Treatment Strategies for Coronary Artery Calcification

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• Ajay J. Kirtane

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- No speaking/consulting fees personally received
The Underexpanded Stent: This is a Real Problem

7F EBU 3.5

IVUS – Wouldn’t cross
2.0 x 15 balloon: would not cross  
1.25 x 6 followed by 1.5 mm balloon
NC Quantum 3.0 x 15 @ 30 (x4 times)  NC Euphora 3.0 x 15 @ 30 (x2 times)
How/Why Did This Happen?
Lesion Preparation =

Plaque modification + lumen expansion

- *Facilitates procedural success* when treating calcified/complex lesions
  - enables lesion access for balloons and especially stents
- *Plaque modification*: changing lesion compliance
  - minimizes vessel “trauma” (severe dissections)
  - creates a larger MLD
Detection and frequency of coronary calcification
Calcification on Angiography

- **Moderate:**
  Seen only during cardiac motion, usually one side of vessel

- **Severe:**
  Seen on still frame, usually both sides of vessel
Frequency of angio core lab moderate-severe calcification in 13 DES studies
(despite being an exclusion criterion in most studies)

<table>
<thead>
<tr>
<th>Study</th>
<th>Frequency</th>
<th>(Number/Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAVEL</td>
<td>23.3%</td>
<td>(27/116)</td>
</tr>
<tr>
<td>SIRIUS</td>
<td>17.1%</td>
<td>(91/531)</td>
</tr>
<tr>
<td>E-SIRIUS</td>
<td>16.1%</td>
<td>(28/174)</td>
</tr>
<tr>
<td>C-SIRIUS</td>
<td>12.0%</td>
<td>(6/50)</td>
</tr>
<tr>
<td>TAXUS IV</td>
<td>18.3%</td>
<td>(121/660)</td>
</tr>
<tr>
<td>TAXUS V</td>
<td>32.5%</td>
<td>(185/570)</td>
</tr>
<tr>
<td>TAXUS VI</td>
<td>29.7%</td>
<td>(65/219)</td>
</tr>
<tr>
<td>ENDEAVOR II</td>
<td>23.7%</td>
<td>(140/590)</td>
</tr>
<tr>
<td>ENDEAVOR III</td>
<td>17.9%</td>
<td>(78/436)</td>
</tr>
<tr>
<td>ENDEAVOR IV</td>
<td>33.2%</td>
<td>(513/1546)</td>
</tr>
<tr>
<td>SPIRIT II</td>
<td>31.4%</td>
<td>(91/290)</td>
</tr>
<tr>
<td>SPIRIT III</td>
<td>27.8%</td>
<td>(277/997)</td>
</tr>
<tr>
<td>COMPARE</td>
<td>38.5%</td>
<td>(693/1799)</td>
</tr>
<tr>
<td><strong>Pooled</strong></td>
<td><strong>29.0%</strong></td>
<td><strong>(2,315/7,978)</strong></td>
</tr>
</tbody>
</table>
Definition of the CHIP Population: Complex Higher-Risk (and Indicated) Patients

Are we treating these patients effectively?

Adapted from Kirtane et al, Circulation 2016
Frequency of “heavy” calcification in the SYNTAX trial: Randomized + Registry

N=2,636 pts with LM or 3VD

PCI (n=1,095)

- Heavy calcification: 50.6%
- No heavy calcification

CABG (n=1,541)

- Heavy calcification: 54.2%
- No heavy calcification

IVUS Detection of Calcium

Because IVUS does not penetrate into calcium...

1) It cannot measure thickness or mass, only arc and length
2) We assume that superficial calcium is thicker than deep calcium
Unlike IVUS, OCT penetrates calcium and is able to assess calcium thickness and area/volume as well as arc. However, there is little data assessing the impact of OCT-measured calcium (arc, thickness, etc) on stent expansion.

<table>
<thead>
<tr>
<th>Stent expansion</th>
<th>Calcium Arc &lt;90°</th>
<th>Calcium Arc &gt;90°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Area &lt;1.58 mm²</td>
<td>77.9%*</td>
<td>73.6%</td>
</tr>
<tr>
<td>Calcium Area &gt;1.58 mm²</td>
<td>71.5%</td>
<td>69.3%*</td>
</tr>
</tbody>
</table>

ANOVA p=0.02
*p=0.01

Yamada et al. TCT2013
Implications of coronary calcification
Why is Appropriate Lesion Preparation for Coronary Calcification Important?

Lesion calcification:
- May impair stent delivery or expansion
- May abrade polymers off DES

Stentablation
Kobayashi et al.
CCI
2001;52:208-11
*There was a similar, albeit less strong, correlation after 20 atm inflation (r=-0.58, p=0.0007)
79 yo, Recurrent ISR

- Pre-dilation
- Post-dilation

Minimum Stent Area
2.95mm²

Distal  Proximal
TWENTE and DUTCH PEERS (TWENTE II):
Impact of Severe Calcification with 2nd Generation DES

1,423 pts with stable angina; 342 with severe calcification (24%)

At 2 years, TVF was 16.4% vs. 9.8%, p=0.001
predominantly driven by events in the first 48 hours and up to 1 year

Of note, 2 year definite ST was 1.8% vs. 0.4%, p=0.02
Implications of coronary calcification

- **Coronary calcification results in:**
  - Impaired stent delivery, decreased stent expansion, increased malapposition and stent asymmetry
  - Increased procedural complications (edge dissections and perforations)
  - Increased rates of stent thrombosis and restenosis
Treatment of coronary calcification
Treatment of Calcified Lesions: Options

- NC Balloons
- Cutting Balloon
- Angiosculpt
- Laser
- Rotational Atherectomy
- Orbital Atherectomy
- Intravascular Lithotripsy
Calcium Fracture and Relation to Outcomes

61 pts with heavily calcified lesions studied serially with OCT
Fracture was seen in 48% (more frequently with CB or atherectomy)

Fracture was associated with greater MSA and less restenosis/ID-TLR
Calcium Volume Index (CVI) Scoring System

1. Maximum Angle
2. Maximum Thickness
3. Length

### OCT-based CVI Score

<table>
<thead>
<tr>
<th>Angle</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 180°</td>
<td>0 point</td>
</tr>
<tr>
<td>&gt; 180°</td>
<td>2 points</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Thickness</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.5 mm</td>
<td>0 point</td>
</tr>
<tr>
<td>&gt; 0.5 mm</td>
<td>1 point</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Length</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 5.0 mm</td>
<td>0 point</td>
</tr>
<tr>
<td>&gt; 5.0 mm</td>
<td>1 point</td>
</tr>
</tbody>
</table>

Total score: 0 to 4 points

Fujino et al, Eurointervention 2018
**IVUS-Based Calcium Scoring System**

**Example:**
- **Calcium Score=0**
  - Length of Ca >270° = 4.1mm
  - Calcified nodule (-)
  - Vessel diameter = 4.4mm
  - Reverberation arc >90°

<table>
<thead>
<tr>
<th></th>
<th>Cut-off value</th>
<th>AUC</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of Calcium &gt; 270°</td>
<td>5.4</td>
<td>0.73</td>
<td>≤5mm → 0 point</td>
</tr>
<tr>
<td>(per 5mm)</td>
<td></td>
<td></td>
<td>&gt;5mm → 1 point</td>
</tr>
<tr>
<td>Vessel diameter</td>
<td>3.4</td>
<td>0.74</td>
<td>≤3.5mm → 0 point</td>
</tr>
<tr>
<td>(per 1mm)</td>
<td></td>
<td></td>
<td>&gt;3.5mm → 1 point</td>
</tr>
<tr>
<td>Calcified nodule</td>
<td>NA</td>
<td>NA</td>
<td>Absent → 0 point</td>
</tr>
<tr>
<td>Reverberation arc</td>
<td>97°</td>
<td>0.81</td>
<td>Present → 1 point</td>
</tr>
<tr>
<td>(per 90°)</td>
<td></td>
<td></td>
<td>≤90° → 1 point</td>
</tr>
</tbody>
</table>

Excellent expansion despite severe Ca fracture (newly visible perivascular tissue, double-headed white arrow)

Zhang et al, TCT2019
## Treatment of Calcified Lesions: PCI guidelines

<table>
<thead>
<tr>
<th>Device</th>
<th>ACCF/AHA/SCAI 2011</th>
<th>ESC/EAPCI 2014</th>
</tr>
</thead>
</table>
| **Cutting/scoring balloon angioplasty** | • Might be considered to avoid slippage induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches (**Class IIb-C**)  
   • Should not be performed routinely during PCI (**Class III-A**) | May be useful in highly calcified, rigid ostial lesions (also applies to scoring). |
| **Rotational atherectomy**           | • Reasonable for fibrotic or **heavily calcified lesions** that might not be crossed by a balloon catheter or adequately dilated before stent implantation (**Class IIa-C**)  
   • Should not be performed routinely for de novo lesions or in-stent restenosis (**Class III-A**) | Might technically be required in cases of tight and calcified lesions, to allow subsequent passage of balloons and stents. |
| **Laser angioplasty**               | • Might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty (**Class IIb-C**)  
   • Should not be used routinely during PCI (**Class III-A**) | (Laser not mentioned for calcification) |

Levine GN et al. JACC 2011;58:e44-122  
Windecker S et al. EHJ 2014;35:3541-619
Strategy for Approaching Calcified Lesions

Angiographic Calcification?

- Mild
- Moderate
- Severe

Calcification on Imaging?

- -
- +

Mild, Adventitial

Mod/severe, Luminal

Non-atherectomy strategy

Atherectomy Strategy

Strategic Failure

Adapted from Tomey et al, JACC CV Intv 2014
Nearly half of operators performed fewer than 50 PCIs per year, the minimum number recommended by an ACC/AHA/SCAI scientific statement.

Median operator volume was less than 50 in 9 states plus the District of Columbia.

Compared with high-volume operators, low-volume operators:
- Operated at lower volume hospitals.
- More frequently performed emergency PCI and PCI for STEMI.
- Less frequently used radial access.
- Used a greater volume of contrast dye and had longer fluoroscopy times.

In-hospital mortality following PCI was low, but higher for lower volume operators:
- Low volume operators had 16% mortality, compared to 5% for high volume operators.

Risk-adjusted OR for mortality was 1.16 (95% CI 1.12-1.21) for low- versus high-volume operators.

Risk-adjusted OR for mortality was 1.05 (95% CI 1.02-1.09) for intermediate- versus high-volume operators.

Annual PCI volumes in the USA
N=10,496 operators 2009-2015

Duke Clinical Research Institute

Fanaroff A, et. al. JACC 2017
Cutting Balloon vs. Conventional Balloon for Severely Calcified Lesions

92 patients randomized to CB vs. conventional balloon
7 pts in the conventional group received subsequent CB (analyzed as CB)

![Graph showing comparison between BA and CB groups for pre-stent, min.CSA, min.stent CSA, and acute lumen gain.](image)
Shockwave IVL (Investigational)

Balloon Sizes

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 mm</td>
<td>12 mm</td>
</tr>
<tr>
<td>2.75 mm</td>
<td>12 mm</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>12 mm</td>
</tr>
<tr>
<td>3.25 mm</td>
<td>12 mm</td>
</tr>
<tr>
<td>3.5 mm</td>
<td>12 mm</td>
</tr>
<tr>
<td>3.75 mm</td>
<td>12 mm</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>12 mm</td>
</tr>
</tbody>
</table>

Lithotripsy delivery: 4 atm  
Nominal: 6 atm  
RBP: 10 atm

0.014” guidewire compatible  
6F sheath compatibility
Mechanism of IVL

Circumferential Calcium Fracture

Calcium Angle: 327°

Pre-Procedure

Calcium
Fracture
Calcium

Final
Coronary Intravascular Lithotripsy (IVL)

Ali Z et al, JACC CV Imaging 2017
DISRUPT CAD II

120 patient multicenter study of IVL in severely calcific coronary lesions

Predilation needed in 42% of cases

30-day MACE: 7.6%

Among OCT subgroup, fracture seen in 79%

<table>
<thead>
<tr>
<th>Effectiveness Outcomes</th>
<th>Results (n=120)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical success</td>
<td>94.2 (113)</td>
</tr>
<tr>
<td>Angiographic success</td>
<td>100.0 (120)</td>
</tr>
<tr>
<td>Stent delivery</td>
<td>100.0 (120)</td>
</tr>
<tr>
<td>Final in-segment angiographic outcomes (core laboratory)</td>
<td></td>
</tr>
<tr>
<td>Minimum lumen diameter, mm</td>
<td>2.83±0.48</td>
</tr>
<tr>
<td>Residual diameter stenosis, %</td>
<td>9.4±7.5</td>
</tr>
<tr>
<td>Acute gain, mm</td>
<td>1.63±0.49</td>
</tr>
<tr>
<td>Residual diameter stenosis &lt;50%</td>
<td>100.0 (120)</td>
</tr>
<tr>
<td>Residual diameter stenosis &lt;30%</td>
<td>99.2 (119)</td>
</tr>
<tr>
<td>Final in-stent angiographic outcomes (core laboratory)</td>
<td></td>
</tr>
<tr>
<td>Minimum lumen diameter, mm</td>
<td>2.88±0.47</td>
</tr>
<tr>
<td>Residual diameter stenosis, %</td>
<td>7.8±7.1</td>
</tr>
<tr>
<td>Acute gain, mm</td>
<td>1.67±0.49</td>
</tr>
<tr>
<td>Residual diameter stenosis &lt;50%</td>
<td>100.0 (120)</td>
</tr>
<tr>
<td>Residual diameter stenosis &lt;30%</td>
<td>100.0 (120)</td>
</tr>
</tbody>
</table>
Rotablator: Rotational Atherectomy System

- Drive shaft
- Guide wire
- Diamond coated burr (1.25 mm - 2.5 mm, 0.25 mm increments)
- Sheath (4.3 French O.D.)

FDA approved May 1993
**Design Goals:**
- Easier to learn & use (no foot pedal)
- Easier to set up (consolidated cables)
**Rotablator** Rotational Atherectomy System

**TECHNICAL CONSIDERATIONS**
- Single burr with burr-to-artery ratio of 0.5 to 0.6
- Rotational speed of 140,000 to 150,000 rpm

**OPERATOR TECHNIQUE**
- Gradual burr advancement using a pecking motion
- Short ablation runs of 15 – 30 sec
- Avoidance of decelerations > 5,000 rpm
- Final polishing run
Among hospitals performing PCI, 34.5% performed no atherectomy
Calcium in the VA-CART Registry

Series of 9,719 patients with 11,595 calcified lesions within the VA system
Prevalence of calcium in native single vessel (not STEMI) lesions increased over time

Atherectomy was used in 18% of single-vessel PCI cases of native calcific coronary artery lesions and was associated with a decrease in procedural/clinical complications

Armstrong et al, CCI 2017
### ROTATE: Procedural outcomes

<table>
<thead>
<tr>
<th></th>
<th>Planned ROTA</th>
<th>Provisional ROTA</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 358 (433 lesions)</td>
<td>n = 309 (349 lesions)</td>
<td></td>
</tr>
<tr>
<td><strong>Total No. of pre-balloon</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1.17 ± 0.60</td>
<td>1.47 ± 0.76</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>0 (No pre-dilation)</td>
<td>27 (7.6)</td>
<td>7 (2.1)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>1</td>
<td>251 (70.7)</td>
<td>211 (62.6)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>65 (18.3)</td>
<td>74 (22.0)</td>
<td></td>
</tr>
<tr>
<td>&gt;3</td>
<td>12 (3.4)</td>
<td>45 (13.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Maximum pre-balloon size</strong></td>
<td>2.66 ± 0.48</td>
<td>2.60 ± 0.43</td>
<td>0.09</td>
</tr>
<tr>
<td><strong>Total No. of post-balloon</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1.12 ± 0.43</td>
<td>1.10 ± 0.44</td>
<td>0.65</td>
</tr>
<tr>
<td>0 (No post-dilation)</td>
<td>12 (2.8)</td>
<td>12 (3.5)</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td>355 (83.9)</td>
<td>292 (84.6)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>51 (12.1)</td>
<td>35 (10.1)</td>
<td></td>
</tr>
<tr>
<td>&gt;3</td>
<td>5 (1.2)</td>
<td>6 (1.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Maximum post-balloon size</strong></td>
<td>3.27 ± 0.62</td>
<td>3.12 ± 0.52</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Final TIMI flow 3</strong></td>
<td>430 (99.8)</td>
<td>345 (99.1)</td>
<td>0.33</td>
</tr>
<tr>
<td>Procedure time, min</td>
<td>65.2 ± 36.8</td>
<td>84.4 ± 43.1</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Fluoroscopy time, min</td>
<td>33.1 ± 22.9</td>
<td>51.2 ± 29.6</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Contrast volume, ml</td>
<td>232.9 ± 141.6</td>
<td>302.9 ± 150.3</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

Kawamoto et al, CCI 2016
ROTAXUS

240 pts with mod/sev calcified lesions enrolled between August 2006 and March 2010 at 3 clinical sites in Germany

Mean age 71
DM 28%
MVD 74%

1:1 randomization

IVUS not used

Rotablator + PES
(N=120)

PTCA + PES
(N=120)

- 2 patients died in-hospital
- 6 patients withdrew consent
- 5 patients lost at follow-up

Clinical follow-up at 9 months in 96.2%
(N=227)

Angio follow-up at 9 months in 80.5%
(N=190)

*Primary endpoint: In-stent late loss

Abdel-Wahab M et al. JACC CV Interv 2013;6:10-19
ROTAXUS: Primary Endpoint
In-Stent Late Lumen Loss at 9 Months

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Mean ± SD</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rota+PES (n=123)</td>
<td>0.44 mm ± 0.58 mm</td>
<td>0.04</td>
</tr>
<tr>
<td>PTCA+PES (n=132)</td>
<td>0.31 mm ± 0.52 mm</td>
<td></td>
</tr>
</tbody>
</table>

Restenosis = 12.2% vs. 12.9%, P=0.89

Abdel-Wahab M et al. JACC CV Interv 2013;6:10-19
**ROTAXUS: Procedural Outcomes**

- **Stent loss**: 0.0% (Rota+PES) vs 2.5% (PTCA+PES), p = 0.08
- **Crossover**: 4.2% (Rota+PES) vs 12.5% (PTCA+PES), p = 0.02
- **Strategy success**: 92.5% (Rota+PES) vs 83.3% (PTCA+PES), p = 0.03
- **Angiographic success**: 96.7% (Rota+PES) vs 96.7% (PTCA+PES), p = 1.0

*Defined as <20% residual stenosis + TIMI 3 flow*

**Defined as angiographic success with no crossover or stent loss**

Abdel-Wahab M et al. JACC CV Interv 2013;6:10-19
ROTAXUS: Strategy Success according to calcification

Abdel-Wahab M et al. JACC CV Interv 2013;6:10-19
Atherectomy + Cutting PTCA vs. Atherectomy Alone

71 pt pilot RCT; MSA (5.9 vs. 5.0 mm²) and acute gain (4.5 vs. 3.8 mm²) were greater with adjunctive cutting balloon prior to DES implantation.
PREPARE-CALC: Study design

200 patients, elective PCI, native coronaries, **severe calcification**

2 German centers (Bad Segeberg, Munich)

Randomization 1:1

- Scoring Balloon + Biodegradable polymer SES
- Rotablation + Biodegradable polymer SES

Primary endpoint: Strategy success
Co-primary endpoint: In-stent late lumen loss at 9 months
Subgroup with OCT imaging prior to lesion preparation

*Enrollment completed in October 2017*
Primary Endpoint – Strategy Success

<table>
<thead>
<tr>
<th></th>
<th>Modified balloon (n = 100 pts.)</th>
<th>Rotational atherectomy (n = 100 pts.)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategy success</td>
<td>81 (81%)</td>
<td>98 (98%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Final TIMI flow &lt; III</td>
<td>0 (0%)</td>
<td>1 (1%)</td>
<td>0.99</td>
</tr>
<tr>
<td>Residual stenosis &gt;20%</td>
<td>2 (2%)</td>
<td>0 (0%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Stent failure</td>
<td>4 (4%)</td>
<td>1 (1%)</td>
<td>0.36</td>
</tr>
<tr>
<td>Crossover</td>
<td>16 (16%)</td>
<td>0 (0%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

200 patients, elective PCI, native coronaries, **severe calcification**

2 German centers (Bad Segeberg, Munich)
Rotational Atherectomy Burr Speed and Debulking

30 lesions with severe calcification and pre-set burr speeds

Lower speeds were associated with more debulking with also less transient bradycardia.
Low vs. High Speed for Rotational Atherectomy

100 patient RCT of 140,000 rpm vs. 190,000 rpm, mostly 1.25 mm single burrs
Total run time of 120 seconds; mean run time of ~20 seconds
Only 6% of patients needed higher burr speed than assigned

OR: 1.00
(95% CI: 0.40-2.50)
P=1.00

Incidence of Slow flow (%)
DIAMONDBACK 360: Coronary Orbital Atherectomy System

Device Features
- Simple device setup
- Microsecond feedback to changes in loading
- 135cm usable length

On-handle speed control
- Low (80K) and High Speed (120K)

Power on/off switch
- 8 cm axial travel

Eccentric diamond coated handle

6Fr Guide Compatible

Saline Infusion Pump
- Mounts directly on to an IV pole
- Provides power
- Delivers fluid

ViperSlide® Lubricant
- ViperSlide reduces friction during operation
- 20ml ViperSlide per liter of saline

0.012” Viper Wire

6Fr Guide Compatible

Saline Infusion Pump
- Mounts directly on to an IV pole
- Provides power
- Delivers fluid

ViperSlide® Lubricant
- ViperSlide reduces friction during operation
- 20ml ViperSlide per liter of saline

0.012” Viper Wire
OAS: Mechanism is Differential Sanding
Orbital Atherectomy is Time-Dependent
Orbit in a Carbon Block Model System

![Graph showing size at pass vs. number of passes for different traversal rates and revolutions per minute.](image)

**Rate of Traversal**
- 1 cm/sec Traversal
- 1 mm/sec Traversal

*Lines representing drill are not based on data, but are a representation to illustrate lack of luminal gain over time.*

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[Cardiovascular Research Foundation]

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[New York Presbyterian]
Mechanism of Action: Pulsatile Forces

Dual Frequency
- Orbital Frequency: low frequency of the crown orbiting against vessel wall
- Rotational Frequency: high frequency corresponding to crown rotation
**ORBIT II**: Single arm study in severely calcified lesions (n=443 at 49 US sites)

1° **efficacy endpoint**: Procedural success (stent delivery with DS <50% without in-hospital MACE) = 88.9%

- Successful stent delivery: 97.7%
- DS <50%: 98.6%
- In hospital MACE: 9.8%
### ORBIT II: Single arm study in severely calcified lesions (n=443 at 49 US sites)

**Angiographic Complications**

<table>
<thead>
<tr>
<th></th>
<th>Prior to OAS</th>
<th>Post OAS</th>
<th>Post PTCA/Stent</th>
<th>Unknown</th>
<th>Overall N=443</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissection C-F</td>
<td>0.2%</td>
<td>2.3%</td>
<td>0.9%</td>
<td>0.0%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Perforation</td>
<td>0.0%</td>
<td>0.9%</td>
<td>0.9%</td>
<td>0.0%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Slow/no reflow</td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.5%</td>
<td>0.0%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Abrupt Closure</td>
<td>0.2%</td>
<td>0.9%</td>
<td>0.2%</td>
<td>0.5%</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

Chambers JW et al. JACC CV Interv. 2014;7:510-8
ORBIT II: Late Outcomes

- Cardiac death
  - 30 Days: 6.7%
  - 1 Year to 2 Years: 2.0%
  - 2 Years to 3 Years: 3.0%

- TVR/TLR
  - 30 Days to 1 Year: 10.2%
  - 1 Year to 2 Years: 2.1%
  - 2 Years to 3 Years: 4.4%

- MI*
  - 30 Days to 1 Year: 11.2%
  - 1 Year to 2 Years: 0.9%
  - 2 Years to 3 Years: 9.7%

- MACE
  - 30 Days to 1 Year: 23.5%
  - 1 Year to 2 Years: 3.5%
  - 2 Years to 3 Years: 6.5%

*Per protocol analysis. Based on reported CK-MB > 3X ULN.

Certain 1 and 2 year rates updated at 3 year data extract. Kaplan Meier method used to estimate event rates.

Relative Advantages of OAS and RA

<table>
<thead>
<tr>
<th>OAS</th>
<th>RA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.012” stiff wire</td>
<td>0.009” wire, 2 choices</td>
</tr>
</tbody>
</table>

- Hardware/set-up
- Faster learning curve
- Single device for all lesions/vessel diameters
- Full 6 Fr compatibility (including guide extension)
- Hemodynamic stability (less slow flow/pacer?)
- +/- distal/multiple lesions using low speed glide assist

- Aorto-ostial lesions
- Severe angulation/bias
- Subintimal crossing
- Front cutting for uncrossable lesions
- ISR/underexpansion for stent ablation
- Specific scenarios with need for 2.0+ mm burr
- Lower cost of single device

Either can be used in most cases of severe calcium!
Case Presentation

- 73F with PAF on anticoagulation with unstable angina (some atypical features) that “stabilized” with medical therapy
- Nuclear stress test: anteroseptal ischemia
- No further recurrence of rest chest pain though has CCS III angina despite beta-blocker and CCB
Left Coronary System
How Would You Treat?

• Atherectomy
• Specialty Balloon
• NC Balloon
• Imaging

Randomized in ECLIPSE
**ECLIPSE**

**Evaluation of Treatment Strategies for Severe Calcific Coronary Arteries: Orbital Atherectomy vs. Conventional Angioplasty Prior to Implantation of Drug Eluting Stents**

~2000 pts with severely calcified lesions; ~60 US sites

Randomize 1:1

**Orbital Atherectomy Strategy**
(1.25 mm Crown followed by non-compliant balloon optimization)

2nd generation DES implantation and optimization

1* endpoints: 1) Post-PCI in-stent MSA (N~400 in imaging study)
2) 1-year TVF (all patients)

2* endpoint: Procedural Success (stent deployed w/RS<20% & no maj complications)

**Conventional Angioplasty Strategy**
(conventional and/or specialty balloons per operator discretion)

2nd generation DES implantation and optimization

Principal investigators: Ajay J. Kirtane, Philippe Généreux; Study chairman: Gregg W. Stone
Sponsor: Cardiovascular Systems Inc.
Final Angiogram
Post Dilatation OCT
Mid LAD MLA 4.2 mm²
Proximal LAD MLA 7.1 mm²
RCA CTO Case
Turnpike Spiral
Sion Blue > Fielder XTA > Pilot 200
Radiation 324 mGy / Flouro time 8 minutes / 30 cc contrast
8 Fr Trapliner
3.00 x 20 proximal
Turnpike Spiral
Turnpike LP
Mamba
1.5 x 15
Turnpike Gold
1.25 x 6
Corsair Pro
Mamba Flex
What Next?
Potential Uses for Laser in Current-Day PCI

- Balloon uncrossable lesion
  - Wire across (but nothing else crosses)
- ISR due to stent underexpansion
  - due to diffuse neointimal hyperplasia
- Severe thrombus in ACS
Absorption creates molecular vibration in tissue
Vibration of molecules heats intracellular water
Water vaporizes, rupturing cells
Steam forms expanding vapor bubble
Occurs in 100 millionths of a second

125 ns to 120 us

• UV light pulse hits tissue
• 125 nanosecond duration
• 100 microns penetration
• Billions of tissue bonds fracture per pulse

0 - 125 ns

• Expansion and collapse of vapor bubble breaks down tissue and sweeps debris away from tip
• Debris is water, gas, small particles (90% < 10 microns)
• Ablation depth - 10 microns per pulse
• Entire process time per pulse is 500 millionths of a second

120-500 us
Timeline of a Single Laser Pulse

- Rest Period
  - 125 billionths of a second
  - 100 millionths of a second
  - 400 millionths of a second

- Bonds dissolve
- Thermal energy
- Kinetic energy

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Photoablation</th>
<th>Rest Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 Hz</td>
<td>1.3%</td>
<td>98.7%</td>
</tr>
<tr>
<td>80 Hz</td>
<td>4.0%</td>
<td>96.0%</td>
</tr>
</tbody>
</table>
Laser – Mechanism of Action

Distal Effect

- Photochemical
- Photothermal

Distal & Lateral Effect

- Photomechanical

Vapor bubble size determined by the Pulse Energy delivered (Fluence and Active Area) and the absorbance of the tissue/medium:  
  Saline < Plaque < Blood

Greater vapor bubble = greater photomechanical effect
Relation of Photomechanical Effect to Energy Settings

20 fluence

60 fluence
Photomechanical Effect
Laser: Importance of Flush Medium

Contrast media

Saline solution
Laser Atherectomy Technique

**SIZE:** Laser catheter diameter should not exceed 2/3 of the reference vessel diameter

**SALINE:** Essential to remove contrast from the photoablation location

**SLOW:** Advance SLOWLY at a rate of <1mm/sec for cleaner and larger lumens
0.9 RX Laser 80 Hz 80 mJ/mm²
Optimal Laser Technique for Uncrossable Lesions

- Goal: Maximize tissue ablation and minimize photomechanical effect
- Heparinized flush technique to eliminate contrast from the lasing field and minimize acoustic injury
- Advance the catheter slowly (0.2-0.5 m/sec) during laser emission
  - Retract the catheter between laser emissions and give vasodilators as necessary
Microcatheter Down
NC Balloon Still Won’t Expand
What Next?
Treatment of Calcified Lesions: Options

- NC balloons
- Cutting balloon
- Angiosculpt
- Laser
- Rotational atherectomy
- Orbital atherectomy
Calcium Fracture and Relation to Outcomes

61 pts with heavily calcified lesions studied serially with OCT.
Fracture was seen in 48% (more frequently with CB or atherectomy).

Fracture was associated with greater MSA and less restenosis/ID-TLR.
After Atherectomy
IVUS After Atherectomy
IVUS > True lumen
Two 4.0 x 38 DES prox to distal RCA
NC 4.0 x 15 at 20 atms
IVUS: Post stent
Final Angiogram
7F EBU 3.5

IVUS – Wouldn’t cross
NC Quantum 3.0 x 15 @ 30 (x4 times)   NC Euphora 3.0 x 15 @ 30 (x2 times)
Unable to advance 3.0 balloon past pLAD stent

What Next?
Exchanged for Wiggle wire via microcatheter
3.0 x 15 AngioSculpt

→ did not cross

*What Next?*
After Laser Atherectomy (Contrast)

NC 3.0 x 15 @ 26
Still unable to deliver 3.5 x 24 DES
Wiggle Guidewire Manipulation
Final Result
Final IVUS
Case Presentation

- 69 y.o. male with HTN, HLD, CVA (25 years ago, residual R hemiparesis)
- CAD (with MI in the past)
- Worsening exertional angina, no rest symptoms
- Medications:
  - Aspirin, Clopidogrel, Atorvastatin 20, Furosemide 20 mg, Metoprolol succinate 100 mg, Baclofen, Phenytoin, Ranitidine
- Vitals: T 36.4, HR 75, BP: 139/82, RR 18, SpO2 98% on RA.
- PE: No JVD, RRR, nml S1/S2, no murmur
- CTA B/L
- +2 pulses b/l, no edema

Labs:
- WBC: 9.43 / Hb: 15.5 (MCV: 91.1) / Hct: 44.9 / Plt: 203
- 144 | 101 | 12
- ------------------------< 113
- 4.3 | 28 | 0.88
- pro-BNP: 223, Coags: normal
- Troponin mildly positive and stable
Case Presentation

- Echocardiogram:
  - EF 20-25%
  - Anterior/anteroseptal/apical akinesis (without thrombus)
  - Remaining walls variably hypokinetic
Diagnostic Catheterization

RHC:
RA 17/10 (10)
RV 31/17
PA 31/20 (25)
PW 24/20 (19)

PA sat 66%
AO sat 94%

CO 4.6
CI 2.3

AoP: 89/58/72
Diagnostic Catheterization
Diagnostic Catheterization
What Next?
What Next?

Viability Study: no significant viability in the LAD distribution. All other walls are viable.
Access and Setup

6-7F slender RRA

Ultrasound-guided 5F RFA

(swapped for 14F Impella sheath)

7F RFV

Ao 105/77/88

RA 13/9 (8)
RV 33/13
PA 33/16 (22)
PW 12/9 (8)

AO sat 96%
PA sat 63%

CO 4.27
CI 2.18
Access and Setup

JL3.5, angled glide wire, Amplatz SS to advance guide

Impella CP
7F AL 0.75 SH guide
PCI: Atherectomy
PCI: Post-Atherectomy
PCI: Thrombectomy
PCI: 3.0 mm NC Predil, 4.5 mm DES
Final result

Fellows
25th Annual Interventional Cardiology Fellows Course
### Finishing Up / Impella Explant

<table>
<thead>
<tr>
<th>Hemodynamics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ao 101/74/84</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>RHC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA 44/13/30</td>
</tr>
<tr>
<td>PCWP: mean 23</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PA sat 62%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO 3.71</td>
</tr>
<tr>
<td>CI 1.89</td>
</tr>
</tbody>
</table>

| Long multipurpose catheter placed in right iliac artery via RRA |

| Perclose sutures tied |

| Light manual pressure for track ooze |
Conclusions

• Coronary calcium is becoming more and more prevalent in the modern-day cath lab / CHIP era
  • Aging population
  • Comorbidities
  • “Downstream” presentations

• Calcified lesions are among the highest-risk lesions we treat
  • Short-term pain/suffering + risk
  • Longer-term outcomes
Conclusions

• Imaging is a MUST
  • Diagnosis of calcium
  • Treatment algorithms (based upon length, arc, thickness)
  • After initial lesion preparation / prior to stent implantation
  • Stent optimization

• The field of adjunctive therapies for calcific lesions is heating up with more and more data emerging soon…