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Atherectomy In Patients With CLTI, ISR And Diabetes: When Is It Helpful; How Durable Is It: Which Devices Are The Best

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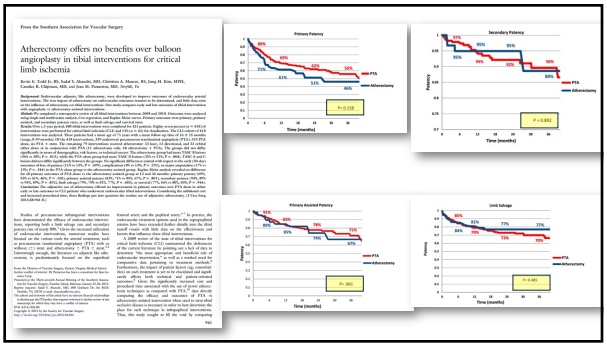
Disclosures

- Speaker and consultant:
  - COOK Medical™, Boston Scientific™, Servier, Bayer, Boheringer, Merck Seromo, Essity, Sigvaris.

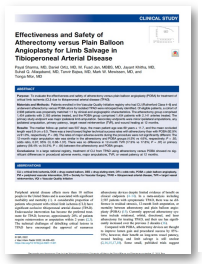
Atherectomy solves clinical problems

Characteristics of the lesion	Objectives of the procedure

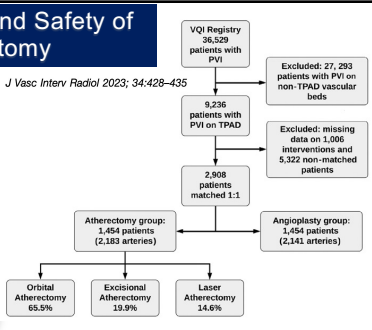
• Calcium
• In-stent restenosis
• Chronic Total Occlusions (OCTs)
• Soft Plaque
• Thrombus (thrombectomy)
	• Avoiding stenting
	• Preparing the vessel
	  • Release the drug
	  • Modify the compliance of the vessel
	  • Gain lumen



Effectiveness and Safety of Atherectomy



J Vasc Interv Radiol 2023; 34:428–435



Effectiveness and Safety of Atherectomy

Table 2. Procedural Outcomes Compared between Atherectomy and Plain Balloon Angioplasty

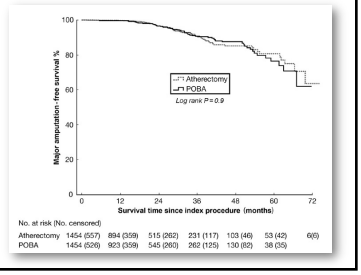
	Atherectomy		POBA		*P* value
	Data	n°	Data	n°	
Technical success	92.9	1,438	91.0	1,441	.06
Stent use	4.5	1,450	6.3	1,451	.03
Arterial dissection	2.3	1,407	2.5	1,428	.67
Arterial perforation	1.3	1,447	0.6	1,448	.06
Distal embolization	1.2	1,445	1.1	1,448	.73
Hematoma	2.8	1,445	2.6	1,450	.72
In-hospital mortality	0.8	1,454	0.6	1,454	.65
30-d mortality	1.7	1,454	1.8	1,454	.78
Contrast volume (mL)	103.6 ± 65.7	1,415	86.7 ± 58.3	1,413	<.001
Fluoroscopy time (min)	24.9 ± 16.9	1,384	20.3 ± 15.4	1,366	<.001

Table 4. Comparison of Outcomes between Types of Atherectomy Devices Used for Treatment of Tibioperoneal Arterial Disease

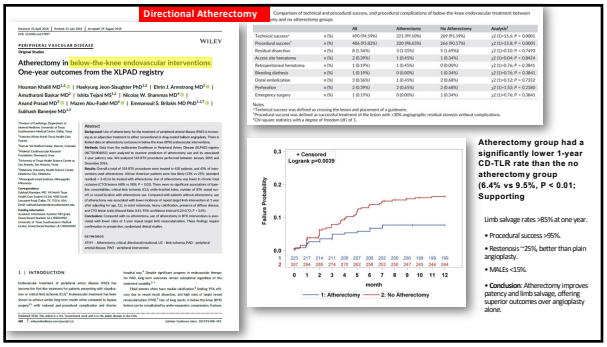
	Number of patients	Laser (%)	Orbital (%)	Excisional (%)	*P* value
Technical success	1,438	90.8	92.6	93.9	.18
Stent use	1,450	4.0	4.7	4.8	.67
Artery dissection	1,407	2.6	2.1	2.5	.89
Artery perforation	1,447	1.0	1.3	1.8	.84
Distal embolization	1,445	0	1.9	0.1	.35
Major amputation	1,454	8.7	3.8	3.8	.01
Minor amputation	1,454	2.9	2.8	3.5	.83
Any amputation	1,454	11.1	6.3	6.5	.04
Primary patency	1,106	52.8	55.2	65.1	.01
Target vessel revascularization	792	14.7	21.3	11.1	.03

Effectiveness and Safety of Atherectomy

J Vasc Interv Radiol 2023; 34:428–435



Directional Atherectomy



Atherectomy group had a significantly lower 1-year CD-TLR rate than the no atherectomy group (6.4% vs 9.5%, P < 0.01; Supporting

Limb salvage rates >85% at one year.

- Procedural success >95%.
- Restenosis ~25%, better than plain angioplasty.
- MALEs <15%.
- **Conclusion:** Atherectomy improves patency and limb salvage, offering superior outcomes over angioplasty alone.

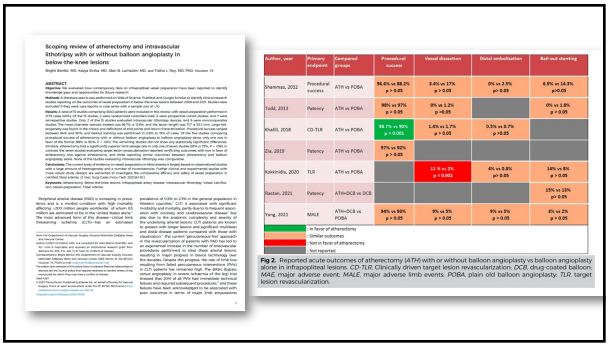
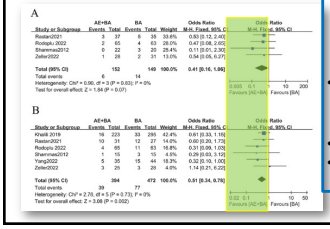


Fig 2. Reported acute outcomes of atherectomy (ATH) with or without balloon angioplasty vs balloon angioplasty alone in infrapopliteal lesions. *CD-TLR*, Clinically driven target lesion revascularization. *DCB*, drug-coated balloon; *MALE*, major adverse event; *MALE*, major adverse limb events. POBA, plain old balloon angioplasty. *TLR*, target lesion revascularization.

Atherectomy+BA vs Balloon Angioplasty alone for infrapopliteal artery occlusive lesions.



- **AE+BA (Atherectomy + BA) reduce:**
  - Need for CD-TLR
  - Incidence of target limb major amputation at 12-month follow-up.
  - No significant advantages in:
    The technical success
    Primary patency
    Periprocedural complications
    Distal embolization
    All-cause mortality.
- **AE+DCB (Atherectomy + DCB) shows:**
  - Significant benefits in primary patency.
  - CD-TLR
  - Target limb major amputation rate.
- Atherectomy + POBA does not.
- RCTs are needed to confirm these conclusions.

J Endovasc Ther. 2023 Nov

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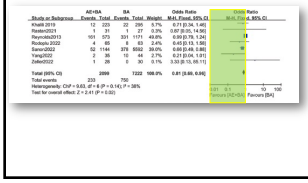

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J Endovasc Ther. 2023 Nov

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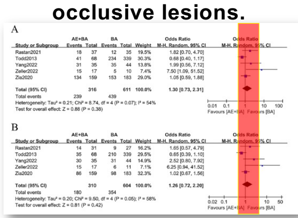

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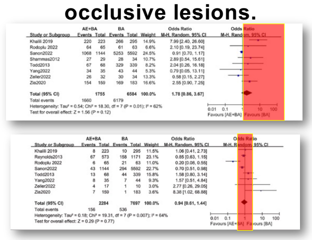

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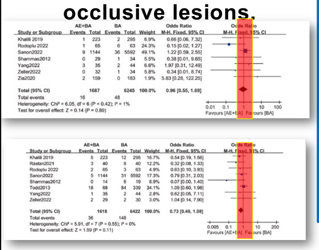

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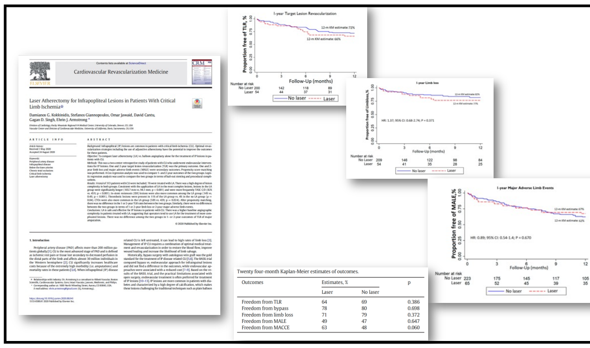
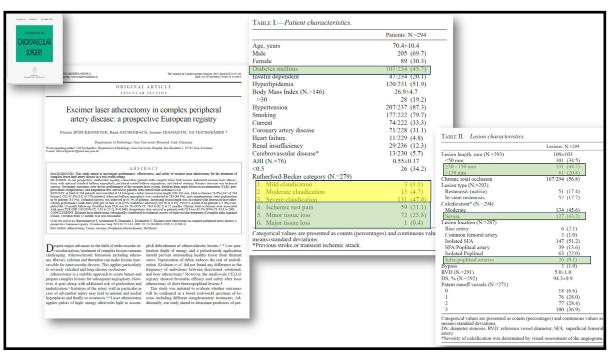
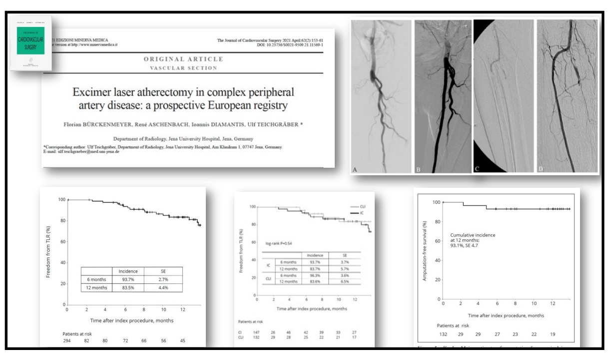
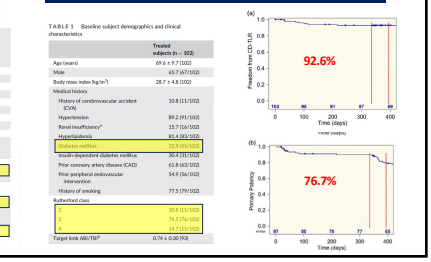






Directional Atherectomy

Directional Atherectomy
Hawk-1 + INPACT DCB



Directional Atherectomy

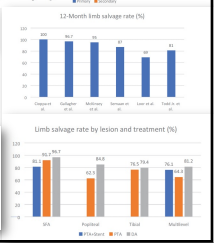
The role of directional atherectomy in critical-limb ischemia

Prakash Krishnan, Arthur Tarricone, Simon Chen and Samin Sharma

Abstract
Background: Our aim was to review the current literature of the use of directional atherectomy (DA) in the treatment of lower extremity critical-limb ischemia.
Methods: A search for relevant literature was performed in PubMed and PubMed Central on 16 April 2020, sorted by best match. Three searches across two databases were performed. Articles were included that contained clinical and procedural data of DA interventions in lower extremity critical-limb ischemia patients. All studies that were systematic reviews were excluded.

Ther Adv Cardiovasc Dis
2022, Vol. 16: 1–11

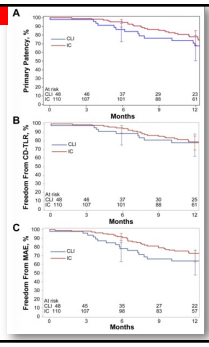
- Primary Patency rates: **56.3% to 95.0%**
- Secondary Patency rates: **76.4% to 100%,**
- Limb salvage rates: **69% to 100%.**
- Lesion lengths **30 ± 33** mm to **142.4 ± 107.9** mm.



Directional Atherectomy

Directional Atherectomy
SilverHawk or TurboHawk + DCB in Popliteal A

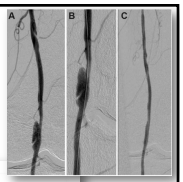
DA in Pop-Art leads to favorable technical and clinical results at 1 year for claudicant as well as CLI patients.

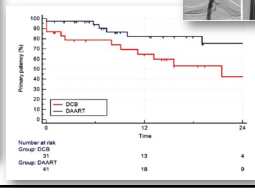


Directional Atherectomy

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

- DAART was associated with a higher primary patency rate compared with DCB angioplasty for isolated popliteal lesions.
- Both treatment options were associated with excellent 12-month secondary patency. .



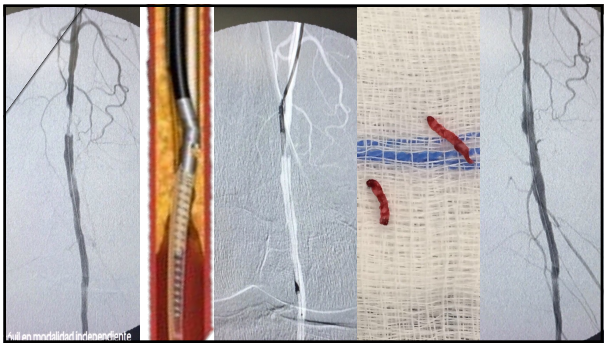


Journal of Endovascular Therapy
Volume 24, Issue 2
Apr 2017

Directional Atherectomy

Directional Atherectomy
SilverHawk or TurboHawk + DCB

- **Technical success was superior for DA+DCB** (89.6% versus 64.2%; P=0.004).
- **Overall bail-out stenting rate was 3.7%.**
- **Rate of flow-limiting dissections was** 19% for DCB and 2% for DA+DCB (P=0.01).
- **One-year primary outcome of angiographic percent diameter stenosis was** 33.6±17.7% for DA+DCB versus 36.4±17.6% for DCB (P=0.48)
- **Clinically driven target lesion revascularization was** 7.3% for DA+DCB and 8.0% for DCB (P=0.90).
- **Duplex ultrasound patency was** 84.6% for DA+DCB, 81.3% for DCB (P=0.78), and 68.8% **for calcified lesions.**
- **Freedom from major adverse events at 1 year** was 89.3% for DA+DCB and 90.0% for DCB (P=0.86).



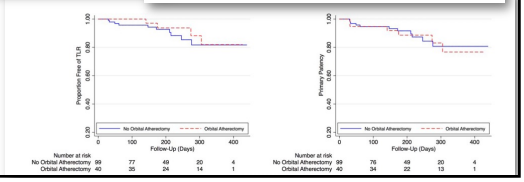
Orbital Atherectomy for CLI

Mid-Term Outcomes of Orbital Atherectomy Combined With Drug-Coated Balloon Angioplasty for Treatment of Femoropopliteal Disease

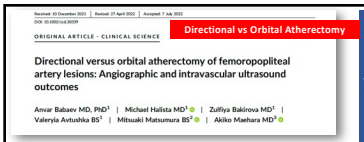
Retrospective, single-center study of 89 patients undergoing DCB angioplasty for lifestyle limiting claudication or CLI,

OA was:
-Most likely to be used for heavily calcified lesions
-Associated with less bailout stenting compared to DCB angioplasty alone.

Catheterization and Cardiovascular Interventions 89:1078–1085 (2017)



Directional vs Orbital Atherectomy



ORIGINAL ARTICLE – CLINICAL SCIENCE

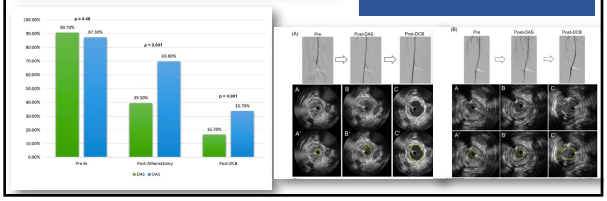
Directional versus orbital atherectomy of femoropoliteal artery lesions: Angiographic and intravascular ultrasound outcomes

Anvar Babaev MD, PhD[1] | Michael Halista MD[1] | Zulfiya Bakirova MD[1] | Valeryia Avtushka BS[1] | Mitsuaki Matsumura BS[2] | Akiko Maehara MD[2]

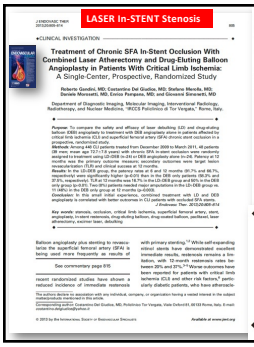
DIRECT TRIAL
Stenosis were significantly lower in :

-DAS group than in the OAS group following atherectomy
(39.5 ± 14.2% vs. 69.8 ± 12.1%, p < 0.001)

-Following intervention with a DCB
(16.7 ± 12.7 vs. 33.7 ± 16.1%, p < 0.001)



LASER In-STENT Stenosis



Treatment of Chronic SFA In-Stent Occlusion With Combined Laser Atherectomy and Drug-Eluting Balloon Angioplasty in Patients With Critical Limb Ischemia: A Single-Center, Prospective, Randomized Study

Journal of Endovascular Therapy
Volume 20, Issue 6
Dec 2013

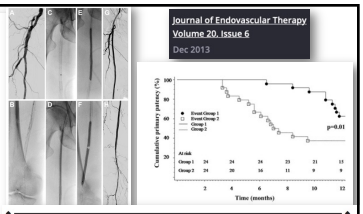


TABLE 3
Outcome Measures in Patients Treated With Laser Debulking (LD) + Drug-Eluting Balloon (DEB) Angioplasty vs. DEB Alone

	LD+DEB (n=24)	DEB Only (n=24)	p
Patency			
At 6 months	91.7%	58.3%	0.01
At 12 months	66.7%	33.3%	0.01
TLR at 12 months	16.7%	50%	0.01
Limb salvage at 12 months	91.7%	54.2%	0.003
Healing at 12 months	87.5%	62.5%	0.04
Major amputation	2 (8%)	11 (46%)	0.003
Death	3 (12%)	9 (37%)	0.04

Categorical data are given as the counts (percentage).

JETSTREAM In-STENT Stenosis

In-Stent Stenosis

Treatment of intra-stent restenosis (ISR) by balloon angioplasty (BA) of the femoropopliteal segment (FP) is associated with a high rate of restenosis

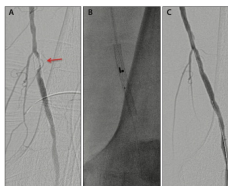
TLR rate of 31% to 47% and patency rates as low as 28% to 37% at 1 year.

- Bosiers M, Deloose K, Callaert J, et al. Superiority of stentgrafts for in-stent restenosis in the superficial femoral artery: twelve-month results from a multicenter randomized trial. **J Endovasc Ther. 2015;22:1–10.**
- Dick P, Sabeti S, Mlekusch W, et al. Conventional balloon angioplasty versus peripheral cutting balloon angioplasty for treatment of femoropopliteal artery in-stent restenosis: initial experience. ***Radiology*. 2008;248:297–302**.
- Liistro F, Angioli P, Porto I, et al. Paclitaxel-eluting balloon vs. standard angioplasty to reduce recurrent restenosis in diabetic patients with in-stent restenosis of the superficial femoral and proximal popliteal arteries: the DEBATE-ISR study. ***J Endovasc Ther*. 2014;21:1–8.**
- Krankenberg H, Tübler T, Ingwersen M, et al. Drug-coated balloon versus standard balloon for superficial femoral artery in-stent restenosis: the randomized Femoral Artery In-Stent Restenosis (FAIR) trial. ***Circulation*. 2015;132:2230–2236**.
- Dippel EJ, Makam P, Kovach R, et al. Randomized controlled study of excimer laser atherectomy for treatment of femoropopliteal in-stent restenosis: initial results from the EXCITE ISR trial (EXCImer Laser Randomized Controlled Study for Treatment of FemoropoplitEal In-Stent Restenosis). ***JACC Cardiovasc Interv*. 2015;8(1 Pt A):92–101.**

In-STENT Stenosis

Aterectomía. EXCITE-ISR trial

- Turbo Elite Laser (Philips)
- 250 patients
  - (TLR) of 73.5% vs. 51.8% ATP (P < 0.005),
- 52% TLR reduction.



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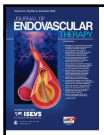


JETSTREAM In-STENT Stenosis

Possible Predictors of Restenosis Following Percutaneous Peripheral Interventions

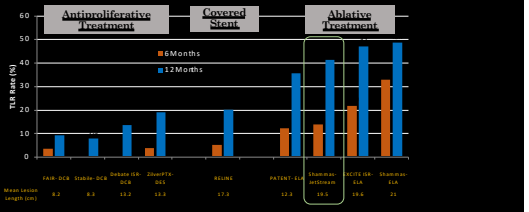
Biomarkers
- High-sensitivity C-reactive protein
- Fibrinogen
- Complement component C5a
- D-dimer
- Baseline monocyte count
- Plasma tissue factor
- Low platelet count
- Plasma viscosity
- Lipoprotein a
- Postprocedure von Willebrand factor
- Plasminogen activator inhibitor-1 antigen

Angiographic Factors
- Longer lesion length
- Infrainguinal vascular bed
- Total occlusion
- Reduced tibial runoff
- Severe lesions
- High residual stenosis post intervention
- Vessel diameter

Clinical Factors
- Diabetes
- Lack of hypertension
- Female gender
- Advanced limb ischemia
- Tobacco use
- Renal disease
- Younger age
- Diffuse cardiovascular disease

JETSTREAM In-STENT Stenosis

Femoropopliteal treatment ISR



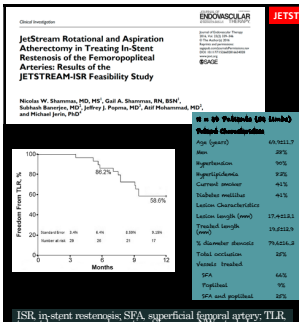
Note: Bailout stent not included as TLR

DCB, drug-coated balloon; DES, drug-eluting stent; ELA, excimer laser atherectomy; ISR, in-stent restenosis; TLR, target lesion revascularization.

Krankenberg. FAIR Trial, LINC 2014. Stabile E. J Am Coll Cardiol 2012;60:1719-12. Liistro F. DEBATE-ISR. J Endovasc Ther 2014;21:1-8. Zeller T. JACC Cardiovasc Interv 2013;6:274-81. Steiner M. et al. J Endovasc Ther 2015;22:1-10. Schmidt A. PATENT. J Endovasc Ther 2014;21:52-60. Shammas N. LINC 2016. Dippel EJ. EXCITE ISR. JACC Cardiovasc Interv 2015;8 (1 Pt A):92-101. Shammas NW Cardiovasc Revasc Med 2012;13:341-4.

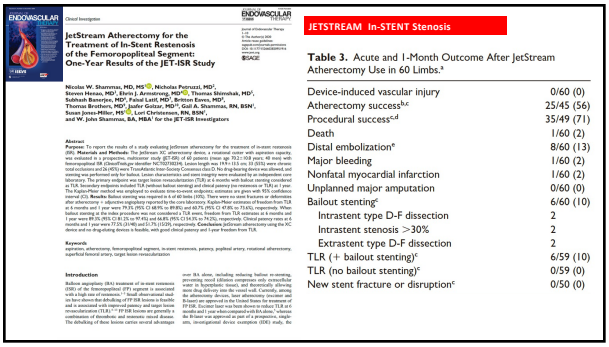
JETSTREAM In-STENT Stenosis

Jetstream ISR Feasibility Study



- Prospective viability registry at 2 U.S. centers, evaluating JetStream atheroectomy in the treatment of femoropopliteal restenosis in the stent (60%)
- Jetstream was the first treatment modality, all patients had adjuvant balloon angioplasty
- Results
- 91% Technical Success (<30% residual stenosis without EAS)
- No new fracture or interruption of the stent (CORE LAB)
- TLR: 14% at 6 months and 41% at 12 months

ISR, in-stent restenosis; SFA, superficial femoral artery; TLR, target lesion revascularization Shammas NW, et al. J Endovasc Ther. 2016;23(2):333-46.



Clinical Investigation

JetStream Atherectomy for the Treatment of In-Stent Restenosis of the Femoropopliteal Segment: One-Year Results of the JET-ISR Study

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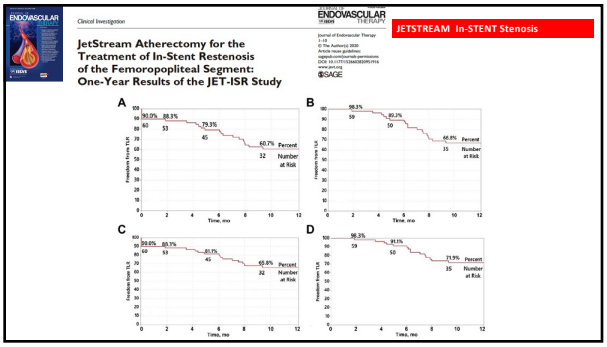
Table 3. Acute and 1-Month Outcome After JetStream Atherectomy Use in 60 Limbs.[a]

Device-induced vascular injury	0/60 (0)
Atherectomy success[b,c]	25/45 (56)
Procedural success[c,d]	35/49 (71)
Death	1/60 (2)
Distal embolization[e]	8/60 (13)
Major bleeding	1/60 (2)
Nonfatal myocardial infarction	1/60 (2)
Unplanned major amputation	0/60 (0)
Bailout stenting[c]	6/60 (10)
Intrastent type D-F dissection	2
Intrastent stenosis >30%	2
Extrastent type D-F dissection	2
TLR (+ bailout stenting)[c]	6/59 (10)
TLR (no bailout stenting)[c]	0/59 (0)
New stent fracture or disruption[c]	0/50 (0)



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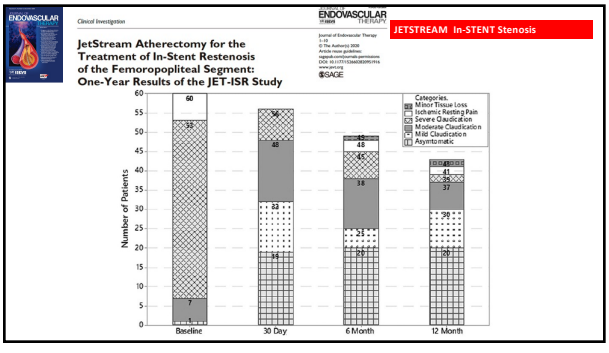

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JETSTREAM In-STENT Stenosis

Conclusions

- Atherectomy can help not only prepare the vessels, but also avoid dissections and get the right light.
- Atherectomy is also a good option in patients with CLTI and DM patients with PAD
- Each device can have different applications depending on the case.
- Directional and rotational atherectomy works well with eccentric and/or calcified lesions
- For ISR laser and rotational atherectomy are good options