

# New Trends in Treating SFA

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For applicable products, consult instructions for use on [manuals.medtronic.com](http://manuals.medtronic.com). Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

# New Trends

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- Vessel preparation
  - Specialty balloons
  - Atherectomy
- DCB (new paclitaxel formulations, -limus)
- Stents
  - Focal stenting
  - ‘TACK’
  - New stent designs (‘whirl-flow’ etc.)

# Common denominator in all new trends

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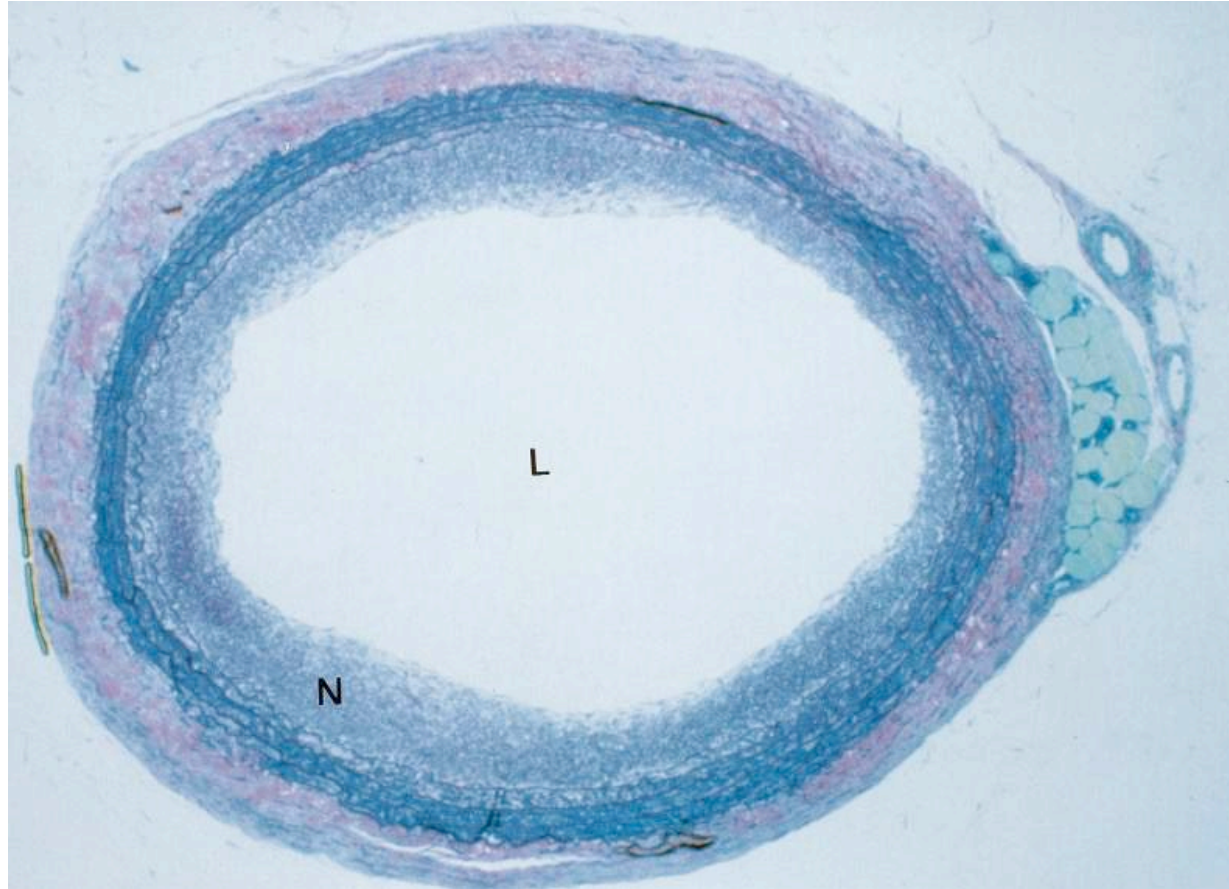
- Importance of choice of right material
  - Diameter
  - Length
  - Avoid overtreatment

# Deleterious effect of oversizing

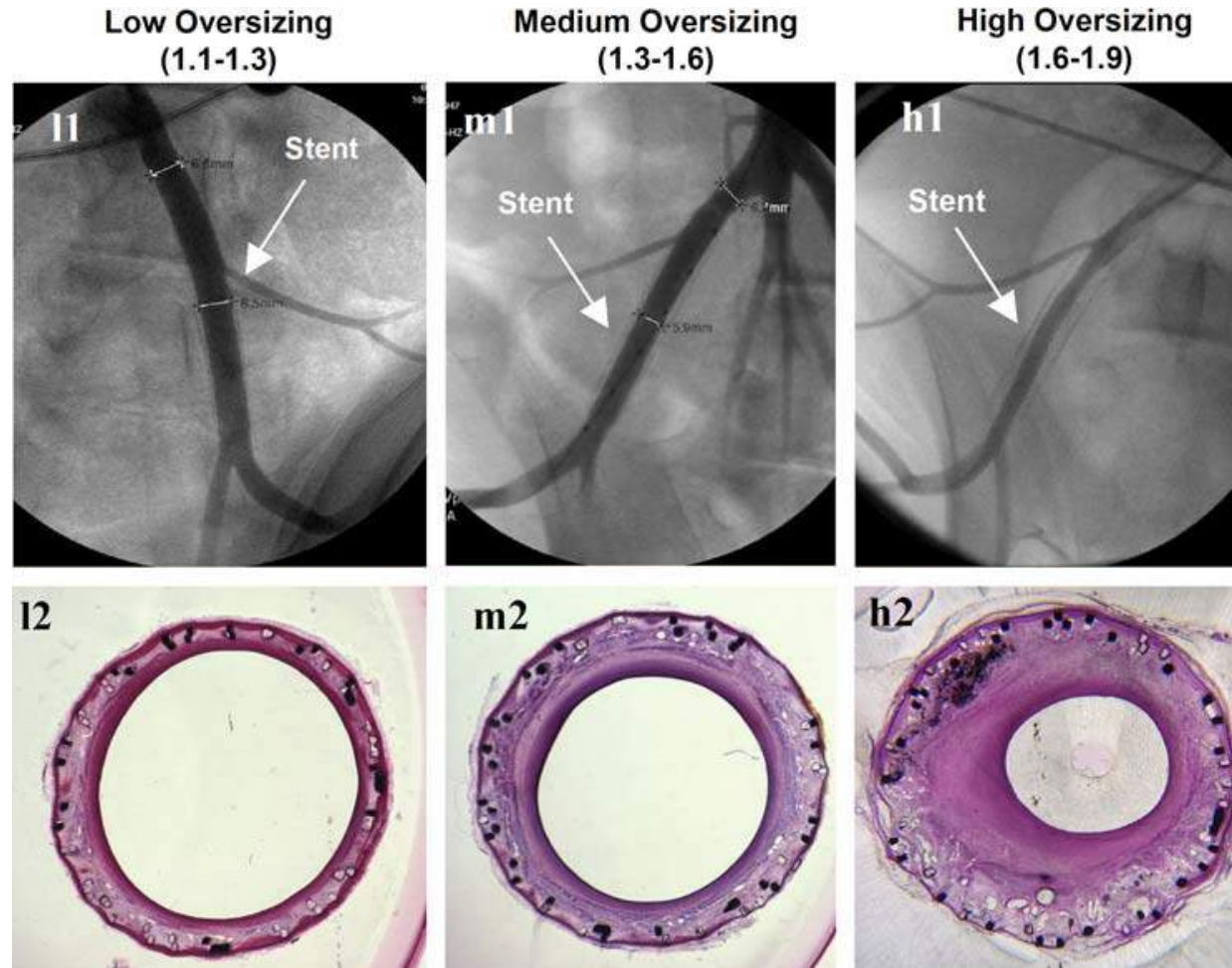
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- More dissections
- Early re-stenosis
- Excessive neointimal hyperplasia

# Balloon-induced stenosis (rat model)

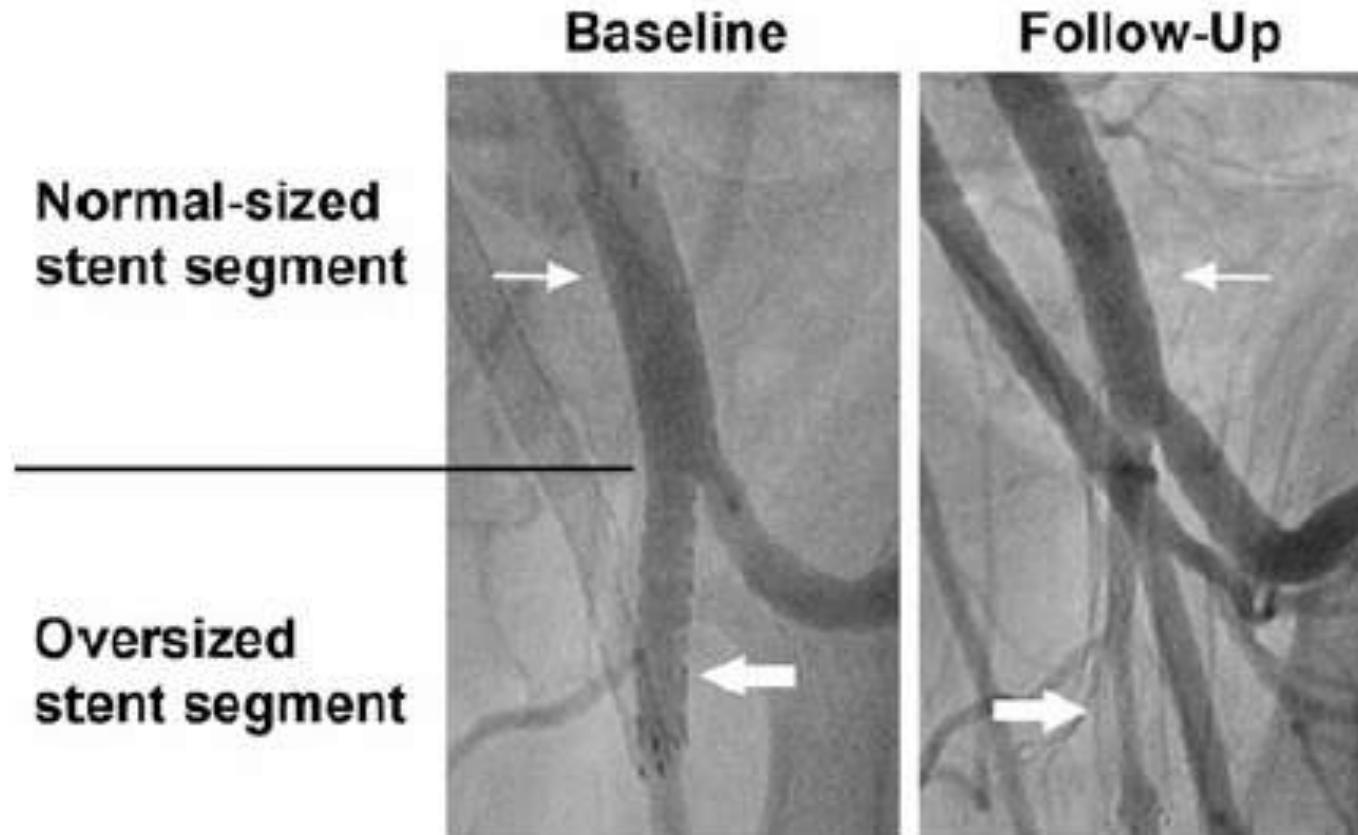


# Importance of sizing-excessive neo-intimal hyperplasia





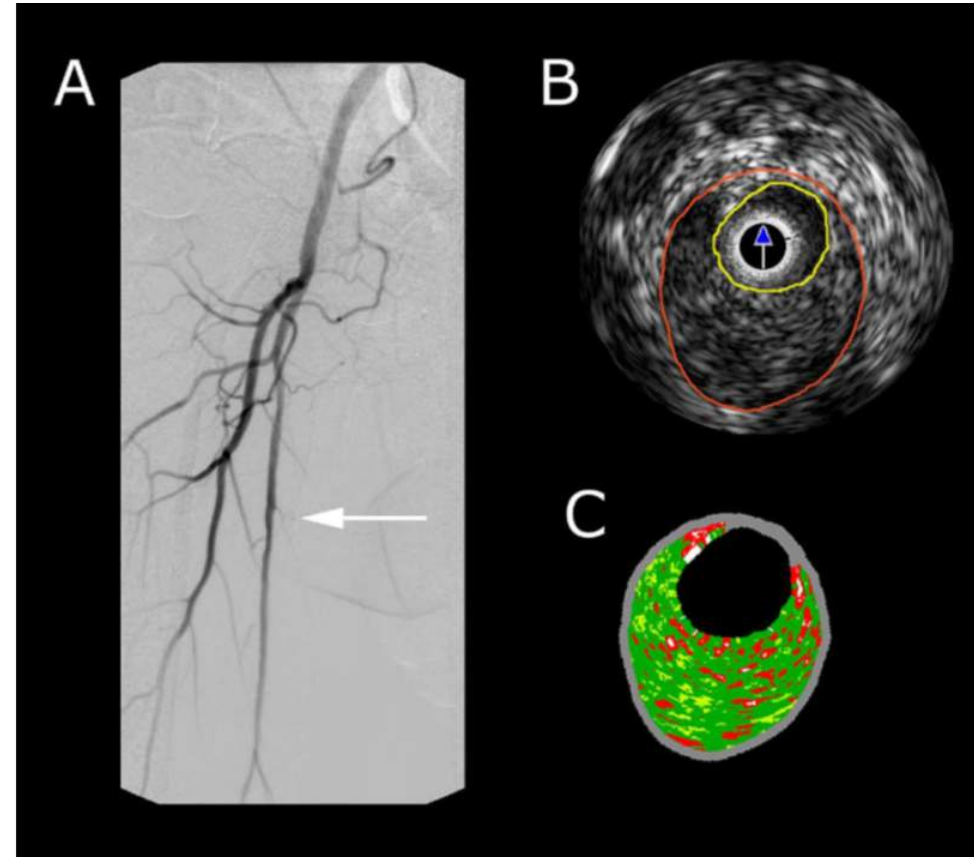
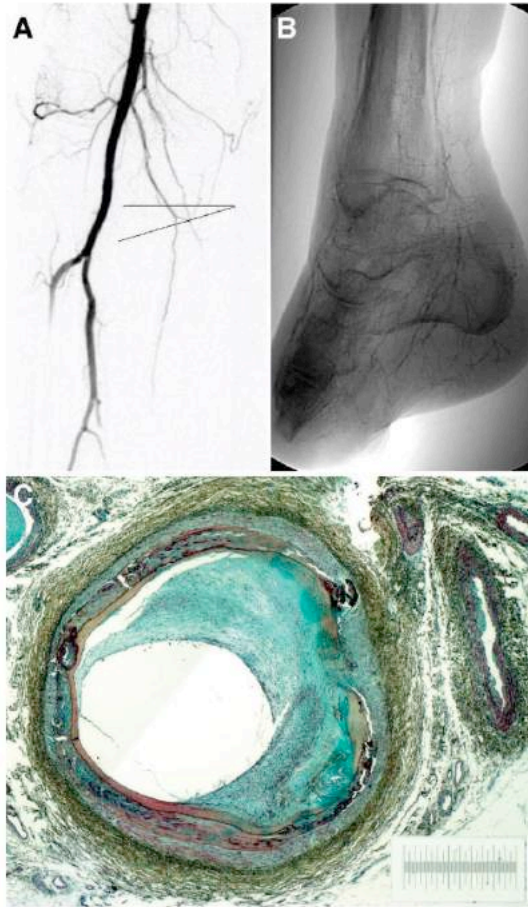
# Importance of sizing-excessive neo-intimal hyperplasia



# What is the true diameter of a vessel?

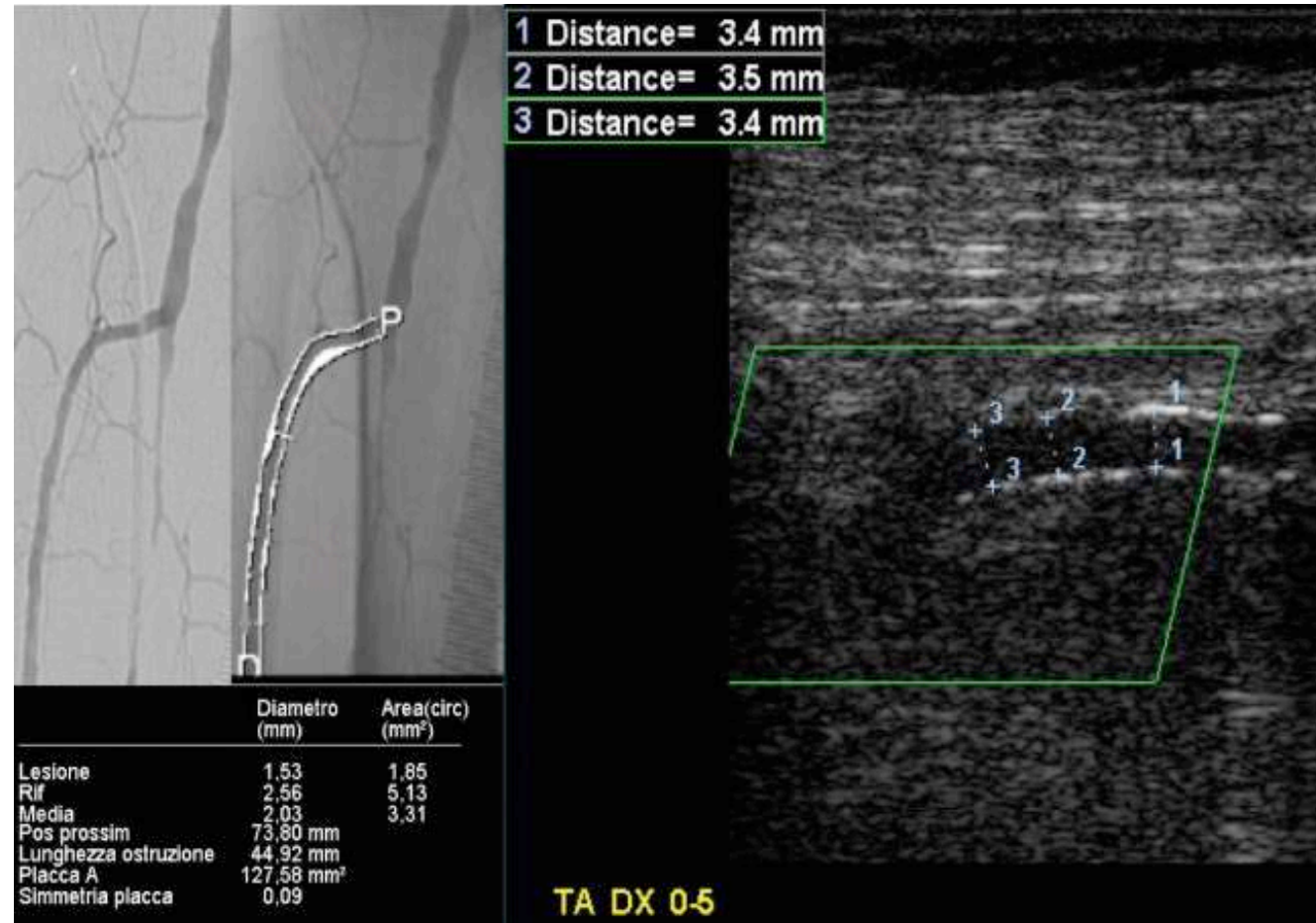
- Angiography vs. histology (even normal appearing arteries carry large burden of disease)
- Histological diameter (media-media)
  - Popliteal artery 6.2 mm
  - Tibial arteries 3.1 mm
- Lumen size detected by angiography usually tends to cause undersizing of the balloon diameter particularly in BTK vessels (large burden of atherosclerosis)
- Alternative techniques
  - IVUS
  - OCT
  - EVUS (sizing and dynamic information)

# Angiography vs. histology/IVUS



Angiographic stenosis 30%      IVUS stenosis 76%  
yellow line IEL, red line EEL

# EVUS vs. angiography (QVA)



# Importance of sizing

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- RCT-BTK trial
- Angiographic analysis after completion of procedure demonstrated final mean residual stenosis of  $29.5 \pm 13.8\%$  in the DCB group and  $30.0 \pm 12.8\%$  in the PTA group

# Optimal sizing

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- Lumen size detected by angiography usually tends to cause undersizing of the balloon diameter particularly in BTK vessels (large burden of atherosclerosis)
- Alternative techniques
  - IVUS
  - OCT
  - EVUS (sizing and dynamic information)

# Role of intravascular imaging

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- Sizing
- Detection of recoil and dissection

# IVUS and sizing

*Clinical Investigation*

*Journal of Endovascular Therapy*

## **Optimal Vessel Sizing and Understanding Dissections in Infrapopliteal Interventions: Data from the iDissection Below the knee study**

Nicolas W, Shammass, W John Shammass, Susan Jones-Miller, James T Torey, PA-C, Ehrin J. Armstrong, Qais Radaideh, Gail Shammass

*Journal of Endovascular Therapy* 2020 Vol 27(4) 575-80

*Clinical Investigation*

*Journal of Endovascular Therapy*

## **Vessel Diameter Evaluated by Intravascular Ultrasound Versus Angiography**

Osamu Iida, Mitsuyoshi Takahara, Yoshimitsu Soga, Masahiko Fujihara, Daizo Kawasaki, Kaisuke Hirano, Donghoon Choi and Toshiaki Mano on behalf of the IVORY investigators

*J Endovasc Ther* 2021 Sep 27;15266028211047946. doi: 10.1177/15266028211047946.

*Clinical Investigation*

*Journal of Endovascular Therapy*

## **Intravascular Ultrasound-Guided Interventions for Below-the-Knee Disease in Patients With Chronic Limb-Threatening Ischemia**

Nmasahiko Fujihara, Yuko Yazu and Mitsuyoshi Takahara

*Journal of Endovascular Therapy* 2020 Aug;27(4):565-574. doi: 10.1177/1526602820935606.

### ORIGINAL CONTRIBUTION

## **Intravascular Ultrasound Imaging Versus Digital Subtraction Angiography in Patients with Peripheral Vascular Disease**

George Pliagas, Fadi Saab, Konstantinos Stavroulakis, Theodosios Bisdas, Sara Finton, Carmen Heaney, Theresa McGoff, Kimberly Hardy, George Adams

*J Invasive Cardiol* . 2020 Mar;32(3):99-103.



# IVUS and sizing

- Angiography predictably leads to undersizing of the treated segment (mean vessel diameter by QVA  $2.9 \pm 0.6$  mm vs  $4.0 \pm 1.0$  mm by IVUS;  $\Delta=25\%$ )
- Mean balloon size for IVUS-guided procedures significantly larger ( $\Delta=10\%$ )
- Difference between angiography-assessed reference lumen diameter and IVUS-assessed reference EEM diameter of FP lesions (half of population had  $\Delta RVD \geq 1$  mm)
- IVUS-assessed RVD was more likely to be different by angiography in cases with small vessels, CTO, bilateral calcification, and history of stent implantation
- IVUS appears to offer a greater degree of accuracy in measuring arterial lumen diameter (angiographic imaging consistently under-estimated vessel size)

Shammas NW et al JET 2020;27:575-580  
Fujihara M et al JET 2019;26:322-330  
Iida O et al JET 2021 DOI: 10.1177/15266028211047946  
Pliagas G et al JIC 2020;32:99-103

# IVUS and detection of dissection

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## **Optimal Vessel Sizing and Understanding Dissections in Infrapopliteal Interventions: Data from the iDissection Below the knee study**

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*Journal of Endovascular Therapy* 2020 Vol 27(4) 575-80

*Clinical Investigation*

*Journal of Endovascular Therapy*

## **Comparison of Angiographic Dissection Classification Systems in the Femoropopliteal Arteries Using IVUS Validation and Reliability Testing**

Richard Barry Allan, Nadia Clare Wise, Yew Toh Wong and Christopher Luke Delaney

*J Endovasc Ther.* 2021 Oct 5;15266028211047952. doi: 10.1177/15266028211047952. Online ahead of print.

### PERIPHERAL VASCULAR DISEASE

## **Intravascular Ultrasound Assessment and Correlation with Angiographic Findings Demonstrating Femoropopliteal Arterial Dissections Post Atherectomy: Results from the iDessection Study**

Nicolas W, Shammam, James T Torey, W John Shammam, Susan Jones-Miller,, Gail Shammam

*J Invasive Cardiol . J Invasive Cardiol* 2018 Jul;30(7):240-244

# IVUS and detection of dissection

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- Angiography underestimates the presence and severity of dissections
- IVUS imaging is more sensitive for detecting dissection than angiography
- Dissections post atherectomy are grossly under-appreciated on angiogram when compared to IVUS

# IVUS and atherectomy

*Clinical Investigation*

*Journal of Endovascular Therapy*

## **Lumen Gain After Endovascular Therapy in Calcified Superficial Femoral Artery Occlusive Disease Assessed by Intravascular Ultrasound (CODE Study)**

Masshiko Fujohara, Amane Kozuki, Yoshinori Tsubaskimoto, Mitsuyoshi Takahara, Yoshiaki Shintani, Massahi Fukunaga, Yusuke Iwasaki, Tatsuya Nakama and Yoshiaki Yokoi

J Endovasc Ther. 2019 Jun;26(3):322-330. doi: 10.1177/1526602819836095. Epub 2019 Mar 15.

*Therapeutic Advances in Cardiovascular Disease*

*Original Research*

## **Intravascular ultrasound guided directional atherectomy versus directional atherectomy guided by angiography for the treatment of femoropopliteal in-stent restenosis**

[Prakash Krishnan](#)<sup>1</sup>, [Arthur Tarricone](#)<sup>2</sup>, [Purushothaman K-Raman](#)<sup>3</sup>, [Farhan Majeed](#)<sup>2</sup>, [Vishal Kapur](#)<sup>2</sup>, [Karthik Gujja](#)<sup>2</sup>, [Jose Wiley](#)<sup>2</sup>, [Miguel Vasquez](#)<sup>2</sup>, [Rheoneil A Lascano](#)<sup>2</sup>, [Katherine G Quiles](#)<sup>2</sup>, [Tashanne Distin](#)<sup>2</sup>, [Ran Fontenelle](#)<sup>2</sup>, [Farah Atallah-Lajam](#)<sup>2</sup>, [Annapoorna Kini](#)<sup>2</sup>, [Samin Sharma](#)<sup>2</sup>

Ther Adv Cardiovasc Dis . 2018 Jan;12(1):17-22. doi: 10.1177/1753944717745509

# IVUS and atherectomy

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- IVUS evaluation of calcification in SFA lesions predicted lumen gain after EVT
- Severe calcification in a  $\geq 180^\circ$  arc prevented successful dilation of the lesion with either plain balloon angioplasty or a nitinol stent
- Accurate assessment of calcification patterns by IVUS is useful in maximizing the efficacy of endovascular therapy
- Directional atherectomy guided by IVUS reduces clinically driven target lesion revascularization for patients with femoropopliteal in-stent restenosis

# IVUS and clinical outcomes

Original Article

[Vascular and Endovascular Surgery](#)

## Utility of Intravascular Ultrasound in Peripheral Vascular Interventions: Systematic Review and Meta-Analysis

Azfar Bilal Sheikh, , Mahesh Anantha-Narayanan, MD, Kim G. Smolderen, PhD, Qurat-UI-Ain Jelani, MD, Sameer Nagpal, MD, Marabel Schneider, MD, Fiorella Llanos, MD, Costin Ionescu, MD, Christopher Regan, MD, Robert Attaran, MD, S. Elissa Altin, MD, Carlos Mena-Hurtado, MD

First Published April 26, 2020 Research Article Find in PubMed  
<https://doi.org/10.1177/1538574420920998>

Original Article

[Heart Vessels](#)

## Clinical outcome of drug-coated balloon versus scaffold device in patients with superficial femoral artery chronic total occlusion

[Naoki Hayakawa<sup>1</sup>](#), [Satoshi Kodera<sup>2</sup>](#), [Masataka Arakawa<sup>3</sup>](#), [Satoshi Hirano<sup>3</sup>](#), [Sandeep Shakya<sup>3</sup>](#), [Junji Kanda<sup>3</sup>](#)

Heart Vessels. 2021 Jul 19. doi: 10.1007/s00380-021-01912-0. Online ahead of print

*Clinical Investigation*

*Journal of Endovascular Therapy*

## Intravascular Ultrasound-Derived Stent Dimensions as Predictors of Angiographic Restenosis Following Nitinol Stent Implantation in the Superficial Femoral Artery

[Kojiro Miki<sup>1</sup>](#), [Kenichi Fujii<sup>2</sup>](#), [Daizo Kawasaki<sup>3</sup>](#), [Masahiko Shibuya<sup>4</sup>](#), [Masashi Fukunaga<sup>3</sup>](#), [Takahiro Imanaka<sup>4</sup>](#), [Hiroto Tamaru<sup>4</sup>](#), [Akinori Sumiyoshi<sup>4</sup>](#), [Machiko Nishimura<sup>4</sup>](#), [Tetsuo Horimatsu<sup>4</sup>](#), [Ten Saita<sup>4</sup>](#), [Kozo Okada<sup>1</sup>](#), [Takumi Kimura<sup>1</sup>](#), [Yasuhiro Honda<sup>1</sup>](#), [Peter J Fitzgerald<sup>1</sup>](#), [Tohru Masuyama<sup>4</sup>](#), [Masaharu Ishihara<sup>4</sup>](#)

J Endovasc Ther. 2016 Jun;23(3):424-32. doi: 10.1177/1526602816641669. Epub 2016 Apr 4..

*Clinical Investigation*

*Journal of Endovascular Therapy*

## Intravascular Ultrasound-Guided Interventions for Below-the-knee Disease in Patients With Chronic Limb-Threatening Ischemia

Masshiko Fujohara,,Yukp Yazu and Mitsuyoshi Takahara,

J Endovasc Ther. 2019 Jun;26(3):322-330. doi: 10.1177/1526602819836095. Epub 2019 Mar 15.

# IVUS and clinical outcomes

- IVUS-guided PVIs had similar primary patency and reintervention rates compared with angiography-guided PVIs
- IVUS-guided group significantly lower rates of periprocedural adverse events and vascular complications
- Technical success, complication rates, fTLR and limb salvage similar however more improvement in SPP and wound healing rate in IVUS-guided group
- Postprocedure Minimum Stent Area can predict ISR in SFA lesions, which suggests that adequate stent enlargement during angioplasty might be required for superior patency

# IVUS and clinical outcomes

- DCBs were performed using an intravascular ultrasound (IVUS)-guided approach (no bail-out stenting)
- 12-month primary patency tended to be higher in the DCB than in the scaffold group (92.7 vs. 76.6%,  $p = 0.073$ )
- Freedom from CD-TLR did not differ significantly between the two groups (96.8 vs. 86.3%,  $p = 0.17$ )
- Freedom from re-occlusion rate at 12 months lower in the Scaffold than in the DCB group (96.8 vs. 79.3%,  $p = 0.045$ )



# Summary

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- Utilization of IVUS may aid in the determination of treatment algorithms and lead to improved endovascular outcomes
- IVUS enables assessment of the plaque morphology, vessel diameter, and the presence of arterial dissections
- IVUS is able to properly guide the best choice of appropriate percutaneous transluminal angioplasty (PTA) technique, guide the delivery of different devices, and assess the immediate result of any endovascular intervention
- The cost-effectiveness of the routine use of IVUS during vascular procedures needs to be further studied

# Applicable to all vascular segments?

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## **Intravascular Ultrasound Imaging During Aortoiliac Stenting: No Impact on Outcomes at 1 Year**

[Takuya Tsujimura](#), MD, [Mitsuyoshi Takahara](#), MD, PhD, [Osamu Iida](#), MD, [Yasutaka Yamauchi](#), MD, PhD, [Yoshiaki Shintani](#), MD, [Teruyasu Sugano](#), MD, PhD, [Yoshito Yamamoto](#), MD, [Daizo Kawasaki](#), MD, PhD, [Hiroyoshi Yokoi](#), MD, [Akira Miyamoto](#), MD, PhD, [Toshiaki Mano](#), MD, PhD, [Masato Nakamura](#), MD, PhD on behalf of the OMOTENASHI Investigators

Journal of Endovascular Therapy. 2021;28(1):139-145. doi:10.1177/1526602820949872

Propensity score matching analysis revealed that duration and fluoroscopy time during IVUS-supported procedures were significantly longer than in cases without IVUS use  
12-month restenosis rate was not significantly different between the groups  
IVUS use in aortoiliac lesions may be unnecessary

# Conclusions

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- IVUS offers precise imaging of the vessel size, plaque morphology and the presence of dissections and guides interventional procedures including stent sizing, assessing residual narrowing and stent apposition and expansion
- IVUS-guided treatment has shown to yield superior acute outcomes when compared to angiography-only guided therapy but the effect in the long-term needs to be established further