



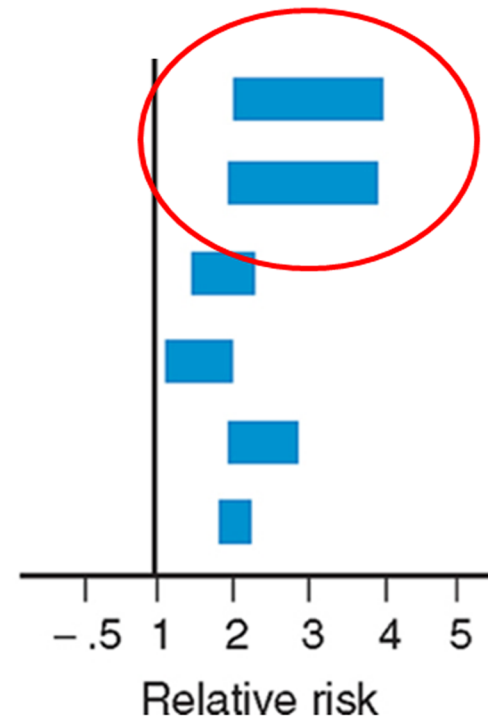
TemREN[®]

ATHERECTOMY



Risk Factors in Peripheral Arterial Diseases (PAD)

- Smoking
- Diabetes
- Hypertension
- Hypercholesterolemia
- Hyperhomocysteinemia
- C-Reactive protein



SYMPTOMS

Peripheral arterial diseases are often diagnosed at a higher rate because they have silent and progressive diseases progressing asymptotically over the years.

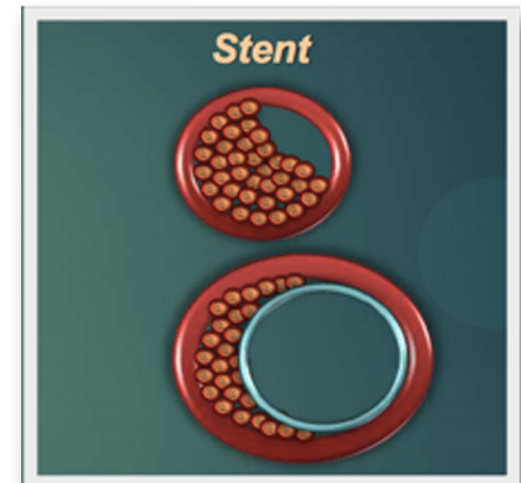
- Claudication
- Paresthesia
- Cold on the extremities
- Color change
- Pulselessness

CURRENT TREATMENT METHODS

- Lifestyle Change
- Medical Treatment
- Open Surgery (Graft Bypass / Endarterectomy)
- **ENDOVASCULAR APPROACH:**
 - Peripheral atherectomy
 - Balloon Angioplasty
 - Peripheral Stenting

ADVANTAGES OF ATHERECTOMY

- Allows recanalization without disrupting elastic recoil
- By reducing the plate load, it contributes to longer primer and secondary opening rates
- As long as there is no complication, the right of stenting and surgical bypass is always reserved for the patient
- Clearance rates in calcific lesions are higher than in the primary stenting



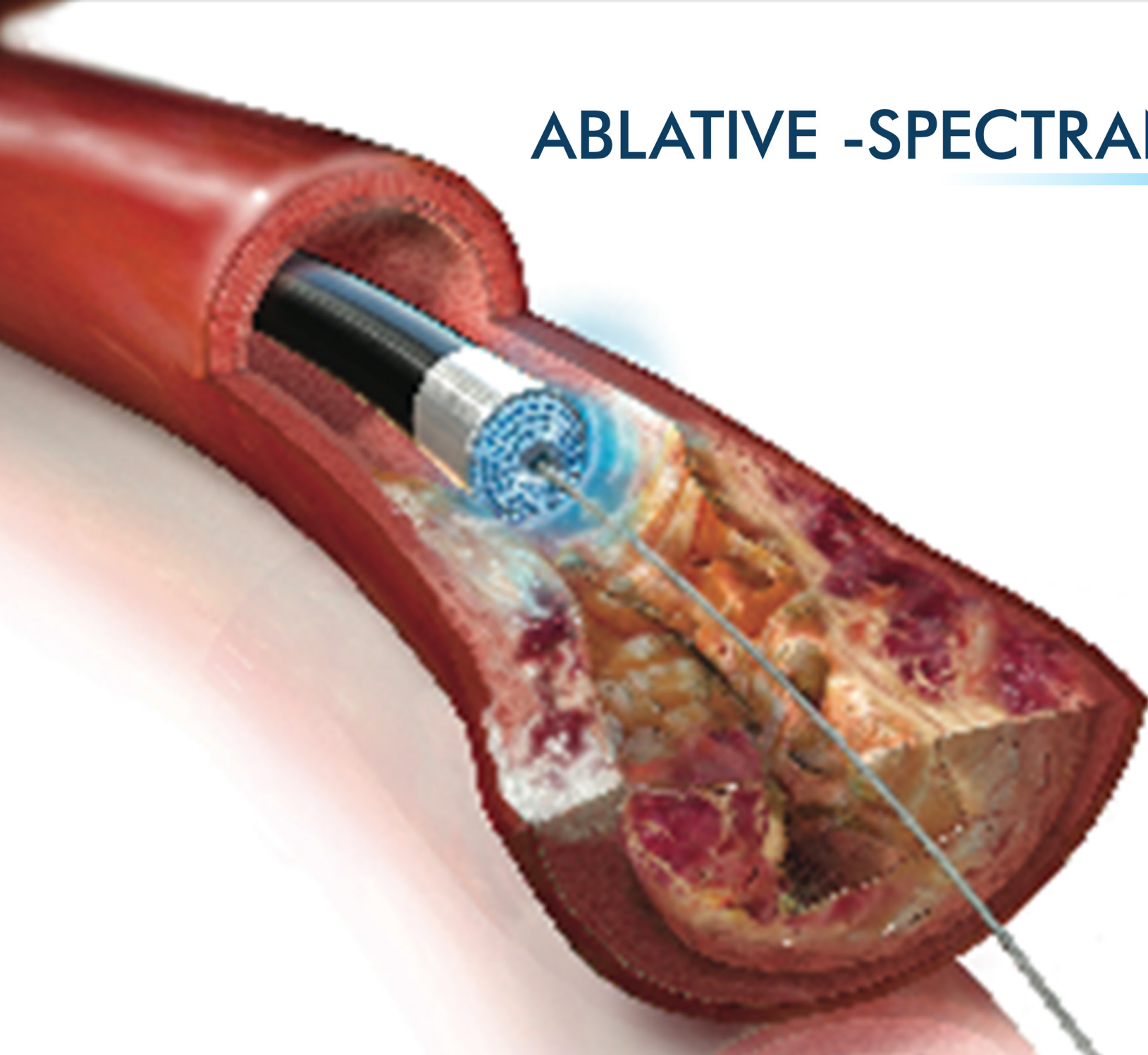
PERIPHERAL ATHERECTOMY

- **Excisional (directional)**
Silverhawk/Turbohawk
- **Ablation (excimer laser)**
Spectranetics
- **High frequency vibration**
Crosser
- **Rotational**
Phoenix
Rotablator
TemREN

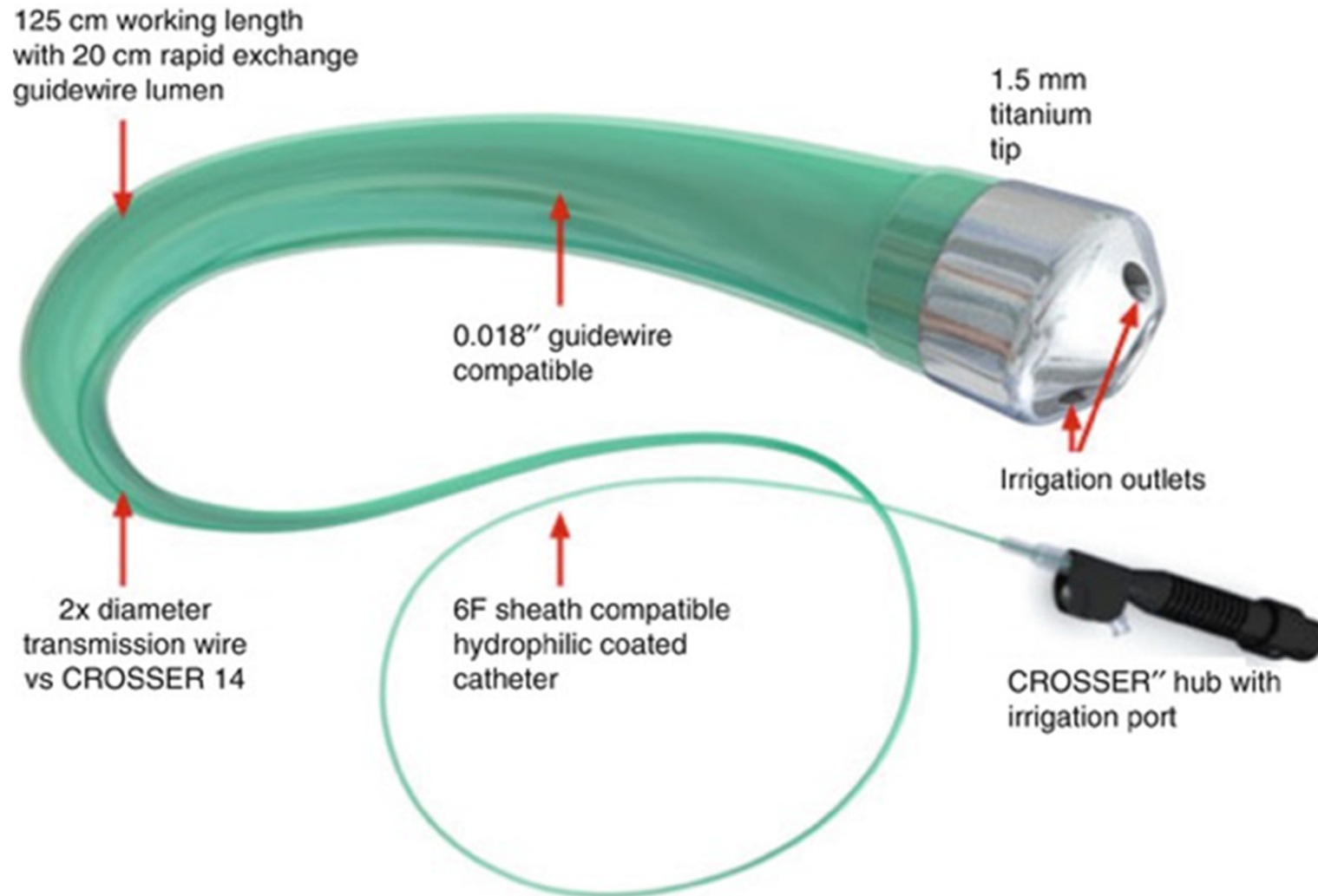
EXCISIONAL-TURBOHAWK



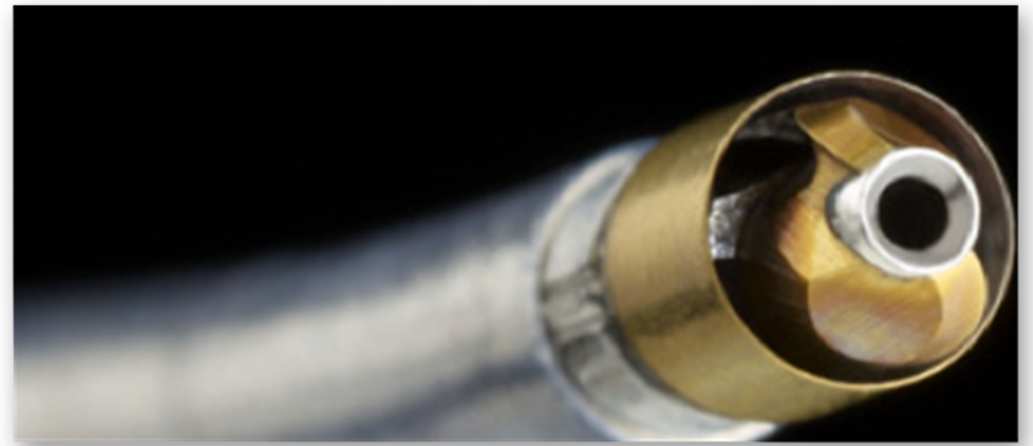
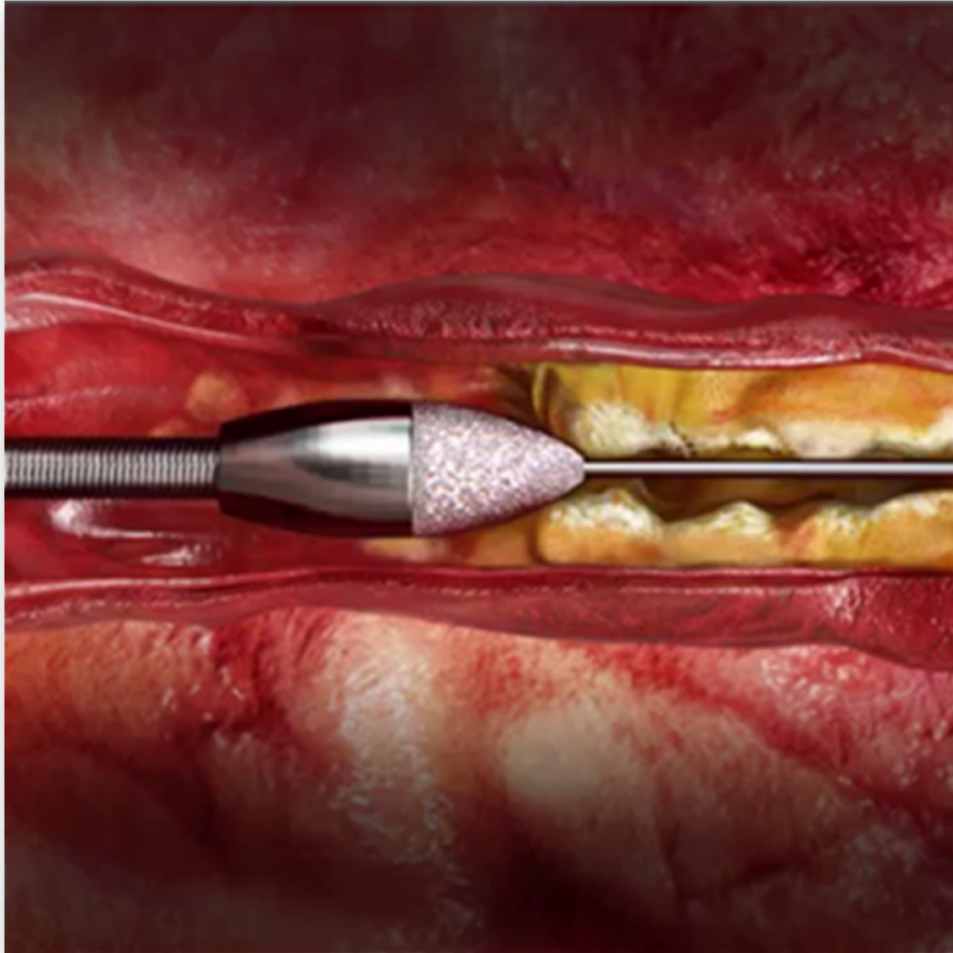
ABLATIVE -SPECTRANETICS



HIGH FREQUENCY VIBRATION-CROSSER



ROTATIONAL (PHOENIX, ROTABLATOR)



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ATHERECTOMY

Braided
Radiopaque
Catheter

Infusion &
Aspiration
Port

Single Handed
Easy procedure
Control with
Adjustable
Rotation Speed

- ✓ Ready to use set content provides a practical application option
- ✓ No additional installation equipment required before the process
- ✓ Rotation speed can be adjusted easily and provide safe space to surgeon



ADVANTAGES



- The ready-to-use set content provides a practical application option.
- No additional installation is required before the process.
- The internal helix structure minimizes the risk of distal embolization with aspiration.
- The distal rotational tip acts on the calcified lesion invasively.
- Expanding protective tip cap and proximal design, reduces risk of subintimal obstruction and rupture.
- By blocking subintimal pass, it facilitates real lumen pass.
- Rotation speed can be adjusted.



PROCEDURE

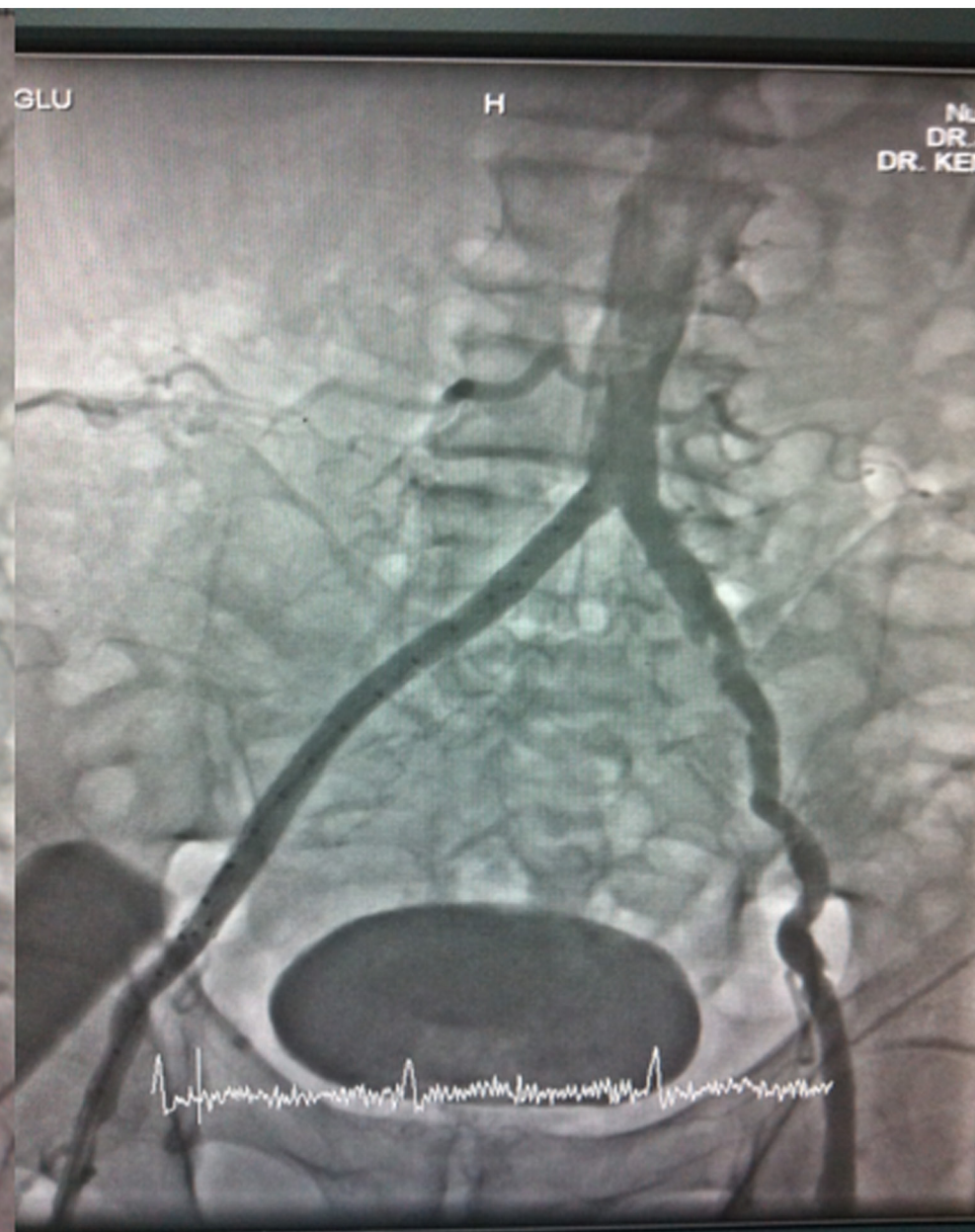
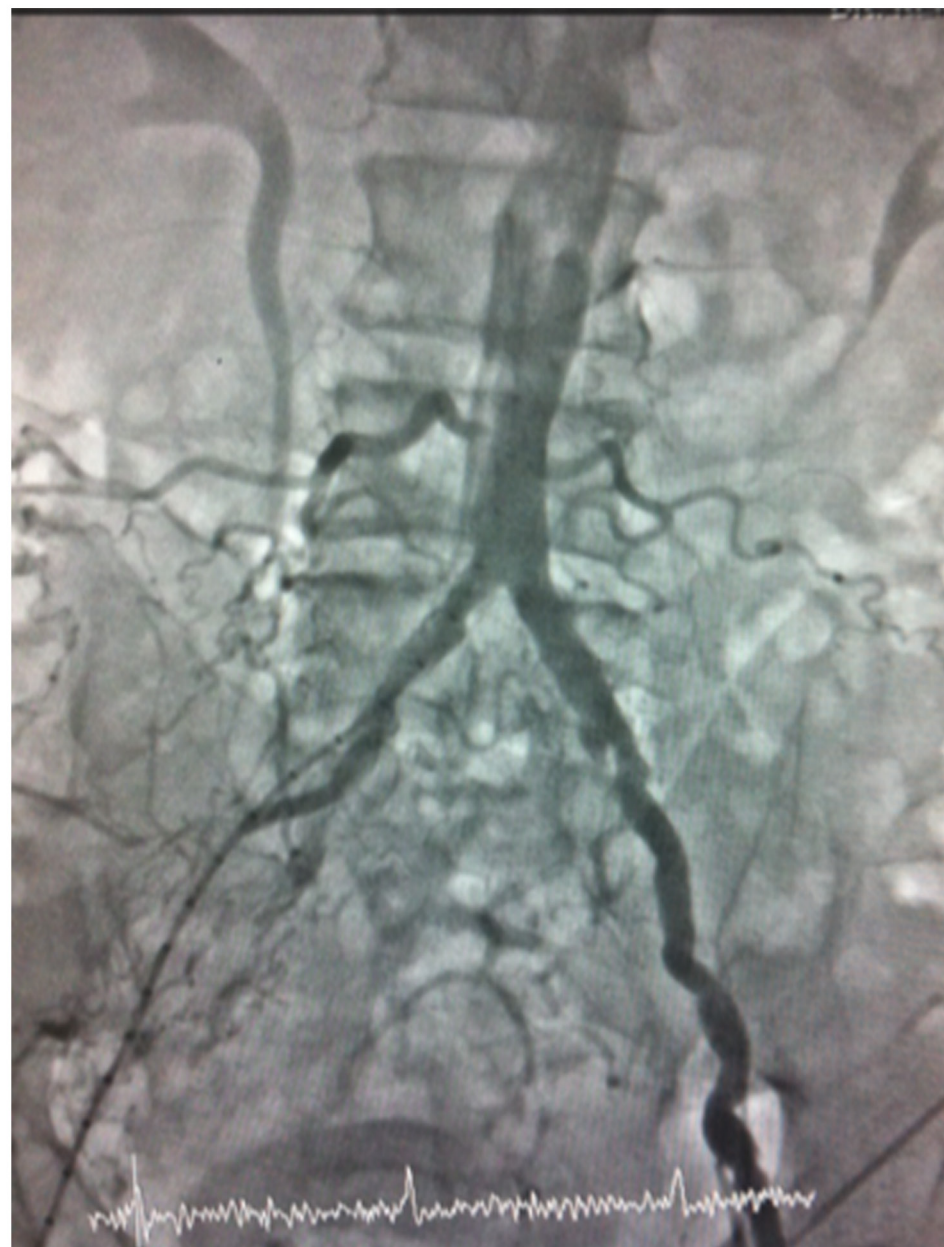


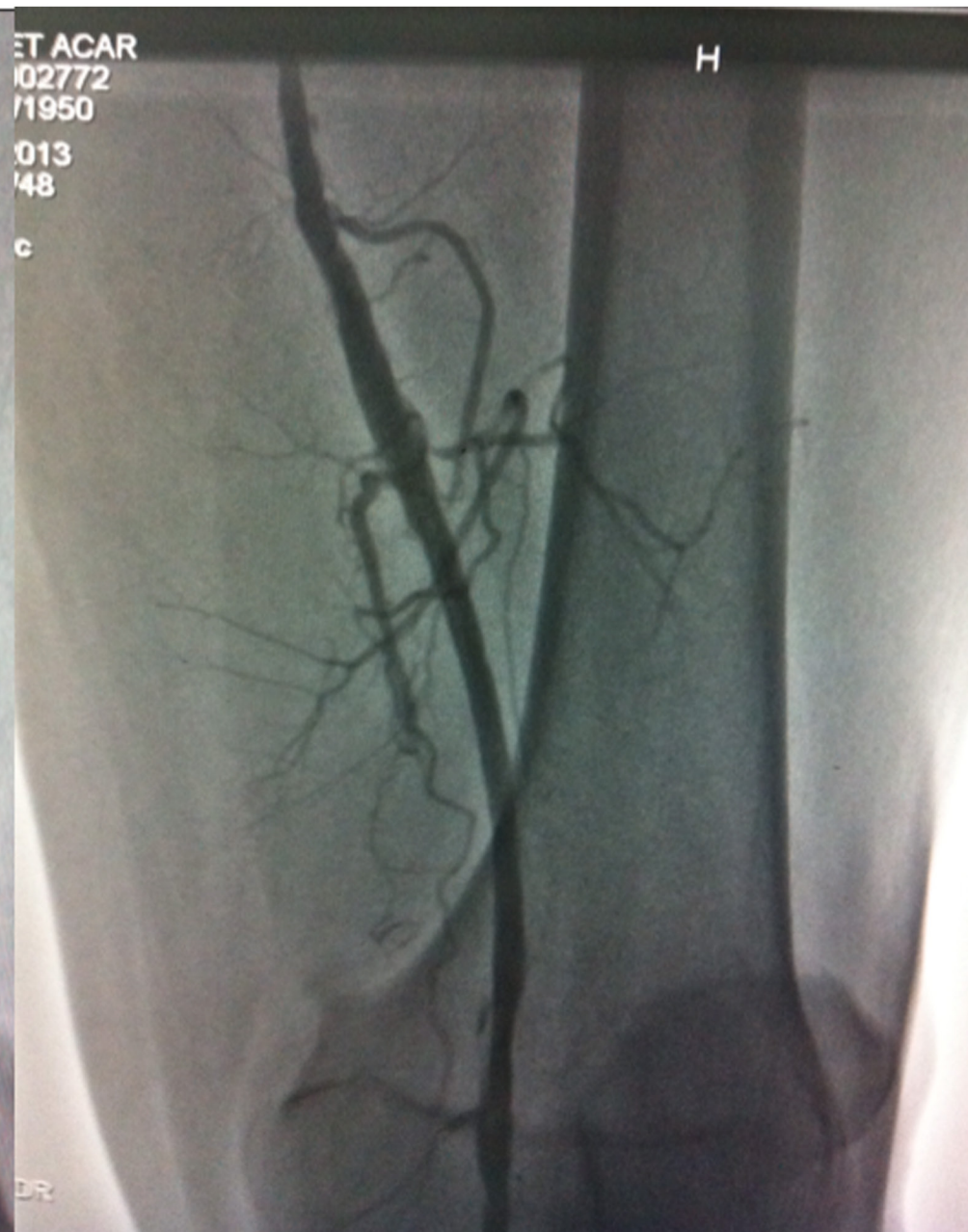













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CLINICAL BACKGROUND

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- In a study of 335 patients with 658 lesions, the 20-month results of directional atherectomy revealed a primary opening rate of 82% and 78% in diabetic and non-diabetic patients, respectively.
 - Zeller et al. in the total occlusion of the infrapopliteal level, 67% of the one-year primer patency and 91% of the secondary opening patency were performed by post-dilation with PTA.
 - The same series found two-year opening rates as primers and secondary, 60% and 80% respectively.
 - Gedik and his colleagues conducted a series of 1000 studies. The two year opening rate was 87%. (Innovations 2016)
 - In another study evaluating total occlusions at infrapopliteal level, the one-year primary opening rate was 72% and the secondary opening rate was 93%. (Gedik et al., Innovations 2016)

Atherectomy of the femoropopliteal artery: a systematic review and meta-analysis of randomized controlled trials

A. DIAMANTOPOULOS, K. KATSANOS

TABLE II.—*Meta-analysis pooled results (total of 287 enrolled patients with 328 lesions analyzed).*

Endpoint	Outcomes (Atherectomy vs. Angioplasty)	Pooled RR (95%CI)	P value	I ² (%)
Technical success	93.6% vs. 96.2%	0.99 (0.95-1.03)	0.57	0
Primary patency	51.1% vs. 60.8%	0.90 (0.56-1.46)	0.68	69
Re-interventions	16.5% vs. 32.9%	0.54 (0.24-1.22)	0.14	34
Amputations	4.2% vs. 25.0%	0.20 (0.06-0.72)	0.01	0
Mortality	9.4% vs. 25.5%	0.37 (0.14-0.97)	0.04	0
Bail-out stenting	11.2% vs. 41.3%	0.37 (0.06-2.22)	0.28	79
Distal embolization	17.9% vs. 2.1%	3.90 (0.29-52.9)	0.31	66
Complications (excluding embolization)	6.2% vs. 12.2%	0.51 (0.19-1.35)	0.17	0

Endovascular Repair of Peripheral Arterial Disease

Midterm Results From a Single Center

Kemal Korkmaz, MD,* Hikmet Selcuk Gedik, MD,* Ali Baran Budak, MD,*
Serdar Gunaydin, MD,* and Kerim Cagli, MD†

TABLE 2. Preoperative Angiographic Data

	Iliac Artery	Common Femoral Artery	SFA	Popliteal Artery	Tibioperoneal Trunk	Peroneal Artery	Anterior Tibial Artery	Posterior Tibial Artery
Total occlusion (n = 592, 59.2%)	72	98	90	78	30	98	52	74
Stenosis (n = 916, 91.6%)	94	119	38	56	64	178	183	184

SFA, superficial femoral artery.

- In 847 atherectomy procedure out of 1000 patients, 84% was successful.
- All patients were followed up with mean \pm SD duration of 32.34 ± 8.14 months (range = 5-58 months). Early death did not occur.
- There were 151 early occlusions (95 surgical interventions, 56 surgical stents), 121 dissections (39 surgical interventions, 56 surgical interventions, 26 surgical interventions), 32 hematomas and 13 early leaks.
- The mean \pm SD Rutherford class increased from 3.29 ± 0.8 to 3.02 ± 0.9 before the procedure ($P = 0.045$). The 8-year recurrence rate was 76% (1255/1652) (aortoiliac = 81.4%: 162/199, SFA = 83 : 4%: 477/572, distal = 69.5%: 613/881).
- Sixty-three patients underwent surgery and 59 received cellular therapy. A total of 134 fingers, 142 knee and 29 knee amputations were reported for a long time.

TABLE 3. List of Endovascular Interventions Throughout the Years

Procedure	Iliac	SFA	Distal	Total
PTA only	18	114	315	447
Drug-coated balloon	19	186	445	650
Atherectomy	8	113	32	153
Stents	116	98	17	231
Hybrid	38	61	72	171

PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery.

POSSIBLE COMPLICATIONS



The most common complications rotational and directional atherectomy cases are:

- 17% of arterial spasm
 - 8% acute thrombosis
 - 3% dissection / perforation
 - 1.7% distal emboli
-
- Thrombosis complications – Fibrolithic Treatment
 - Disintegration / perforation – Stenting
 - Distal embolization – Aspiration Thrombectomy



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