Update On Atherectomy Devices: Do They Still Have A Role In 2024? Which One Or Ones Are Best? Has Their Benefit Been Proven?

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Vascular Surgery

MU SCORE
Surgical Center for Outcomes Research and Effectiveness

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Disclosures

Nothing to Disclose

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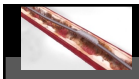
Atherectomy



- Debulk
  - Excision, Drilling or "Sanding" luminal plaque
- Can increase luminal diameter
  - Compliance?
- "May" prepare the vessel wall for adjunctive treatment

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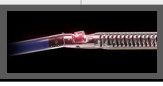
Atherectomy Devices

Type	Description	Examples
Directional Excisional	Use side-cutting blades with a reservoir to capture excised plaque. The Pantheris also has optical coherence tomography to identify plaque	SilverHawk, TurboHawk, HawkOne, Pantheris
Rotational	Use front-cutting blades to debulk calcium. All devices allow thrombectomy except the RotaLink	Phoenix, Jetstream, RotaLink, Rotarex
Orbital	Use diamond-coated crown mounted eccentrically to debulk a larger diameter than the device	Diamondback 360
Laser	Use laser pulses to vaporize plaque. The Auryon uses an Nd:YAG laser. The Turbo-Elite, Turbo-Power, and DABRA use an excimer laser. The DABRA is not over-the-wire. The Turbo and Auryon lasers are indicated for in-stent restenosis	Turbo-Elite, Turbo-Power, Auryon, DABRA



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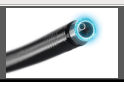

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Atherectomy Devices

	Attributes	Challenges
Directional Excisional	• Best luminal gain • Excised tissue removed from the body • OCT imaging reduces injury to healthy tissue	• Distal embolization possible • Difficult to address calcium
Orbital	• Targeted eccentric plaque removal • Treats luminal calcium well • Low profile	• Limited luminal gain • Limited reduction of tissue other than calcium • Distal embolization possible
Rotational	• Easy to use in long lesions • Most have active aspiration • Use in multiple vessel morphologies	• Limited luminal gain • Difficult to address calcium • Distal embolization possible • Cannot modify the depth of treatment
Laser	• Low profile	• Limited luminal gain • Limited efficacy against calcium • Best used in true lumen

Sanders et al Semi Vasc Surg 2014; 34: 171-187

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Reporting and Data

Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease: Executive summary

- Data on outcomes of Atherectomy has variety of outcome measures
  - Adds difficulty in interpretation
  - TLR (Target Lesion Revascularization)
    - Driven by clinical, anatomic, and hemodynamic indications
    - Does not always contribute to the assessment of clinical failure
    - It should not be used as a primary end point
  - Patency
    - Duplex ultrasound should be considered the standard for patency

Fanelli et al. Cardiovasc Interv Radiol 2014; Tzafriri et al. J Controlled Release 2015; Mosarla et al. JSCAI 2022; Stavroulakis et al. J Endovasc Ther 2023; Kavala et al. Ann Vasc Surg 2023; Wei et al. Vasa 2021; Stavroulakis et al. J Endovasc Ther 2018, Cioppa et al. Cath Cardiovasc Interv 2022, Regine et al. Radiol Med 2020, Stavroulakis et al J Endovasc Ther 2021; Ciet et al. Vasa 2020; Zeller et al. Vasc Interv Radiol 2024, Shammas et al. Vasc Health Risk Manag 2022;

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Atherectomy of Fem-Pop Lesions

Device	Study	Outcomes	Adverse Events
Orbital	CONFIRM	Not Reported	<1% perforation; 2% embolization
	OASIS (Diamondback)	FF TLR at 6 mo 94%	FF MAE at 6 mo 90%
	LIBERTY 360 (Diamondback)	FF TLR at 1 yr 75% to 84%	FF MAE at 1 yr 59% to 83%
	COMPLIANCE 360 (Dback)	FF TLR at 1 yr 81%	
Rotational	EASE (Phoenix)	FF TLR at 6 mo 88%	FF MAE at 6 mo 90%
	Phoenix Registry	FF TLR at 1 yr 83%	Not Reported
	Pathway PVD (JetStream)	FF TLR at 6 mo 85%	FF MAE at 6 mo 89%
	JET Registry (JetStream)	FF TLR at 1 yr 82%	FF MAE at 1 yr 97%
Directional Excisional	DEFINITIVE-AR (SilverHawk)	FF TLR at 1 yr 93%	FF MAE at 1 yr 89%
	VISION (Pantheris)	FF TLR at 6 mo 94%	FF MAE at 6 mo 92%
Laser	CELLO Registry (Excimer)	FF TLR at 1 yr 77%	FF MAE at 6 mo 100%
	EX-PAD-03 (Auryon)	FF TLR at 6 mo 97%	FF MAE at 6 mo 98%

Das et al. Cath Cardiovasc Interv 2014; 83(1):115-122. Mustapha et al J CLI 2021; 1(3):E118-E125; Mustapha et al. J Endovasc Ther 2019; 26(2):143-154; Safian et al. Cath Cardiovasc Interv 2009; 73:406-422; Dattilo et al. J Invas Cardiol 2014; 26:355-360; Zeller et al. J Endovasc Ther 2019; 16:653-662; Davis et al. Vascular 2017; 25(6):563-575; Dave et al. J Endovasc Ther 2019; 16:665-675; Gray et al. Cardiovasc Revasc Med 2018; 19:516-521; Zeller et al. Circ Cardiol Interv 2017; 10:e004848; Schwindt et al. J Endovasc Ther 2017; 24(3):355-366; Rundback et al. Cath Cardio Vasc 2019; 94:1010-1017.

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Atherectomy Still a role in 2024? YES

- Vessel atherectomy may increase drug penetration of DCBs
- Atherectomy + Angioplasty Outperforms Angioplasty Alone
  - Higher FF TLR rates in combination with angioplasty
  - Directional atherectomy with antirestenotic therapy
    - Atherectomy with DCBs (DAART) demonstrated higher patency

Fanelli et al. Cardiovasc Interv Radiol 2014; Tzafriri et al. J Controlled Release 2015; Mosarla et al. JSCAI 2022; Stavroulakis et al. J Endovasc Ther 2023; Kavala et al. Ann Vasc Surg 2023; Wei et al. Vasa 2021; Stavroulakis et al. J Endovasc Ther 2018, Cioppa et al. Cath Cardiovasc Interv 2022, Regine et al. Radiol Med 2020, Stavroulakis et al J Endovasc Ther 2021; Ciet et al. Vasa 2020; Zeller et al. Vasc Interv Radiol 2024, Shammas et al. Vasc Health Risk Manag 2022;

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Lower Extremity Revascularization Using Directional Atherectomy

12-Month Prospective Results of the DEFINITIVE LE Study

James F. McKinsey, MD,† Thomas Zeller, MD,‡ Krishna J. Rocha-Singh, MD,§ Michael R. Jaff, DO,§ Lawrence A. Garcia, MD,§ on behalf of the DEFINITIVE LE Investigators

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 8, 2014
AUGUST 2014:925–33

- Large multicenter studies conducted across Europe and the United States
  - SilverHawk directional atherectomy for PAD treatment
- 800 subjects with infrainguinal lesions up to 20 cm were enrolled
- Adjunctive therapy after DA treatment was performed in 35.3%: POBA primarily
- The primary patency over 12 months was 78% (95% confidence interval 74.0%-80.6%)
- The rate of freedom from major unplanned amputation of the target limb:
  - 12months in patients with CLI was 95%

McKinsey JF, Zeller T, Rocha-Singh KJ, et al. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the DEFINITIVE LE study. JACC Cardiovasc Interv 2014;7:923933

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Directional Atherectomy With Antirestenotic Therapy vs Drug-Coated Balloon Angioplasty Alone for Isolated Popliteal Artery Lesions

Konstantinos Stavroulakis, MD[1,2], Arne Schwindt, MD[1,2], Giovanni Torsello, MD, PhD[1,2], Arne Stachmann[1,2], Christiane Hericks[1,2], Michel J. Bosiers, MD[1,2], Efthymios Beropoulis, MD[1,2], Stefan Stahlhoff, MD[1,2], and Theodosios Bisdas, MD[1,2]

JOURNAL OF ENDOVASCULAR THERAPY

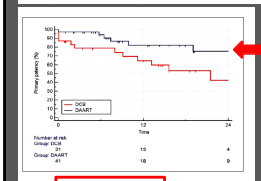

Figure 1 Primary patency at 12 months for the drug-coated balloon (DCB) group (standard error >10% at 13.1 months) vs the directional atherectomy with antirestenotic therapy (DAART) group (standard error >10% at 19.1 months). Hazard ratio 2.64 (95% confidence interval 1.09 to 6.37, p=0.021).

- 72 patients were treated with either DCB angioplasty alone (n=31) or with DAART (n=41)
  - Directional atherectomy with antirestenotic therapy (DAART)
- TurboHawk, SilverHawk, Pantheris Optical Coherence, HawkOne
- The 12-month primary patency rate was:
  - DAART vs. DCB (82% vs. 62%; p=0.021)
  - TLR did not differ

Journal of Endovascular Therapy2017, Vol. 24(2) 181–188

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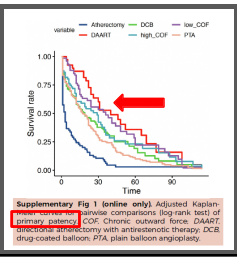
Different endovascular modalities of treatment for isolated atherosclerotic popliteal artery lesions (EMO-POP) registry

Nicola Troisi, MD,[a] Athanasios Saratzis, MD,[b] Emmanuel Katsogridakis, MD,[b] Konstantinos Stavroulakis, MD,[c] Raffaella Berchiolli, MD,[d] Hany Zayed, MD,[e] and Giovanni Torsello, MD,[e] for the EMO-POP Registry Collaborative Group.[a] *Pisa, Italy; Leicester and London, UK; and Munich and Münster, Germany*

Journal of Vascular Surgery
January 2023



Supplementary Fig 1 (online only). Adjusted Kaplan-Meier curves for pairwise comparisons (log-rank test) of primary patency. *COF,* Chronic outward force. *DAART,* directional atherectomy with antirestenotic therapy. *DCB,* drug-coated balloon. *PTA,* plain balloon angioplasty.

- Multicenter; 15 hospitals in five countries
- 651 consecutive patients with isolated popliteal lesions using endovascular methods
- PTA appeared inferior in the pairwise comparisons to other treatments
  - P < .001 vs atherectomy
  - P = .002 vs DAART
  - P = .002 vs stenting
- Directional atherectomy with antirestenotic therapy (DAART)

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Atherectomy Still a role in 2024? YES

- Suggested favorable Long-term Outcomes
  - Improved primary patency of target vessels
    - Majority of Data with Directional Atherectomy
    - Atherectomy with DCBs (DAART) demonstrated higher patency
  - Durable Freedom from TLR and Amputation
    - FF TLR 3 yrs after the procedure up to 86%
    - FF Amputation at 2 yrs up to 97%

Fanelli *et al. Cardiovasc Interv Radiol* 2014; Tzafriri et al. J Controlled Release 2017; Mosarla *et al. JSCAI* 2022; Stavroulakis *et al. J Endovasc Ther* 2017; Kavala *et al. Ann Vasc Surg* 2013; Wei *et al. Vasa* 2022; Stavroulakis *et al. J Endovasc Ther* 2018; Cioppa *et al. Cath Cardiovasc Interv* 2022; Regine *et al. Radiol Med* 2016; Stavroulakis *et al. J Endovasc Ther* 2015; Sixt *et al. Vasa* 2016; Zeller *et al. Vasc Interv Radiol* 2004; Shammas *et al. Vasc Health Risk Manag* 2022;

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Atherectomy of BTK Lesions

Device	Study	Outcomes	Adverse Events
Orbital	OASIS (Diamondback)	FF TLR at 6 mo 94%	FF MAE at 30 days 97%
Rotational	No published studies to date		
Directional	DEFINITIVE LE (SilverHawk)	Primary Patency at 1 yr 78%	FF MAE at 30 days 98%
Excisional	IMAGE BTK (Pantheris)	Primary Patency at 1 yr 92% FF TLR at 6 mo 94%	FF MAE at 30 days 100%
Laser	LACI (Excimer)	FF TLR at 6 mo 81%	FF MAE at 30 days 88%

Safian *et al. Cath Cardiovasc Interven* 2009; 73:406-412; Tummala *et al. J Clin Med* 2020; 9:3321; *McKinsey et al. JACC Cardiovasc Interv* 2014; 7:923-933; IMAGE BTK data on file at Avinger, Inc.; Laird *et al. J Endovasc Ther* 2006; 13:1-11.

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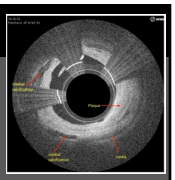
IMAGE BTK Study at 6 months



- Single-arm, prospective, multicenter post-market study
  - Effectiveness of the Pantheris SV atherectomy catheter
- 58 lesions were treated
  - Mean lesion length was 11.1 cm
- Technical success was 98%; Mean percent luminal stenosis was reduced to:
  - 21% after atherectomy ($p<0.001$)
  - 9% after adjunctive treatment ($p<0.0001$) as compared to baseline
- Freedom from TLR was 94% at 6 months for all subjects
  - Significant improvement in both ABI and Rutherford Class
- Primary patency by duplex ultrasound 6 and 12 months: 96% and 92%

IMAGE BTK data on file at Avinger, Inc.

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Trends in Utilization and Outcomes of Orbital, Laser, and Excisional Atherectomy for Lower Extremity Revascularization.

Journal of Endovascular Therapy (J ENDOVASC THER). Jun2022; 29(3): 389-401. (13p)

- Patients undergoing atherectomy in the 2010–2016
  - Vascular Quality Initiative Database
- Atherectomy use increased from 10.3% to 18.3% (n = 122,938)
  - Orbital atherectomy was most utilized (Increased from 59.4% to 63.2%)
  - No significant differences in 1-year outcomes between rotational, laser, and orbital atherectomy for isolated femoropopliteal disease
- In isolated tibial disease treatment, excisional atherectomy was associated with:
  - Higher 1-year primary patency compared with orbital atherectomy
  - Decreased major ipsilateral amputation rates compared with laser atherectomy

Bai H, Fereydooni A, Zhang Y, et al. Trends in utilization and outcomes of orbital, laser, and excisional atherectomy for lower extremity revascularization. J Endovasc Ther 2022;29:385e401.

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In-Stent Restenosis ISR

Device	Study	Outcomes	Adverse Events
Orbital	No published studies to date		
Rotational	JET-ISR (JetStream)	FF TLR at 6 mo 64%	FF MAE at 1 yr 88%
Directional	INSIGHT (Pantheris)	FF TLR at 1 yr 89%	FF MAE at 1 yr 98%
	Individual (SilverHawk)	FF TLR at 1 yr 53%	Not Reported
Laser	EXCITE ISR (Excimer)	FF TLR at 1 yr 45%	FF MAE at 6 mo 79%
	Retrospective (Excimer)	FF TLR at 1 yr 72%	FF MAE at 1 yr 60%

Shammas *et al. J Invasive Cardiol* 2020; 32(8):289-294; Dippel *et al. JACC Cardiovasc Interv* 2015; 8:92-101; INSIGHT data on file at Avinger, Inc.; Zeller *et al. J Am Coll Cardiol* 2006; 48:1573-1578;

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In-Stent Restenosis ISR

INSIGHT

Evaluation of the Pantheris OCT-Imaging Atherectomy System for Treatment of In-Stent Restenosis in Lower Extremity Arteries (INSIGHT)

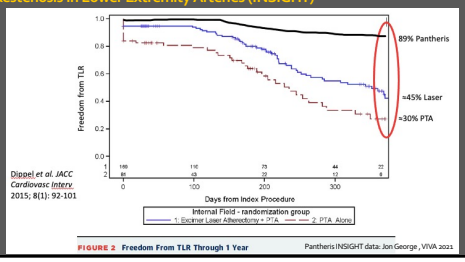

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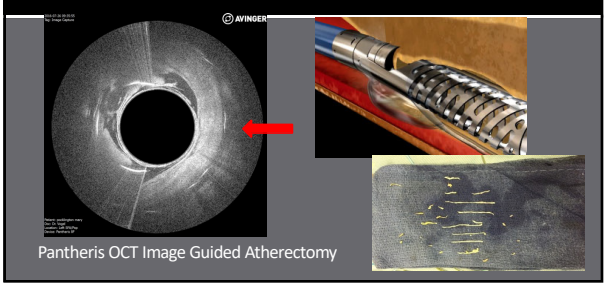
Image-Guided Directional Atherectomy for ISR



Pantheris OCT Image Guided Atherectomy

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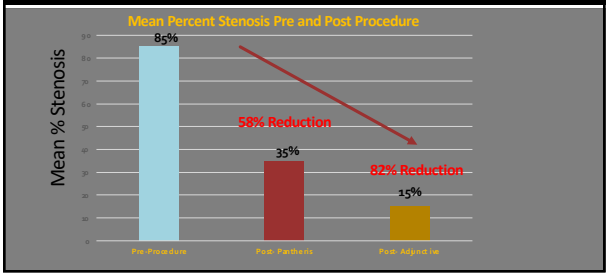
Reduction in Percent Stenosis

INSIGHT



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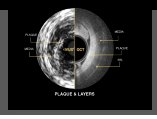
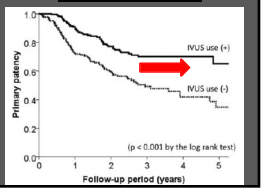
Advantages of Intravascular Imaging in Atherectomy

- Permits in-vessel assessment of disease
- The "live" OCT on the Pantheris catheter clearly distinguishes normal anatomy from plaque pathology
- Precise vessel measurement
- Reduces radiation
- Optimizes debulking while avoiding adventitia & vascular injury





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Conclusions for Atherectomy Devices

- The clinical benefits of Atherectomy
  - Increased luminal gain with low procedure complication rates
    - Directional
  - Associated with freedom from amputation and restenosis rates
- When combined with adjunctive therapy, such as DCB, freedom from repeating revascularization procedures is increased substantially
  - Directional atherectomy with antirestenotic therapy (DAART)
  - Patency data
- Directional atherectomy associated with greater patency
  - Tibial vessels

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Conclusions for Atherectomy Devices

- Intravascular imaging improves success significantly
  - Particularly useful for in-stent restenosis
  - Visualization provides guidance to avoid stent struts
  - Distinguish normal anatomy from plaque pathology
    - Pantheris OCT Directional
- Atherectomy continues to provide improved clinical benefits in the treatment of PAD
  - TLR data vs. Patency data
- Further studies are needed on types of atherectomy & long-term efficacy
  - Improved Outcome measures for studies (Patency)

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