


How Does The SoundBite Active Wire Help To Cross Calcified Lesions, Especially BTK; Updated Experience

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CLI, CALCIUM AND CTOs: A BAD COMBINATION

High CTO & Calcium Burden In PAD Pose Treatment Challenges In Endovascular Interventions

Calcium: 40-50%
CTO: 30-40%

Treatment failure: 20-40%


Calcium > 65%
CTO: 40-50%

Treatment failure: 50% in lesions >15cm

Leading Failure Modalities:

Failure to Cross	Early Technical Failure
<ul style="list-style-type: none"> Heavy calcium Ambiguous cap Long CTO 	<ul style="list-style-type: none"> Recall Dissection

Intervention goal is to restore flow, promote wound healing and prevent amputations



Calcification Exceedingly Common in CTOs BTK

Chronic Total Occlusions: Association Between Characteristics and Mid-Term Outcomes in Critical Limb Ischemia

- 485 CTOs in 411 patients
- 37% BTK CTOs (34% ATK & 29% multi-level)
- 95% of BTK CTOs have calcification (86% in full cohort)

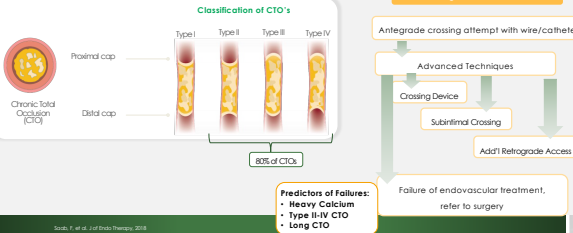
BTK CTO High Risk for Mortality and Amputation at 1 year

Characteristic	Mortality			Major Amputation		
	Risk Ratio	95% CI	P-Value	Risk Ratio	95% CI	P-Value
Multivariate model						
CTO location, BTK/multilevel vs ATK	3.48	1.22-9.94	.02	4.80	1.12-20.6	.03
Disease severity, CLI vs PAD	5.30	1.22-22.1	.03	—	—	—
Dialysis, yes vs no	—	—	—	8.78	3.55-21.7	<.001

"Patients with CTOs located BTK were found to have the highest mortality and amputation in comparison to those ATK or multilevel."

CROSSING ALGORITHMS CAN BE COMPLEX BASED ON LOCATION AND MORPHOLOGY

Escalation Algorithm for CTO Treatment



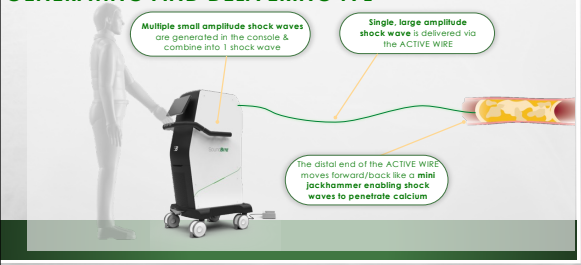
Classification of CTO's

Type I, Type II, Type III, Type IV

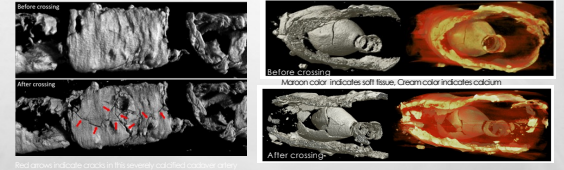
Predictors of failures:

- Heavy Calcium
- Type II-IV CTO
- Long CTO

SOUNDBITE® TECHNOLOGY: UNIQUE METHOD FOR GENERATING AND DELIVERING IVL



CADAVER MODEL: CROSSING AND PLAQUE MODIFICATION



- Creates channel with forward drilling
- Impacts calcific plaque with radial mechanical forces

POSITIVE EARLY RESULTS SEEN IN THE PROSPECTOR STUDY

Design	Prospective, Single-arm, Multi-Center in EU and CA
Objective	Evaluate the safety and efficacy of the SoundBite® Crossing System for recanalization of CTOs (0.018" Active Wire)
Study Population	52 patients with 56 symptomatic infrainguinal CTOs, across 4 sites
Primary Endpoint	30-day technical device success + Freedom from MAEs (technical success = ability to facilitate treatment of the target lesion by allowing additional crossing and/or treatment devices to cross the CTO)

Therasse, E. et al. J Vasc Interv Radiol 2022; 33:50-59

RESULTS OF THE PROSPECTOR STUDY

Promising Early Performance in Complex, Highly Calcified CTOs

	N = 56
CTOs lesions, #	56
CTO lesion location (ATK), mean	93%
Calcification (Moderate/Severe), %	61%
Rutherford Classification ≥ 4	27%
Lesion length (mm), mean	98.4
Device Success, %	92.9%
CTO Crossing time (min), mean	22.56
Procedure time (min), mean*	115.4
AW Use Only, mean	61%
AW Activation Time (min), mean	3.58

Majority of cases were completed antegrade access and true lumen

- 40% of cases had no additional guidewires or re-entry devices
- 98% of cases were single access

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Device Success = ability to facilitate treatment of target lesion
AW Use only = No additional wire body used to cross lesion
Activation time = the amount of time the Active Wire was set
*calculated per patient, n = 52

RESULTS OF THE PROSPECTOR STUDY: CLI SUBGROUP

Promising Early Performance in Complex, Highly Calcified CTOs... in CLI patients Despite - more calcification and longer lesions

	ALL	CLI Subgroup
CTOs lesions, #	56	15
Calcification (Moderate/Severe), %	61%	59%
Device Success, %	92.9%	93.3%
CTO Crossing time (min), mean	22.56	13.2
Procedure time (min), mean*	115.4	114.1
Lesion length (mm), mean	98.4	99.9
AW Use Only, mean	61%	73%
AW Activation Time (min), mean	3.58	3.53

Mean Rutherford Category Change from Baseline (overall)

At baseline: 2.4 → At 30-day baseline: -2.4

Mean Rutherford Category Change (CLI Subgroup)

At baseline: 3.0 → At 30-day baseline: -3.0

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On file with manufacturer in study report.

GROWING EVIDENCE: CONSISTENT RESULTS

23 cases have been done at the Medical University of Graz

- Excellent performance of the Active Wire 0.014" in BTK CTOs
- No dissections or perforations

	N = 23
CTOs lesions, #	23
CTO lesion location (BTK), %	78%
Calcification, %	30% Moderate 70% Severe
Lesion length (mm), mean	80.4
Device Success, %	87%
Single Access, %	100
True lumen crossing, %	65.2
Re-entry Device Used, &	0
Active Wire Activation Time (min), mean	3.2

6 sites across EU, CA and US currently performing cases

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Device Success = ability to facilitate treatment of target lesion
Active Wire Time = the amount of time the Active Wire was set

BASED ON PROSPECTOR STUDY RESULTS AND CLEAR UNMET NEED FOR BTK LESIONS – SOUNDBITE MEDICAL FOCUSED ON OPTIMIZING ACTIVE WIRE FOR BTK LESIONS, LEVERAGING CORONARY WORK AND MOVED TO A 0.014" PLATFORM

CATO-PAD CLINICAL STUDY

Design	Prospective, Single-arm, Multi-Center in EU and US
Objective	Evaluate the safety and performance of the SoundBite® Crossing System XS Peripheral for recanalization of CTOs (0.014" Active Wire)
Study Population	110 patients with calcific, refractory infrainguinal CTOs, up to 10 sites
Primary Performance Endpoint	Crossing of the lesion, regardless of method or modality (e.g. antegrade or retrograde)
Primary Safety Endpoint	Procedural incidence of the following: <ul style="list-style-type: none"> No reflow Thrombus formation Artery closure Distal embolization Dissection or perforation Sticky MAE consisting of: <ul style="list-style-type: none"> Death Emergency surgical amputation of target limb Unplanned major amputation of target limb Symptomatic distal thrombus or embol requiring intervention Perforation requiring treatment
Secondary Performance Endpoints	<ul style="list-style-type: none"> Antegrade true lumen crossing CTO crossing time Acute gain of end of the procedure Procedure and fluoroscopy time Device utilization (e.g. guidewires, microcatheter, catheter, etc.)
Secondary Safety Endpoints	

KEY INCLUSION/EXCLUSION CRITERIA

Inclusion <ul style="list-style-type: none"> De-novo lesion of native infrainguinal arteries At least 1 CTO Target lesion with moderate or severe calcification by PARC Target lesion refractory - failed attempt to cross with guidewire 	Exclusion <ul style="list-style-type: none"> Target lesion crossed by conventional wire Treatment of inflow lesion results in no reflow, thrombus formation, abrupt closure, embolization, dissection or perforation
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SOUNDBITE XS CROSSING SYSTEM FOR CATO TRIAL

Updated Console XS

- Significantly smaller footprint
- Quieter operation
- Intuitive user interface (touchscreen)
- Intelligent connection
- Similar shock wave output
 - 20Hz (6000 pulses per Active Wire)



Enhanced Active Wire and Accessories

- New torquer designed to work with Active Wire XS
- Updated curving tool to offer small and large curve options
- Updated connector allowing for easier connection to the XS console



SUMMARY

- CROSSING CALCIFIED CTOS REMAINS PROBLEMATIC EVEN FOR EXPERIENCED INTERVENTIONALISTS
- SOUNDBITE CROSSING SYSTEM UNIQUELY DELIVERS INTRAVASCULAR LITHOTRIPSY TO CREATE A CHANNEL AND MODIFY PLAQUE
- EARLY CLINICAL DATA DEMONSTRATED SAFETY AND EFFECTIVENESS
- REAL-WORLD EXPERIENCE WITH THE OPTIMIZED ACTIVE WIRE 0.014" HAS SHOWN CONSISTENT, EXCELLENT RESULTS EVEN IN COMPLEX, HIGHLY CALCIFIED CLI LESIONS
- CATO-PAD IS CURRENTLY ENROLLING

Thank you for your
attention