Update on Orbital And Laser Atherectomy: Indications, Advantages and Precautions With Above and Below Knee, De Novo Lesions and ISR

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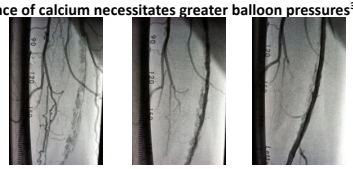
Theoretical Advantages of Atherectomy Before DCB

- Larger initial lumen size than balloon without permanent implant, which may fracture
- Less dissections than PTA -- less stents
- Removing the barrier of organized thrombus and calcium to drug absorption

Why Remove Calcium?

- Calcium might influence drug-coated balloon efficacy[1]
- Plaques associated with arterial dissections commonly have significant calcium deposits[2]
- Presence of calcium necessitates greater balloon pressures[3,4]



1. Fanelli F, et al. Cardiovasc Intervent Radiol. 2014 ;37(4):898-907.
2. Fitzgerald, et al. Circulation. 1992;86(1):64-70.
3. Demer. Circulation. 1991;83:2083-2093.
4. Makam, J Invasive Cardiol. 2013;25(2):81-8.

Images Courtesy of Dr. Raja Sharma
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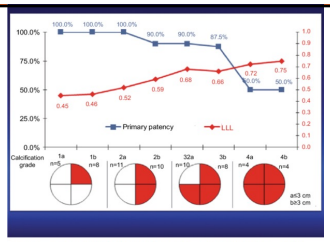
Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.



Primary patency and LLL at 12 months after the treatment in eight groups that were classified according to circumferential and longitudinal distribution of calcification. Note: There is an inverse relationship between the primary patency and LLL with groups with severe calcification (4a and 4b). Source: Reprinted by permission from Springer Nature Customer Service Centre GmbH: Springer Nature Cardiovascular and Interventional Radiology Fanelli F, Cannavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014;37(4):898-907, © 2014. 59 Abbreviation: LLL, late lumen loss.

Orbital and Laser Atherectomy

- Commonly used in treating Femoral, Popliteal, and Infrapopliteal lesions
- Multiple registries suggest improved patency in calcific lesions with orbital atherectomy
- LIBERTY 360 trial suggested improved outcomes with atherectomy (majority of cases utilized orbital atherectomy)
- No randomized controlled trials in DeNovo lesions
- 308nm Laser shown to be superior to PTA for treating ISR (less TLR and MACE) (EXCITE Trial – Randomized Control)
- LACI Trial (non-randomized) suggested 308nm Laser improved limb salvage with IP intervention

EXCITE ISR

(308 nm excimer laser atherectomy to treat ISR)

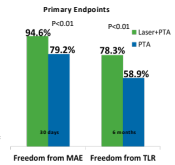
Principal Investigator
Eric Dippel, MD

Laser atherectomy is superior to PTA alone for treatment of femoropopliteal ISR

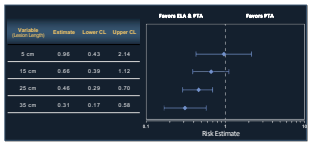
	Laser + PTA n=170	PTA n=82
Mean lesion length	19.6 cm	19.3 cm
Calcium (mod/sev)	27.6 %**	10.0 %
Stent Fracture		
Type 1 or 2	11.0 %**	2.5 %
Type 3, 4 or 5	3.0 %	0 %
Residual Stenosis >30%	4.2%*	13.4%
Procedural Success#	93.5%**	82.7%
Ballout stenting after treatment	4.1%	11.1%
Major dissection	2.4%	7.4%

20% of lesions > 30 cm

*<30% residual stenosis by visual assessment without bailout procedure
†P<0.05
‡P<0.01

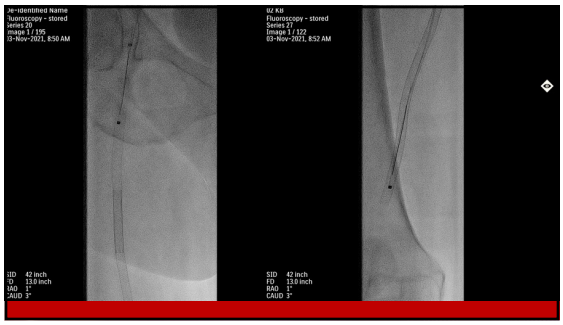


Lesion Length and TLR



Dippel et al. JACC CI. 2015;8:92-101

Laser can help cross ISR lesions, not crossable by wire



Post PTA

In-Stent Restenosis

TABLE 1. OUTCOMES FOR LASER, DCBs, AND THE COMBINATION IN TREATING FEMOROPOPLITEAL ISR

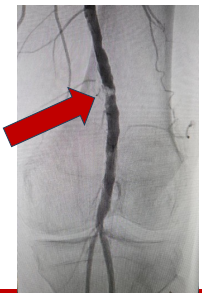
Study (ordered by mean lesion length)	Treatment	Patients (n)	Lesions (n)	Lesion Length (cm)	Primary Patency			Freedom From TLR		
					6 months	12 months	24 months	6 months	12 months	24 months
FAIR[8]	PTA	57	57	8.1	55.3%	37.5%	–	81%	52.6%	–
	DCB	62	62	8.2	84.6%	70.5%	–	96.4%	90.8%	–
Virga/ Stabile[9,10]	DCB	39	39	8.3	–	92%	70.3%	–	92%	78.4%
DEBATE-ISR[11]	PTA	44	44	13.7	–	28%	–	–	69%	–
	DCB	42	42	13.2	–	81%	–	–	86%	–
van den Berg[12]	Laser + DCB	14	14	13.3	–	100%	91.7%	–	100%	92.9%
EXCITE ISR[4,5]	PTA	81	81	19.3	–	–	–	51.8%	41.7%	–
	Laser + PTA	169	169	19.6	–	–	–	73.5%	53.8%	–
Gandini[13]	DCB	24	24	23.3	58.3%	37.5%	–	–	50%	–
	Laser + DCB	24	24	20	91.7%	66.7%	–	–	83.3%	–

Orbital Atherectomy

- **Can debulk calcific lesions**
  - **May help prevent plaque shift at bifurcations**
  - **May limit dissections in long calcific lesions avoiding need for stenting in areas typically thought to represent "No-Stent Zones"**
  - **May facilitate vessel preparation for stenting in densely calcific lesions where stent expansion may otherwise be limited**
  - **May improve patency in long IP occlusions**
  - **Available lengths up to 200cm to facilitate radial access cases**

Orbital Atherectomy Cases

Calcified Popliteal Stenosis



Orbital Atherectomy

Low Pressure Balloon 3atm

Final Result with DCB

Orbital Atherectomy

- Ideally should be true luminal crossing
- Advance device slowly (very helpful in calcified lesions)
- Adequate anti-coagulation mandatory
- May induce "no reflow" (Vasodilators may help to prevent "no reflow". Shorter runs may also help to prevent "no reflow")
- Available in lengths up to 200cm for radial cases

Conclusions

- We need randomized controlled trials in the utilization of all atherectomy devices in DeNovo lesions
  - We lack randomized controlled trials in many standard surgical procedures as well
  - Several registries suggest improved outcomes in DeNovo lesions
- 308nm Laser has been shown with randomized controlled trials to be superior to angioplasty in treating ISR
- 308nm Laser may help cross lesions uncrossable by guidewires