APPLYING LUMIVASCULAR IN THE OFFICE BASED LAB SETTING

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Disclosures

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I have the following potential conflicts of interest to report:

Faculty/Consulting/Speaking: Medtronic, Cardiovascular Systems Inc, Spectranetics, Avinger, Astra Zeneca, Amgen

Research: Medtronic, Cardiovascular Systems Inc, Spectranetics, Astra Zeneca, Veryan Medical, Novartis, Advanced Cardiovascular Therapies
PAD Prevalence and Growth

Prevalence of PAD\(^1,2,3\)

- PAD
- CAD
- CANCER
- STROKE
- HIV

PAD Growth\(^1\)

- 2010: 17
- 2015: 19
- 2020: 21

PAD is undertreated\(^1,4,5,6\)

- 95% non-treatment or medical management
- 5% intervention
  - 3% endovascular
  - 1% amputation
  - 1% bypass

Lumivascular Value in the Office Based Lab Setting:

1. Clinical Safety (secure and predictable)
2. Clinical Outcomes
3. Maximized precision and efficiency
4. Minimized adjunctive therapy (Patient Example 1)
5. Minimized radiation/contrast (Patient Example 2)
6. Practice Growth (Help more patients)
   • Expanded Indications
   • Cutting Edge technology differentiator
Connect II – Ocelot clinical data

Crossing Success & Freedom from MAEs

- Number of Patients: 100
- Number of Sites: 14
- Mean Lesion Length: 166mm
- Lesion Location: SFA & Popliteal

- Crossing Success: 97%
- Freedom from MAEs: 98%

Luminal Crossing

N=97 patients

- True Lumen: 93%
- Subintimal: 7%
Patient 1

- 62 yo WM smoker
- Resting B leg pain
- Rutherford Class 4
- ABI: R 0.47   L 0.43

1\textsuperscript{st} Intervention Left SFA:
- First Ocelot case, long CTO (20cm)
- Full Metal Jacket

2\textsuperscript{nd} Intervention Right SFA (6 weeks later)
- Long CTO (26cm)
- Confirmed and confident central lumen crossing
- Targeted directional atherectomy
- Nothing left behind
Patient 1, Case 1

- Bilateral SFA
- Left SFA
  - First Ocelot case, long CTO (20cm)
Patient 1, Case 1

Ocelot, working through eccentric disease
Patient 1, Case 1

PTA, proximal and distal
Patient 1, Case 1

Post PTA

Post Stents
Right SFA (6 weeks later)

- 26cm SFA CTO
- OCT confirmation of central lumen crossing
- Therapy: directional atherectomy (HawkOne, Medtronic, Minneapolis, MN)
- Nothing left behind
Patient 1, Case 2

- Right SFA
- Diagnostic Angiography

![Angiography Images]

Prox Cap
Distal Cap
Patient 1, Case 2

- Right SFA
- Ocelot Thru Distal Cap, Post Ocelot Run-Off
Patient 1, Case 2

- Right SFA
- HawkOne Directional Atherectomy
Patient 1, Case 2

- Right SFA
- Post PTA... and final
Patient 1 – Final Results

Post Right SFA

(HawkOne + PTA)

Post Left SFA

(PTA + BMS [250mm])
Patient 2 - CLI

47 yo M: 4 yr old non-healing left heel ulcer, s/p failed HBO, skin grafts, aggressive wound care, disabled from wound

- HTN
- DM
- CMY: EF 25%
- CKD: Cr 3.7  GFR 14
- Non-compressible ABI—DUS: occluded L SFA

- Diagnostic CO2 Angio
- CTO Crossing: Ocelot Catheter
- Therapy: SilverHawk + PTA
Patient 2 – 6cm Left SFA CTO – de novo

- Nephrotoxicity concerns – Cr 3.7
- CO2 Angio
Patient 2
Patient 2

- Ocelot Thru Cap (OCT and Angio)
Patient 2

- Targeted SilverHawk, based on OCT
Patient 2

- Targeted PTA, based on OCT
Patient 2

- Final images – No iodinated Contrast, No stent
Physician Radiation Effects

**BRAIN**
Increasing prevalence of left sided brain tumors (85%) in interventional physicians \( n=31 \) \(^1\)

**EYES**
>3.2X risk of accelerated lens opacification (cataracts) among interventional practitioners \(^2\)

**BLOOD**
Exacerbation of reactive oxygen species and blood-borne cancers \(^3\)

**SKIN**
Soft tissue cancers, hair loss, and skin mottling noticeable in non-dominant hand of MDs \(^4\)

**LOWER EXTREMITY**
Revascularization procedures pose the greatest radiation risk in the hospital \(^5\)

5. Segal E. et al. AJR. 2013 May; 190(5): 1150-62
Average CTO Crossing Fluoroscopy Time (Lesions 15-25cm)

1. Davis, T. Lumivascular approach to crossing chronic total occlusions. JACC. 64; 11 Supplement B, pg B157-158
Early Tyler Experience
– Changing CTO to Algorithm

**Standard 20-30cm CTO**
- Wires
- Support Cath(s)
- Fluoro = 10-15min
- Contrast incremental
- Wire Escalation?
- Device Escalation?
- Re-Entry?
- Balloon(s)
- Stents (20-30cm)

**Lumivascular 20-30cm CTO**
- Wire
- Ocelot
- Fluoro <1m
- Limited iodinated contrast used
- Balloon?
- Stent? (fewer and shorter)
Implementation of the program has generated:

- 4-5 additional cases per month
- $625,185 incremental revenue
- $251,625 incremental margin

After one year, we have already recouped our investment

– Garrick Stoldt, CPA, FHIMA
CFO, St. Peter's University Healthcare System
Conclusion

- Paradigm shift in approaching cases
- Confidence in true lumen access and intervention
- Treat targeted lesions, not necessarily the whole vessel
- More efficient cases improves safety and success
- Access to more complicated lesions in office lab
- Improved or constant margins
THE LUMIVASCULAR FUTURE

IMAGE GUIDED THERAPY
PANTHERIS & OCELOT