

Peripheral CTO Crossing with the SoundBite™ Active Wire

Marianne Brodmann, MD¹, Éric Therasse, MD², Andrew Benko, MD³, Adnan Hadziomerovic, MD⁴, Krishna Rocha-Singh, MD⁵, Louis-Philippe Riel⁶, Steven Dion⁶, Denis Bilodeau⁶, Martin Brouillette⁶

1. Division of Angiology, Medical University of Graz, Austria; 2. Department of Radiology, Centre Hospitalier de l'Université de Montréal (CHUM), Canada; 3. Department of Radiology, Centre Hospitalier Universitaire de Sherbrooke (CHUS), Canada; 4. Department of Radiology, The Ottawa Hospital (TOH), Canada; 5. Prairie Heart Institute, USA; 6. SoundBite™ Medical Solutions, Montreal, Canada.

Disclosure

Speaker name:

.....

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

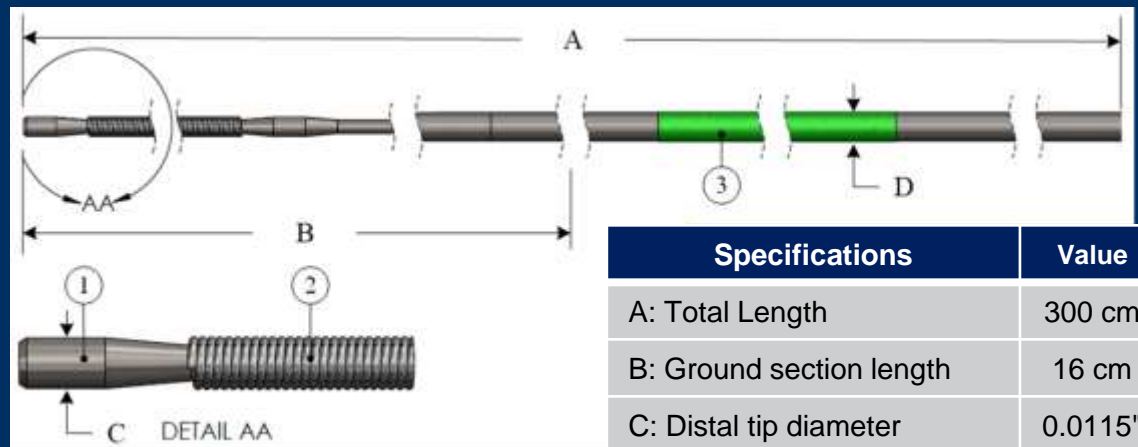
SoundBite™ Crossing System



SoundBite™ Console
(re-usable)



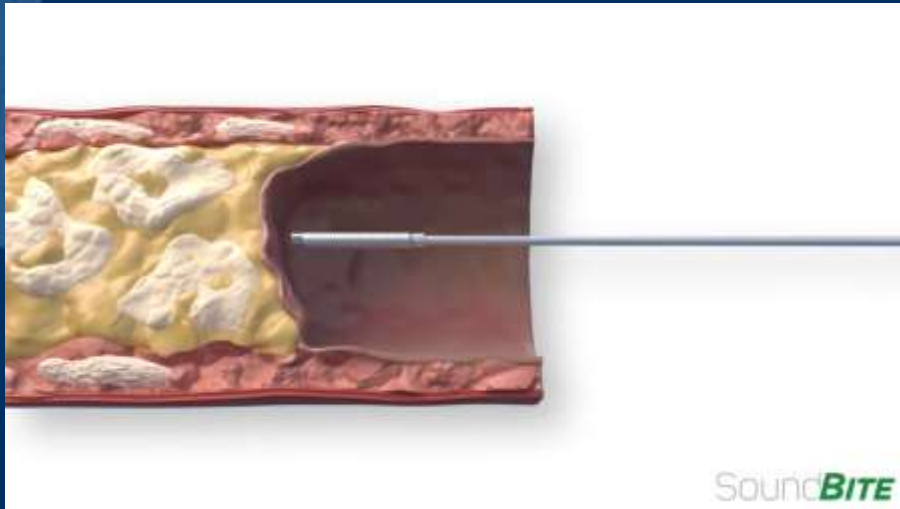
SoundBite™
Active Wire
(single use)



Specifications	Value
A: Total Length	300 cm
B: Ground section length	16 cm
C: Distal tip diameter	0.0115"
D: Wire diameter	0.018"

Mechanism of Action

Active Wire micro-jackhammer effect



PROSPECTOR Peripheral Clinical Trial

PRIMARY ENDPOINT

- **30-day device success:** Ability to facilitate treatment of the target lesion by allowing additional crossing and/or treatment devices to cross the CTO + Freedom from MAEs

STUDY POPULATION

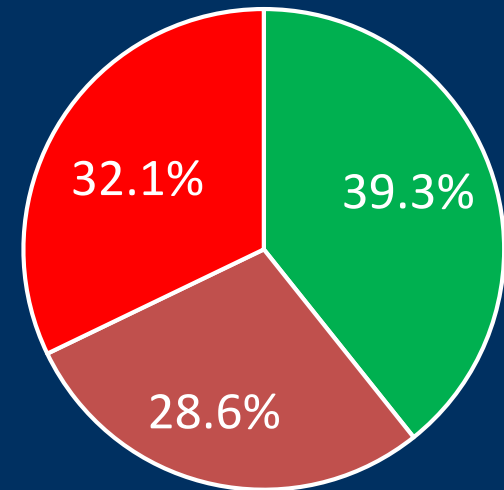
- **52 Subjects** (56 CTOs)
- **Canada** (Montreal, Sherbrooke, Ottawa) & **Europe** (Graz)
- **CTO length = 1 cm to 32 cm (mean 10 cm +/- 8 cm)**

PROSPECTOR Peripheral Clinical Trial

TRIAL RESULTS

- 30-day **Device Success 92.3%**
 - **0% MAEs**
- Mean **Active Wire Activation Time = 3.58 min ± 3.16 min**
- **Median CTO Crossing Time = 10 min** (\bar{X} =20 min.)
- The Active Wire crossed the full CTO length in 86.5% of subjects.

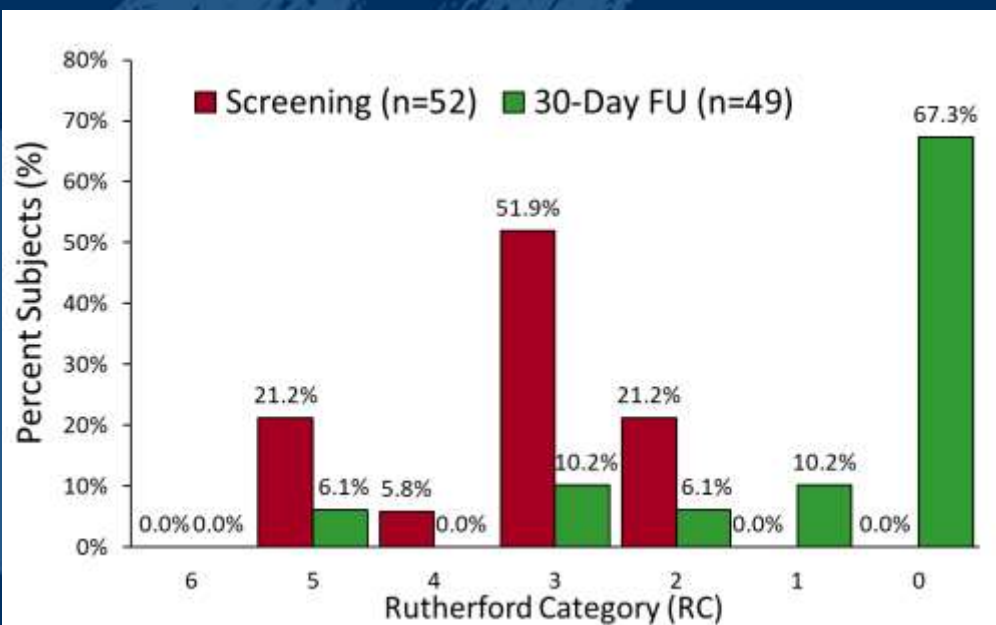
- Over 60% subjects with **moderate to severe CTO calcification**



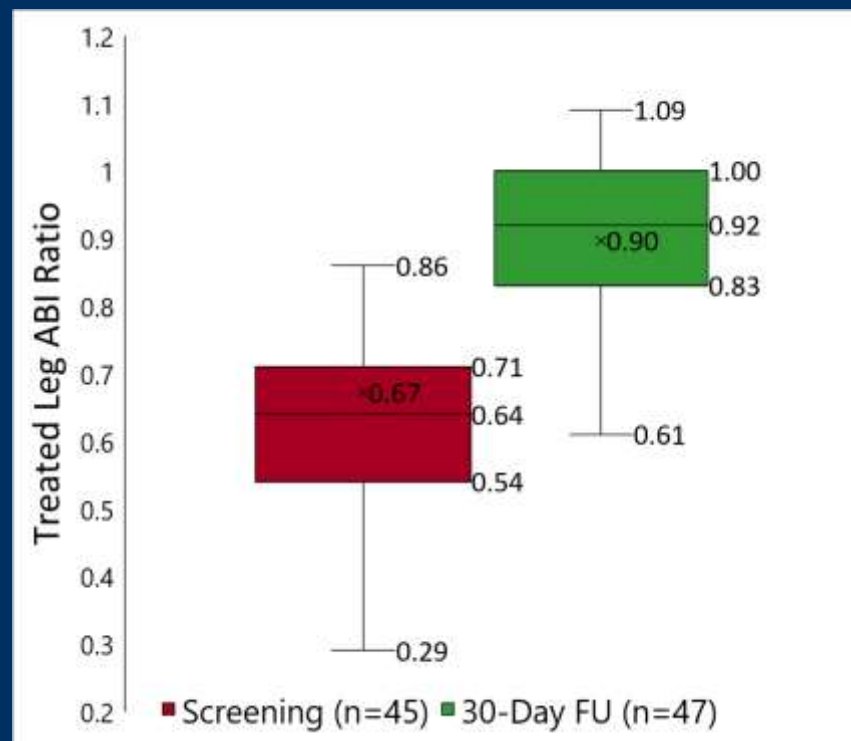
■ Mild ■ Moderate ■ Severe

Trial Results: Rutherford Category and ABI Improvements

Rutherford Category

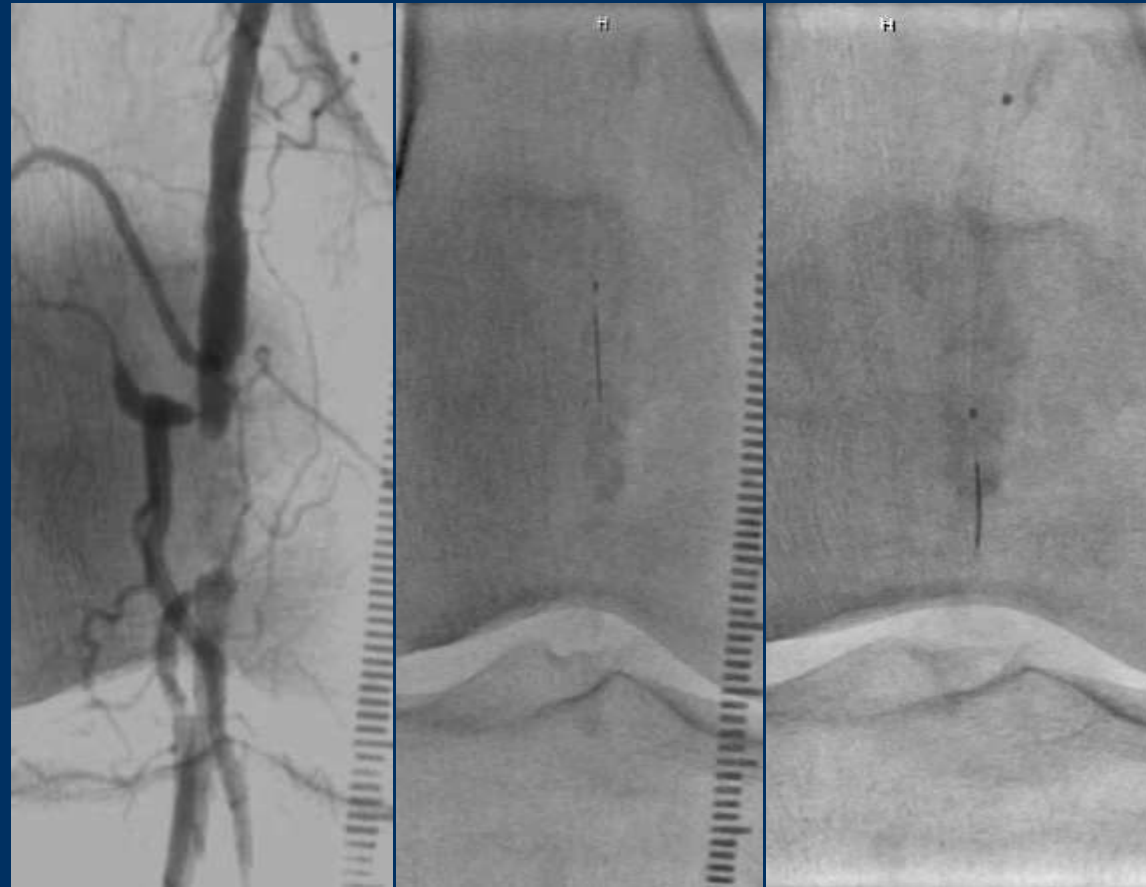


ABI Ratio



Case Presentation 2

- 77 y.o. male
- Rutherford III
- R. 14 mm popliteal CTO
- Severe Ca++
- Activation time: 26 sec.



Conclusion

- Efficient device: **92.3%** Device Success
- Good safety record: **no MAEs**
 - AW action on **hard tissues**, innocuous on soft tissues
 - 0.018: **perforation less likely** to be problematic
- **Easy and fast** to operate
 - **Compatible** with standard 0.018'' platform tools
 - **No saline solution**, cooling or specialized catheter
 - **No need to push hard** on the wire
- Coronary Trial presently ongoing with 0.014'' wire

Peripheral CTO Crossing with the SoundBite™ Active Wire

Marianne Brodmann, MD¹, Éric Therasse, MD², Andrew Benko, MD³, Adnan Hadziomerovic, MD⁴, Krishna Rocha-Singh, MD⁵, Louis-Philippe Riel⁶, Steven Dion⁶, Denis Bilodeau⁶, Martin Brouillette⁶

1. Division of Angiology, Medical University of Graz, Austria; 2. Department of Radiology, Centre Hospitalier de l'Université de Montréal (CHUM), Canada; 3. Department of Radiology, Centre Hospitalier Universitaire de Sherbrooke (CHUS), Canada; 4. Department of Radiology, The Ottawa Hospital (TOH), Canada; 5. Prairie Heart Institute, USA; 6. SoundBite™ Medical Solutions, Montreal, Canada.