

# A Review of Atherectomy in Peripheral Arterial Disease

Grant T. Fankhauser, Garold E. Motes, Jennifer L. Worsham

*Department of Vascular Surgery, University of Texas Medical Branch, Galveston, Texas, USA*

## ABSTRACT

Atherectomy involves exciting technology and offers expanded treatment options for PAD. Data are scant so far in most lower extremity territories to support its use over other interventions, but newer results are promising. There is still a financial benefit to choosing atherectomy in the outpatient setting that likely drives much of its popularity among interventionalists. Atherectomy is an exciting technology for peripheral vascular intervention. Its use has greatly increased over the last decade. Data on its superiority to angioplasty or angioplasty with stenting are scant. Here, we review atherectomy techniques and principles along with results and controversy surrounding its use.

**Key words:** Angiography, atherectomy, endovascular, peripheral

## INTRODUCTION

Peripheral arterial disease (PAD) affects millions worldwide. Roughly 12–15 million Americans suffer from PAD and as many as 200 million are affected worldwide.<sup>[1,2]</sup> Given how many patients suffer from PAD, the cost of treatment and care is considerable. In the United States in 2014, Medicare expenditures alone exceeded \$22 billion for diagnoses related to PAD.<sup>[3]</sup> Many treatments are available for PAD including lifestyle modification, medications, exercise programs, endovascular interventions, endarterectomy, and open surgical bypass. As in many other fields, there has been a move toward less invasive intervention over the past 20 years.<sup>[4,5]</sup> Many peripheral vascular lesions are amenable to various treatment options. There are several guidelines that offer recommendations for treating different lesions in PAD.<sup>[6-8]</sup> However, there is still not a gold standard treatment for all peripheral vascular lesions.<sup>[9]</sup>

Peripheral vascular intervention is occurring with increasing frequency and is being performed more often in the outpatient setting, either in hospitals or office-based practices that have angiography capabilities.<sup>[10]</sup> Atherectomy is one technique

for treating PAD whose use in the outpatient setting has skyrocketed in the last decade. In 2008, Medicare issued a payment ruling that increased the non-facility payment for atherectomy for PAD. The final ruling in 2011 cemented the reimbursement for non-facility atherectomy.<sup>[11]</sup> Since 2011, there has been a notable increase in outpatient atherectomy procedures.<sup>[12]</sup> Despite the increasing use of atherectomy for treating PAD, there have been a few controlled trials comparing it to other endovascular interventions. A Cochrane review went so far as to declare that there was no evidence of the superiority of atherectomy over angioplasty.<sup>[13]</sup> Here, we review the use of atherectomy in PAD, the technology involved, and the results.

## ATHERECTOMY PRINCIPLES

Stenting has been shown to be superior to angioplasty alone in many lower extremity lesions, especially longer lesions, and those that are densely calcified.<sup>[14]</sup> Not all lower extremity lesions are amenable to stenting. Rarely it is advisable to place a stent in the common femoral artery, and stents in arteries over joint spaces may be more susceptible to fracture or occlusion.<sup>[9]</sup> The appeal of atherectomy has been to offer

### Address for correspondence:

Grant T. Fankhauser, Department of Vascular Surgery, University of Texas Medical Branch, Galveston, Texas, USA.  
Phone: 409-772-6366. E-mail: gtfankha@utmb.edu

© 2018 The Author(s). This open access article is distributed under a Creative Commons Attribution (CC-BY) 4.0 license.

treatment in areas where stents are not feasible and to debulk atherosclerotic lesions to allow lower insufflation pressures during angioplasty.<sup>[15-17]</sup>

## ATHERECTOMY TECHNOLOGY

Several different atherectomy technologies are available and all work in slightly different ways. These include rotational atherectomy, directional atherectomy, orbital atherectomy, and laser atherectomy.

Rotational atherectomy uses a high-speed concentric spinning blade to cut atheroma.<sup>[9]</sup> Approved rotational atherectomy systems include Rotablator (Boston Scientific/Scimed), the Phoenix atherectomy catheter (Volcano Corporation), and the Pathway Jetstream atherectomy system (Boston Scientific). These devices offer various sized heads to accommodate lower extremity vessels from the iliac arteries through the tibial arteries. Not all devices are approved for each vessel. Because these devices work over the wire, they can be used in conjunction with a distal embolic protection device (filter). However, the use of filters in these settings may be off label. The Phoenix atherectomy catheter is a dual lumen catheter that shaves plaque with its rotating distal tip while capturing the dislodged plaque into its own catheter.

Orbital atherectomy devices utilize an eccentric rotating crown. The speed of the device can be varied to alter the width of the orbit of the rotating crown. Orbital atherectomy devices include the Diamondback Systems (Cardiovascular Systems, Inc.). The debris generated is believed to be sufficiently small (smaller than a red blood cell) to allow it to pass through the capillary system rather than cause symptomatic distal embolization.<sup>[15]</sup> The device works best on calcific lesions but may be less effective on soft plaque and is not indicated for in-stent restenosis. The Diamondback System may be especially effective in modifying plaque to improve vessel compliance for angioplasty, which may result in a longer freedom from reintervention and greater cost-effectiveness.<sup>[18]</sup> A cadaver study demonstrated that vessels treated by orbital atherectomy had an increased drug uptake when treated after atherectomy by drug-coated balloon (DCB) angioplasty.<sup>[19]</sup>

Directional atherectomy is a process of removing plaque from arterial walls in a controlled and directional fashion. The plaque is removed and captured in a portion of the atherectomy device. Approved devices include the SilverHawk (Medtronic/Covidien), TurboHawk (Medtronic/Covidien), HawkOne (Medtronic/Covidien), and Pantheris (Avinger) devices. These devices can be used with either calcified or soft lesions. They must be directed under visual guidance toward the area of plaque. Despite the plaque capturing technology, distal embolization remains a concern and these devices are frequently used with a distal filter.<sup>[20]</sup> Directional

atherectomy can be used to debulk atherosclerotic lesions as well as prepare vessels for angioplasty or DCB angioplasty.<sup>[21]</sup> The Pantheris uses Lumivascular technology to visualize the layers of the arterial wall and plaque morphology. This may prevent the injury of the elastic lamina that is hypothesized to result in earlier restenosis.<sup>[22]</sup>

Laser atherectomy uses a xenon chloride laser operating at a pulsed 308-nanometer wavelength.<sup>[23]</sup> Currently approved systems include the excimer laser system from Spectranetics. This device uses ultraviolet laser light in a process referred to as “photoablation” of plaque.<sup>[24]</sup> While most of the debris generated during laser atherectomy is small enough to pass through the capillary system (smaller than 10  $\mu$ ), macroparticle distal embolization is still a concern and filters are often employed during laser atherectomy. The Spectranetics system is also approved for the treatment of in-stent restenosis.

### Indications

The primary indication for atherectomy is debulking of atherosclerotic disease or vessel preparation for angioplasty when stenting is not planned. The advent of paclitaxel-coated balloons (Lutonix from Bard, IN.PACT from Medtronic) for peripheral use is a promising area for atherectomy. *In vitro* and *in vivo* studies demonstrate better absorption of paclitaxel into the arterial tissue and more durable results after vessel preparation by atherectomy.<sup>[21,25-27]</sup> Areas where stents are not recommended, such as the common femoral and mobile portions of the superficial femoral or popliteal arteries are commonly targeted with this technique.

Infrapopliteal lesions are another area frequently targeted with atherectomy. Vessel preparation before angioplasty may reduce the required inflation pressures during angioplasty, thus reducing this risk of dissection. Atherectomy may also help debulk lesions in infrapopliteal vessels unlikely to respond well to angioplasty alone.<sup>[23,28,29]</sup>

The excimer laser is the only atherectomy device approved for use in the United States for treating in-stent restenosis. There have been favorable results in its use compared to angioplasty alone.<sup>[30]</sup> Orbital and rotational atherectomy systems are occasionally used off label for in-stent restenosis. Directional atherectomy devices are less often used in this manner as there is a concern for the cutting mechanism becoming lodged in the stent struts. However, some groups have had success with the technique.<sup>[31,32]</sup>

## RESULTS

The Cochrane review provides some of the most rigorous outcome data for atherectomy.<sup>[13]</sup> This review looked at the available studies comparing atherectomy to balloon angioplasty. In cases treated with atherectomy, there tended to

be fewer dissections and needs for bailout stenting. There was also a lower required inflation pressure during angioplasty. Atherectomy also showed a lower overall mortality, however, that may have been influenced by the relatively high mortality noted in one study in the angioplasty arm.<sup>[16]</sup>

Furthermore, noted in the Cochrane review was the higher embolization rate with atherectomy.<sup>[13]</sup> Most importantly, there was no benefit in primary patency for atherectomy over angioplasty. Other studies have failed to demonstrate a difference in clinical outcomes with atherectomy use but have noted higher costs.<sup>[16,33,34]</sup>

There is also some data that the complications associated with atherectomy may lead to worse outcomes. Mukherjee *et al.* looked at outpatient atherectomy in claudicants. Their study found a higher rate of recent intervention than with other forms of endovascular intervention and also noted a higher rate of major amputation (proximal to ankle).<sup>[35]</sup>

### Controversies

Few would argue that atherectomy is a valuable adjunct in lower extremity intervention. The degree of its benefit and how widely applicable it may be is more debatable. There are little data showing a clear benefit of atherectomy with angioplasty over angioplasty alone.<sup>[36]</sup> The use of drug-coated balloons after atherectomy is showing promise but how much better it might be over drug-coated balloon angioplasty alone is also not clear nor is how long any apparent benefit might endure. There is scant if any data thus far that in suitable territories, atherectomy followed by balloon angioplasty is superior to angioplasty with stenting.<sup>[36]</sup> However, the reimbursement for atherectomy and angioplasty far exceeds that of stenting with angioplasty. The reimbursement “bonus” for atherectomy is the cloud looming over its head and raises questions regarding the motivation for the growth of atherectomy in the past 5–10 years.<sup>[10,36]</sup>

Atherectomy is clearly not a superior intervention in most lower extremity applications. Moreover, it is not technically any easier than angioplasty alone or stenting with angioplasty. The cost of disposables and/or implants with atherectomy and angioplasty is no less expensive than stenting with angioplasty. Hence, why are so many interventionalists choosing atherectomy, especially in non-facility settings? Unfortunately, the financial benefit of atherectomy may answer the question since there seems to be no other explanation.

### Summary

Atherectomy involves exciting technology and offers expanded treatment options for PAD. Data are scant so far in most lower extremity territories to support its use over other interventions, but newer results are promising. There is still a financial benefit to choosing atherectomy in the outpatient

setting that likely drives much of its popularity among interventionalists.

## REFERENCES

- Hirsch AT, Criqui MH, Treat-Jacobson D, Regensteiner JG, Creager MA, Olin JW, *et al.* Peripheral arterial disease detection, awareness, and treatment in primary care. *JAMA* 2001;286:1317-24.
- Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott M, *et al.* Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: A systematic review and analysis. *Lancet* 2013;382:1329-40.
- Centers for Medicare & Medicaid Services (CMS), HHS. Medicare program; Revisions to payment policies under the physician fee schedule and other revisions to part B for CY 2018; Medicare shared savings program requirements; And medicare diabetes prevention program. Final rule. *Fed Regist* 2017;82:52976-3371.
- Rowe VL, Lee W, Weaver FA, Etzioni D. Patterns of treatment for peripheral arterial disease in the United States: 1996-2005. *J Vasc Surg* 2009;49:910-7.
- Goodney PP, Beck AW, Nagle J, Welch HG, Zwolak RM. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. *J Vasc Surg* 2009;50:54-60.
- Aboyans V, Ricco JB, Bartelink ME, Bjorck M, Brodmann M, Cohnert T, *et al.* 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the european society for vascular surgery (ESVS). *Rev Esp Cardiol (Engl Ed)* 2018;71:111.
- Pentecost MJ, Criqui MH, Dorros G, Goldstone J, Johnston KW, Martin EC, *et al.* Guidelines for peripheral percutaneous transluminal angioplasty of the abdominal aorta and lower extremity vessels. A statement for health professionals from a special writing group of the councils on cardiovascular radiology, arteriosclerosis, cardio-thoracic and vascular surgery, clinical cardiology, and epidemiology and prevention, the American heart association. *J Vasc Interv Radiol* 2003;14:S495-515.
- Writing Committee to Develop Clinical Data Standards for Peripheral Atherosclerotic Vascular Disease, Creager MA, Belkin M, Bluth EI, Casey DE Jr., Chaturvedi S, *et al* 2012 ACCF/AHA/ACR/SCAI/SIR/STS/SVM/SVN/SVS key data elements and definitions for peripheral atherosclerotic vascular disease: A report of the American college of cardiology foundation/American heart association task force on clinical data standards (Writing committee to develop clinical data standards for peripheral atherosclerotic vascular disease). *Circulation* 2012;125:395-467.
- Bhat TM, Afari ME, Garcia LA. Atherectomy in peripheral artery disease: A Review. *J Invasive Cardiol* 2017;29:135-44.
- Mukherjee D, Hashemi H, Contos B. The disproportionate growth of office-based atherectomy. *J Vasc Surg* 2017;65:495-500.
- Centers for M, Medicaid Services HHS. Medicare program; Payment policies under the physician fee schedule and other revisions to Part B for CY 2011. Final rule with comment

- period. *Fed Regist* 2010;75:73169-860.
12. Jones WS, Mi X, Qualls LG, Vemulapalli S, Peterson ED, Patel MR, *et al.* Trends in settings for peripheral vascular intervention and the effect of changes in the outpatient prospective payment system. *J Am Coll Cardiol* 2015;65:920-7.
  13. Ambler GK, Radwan R, Hayes PD, Twine CP. Atherectomy for peripheral arterial disease. *Cochrane Database Syst Rev* 2014;3:CD006680.
  14. Garcia LA, Lyden SP. Atherectomy for infrainguinal peripheral artery disease. *J Endovasc Ther* 2009;16:III05-15.
  15. Dattilo R, Himmelstein SI, Cuff RF. The COMPLIANCE 360° trial: A randomized, prospective, multicenter, pilot study comparing acute and long-term results of orbital atherectomy to balloon angioplasty for calcified femoropopliteal disease. *J Invasive Cardiol* 2014;26:355-60.
  16. Shammass NW, Lam R, Mustapha J, Ellichman J, Aggarwala G, Rivera E, *et al.* Comparison of orbital atherectomy plus balloon angioplasty vs. Balloon angioplasty alone in patients with critical limb ischemia: Results of the CALCIUM 360 randomized pilot trial. *J Endovasc Ther* 2012;19:480-8.
  17. Shafique S, Nachreiner RD, Murphy MP, Cikrit DF, Sawchuk AP, Dalsing MC, *et al.* Recanalization of infrainguinal vessels: Silverhawk, laser, and the remote superficial femoral artery endarterectomy. *Semin Vasc Surg* 2007;20:29-36.
  18. Weinstock B, Dattilo R, Diage T. Cost-effectiveness analysis of orbital atherectomy plus balloon angioplasty vs balloon angioplasty alone in subjects with calcified femoropopliteal lesions. *Clinicoecon Outcomes Res* 2014;6:133-9.
  19. Tzafiriri AR, Garcia-Polite F, Zani B, Stanley J, Muraj B, Knutson J, *et al.* Calcified plaque modification alters local drug delivery in the treatment of peripheral atherosclerosis. *J Control Release* 2017;264:203-10.
  20. Roberts D, Niazi K, Miller W, Krishnan P, Gammon R, Schreiber T, *et al.* Effective endovascular treatment of calcified femoropopliteal disease with directional atherectomy and distal embolic protection: Final results of the DEFINITIVE ca++ trial. *Catheter Cardiovasc Interv* 2014;84:236-44.
  21. Zeller T, Langhoff R, Rocha-Singh KJ, Jaff MR, Blessing E, Amann-Vesti B, *et al.* Directional atherectomy followed by a paclitaxel-coated balloon to inhibit restenosis and maintain vessel patency: Twelve-month results of the DEFINITIVE AR study. *Circ Cardiovasc Interv* 2017;10: pii: e004848.
  22. Schwindt AG, Bennett JG Jr, Crowder WH, Dohad S, Janzer SF, George JC, *et al.* Lower extremity revascularization using optical coherence tomography-guided directional atherectomy: Final results of the evaluation of the pantheris optical coherence tomography imaging atherectomy system for use in the peripheral vasculature (VISION) study. *J Endovasc Ther* 2017;24:355-66.
  23. Shammass NW. Current role of atherectomy for treatment of femoropopliteal and infrapopliteal disease. *Interv Cardiol Clin* 2017;6:235-49.
  24. Idemoto A, Okamoto N, Tanaka A, Mori N, Nakamura D, Yano M, *et al.* Impact of angioscopic evaluation for femoropopliteal in-stent restenosis before and after excimer laser atherectomy. *Vasc Endovascular Surg* 2017;51:335-7.
  25. Tellez A, Dattilo R, Mustapha JA, Gongora CA, Hyon CM, Palmieri T, *et al.* Biological effect of orbital atherectomy and adjunctive paclitaxel-coated balloon therapy on vascular healing and drug retention: Early experimental insights into the familial hypercholesterolaemic swine model of femoral artery stenosis. *EuroIntervention* 2014;10:1002-8.
  26. Beschoner U, Zeller T. Combination of mechanical atherectomy and drug-eluting balloons for femoropopliteal in-stent restenosis. *J Cardiovasc Surg (Torino)* 2014;55:347-9.
  27. Ott I, Cassese S, Groha P, Steppich B, Hadamitzky M, Ibrahim T, *et al.* Randomized comparison of paclitaxel-eluting balloon and stenting versus plain balloon plus stenting versus directional atherectomy for femoral artery disease (ISAR-STATH). *Circulation* 2017;135:2218-26.
  28. Tan TW, Semaan E, Nasr W, Eberhardt RT, Hamburg N, Doros G, *et al.* Endovascular revascularization of symptomatic infrapopliteal arteriosclerotic occlusive disease: Comparison of atherectomy and angioplasty. *Int J Angiol* 2011;20:19-24.
  29. Zeller T, Frank U, Bürgelin K, Schwarzwälder U, Flügel PC, Neumann FJ, *et al.* Initial clinical experience with percutaneous atherectomy in the infragenicular arteries. *J Endovasc Ther* 2003;10:987-93.
  30. Kokkinidis DG, Hossain P, Jawaid O, Alvandi B, Foley TR, Singh GD, *et al.* Laser atherectomy combined with drug-coated balloon angioplasty is associated with improved 1-year outcomes for treatment of femoropopliteal in-stent restenosis. *J Endovasc Ther* 2018;25:81-8.
  31. Trentmann J, Charalambous N, Djawanscher M, Schäfer J-, Jahnke T. Safety and efficacy of directional atherectomy for the treatment of in-stent restenosis of the femoropopliteal artery. *J Cardiovasc Surg (Torino)* 2010;51:551-60.
  32. Shammass NW, Shammass GA, Helou TJ, Voelliger CM, Mrad L, Jerin M, *et al.* Safety and 1-year revascularization outcome of silverHawk atherectomy in treating in-stent restenosis of femoropopliteal arteries: A retrospective review from a single center. *Cardiovasc Revasc Med* 2012;13:224-7.
  33. Quevedo HC, Arain SA, Ali G, Abi Rafeh N. A critical view of the peripheral atherectomy data in the treatment of infrainguinal arterial disease. *J Invasive Cardiol* 2014;26:22-9.
  34. Todd KE Jr., Ahanchi SS, Maurer CA, Kim JH, Chipman CR, Panneton JM, *et al.* Atherectomy offers no benefits over balloon angioplasty in tibial interventions for critical limb ischemia. *J Vasc Surg* 2013;58:941-8.
  35. Mukherjee D, Contos B, Emery E, Collins DT, Black JH 3<sup>rd</sup>. High reintervention and amputation rates after outpatient atherectomy for claudication. *Vasc Endovascular Surg* 2018;52:427-33.
  36. Mohan S, Flahive JM, Arous EJ, Judelson DR, Aiello FA, Schanzer A, *et al.* Peripheral atherectomy practice patterns in the United States from the vascular quality initiative. *J Vasc Surg* 2018; pii: S0741-5214(18)30910-8.

**How to cite this article:** Fankhauser GT, Motes GE, Worsham JL. A Review of Atherectomy in Peripheral Arterial Disease. *J Clin Cardiol Diagn* 2018;1(1):1-4.