

REALITY Study 12-Month Outcomes: Safety and Effectiveness of Directional Atherectomy followed by DCB

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Disclosure

Company

- Abbott Vascular
- Medtronic
- Boston Scientific

Affiliation/Financial Relationship

- Advisory Board
- Consulting agreement
- Speakers fees / Honorarium
- Advisory Board
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- Speakers fees / Honorarium
- Advisory Board

REALITY STUDY¹

Objective & Design

Study Objective

Evaluate the effectiveness of the HawkOne Directional Atherectomy System followed by the IN.PACT Admiral Drug Coated Balloon to debulk moderate and severely calcified femoropopliteal artery atherosclerotic lesions.

- Primary Endpoints:
 - Effectiveness: Primary Patency at 12 months²
 - Safety: Freedom from Major Adverse Events (MAE) through 30 days³
- Primary Investigators: Dr. Krishna Rocha-Singh, Dr. Brian DeRubertis & VIVA Physicians

Study Design & Oversight

- Prospective, non-randomized, single-arm study
- 102 subjects enrolled at 13 sites in the US & Germany
- Angiographic and duplex ultrasound (DUS) core lab adjudicated
- Change in maximal luminal plaque area adjudicated by an independent intravascular ultrasound (IVUS) core lab

1. Sponsored and conducted by VIVA Physicians; funded by Medtronic.

2. Primary patency defined as freedom from restenosis (DUS peak systolic velocity ratio >2.4) and CD-TLR, defined as any reintervention to the target lesion due to a return of symptoms and/or ankle-brachial index (ABI) decrease of 20% or > 0.15 when compared with the post index procedure baseline ABI.

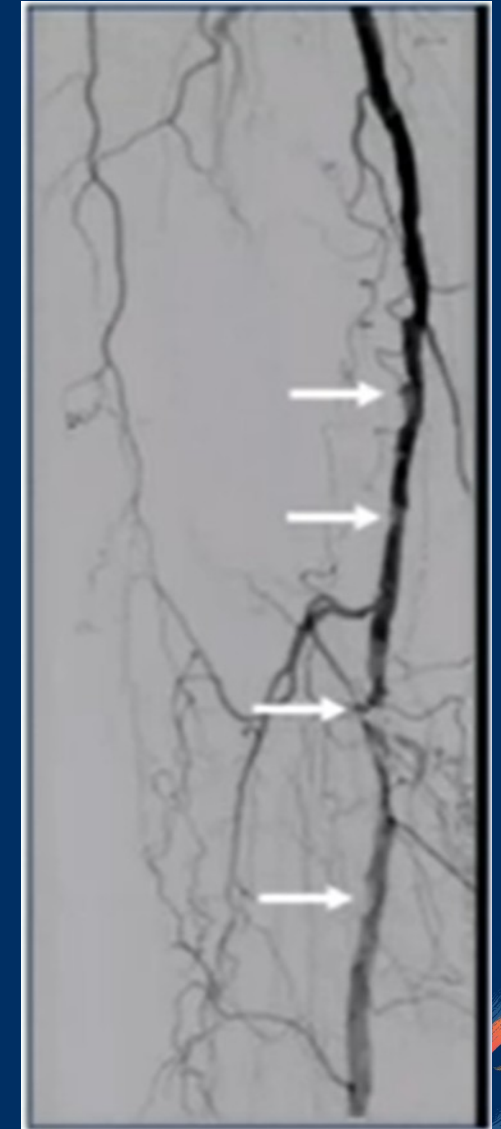
3. Major Adverse Events (MAE) defined as flow-limiting dissections (D-F), vessel perforation(s) requiring bare metal stents or stent-grafts implantation, unplanned major amputation, intra-procedure distal atheroembolization and CD-TVR.



REALITY INCLUSION CRITERIA

Defining “Complex” Lesion Morphologies

- Femoropopliteal lesion lengths: 8-36 cm
- Long chronic total occlusion lengths: >10cm
- Bilateral vessel wall calcification **required** in all lesions



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Participating sites from the US and Germany



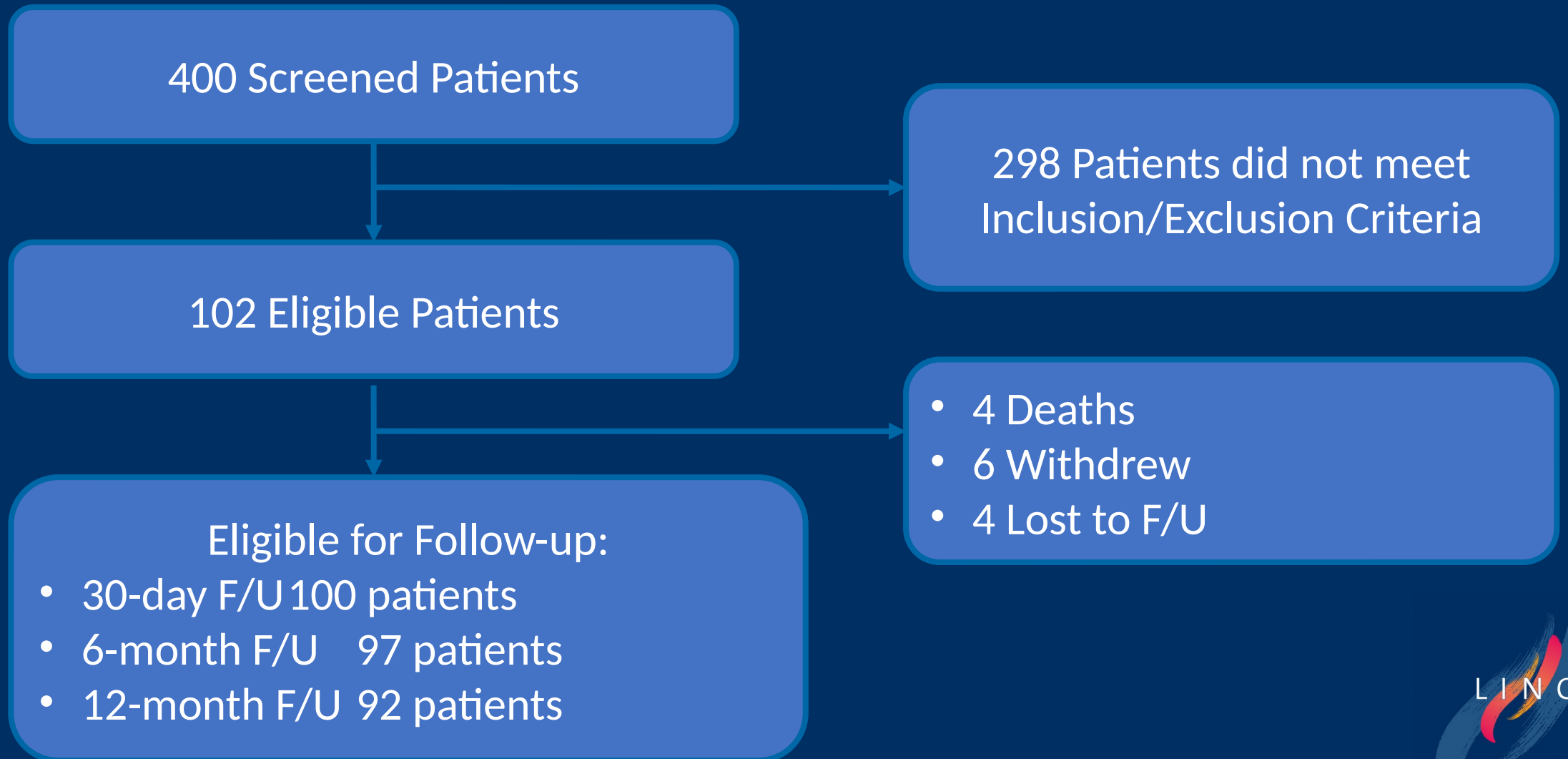
- Dr. Ravish Sa
- Dr. Prakash K
- Dr. Brian De
- Dr. Lawrence Garcia - Boston, MA
- Dr. Eric Scott - Iowa Methodist, IA
- Dr. John Winscott - University of Mississippi
- Dr. Samir Germanwala - Longview, TX
- Dr. Roger Gammon - Austin, TX
- Dr. Miles McClure - Saginaw, MI



- Dr. Thomas Zeller - Bad Krozingen
- Dr. Giovanni Torsello - Munster
- Dr. Claus Nolte-Ernsting - Mulheim
- Dr. Erwin Blessing - Karlsbad

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Patient Flow



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Clinical & Lesion Characteristics

| Key Baseline Clinical Characteristics | N = 102 |
|---------------------------------------|------------|
| Age (years); ± SD | 69.6 ± 9.7 |
| Sex (male) | 65.7% |
| Hypertension | 89.2% |
| Hyperlipidemia | 81.4% |
| Diabetes Mellitus | 53.9% |
| History of Coronary Artery Disease | 61.8% |
| Prior Peripheral Vascular Disease | 74.5% |

| Key Lesion Characteristics | |
|---|---------------|
| Lesion Length (mm) | 179.36 ± 81.4 |
| Lesion Length ≥ 150 mm | 55.6% |
| MLD (mm) at Baseline | 0.57 ± 0.6 |
| Chronic total occlusion length (mm) | 226.0 ± 86.0 |
| Diameter Stenosis (%) at Baseline | 88.8 ± 11.7 |
| Procedure Metrics: | |
| Diameter Stenosis (%) Post-DA Treatment | 28.1 ± 12.0 |
| Procedural Success* | 57.6% |

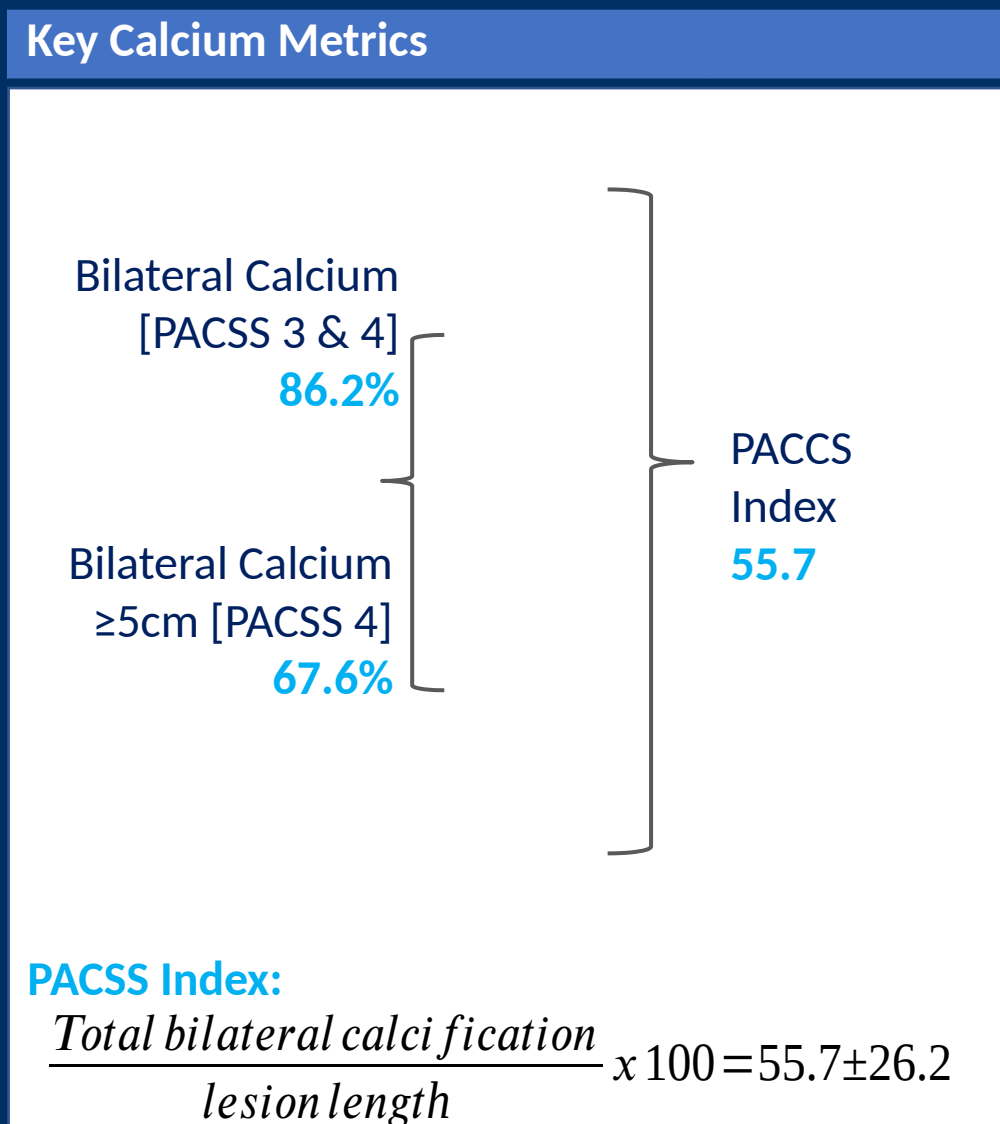
*Procedural success defined as ≤30% post DA+DCB as assessed by the angiographic core lab



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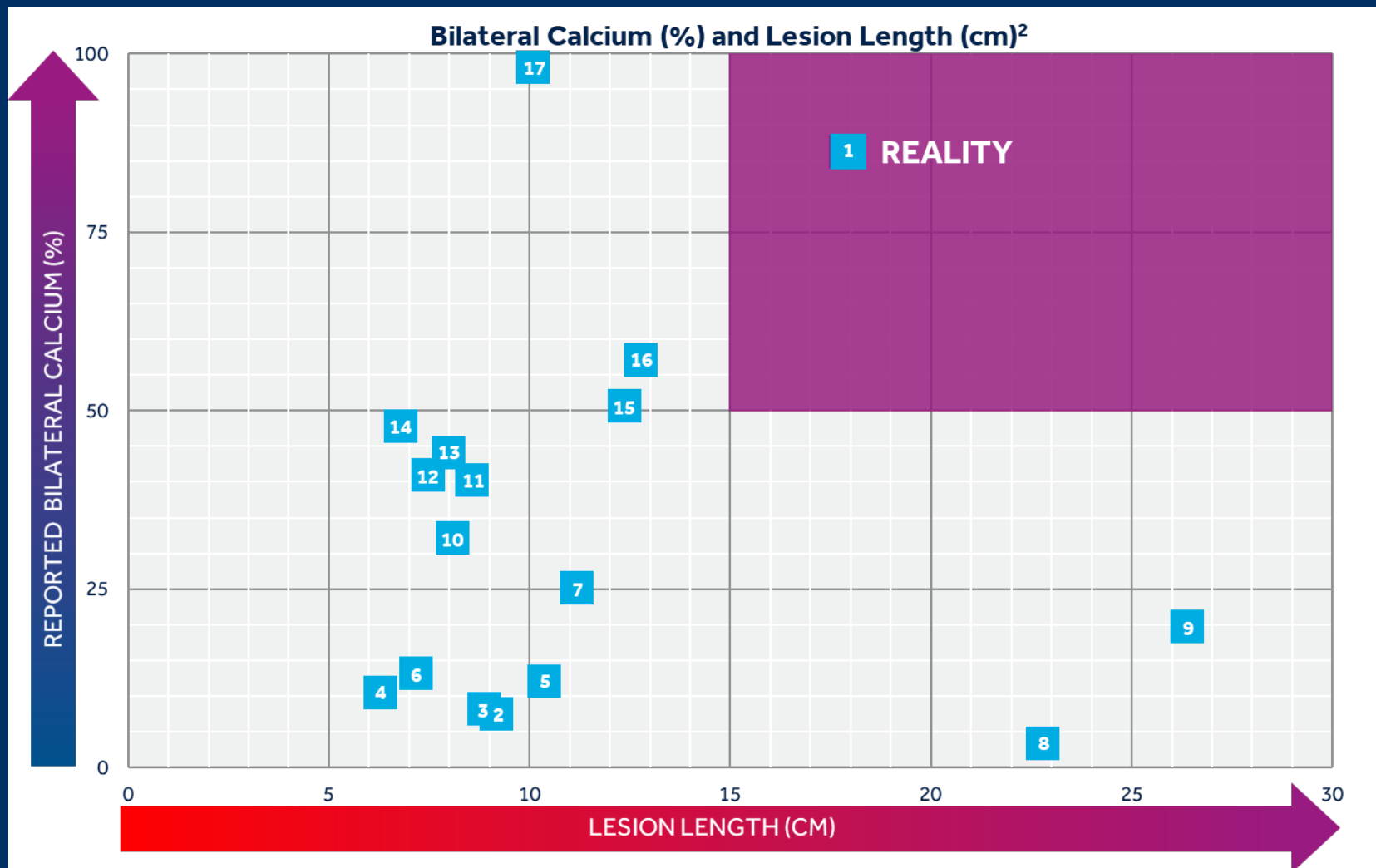
Calcium Severity Assessment

| Key Baseline Clinical Characteristics | N = 102 |
|---------------------------------------|---------|
| PACSS Score | |
| Grade 0 | 1.0% |
| Grade 1 | 2.9% |
| Grade 2 | 0.0% |
| Grade 3 | 18.6% |
| Grade 4 Bilateral wall Ca++ ≥5cm | 67.6% |
| Not assessable | 8.8% |
| Type of calcification | |
| Type A: Intimal | 0.0% |
| Type B: Medial | 1.0% |
| Type C: Mixed Intimal + Medial Ca+ | 86.3% |
| + | |
| Not assessable | 12.7% |



REALITY STUDY¹

Uniquely Long and Complex



With a focus on uniquely long and complex lesions, the REALITY study was designed to explore the boundaries of endovascular therapy.

1. Sponsored and conducted by VIVA Physicians; funded by Medtronic.
2. Calcium definitions differ across studies. These are angiographic, core lab adjudicated reported calcium results. This graph is for illustration purposes only. References are at the end of this presentation.

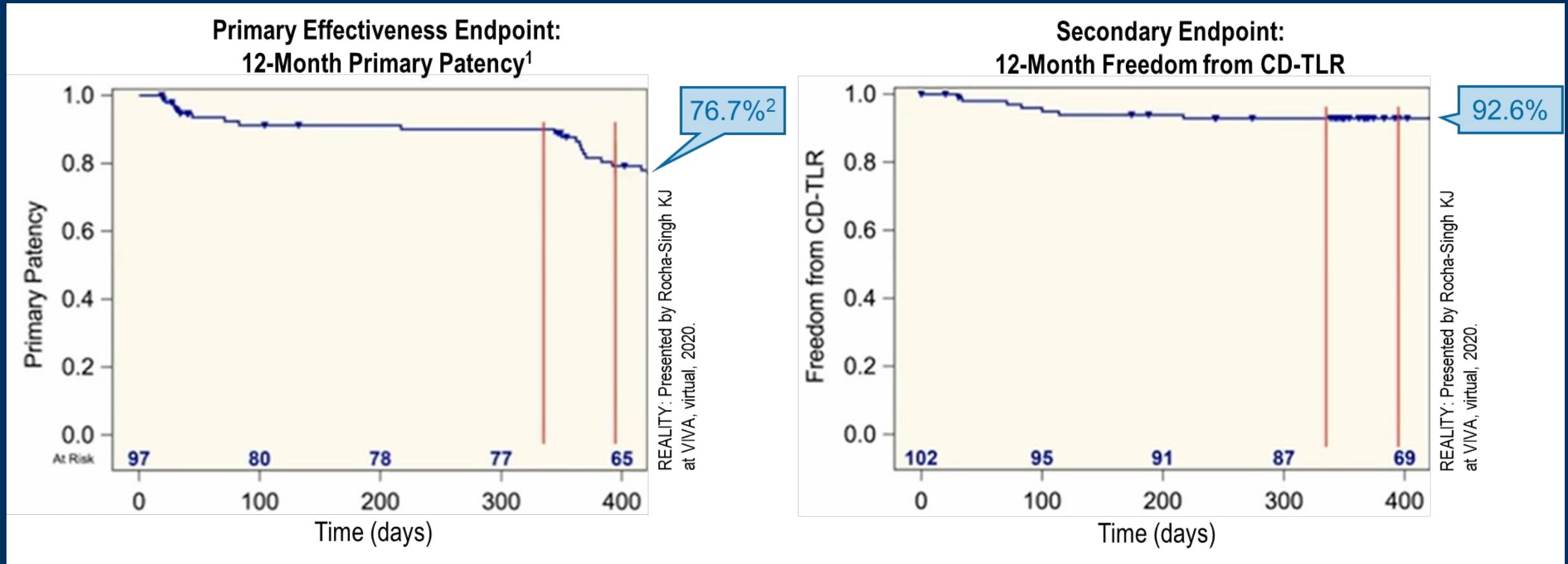
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Procedure-Related Complications

| Procedural Characteristics | |
|-----------------------------------|---------------|
| Perforations | 3.1% (3/98) |
| Dissection \geq Grade C | 14.3% (14/98) |
| Distal Embolization | 12.8% (11/86) |
| Provisional Stenting | 8.8% (9/102) |
| Stenting for Perforations (cases) | 3 |
| Stenting for Dissection (cases) | 5 |
| Stenting for Embolization (cases) | 1 |

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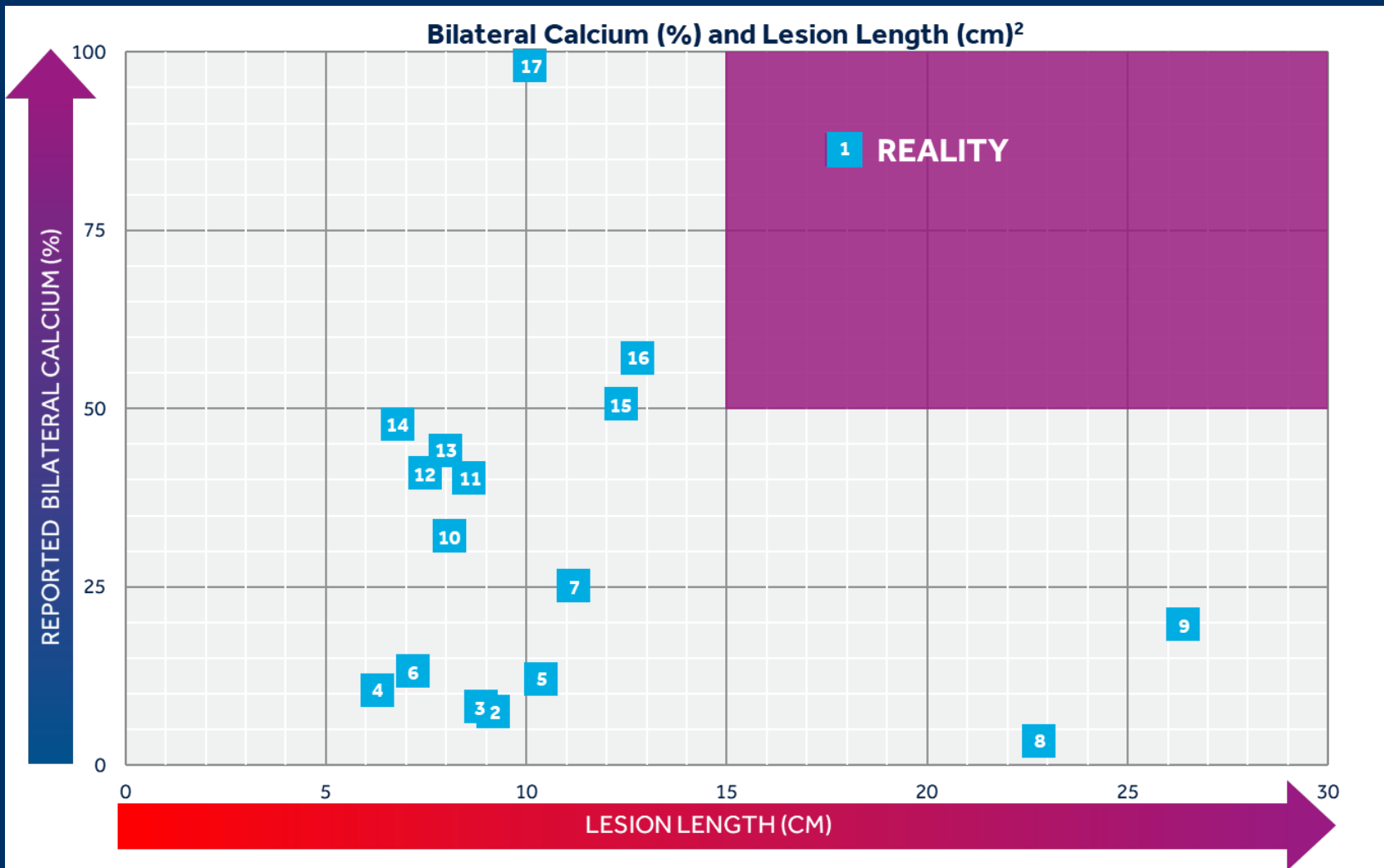
Primary Effectiveness Outcomes



1. Primary patency defined as freedom from restenosis (DUS peak systolic velocity ratio >2.4) and CD-TLR, defined as any reintervention to the target lesion due to a return of symptoms and/or ankle-brachial index (ABI) decrease of 20% or > 0.15 when compared with the post index procedure baseline ABI.
2. 12-month data include patients beyond the follow-up window. Red lines indicate the 12-month follow-up window.

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Summary



UNMATCHED LESIONS

86.2% Bilateral Calcium

17.9c Average Lesion Length

39.0% Chronic Total Occlusion

COMPELLING OUTCOMES

92.6% **76.7%** Patency

12-month data include patients beyond the follow-up window.

PRESERVED TREATMENT OPTIONS

8.8% Bailout stent rate

REALITY: Presented by Rocha-Singh KJ at VIVA, virtual, 2020.

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DiRectional AthErectomy + Drug CoAted BaLloons to Treat Long Calcified Femoropopliteal Artery Lesions - REALITY

Summary:

- The REALITY Study investigated the use of directional atherectomy using HawkOne followed by IN.PACT Admiral DCB in **uniquely long and calcified lesions**
- The REALITY Study demonstrated that this vessel preparation treatment strategy is **effective up to 12-months** with an acceptable safety profile
- The directional atherectomy vessel preparation strategy used in the REALITY Study is associated with a **low provisional stent rate**



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