



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:

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St. David's Round Rock Medical Center
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Seton Medical Center
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RESEARCH COMMITTEE:

Faraz Kerendi, MD - Chair
Stephen Dewan, MD
Brannon Hyde, MD
Jonathan Yang, MD
Daniel Fortes, MD
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Mazin Foteh, MD
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DEPARTMENT MANAGERS:

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RESEARCH STAFF:

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Clinical Research Coordinator

Gina Briones, CCRC
Clinical Research Coordinator

Kathlyne Brown, DO, CCRP
Clinical Research Assistant

RESEARCH STUDIES:

Current Research Studies:

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

CROSS-SEAL – Prospective, Multi-center, Single Arm Study of the Cross-Seal™ Suture-Medicated Vascular Closure Device System. Sponsor: Terumo Medical Corporation, Principal Investigator: Mazin Foteh, MD

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, 4/18

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, 12/17

ANCHOR Registry - Aneurysm Treatment using the Aptus™ Heli-FX™ EndoAnchor System Global Registry Sponsor: Medtronic Vascular Inc., Principal Investigator: Mazin Foteh, MD, 1/18

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: Daniel Fortes, MD, 11/17

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, 2/17

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, 9/16

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 5/16

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, 11/15

ENDURANT EVO – Endurant Evo US Clinical Trial. Sponsor: Medtronic Endovascular Principal Investigator: Stephen Settle, MD, 8/15

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, 6/15

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, 11/15

CREST-2 – Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial. Sponsor: National Institutes of Health, Principal Investigator: Mazin Foteh, MD, 4/15

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, 3/15

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, 2/15

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, 5/14

GREAT - "GREAT" Global Registry for Endovascular Aortic Treatment Outcomes Evaluation. Sponsor: W.L. Gore & Associates, Principal Investigator: Stephen Settle, MD 5/14

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, 2/13

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, 8/16

ALCHEMIST - Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial
Sponsor: National Cancer Institute (NCI), Investigator: Daniel Fortes, MD, 10/15

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 5/14

COAPT Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation. Sponsor: Evalve, Investigator: William Kessler, MD, 8/12

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. Principal Investigator: Faraz Kerendi, MD
Sponsor: St. Jude Medical, 9/14

Completed Research Studies:

RECON Study – A Post Market Observational Study to Obtain Additional Information on the Use of CorMatrix ECM for Pericardial Reconstruction. Sponsor: CorMatrix Cardiovascular Inc., Principal Investigator: Faraz Kerendi, MD, 2/17

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, 8/14

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, 12/13

C2R – CREST2 Registry. Sponsor: National Institutes of Health, Principal Investigator: Mazin Foteh, MD, 4/15
Revised 1/25/2018

CONTEGRA - Use of Contegra Pulmonary Valve Conduit Designated as Humanitarian Use Device. Sponsor: Medtronic, Principal Investigator: Kenneth Fox, MD 1/11

RETRO-OP - Retrospective Study of Outcomes of Pain Management using Liposomal Bupivacaine following Surgical Procedure, Principal Investigator: Brannon Hyde, MD, 4/15

ROADSTER – Investigation of flow altered, short transcervical carotid artery stenting in patient with significant carotidartery disease with filter. Sponsor: Silk Road Medical, Principal Investigator: Mazin Foteh, MD 5/13

PERCEVAL - Clinical Investigation of the Perceval S Sutureless Heart Valve. Sponsor: Sorin Group USA, Inc., Principal Investigator: William Kessler, MD 4/13

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 2/12

CRYOVALVE - CryoValve SG Pulmonary Valve, Post Clearance Study. Sponsor: CryoLife, Inc, Principal Investigator: John Oswalt, MD 1/10

TRIFECTA - An Observational, Prospective Evaluation of the Trifecta™ Valve. Sponsor: St. Jude Medical, Principal Investigator: John Oswalt, MD 11/07

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 08/08

GRAFTCATH - GRAFTcath Vascular Access System (GVAS) Clinical Study Protocol. Sponsor: GRAFTcath, Principal Investigator: Stephen Settle, MD 10/05

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 02/05

EPIC - An Observational Prospective Evaluation of the SJM Epic™ Valve. Sponsor: St. Jude Medical, Inc, Principal Investigator: John D. Oswalt, MD 05/04

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 02/03

BI-LINX - An Observational Prospective Evaluation of the SJM Toronto Bioprosthesis with BiLinx™, Sponsor: St. Jude Medical, Inc, Principal Investigator: John D. Oswalt, MD 10/02

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 10/99

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, 12/15

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.

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