

BIOGRAPHICAL SKETCH

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NAME: Henri Justino

eRA COMMONS USER NAME: HJUSTINO

POSITION TITLE: Director of Cardiovascular Innovation, Rady Children's Hospital, and Professor of Clinical Pediatrics, University of California, San Diego

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
McGill University, Montreal, QC, Canada	MD, CM	05/1994	Medicine
McGill University, Montreal, QC, Canada	Residency	06/1997	Pediatrics
Hospital for Sick Children, University of Toronto, Toronto, ON, Canada	Fellowship	06/1999	Pediatric Cardiology
Hospital for Sick Children, University of Toronto, Toronto, ON, Canada	Fellowship	06/2000	Interventional Pediatric Cardiology

A. Personal Statement

As an interventional pediatric cardiologist and Director of Cardiovascular Innovation, Rady Children's Hospital, and Professor of Clinical Pediatrics, University of California, San Diego, I treat a wide variety of children with cardiovascular anomalies, such as atrial septal defects, patent ductus arteriosus, coarctation of the aorta, and pulmonary artery stenosis. Recent advances have allowed many patients to be treated by minimally-invasive cardiac catheterization techniques rather than open-heart surgery. Still, much work is required to make these advances possible for young children. This is especially apparent in the field of transcatheter pediatric valve replacement. Small children are currently not candidates to receive these valves because these are not made in sizes suitable for small hearts, and their delivery systems are too bulky to fit through the small groin vessels of young children. To address this unmet need, I **co-founded PolyVascular** to develop a novel pediatric heart valve that could be scaled to the dimensions needed for small children. We aim to have a significant impact on the quality of life of pediatric patients by reducing the frequency of open-heart surgeries they require. In addition, the proprietary polymeric platform can impact congenital heart disease care globally by making transcatheter heart valves more affordable in developing countries.

Research Support

CobiCure Grant 06/2023 – 12/2024
Goals: Support development of polymer transcatheter heart valve for clinical readiness
Role: consultant
Award: \$2,000,000

2R44HL129577-02A1 (Clifton) 02/01/2021 – 12/31/2022
NIH/NHLBI SBIR Phase II
Development of a Polymeric Percutaneous Pulmonary Valve for Use in Young Children
Goals: to generate data that clarify overall SMV platform performance, and potential use cases, and support first in human trials.
Role: Subaward Investigator
Award: \$2,416,359

NCT02979587 (Justino site PI until 6/30/21) 01/01/2017 – 12/31/2024
Medtronic, Inc.

The Medtronic Harmony Transcatheter Pulmonary Valve (TPV) Clinical Study

The primary objective of this study is to demonstrate the safety and effectiveness of the Harmony TPV system as measured by freedom from procedure or device-related mortality at 30 days and percentage of subjects with acceptable hemodynamic function at 6 months. Primary Safety Endpoint: Freedom from procedure- or device-related mortality at 30 days.

NCT03130777 (Justino site PI until 6/30/21)

03/27/2019 – 09/26/2022

Edwards Lifesciences

Multicenter Study of Congenital Pulmonic Valve Dysfunction Studying the SAPIEN 3 Transcatheter Heart Valve with the Alterra Adaptive Present

The purpose of this study is to demonstrate the safety and effectiveness of the Edwards Alterra Adaptive Present in conjunction with the Edwards SAPIEN 3 Transcatheter Heart Valve (THV) System in subjects with a dysfunctional right ventricular outflow tract/pulmonary valve (RVOT/PV) who are indicated for treatment of pulmonary regurgitation (PR).

B. Positions, Scientific Appointments, and Honors

Positions and Employment:

2001-2003	Assistant Professor of Pediatrics, University of Ottawa, and Director, Cardiac Catheterization Laboratory, Children's Hospital of Eastern Ontario, Ottawa, ON, Canada
2003-2011	Assistant Professor of Pediatrics, Baylor College of Medicine, Houston, TX
2008-2012	Associate Director, Cardiac Catheterization Laboratories, Texas Children's Hospital
2011-2020	Associate Professor of Pediatrics, Baylor College of Medicine, Houston, TX
2013-2021	Director, Cardiac Catheterization Laboratories, Texas Children's Hospital
2019-2021	Professor (Tenured) of Pediatrics, Baylor College of Medicine, Houston, TX
2021-present	Director of Cardiovascular Innovation, Rady Children's Hospital, and Professor of Clinical Pediatrics, University of California, San Diego

Honors:

1990	McGill University Faculty Scholar
1991	Pharmaceutical Manufacturers Association of Canada - Health Research Foundation Bursary
1991	Merck, Sharp, & Dohme Award in Therapeutics, McGill University
1991	Ciba-Geigy Scholarship for Excellence in Research, McGill University
1992	Pharmaceutical Manufacturers Association of Canada - Health Research Foundation Bursary
1992	Pharmaceutical Manufacturers Association of Canada - Health Research Foundation Travel Grant
2007	Dan G. McNamara Teaching Award, Section of Pediatric Cardiology, Texas Children's Hospital (most outstanding teaching in the division of ~50 faculty)
2010	Award of Excellence in Teaching, Department of Pediatrics, Baylor College of Medicine (most outstanding teaching in the department of ~900 faculty)
2011	Fulbright & Jaworski LLP Faculty Excellence Award
2011	Inducted to Academy of Distinguished Educators, Baylor College of Medicine
2011	Medical Innovation Award, Institute of Biosciences and Bioengineering, Rice University
2012	Scientific Scholarship Award, Pediatric and Adult Interventional Cardiac Symposium (PICS)
2013	Outstanding Clinician Award, Department of Pediatrics, Baylor College of Medicine (1 of 2 awards given to the top clinician as chosen by peers, from among >950 faculty in the department)
2017	Star Award for Excellence in Patient Care, Baylor College of Medicine
2021	Provider Excellence Award, Texas Children's Hospital (>99th percentile on Press Ganey surveys)
2021	Dan G. McNamara Teaching Award, Section of Pediatric Cardiology, Texas Children's Hospital

Other Experience and Professional Memberships:

1998-2021	Fellow of the Royal College of Physicians and Surgeons of Canada
1998-2017	Associate Member, Canadian Cardiovascular Society
2001-present	Member, Society for Cardiovascular Angiography and Interventions
2002-2017	Member, Canadian Pediatric Cardiology Association
2002-present	Fellow of the American College of Cardiology

2003-2020	Member, American Heart Association
2008-present	Fellow of the Society for Cardiovascular Angiography and Interventions (SCAI)
2011-2014	SCAI Bioabsorbable Products Pre-clinical and Clinical Task Forces
2012-2018	Chair, Pediatric Quality Improvement Committee, SCAI
2013-2018	Member, Society of Physician Entrepreneurs (Houston Chapter)
2014-2022	Fellow of the American Academy of Pediatrics
2015-2016	Co-Chair, Congenital Heart Disease Program Committee, SCAI
2015-present	Member, Executive Committee, Rivaroxaban Open-label Clinical Trial
2016-2017	Chair, SCAI Annual Scientific Sessions, Congenital Heart Disease Program
2016-2017	Member, Steering Committee, Image Gently Pediatric Cardiology Radiation Safety Campaign
2021-present	Member, Medical Advisory Board, Mended <i>Little</i> Hearts
2021-2024	Member, SCAI Congenital heart disease Council
2021-present	Founding Fellow, Pediatric and Congenital Interventional Cardiovascular Society (FPICS)

C. Contributions to Science

1. **Development of a Novel Pediatric Pulmonary Valve:** Very few catheters and medical devices are developed expressly for children, and in clinical practice we are constantly challenged to adapt adult devices to pediatric uses. There is little incentive for major medical device manufacturers to develop pediatric-specific devices, because of the small market and high regulatory costs. My laboratory team intends to tackle this problem by performing the early stages of pediatric device development within an academic environment. Our first device is a catheter-based pulmonary valve. Using a pulse duplicator and high-cycle testers, and after a series of iterations, we now have fully functional prototypes that surpass the required durability testing for flexible valves (200 million cycles, as per ISO 5840-3). We created valves of 17-21 mm diameters suitable for older children and adolescents, and miniaturized the device to achieve 13-17 mm diameters realistic for toddlers and young children. We are currently performing animal implants for assessment of *in vivo* performance.

- Stent-mounted valve for percutaneous insertion. Inventor: **H. Justino**, US Patent 7261732, published 08/28/2007
- Justino H**, Harrington D, Chun K, inventors. Transcatheter and serially-expandable artificial heart valve. US Patent 11,464,632. 2022 Oct 11.
- Justino H**, Harrington D, Chun K, inventors. Serially expanding an artificial heart valve within a pediatric patient. US Patent 11,571,300. 2023 Feb 7.
- Pedra CAC, **Justino H**, Nykanen DG, VanArsdell G, Coles JG, Williams WG, Freedom RM, Benson LN. Percutaneous Stent Implantation to Stenotic Bioprosthetic Valves in the Pulmonary Position. *J Thorac Cardiovasc Surg* 2002 Jul;124(1):82-7. PMID: 12091812
- Petit CJ, **Justino H**, Ing FF. Melody valve implantation in the pulmonary and tricuspid position. *Catheter Cardiovasc Interv*. 2013 Dec 1;82(7):E944-6. doi: 10.1002/ccd.24764. PMID: 23197462

2. **Catheter-Based Closure of Patent Ductus Arteriosus (PDA):** PDA can lead to congestive heart failure, and was previously treated by surgical ligation. A variety of devices have been utilized to occlude PDA less invasively via a catheter-based approach. In 2001 I authored the first randomized controlled trial comparing 2 devices for PDA occlusion; this publication was also significant because it was the first clinical trial in the field of pediatric and congenital heart disease in which therapy was randomized (as cited in *Circulation* 2011;124:2388-2396). While device occlusion of PDA became standard in larger children, the labeled indication for use of the Amplatzer PDA Occluder was a weight >6kg, which limited the application of this technology in smaller children. Our group reported on the very favorable results of PDA occlusion using this device in children <6kg, suggesting that this weight limitation is unnecessary. Our group also described techniques for treating PDA in the setting of pulmonary hypertension, a very challenging clinical problem. More recently we have tackled the next challenge in our field: closure of PDA in premature babies.

- Justino H**, Justo RN, Ovaert C, Magee A, Lee KJ, Hashmi A, Nykanen DG, McCrindle BW, Freedom RM, Benson LN. Comparison of Two Transcatheter Closure Methods of Persistently Patent Arterial Duct. *Am J Cardiol* 2001 Jan 1;87(1):76-81. PMID: 11137838
- Dimas VV, Takao C, Ing FF, Mattamal R, Nugent AW, Grifka RG, Mullins CE, **Justino H**. Outcomes of transcatheter occlusion of patent ductus arteriosus in infants weighing \leq 6 kg. *JACC Cardiovasc Interv*. 2010 Dec;3(12):1295-9. PMID: 21232725

- c. Transcatheter closure of patent ductus arteriosus using the AMPLATZER™ duct occluder II (ADO II). Gruenstein DH, Ebeid M, Radtke W, Moore P, Holzer R, **Justino H**. *Catheter Cardiovasc Interv*. 2017 May;89(6):1118-1128. doi: 10.1002/ccd.26968. Epub 2017 Mar 4. PMID: 28258658
- d. Initial Clinical Experience with the Medtronic Micro Vascular Plug™ in Transcatheter Occlusion of PDAs in Extremely Premature Infants. Sathanandam S, **Justino H**, Waller BR 3rd, Radtke W, Qureshi AM. *Catheter Cardiovasc Interv*. 2017 May;89(6):1051-1058. doi: 10.1002/ccd.26878. Epub 2016 Nov 26. PMID: 27888552

3. Treatment of Pulmonary Artery Anomalies - Stenosis and Ductal Origin: Pulmonary artery stenosis, whether congenital or acquired post-surgery, may require treatment using a variety of modalities. I was a co-investigator and co-author on a large multi-center clinical trial comparing efficacy of cutting-balloon vs. high-pressure angioplasty. I have co-authored several manuscripts on stent implantation for pulmonary artery stenosis. Finally, I have taken a particular interest in the condition known as “ductal origin of the pulmonary artery”, and was the PI on a study of outcomes of these patients with a consistent management strategy, and in our paper we counter the erroneous belief that these patients have an “absent pulmonary artery”.

- a. Mery CM, Molina KM, Krishnamurthy R, Fraser CD, **Justino H**. Pulmonary Artery Resuscitation for Isolated Ductal Origin of a Pulmonary Artery. *J Thorac Cardiovasc Surg*. 2014 Nov;148(5):2235-2244.e1. doi: 10.1016/j.jtcvs.2013.11.041, PMID: 24503322
- b. Bergersen L, Gauvreau K, **Justino H**, Nugent A, Rome J, Kreutzer J, Rhodes J, Nykanen D, Zahn E, Latson L, Moore P, Lock JE, Jenkins KJ. A Randomized Trial of Cutting Balloon Compared to High Pressure Angioplasty for the Treatment of Pulmonary Artery Stenosis. *Circulation*. 2011 Nov 29;124(22):2388-96. doi: 10.1161/CIRCULATIONAHA.111.018200. PMID: 22042887
- c. Law MA, Shamszad P, Nugent AW, **Justino H**, Breinholt JP, Mullins CE, Ing FF. Pulmonary Artery Stents: Long-Term Follow-Up. *Catheter Cardiovasc Interv*. 2010 Apr 1;75(5):757-64. doi: 10.1002/ccd.22356. PMID: 20146310
- d. Law MA, Breinholt JP, Shamszad P, **Justino H**, Mullins CE, Ing FF. The Outcome of Pulmonary Artery Stents Following Surgical Manipulation. *Catheter Cardiovasc Interv*. 2011 Feb 15;77(3):390-4. doi: 10.1002/ccd.22694. PMID: 20549686

4. Atrial Septal Defects: Creation and Closure. I authored the first report of radiofrequency (RF) perforation of the intact atrial septum as an alternative to transseptal needle puncture; since then, RF perforation has become the standard of care in neonates and small infants. Our group also published one of the large series of atrial septal stent implantation for left atrial decompression. I have published on the management of higher-risk atrial septal defect closure, such as in the setting of altered anatomy or in small patients.

- a. **Justino H**, Benson LN, Nykanen DG. Transcatheter Creation of an Atrial Septal Defect Using Radiofrequency Perforation. *Cathet Cardiovasc Interv* 2001 Sep; 54(1):83-7. PMID: 11553955
- b. **Justino H**. Transcatheter Device Closure of Atrial Septal Defects in Small Children – Sound Judgment is Key! (Editorial). *Rev Bras Cardiol Invasiva* 2013 Jun;21(2).101-2
- c. Leonard GT, **Justino H**, Carlson KM, Neish SR, Mullins CE, Grifka RG. Atrial Septal Stent Implantation for the Management of Complex Congenital Heart Disease in Infants. *Congenit Heart Dis* 2006 May;1(3):129-35. PMID: 18377559
- d. Petit CJ, **Justino H**, Pignatelli RH, Crystal MA, Payne WA, Ing FF. Percutaneous Atrial Septal Defect Closure in Infants and Toddlers: Predictors of Success. *Pediatr Cardiol*. 2013 Feb;34(2):220-5. doi: 10.1007/s00246-012-0413-6. PMID: 22806712

5. Mechanical Circulatory Support Using Percutaneous Devices: Mechanical support of the failing heart, particularly in children, had always required surgically-placed ventricular assist devices. The use of minimally-invasive percutaneous devices (such as the Impella devices) are common for temporary support of adults, but rarely reported in children. I am the clinical lead for the use of the Impella device at my institution, and we have become the largest pediatric center using these devices. We published our own center’s experience, as well as contributing to a large multicenter registry of pediatric patients, and we have also contributed to a multicenter experience with these devices in single-ventricle hearts.

- a. A multicenter study of the Impella device for mechanical support of the systemic circulation in pediatric and adolescent patients. Dimas VV, Morray BH, Kim DW, Almond CS, Shahanavaz S, Tume SC, Peng LF, McElhinney DB, **Justino H**. *Catheter Cardiovasc Interv*. 2017 Jul;90(1):124-129. doi: 10.1002/ccd.26973. Epub 2017 Mar 15. PMID: 28295963 PMCID: PMC5511055

- b. Percutaneous Mechanical Circulatory Support Using Impella® Devices for Decompensated Cardiogenic Shock: A Pediatric Heart Center Experience. Parekh D, Jeewa A, Tume SC, Dreyer WJ, Pignatelli R, Horne D, **Justino H**, Qureshi AM. ASAIO J. 2018 Jan/Feb;64(1):98-104. doi: 10.1097/MAT.0000000000000581. PMID: 28394814
- c. Circulatory Support Using the Impella Device in Fontan Patients with Systemic Ventricular Dysfunction: A Multicenter Experience. Morray BH, Dimas VV, Lim S, Balzer DT, Parekh DR, Van Mieghem NM, Ewert P, Kim DW, **Justino H**, McElhinney DB, Jones TK. Catheter Cardiovasc Interv. 2017 Jul;90(1):118-123. doi: 10.1002/ccd.26885. Epub 2017 Jan 23. PMID: 28112463

Full publication list:

<https://www.ncbi.nlm.nih.gov/myncbi/henri.justino.1/bibliography/public/>