



Case Study

Redefine Lower Extremity Intervention with High Definition (Hi-Def) Imaging



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Visualization Like Never Before with the World's First High Definition Modes

The Alphenix interventional systems feature the all-new and exclusive true high definition (Hi-Def) detector* with 76 micron pixel imaging modes, helping clinicians visualize fine details in real time during complex endovascular procedures.

The world's first true Hi-Def detector—with more than double the spatial resolution of conventional flat panel detectors (FPDs)**—provides imaging capabilities never before possible. The unique hybrid 12" x 12" and 12" x 16" FPD combines high definition imaging technology based on crystalline silicon that increases inherent spatial resolution to 6.6 line pairs per millimeter in addition to the standard imaging modes for larger field-of-view (FOV) imaging.

The Hi-Def imaging system has been successfully used in interventional neuroradiology and cardiology procedures,

with demonstrable capability to enhance visualization of vascular anatomy and interventional devices in real-time with no observable increase in patient dose.¹⁻⁴

Hi-Def: See What You've Been Missing

The unique Alphenix system offers standard modes at 16", 12", 10", 8", 6", or 4.3" FOV and three Hi-Def modes with 3", 2.3" or 1.5" FOV, delivering increased spatial resolution without interruption of procedure workflow. Alphenix's advanced 16-bit imaging chain, including Illuvis triple-phase image processing and noise reduction technology, provides clean, sharp, more defined images during wire manipulation and device placement with enhanced visualization of the surrounding vessels and devices.



The Alphenix interventional systems feature the all-new and exclusive high definition (Hi-Def) imaging detector* with the highest spatial resolution available, helping clinicians see fine details with increased confidence.

*Available as an option for Alphenix Core + (FPD12), Alphenix Biplane (FPD12/FPD12), Alphenix Sky + (FPD1216/Tilt. table), Alphenix 4D CT (FPD1216/CAS-930A)

**Documented testing has demonstrated imaging capabilities with up to 2.5x greater resolution.

Lower Extremity Intervention with Hi-Def Imaging: Case Reports

Case 1: Navigate Through Challenging Vasculature with Hi-Def

Courtesy of Salman A. Arain, MD, FACC, FSCAI
The University of Texas Health Science Center at Houston,
Houston, TX

History: A 71-year-old man with prior heart and kidney transplant, chronic renal insufficiency, and peripheral arterial disease presented with a chronic right foot wound. Angiography showed diffuse calcification within the anterior tibial artery (ATA) (Figure 1) and a severe stenosis within the tibioperoneal trunk (TPT) (Figure 2).

Intervention: A 0.014 nitinol tipped wire was used to cross the multiple stenoses within the anterior tibial artery. Attempts to advance two different types of microcatheters across a stenosis within the mid-distal ATA were unsuccessful. Standard FPD imaging using a secondary zoom feature was unable to identify the mechanism of obstruction.

Hi-def images revealed a focal, high grade stenosis as well as distortion of the microcatheter tip as it engaged the calcified segment. (Figure 1). Hi-Def imaging was used to exchange the initial wire for a dedicated stainless-steel wire in anticipation of atherectomy. Orbital atherectomy was successfully performed using a 1.5 mm crown. The residual stenosis within the mid-distal ATA was successfully treated with angioplasty.

The wire was subsequently redirected into the posterior tibial artery. A high-grade stenosis at the ostium of the TPT was treated with angioplasty and drug eluting stent placement (Figure 2).



Figure 1: (Left) Digital subtraction angiography image acquired using 12.0" x 12.0" FOV standard FPD mode showing diffuse calcification within the ATA. (Right) Hi-Def images showing different phases of microcatheter tip passing through the calcified lesion in the ATA under Hi-Def 2.3" x 2.3" FOV guidance.

“Hi-def images revealed a focal, high grade stenosis as well as distortion of the microcatheter tip as it engaged the calcified segment.”

Follow-up: The patient was referred back to wound care and had successful healing of his wound.

Discussion: Hi-Def imaging was able to define the vascular anatomy at much higher resolution than FPD. Initial

attempts to cross a high-grade stenosis within the ATA were unsuccessful. Hi-Def imaging allowed us to identify the mechanism of and exact location of obstruction. It also enable us to guide a support wire across the near-occlusion and perform successful angioplasty.

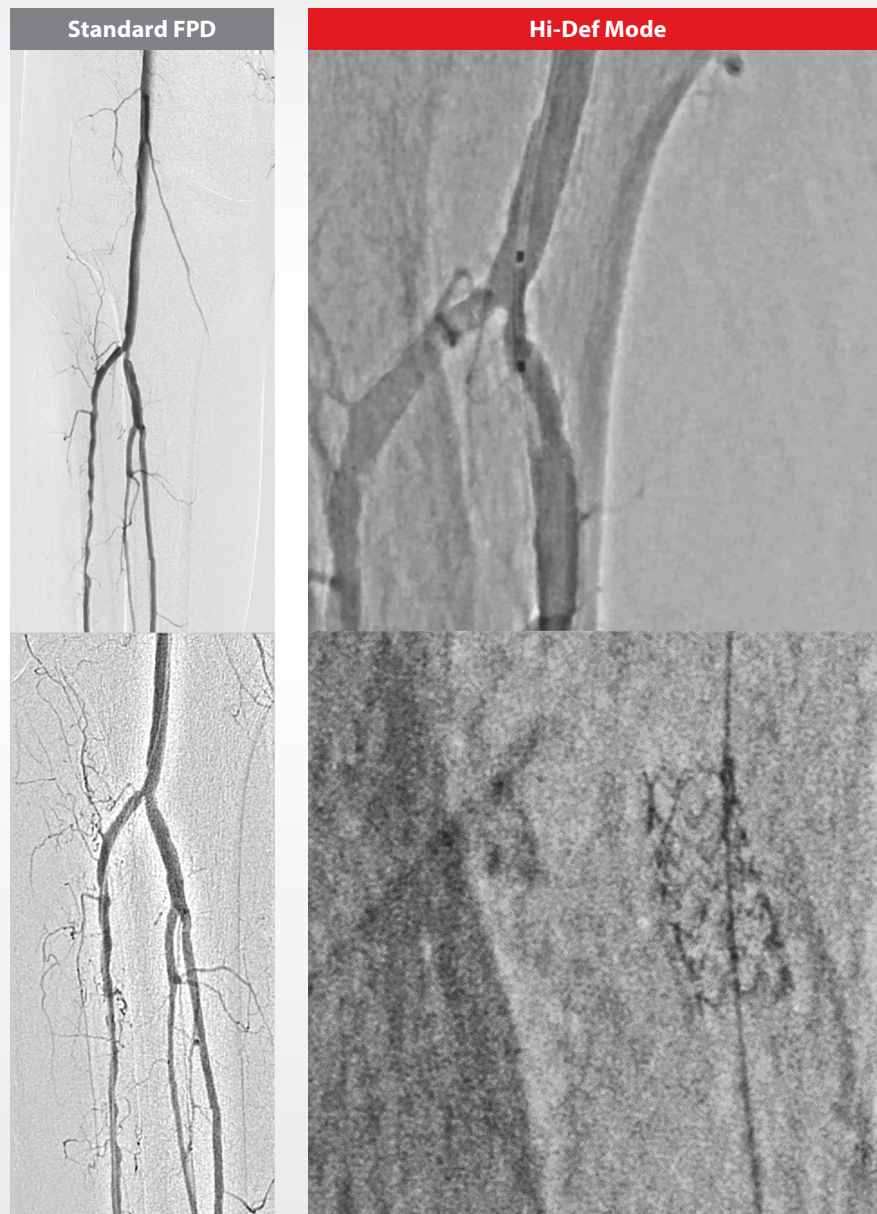


Figure 2: A high-grade stenosis was seen at the ostium of the TPT under 12" x 12" FOV standard FPD mode (top left) and under 3" x 3" FOV Hi-Def mode (top right). This lesion was treated with angioplasty and drug eluting stent placement. Angiography images showing under 8" x 8" FOV standard FPD mode (bottom left) and under 1.5" x 1.5" FOV Hi-Def mode (bottom right).

Case 2: Enhanced Visualization of Stent Architecture While Minimizing Contrast Use

Courtesy of Salman A. Arain, MD, FACC, FSCAI
The University of Texas Health Science Center at Houston,
Houston, TX

History: An 82-year-old man with coronary artery disease, peripheral arterial disease, hypertension, diabetes and chronic renal insufficiency presented with recurrent, life style limiting left calf claudication. Ultrasonography revealed a severe stenosis in the distal popliteal artery. The patient had an elevated creatinine (2.8) and was referred for “low contrast” angiography and possible intervention. Femoral and popliteal angiography confirmed the presence of a high-grade stenosis proximal to previously placed stents in the popliteal artery and the anterior tibial artery.

Intervention: An 0.014 soft-tipped wire was advanced to the popliteal artery. There was difficulty in advancing the wire across the stenosis within the distal segment of the artery using standard FPD imaging with secondary zoom.

Hi-Def imaging was used to better visualize the previously placed stents and to guide the wire across the stenosis. An Hi-Def road map was then used to place a stent within the popliteal artery (Figure 3). Final angiography showed complete resolution of the stenosis with no residual dissection. The total of 12 cc of contrast was used to perform the intervention.

Follow-up: The patient has complete resolution of his claudication. His creatinine remained unchanged after the intervention.

Discussion: Hi-Def imaging was able to visualize vascular anatomy at a much higher resolution than FPD alone. This also allowed us to successfully pass a wire across the stenosis by avoiding side branches. The Hi-Def mode also revealed features of the previously placed stents that were not seen by FPD, for e.g. complete fracture and avulsion of one of the stents (Figure 3).

The use of Hi-Def roadmap enabled us to accurately size and deploy a stent with minimal contrast use. In this particular case, the use of Hi-Def imaging obviated the need for intravascular imaging which has also been shown to improve accuracy of stent placement in vascular interventions.

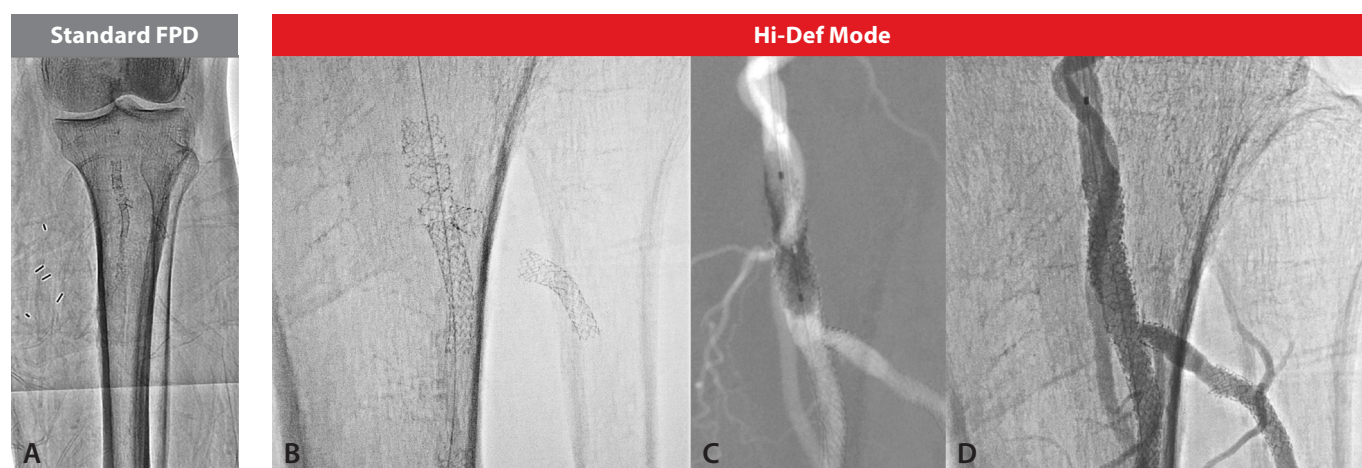


Figure 3: The 3" x 3" Hi-Def mode (B) showing complete fracture and avulsion of one of the previously placed stents which was not visible under the 12" x 12" FOV FPD mode (A). The Hi-Def mode was subsequently used to accurately size and precisely deploy a stent across the stenosis within the popliteal artery (C, D).

“The Hi-Def mode also revealed features of the previously placed stents that were not seen by FPD, for e.g. complete fracture and avulsion of one of the stents.”

Case 3: **Aid Wire Navigation Through Hostile Anatomy**

Courtesy of Salman A. Arain, MD, FACC, FSCAI
The University of Texas Health Science Center at Houston,
Houston, TX

History: A 74-year-old man with coronary artery disease, long standing diabetes, peripheral arterial disease, and a non-healing left foot arterial ulcer was referred for angiography after a failed intervention upon the anterior tibial artery (ATA). His angiogram also showed occlusion of the posterior tibial artery (PTA).

Intervention: The occluded segment of the PTA was crossed with a hydrophilic support wire and microcatheter and treated successfully with long balloon angioplasty. We then attempted to revascularize the ATA. Angiography using standard FPD settings revealed a high-grade stenosis at the ostium and a short occlusion with proximal segment of the artery. Our initial attempts to wire the ATA were unsuccessful because of ambiguity about the location of the ostium.

Hi-Def digital subtraction images showed the presence of a partially healed dissection at this location, and adjacent

branched running parallel to the proximal ATA. An Hi-Def roadmap was used to pass a tapered tip wire into the true lumen of the artery, and to direct it towards the proximal cap of the occlusion. A high penetration hydrophilic wire was then used to cross the occlusion. The proximal ATA was treated with angioplasty followed by stent placement.

Intravascular ultrasonography confirmed successful stent deployment as well as thrombus beyond the treated segment—likely subacute. The patient was treated with a short course of systemic thrombolytics for 12 hours after the procedure.

Follow-up: The patient had palpable pedal pulses the next day. His foot ulcer healed completely over the next 6 weeks.

Discussion: Hi-Def imaging was able to define the vascular anatomy at much higher resolution than FPD. Our initial attempts to enter the ATA were unsuccessful on account of a dissection flap not seen by standard imaging—even with the zoom feature enabled. Hi-Def imaging allowed us to identify the true vessel lumen and avoid passing the wire into adjacent branches. The Hi-Def roadmap feature enabled us to successfully cross the occlusion and complete the revascularization.

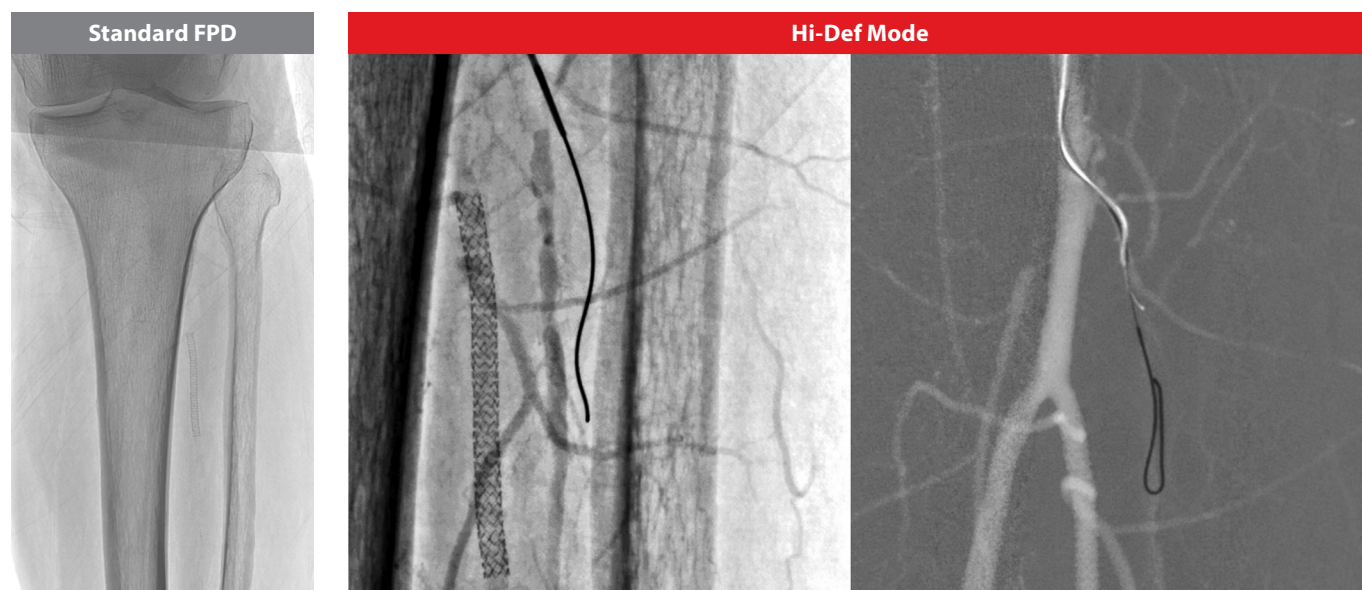


Figure 4: A previously deployed stent is hardly visible under the standard FOV (left) whereas Hi-Def (middle) revealed a clear stent structure and high-grade stenosis at the ostium and a short occlusion with proximal segment of the PTA. An Hi-Def roadmap (right) was used to pass a tapered tip wire into the true lumen of the artery, and to direct it towards the proximal cap of the occlusion.

**“Hi-Def imaging allowed us to identify the true vessel lumen
and avoid passing the wire into adjacent branches.”**

Lower Extremity Intervention with Hi-Def Imaging: Summary

Courtesy of Salman A. Arain, MD, FACC, FSCAI
The University of Texas Health Science Center at Houston,
Houston, TX

Our initial experience using a novel Hi-Def imaging system shows that it can effectively be used in real time to improve visualization of lower extremity vasculature and interventional devices during complex peripheral arterial interventions. Images obtained in the Hi-Def setting have a higher resolution and improved quality compared to standard imaging modes, allowing visual analysis of vessel anatomy and stent structure with a high level of accuracy and may be used to improve technical outcomes.

The clinical results, performance and views described in this case study are the experience of the author. Results may vary due to clinical setting, patient presentation and other factors. Many factors could cause the actual results and performance of Canon Medical's product to be materially different from any of the aforementioned.

References

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