New endovascular approaches to peripheral arterial disease

Atherectomy devices

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Disclosure
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I do not have any potential conflict of interest
Atherectomy techniques debulk and remove atherosclerotic plaque by cutting, pulverizing, or shaving with catheter-deliverable devices.

They offer the theoretical advantages of eliminating stretch injury on arterial walls, limiting acute dissection (and the need for adjunctive stenting), and reducing elastic recoil, thereby potentially reducing the rate of restenosis.
Angioplasty + Stent

Atherectomy
Atherectomy Devices

Directional - Silverhawk™

Rotational - Jetstream™

Orbital - Diamondback 360° system
Types of atherectomy

- (Excimer) Laser

  - Directional atherectomy
    Simpson catheter
    Silverhawk; Turbohawk

  - Rotational atherectomy
    Rotablator
    CSI Diamondback 360
    Pathway-Jetstream
Historically neither rotational nor directional atherectomy has shown any significant long-term benefit over PTA alone in the coronary or peripheral arteries.
Rotational Atherectomy Does Not Reduce Recurrent In-Stent Restenosis

Results of the Angioplasty Versus Rotational Atherectomy for Treatment of Diffuse In-Stent Restenosis Trial (ARTIST)

Juergen vom Dahl, MD; Ulrich Dietz, MD; Philipp K. Haager, MD; Sigmund Silber, MD; Luigi Niccoli, MD; Hans Juergen Buettner, MD; Francois Schiele, MD; Martyn Thomas, MD; Philippe Commeau, MD; David R. Ramsdale, MD; Eulogio Garcia, MD; Christian W. Hamm, MD; Rainer Hoffmann, MD; Thorsten Reineke, Dipl Math; Heinrich G. Klues, MD; for the ARTIST Investigators

Background — Aim of this trial was to compare rotational atherectomy followed by balloon angioplasty (rotablation [ROTA] group) with balloon angioplasty (percutaneous transluminal coronary angioplasty [PTCA] group) alone in patients with diffuse in-stent restenosis.

Methods and Results — The ARTIST study is a multicenter, randomized, prospective European trial with 298 patients with in-stent restenosis >70% (mean duration 6 months). In the PTCA group, angioplasty was performed with a stepwise approach by one local investigator, and rotablation of ROTA with low (≤6 atm) inflation pressure. Intravascular ultrasound (IVUS) was performed in a substudy in 86 patients (45 PTCA, 41 ROTA). Angiographic success rates were 91% (PTCA) and 92% (ROTA) with equivalent short-term outcome, with equivalent procedural success rates defined as >80% (PTCA and 85% ROTA). However, the results showed that, in the long term, percent stenosis was 25% and 17% (P = 0.0019). Mean gain in diameter after ROTA was 0.51% (PTCA) and 65% (ROTA) (P = 0.039). By intravascular ultrasound (IVUS), percent over-expansion during PTCA was 91.3% compared with ROTA (78.6%, P = 0.0052).

Conclusions — In terms of the primary objective of the study, PTCA produced a significantly better long-term outcome than ROTA followed by adjunctive low-pressure PTCA. (Circulation. 2002;105:583-588.)
Comparison of balloon angioplasty and Simpson atherectomy for lesions in the femoropopliteal artery: angiographic and clinical results of a prospective randomized trial.

Keep Those Blades Out of My Patients!

The Revival of Debulking is NOT Justified!

Stephen Ramee, MD
Section Head, Interventional Cardiology
Ochsner Heart & Vascular Institute
New Orleans, LA
The SilverHawk Plaque Excision System has produced positive results in single-center prospective registries of patients with infrainguinal lesions, with reduced adjunctive PTA, minimal adjunctive stenting, and competitive 6-month and 12-month patency rates.
De novo lesions
Mean length: 4.3 cm

Zeller et al; JACC 2006; 48:1573
Acute and long-term outcome of silverhawk assisted atherectomy for femoro-popliteal lesions according the TASC II classification: a single-center experience

Sixt S et al; VASA 2010; 39: 229–236
Courtesy Th. Zeller
Acute and long-term outcome of silverhawk assisted atherectomy for femoro-popliteal lesions according the TASC II classification: a single-center experience

*Sixt S et al; VASA 2010; 39: 229–236*

Stenting in 7% (n = 11)

At 12 months primary patency rate was 61% (85 / 140).

*Conclusions:*
The results in TASC D lesions are inferior to those in the lesser stages. Better long-term technical and clinical outcome in de novo lesions compared to restenotic lesions.
601 patients; 1258 lesions

73% of the lesions did not require adjunctive therapy

The 6- and 12-month rates of survival free of TLR were 90% and 80%, respectively.
Lesion length: 4.6 ± 4.1 cm

Primary patency: 67% after 1 year
  60% after 2 years
DEFINITIVE LE

TASC A,B,C lesions (lesion length ≤ 20 cm)
Reference vessel ≥ 1.5 mm and ≤ 7.0 mm)
Silverhawk® or Turbohawk®

800 subjects enrolled in 47 centers
DEFINITIVE LE: 6-months results

- Comparable patency rates to current stent technology outcomes

- Diabetic patients do as well as non-diabetic patients

- In claudicants with $\leq 30\%$ diameter stenosis: additional adjunctive therapy had no significant impact on 6-month patency
DEFINITIVE LE: Subjects with/without Diabetes

Mean lesion length: 7.5 ± 5.3 cm

Courtesy Th. Zeller
Clinically significant (≥ 2 mm in diameter) macrodebris was found in 91% in the atherectomy group (Silverhawk).
SilverHawk
Smooth cutting blade

TurboHawk
Four cutting blades

Large vessels TH straight blades

Small vessels TH contoured blades
Diamondback

Eccentrically mounted, diamondcoated crown that rotates at high speed to sand away plaque material.

The faster the crown rotates, the wider the orbit, which creates a larger lumen.
Conclusions: Debulking with orbital atherectomy appeared to increase the chance of reaching a desirable angioplasty result with less need for bailout stenting.
Pathway system: expandable blade technology - cutting catheter tip remaining at a defined nominal diameter (2.1 mm) when spinning clockwise but expands to a defined maximum diameter (3.0 mm) when rotating counterclockwise.

Ports between the flutes for aspiration
Advantage in treating lesions where a combination of plaque and thrombus reside together
One-Year Outcome of Percutaneous Rotational Atherectomy With Aspiration in Infrainguinal Peripheral Arterial Occlusive Disease: The Multicenter Pathway PVD Trial

Zeller Th et al; J Endovasc Ther 2009;16:653–662

172 patients – 210 lesions; mean LL 2.7 cm

Device success was 99% (208/210 lesions).

The 1-year restenosis rate was 38.2% based on duplex imaging.
Lasereffects

Photochemical: Breaking molecular bonds

Photothermal: Producing thermal energy

Photomechanical: Creating kinetic energy
Excimer Laser Recanalization of Femoropopliteal Lesions and 1-Year Patency: Results of the CELLO Registry

Dave R et al; J Endovasc Ther 2009;16:665–675

CliRpath Excimer Laser System to Enlarge Lumen Openings (CELLO)

Lesion length: 5.6 ± 4.7 cm

Patency rates (DS <50%) were 59% and 54% at 6 and 12 months, respectively
The addition of the Turbo-Booster to the laser is designed to direct the laser tip away from the center of the vessel toward the vessel wall where plaque resides.
Courtesy G.Biamino
Potential indications for atherectomy

- Calcified lesions
- Dissection membrane
- Instent-Restenosis
- No stent zones.
Calcified lesions: frequently observed especially in patients with diabetes and renal failure

- Lower success rates (uncrossable occlusions)
- Higher rate of stenting (dissections and residual stenosis)
- Higher risk of stent underexpansion
No stent zones
Percutaneous lower-extremity arterial interventions with primary balloon angioplasty versus Silverhawk atherectomy and adjunctive balloon angioplasty: randomized trial.


Primary endpoint: TLR at 1 year
Secondary endpoint: rate of "bailout" stent placement for suboptimal result
N=58

Results:
No difference in TLR (16.7% vs 11.1%) or TVR (21.4% vs 11.1%).
Bailout stent placement was performed in 18/29 patients (62.1%) in the PTA arm and 8/29 (27.6%) in the atherectomy arm (P = .017).
Debulking for **Instent Restenosis**

Potential advantages:
* Better angiographic and hemodynamic result
* Thrombus removal within stent to reduce distal embolization (Laser, Pathway)
PATENT: Photo-Ablation using the TURBO-Booster® and Excimer laser for iN-stent restenosis Treatment

EXCITE ISR: EXCImer laser randomized controlled study for treatment of femoropopliteal In-Stent Restenosis

PHOTOPAC
Excisional Atherectomy for ISR

Courtesy J. Laird
Event-free survival without TVR

De novo lesions

Instant restenosis

Native vessel restenosis

P = 0.005 by log-rank

Zeller et al; JACC 2006; 48:1573
SFA – Instent Restenosis

Improved but not optimal results with debulking
The combination of atherectomy and drug coated balloons will potentially increase the acute treatment success and long term patency.
Randomized controlled pilot trial (N=19) comparing Silverhawk atherectomy with POBA in patients with a first instent reobstruction in the femoropopliteal arteries.

**Results:**
Intima-Media-Thickness (duplex) within the treated segment was significantly increased in all patients treated with the silverhawk device versus the patients treated with POBA.
1-year outcome of atherectomy in conjunction with either DEB or POBA

| Primary patency @ 12 months [n/%] | Entire cohort | PTA (43) | DEB (88) | P  
|----------------------------------|---------------|----------|----------|---
| 48/86 (55)                      | 27/62         | 21/24    | <0.001*  |
| TLR @ 12 months [n/%]            | 31/86 (36%)   | 29/62    | 2/24 (8%)| 0.001* |
| Restenosis@ 12 months [n/%]      | 39/86 (45%)   | 36/62    | 3/24 (13%)| <0.001* |
| Secondary patency @ 12 months [n/%]| 61/86 (71%) | 39/62    | 22/24 (92%)| 0.015* |

Sixt et al; in press
Atherectomy and Drug coated balloon

DEFINITIVE AR
Plaque excision plus DCB versus DCB alone in native vessels

* Removal of perfusion barrier → better and more homogenous drug uptake
* Reduced likelihood of bail-out stenting
Endovascular therapy

Primary result

Longterm patency
Endovascular therapy

„Tailored“ approach specific to the anatomy

Atherectomy devices are useful tools within this strategy

A one-size-fits all atherectomy device does not exist
Each has a unique ability in the hands of different operators.

Operator preference and comfort is a considerable factor in the decision of which atherectomy device should be used.

The combination of the appropriate device and the skill of the operator is essential for successful plaque removal without increasing the risk of plaque dissection.
# Atherectomy Today: Go Slow to Finish Fast

**Jihad A. Mustapha**

## Table 2. Effectiveness of Different Types of Atherectomy Devices for Treating Forms of Plaque Composition and Thrombus\(^a\)

<table>
<thead>
<tr>
<th></th>
<th>Thrombus</th>
<th>Soft Plaque</th>
<th>In-Stent Restenosis(^b)</th>
<th>Mild Calcification</th>
<th>Moderate Calcification</th>
<th>Severe Calcification</th>
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<tbody>
<tr>
<td>Diamondback 360°</td>
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<td>+</td>
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<td>++</td>
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<tr>
<td>Excimer laser</td>
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<td>TurboHawk</td>
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<td>++</td>
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</tr>
<tr>
<td>Jetstream Navitus</td>
<td>++</td>
<td>++</td>
<td>Not known</td>
<td>++</td>
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<tr>
<td>Crosser recanalization</td>
<td>++</td>
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\(^a\) effective; ++, very effective; --, less effective; --, ineffective.
Complete and comprehensive comparative studies have not been performed - until recently - to address the question of superiority, durability, and longterm patency among atherectomy versus (drug coated) balloon angioplasty versus stenting.
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Stephen Ramee, MD
Section Head, Interventional Cardiology
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Which device for which lesion

and

Which adjunctive therapy?