANTIFIER may be used to adjust surgical and perfusionist technique to minimize GME delivered to the patient during bypass and improve patient outcomes.

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## Comparison of Two Different Blood Pumps on Delivery of Gaseous Microemboli During Pulsatile and Non-Pulsatile Perfusion in a Simulated Infant CPB Model

Shigang Wang, MD, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, and Bioengineering  
Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

### Purpose:

The purpose of this study was to compare two different blood pumps (Jostra roller pump vs. Medos deltastream DP1 rotary pump) on delivery of gaseous microemboli during pulsatile and non-pulsatile perfusion in a simulated infant CPB model.

### Methods:

The Jostra roller pump and Medos deltastream DP1 rotary pump were used in parallel pattern. The circuit was primed with lactated ringer's solution (650 ml) and post-filter pressure was maintained at 100 mmHg using a Hoffman clamp. Three transducers (post-pump, post-oxygenator and post-filter sites) of the Emboli Detection and Classification (EDAC™) Quantifier were inserted into the CPB circuit to detect and classify gaseous microemboli. Trials were conducted at flow rates ranging from 500-1250 ml/min (250 ml/min increments). The purge line of the arterial filter was kept open during all trials. After injecting 20 cc

air into the venous line via an 18G needle, 2-minute segments of data were recorded simultaneously through three transducers. This entire process was repeated six times for each unique combination of blood pump, flow rate and perfusion mode, yielding a total of 96 experiments.

### Results:

Independent of perfusion mode and flow rate, Medos rotary pump delivered significantly less gaseous microemboli at the post-pump site. There was no difference in delivery at the post-filter site. Compared with non-pulsatile flow, pulsatile flow transferred more gaseous microemboli at the post-pump site at all four flow rates with Jostra and Medos pump. The majority of gaseous microemboli were trapped by the Capiiox Baby-RX hollow-fiber membrane oxygenator. The following table represents the total microemboli count at different flow rate with pulsatile and non-pulsatile using Jostra roller pump and Medos rotary pump.

Results of the Total Microemboli Count at Post-pump, Post-oxygenator and Post-filter sites at different flow rates with Non-pulsatile vs. Pulsatile using Jostra roller pump and Medos rotary pump

Pump Flow (ml/min)	Blood Pump	Post-pump		Post-oxygenator		Post-filter	
		NP	P	NP	P	NP	P
500	Jostra	18.2±7.0	22.5±16.3	0.3±0.8	0.2±0.4	0.0±0.0	0.0±0.0
	Medos	7.7±6.0	17.7±15.2	0.0±0.0	0.0±0.0	0.0±0.0	0.0±0.0
750	Jostra	69.3±18.3	128.5±19.8	1.2±1.2	1.3±1.2	0.0±0.0	0.0±0.0
	Medos	37.0±7.9	60.0±21.9	0.7±1.2	1.0±1.7	0.0±0.0	0.0±0.0
1000	Jostra	236.0±39.8	344.3±50.3	8.8±4.3	6.7±3.8	0.5±1.2	0.3±0.5
	Medos	134.2±32.4	229.3±26.1	4.2±3.3	6.3±1.5	0.0±0.0	0.2±0.4
1250	Jostra	1449.0±219.6	*3200.7±428.1	41.3±7.3	44.8±7.8	1.7±1.0	1.5±1.5
	Medos	†808.0±107.3	*†1311.2±234.3	†21.2±5.0	†25.8±6.4	1.0±1.3	0.3±0.5

NP=Non-pulsatile P=Pulsatile \* P < 0.01 P vs. NP † P < 0.01 Jostra vs. Medos

### Conclusions:

The results of this study confirm that rotary pump could deliver less gaseous microemboli than roller pump at the post-pump site when a fixed volume air is introduced into the venous line. Pulsatile flow could transfer more gaseous microemboli at post-pump site, no matter which blood pump was used. The majority of gaseous microemboli were trapped by the Capiiox Baby-RX hollow-fiber membrane oxygenator. Only few gaseous microemboli appeared at post-filter site at high flow rates with an open arterial filter purge line.

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**The Capability of Trapping Gaseous Microemboli of Two Pediatric Arterial Filters with Pulsatile and Non-pulsatile Flow in Simulated Infant CPB Model**

Shigang Wang, MD, Khin N. Win, BS, Karl Woitas, CCP, John L. Myers, MD, Akif Ündar, PhD  
Pediatric Cardiac Research Laboratories, Departments of Pediatrics, Surgery, and Bioengineering  
Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

**Purpose:**

With the aid of new gaseous microemboli detector - Emboli Detection and Classification (EDAC™) Quantifier, it is possible to test performance of trapping bubbles of the arterial filter in extracorporeal circuit. The objective of this study is to test the capability of trapping gaseous microemboli of Medtronic Affinity and Terumo Capiiox pediatric arterial filters in a simulated infant cardiopulmonary bypass (CPB) model.

**Methods:**

Medtronic Affinity and Terumo Capiiox pediatric arterial filters were used in parallel pattern. The circuit was primed with lactated ringer's solution (700 ml) and post-filter pressure was maintained at 100 mmHg using a Hoffman clamp. Two transducers (pre-filter and post-filter sites) of EDAC™ Quantifier were inserted into the CPB circuit to detect and classify gaseous microemboli. Trials were conducted at flow rates ranging from 500-1,250 ml/min (250 ml/min increments). The purge line of the arterial filter was kept open during all trials, and the oxygenator

was bypassed. After introducing 20 cc air into the venous line via an 18G needle, 2-minute segments of data were recorded simultaneously through two transducers. This entire process was repeated six times for each unique combination of arterial filter, flow rate and perfusion mode, yielding a total of 96 experiments.

**Results:**

More than 80% of gaseous microemboli at the inlet of the filters were trapped by the two pediatric arterial filters. With increased flow rates and pulsatile mode, more gaseous microemboli passed through the arterial filter in the setting of an open arterial purge line, and the percentages of trapping microemboli decreased. There were no differences in term of the percentage of trapping gaseous microemboli and pressure drops between Medtronic Affinity and Terumo Capiiox pediatric arterial filters. The following table represents total emboli counts at the inlet and outlet of Medtronic and Terumo pediatric arterial filters at different flow rates with pulsatile and non-pulsatile flow.

Total emboli counts at the inlet and outlet of Medtronic and Terumo pediatric arterial filters

Pump Flow (ml/min)		Medtronic Affinity			Terumo Capiiox		
		Inlet	Outlet	Trap (%)	Inlet	Outlet	Trap (%)
500	NP	27.5±10.7	0.3±0.5	98.1±3.6	25.5±11.9	0.7±0.8	98.1±2.4
	P	27.8±9.3	0.7±0.8	97.2±3.7	27.7±10.1	0.2±0.4	99.2±1.9
750	NP	86.8±10.3	13.5±6.3	84.8±5.7	82.0±17.1	11.5±7.6	86.0±7.7
	P	144.3±53.2	†20.3±6.0	84.4±6.1	161.2±44.1	†16.3±3.5	89.0±4.5
1000	NP	313.7±25.9	†60.0±7.8	80.7±3.2	318.3±51.9	†55.2±11.1	82.5±3.6
	P	345.5±31.6	†58.0±9.0	83.1±3.2	335.5±24.3	†59.3±10.2	82.3±3.0
1250	NP	1230.8±95.4	†262.8±37.7	78.7±2.4	1180.8±103.4	†249.7±36.1	78.9±1.6
	P	*1384.8±139.4	†297.7±38.9	78.5±1.1	*1326.2±77.8	†277.2±20.4	79.1±1.2

NP=Non-pulsatile P=Pulsatile \* P < 0.05 NP vs. P † P < 0.05 Inlet vs. Outlet

**Conclusions:**

The results of this study demonstrated that Medtronic Affinity and Terumo Capiiox pediatric arterial filters could trap the majority of gaseous microemboli in the setting of an open arterial filter purge line in a simulated infant CPB circuit with pulsatile and non-pulsatile flow.

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**Fetal Surgical Management of Congenital Heart Block in a Hydropic Fetus:  
Lessons Learned from a Clinical Experience**

Pirootz Eghtesady, MD, PhD, Erik Michelfelder, MD, Timothy K. Knilans, MD, Jeffrey Livingston, MD, Peter B. Manning, MD, and Timothy Crombleholme, MD, PhD  
Pediatric Cardiac Surgery, Pediatric Cardiology and The Fetal Care Center of Cincinnati, Cincinnati Children's Hospital, Cincinnati, Ohio, USA

**Purpose:**

Hydrops fetalis due to fetal bradycardia, usually secondary to complete heart block (CHB) is a rare and potentially fatal condition. Medical management of this condition has had limited success. Although a few have attempted fetal pacing, there are no reports of survival beyond the intra-operative period. The purpose of this report is to share some valuable lessons learned from a unique clinical experience.

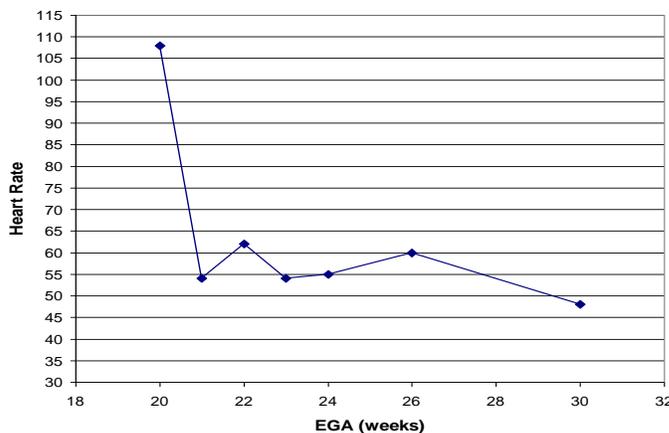
**Case History:**

A 32 year-old G1P0, with systemic lupus erythematosus and anti-Ro and anti-La antibodies, was referred to our institution for suspected CHB and small pericardial effusion at 22 wks gestation. Fetal echocardiogram showed apparent absence of atrial mechanical activity and a ventricular rate of 54 beats/minute and diffuse predominantly atrial endocardial fibroelastosis with preserved ventricular systolic function. Worsening fetal hydrops occurred as the ventricular rate progressively

slowed to 38 beats/minute, despite maternal steroid and beta-mimetic treatment. At 29 Weeks gestation, the parents elected to undergo open fetal surgery for placement of a fetal cardiac pacemaker.

**Results:**

Maternal hysterotomy and fetal anterior thoracotomy were performed to place a unipolar pacing lead on the fetal left ventricle. Intravenous dobutamine was used to augment fetal cardiac output during the procedure. Continuous fetal echocardiography during the procedure demonstrated doubling of the combined ventricular output with activation of pacemaker at a rate of 65 beats/minute. Postoperative course was complicated by persistent oligohydramnios, but serial fetal echocardiograms demonstrated adequacy of fetal cardiac output. On post-operative day 5, fetal demise was noted. Autopsy demonstrated evidence of sub-acute multi-organ injury particularly in the fetal kidney and liver which appeared antecedent to fetal intervention.



**Conclusions:**

Successful fetal pacemaker placement is feasible for the fetus with medically refractory bradycardia. Intervention, however, should be performed before multi-organ injury has occurred. Special consideration should be given to techniques and strategies required for this complex multi-team procedure.

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**Enteroviral Sepsis and Ischemic Cardiomyopathy in a Neonate**

Meena Nathan MD, Rowan Walsh MD, Joel Hardin MD, Stanley Einzig MD, Brian O Connor MD, Duraisamy Balaguru MD, Rajiv Verma MD, Joanne Starr MD  
Division of Pediatric Cardiac Surgery, Division of Pediatric Cardiology, Children's Hospital of New Jersey at Newark Beth Israel Medical Center, Newark, NJ

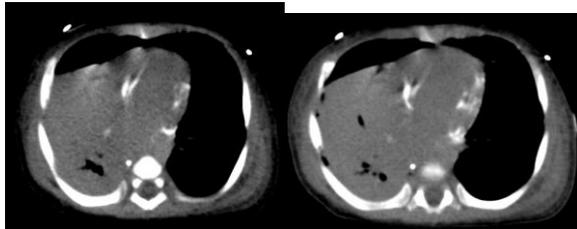
**Introduction:** Neonatal entero-viral sepsis is a rare but fulminant infection with multisystem involvement, often presenting with hepatitis, meningo-encephalitis, disseminated intravascular coagulation (DIC), and myocarditis. Neonatal myocarditis often proves fatal. We report here a case of neonatal enteroviral myocarditis with multisystem organ failure and ischemic cardiomyopathy that was managed medically.

**Case Report:** An 8 day old, 2.64 kg infant was transferred to our center for further management of resistant narrow complex tachycardia and cardiogenic shock. Rectal and nasal cultures were positive for enterovirus. Upon admission to our institution wide QRS tachycardia with nonspecific strain pattern at a rate of 200/minute was noted. Echocardiogram revealed biventricular dysfunction (left ventricular fractional shortening (LVFS) 16%); normal LV dimensions, segmental wall motion abnormality, and diffuse coronary ectasia. Cardiac catheterization revealed normal origin and course of coronary arteries. There was no angiographic demonstration of a coronary fistula. The distribution and caliber of the left anterior descending (LAD) artery appeared small and inadequate for age. Laboratory data were consistent with ongoing hepatic dysfunction, DIC, worsening renal function, and evidence of myocardial damage with a troponin level of 65.6 ng/ml. He was managed with multiple inotropes, aggressive

diuretic therapy and mechanical ventilation. He could not enter the Pleconaril trial as it would have entailed transfer to another facility lacking ECMO support. Extracorporeal Membrane Oxygenation (ECMO) as a bridge to either recovery or transplantation was deferred due to ineligibility secondary to active viral infection. With continued conventional management he was weaned off inotropes and mechanical ventilation over a period of 10 weeks. There was echocardiographic evidence of progressive cardiomegaly, LV free wall and basal septum akinesis with evidence of endocardial fibroelastosis. An interim computerized tomography of the chest (see images below) revealed LAD calcification and endocardial, myocardial and pericardial calcification. He was discharged home after a 13 week hospitalization. His most recent echocardiogram revealed LV diastolic diameter of 2.7 cm, FS 23%, moderate mitral regurgitation, and akinesis of LV posterior wall and basal septum. He is receiving furosemide, enalapril and digoxin. He is being evaluated for cardiac transplantation.

**Discussion:** Neonatal enteroviral infection is often fulminant and fatal if associated with multisystem organ failure. Mortality rates with myocarditis have been reported at 50-75%, despite antiviral (Pleconaril) therapy. The association of myocarditis and hepatitis carried the highest risk of fatality.

**Conclusions:** Our case highlights the fact that medical management of a newborn with fulminant enteroviral myocarditis, is possible. Short term mechanical support in the form of ECMO remains an excellent option as a bridge to recovery or transplantation in severe cardiogenic shock. However, because of its inherent risk of bleeding and thrombotic complications with time, it is not applicable in patients who will require prolonged support. Medical management may not mitigate long term disability from prolonged low cardiac output state. Therefore better means of long term mechanical support in the neonatal period is essential for these rare diagnoses.



Non contrast CT scan showing calcification in left coronary artery territory and evidence of endocardial and pericardial calcification

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## An Implementation of Sensor-Based Force-Feedback in a Compact Laparoscopic Surgery Robot

<sup>1</sup>Jaesoon Choi, PhD, <sup>2</sup>Duk H. Lee, MA, <sup>2</sup>Jun W. Park, PhD, <sup>2</sup>Doo J. Bach, MA, <sup>1</sup>Seung J. Song, MA, <sup>1</sup>Yoon H. Kim, MA, <sup>2</sup>Yungho Jo, PhD, <sup>1</sup>Kyung Sun, MD, PhD, MBA  
<sup>1</sup>Korea Artificial Organ Center, College of Medicine, Korea University, Seoul, Korea  
<sup>2</sup>Biomedical Engineering Branch, Research Institute, National Cancer Center, Gyeonggi, Korea

### Purpose:

Despite of the rapid progress in the clinical application of laparoscopic surgery robot in various types of surgery, many shortcomings have not yet been fully overcome, one of which is the lack of reliable haptic feedback. This study attempted to implement a force feedback control in our compact laparoscopic surgery robot, and evaluate the performance and feasibility of the implementation.

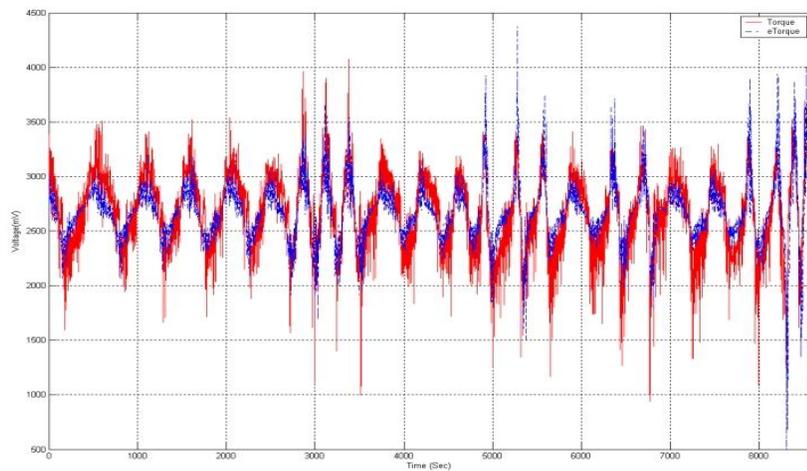
### Methods:

The surgery robot is a master-slave configuration robot with a surgeon console as the master robot and a set of compact robotic arms as the slave robots, and has 5 active joints that correspond to 5 DOF (Degree-Of-Freedom) of conventional laparoscopic surgical motion. The force feedback implementation setup was made in the working model of the robot, not in a separately made experimental mockup. The torque sensor was installed in the pitch joint of the slave robot. Since there are a few force transmission stages between the sensor and the actual point of force

reflection, a simple dynamics model was proposed, through which the reflective force was estimated and fed back to master side. At the master robot, the reflective force value was converted to according motor current and set in the motor through a motor current controller. To quantitatively measure and evaluate the generated reflective force at the master side, a simple jig for force sensing that is attached to the grip of the master manipulator was designed and set up.

### Results:

The results of the experiments showed the system model could be identified with significant fidelity (as shown in the figure below) and the force feedback at the master robot was feasible. However, the qualitative human assessment of the fed-back force at the master side showed only limited level of object discrimination ability. This leads to that it is required to use of more sensitive force sensor than the one currently used, and the problem of vibration at the slave robot arm has to be improved for finer reflective force sensing.



### Conclusions:

The results suggest that the proposed implementation has appropriate performance and feasibility of the system. Further studies are underway on the method of extending this result to whole 5-DOF joints of the slave robot and various control algorithms and methods for better feedback performance.

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**Delivery of Gaseous Microemboli with Vacuum-Assisted Venous Drainage During Pulsatile and Non-Pulsatile Perfusion in a Simulated Infant CPB Model**

Shigang Wang, MD, Larry Baer, CCP, Allen R. Kunselman, MA, John L. Myers, MD, Akif Ündar, PhD  
Departments of Pediatrics, Surgery, Bioengineering, and Health Evaluation Sciences,  
Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

**Purpose:**

The purpose of this study was to investigate the delivery of gaseous microemboli with vacuum-assisted venous drainage (VAVD) at various flow rates and perfusion modes in a simulated infant cardiopulmonary bypass model.

**Methods:**

Four transducers (post-pump, post-oxygenator, post-filter and venous line) of the Emboli Detection and Classification (EDAC™) Quantifier were inserted into the CPB circuit to detect and classify gaseous microemboli. Four negative pressures (0, -15, -30, -45 mmHg), three flow rates (750 ml/min, 1000 ml/min and 1250 ml/min) and two perfusion modes (pulsatile and non-pulsatile) were tested. The circuit was primed with lactated ringer's solution. After injecting 10 cc air into the venous line via an 18G needle, 2-minute segments of data were recorded simultaneously through

four transducers. This entire process was repeated six times for each unique combination of pressure, flow rate and perfusion mode, yielding a total of 144 experiments.

**Results:**

Independent of perfusion mode and flow rate, the use of VAVD with higher negative pressures delivered significantly more gaseous microemboli at the post-pump site. There was no difference in delivery at the post-filter site. The majority of gaseous microemboli were trapped by the Capiox Baby-RX hollow-fiber membrane oxygenator. Compared with non-pulsatile flow, pulsatile flow transferred more gaseous microemboli at the post-pump site at all three flow rates. The following table represents the total microemboli count at the flow rate 1000ml/min with pulsatile and non-pulsatile.

Results of the Total Microemboli Count at Post-pump, Post-oxygenator, Post-filter and Venous Line Sites with Non-pulsatile vs. Pulsatile and VAVD at the Flow Rate 1000 ml/min

VAVD (mmHg)	Post-pump		Post-oxygenator		Post-filter		Venous line	
	NP	P	NP	P	NP	P	NP	P
0	385.7±33.7	447.8±58.9	2.7±3.1	5.8±3.7	0.0±0.0	0.0±0.0	2537.5±277.6	2247.2±149.7
-15	554.3±28.5	555.3±61.5	4.8±1.5	5.7±5.2	0.0±0.0	0.2±0.4	2332.3±147.2	2351.2±70.9
-30	602.2±79.5	648.5±128.2	3.7±1.6	3.3±1.5	0.0±0.0	0.3±0.8	2348.3±116.5	2600.0±175.6
-45	869.0±167.0	*1257.0±225.7	6.3±1.0	11.2±6.2	0.0±0.0	0.0±0.0	2531.0±153.2	2319.8±73.7

\* P < 0.05 P vs. NP NP=Non-pulsatile P=Pulsatile

**Conclusions:**

Our results confirm that VAVD with higher negative pressures, increased flow rates and pulsatile flow could deliver more gaseous microemboli at the post-pump site when a fixed volume air is introduced into the venous line. The majority of gaseous microemboli were trapped by the Capiox Baby-RX hollow-fiber membrane oxygenator. Only few gaseous microemboli appeared at post-filter site. Further study will be tested using bovine blood with an open arterial filter purge line.

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**Microemboli Detection and Classification by Innovative Ultrasound  
Technology During Simulated Neonatal CPB at Different Flow Rates,  
Perfusion Modes and Perfusate Temperatures**

Robert S. Schreiner, Alan R. Rider, John W. Myers, Bingyang Ji, MD, Allen R. Kunselman, MA, John L. Myers, MD,  
Akif Ündar, PhD

Departments of Pediatrics, Surgery, Bioengineering, and Health Evaluation Sciences

Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

**Purpose:**

The objective of this study was to detect and classify the number and size of gaseous microemboli in a simulated pediatric model of cardiopulmonary bypass (CPB). Tests were conducted at different flow rates, pulsatile versus non-pulsatile perfusion modes, and under normothermic, hypothermic, and deep hypothermic conditions.

**Methods:**

The components of the circuit designed for this experiment simulated a pediatric patient undergoing cardiopulmonary bypass procedure. The circuit consisted of several components including a Jostra HL-20 heart-lung machine (Jostra USA, Austin, TX) capable of both pulsatile and non-pulsatile perfusion, a Jostra-30 heat-cooler system (Jostra USA, Austin, TX), a Capiiox Baby RX hollow-fiber membrane oxygenator with a Terumo hard shell venous reservoir and integrated heat exchanger (Terumo Corporation, Tokyo, Japan), a Capiiox pediatric 35µm arterial filter (Terumo Corporation, Tokyo, Japan), 5 feet of arterial tubing, and 6 feet of venous tubing from a COBE Heart/Lung Perfusion Pack (COBE Cardiovascular Inc., Arvada, USA) for pediatric patients with a ¼ inch diameter.

During the experiment, the purge line of the arterial filter was closed. When the target pump flow rate was achieved, 5 cc of air were introduced into the venous line via the luer port of the oxygenator. In order to collect the data, three transducers from the EDAC™ quantification system were attached to EDAC™ connectors inserted in the circuit at post-pump, post-oxygenator and post-arterial filter sites. Data were collected from five flow rates between 400-1200 L/min with 200 L/min increments. Five minute data clips were simultaneously collected from the three transducer sites at each of these flow rates under pulsatile and non-pulsatile flow. This entire process was repeated six times at each pump flow rate, under three different temperatures (35°C normothermic, 25°C hypothermic, 15°C deep hypothermic) yielding a total of 180 experiments.

**Results:**

The following table represents the total gaseous microemboli count at post-pump, post-oxygenator, and post-filter sites with non-pulsatile (NP) or pulsatile (P) flow at hypothermic conditions (25°C). Percentages indicate the amount of total emboli 0-40 microns in size (n=6). The complete data sets, including normothermic and deep hypothermic conditions, reveal an increasing trend of microemboli count when decreasing the temperature.

Flow Rate (ml/min)	Post-pump		Post-oxygenator		Post-arterial filter	
	NP	P	NP	P	NP	P
400	6319±1338 95.30%	7566±1531 94.80%	344±85 99.20%	376±45 99.70%	1±1 100%	3±3 100%
600	7838±2215 94.40%	8832±2613 93.50%	† 1762±696 98.60%	† 1929±531 98.70%	52±19 99.60%	67±14 99.60%
800	9343±1681 93.90%	10623±3324 93.30%	† 3644±672 98.30%	† 3921±887 98.50%	† 483±66 98.60%	† 512±127 99.70%
1000	† 10623±3275 93.60%	† 14939±4664 94.30%	† 4353±1010 98.20%	*† 6023±1052 98.10%	† 945±212 99.30%	† 1292±251 99.50%
1200	† 11164±3165 93.90%	*† 20046±6992 94.90%	† 4797±948 97.70%	*† 7978±1750 98%	† 1152±223 99.30%	*† 1942±440 99.60%

\* p < 0.01 P vs. NP † p < 0.05 Comparison at the following flow rate vs. 400 ml/min within P or NP groups

NP = Non Pulsatile P = Pulsatile

**Conclusions:**

The results suggest that more than 90% of the emboli that fall into the 0-40 micron size class, a class generally undetectable by traditional means, remain unfiltered at any flow rate, perfusion mode, or temperature.

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**Pediatric Heart Support with a Catheter Based Pulsatile 12F Rotary Blood Pump  
or a Small Implantable VAD – a Moving Target?**

Thorsten Siess, Frank Kirchhoff, Christoph Welp, Rainer Damen, Sebastian Schwandtner, Roy Wallen, Bart Meyns\*  
Abiomed Europe, Aachen, Germany; Abiomed, Inc., Danvers, USA  
\*Cardiale Heelkunde UZ Gasthuisberg, Leuven, Belgium

**Purpose:**

The initial objective of this pump development has been to provide the smallest cardiac patients (3-10kg) with temporary direct or peripherally inserted left heart support for up to 14 days as a less traumatic alternative to extracorporeal membrane oxygenation (ECMO). Another group of patients with increased weight and body mass index, however, may require temporary right heart replacement to overcome decompensated Fontan conditions, which cannot be addressed appropriately with other proposed solutions.

**Methods:**

Abiomed has introduced the Impella LP 2.5 with target max flows up to 2.5 l/min clinically for temporary heart support for prophylactic use in high risk interventions and for transient hemodynamically compromised patients. The percutaneous catheter based 12F device has been well received in the clinical community with more than 1000 reported implants.

Meanwhile modifications have been successfully made and tested in vivo in a small lamb model, which adopt the device to the needs of our smallest patients with target flows around 0.5l/min and a pulsatile flow pattern for improved end organ perfusion.

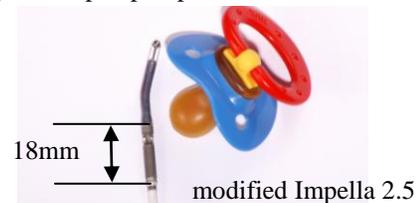
In addition, the outer diameter of the transvalvularly placed inflow cannula has been further reduced to 9F in order to avoid any valve obstruction and the cannula length has been adopted to a ventricular cavity similar in size to a plumb (> 15cc). Furthermore, the cannula has been precurved to obtain a second degree of freedom for placement of the inflow cage within the ventricular cavity rather than adjacent to any cardiac structure by mere pump and respective cannula rotation.

**Conclusions:**

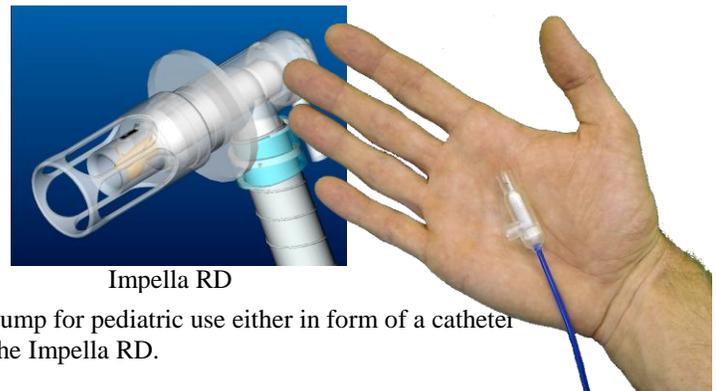
Further clinician feedback is needed to define the best suitable pump for pediatric use either in form of a catheter based pump or in form of a temporarily implantable version of the Impella RD.

**Results:**

The newly developed pump is illustrated below.



Based on human fit and human cadaver fit studies in 3kg-5kg patients we acknowledge that the current version as described above does not fulfill the requirement of a suitable transvalvular pump position in a 3kg neonate due to the small heart, short ascending aorta and the 18mm rigid length of the pump motor and housing. The smallest suitable patient appears to be +4kg, which reduces the potentially treatable patient cohort for this device, which is already limited to left heart support. Henceforth, additional customer feedback revealed that a modified Impella RD may in fact be the more versatile solution for heart support up to 30d. This device, with its classical layout with an in- and outflow cannulation or incision site may be a more universal approach to a larger patient cohort for left and/or right heart support. This device, as illustrated below, can be operated within a large range of target flows at 1.0 l/min in a pulsatile mode up to 5.5 l/min in a non pulsatile mode.



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**Development of the Levitronix® PediVAS™ Assist System**

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Kurt A. Dasse, PhD<sup>1</sup>, Peter Wearden, MD<sup>3</sup>, Steven Webber, MBChB, MRCP<sup>3</sup>, Thomas Gempp, PhD<sup>2</sup>, John D. Marks, PhD<sup>1</sup>, Stella Kent, PhD<sup>2</sup>, William Wagner, PhD<sup>3,4</sup>, Marina Kameneva, PhD<sup>3,4</sup>, Carl Johnson, BS<sup>3,4</sup>, Josh Woolley, BS<sup>3,4</sup>, Barry Gellman, MS<sup>1</sup>, J. Scott Richardson<sup>1</sup>, Steve Franklin<sup>1</sup>, Harvey Borovetz, PhD<sup>3,4</sup>

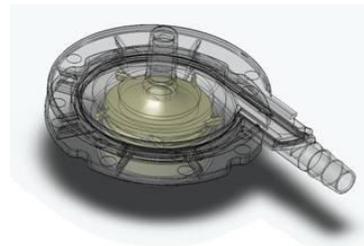
<sup>1</sup>Levitronix LLC, Waltham Massachusetts, USA; <sup>2</sup>Levitronix GmbH, Zurich, Switzerland; <sup>3</sup>University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania; <sup>4</sup>University of Pittsburgh School of Engineering, Pittsburgh, Pennsylvania, USA.

**Purpose:** Over 2,500 cardiac and cardiopulmonary support patients have been treated worldwide with CentriMag® devices, including 55 pediatric patients. A new pediatric version of this device (PediVAS), designed for VAD or ECLS support, has been developed. PediVAS is intended for use for up to 30 days of VAD or ECLS extracorporeal support. This article describes this unique technology, preclinical validation, and reports on the worldwide clinical pediatric experience with the CentriMag and PediVAS systems.

**Methods:** PediVAS is a polycarbonate centrifugal pump without mechanical bearings or seals (Figure). The only moving part is a magnetically levitated impeller. PediVAS has a 14 ml priming volume, can provide clinical flows ranging from 0.5 – 1.7 lpm with commercially available cannulae, and is compatible with all CentriMag hardware. PediVAS

was studied in 18 pediatric ovine animals with flow rates from 0.5 to 3.0 lpm. Upon successful completion of preclinical validation studies, and CE Mark approval, the device was commercially released in Europe.

**Results:** Successful studies were completed demonstrating safe operation, reliable hemodynamic performance and excellent biocompatibility of the PediVAS for 30 days of pediatric animal support. The combined worldwide pediatric experience with the CentriMag and PediVAS pumps includes 55 patients. The majority of pediatric patients were treated with the device in an ECMO circuit. The average survival in this cohort of patients was 57%. Two patients have been supported in Europe with the PediVAS pump. The device performed well in both cases.



**Conclusions:** With safety, performance and reliability features similar to the CentriMag, the PediVAS was optimized for pediatric applications. Preclinical validation testing and initial clinical use in Europe of PediVAS in an extracorporeal circuit has been successful. A clinical trial is being prepared in the United States to evaluate PediVAS for use as a VAD.

**Supported in part from NIH Grants R44 HL071376 and R44 HL074628**

THE LEVITRONIX CENTRIMAG VAS IS LIMITED BY U.S. FEDERAL LAW TO INVESTIGATIONAL USE.  
PEDIVAS IS NOT YET AVAILABLE IN THE UNITED STATES.

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### **Emboli – Strategies to Reduce Incidence and Impact**

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Timothy J. Jones, MD FRCS (CTh)  
Cardiac Unit, Birmingham Children's Hospital, Birmingham, UK.

The exact aetiology of CPB associated morbidity and mortality remains unclear and is probably multifactorial resulting from the interactions of a variety of mechanisms: emboli, activation of inflammatory processes, temperature and alterations in blood flow.

Emboli can be classified according to size (macro and micro) and composition: gaseous, biological (atheroma, thrombus, platelet and cellular aggregates, fat), and inorganic (fragments from the CPB circuit, silicone antifoam, glove powder, cotton fibres). The number of emboli detected intra-operatively has been demonstrated to be associated with post-operative neuropsychological deficit. Further work has identified when emboli occur during surgery. Laboratory and clinical research has identified surgical and perfusion techniques that are associated with increased embolic activity.

Identification and avoidance of surgical techniques associated with high emboli counts may reduce the number of emboli being created. Anaesthetic and pharmacological interventions may influence the distribution of emboli as well as minimise their ischaemic effect. Alterations in perfusion techniques and equipment may reduce the number of emboli created, remove circulating emboli and influence the distribution and effects of emboli.

The perfusionist plays a key role in minimising embolisation during cardiac surgery. It has been shown that the number of perfusion interventions is positively correlated with the incidence of

embolisation and neurocognitive outcome. Intervening with the circuit to sample blood or administer drugs should be kept to a minimum using techniques aimed at reducing the potential for air embolisation. Other important associations include purging of sampling lines, high flow rates, reservoir volumes of less than 800ml and bolus injections. Air entrained in the venous line at the start of, or during CPB is a recognised source of microembolisation. It is therefore key to minimise this, particularly in low prime circuits. Vacuum-assisted venous drainage at high vacuum levels is also a potential source of gaseous microemboli.

Cardiotomy suction allows blood with a high fat content to enter the circuit therefore filtration of this blood helps in reducing fat embolisation. Cell savers should be used in preference as this has been shown to reduce small capillary and arteriolar dilatations which are a marker of cerebral embolisation.

The components in the CPB circuit also influence the production and removal of microemboli, particularly gaseous microemboli. It is well established that membrane oxygenators are superior to bubble oxygenators but there continues to be variation in the embolic performance of modern circuit components. The incorporation of a micropore filter in the arterial return line of the CPB circuit not only reduces particle counts in the arterial line downstream from the filter, but it also reduced the number of emboli detected in the middle cerebral artery with an associated reduction in postoperative cerebral dysfunction.

#### **Conclusions:**

Neurological dysfunction due to embolisation continues to be a significant cause of post-cardiac surgery morbidity and mortality. Atherosclerotic emboli originating from aortic manipulations are predominant in adults and gaseous microemboli are predominant in children undergoing cardiac surgery. A threefold strategy of avoiding the creation of emboli, using equipment to reduce the number of circulating emboli and finally techniques to limit the clinical impact of emboli would appear beneficial. It is therefore the responsibility of the surgeon, anaesthetist and perfusionist to help reduce the embolic load patients are subjected to in order to maximise neurological outcome.

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**Ventricular Assist Device Implantation in the Pediatric Population: Does Pump Size Selection and Associated Hemodynamics Impact Outcomes?**

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Husain SA<sup>1</sup>, Wallis G<sup>1</sup>, Fricker FJ<sup>1</sup>, Bleiweis MS<sup>1</sup>, Staples ED<sup>1</sup>, Klodell CT<sup>1</sup>, Brown JW<sup>2</sup>, Turrentine MW<sup>2</sup>  
<sup>1</sup>Departments of Pediatrics and Surgery – Congenital Heart Center - University of Florida College of Medicine  
<sup>2</sup>Division of Cardiothoracic Surgery – Riley Hospital for Children – Indiana University School of Medicine

**Objective:**

Obtaining mechanical circulatory support with use of a Ventricular Assist Device (VAD) continues to evolve within the pediatric population. The availability of smaller blood pumps has increased selection options within this challenging subset of patients. This study seeks to examine the hypothesis that use of appropriate blood pump size correlates with a lower incidence of VAD related complications (VADRC).

**Methods:**

A 7 year retrospective review was undertaken for all patients under 18 years of age undergoing VAD implantation. Patient demographics, VADRC and blood pump sizes / hemodynamics were reviewed. Optimal VAD hemodynamics were defined as a cardiac index of 2.7 L/m and rate of 80 bpm with complete fill/empty of the blood pump. Body surface area (BSA) data was used to calculate desired blood pump size to achieve optimal VAD hemodynamics. Patient / blood pump size match, VAD rate and

fill/empty ratios were calculated (optimum = 1.0) and then correlated with incidence of VADRC.

**Results:**

22 patients (14 male / 9 female), mean age 9.77 years (6mo-18yrs) underwent VAD implantation. Patients received either a Thoratec PVAD (n=13), Berlin Heart (n=8) or Heartmate XVE (n=1). Mean body surface area (BSA) of 1.14m<sup>2</sup> (0.14m<sup>2</sup>-2.32m<sup>2</sup>). Mean length of time on VAD support was 55.5 days (1-202). 13 patients were bridged to transplantation (59%) and 4 were weaned from support (18%). VADRC included death while on support (n=5), bleeding requiring reoperation (n=8), hemolysis (n=2), neurologic events (n=2), thrombus formation (n=3), and infection/sepsis (n=3). 6 patients were bridged to transplant without any VADRC. This subset of patients had a mean blood pump size match ratio of 0.98, VAD rate ratio of 0.92 and fill/empty ratio of 1.00. Patients with VADRC (n=16) were found to have a mean blood pump size match ratio of 0.72, VAD rate ratio of 0.72 and fill/empty ratio of 0.78.

**Conclusions:**

We report a series of pediatric patients with wide ranging BSA receiving VAD implantation. Selection of appropriate sized blood pumps in this population can be correlated with a decreased incidence of VADRC.

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**The PediPump: Development Status of a New Pediatric Ventricular Assist Device**

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Brian W. Duncan, M.D.

The Department of Pediatric and Congenital Heart Surgery, Children's Hospital, Cleveland Clinic and  
The Department of Biomedical Engineering, The Lerner Research Institute of The Cleveland Clinic

**Introduction:**

The PediPump™ is a ventricular assist device in development at the Cleveland Clinic designed for the support of pediatric patients. The development program is currently beginning the fourth year of funding under the NHLBI's Pediatric Circulatory Support Program.

**Methods and Results**

Substantial work has been performed regarding the engineering aspects of the PediPump: Over the last year significant design refinements have addressed thrombus formation in the wash flow entry region, optimized the radial and axial stiffness of the passive magnetic bearings, and streamlined hardware fabrication. Component and system level testing of the new pump hardware is underway. Development

of clinically applicable anatomic fitting studies has also been a major focus of the PediPump project. We have developed 3D reconstructions of CT and MRI studies that provide accurate virtual models of intra-thoracic device placement in children. Currently, these 3D virtual imaging studies are being validated by intra-operative fitting studies using mock-ups of the PediPump to assess device placement and fit in patients over a wide range of sizes and anatomic subtypes. In vivo evaluation of PediPump performance is a particular focus of this fifth year of funding. Acute studies performed in year four, established pump performance during short-term use. Chronic animal studies were initiated in early 2008 to assess long-term host impact and to establish a pre-clinical testing program.

**Conclusions:**

The current focus of the PediPump program is the evaluation of device performance during chronic applications. Engineering efforts are focused on supporting the chronic in vivo program as well as durability bench testing that will be performed in this fifth and final year of the NHLBI's Pediatric Circulatory Support Program.

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### **The Penn State Pediatric Ventricular Assist Device: Progress Update**

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William J. Weiss, Ph.D., Gerson Rosenberg, Ph.D., Christopher A. Siedlecki, Ph.D., Dennis Hicks, John Reibson, Branka Lukic, M.S., Eric Yeager, Brad Doxtater, Kathryn Richards, Keefe B. Manning, Ph.D., Steven Deutsch, Ph.D., James P. Runt, Ph.D., Taeyi Choi, Ph.D., Tigran Khalapyan, M.D., John Myers, M.D., J. Brian Clark, M.D., Elizabeth Carney, D.V.M., William S. Pierce, M.D.

Departments of Surgery, Bioengineering, Pediatrics, Comparative Medicine, and Materials Science and Engineering.  
The Pennsylvania State University, Hershey and University Park, Pennsylvania, USA

Penn State is developing a pulsatile pneumatic sac-type Pediatric Ventricular Assist Device (PVAD) based on the design of the adult-sized Pierce-Donachy (Thoratec®) VAD. An infant-sized pump with a dynamic stroke volume of 12-14 ml is under development, and a child-sized 25 ml PVAD is planned.

*In vitro* valve testing and selection of the Björk-Shiley Monostrut valve has been completed. We have created a 17 mm custom valve flange (tube valve) which is designed to mate precisely with the pump sac and pump connectors. This approach minimizes gaps and discontinuities in the flow path which will reduce the risk of thrombosis. The new valve is being integrated into the final pump design.

Experimental fluid dynamics studies have focused on valve selection, the effect of valve angle on pump flow, the effect of weaning on pump flow profiles, and flow profiles in the tapered outlet cannula. Computational fluid dynamics were used to study shear stresses in the cannulae and aorta.

The PVAD was initially tested in 5 lambs (15-19 kg), but poor survival, mainly due to respiratory failure, led to a series of 4 implants in goats (12.3-14.4 kg) in which the experimental protocol was revised and tested. Improvements included more extensive respiratory monitoring during anesthesia, a change to pressure-mode ventilation, minimizing the extent and duration of the descending aortic occlusion during the outlet cannula anastomosis, and improved post-operative analgesia and ventilator support.

We also completed two sham studies in 20-25 kg lambs to evaluate lung function, anesthesia, post-operative sedation

#### **Acknowledgments:**

This research is supported by NIHBI contract N01-HV-48191 and the Donald B. and Dorothy L. Stabler Foundation.

and analgesia, and hematologic parameters. Implant studies in 20-25 kg lambs are currently underway.

Despite the challenges in achieving a stable chronic animal model, the results of the pump testing have been encouraging. The blood contact surfaces (blood sac, valves, connectors, and cannulae) have been largely free of thrombus depositions, except for a thin fibrin ring at the valve junctions, and renal infarctions have been few, except in cases of ischemia due to intraoperative aortic cross clamping or intraventricular thrombus. We are currently developing a more flexible inlet cannula. Otherwise, the animal results to date indicate that drastic design changes are not required. This is significant because during animal testing of the previous Penn State PVAD (with 6 mm ball valves) in 1988-1992, thrombus was frequently found in the valve and connector areas, and occasionally in the pump chamber.

Biocompatibility efforts have focused on development of antibody-based flow cytometry assays and application of clinical hematological testing to *in-vivo* experimental procedures. These methods require large amounts of blood which has led us to focus on bovine data to date with the goal of translating methodology to the ovine model. We have identified appropriate antibodies for measuring platelet activation and conducted 3 sham bovine implants.

Coagulation assays were completed on candidate polymers, and samples have been prepared for platelet adhesion experiments. Polymer studies included investigations into the effects of filtration and heat-forming, and mechanical properties of candidate polymers.

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**Development and Analysis of the PediaFlow Pediatric Ventricular Assist Device**

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Peter D. Wearden, MD, PhD for the PediaFlow Consortium  
Pittsburgh, Pennsylvania, USA

The available clinical options for circulatory support of pediatric patients, particularly neonates, in heart failure is currently limited to extracorporeal membrane oxygenation (ECMO) and compassionate use exemptions for the Berlin Heart. Overall, the survival rates for patients requiring ECMO and the Berlin Heart for cardiac support are 66% and 86%, respectively. We are developing the PediaFlow™ ventricular assist device (VAD) for long-term mechanical circulatory support in the pediatric patient. PediaFlow™ is a miniature mixed-flow axial impeller pump that utilizes magnetic levitation to eliminate the need for bearings. It was designed using computational fluid dynamics and anatomic models as a fully implantable VAD for 3-15 kg patients (0.3 – 1.5 L/min). The size of the first prototype was 51mm x 28mm diameter and weighing 100g. *In vitro* testing of the pump has demonstrated minimal hemolysis relative to other available pumps such as the BP-50 (Medtronic).

The *in vivo* performance has been evaluated in four pediatric ovine models for durations between 6 hours and 17 days. To date our *in vivo* results demonstrate

the superior biocompatibility and pumping characteristics of our design. Platelet activation was similar to sham surgeries, and serum free hemoglobin levels throughout the studies were well within acceptable limits (<10 mg/dL). In addition to the pump itself, we are designing improved inflow cannulae with optimal hemodynamics independent of placement within the left ventricle (LV). *In vitro* experiments in isolated bovine hearts have demonstrated higher ranges of flow before suction events with less sensitivity to position within the LV compared with standard ECMO cannula. Furthermore, release from suction events was accomplished by a smaller decrease in flow rate.

We are currently in production of a second generation pump prototype that will employ improved cannula connectors, driveline durability, and reduce the pump size by approximately 33%. More long-term *in vivo* studies are currently being planned to further test the biocompatibility of our pump design and cannulae.

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**Interagency Registry for Mechanical Circulatory Support (INTERMACS):  
Pediatric Update**

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CS Almond<sup>1</sup>, DC Naftel<sup>2</sup>, SL Meyers<sup>2</sup>, JK Kirklin<sup>2</sup>, ED Blume<sup>1</sup>

<sup>1</sup>Children's Hospital Boston, Harvard Medical School, Boston, MA

<sup>2</sup>University of Alabama at Birmingham, Birmingham, AL

**Background:**

INTERMACS, a federally-supported national registry for FDA-approved durable VADs, has recently released data from its first group of INTERMACS registrants. While the overall number of pediatric registrants remains limited due to the lack of FDA approved durable VADs in children, an overview of the early adult and available pediatric experience provides an opportunity to review the tremendous potential and possible challenges of applying INTERMACS to the pediatric population.

**Methods:**

The purpose is to review the most recent data from INTERMACS including the available pediatric experience. All patients reported to INTERMACS during the first 18 months of the registry were analyzed. Recipient characteristics, outcomes, and adverse events were reported using standardized adverse event definitions developed by INTERMACS. The potential feasibility and limitations of using INTERMACS for pre-market studies will be explored.

**Conclusion:**

INTERMACS is rapidly emerging as a comprehensive data source on FDA approved durable mechanical support devices in the United States fulfilling its intended purpose. The total number of pediatric patients enrolled to date is small but growing. INTERMACS is poised to play a vital role in the evaluation of evolving pediatric VADs.

**Results:**

Between June 2006 and December 2007, 420 patients were officially enrolled in INTERMACS. Of these enrolled, 12 patients (3%) were less than 19 years of age (range 4 to 18 years of age). The majority of patients undergoing VAD implantation were classified as INTERMACS heart failure profile levels 1 ('critical cardiogenic shock') or 2 ('progressive decline'). Overall, 179 (43%) were listed for transplantation at the time of VAD implantation. Of these, 123 (69%) received LVAD support; 35 (20%) received BIVAD support. Overall mortality for patients supported as a BTT was 18% (33/179). Multivariate factors associated with MCS mortality among all patients were Intermacs profile 1, older age, ascites, elevated bilirubin, and BIVAD and Total Assist Heart support. Among 104 overall deaths, the most common primary cause of death was CNS event in 18.3%, multi-organ failure in 16.4%, and cardiac failure in 15.4%.

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### **Single Ventricle – What Does the Future Hold?**

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Thomas L. Spray, MD  
Philadelphia, Pennsylvania, USA

The evolution of treatment for single ventricle since the first successful clinical application of the Fontan-Kreutzer procedure in the late 1960's and early 1970's has resulted in an increasing population of patients with single ventricle physiology and non-pulsatile pulmonary blood flow. Survivors with the Fontan circulation are unlikely to have a normal life expectancy; and the application of the Fontan-Kreutzer operation in patients with systemic right ventricles, such as hypoplastic left heart syndrome has resulted in an increasing population of patients now in late childhood who will likely have significant morbidities as they grow into adulthood. Thus, it is imperative that attention is given to this population of patients to try to decrease, as much as possible, late morbidity and to prolong survival<sup>(1)</sup>.

The Fontan operation is now associated with excellent early survival rates, approaching 95 to 97 percent in most series. Nevertheless, despite encouraging early survival there continue to be problems with late Fontan failure, ventricular dysfunction, low cardiac output, thromboembolism, arrhythmias, protein losing enteropathy, and other issues that decrease the quality of life for many of the patients and may well limit the survival for the majority of patients with single ventricle physiology<sup>(2-6)</sup>. While there has been reasonable success in treating some of the complications of the Fontan circulation, patients presenting with either Fontan failure and associated organ dysfunction or ventricular dysfunction may require cardiac transplantation<sup>(7)</sup>. Unfortunately, many patients with the Fontan circulation who come to cardiac transplantation have associated significant risk factors that decrease survival and increase morbidity even after successful transplantation<sup>(8,9)</sup>. Several reports of cardiac transplantation after the Fontan circulation have suggested that these patients may have an increased pulmonary vascular resistance and small lungs, and in addition, many of the patients have evidence for chronic thromboemboli in the pulmonary vascular bed<sup>(10,11)</sup>. These pulmonary issues may significantly affect the function of the donor heart. The right ventricle of the transplanted heart may have a higher failure rate in patients undergoing transplantation for the Fontan circulation. Many of these patients have unsuspected associated organ dysfunction including hepatic dysfunction which may only be identified after a successful transplant. In addition, renal dysfunction is not uncommon in the failing Fontan circulation in association with ascities and protein-losing enteropathy. Cachexia and other nutritional abnormalities associated with protein loss can certainly debilitate these patients and increase the morbidity after transplant. Thus, the Fontan population represents a challenge for development of therapies to maintain cardiac function and improve quality of life. These patients could potentially benefit from the same successful use of ventricular assist devices that has improved the outcomes for cardiac transplantation in adults with other cardiac anomalies. There is very little experience, however, in the use of assist devices in single ventricle physiology patients, and the wide variety of hemodynamic issues with the Fontan population and the often complex anatomy make use of these devices difficult.

There has been increasing interest in developing assist devices which may be particularly applicable to the single ventricle circulation<sup>(12-18)</sup>. Use of axial flow devices on the venous side may push blood through the lungs in such a way as to improve cardiac output in patients who have otherwise preserved systolic ventricular function. The use of pulsatile assist devices on the ventricular side may improve pulmonary flow by actively lowering the ventricular filling pressures; however in patients with preserved systolic function it is not clear that "left-sided" ventricular support will always improve venous flow. Patients with the failing Fontan circulation may have ventricular diastolic dysfunction, but preserved systolic function and a somewhat elevated pulmonary vascular resistance, making use of single ventricular pulsatile assist devices potentially less successful. In addition, Fontan patients may represent co-morbidities that preclude transplantation, leaving medical and device approaches to management of chronic heart

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failure as destination therapy a necessary area for increased study. Perhaps these patients will be a group well served by the development of the total artificial heart.

A major problem with the Fontan population is that when failure of the Fontan circulation occurs, the patient may rapidly deteriorate. There is a tendency to wait too long prior to listing patients for transplant since they have a chronic low output state and may have preserved systolic function and only gradual deterioration in exercise tolerance; however, when the Fontan circulation fails there can be a dramatic progression with onset of liver dysfunction, renal dysfunction and progressive cachexia that is relatively unresponsive to medical treatment.

The challenges of the single ventricle population and the fact that these patients are approaching adulthood in large numbers (partly due to the success of the hypoplastic left heart syndrome operations) makes a major effort to understand late single ventricle outcomes and optimize medical and surgical management mandatory. A major research effort to improve assist device support for this population of patients is necessary and the application of these devices almost certainly will increase significantly in the near future.

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## **Hypoplastic Left Heart Syndrome with Post-Op Support**

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Shunji Sano, MD  
Department of Cardiovascular Surgery  
Okayama University Hospital, Okayama, Japan

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**Novel Approaches to ECMO Following Cardiac Surgery**

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Gordon A. Cohen, MD and D. Michael McMullan, MD

Division of Cardiac Surgery, Children's Hospital & Regional Medical Center, Seattle, Washington, USA

ECMO-associated complications, including catastrophic bleeding and thromboembolic events, may limit the usefulness of ECMO as a supportive therapy to facilitate myocardial recovery following open cardiac surgery. The incidence of significant postoperative surgical site hemorrhage in patients supported by ECMO is as high as 35% (2008 ELSO Registry Data). The use of a specialized heparin-bonded centrifugal pump system (CPS) that does not require systemic anticoagulation during the initial postoperative period may be used to limit surgical bleeding. Compared with patients placed on ECMO during the first 24 hours postcardiotomy, CPS patients exhibit significantly less postoperative bleeding and have a significantly lower transfusion requirement. This has important implications when deciding when to use mechanical support for ventricular failure in the immediate postoperative

period. Important etiologic factors for postcardiotomy heart failure include hypoxemia and increased pulmonary vascular resistance in the setting of cardiopulmonary bypass-induced myocardial depression. In many of these patients venovenous ECMO may be preferentially used to reduce pulmonary vascular resistance and augment systemic cardiac output and oxygen delivery, while decreasing the risk of thromboembolic complications associated with venoarterial ECMO. Similarly, patients initially requiring venoarterial ECMO support may benefit from staged conversion to venovenous ECMO prior to discontinuation of ECMO support. ECMO is a safe and effective alternative to increasing inotropic support when an individualized approach to postoperative mechanical cardiopulmonary support is undertaken.

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**Mechanical Assist Following Stage-1 Palliation**

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Mark Rodefeld, MD  
Indianapolis, Indiana, USA

Mechanical circulatory support of the univentricular circulation is a complex and significant challenge. Infants undergoing Stage-1 repair of single ventricle heart disease frequently require temporary bridge support to get them through the period of maximal instability risk following repair.

There are few mechanical circulatory support devices which can satisfactorily provide this type of support after Stage-1 repair of functional single ventricle, and none are ideal. ECMO is the most commonly utilized option; it provides both systemic circulatory support and gas exchange capability. ECMO, however, has serious inherent risks and limitations. Other support options may include systemic support

without an oxygenator, which is typically not desirable in these patients who may be profoundly hypoxemic.

Theoretical consideration for mechanical circulatory support of the cavopulmonary circulation (cavopulmonary assist) at the same time as Stage-1 repair is an exciting and compelling concept that may dramatically improve the circulatory status of these patients. However, the physiologic and bioengineering considerations to safely provide cavopulmonary assist are markedly dissimilar to other mechanical circulatory support options. The concept and rationale of assisted cavopulmonary blood flow will be outlined and discussed.

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## Mobile ECMO

Robert D.B. Jaquiss, M.D.  
Arkansas Children's Hospital, Little Rock, Arkansas, USA

### Background:

Although extracorporeal membrane oxygenation (ECMO) is mature technology with over 30,000 patients in the Extracorporeal Life Support Organization Registry (ELSO), it is not available in all medical centers caring for children who may require such support. In other circumstances children on ECMO may require therapy such as heart transplantation which may not be locally available. In order to serve the needs of these two populations of children, a program of inter-hospital transport of children supported on ECMO (mobile ECMO) was initiated at Arkansas Children's Hospital in 1990, the results of which were recently reviewed.

### Methods:

Data including age, weight, diagnosis, ECMO course, hospital course, mode of transport, and ultimate

outcome were abstracted from an IRB approved surgical database. Results were compared with data available from the most recent ELSO registry report.

### Results:

Since the inception of the program our mobile ECMO team has transported a total of 110 patients. Ten patients were transported between two other institutions, and 100 patients were transported back to our institution. Among patients ultimately cared for at our institution, indications for ECMO were neonatal respiratory failure 35%, pediatric respiratory failure 20%, and cardiac failure 45%. Survival to hospital discharge for these groups is shown in the table and compared to our local results and results from the ELSO registry.

	ACH Mobile	ACH In-House	ELSO Registry 2004
Neonatal	81%	80%	77%
Pediatric	60%	57%	56%
Cardiac	42%	63%	40%

Of mobile ECMO on support for cardiac indications 18/45 were listed for transplantation, 12 of whom were transplanted, and 9 of whom survived to hospital discharge. Among these patients were two patients transported to our institution on ECMO who were converted to Berlin Heart EXCOR ventricular assist device support prior to transplantation.

### Conclusions:

Although inter-hospital transport of patients supported on ECMO is logistically challenging and expensive, patient outcomes are equal to those patients on ECMO who did not require transport. Because it is unlikely that ECMO and pediatric cardiac transplantation will ever be available in all hospitals caring for children, it is likely that there will always be a demand for mobile ECMO programs.

### References

1. Arlt M, Philipp A, Zimmermann M, et al. First experiences with a new miniaturized life support system for mobile percutaneous cardiopulmonary bypass. Resuscitation. 2008 Feb 26

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## **Adult Congenital Heart Surgery is Best Performed by Congenital Heart Surgeons**

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Tara Karamlou, MD  
Oregon Health & Science University  
Portland, Oregon, USA

### **Background:**

Repair for grown-up ( $\geq$  age 18 years) patients with congenital heart disease (GUCH) is frequently performed by surgeons without specialization in pediatric heart surgery. We sought to define national practice patterns and determine whether outcomes for GUCH patients are improved if they are treated by specialized congenital heart surgeons (CHS) compared to non-congenital heart surgeons (NCHS).

### **Methods:**

Index cardiac procedures in patients with 12 congenital heart disease diagnostic groups were retrospectively identified using the Nationwide Inpatient Sample 1988 - 2003. Surgeons were profiled by 2 methods: 1) absolute number of annual pediatric heart cases; 2) the percentage of their total annual index cases that were pediatric cases. CHS were defined as those surgeons whose practice volume was comprised of greater than 75% annual pediatric heart cases. GUCH cases were then defined as those cases within these specified 12 diagnoses

occurring in patients greater than or equal to age 18 years.

### **Results:**

Overall, there were 30,024 cases identified between 1988 - 2003, yielding a national estimate of  $151,184 \pm 7,747$  cases. Of these,  $110,815 \pm 7330$  (73%) were pediatric heart cases, and  $40369 \pm 1364$  (27%) were GUCH cases. CHS performed 82% of pediatric heart cases in all diagnostic groups, whereas NCHS performed 95% of GUCH cases within the same diagnostic groups ( $P < 0.0001$ ). Estimated in-hospital mortality for GUCH patients operated by pediatric heart surgeons was significantly lower than the estimated mortality for GUCH patients operated by non-pediatric heart surgeons (2.58% [95% Confidence Interval 1.24%-3.91%] vs. 4.82% [4.27%-5.36%],  $P < 0.0001$ ). The survival advantage increased as an individual surgeons' annual percentage of pediatric heart cases increases ( $P = 0.0031$ ).

### **Conclusions:**

1) Pediatric patients within specific diagnostic groups are significantly more likely to undergo operation by a surgeon whose practice is comprised of more than 75% pediatric heart cases. 2) GUCH patients within the same diagnostic groups are significantly more likely to undergo operation by NCHS. 3) In-hospital mortality is lower for GUCH patients operated by CHS. 4) GUCH patients should be encouraged to obtain surgical repair by CHS.

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**Fetal Cardiac Surgery: Mission Impossible?**

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Pirooz Eghtesady, MD, PhD  
Surgical Director, Pediatric Heart Transplantation  
Cincinnati Children's Hospital Medical Center  
Cincinnati, Ohio, USA

Numerous investigations have been carried out since the 1980s, looking at the feasibility of fetal cardiac surgery with the goal of altering the unfavorable natural history of certain congenital heart defects through in utero intervention. This presentation gives an overview of these past studies and progress to date using primarily the experimental fetal sheep model. Placental dysfunction has been the primary obstacle in the past and much effort has been directed to identifying the single culprit mechanism or biochemical pathway. It is increasingly clear, however, that this pathophysiology is not secondary to one single derangement (and hence, not amenable to one magic bullet), but rather due to a constellation

of events that converge and result in deterioration of fetal gas exchange. A brief overview of the conduct of fetal bypass will also be provided, including prior attempts at use of hypothermia, the use of various circuit designs (with or without an oxygenator), and circuit prime and volume. Limited data will also be presented on optimal maternal and fetal anesthesia in this setting and the implications of fetal stress response in the outcomes. Finally, we summarize experience from our laboratory obtained over the last 6 years, with some lessons learned from initial studies aimed at performing open-heart procedures in the fetus.

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### **ECMO for Single Ventricle**

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Chitra Ravishankar, MD  
Philadelphia, Pennsylvania, USA

#### **Introduction:**

Children with a functional single ventricle constitute just over 1% of congenital heart defects. A majority of these children undergo a three-staged reconstruction to achieve completion of the Fontan circulation. The syndrome of low cardiac output is quite common in this population through all three stages of reconstruction. While conventional therapy with inotropic support and afterload reduction remains the mainstay of therapy, there is a role for mechanical circulatory support in this patient population. Most of this experience is limited to extracorporeal membrane oxygenation (ECMO).

#### **Purpose:**

This presentation reviews the indications, the unique features, and the outcomes with ECMO in patients with single ventricle physiology through all three stages.

#### **Results:**

The registry of the Extracorporeal Life Support Organization (ELSO) recently reported the outcome

#### **Conclusions:**

ECMO can be effective for resuscitation in shunted patients with single ventricle circulation. It is particularly useful in potentially reversible conditions such as acute shunt thrombosis and transient depression of ventricular function. There is limited experience with ECMO after cavopulmonary connections, and mortality remains high in these patients.

of ECMO for neonates with cardiac indications from 1996 to 2000. Of the 740 neonates, 118 had hypoplastic left heart syndrome. Survival for the whole group was 28%; there was no significant difference in survival between patients with HLHS compared with other defects. Other single center studies report early survival of 30-50% for shunted single ventricle patients. Risk factors for poor outcome include a prolonged intraoperative course, need for ECMO in the early postoperative period, and longer duration of support. Most studies report good outcome when the indication for ECMO is hypoxemia/acute shunt thrombosis. Some centers use mechanical support as a 'routine' after the Norwood operation with excellent early survival, and improved early neurodevelopmental outcome. There is limited experience with ECMO in patients with cavopulmonary connections. ELSO reports survival in a quarter of patients with this physiology. These patients are particularly difficult to resuscitate; achieving adequate venous drainage is also quite challenging in this patient population.

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**Preliminary Single Center North American Experience with the Berlin Heart Pediatric EXCOR Device**

S.R. Rockett, J.C. Bryant, W.A. McKamie, C.E. Johnson, C.W. Chipman, M. Imamura, R.D.B. Jaquiss

Division of Pediatric Cardiothoracic Surgery

University of Arkansas for Health Sciences and Arkansas Children's Hospital, Little Rock, Arkansas, USA

**Purpose:**

The Berlin Heart EXCOR pediatric ventricular assist device represents a new option for the management of cardiac failure in children who in the past would have required extracorporeal membrane oxygenation (ECMO). We reviewed our experience with this technology with particular focus on outcomes and complications.

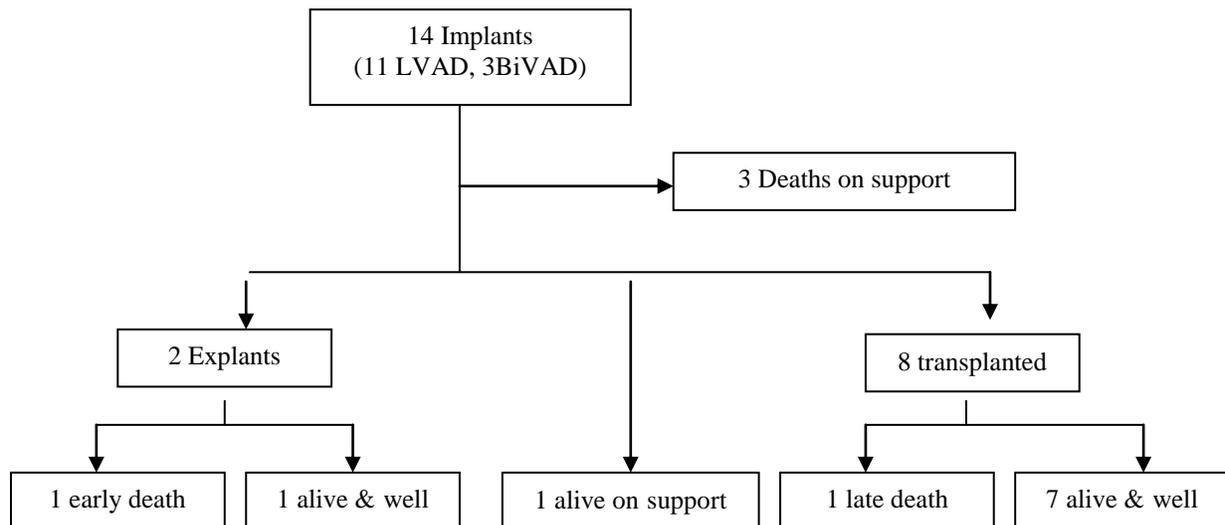
**Methods:**

An IRB-approved review of hospital charts and our cardiac surgical database was conducted to identify all patients who underwent EXCOR implantation since our first implant in February 2005. Data abstracted included patient diagnosis, age and size, pump configuration (biventricular versus univentricular), whether on ECMO at implant, and ultimate outcome (death on support, transplantation, or recovery).

Late outcomes after transplant were recorded, as were CNS complications.

**Results:**

Fourteen children have undergone EXCOR implantation at our institution; one remains on support. Eleven had myocarditis or cardiomyopathy; three had structural congenital heart disease. Median support time was 33 days (1-140 days). Median weight at implant was 11 kg (3.2 to 43 kg), and median age at implant was 21.4 months (0.6 – 190 months). Four children were on ECMO when converted to EXCOR support: one died after EXCOR explant, two died while on EXCOR, and one remains on EXCOR. Three children received BiVAD support: two died while on support, one was transplanted and died 19 months later of fungal infection. Five children had strokes while on EXCOR, two of which were fatal.



**Conclusions:**

The EXCOR device provided excellent short and intermediate support as bridge to transplant or recovery for children with cardiac failure. Children on ECMO prior to EXCOR fared worse, as did those requiring BiVAD. No patient with LVAD alone required subsequent BiVAD conversion. Stroke was a common complication.

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**Initial Experience with the TandemHeart Circulatory Support System in Pediatric Patients**

Marco Ricci, MD, Colleen B. Gaughan, MD, Courtney Novello, CCP, Michael Rossi, DO, Fotios M. Andreopoulos, PhD, Tomas A. Salerno, MD, Anthony L. Panos, MD

From the Division of Cardiothoracic Surgery, Holtz Children's Hospital/Jackson Memorial Hospital, University of Miami Miller School of Medicine, Miami, FL

**Purpose:**

Options for short-term right ventricular (RV) support are limited in children. The purpose of this paper is to describe our experience in two children with the TandemHeart centrifugal paracorporeal device, a system designed for adult cardiac support.

**Methods:**

**Patient 1:** A 9 year-old girl (weight=44kg, BSA=1.3m<sup>2</sup>) received a heart transplant for restrictive cardiomyopathy. Pre-transplant pulmonary vascular resistance (PVR) was elevated (10.5 woods.m<sup>2</sup>), but reactive to pulmonary vasodilators. After transplantation, severe RV dysfunction was noted. A TandemHeart was implanted as RV assist (Fig 1) with inflow from the femoral vein and outflow by direct pulmonary artery cannulation. The patient was weaned from CPB to the TandemHeart RVAD obtaining flows of 3.5-4L/min (2.7-3.0L/min/m<sup>2</sup>). By day 4, the RV

had recovered and the device was explanted. The patient made an uneventful recovery.

**Patient 2:** A 15 year-old male (weight=40kg, BSA=1.3m<sup>2</sup>) with hypoplastic left heart syndrome, failed Fontan physiology, and liver cirrhosis was considered for combined heart/liver transplant. Due to sudden hemodynamic deterioration, extracorporeal membrane oxygenation support (ECMO) was initiated. The following day he was converted to a TandemHeart supporting the systemic RV. A small subxyphoid incision (Fig 2) allowed insertion of a 21 Fr. Cannula into the RV for device inflow. The femoral artery was used as device outflow. The patient was weaned successfully to RVAD obtaining flows between 5.2-5.8 L/min, and supported for 10 days. However, he died for multi-system organ failure due to pulmonary AV fistulae and aorto-pulmonary collaterals.

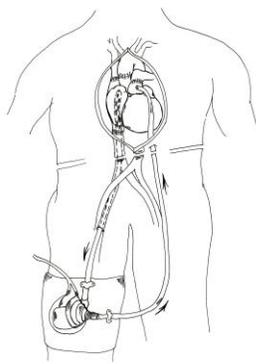


Fig 1

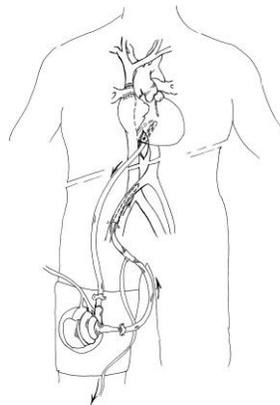


Fig 2

**Conclusions:**

Our initial experience with the TandemHeart circulatory support system suggests that this device can be used safely for RV support in children with a BSA of 1.3m<sup>2</sup> or greater. This device may offer reduced risk of coagulopathy and bleeding compared to ECMO. Further studies are needed to determine the suitability of this device in smaller patients.

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**Evolving Practice with the Use of Mechanical Support for End-Stage Dilated Cardiomyopathy in Children : A Three-Year Experience from a Large Pediatric Transplant Centre**

Jef Willems, Carin van Doorn, Aparna Hoskote, Allan Goldman, Liz Smith, Nigel Cross, Ann Karimova  
Cardiac Critical Care Unit, Cardiothoracic Surgery, Perfusion Dept, Great Ormond Street Hospital London, UK

**Purpose:**

Long term mechanical bridge (MB) with paracorporeal ventricular assist devices (VAD – such as Berlin Heart EXCOR) has the potential to revolutionise waiting for heart transplantation (HTx) for pediatric patients. We present our experience with MB in the last 3 years, focusing on the most difficult group < 10 kg.

**Methods:**

Retrospective review of all patients which were mechanically bridged to transplant at our institution between Dec 2004 and Jan 2008: type of support (ECMO versus VAD), length of support, outcomes.

ECMO remains our device of choice if short-term support is anticipated, in patients requiring emergency mechanical assist or evaluation for suitability for HTx.

**Results:**

Between Dec 2004 and Jan 2008 twelve patients underwent MB (5 had ECMO prior to VAD). Patients <10kg had considerably longer time on assist compared to those > 10 kg.

A progressive reduction in post-transplantation ICU support was achieved in all VAD survivors compared to those on ECMO.

weight MB	Type	Transplanted			Died	
		No home Pts	Time on assist (days)	discharge (days post HTx)	No Pts	Time on assist (days)
< 10 kg	VAD +/- ECMO	5	82.8 (24-172)	14.2(10-20)(4/5)	1	30
> 10 kg	ECMO	4	13.5 (6-20)	42.2 (11-85)	2	7 (4-10)
	VAD +/- ECMO	2	7 (3-11)	16.5 (11-22)	4	14.7 (5-25)

All data in number of days: mean (range)

**Conclusions:**

A key problem in HTx is to have an appropriate heart available for the right patient at the right time. Compared to ECMO, bridging with VAD offers longer and better quality waiting time together with excellent post HTx recovery, particularly in the <10kg group. Expanding the number of patients on long-term MB to Tx will have a serious impact on the waiting list and on financial resources, which has to be carefully evaluated.

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**Antithrombotic Therapy During Mechanical Circulatory Support in Pediatric Patients**

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Ulrich Schweigmann and Werner Streif  
Department Pediatrics, Innsbruck Medical University, Austria

Based on the experience of 17 pediatric patients, supported with ventricular assist devices (VADs), including two patients, who developed heparin induced thrombocytopenia (HIT) and 14 children, supported with venovenous extracorporeal membrane oxygenation (ECMO – 4 of them switched to a VAD later), a standardised protocol for anticoagulation was developed:

Patients on ECMO are anticoagulated with intravenous unfractionated heparin (ufHep, PTT 50-70 seconds).

Bypass-surgery for VAD-implantation or explantation is managed with ufHep in all cases (including HIT-patients). After implantation of VAD, patients are treated with subcutaneous low molecular weight heparin (LWH) without use of ufHep. In HIT-patients, LWH is replaced by agathroban, monitored with PTT (50-70 seconds). Acetylsalicylic acid (ASA) and clopidogrel are added at the seventh post operative day. Inhibition of

thrombocyte-aggregation is monitored by multiplate electrode aggregometry (MEA), using the Multiplate<sup>®</sup> (Dynabite GmbH, Munich, Germany) facility. When all chest-tubes are removed, phenprocoumon is started and LWH or agathroban is stopped, when INR is in the target-range (2,5-3,5) for at least 24 hours. Pumps are changed as instructed by the manufacturer.

This protocol differs from the “Edmonton-protocol” in the timing of thrombocyte-inhibition and in the drugs used. We use only LWH in our VAD-patients postoperatively and clopidogrel is used instead of dipyridamole. For monitoring of thrombocyte-aggregation-inhibition we don't use the haemoscope thrombelastogramm because we had quicker and more reliable results with the multiplate<sup>®</sup> facility at significantly lower costs.

Using this protocol, excellent results were achieved.

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**ECMO vs. Berlin Heart: Support Mode Affects Cerebral and Somatic NIRS Saturation During Bridge to Transplantation for Cardiac Failure in Children**

Michael E. Mitchell, MD, James S. Tweddell, MD, Nancy S. Ghanayem, MD, Ndidi Musa, MD, Richard J. Berens, MD, Kimberly L. Gandy, MD, Kathleen Mussatto, RN, and George M. Hoffman, MD  
 Departments of Pediatrics, Surgery, Cardiothoracic Surgery,  
 Medical College of Wisconsin, Children's Hospital of Wisconsin, Milwaukee, Wisconsin, USA

**Purpose:**

The purpose of this investigation is to characterize cerebral and end organ tissue perfusion during different hemodynamic support conditions in children. We hypothesize that there will be differences in tissue oxygen saturation curves during continuous vs. pulsatile asynchronous vs. pulsatile synchronous perfusion.

**Methods:**

A retrospective data extraction was conducted on all 30 patients who survived ECMO to discharge (n=24), or who were placed on the Berlin heart (n=6), since January, 2004 at our pediatric heart center. The sequence of support was identified for all patients (e.g., failure to ECMO to Berlin Heart to Transplant). Cerebral and Somatic NIRS regional oxygen saturation levels (Somanetics 5100B, rSO<sub>2</sub>) were recorded hourly for the 24 hrs. before and after changes in support status. Comparison of rSO<sub>2</sub> between support modes was performed using time series regression, with the significance cut off defined at p < .05.

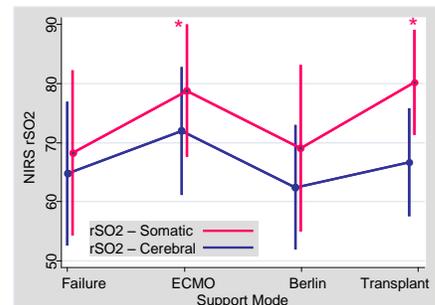
**Results:**

In the group of 24 ECMO survivors, rSO<sub>2</sub>-Cerebral was significantly higher with initiation of ECMO (71 ± 1 [69-74] vs. 63 ± 1 [59-67], p<0.01), but did not fall with decannulation. However, rSO<sub>2</sub>-Somatic levels declined moderately following successful decannulation (78 ± 1 [76-81] to 72 ± 1 [70-75], p<.01).

In the group of patients who required long term mechanical support with the Berlin Heart, r-SO<sub>2</sub>-Somatic was only improved by ECMO or transplantation; cerebral saturation was relatively unchanged regardless of support mode. During the transition from ECMO to Berlin Heart there was a significant drop in rSO<sub>2</sub>-Somatic. Transplantation improved both measures of organ perfusion compared to support with the Berlin Heart.

Mode of Support		rSO <sub>2</sub> -Cerebral	rSO <sub>2</sub> -Somatic
Initiation of Support	Failure	61 ± 3 [54-67]	53 ± 5 [43-62]
	ECMO	65 ± 3 [58-71]	81 ± 5 [72-90] *
	Berlin	62 ± 3 [56-69]	68 ± 5 [58-77]
Transition of Support	ECMO	64 ± 4 [57-71]	76 ± 4 [67-84]
	Berlin	61 ± 3 [54-68]	62 ± 4 [53-70] *
Transplant	Berlin	62 ± 2 [58-66]	66 ± 3 [61-71]
	Transplant	67 ± 2 [63-70] *	81 ± 2 [77-86] *

\* p<0.01



**Conclusions:**

Although the Berlin Heart may have advantage for longer term support, ECMO apparently provides consistently better organ perfusion as measured by NIRS. NIRS derived perfusion parameters should be used to characterize support of the failing circulation.

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**Use of Pulsatile Ventricular Assist Device (Berlin Heart EXCOR<sup>®</sup>) and  
Interventional Lung Assist Device (NovaLung<sup>®</sup>) in an Animal Model**

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Tilman Humpl MD, PhD, Julius Z. Wermelt MD; Osami Honjo, MD; Glen van Arsdell MD; Coleen Gruenwald RRT; Johannes Müller MD, Ali Kilic BioMed Engineer

Department of Critical Care Medicine, Department of Cardiovascular Surgery, The Hospital for Sick Children, 555 University Avenue, Toronto, ON, M5G 1X8, Canada; Berlin Heart GmbH, Wiesenweg 10, 12247 Berlin, Germany

**Introduction:**

Ventricular assist devices (VAD) have been successfully used for patients with end stage heart failure as a bridge to transplant. Some patients also suffer from pulmonary insufficiency or failure. In this setting an Interventional Lung Assist Device (iLA) may improve oxygenation and CO<sub>2</sub>-clearance. The aim of this study was to assess feasibility and practicability of the combined use of both devices.

**Methods:**

The study was approved by the local animal research ethics board. Three 30kg and three 10kg pigs were anaesthetized and cannulated for cardiopulmonary bypass (CPB, right atrium to right femoral artery). A 30ml pump was used for the 30kg pigs and a 10ml pump for the 10kg pigs. The VAD was placed

between left ventricular apex and the ascending aorta. The iLA was placed between the VAD and the aortic cannula. Flow measurements were performed with the HT 110 bypass flowmeter (Transonic Systems Inc., Ithaca, NY) before and after the iLA. Pressures pre/post iLA were measured using standard transducers. Blood gas, haemoglobin, platelet count and free haemoglobin were measured during CPB, at the start of EXCOR / iLA and at 2 hrs.

**Results:**

The flow was unchanged before and after the iLA. The mean arterial pressure (MAP) pre-/postmembrane was decreased by a mean of 14 mmHg in all pigs while systolic pressure was damped significantly in some individuals by the iLA. The iLA could effectively improve the gas exchange.

**Conclusions:**

The combination of a VAD and iLA in an animal model is feasible. There was no adverse effect with regards to hemodynamics. Oxygenation and CO<sub>2</sub> clearance was effectively supported by the iLA. Patients with heart failure and pulmonary insufficiency may benefit from this setup.

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**In Vitro Performance Evaluation of the Integrated Pediatric Cardiopulmonary Support System (pCAS)**

George M. Pantalos, Ph.D., Tracy Merkley, M.S., Jeffrey Speakman, Gregory Johnson, Ph.D., Mark J. Gartner, Ph.D. University of Louisville, Cardiovascular Innovation Institute, Louisville, KY, & Ension, Inc., Pittsburgh, PA

**Purpose:** To evaluate the pumping performance of the integrated, neonatal pediatric cardiopulmonary support system (pCAS), revision 4 (rev 4) when using clinically relevant cannulae and tubing.

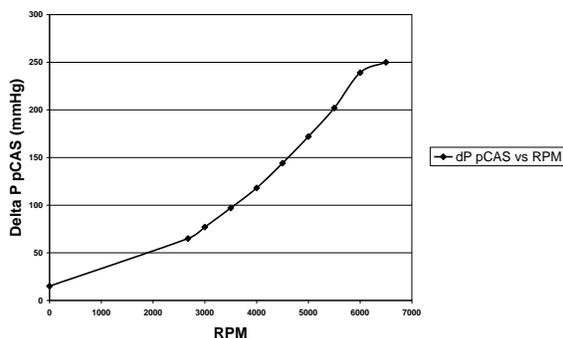
**Methods:** In vitro pumping performance of Revision 4 of the pediatric cardiopulmonary support system (pCAS) was evaluated using a mock circulation loop that approximates key anatomic features and hemodynamics of a 1 year old patient on extracorporeal membrane oxygenation (ECMO). Consistent with the anticipated clinical use, the right atrium was cannulated with a 10 Fr. Medtronic/Biomedicus ECMO inflow cannula; the aorta was cannulated with an 8 Fr. ECMO arterial cannula for the pump outflow. The cannulae were connected to the pCAS inlet and outlet using 60 cm of 1/4" I.D. bypass tubing. The total priming volume of the cannulae, tubing and pump/oxygenator was 80 cc. Right atrial pressure (RAP), pCAS inlet and outlet pressures, and aortic pressure (AoP) were measured with high fidelity pressure catheters (Millar Instruments). The aortic flow and the pCAS outflow were measured with ultrasonic, transit-time flow probes (Transonic Systems, Inc). The test fluid was a 40% glycerin/water, blood-analog fluid ( $\mu = 3.7 \text{ cP @ } 20^\circ\text{C}$ ).

Each test run was initiated by establishing baseline hemodynamic conditions (heart rate = 120 bpm, cardiac output (CO) = 800 ml/min, mean aortic pressure (AoP) =

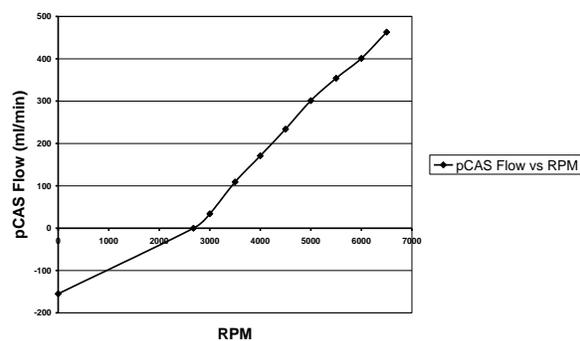
75 mm Hg, mean right atrial pressure (RAP) = 4 to 8 mm Hg, and mean left atrial pressure (LAP) = 8 to 12 mm Hg). Pump-stop reverse flow was determined by unclamping the cannulae with the pump at 0 RPM. The RPM was initially increased until the "zero-flow" RPM was identified. The RPM was then increased in 500 RPM increments with the systemic vascular resistance element adjusted to maintain a mean AoP of 75 mm Hg for each RPM setting with the resulting pump outflow rate noted. The RPM increments were continued until the controller reached the maximum RPM.

**Results:** The pCAS flow increased with increasing RPM to nearly 0.5 l/min at 6500 RPM (top chart). The pump-stop reverse flow was -160 ml/min and the "zero-flow" RPM was 2700. The pressure difference ( $\Delta P$ ) across the pump was 60 mm Hg at the "zero-flow" condition and increased to 250 mmHg at the maximum flow achieved (bottom chart). The pCAS inlet pressure ranged from 0 mm Hg at "zero flow" to -50 mm Hg at the maximum flow rate and the outlet pressure ranged from 60 mm Hg at "zero-flow" to 200 mm Hg at the maximum flow rate. The  $\Delta P$  across the inflow tubing and cannulae at the maximum flow rate was 53 mm Hg and the  $\Delta P$  across the outflow tubing and cannulae at the maximum flow rate was 130 mm Hg.

Delta P pCAS vs RPM



pCAS Flow vs RPM



**Discussion:** When incorporated with clinically relevant cannula and tubing, the pCAS Rev 4 can pump acceptable flow rates for neonatal support. Current impeller design changes will improve pumping efficiency permitting pCAS operation at a lower RPM reducing hemolysis potential.

**Acknowledgement:** Supported by National Heart, Lung, and Blood Institute Contract No. HHSN268200449189C, the Jewish Hospital & St. Mary's Foundation, and Kosair Charities.

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**Debate: Pulsatile vs. Non-Pulsatile Flow**  
**Pro: Pulsatile Flow**

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Akif Ündar, PhD

Departments of Pediatrics, Surgery, and Bioengineering

Penn State College of Medicine, Penn State Children's Hospital, Hershey, Pennsylvania, USA

The debate over the benefits of pulsatile vs. non-pulsatile perfusion on vital organ recovery during cardiopulmonary bypass procedures started in the mid-1950s and still continues. In the literature, it is possible to find several pro and con articles published on this controversy, but the majority of publications that cannot show any differences suffer study-design limitations.

In order to make meaningful and valid comparisons between the perfusion modes, two distinct groups (one pulsatile and one non-pulsatile) must be included in the study design. Each group must be subjected to only one perfusion mode.

Patients in both groups must have similar demographics in terms of severity of heart defects, age, weight, etc. In addition, during CPB, cross clamp time, hemodilution, temperature, mean arterial pressure and pump flow rates must be similar in each group.

The same components of the extracorporeal circuit, not just the pump, but the oxygenator, arterial filter,

and aortic cannula, must be used in both groups. The only difference between the groups should be the perfusion mode, nothing else.

Pressure-flow waveforms must be precisely quantified in terms of hemodynamic energy levels, Energy Equivalent Pressure (EEP) and Surplus Hemodynamic Energy (SHE), because the generation of pulsatile flow depends on energy gradient. It has been clearly shown that, at identical mean arterial pressure and pump flow rates, pulsatile perfusion generates up to 7-10 fold more surplus hemodynamic energy (extra energy) compared to non-pulsatile flow.

With adequate quality of pulsatility, it is documented that pulsatile flow maintains better regional and global cerebral, renal and myocardial perfusion, and faster vital organ recovery in pediatric patients as well as in animal experiments. Pulsatile flow results in less inotropic support, intubation time, ICU and hospital stay.

**Summary:**

Pro-nonpulsatile flow investigators only claim that there is no difference between the perfusion modes in terms of end organ recovery. They do not claim that non-pulsatile flow is superior to pulsatile flow. However, pro-pulsatile flow investigators have documented that the use of pulsatile flow results in less vital organ damage and faster recovery compared to non-pulsatile flow.

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**Debate: Pulsatile vs. Non-Pulsatile Flow**

**Con: Non-Pulsatile Flow**

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Yukihiko Nosé, MD  
Professor of Surgery  
Michael E. DeBakey Department of Surgery, Houston, Texas, USA

Since the initiation of the cardiopulmonary bypass by John Gibbons in 1953, physiological acceptance of non-pulsatile flow typically used for such clinical application has been discussed again and again.

As early as 1955, Adam Wesolowsky in Brooklyn, NY reported that there are no physiological differences between pulsatile and non-pulsatile flows at the same mean pressure and a same flow rate of 130ml/kg/min in dogs. However, lower flow rates, less than 100ml/kg/min pulse-less flows revealed many physiological abnormalities.

In 1960, Ogata and others, Japan, also reported that there are no differences between the two groups when utilizing over 100 ml/kg/min. These results have since been confirmed by Nakagawa and his group in Chiba, Japan. This author also demonstrated during the early 1980's that calves of non-pulsatile total body perfusion with flows of over 100ml/kg/min for 6 weeks did not reveal any

difference in physiology. After 6 weeks, the non-pulsatile flow perfused animals can be physiologically normal below with blood flows of 100ml/kg/min. (Nosé Y. Non-pulsatile mode of blood flow required for cardiopulmonary bypass and total body perfusion; *Artificial Organs* 17(2) 92-102, 1993)

So it is this author's opinion that for the maintenance of physiology of our body, it does not matter whether we used a non-pulsatile flow or a pulsatile flow.

The most important issue is whether we should provide enough flow to the body. As described many times, it is necessary to provide 20% more pulse-less blood flows over above the pulsatile blood flow, in order to provide normal body physiologies for at least 6 weeks. It requires over 100ml/kg/min flows. The reason is that pulse-less flows in capillaries is less efficient to provide proper gas exchange for tissues.

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## **An Axial Flow Turbo Pump with Hydrodynamic Bearings as a Ventricular Assist Device Applicable to Pediatric Patients**

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Y.Taenaka<sup>1</sup>, T.Tsukiya<sup>1</sup>, T.Mizuno<sup>1</sup>, H.Tanaka<sup>1</sup>, E.Tatsumi<sup>1</sup>  
Y.Kakiuchi<sup>2</sup>, T.Hidaka<sup>2</sup>, T.Okubo<sup>2</sup>, T.Osada<sup>2</sup>, R.Kosaka<sup>3</sup>, O.Maruyama<sup>3</sup>, M.Nishida<sup>3</sup>, T.Yamane<sup>3</sup>,  
National Cardiovascular Center, Osaka, Japan<sup>1</sup>, Mitsubishi Heavy Industries Ltd., Hyogo, Japan<sup>2</sup>,  
National Institute of Advanced Industrial Science and Technology (AIST), Ibaraki, Japan<sup>3</sup>

### **Purpose:**

An axial flow turbo pump with hydrodynamic bearings has been developed as an implantable ventricular assist device which can be applied to pediatric patients by virtue of its smaller size. The purpose of this study is to evaluate performances of the device in chronic animal experiments.

### **Materials and Methods:**

The pump is 29 mm in diameter and 70 mm in length and weighs 150 g with a titanium-made casing. The flow rate of 5 L/min against the pump head of 100 mmHg is achieved at the impeller rotational speed of 9,000 rpm and 1 L/min at 8,400 rpm. The hemolysis rate of the pump is as low as that of Biomedicus BP-80. Five pumps were implanted between the left ventricular apex and the descending aorta in 2 calves paracorporeally as an early-phase evaluation and in 3 calves in the chest cavity in recent experiments.

### **Conclusions:**

The smaller-sized axial flow turbo pump itself has favorable in vivo performances such as antithrombogenicity and hemolytic properties. This pump is a potential future device for pediatric use with further improvements of other important parts including conduits.

Antithrombotic therapies were conducted with oral coumadin intake and INR was controlled to be 3.0-5.0.

### **Results:**

Two early-phase calves survived for 78 and 50 days and the latter 3 cases for 90, 40, 68 days, respectively. Significant hemolysis was not observed in any of the cases. Thrombus formation in the conduits caused decline in the pump flow to result in the termination of the experiments in the 78, 50 and 68-day experiment. A pump stopped by a broken wire accident on the 40th experimental day. An experiment was carried out for 90 days uneventfully until an elective termination. In all experiments no thrombus formation was observed in the blood pumps.

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**In Vivo Performance of the Percutaneous Transhepatic Transseptal TandemHeart® Circulatory Support System**

D. Scott Lim<sup>†</sup>, M.D., Cory J. Cortese<sup>‡</sup>, B.S., Amber N. Loree<sup>‡</sup>, B.S., David A. Dean<sup>§</sup>, M.D., Robert G. Svittek<sup>‡</sup>, Ph.D.

<sup>†</sup>Department of Pediatrics, Division of Pediatric Cardiology, University of Virginia, Charlottesville, Va.

<sup>‡</sup>R&D and Engineering Department, CardiacAssist, Inc., Pittsburgh, Pa

<sup>§</sup>Allegheny-Singer Research Institute, Pittsburgh, PA

**Purpose:**

Percutaneous circulatory assist poses particular challenges in the pediatric population. We are developing a percutaneous circulatory assist system consisting of a venous cannula inserted into the left atrium, a centrifugal pump, and an arterial cannula. We report on the in vivo testing of transhepatic, transseptal cannula insertion to support the left ventricle.

**Methods:**

Yorkshire swine 17 – 21 kg (n=2) were anesthetized for the procedure. After hepatic venous angiography, percutaneous puncture of the middle hepatic vein was performed. From this access, transseptal puncture was performed with echocardiographic guidance. After anticoagulation, a custom wire-wound 14 Fr, 26 cm venous inflow cannula was placed in the left atrium via hepatic approach. A 10 Fr femoral arterial cannula was placed percutaneously, and the circuit completed with the TandemHeart centrifugal pump. Hemodynamics and plasma free hemoglobin (pfHb) were measured for up to 5 hours of mechanical support.

**Results:**

Baseline cardiac output was 1.6 L/min. The pump delivered flows ranging from 0.9 - 1.4 L/min (max 1.9 L/min/m<sup>2</sup>), which corresponded to >85% of baseline systemic outputs. PfHb level rose from an insertion level of 26 mg/dL to a maximum of 32 mg/dL and then fell below insertion levels before sacrifice. Hematocrit, pulmonary artery pressure, and systemic oxygen

saturations remained stable during support. Mixed venous oxygen saturation and cardiac output increased as expected. Post-mortem examination of the first animal, with cannulae in place, showed no bleeding. The second animal, after failed device occlusion of hepatic tract, was found to have bleeding into the abdominal cavity.

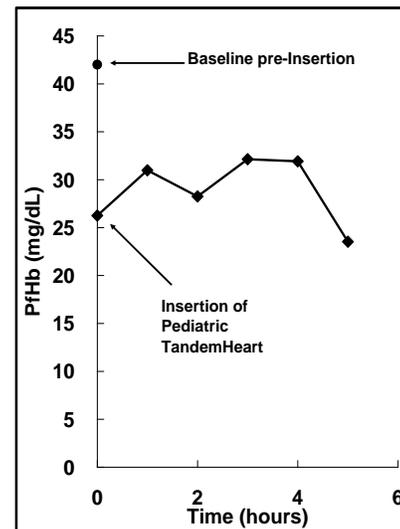


Figure 1. PfHb (second animal) remained relatively constant. PfHb was not measured for the first experiment.

**Conclusions:**

The transhepatic, transseptal insertion of the venous inflow cannula, coupled with the TandemHeart centrifugal pump and femoral arterial cannulation allows percutaneous mechanical support in pediatric-sized circulations, 17 – 21 kg.

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**A Novel, Low Cost, Disposable Pediatric Pulsatile Rotary Ventricular Pump (PRVP) for Cardiac Surgery that Provides a Physiological Flow Pattern**

Daniel E. Mazur, Kathryn Osterholzer, PhD, Scott I. Merz, PhD.  
MC3 Corp., Ann Arbor, Michigan, USA

**Purpose:**

Research is underway to develop a novel, low cost, disposable pediatric pulsatile rotary ventricular pump (PRVP) for cardiac surgery that provides a physiological flow pattern. Computational modeling, prototype configuration and initial bench testing are presented.

**Methods:**

A finite element based fluid-structure interaction model (FSI) of the generalized pump chamber was created and used to predict geometry resulting in flow and pressure performance suitable for pediatric bypass use. A pulsatile version of the chamber was fabricated and tested in a pediatric CPB loop with Capiiox oxygenator, DLP 10 French arterial cannula and a simplified pediatric patient mock. Pressure and flow waveforms were recorded distal to the cannula for mean flows of 0.5 L/min and 1.0 L/min, at 40 mmHg mean arterial pressure (MAP). Surplus

hemodynamic energy (SHE) level was calculated with the following formula:

$$SHE \text{ (ergs/cm}^3\text{)} = 1332 \left[ \frac{(\int f_{pdt})}{(\int f_{dt})} - MAP \right]$$

**Results:**

Performance target for pediatric use of 2 L/min at 100 RPM was met using a 40 c.c. chamber on a 4" diameter pumphead.

Pulsatile chamber results are listed in the following table and indicate significant surplus hydraulic energy is capable of being generated.

Flowrate ( L/min Average)	0.5	1.0 L/min
MAP	42.26	40.94
EEP	47.20	55.61
% increase EEP over MAP	11.68	35.83
SHE	6577	19541

**Conclusions:**

A novel pump for pediatric cardiac surgery has been prototyped based on a scaled embodiment of a proprietary MC3 pump technology and shown capable of meeting targeted pulsatile performance. The PRVP pump promises to provide needed safety and performance improvements to pediatric bypass surgery and post surgical ventricular support.

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## **Management of a Pediatric Patient on the Berlin EXCOR<sup>®</sup> Ventricular Assist Device with Argatroban After Heparin-Induced Thrombocytopenia**

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Michael L. Schmitz, M.D., Sherry C. Faulkner, C.C.P., Adnan T. Bhutta, M.D., Paul M. Seib, M.D., Elizabeth A. Frazier, M.D., Michiaki Imamura, M.D., Ph.D., Robert D. B. Jaquiss, M.D., The University of Arkansas for Medical Sciences, College of Medicine, and Arkansas Children's Hospital

### **Case Report:**

A 15 yo boy with Gitelman syndrome, asthma, and a dilated viral cardiomyopathy and ASD was initially treated with digoxin, furosemide, captopril and later, milrinone. He received heparin to flush his PICC and then 11d later, a heparin infusion for low cardiac output, recalcitrant SVT, and potential intracardiac thrombosis. Platelet counts dropped from 250-300K to 100-150K 4wk later. After 40d, a 60 ml Berlin EXCOR<sup>®</sup> LVAD was placed using 18K U of heparin and protamine reversal. Heparin was restarted but stopped after 24hr when an ELISA for PF4/heparin complex antibodies result returned as positive from blood sent the day prior to LVAD placement. On POD2, argatroban began at 2 mcg/kg/min to maintain an aPTT of 1.5-2 times the control value. Targeting

an INR of 3, warfarin was increased as argatroban was weaned by POD17. Anticoagulation then included warfarin, aspirin, and persantine monitored with INR and TEG platelet mapping. The ELISA had been negative for 6wk and heparin was used for cardiac transplantation 56d after LVAD without complications. The child was discharged home 43d later.

### **Discussion:**

Argatroban is a direct thrombin inhibitor with no reports of its use in humans for VAD's. Disadvantages include a lack of anticoagulant monitoring. It prolongs PT, aPTT, and INR in a non-linear and poorly reproducible manner. There are no reversal agents but its hepatic clearance  $t_{1/2}$  is 50 min.

### **Conclusions:**

Argatroban can be used successfully for a child with an LVAD and HIT.

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**Berlin Heart in Congenital Heart Disease: Crossing the Border of Septated  
Hearts**

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Davide F. Calvaruso, MD, Antonio Rubino, MD, Salvatore Ocello, MD, David F. Petruccelli, MD, Diego Guardi, MD, Nicoletta Salviato, MD, Salvo Colletto, CCP, Adriano Cipriani, MD, Carlo F. Marcelletti, MD.  
Department of Pediatric Cardiac Surgery, ARNAS Ospedale Civico, Palermo (Italy)

**Introduction:**

Different authors have reported the use of Berlin Heart EXCOR ventricular assist device (VAD) in pediatric age. But VAD use in pediatric population does not mean its application on congenital heart disease (CHD).

We describe our experience with implantations of Berlin Heart EXCOR ventricular assist device (VAD) as a bridge to transplantation, on patients with CHD.

**Methods:**

From 2001 to 2007, 11 consecutive patients, median age  $10 \pm 6.5$  years (ranging 24 days to 22 years), median weight  $24 \pm 19$  Kg (ranging 3.7 to 59 Kg) were treated with Berlin Heart VAD as mechanical support for cardiac failure.

Before VAD implantation 3 patients required cardiopulmonary resuscitation and 2 were assisted with arteriovenous extracorporeal membrane oxygenation. Five patients received a biventricular VAD support and the other 6 a single VAD support. All patients were listed for heart transplantation.

**Conclusions:**

Our experience shows that there is still room for new applications of the Berlin Heart EXCOR VAD on unseptated hearts.

We feel that the Berlin Heart VAD may be considered as feasible treatment for heart failure in the pediatric population affected by CHD with a preserved respiratory function.

**Results:**

All patients increased systemic blood pressure, base excess and  $pO_2/F_iO_2$  after Berlin Heart implantation.

Seven comprehensive deaths occurred. Four patients died while on waiting list. Three deaths occurred after graft implantation.

Four patients are still alive in good clinical conditions after heart transplantation.

In our series, we reported two cases of original use of the Berlin Heart in patients with unseptated hearts and preserved respiratory function until a successful heart transplantation.

One patient received a VAD as single systemic artificial ventricle to support an extracardiac Fontan circulation.

In another one, a single VAD was used to support a univentricular heart with a severe pulmonary stenosis, with the outflow cannula serving both aorta and pulmonary arteries through a modified B-T shunt.

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**A New Dressing Technique to Prevent Cannula Infection After Berlin Heart  
EXCOR® Pediatric Implantation**

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Jodi Conway, BScN, Holger Buchholz, MD, Laurence Lequier, MD, David Ross MD, Bev Wiwchar BCcN, Patti Massicotte, MD, Mary Bauman, MScN NP, David Darlington, CPC CCP, Ivan Rebeyka, MD

Pediatric Ventricular Assist Device Program and the Departments of Pediatrics and Surgery, Stollery Children's Hospital and the University of Alberta, Edmonton, Alberta, Canada

**Purpose:**

The EXCOR® Pediatric is used in children with severe heart failure. The duration of support may last months or years. A major complication of treatment is cannula site infection. In addition, mobilization and routine daily activities are high priorities in caring for these patients. This creates a challenge to develop an optimal dressing change technique.

**Methods:**

5 Berlin Heart patients between 2month and 17years (mean 7.2years) were on VAD support for 23days to 274days (mean 131 days). Dressing changes were completed: once a day for the first 10days then every second day. The goal is twice a week. The old dressing was removed and the exposed cannula and pump head were cleansed. The cannulas and sites were visually examined and documented. If the skin around the cannula site was open, normal saline was

used to irrigate around the cannula. Each cannula was cleansed with 2%chlorhexidine solution and non sting barrier film was used to prevent skin maceration. Metaline® wound dressing was placed as it is non-adherent which promote the healing process. Each cannula site was wrapped with 4x4 gauze using a Y-shaped technique to lift the cannula away from the skin. The remainder of the dressing technique entailed the use of 4x4's and abdominal pads to lift the cannulas off the skin to prevent pressure lesions. The entire dressing was then covered with an abdominal pad and secured with tubular bandage.

**Results:**

The use of this technique promoted healing with a low rate of cannula site infection. Lifting and repositioning the cannula resulted in a low incidence of pressure related injury.

**Conclusions:**

The implementation of a standardized technique has demonstrated a low incidence of cannula site infection and no pressure related injury. It is important that a small group of specially trained nurses monitor and assess the cannula sites.

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### **Development of an Interprofessional Pediatric Ventricular Assist Device Support Team**

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Sarah Furness RN, Cecilia Hyslop-St. George, RN Med., Barbara Pound RN, Misty Earle, RN, Andrea Maurich RN, Danika Rice RN, Tilman Humpl MD PhD.

#### **Background:**

The Berlin Heart EXCOR® Pediatric Ventricular Assist Device (VAD) was introduced to SickKids Hospital, Toronto in 2004, to support critically ill children in heart failure, as a bridge to cardiac transplantation. Caring for paediatric patients with a VAD, requires a collaborative approach from an interprofessional team to ensure maximum patient safety and optimal outcomes. Initiating a VAD program is challenging, due to the complex medical and technical nature of this device, and associated learning needs. Consideration of varied roles and responsibilities of each interprofessional team member involved in the care is critical.

#### **Methods:**

In 2004 seven team members of the SickKids cardiac program travelled to Berlin to learn about the Berlin Heart from the German Heart Centre, a well established centre for VAD care. The core VAD team was made up of a Cardiac Intensivist, cardiac critical care nursing staff and a nurse educator. Their responsibilities included educating involved health care professionals, patients and families about the VAD. The core team also provided wound care (cannulation sites, chest tubes, sternal incision) as well as daily follow up. 24hr "on call" support was provided those involved in care. After initial training of the experts, all efforts were directed towards development of a larger core team that could act as a

resource for health care professionals. These experts successfully maintained continuity of care.

An initial comprehensive infra-structure of supports was put into place by the core group to support primary caregivers of VAD patients and families. The comprehensive infra-structure included perfusionists (pre-implant equipment organization and perfusion), biomedical engineers (maintenance/service/education of the IKUS driving unit), transplant/heart failure services (pre-transplant patient management/listing), physiotherapy (rehabilitation after implantation), social work (family and patient support throughout the trajectory of illness), pharmacy (drug therapy), psychiatry (support of patients and families), haematology (anticoagulation), and trained nurses from critical care and the cardiology ward.

#### **Results:**

From October 2004 to November 2007, 10 Berlin Heart EXCOR® Pediatric Ventricular Assist Devices were implanted in pediatric patients with a diagnosis of cardiomyopathy or heart failure. Out of 9 patients, eight (88%) were successfully transplanted, and 77% survived to hospital discharge. One patient was transitioned from the cardiac critical care unit to the cardiac ward on the Berlin Heart. One patient is currently being supported on the Berlin Heart.

#### **Conclusions:**

The complex care of a patient on a VAD needs a specialized team approach to cover all patient care needs. Ongoing interprofessional education continues to improve competency of care. Continuity of care was assured on all levels of service to guarantee the best possible outcomes.

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**Prolonged But Successful Weaning from LVAD After Cardiac  
Decompensation Due to Late-Recognized Coarctation of the Aorta in a  
Toddler**

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Christian Meierhofer, MD<sup>1</sup>, Ludwig Mueller, MD<sup>2</sup>, Herwig Antretter, MD<sup>2</sup>, Guenther Laufer, MD<sup>2</sup>, Peter Mair, MD<sup>3</sup>, Corinna Velik-Salchner, MD<sup>3</sup>, Martin Fruehwirth, MD<sup>4</sup>, Nikolaus Neu, MD<sup>4</sup>, Elisabeth Schermer, MD<sup>1</sup>, Jorrit Brunnemann, MD<sup>1</sup>, Ralf Geiger, MD<sup>1</sup>, Joerg-Ingolf Stein, MD<sup>1</sup>, Ulrich Schweigmann, MD<sup>1</sup>

<sup>5</sup>. Department of Pediatrics, Division of Pediatric Cardiology, Pneumology, Allergology and Cystic Fibrosis

<sup>6</sup>. Department of Cardiac Surgery

<sup>7</sup>. Department Anaesthesia and Intensive Care Medicine

<sup>8</sup>. Department of Pediatrics, Pediatric Intensive Care Unit  
Medical University Innsbruck, Austria

**Case presentation:**

A 2-year-old boy was presented with late-recognized coarctation of the aorta, and pulmonary hypertension, due to left ventricular failure. The coarctation was corrected the day of admission by end-to-end anastomosis. Echocardiography and angiography showed a good postoperative result. Weaning from the respirator failed under support with inotropes, Calcium-sensitizer and diuretics, followed by beta-blockers and ACE-inhibitors over a 3 week-period due to left ventricular failure. Consequently a left ventricular assist device (EXCOR-Pediatric®, 25cc ventricle, Berlin Heart, Germany) was implanted.

While on LVAD, the boy developed paradox hypertension, requiring extensive antihypertensive drug therapy. Remaining pulmonary hypertension was treated with phosphodiesterase inhibitor and endothelin-1 receptor blocker. Hence this drug regime it was possible to reduce systemic and pulmonary blood

pressures. Left ventricle was unloaded completely by the assist-device for two weeks (pump-rate 80/min).

An attempt to wean from LVAD was started with reduction of the pump-rate every three days by ten. Left ventricular diameter increased significantly and ejection fraction deteriorated.

Left ventricle was completely unloaded for additional 4 weeks. Then a very smooth weaning-protocol was started with a reduction of 5 cycles/minute every week.

The assist device was successfully explanted 119 days after implantation.

150 days after admission the patient was discharged with normal cardiac function. Treatment with beta-blocker, diuretics and ACE-inhibitor is still needed for blood pressure control.

**Conclusions:**

We present prolonged, but successful weaning from LVAD of a toddler with a pressure-damaged left ventricle. Probably patient reduction of the LVAD in small steps leads to successful weaning. Long-time follow-up is still pending in this patient with congenital heart disease.

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## **Rapidly Deployed ECMO as an Extension of CPR: Sigle Center Results**

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Peter Wearden MD, Ana Manrique, MD, Margarita Arroyo, MD, Kent Kelly CCP, Ricardo Munoz MD, Victor Morell MD

Departments of Pediatrics, Heart Center - Cardiothoracic Surgery

University of Pittsburgh, Children's Hospital of Pittsburgh-UPMC, Pittsburgh, Pennsylvania, USA

### **Purpose:**

We reviewed those patients who underwent ECMO between 2003 -2007. Patients were divided in two groups: those with resuscitation ECMO (E-ECMO) after cardiopulmonary arrest and those where ECMO was instituted for other reasons. We compared patient characteristics, ECMO support, complications and survival between both groups.

### **Methods:**

A retrospective review was performed from the medical charts and ECMO hospital database. Continuous variables were analyzed between groups using Student's t test. Categorical variables were expressed as percentages and analyzed using chi-square analysis or Fisher's exact test.

### **Results:**

From a total of 86 patients who underwent cardiac ECMO during the study period, 27 (31.4%) were in the E-ECMO group.

### **Conclusions:**

Patients receiving rapidly deployed ECMO as an extension of CPR have similar outcomes to those patients placed on ECMO for cardiac support for other reasons. Our data suggests that it is reasonable to deploy ECMO in these patients even after over 30 minutes of CPR.

For the E-ECMO group median age was 1.3 (0.03-516) months, mean CPR time before ECMO instauration was  $36.5 \pm 15$  minutes, median ECMO time was 75.9 (0.7-413) hours and Hospital length of Stay was 31 ( 1- 115) days. No significant differences for these variables were found between the two groups. Successful weaning (63% vs. 78%), early survival (59.3% vs. 72.9%) and Hospital Discharge survival (55.6% vs. 62.7%) were not significantly different between groups.

We found differences for Complications related with ECMO (88.9% vs. 54.2%)  $p 0.002$ , and a trend toward greater incidence of neurologic injury in E-ECMO group (22.2% vs. 8.5%).

An increase in survival was found through the study years for the E-ECMO group with 33% in 2003 and 83% in 2007.

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**Mock Circulation Simulation of Pediatric Extracorporeal Membrane  
Oxygenation (ECMO) in the Presence of a Congenital Heart Defect**

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George M. Pantalos, Ph.D., Tracy Merkley, M.S., Erle H. Austin, III, M.D., Christopher Mascio, M.D.  
University of Louisville, Department of Surgery and the Cardiovascular Innovation Institute, Louisville, Kentucky

**Purpose:** The performance of blood pumping systems being developed to provide circulatory support for infants and small children often presumes the presence of normal cardiac anatomy. However, circulatory support is often clinically necessary in the presence of unknown congenital defects. Sometimes, it is necessary to create a defect to achieve acceptable hemodynamics. The purpose of this investigation was to examine the hemodynamic consequence of extracorporeal membrane oxygenation (ECMO) in mock circulation experiments in the absence or presence of an atrial septal defect (ASD).

**Methods:** The effect of ECMO in the absence or presence of an ASD was evaluated using a mock circulation loop that approximates key anatomic features and hemodynamics of a 1 year old patient. Consistent with the anticipated clinical use, the right atrium (RA) was cannulated with a 10 Fr. Medtronic/Biomedicus ECMO venous cannula; the aorta was cannulated with an 8 Fr. ECMO arterial cannula for the pump outflow. The cannulae were connected to the inlet and outlet of a pediatric cardiopulmonary support device (pCAS, Enson, Inc. Pittsburgh, PA) using 60 cm of 1/4" I.D. bypass tubing. A graded ASD was created by incorporating a 6 mm I.D. tube between the left atrium (LA) and RA in the mock circulation with an adjustable pinch clamp to control the size of the ASD. RA pressure (RAP), LA pressure (LAP), pulmonary artery pressure (PAP), and aortic pressure (AoP) were measured with high fidelity pressure catheters (Millar Instruments, Houston, TX). The aortic flow, pulmonary artery flow, pCAS outflow, and ASD flow were measured with ultrasonic, transit-time flow probes (Transonic Systems, Inc, Ithaca, NY). The test fluid was a 40% glycerin/water, blood-analog fluid ( $\mu = 3.7$  cP @ 20°C).

A baseline for normal hemodynamic conditions was established (heart rate = 120 bpm, cardiac output (CO) = 800 ml/min, mean aortic pressure (AoP) = 75 mm Hg,

mean right atrial pressure (RAP) = 4 to 8 mm Hg, and mean left atrial pressure (LAP) = 8 to 12 mm Hg). The ASD was then opened 0%, 25%, 50%, 75%, and 100% and data was collected as the pCAS flow rate was incrementally increased. Tests were repeated with a greater circulating fluid volume and adjustments to the mock circulation so that the RAP, LAP, and PAP were elevated consistent with a degree of heart failure.

**Results:** Bi-phasic flow was observed through the ASD with the net flow being from the LA to RA. ASD flow varied from 0 to 200 ml/min depending on the situation. With no ASD, LAP did not rise indicating adequate left ventricular (LV) function was present. Opening the ASD usually resulted in a small lowering of the LAP pressure depending on the pressure level in the RA. Initiating ECMO flow simultaneously lowered RAP 5 to 8 mm Hg, LAP 11 to 16 mm Hg, and PAP 15 to 23 mm Hg while inducing a greater flow through the ASD.

**Discussion:** When initiating ECMO support in a septated heart, attention must be given to left ventricular function. Poor LV function and resultant LV distension may not allow recovery of cardiac function while on ECMO. It is sometimes necessary to create an ASD to decompress the left heart in this situation. This investigation has demonstrated that it is possible to simulate the hemodynamic aspects of ECMO support in the presence of an atrial septal defect of varying size. Many factors, including the left and right atrial pressures, status of left and right ventricular function, level of ECMO flow, and size of the ASD should be considered when exploring ways to optimize the resulting hemodynamic parameters. The versatility of the mock circulation simulation also lends itself to exploring the hemodynamic response to other kinds of circulatory support devices and to other congenital heart defects.

**Conclusions:** An appropriately configured pediatric mock circulatory system can be used to simulate the hemodynamic response and clinical intervention to ECMO support in the absence or presence of an ASD.

**Acknowledgement:** Support for this investigation was provided by the Jewish Hospital & St. Mary's Foundation and Kosair Charities. The pCAS pediatric pump/oxygenator was generously provided by Enson, Inc.

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**Extracorporeal Membrane Oxygenation Circulatory Support After  
Congenital Cardiac Surgery**

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Yasuyuki Suzuki, MD, Sanae Yamauchi, MD, Kazuyuki Daitoku, MD  
Kozo Fukui, MD, Ikou Fukuda, MD

Department of Thoracic and Cardiovascular Surgery, Hirosaki University School of Medicine.  
5 Zaifucho, Hirosaki, Aomori, 036-8562, Japan

**Purpose:**

Extracorporeal membrane oxygenation (ECMO) is widely used for circulatory support in pediatric cardiac patients with low cardiac output and hypoxemia after the cardiac surgery. But survival after the ECMO was reported about 50%, and there are controversies about indication because anatomic diagnosis and surgical procedure of children have more variability than adult patients. We evaluate retrospectively the efficacy of postoperative ECMO support following congenital cardiac surgery in infants and children.

**Methods:**

From April 2002 to February 2008, 7 patients aged 2 months to 9 years (median 30 months) who underwent surgical procedures for congenital heart disease received postoperative mechanical support for failing cardiac function and hypoxemia despite optimal medical therapy. Two patients had single-ventricle physiology, two had double outflow tract right ventricle with IVC interruption, two had

pulmonary atresia and one had AVSD. All operation was performed under the cardiopulmonary bypass, three of them were complete repair including Fontan circulation and four of them were palliative repair. In 4 patients ECMO was instituted in the operating room and in 3 patients this was introduced in the intensive care unit 2 to 48 hours postoperatively.

**Results:**

Six patients (86%) were successfully weaned from ECMO, while support was withdrawn in the remaining one due to irreversible heart damage. The mean duration of ECMO support was 106 hours (range 19-260 hours). Although management of the ECMO circuit, including anticoagulation (ACT: 150-250) was conducted following the institutional practice guidelines, it was difficult to control the bleeding. Following successful weaning, one patient died 12 hours later from hypoxemia. The other five survived to hospital discharge but one died 4 months after the operation, due to pneumonia and septic shock.

**Conclusions:**

We conclude that ECMO for the heart failure and respiratory insufficiency after congenital cardiac surgery was effective regardless of morphology of the heart and surgical procedure.

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**Acute Lung Failure During Mechanical Circulatory Support**

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Ulrich Schweigmann <sup>1)</sup>, Birgit Schwarz <sup>3)</sup>, Corinna Velik-Salchner <sup>3)</sup>, Herbert Hangler <sup>4)</sup>, Jorrit Brunnemann <sup>1)</sup>, Ralf Geiger <sup>1)</sup>, Jörg-Ingolf Stein <sup>1)</sup>, Martin Frühwirth <sup>2)</sup>, Nikolaus Neu <sup>2)</sup>, Elisabeth Schermer <sup>1)</sup>

- <sup>5)</sup> Dept. Pediatrics, Pediatric Cardiology
- <sup>6)</sup> Dept. Pediatrics, Pediatric Intensive Care
- <sup>7)</sup> Dept. Anaesthesia and Intensive Care Medicine
- <sup>8)</sup> Dept. Cardiac Surgery  
Innsbruck Medical University, Austria

The use of venoarterial extracorporeal membrane oxygenation (ECMO) and ventricular assist-devices (VADs) in pediatric patients with acute heart failure, refractory to intensive care therapy, is well established. Using a combined bridge or bridge-to-bridge strategy results in excellent survival rates in the pediatric population. We describe a pediatric patient who acquired acute respiratory failure due to transfusion related lung injury (TRALI) during VAD-implantation and was successfully treated with venovenous ECMO while on biventricular VAD support:

Patient: 15 year old girl, transferred with well documented progressive dilated cardiomyopathy, following acute myocarditis three month ago. Despite optimised drug therapy and intensive care management signs of end organ failure occurred. A biventricular VAD (Berlinheart EXCOR pediatric) was implanted. Surgery was uneventful. Thereafter she developed acute respiratory failure and a venovenous ECMO circuit was installed. ECMO was necessary for three days. Extubation was possible five days later and after 31 days of VAD support she underwent successful heart transplantation. The follow-up is seven month now and the patient is doing very well (NYHA Class I, normal neurology).

Acute lung failure can occur as complication of VAD-implantation, if transfusions (thrombocytes in the presented case) are needed. Venovenous ECMO can be used successfully to overcome this acute life threatening complication. Implementation of an oxygenator into the VAD-circuit therefore is a useful upcoming option (Berlinheart/Novalung).

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**Hematological Testing in Animal Implant Studies**

Kathryn E Richards<sup>1</sup>, Thomas P Nifong<sup>3</sup>, Tigran Khalapyan<sup>2</sup>, William J Weiss<sup>2</sup>, Gerson Rosenberg<sup>2</sup>, Christopher A Siedlecki<sup>2</sup>  
<sup>1</sup>Department of Bioengineering, The Pennsylvania State University, Hershey, PA, USA, <sup>2</sup>Department of Surgery, Penn State College of Medicine, Hershey, PA, USA, <sup>3</sup>Department of Pathology, Penn State College of Medicine, Hershey, PA, USA

**Purpose:**

Some significant problems associated with the use of mechanical circulatory support are coagulation and thrombosis. The purpose of the study is to assess coagulation state and platelet function in sham surgery and compare to VAD implanted bovine models.

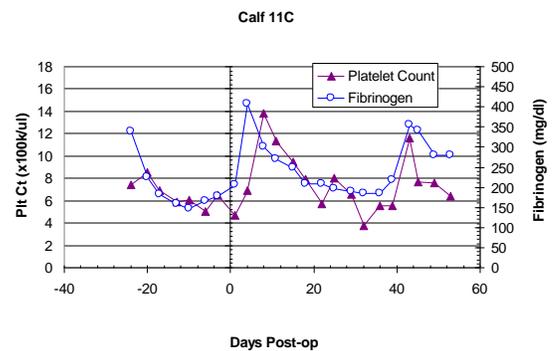
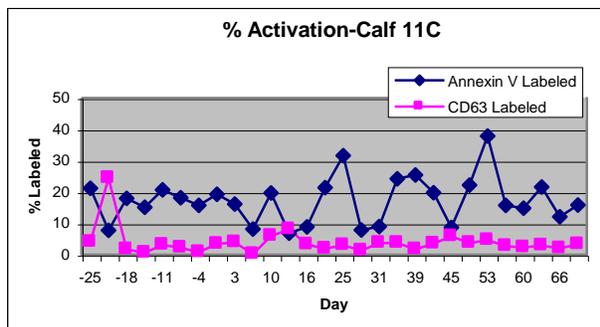
**Methods:**

Calves were subject to either a sham surgery or a VAD implant. Sham surgeries included all steps of the VAD surgery except device implantation. Studies were performed in AAALAC accredited animal facilities under Penn State IACUC approval. Animals received normal postoperative care including acute heparin therapy and long-term coumadin. Blood draws occurred twice weekly and blood was subjected to many hematological tests. These included thromboelastography, platelet count,

platelet aggregation, as well as clinical hematological tests for fibrinogen levels, PT, PTT, d-dimer and ATIII. Platelet function was assessed using antibody labeling of activated platelets in platelet rich plasma and evaluated using flow cytometry. This method is undergoing modification for use with ovine pediatric models.

**Results:**

The first graph shows activation levels, during the calf 11c sham implant procedure, labeled with 2 different antibodies for activation. These results are expressed as a percent of total platelets. The second graph shows platelet count and fibrinogen levels over the course of the sham implant.



**Conclusions:**

The changes revealed in platelet number and activation levels with the procedures were as expected. Fibrinogen and platelet levels were found follow similar patterns and were responsive to stress events such as surgery and travel to/from the animal facility. An understanding of the dynamic hematological environment explored in these studies will be critical in assessing response to implanted devices. We believe that this broad series of tests will offer one of the most thorough animal characterization studies to date and will be of use in future implantation studies, including use in other animal models.

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**Treatment with ECMO in a Newborn with Malignant Arrhythmias After  
Resection of Cardiac Tumor Resulting in Low Cardiac Output Syndrome**

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Theodor Tirilomis, PhD, Oguz Coskun, MD, Heike Schneider, PhD, Wolfgang Ruschewski, PhD  
Department for Thoracic, Cardiac, and Vascular Surgery, and Department for Pediatric Cardiology, University of  
Goettingen, Goettingen, Germany

**Purpose:**

The case of a newborn with malignant arrhythmias after heart surgery treated with ECMO is presented.

**Case:**

A male newborn with large tumor of the right atrium underwent emergency surgery with resection of the tumor. After surgery patient developed supraventricular and ventricular arrhythmias. Antiarrhythmic medication could not restore rhythm and patient progressively developed low

cardiac output syndrome. For mechanical circulatory support patient was connected on cardiac ECMO. After hemodynamic stabilization patient could weaned from ECMO and four days later mechanical circulatory support was stopped. Rhythm was immediately after ECMO treatment mainly sinus rhythm with intermittend supraventricular arrhythmias. At discharge from hospital there was stable sinus rhythm without any antiarrhythmic medication.

**Conclusions:**

Malignant and drug resistend arrhythmias after heart surgery in newborn and children may result in low cardiac output syndrome. A option of treated may be use of cardiac ECMO for circulatory support.

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**Reoperations in Adults After Correction of Tetralogy of Fallot**

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S.Tolga Coskun<sup>1</sup>, MD, K.Oguz Coskun<sup>2</sup>, MD, Aron Popov<sup>2</sup>, MD, Kerstin Bockhorst<sup>3</sup>, BSc, Ute Blanz<sup>1</sup>, MD, Andreas Bairaktaris<sup>1</sup>, MD, Reiner Koerfer<sup>1</sup>, PhD.

<sup>1</sup>Department of Cardiac Surgery, Heart Center North Rhein Westphalia, Bad Oeynhausen ,Germany

<sup>2</sup>Department of Thorax and Cardiovascular Surgery, Göttingen University, Germany

<sup>3</sup>Department of Health Sciences Research, University Bielefeld, Germany

**Purpose:**

Adults with congenital heart diseases are an increasing patient population. Since first successful palliative procedure in 1944 and first corrective operation in 1955 have patients with Tetralogy of Fallot excellent long term results and good quality of life. However in long term these patients are under risk of sudden death and congestive heart disease.

**Methods:**

We present 2 grown-ups who underwent reoperations as adults after correction of Tetralogy of Fallot.

Case 1: A 38 years old man who had Blalock-Taussig anastomose in 1972 and a repair operation in 1976 because of Tetralogy of Fallot.

**Conclusions:**

Reoperations in grown-up patients with congenital heart disease are seen frequently but still limited knowledge exists on reoperation timing and long term benefits of initial repair possibilities.

A successful outcome can be achieved with careful evaluation of cardiac anatomy and proper selection of surgical techniques. Cardio MRT is the gold standard for right ventricle volume measurements and quantification of structures.

Challenges are perfect patient selection and surgical timing to increase long term survival because pulmonary valve replacement should be performed before irreversible right ventricle damage occurs.

Case 2: A 52 years old man whose total correction was performed at an age of 15 years because of Tetralogy of Fallot.

In both cases Cardio MRT demonstrated extremely dilated right ventricles and echocardiography showed pulmonary valve insufficiency grade III at first case and combined high grade pulmonary valve stenosis with insufficiency, aortic valve insufficiency grade III at second case. We replaced defect valves with alloprothesis and reconstructed the right ventricle outflow tract.

The postoperative courses of the patients were uneventful. We discharged the patients after 10 days.

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**Should the Activated Coagulation Time Be Used for Infant Patients  
Undergoing Cardiopulmonary Bypass for Cardiac Surgery?**

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Colleen Gruenwald, MHSc, RN, CCP, CPC, Cardiovascular Perfusion, The Labatt Family Heart Centre, The University of Toronto, The Hospital for Sick Children, Toronto, Canada

**Background:**

Cardiopulmonary bypass (CPB) results in significant activation of the coagulation and fibrinolytic systems. Factors such as hemodilution, hypothermic circulatory arrest, hypoxia, and the immature coagulation system of the infant have been shown to exacerbate the risk of peri-operative bleeding and thrombosis. There is minimal information on appropriate anticoagulation strategy for infants undergoing CPB, especially regarding target heparin dose and monitoring during and following heart surgery.

**Purpose:**

Anticoagulation during CPB is most often accomplished by the administration of heparin. The activated coagulation time (ACT) is currently the predominant device used to monitor the anticoagulation status during CPB and the effect of protamine reversal. However, the prolongation of the ACT during infant heart surgery may not be a true reflection of anticoagulation. Furthermore,

measurements of the ACT do not correlate with plasma concentration of circulating heparin. Few studies have now shown that maintenance of higher patient-specific heparin concentrations during CPB are associated with greater suppression of hemostatic system activation than do standard heparin doses based on body weight and measurement by the ACT.

**Results:**

The ACT is an unreliable index of anticoagulation during CPB in infants. A few studies have examined the use of individualized heparin and protamine dosing by monitoring with a protamine titration device that monitors heparin levels. A "steady state" anticoagulation can be better achieved using this method of monitoring and results in less activation of the coagulation and fibrinolytic systems. There is minimal data that examines clinical outcome measures between these two strategies for dosing heparin, protamine and methods of monitoring anticoagulation during infant CPB.

**Conclusions:**

Anticoagulation management for infants undergoing CPB for cardiac surgery has been extrapolated from adult experience. Recent evaluation of these protocols has shown that excessive or inadequate anticoagulation exists during CPB, often going unrecognized until the early post-operative period. It appears that the use of the ACT device as the sole monitoring tool overestimates the status of anticoagulation during CPB in infant patients. Further research is needed to determine if any clinical benefits exist in using the individualized heparin dosing regime.

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### **Vacuum-Assisted Venous Drainage**

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Chris Brabant, CCP  
Chief Perfusionist Herma Heart Center  
Children's Hospital of Wisconsin, Milwaukee, Wisconsin, USA

Vacuum-assisted venous drainage (VAVD) was introduced in the late 1990s as a technical modification to conventional cardiopulmonary bypass. This session will provide a discussion and comparison between current and historical data about vacuum assist technique. We will also discuss efficacy, advantages and precautions associated with VAVD.

The potential benefits of vacuum-assisted venous drainage are that its use allows for a reduction in venous cannula size, a reduction in cardiopulmonary bypass circuit size and it results in a decreased inflammatory response to cardiopulmonary bypass. Limitations of VAVD include increased production and delivery of gaseous micro-emboli to the patient, damage to cellular blood components, decreased blood flow from the cardiopulmonary bypass pump and the requirement for a more complex cardiopulmonary bypass circuit.

We will conclude with an overview of the utilization of vacuum-assisted venous drainage with specific emphasis on its use in micro-circuitry for neonatal cardiopulmonary bypass. We will also discuss the role of VAVD in an institutional blood conservation program as well as potential areas of research involving VAVD.

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**Single-Ventricle Palliation using a PediVAS Ventricular Assist Device**

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James J. Gangemi, MD, Andrew N. Winterborn, DVM, Ron Angona, CCP, Kevin Belmont, CCP, Karen L. Jones, CCP, and George M Alfieri, MD

Department of Pediatric Cardiac Surgery, University of Rochester Medical Center, Rochester NY

**Background:**

Neonates born with single ventricle physiology are complex patients often requiring extensive surgical intervention during the neonatal period. The parallel pulmonary and systemic circulation following Stage I palliation contributes to an unstable physiology which leads to considerable morbidity and mortality. The concept of using a pediatric ventricular assist device (VAD) to convert a univentricular circulation to a 2-ventricular physiology, in series circulation, early in life may avoid the deleterious effects of single ventricular physiology. We hypothesize that an acute newborn lamb model of complete, pump-assisted cavopulmonary diversion using a Levitronix PediVAS, a pediatric version of the CentriMag VAD, would yield hemodynamic stability.

**Methods:**

Newborn lambs (n=8, mean age  $5.3 \pm 2.5$  days, mean weight  $4.0 \pm 1.3$  kg, mean BSA  $0.21 \pm 0.04$  m<sup>2</sup>) were anesthetized and mechanically ventilated throughout the entire 8 hour period. Complete, pump-assisted cavopulmonary diversion using a Levitronix

**Conclusion:**

Complete cavopulmonary diversion using the PediVAS VAD yields hemodynamic stability, adequate gas exchange and unchanged pulmonary vascular resistance in an acute neonatal animal model. This data provides an indication for a longer-term, potentially implantable device which could protect the ventricle from the deleterious effects of single ventricle physiology.

PediVAS VAD was accomplished following bicaval venous (inflow) cannulation, distal main pulmonary artery (outflow) cannulation, and complete occlusion of the proximal main pulmonary artery. Extensive hemodynamic data, as well as lactate levels and assessment of pulmonary gas exchange were taken at baseline prior to diversion and at hourly intervals for a total of 8 hours. The stability of each measure over time was evaluated using linear mixed models and t-tests were used to compare the differences for various time intervals.

**Results:**

Hemodynamically, the animals remained stable throughout the 8 hour study requiring little intervention. Hemodynamic measures including mean arterial pressure, heart rate, lactate levels, and cardiac index were not significantly different at 1, 2, 4, and 8 hours compared to baseline. Arterial blood gasses, pulmonary artery pressures and pulmonary vascular resistance were also not significantly different during this time period.

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### **Berlin Heart EXCOR in Neonates and Infants - an Update**

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Johannes Mueller, Bob Kroslowitz, Peter Branecky, Holger Buchholz, Anne Dierlam, Peter Goettel  
Berlin Heart, Berlin, Germany

The Berlin Heart EXCOR device is a pneumatically - driven paracorporeal mechanical cardiac assist device. Due to the wide range of available pump sizes it can provide support in infants and adults. First implantations in children were performed in Europe in 1990, in North America the device was placed the first time in 2000.

As of this writing, in North America 144 children (f, 70; m, 74) have been supported in 37 institutions. Out of these institutions, ten have experience with one implantation, three with more than 10 implantations and one with 16 implantations. Nine children are currently on the device. The cumulative experience amounts to 19 patient years, with a mean time on support of 49 days (median, 28 days; range, 1 to 419 days). The mean age of all supported children was 4.1 years (median, 2 years; range, 1 day to 17 years). 30 children were younger than one year, 28 were one and 28 two years of age. With regards to weight, mean weight was 18.6 kg (median, 12; range, 2.2 to 90 kg).

The indication for device placement was idiopathic dilated cardiomyopathy (86 patients, 60%) in the majority of children, complex congenital heart disease in 21% (31 patients) and acute myocarditis in 8% (12 patients). Due to the severe clinical status of the children, 58 patients were in need for bi-ventricular support and 86 patients for mono-ventricular. Out of the patients with bi-ventricular support, 45 were supported with ECMO before EXCOR implantation. The 86 children with mono-ventricular support only had ECMO support in 52 cases. With regard to the outcome, 86 children

(60%) were transplanted, 13 (9%) could be weaned from the device due to functional cardiac improvement and 36 (25%) died. Main causes of death were multiorgan failure (11 patients), intracerebral bleeding (8 patients), bleeding (6 patients) and stroke (5 patients).

Thirty-four of the patients with bi-ventricular support (58) received a donor heart, one could be weaned off support, 4 are on the device and 19 died. Out of the 86 patients with mono-ventricular support 52 were transplanted, 5 are on the device and 12 were weaned off and 16 died.

There is a standardized anticoagulation protocol recommended which - if applied - keeps the number of severe neurological events (bleeding or strokes) very low. Anticoagulation consists of unfractionated and then fractionated heparin at the beginning with a switch to coumadin if longer time support is anticipated. Aspirin (plus clopidogrel under special conditions) is recommended as an anti-platelet agent.

There is a trend to an extension of the time on device over the last three years and to a reduced number of cerebral vascular events since the experience with the device is growing and an increasing numbers of institutions accept a standardized anti- coagulation and anti-platelet protocol.

So in conclusion, the Berlin Heart device applied in children shows very convincing results with a trend toward better outcome. There is room for further improvements which should be utilized within the near future.

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**Deep Hypothermic Circulatory Arrest with Intermittent Perfusion for Neonatal Heart Surgery**

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Christian Pizarro, MD

Chief, Cardiothoracic Surgery; Associate Professor of Surgery, Jefferson Medical College  
Director, Nemours Cardiac Center, Alfred I. duPont Hospital  
Wilmington, Delaware, USA

Despite ongoing controversy, deep hypothermic circulatory arrest (DHCA) remains a useful tool in the armamentarium of the congenital heart surgeon. DHCA offers distinct advantages, reducing the duration of cardiopulmonary bypass, decreasing edema formation, facilitating the exposure for a precise anatomic repair and decreasing the incidence of postoperative cardiac and pulmonary dysfunction. However, the potential for neurological insult due to hypoxic-ischemic injury remains a formidable limitation. Important advances in pediatric perfusion have provided a rationale for increased neuroprotection and a better understanding of this technique; however, its safe duration remains unknown.

As demonstrated by the Boston circulatory arrest study, patients undergoing neonatal cardiac surgery in this trial were below the general population on many of the endpoints and no differences in IQ were observed between the patients who underwent continuous bypass versus circulatory arrest. Nevertheless, a period of circulatory arrest beyond 40 minutes correlated with a linear decline in full-scale IQ. These observations have influenced many congenital cardiac surgeons to completely avoid or reserve the use of deep hypothermic circulatory arrest exclusively for surgery involving the aortic arch. Since the description of regional cerebral perfusion by Asoue et al, this technique has gained increasing popularity and has been embraced as a superior strategy, although the data available on neuron-developmental outcome, including a prospective randomized trial, have not only failed to demonstrate an advantage but suggest that patients who did not receive regional cerebral perfusion have less deleterious effects. These findings raise concern about the lack of knowledge regarding the appropriate flow and pressure for cerebral perfusion (under the special conditions of hypothermia and non-pulsatile flow) as well as the false sense of security regarding appropriate cerebral perfusion this technique might confer.

In order to extend a safe duration of the period of deep hypothermia circulatory arrest, several experimental studies have been undertaken recently. While studying the intermittent perfusion with somatoplegia, Miura et al, unexpectedly found that animals subjected to DHCA with intermittent periods of reperfusion demonstrated a significantly improved outcome relative to the uninterrupted DHCA. Langley et al demonstrated that intermittent perfusion was associated with a normal pattern of cerebral oxygen metabolism and preservation of the cerebrovascular bed under electron microscopy. More recently, investigations to assess whether intermittent perfusion during DHCA can increase cortical oxygenation and delay detrimental metabolic changes in the brain have been undertaken by Schultz and colleagues. Using methods to directly measure free oxygen in the microcirculation within the neocortical tissue and measure the changes in striatal extracellular levels of Dopamine, a sensitive marker of brain oxygenation, they confirmed that periods of deep hypothermia circulatory arrest longer than forty-five minutes may be associated with major changes in brain metabolism and progressive increase in the risk of neuronal injury. They also demonstrated that intermittent circulatory arrest with periods of blood flow could prolong the safe duration of circulatory arrest.

Based on this experimental data and due to concerns regarding the neuro-developmental outcome associated with regional cerebral perfusion, we have used a strategy of deep hypothermic circulatory arrest with intermittent perfusion for the repair of congenital heart lesions, requiring arch reconstruction. Fifteen

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patients, including nine who underwent a Norwood procedure, underwent cardiac surgery, which involved aortic arch reconstruction. The median duration of cardiopulmonary bypass was 148 minutes, including a median duration of circulatory arrest of 65 minutes. DHCA was divided by a period of reperfusion of 6 minutes at a median flow of 55 cc/kg/min while at 18°C. There were two early deaths, which involved patients with hypoplastic left heart syndrome and a highly restrictive atrial septal communication. None of the patients in this cohort exhibited a new neurological finding or seizure activity in the postoperative period. Intermittent perfusion during deep hypothermia circulatory arrest can prolong the safe period of circulatory arrest significantly reducing the potential deleterious effects of this perfusion strategy. The technique is simple and provides not only cerebral but somatic circulatory support while eliminates the potential of injury related to direct brain perfusion with arbitrarily chosen flows or pressures. Prospective neuro-developmental assessment patients subjected to this technique is being undertaken.

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## MECC from the Perfusion Perspective

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Stuart Sheppard, Ph.D. FCP. AACP. ECCP.  
Consultant Perfusionist, Southampton, UK

Minimized ExtraCorporeal Circulation or MECC as it has become known is the end product of a combination of different perfusion techniques. The main difference immediately visible to the perfusionist is the absence of a cardiotomy reservoir and pump suckers making the circuit similar to a centrifugal system designed for use during extracorporeal membrane oxygenation (ECMO). This modification alone has dramatically reduced the priming volume of the circuit; indeed our current adult circuit only requires 400ml to prime it including the cardioplegia system. With such low priming volumes it is now possible to completely retrograde autologous prime (RAP) the entire circuit from the patient following cannulation. In our hospital we have found that using this technique the mean drop in haemoglobin between the pre and on bypass level is approx 1.0-1.6g/dl.

In addition to the small priming volume both the circuit and cannulae are all coated with each

manufacturer's proprietary surface coating which has been demonstrated to reduce the inflammatory response seen during CPB.

Without the use of pump suckers all operating field blood loss is collected and processed via a cell saver for re-transfusion either during or after bypass. The MECC circuit also allows venting the aortic root or pulmonary artery using the negative inflow pressure generated by the centrifugal pump. Although air is not normally a problem big problem during venting a venous bubble trap is fitted into the venous line to capture and evacuate any air which may enter the circuit from the vents or venous cannulation site.

The technique requires close co-operation between all members of the surgical team for it to be successful. During this presentation I will discuss the main considerations from the Perfusionist's perspective and give an overview of our recent results with the technique.

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**Debate: “Circuit Miniaturization Will Add Risk for the Patient”**

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Pro: Richard M. Ginther, Jr., CCP  
Dallas, Texas, USA

**Introduction:**

In pediatric cardiopulmonary bypass surgery (CPB), circuit miniaturization has become a popular technique to reduce hemodilution, allogeneic blood transfusion and the systemic inflammatory response. Clinicians are using smaller tubing sizes, augmenting venous drainage, decreasing tubing length, stocking various custom tubing packs and eliminating pump components such as arterial line filters. Manufacturers have also responded by releasing assorted product lines of neonatal, infant and pediatric products and mast-mounted pump consoles. Though the benefits of these techniques are widely supported, there are many issues that must be addressed to ensure that the patient is not subjected to unnecessary risk.

**Risks:**

Recent publications have shown that low-prime CPB components are not effective in removing

gaseous microemboli. In addition, the use of vacuum assisted venous drainage to facilitate smaller venous line diameter and cannulae size has been associated with significant gaseous microemboli activity post arterial line filter. These findings have been the focus of many neurocognitive outcome studies and efforts are being made to attenuate embolic sequelae. Aggressive miniaturization of tubing size has been linked as a source of blood trauma due to excessive system pressures and high revolutions per minute in the arterial roller head. Additional techniques such as eliminating arterial line filters, operating low reservoir levels and emptying cardioplegia lines are used to reduce prime volume and maintain a higher hematocrit, but these strategies compromise the level of patient safety. Large circuit volume reductions could also drastically alter prime electrolyte, protein, and drug concentrations resulting in harmful, nonphysiologic values.

**Action:**

The benefits of circuit miniaturization should not overshadow the risk in which a patient could potentially be exposed. Circuit miniaturization techniques must be carefully selected and evidence based. The surgical team must critically evaluate their systems to make sure that the best possible care is provided to the patient.

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**Debate: “Circuit Miniaturization Will Add Risk for the Patient”**

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Con: Ed Darling, CCP  
Syracuse, New York, USA

**Introduction:**

In pediatric cardiopulmonary bypass, there has been a progressive and concerted effort by both clinicians and industry to reduce the size, surface area and priming volume of neonatal, pediatric, and adult cardiopulmonary bypass (CPB) circuit. The impetus for this rests upon two pillars that are thought to be beneficial in attenuating the inflammatory side effects of CPB; (1) reduction of foreign surface area, and (2) the avoidance of allogeneic blood products.

**Miniaturization is Occurring:**

Over the last decade there have been numerous publications, and textbook chapters specifically related to pediatric circuit miniaturization. Undoubtedly, few, if any pediatric perfusion teams have not seen reductions in their own circuits prime volumes. Facilitating this trend has been changes in consoles, disposable components, and adoption of new techniques.

**Changes in Circuitry:**

Perfusion components, specifically oxygenators, arterial line filters, and cardioplegia delivery sets have all been significantly reduced in size.

With the goal of reducing the dead space of the

CPB circuit, two strategies have emerged, (1) using smaller diameter tubing, and (2) shortening tubing lengths through console reconfiguration and by bringing the pump and circuit higher and closer to the patient.

**Changes in Techniques:**

To optimize miniaturization, the vacuum assisted venous drainage technique has become increasingly employed to provide drainage in circuit configurations that are closer to the patient.

**Are We Sacrificing Patient Safety?**

While incorporating *any change* into a highly organized system (eg. pediatric cardiac surgery) can introduce an element of risk, aggressive circuit miniaturization can be accomplished safely without adding risk to the patient if planned for appropriately. This planning includes (1) the use of current pump technologies that have systems in place to servo-regulate the pump (level, bubble, pressure), (2) development and communication of protocols (3) Non-clinical trials with the entire heart team (surgeon, anesthesia, perfusion, nursing).

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**Tell Me What You Need and I Will Tell You How We Get by Without It:  
CPB in Underdeveloped Countries**

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Aubyn Marath, MBBS MS FRCSEd, President, CardioStart International, Department of Pediatric Heart Surgery, Oregon Health & Science University, Portland, Oregon, USA

**Introduction:**

Five cardinal features of neonatal and pediatric heart surgery contribute towards, but do not guarantee, a satisfactory result. These are: a high standard of cardiological investigation and work-up; obsessional and timely surgical management; meticulous anesthesia and perfusion using intensive monitoring by dedicated specialists in pediatric care; expertise in delivering ICU care for extended periods of time by a cohesive team using well-tried protocols; and the most up-to-date equipment. These are regularly proclaimed as essentials for safe modern practice in international meetings in our specialty and from intra-hospital departmental morbidity and mortality discussions. What happens, however, when one or more of these ingredients are missing? Should surgery be undertaken without the specialists or advanced equipment? What equipment can be left out? Which standard is acceptable or too low? What are the ethical and legally culpable defining lines?

In this backdrop provided by the world centers of excellence are the very depressing statistics confirming the failure of cardiology and cardiac surgery delivery throughout the rest of the world. Most afflicted children simply die without even access to evaluation or treatment. In an attempt to help, CardioStart International has provided free counseling and operative correction of heart disease to children and adults in many developing countries, over a 20-year period to assist any country seeking assistance, irrespective of political position or religious creed. Volunteer teams drawn from specialties including cardiac surgery, cardiology, anesthesia, nursing and biomedical technology are

convened to perform complex heart operations, and provide instruction and education to develop the local heart surgery programs and related specialties. On most occasions the mission lasts two weeks, no team is the same, few know each other, and all arrive with different training backgrounds and experience levels from hospitals around the globe.

**Results:**

The outcomes of this enterprise have been positive, fascinating and are currently being analyzed by a unique international database. What can be stated thus far is:

- Surgical procedures can be safely modified and adapted from standard approaches due to the unavailability of even basic supplies.
- Dedicated blood donation does provide sufficient perioperative support to deal with hemodynamic changes and perioperative coagulopathies.
- Aprotinin is not a mandatory requirement.
- Medications are not uniform with those used by advanced healthcare systems.
- The equipment donations are sufficient to permit safe surgery and subsequent care.
- Educational material using teaching programs from advanced centers do help accelerate evolution of the program.
- Efficient knowledge transfer does occur.
- Substantial cost-savings do positively impact on later advancement of specialist center development.
- The term "Gold Standard" is not a directly applicable term nor necessarily transferable in diverse cultures.

**Conclusion:**

The early quality of life and hemodynamic outcomes of children operated on international settings, with early and late-presenting congenital heart disease, are encouraging. To date, CardioStart International has accomplished 40 missions to 19 countries.

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## How Do We Help When Our Help No Longer Works?

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Carmen Giacomuzzi, BSN, CCP  
Oregon Health & Science University  
Portland, Oregon, USA

We are born, we live, and when our time comes, we die. It is the natural cycle of life. Yet from the very moment we begin our professional journey we do everything humanly possible to prolong life. After all, we *are* in the business of helping people live, not die, aren't we? But what do we do when our therapies no longer help? Are we so focused on our therapies and frenetic energies of modern technology that we fail to address the emotional needs of our dying patients and families? Do we follow those infamous "rules" of always remaining objective and maintaining a safe emotional distance? Do we remain aloof and avoid becoming too emotionally attached to our patients and families?

The miracle inside all of us is our human empathy. In this session, we will explore and cite examples of methods that we can use to help provide comfort and support for dying patients and their families, as well as advocate a flexible approach to address their individual cultural and spiritual needs. In addition, I will provide some thoughts for "rules transformations," to help us as both skilled technicians and as compassionate human beings in addressing the needs of our patients.

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### **Human Factors and CPB**

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Thoralf M. Sundt, III, M.D.  
Mayo Clinic  
Rochester, New York, USA

High consequence industries, those in which errors can lead to catastrophic consequences, have largely come to grips with the inevitability of error as a product of complexity. By recognizing this, they have been able to make remarkable progress in reducing the ultimate occurrence of adverse events. By embracing the concept of error management which includes error prevention (our current focus in medicine with checklists, protocols, and procedures), error capture, and error recovery (the traditional focus in clinical medicine), they have been able to accomplish remarkable reliability in the context of "normal accidents." A new class of organizations has evolved termed by some "high reliability organizations" characterized by "mindfulness" in operations.<sup>1</sup> Medicine must be on the verge of a similar transformation. Surely all would agree that we are both highly complex and high consequence.

At Mayo Clinic, we have initiated a program to systemically study error in cardiovascular surgery. Our initial focus has been within the operating room for a variety of reasons. First, this is a geographically defined area within which intensive studies can be performed. Clearly the interactions with the remainder of the medical system are intense, but at least inflows and outflows can be identified. In addition, the operating room is an area of high likelihood for error as it is widely recognized that highly coupled and highly complex procedures, particularly with interface between teams of varying background and expertise as well as frequent interface with technologies occurs. It is also an area in which our colleagues in anesthesia have already made remarkable progress, and concepts of interdependence and teamwork are familiar.

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Our initial studies at Mayo Clinic have documented the impact of teamwork and communication on perceptions of safety in the operating room<sup>2</sup>. We have also demonstrated the impact of teamwork disruptions on technical errors during operative procedures<sup>3</sup>. Accordingly, we have recently initiated some broad interventions intended to improve communication and teamwork including the initiation of preoperative briefing protocol. This has been studied and demonstrated to improve work flow.

Within the operating room, we have had particular interest in the relationship between the surgeons and the perfusionists. Again, the episode of care is a discrete and definable one. The interface of both surgeons and perfusionists with the technology of cardiopulmonary bypass makes this a rich area for investigation and provides opportunity for genuine contributions to the field to improve safety. Stimulated several years ago by our celebration of the 50<sup>th</sup> anniversary of the first use of the Mayo-Gibbon machine at Mayo Clinic (1955) we initiated a formal study of the cardiopulmonary bypass machine. The results of this observational study have demonstrated numerous ergonomic issues and opportunities for improvement. It also confirmed the impact of communication issues. Accordingly, we have initiated programs utilizing our Simulation Center to further study the human technology interface as well as human interactions in teamwork settings centered around the conduct of cardiopulmonary bypass. We have initiated programs in standardized communication as well. These studies are currently ongoing.

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