ΠΕΡΙΣΤΡΟΦΙΚΗ ΑΘΗΡΕΚΤΟΜΗ

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Επεμβατικός καρδιολόγος
ΣΙΣΜΑΝΟΓΛΕΙΟ ΝΟΣΟΚΟΜΕΙΟ

ΟΜΑΔΕΣ ΕΡΓΑΣΙΑΣ 2018
Θεσσαλονίκη
Rotational atherectomy

1989: first application in human patients in
- Lille, France (Bertrand) and Essen, Germany (Erbel)
- It was invented by D.C. Auth (Boston Scientific)
How Does The Rotablator Look Like?

**Hardware**

#4 Console
Gives a visual readout of RPM and length of procedure and allows physician to control the speed and air inflow

#5 Air Supply Set Up
Air pressure air to provide rotational energy

#6 Foot Pedal
Serves as an On/Off Control

**Disposables**

#1 Burr Catheter
Elliptical shape, 1.25-2.50mm in diameter, nickel coated, with diamond crystals embedded in the distal edge

#2 Advance
Acts as a support for the air turbine and as a guide for the sliding elements which control the burr extension

#3 Rotawires
Floppy and Extra Support
Catheter Components

Forward Pressure defines depth of diamonds “digging into vessel

Continuous movement keeps device from becoming warm especially in angled/tortuous vessels.

drive shaft

diamond coated burr 1.25 mm - 2.5 mm (0.25 mm increments)

sheath 4.3 french O.D.

guide wire
Differential Cutting

Elastic Tissue  In-elastic Tissue

PTCRA Defined

Orthogonal Displacement of Friction permits burr advancement through tight, tortuous vessels and lesions.

This principle involves change in the effective friction in one direction between two adjacent sliding surfaces that results from relative motion between the two surfaces in a plane perpendicular to that direction.

Orthogonal displacement of friction can be explained with the following:

- Friction acts as a brake i.e. a turning wheel on a bicycle or a car, slows and eventually stops when friction is applied.
- If we seek to remove a ring from our finger or a cork from a bottle of wine or champagne, we discover it is much easier if we turn the ring or cork.
- This principle of orthogonal displacement of friction applied to the Rotablator® System, means the turning burr can more readily be advanced against inelastic obstructions.
ΕΝΔΕΙΞΕΙΣ

• Στομιακές στενώσεις-Απροστάτευτο στέλεχος
• Σκληρές και δύσκολες(tight and ugly)
• Επιμήκεις και ασβεστωμένες
• Βλάβες διχασμού
• Επαναστένωση εντός stent
• Βλάβες μη προσβάσιμες, μη διάτασιμες (uncrossable,undilatable)
ΜΕΛΕΤΕΣ ΤΗΣ ΠΡΟΗΓΟΥΜΕΝΗΣ ΔΕΚΑΕΤΙΑΣ

• **ROTA vs POBA**

  1. **ERBAC** (Randomized in complex lesions) Μεγαλύτερη άμεση επιτυχία με Rota, μεγαλύτερη και επαναστένωση

  2. **DART** (Randomized in non-complex lesions). Ουδεμία διαφορά στο εξάμηνο follow-up. Συχνότερα slow-flow λιγότερα bail-out stents με το Rota.

  3. **SPORT** (Randomized, Rota before stenting). Καλύτερα άμεσα αποτελέσματα, παρόμοια MACE στους 6 μήνες.

  4. **COBRA** (Randomized in complex lesions). Συγκρίσιμα MACE στους 6 μήνες. Λιγότερα bail-out stents με Rota.
ΕΠΑΝΑΣΤΕΝΩΣΗ ΕΝΤΟΣ STENT ( ISR )

- **BARASTER** ( Registry ).
  Ασφάλεια και αποτελεσματικότητα για ISR. Η χρήση του Rota απεδείχθη ασφαλής και αποτελεσματικότερη αν συνδυασθεί με POBA σε υψηλές atm.

- **ROSTER** ( Single center, randomized )
  Με χρήση IVUS εξαιρούντο τα underexpanded stents. Υπεροχή του Rota έναντι της POBA . 40% των stents underexpanded

- **ARTIST** ( Randomized )
  Απέτυχε να δείξει ωφέλεια από το Rota. Πιθανόν λόγω των χαμηλών διατάσεων με μπαλόνι μετά το Rota
1. 150 pts underwent rotablation +des
2. 2 burr stepped approach
3. Mean follow-up 3 years – angio f/u 18.7%
4. No MACE during hospitalization
5. Recurrent angina and MI 3.3, MACE 11.3
6. No relationship between clopidogrel discontinuation, death and MI
To assess long-term outcome after rotational atherectomy (RA) is followed by drug-eluting stent (DES) implantation in complex calcified coronary lesions.
ΜΕΘΟΔΟΙ ΚΑΙ ΑΠΟΤΕΛΕΣΜΑΤΑ

• 205 pts με σοβαρά ασβεστωμένες βλάβες
  Διαβητικοί 63 (31%), με ΧΝΑ 21 (10%)
  Συνολικό μήκος stent/ασθενή 32mm, 64% PES και 30%SES

• ΑΠΟΤΕΛΕΣΜΑΤΑ
  ➢ Αγγειογραφική επιτυχία 98%
  ➢ Ενδονοσοκομειακά MACE 4,4%

• Μακροπρόθεσμα αποτελέσματα (15 μήνες)
  ✓ Συνολικά MACE 17,7%
  ✓ Θάνατος 4,4, TLR 6,8%, OEM 3,4%
  ✓ Θρόμβωση stent 1%
A total of 34 consecutive patients were recruited with a mean age 77.2 ± 10.2 years. There were 82.4% presented with acute coronary syndrome and 11.8% with cardiogenic shock.
METHODS AND RESULTS

The mean SYNTAX score was 50 ± 15 and EuroSCORE II scale 5.6 ± 4.8. The angiographic success rate was 100% with a *procedural success rate of 91.2%*. The mean number of burrs per patient was 1.7 ± 0.5. Crossing-over stenting was used in 64.7%. Most stents were drug-eluting (67.6%). Intra-aortic balloon pump was used in 20.6% of the procedures. Three patients died during hospitalization, all due to presenting cardiogenic shock. No major complication occurred. Among 31 hospital survivors, the major adverse cardiac events (MACE) rate was 16.1%, all due to target lesion revascularization or target vessel revascularization.

Conclusions In high-surgical-risk elderly patients, plaque modification with RA in PCI of heavily-calcified LMCA could be safely accomplished with a minimal complication rate and low out-of-hospital MACE.
240 patients enrolled between August 2006 and March 2010 at 3 clinical sites in Germany

1:1 randomization

Rota + PES (N=120)  PTCA + PES (N=120)

240 patients analyzed with complete in-hospital follow-up

- 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)  Angiographic follow-up at 9 months in 80.5% (N=190)
Inclusion Criteria

• **Clinical inclusion criteria**
  1. Age above 18 years
  2. Angina and/or reproducible ischemia
  3. Informed written consent

• **Angiographic inclusion criteria**

  First degree criteria (all)
  1. De-novo lesion in a native coronary artery
  2. Moderate to severe calcification

  Second degree criteria (at least one)
  1. Ostial location
  2. Bifurcational lesion
  3. Long lesion (≥ 15mm)
Procedural Outcome (II)

- Angiographic success: 96.7% (Rota+PES) vs. 96.7% (PTCA+PES)
  - p = 1.0

- Stent loss: 0% (Rota+PES) vs. 2.5% (PTCA+PES)
  - p = 0.08

- Crossover: 4.2% (Rota+PES) vs. 12.3% (PTCA+PES)
  - p = 0.02

- Strategy success: 92.5% (Rota+PES) vs. 83.3% (PTCA+PES)
  - p = 0.03

* Defined as <20% residual stenosis + TIMI 3 flow
** Defined as angiographic success with no crossover or stent loss
Events at Follow-Up

- Death: 5.0% (Rota+PES), 5.8% (PTCA+PES), p = 0.78
- MI: 6.7% (Rota+PES), 5.8% (PTCA+PES), p = 0.79
- TVR: 16.7% (Rota+PES), 18.3% (PTCA+PES), p = 0.73
- TLR: 11.7% (Rota+PES), 12.5% (PTCA+PES), p = 0.84
- MACE*: 24.2% (Rota+PES), 28.3% (PTCA+PES), p = 0.46
- Definite ST: 0.8% (Rota+PES), 0 (PTCA+PES), p = 1.0

* Defined as death, MI and TVR
UNCROSSABLE-UNDILATABLE LESIONS

- Subset of complex lesions that represent 1-2% of the whole.
- Failure to cross the lesion or failure to expand the balloon.
- Often heavily calcified lesions
- Severe risk of dissection or extravasation during high pressure inflations.
- Dedicated for calcium devices (cutting balloon, minirail, angiosculpt) cannot cross such lesions
Management with Rotablalator

- Small burrs 1.25-1.50 are capable of disrupting the plaque’s superficial calcium and make the lesion dilatable
- No of undilatable- uncrossable lesions : 31
- Multi vessel : 23
- Prior unsuccessful attempt to dilate with balloon in all
- Burrs used : 14 with 1.25 diam. 4 with 1.50 and 3 with 1.75mm.
- Additional with cutting balloon dilatation : 6
- Stenting with DES in all
- Excellent angiographic results. Negative stress test after 6 and 12 months
Περιφερική ασβέστωση και ελίκωση

Έντονη ασβέστωση

Τελικό αποτέλεσμα μετά εμφύτευση δύο DES

Παραμονή κλεψύδρας στις 26 atm με μπαλόνι 3.0χ12 NC
➢ Μη διατάσιμη βλάβη

➢ Προδιαστολή με 1.75 burr

➢ Μετά προδιαστολή

➢ Οmega BMS 4x20 stent
ΕΠΙΠΛΟΚΕΣ

• No or slow flow φαινόμενο

• Σπασμός, διαχωρισμός των στεφανιαίων, οξεία απόφραξη

• Αύξηση μυοκαρδιακών ενζύμων

• Διάτρηση αγγείου-Παγίδευση του burr

• Υπερθέρμανση- Κακή θέση οδηγού σύρματος(wire bias)
ΑΠΟΦΥΓΗ ΕΠΙΠΛΟΚΩΝ

• Εκκίνηση με μικρά burr. Όχι μεγαλύτερα του 0,5 του αγγείου

• Αργή και ομαλή προώθηση burr. Κίνηση ως επί ραμφίσματος (pecking)

• Περάσματα 15-20 sec. Συχνότητα 135-150.000rpm

• Αποφυγή πτώσης στροφών >5000/min. Συνεχής εφύγρανση συστήματος

• Όχι αλλεπάλληλα περάσματα. Αποφυγή ελικωμένων αγγείων

• Διατήρηση ΣΑΠ >100mmHg
Αδυναμία διέλευσης μικροκαθετήρα
Αλλαγή μέσω του μικροκαθετήρα του υδρόφιλου σύρματος με extra support, περιφερική προώθηση μικροκαθετήρα, αλλαγή με Rotawire
ΠΡΟΔΙΑΣΤΟΛΗ ΜΕ ΜΠΑΛΟΝΙ 3x15, DES 3,0x24, ΜΕΤΑΔΙΑΣΤΟΛΗ ΜΕ NC 3.5x12. ΜΕΤΡΙΟ ΑΠΟΤΕΛΕΣΜΑ. ΣΤΗΘΑΓΧΙΚΟ ΑΛΓΟΣ, ΥΠΟΤΑΣΗ, ΑΝΑΣΠΑΣΗ – ST LBBB
DES 3.5x20. ΤΕΛΙΚΟ ΑΠΟΤΕΛΕΣΜΑ. ΥΦΕΣΗ ΠΟΝΟΥ
ΑΠΟΚΑΤΑΣΤΑΣΗ ΠΙΕΣΗΣ ΚΑΙ ΗΚΓ
Different approaches for the same patient

Calcified lesion

Balloon 2.0x15

Rota 1.25mm
Symposium: Rotational atherectomy updating  Open Access

Guest Editor: Prof. Wei-Hsian Yin

IVUS-guided rotational atherectomy for unexpandable paclitaxel-eluting stent: A case report and review of literature

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ΕΠΑΝΑΣΤΕΝΩΣΗ ΕΝΤΟΣ 3 STENTS

ΔΥΣΧΕΡΕΙΑ ΠΡΟΩΘΗΣΗΣ ROTAWIRE
ΔΙΕΛΕΥΣΗ BURRS 1,25 ΚΑΙ 1,50mm
ΑΔΥΝΑΜΙΑ ΔΙΕΛΕΥΣΗΣ ΜΙΚΡΟΚΑΘΕΤΗΡΑ
ΑΛΛΑΓΗ ΟΔΗΓΟΥ-ΔΙΕΛΕΥΣΗ 1,25 ΚΑΙ 1,50 BURRS
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

6Fr Guide Compatible Saline Sheath

Electric motor powered handle

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

ViperSlide® Lubricant
- ViperSlide reduces friction during operation
- 20ml ViperSlide per liter of saline
Prototype Next Generation Rotablator Advancer

Design Goals:
- Easier to learn & use (no foot pedal)
- Easier to set up (consolidated cables)
- Allows single operator use

* The next generation Rotablator devices are under development not available for sale
ΑΙΤΙΕΣ ΠΟΥ ΑΠΟΘΑΡΡΥΝΟΥΝ ΤΗΝ ΧΡΗΣΗ ΤΟΥ

• Απαιτεί εμπειρία πέραν από την συνήθη. Αναγκαία καμπύλη εκμάθησης ακόμη και για έμπειρο επεμβατικό.
• Η όχι συχνή χρήση δεν συντηρεί την δεξιότητα και εμπειρία.
• Σύμπλοκη συνδεσμολογία, χρονοβόρος επέμβαση
• Πιο συχνές κάποιες επιπλοκές ( διάτρηση, no-reflow, παγίδευση )
• Το κόστος, ιδίως αν χρησιμοποιηθούν> 1 burr

• Τα παραπάνω συν το γεγονός ότι οι βλάβες που παραπέμπονται για Rota είναι σύμπλοκες ( ασβεστωμένες, μη διατάσιμες κλπ ) συνθέτουν ένα απωθητικό σκηνικό για την μέθοδο. Για τον λόγο αυτό χρησιμοποιείται από ανάγκη και μόνο όταν αποτύχουν τα συμβατικά μέσα.
ΣΥΝΟΠΤΙΚΑ ΣΥΜΠΕΡΑΣΜΑΤΑ

• Το Rotablator δεν προσφέρεται σαν “workhorse” εργαλείο στην επεμβατική θεραπεία των στεφανιαίων.
• Επιφυλάσσεται σε σύμπλοκες βλάβες χαρακτηριστικό των οποίων είναι η έντονη ασβέστωση
• Βελτιώνει την άμεση επιτυχία και πιθανόν την αποτελεσματικότητα των DES στις ως άνω βλάβες αν συνδυάζεται και με την κατάλληλη τεχνική
• Αποτελεί μονόδρομο για μη διατάσιμες και μη προσπελάσιμες βλάβες ενώ δύσκολες επεμβάσεις μπορεί να τις μετατρέψει σε σχετικά εύκολες.
• Αποτελεί ένα χρήσιμο και μοναδικό εργαλείο για κάθε αιμοδυναμικό εργαστήριο προσφέροντας λύσεις όπου τα άλλα μέσα αποτυγχάνουν. Αυτό δεν σημαίνει ότι πρέπει μόνο τότε να χρησιμοποιείται
Optimal Rotablator Technique in 2013

- Slow advancement of the burr, with a to-and-from pecking motion
- Short run times (15–20 s) at “low” speed (140,000 –160,000 rpm)
- Avoid any “significant” (>5000 rpm) drop in burr speed.
- Beware of guidewire bias, especially in tortuous segments.
- Use of multiple rotational atherectomy burrs (the “step-up” technique) has been abandoned, as well as the concept of rotational atherectomy as a “stand-alone” technique.
  - Rotational atherectomy is used as a “facilitation” for subsequent balloon or stent expansion, with a single burr selected with a burr/artery ratio in the range of 0.5–0.6
  - A 0.7 ratio can be used when treating a segment already “protected” by a stent previously deployed, as in the case of in-stent restenosis.
Examples of Orthogonal Displacement of Friction

* Removal of a cork from a wine bottle. If a cork is twisted as it is pulled, the friction is reduced and the cork can be withdrawn easily.

* Removal of a ring from a finger. If it is twisted the removal can be much easier.
Results

• Mace: no difference
• Restenosis: No difference
  • Angiographic: 52% vs 48%
  • TLR: 22% vs 18%
• Less major dissection with RA
• Less stent use
DART


- Randomized trial of RA vs PTCA in non-complex lesions (A & B1)
- Low pressure balloon inflations post PTCA
- Lesions < 20 mm
- No calcification
Lesion Preparation Defined

- Plaque Modification
  - (atherectomy/atherotomy)
    - To change lesion compliance
    - To help minimize vessel trauma
    - To increase MLD
    - To facilitate stent deployment (and delivery)
    - To reduce plaque burden and/or minimize plaque shift
PTCRA Defined

Differential Cutting

- Results in preferential cutting of inelastic substrate
- Is functional at low and high speeds

Differential cutting is the ability to cut one material while sparing another based on differences in composition.

Elastic Tissue
Normal vascular tissue has elastic properties that allow it to deflect away from the advancing diamonds on the rotating burr.

Inelastic Tissue
The Rotablator® System selectively ablates inelastic tissue (i.e. plaque) whether composed of calcium, fibrotic tissue, neointima or lipid-rich material.

Helpful Analogy: When you shave, the very sharp razor blade cuts the inelastic hair or whiskers you are trying to remove but does not cut the elastic skin. By this same principle, the Rotablator System differentially cuts inelastic plaque inside coronary arteries while retaining the integrity of the elastic artery wall itself.
STRATAS TRIAL

- STRATAS tested an aggressive vs. Routine strategy for debulking.
  - Restenosis high in the both arms A vs R (57% vs 58%).
- No or slow reflow was 15.7% in the aggressive arm (burr to artery ratio > .7) and 7.7% in the routine arm (burr to artery ratio < .7) (p = .008). Independent predictors were decelerations of > 5000 rpm for more than 5 seconds.
- **This study was performed prior to the recommendation of reduced rpms (150,000). The lower rpms put less torque in the system and thus for any given reduction release less energy—essentially, less heat.**

Lesion specific management

- Calcification
- Bifurcations
- Ostial lesions
- ISR
- Tortuosity
Endpoints

- **Primary endpoint**
  
  In-stent late lumen loss at 9 months

- **Secondary endpoints**
  
  1. Major adverse cardiac events (MACE)
  2. Definite stent thrombosis
  3. In-segment late lumen loss
  4. In-segment binary restenosis
  5. Angiographic success
  6. Strategy success (angiogr. success without crossover or stent loss)
  7. Procedural duration
  8. Contrast amount
Procedural Outcome (II)

**Angiographic success***: 96.7% (Rota+PES) vs 96.7% (PTCA+PES) (p = 1.0)

**Stent loss**: 2.5% (Rota+PES) vs 0% (PTCA+PES) (p = 0.08)

**Crossover**: 12.3% (Rota+PES) vs 4.2% (PTCA+PES) (p = 0.02)

**Strategy success**: 92.5% (Rota+PES) vs 83.3% (PTCA+PES) (p = 0.03)

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

**Defined as angiographic success with no crossover or stent loss
Primary Endpoint
In-Stent Late Lumen Loss at 9 Months

- Rota+PES
- PTCA+PES

p = 0.01

0.44 mm

0.31 mm
In-Hospital Outcome

- **Death**: Rota+PES 1.7%, PTCA+PES 0%
- **MI**: Rota+PES 1.7%, PTCA+PES 3.4%
- **TV Re-PCI**: Rota+PES 0.8%, PTCA+PES 0.8%
- **CABG**: Rota+PES 0%, PTCA+PES 0%
- **MACE***: Rota+PES 4.2%, PTCA+PES 4.2%
- **ST**: Rota+PES 0%, PTCA+PES 0%
- **Access site compl.**: Rota+PES 5.9%, PTCA+PES 1.7%

* Defined as death, MI and TVR

**p = 0.17**
Events at Follow-Up

- **Death**: 5.0% (Rota+PES), 5.8% (PTCA+PES)  
  - p = 0.78

- **MI**: 6.7% (Rota+PES), 5.8% (PTCA+PES)  
  - p = 0.79

- **TVR**: 16.7% (Rota+PES), 18.3% (PTCA+PES)  
  - p = 0.73

- **TLR**: 11.7% (Rota+PES), 12.5% (PTCA+PES)  
  - p = 0.84

- **MACE***: 24.2% (Rota+PES), 28.3% (PTCA+PES)  
  - p = 0.46

- **Definite ST**: 0.8% (Rota+PES), 0% (PTCA+PES)  
  - p = 1.0

*Defined as death, MI and TVR*
Rotational atherectomy in the drug-eluting stent era: a recent single-center experience.

[Article in Portuguese]


Source
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CONCLUSIONS:
This study demonstrates that rotational atherectomy followed by stenting in heavily calcified lesions can nowadays be performed with high success rates and few complications, extending the possibility of coronary revascularization to a greater number of patients.

Rev Port Cardiol. 2012 Jan
1. 150 pts underwent rotablation + des
2. 2 burr stepped approach
3. Mean follow-up 3 years – angio f/u 18.7%
4. No MACE during hospitalization
5. Recurrent angina and MI 3.3, MACE 11.3
6. No relationship between clopidogrel discontinuation, death and MI
<table>
<thead>
<tr>
<th>Lesion Morphology</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Lesions with localised calcification</td>
<td>6</td>
</tr>
<tr>
<td>Diffuse-calcified lesions</td>
<td>29</td>
</tr>
<tr>
<td>Calcified bifurcations</td>
<td>25</td>
</tr>
<tr>
<td>Ostial lesions</td>
<td>86</td>
</tr>
</tbody>
</table>

<p>| TABLE 2 |
|---------|-----|
| Short-heavily calcified lesions | 25 |
| Diffuse-calcified lesions | 86 |
| Calcified bifurcations | 38 |
| Ostial lesions | 29 |
| Chronic total occlusions with extensive calcification | 6 |</p>
<table>
<thead>
<tr>
<th>Event</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>4% (6/150)</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>83.3% (5/6)</td>
</tr>
<tr>
<td>MI</td>
<td>5.3% (8/150)</td>
</tr>
<tr>
<td>TLR PTCA</td>
<td>3%</td>
</tr>
<tr>
<td>TLR CABG</td>
<td>3%</td>
</tr>
<tr>
<td>Angina</td>
<td>7.3% (11/150)</td>
</tr>
<tr>
<td>Stroke</td>
<td>2% (3/150)</td>
</tr>
</tbody>
</table>
Debulking by Rotational Atherectomy with a Modified Protocol Increases Longterm Survival

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\textsuperscript{3} Institute for Clinical Evaluative Sciences (ICES), Toronto, ON, Canada.

Background:
Our study aims to evaluate the success of rotational atherectomy with a modified protocol using a platform speed of 135 krpm, pecking technique and a step-up burr sizing up to a debulking burn-to-artery ratio of greater than 0.6 relative to conventional stenting procedures without atherectomy by comparing overall long time survival.

Methods:
Out of a 5 year period we selected all 1033 patients treated with single vessel intervention. 144 cases were excluded because of incomplete data sets. Propensity-score matching based on 26 clinical and angiographic variables was used to reduce treatment-selection bias for rotational atherectomy resulting in the formation of 279 matched pairs (i.e. 578 patients). To compare long time survival up to 80 months Kaplan Mayer curves were calculated.

Results:
With respect to postprocedural variables Non-Rota and Rota patients did not differ significantly regarding final lumen diameter, stent length, number of stents, percentage of DES and IVUS. Significant differences were found regarding lumen gain and percentage of GP IIb/IIIa receptor blocker treatment (Tab.).

Long term overall survival plots (Fig.) demonstrate a significant advantage for the Rota group (<0.01) with a hazard ratio of 0.52 (CI 0.32–0.85). Multivariate Cox regressions showed that this advantage is not due to differences in GP IIb/IIIa blocker treatment.

Conclusion:
With our redefined protocol of rotational atherectomy we could reduce long-term mortality for matched pairs by 48% on average. We explain this result by the less traumatizing atherectomy procedure compared to previous trials and the greater lumen increase assuming a better stent apposition.

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Rotational Atherectomy: Complications

**Mechanism of No/Slow-flow**

- Atheromatous debris embolism
- Platelet and microthrombi
- Platelet activation, aggregation, lysis (by rota burr)
- Microcirculatory (vasculature) spasm
- Heightened microvasculature reactivity / tone
- Microcavitation
- Impaired local synthesis of EDRF
- Neuro-humoral reflex
- Lower epicardial vessel pressure and higher LVEDP
- Extreme cases: free radical injury, local edema, microvascular plugging, no-reflow

EDRF = endothelium-derived relaxing factor; LVEDP = left ventricular end-diastolic pressure
Microcavitations [Zotz CCD 1992]

Temperature rise at vessel wall [Reisman, CCI 1998]

Hemolysis [Reisman, CCI 1998]

Activation of platelets [Williams, Circulation 1998; Reisman, CCI 1998]
Rotational Atherectomy

Mount Sinai Hospital Experience (6%-9% of PCI)

Complications

- short burr runs, rota-flush, abciximab, stent, experience
- slow speed (140-150,000 rpm)
- rotational atherectomy, BA: 0.4-0.5

---DES---
STRATAS Trial

Technique Matters: Incidence of Slow-Flow

- Predictors of CK-MB release:
  - deceleration > 5000 rpm > 5 sec

- Predictors of restenosis:
  - deceleration > 5000 rpm
  - LAD location

\[ P = .008 \]

Aggressive strategy
(n = 249)
BA: > 0.9

Routine strategy
(n = 248)
BA: < 0.8

Current optimal Burr-to-Artery Ratio (BA): 0.3-0.5

Rotational Atherectomy (RA, PRCA, PTRCA)

Indications:
- Calcified lesion
- Undilatable/chronic lesion
- Diffuse long lesion
- Small vessels (< 2.5 mm)
- In-stent restenosis
- Bifurcation lesion
- Ostial lesion
- Rotastent (SPORT trial)

Limitations:
- Slow flow / No flow
- Perforation
- CK-MB release
- Wire bias and dissection
- Technically challenging

PRCA = percutaneous rotational coronary atherectomy; PTCRA = percutaneous transluminal coronary rotational ablation; CK-MB = creatine kinase-MB isoenzyme
Rotational Atherectomy: Current Issues

- Slow / no-flow
- CPK, CK-MB release
- Coronary spasm
- Intimal dissections and acute closure
- Perforation
- Wire bias problems
- Heat generation

*CPK = creatine phosphokinase*
Technique modification #2

- After Rota → hazy vessel contours →
  - low pressure (max. 4 bar) dilatation with oversized balloons (~ 1.3)

- Only in cases needed >> POBA

- IIb/IIIa-blockers with intensive debulking

- Stenting:
  Nowadays more or less always
ROTA DES studies

- **Colombo et al.** Rotational atherectomy followed by DES in calcified coronary lesions. *Eurointervention* 2009
  - Registry – 96 pts
  - High procedural success
  - Low TLR

- **Pagnotta et al.**, *Catheter Cardiovasc Interv*, 2010:
  - Safety and effectiveness of Rota + DES strategy to tackle HCCL with good long-term clinical outcomes
  - Procedure was successful in 97% of cases
Different approaches for the same patient

Calcified lesion

Balloon 2.0x15

Rota 1.5
UNCROSSABLE-UNDILATABLE LESIONS

• Subset of complex lesions that represent 1-2% of the whole.
• Failure to cross the lesion or failure to expand the balloon.
• Often heavily calcified lesions
• Severe risk of dissection or extravasation during high pressure inflations.
• Dedicated for calcium devices (cutting balloon, minirail, angiosculpt) cannot cross such lesions
Management with Rotablator

• Small burrs 1.25-1.50 are capable of disrupting the plaque’s superficial calcium and make the lesion dilatable
• No of undilatable- uncrossable lesions 22
• Multi vessel : 14
• Prior unsuccessful attempt to dilate with balloon in all
• Burrs used : 10 with 1.25 diam. 4 with 1.50 and 2 with 1.75mm.
• Stenting with DES in all
• Excellent angiographic results. Negative stress test after 6 and 12 months
Inclusion/Exclusion Criteria

Key Inclusion:
- The target lesion must have fluoroscopic or IVUS evidence of severe calcification
- Presence of radiopacities noted without cardiac motion prior to contrast injection involving both sides of the arterial wall with calcification length at least 15 mm and extend partially into the target lesion
- OR presence of \( \geq 270^\circ \) of calcium at one cross section via IVUS
- The target vessel reference diameter \( \geq 2.5 \text{ mm and } \leq 4.0 \text{ mm} \) and lesion length not exceed 40 mm in length

Key Exclusion:
- Diagnosed with chronic renal failure (CR > 2.5 mg/dl) unless under hemodialysis
- Evidence of current LVEF \( \leq 25\% \)
- More than 1 lesion requiring intervention unless the lesions are staged
- In-stent treatment
- Target lesion is an ostial location, bifurcation or has a \( \geq 1.5 \text{ mm side branch} \)
- Target lesion has thrombus or dissection
## Procedural Outcome (I)

<table>
<thead>
<tr>
<th></th>
<th>Rota + PES n = 120</th>
<th>PTCA + PES n = 120</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural duration (min)</td>
<td>66.4±44.5</td>
<td>57.4±34.5</td>
<td>0.05</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>22.8±21.9</td>
<td>18.1±16.7</td>
<td>0.04</td>
</tr>
<tr>
<td>Contrast amount (ml)</td>
<td>201.0±113.6</td>
<td>181.8±93.6</td>
<td>0.11</td>
</tr>
<tr>
<td>Dissections</td>
<td>4 (3.3%)</td>
<td>4 (3.3%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Perforations</td>
<td>2 (1.7%)</td>
<td>1 (0.8%)</td>
<td>0.56</td>
</tr>
<tr>
<td>No/slow flow</td>
<td>0</td>
<td>1 (0.8%)</td>
<td>0.32</td>
</tr>
</tbody>
</table>
Rotational atherectomy and DES

- Moussa et al. found no difference in late loss when compared to noncalcified lesions, but notably there was an 8.2% stent delivery failure among calcified lesions when compared to noncalcified lesions in a trial not permitting use of Rotational atherectomy.
- Three studies have suggested that DES reduced late loss similar to that seen in noncomplex lesions and can be expanded to patients who have adjunctive RA in heavily calcified arteries and complex anatomy without incurring a higher adverse event rate or increased restenosis rate.
<table>
<thead>
<tr>
<th>Lesion Morphology</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions with localised calcification</td>
<td>6</td>
</tr>
<tr>
<td>Diffuse-calcified lesions</td>
<td>29</td>
</tr>
<tr>
<td>Calcified bifurcations</td>
<td>25</td>
</tr>
<tr>
<td>Ostial lesions</td>
<td>86</td>
</tr>
<tr>
<td>Chronic total occlusions with extensive calcification</td>
<td>38</td>
</tr>
</tbody>
</table>

**TABLE 2**

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-heavily calcified lesions</td>
<td>25</td>
</tr>
<tr>
<td>Diffuse-calcified lesions</td>
<td>86</td>
</tr>
<tr>
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<td>Chronic total occlusions with extensive calcification</td>
<td>6</td>
</tr>
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</table>
Comparison of PTA versus Atherectomy in Diabetic Population

Total number of lesions: 961
Total number of patients: 401

Angioplasty (PTA)
- Lesions: 552
- Patients: 277
- Mean age: 70.3 ± 12.8
- Male: 59.9%
- Follow up: 10.7 ± 10.2

Atherectomy
- Lesions: 409
- Patients: 194
- Mean age: 69.1 ± 13.7
- Male: 62.9%
- Follow up: 12.4 ± 9.9
<table>
<thead>
<tr>
<th>Lesion Distribution</th>
<th>Length (mm)</th>
<th>% Stenosis</th>
<th># CTO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SFA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTA (n=203)</td>
<td>91.3 ± 88.3</td>
<td>85.1 ± 12.6</td>
<td>48 (23.6)</td>
</tr>
<tr>
<td>Atherectomy (n=120)</td>
<td>91.3 ± 88.8</td>
<td>86.6 ± 14.0</td>
<td>40 (33.3)</td>
</tr>
<tr>
<td><strong>Pop</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTA (n=83)</td>
<td>51.3 ± 45.6</td>
<td>83.4 ± 13.4</td>
<td>17 (20.5)</td>
</tr>
<tr>
<td>Atherectomy (n=73)</td>
<td>36.4 ± 30.9</td>
<td>84.4 ± 13.1</td>
<td>16 (21.9)</td>
</tr>
<tr>
<td><strong>Tibial</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTA (n=155)</td>
<td>61.7 ± 62.9</td>
<td>84.1 ± 13.5</td>
<td>45 (29.0)</td>
</tr>
<tr>
<td>Atherectomy (n=179)</td>
<td>45.2 ± 46.0</td>
<td>91.7 ± 12.0</td>
<td>97 (54.2)</td>
</tr>
<tr>
<td><strong>Multi level</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTA (n=111)</td>
<td>216.3 ± 116.6</td>
<td>88.2 ± 12.4</td>
<td>44 (39.6)</td>
</tr>
<tr>
<td>Atherectomy (n=37)</td>
<td>180.2 ± 114.9</td>
<td>98.3 ± 4.4</td>
<td>32 (86.5)</td>
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</table>
Death Rates in Severely Calcified Lesions

In Hospital:
- Orbit II (OAS+DES/BMS): 1.6
- Mosseri (RA w/ or w/o DES): 1.7
- Abdel-Wahab (RA+DES): 0.2

30 Day:
- Orbit II (OAS+DES/BMS): 2.6
- Clavijo (DES): 1.5
- Clavijo (RA+DES): 0.2
<table>
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<tr>
<th>Condition</th>
<th>Rate</th>
</tr>
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<tr>
<td>Death</td>
<td>4% (6/150)</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>83.3% (5/6)</td>
</tr>
<tr>
<td>MI</td>
<td>5.3% (8/150)</td>
</tr>
<tr>
<td>TLR</td>
<td>3%</td>
</tr>
<tr>
<td>PTCA</td>
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<tr>
<td>CABG</td>
<td>3%</td>
</tr>
<tr>
<td>Angina</td>
<td>7.3% (11/150)</td>
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<tr>
<td>Stroke</td>
<td>2% (3/150)</td>
</tr>
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Unique Mechanism of Action

Differential Orbital Sanding

- Orbital mechanism:\n  - Increased speed = Increased centrifugal force
  - Greater centrifugal force = Larger orbital diameter

- One crown treats different vessel diameters based on speed

- Continuous flow of blood and saline:
  - Potentially minimizes thermal injury
  - Potentially decreases no-reflow
ORBIT II Study Design

- To evaluate safety and efficacy of coronary OAS to prepare *de novo*, severely calcified coronary lesions for stent placement
  - Prospective, multi-center trial
  - Single arm - FDA recommendation as there are no FDA-approved percutaneous treatments for patients with severely calcified lesions

443 patients enrolled in 49 US sites

30 day follow-up

Complete in 99.3% (N=437/440)

Primary Safety Endpoint: 30-Day MACE
- MI (CK-MB >3x ULN), TVR, cardiac death

Primary Efficacy Endpoint: Procedural Success
- Success in facilitating stent delivery with a final residual stenosis of <50% (as determined by Angiographic Core Lab) and without in-hospital MACE
Procedural Success Components:

- Successful Stent delivered: 97.7%
- Less than 50% residual stenosis: 98.6%
- In hospital MACE: 9.5%
  - MI (CK-MB >3x ULN): 9.3%
    - Non Q-wave: 8.8%
    - Q-wave: 0.9%
- TVR: 0.7%
- Cardiac death: 0.2%

Performance Goal = 82%

Procedural Success = 89.1%

(95% CI = 85.8%, 91.8%)
Angiographic Complications Compared to Rotational Atherectomy Literature (RA)¹
Debulking by Rotational Atherectomy with a Modified Protocol Increases Longterm Survival

Georg Gaul\textsuperscript{1,2}, Oliver C. Friedrich\textsuperscript{1}, Niki Viertl\textsuperscript{1}, Peter C. Austin\textsuperscript{3}, Michael Winkler\textsuperscript{1,2}, Johann Sipoetz\textsuperscript{1,2}

\textsuperscript{1} KLI for Clinical Research in Cardiology, Vienna, Austria.
\textsuperscript{2} HKH Department of Cardiology Cardiology, Vienna, Austria.
\textsuperscript{3} Institute for Clinical Evaluative Sciences (ICES), Toronto, ON, Canada.

Background:
Our study aims to evaluate the success of rotational atherectomy with a modified protocol using a platform speed of 135 krpm, pecking technique and a step-up burr sizing up to a debulking burr-to-artery ratio of greater than 0.6 relative to conventional stenting procedures without atherectomy by comparing overall long time survival.

Methods
Out of a 5 year period we selected all 1033 patients treated with single vessel intervention. 144 cases were excluded because of incomplete data sets. Propensity-score matching based on 26 clinical and angiographic variables was used to reduce treatment-selection bias for rotational atherectomy resulting in the formation of 279 matched pairs (i.e. 578 patients). To compare long time survival up to 80 months Kaplan-Mayer curves were calculated.

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