US IDE Consortium: The Best Data on F/BEVAR?

Andres Schanzer, MD

December 17th, 2021
Critical Issues, Paris, France

Disclosures

- Cook Medical, Phillips Imaging, Cryolife
  - Research grants
  - Case proctor
  - Consult

All compensation goes to UMass Memorial Foundation and none to me personally.


UMassMemorial
CENTER FOR COMPLEX AORTIC DISEASE

Developing a complex endovascular fenestrated and branched aortic program

Andres Schanzer, MD,[a] Donald Baril, MD,[b] William P. Robinson III, MD,[a] Jessica P. Simons, MD, MPH,[a] Francesco A. Aiello, MD,[a] and Louis M. Messina, MD,[a] *Worcester, Mass; and Pittsburgh, Pa*

In 2008, the top priority in our division's 5-year strategic plan was "to become an internationally recognized center of excellence for the endovascular treatment of complex aortic pathology extending from the aortic valve to the external iliac artery." Five components were identified as "most critical" to achieve this strategic priority: (1) training at centers of excellence in complex endovascular repair; (2) industry partnership to improve access to developing technologies; (3) a fully integrated team approach with one leader involved in all steps of all cases; (4) prospective data collection; and (5) development and implementation of a physician-sponsored investigational device exemption for juxtarenal, pararenal, and thoracoabdominal aneurysms. We have now performed 49 repairs (16 commercially manufactured devices, 33 physician-modified devices) for 3 common iliac, 20 juxtarenal, 9 pararenal, and 17 thoracoabdominal aneurysms, using 142 fenestrations, branches, and scallops. All patients had complete 30-day follow-up for calculation of 30-day events. Kaplan-Meier analysis was used to calculate 1-year events. In 5 years, we developed a successful complex endovascular aortic program that uses fenestrated/branched repair techniques. A focused team strategic planning approach to program development is an effective way for vascular surgery divisions to gain experience and expertise with new complex technologies while ensuring acceptable patient outcomes. (J Vasc Surg 2015;■:1-6.)

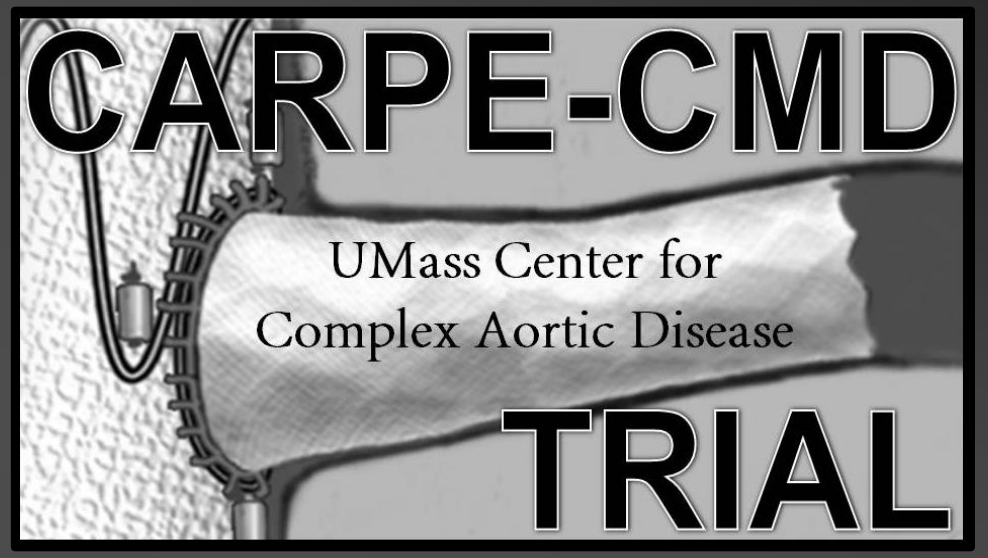
DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

PRIMARY OBJECTIVE:

To evaluate custom made devices and physician-modified FDA-approved devices for the treatment of patients with complex abdominal, thoracoabdominal, and arch aneurysms.

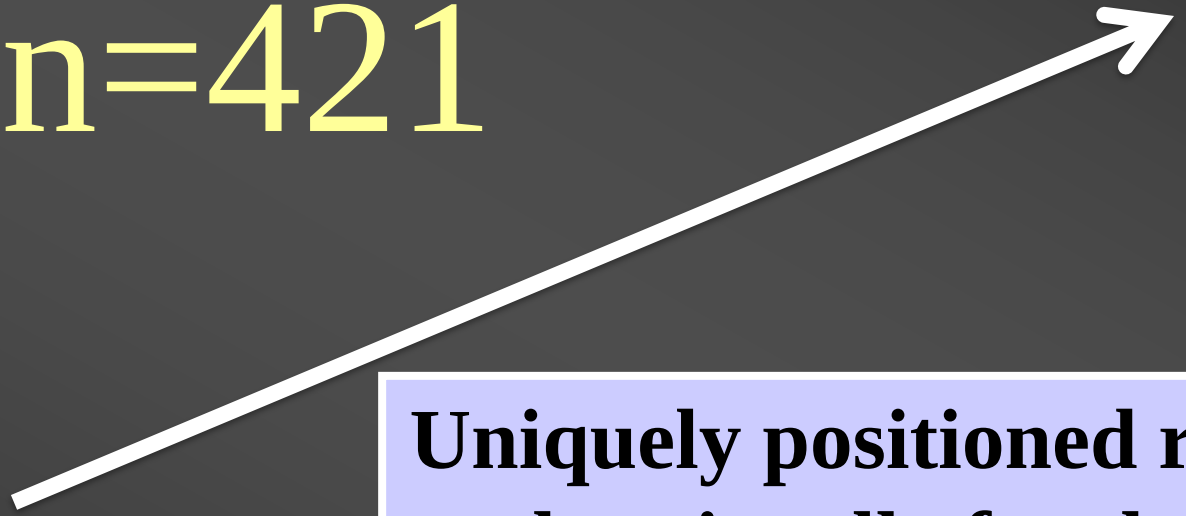
External CRO, CEC, Imaging Lab.



October 10, 2013

2021

n=421



2008

Uniquely positioned regionally and nationally for the breadth of aortic pathology that we can now treat with minimally invasive endovascular grafts.

Current State: Iterative Single Center Reports

Preoperative functional status
undergoing fenestrated/branch

Colleen P. Flanagan, MD,[a] Allison S. Crawford, M
Francesco A. Aiello, MD, MBA,[b] Andres Schanzer,
and Worcester, Mass

ABSTRACT

Background: I
tients at high r
have required
year survival in
patients unde

Methods: The
board-approv
were reviewe
comorbidities
status was de
facility), partia
in activities
($P < .2$), a Cox
mortality.

Results: For the
pararenal [14%], 119
modeling, the only independent preoperative pred
(totally dependent: hazard ratio [HR], 5.4; 95% confider
CI, 2.4-8.7; $P < .0000019$). A history of an implanted
$P = .0495$). Factors such as age, congestive heart failure
disease, aneurysm extent, and previous aortic surgery
(n = 176; 69%), partially dependent (n = 69; 27%), and
respectively.

Conclusions: For patients undergoing F/BEVAR, decrea
2-year mortality, with totally dependent patients expe
pendently significant, perhaps reflecting the high p
participating in an IDE trial. For the independent patien
survival after infrarenal EVAR. Therefore, for independe
BEVAR to low-risk patients. (J Vasc Surg 2021;74:383-95

Effect of thoracoabdomi
patients undergoing fen
repair

Kyle R. Diamond, MD, Jessica P. Simo
Dejah R. Judelson, MD, Francesco Aiel

extensive TAAAs (71%). Most repairs
two groups, no perioperative difference
target artery occlusion, access site complic
paraparesis was greater in the extensive TA
ralysis was equivalent (2.3% vs 0.5%; $P = .20$
Kaplan-Meier analysis, no differences in sur
3 years ($P > .05$ for all). Freedom from type
significantly worse in the extensive TAAA
extensive TAAA was not associated with 1-y

Conclusions: Unlike open TAAA repair, the
differences in perioperative paraparesis, bran
of aortic coverage and number of target art
BEVAR should expect comparable outcome

Evolution of fenestrated/branched endovascular aortic aneurysm repair complexity and outcomes at an organized center for the treatment of complex aortic disease

Jessica P. Simons, MD, MPH, Allison S. Crawford, MS, Colleen P. Flanagan, BA, Francesco A. Aiello, MD, MBA, Edward J. Arous, MD, MPH, Dejah R. Judelson, MD, Louis M. Messina, MD, Devon I. Robichaud, MS, Shaunnon A. Valliere, MS, and Andres Schanzer, MD, *Worcester, Mass*

scular aneurysm repair (F/BEVAR) volume has increased rapidly, with favor-
evaluated changes over time in F/BEVAR complexity and associated out-
ease program.

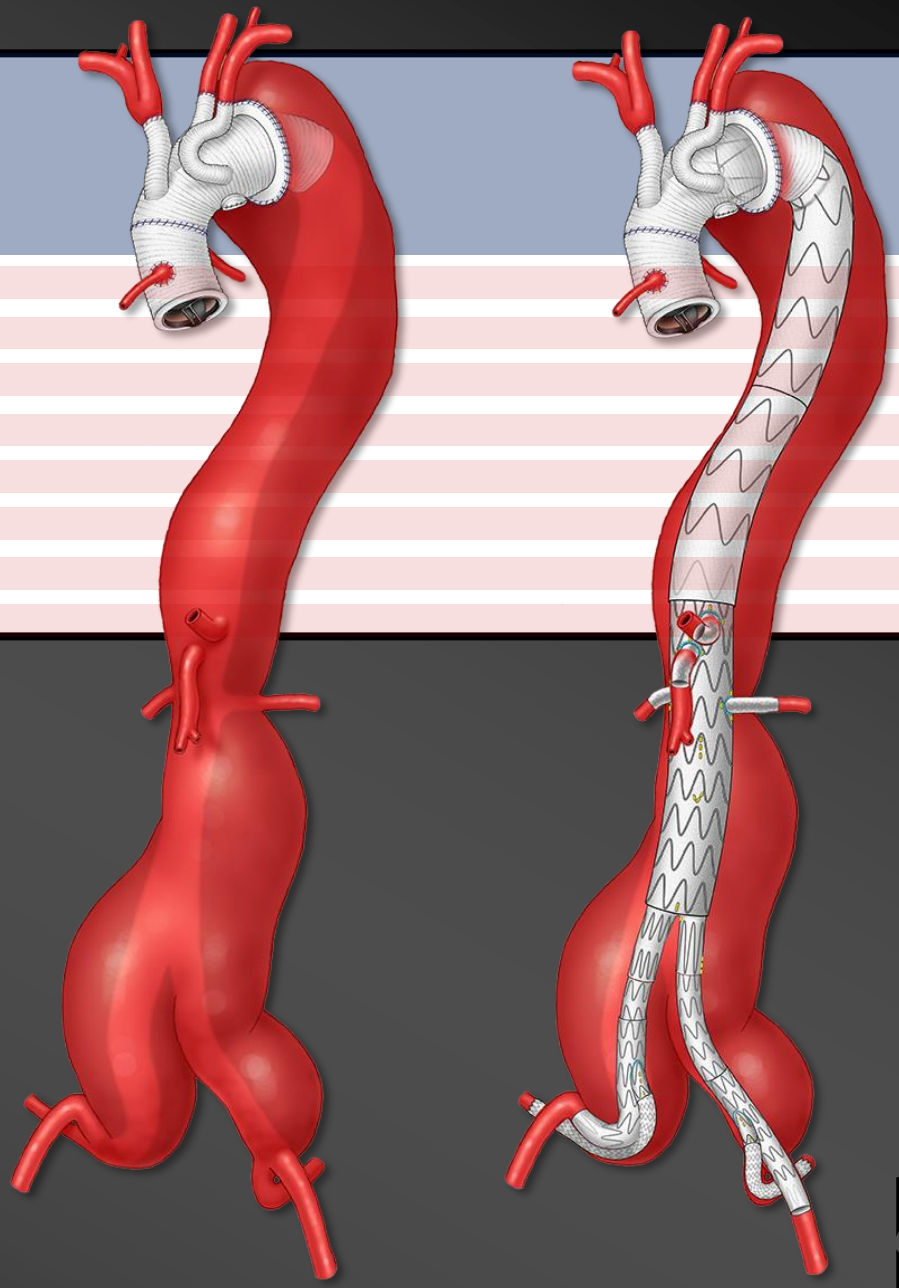
ll F/BEVAR (definition: requiring ≥1 fenestration/branch), procedures per-
roved registry and/or physician-sponsored investigational device exemption
2/2019). Patients were stratified by surgery date into thirds: early experience,
atient and operative characteristics, aneurysm morphology, device types,
al, freedom from type I or III endoleak, target artery patency, freedom from
os.

arly experience, n = 84, mid experience, n = 84, recent experience,
d custom-made devices, 11 (4.4%) company-manufactured off-the-shelf
devices, were used to treat 5 (2.0%) common iliac, 97 (39%) juxtarenal,
bdominal, and 2 (0.8%) arch aneurysms. All patients had follow-up for
ean follow-up time for the entire cohort was 589 days (interquartile range, 149-813 days).
analysis, survival was 88%, freedom from type I or III endoleak was 91%, and target
%. When stratified by time period, significant differences included aneurysm extent
(tho
arly experience, 40% mid experience, and 64% recent experience; $P < .001$) and target
vessels p
l case, 31% early experience, 39% mid experience, and 67% recent experience; $P <$
.0001). There
nce, but a trend toward improvement in composite 30-day events (early experience,
39%; mid experi
ent experience, 27%; $P = .05$). On Kaplan-Meier analysis, there was no difference in
survival ($P = .19$) or t
ry patency ($P = .6$). There were differences in freedom from reintervention ($P <$
.01) and from type I or
oleak ($P = .02$), with more reinterventions in the early experience, and more
endoleaks in the recent perio

Conclusions: Despite increasing repair complexity, there has been no significant change in perioperative complications, overall survival, or target artery patency, with favorable outcomes overall. Type I or III endoleaks remain a significant limitation, with increased incidence as the number of branch arteries incorporated into the repairs has increased. (J Vasc Surg 2021;73:1148-55.)

"These findings may be limited due to the potential for a type 1 error secondary to limited statistical power…."

UNITED STATES AORTIC RESEARCH CONSORTIUM



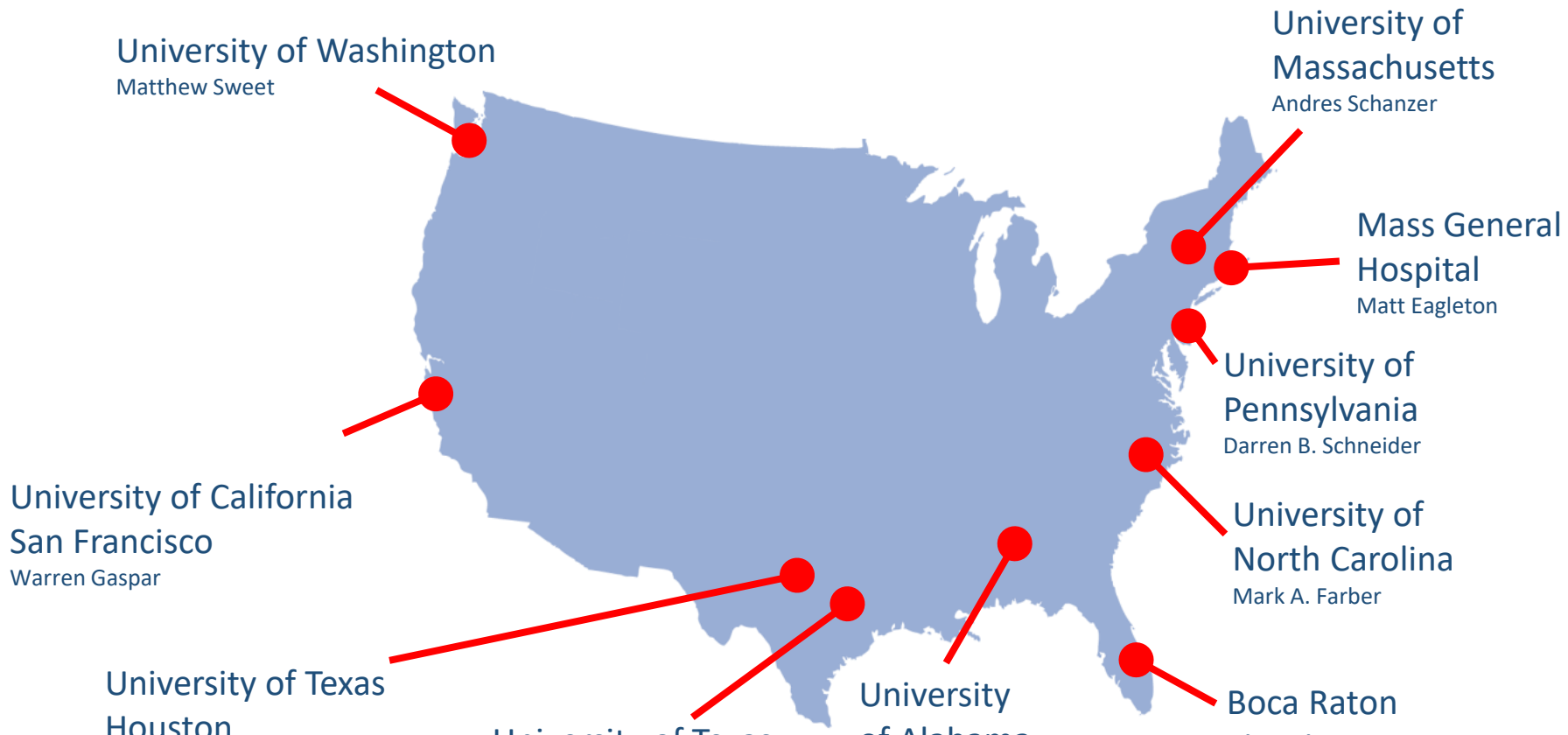
US-ARC

United States Aortic Research Consortium

PS-IDE x 10

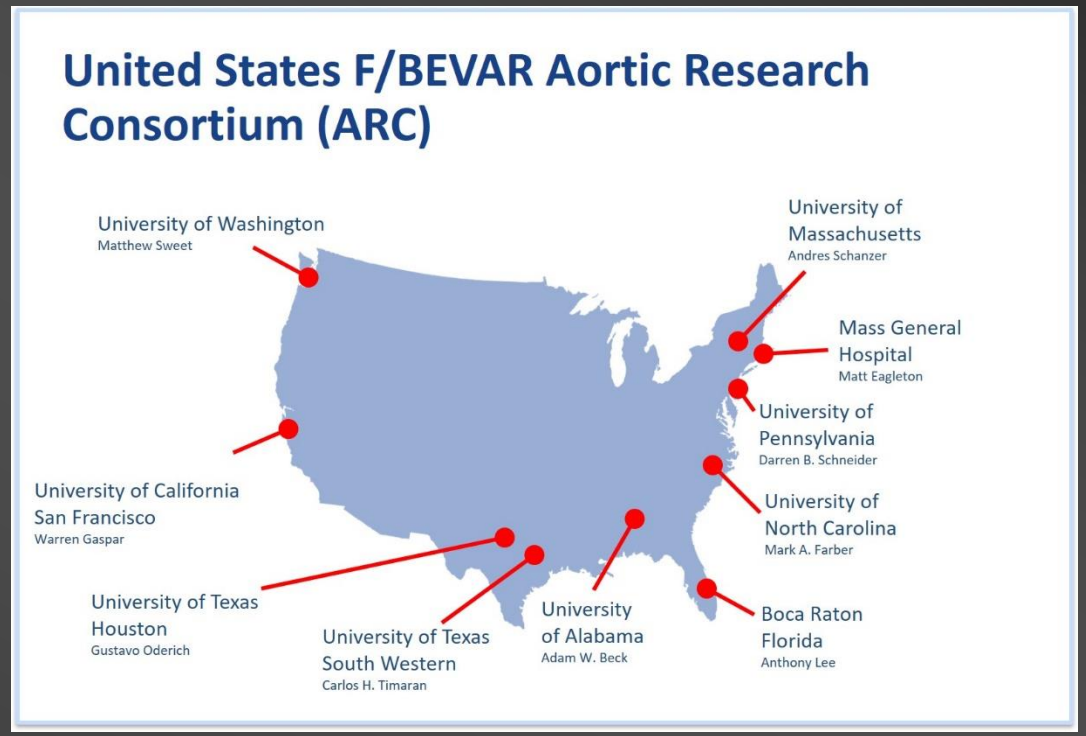
United States F/BEVAR Aortic Research Consortium (ARC)

- 10 US sites
- Prospective, physician-sponsored studies
- Independent monitoring, FDA audited
- Similar device design with selective use of fenestrations and branches



Past

Future


United States F/BEVAR Aortic Research Consortium (ARC)
University of Washington
Matthew Sweet
University of Massachusetts
Andres Schanzer
Mass General Hospital
Matt Eagleton
University of Pennsylvania
Darren B. Schneider
University of North Carolina
Mark A. Farber
Boca Raton Florida
Anthony Lee
University of Alabama
Adam W. Beck
University of Texas South Western
Carlos H. Timaran
University of Texas Houston
Gustavo Oderich
University of California San Francisco
Warren Gaspar

United States Aortic Research Consortium 1.0

From: "Schanzer, Andres" <Andres.Schanzer@umassmemorial.org>
Date: Saturday, February 10, 2018 at 5:55 AM
To: "'Farber, Mark A'" <mark_farber@med.unc.edu>, Matthew Eagleton <meagleton@mgh.harvard.edu>, "Gustavo S. Oderich M.D." <Oderich.Gustavo@mayo.edu>, "Beck, Adam W" <awbeck@uabmc.edu>, Anthony Lee <WLee@brrh.com>, "Darren B. Schneider" <dbs9003@med.cornell.edu>, "Matthew P. Sweet" <mpsweet@uw.edu>, Carlos Timaran <timaran1@msn.com>
Subject: Re: Syntactx Database in a Box

Dear Team,
It was great to meet up and discuss ways in which to move forward with an effort to facilitate multicenter research and merged data analyses. If we are able to pull this off and figure out a way to aggregate our data in a relatively seamless way, I believe we have the potential to make a much more significant impact than multiple iterative single center reports. I would like to commit to trying to make this happen. As a starting point, I've created a shared dropbox folder:

https://www.dropbox.com/sh/zjaxewgntnyvcu5/AAAumCYqlmTolAOpKV3mfjjEa?dl=0[dropbox.com]

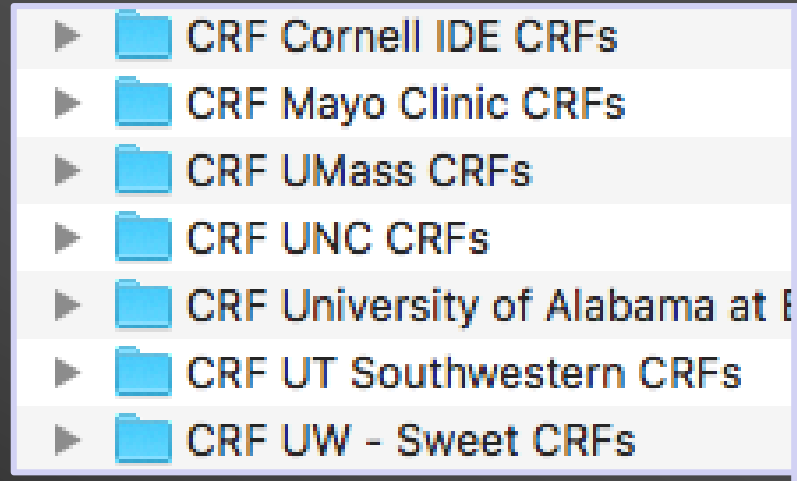
Potential next steps:

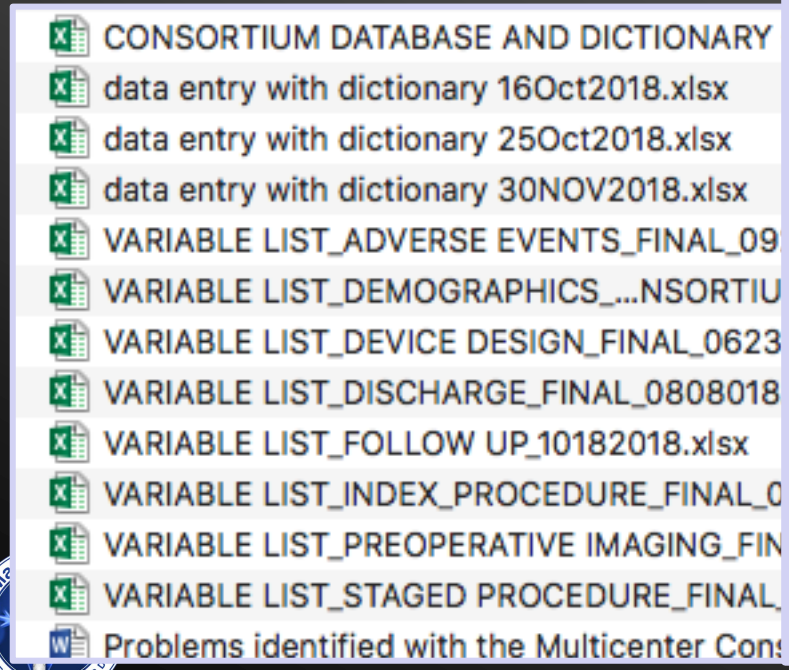
1. I added all of my CRF forms to this folder. It would be great if others could do this as well.
2. Gustavo, can you ask your research fellow to look through the two analyses that were submitted for VAM and create a list of all variables that were used for this analysis. This might be a good starting point to assign consistent variable names across all of our datasets. We can then take that list and split it up among us to suggest clear definitions for each variable. We can then discuss the definitions we come up with in order to arrive at a list of common variables called by the same name with the same definitions.
3. I will look through everyone's CRF forms and try to augment the list of common variables with ones that we may all want to collect but were not used in the first two initial analyses. We can then discuss them and if everyone agrees, go through the same process of creating common variable names with standard definitions.
4. Stephan Haulon has offered to share the Loreta database and data dictionary with me and this may also be a helpful starting point for us. If their variable definitions are clear, we don't need to reinvent the wheel.
5. In order to keep this moving and not have it get lost in all of our busy lives, I recommend we have a monthly conference call to monitor progress. Do others agree? If so, in order to accommodate both east and west coast, what about the first Monday of the month from 9 pm to 10 pm. I can set up a webex and recurring invitation if people feel this is worth the time.

Let me know what you think? Worthwhile, not worthwhile, I'm in, no thanks, etc....
Thanks, Andy

Andres Schanzer, MD, FACS

Aortic Research Consortium 1.0





CONSORTIUM DATABASE AND DICTIONARY 01142019

Home | Insert | Page Layout | Formulas | Data | Review | View

Paste | Cut | Copy | Format | Calibri (Body) | 11 | Wrap Text | Merge & Center | General | Conditional Formatting | Forma as Tabl

A339 | fx | proc_rdtn_dap

	A	B	
1	**VARIABLE NAME**	**VARIABLE DEFINITION**	**VARIABLE CODING**
2			
3	pt_id	site_enrollment #	text site descriptor and enrollment number
4	gender	gender	0, Female | 1, Male
5	dob	Date of Birth (mm/dd/yyyy)	date_mdy
6	ethnicity	Ethnicity	1, White | 2, Black or African American | 3, Asian | 4,
7			
8	indicat_diam	Aortic or aortoiliac aneurysm with diameter ≥ 5.0 cm	1, Yes | 0, No
9	indicat_growth	Aortic or aortoiliac aneurysm with a history of growth ≥ 1.0 cm per year	1, Yes | 0, No
10	indicat_rupture	Aortic or aortoiliac aneurysm with symptoms or rupture	1, Yes | 0, No
11	indicat_pau	Pentrating aortic ulcer (PAU) depth ≥ 1.5 cm	1, Yes | 0, No
12	indicat_saccular	Saccular aortic aneurysm or pseudoaneurysm	1, Yes | 0, No
13	indicat_endoleak	Type 1 endoleak after prior EVAR/TEVAR	1, Yes | 0, No
14			
15	sx_asx	Asymptomatic	1, Yes | 0, No
16	sx_pain	Symptomatic, pain (non_ruptured)	1, Yes | 0, No
17	sx_stablerup	Symptomatic, rupture without hypotension (SBP>90)	1, Yes | 0, No
18	sx_freerup	Symptomatic, rupture with hypotension (SBP<90)	1, Yes | 0, No
19			
20	hx_cad	Previous diagnosis of coronary artery disease	1, Yes | 0, No | 3, Unknown
21	hx_mi	Previous myocardial infarction	1, Yes | 0, No | 3, Unknown
22	hx_chf	Previous diagnosis of symptomatic congestive heart failure	1, Yes | 0, No | 3, Unknown
23	hx_arrhyth	Previous diagnosis of cardiac arrhythmia	1, Yes | 0, No | 3, Unknown
24	hx_nyhc	If previous diangosis of symptomatic congestive heart failure, NYHA classification	1, 1 | 2, 2 | 3, 3 | 4, 4 | 5, Unknown

Aortic Resea

- **Dorothy Abel**
- **Brian Pullin**
- **Valerie Merkle**
- **Pablo Morales**
- **Carmen Gacchina**

Reply Reply All Forward

Thu 12/6/2018 1:34 PM

GJ Gacchina Johnson, Carmen <Carmen.Gacchina@fda.

RE: MULTICENTER CONSORTIUM OF PS-IDE FENESTRATED/BRANCHED

To Schanzer, Andres; oderich.gustavo@mayo.edu

Cc Pullin, Brian; Zinkus, Rose Marie; Merkle, Valerie

You forwarded this message on 12/10/2018 8:50 AM.

From: Schanzer, Andres <Andres.Schanzer@umassmemorial.org>
Sent: Thursday, December 06, 2018 10:36 AM
To: Gacchina Johnson, Carmen <Carmen.Gacchina@fda.hhs.gov>
Cc: oderich.gustavo@mayo.edu; Pullin, Brian <Brian.Pullin@fda.hhs.gov>; Zinkus, Rose Marie <RoseMarie.Zinkus@umassmemorial.org>; Merkle, Valerie <Valerie.Merkle@fda.hhs.gov>
Subject: RE: MULTICENTER CONSORTIUM OF PS-IDE FENESTRATED/BRANCHED STUDIES

Carmen,
I'm happy to clarify the scope. Gustavo and I have been working with 8 PS-IDE fenestrated/branched primary investigators (Schanzer, Oderich, Sweet, Eagleton, Beck, Farber, Schneider, Timaran) on standardizing definitions and ensuring a common set of data variables across all of our trials. The goal is to facilitate merged analyses with greater power and improved generalizability across sites. This process has led us to the obvious conclusion that it would be great if all of our sites were able to use a central EDC platform where we would still own all of our individual data but where we could perform merged, blinded, consortium analyses with greater efficiency and accuracy. We believe this will bring the PS-IDE effort to the next level and allow for higher impact contributions to field and more rigorous evaluation of these technologies.

We were hoping to update you on this process with the goal of getting your thoughts from the FDA perspective on three primary issues: 1) Assuming all database compliance issues are met, does utilization of a common EDC platform raise any concerns with the FDA, 2) If we were able to implement this, would the FDA be open to receiving standardized annual reports that would be generated for each site and look the same, 3) Would leveraging industry relationships to help fund a central EDC platform be acceptable.
Thank you,
Andy

United States Aortic Research Consortium (ARC) 2.0

Edits as of 10/22/19

MEMORANDUM OF UNDERSTANDING

I. Scope

A. It is the desire of the parties that this Memorandum should not and therefore does not establish nor create any form or manner of a formal agreement, but rather is an understanding between the parties to work together in a manner that promotes collaboration and alliance in support of an effective and efficient partnership and leadership meant to maintain, safeguard, and sustain optimal managerial, financial, and administrative commitment to matters related to the design and implementation of ARC.

B. This Memorandum encompasses discussions between Physician Members, including each party's employees, directors, affiliates, contractors, subcontractors, and agents, related to ARC.

C. This Memorandum does not include any party's discussions or projects involving Investigational Devices and PS-IDEs unrelated to ARC.

II. Framework and Principles of ARC

A. Compliance.

i. The parties will collaborate under this Memorandum in accordance with applicable federal, state, and local laws and regulations.

ii. The parties expressly agree that nothing in this Memorandum requires or will be construed to require Physician Members to use, order, purchase or recommend the use of Cook or Cook affiliate's products or services.

B. Participation.

i. Only clinical investigation sites located in the United States conducting PS-IDEs involving Cook Medical's Investigational Devices will be invited to become an ARC Member Site upon ARC majority vote approval.

ii. The parties understand that Cook retains the exclusive right to approve use of its Investigational Devices in PS-IDEs independent of ARC.

iii. Physician Members and Cook will notify all participating ARC members if approached by non-ARC members seeking access to any data or information in the ARC database.

C. Data Coordinating Center (DCC).

i. The parties will collaborate to identify and select a qualified data coordinating center to process ARC clinical data based on agreed upon criteria, including but not limited to audit results, user requirements, functionality, cost, projected timelines, experience, and resourcing.

ii. Cook reserves the right to decline executing an agreement with and paying a DCC that Cook does not believe capable of providing the required services.

iii. The DCC will prepare data tables and figures for each Physician Member for inclusion in regulatory submissions as required by each individual PS-IDE.

D. ARC Dataset.

i. Clinical data entered into the ARC database will include all PS-IDE patients treated with Cook Medical's Investigational Devices. Urgent, emergent, and compassionate use cases will also be entered if permitted by Physician Member's site-specific Institutional Review Board.

US Aortic Research Consortium (ARC)

Final Version 05May2020

Bylaws

I. **Name:** The organization shall be called the "US Aortic Research Consortium" ("ARC").

II. **Purpose:** ARC is a research partnership between selected US physicians conducting Physician-Sponsored Investigational Device Exemptions ("PS-IDEs") and Cook Research Incorporated and its affiliate medical device companies. ARC is dedicated to the advancement of the science and treatment of patients with aortic pathology using minimally invasive endovascular technologies. The purposes of ARC are:

a) To establish and maintain a multicenter prospective database including clinical data from all consecutive patients treated by Physician Members and their relative site investigators conducting an FDA-approved PS-IDE evaluating outcomes of fenestrated and branched endografts. The database will also include retrospective clinical data from PS-IDE patients. ARC will agree on a set of datapoints that will be uniformly collected in the database by all PS-IDE sites ("Core ARC Data").

b) To use the database to encourage and stimulate basic and clinical research in the field of minimally invasive endovascular aortic surgery and to promote new therapeutic strategies.

c) To use the database to fulfill regulatory needs, inform device design and development, develop and conduct physician training, and other related uses as identified.

III. **Participation:** There shall be three classes of participation: Voting Physician Member, Non-voting Physician Member, and Industry Member (collectively, "ARC Members"). Voting Physician Member and Non-voting Physician Member are collectively referred herein as "Physician Members." For the avoidance of doubt, the term "Physician Members" as used in the Memorandum of Understanding effective January 27, 2020, excludes Non-voting Physician Members. Each Physician Member, or its designated surrogate, must participate in at least fifty percent (50%) of ARC calls and meetings over a rolling six-month period. If not, the Medical Director may call for a vote on whether to exclude Physician Member from ARC.

a) Voting Physician Member: Only PS-IDE sponsor-investigators with clinical investigation sites located in the United States will be invited to become a Voting Physician Member. The sponsor-investigator of each PS-IDE will designate one (1) Voting Physician Member to participate in ARC. Each Voting Physician Member is allowed one (1) vote for ARC decisions, including those concerning research proposals and publications described in Section IX(b) below, membership, ARC Data, and operations. Voting Physician Members are invited to attend ARC calls and meetings.

Select Patient
+ Add Form | Summary
Patient Inclusion
Site Enrollment Number
xcvsd
Demographics
Preoperative Imaging
Device Design
Index Procedure
Discharge
Study Exit

Site Enrollment Number : **xcvsd** View Form Counts

Not Started

Device Design

Print View

Main Aortic Device

Main Device Type
- ○ t-Branch
- ○ p-Branch
- ○ CMD
- ○ PMEG
- ○ ARCH Branch

Clear Selection

Optional / Non-core

Stent Type
- ○ No Bare Stent
- ○ Bare Stent

Clear Selection

Graft Diameter of Proximal Aspect of Main Aortic Device (mm) Allowable range: 20 - 50

Optional / Non-core

Graft Diameter of Distal Aspect of Main Aortic Device (mm) Allowable range: 5 - 50

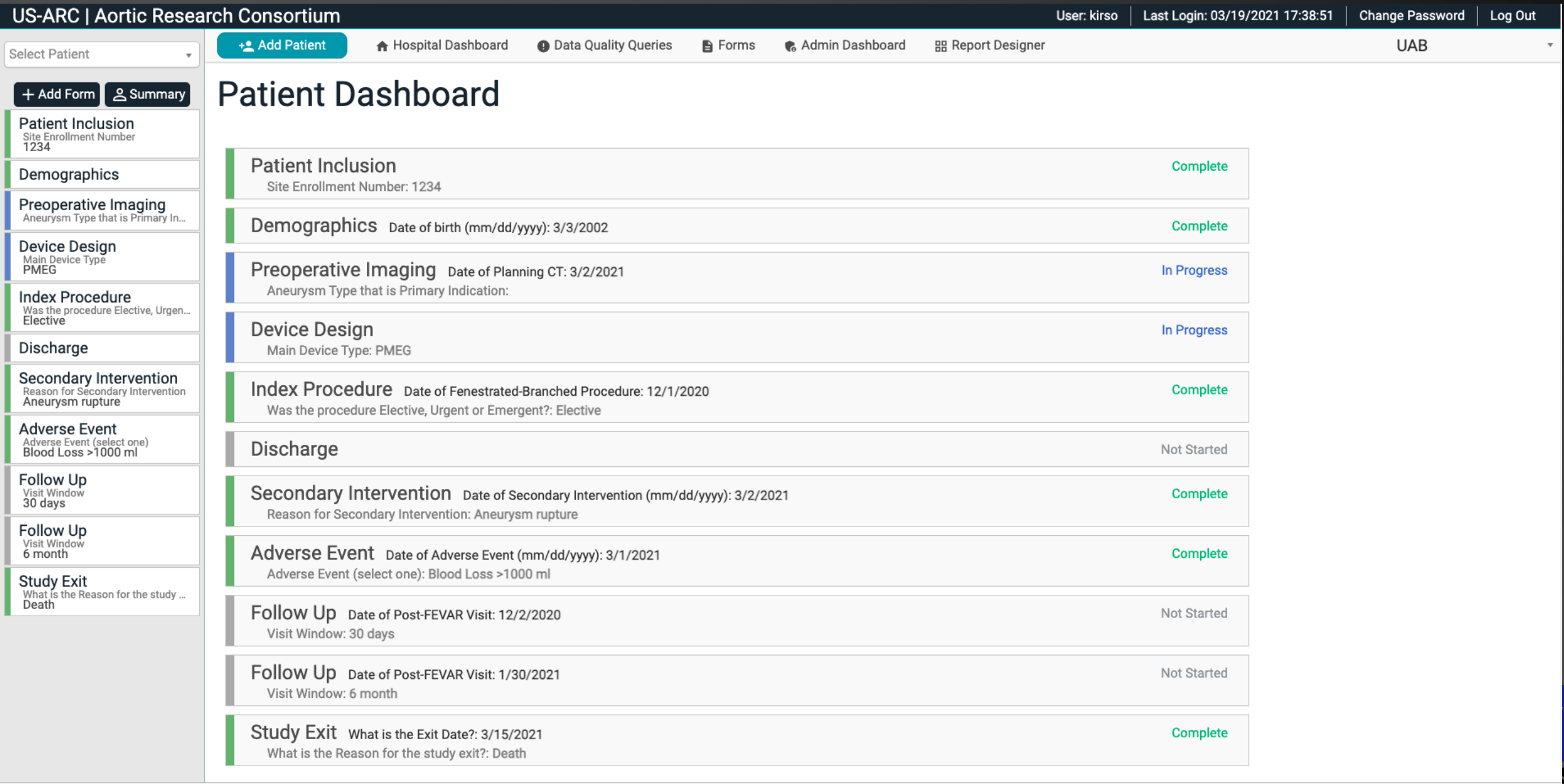
Low Profile
- ○ Yes
- ○ No

Optional / Non-core

Material used for Seal Stent
- ○ Steel
- ○ Nitinol

Clear Selection

Patient Dashboard



Data Quality Query Dashboard

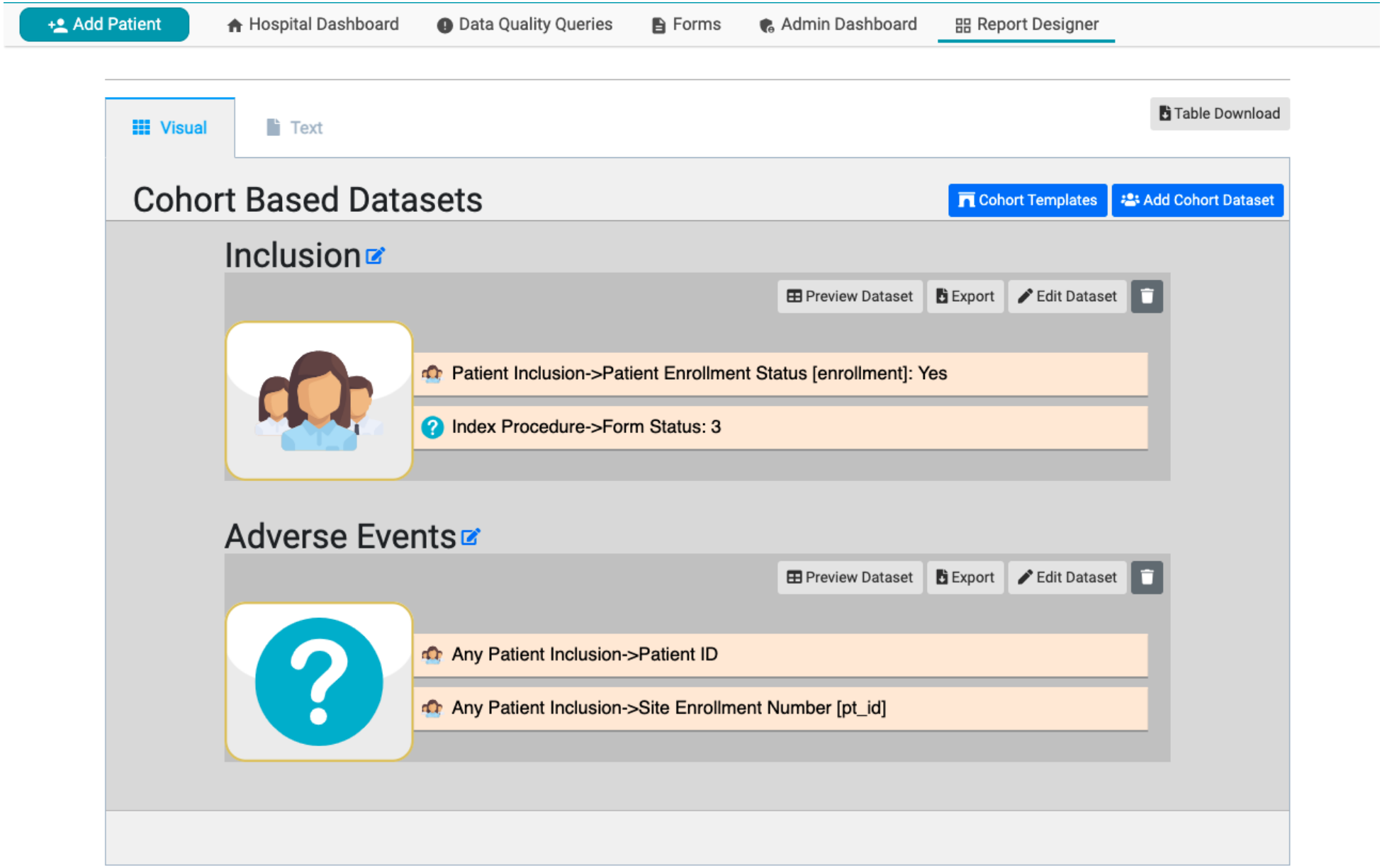
Data Quality Queries

Show 10 entries

Search:

Hospital	Patient	Form	Error	Status	Dismissed By	Dismissed Reason
UAB	Site Enrollment Number: 1234	Index Procedure Was the procedure Elective, Urgent or Emergent?: Elective	Date of Fenestrated-Branched Procedure (03/01/2020) must be after Date of Birth (03/03/2021)	Deleted (Resolved)		
UAB	Site Enrollment Number: 1234	Index Procedure Was the procedure Elective, Urgent or Emergent?: Elective	Date of Fenestrated-Branched Procedure (03/01/2020) must be after Date of Birth (03/03/2021)	Deleted (Resolved)		
UAB	Site Enrollment Number: 1234	Index Procedure Was the procedure Elective, Urgent or Emergent?: Elective	Date of Fenestrated-Branched Procedure (08/01/2020) must be before Study Exit date (02/02/2020)	Deleted (Resolved)		
UAB	Site Enrollment Number: 1234	Index Procedure Was the procedure Elective, Urgent or Emergent?: Elective	Date of Fenestrated-Branched Procedure (07/01/2020) must be before Study Exit date (02/02/2020)	Override (Resolved)	uab_researchcoordinator	The clinical data is correct. I double checked it.
UAB	Site Enrollment Number: 1234	Adverse Event Adverse Event (select one): Blood Loss >1000 ml	Adverse Event (03/04/2021) cannot come after Study Exit date (02/02/2020)	Deleted (Resolved)		
UAB	Site Enrollment Number: 1234	Adverse Event Adverse Event (select one): Blood Loss >1000 ml	Adverse Event (03/04/2021) cannot come after Study Exit date (08/02/2020)	Deleted (Resolved)		
UAB	Site Enrollment Number: 1234	Index Procedure Was the procedure Elective, Urgent or Emergent?: Elective	Date of Fenestrated-Branched Procedure (07/01/2020) must be before Study Exit date (08/02/2019)	Deleted (Resolved)		
UAB	Site Enrollment Number: 1234	Adverse Event Adverse Event (select one): Blood Loss >1000 ml	Adverse Event (03/04/2021) cannot come after Study Exit date (08/02/2019)	Deleted (Resolved)		

Report Designer & Custom Cohort Data Download



Site Statistics

Search:

Site	Migrated Patients	YTD Patients (2021)	Total Patients (C/E)	Total Patients (Included)	Total Patients (All)
	170	5	0	143	168
	125	19	1	122	123
	195	27	0	220	223
	0	0	0	0	0
	316	50	6	312	351
	372	33	0	375	394
	0	1	0	11	11
	430	39	17	469	486
	254	58	0	294	294
	0	0	0	0	0
All Sites	**1862**	**232**	**24**	**1946**	**2050**

Column visibility | Copy | Excel | PDF | CSV

Column Definitions

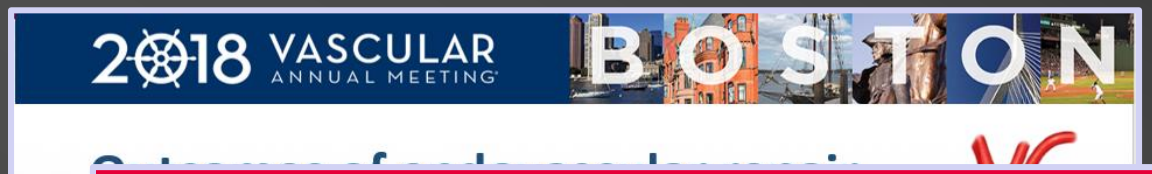
Migrated Patients: Patients migrated from a local site system to the US-ARC database. These patients may have missing data points, such as enrollment information.

YTD Patients (2021): Patients with an index procedure date in the current calendar year. Only patients with a completed index procedure form are counted.

Total Patients (C/E): Number of patients with a completed inclusion form that have enrollment status of "Compassionate/Emergent Use," regardless of date.

Total Patients (Included): Number of patients with a completed inclusion form that have enrollment status of "Yes" regardless of date.

Total Patients (All): Total patients entered with a completed inclusion form and patient enrollment status field, regardless of date.



n=240

n=564

n=661

n=886

n=893

n=893

Fenestrat
Complex Ao

On Behalf of

ESVS 32nd Annual M
24–28 September 2018

Target A
and Fer
Pararen
Aortic A
Experie

Darren B. S
Andres Sch
P. Sweet, ar

On Behalf c
Research Cc

Disclosures
DBS: consulting and resea
WL Gore paid to Mayo Cli
research grants from Cook

FENESTRATED-BRANCHED ENDOVASCULAR AORTIC
REPAIR (F
OCTO
ANEURYS

Fernando
Schneider[5],

[1]The University of Nort
States, [4]University of
Washington, Seattle,

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Results of Fenestrated and Branched Endovascular Aortic Aneurysm Repair After Failed Infrarenal End

Andres Schanz
Matt Eagleton,
Darren Schnei

On Behalf of the Unit
Branched Research C

SV

Secondary Interventions After Fenestrated/Branched Aortic Aneurysm Repair are Common and Non-detrimental to Long-term Survival

n=1681

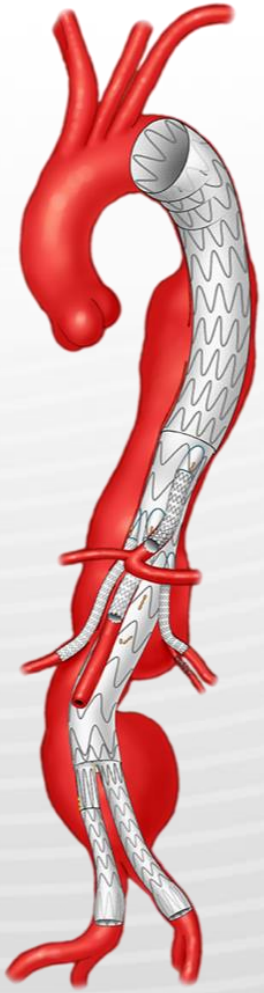
Sara L. Zettervall MD, MPH
Assistant Professor of Surgery
University of Washington
Seattle, WA

On behalf of the Aortic Research Consortium

Sara L. Zettervall, Emanuel Ramos Tenorio, Andres Schanzer, Gustavo S Oderich,
Carlos H Timaran, Darren B. Schneider, Matthew Eagleton,
Mark A Farber, Warren J Gasper, Adam W. Beck, Matthew P. Sweet

2018 VASCULAR ANNUAL MEETING
BOSTON

Outcomes of endovascular repair of post-dissection and degenerative thoracoabdominal aortic aneurysms using fenestrated-branched stent-grafts

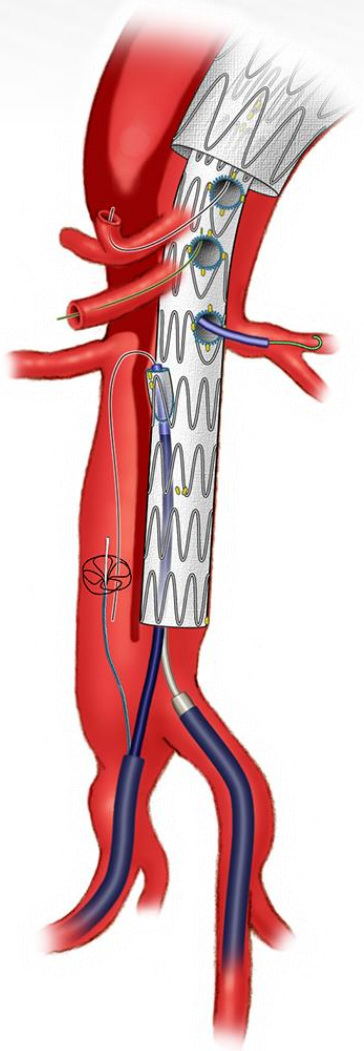


Emanuel R. Tenorio, Gustavo S. Oderich, Mark A. Farber, Darren B. Schneider, Carlos H. Timaran, Andres Schanzer, Adam W. Beck and Matthew P. Sweet

On Behalf of the United States Fenestrated and Branched Research Consortium Investigators

Conclusions

- F-BEVAR was safe and effective with nearly similar outcomes in patients with post-dissection and degenerative TAAAs;
- Patients with post-dissection had more type II endoleak during follow-up;
- Larger clinical experience and longer follow up is needed to better evaluate differences in mortality, spinal cord injury, target vessel instability and secondary interventions.



Expanded Use of Preloaded Branched and Fenestrated Endografts for Endovascular Repair of Complex Aortic Aneurysms in the US IDE Experience

Carlos H. Timaran, Gustavo S. Oderich, Mark A. Farber,
Darren B. Schneider, Carlos H. Timaran, Andres Schanzer,
Adam W. Beck and Matthew P. Sweet

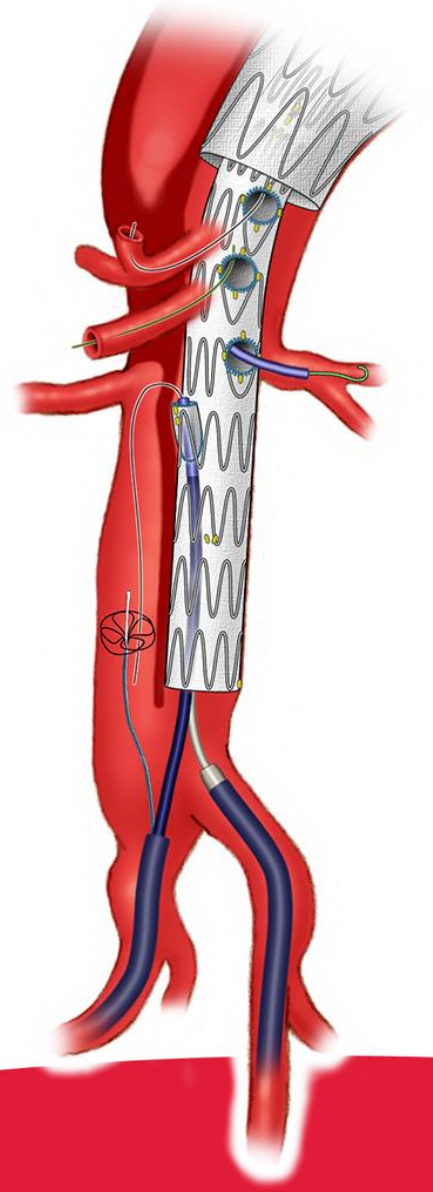
On Behalf of the United States Fenestrated and Branched Research Consortium Investigators

ESVS 32nd Annual Meeting
24–28 September 2018

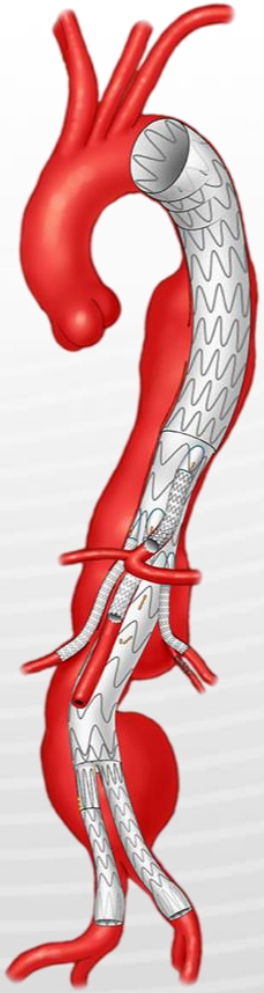
esvs Valencia 2018

Conclusions

- The expanded use of preloaded catheters and wires of fenestrations and directional branches for target artery incorporation is associated with even higher technical success and lower early mortality.



Target Artery Outcomes After Branched and Fenestrated Endovascular Repair of Pararenal and Thoracoabdominal Aortic Aneurysms in the US IDE Experience



Darren B. Schneider, Gustavo S. Oderich, Mark A. Farber, Andres Schanzer, Adam W. Beck, Carlos H. Timaran, Matthew P. Sweet, and Emanuel R. Tenorio

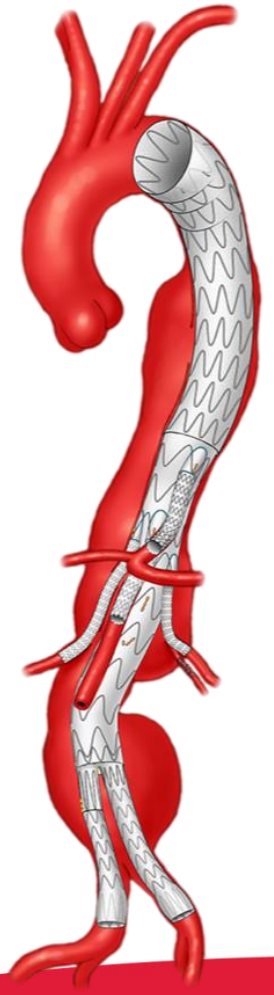
On Behalf of the United States Fenestrated and Branched Research Consortium Investigators

Disclosures

DBS: consulting and research grants from Cook, WL Gore, Endologix and Medtronic; GSO: consulting and research grants from Cook and WL Gore paid to Mayo Clinic; MAF: consulting and research grants from Cook, WL Gore, Endologix and Medtronic; AS: consulting and research grants from Cook; AWB: none; CHT: consulting and research grants from Cook; MPS: none ; ERT: none

Conclusions

- Selective use of fenestrations and directional branches for visceral artery incorporation is durable
- Risk of target artery instability is higher for renal versus mesenteric arteries
- Greater TAAA extent is associated with increased target artery instability
- Future efforts should focus on improving renal artery patency and reducing reinterventions



FENESTRATED-BRANCHED ENDOVASCULAR AORTIC REPAIR (F-BEVAR) IS A SAFE AND EFFECTIVE OPTION FOR OCTOGENARIANS IN TREATING COMPLEX AORTIC ANEURYSM (CAA) COMPARED TO NON-OCTOGENARIANS

Fernando Motta[1], Gustavo Oderich[2], Andres Schanzer[3], Carlos Timaran[4], Darren Schneider[5], Matthew Sweet[6], Adam Beck[7], Matthew Eagleton[8], **Mark Farber[1]**, The United States Fenestrated-Branched Research Consortium

[1]The University of North Carolina, Chapel Hill, United States, [2]Mayo Clinic, Rochester, United States, [3]University of Massachusetts Medical School, Worcester, United States, [4]University of Texas South Western, Dallas, United States, [5]Weill Cornell Medicine, NewYork-Presbyterian Hospital, New York, United States, [6]University of Washington, Seattle, United States, [7]University of Alabama at Birmingham, Birmingham, United States, [8]Massachusetts General Hospital, Boston, United States

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL



ESVS 33RD ANNUAL MEETING
24-27 SEPTEMBER 2019
MESSE HALLS, HAMBURG, GERMANY

esvs
European Society for Vascular Surgery
Science, Innovation and Education

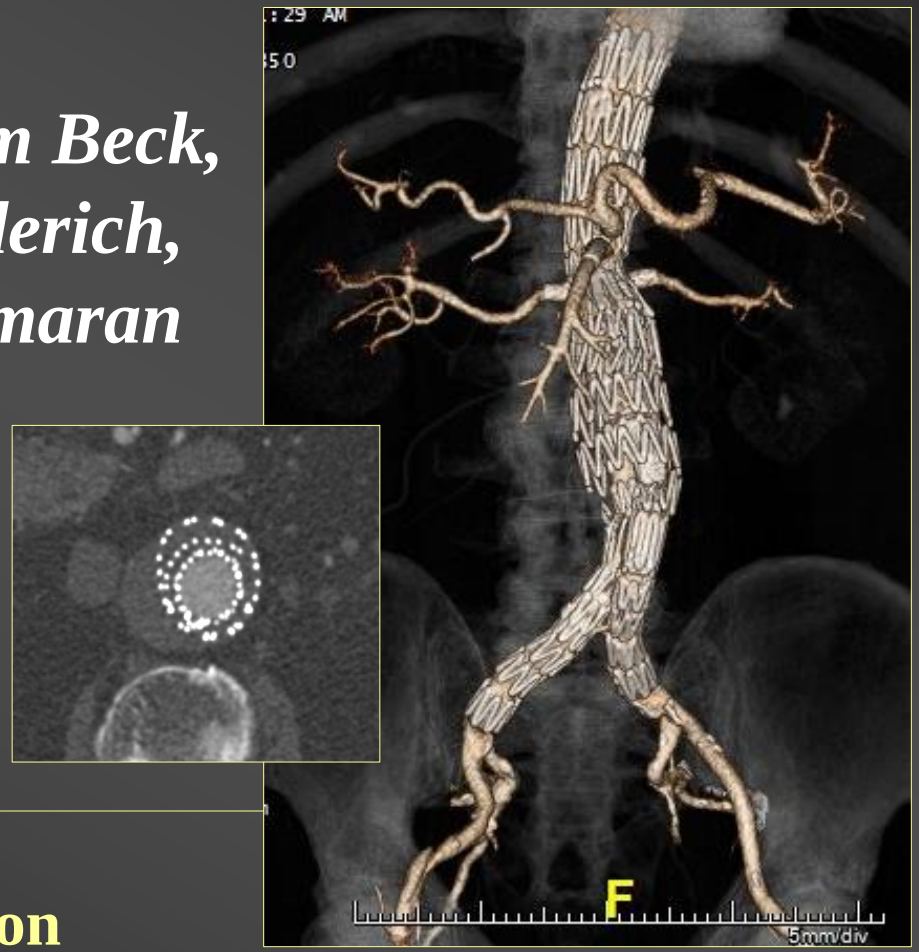
Conclusions:

- F-BEVAR was safe and effective with nearly identical early outcomes in octogenarians.
- Mid-term freedom from branch instability and secondary intervention were also similar between groups.

Results of Fenestrated and Branched Endovascular Aortic Aneurysm Repair After Failed Infrarenal Endovascular Aortic Aneurysm Repair

Andres Schanzer, Allison Crawford, Adam Beck, Matt Eagleton, Mark Farber, Gustavo Oderich, Darren Schneider, Matt Sweet, Carlos Timaran

On Behalf of the United States Fenestrated and Branched Research Consortium Investigators



June 13th, 2019

SVS Annual Meeting, Washington

In Summary

F/BEVAR was safe and effective in patients with prior failed EVAR, with nearly identical outcomes as compared to patients without prior EVAR.

Differences in procedural metrics indicate higher level of technical challenge when performing F/BEVAR in patients with prior failed EVAR.

F/BEVAR, at high volume centers, is a viable option for the treatment of EVAR failure that compares favorably to historical reports of open conversion.

Sex-related Outcomes after Fenestrated-Branched Endovascular Aneurysm Repair for Thoracoabdominal Aortic Aneurysms

in the U.S. Aortic Research Consortium

European Society for Vascular Surgery
October 22, 2020

Matthew P. Sweet, MD MS
Associate Professor of Surgery
University of Washington
Division of Vascular Surgery

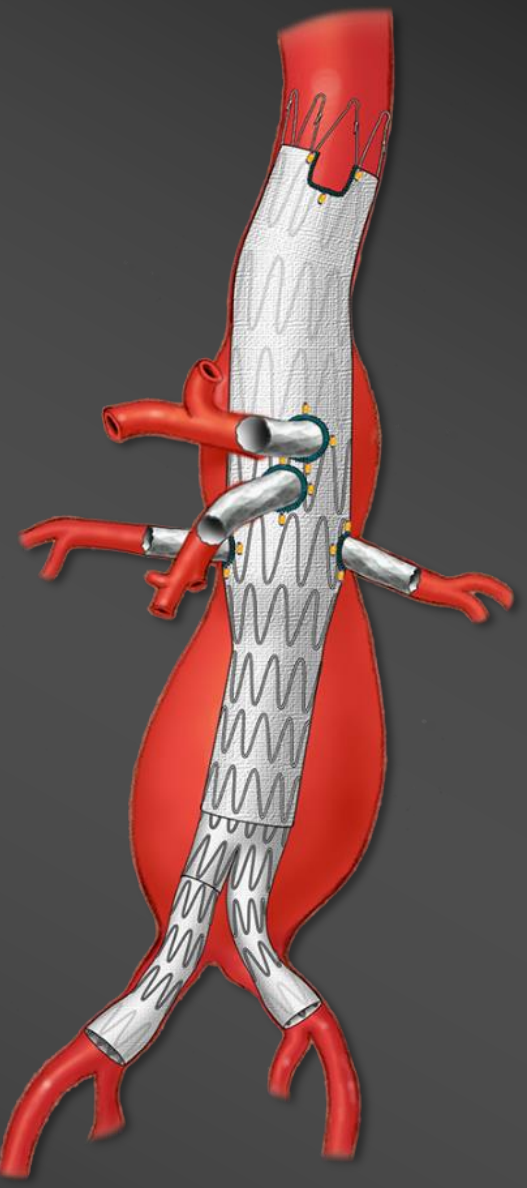
Conclusions

- Women experienced higher rates of:
  - Technical failure (for extensive aneurysms)
  - Non-home discharge
  - Postoperative sac expansion
- Further efforts needed to improve outcome parity
- Further efforts needed to understand why women remain disproportionately less likely to undergo operation

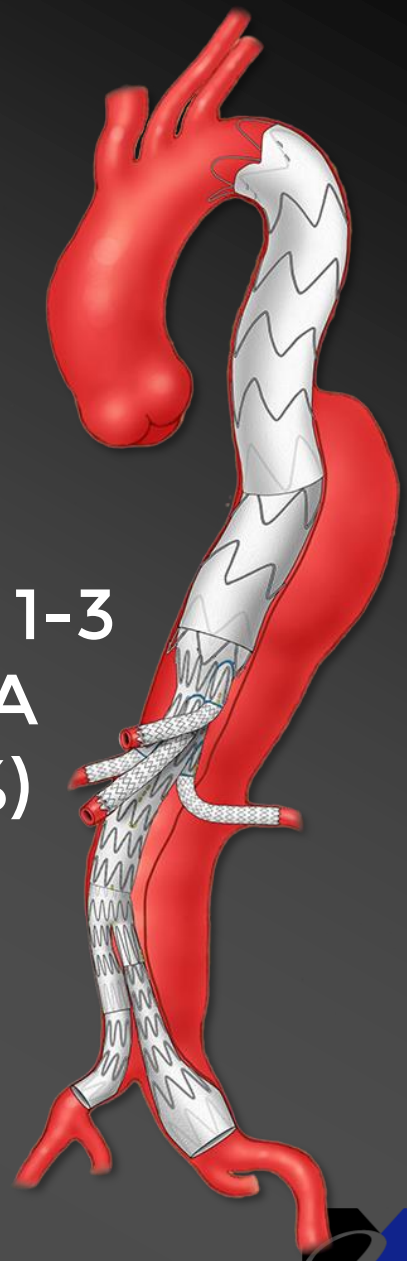
n=1681 patients

502
Complex
Abdominal
(30%)

535
Extent 4
TAAA
(32%)



644
Extent 1-3
TAAA
(38%)



30-day or in-hospital mortality

Classification	n	30-day mortality n (%)
Complex abdominal	**502**	10 (2)
Extent IV TAAA	**535**	13 (2)
Extent I to III TAAA	644	24 (4)
Total	1681	47 (3)

A Quarter Century of Organ Protection in Open Thoracoabdominal Repair

Anthony L. Estrera, MD, Harleen K. Sandhu, MD, MPH, Kristofer M. Charlton-Ouw, MD, Rana O. Afifi, MD, Ali Azizzadeh, MD, Charles C. Miller III, PhD, and Hazim J. Safi, MD

Ann Surg. 2015.

Dr. Safi– 1896 patients

30 Day Mortality 16%

Outcomes of 3309 thoracoabdominal aortic aneurysm repairs

Joseph S. Coselli, MD,[a,d,e] Scott A. LeMaire, MD,[a,b,c,d,e] Ourania Preventza, MD,[a,d,e] Kim I. de la Cruz, MD,[a,d,e] Denton A. Cooley, MD,[d] Matt D. Price, MS,[a,d] Alan P. Stolz, MEd,[a,d] Susan Y. Green, MPH,[a,d] Courtney N. Arredondo, MSPH,[b] and Todd K. Rosengart, MD[a,c,d,e]

J Thorac Cardiovasc Surg. 2016.

Dr. Coselli – 3,309 patients

30 Day Mortality 7%

Durability of open surgical repair of type I-III thoracoabdominal aortic aneurysm

Christopher A. Latz, MD,[a] Richard P. Cambria, MD,[b] Virendra I. Patel, MD, MPH,[c] Jahan Mohebali, MD,[a] Emel A. Ergul, MS,[a] R. Todd Lancaster, MD, MPH,[a] Mark F. Conrad, MD, MMSc,[a] *and* W. Darrin Clouse, MD,[a]

Boston and Brighton, Mass; and New York, NY

J Vasc Surg. 2019.

Dr. Cambria – 516 patients

30 Day Mortality 8%

United States Aortic Research Consortium

- Deliverables
  - Largest dataset of F/BEVAR in the world
  - A core group of investigators committed to improving patient care and pushing the envelope on endovascular therapies from the aortic valve to the common femoral artery
  - High quality adjudicated data that is harmonized across sites
    - Data that can be leveraged to inform successful trial design
    - Data that can be leveraged with the FDA to shorten approval cycles
    - Data that is valued by the SVS and the ESVS
  - Engine for exchange of ideas and promotion of these technologies, ideally within the US and across the globe

United States Fenestrated Branched Research Consortium

- Deliverables
  - Infrastructure and more agile regulatory pathway for testing emerging technologies to obtain preliminary data
    - Example: a purpose-built bridging stent graft
    - Marked acceleration of development, testing, and approval of new devices
    - Investigators engaging FDA, not just industry
    - The FDA has been engaged at the highest levels and is in full support of this effort
  - Generalizable data
    - Departure from single center reports
  - Standardization of best practices
    - Decrease number of device types/configurations
    - Build consensus around a suite of products, not an unlimited number of products

Spinal cord protection practices used during endovascular repair of complex aortic aneurysms by the U.S. Aortic Research Consortium

Victoria J. Aucoin, MD,[a] Matthew J. Eagleton, MD,[b] Mark A. Farber, MD,[c] Gustavo S. Oderich, MD,[d] Andres Schanzer, MD,[e] Carlos H. Timaran, MD,[f] Darren B. Schneider, MD,[g] Matthew P. Sweet, MD,[h] *and* Adam W. Beck, MD,[a] *Birmingham, Ala; Boston, Mass; Chapel Hill, NC; Houston and Dallas, Tex; Worcester, Mass; Philadelphia, Pa; and Seattle, Wash*

ABSTRACT

Background: Spinal cord ischemia/infarction (SCI) is a devastating complication of thoracoabdominal aortic aneurysm repair that can result in permanent paresis or paralysis. The reported incidence of SCI after aortic interventions has ranged from 2% to 10%. Methods to prevent SCI are a topic of ongoing research, and many current practices have been based on expert opinion.

Methods: In an effort to better delineate the best practice models for SCI prevention during endovascular thoracoabdominal aortic aneurysm repair, a 65-question survey was completed by the eight principal investigators of the U.S. Aortic Research Consortium to capture data related to current practices and management strategies related to the prevention and treatment of SCI. Specific categories of interest included considerations for the "high-risk" classification of SCI, current perioperative prevention practices, indications for and management of spinal drains, and SCI rescue maneuvers.

Results: The most common practices routinely included blood pressure elevation (7 of 8; 87.5%), with most having a mean arterial pressure goal of not less than 90 mm Hg in the perioperative period (5 of 7; 71%), a hemoglobin goal intra- and postoperatively of not less than 10 mg/dL (6 of 8; 75%), and the use of prophylactic spinal drains in high-risk patients (6 of 8; 75%). Significant variation was found among the group for the timing of the resumption of antihypertensive medications, duration of hemoglobin goals after the procedure, and management of spinal drains. Many methods described in reported studies were not routinely used by most of the group, including a perioperative steroid bolus (1 of 8; 12.5%), mannitol (2 of 8; 25%), and naloxone infusion (1 of 8; 12.5%). Rescue maneuvers included placement of a cerebrospinal fluid (CSF) drain if not already present (8 of 8; 100%), decreasing the target CSF drain pop-off pressure (6 of 8; 75%), increasing the CSF drainage volume (5 of 8; 62.5%), increasing the mean arterial pressure goal (8 of 8; 100%), increasing the hemoglobin goal (8 of 8; 100%), and imaging the spine using computed tomography or magnetic resonance imaging (7 of 8; 87.5).

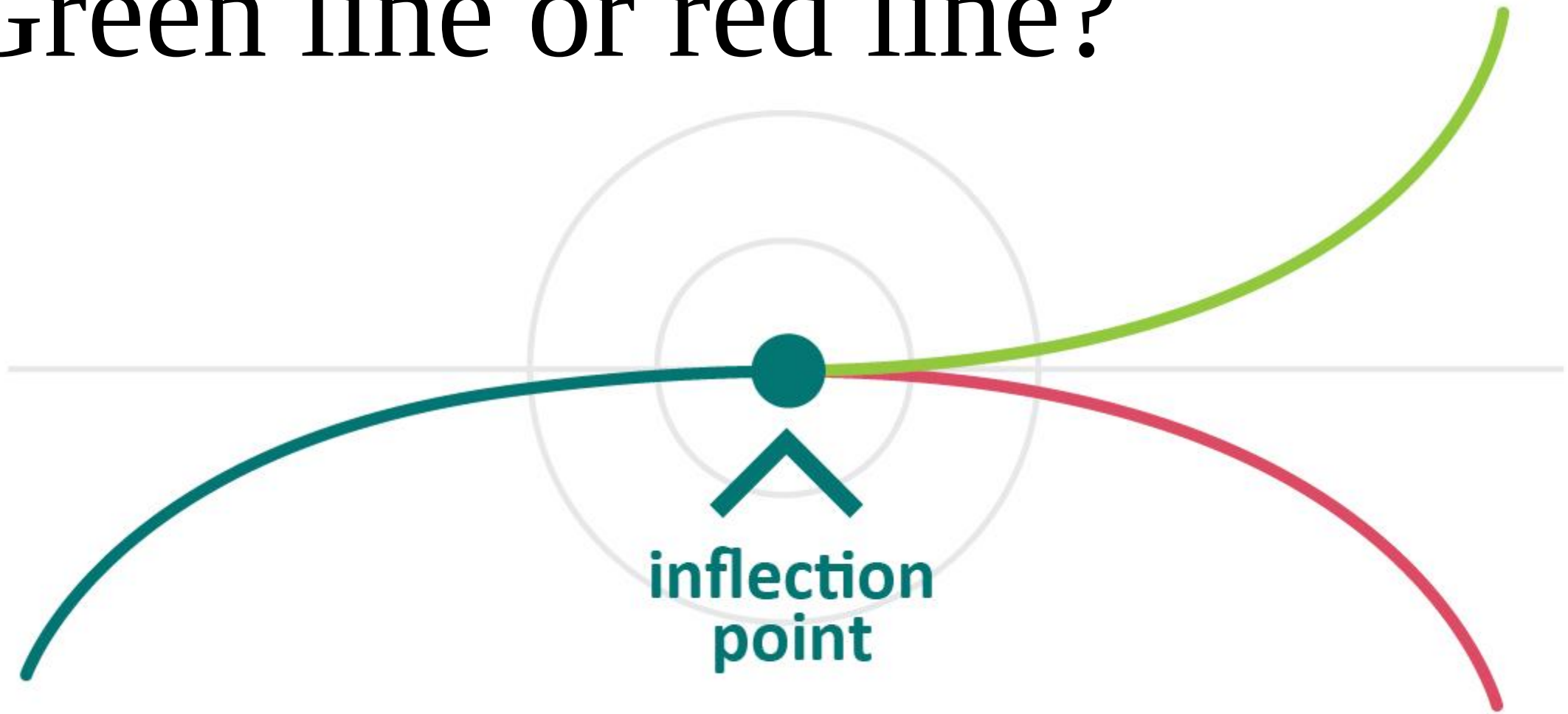
Conclusions: In general, consistent broad practices were used by most of the consortium; however, the details of specific parameters (ie, spinal drain management, therapy duration, and timing of resumption of antihypertensive medication) varied among the group. The U.S. Aortic Research Consortium group used the results of the survey for discussion and agreed on standardized SCI prevention recommendations in accordance with the group's collective expert opinion and experience. Variations in current practice were also identified to act as a foundation for future study, the most notable of which was the comparative effectiveness of therapeutic vs prophylactic use of CSF drains in the prevention of SCI. (J Vasc Surg 2020;■:1-8.)

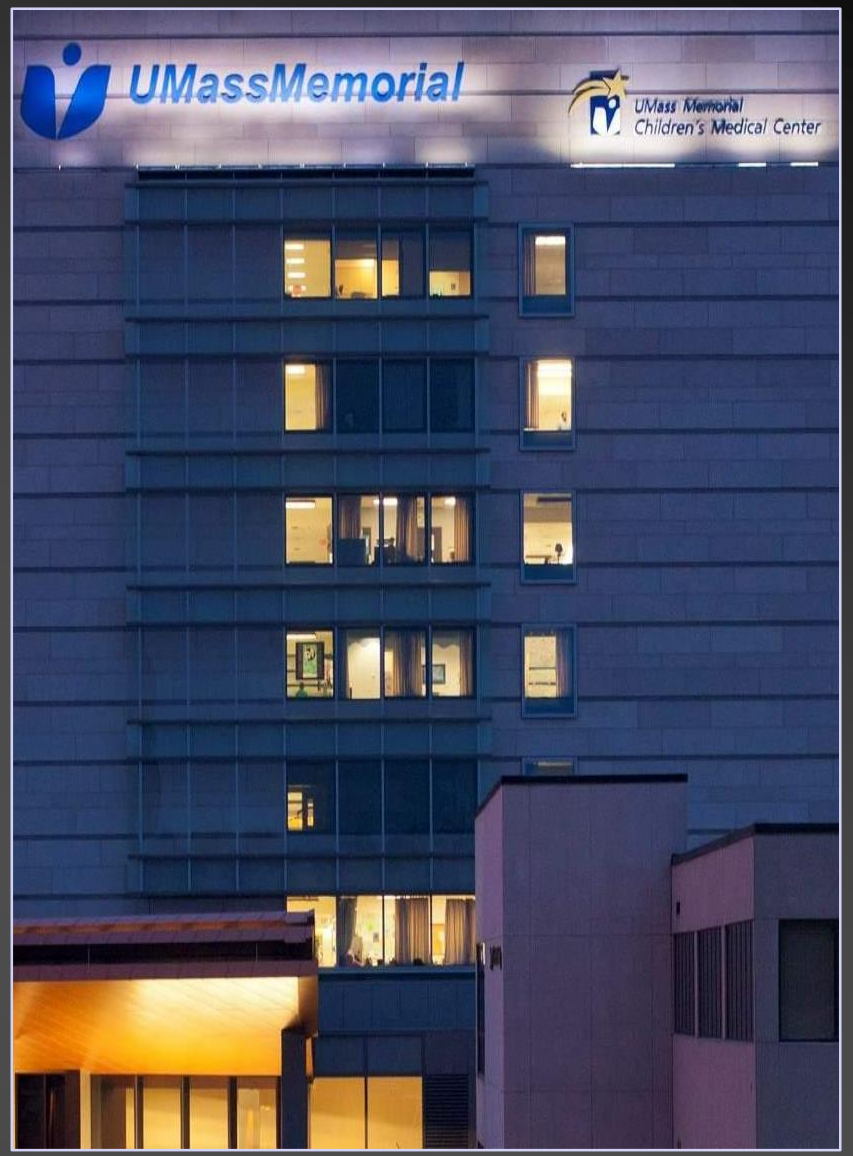
United States Fenestrated Branched Research Consortium

- Deliverables
  - Mitigate risk of CMD to commercialization as preliminary testing and market analysis will already have been completed
  - Infrastructure to conduct randomized trials

More patients getting better care, by more providers, using F/BEVAR devices.

Green line or red line?





Thank You.