LUMIVASCULAR CASE SERIES

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Disclosure

Speaker name: Marianne Brodmann, MD

I have the following potential conflicts of interest to report:

- Consulting, Avinger Inc., CSI, Spectranetics, Daichi, Bayer
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Case Series

Series Design
- Prospective, non-randomized, single center
- CTOs crossed using Ocelot OCT guided CTO crossing catheter (Avinger Inc., Redwood City, CA)
- Therapy using Pantheris OCT guided atherectomy catheter (Avinger Inc. Redwood City, CA)
- Adjunctive therapy at the discretion of the operator

Follow-up
- Dates of treatment: July 2015 - December 2015
- Planned DUS, ABI, and MRA at baseline and 6 month follow-up
- Planned DUS and ABI at 12, 24 months, 36, 48, and 60 months
CASE EXAMPLES
Patient details – case 1

- Male / 55 y.o.
- Left + Right SFA CTOs
- Ocelot + Pantheris (Standalone)

Treatment Dates:
- Left - 29 July 2015
- Right - 9 Sept 2015
Case Summary – Right Leg

Pre-CTO  Post-Ocelot  Post-Pantheris

Eccentric Disease @ 9 o'clock

Eccentric Plaque

Starburst

Tissue
Tissue Weight: 140.7mg
Small Media Resection in yellow
Abundant Thrombus with Mixed Cellularity Plaque
Beginning of Organized, New Capillaries Growing into Thrombus
Pre-Intervention

Left (7/29/15): Ocelot + Pantheris
Right (9/9/15): Ocelot + Pantheris

6 Month MRA Follow-Up

Left: 6 month follow-up MRA
Right: 5 month follow-up MRA
Patient details – case 2

- Male / 68 y.o.
- Left SFA CTO
- Ocelot + Pantheris + DEB

Treatment Date:
- 28 July 2015
Case Summary
Tissue Weight 196.7mg
Very Small Media Component (Yellow) and Fragment of EEL (Red)
Focal Calcification
Lipid Deposit and Inflammation Infiltration
Pre-Intervention

Left (7/28/15): Ocelot + Pantheris + DEB

6 Month MRA Follow-Up

Left: 6 month follow-up MRA
Case Series Breakdown

Total Cohort

- Patients treated $n=30$ (35 lesions)
- Average lesion length 9.5cm

CTO Cohort

- Patients/lesions treated $n=13$ (37% total cohort lesions)
- Average CTO lesion length 11.4cm
- Ocelot standalone success ($n=12/13$ true lumen): 92.3%
Case Series: Lesion Breakdown

Calcification Grade

- None: 48%
- Mild: 36%
- Moderate: 12%
- Severe: 4%

Lesion Etiology

- Denovo: 68%
- In-Stent Restenosis: 24%
- Restenosis: 8%
Case Series: Lesion Breakdown
(n=30 patients; 34 lesions)

Luminal Gain Following Therapy

- Pantheris Standalone Luminal Gain: 77%
- Pantheris +/- Adjunctive Luminal Gain: 95%
- Adjunctive PTA (n=0 lesions): 0%
- Adjunctive DCB (n=24 lesions): 69%
- Adjunctive Stent (n=5 lesions) [Average stent length 60 mm]: 14%
Fluoroscopic Measurement Cohort
(Subset Analysis)

Patients Treated
n=14 patients (14 lesions)

Average Lesion Length
62.3 mm

Luminal Gain (Standalone Pantheris)
77%

%CTOs Treated
57% (n=8)

Adjunctive DEB rate
54%

Adjunctive stent rate
15%

Average Total Fluoroscopy Time
14.7 mins

Average Pantheris Atherectomy Fluoroscopy Time
5.3 mins
LE Revascularization Total Fluoroscopy Time
(Published Peer Reviewed Data)


* Atherectomy time only
Case Series Outcomes

- 9 patients eligible for 6 month follow-up as of 1/28/16
- 6 month TLR rate 11% (n=1*)
  * CTO lesion re-occluded 2 months after index procedure
- 6 month MRA patency 89% (n=8)
- Average ABI (baseline): 0.8
- Average ABI @ follow-up (6 months): 1.14
- DUS: Not available at this time
- Final 6 and 12 month interval results will be presented in 2016
Conclusions

1. Learning curve for both Ocelot and Pantheris catheters (3-5 cases)
2. Histologic analysis confirms “true lumen” CTO crossing followed by “true lumen” directional atherectomy
3. Pantheris effectively debulks mild and moderate calcium
4. OCT guided atherectomy may reduce need for adjunctive angioplasty and/or stenting
5. Pantheris provides visual confirmation of exposed arterial layer for drug delivery
6. Potential to dramatically reduce radiation and contrast exposure during revascularization (including CTOs)
7. Limited results with ongoing follow-up to confirm outcomes benefit
THE LUMIVASCULAR FUTURE

IMAGE GUIDED THERAPY
PANTHERIS & OCELOT