

# JANUARY 25-27 2018

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER, PARIS, FRANCE
Contraindications, Limits of MOCA:
When Not To Do It

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#### **Disclosures**

- Medtronic Inc. Scientific Advisory Board
- Vascular Insights Scientific Advisory Board
- Le Maitre Inc. Consultant
- Hancock-Jaffe Laboratories Consultant

#### **Questions To Be Answered**

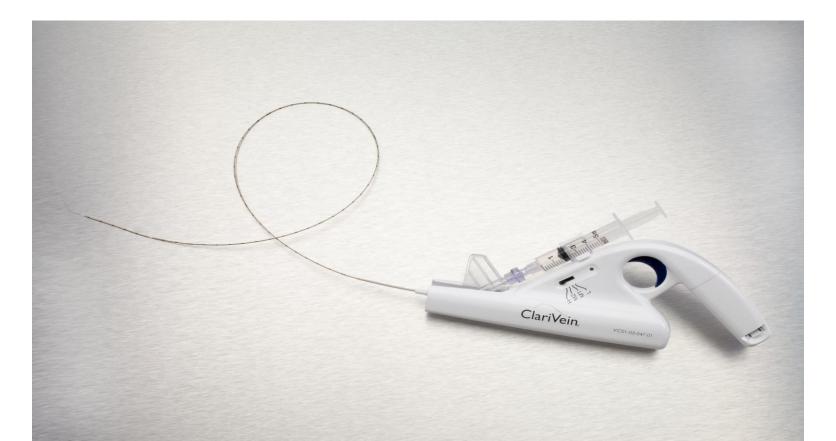
What is it?

How does it work?

When not to do it

Contraindications and limits

### Mechanical Occlusion Chemically Assisted (MOCA): ClariVein™(NTNT)



# MOCA: Clarivein® (NTNT)

sclerosant (STS, PLD) Chemical

"Developed to minimize negative aspects of ETA and Sclerotherapy while incorporating the benefits of each"



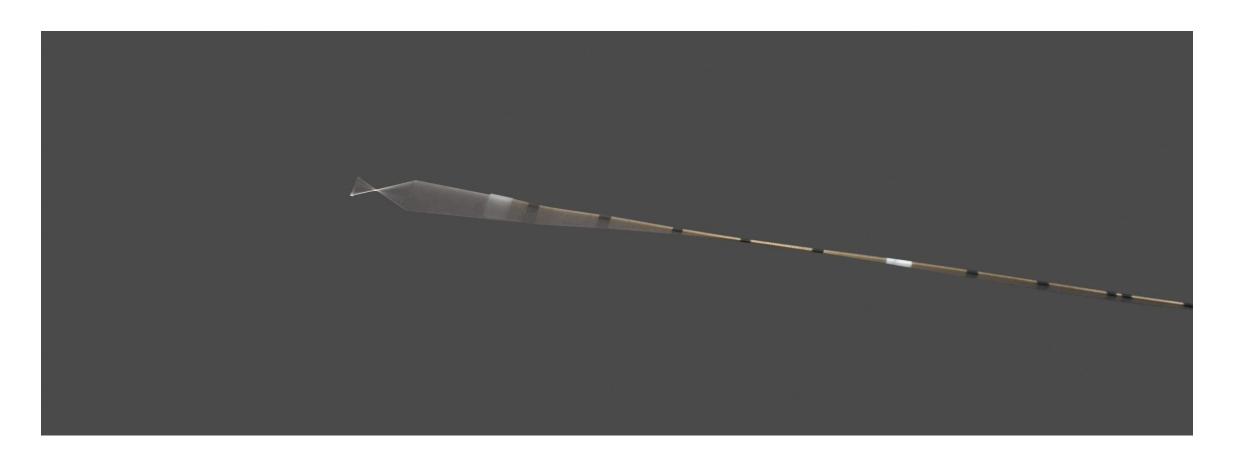
Rotating wire: 3,500

rpm *Mechanical* 

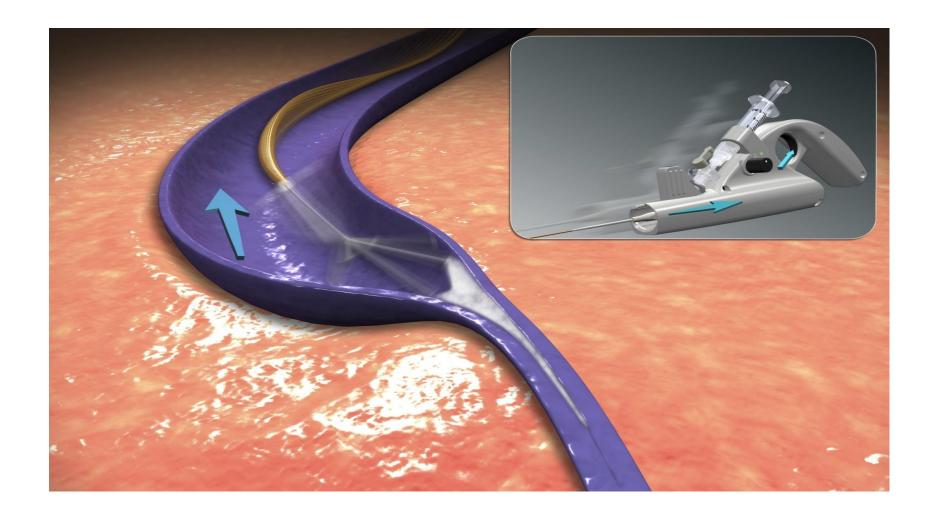
#### **MOCA: Wire Unsheathed**



## Wire Rotating



#### **MOCA:** Mechanism of action



#### When Not To Do It

Really small axial veins <3.5 – 4 mm</li>

Normal superficial axial veins

You don't know how to do it, but think you do

Allergy to STD, Fibrovein, PLD, Asclera etc.

## When Not To Do It (continued)

You enjoy infusing tumescence

You enjoy inflicting pain

You don't like your patients

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE CONTROVERSIES & UPDATES IN VASCULAR SURGERY

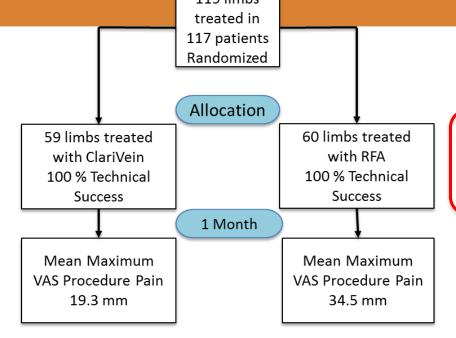
RCT: Bootun, et al:

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WWW.CACVS.ORG

PARIS, FRANCE Key Results



| Adverse Events   |  |  |  |
|------------------|--|--|--|
| <u>ClariVein</u> | <u>RFA</u>   |  |  |
| None             | Thrombophlebitis- 3.4%<br>Deep Vein Thrombosis- 1.7% |  |  |

- Procedure blinding was not possible due to the difference in techniques.
- Investigator follow-up was blinded.

|                             |                  | Score      |
|-----------------------------|------------------|------------|
|                             | <u>ClariVein</u> | <u>RFA</u> |
| 100 mm VAS                  | 19.3 mm          | 34.5 mm *  |
| Corresponding<br>Pain Score | 2.6              | 4.4 **     |

\* p < 0.001 \*\* p = 0.001

Both groups showed improvement at one month in all clinical and QOL measures with no significant differences.

|                   | <u>ClariVein</u> | <u>RFA</u> |  |
|-------------------|------------------|------------|--|
| Normal Activities | 3.5 days         | 4.8 days   |  |
| Work              | 5.3 days         | 4.9 days   |  |

p = 0.235

\*\*UK Study- return to normal activities and work may vary based on geographic environment. However, clinical significant differences in this study are consistent with other studies.

#### **Phlebology**

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**\$**SAGE

A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins – Final results of the Venefit versus Clarivein for varicose veins trial

Tristan Lane<sup>1,2,3</sup>, Roshan Bootun<sup>1,2</sup>, Brahman Dharmarajah<sup>1,2,3</sup>, Chung S Lim<sup>1,2,3</sup>, Mojahid Najem<sup>3</sup>, Sophie Renton<sup>3</sup>, Kaji Sritharan<sup>1,2</sup> and Alun H Davies<sup>1,2</sup>

#### MOCA

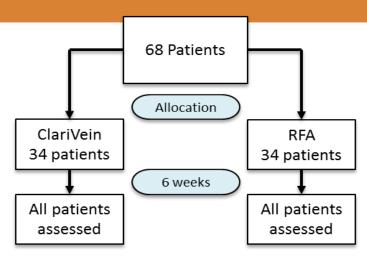
- One month: 93% complete or proximal occlusion
- Six months: 87% complete or proximal occlusion

#### • <u>RFA</u>

- One month: 92% complete or proximal occlusion
- Six months: 93% complete or proximal occlusion







| 90 г                                 | VC   | SS as c | letermir | ned by | Vascula | ır  |
|--------------------------------------|------|---------|----------|--------|---------|-----|
| 80                                   | 82   |         |          |        |         |     |
| 70 -<br>60 -<br>50 -<br>40 -<br>30 - |      | 72      |          |        |         |     |
| 70                                   |      |         |          |        |         |     |
| 60                                   |      | _       |          |        |         |     |
| 50                                   | _    |         |          |        |         |     |
| 40                                   |      |         |          |        |         |     |
|                                      |      |         |          |        |         |     |
| 30                                   |      |         |          |        |         |     |
| 20                                   |      |         | 15       | 16     |         | 12  |
| 10                                   |      |         |          |        | 3       |     |
| 0                                    |      |         |          |        | 3       |     |
| •                                    | MOCA | RFA     | MOCA     | RFA    | MOCA    | RFA |

Identical

Improvement

Deterioration

| Quality of Life and Clinical Outcomes          |                             |                              |  |  |
|--|-----------------------------|------------------------------|--|--|
| ClariVein RFA                                  |                             |                              |  |  |
| Venous Clinical Severity<br>Score (VCSS)       | Improved from 3.0 to 1.0    | Improved from<br>6.2 to 4.8* |  |  |
| Aberdeen Varicose Vein<br>Questionnaire (AVVQ) | Improved from<br>4.0 to 3.0 | Improved from<br>9.5 to 4.5* |  |  |

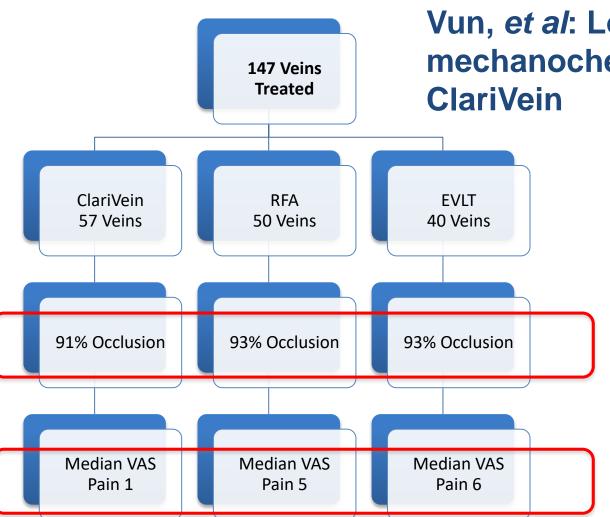
<sup>\*</sup> No statistical difference

|                | Pain and Analgesic Use              |          |          |         |  |
|----------------|-------------------------------------|----------|----------|---------|--|
|                | <u>ClariVein</u> <u>RFA</u> p value |          |          |         |  |
| Procedural VAS |                                     | 22       | 27       | 0.16    |  |
| I              | Mean VAS 3 Days Post-op             | 6.2      | 20.5     | 0.004   |  |
|                | Mean VAS 14 Days Post-op            | 4.8      | 18.6     | < 0.001 |  |
|                | Post-Op Analgesic Use               | 0.5 days | 2.8 days | 0.008   |  |

| Recovery Time   |              |                  |            |         |
|-----------------|--------------|------------------|------------|---------|
|                 |              | <u>ClariVein</u> | <u>RFA</u> | p value |
| Return to Norma | l Activities | 1.2 days         | 3.3 days   | 0.02    |
| Return to \     | Work         | 2.4 days         | 5.6 days   | 0.02    |



\*No attempt at randomization was made



Vun, et al: Lower pain and faster treatment with mechanochemical endovenous ablation using ClariVein

No major adverse events

Comparable closure rates

Significantly lower pain scores in ClariVein group (p < 0.01)

## When Not To Do It (continued more)

You like flirting with disaster

You like nerve damage or skin damage

You like lawyers – 15% malpractice is nerve issues

NO nerve injury reported with MOCA

# The Real Contraindications and Limits of MOCA: When Not To Do It?

• Size - >10 -12 mm (19mm)

Previous SVT with synechiae/scar

Tortuosity – severe

5% of veins we treat (95% we can do it)

# Summary

- Big veins NO
- Post-thrombotic veins NO
- Tortuous veins YES
- Extrafascial veins YES
- YES 95% NO 5%