Setting an exciting new trend
in clinical data collection

XLPAD REDCAP SURVEY AND DATA MANAGEMENT TOOL TRAINING MODULE

EXCELLENCE IN PERIPHERAL ARTERY DISAEASE

MULTICENTER PERIPHERAL ARTERY INTERVENTION REGISTRY

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

https://www.bswhealth.med/Pages/xlpad.aspx

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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 an investigator from the Baylor Scott & White Research Institute. It is a real-world core lab adjudicated and rigorously audited PAD intervention registry which uses the REDCap electronic data capture tools and the IT infrastructure of the Baylor Scott & White Research Institute [5][6]. 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

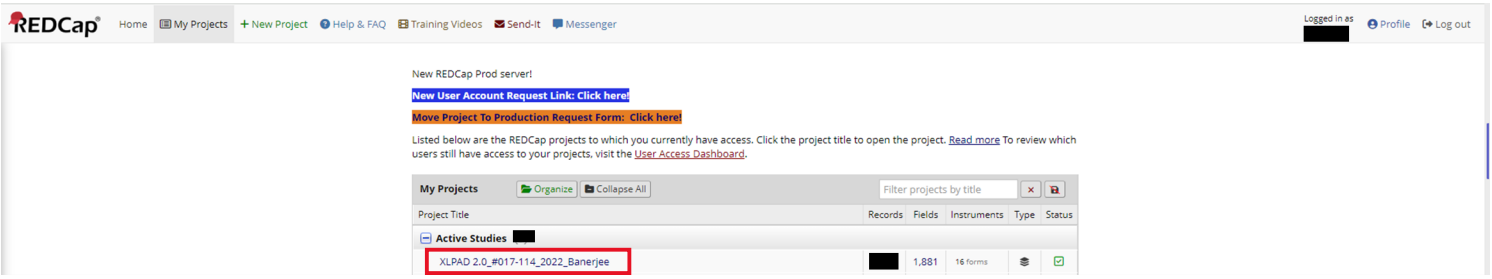
To enter the XLPAD study, you first need to go to the Baylor Scott & White Research Institute REDCap Website:

https://redcap.bswhealth.org/

Type in the username and password and click “Log In”.

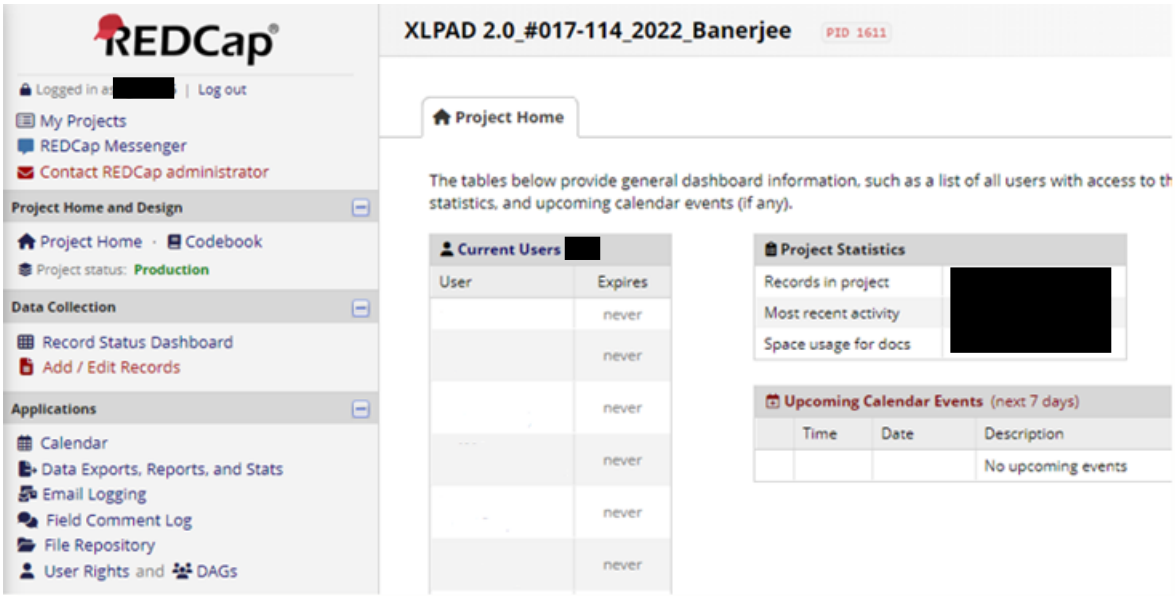
ENTER THE XLPAD STUDY

After logging into the Baylor Scott & White Research Institute REDcap website, simply click “XLPAD 2.0 _#017-114_2022_Banerjee” under the “My Projects” tab.

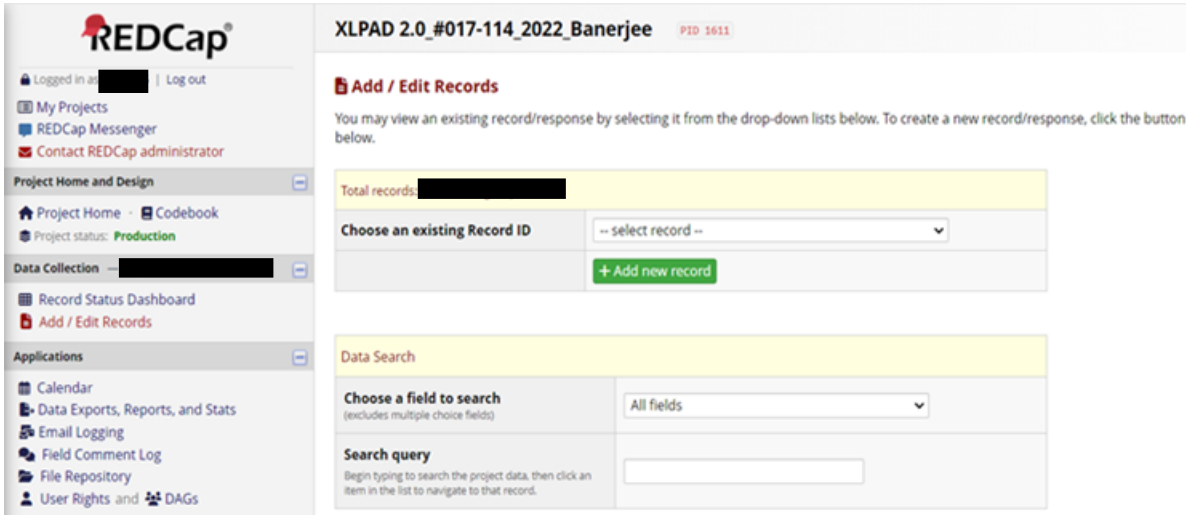


ADD A NEW PATIENT

To add a new patient into the XLPAD database, first click the “Add/Edit Records” button on the “Project Home” main screen.

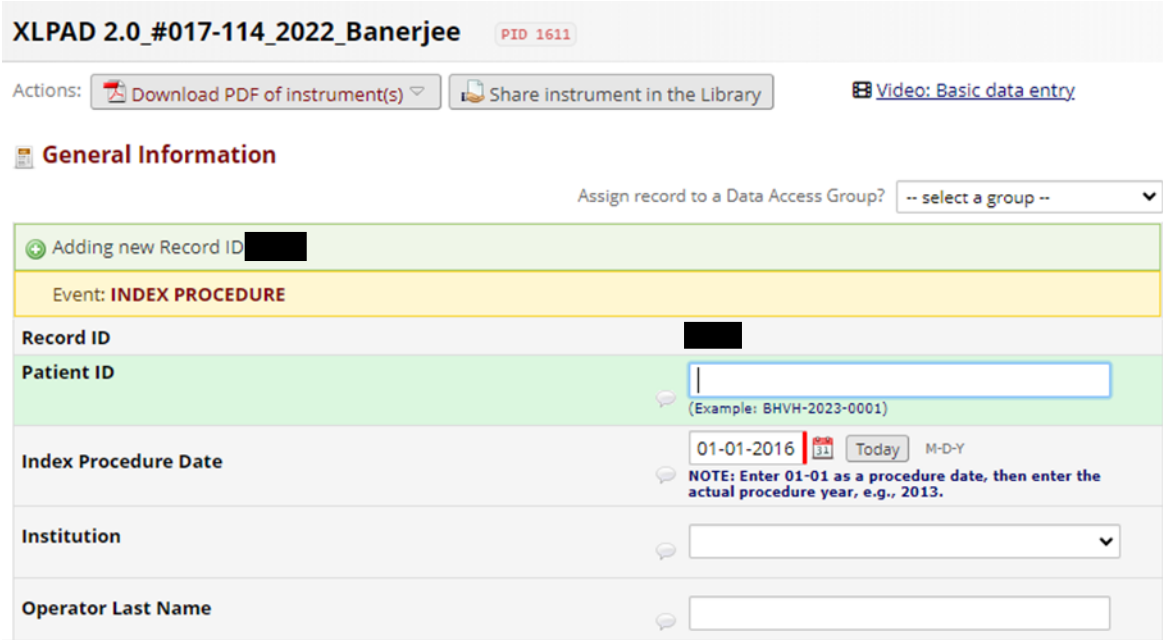


Next, on the “Add/Edit Records” page, click the “Add new record” button. You can now add a new record to the XLPAD database.



PATIENT GENERAL INFORMATION

Note: All the patient general information will be collected from the institution's electronic medical records 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, BHVH-2012-0001.

INSTITUTION

Enter the procedure performing institution from the drop-down menu.

AGE

Enter the integer years of the patient age (e.g., 65).

INDEX PROCEDURE DATE

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

OPERATOR

Enter the procedure operator's last name.

GENDER

Select Male or Female.

RACE

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

ETHNICITY

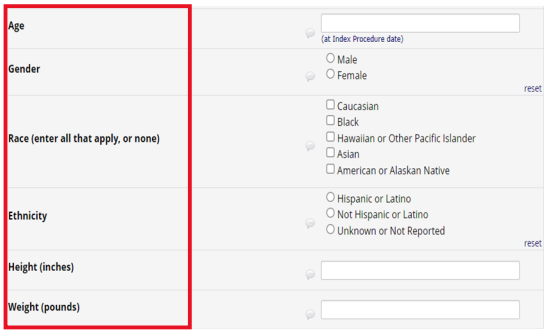
Enter the patient ethnicity as Hispanic or Latino, not Hispanic or Latino, or Unknown or Not Reported

HEIGHT (INCHES)

Enter the patient height in inches.

WEIGHT (POUNDS)

Enter the patient weight in pounds.



AMBULATORY STATUS?

Select the patient ambulatory status from the drop-down menu: Not Ambulatory, 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 (e.g., 50.0).

LEFT ABI

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

RIGHT ABI

Enter the patient right side ABI.

ABI NON-COMPRESSIBLE?

Select if the Left, Right, or Both ABI(s) is/are non-compressible.

LEFT TBI

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

RIGHT TBI

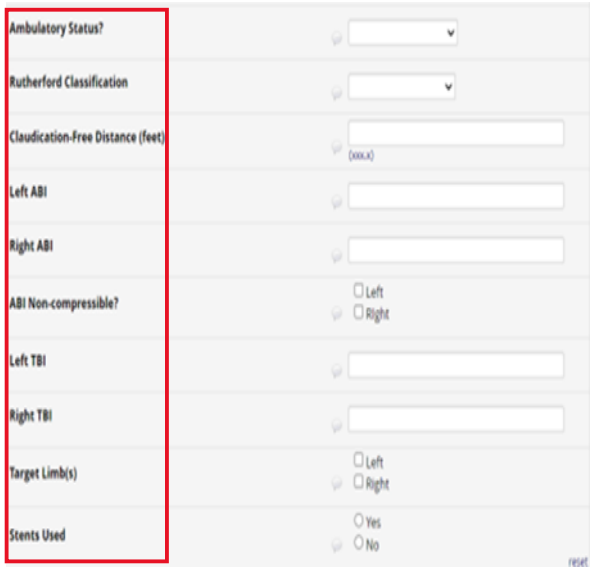
Enter the patient's right side TBI.

TARGET LIMB(S)

Enter the patient procedure target limb as Left, Right, or both.

STENTS USED

Select 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

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

DYSLIPIDEMIA

Additional Criteria: medications for the treatment of dyslipidemia

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

HYPERTENSION

Additional Criteria: medications for the treatment of hypertension

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

SMOKING

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

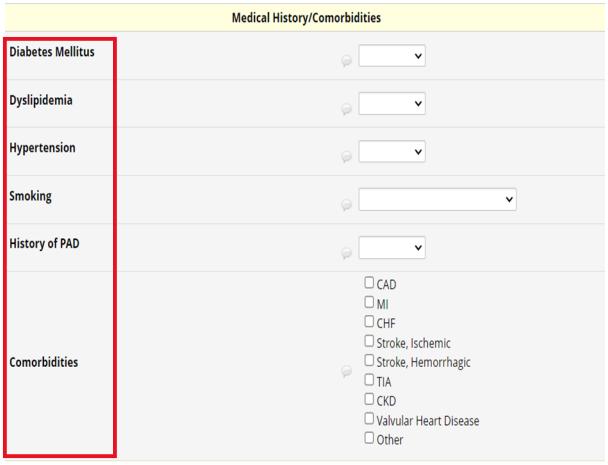
HISTORY OF PAD

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

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

COMORBIDITIES

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



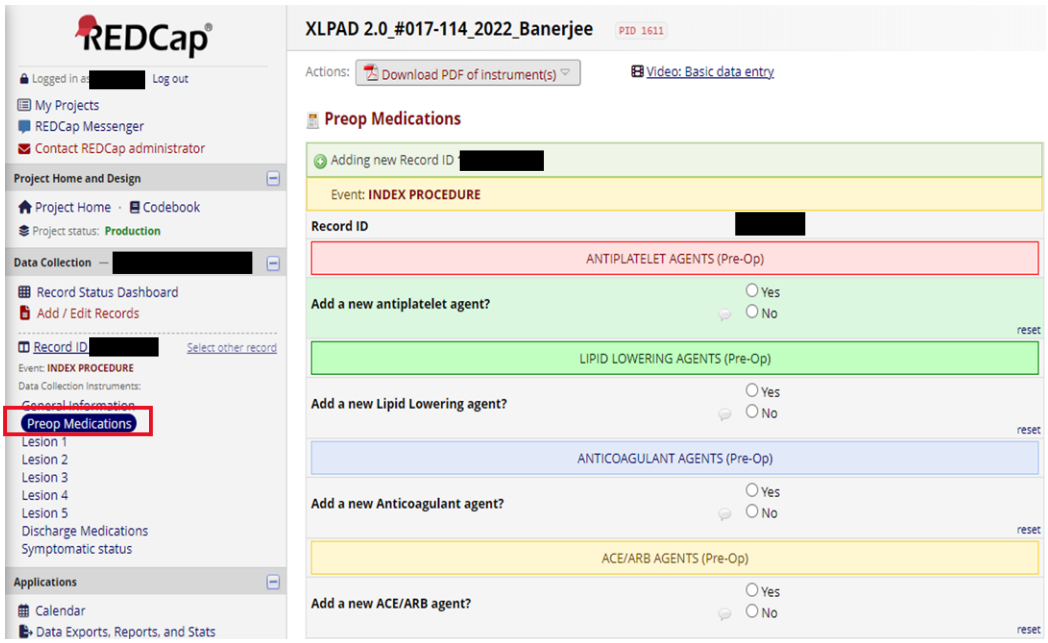
FORM STATUS

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.

PREOP MEDICATIONS

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

To Add new agents to the Preop Medications, select yes and chose the medication name from the dropdown. Enter dose (mg), select frequency "OD, BID, TID, QD", and select to "carry this medication forward" to automatically populate this in the follow-up medications.



ANTIPLATELET AGENTS (Pre-Op)

Ticagrelor, Prasugrel, Clopidogrel, Cilastozol, Dipyridamole, Aspirin, or Other.

LIPID LOWERING AGENTS (Pre-Op)

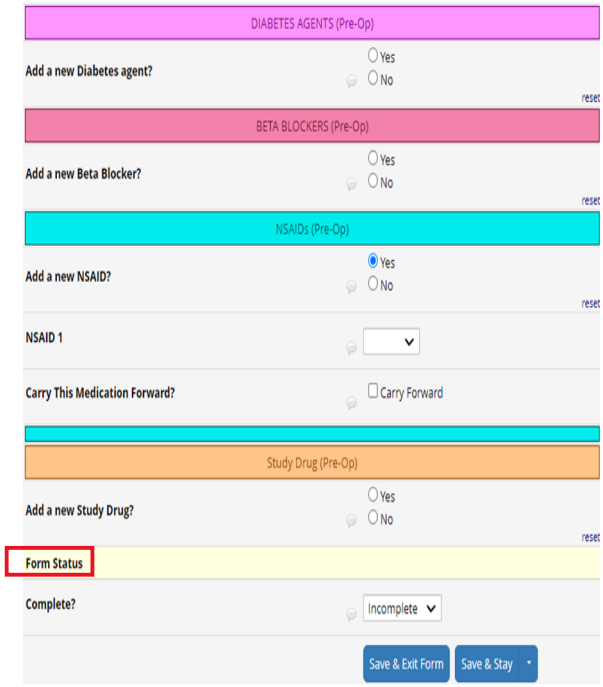
Simvastatin, Atorvastatin, Rosuvastatin, Pravastatin, Gemfibrozil, Fibric Acid, Zetia, or Other.

ANTICOAGULANT AGENTS (Pre-Op)

Warfarin, Dabigatran, Rivaroxaban, Vorapaxar, Edoxaban, or Other.

ACE/ARB AGENTS (Pre-Op)

Lisinopril, Captopril, Ramipril, Tadanopril, Losartan, or Other.



DIABETES AGENTS (Pre-Op)

Insulin, Metformin, Sulphonylurea, Meglitinides, Phenylalanine, TZD, DPP-4 inhibitors, Other, SGLT2 inhibitors, or GLP-1 agonist.

BETA BLOCKERS (Pre-Op)

Select Yes or No.

NSAIDS (Pre-Op)

Select Yes or No.

STUDY DRUG (Pre-Op)

Select Yes or No.

FORM STATUS

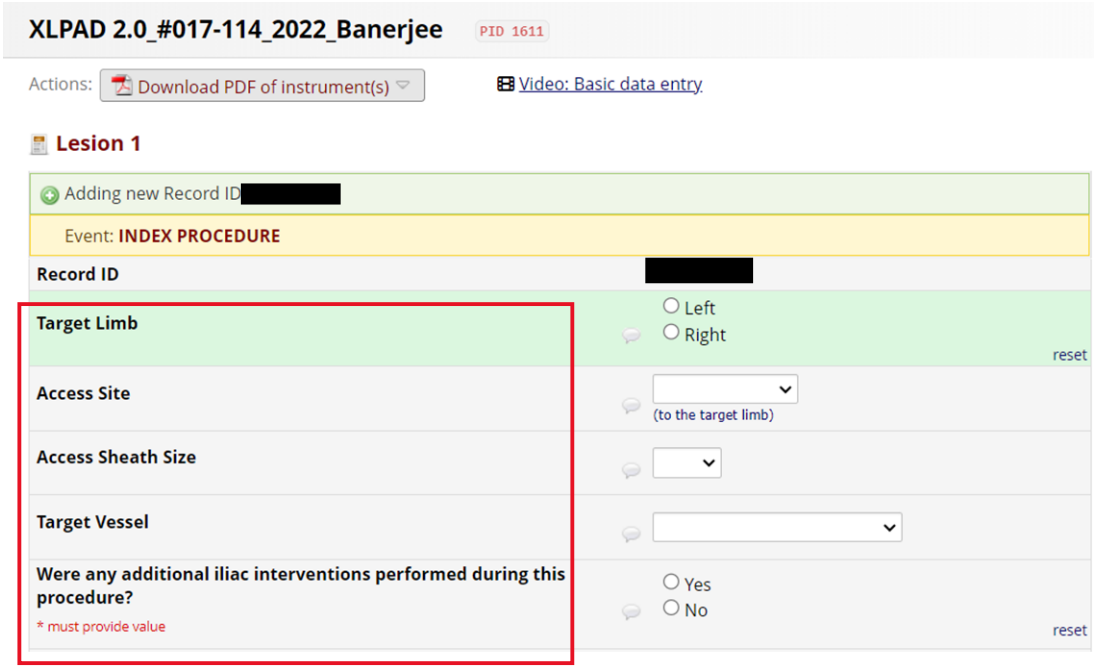
You can save the uncompleted record at any time by clicking the Save Record button. After entering all the required information, change the form status to Complete, then clicking the Save and Continue or the Save and go to Next Form button.

LESION ONE

Note: All the information for lesion 1 will be collected from the institution's electronic medical records system and from the Angiogram Analysis Core Lab by credentialed technicians at Baylor Scott & White Research Institute. 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:



TARGET LIMB

Select whether the Left or Right limb is receiving intervention.

ACCESS SITE

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

ACCESS SHEATH SIZE

Select the sheath size from 4F to 14F from the drop-down menu.

TARGET VESSEL

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

WERE ANY ILIAC INTERVENTIONS PERFORMED?

Select 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

Select Ostial, Proximal, Mid, or Distal from the drop-down menu.

NUMBER OF BTK RUNOFF VESSELS

Select the number of below-the-knee arteries (0-3) with less than 50% stenosis.

PRESENCE OF BTK DISEASE

Select Yes if there is 50% or more stenosis in any BTK arteries, or No if there is less than 50% stenosis.

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.

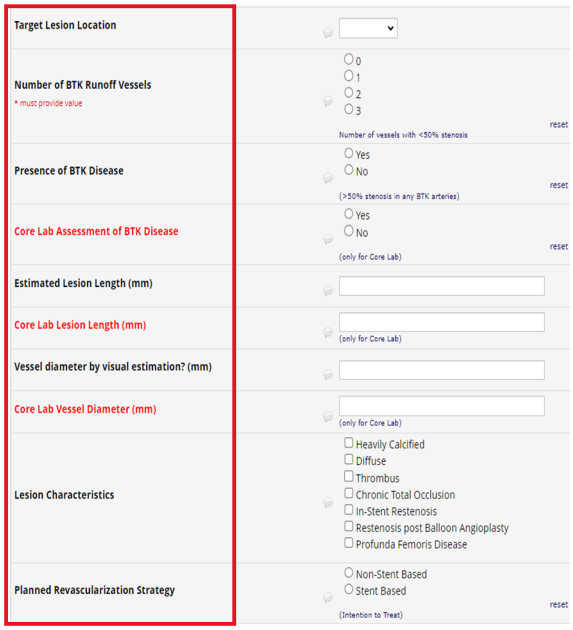
LESION CHARACTERISTICS

Select 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?

Select Non-Stent Based or Stent Based. Based on procedure documentation of primary and/or need for bail-out or provisional stenting.



DEBULKING

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

EMBOLIC PROTECTION DEVICE USED

Select Distal filter, Angioslide Balloon, or None.

NUMBER OF BALLOON(S) FOR ANGIOPLASTY

Select the number of balloons (0-3) for angioplasty from the drop-down menu.

ASPIRATION/THROMBECTOMY

Select Yes or No.

THROMBOLYTIC THERAPY (SYSTEMIC OR LOCALIZED)

Select Yes or No.

NUMBER OF STENTS

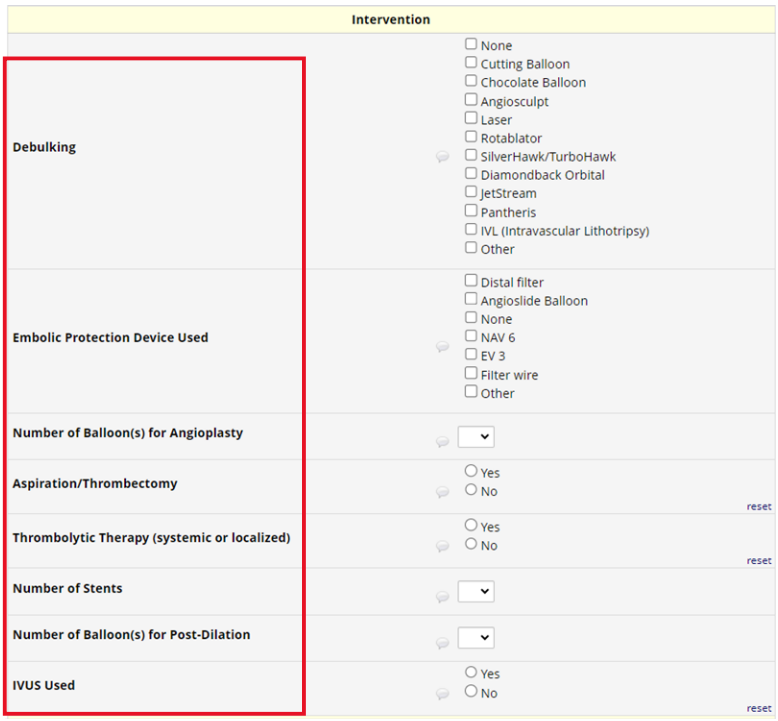
Select the number of stents (0-5) used for angioplasty from the drop-down menu.

NUMBER OF BALLOONS FOR POST-DILATION

Select the number of balloons (0-2) for post-dilation from the drop-down menu.

IVUS USED

Select 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).

BASELINE TIMI FLOW

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

FINAL TIMI FLOW

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

TIMI GRADE FLOW

GRADE	DEFINITION
0	No perfusion. Defined as absence of any ante-grade 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

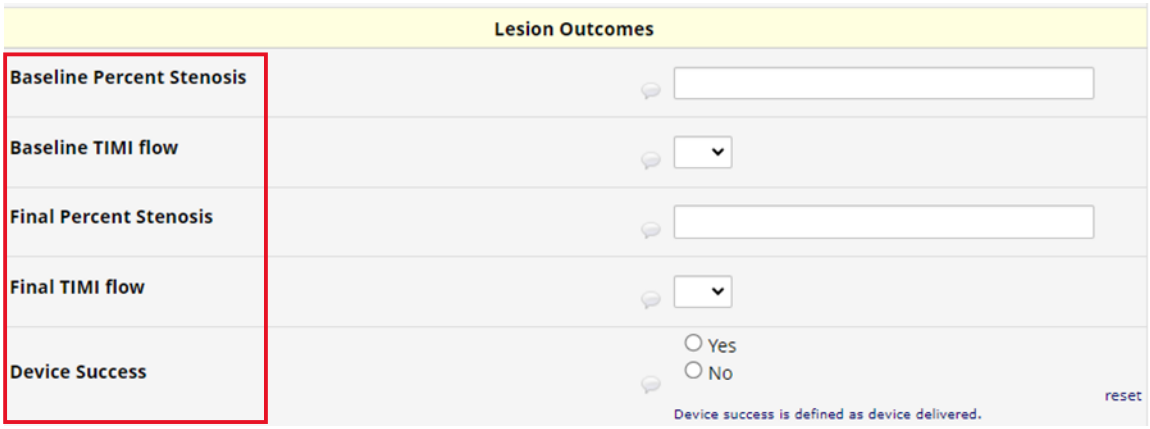
Reported Percent Stenosis is based on visual angiographic analysis; could be verified with core lab measurement. Core lab: enter the percentage (%) of the lesion diameter stenosis compared to normal reference vessel of angiogram after intervention.

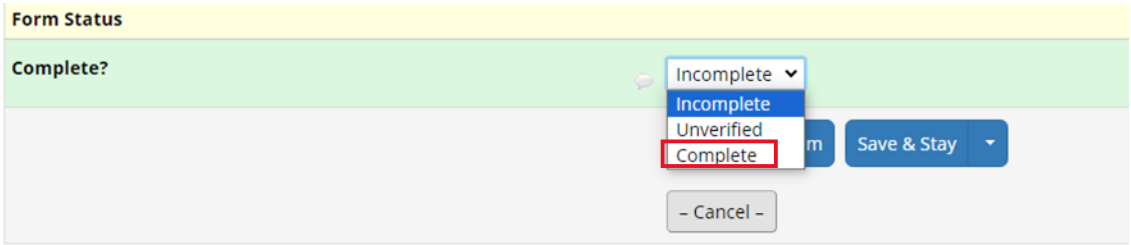
DEVICE SUCCESS

Select Yes or No.

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 to Complete, then clicking the Save and Continue or the Save and go to Next Form button.

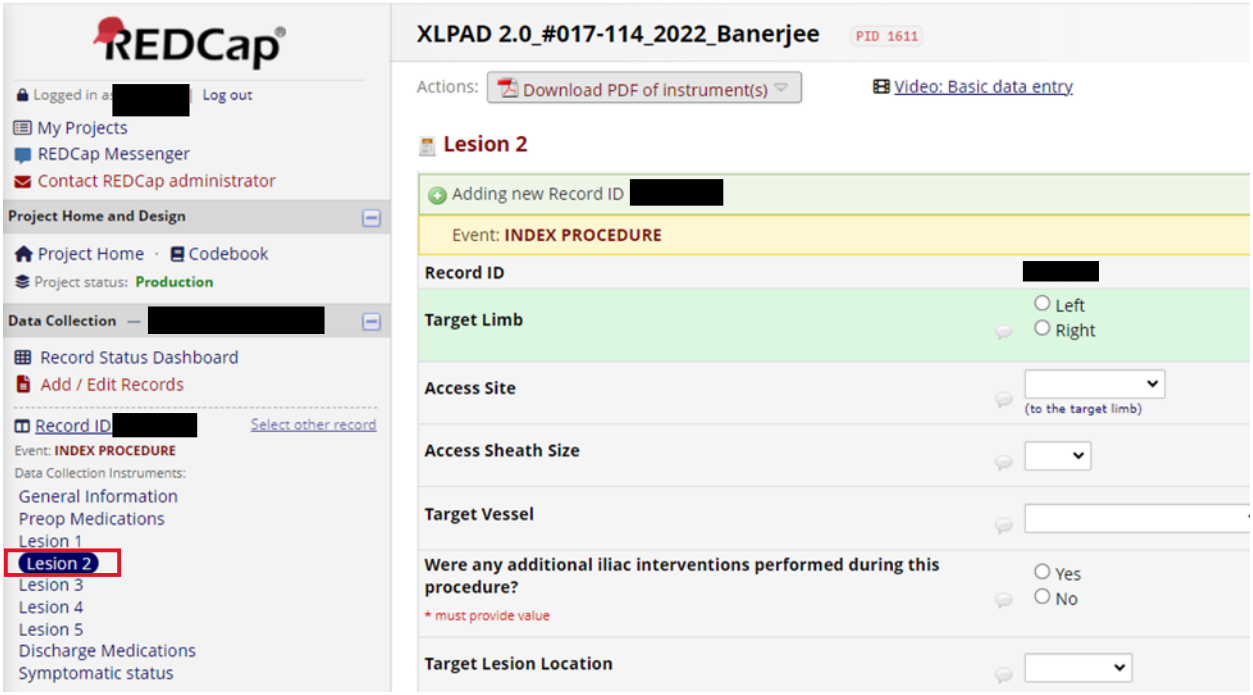




SUBSEQUENT LESIONS

Note: All the information for lesion 2, Lesion 3, Lesion 4, and Lesion 5 will be collected from the institution's electronic medical records system and from the Angiogram analysis core lab by credentialed technicians at Baylor Scott & White Research Institute. 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. Continue to enter the lesion 2 information, using the same directions as lesion 1. Add data to lesion 3 - 5 if there were more lesions treated.



OUTCOMES

Note: All the information for Outcomes will be collected from the institution's electronic medical records 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).

Select Yes, or No.

PROCEDURE SUCCESS

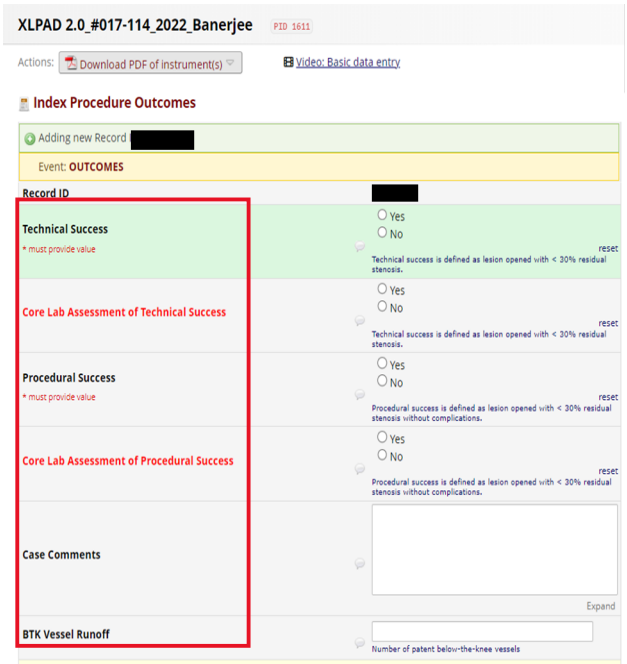
Procedure success is defined as a lesion opened with <30% residual stenosis without complications. Select Yes, or No.

CASE COMMENTS

Enter relevant comments for the interventional case.

BTK VESSEL RUNOFF

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



Next, enter the medications utilized during the procedure.

ANTI-COAGULATION USED

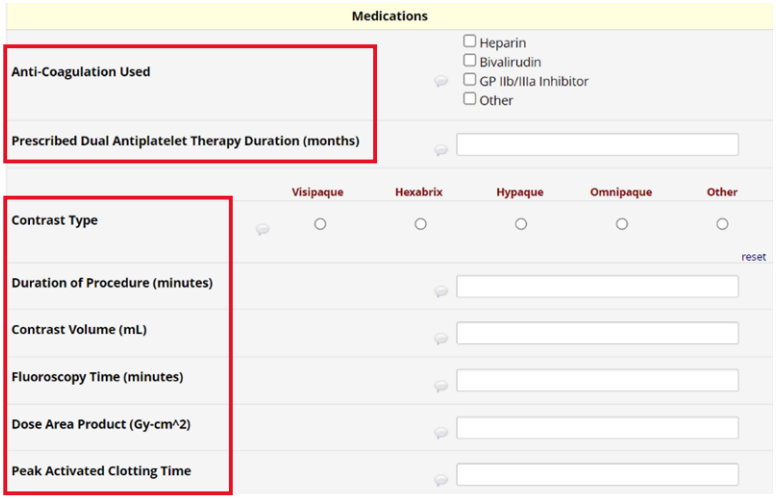
Select Heparin, Bivalirudin, GPIIb/IIIa Inhibitor, or Other.

PRESCRIBED DUAL ANTIPLATELET THERAPY DURATION (MONTHS)

Enter the number of months of prescribed Dual Antiplatelet Therapy.

CATH LAB DATA

Select contrast Type (check Visipaque, Hexabrix, Hypaque, Omnipaque, or Other), Duration of Procedure (minutes), Contrast Volume (mL), Fluoroscopy Time (minutes), Dose Area Product (Gy-cm^2), and Peak Activated Clotting Time.



Next, enter the index procedure complications.

PROCEDURAL COMPLICATIONS

Select Yes or No.

If yes, check all complication types that apply: Dissection (Flow-Limiting), Dissection (Non Flow-Limiting), Access Site Hematoma (< 5 cm), Access Site Hematoma (>5 cm), Retroperitoneal Hematoma, Distal Embolization, Bleeding Diathesis, Allergic Reaction, Acute Renal Failure, Perforation, Emergency Surgery, or Other.

Note: All the following Adverse Events relate to anytime during the 12 months follow-up, they will also be collected on the Adverse Events Form, please verify that the time to events match on both forms.

DEATH

Select Yes or No.

If yes, enter the number of days within the index procedure death occurred and cause of death: Cardiovascular, Non-

cardiovascular, Bleeding, Sepsis, Malignancy, Procedure complication, or Other.

MYOCARDIAL INFARCTION

Select Yes or No.

If yes, enter the number of days within the index procedure myocardial infarction occurred.

STROKE

Select Yes or No.

If yes, enter the number of days within the index procedure stroke occurred.

PERIPHERAL ARTERY STENT THROMBOSIS

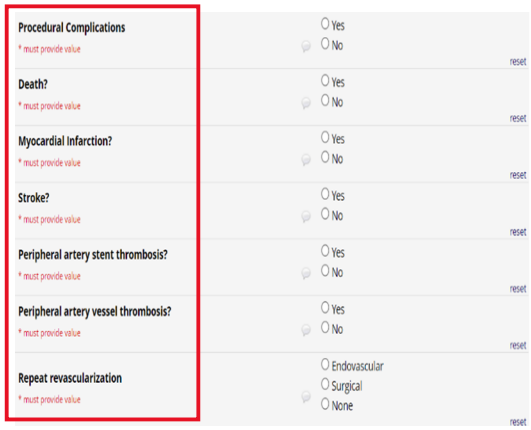
Select Yes or No.

If yes, enter the number of days within the index procedure peripheral artery stent thrombosis occurred.

PERIPHERAL ARTERY VESSEL THROMBOSIS

Select Yes or No.

If yes, enter the number of days within the index procedure peripheral artery vessel thrombosis occurred.



REPEAT REVASCUALRIZATION

Select Endovascular, Surgical, or None.

If Endovascular or Surgical, enter number of days within the index procedure repeat revascularization occurred, select weather repeat revascularization was planned or not planned, and if the revascularization site was located on the Target limb, Non-target limb, or both.

WAS AMPUTATION PERFORMED?

Select Yes or No.

WILL A DEIDENTIFIED ANGIOGRAM BE PROVIDED TO THE STUDY CORE LAB?

Select Yes or No.

DAY OF DISCHARGE

Enter number of days from Index Date.

(if discharge the same day of procedure: 0 days)

WERE IVF GIVEN UP TO 12 HOURS BEFORE PROCEDURE?

Select True or False.

WERE IVF GIVEN UP TO 12 HOURS AFTER?

Select True or False.

CONTRAST INDUCED NEUROPATHY?

Select True or False.

AKI at 24-48 hours (increase in Serum Cr > 0.3 mg/dL from pre-procedure).

REQUIRED DIALYSIS?

Select True or False (During admission).

IF PATIENT RECEIVED DIALYSIS, WAS DIALYSIS DISCONTINUED BEFORE DISCHARGE?

Select True or False.

PEAK CREATININE DURING ADMISSION (mg/dL)

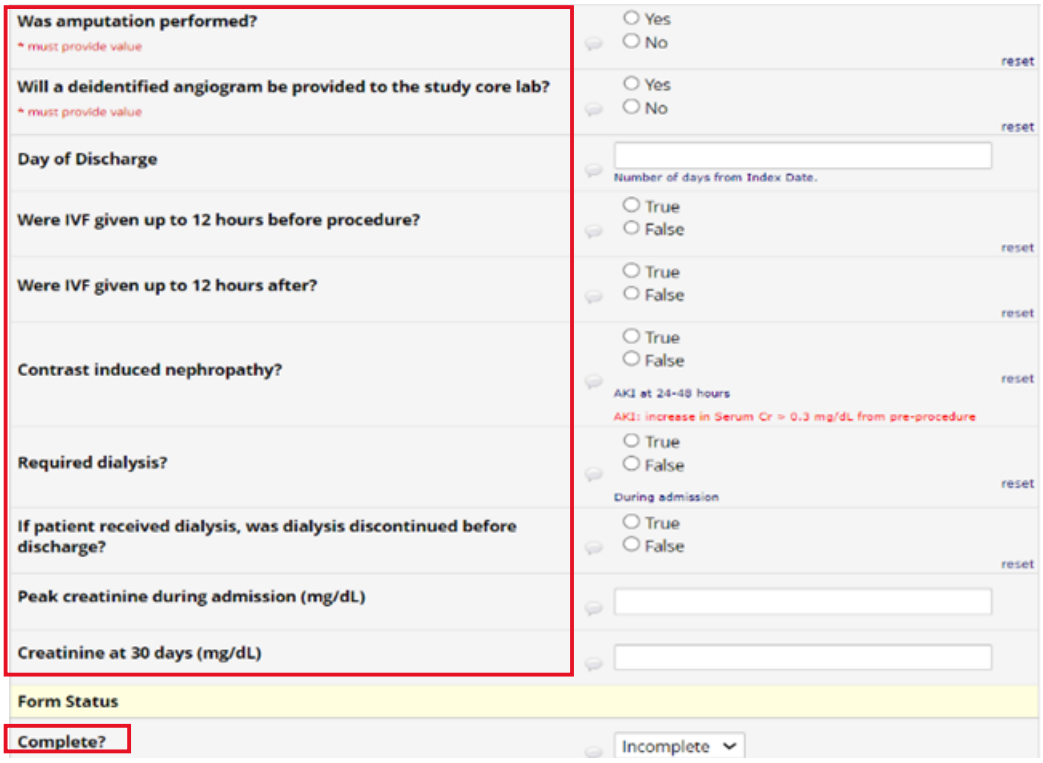
Enter Peak creatinine during admission.

CREATININE AT 30 DAYS (mg/dL)

Enter creatinine at 30 days.

FORM STATUS

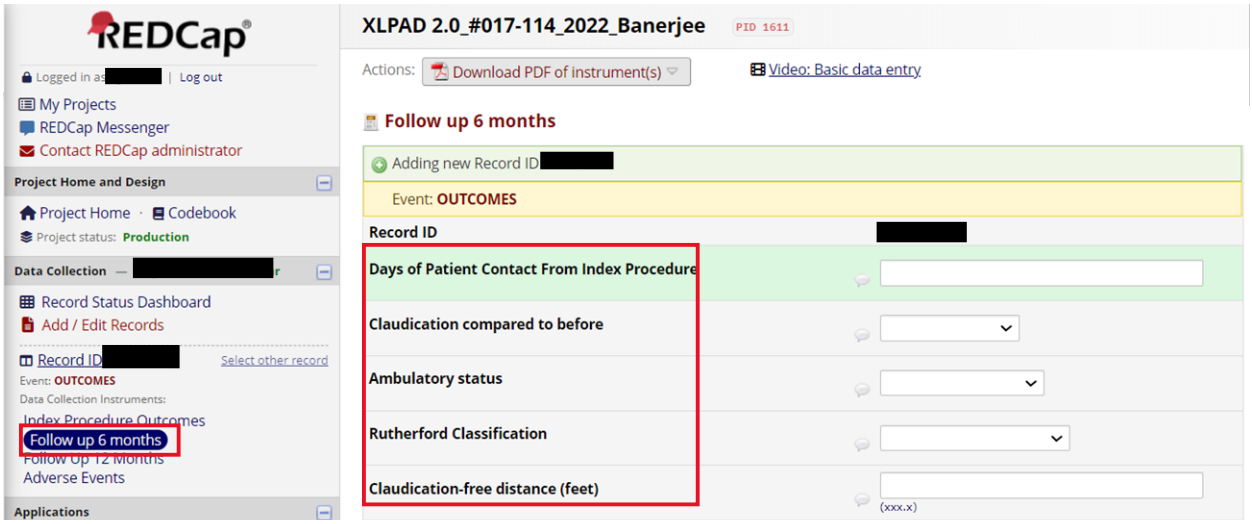
After completing the outcome results, save the data as described before.



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 records system and entered into the XLPAD registry by the study team. Data will be verified periodically by the primary investigator.



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 (e.g., 50).

ABI/TBI

Select Yes or No.

If yes, enter the value of Left ABI, Right ABI, Left TBI, and Right TBI.

DUPLEX ULTRASOUND FOLLOW UP

Select Yes or No.

If yes, enter days from index procedure and select peak systolic velocity ratio from the dropdown (<2.5 or >2.5).

WERE ANY ADVERSE EVENTS EXPERIENCED?

Select Yes or No.

CREATININE AT 6 MONTH FOLLOW UP

Enter creatinine at 6 months follow up (mg/dL).

TOTAL CHOLESTEROL AT 6 MONTHS

Enter total cholesterol at 6 months follow up (mg/dL).

LDL AT 6 MONTHS FOLLOW UP

Enter LDL at 6 months follow up (mg/dL).

HDL AT 6 MONTHS FOLLOW UP

Enter HDL at 6 months follow up.

TRIGLYCERIDES AT 6 MONTHS FOLLOW UP

Enter triglycerides at 6 months follow up.

HEMOGLOBIN AT 6 MONTHS FOLLOW UP

Enter hemoglobin at 6 months follow up (g/dL).

PATIENT ON DIALYSIS?

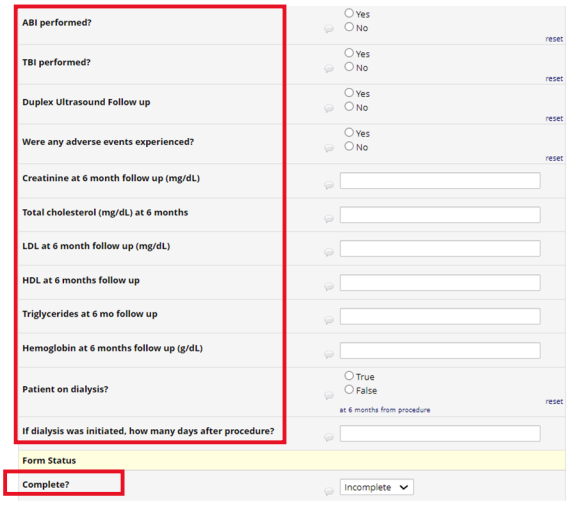
Select True or False at 6 months from procedure.

IF DIALYSIS WAS INITIATED, HOW MANY DAYS AFTER PROCEDURE?

Enter number of days since index procedure if applicable.

FORM STATUS

After completing the form, 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 records 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.

ADVERSE EVENTS

Note: All data points from the Adverse Events Form are also collected on the Index Procedure Outcomes, please verify that the time to events match on both forms.

DEATH

Select Yes or No.

If yes, enter the number of days within the index procedure death occurred and cause of death: Cardiovascular, Non-cardiovascular, Bleeding, Sepsis, Malignancy, Procedure complication, or Other.

MYOCARDIAL INFARCTION

Select Yes or No.

If yes, enter the number of days within the index procedure myocardial infarction occurred and the type of MI (STEMI vs. NSTEMI).

STROKE

Select Yes or No.

If yes, enter the number of days within the index procedure stroke occurred and the type of stroke (Ischemic vs. Hemorrhagic).

REPEAT REVASCUALRIZATION

Select Endovascular, Surgical-Peripheral, PCI, CABG, or None.

If Endovascular or Surgical, enter number of days within the index procedure repeat revascularization occurred, select weather repeat revascularization was planned or not planned, and if the revascularization site was located on the Target limb, Non-target limb, or both.

WAS AMPUTATION PERFORMED?

Select Yes or No.

If yes, enter the number of days within the index procedure amputation occurred, whether the amputation was planned or not; was it on the target limb, opposite limb, or both; and whether it was a major (above the ankle) or minor amputation.

BLEEDING

Select Yes or No.

If yes, enter the number of days within the index procedure bleeding occurred and the BARC Classification of the bleeding.

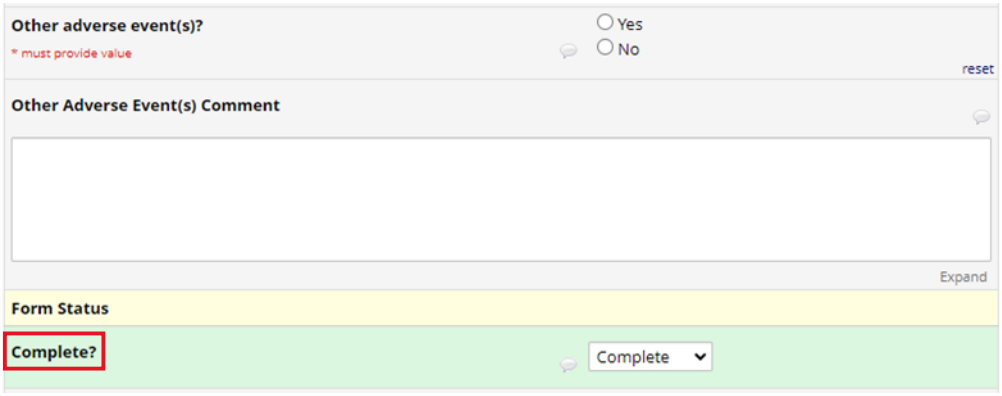
OTHER ADVERSE EVENTS

Select Yes or No if Other Relevant Adverse Events have occurred during the 12 months follow-up.

Provide more information in the comment box.

FORM STATUS

After completing the form, save the data as described before.



Note: A repeating instrument (a new form) of Adverse Events can be created by clicking the plus button, in the case two or more events of the same type (e.g. two Myocardial Infarctions) occurred during the 12 months follow-up.

DO NOT CREATE A NEW FORM IF DIFFERENT EVENTS HAPPENED, only if there were 2 or more of the same type.

CORE LABORATORY ANGIOGRAPHIC ANALYSIS

CERTIFICATION OF ANGIOGRAPHER

For the Baylor Scott & White Research Institute (BSWRI) 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 Principal Investigator. Prior to study data analysis and technical certification, all core lab analysts will review 20 cases with the core lab director for intra and inter-observer verification to be certified. In addition, the certified angiographer will be required to complete CITI HSP, GCP, and required study protocol training.

QUANTITATIVE VASCULAR ANALYSIS
(PIE MEDICAL IMAGING-CAAS QVA VERSION 8.5)

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

(1) Image acquisition and digital processing
(2) Image Selection
(3) Calibration
(4) 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 re-quired 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 all runs of the angiogram.

2) Select up to 12 images for QVA. At least 2-3 im-ages 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

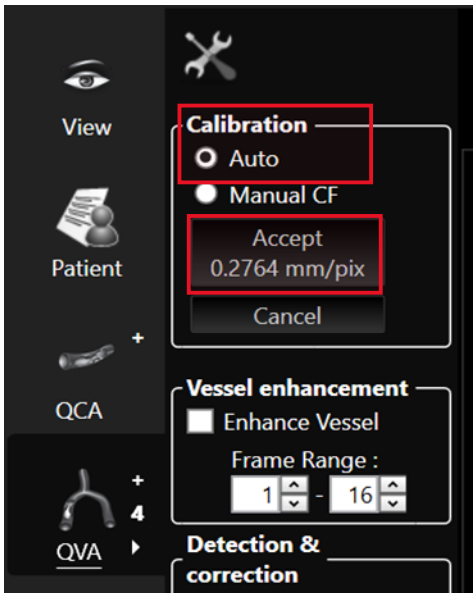
Calculation of Calibration Factor (CF) is necessary for accurate analysis. The Calibration Factor converts distances in images in pixels to real world distances in millimeters. Following calibration methods are used:

(1) Automatic Calibration (pix)
(2) Manual Catheter Calibration
(3) Manual Calibration using ruler

Always first attempt for automatic pixel calibration as it is most accurate and minimizes variability between analysts. If the software is not able to automatically calibrate based on pixels, enter Calibration factor manually by catheter. If neither of these are viable options, calibrate manually by ruler.

Automatic Calibration (Pix)

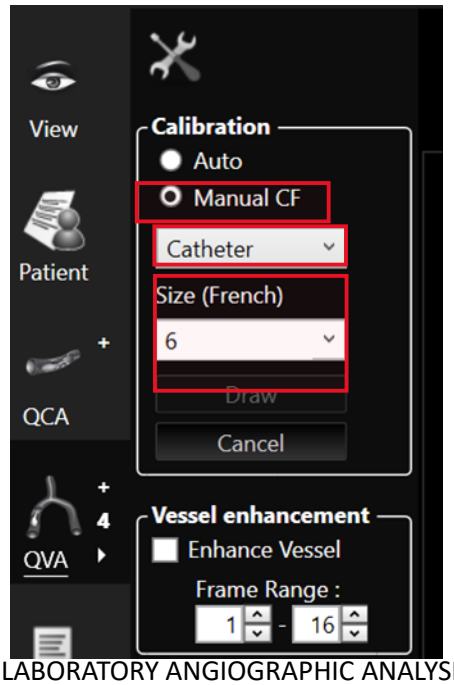
CAAS Software automatically calibrates based off pixels of each image selected.



Catheter Calibration

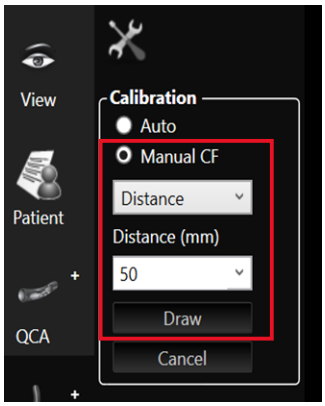
1) Click Catheter to start Calibration.
2) Select catheter size in French (3 French=1 mm) from drop down box values or enter it manually. Click Apply to accept the change.
3) Select the catheter in the image. Left mouse click on the centerline of catheter and double click on the center of the catheter.
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.



Ruler Calibration

(1) Select Manual CF.
(2) Select Distance.
(3) Select 50 mm from the drop-down menu and click the Draw button.
(4) Select 5 cm from the ruler shown in the image and select accept.



QUANTITATIVE ANGIOGRAPHIC ANALYSIS

Following steps are involved after calculating Calibration Factor

(1) Contours Selection
(2) Obstruction Analysis
(3) Sub-segment Analysis
(4) Graphical presentation
(5) Results

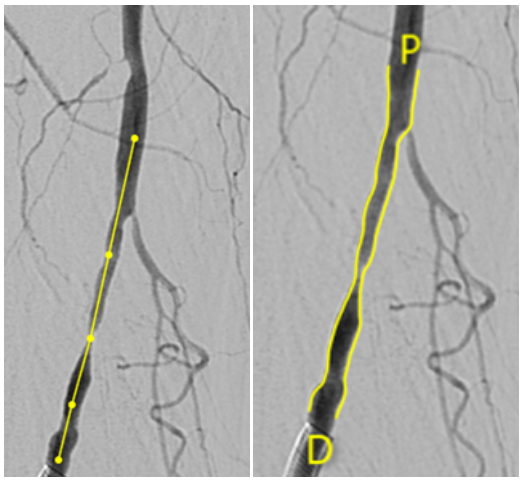
Contours Selection

Correct contour selection of image being analyzed is necessary for accurate analysis. Following steps are involved in contour selection:

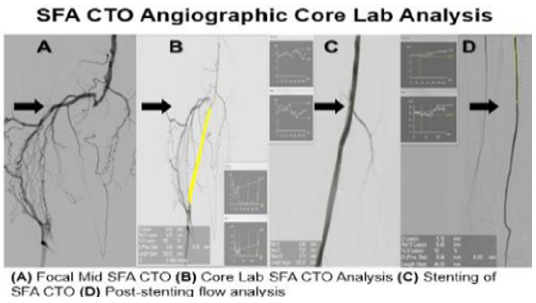
Contour detection starts with single left click and creating a centerline at the start of arterial segment in the direction of blood flow.

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.



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

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.

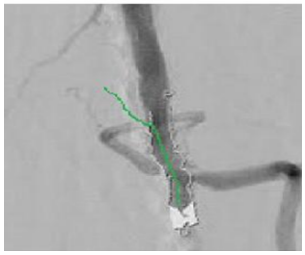
(1) Draw a line outside the vessel.

(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.



Correction

One can select Soft Correction if allowing software to change contours automatically or Hard Correction if changed manually by user. Note that less correction is preferred as it minimizes variability between analysts.

(1) Draw a line towards the vessel.

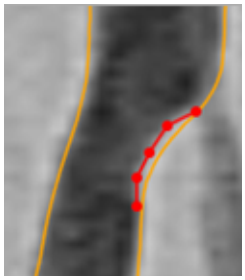
(2) Move the mouse until a black and white pencil appears.

(3) After a single left click, a green line will be drawn.

(4) Continue to click and move the mouse until re-quired 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.



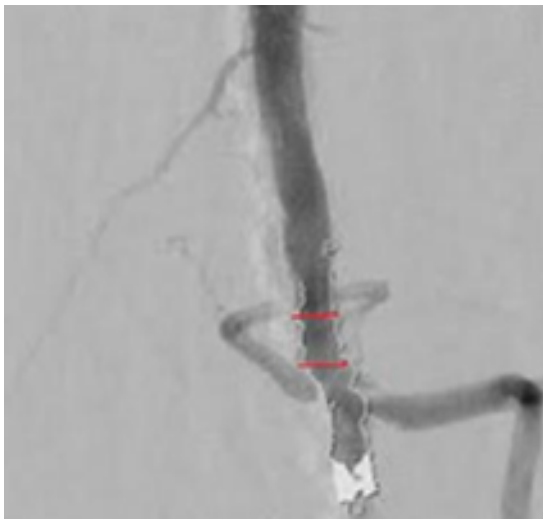
Obstruction Analysis

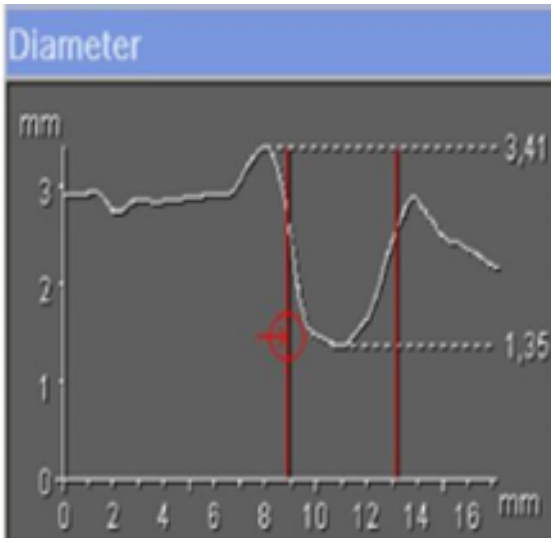
Obstruction analysis is done to calculate the Minimal Luminal Diameter (MLD) compared with the Reference Diameter. The reference diameter is the diameter at position of MLD if there was no stenosis present.

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.

Sub-segment Analysis

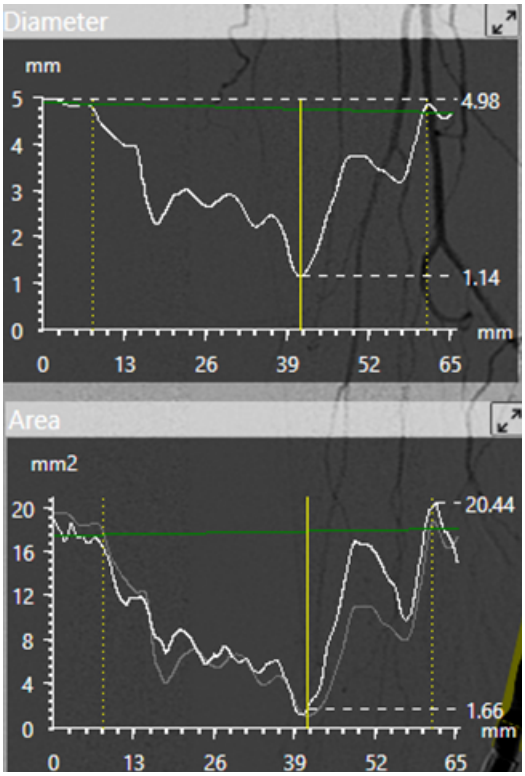
(1) Sub-segment analysis can be done by clicking on User Define.
(2) After clicking on User Define, move the mouse cursor on the position borders to change its shape.
(3) Hold the mouse and drag the line to move the border.
(4) Once mouse is released, borders will be repositioned.





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.



Report

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.

Stent Analysis

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

(1) In-segment percent stenosis

This is calculated by following formula:

1-SegmentMLD/Reference Diameter*100

(2) In-stent percent stenosis

This is calculated by following formula:

1-Stent MLD/Reference Diameter*100

OTHER ANGIOGRAPHIC VARIABLES

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

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	Normal flow which fills the distal vascular bed completely.

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

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:

(1) Mild-the presence of either isolated foci of calcification.
(2) Moderate-contiguous segments of calcification on one or alternating sides of the vessel.
(3) Severe-contiguous calcification on both sides of the vessel.

Thrombus

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. The 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 diagnostic of thrombus.
2	Thrombus present small size –Greatest dimensions present or equal to 1/2 vessel diameter
3	Thrombus present moderate size – greater than 1/2 vessel diameter but still less than 2 vessel diameters.
4	Thrombus bigger than grade 3 with dimensions present equal or greater than 2 vessel diameters.
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: When there is abrupt occlusion with no microchannel at the proximal end of chronic total occlusion.

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

Stumpless or No stump: 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. (<50 disease in any artery classifies that artery as having runoff)

Blow the Knee Anatomy Variants

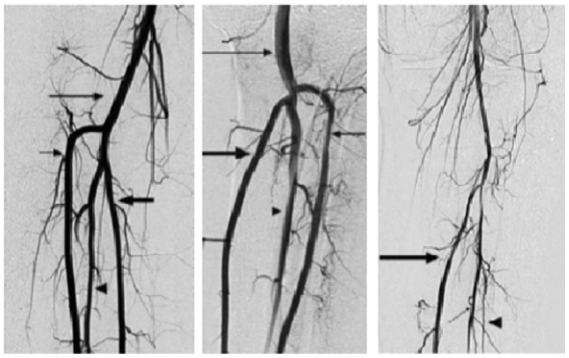
Below the Knee (BTK) Anatomy is graded into 3 types:

Type I: Variations of BTK 85%

Type IA: Presence of Tibioperonal (TP) trunk

Type IB: No TP trunk

Type IC: Peroneal Artery (PA) arising from Anterior Tibial (AT) artery.



IA: TP Trunk IB: No TP Trunk IC: PA from AT

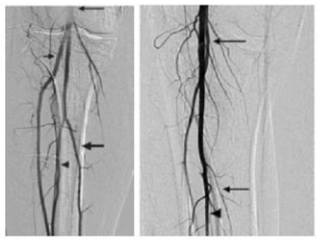
Type II: Variations of ATK origin (10%)

Type IIA1: AT arises above the knee; normal course.

Type IIA2: AT arises above the knee; initial medial course.

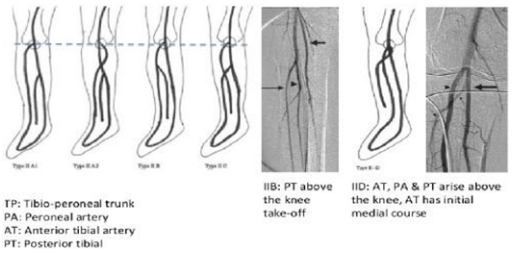
Type IIB: Posterior Tibial (PT) above the knee take-off. Type IIC: Posterior Tibial (PT) arises below the knee take-off.

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



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

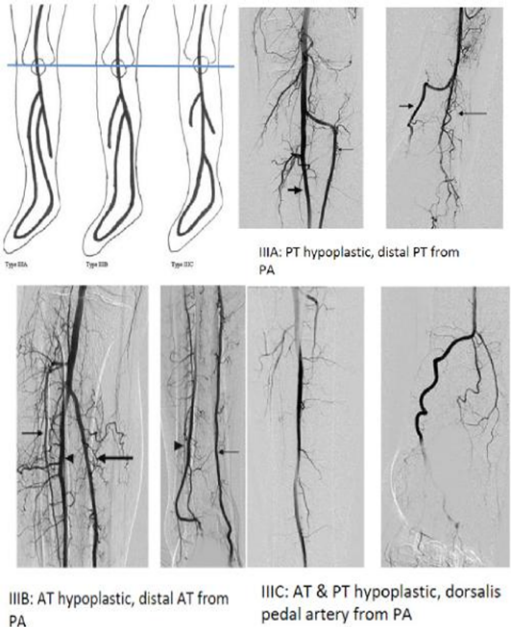
IIB: PT above the knee take-off

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

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.



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.

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.

INTRAVASCULAR ULTRASOUND ANALYSIS

(INDEC ECHOPLAQUE VERSION 4.3)

(1) To detect stent expansion
(2) To detect lumen of occluded artery
(3) To detect degree of calcification

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)

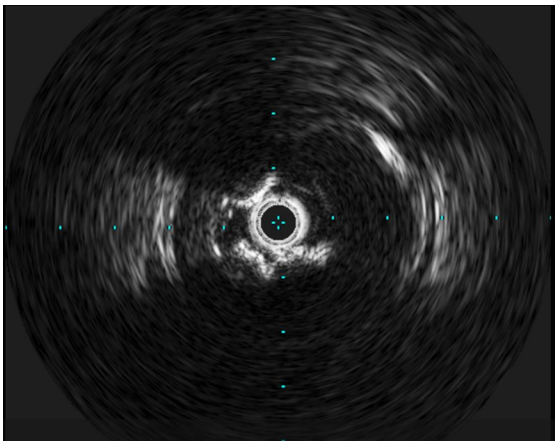
Grade 2: contiguous segments of calcification on one
side of the vessel <5 cm in length (score 2)

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



IVUS ANALYSIS SOFTWARE UPDATES SOON TO BE AVAILABLE.

SHIPPING INFORMATION

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

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Baylor Heart & Vascular Hospital

621 N Hall Street

Suite H-030

Dallas TX 75226

Phone: 214.820.2927

XLPAD STUDY TEAM

Subhash Banerjee, MD, FACC, FSCAI
Principal Investigator

Publications

As a board-certified interventional cardiologist, Dr. Banerjee is internationally recognized for his expertise in minimally invasive treatments of coronary artery disease, peripheral artery disease and transcatheter aortic valve replacement. He is currently serving as the Paul J. Thomas Endowed Chair in Cardiology and chief of cardiovascular research and innovation for Baylor Scott & White Heart and Vascular Services-Dallas.

Dr. Banerjee is the editor-in-chief of the American Journal of Cardiology, one of the premier cardiology journals in the world. He also serves as one of the founding directors of the Cardiovascular Innovations Foundation. He has led many landmark clinical trials, published over 450 peer-reviewed manuscripts, and is an invited faculty at national and international cardiovascular conferences.

David Fernandez Vazquez, MD
Project Manager

Publications

CORE LAB

Sarah Weideman, BS

Publications

Kennedy Adelman, BBA

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3. Fowkes, F.G., et al., Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. Lancet, 2013. 382(9901): p. 1329-40.
4. Mortality, G.B.D. and C. Causes of Death, Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet, 2015. 385(9963): p. 117-71.
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