XLPAD

Setting an exciting new trend
in clinical data collection

XLPAD REDCAP SURVEY AND DATA MANAGEMENT TOOL TRAINING MODULE

EXCELLENCE IN PERIPHERAL ARTERY DISEASE

MULTICENTER PERIPHERAL ARTERY INTERVENTION REGISTRY

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CORE LABORATORY ADJUDICATED & ON-SITE
AUDITED REAL-WORLD REGISTRY

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INTRODUCTION

Peripheral artery disease (PAD), also known as peripheral vascular disease (PVD), is the narrowing of the arteries other than those that supply the heart or the brain.[1] It is often caused by the atherosclerotic plaque buildup in the lumen of the arteries. PAD most commonly affects the legs, including the iliac artery, femoral artery, popliteal artery, and the tibial arteries. The classic symptom is claudication, i.e., leg pain when walking which resolves with rest. Other symptoms include cold skin, poor nail and hair growth and tissue ulceration.

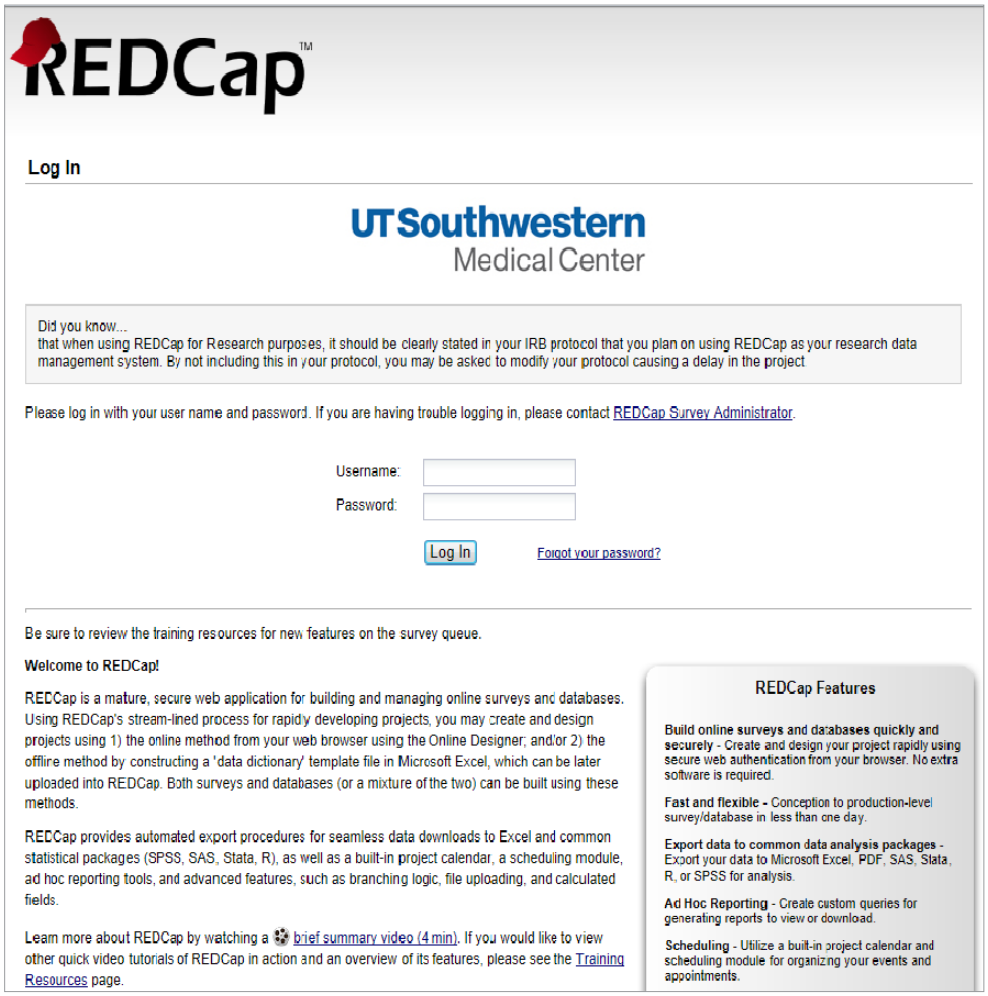
PAD is part of a global vascular problem of diffuse atherosclerosis. It affects 12%–14% of the general population and its prevalence increases with age affecting up to 20% of patients over the age of 75. [2] It is estimated that about 202 million people had PAD in 2010.[3] Coexistent coronary artery disease (CAD) and cerebrovascular disease (CVD) are highly prevalent in patients with PAD particularly in the elderly population. The PAD patients are at an exceptionally high risk for cardiovascular events and the majority will eventually die of a cardiac or cerebrovascular etiology. It has been classified as a coronary heart disease risk equivalent which carries >20% risk of a coronary event in 10 years. In 2013 PAD resulted in about 41,000 deaths.[4] Risk factors contributing to PAD are the same as those for atherosclerosis, including diabetes mellitus, hypertension, cigarette smoking, dyslipidemia, old age, obese, history of heart attack or stroke.

Treatment of PAD include lifestyle changes (such as smoking cessation, better control of blood sugar and blood pressure), medications (such as cilostazol), and vascular intervention for patients having severe pains that are unresponsive to medications and those having ischemic symptoms. In the past decades, minimally invasive procedures such as percutaneous transluminal angioplasty (PTA) are getting more popular as it offers inherent advantages such as considerably less patient discomfort and shorter hospital length of stay over traditional surgical revascularization.

The Excellence in Peripheral Artery Disease (XLPAD) study is a multicenter peripheral artery intervention registry led by investigators from the University of Texas Southwestern Medical Center & VA North Texas Health Care System in Dallas. It is a real-world core lab adjudicated and rigorously audited PAD intervention registry which leverages the REDCAP survey and data management tool and the IT infrastructure of the University of Texas Southwestern Medical Center. This will set a new and exciting trend in clinical data collection and will be extremely valuable for future PAD studies and management.

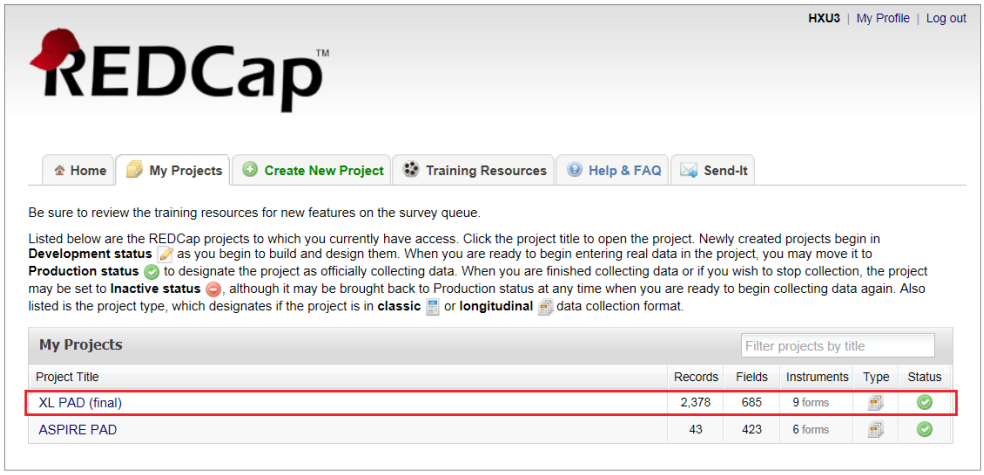
LOG IN TO REDCAP

To enter the XLPAD study, you first need to go to the UT Southwestern REDcap website:
https://ais.swmed.edu/redcap/index.php
Type in the username and password and click log in.



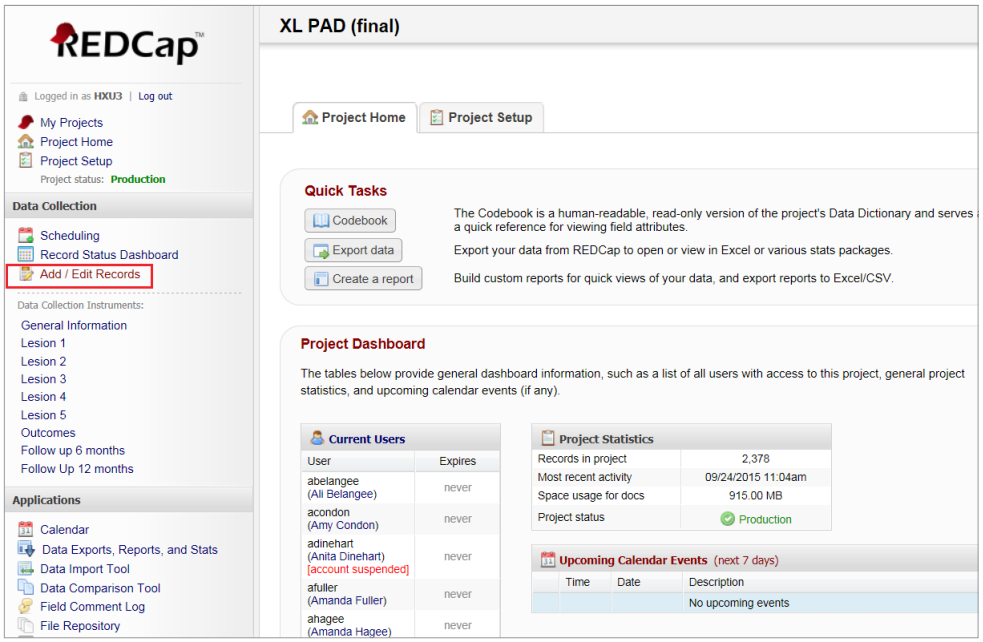
ENTER THE XLPAD STUDY

After logging into the UT Southwestern REDcap website, simply click XLPAD (final) under the My Projects tab.

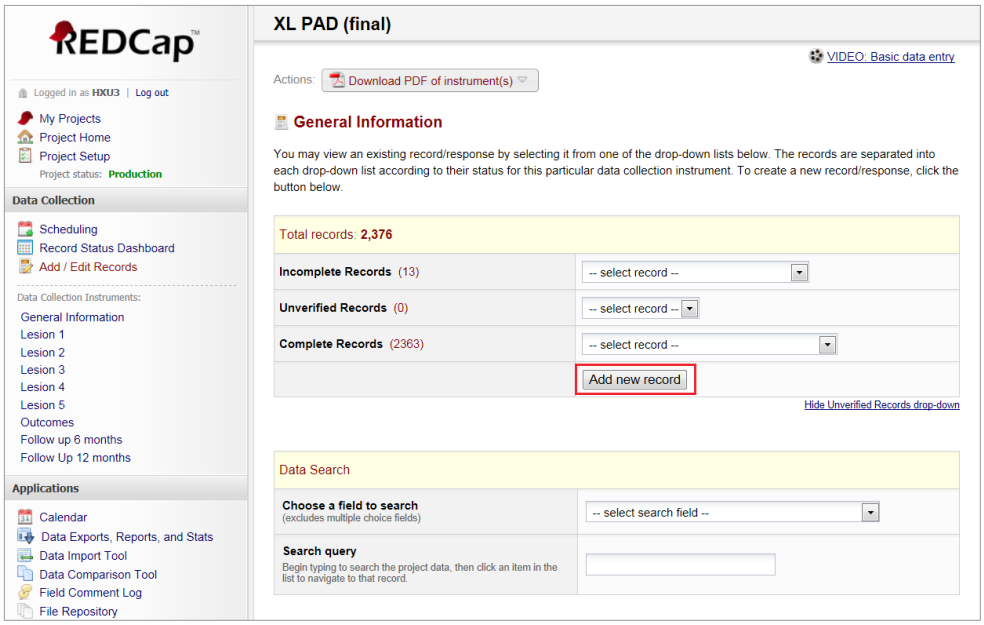


ADD A NEW PATIENT

To add a new patient into the XLPAD data base, first click the Add/Edit Records button on the Project home main screen.

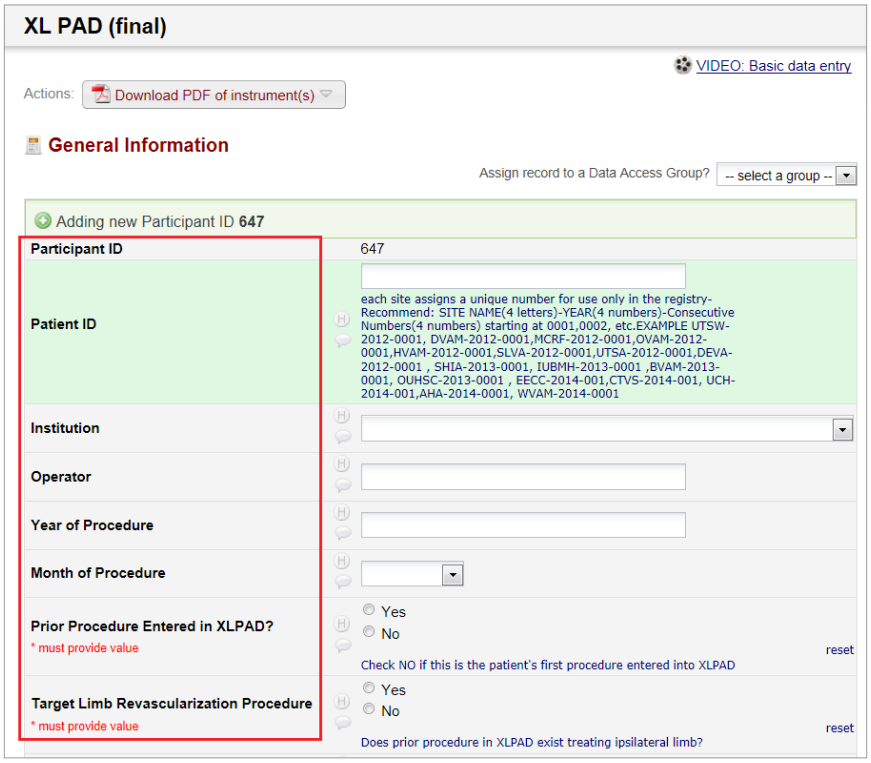


Next, on the General Information page, click the Add new record button. You can now add a new record to the XLPAD data base.



PATIENT GENERAL INFORMATION

Note: All the patient general information will be collected from the institution's electronic medical data system and entered into the XLPAD registry by the study team. Data will be verified periodically by the primary investigator.



PATIENT ID

Use format as SITE NAME(4 letters)-YEAR(4 numbers)-Consecutive Numbers(4 numbers) starting at 0001. For example UTSW-2012-0001, DVAM-2012-0001, MCRF-2012-0001, OVAM-2012-0001, HVAM-2012-0001, SLVA-2012-0001, UTSA-2012-0001, DEVA-2012-0001, SHIA-2013-0001, IUBMH-2013-0001, BVAM-2013-0001, OUHSC-2013-0001, EECC-2014-001, CTVS-2014-001, UCH-2014-001, AHA-2014-0001, WVAM-2014-0001.

INSTITUTION

Enter the procedure performing institution from the drop down menu.

OPERATOR

Enter the procedure operator's last name.

DATE OF PROCEDURE

Enter index procedure date. This date will be converted to a dummy date and recorded by the system.

PRIOR PROCEDURE ENTERED IN XLPAD?

Enter YES or NO.

TARGET LIMB REVASCULARIZATION PROCEDURE

Enter YES or NO.

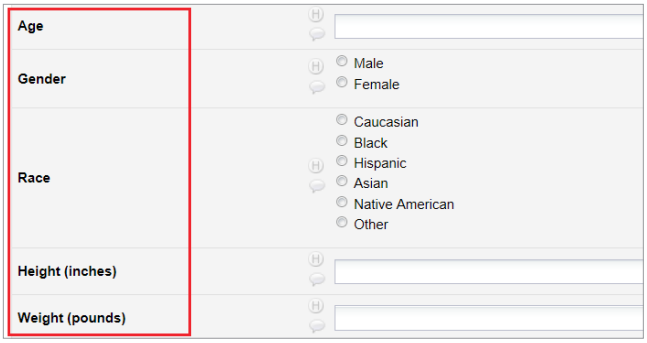
AGE
Enter the integer years of the patient age (eg., 65).

GENDER
Enter Male or Female.

RACE
Enter the patient race as Caucasian, Black, Hispanic, Asian, Native American, or Other.

HEIGHT (INCHES)
Enter the patient height in inches.

WEIGHT (POUNDS)
Enter the patient weight in pounds.



AMBULATORY STATUS?
Enter the patient ambulatory status from the drop-down menu: Not Ambulatory or Walk, assisted, or Walk, unassisted.

RUTHERFORD CLASSIFICATION
Enter the patient's peripheral arterial disease stage of Rutherford classification from the drop-down menu: No claudication, or Rutherford classification I to VI.

RUTHERFORD CLASSIFICATION

CATEGORY	DEFINITION
0	No claudication
I	Mild claudication
II	Moderate claudication
III	Severe claudication
IV	Rest pain
V	Ischemic ulceration not exceeding ulcer of the digits of the foot
VI	Severe ischemic ulcers or frank gangrene

CLAUDICATION-FREE DISTANCE (FEET)
Enter the patient walking claudication-free distance in feet (eg., 50).

LEFT ABI
Enter the patient left side ankle-brachial index (ABI).

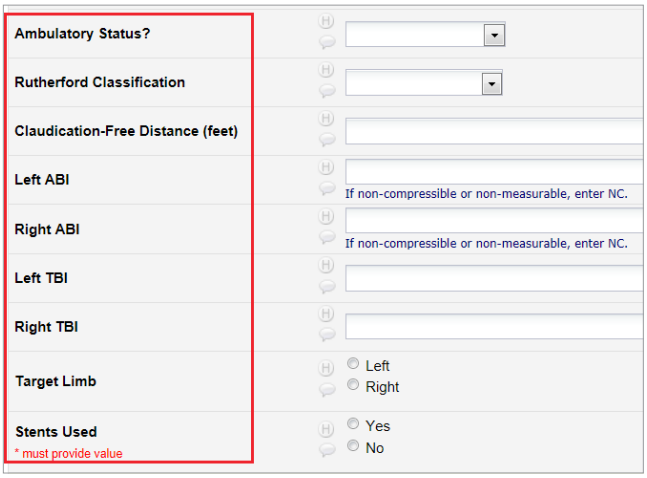
RIGHT ABI
Enter the patient right side ABI.

LEFT TBI
Enter the patient left side toe-brachial index (TBI) if clinically applicable. Either ABI or TBI information is mandatory.

RIGHT TBI
Enter the patient right side TBI.

TARGET LIMB
Enter the patient procedure target limb as Left or Right.

STENTS USED
Enter Yes or No.



Next, enter the patient medical history and comorbidities. These fields should be based on patient's medical record diagnosis, ICD9 or 10 codes and additional criteria listed for each item below.

DIABETES MELLITUS

Additional Criteria: oral medications or insulin for the treatment of diabetes

Enter Yes, No, or Unknown from the drop-down menu.

DYSLIPIDEMIA

Additional Criteria: medications for the treatment of dyslipidemia

Enter Yes, No, or Unknown from the drop-down menu.

HYPERTENSION

Additional Criteria: medications for the treatment of hypertension

Enter Yes, No, or Unknown from the drop-down menu.

SMOKING

Enter Current/Recent (within 1 year), Past (>1 year ago), or Never from the drop-down menu.

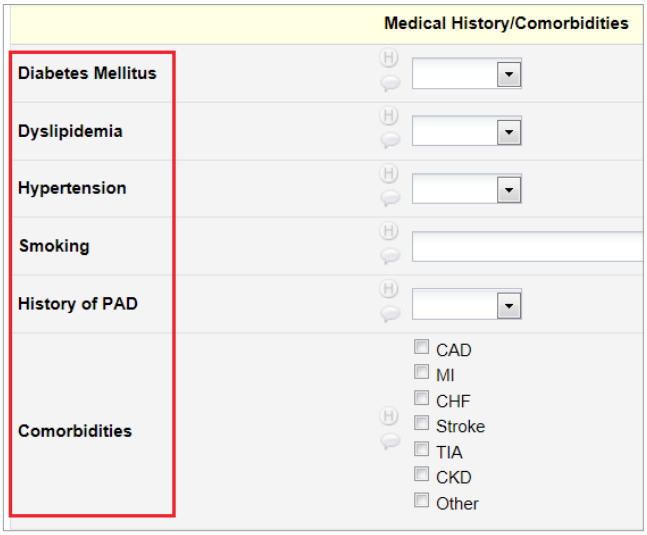
HISTORY OF PAD

Additional Criteria: prior endovascular or surgical non-coronary arterial procedure, abnormal ABI diagnostic of PAD, Duplex US, CT or MR imaging evidence of PAD)

Enter Yes, No, or Unknown from the drop-down menu.

COMORBIDITIES

Enter patient comorbidities from the list of CAD, MI, CHF, Stroke, TIA, CKD, and other. (These comorbidities to be entered based on medical record documentation and/or ICD9-10 codes)



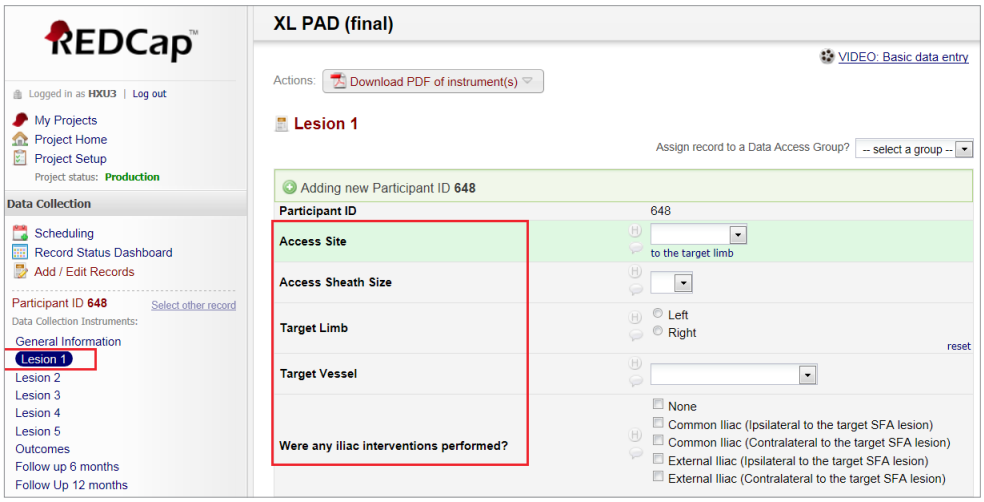
FORM STATUS

You can save the uncompleted record at any time by clicking the Save Record button. After entering all the required information, change the form status from Incomplete to Complete, then click the Save and Continue or the Save and go to Next Form button.

LESION ONE

Note: All the information for lesion 1 will be collected from the institution's electronic medical data system and from the Angiogram analysis core lab by credentialed technicians at Dallas VA hospital. Data will be entered into the XLPAD registry by the study team. Data will be verified periodically by the primary investigator.

The current section is about a lesion treated during the procedure. If there was more than one lesion being treated, please complete Lesion one section with the first lesion and move on the next lesion by clicking the Lesion 2 button on the left side panel.



Click the Lesion 1 button on the left side panel and you can now input the first lesion information that includes the following:

ACCESS SITE

Enter Ipsilateral, or Contralateral from the drop-down menu.

ACCESS SHEATH SIZE

Enter the sheath size from 5F to 9F from the drop-down menu.

TARGET LIMB

Enter Left or Right.

TARGET VESSEL

Enter Superficial Femoral Artery, Popliteal Artery, Posterior Tibial, Anterior Tibial, Peroneal, or Tibioperoneal Trunk from the drop-down menu.

WERE ANY ILIAC INTERVENTIONS PERFORMED?

Enter None, Common Iliac (ipsilateral to the target SFA lesion), Common iliac (Contralateral to the target SFA lesion, External Iliac (ipsilateral to the target SFA lesion, or External Iliac (Contralateral to the target SFA lesion).

TARGET LESION LOCATION
Enter Ostial, Proximal, Mid, or Distal from the drop-down menu.

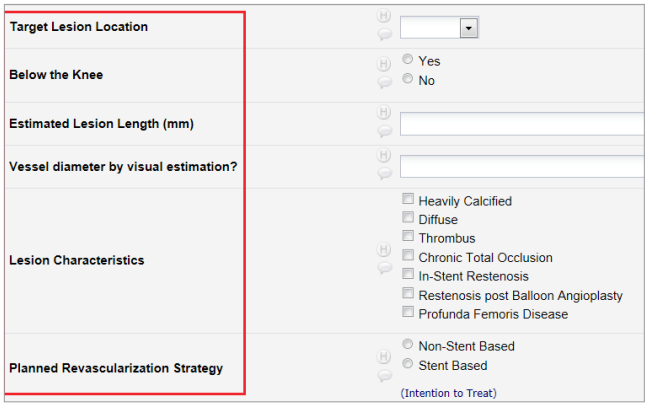
BELOW THE KNEE
Enter YES or NO.

ESTIMATED LESION LENGTH (MM)
Reported lesion length is based on visual estimate from review of procedural angiograms or documented length by the operator. Core lab: Enter the lesion length in millimeter measured with the angiography analysis software.

VESSEL DIAMETER BY VISUAL ESTIMATION?
Reported lesion length is based on visual estimate from review of procedural angiograms or documented length by the operator. This variable will be verified by core laboratory assessment of the variable. Core lab: Enter the vessel diameter in millimeter measured with the angiography analysis software.

LESION CHARACTERISTICS?
Enter Heavily Calcified, Diffuse, Thrombus, Chronic Total Occlusion, In-stent Restenosis, Restenosis post Balloon Angioplasty, or Profunda Femoris Disease. Heavy calcification is defined as presence of at least 5 mm of calcification on both sides of the vessel. Diffuse disease is defined by presence of angiographic disease >30% diameter stenosis compared to reference segment (if present) or in the judgement of the reviewer for at least 20 mm vessel segment.

PLANNED REVASCULARIZATION STRATEGY?
Enter Non-Stent Based or Stent Based. Based on procedure documentation of primary and/or need for bail-out or provisional stenting.



Next, enter patient medical histories and comorbidities.

DEBULKING
Enter None, Cutting Balloon, Laser, Rotablator, Silverhawk/Turbohawk, Diamondback Orbital, or Jetstream.

EMBOLIC PROTECTION DEVICE USED
Enter Distal filter, Angioslide Balloon, or None.

NUMBER OF BALLOON(S) FOR ANGIOPLASTY
Enter the number of balloons (0-3) for angioplasty from the drop-down menu.

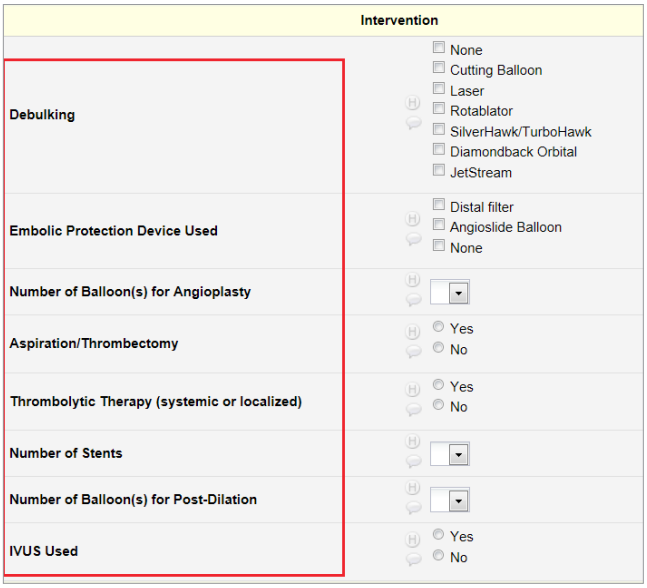
ASPIRATION/THROMBECTOMY
Enter Yes or No.

THROMBOLYTIC THERAPY (SYSTEMIC OR LOCALIZED)
Enter Yes or No.

NUMBER OF STENTS
Enter the number of stents (0-5) used for angioplasty from the drop-down menu.

NUMBER OF BALLOONS FOR POST-DILATION
Enter the number of balloons (0-2) for post-dilation from the drop-down menu.

IVUS USED
Enter Yes or No.



Next, enter the lesion outcomes information.

BASELINE PERCENT STENOSIS

Reported Percent Stenosis is based on visual angiographic analysis; could be verified with core lab measurement).
Core lab: enter the percentage (%) of the lesion diameter stenosis compared to normal reference vessel of angiogram before intervention.

BASELINE TIMI FLOW

Enter the TIMI flow (0-III) of the lesion before intervention from the drop-down menu.

TIMI GRADE FLOW

GRADE	DEFINITION
0	No perfusion. Defined as absence of any antegrade flow beyond the occlusion
I	Penetration without perfusion. Defined as faint antegrade flow beyond the occlusion, with incomplete filling of the distal vessel
II	Partial reperfusion. Defined as delayed or sluggish antegrade flow with complete filling of the distal vessel.
III	Normal flow which fills the distal vessel completely

FINAL PERCENT STENOSIS

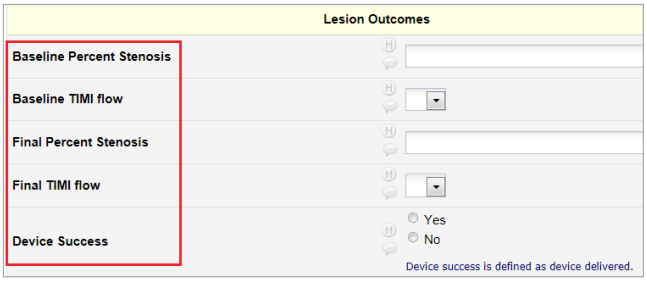
Reported Percent Stenosis is based on visual angiographic analysis; could be verified with core lab measurement. Core lab: enter the percentage (%) of the lesion diameter stenosis compared to normal reference vessel of angiogram after intervention.

FINAL TIMI FLOW

Enter the TIMI flow (0-III) of the lesion after intervention from the drop-down menu.

DEVICE SUCCESS

Enter Yes or No.



FORM STATUS

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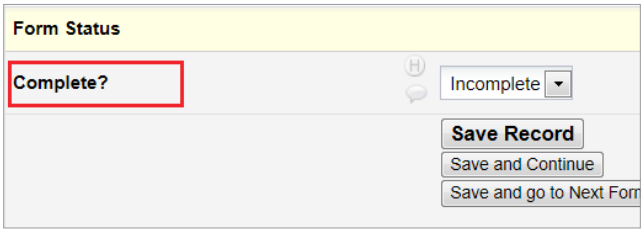
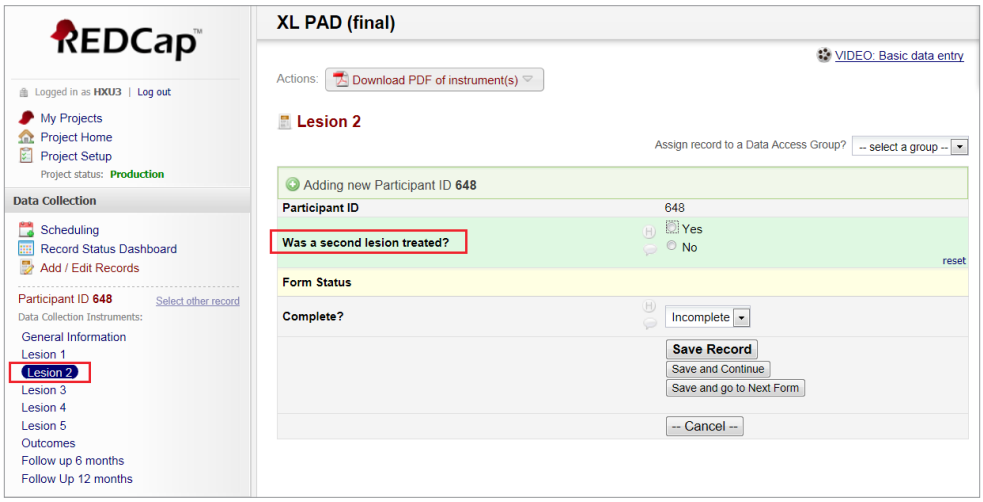


SUBSEQUENT LESIONS

Note: All the information for lesion 2, Lesion 3, Lesion 4, and Lesion 5 will be collected from the institution's electronic medical data system and from the Angiogram analysis core lab by credentialed technicians at Dallas VA hospital. Data will be entered into the XLPAD registry by the study team. Data will be verified periodically by the primary investigator.

If there was more than one lesion treated, click the Lesion 2 button on the left side panel. Enter Yes for the question Was a second lesion treated? and continue to enter the lesion information, the same as lesion 1. Add data to lesion 3 to 5 if there were more lesions treated.



OUTCOMES

Note: All the information for Outcomes will be collected from the institution's electronic medical data system and entered into the XLPAD registry by the study team. Data will be verified periodically by the primary investigator.

TECHNICAL SUCCESS

Technical success is defined as placement of a guidewire in the distal true lumen, past the distal CTO cap, confirmed by either angiography or intravascular ultrasound (IVUS).
Enter Yes, or No.

PROCEDURE SUCCESS

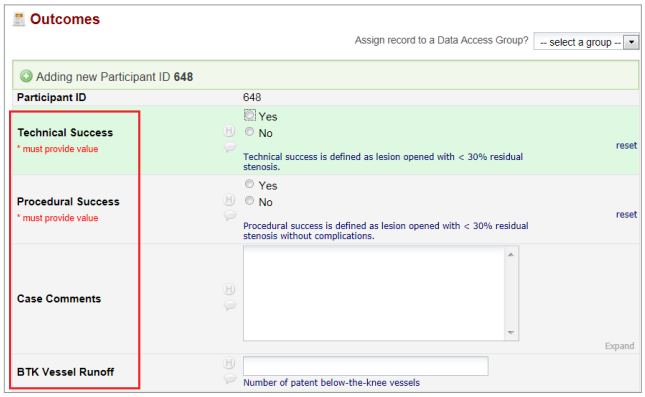
Procedure success is defined as a lesion opened with <30% residual stenosis without complications.
Enter Yes, or No.

CASE COMMENTS

Enter relevant comments for the interventional case.

BTK VESSEL RUNOFF

Enter the number of patent below-the-knee vessels.



Next, enter medications the patient is taking prescribed before, during and after the procedure.

ANTI-COAGULATION USED

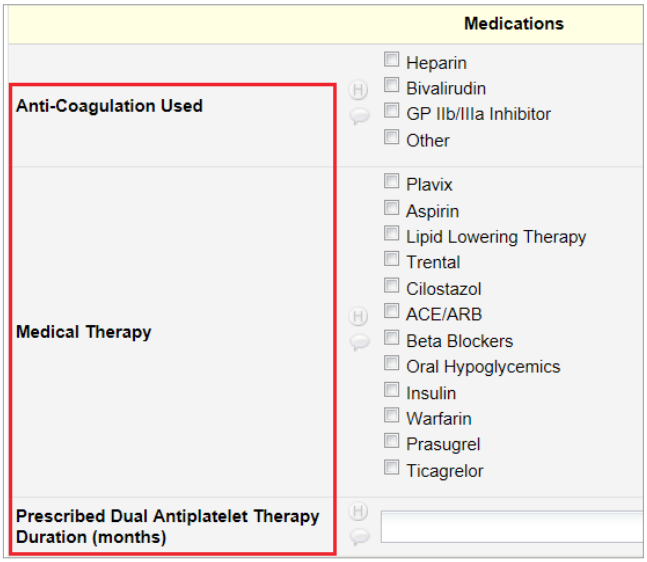
Enter Heparin, Bivalirudin, GPIIb/IIIa Inhibitor, or Other.

MEDICAL THERAPY

Enter Plavix, Aspirin, Lipid Lowering Therapy, Trental, Cilostazol, ACE/ARB, Beta Blockers, Oral Hypoglycemics, Insulin, Warfarin, Prasugrel, or Ticagrelor.

PRESCRIBED DUAL ANTIPLATELET THERAPY DURATION (MONTHS) RIGHT AFTER THE PROCEDURE

Enter the number of months of prescribed Dual Antiplatelet Therapy.



LABS

Enter most recent lab results before the procedure including WBC, Hgb, HCT, RBC, Platelets, Sodium, Potassium, Glucose, Creatinine, Total Cholesterol, LDL, HDL, and Triglyceride. Please make sure these are Pre-op before procedure.

Labs	
WBC	
HgB	
HCT	
RBC	
Platelets	
Sodium	
Potassium	
Glucose	
Creatinine	
Lipid Profile	
Total Cholesterol	
LDL	
HDL	
Triglyceride	

CATH LAB DATA

Enter contrast Type (check Visipaque, Hexabrix, Hypaque, Omnipaque, or Other), Duration of Procedure, Contrast Volume, Fluoroscopy Time (minutes), Dose Area Product, and Peak Activated Clotting Time.

	Visipaque	Hexabrix	Hypaque	Omnipaque	Other
Contrast Type	☐	☐	☐	☐	☐
If other please mention:					
Duration of Procedure (minutes)					
Contrast Volume (mL)					
Fluoroscopy Time (minutes)					
Dose Area Product (Gy-cm^2)					
Peak Activated Clotting Time					

PROCEDURAL COMPLICATIONS

Enter Yes or No.

BARC CLASSIFICATION

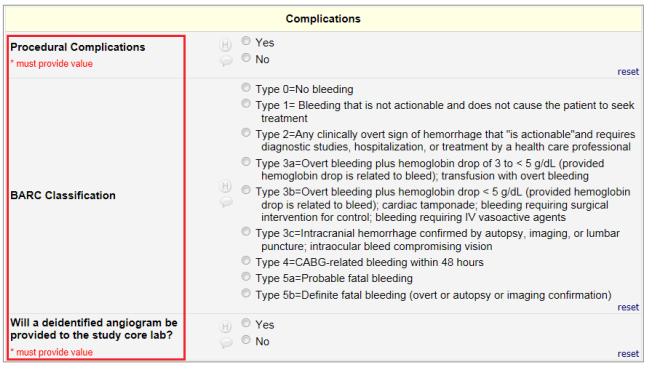
Enter the BARC classification from Type 0-5b.

BLEEDING ACADEMIC RESEARCH CONSORTIUM (BARC) CLASSIFICATION

TYPE	DEFINITION
0	No evidence of bleeding
1	Bleeding that is not actionable and does not cause the patient to seek treatment by a healthcare professional
2	Any clinically overt sign of hemorrhage that is actionable and requires diagnostic studies, hospitalization, or treatment by a healthcare professional
3a	Overt bleeding plus hemoglobin drop ≥3 to <5 g/dL (provided hemoglobin drop is related to bleeding). Cardiac tamponed, bleeding requiring surgical intervention for control; bleeding requiring IV vasoactive agents
3b	Overt bleeding plus hemoglobin drop ≥5 g/dL (provided hemoglobin drop is related to bleed).
3c	Intracranial hemorrhage confirmed by autopsy, imaging, or lumbar puncture. Intraocular bleed compromising vision
4	Coronary Artery Bypass Graft–related bleeding within 48 hours
5a	Probable fatal bleeding
5b	Definite fatal bleeding (overt or autopsy or imaging confirmed)

WILL A DE-IDENTIFIED ANGIOGRAM BE PROVIDED TO THE STUDY CORE LAB

Enter Yes or No.

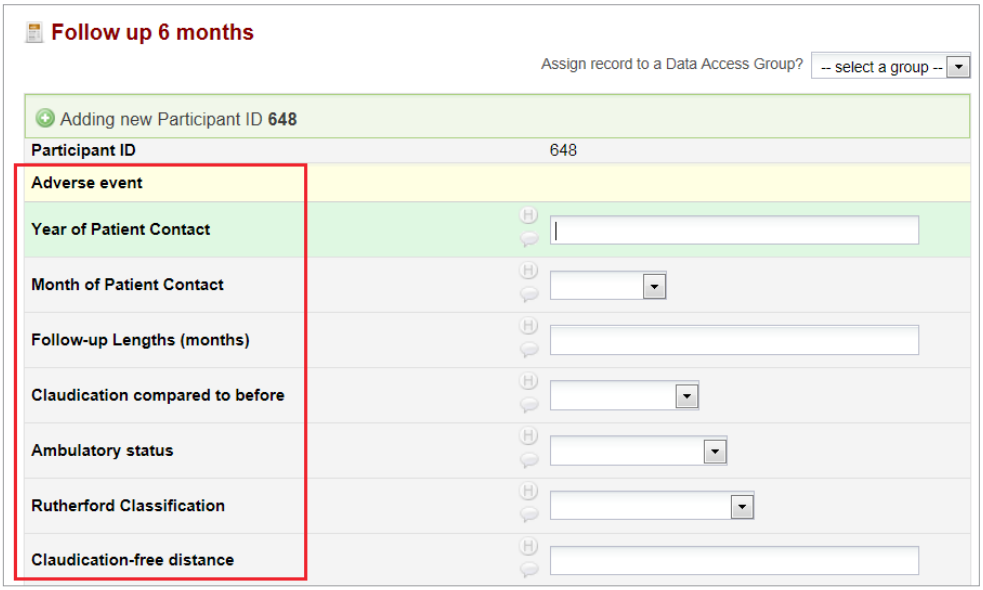


FORM STATUS

After completing the outcome results, save the data as described before.

FOLLOW UP 6 MONTHS
SINCE THE PROCEDURE

Note: All the information for Follow up 6 months will be collected from the institution's electronic medical data system and entered into the XLPAD registry by the study team. Data will be verified periodically by the primary investigator.



YEAR OF PATIENT CONTACT
Enter the year (YYYY) of contacting patient for follow up.

DATE OF PATIENT CONTACT
Enter the date of patient contact. The system will then generate a dummy date automatically.

FOLLOW-UP LENGTHS (MONTHS)
Enter how many months the patient has been followed-up.

CLAUDICATION COMPARED TO BEFORE
Enter Improved, same as before, or worsened from the drop-down menu.

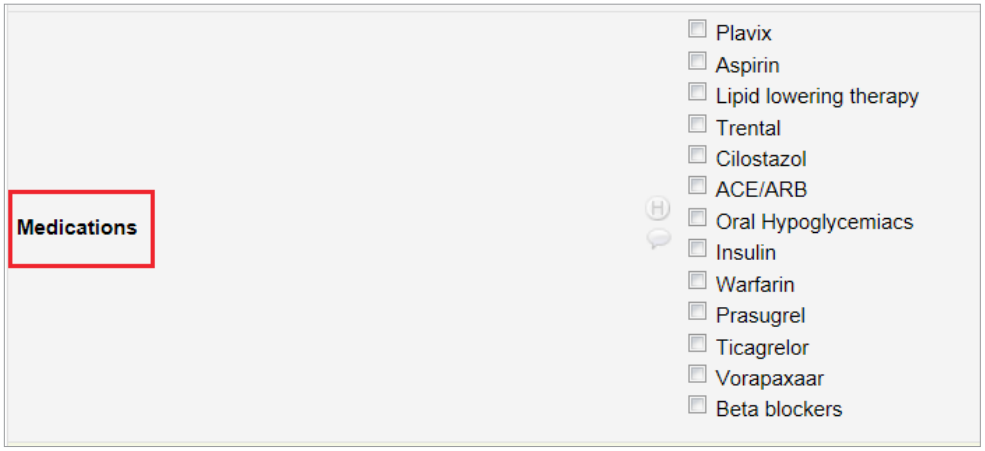
AMBULATORY STATUS
Enter the patient ambulatory status from the drop-down menu: Not Ambulatory or Walk, assisted, or Walk, unassisted.

RUTHERFORD CLASSIFICATION
Enter the Rutherford classification from the drop-down menu: No claudication, or Rutherford classification I to V.

CLAUDICATION-FREE DISTANCE
Enter the patient walking claudication-free distance in feet (eg., 50).

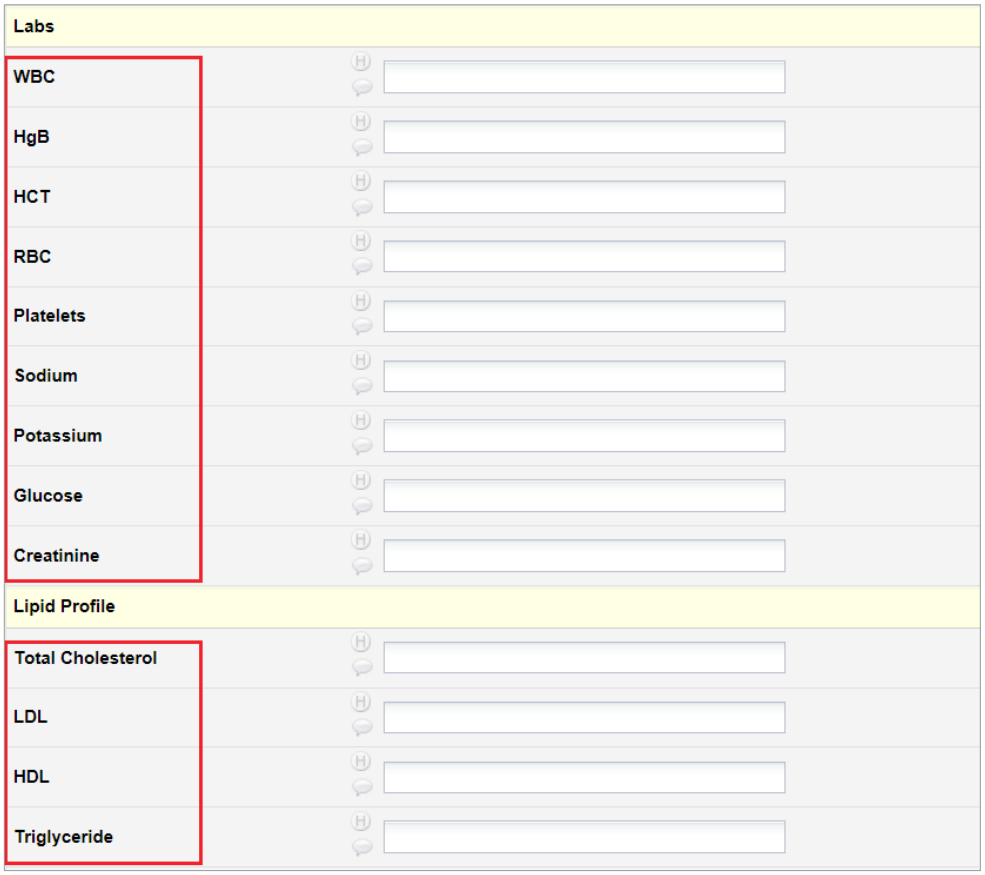
MEDICATION

Enter the current medication the patient is taking at the 6-month follow up: Plavix, Aspirin, Lipid Lowering Therapy, Trental, Cilostazol, ACE/ARB, Oral Hypoglycemics, Insulin, Warfarin, Prasugrel, Ticagrelor, Vorapaxar, or Beta Blockers.



LABS

Enter most recent lab results at the 6-month follow up: WBC, Hgb, HCT, RBC, Platelets, Sodium, Potassium, Glucose, Creatinine, Total Cholesterol, LDL, HDL, and Triglyceride.



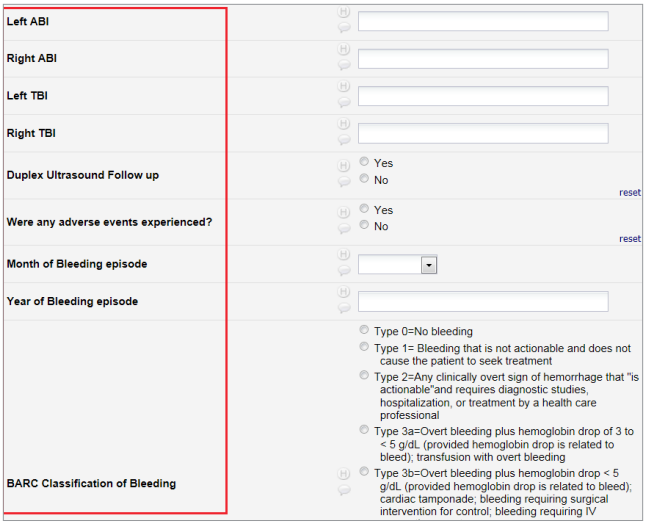
ABI/TBI
Enter the value of Left ABI, Right ABI, Left TBI, and Right TBI.

DUPLEX ULTRASOUND FOLLOW UP
Enter YES or NO.

WERE ANY ADVERSE EVENTS EXPERIENCED?
Enter YES or NO.

DATE OF BLEEDING EVENT
Enter the date of the bleeding event. The system will then generate a dummy date automatically.

BARC CLASSIFICATION
Enter the BARC classification from Type 0-5b.



FORM STATUS
After completing the outcome results, save the data as described before.

FOLLOW UP 12 MONTHS
SINCE THE PROCEDURE

Note: All the information for Follow up 12 months will be collected from the institution's electronic medical data system and entered into the XLPAD registry by the study team. Data will be verified periodically by the primary investigator.

The format is the same as follow up 6 months.

CORE LABORATORY ANGIOGRAPHIC ANALYSIS

CERTIFICATION OF ANGIOGRAPHER

For the VA North Texas Health Care System (VANTHCS) peripheral artery angiography and ultrasound core laboratory is of utmost importance to assess on a regular basis the inter- and intra-observer variability within the core lab, thereby making sure that each core lab analyst meets the strict requirements for offline core lab analysis. To minimize variability as much as possible, assessment programs, standard operating procedures and detailed training on a large variety of real world applications are conducted. Maintenance of training records and levels of experience is another vital element. This process is under oversight of the core lab director. Prior to study data analysis and technical certification, all core lab analysts will review 10 cases with the core lab director for intra and inter-observer verification to be certified. In addition, the certified angiographer will have to complete VA HIPAA, HSP, GCP and required study protocol training.

QUANTITATIVE VASCULAR ANALYSIS (PIE MEDICAL IMAGING-CAAS QVA VERSION 3)

There are 4 components to Quantitative Vascular Analysis in the core laboratory

- Image acquisition and digital processing
- Image Selection
- Calibration
- Quantitative Angiographic Analysis

IMAGE ACQUISITION AND DIGITAL PROCESSING

Image acquisition is done according to Good Clinical Practices (GCP) in a de-identified manner.

After placing a blank cd/dvd in the dvd drive, the required study images are selected.

1) Right click and select 'Copy File'.
2) A pop-up window will come up asking to upload image on server or cd/dvd. Click cd/dvd.
3) Click on anonymize. Then a pop-up window will give it an anonymized number. Click OK.
4) Image will be uploaded on to the server. After that it will be uploaded on the cd/dvd.
5) Place a label with subject number, date and site number, location and file it accordingly.

IMAGE SELECTION

1) Open the cd/dvd in the RUBO Dicom viewer software. The dicom viewer should be able to open up all runs of the angiogram.
2) Select up to 12 images for QVA. At least 2-3 images should be selected for Catheter Calibration.
3) Desired images can be selected by pausing the run where it is best suited for analysis.
4) After pausing, right click and select Save Image for Analysis in the desired location.

CALIBRATION

Calculation of Calibration Factor (CF) is necessary for accurate analysis. The Calibration Factor converts distances in images in pixels to real world distances in mm. Following calibration methods are used:

- Catheter Calibration
- Manual Calibration

Always first attempt for catheter based calibration as it is most commonly used method for calibration. If not successful, enter Calibration factor manually (mm/pix).

Figure 2 Calibration Factor

Catheter Calibration

1) Click Catheter to start Calibration
2) Select catheter size in French (3 French=1 mm) from drop down box values or enter it manually. Click Apply to accept the change.

Figure 1 Catheter selection

3) Select the catheter in the image. Left mouse click on the centerline of catheter and double click on the center of the catheter.
4) Click Accept to apply the Calibration Factor.

The selected area within the catheter can be curved or straight. Make sure that the selected area is no longer than 10 mm in length otherwise error can occur in calculating the correct Calibration factor. Contrast filled or empty catheters can be used.

Same Calibration Factor for Multiple Images

Use the same CF for all images to maintain consistency of all analyses. After calculating the Calibration Factor, select Copy Calibration. The CAAS program will show all selected images. Select the image required and double click to apply the Calibration Factor on second image. In this way, multiple images can be selected.

Delete Calibration

If the calibration is incorrect, click Delete Last and previous calibration factor can be used. If needed, click Delete All to remove all calibrations.

QUANTITATIVE ANGIOGRAPHIC ANALYSIS

Following steps are involved after calculating Calibration Factor

- Contours Selection
- Obstruction Analysis
- Sub-segment Analysis
- Graphical presentation
- Results

Contours Selection

Correct contour selection of image being analyzed is necessary for accurate analysis. Following steps are involved in contour selection:
Contour detection starts with single left click and creating a centerline at the start of arterial segment in the direction of blood flow.
Continuously make single left clicks until reaching at the end of the arterial segment.
Double click at the end of segment. The centerline drawn should be within the lumen of the arterial segment.

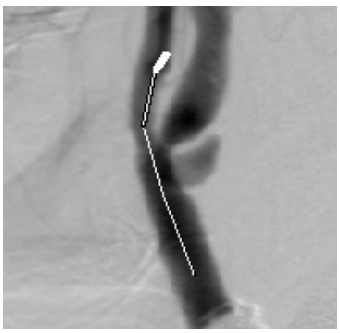
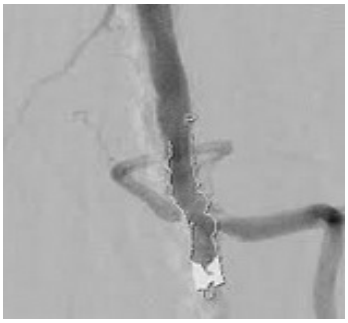
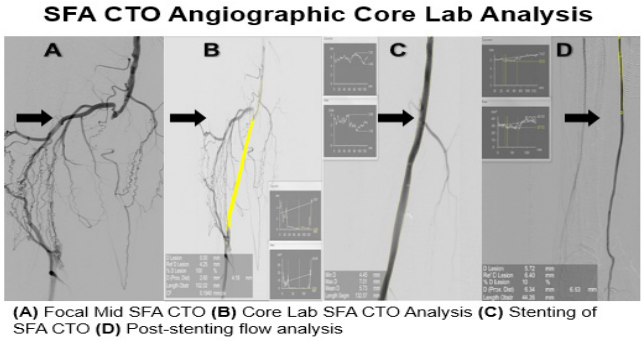


Figure 3 Contours Selection

Make sure that proximal and distal ends of the segment are clear landmarks. Side branches can be a good reference point. The software will calculate proximal and distal of the arterial segment separately as P (Proximal) and D (Distal). Contour detection cannot be done for totally occluded arterial segments.





(A) Focal Mid SFA CTO **(B)** Core Lab SFA CTO Analysis **(C)** Stenting of SFA CTO **(D)** Post-stenting flow analysis

Figure 4 Contours Detection and CTO Analysis

Contour Editing

Contour editing can be done if changes are needed. This can be done by restricting or correcting the contours. Restriction: Restriction can be done after contours are selected.

1) Draw a line outside the vessel.
2) Move the mouse until a black and white pencil appears.
3) After a single left click, a green line will be drawn.
4) Continue to click and move the mouse until required green line is drawn (restriction line).
5) Double click to complete the restriction line which will change right away.

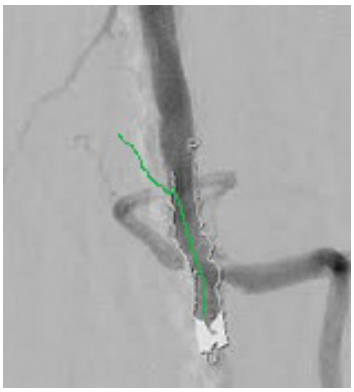


Figure 5 Contours Restriction

Correction

One can select Soft Correction if allowing software to change contours automatically or Hard Correction if changed manually by user.

1) Draw a line towards the vessel.
2) Move the mouse until a black and white pencil appears.
3) After a single left click, a green line will be drawn.
4) Continue to click and move the mouse until required green line is drawn (corrected line).
5) Double click to complete the corrected line which will change right away.

Selecting the soft or hard option will have it corrected accordingly. Once done, correction cannot be altered. Click Discard to re-do correction.

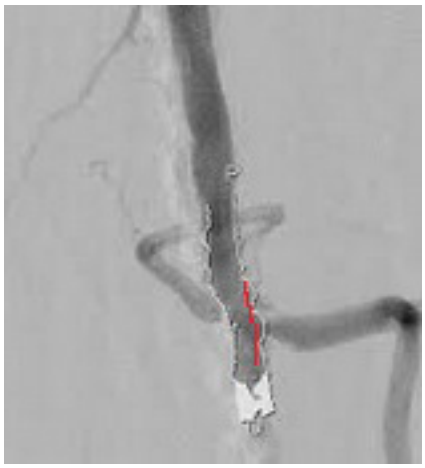


Figure 6 Contours Correction

Obstruction Analysis

Obstruction analysis is done to calculate the Minimal Luminal Diameter (MLD) compared with the Reference Diameter. The reference diameter is the diameter at position of MLD if there was no stenosis present. Percentage diameter stenosis is calculated as follows:
% MLD = (1-MLD/Reference diameter) ×100%
After finalizing the contours, move the mouse towards Obstruction Analysis and click on Automatic .The software will automatically calculate MLD, proximal and distal boundaries and reference diameter.

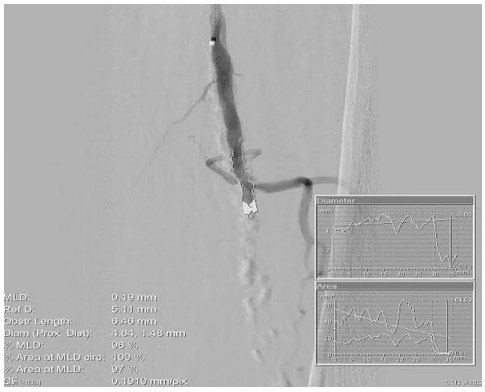


Figure 7 Obstruction Analysis

Sub-segment Analysis

1) Sub-segment analysis can be done by clicking on User Define.
2) After clicking on User Define, move the mouse cursor on the position borders to change its shape.
3) Hold the mouse and drag the line to move the border.
4) Once mouse is released, borders will be repositioned.

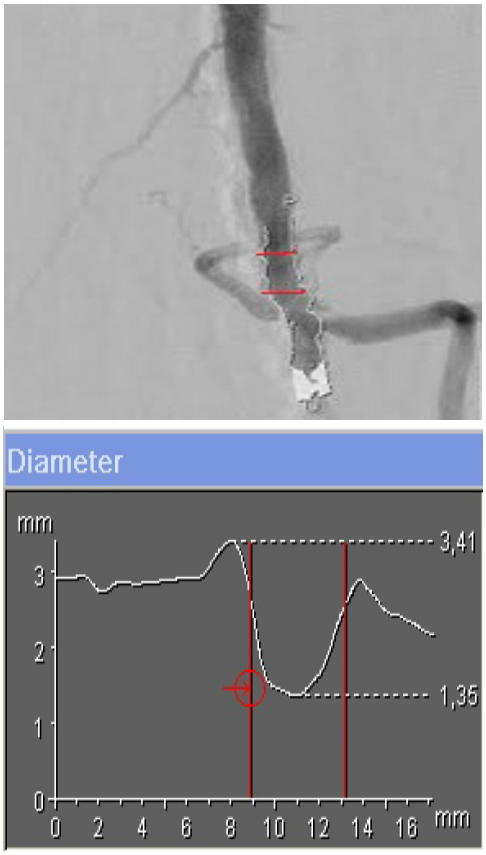


Figure 8 Sub-segment Analysis

Graphical Representation

For graphical results, please select Diameter and Area.
The diameter graph will show maximal and minimal diameter and Area curve if plaque distribution is symmetrical or asymmetrical within the segment.

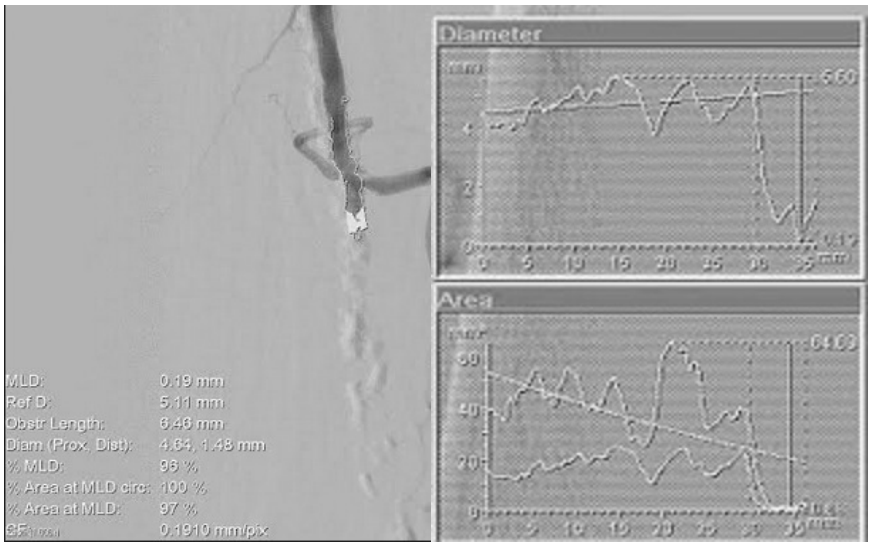


Figure 9 Graphical

Report

The results can be seen on left hand corner of image.
Click Report to generate results of the analyzed segment. Save the report in respected folder for computing the data into the electronic data capture system of study per study protocol.
After final analysis and report generation, file cd/dvd in site specific folder per study protocol.

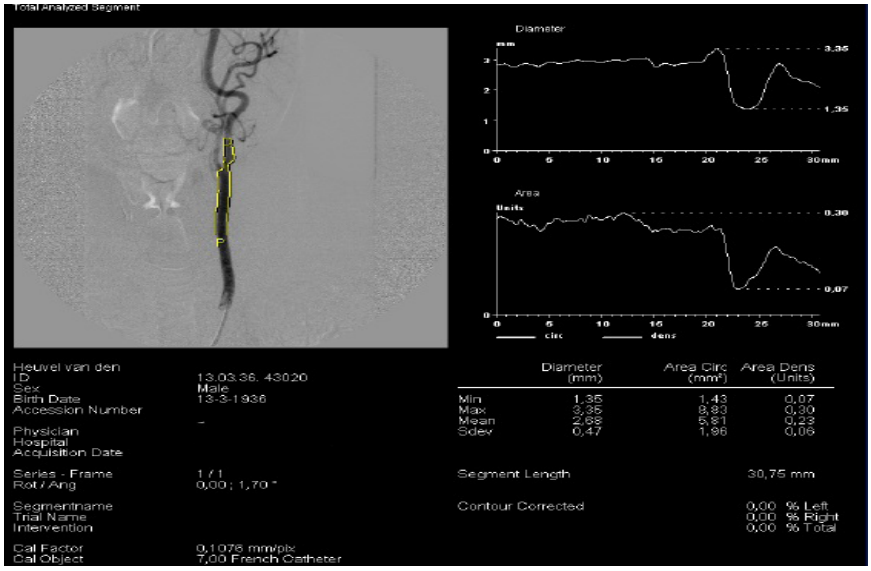


Figure 10 Report

Stent Analysis

Angiographic analysis within the stent is done in a similar fashion as target lesion with following additional variables:

- In-segment percent stenosis
- In-stent percent stenosis

In-segment percent stenosis
This is calculated by following formula:
1-Segment MLD/Reference Diameter*100

In-stent percent stenosis
This is calculated by following formula:
1-Stent MLD/Reference Diameter*100

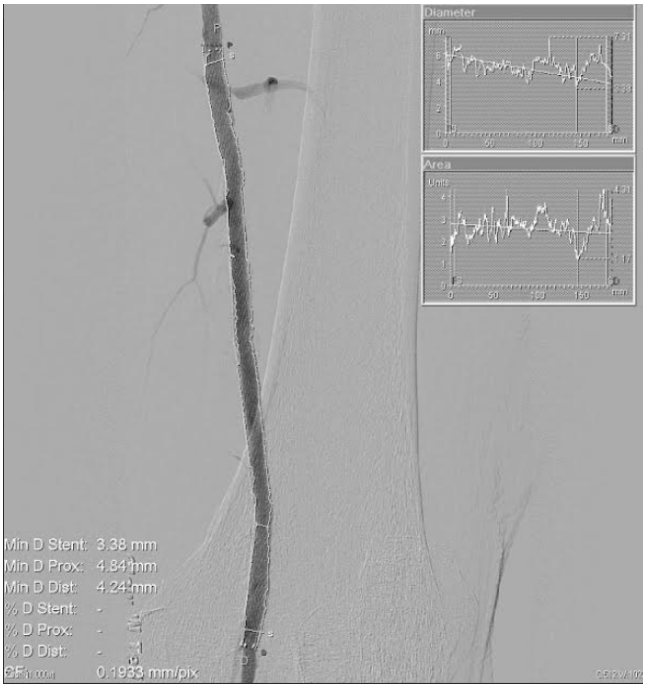


Figure 11 Stent Analysis

OTHER ANGIOGRAPHIC VARIABLES

The following angiographic variables have to be analyzed, however these will be performed in a subjective fashion and done visually by the angiographer.

- TIMI flow
- Lesion Length
- Location
- Calcification
- Thrombus
- Concentric/Eccentric
- Stump of Chronic Total Occlusion
- Distal Reconstitution
- Collaterals
- Run-off
- Below the Knee Anatomy Variants
- Dissection
- Perforation
- Bend
- Tortuosity
- No reflow
- Spasm
- Distal embolism

TIMI Flow

TIMI (Thrombolysis in Myocardial Infarction) flow is graded according to velocity of blood flow through diseased segment into 4 grades

TIMI 0 flow (Most commonly seen in totally occluded arteries).

TIMI 1 flow (penetration without perfusion) is faint antegrade flow beyond the occlusion, with incomplete filling of the distal vascular bed.

TIMI 2 flow (partial reperfusion) is delayed or sluggish antegrade flow with complete filling of the distal territory.

TIMI 3 is normal flow which fills the distal vascular bed completely

Lesion Length

Lesion length is length of diseased vessel which can be measured by clicking on MEAS to measure desired segment from top to bottom.

Figure 12 Measuring tool

This will give length of lesion in mm.

Location

Lesion location can be Ostial (origin point of artery) Proximal (first 1/3rd of artery) Mid (Middle 1/3 rd. of artery) and Distal (distal 1/3 rd. of artery).

Calcification

Calcification whitening deposits seen at times during injection of dye or even at times before injection of dye. It is measured into 3 grades based on angiographic exam.

- Mild-the presence of either isolated foci of calcification
- Moderate-contiguous segments of calcification on one or alternating sides of the vessel
- Severe-contiguous calcification on both sides of the vessel

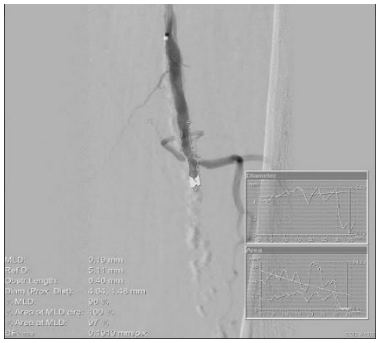


Figure 13 Severe Calcification

Thrombus

Thrombus is defined as the presence of a roundish filling defect of the lumen during dye injection (in multiple projections) with or without persistence of luminal contrast following dye injection. It is most commonly seen in chronic total occlusions. Following are grades of thrombus:

0: No cine angiographic characteristic of thrombus present

1: Possible thrombus present.Angiography demonstrates reduced contrast haziness,irregular lesion contour or a smooth convex meniscus at the site of chronic total occlusion suggestive but not idagnostic of thrombus.

2: Thrombus present small size –Greatest dimensions present or equal to ½ vessel diameter

3: Thrombus present moderate size –greater than ½ vessel diameter but still less than 2 vessle diameters.

4: Thrombus bgger than grade 3 with dimensions present equal or greater than 2 vessel diameter

5: Total occlusion

Concentric/Eccentric

Concentric means lesion/plaque is present circumferentially on all sides of vessel wall.

Eccentric means lesion having one of its edges in the outer one quarter of the apparently normal lumen (indicating that there was three times as much plaque on one side of the lesion as on the other); in most angiographic studies, 50% to 60% of lesions appear to be eccentric.

Stump or Cap of Chronic Total Occlusion

Stump is starting and ending point of a chronic total occlusion. It can be either blunt, tapered or stumpless.

Blunt Stump: A blunt stump of chronic total occlusion is when there is abrupt occlusion with no microchannel at the proximal end of chronic total occlusion.

Tapered Stump: It is defined as progressive narrowing of the proximal or distal cap with or without a clear microchannel.

Stumpless or No stump: It occurs when proximal or distal cap could not be angiographically defined.

Distal Reconstitution

Distal reconstitution is defined as restoration of blood flow distal to a totally occluded or diseased segment due to collateralization of distal blood vessels.

Collaterals

Collaterals are small blood vessels that grow over time to supply blood flow to the totally occluded segment or diseased segment. The extent of collaterals can give an idea of how long the vessel has been totally occluded. For CTOs, collaterals or collateral connections can be graded as:

Grade 0: no continuous connection between collateral supplying and receiving vessel

Grade 1: threadlike continuous connection

Grade 2: side-branch–like connection

Run-Off

Distal run-off refers to infra-popliteal blood flow which is critical to determine for crossing fem-popliteal lesions. It can be from 0-3 vessel run-off depending on presence of disease in Anterior Tibial Artery, Posterior Tibial Artery and Peroneal Artery.

- If all 3 blood vessels are normal then it is graded as 3 vessel run-off.
- If 2 blood vessels are normal then it is graded as 2 vessel run-off.
- If 1 blood vessel is normal then it is graded as 1 vessel run-off.
- If 0 blood vessels are normal then it is graded as 0 vessel run-off.

Blow the Knee Anatomy variants

Below the Knee(BTK) Anatomy is graded into 3 types:

Type I: Variations of BTK 85%
Type IA: Presence of tibioperoneal (TP) trunk
Type IB: No TP trunk
Type IC: Peroneal Artery (PA) arising from Anterior Tibial (AT) artery.

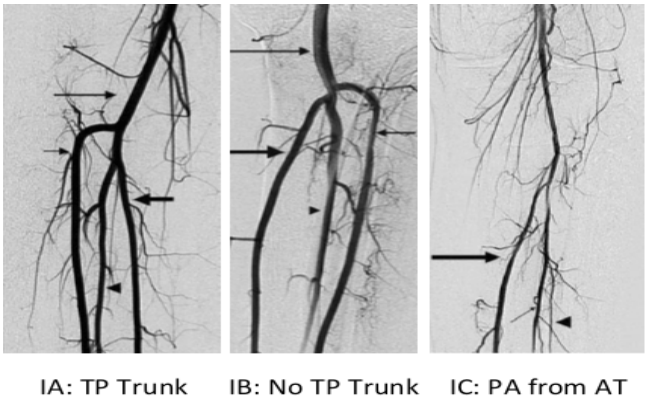
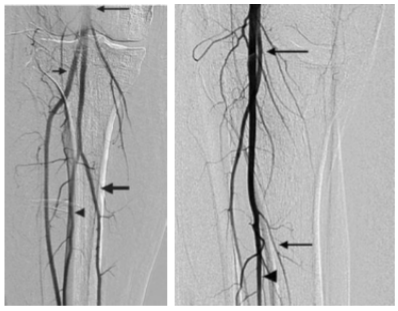


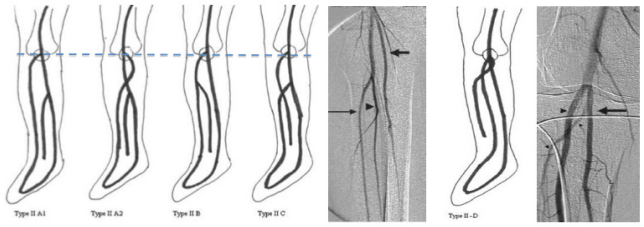
Figure 14 Type I Variations

Type II: Variations of ATK origin (10%)
Type IIA1: AT arises above the knee; normal course.
Type IIA2: AT arises above the knee; initial medial course.
Type IIB: Posterior Tibial (PT) above the knee take-off.
Type IIC: Posterior Tibial (PT) arises below the knee take-off.
Type IID: AT, PA & PT arise above the knee, AT has initial medial course.



IIA1: AT arises above The knee; normal course

IIA2: AT arises above the knee; initial medial course



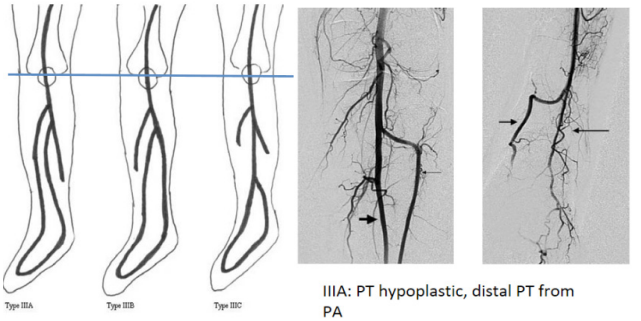
IIB: PT above the knee take-off

IID: AT, PA & PT arise above the knee, AT has initial medial course

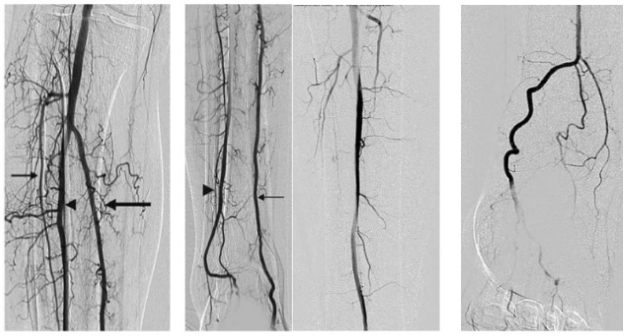
TP: Tibio-peroneal trunk
PA: Peroneal artery
AT: Anterior tibial artery
PT: Posterior tibial

Figure 15 Type II Variations

Type III: Variations of hypoplastic arteries (5%). Type III is divided into 3 types based on which vessel is hypoplastic.
Type III A: PT is hypoplastic
Type III B: AT is hypoplastic. Distal AT arises from PA.
Type IIIC: AT & PT hypoplastic, dorsalis pedal artery arises from PA



IIIA: PT hypoplastic, distal PT from PA



IIIB: AT hypoplastic, distal AT from PA

IIIC: AT & PT hypoplastic, dorsalis pedal artery from PA

Figure 16 Type III Variations

Dissection

Dissection or tear is defined as a marked irregularity of the vessel wall after the procedure, luminal filling defect suggestive of intimal flap, or extravasation of contrast outside the lumen after dilatation. The length of the filling defect is measured in mm.
Dissection can be flow-limiting (Flow-limiting dissection was defined on the basis of (a) a persistent diameter reduction of greater than 30% at visual determination or (b) slow contrast material runoff similar to TIMI (thrombolysis in myocardial infarction) I or TIMI II flow) or non-flow limiting (no change in lumen) and classified into following types:

Type A dissections represent minor radiolucent areas within the coronary lumen during contrast injection with little or no persistence of contrast after the dye has cleared.

Type B dissections are parallel tracts or a double lumen separated by a radiolucent area during contrast injection, with minimal or no persistence after dye clearance.

Type C dissections appear as contrast outside the coronary lumen ("extraluminal cap") with persistence of contrast after dye has cleared from the lumen.

Type D dissections represent spiral ("barber shop pole") luminal filling defects, frequently with excessive contrast staining of the dissected false lumen.

Type E dissections appear as new, persistent filling defects within the coronary lumen.

Type F dissections represent those that lead to total occlusion of the coronary lumen without distal antegrade flow.

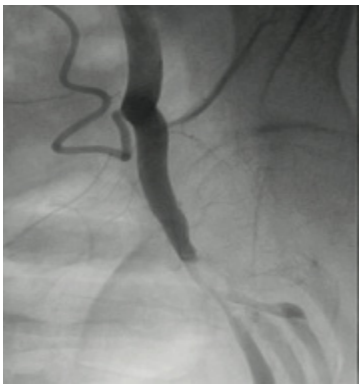


Figure 17A Dissection in External Iliac Artery

Perforation
Perforation is defined as extravasation of contrast outside vessel wall.

Bend
The lesion is assigned to have a Bend point if there is bending of > 45 degrees.

Tortuosity
Tortuosity is more common in coronary arteries is defined as more than 1 bending points of > 45 degrees. Severe tortuosity is defined as more than 2 points of bending > 90.

No reflow
No-reflow is reduction in flow to TIMI grade 1 or 2 after percutaneous intervention without any obstruction.

Spasm
Spasm is reduction in blood flow due to catheter during the procedure.

Distal Embolization
Distal embolization leads to occlusion of artery distal to intervened artery due to embolization of atherosclerotic debris.

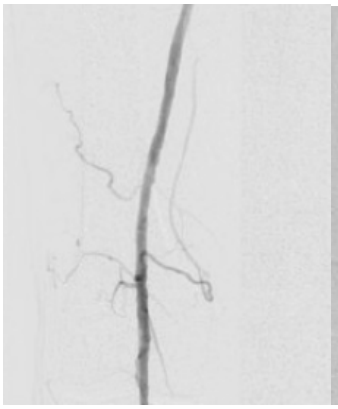


Figure 18 A- Treated SFA

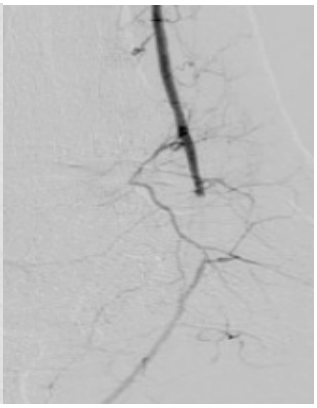


Figure 18 B- Distal emboli in Posterior Tibial Artery

INTRAVASCULAR ULTRASOUND ANALYSIS (INDEC ECHOPLAQUE AND LIBERATOR SYSTEMS, VERSION 4)

- To detect stent expansion
- To detect lumen of occluded artery
- To detect degree of calcification

DETECTION OF TRUE VERSUS FALSE LUMEN IN CASES WITH DISSECTION OR UNDERGOING SUBINTIMAL ANGIOPLASTY

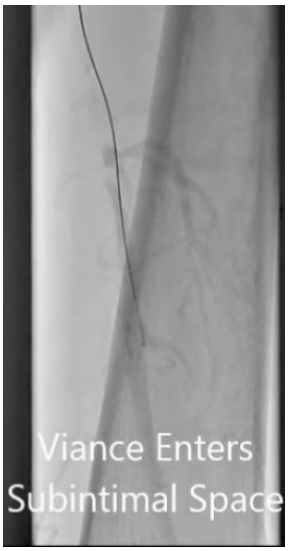


Figure 19A-Viance entry into subintimal space

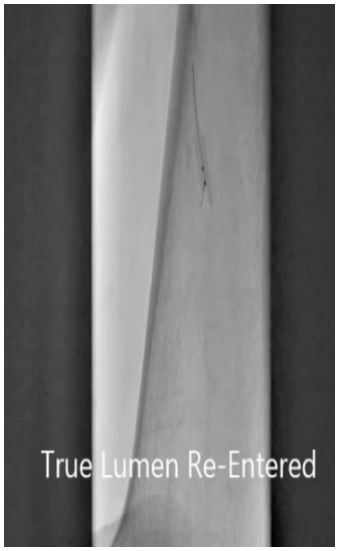


Figure 19B- Re-entry of true lumen

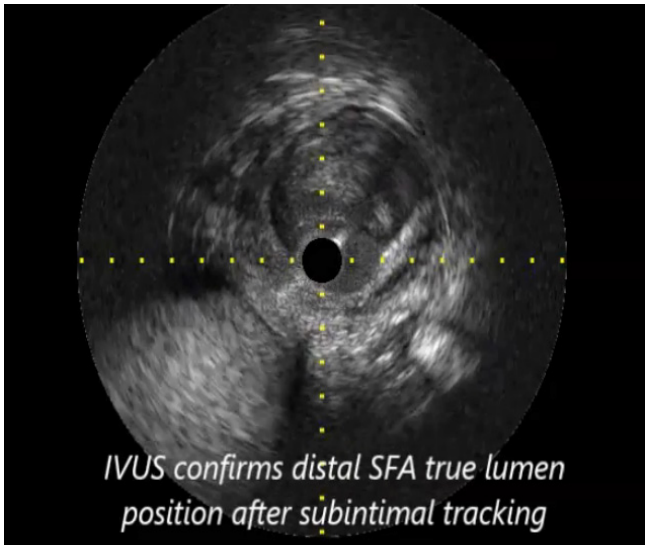


Figure 19C-IVUS confirmation of True Lumen

DEGREE OF CALCIFICATION

IVUS helps in detecting degree of calcification if it is Superficial or Deep. Following are grades of Calcification:

Grade 0: no calcification (score 0)
Grade I: isolated foci of calcification (score 1)
Grade 2: contiguous segments of calcification on one side of the vessel <5 cm in length (score 2)
Grade 3: contiguous segments of calcification on one side of the vessel ≥5 cm in length (score 3)
Grade 4: contiguous calcification on both sides of the vessel <5 cm in length on either side (score 4)
Grade 5: contiguous calcification on both sides of the vessel ≥5 cm in length on either side (score 5)
Add score of 1 to each grade score for calcification involving ≥50% of the diameter of the reference vessel, whenever available. Max. score=6; Min. score=0

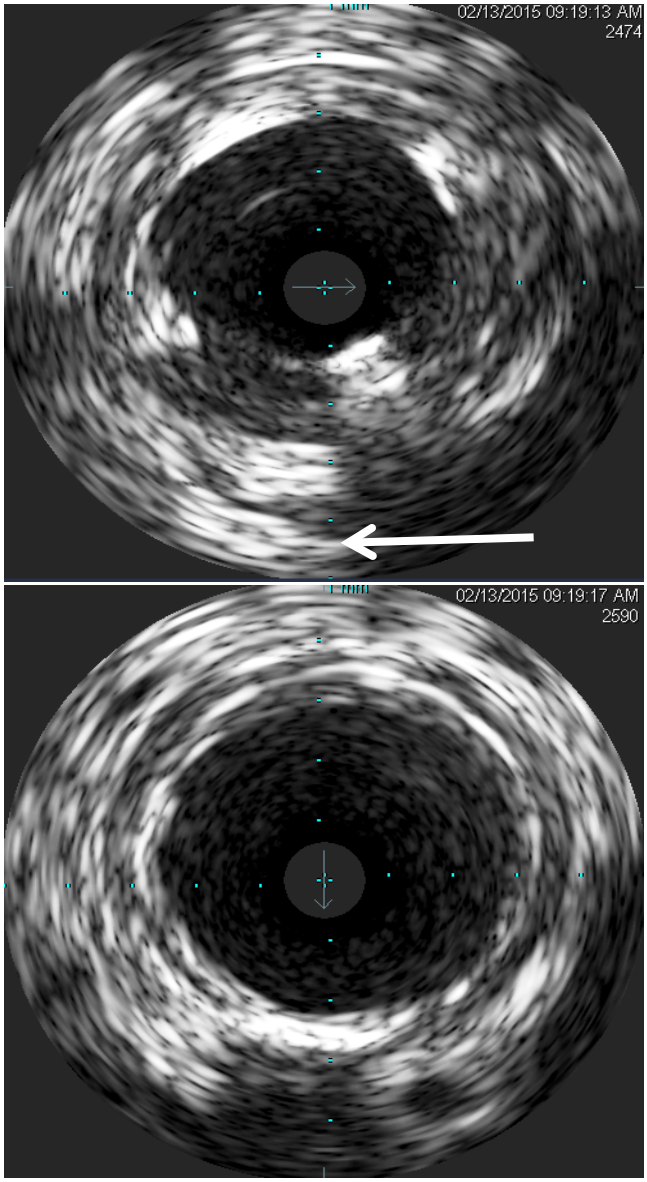


Figure 20 Stent expansion and Superficial and deep calcification on IVUS (white arrows).

NEAR INFRAREDX SPECTROSCOPY LIPISCAN ANALYSIS

Lipiscan is used for analysis of lipid plaque content within the blood vessel. The Lipid Core Burden Index (LCBI) is a measurement quantifying the degree of Lipid Core Plaques (LCP) present within a scanned region, and is computed as the fraction of pixels that exceeds the LCP probability of 0.6, multiplied by 1,000. It helps with true vessel characterization of blood vessels by detecting lipid plaque content within the target vessel.

Clinical Benefits

Discover Culprit Lesions

- See real-time information about vessel structure including plaque burden and composition
- Assess lesion size, shape, and structure to manage patient risk

Optimize Procedures

- Define normal-to-normal to plan local treatment areas and stent landing zones
- Determine stent diameter and length for complete lesion coverage
- Personalize medical therapy plans

Monitor Outcomes

- Confirm stent expansion and apposition
- Evaluate a patient's disease profile over time

NIRS IVUS LIPISCAN ANALYSIS

We analyze NIRS-IVUS automated pullback runs performed on patients undergoing percutaneous endovascular intervention for symptomatic lower extremity PAD.

The 3.2 French NIRS-IVUS coronary catheter has a working length of 165 cm, is compatible with 6 French guide catheters, and can be introduced into the target vessel over a 0.014" guidewire. Automatic pullback is accomplished using a mechanical pullback and rotation device at a speed of 0.5 mm/sec and 960 RPM, and the maximum pullback length is 120 mm before the NIRS-IVUS catheter is withdrawn into the guide catheter. The IVUS modality of the catheter is conventional 40 MHz rotational ultrasound which

usually gives the best compromise between resolution, penetration depth, and blood speckle for effective visualization of the vessel structure. Laser-based near-infrared spectroscopy is acquired simultaneously with the IVUS, and is inherently co-registered. The system acquires 4,000 NIR spectra per 12.5-mm of artery scanned, with each interrogating a volume of about 1 mm3 in the vessel wall. The majority of tissue information obtained is from a depth of 1-mm or less from the lumen surface towards the adventitia. The presence of lipid core plaque (LCP) as detected by NIR is displayed as a 2-dimensional image called the chemogram, which is a color-coded probability map with high LCP probability displayed as yellow and low probability red (x-axis is pullback and y-axis rotation, as if the artery were cut longitudinally and laid flat). The combined NIRS-IVUS findings are displayed on a composite image along with the transverse IVUS (Figure 1A). A summary display shows the probability of LCP within each 2-mm block of the pullback without regard to angular location of LCP. The color scale indicates increasing levels of probability whether LCP is present: red indicates P<0.57, orange 0.57≤P<0.84, tan 0.84≤P<0.98, and yellow P≥0.98 (block chemogram, Figure 1B). The system also computes the lipid core burden index (LCBI), a semi-quantitative parameter of the amount of LCP predicted in the entire pullback, (Figure 1B). The LCBI is computed as the fraction of pixels that exceeds the LCP probability of 0.6, multiplied by 1,000. The maximum LCBI present within a 4-mm segment (maxLCBI4mm) is an additional value calculated as the maximum LCBI measured for any 4-mm segment within a particular scanned region. For the purposes of analysis, the entire length of the run is the scanned region used to calculate the maxLCBI4mm value. Additionally, minimum/maximum vessel and lumen diameters, vessel and lumen areas, and degree of plaque burden were calculated (Figure 1A). Lumen measurements are made by manually tracing along the edge of the lumen after observation of differences in intensity of the lumen relative to the surrounding tissue, and such measurements along with associated presence of LCP were obtained at every 10mm interval (Figure 1B).

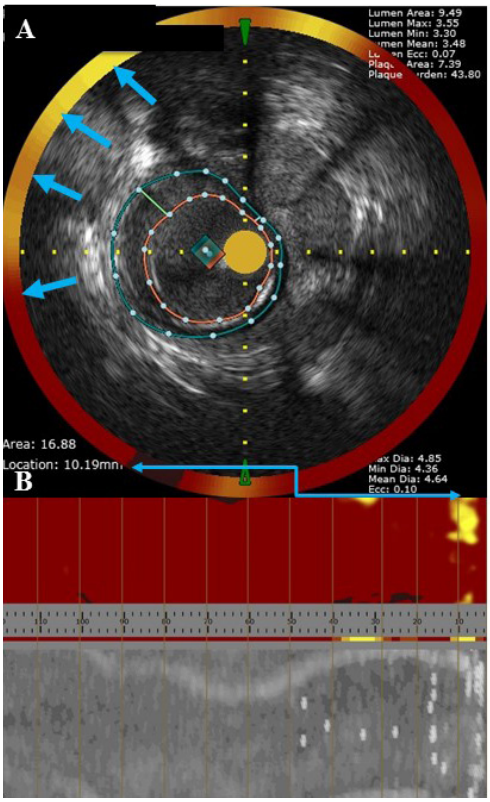


Figure 1: NIRS-IVUS: Chemogram with Intravascular Ultrasound

A) Grayscale intravascular ultrasound run surrounded by corresponding vertical slice of the chemogram. Outer green line area traces external elastic media area and the inner red line traces lumen area. Vessel diameter calculations are shown in bottom right corner and other lumen and plaque calculations are shown in the top right corner. Blue double arrow equates the longitudinal location on the chemogram that corresponds to the transverse frame display of the cross-sectional NIRS-IVUS. Blue arrows, going counter-clockwise, indicate differing probabilities of presence of LCP.

B) The chemogram is a 2-dimentional display of LCP presence, shown as if the artery were cut longitudinally and laid flat. LCP presence is shown as a color-coded probability map where yellow indicates high probability and red low. The x-axis is pullback distance, and the y-axis is rotation.

4-DUPLEX ULTRASOUND ANALYSIS

Objectives

- A procedural operations manual describing in detail, image acquisition, annotation and shipping.
- Review all studies for quality accuracy blinded of clinical presentation
- Analyze data and submit data management team
- Maintain data privacy and confidentiality

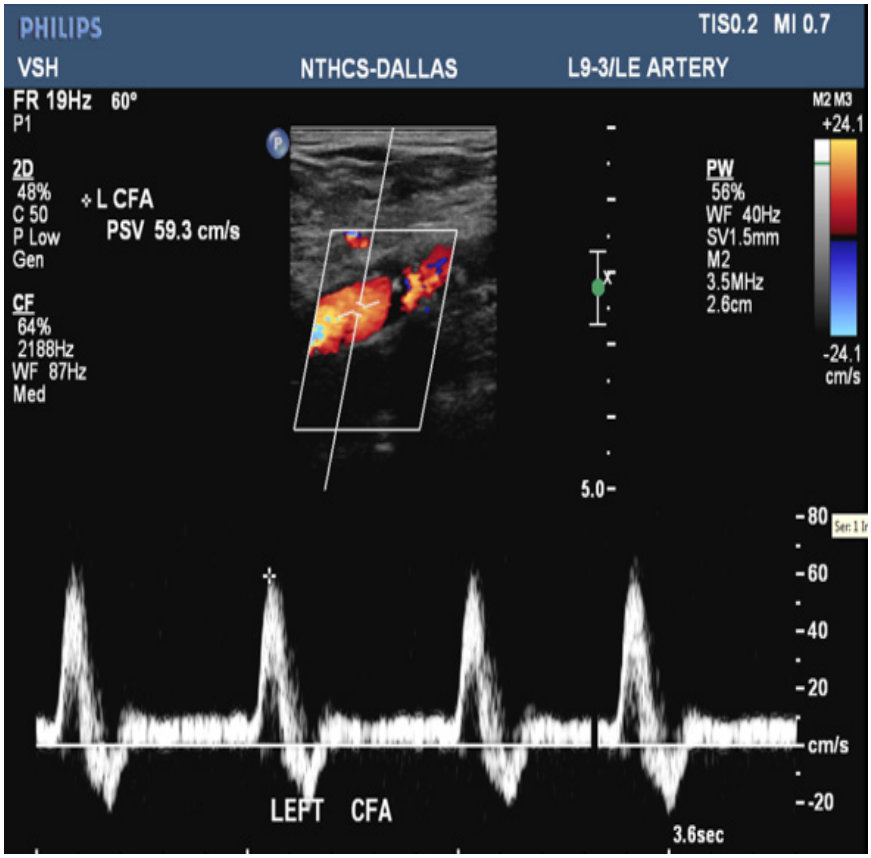
Site Certification and Reporting Of Images

The following protocol should be followed for site certification and proper reporting of images

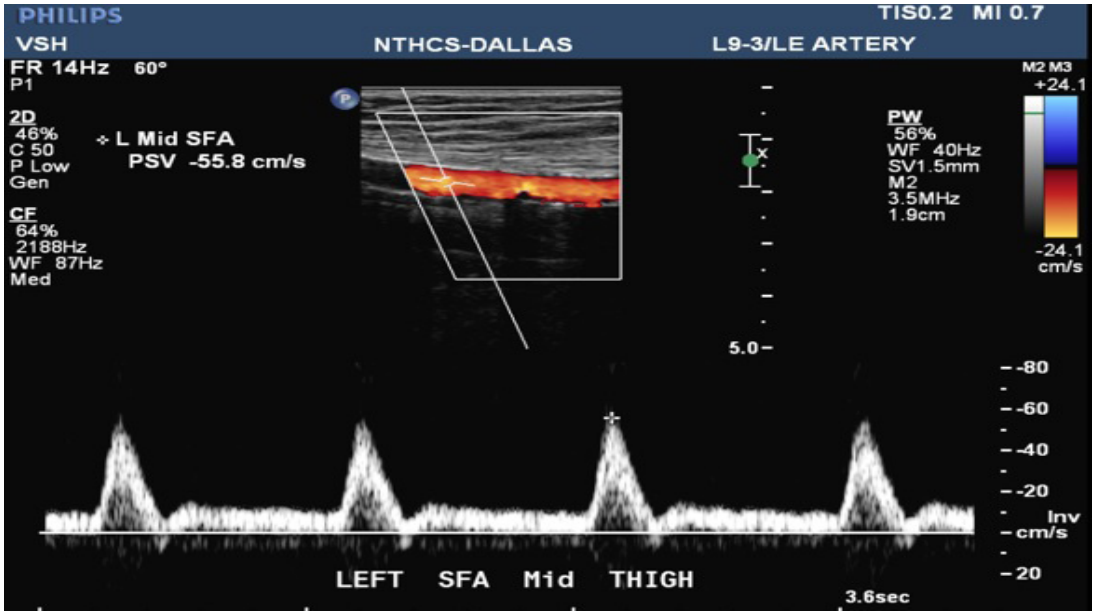
1) 2D ultrasound system
2) Appropriate and transduced. The transducer should operate at the highest clinically appropriate frequency, recognizing that there is a trade-off between resolution and penetration. This should usually be at a frequency of 3.5 MHz or greater, with the occasional need for a lower-frequency transducer.
3) Recording device of appropriate dicom format
4) Identify and use color doppler for proper assessment of vessels
5) Measure PSV (Peak Systolic Velocity) and EDV (End Diastolic Velocity) every 30 mm of Distal CFA, Prox Mid and Distal SFA And Prox Popliteal. Label all vessel according to anatomy and intervention status pre and post intervention.
6) In patients with a significant SFA stenosis or occlusion, flow into the popliteal artery should be examined with CDI to determine degree and integrity of flow reconstitution

For spectral examination

1) Only angles of 60 degrees or less will be acceptable and document PSV nearest proximal vessel for increase of PSV at any point
2) Calculate the PSV ratio
3) Cross-sectional or longitudinal residual diameter measurements with or without the use of CDI are notoriously inaccurate and do not correlate well with contrast angiographic findings.



Calculation of PSV



Criteria for Grading

DUPLEX CRITERIA FOR GRADING ARTERIAL STENOSES

	PEAK SYSTOLIC VELOCITY (PSV)	SPECTRAL WAVEFORM
Normal	70 – 100 cm/sec	Triphasic
< 50% stenosis	30 – 100% increase over proximal segment	Triphasic
> 50% stenosis	> 100% increase over proximal segment	Monophasic Turbulent
> 75% stenosis	PSV > 400cm/sec Pre-stenotic: stenotic radio; > 4:1	Monophasic High velocity Bruit may be heard
Occlusion	Absent flow Collaterals may be seen adjacent	Dampened proximal to occlusion
Aortoiliac disease	PSV in CFA ≤ 45cm/sec[29]	Monophasic

Recommendations for a good quality exam

- Apply heal toe technique for 60 degree angle measurement
- Doppler sample volume should be through entire course of vessel
- Obtain measurements every 30 mm of distal CFA prox, mid and distal SFA and prox Popliteal artery. For transverse B mode use 90 degrees between vessel and beam

Reasons for paucities in exam

- Incorrect angles
- Label mismatch for blood vessel
- Low quality images
- Incomplete worksheet, no gray scale images

Quality of Life Analysis

Rutherford Category

This classification is used to classify degree of lifestyle limiting claudication of patients.

Stage 0 – Asymptomatic

Stage 1 – Mild claudication

Stage 2 – Moderate claudication – The distance that delineates mild, moderate and severe claudication is not specified in the Rutherford classification, but is mentioned in the Fontaine classification as 200 meters.

Stage 3 – Severe claudication

Stage 4 – Rest pain

Stage 5 – Ischemic ulceration not exceeding ulcer of the digits of the foot

Stage 6 – Severe ischemic ulcers or frank gangrene

Ankle Brachial Index

1) Place the patient in the supine position, with the arms and legs at the same level as the heart, for a minimum of 10 minutes before measurement.

2) Select an appropriately sized blood pressure cuff for both the ankle and the arms; the cuff width should be at a minimum, 20% greater than the diameter of the extremity. The ankle cuff should go on the leg between the malleolus and the calf. Enough room should be left below the cuffs to permit placement of the ultrasound gel, so that the Doppler device can adequately detect the brachial, dorsalis pedis (DP), and posterior tibial (PT) pulses.

3) Obtain the brachial systolic pressures of both arms, and choose the higher of the 2 values as the brachial systolic pressure (the difference between them should be less than 10 mm Hg). The brachial pulse is best appreciated on the medial side of the antecubital fossa.

4) Obtain the anterior tibial and posterior tibial systolic pressures of the extremity in question, and select the higher of the 2 values as the ankle pressure measurement. The posterior tibial pulse is best appreciated just dorsal and inferior to the medial malleolus. The dorsalis pedis pulse is best appreciated on the dorsum of the foot between the proximal section of the first and second metatarsals, usually above the navicular bone.

5) Divide the ankle pressure by the brachial artery pressure; the result is the ABI.

6) The ABI of each leg should be calculated by dividing the higher of the PT or DP pressure by the highest of the right or left arm SBP.

7) The lower of the two limb ABI is assigned to the patient

TYPE	DEFINITION
Resting ABI	The ABI of each leg should be calculated by dividing the higher of the posterior tibial artery (PT) or dorsal pedal artery (DP) pressure by the higher of the right or left arm systolic blood pressure (SBP)
Exercise ABI	A 20% drop in ABI following exercise stopped due to onset patient symptoms of claudication. This can be performed with treadmill testing or alternatively with the active pedal plantar flexion. This technique consists of repetitive active plantar flexion (heel raising) while standing, with an excellent correlation between ABI obtained after this method compared with treadmill exercise in claudicants.

Walking Impairment Questionnaire (WIQ)

This is used to score patients' walking capacity before stopping for claudication like symptoms.

DISTANCE	DEGREE OF DIFFICULTY					WEIGHT	SCORE
	None	Slight	Some	Much	Very	Feet	
Walking indoors such as around your home?	4	3	2	1	0	x 20=	
Walking 50 feet?	4	3	2	1	0	x 50=	
Walking 150 feet (1/2 block)?	4	3	2	1	0	x 150=	
Walking 300 feet (1 block)?	4	3	2	1	0	x 300=	
Walking 600 feet (2 blocks)?	4	3	2	1	0	x 600=	
Walking 900 feet (3 block)?	4	3	2	1	0	x 900=	
Walking 1500 feet (5 block)?	4	3	2	1	0	x 1500=	
% Score=(Sum of individual score/14,080) x100							
Minimum walking distance score= 0; Maximum walking distance score= 14,080							

SPEED	DEGREE OF DIFFICULTY					WEIGHT	SCORE
	None	Slight	Some	Much	Very	Feet	
Walking one block slowly (about 1.5 mph)?	4	3	2	1	0	x 1.5=	
Walking one block at an average speed (about 2.0 mph)?	4	3	2	1	0	x 2=	
Walking one block quickly (about 3.0 mph)?	4	3	2	1	0	x 3=	
Walking or jogging one block (about 5.0 mph)?	4	3	2	1	0	x 5=	
% Score=(Sum of individual score/46) x100							
Minimum walking distance score= 0; Maximum walking distance score= 46							

SYMPTOMS	DEGREE OF DIFFICULTY					SCORE
	None	Slight	Some	Much	Very	
Pain, aching or cramps in your right leg, calve or buttock?	4	3	2	1	0	
Pain, aching or cramps in your left leg, calve or buttock?	4	3	2	1	0	
Pain, aching or cramps in your both legs, calves and buttocks?	4	3	2	1	0	
Walking or jogging one block (about 5.0 mph)?	4	3	2	1	0	

SF-12 Survey

Question 1	Response					
	Excellent	Very good	Good	Fair	Poor	**Score**
In general would you say your health is?	1	2	3	4	5	

Question 2	Response			
	A lot	Little	None	**Score**
Does your health limit moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3	

Question 3	Response			
	A lot	Little	None	**Score**
Does your health limit climbing several flights of stairs?	1	2	3	

Question 4	Response		
	Yes	No	**Score**
In the last 4 weeks as a result of your physical health have you accomplished less than you would like?	1	2	

Question 5	Response		
	Yes	No	**Score**
In the last 4 weeks as a result of your physical health were you limited in the kind of work or other activities?	1	2	

Question 6	Response		
	Yes	No	**Score**
In the last 4 weeks as a result of your emotional health have you accomplished less than you would like?	1	2	

Question 7	Response		
	Yes	No	**Score**
In the last 4 weeks as a result of your emotional health you did not do work or other activities as carefully as usual?	1	2	

Question 8	Response					
	None	Little	Moderate	Quite a bit	Extreme	**Score**
In the last 4 weeks how much did pain interfere with your normal work (both inside and outside home)?	1	2	3	4	5	

Question 9	Response						
	All the time	Most of the time	Good bit of time	Some-time	Little	No	**Score**
For the last 4 weeks have you felt calm and peaceful?	1	2	3	4	5	6	

Question 10	Response						
	All the time	Most of the time	Good bit of time	Some-time	Little	No	**Score**
For the last 4 weeks did you have lot of energy?	1	2	3	4	5	6	

Question 11	Response						
	All the time	Most of the time	Good bit of time	Some-time	Little	No	**Score**
For the last 4 weeks have you felt downhearted and blue?	1	2	3	4	5	6	

Question 12	Response						
	All the time	Most of the time	Good bit of time	Some-time	Little	No	**Score**
For the last 4 weeks how much did your physical and emotional problems interfere with your social activities (like visiting with friends, relatives, etc.)?	1	2	3	4	5	6	

Graded Exercise Test

Participant monitored home walking log

DATE	ACTIVITY	START TIME	END TIME	STEPS PER MINUTE	COMMENTS
7–17–15	*Walking within my home*	*9.10 am*	*9.45 am*	*40*	*Had left calf and hip pain, that limited my ability to climb stairs, so I walked on a level surface within my home*

6-minute Walking Test

This is a walking based tool to assess walking capacity of patients with PAD. Before the test, HR, BP and ABIs are calculated.

- The 6MT takes place in an indoor, 30-m–long hallway with marks on the wall every 5 m.
- Patients were asked to walk up and down the hallway, covering as many laps as possible in 6 minutes.
- Patients were permitted to stop walking if their claudication became intolerable; however, the time clock continued to run during the rest period, and patients who stopped walking were encouraged to resume walking as soon as possible.
- The procedure has to be performed under technical supervision, with recording of the time to the first stop, the number of non-walking periods when patients stopped because of claudication, and the total distance walked during the test. The investigator provides verbal encouragement every 2 minutes during the test
- At the end of the test, following parameters are noted which are compared on follow up visits.
    1) Total time taken (if stopped prior to completion of 6 minutes)
    2) Total number of laps or distance covered
    3) Number of times stopped and time in minutes of resting between walking periods
    4) Any symptoms of claudication, chest pain, dyspnea etc.
    5) Heart rate, blood pressures and ABIs are calculated to compare before walking.

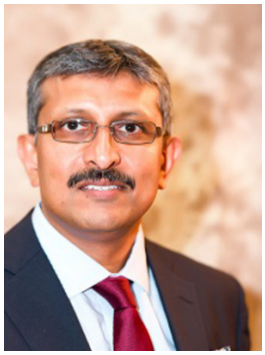
SHIPPING INFORMATION

Please FedEx all images in bubble wrap and FedEx envelope with clearly labeled images and completed Technician work sheet to:

VA North Texas Vascular Ultrasound Laboratory
and Research Offices
Preeti Kamath
VA North Texas Health Care System
4500 South Lancaster Road (Mail Code 151/3S)
Dallas, TX 75216 USA

Phone 214-857-3048 Fax: 214-302-1334

XLPAD STUDY TEAM



STUDY CHAIR

Subhash Banerjee, MD FACC FSCAI

Dr. Subhash Banerjee is the study chair of the XLPAD Study and its research operations. He is a renowned expert in the field of Endovascular Interventions, Chief of Cardiology for VA North Texas Health Care System and Professor of Medicine at University of Texas Southwestern Medical Center at Dallas, TX. He has received numerous awards including post-doctoral fellowship from AHA, Emerging Cardiology Faculty from ACC and Leadership award from Cardiovascular Research Technologies. He has been the principal investigator for several NIH and industry sponsored landmark trials. He serves as faculty mentor for US Department of Veterans Affairs, review committee for NIH and leading faculty for several national and international scientific meetings like ACC, TCT, SCAI and AHA.

DIRECTOR OF THE CARDIAC CATHETERIZATION LABORATORIES

Emmanouil S. Brilakis, MD, PhD, FACC, FAHA, FESC, FSCAI

Dr Brilakis is the Director of the Cardiac Catheterization Laboratories at VA North Texas Healthcare System and Professor of Medicine at the University of Texas Southwestern Medical School.

After graduating from Lycee Leonin de Patissia, Dr. Brilakis received his medical degree from the National Kapodistrian University of Athens, Greece. He trained in Internal Medicine, Cardiovascular Diseases and Interventional Cardiology at the Mayo Clinic. He also completed a Masters in Clinical Research at the Mayo Clinic and a PhD in Clinical Research at the National Kapodistrian University of Athens, Greece.

Dr. Brilakis leads a large clinical trial group investigating treatment of chronic total occlusions, prevention and treatment of saphenous vein graft disease, intracoronary imaging (near-infrared spectroscopy and optical coherence tomography), antiplatelet treatment optimization post coronary stenting, radiation safety in the catheterization laboratory, and implementation of novel technologies (such as Google Glass) in healthcare.

Dr. Brilakis has authored or co-authored over 350 manuscripts and has written the Manual of CTO Interventions. He is the PI and study chair of VA Cooperative Trial #571, Drug-Eluting Stenting Stents in Saphenous Vein Graft Angioplasty). He directs the Complex Coronary Interventions Webcast series and the Dallas Cardiovascular Innovations meeting. He is a reviewer and editorial board member for several journals and grant agencies and is lecturing and proctoring at several institutions in the United States and abroad

CLINICAL DIRECTOR, XLPAD CORE LABORATORY

Shirling Tsai, MD FACS

Dr. Shirling Tsai is an Assistant Professor of Surgery at University of Texas Southwestern Medical Center and Dallas VA Medical Center. She is the clinical director of the XLPAD Core Analysis Lab. She did her medical school and residency training from Columbia University School of Medicine and fellowship from Weil-Cornell School of Medicine and Massachusetts General Hospital with Harvard Medical School, Boston, MA. Her research interests are cost-effectiveness and device based outcomes for Peripheral Arterial Disease, Genetics of Aortic Aneurysms and Lipoprotein Receptor signaling mechanisms in aortic aneurysm pathogenesis.

CORE LABORATORY

Atif Mohammad, MD

Atif Mohammad is a Senior Research Associate at University of Texas Southwestern Medical Center at Dallas and Assistant Professor of Bioengineering at University of Texas at Arlington, TX. He runs the XLPAD Core laboratory activities including Angiographic, IVUS, OCT and lipiscan analysis. He also oversees all database activities related to XLPAD study. He has received grant funding from InfraRedx, travel awards from Medtronic and Young Leadership award from Cardiovascular Research Technologies. He has published over 40 peer-reviewed articles in field of Interventional Cardiology and Cardiovascular Pharmacology. He has served on review committees for American Heart Association, SigmaXi, University of Texas Arlington and American College of Cardiology.

CORE LABORATORY

Hao Xu, MD, PhD

Hao Xu runs Core Lab Imaging Analysis for XLPAD. Dr. Xu is originally from China where he received his initial medical training. Drawn by the opportunity for the harmonious integration of medicine and engineering, he came to the University of Texas at Arlington and completed his doctoral training in bioengineering. Subsequently, he completed his postdoctoral fellowship at UT Southwestern Medical Center. Dr. Xu's research is focused on cardiovascular biology and the treatment of cardiovascular disease using bioengineering approaches.

PROJECT MANAGER

Preeti Kamath, BDS, MHA, CCRP

Preeti Kamath is currently the Clinical Research Manager with the Department of Cardiology at the University Of Texas Southwestern Medical Center and heads the research operations for Dr. Banerjee, both at the University and its affiliate-VA North Texas Health Care System. She has held this position since March of 2014. Prior to this, she served CHRISTUS Health Care as an IRB Manager for a year at their corporate office and the Dallas VA Research Corporation as Senior Research Coordinator in Cardiology for 6.5 years.

Preeti graduated with Bachelors in Dental Surgery from Bangalore, India in 2001 and moved to the United States in late 2003. She completed a Master's in Health Care Administration from the University of Texas at Arlington in 2006 and graduated at the top of her class as the University Scholar from the School of Business at UTA.

Her primary interest is Clinical Research Administration and she stays current with the industry through memberships with the Society of ClinicalResearch Associates and the Association of Clinical Research Professionals.

DATABASE AND STATISTICAL ANALYSIS

Haekyung (Hattie) Jeon-Slaughter, Ph.D

Haekyung (Hattie) Jeon-Slaughter is a biostatistician in Cardiology, Department of Internal medicine at University of Texas Southwestern Medical Center, Dallas Texas. She is also a Dallas Veterans Affairs (VA) Research Corporation researcher with a joint appointment at Dallas VA Medical Center. Before joining Cardiology division as a biostatistician in 2015, she held a biostatistician position with a rank of non-tenure research track Assistant Professor in the department of Psychiatry at UT Southwestern and The University of Oklahoma Health Sciences Center. She received a Ph.D. in Consumer Economics and Housing (currently Policy Analysis and Management) at Cornell University in 1999, and prior to Ph.D. received Master's degree in Economics from the State University of New York at Buffalo in 1995 and Seoul National University, in South Korea, in 1992.

She has published over 30 peer-reviewed articles in the fields of applied statistics, psychiatry, public health, consumer policy, and behavioral economics. Her current and past projects have encompassed research topics of cost-effective analysis of peripheral artery disease intervention, tobacco and drug control and regulations, cost-effectiveness of hospital care services, and online publishing business models.

She has served as an investigator and a statistician in numerous research grants funded by the National Institute of Health, Substance Abuse and Mental Health Services Administration (SAMHSA), private research foundations, Pharmaceutical companies, and the University of Texas at Dallas.

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