The Cornerstone of the VIVA Experience: Laptop Learning™

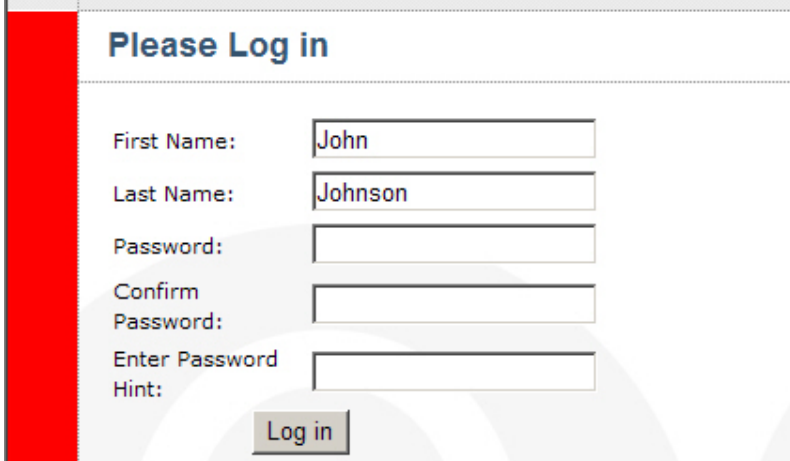
The Genesis of VIVA

- Representatives from all major vascular specialties discovered several things in common
  - We love to teach
  - The endovascular workforce is not large enough to care for all patients with non-coronary vascular disease
  - There are several ways to take care of the same patient…
  - We are tired of traveling to meeting after meeting

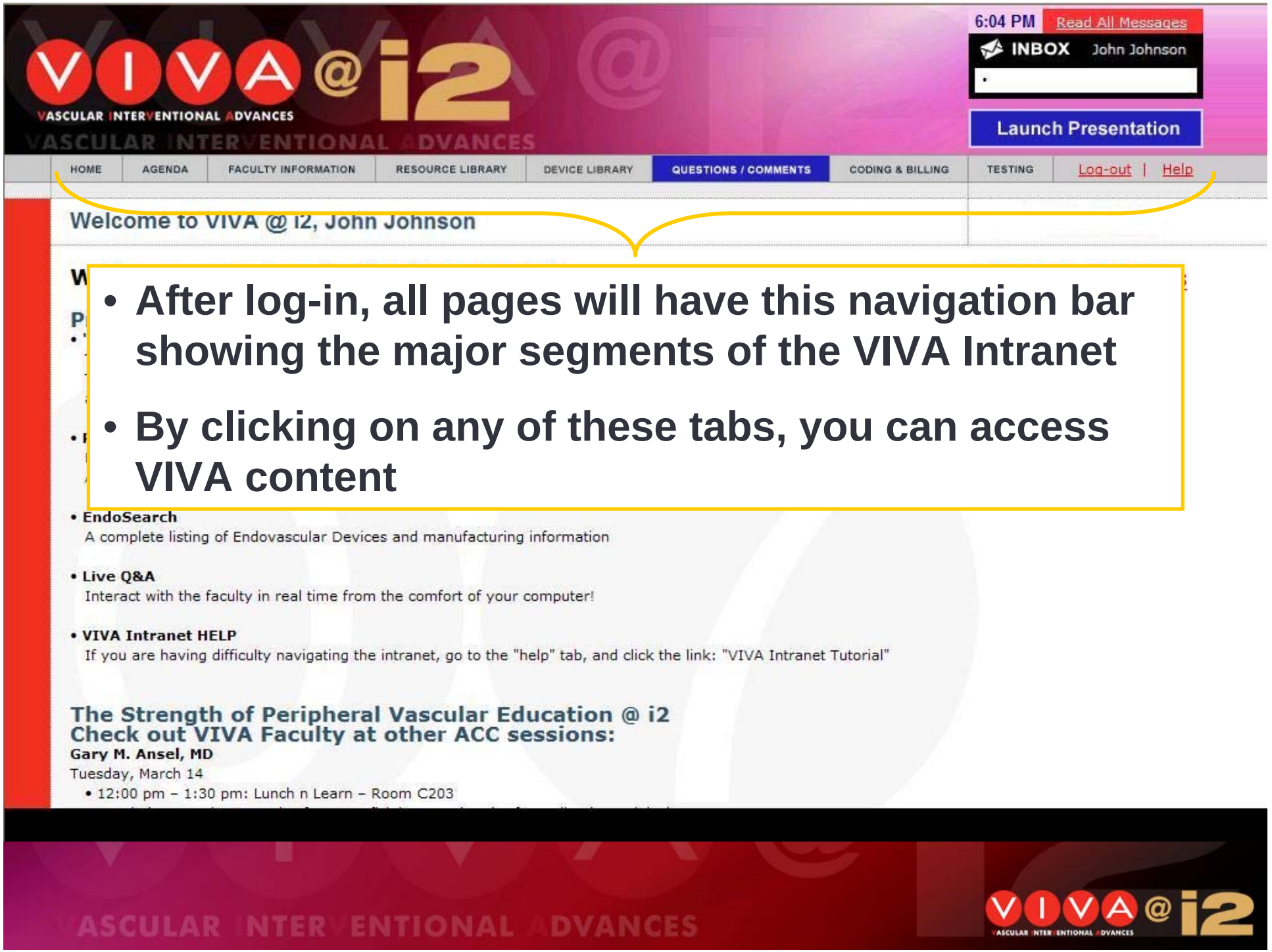
Next Steps…

- Directors of several well established vascular meetings merged their talents/experience into a new entity: *VIVA*
- We came to Las Vegas
- We use the power of computer-based learning for the first time in a major vascular symposium
- Basic Philosophy: Incorporate the knowledge/expertise of all specialties involved in the management of vascular disease into one faculty
- First VIVA---2003

Laptop Learning Overview



- **This is the Log In Page with Password Protection**


VIVA @ i2
VASCULAR INTERVENTIONAL ADVANCES
6:04 PM
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DEVICE LIBRARY
QUESTIONS / COMMENTS
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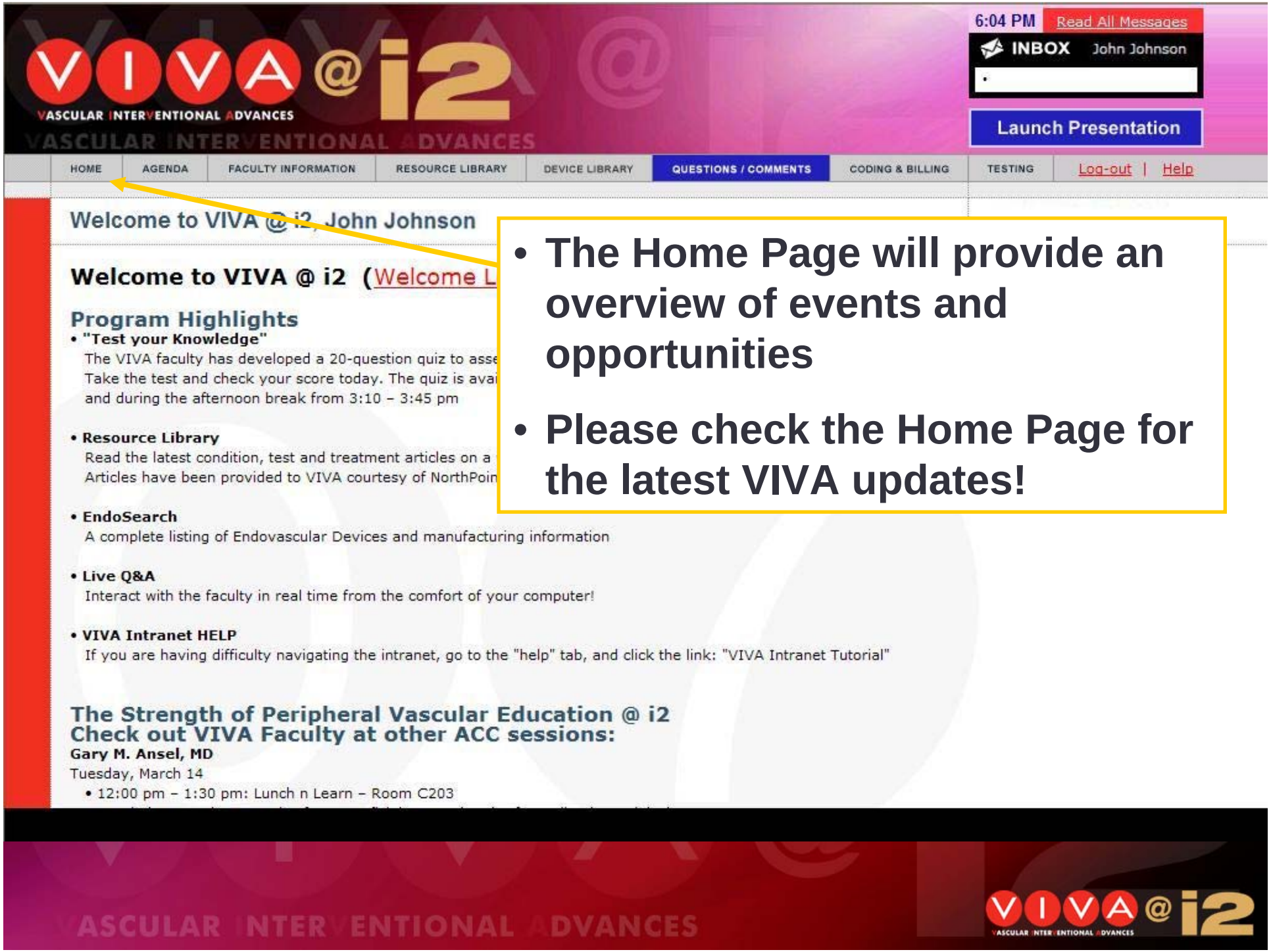
Log-out | Help
Welcome to VIVA @ i2, John Johnson
• After log-in, all pages will have this navigation bar showing the major segments of the VIVA Intranet
• By clicking on any of these tabs, you can access VIVA content
• EndoSearch
A complete listing of Endovascular Devices and manufacturing information
• Live Q&A
Interact with the faculty in real time from the comfort of your computer!
• VIVA Intranet HELP
If you are having difficulty navigating the intranet, go to the "help" tab, and click the link: "VIVA Intranet Tutorial"
The Strength of Peripheral Vascular Education @ i2
Check out VIVA Faculty at other ACC sessions:
Gary M. Ansel, MD
Tuesday, March 14
• 12:00 pm – 1:30 pm: Lunch n Learn – Room C203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Welcome to VIVA @ i2 (Welcome L
Program Highlights
• "Test your Knowledge"
The VIVA faculty has developed a 20-question quiz to asse
Take the test and check your score today. The quiz is avai
and during the afternoon break from 3:10 – 3:45 pm
• Resource Library
Read the latest condition, test and treatment articles on a
Articles have been provided to VIVA courtesy of NorthPoin
• EndoSearch
A complete listing of Endovascular Devices and manufacturing information
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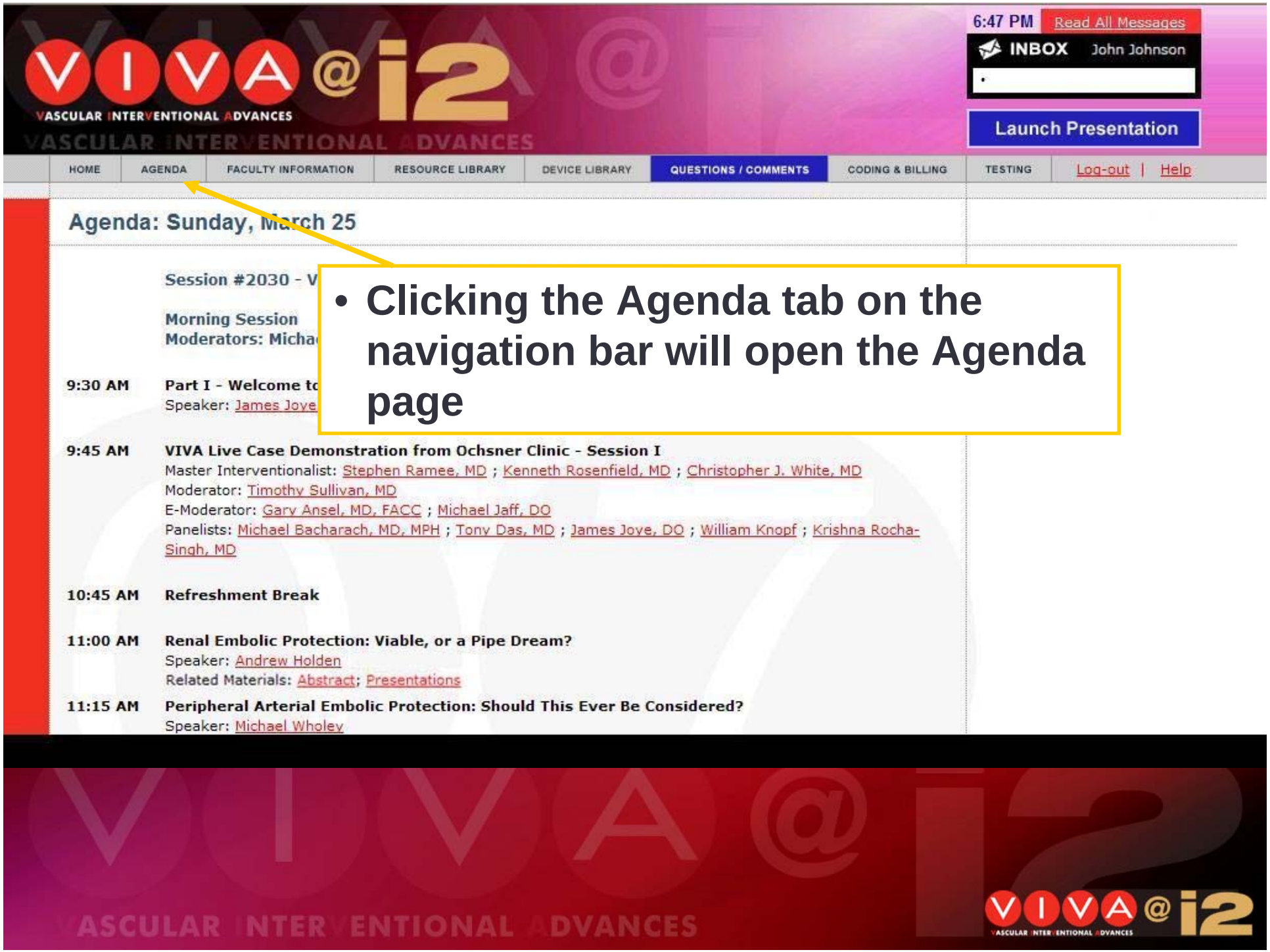
• The Home Page will provide an overview of events and opportunities
• Please check the Home Page for the latest VIVA updates!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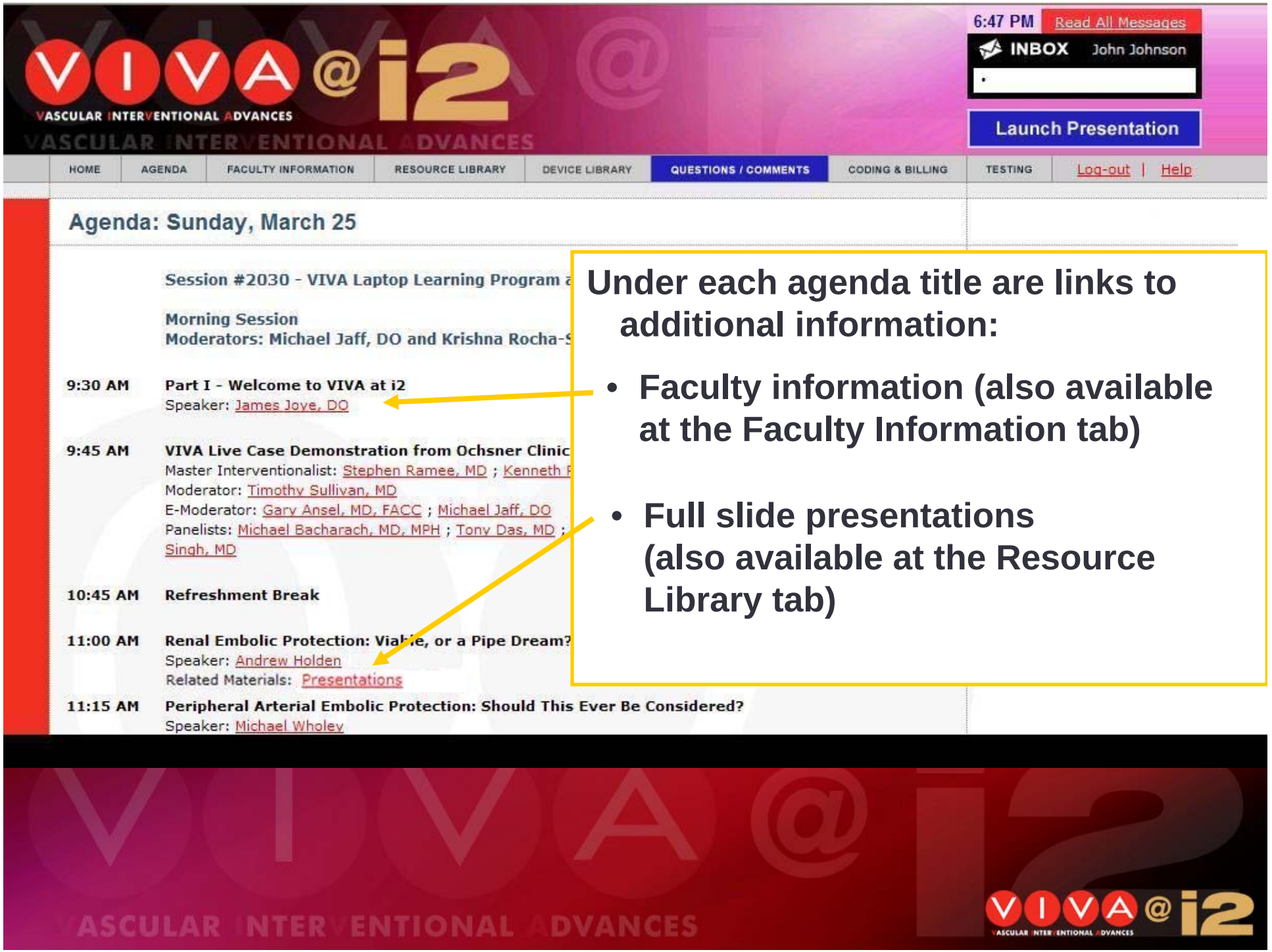
Agenda: Sunday, March 25
Session #2030 - V
Morning Session
Moderators: Micha
9:30 AM
Part I - Welcome to
Speaker: James Joye
9:45 AM
VIVA Live Case Demonstration from Ochsner Clinic - Session I
Master Interventionalist: Stephen Ramee, MD ; Kenneth Rosenfield, MD ; Christopher J. White, MD
Moderator: Timothy Sullivan, MD
E-Moderator: Gary Ansel, MD, FACC ; Michael Jaff, DO
Panelists: Michael Bacharach, MD, MPH ; Tony Das, MD ; James Joye, DO ; William Knopf ; Krishna Rocha-Singh, MD
10:45 AM
Refreshment Break
11:00 AM
Renal Embolic Protection: Viable, or a Pipe Dream?
Speaker: Andrew Holden
Related Materials: Abstract; Presentations
11:15 AM
Peripheral Arterial Embolic Protection: Should This Ever Be Considered?
Speaker: Michael Wholey
• Clicking the Agenda tab on the navigation bar will open the Agenda page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Agenda: Sunday, March 25
Session #2030 - VIVA Laptop Learning Program
Morning Session
Moderators: Michael Jaff, DO and Krishna Rocha-
9:30 AM
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9:45 AM
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Under each agenda title are links to additional information:
• Faculty information (also available at the Faculty Information tab)
• Full slide presentations (also available at the Resource Library tab)

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Faculty Information

Gary M. Ansel, MD, FACC
Cardiology
MidOhio Cardiology and Vascular Consultants, Inc.
Riverside Methodist Hospital
Columbus, Ohio
614-262-6772

- **The Faculty Information tab lists the VIVA faculty**
- **To find a particular faculty member, click a link on the right side of the page**

Gary M. Ansel
Michael Bacharach
Andrew Carter
Michael D. Dake
Tony S. Das
Patrick Geraghty
Andrew Holden
Michael R. Jaff
James D. Jove
William Knopf
John Laird
Jon S. Matsumura

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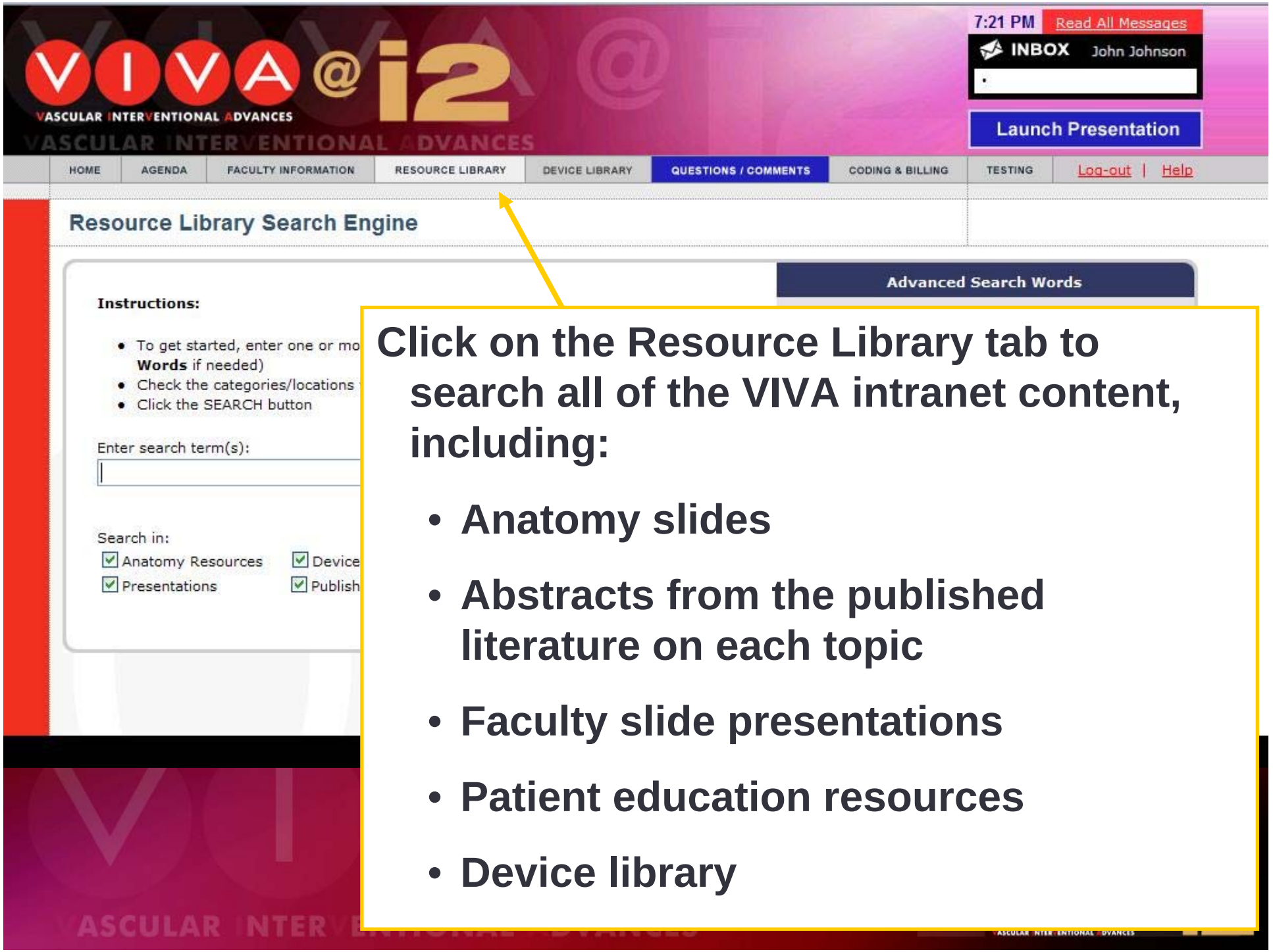

Click on the Resource Library tab to search all of the VIVA intranet content, including:

- **Anatomy slides**
- **Abstracts from the published literature on each topic**
- **Faculty slide presentations**
- **Patient education resources**
- **Device library**


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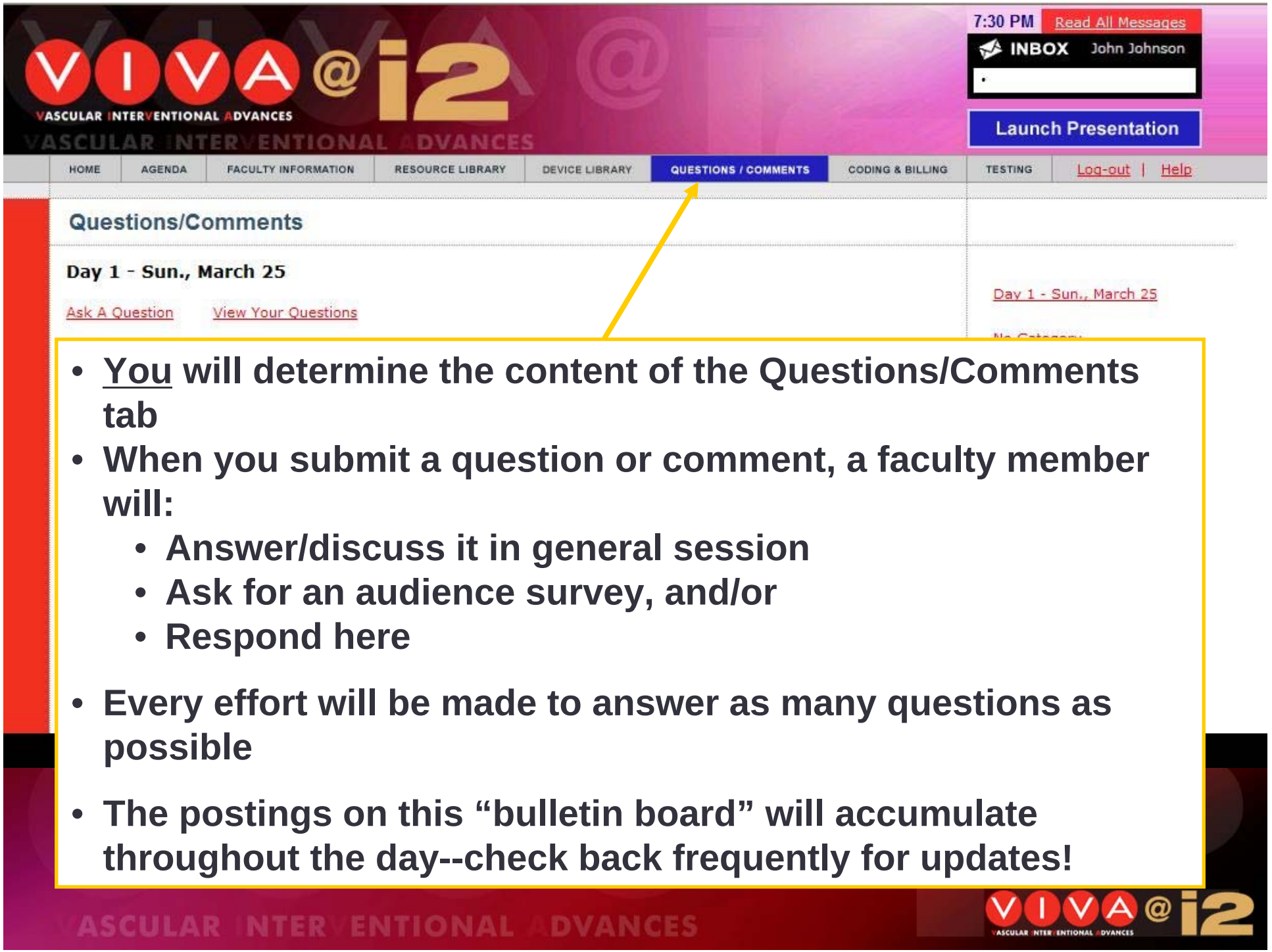
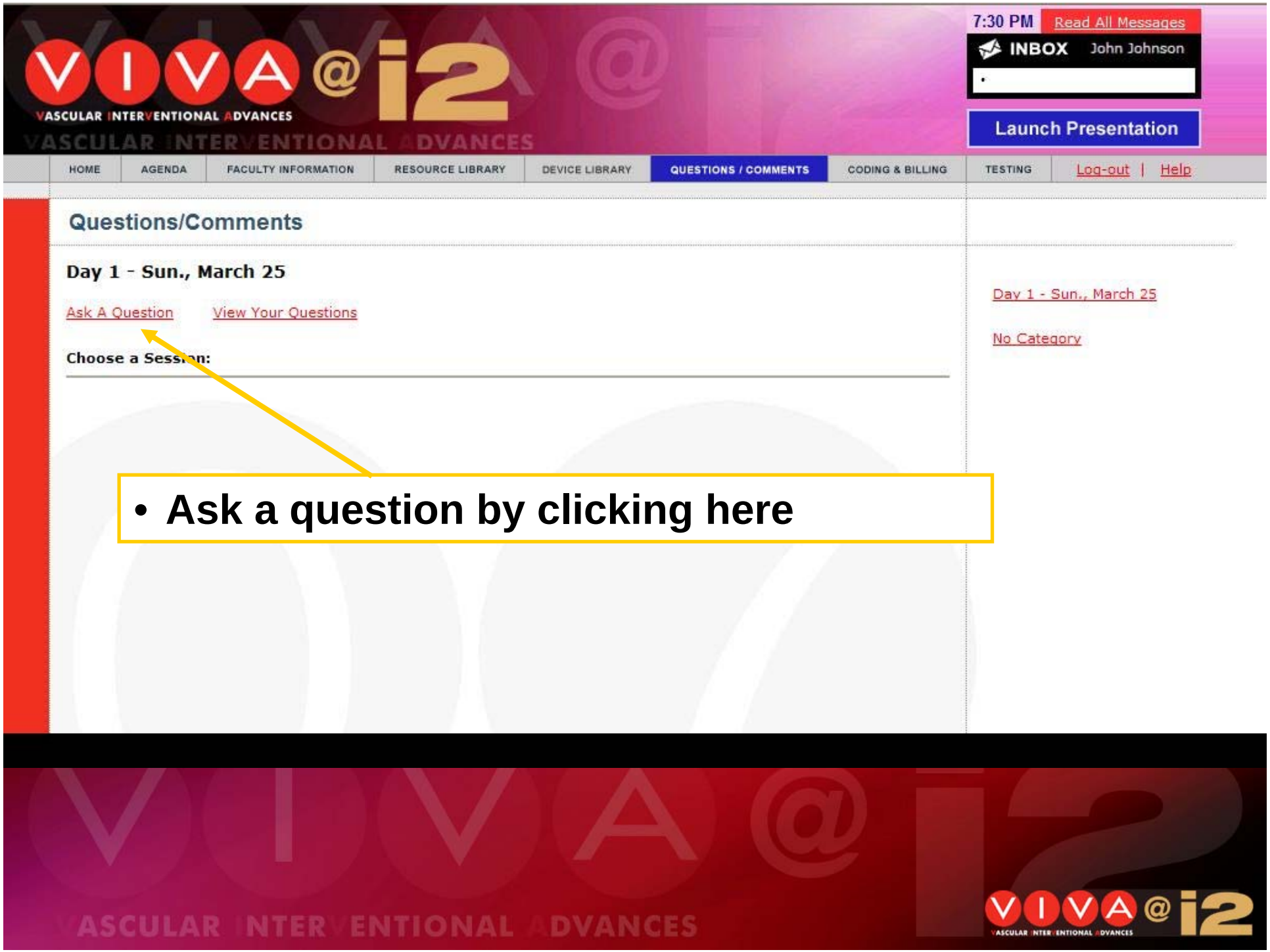
Device Library
Balloon Expandable Stents
Debulking Devices
Distal Embolic Protection Devices
Equipment Overview
Mechanical Thrombectomy
Peripheral Angioplasty Balloons
Self-expanding Stents
To Navigate within a Presentation:
Click the right side of the screen or use the > arrow (or Page Dn) key to display the next screen
Click the left side of the screen or use the < arrow (or Page Up) key to review the next screen
Click X to close the Presentation
• The Device Library tab features device inventory presentations



- <u>You</u> will determine the content of the Questions/Comments tab
- When you submit a question or comment, a faculty member will:
  - Answer/discuss it in general session
  - Ask for an audience survey, and/or
  - Respond here
- Every effort will be made to answer as many questions as possible
- The postings on this “bulletin board” will accumulate throughout the day--check back frequently for updates!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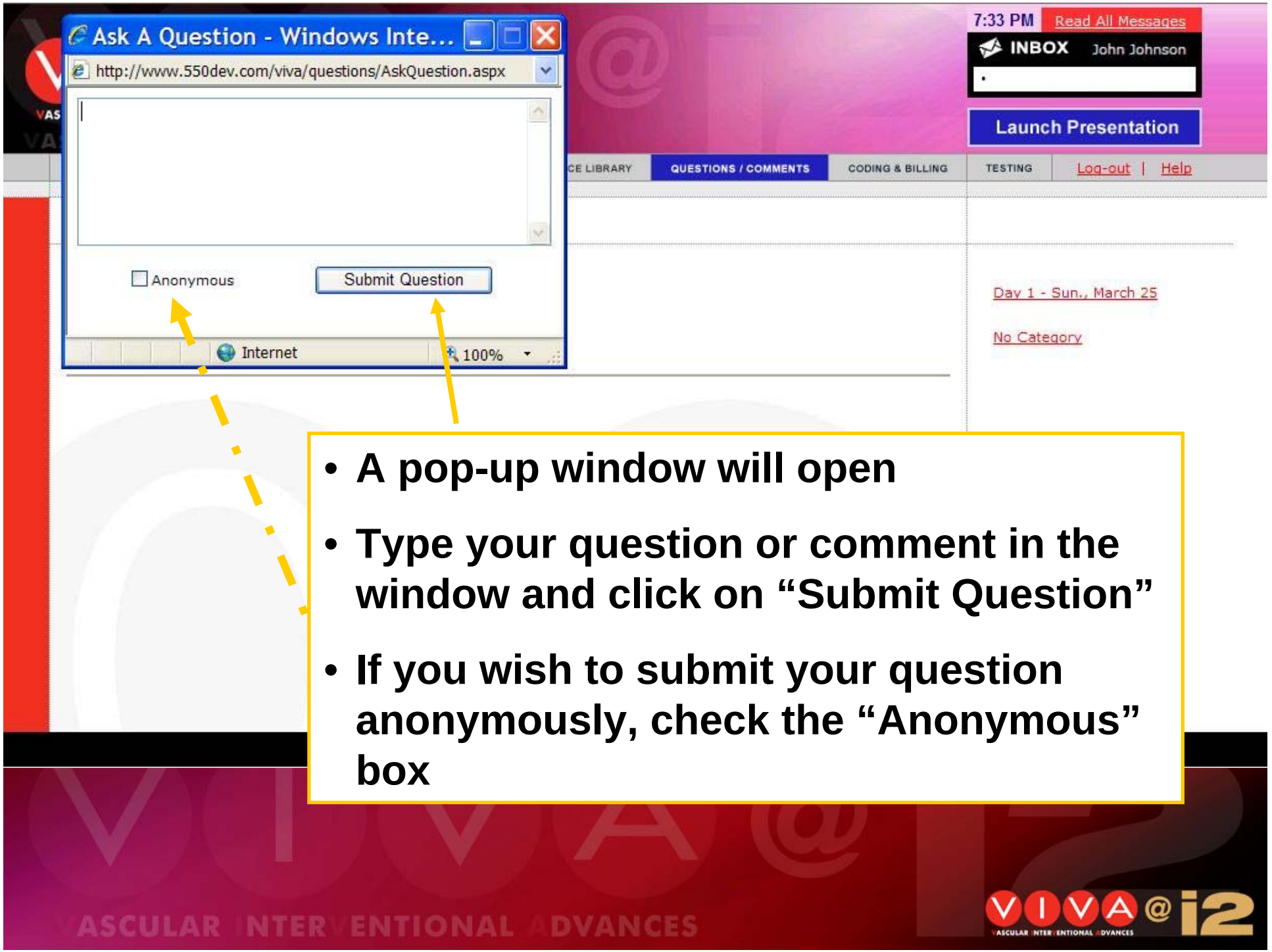
Questions/Comments
Day 1 - Sun., March 25
Ask A Question
View Your Questions
Choose a Session:
Day 1 - Sun., March 25
No Category
• Ask a question by clicking here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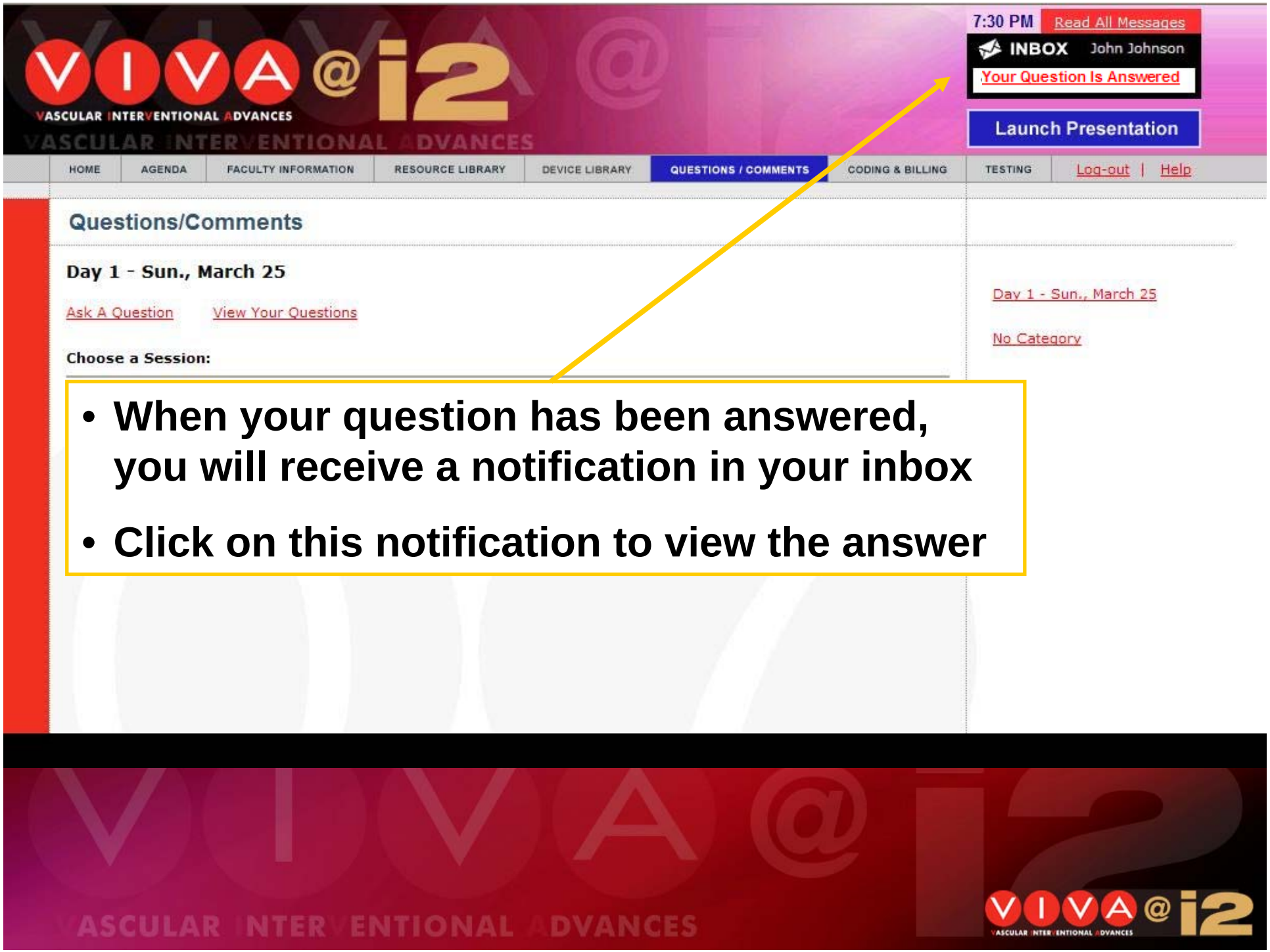
• A pop-up window will open
• Type your question or comment in the window and click on “Submit Question”
• If you wish to submit your question anonymously, check the “Anonymous” box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Questions/Comments
Day 1 - Sun., March 25
Ask A Question
View Your Questions
Choose a Session:
Day 1 - Sun., March 25
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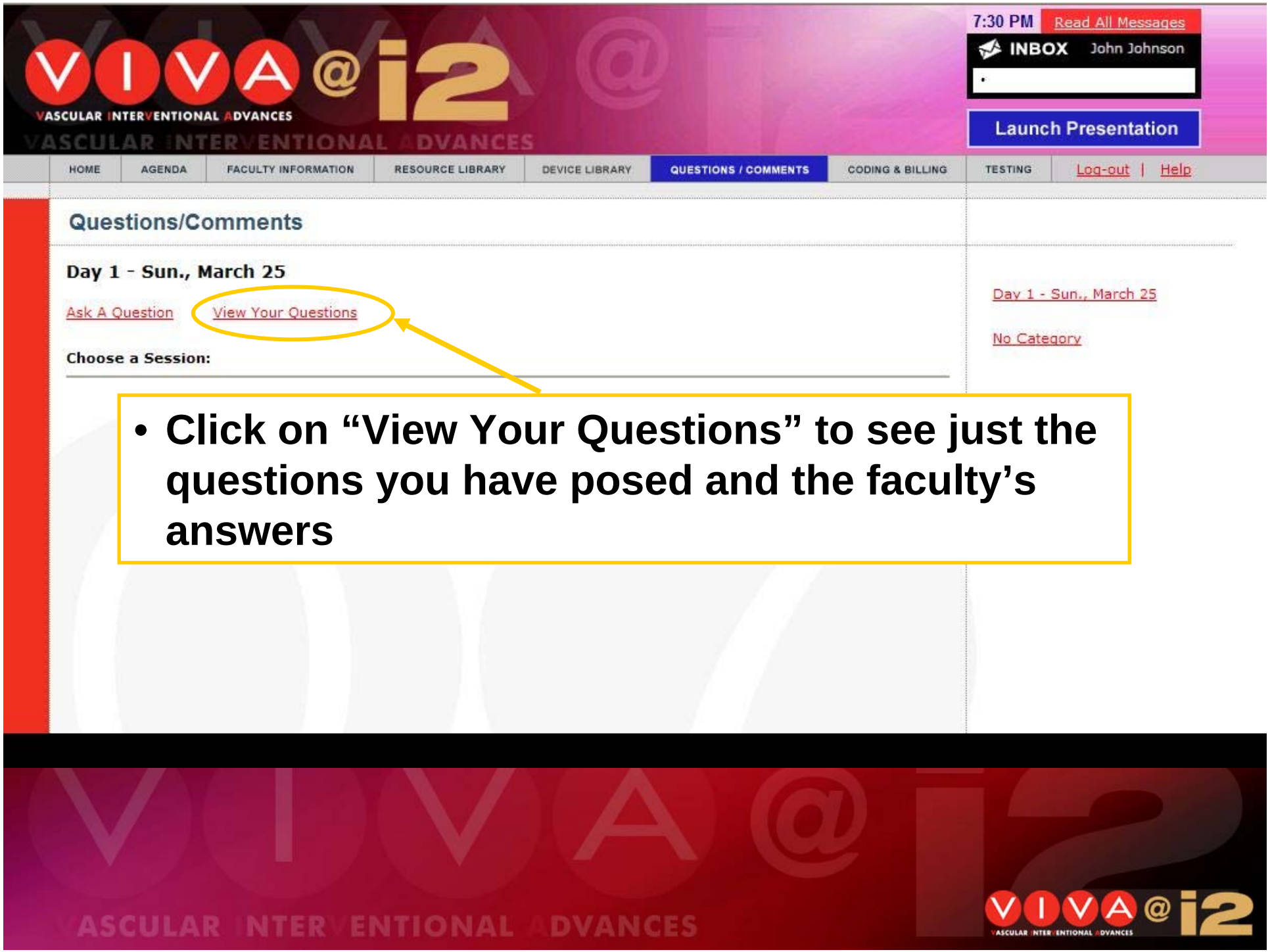
• When your question has been answered, you will receive a notification in your inbox
• Click on this notification to view the answer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Ask A Question
View Your Questions
Choose a Session:
Day 1 - Sun., March 25
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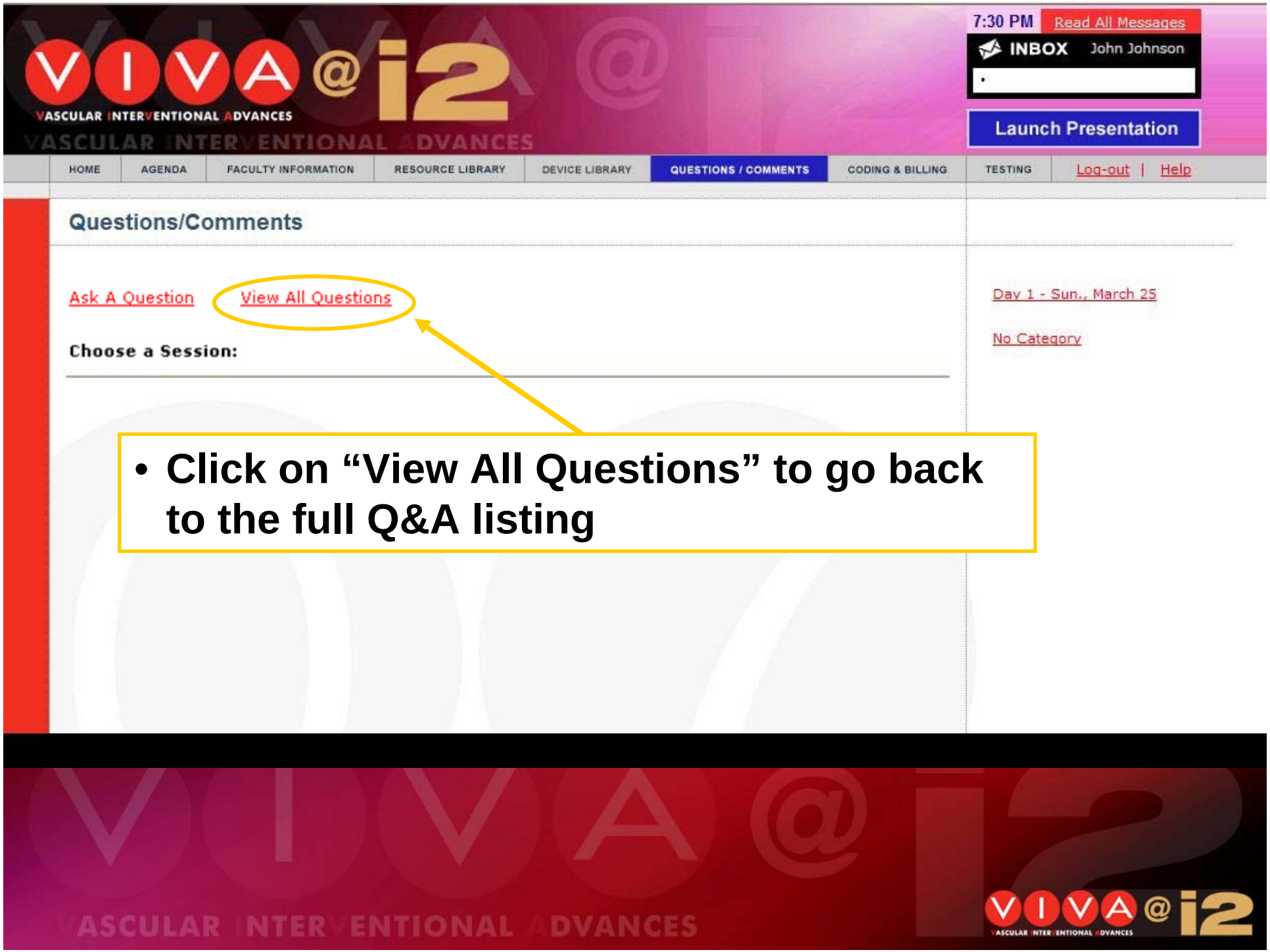
• Click on “View Your Questions” to see just the questions you have posed and the faculty’s answers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Ask A Question
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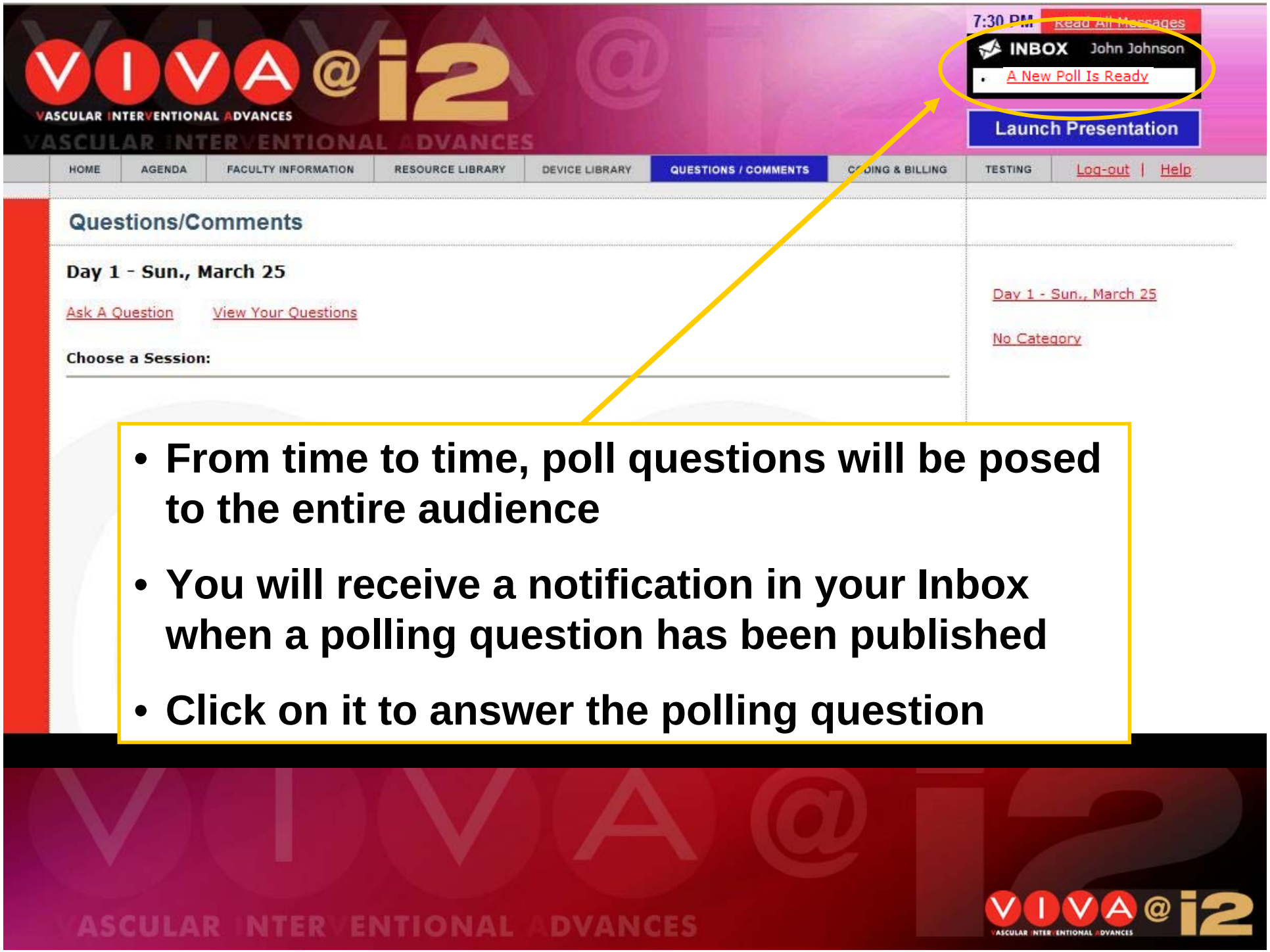
• Click on “View All Questions” to go back to the full Q&A listing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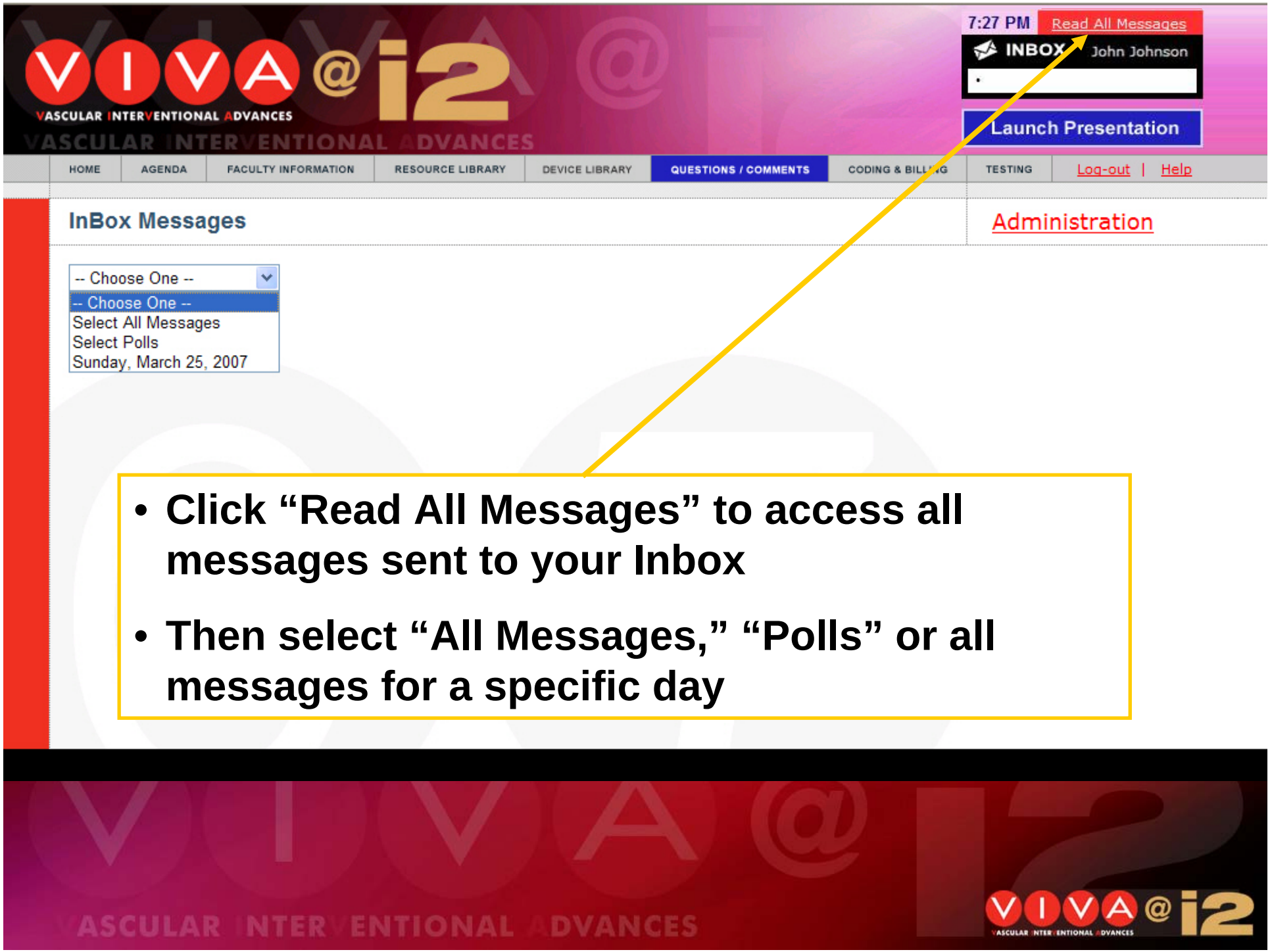
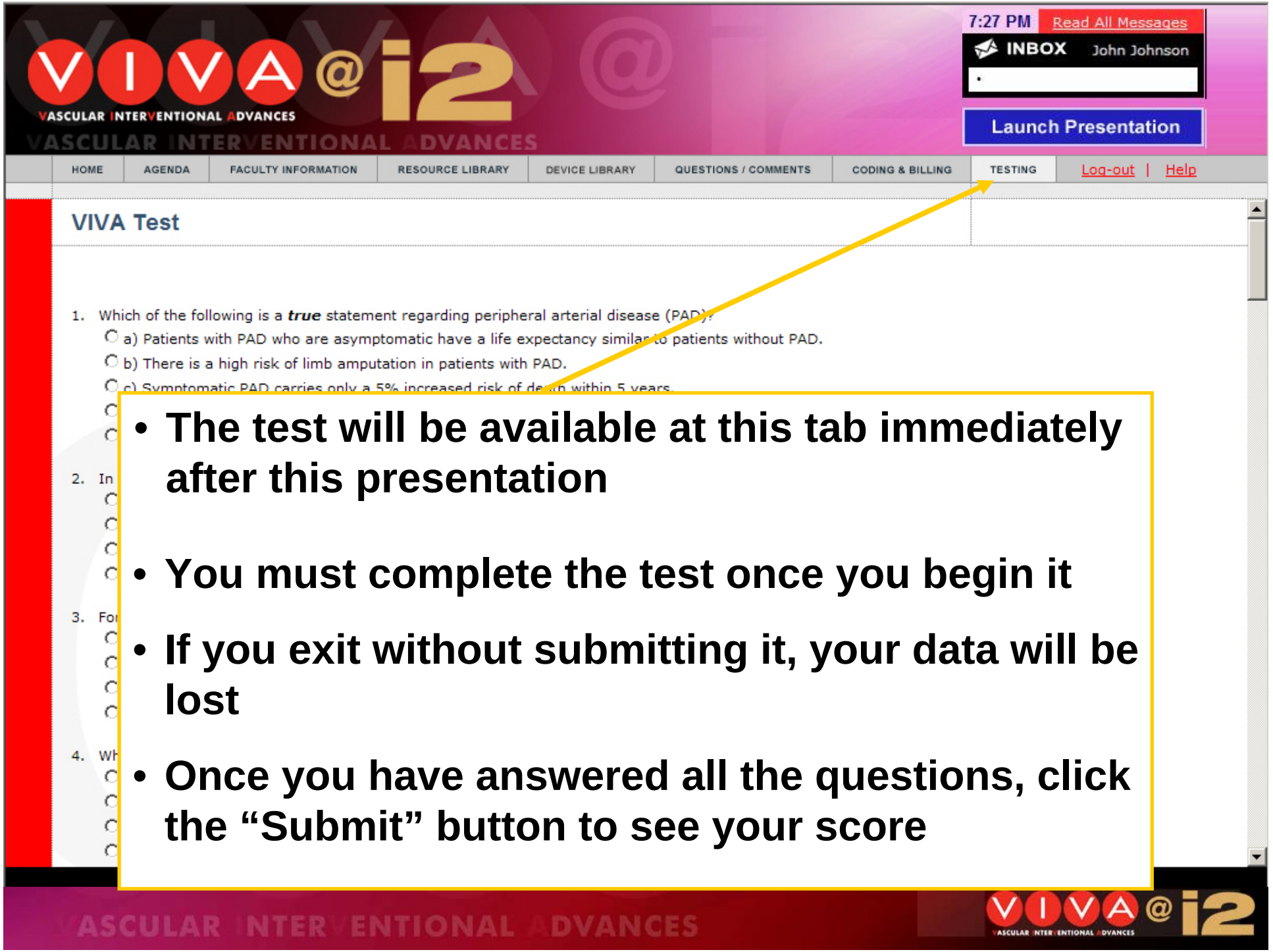
Questions/Comments
Day 1 - Sun., March 25
Ask A Question
View Your Questions
Choose a Session:
Day 1 - Sun., March 25
No Category
• From time to time, poll questions will be posed to the entire audience
• You will receive a notification in your Inbox when a polling question has been published
• Click on it to answer the polling question



- **Click “Read All Messages” to access all messages sent to your Inbox**
- **Then select “All Messages,” “Polls” or all messages for a specific day**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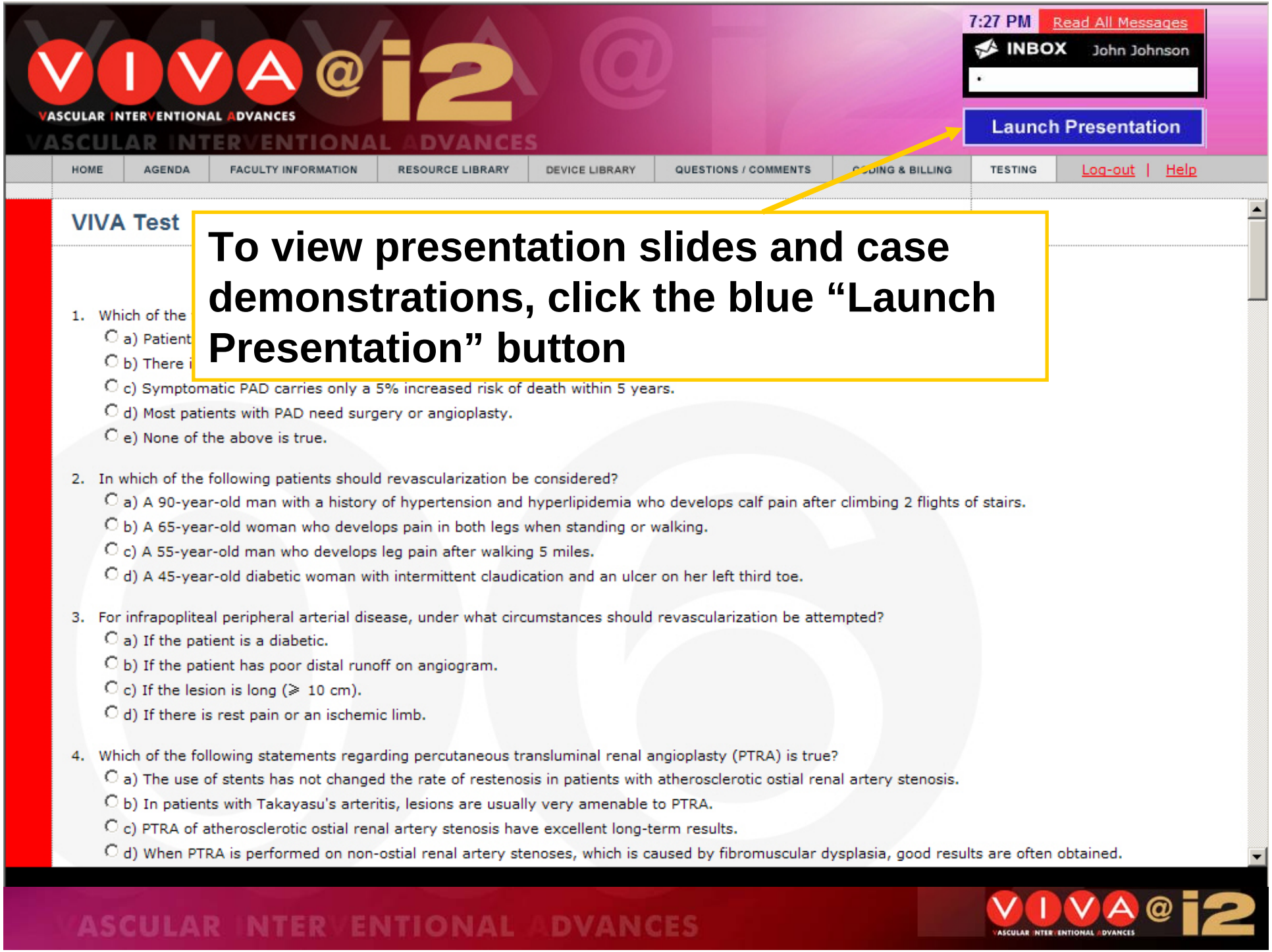
VIVA Test
1. Which of the following is a true statement regarding peripheral arterial disease (PAD)?
a) Patients with PAD who are asymptomatic have a life expectancy similar to patients without PAD.
b) There is a high risk of limb amputation in patients with PAD.
• The test will be available at this tab immediately after this presentation
• You must complete the test once you begin it
• If you exit without submitting it, your data will be lost
• Once you have answered all the questions, click the “Submit” button to see your score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VIVA Test
To view presentation slides and case demonstrations, click the blue “Launch Presentation” button
1. Which of the
a) Patient
b) There i
c) Symptomatic PAD carries only a 5% increased risk of death within 5 years.
d) Most patients with PAD need surgery or angioplasty.
e) None of the above is true.
2. In which of the following patients should revascularization be considered?
a) A 90-year-old man with a history of hypertension and hyperlipidemia who develops calf pain after climbing 2 flights of stairs.
b) A 65-year-old woman who develops pain in both legs when standing or walking.
c) A 55-year-old man who develops leg pain after walking 5 miles.
d) A 45-year-old diabetic woman with intermittent claudication and an ulcer on her left third toe.
3. For infrapopliteal peripheral arterial disease, under what circumstances should revascularization be attempted?
a) If the patient is a diabetic.
b) If the patient has poor distal runoff on angiogram.
c) If the lesion is long (≥ 10 cm).
d) If there is rest pain or an ischemic limb.
4. Which of the following statements regarding percutaneous transluminal renal angioplasty (PTRA) is true?
a) The use of stents has not changed the rate of restenosis in patients with atherosclerotic ostial renal artery stenosis.
b) In patients with Takayasu's arteritis, lesions are usually very amenable to PTRA.
c) PTRA of atherosclerotic ostial renal artery stenosis have excellent long-term results.
d) When PTRA is performed on non-ostial renal artery stenoses, which is caused by fibromuscular dysplasia, good results are often obtained.
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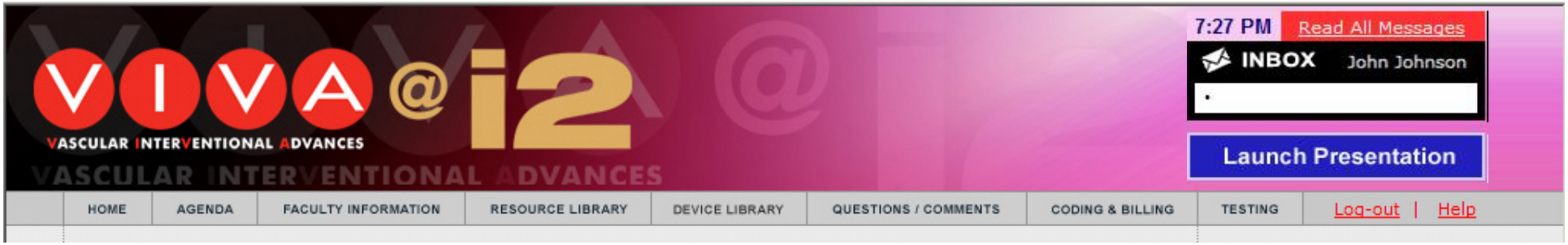
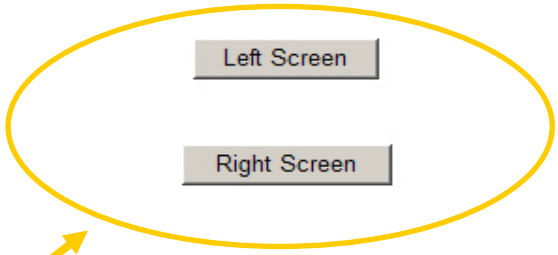
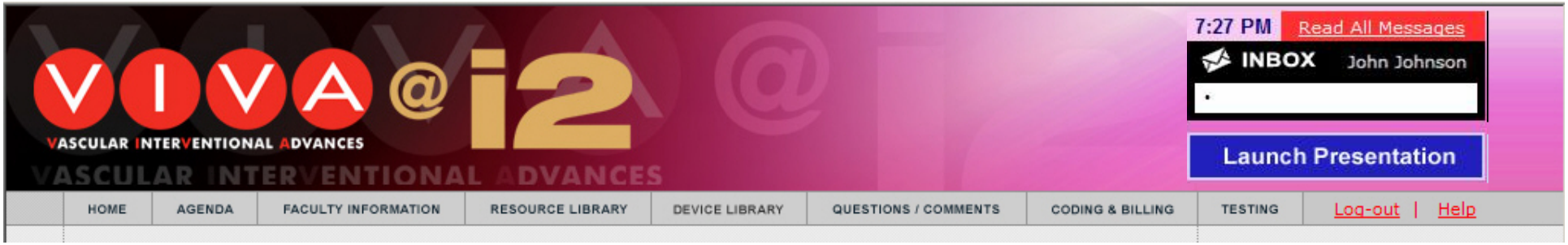
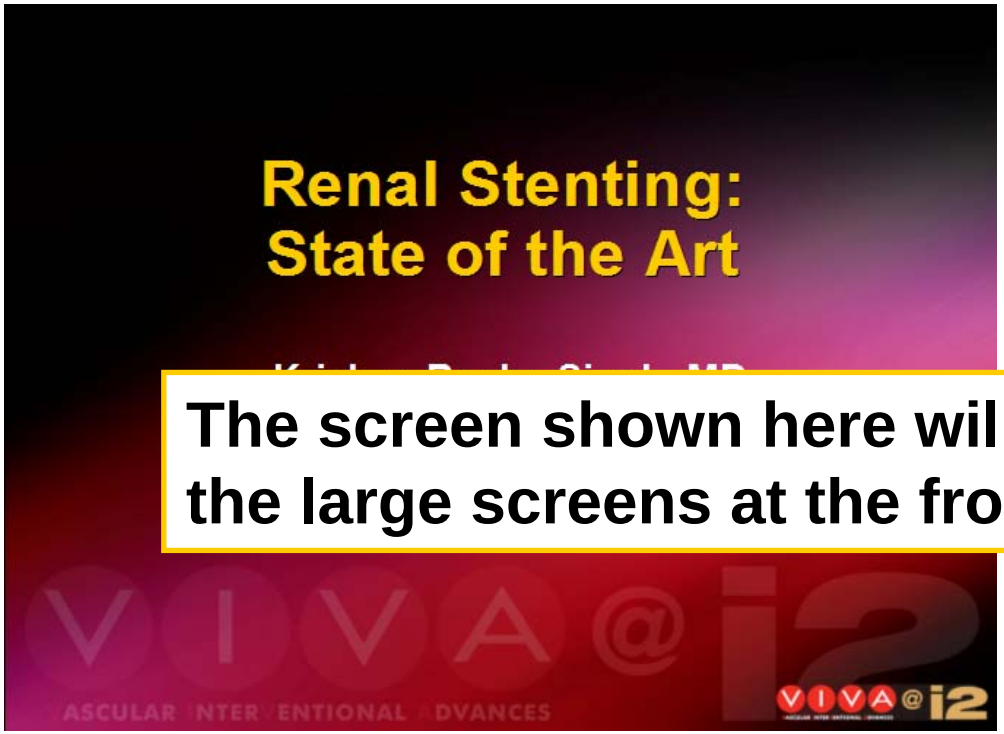


Click on one of the buttons to select which screen to view



You will then have a choice of which screen to view





Left Screen

Right Screen

The screen shown here will match one of the large screens at the front of the room

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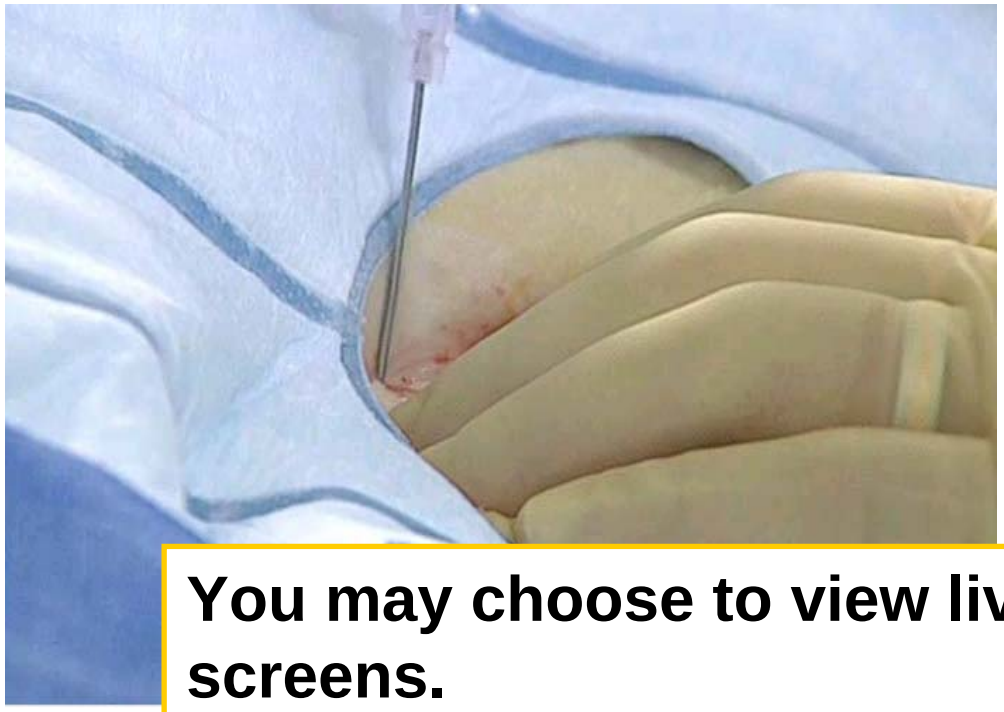

Left Screen

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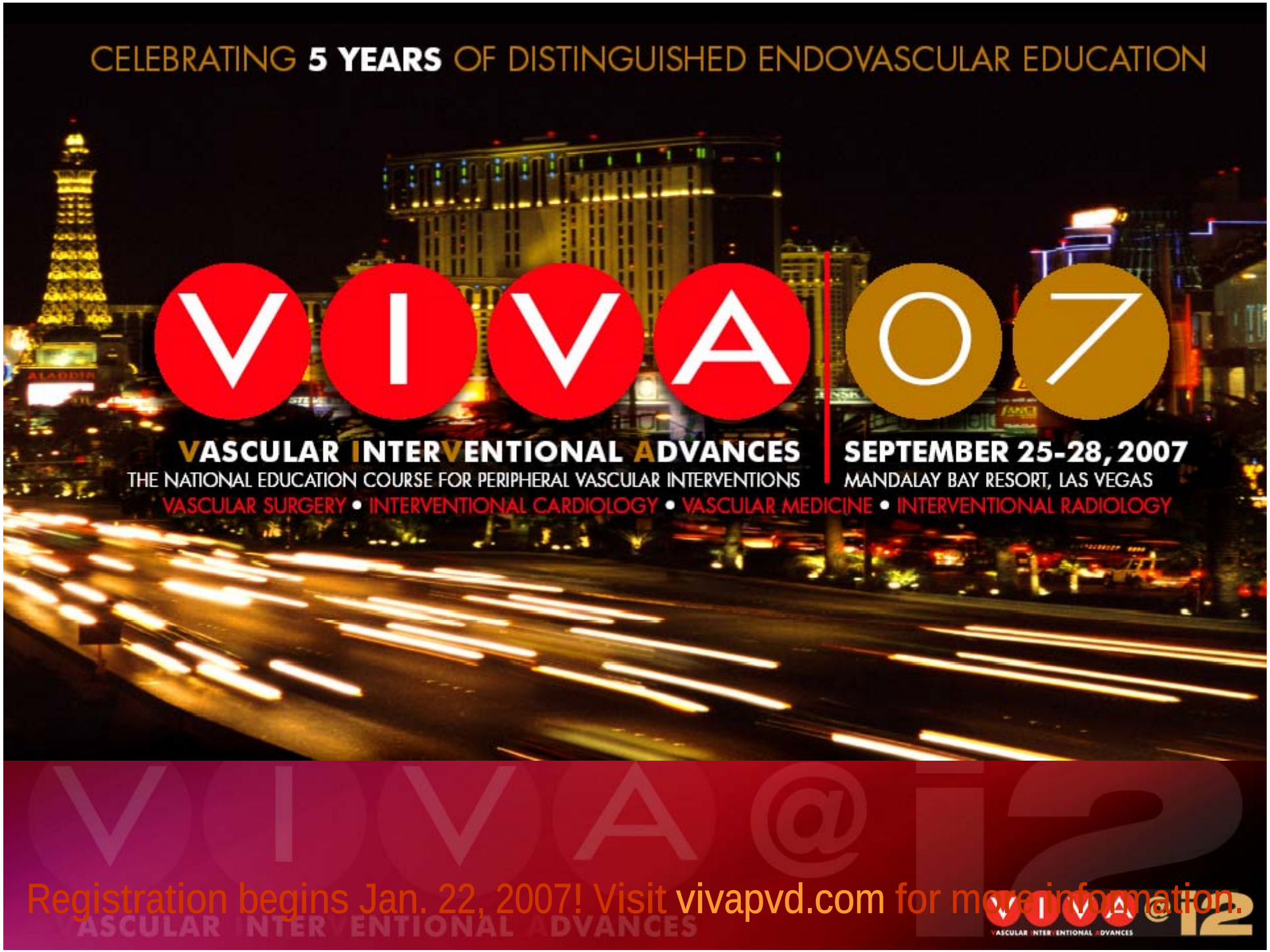
You may choose to view live cases on one of the screens.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SEPTEMBER 25-28, 2007
MANDALAY BAY RESORT, LAS VEGAS
Registration begins Jan. 22, 2007! Visit vivapvd.com for more information.

VIVA @ i2 Laptop Learning:

Highlights of Evolving Technologies: Focus on the SFA

Krishna Rocha-Singh, M.D., FACC
Director, Prairie Vascular Institute
Springfield, IL

Trends in Lower Extremity Interventions

	2002	2003	2004	% Change
Endo	82	123	207	**+152%**
Bypass	138	141	101	**-27%**
FP-PTFE	80	78	43	**-47%**

Geraghty 2005

RCT: Selective vs Primary SE Stent

- Schillinger et al NEJM 2006;354:1879
- One hundred and four patients with claudication (87%) and CLI (13%)
- Fifty-one primary stents vs 53 BA and secondary stents in 32%
- Mean lesion length
  - **132±71 mm primary stent vs 127±55 mm BA**
- Six-month angiographic restenosis
  - 24% primary stent vs 43% BA (*P* = .05)
- Twelve-month duplex restenosis
  - 37% primary stent vs 63% BA (*P* = .01)
- **Treadmill walking further in primary stent group at 6 and 12 months**
- Conclusion: Primary SE stenting is superior at 1 year

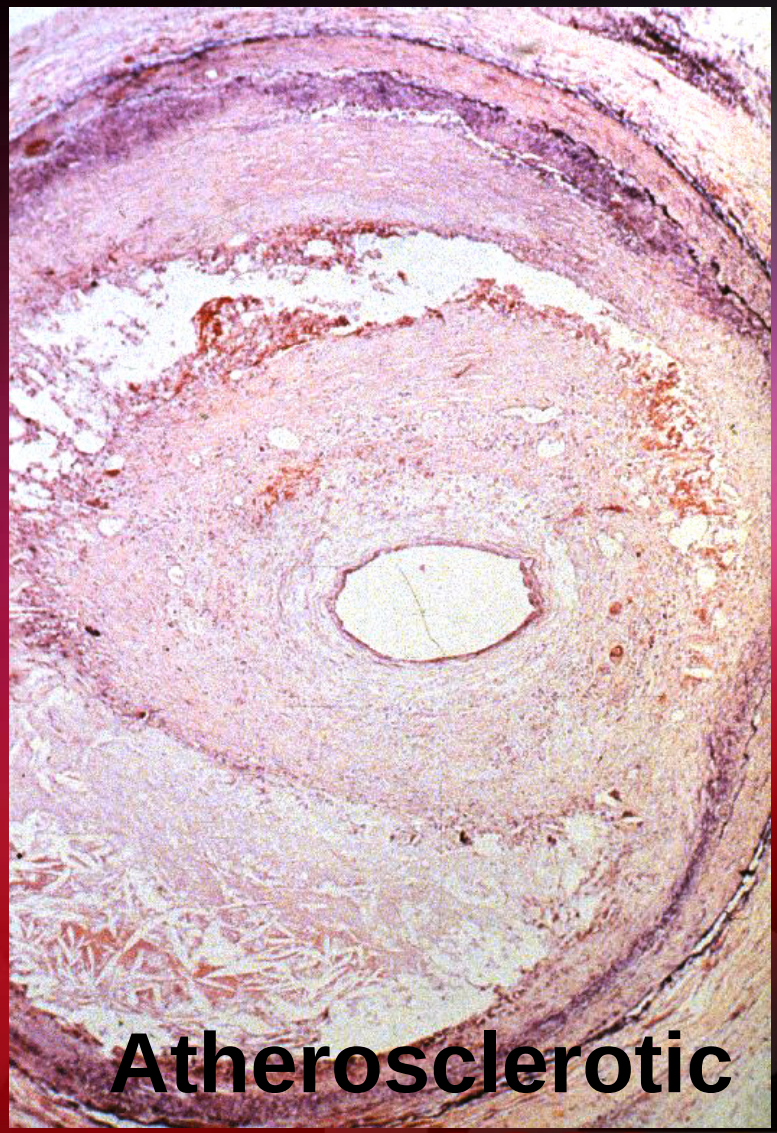
Restenosis Rates by DUS: Time Course

	Stent (n=51)	PTA +/- Stent (n=53)	p-value
Duplex sonographic restenosis @ 3 mo	7/51 (13.7%)	12/53 (22.6%)	0.24
Duplex sonographic restenosis @ 6 mo	13/51 (25.5%)	24/53 (45.3%)	0.035
Duplex sonographic restenosis @ 12 mo	18/49 (36.7%)	33/52 (63.5%)	0.007

Peripheral Vascular Diseases (Arteriosclerosis)

Atherosclerosis

Normal SFA



Atherosclerotic

Pathological Features of Coronary and Peripheral Atherosclerosis

Coronary Disease, PTCA/Stenting

- Relatively focal stenosis (1-3 cm)
- High flow velocity
- Pulsatile and torsional forces
- Muscular, variable elastin content
- Balloon expandable stent, acute barotrauma mediated vessel wall injury

SFA Disease, PTA/Stenting

- Diffuse long lesions (10-30 cm)
- Low flow velocity
- Superficial location
- Unique biomechanical forces
- Muscular, large plaque and thrombus burden
- Thermoelastic metals with potential for chronic stretch mediated vessel wall injury

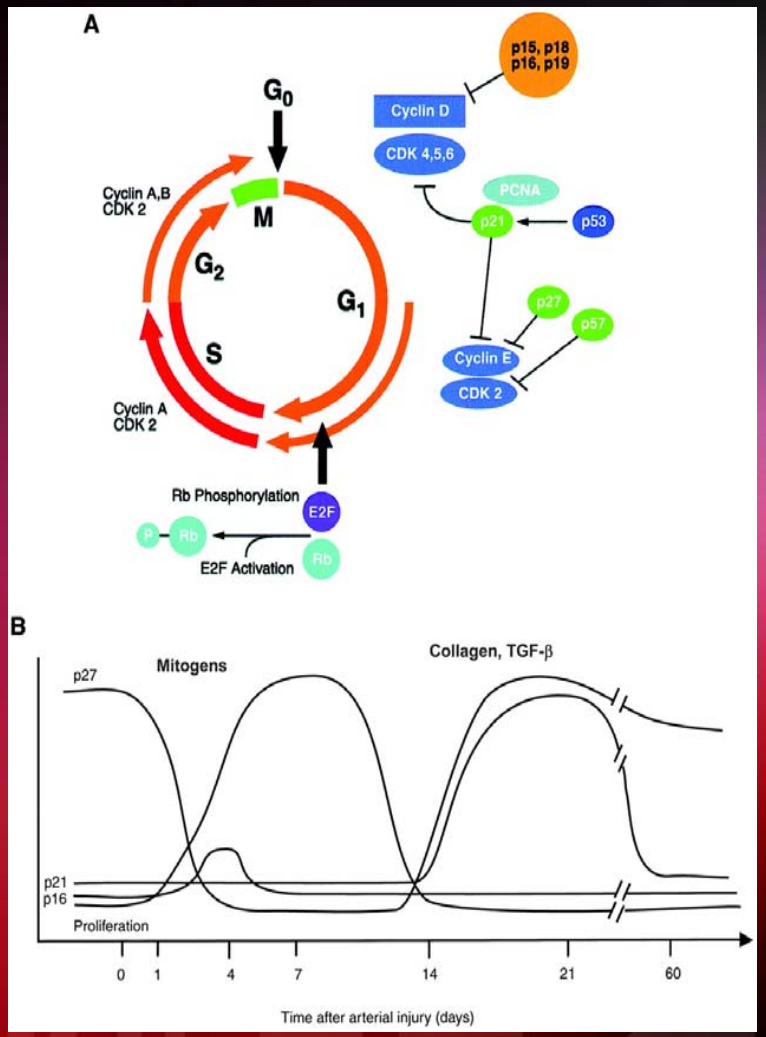
Dr. Carter

Mechanisms of Coronary and SFA Restenosis: cellular proliferation and inflammation

- Time course and critical elements of SFA restenosis undefined.
- Duration and extent of VSMC proliferation likely differs for coronary and SFA after PCI.

O'Brien et al. **(Cir Res 1993;73:223-231)**
82% de novo
74% restenotic
} PCNA (-)

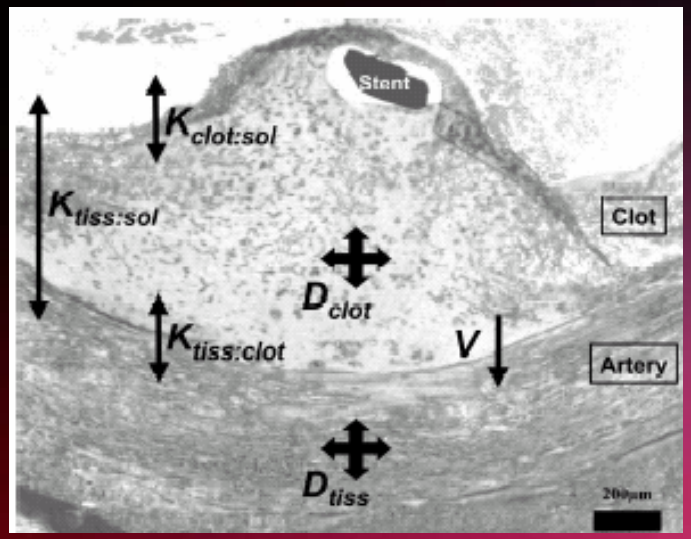
Pickering et al.
(J Clin Invest. 1993;91(4):1469-80)
57% PCNA +
7.2 +/- 10.8% de novo
20.6 +/- 18.2% restenotic

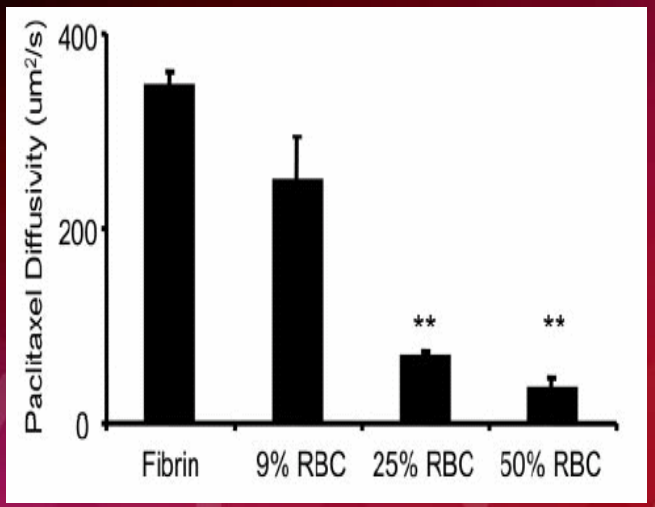


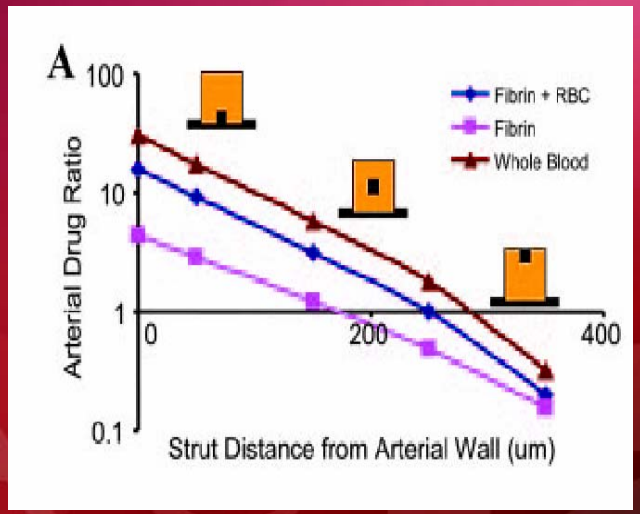
- **SFA stenting is associated with a more extensive inflammatory response than stent placement in the iliac or carotid arteries**

Costa, M. A. et al. Circulation 2005;111:2257-2273

Thrombosis Modulates Arterial Drug Distribution for Drug-eluting Stents

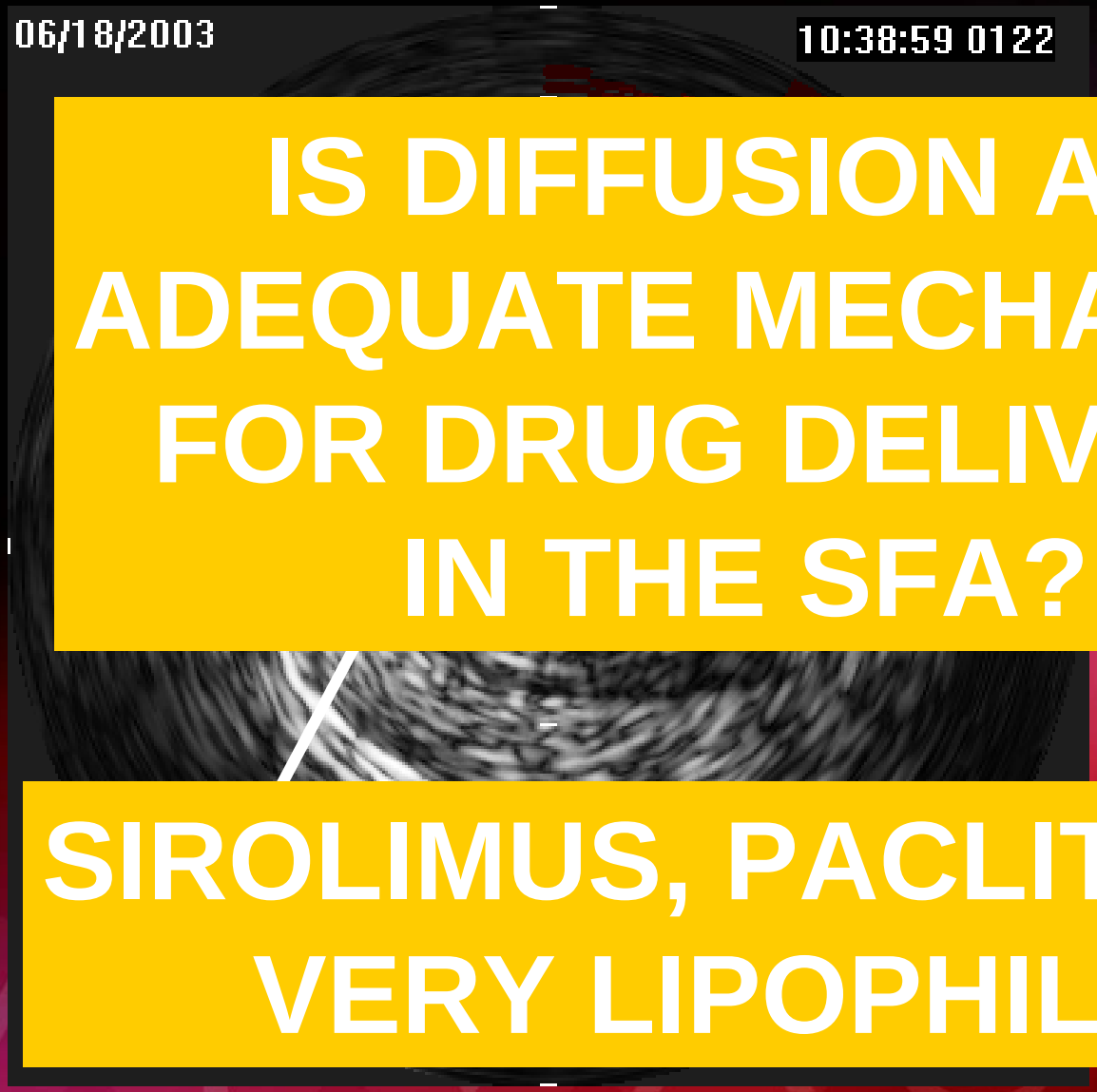






Circulation 2005;111:1619-1626

PLAQUE THICKNESS



IS DIFFUSION AN ADEQUATE MECHANISM FOR DRUG DELIVERY IN THE SFA?

es

ated so

that color flow seen at 12 o'clock

ys

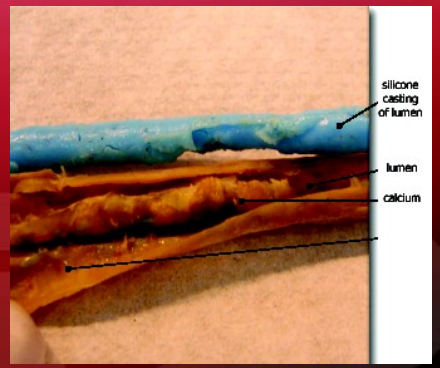
at

SIROLIMUS, PACLITAXEL VERY LIPOPHILIC

SFA Research — Cadaver Studies

- Modeling healthy subjects is *NOT predictive* of PVD subjects
  - Vessel elasticity
  - Areas of kinking/ compression
  - Effects of calcification
- Disease process changes the mechanical properties of vessels
- Investigating modified and new stent designs and ability to reside in SFA/popliteal

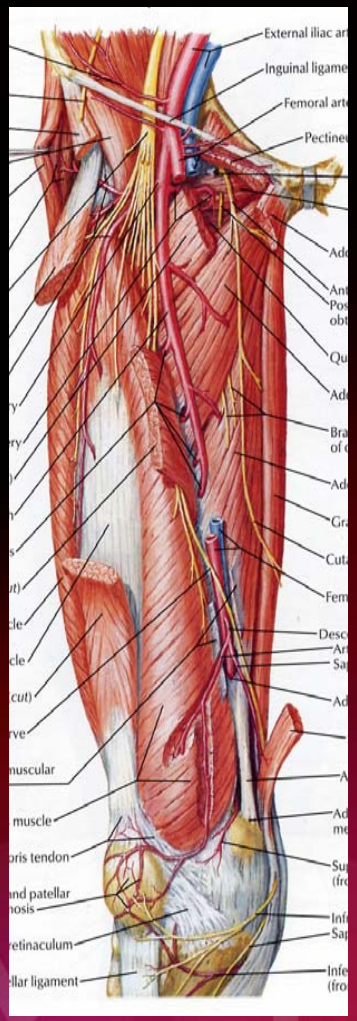
Male, 77yo, normal



Male, 75yo, PVD

Cordis / NDC

In Vivo MR Angiographic Quantification of Axial and Twisting Deformations of the Superficial Femoral Artery Resulting from Maximum Hip and Knee Flexion



- Straightness
  - Supine = 99.1±0.4%
  - Fetal = 98.7±0.6%
- Supine = 16.8–27.6 cm
  Fetal = 13.5–22.4 cm
- Stretch = -12.7 ± 10.6 % ($P < 0.001$)
- Twist: left = 4–113°, right = 14–112°
  - Twist: left ~ CCW, right ~ CW
- Twist regardless of direction = 60±34° ($P < 0.01$)
- Left/Right: length (R = 0.871),
  stretch (R = 0.857)

Source: Cheng, et al. JVIR. 2006;17:979–987

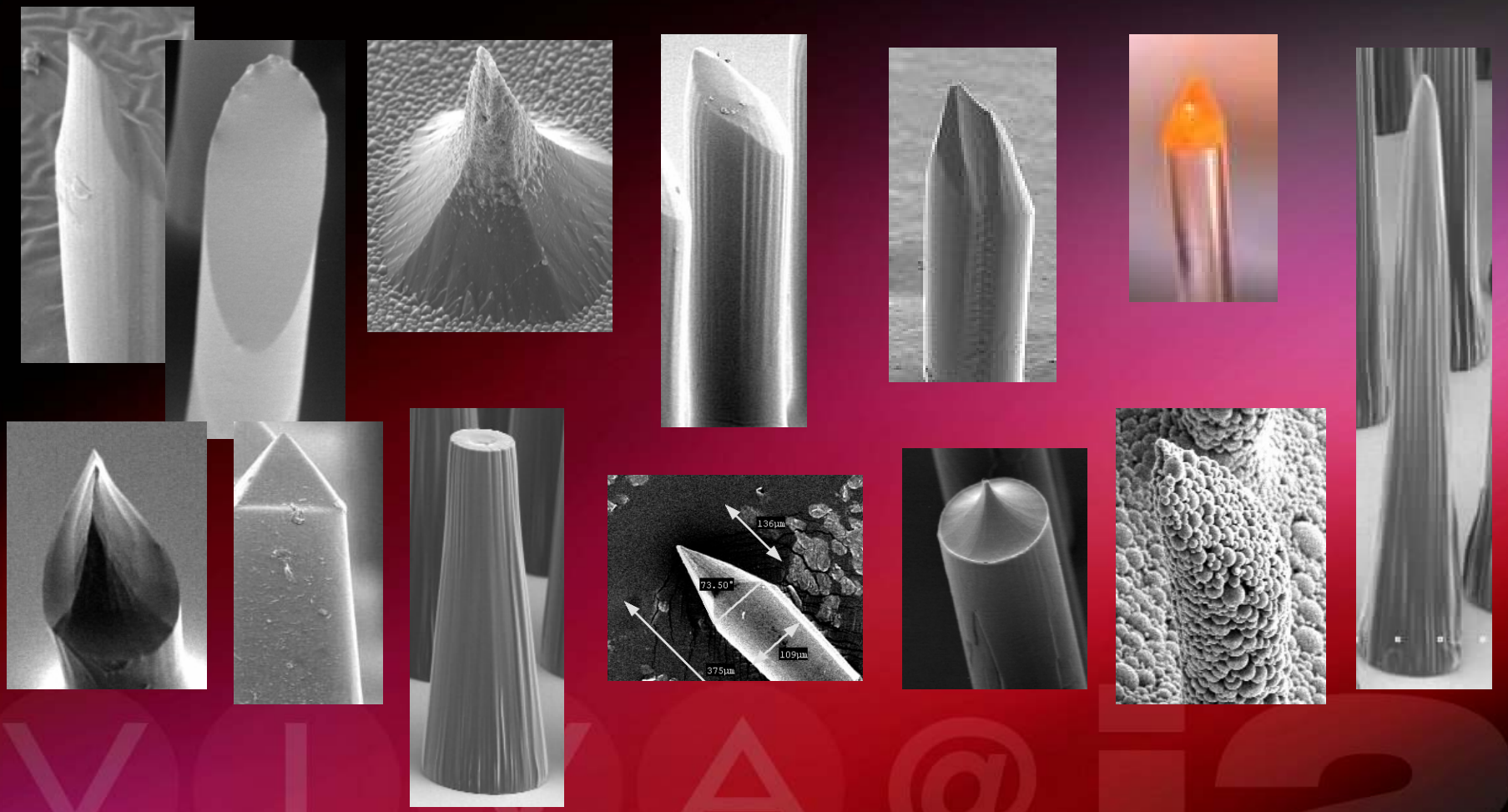
Balloon Expandable vs Nitinol

- Balloon expandable
  - Initial injury followed by slight recoil
  - Prevent further recoil but no significant outward radial force
- Nitinol
  - Initial injury followed by slight recoil
  - Continued significant outward radial force
  - Continued stimulus for cell proliferation

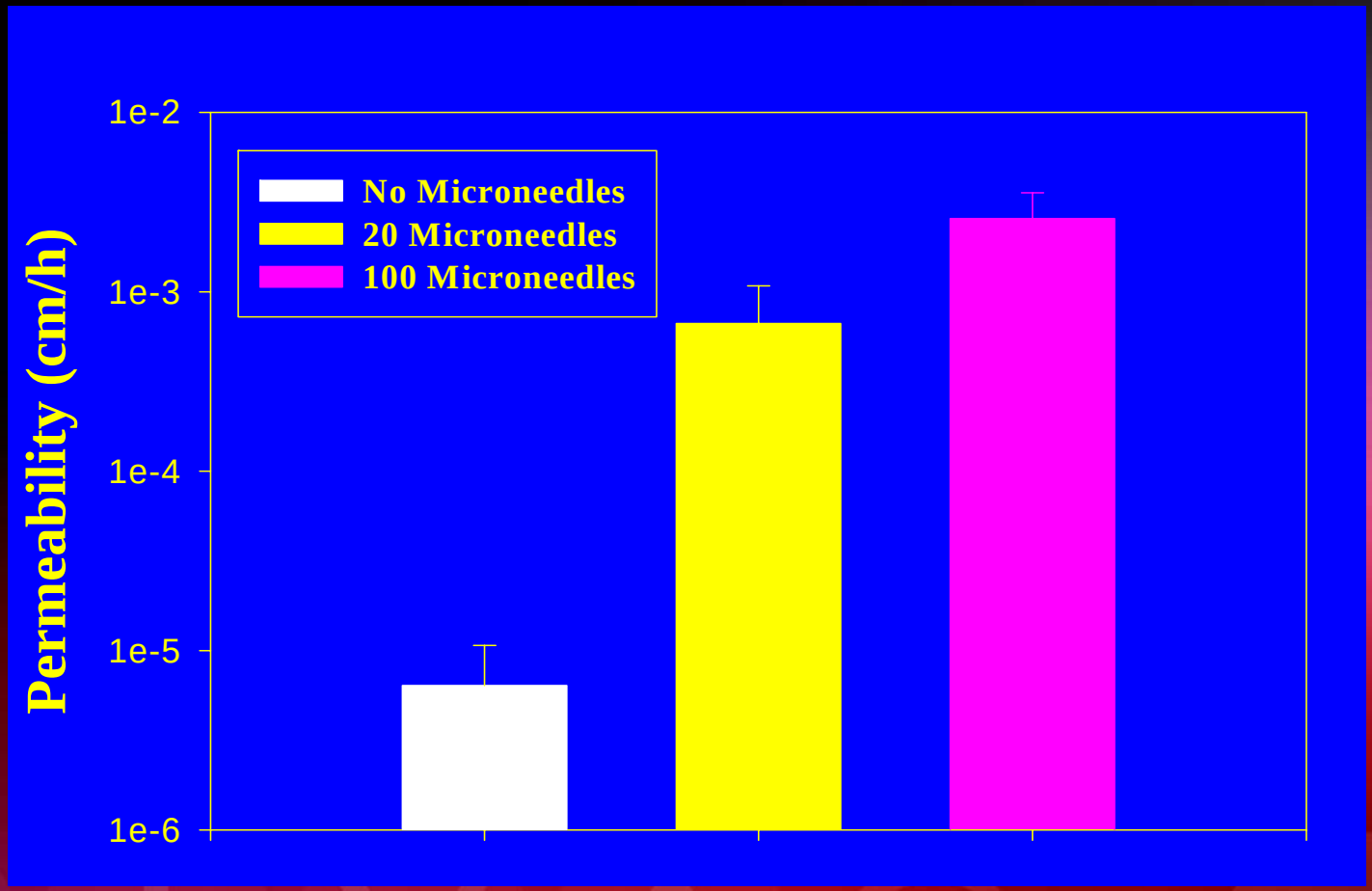
Ideal SFA Stent

- Biodegradable or extremely fatigue resistant alloy
  - No issue of strut fractures
- Limit chronic outward force
  - Biodegradable
- Delivers drug into media/adventitia immediately
  - Diffusion has to be augmented
  - Piercing drug loaded structures
- Prolonged elution kinetics
- Capability for large drug dose

Microneedle Structures and Geometries

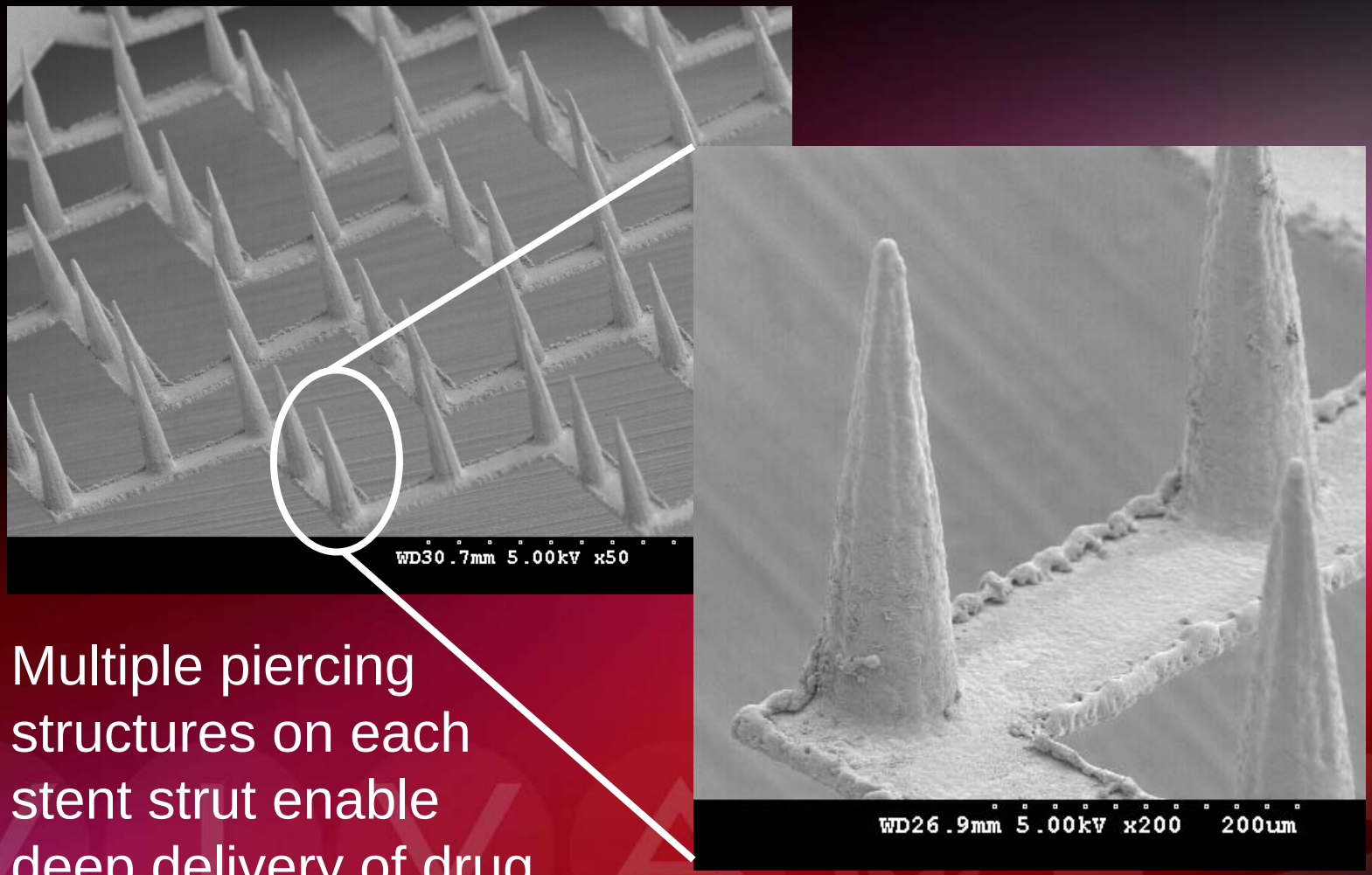


Microneedles Dramatically Increase Skin Permeability of Large Molecules



Microneedle performance
20 or 100 microneedles inserted and then removed

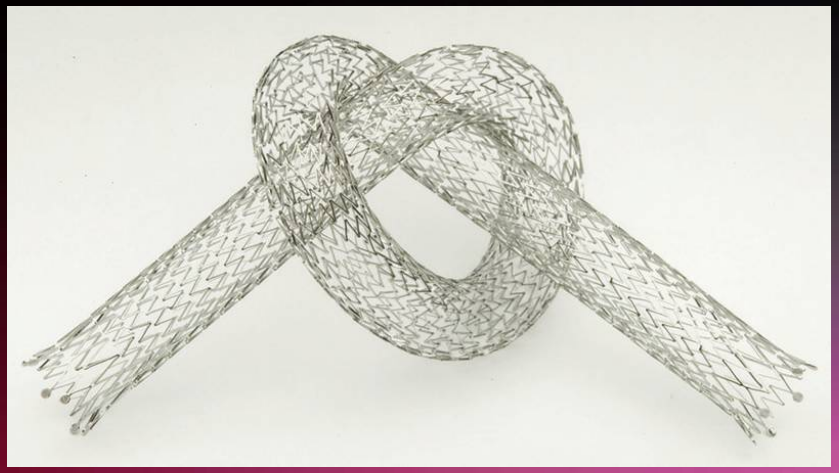
Delivery Enhancement



Multiple piercing structures on each stent strut enable deep delivery of drug

Bioabsorbable Prototypes with Drug Delivery Enhancing Structures

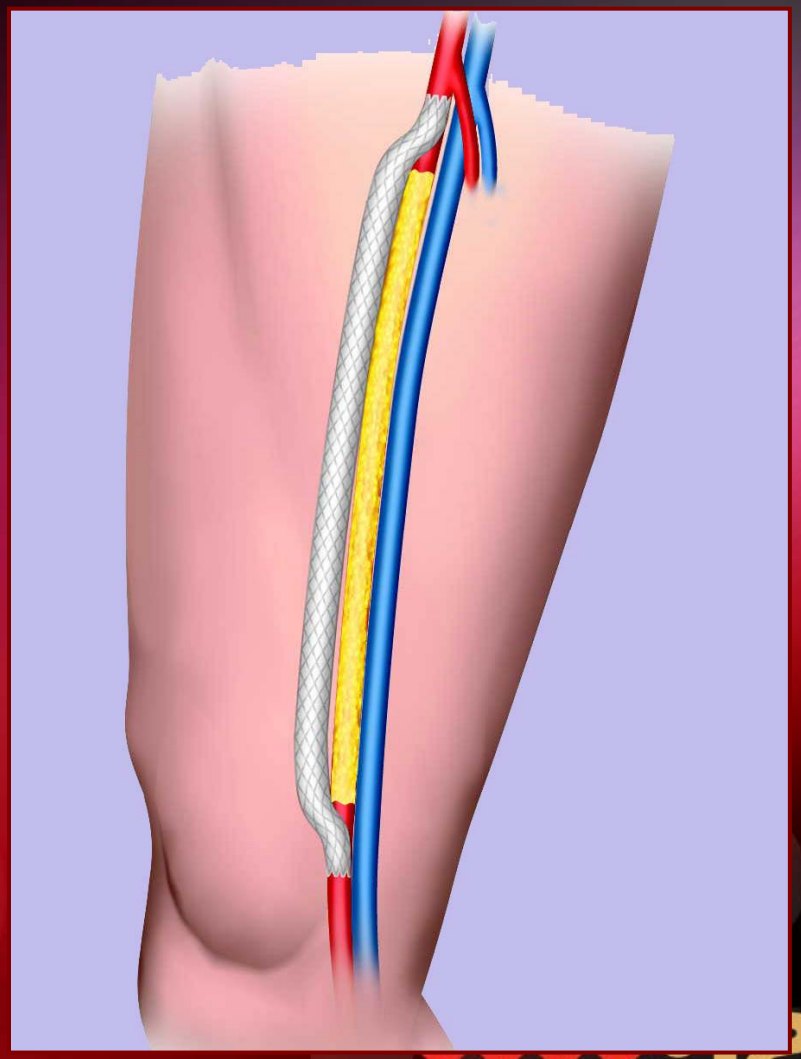
- Short term
  - Fracture-resistant nitinol stents
  - Non-polymeric drug coatings (Cook)
  - Alternative polymeric drug coatings



- Long term
  - Biodegradable
  - Avoid chronic injury
  - Large drug doses
  - Diffusion augmentation

Extravascular Graft Bypass

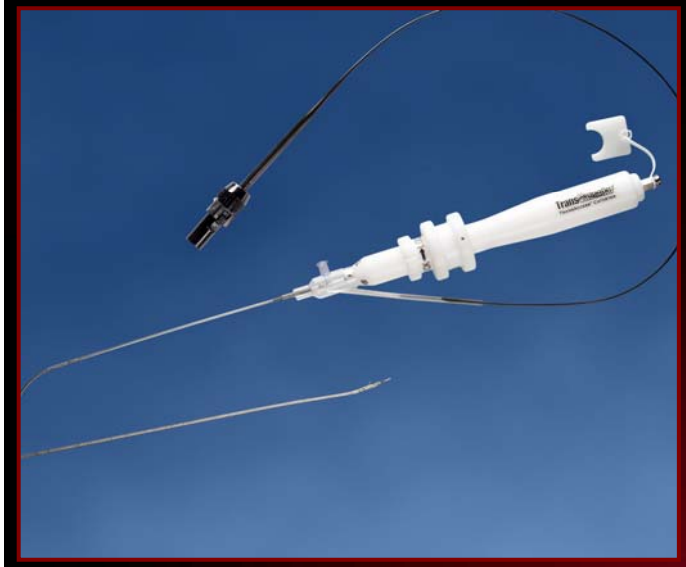
- A complete femoral popliteal bypass in the cath lab
- Does not require use of in situ vein
- Does not prevent later surgery if needed /desired

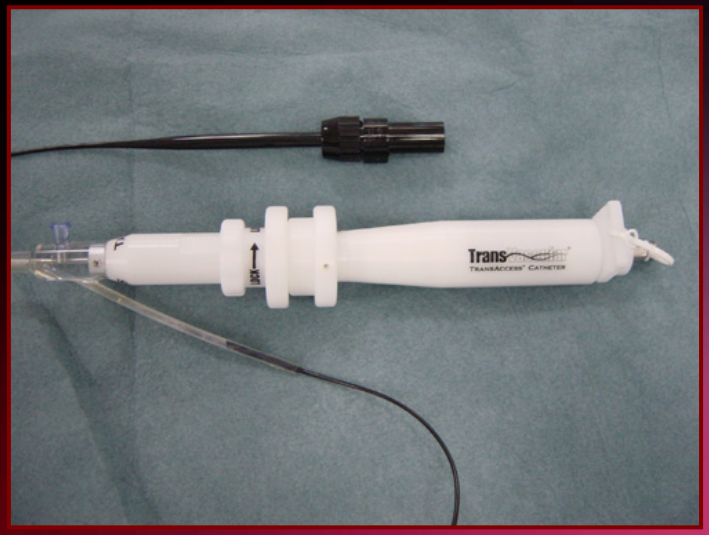


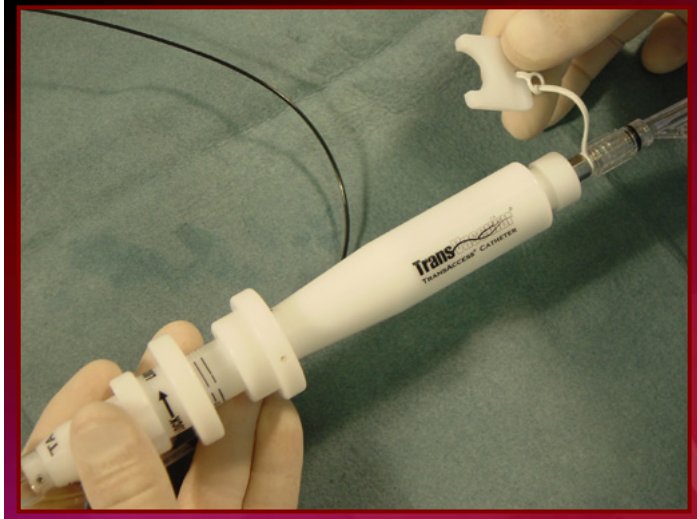
Pioneer® Catheter

- Key Features
  - 24G needle allows for delivery of a 0.014” guidewire
  - Flexible shaft allows for for contralateral approach
  - 6F Introducer sheath compatibility (0.087” I.D.)

Pioneer Images

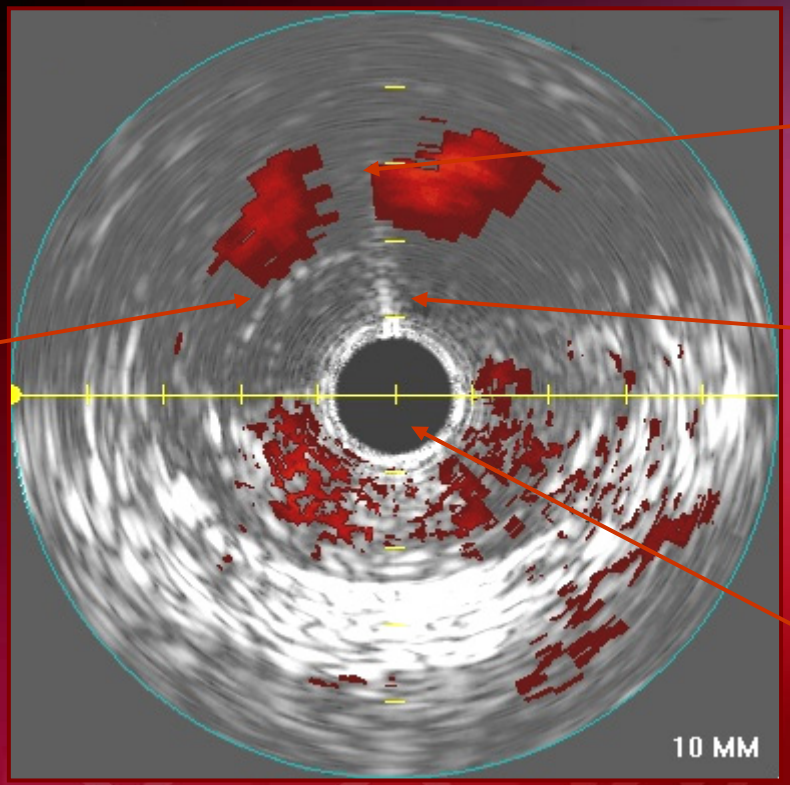






True Lumen Return Application

PIONEER Catheter IVUS Image from within a Dissection of the SFA

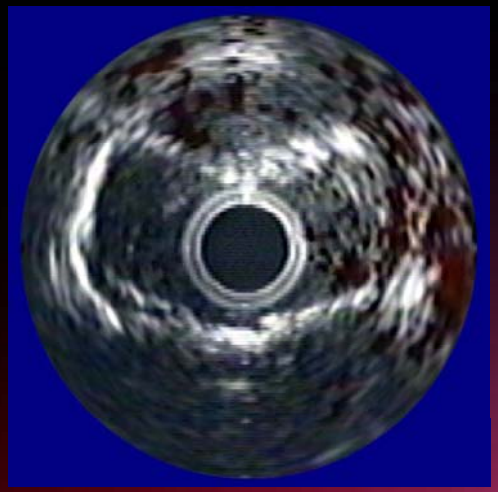


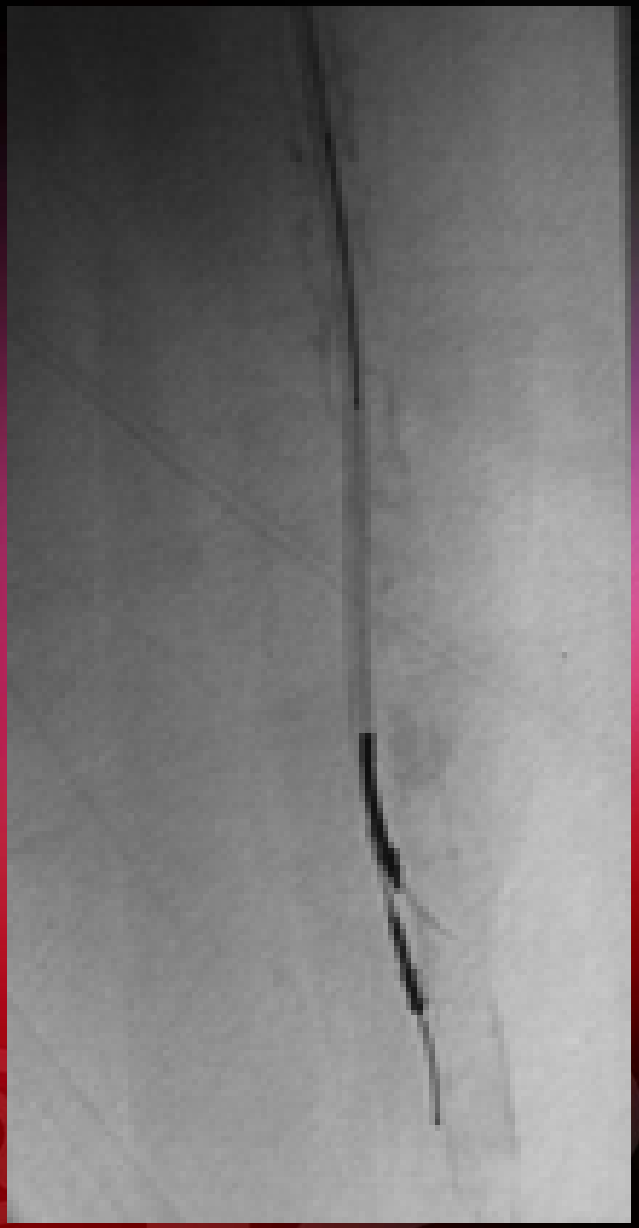
Intima

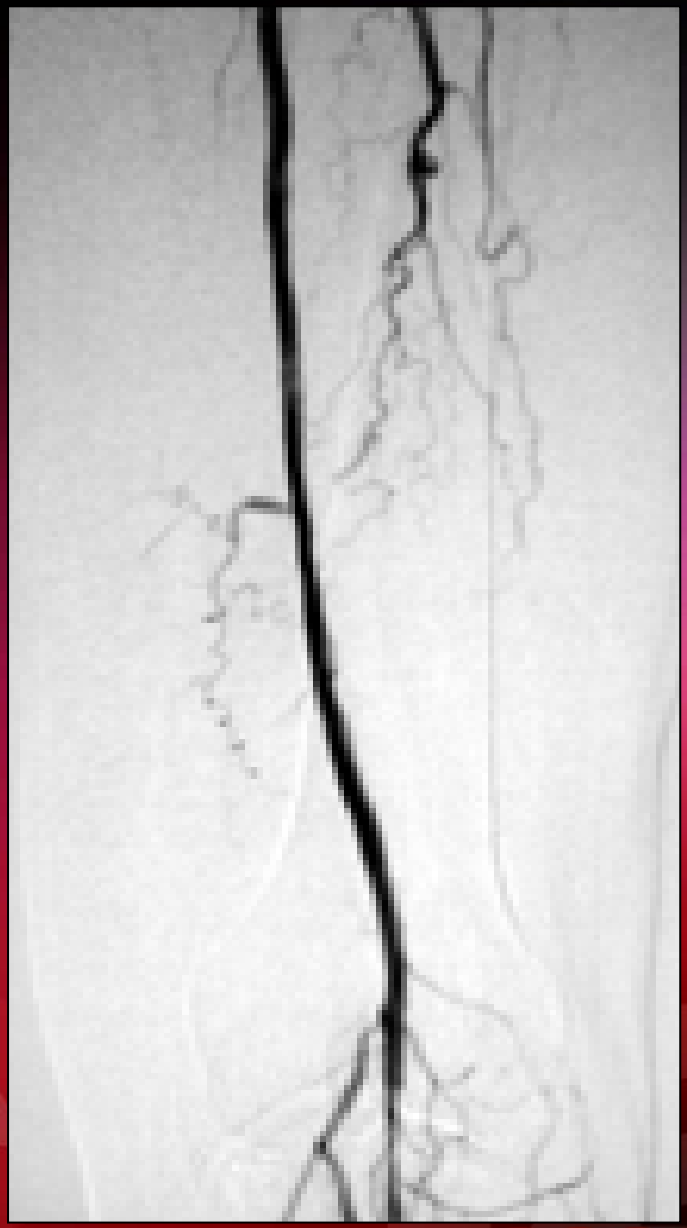
True Lumen with Chroma Flo Feature

Needle Trajectory Indicator

PIONEER Catheter in Subintimal Space





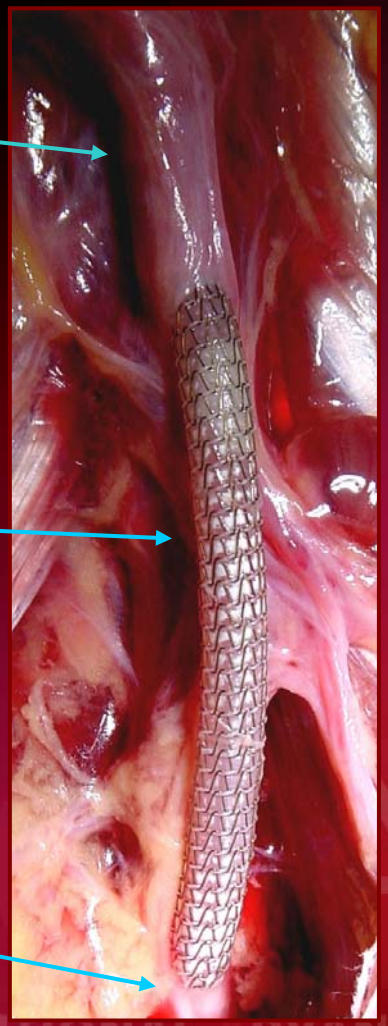


Percutaneous Extravascular Bypass Proof of Concept: Cadaver Model

Proximal Vessel

Extravascular Stent Graft

Distal Vessel



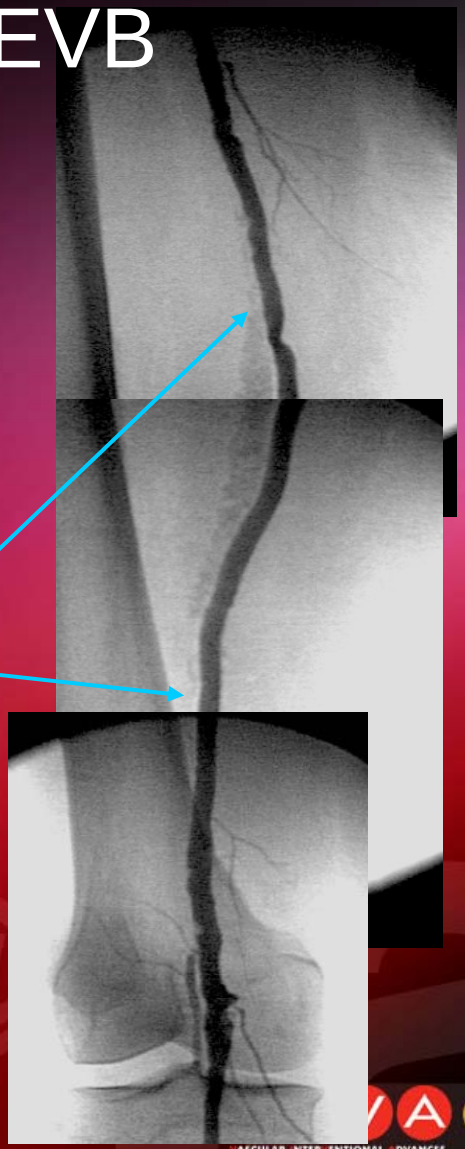
Human EVB Case

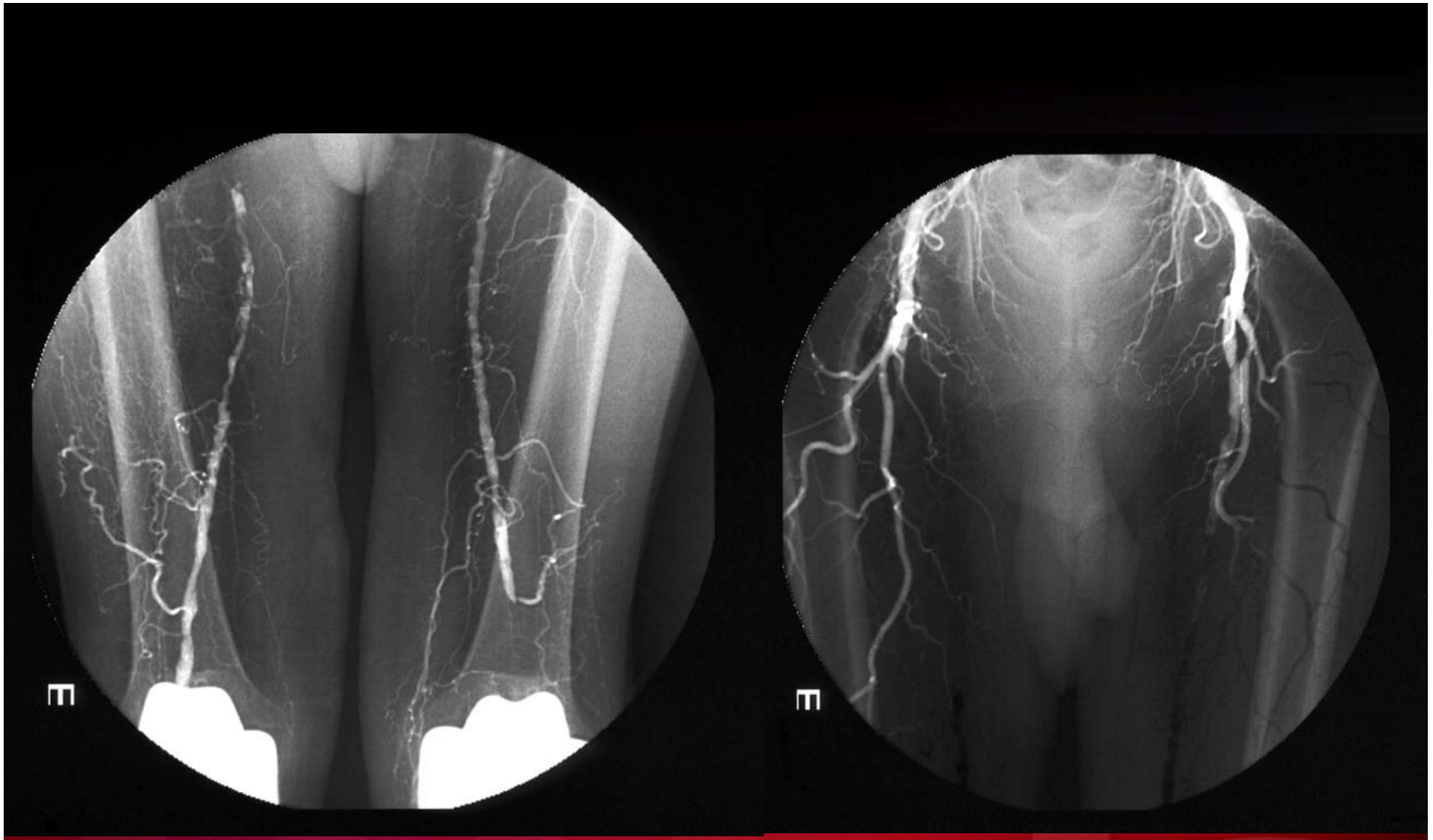
Pre-EVB

Post-EVB

Chronic Total Occlusion

Proximal Exit & Distal Entry Of The Graft





81-year-old man with severe claudication

VIVA @ I2
LIVE CASES

Cases and Controversies!!

VIVA @ I2
Live Case Operators

- Ochsner Clinic
  - Steve Ramee
  - Chris White
  - Tyrone Collins
  - Steve Jenkins
- VIVA Guest Operators
  - Gary Ansel
  - Ken Rosenfield

VIVA@i2
VASCULAR INTERVENTIONAL ADVANCES

Case #1
Long SFA Occlusion

- Long right SFA occlusion from origin of SFA to adductor canal (no proximal stump)
  - Moderate external iliac and CFA disease
  - Moderate stenosis at origin of profunda femoris
- Previous treatment of long left SFA occlusion – stents placed in left SFA and left common femoral artery!
- Treatment approach:
  - Retrograde trans-popliteal access
  - Multiple stents (Edwards Lifestents) placed in right SFA
  - Balloon angioplasty of right common femoral artery

Case #1
Controversies/Questions

- Surgery vs endovascular therapy?
- Best approach – treat inflow first?
- Technique of popliteal access – Need for ultrasound guidance?
- Long-term results when treating long segment disease in SFA with stents (34 cm of stents)?
- Best approach to treament of common femoral artery disease?

Case #2
Branch Renal Artery Stenosis

- Patient with renal insufficiency, poorly controlled HTN and right branch renal artery stenosis
  - No left renal artery stenosis
  - Main right renal artery free of disease
  - Large (4mm) branch off main right renal artery with significant ostial stenosis
- Treatment approach:
  - Two guidewires
  - Treatment of ostial stenosis with 3.5mm x 18 mm Cypher stent

Case #2
Controversies/Questions

- Role that branch renal artery stenosis is playing in chronic renal insufficiency and HTN?
- Optimal technique for treatment of bifurcation disease in the renal arteries?
- Role of DES in the renal vasculature? Is there any evidenced based rationale for their use?

Case #3
Right Iliac Artery and CFA occlusion

- Prior history of bilateral iliac artery stenting
- Recurrent right leg claudication
- Angiography:
  - Total occlusion of right iliac artery extending into right common femoral artery
  - Minimal proximal stump
  - Patent left iliac artery
- Treatment approach:
  - Retrograde right trans-popliteal access
  - Rheolytic thrombectomy
  - Stenting of right iliac and common femoral artery

Case #3
Controversies/Questions

- Best approach – contralateral crossover vs brachial vs retrograde transpopliteal?
- Technique of popliteal access – role of ultrasound?
- Potential complications of subintimal reentry into common femoral artery
- Role of Rheolytic thrombectomy for more chronic iliac occlusion?
- Best treament for instent occlusion? Covered Stent?
- Balloon expandable vs self-expanding stents?
- Stenting of common femoral artery?

Case #4
Inferior Mesenteric Artery Stenosis

- Prior iliac artery stents
- Post-prandial abdominal pain
- Angiography:
  - Patent celiac trunk
  - Occluded SMA
  - Moderate stenosis at origin of IMA (20 mmHg gradient with catheter across). Large meandering collateral from IMA to SMA
- Treatment approach:
  - Femoral access
  - DES at origin of IMA

Case #4
Controversies/Questions

- How much visceral arterial disease is necessary for symptoms of mesenteric ischemia?
- What is the best approach – brachial vs femoral?
- What is the risk of restenosis in this vascular territory?
- Technical challenges associated with downward take off of IMA. How to avoid “watermelon seeding” of stent back into aorta?
- Role of DES in this location?