Cardiothoracic and Vascular Surgeons
Clinical Research Department

SITE CURRICULUM VITAE

At CTVS we are dedicated to providing access to the most advanced, state-of-the-art surgical care for our patients and participating in the scientific advancement of surgical medicine with a commitment to excellence in medical care.

RESEARCH SITE LOCATIONS:

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RESEARCH HOSPITAL AFFILIATIONS:

The Heart Hospital of Austin
3801 North Lamar
Austin, TX 78756

St. David's South Austin Medical Center
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Austin, TX 78704

St. David's Medical Center
919 E 32nd St.
Austin, TX 78705

St. David's Round Rock Medical Center
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Round Rock, TX 78681

Seton Medical Center
1201 W. 38th St.
Austin, TX 78705

RESEARCH COMMITTEE:

Faraz Kerendi, MD - Chair
Stephen Dewan, MD
Brannon Hyde, MD
Jonathan Yang, MD
Robert Neely, MD
Rachel Medbery, MD
Eric Hoenicke, MD
Jeffrey Apple, MD
Mazin Foteh, MD
David Nation, MD
Doug Finley, MBA
Diane Krause, BSN, MSHA, NE-BC

DEPARTMENT MANAGERS:

Faraz Kerendi, MD
Medical Director of Research

RESEARCH STAFF:

Shir Yelovitch, PhD
Clinical Research Coordinator

Emily Rowe, CST, MA
Clinical Research Coordinator

Marcedes Coffman, MA
Clinical Research Coordinator

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RESEARCH STUDIES:

Current Research Studies:

STAND BTK - A Clinical Evaluation of the MicroSTent® PeripherAl Vascular SteNt in Subjects with Arterial Disease Below the Knee (STAND), Micro Medical Solutions, Inc., Principal Investigator: Mazin Foteh, MD, March 2022

DISRUPT PAD BTK II - Prospective, Multi-center, Single-arm Study of the Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System for Treatment of Calcified Peripheral Arterial Disease (PAD) in Below-the-Knee (BTK) Arteries, Shockwave Medical, Inc, Principal Investigator: Mazin Foteh, MD, March 2022

ALCHEMIST - Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial
Sponsor: National Cancer Institute (NCI), Investigator: Rachel Medbery, MD, October 2015

ANCHOR Registry - Aneurysm Treatment using the Aptus™ Heli-FX™ EndoAnchor System Global Registry Sponsor: Medtronic Vascular Inc. Principal Investigator: Mazin Foteh, MD, January 2018

APOLLO - Transcatheter Mitral Valve Replacement with the Medtronic Intrepid™ TMVR System in patients with severe symptomatic mitral regurgitation. Sponsor: Medtronic Inc. Principal Investigator: Faraz Kerendi, MD, December 2017

Atezolizumab - A Phase III, Double-Blinded, Multicenter, Randomized Study Evaluating the Efficacy and Safety of Neo-adjuvant Treatement with Atezolizumab or Placebo in combination with Platinum-Based Chemotherapy in Patients with Resectable Stage II, IIIA , or Select IIIB Non-Small Cell Lung Cancer. Sponsor: F. Hoffmann-La Roche Ltd, Investigator: Eric Hoenicke, MD

Cross-Seal IDE Trial - Prospective, Multi-Center, Single Arm Study of the Cross-Seal™ Suture-Mediated Vascular Closure Device System. Sponsor: Terumo Medical, National Principal Investigator: Mazin Foteh, MD, August 2019

ENDURANT EVO – Endurant Evo US Clinical Trial. Sponsor: Medtronic Endovascular. Principal Investigator: Stephen Settle, MD, August 2015

FASTII - Evaluation of the Cardio Flow FreedomFlow™ Orbital Circumferential Atherectomy System to Treat Peripheral Artery Disease. Sponsor: Cardio Flow, Inc. Principal Investigator: Mazin Foteh, MD, July 2019

GREAT - "GREAT" Global Registry for Endovascular Aortic Treatment Outcomes Evaluation.
Sponsor: W.L. Gore & Associates. Principal Investigator: Stephen Settle, MD, May 2014

InnAVasc AVG - A Study to Evaluate the Safety and Effectiveness of the InnAVasc Arteriovenous Graft for Hemodialysis Access in Patients with End-Stage Renal Disease. Sponsor: InnAVasc. Principal Investigator: Ryan Turley, MD, December 2018

LEOPARD - Multicenter, Post-Market Study to Assess Outcomes of Patients Treated With the AFX System Compared to Other EVAR Devices for Endovascular Abdominal Aortic Aneurysm Repair. Sponsor: Endologix. Principal Investigator: Jeffrey Apple, MD, November 2015

MIMICS-3D - A Prospective, Multicentre Observational Study to Evaluate the BioMimics 3D Vascular Stent System in the Treatment of Peripheral Arterial Disease. Sponsor: Veryan Medical Ltd. Principal Investigator: Mazin Foteh, MD, April 2021

MONARCH – A Prospective, Multi-Center, Single-Arm Real World Study Assessing the Clinical Use of the Caterpillar Arterial Embolization Device for Aterial Embolization in the Peripheral Vasculature. Sponsor: Bard Peripheral Vascular. Principal Investigator: Mazin Foteh, MD, April 2020

PERIGON - Medtronic PERIcardial SurGical AOrtic Valve ReplacemeNt Pivotal Trial A Multi-center, Non-randomized Trial to Determine the Safety and Effectiveness of the Model 400 Aortic Valve Bioprosthesis in Patients With Aortic Valve Disease. Sponsor: Medtronic Cardiovascular. Principal Investigator: Faraz Kerendi, MD, February 2015

RelayPro-D - A Prospective, Multicenter, Non-Blinded, Non-Randomized Study of the RelayPro Thoracic Stent-Graft in Subjects with Acute, Complicated Type B Aortic Dissections. Sponsor: Bolton Medical. Principal Investigator: Ryan Turley, MD. September 2020

STABLE-MATES - A Randomized Phase III Study of Sublobar Resection (SR) versus Stereotactic Ablative Radiotherapy (SAbR) in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC). Sponsor: Sponsored by JoLT-Ca – Joint Lung Cancer Trialist's Coalition, Administered by: Department of Radiation Oncology Clinical Research Office , UT Southwestern Medical Center (UTSW). Principal Investigator: Rachel Medbery, MD, November 2017

SUMMIT - Clinical Trial to Evaluate the Safety and Effectiveness of Using the Tendyne Mitral Valve System for the Treatment of Symptomatic Mitral Regurgitation. Sponsor: Abbott Medical Devices. Principal Investigator: Faraz Kerendi, MD, November 2019

TAMBE - Early Feasibility Assessment of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in the Treatment of Type IV Thoracoabdominal Aortic Aneurysms Involving the Visceral Branch Vessels. Sponsor: W.L.Gore & Associates. Principal Investigator: Mazin Foteh, MD, July 2020

TBE Device - Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) in the Treatment of Lesions of the Aortic Arch and Descending Thoracic Aorta. Sponsor: W. L. Gore & Associates. Principal Investigator: Mark Felger, MD, February 2017

TREO - Post-Approval Study of the TREO Abdominal Stent-Graft System in Patients with Infrarenal Abdominal Aortic and Aorto-iliac Aneurysms. Sponsor: Terumo Aortic. Principal Investigator: Mazin Foteh, MD February 2021

ULTRASCORE - A Prospective, Multi-Center, Single-Arm, Real-World Study Assessing the Clinical Use of the Bard® UltraScore™ Focused Force PTA Balloon. Sponsor: Bard Peripheral Vascular, Inc. Principal Investigator: Mazin Foteh, MD August 2018

VasQ - A Multi-center Prospective Study to Evaluate the Safety and Effectiveness of the VasQ External Support for Arteriovenous Fistula. Sponsor: Laminate Medical Technologies. Principal Investigator: Stephen Settle, MD October 2019

Completed Research Studies:

BI-LINX - An Observational Prospective Evaluation of the SJM Toronto Bioprosthesis with BiLinx™, Sponsor: St. Jude Medical, Inc, Principal Investigator: John D. Oswalt, MD October 2002

BIOCOR – Post-Approval Study Protocol of the St. Jude Medical Biocor and Biocor Supra Valves. Sponsor: St. Jude Medical, Inc. Principal Investigator: Mark Felger, MD, August 2008

C2R - CREST2 Registry. Sponsor: National Institutes of Health. Principal Investigator: Mazin Foteh, MD, April 2015

COAPT - Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation. Sponsor: Evalve, Investigator: William Kessler, MD, August 2012

CONTEGRA - Use of Contegra Pulmonary Valve Conduit Designated as Humanitarian Use Device. Sponsor: Medtronic. Principal Investigator: Kenneth Fox, MD, January 2011

CONVERGE - Convergence Of Epicardial And Endocardial Radiofrequency (RF) Ablation For The Treatment Of Symptomatic Persistent AF. Sponsor: nContact Surgical Inc. Principal Investigator: Faraz Kerendi, MD, December 2013

CONVERGENT - Retrospective Study of Outcomes of the Convergent Procedure for the Treatment of Persistent and Longstanding Persistent Atrial. Sponsors Include: Austin Heart PLLC. Principal Investigator: Faraz Kerendi, MD, August 2014

Convergent LTFU - Long-term Follow-up of Outcomes of the Convergent Procedure for the Treatment of Persistent Atrial Fibrillation. Sponsor: Cardiothoracic and Vascular Surgeons. Principal Investigator: Faraz Kerendi, MD, February 2019

CREST-2 - Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial. Sponsor: National Institutes of Health. Principal Investigator: Mazin Foteh, MD, April 2015

CRYOVALVE - CryoValve SG Pulmonary Valve, Post Clearance Study. Sponsor: CryoLife, Inc, Principal Investigator: John Oswalt, MD, January 2011

EPIC - An Observational Prospective Evaluation of the SJM Epic™ Valve. Sponsor: St. Jude Medical, Inc. Principal Investigator: John D. Oswalt, MD, May 2004

EXCEL - Evaluation of XIENCE PRIME or XIENCE V versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization. Sponsor: Abbott Vascular. Principal Investigator: John Oswalt, MD, February 2012

GRAFTCATH - GRAFTcath Vascular Access System (GVAS) Clinical Study Protocol. Sponsor: GRAFTcath. Principal Investigator: Stephen Settle, MD, October 2005

LIBERTY 360° - Prospective, Observational, Multi-Center Clinical Study to Evaluate Acute and Long Term Clinical and Economic Outcomes of Endovascular Device Intervention in Patients with Distal Outflow Peripheral Arterial Disease (PAD). Sponsor: Cardiovascular Systems, Inc. Principal Investigator: Mazin Foteh, MD, March 2015

MYPRO RETRO - Myocardial Protection in Adult Cardiac Surgery Utilizing del Nido Cardioplegia - A Retrospective Review. Sponsor: Cardiothoracic and Vascular Surgeons. Principal Investigator: William C. Conner, MD, May 2016

ON-X - A Multicenter, Prospective Clinical Trial to Investigate the On-X Prosthetic Heart Valve Aortic and Mitral Models 100 and 200 Safety and Effectiveness in Replacement of Diseased Aortic or Mitral Valves. Sponsor: Procter & Gamble/Alexion Pharmaceuticals. Principal Investigator: Emery Dilling, MD, October 1999

PAD 115 - A Phase 1 Multi-center, Randomized, Double-Blind, Placebo-Controlled, Dose Escalation Study of Vonapanitase Administered Following Angioplasty of a Distal Popliteal, Tibial or Peroneal Artery in Patients with Peripheral Artery Disease Sponsor: Proteon Therapeutics. Principal Investigator: Mazin Foteh, MD, April 2018

PARTNER 3 Trial - A Prospective, Randomized, Controlled, Multi-Center Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients Requiring Aortic Valve Replacement who have Severe, Calcific, Symptomatic Aortic Stenosis. Sponsor: Edwards Lifesciences. Principal Investigator: Faraz Kerendi, MD, August 2016

PARTNER II - SAPIEN XT™ Transcatheter Heart Valve with NovaFlex and Ascendra delivery systems in Intermediate and High Risk for Aortic Valve Surgery and Patients Who Cannot Undergo Surgery. The PARTNER II Trial "Placement of AoRTic TraNscathetER" Valves Trial". Sponsor: Edwards Lifesciences. Principal Investigator: Faraz Kerendi, MD, February 2013

PATENCY 2 - Multicenter, Double Blind, Placebo Controlled Study of Vonapanitase (PRT- 201) Administered Immediately After Radiocephalic Arteriovenous Fistula Creation in Patients With Chronic Kidney Disease. Sponsor: Proteon Therapeutics. Principal Investigator: Stephen Settle, MD, June 2015

PERCEVAL - Clinical Investigation of the Perceval S Sutureless Heart Valve. Sponsor: Sorin Group USA, Inc., Principal Investigator: William Kessler, MD, April 2013

PORTICO - Transcatheter heart valve therapy vs. commercially available trans-catheter valve (CAV) in patients with symptomatic severe native aortic stenosis, who are considered high or extreme surgical risk. Sponsor: St. Jude Medical. Principal Investigator: Faraz Kerendi, MD,September 2014

PREVENT-IV - A Phase III ,Multi-Center Randomized, Double-Blind, Placebo-Controlled Trial of the Ex Vivo Treatment with CGT003 of Coronary Vein Grafts in Patients Undergoing Coronary Artery Bypass Graft Procedures. Sponsor: Corgentech. Principal Investigator: Mark Felger, MD, February 2003

PRIMO-CABII - A Multicenter, Randomized, Double-Blind, Parallel-group, Placebo-Controlled Study of 2 mg/kg Bolus Plus 24-hour 0.5 mg/kg/hr Infusion Pexelizumab in Patients Undergoing Coronary Artery Bypass Grafting with Cardiopulmonary Bypass. Sponsor: Procter & Gamble/Alexion Pharmaceuticals. Principal Investigator: Andrew Hume, MD, February 2005

RECON Study - A Post Market Observational Study to Obtain Additional Information on the Use of CorMatrix ECM for Pericardial Reconstruction. Sponsor: CorMatrix Cardiovascular Inc. Prinicipal Investigator: Faraz Kerendi, MD, February 2017

RETRO-OP - Retrospective Study of Outcomes of Pain Management using Liposomal Bupivacaine following Surgical Procedure. Sponsor: Cardiothoracic and Vascular Surgeons Principal Investigator: Brannon Hyde, MD, April 2015

ROADSTER – Investigation of Flow Altered, Short Transcervical Carotid Artery Stenting in Patients with Significant Carotidartery Disease with Filter. Sponsor: Silk Road Medical. Principal Investigator: Mazin Foteh, MD, May 2013

ROADSTER 2 – Registry of Transcarotid Artery Revascularization in Patients with Significant Carotid Artery Disease. The ROADSTER2 Registry. Sponsor: Silk Road Medical. Principal Investigator: Mazin Foteh, MD, November 2015

SALUS - SALUS Trial TranScatheter Aortic Valve RepLacement System Pivotal Trial The Safety and Effectiveness of the Direct Flow Medical Tanscatheter Aortic Valve System. Sponsor: Direct Flow Medical, Inc. Principal Investigator: Stephen Dewan, MD, December 2015

TEVAR B - SVS PSO Type B Thoracic Aortic Dissection Quality Improvement Project. Sponsor: Society for Vascular Surgery Patient Safety Organization. Principal Investigator: Mazin Foteh, MD, May 2014

TRIFECTA - An Observational, Prospective Evaluation of the Trifecta™ Valve. Sponsor: St. Jude Medical. Principal Investigator: John Oswalt, MD, November 2017

VERNACULAR - The BARD® VENOVO ™ Venous Stent Study – A Prospective, Non-Randomized, Multi-Center, Single-Arm Study of the Treatment of Iliofemoral Occlusive Disease – an Assessment for Effectiveness and Safety. Sponsor: Bard Peripheral Vascular, Inc. Principal Investigator: Jeffrey Apple, MD, September 2016

VIVO - Evaluation of the Zilver Vena Venous Stent in the Treatment of Symptomatic Iliofemoral Venous Outflow Obstruction. Sponsor: Cook Incorporated. Principal Investigator: Jeffrey Apple, MD, May 2014

PRESENTATIONS:

A Novel Pain Management Approach to Pericardial Pain Post Convergent Ablation for Atrial Fibrillation. Brannon Hyde, MD, Daniel Berson, DO, Faraz Kerendi, MD, Mannling Ho, PharmD, and Bonnie B. Punske, PhD, South Texas Chapter of the American College of Surgeons, San Antonio, Texas, Feb 25-27, 2016.

Safety of Non-Vitamin K Anticoagulants Versus Warfarin Following Cardiac Surgery Via Sternotomy. Winborne Hamlin, BS, Alayna Garcia, BS, Bonnie Punske, PhD, Vincent VanBuren, PhD, and Faraz Kerendi, MD. Southern Thoracic Surgical Association, 66th Annual Meeting, Marco Island, Florida, Nov. 6-9-2019.

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