IVUS Studies Before And After PTAs With The Ultrascore Scoring Balloon (from BD) Show the Benefits of Such Balloons And How They Works

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Disclosures

Consultant:
Abbott, Bentley, BSCI, Cardinal Health/Cordis, Centerline BioMedical, Cook Medical, CR BARD/Becton Dickinson, CSI, Endologix, Inari, Medtronic, Micro Medical Solutions, Penumbra, Philips, Terumo, WL Gore

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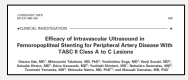
Clinical studies that combine IVUS and endovascular devices in PAD


Intravascular ultrasound-guided drug-coated balloon angioplasty for femoropopliteal artery disease: a clinical trial


Optimal Vessel Sizing and Understanding Dissections in Infrapopliteal Interventions: Data From the iDissection Below the Knee Study


Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions


Impact of Postoperative Lumen Gain on the Reduction of Restenosis Risk after Endovascular Treatment using Drug-coated Balloon for Femoropopliteal Lesions Assessed by Intravascular Ultrasound


Factors in Sufficient Endovascular Vessel Preparation for Severely Calcified Femoropopliteal Lesions

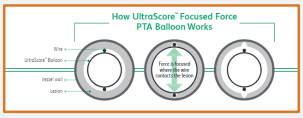
- ✓ Improvement of lumen gain
- ✓ Higher identification of suboptimal vessel prep and dissections.
- ✓ Maximization of technical and procedural success
- ✓ Positive impact on Primary patency, TLR, TVR, MAEs, etc

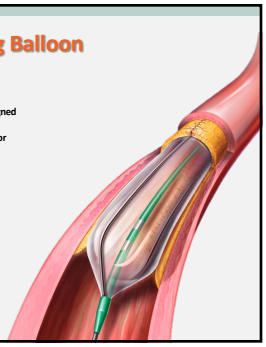
… but what about scoring balloons?

Ultrascore Focused Force Scoring Balloon

Key Characteristics

- **Semi-compliant balloon**
- **Scoring longitudinal wires oriented 180° apart for focused force: designed to longitudinally fracture plaque at lower inflation pressures**
- **The UltraScore™ Focused Force PTA balloon is compatible with .014" or .035" guidewires.**
- **Shaft sizes: 130cm (.035") or 150cm (.014") with GeoAlign® Marking System.**
- **Radiopaque markers to aid in visualization**





Ultrascore US Post Market Study

Study Design

- **Objective:** Assess clinical use of UltraScore Balloon in a heterogeneous population in a real world , on-label clinical application for the treatment of stenotic lesions of the superficial femoral artery (SFA), popliteal artery, and infra-popliteal arteries (posterior tibial, anterior tibial and peroneal arteries).
- **Design:** Prospective, Multi-Center (30 US sites), Single-Arm, Non-Randomized Real World study
  - **350 Subjects treated with study device (ITT population)**
    - **176 femoropopliteal (Fempop); 174 below the knee (BTK)**
- **Follow-Up:** hospital discharge, 30 days, and 6- and 12- months post-index procedure.
- Independent Analysis: Ultrasound Core Lab – VasCor and Angiographic Core Lab – Yale Core Lab

IVUS SUB-STUDY:

Subjects were asked to participate in an optional sub-study involving the use of Intravascular Ultrasound (IVUS)

The following results were collected from the IVUS sub-study population that agreed to participate (N = 20) and analyzed by the core lab:

- **Demography and Baseline Characteristics.**
- **Summary of Procedure.**
- **Summary of Study Device During the Procedure.**
- **Lesion Assessment with and without Adjunctive Therapy.**
- **IVUS Summary of Dissection.**
- **IVUS Reference Segment Assessment.**
- **Analysis of Primary Endpoints.**
- **Analysis of Secondary Endpoints.**

Study Investigators

Lead principal co-investigators for this study were Dr. Craig Walker, Dr. Robert Beasley, and Dr. Miguel Montero Baker

Dr. Michael Ayad
Dr. William Bachinsky
Dr. Richard Heuser
Dr. Louis Lopez
Dr. David Weatherford
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Dr. Jose Wiley
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Dr. Sameer Mehta
Dr. Mazin Foteh
Dr. Sam Tyagi
Dr. John Park
Dr. Genady Geskin
Dr. Frank Parker
Dr. D Christopher Metzger

30 US sites enrolled subjects

Ultrascore Post Market Study

Study Design

Key Inclusion Criteria

- Target lesion (**de novo lesion or prior failed treatment**) that can be treated with the UltraScore balloon
- Target lesion location: **Superficial Femoral Artery (SFA), popliteal, or infra-popliteal arteries** (posterior tibial, anterior tibial, or peroneal arteries) may be treated for this study
- Fempop or Infrapop target lesion with **at least one vessel run-off**
- Target lesion must be able to be crossed using a guidewire (use of chronic total occlusion (CTO) or atherectomy is allowed)

Key Exclusion Criteria

- One or more stents received as adjunctive therapy at the target lesion (bail out stenting is allowed)
- Target lesion that involves both Fempop and Infrapop arteries
- Target lesion in a previously placed stent or stent graft (in-stent restenosis)
- Flow limiting dissection at the target lesion prior to use of the UltraScore balloon
- Acute limb ischemia
- Rutherford category 6

Ultrascore Post Market Study

Study Design

Primary Endpoints

- **Procedural success** defined as less than or equal to (≤) 30% residual stenosis, without major flow limiting dissection
- **Technical success** defined as UltraScore balloon delivered to target lesion and inflated without movement

Secondary Endpoints

After UltraScore balloon:

- Rate of bail-out stenting due to dissection

Through 12 months follow-up:

- Freedom from Target Lesion Revascularization (TLR)
- Freedom from major amputation (above the ankle)
- Improved clinical measures from baseline (Ankle Brachial Index (ABI), Rutherford)
- Primary patency for Fempop subjects only (as measured by Duplex Ultrasound (DUS) core lab; a *PSVR ≥2.5 suggests 50% restenosis)

Ultrascore Post Market Study

Study Design: Demography, baseline characteristics

	ALL Ultrascore (N= 350)	IVUS (N=20)
Mean Age, Years (SD)	70.2 (10.22)	67.4
Male/Female n (%)	238 (68.0%) / 112 (32.0%)	17 (85%) / 3 (15%)
Rutherford Category n (%)		
0	1 (0.3%)	0
1	1 (0.3%)	0
2	17 (4.9%)	0
3	125 (35.7%)	17 (85%)
4	90 (25.7%)	1 (5%)
5	116 (33.1%)	2 (10%)
Previous Target Lesion Intervention n (%)	28 (8.0%)	1 (5%)

Ultrascore Post Market Study

Study Design: Procedural highlights

Adjunctive treatment BEFORE Ultrascore

	ALL Ultrascore	IVUS subgroup
Any adjunctive	78.9%	85%
Atherectomy	68.3%	75%
PTA	20.6%	25%

Overall, IVUS subgroup had more adjunctive treatments, before and after Ultrascore.

Adjunctive treatment AFTER Ultrascore

	ALL Ultrascore	IVUS subgroup
Any adjunctive	46.6%	70%
None	53.3%	30%
PTA	16%	30%
DCB	29.1%	35%
BMS	11.1%	25%
Stent graft	0.6%	0%

Ultrascore Post Market Study

Results

Analysis of Primary Endpoints:	TOTAL STUDY (N=350)	ALL IVUS (N=20)
Procedural success: defined as less than or equal to (≤) 30% residual stenosis, without major flow limiting dissection	254/349 (72.8%)	10/20 (50%) ↓
Residual Stenosis after 2nd inflations > 30%	76/349 (21.8%)	8/20 (40%) ↑
Flow Limiting Dissection	15/350 (4.3%)	2/20 (10%) ↑
Technical Success of Ultrascore	100%	21/21 (100%)

Ultrascore Post Market Study

Results

Analysis of Secondary Endpoints:

	ALL Ultrascore	ALL IVUS (N=20)
Freedom from TLR by timepoint	100%	20/20 (100%)
Freedom from Major Amputation	97.4%	20/20 (100%) ↑
Primary Patency at 30 Days (ATK only)	95.1%	18/18 (100%) ↑

	ALL Ultrascore	ALL IVUS (N=20)
Flow limiting dissection	15/350 (4.3%)	2/20 (10%) ↑
Grade D	8/14	1/1
Grade E	6/14	-
Bailout Stenting	14/15 (93.34%)	1/2 (5%) ↓

Ultrascore Post Market Study

Results

Stenosis reduction :

	ALL Ultrascore	ALL IVUS (N=20)
After adjunctive therapy	68.4%	72.2%
After Ultrascore	58.3%	26.8%
Final residual stenosis (after Ultrascore and/or adjunct)	**8.7%**	**6.8%** ↓

Luminal Gain :

	ALL IVUS (N=20)
Lumen area before treatment	4.69mm2
Lumen area after treatment	11.39 mm2
Luminal gain	**53.7%**

Ultrascore Post Market Study

IVUS Sub-study: Conclusions

Primary endpoints:

- Optimal PTA: 50% (Residual stenosis 40% post PTA and 2 dissections)
- Technical Success 100%

Secondary endpoints:

- Freedom from TLR at 30 days: 100%
- Freedom from Major amputation at 30 days: 100%
- Primary Patency at 30 Days: 100%
- Bail-out stenting: 1 case

After using Ultrascore:

- **Luminal gain 53.7%**
- **Final residual stenosis 6.8%**