



Clinical Case Study

Infinix-i Core+

Use of Parametric Imaging During Peripheral Intervention

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“ Parametric imaging is the future of angiography. The information that PI provides can be analyzed in real time to help guide patient care, particularly in revascularizing patients with critical limb ischemia. ”

—Dr. Eric J. Dippel

*Founder and President of the Vascular Institute of the Midwest
P. C. Interventional Cardiology*

Use of Parametric Imaging During Peripheral Intervention

Several types of vascular abnormalities are now treated with minimally invasive angiographic interventional procedures instead of cut-down or open surgical procedures. Vascular abnormalities such as aneurysms or arteriosclerosis can create changes in the speed or direction of blood flow due to narrowing of the vessel or the result of decreased cardiac output. Vascular abnormalities present as a change from the normal configuration or structure of the vessel and possibly an absence of a vessel. Parametric Imaging (PI) software assists with the visualization of color flow dynamics as well as the hemodynamic properties of a vascular pathology during interventional procedures.

TECHNOLOGY

Infinix™-i angiographic systems offer a comprehensive suite of imaging tools designed to assist clinicians in optimizing their workflow and image quality (IQ) during Angiographic Interventional procedures. Angiography is performed with a single injection of contrast media through a catheter placed in the blood vessel to delineate a two dimensional view of the lumen of the blood vessel.

Dynamic Trace (DT) is a digital acquisition method used in a panning mode to enhance vascular imaging by increasing background compression and reducing the presence of bones. DT is often used during the injection of contrast medium in the common iliac or femoral artery while panning

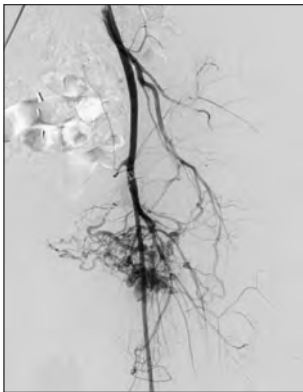
or moving the table following the flow of the contrast down the leg to the foot. Images can then be overlaid to create a panoramic image of the entire extremity.

Digital Subtraction Angiography (DSA). During DSA the anatomy remains fixed and prior to the injection of contrast media, a mask image is acquired at the beginning of the series or run. The mask image is used to subtract out the bone from the entire series in order to visualize only the contrast filled vessels. The flow of contrast medium through a particular vessel is documented per unit of time on each image derived based off of the frame rate performed during the imaging series.

Peak Trace is a function that is used to trace the flow of contrast medium using consecutive angiographic images to generate a single photo image. The image is based off of the start and end frame selected for tracing. The single photo image generated allows the capture of the entire vascular area, however, there is no way to document the time of contrast arrival.

Parametric Imaging (PI) software uses time-density curve parameters which are calculated for each pixel of a 2D-DSA image and each pixel is color coded based on the respective calculated values. The PI maps of Time-to-Peak values with red to blue color-maps represent fast to slow blood flow. The image is displayed in colors corresponding to the elapsed time or to the number of elapsed frames.

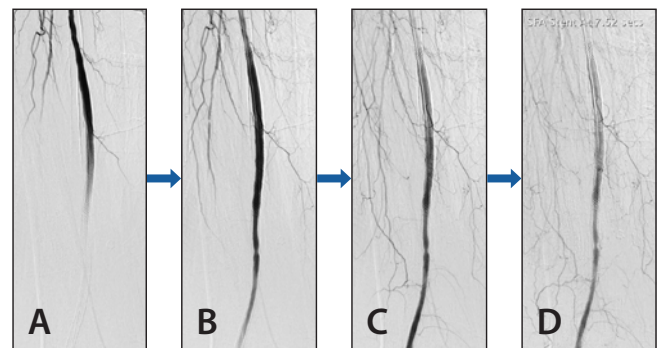
Examples of the various types of vascular abnormalities:



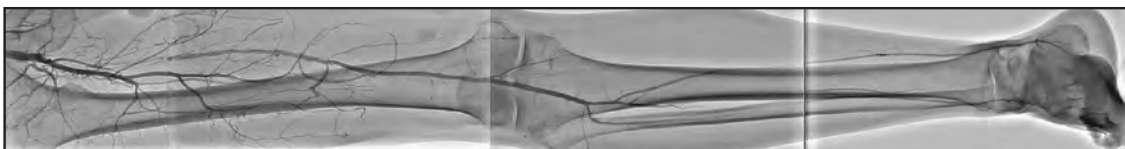
Arteriovenous malformation in the upper leg.



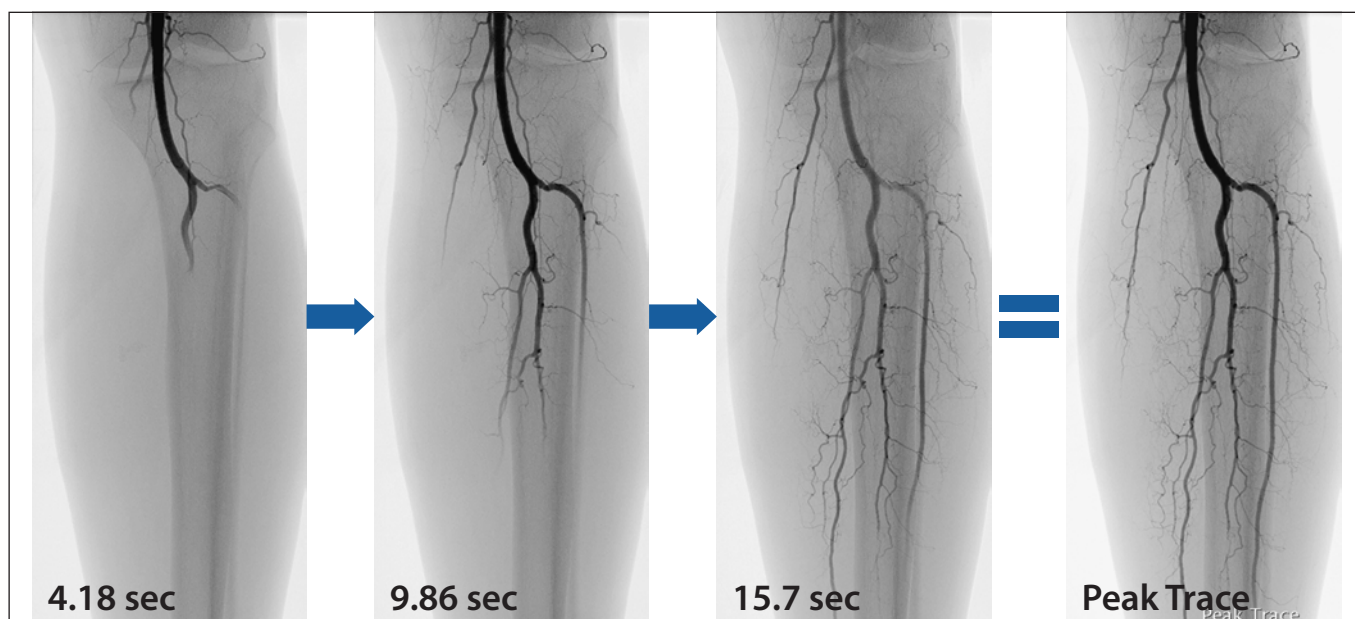
Vessel occlusion with collateral flow.



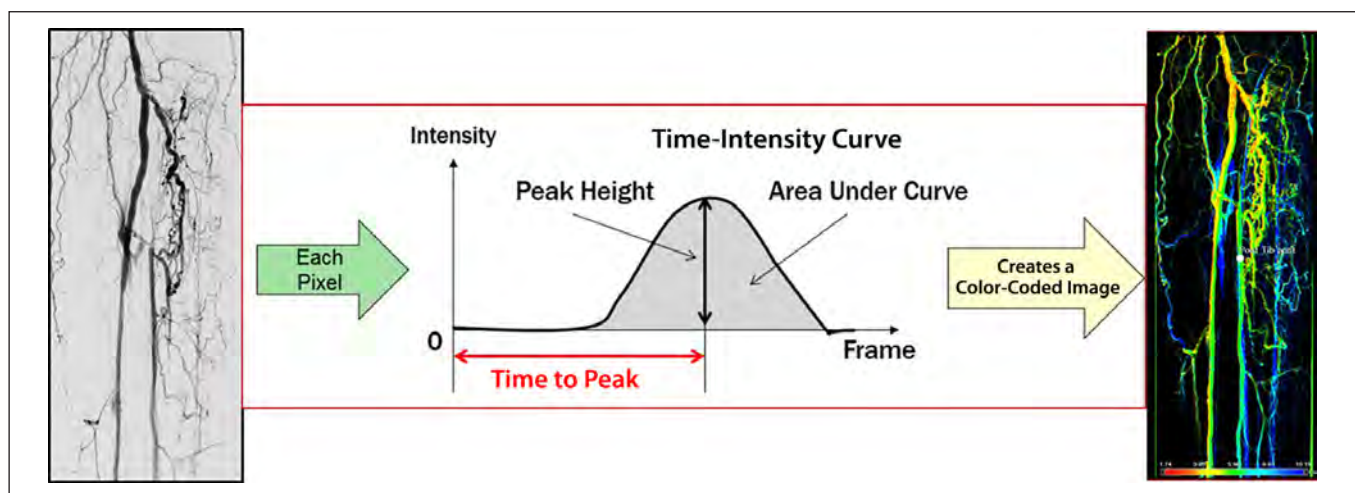
DSA series of blood flow through a stent in the superficial femoral artery showing the flow of blood per unit of time (seconds). Each image represents the flow of contrast through the vessel at a particular time in the series. (Image A = 3.18 seconds, Image B = 4.34 seconds, Image C = 5.85 seconds and Image D = 7.52 seconds.)



Panoramic image acquired using dynamic trace processing while panning from the common femoral artery to arteries of the foot.



Peak Trace: The above image is of the trifurcating vessels of the lower leg from 4.18 seconds to 15.7 seconds combined together to obtain a Peak Trace photo.



PI obtains parameter values using a time-intensity curve for each pixel in a sequence, and assigns color-coded values for display onto a single image where Intensity equals the brightness and Color equals time information.

PI software provides parameters such as:

Time to Peak (TTP)	The period required to reach the peak contrast enhancement is set as the parameter and an image is created using the time-density curves for each of the pixels in the X-ray images.
Time to Peak alpha (TTPa)	The brightness corresponding to PH is applied to each pixel, whose color is determined according to TTP. Pixels with smaller PH values are displayed darker, while pixels with larger PH values are displayed brighter.
Time to Arrival (TTA)	The time or the number of frames required to reach 20% of the maximum pixel value at each pixel, which is as an index for the time of inflow of the contrast medium, is used as the parameter.
Mean Transit Time (MTT)	Index for the contrast medium residence time (period for which contrast medium is present) at each pixel.
Peak Height (PH)	As an index for the contrast medium density, the maximum pixel value at each pixel is set as the parameter.
Area Under Curve (AUC)	As an index for the area under the time-density curve, the cumulative pixel value at each pixel is set as the parameter.

Case Studies using Parametric Imaging

Parametric imaging used during treatment of vascular disorders of the lower extremities can provide instant feedback to help clinicians measure the immediate response of the interventional treatment. When using parametric imaging in the following case studies, all imaging parameters were kept constant pre and post treatment such as: movement of the C-arm or tabletop, change in SID, field of view (FOV), table height, or magnification size, C-arm kept close to the same angulation and the compensation filter kept out of the FOV.

Patient #1

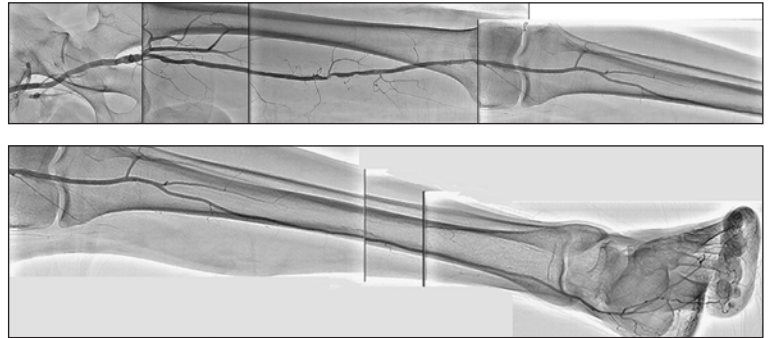
History: A 51-year-old male who previously had an intervention of the right superficial femoral artery that involved stent placement, and is now presenting with a non-healing ulcer on the 2nd toe of the left foot. The patient's left posterior artery at the foot was palpable but the left dorsalis pedis artery could barely be heard by ultrasound doppler.

Workflow: The physician punctured the patient's right femoral artery, advancing the catheter over the aortic bifurcation to the left common femoral artery to obtain images by injection of X-ray contrast using Dynamic Trace image processing. The DT Images showed calcium in the distal superficial femoral artery (SFA) extending to the popliteal artery.

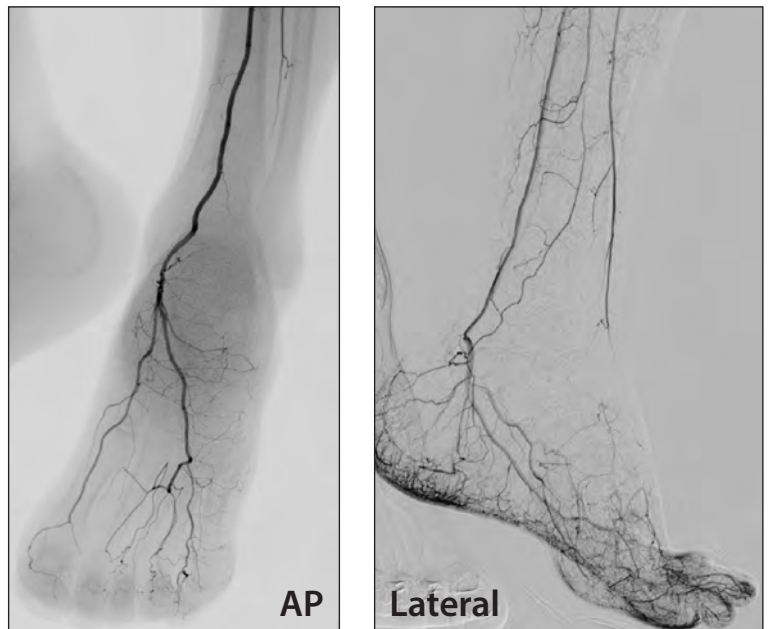
DSA imaging was then performed for visualization of the trifurcation in the lower leg (Posterior Tibial, Anterior Tibial and Peroneal), as well as DSA of the foot placed in the AP projection and lateral projection; both showed an interruption of the anterior tibial artery (AT) to the dorsalis pedis (DP) artery.

DSA of the foot was done in the same AP and LAT views prior to intervention and sent to the PI software.

The physician then advanced a 300 cm 0.014" guidewire down the left superficial femoral artery to the popliteal artery and intravascular ultrasound confirmed plaque in the area of the popliteal artery. The mid SFA to popliteal artery was treated by laser and further dilated by a 6 x 40 mm balloon. After placement of a self-expanding stent, DSA of the foot was repeated in the same AP and LAT views prior to intervention and sent to the PI software.



The DT Images showed calcium in the distal superficial femoral artery (SFA) extending to the popliteal artery with very little flow to the foot.



DSA of the foot was done in the same AP and LAT views showing interruption of blood flow of the Anterior Tibial to the DP artery.

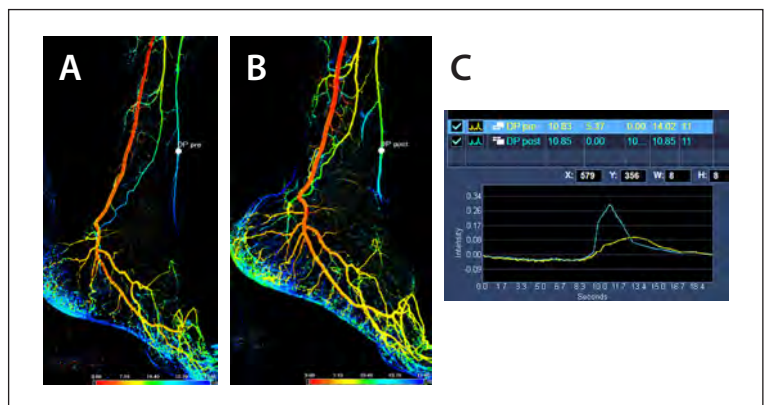


Image A: Anterior Tibial (DP) PI image Pre Intervention: Image B: Anterior Tibial (DP) PI image Post Intervention: Image C: Analysis graph showing histogram of Peak contrast enhancement; the yellow histogram is of the DP Pre Intervention and the green histogram shows the increase in Peak contrast enhancement Post Intervention.

Patient #2

History: A 78-year-old male with a history of heart disease and stroke previously presented with an ulcer on the right foot. Dynamic Trace imaging identified chronic total occlusion of the right leg and disease on the left leg was noted. Interventional treatment was performed on the right leg but the patient returned due to a non-healing ulcer on the left foot which now needed treatment.

Dynamic Trace imaging of the left leg showed occlusion of the vessels below the popliteal artery with collateral formation of the trifurcating vessels. DSA of the trifurcation was performed to further evaluate associated vessels.

A long curved sheath was inserted in the right femoral artery, up and over the aortic bifurcation, and then a 300 cm peripheral guidewire was advanced to the lower leg trifurcating vessels. The occlusion could not be crossed

so the left foot was prepped for needle puncture of the posterior tibial artery. After successful insertion of a catheter, a 0.014 inch 300 cm wire was guided from below the occlusion until a channel was created. DSA confirmed successful crossing and once a wire was guided through the channel from above, the catheter and wire were removed from the foot and manual pressure was held to stop arterial bleeding. A balloon catheter was then placed through the femoral arterial sheath to the area of occlusion and laser atherectomy was performed from the popliteal artery through the occlusion to the foot. Inter-arterial ultrasound determined the proximal popliteal luminal diameter to be at least 3.5 mm and a 3.5 x 38 mm stent was placed in the popliteal artery. Additionally a 2.5 x 38 mm stent was placed through the previously occluded area. DSA was performed post treatment and images were sent to parametric imaging to validate there was indeed an increase in the dynamic flow to the left foot post interventional treatment.

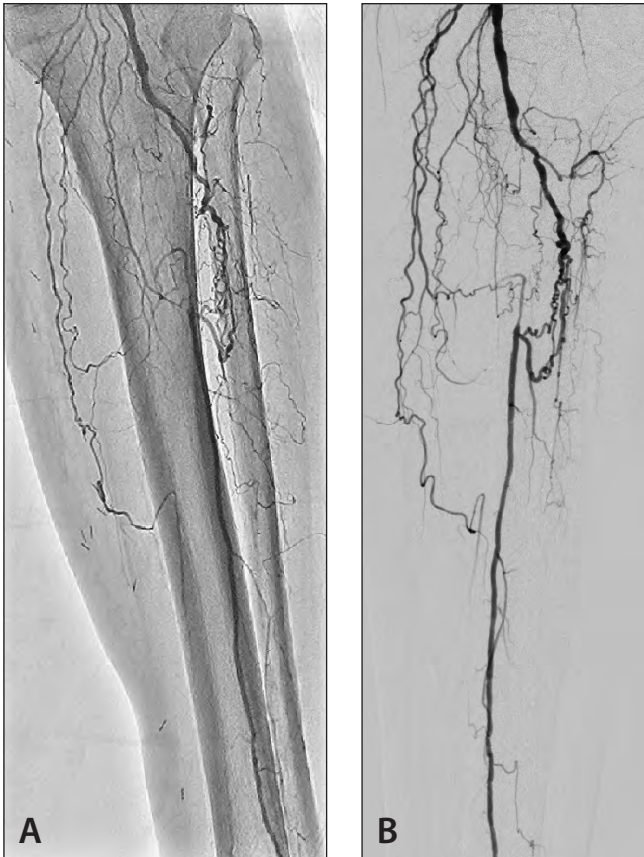


Image A: Dynamic Trace of the lower extremity showing occlusion of the trifurcating arteries.

Image B: DSA of the lower leg identifies collateralization of the vessels.

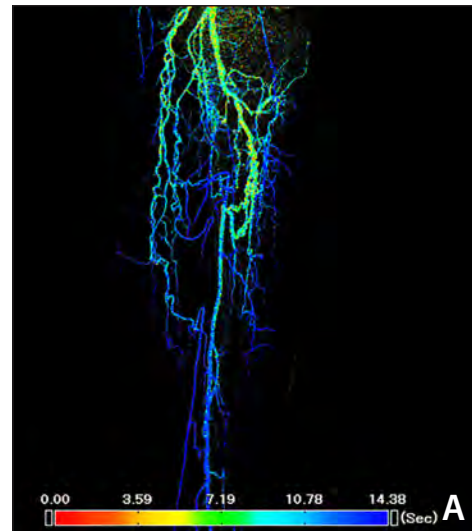


Image A: Parametric imaging pre intervention showing flow to the foot to take at least 14.38 seconds.

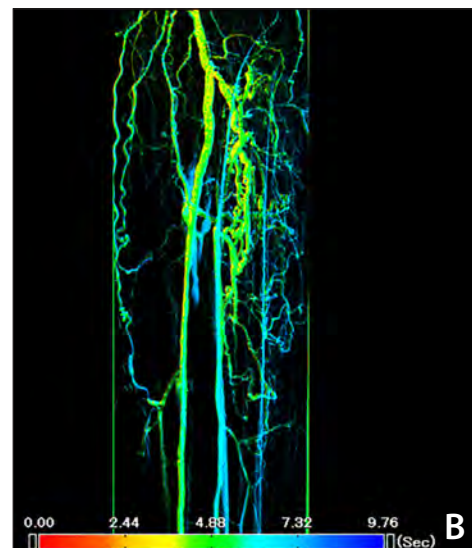


Image B: Parametric Imaging post intervention now shows the flow to the foot to take only 9.76 seconds.

Patient #3

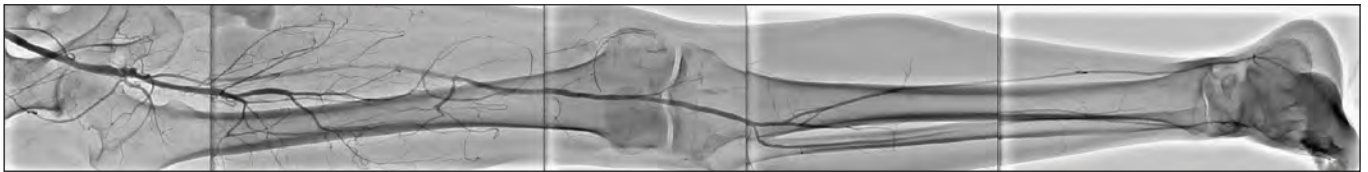
History: A 51-year-old male presents with complaints of right lower leg discomfort and an ulcer of the right foot. Dynamic Trace and DSA showed the patient had a thrombus in the right SFA. After an intra-arterial injection of 300 mcg Nitroglycerin, DSA of the right foot was sent to parametric imaging which showed variation of flow dynamics between the anterior tibial and posterior tibial arteries. Laser atherectomy through the SFA was performed followed by balloon dilatation, and placement of a stent in the proximal portion of the SFA.

DSA of the right foot showed that the clot had occluded the anterior tibial artery. Percutaneous Transluminal Angioplasty (PTA) was performed on the anterior tibial artery down to the dorsalis pedis. Following PTA, an injection of 300 mcg NTG was given, DSA was performed, and the images were sent to

PI software to compare Time-to-Peak contrast enhancement of blood flow pre and post intervention. The PI color map image displays elapsed time in seconds corresponding with the number of frames acquired in the DSA sequence.

Parametric images were compared pre and post intervention using TTPa. Post interventional images showed a decrease in the period of time required to reach the peak contrast enhancement in both the posterior tibial and anterior tibial arteries.

Additionally, the PI software analysis showed in the area of the ROI, there was a difference in the mean and standard deviation between the posterior tibial artery (3.86, 0.43) compared to the anterior tibial artery (9.57, 2.35) representing the variance of dynamic blood flow between the two vessels supplying the right foot.



Panoramic view of Dynamic Trace image processing showing clot in the proximal superficial femoral artery (SFA) with distal filling to the popliteal artery.

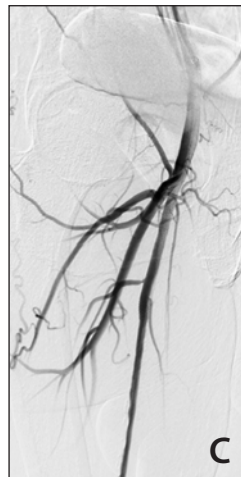
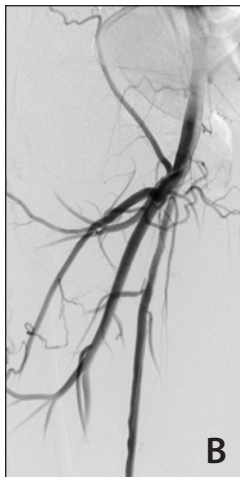
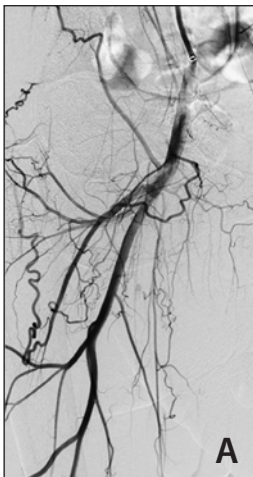


Image A: Initial DSA of the proximal SFA. Image B: DSA of SFA post balloon dilatation. Image C: DSA of SFA post stent placement.

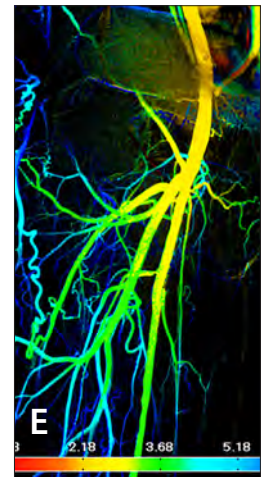
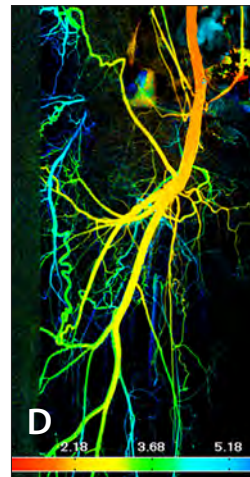


Image D: Parametric image pre intervention. Image E: Parametric imaging post intervention.

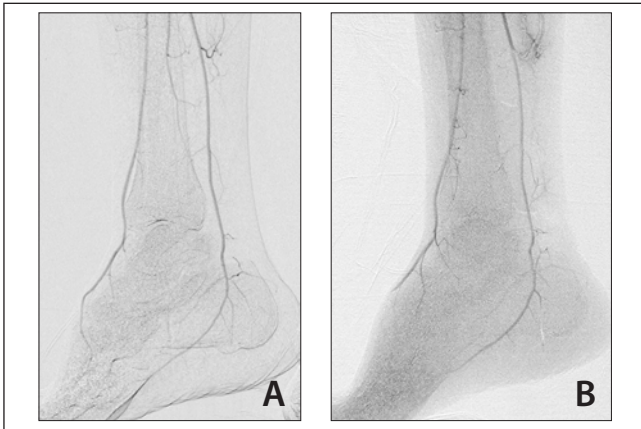


Image A: DSA of right foot pre intervention.
Image B: DSA of right foot post intervention (laser, stent, PTA).

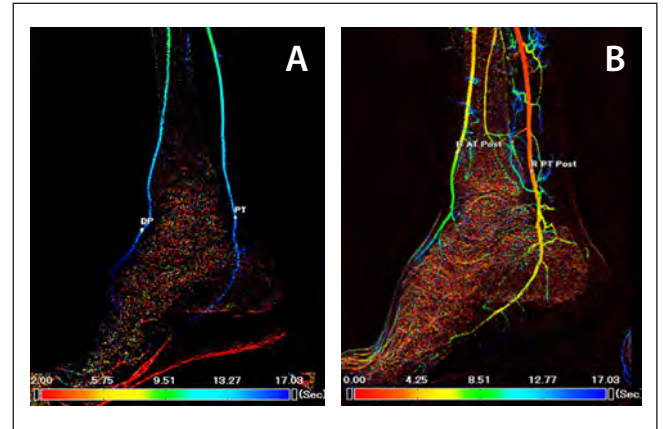


Image A: PI image pre intervention
Image B: PI image post intervention (laser, stent, PTA).



In Image A: The yellow histogram represents the peak contrast enhancement of the dorsalis pedis artery prior to intervention. The green histogram represents the increase in the peak contrast enhancement post intervention in the dorsalis pedis artery.



In Image B: The yellow histogram represents the peak contrast enhancement of the posterior tibial artery prior to intervention. The green histogram represents the increase in the peak contrast enhancement post intervention in the posterior tibial artery.



In the image to the left, the red histogram represents the peak contrast enhancement of the dorsalis pedis artery post intervention in comparison to the yellow histogram with the posterior tibial artery post intervention, identifying the filling of the PT artery to be faster than the AT artery.



Dynamic Trace imaging of the right leg determined in-stent restenosis with minimal flow to the right foot.

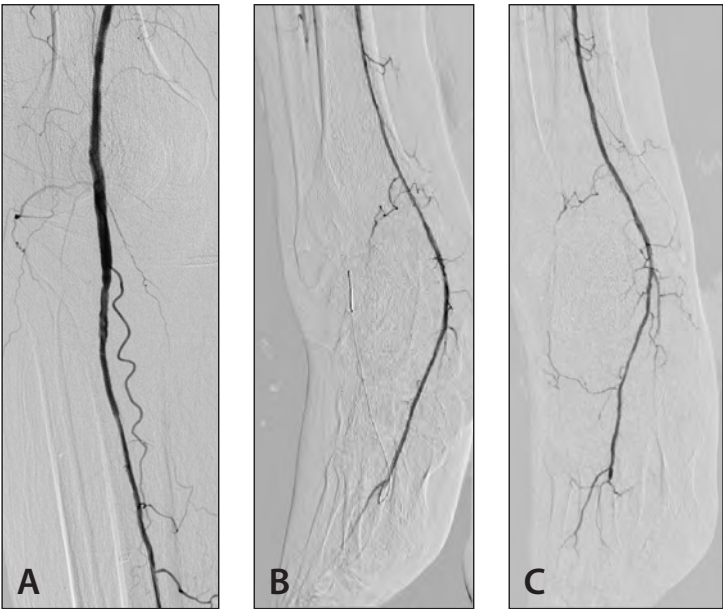


Image A: Popliteal artery post laser atherectomy. Image B: DSA right foot following laser atherectomy. Image C: DSA of posterior tibial artery post balloon dilatation.

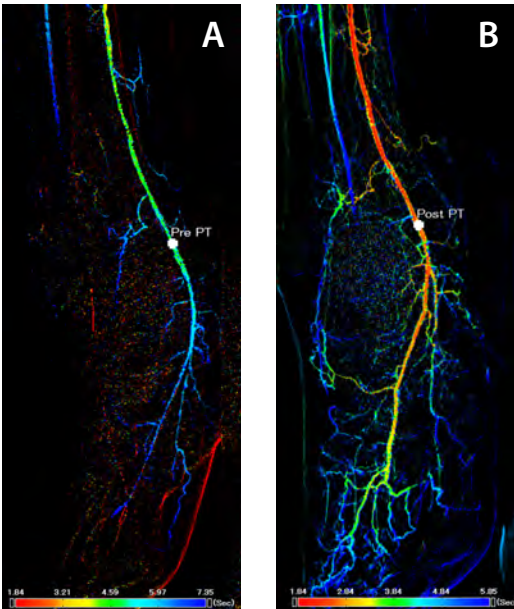
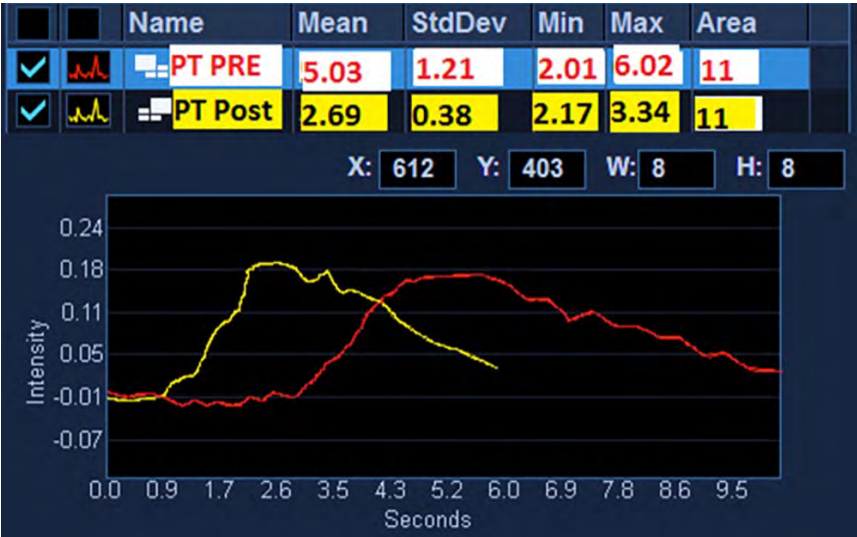


Image A: PI color map of the Posterior tibial artery post laser atherectomy. Image B: Posterior tibial artery PI color map following balloon dilatation.



Analysis histogram obtained post laser atherectomy (red) was compared to the histogram post balloon dilatation (yellow) and visualized the improvement in the peak contrast enhancement in the Posterior Tibial artery.

Patient #4

History: Patient presented with complaints of ongoing symptoms following previous placement of a stent in the patient's right iliac artery as well as the distal superficial femoral artery of their right leg. The patient was taken to the interventional lab for another minimally invasive procedure in which the left femoral artery was used as the entry point for sheath insertion. Dynamic trace imaging of the right leg identified in-stent stenosis of the stent previously placed in the superficial femoral artery.

A 0.018" guidewire was advanced to the right foot. Laser atherectomy was tunneled all the way through the stenosis of the stent followed by balloon dilatation of the popliteal artery down to the posterior tibial artery of the right foot.

The DSA images of the foot taken post laser atherectomy and also following post balloon dilatation were sent to PI software to evaluate arterial flow dynamics.

CONCLUSION

Interventional radiology procedures can be challenging due to the complexity of the vascular anatomy, the pathology of the underlying disease, the fine size of the vasculature, organ motion and the required treatment accuracy. ImagingRite advanced applications give clinicians the tools they want to obtain the images they need during challenging interventional procedures. Infinix-i Flat Panel Detectors with enhanced image processing were used, enabling the physician to identify the location and extent of the disease pathology, as well as assess the condition of the arteries in the lower leg. In this case, pre and post procedural parametric imaging Time-to-Peak maps supported visualization of the change in the blood flow before and after treatment, aiding the physician in the assessment of blood flow restoration.

The Infinix-i Core+ is the INFX-8000V (SP)

Parametric Imaging is intended for use with existing imaging from the cleared device.
The software is not intended for stand-alone use or diagnosis.

The clinical results described in this document are the experience of the author.
Results may vary due to clinical setting, patient presentation and other factors.

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