Percussion Crossing Device (the Piculet™ hammer) to facilitate crossing Heavily Calcified CTOs

Initial Experience With The Piculet™ “Jackhammer” Device

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Arterial Chronic Total Occlusion: The Last Frontier

- Since the last 5 years the intra-luminal crossing of long calcified total occlusions has become an important challenge in endovascular procedures.
- Several new devices became available:
  - CTO Guidewires with different characteristics and properties: Penetration force, Lubricity, Support
  - 0.018": Connect GW, Victory, Paseo
  - 0.014": Fielder XT, Gaia Family, Progress Family
  - Support Catheters: Braided or Non Braided, With or Without Torque control, Angled or Straight
  - Dissection-Re-entry Devices: Outback, Pioneer, Stingray, GW for subintimal angioplasty (Command, Pilot 200)
- New Access: Retrograde, Multiple...
- Navigation Tools: IVUS, OCT

Potential conflicts of interest

Speaker’s name: Max Amor
☐ I do not have any potential conflict of interest

The Bird PICULET

“I want to tap into my higher self”

Small woodpecker with strong bills for drilling and drumming on trees

The Piculet System

Piculet Console:
- Generates longitudinal oscillation at the tip of the Micro-catheter and GW
- Simple plug-and-run interface
- Remotely-Controlled Amplitude & Frequency

Piculet Catheter:
- ~1mm Micro-catheter. Longitudinal oscillation at catheter tip / GW tip
- Accepts any 0.014” GW of choice
- Controlled working range:
  - Frequency: 50-120 Hz
  - Amplitude: 0-200 µm (as opposed to sub-micron amplitude for Crosser)

Calcified Arterial Chronic Total Occlusion Crossing Antegrade & Retrograde

Support Catheter
- Extra stiff GW: 0.018” GW: Connect GWs
- Extra stiff GW: 0.014” GW: Progress
- 40, 80, 140...
- Confianza Pro 9, 12

Presence of Microchannels

Crossing with
- 0.014” Fielder XT GW
- 0.014” Gaia 2 or 3 GW

Crossed Not Crossed

Pre-dilatation
- Low Profile Coronary Balloon
- Exchange for Extra-Support GW
- Stereot

Sub-intimal Angioplasty:
- Dissection & Reentry

Retrograde Approach
- if possible

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“Jackhammer” Concept

- Catheter oscillation is coupled to guidewire tip to deliver up to 60 times more impact at CTO than manually possible.
- Oscillation provides longitudinal, focal and repeated strokes to the CTO resulting in material fatigue, allowing 0.014” guidewire and 0.045” catheter crossing, preparing free balloon catheter crossing.
- The Piculet amplitude and frequency working range is designed to provide efficient crossing in tough fibrotic/calcified CTO’s.

Piculet Device Description

- Ergonomic Handle for easy control of guide wire advancement.
- 90 or 130 cm working length, for ipsi and contra-lateral cases.
- 4F distal shaft (150mm) compatible with any 0.014” guidewire.
- Braided Micro-catheter shaft for support and pushability.
- Guidewire protrusion control button (0 to 5mm protrusion).
- OTW Micro-catheter compatible with any 0.014” guidewire.

Piculet Advantages

- “True-lumen” recanalization, with less vessel trauma, and less risk of compromising collaterals and extending lesion length.
- Increased success rate.
- Reduction of:
  - Procedure time
  - Radiation
  - Contrast.
- Preserve algorithm of wire stiffness escalation.
- Preserve use of preferred guidewire.
- 0.045” route for smooth balloon crossability.
- Independent control of amplitude and frequency to optimize crossing of different lesion types.

Piculet and Other Systems

- Frontruner: No GW guidance.
- Crosser: No Steerability, weak penetration power.
- Laser Angioplasty: Not adapted for calcified lesion.
- Etc: Until now it is an unique device.

Piculet Device in lower limb occlusions at Louis Pasteur Clinic

- Device conceived and developed by Medinol Israel.
- Prior to FIM evaluation, in vitro and in amputated limbs.
- Selection of potentially difficult to cross or impossible to cross CTO.
- 11 patients attempted:
  - 2 iliacs arteries: 1 Aorto-Common iliac, 1 External iliac
  - 7 long calcified SFA CTOs
  - 2 Popliteal and TP.
- Results: No Complication (Perforation or Rupture or embolization...).
- Complete crossing: 6
- Incomplete crossing + adjunct technique: 4
- Failure with dissection at the iliac level: 1.

Piculet Protocol

- Medical Therapy: 5000 units Heparin during procedure, 2500 after one hour.
- Pre-medication: Aspirin 160mg Clopidogrel 75mg.
- Neurolept-analgesia to avoid pain and motion.
- Intra-arterial NTG & Verapamil during procedure.
- 6F braided introducer with permanent flushing.
- Guide wire escalation:
  - Miracle 6
  - Miracle 12
  - Confianza 12.
- Tip of Wire: 1to 2mm 45° angulation.
Example 1: Right Fibrotic SFA CTO

- **Patient:**
  - Long Right SFA
  - Contra-lat
  - 6F introducer
  - Miracle GW
- **Lesion:**
  - 25cm
- **Crossing time:**
  - 7 min

Example 2: Right SFA ISR CTO

- **Patient:**
  - 82 years
  - Contra-lateral
  - 6F introducer
  - Miracle GW
- **Lesion:**
  - 12 cm
  - Above & Below
- **Crossing time:**
  - 14 min

Example 3: Popliteal CTO

- **Patient:**
  - 83 Y
  - Contra-lateral
  - 6F introducer
  - Miracle 12 GW
- **Lesion:**
  - 5cm Occluded
  - Heavily calcified
- **Crossing time:**
  - 17 min

Piculet Summary

- A novel concept for CTO crossing by optimized oscillation of GW and Micro-catheter.
- First clinical cases demonstrate crossing of various CTO material & anatomies (Femoral, Popliteal, Iliac?)
- Can be used antegrade or contralateral
- The learning curve is limited to 3 to 4 cases.
- Streamlined OTW device coupled to standard 0.014", preserving choice of GW and strategy.