RPH Research Foundation

# When are Covered Stents The Best Treatment for Aorto-Iliac Occlusive Disease (AIOD)?

**Bibombe P. Mwipatayi**

MMed, MClinEd, FCS, FRACS

PERTH INSTITUTE OF VASCULAR RESEARCH

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# Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- ☒ Consulting – Getinge, Biotronik, Medtronic
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s) – research funding assistance from Atrium Medical Corporation

☐ I do not have any potential conflict of interest

# What are the currently available covered balloon-expandable stents for aorto-iliac occlusive disease (AIOD)?

# iCAST*/ADVANTA V12
# Balloon Expandable Vascular Covered Stent

Atrium Medical (Merrimack NH)

- **PTFE Encapsulation Technology**
- **Stainless steel, single stent, open cell design**
- Low crossing profile - 6 and 7 Fr introducer sheath compatible
- **Radiopaque markers ensure accurate placement during deployment**

* Atrium's iCAST™ balloon expandable covered stent is FDA 510(k) cleared for the treatment of tracheobronchial strictures

# GORE® VIABAHN® VBX

## Balloon Expandable Endoprosthesis

W.L. Gore & Associates (Flagstaff, AZ)

- **Polymer connected individual stainless steel rings with a segmented design**
- Designed to be flexible and conformable
- 7-8 Fr sheath compatible
- **CBAS Heparin Surface technology**

# LIFESTREAM® Balloon Expandable Vascular Covered Stent

Bard Peripheral Vascular, Inc. (Tempe, AZ)

- **Stainless steel, open cell design**
- 6-8 Fr. Sheath compatible
- **Ease of delivery - stent utilizes non-compliant balloon technology**
- Accurate placement
  - Minimal foreshortening
  - **Radiopaque marker bands at stent ends**
  - Optimized balloon design with short balloon shoulders and cones

# BeGraft Peripheral Stent Graft System

Bentley Innomed GmbH (Hechingen, Germany)

- **L-605 Cobalt Chromium single stent, open cell design**
- Low profile - 6 & 7Fr sheath compatible
- **ePTFE covering is fixed from the inside at both stent ends, with bare metal exposed on inner flow surface**
- Low foreshortening allows for predictable stent behavior

# Objective (Literature Review):

Comparison of published studies of covered balloon expandable stents for AIOD

# Studies Included in the Systematic Review

## Particularly robust iCAST/Advanta V12 data

| | iCast/Advanta V12 | Viabahn VBX | Lifestream | BeGraft | Jostent |
|---|---|---|---|---|---|
| Number of studies | 9 | 2 | 1 | 1 | 1 |
| Clinical trials | 3 | 2 | 1 | 1 | 1 |
| Real-world studies* | 6 | 0 | 0 | 0 | 0 |
| Number of patients | 611 | 164 | 155 | 70 | 12 |
| Follow-up (months) | 8 - 60 | 9-12 | 9 | 12 | 6 |

* Retrospective studies.

** Benchmark Device with long term data

# Baseline Characteristics Review

More severe disease in patients from iCAST/Advanta V12 studies than patients with other stents

| | iCast/Advanta V12 | Viabahn VBX | Lifestream | BeGraft | Jostent |
|---|---|---|---|---|---|
| Male | 26.6 – 78.5% (9 studies) | 59 - 60% (2 studies) | 69.0% (1 study) | 64.3% (1 study) | 73.9% (1 study) |
| Occlusion | 8.8 – 63.3% (6 studies) | 9.3 - 13.3% (2 studies) | 10.7% (1 study) | 14.0% (1 study) | NR |

** Benchmark Device with long term data

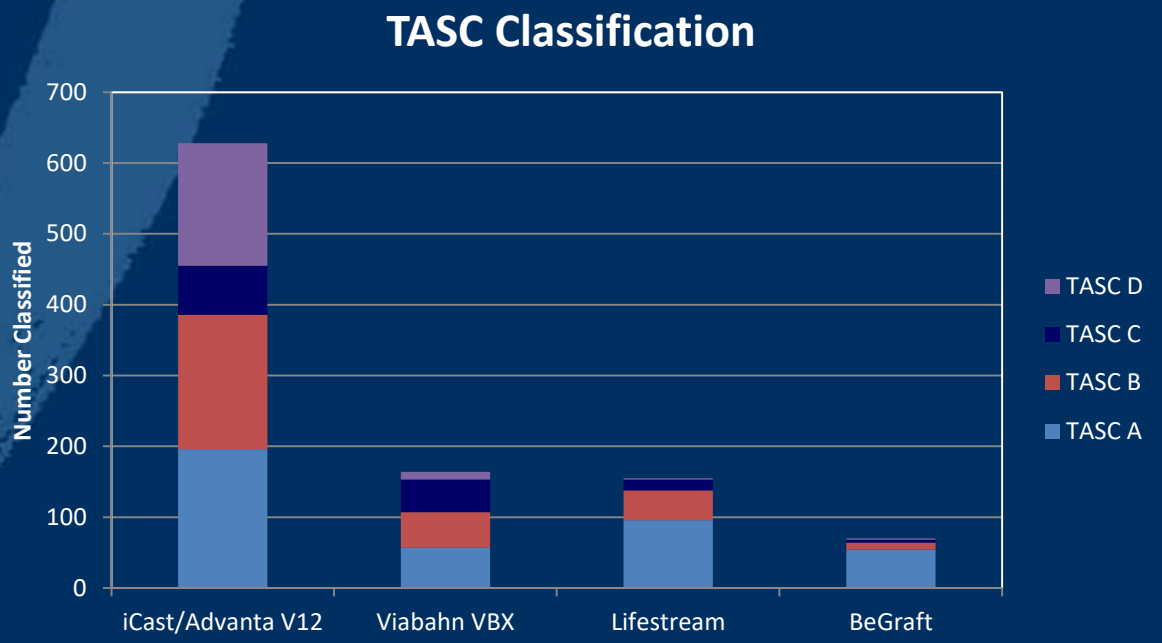
# Baseline Characteristics Review

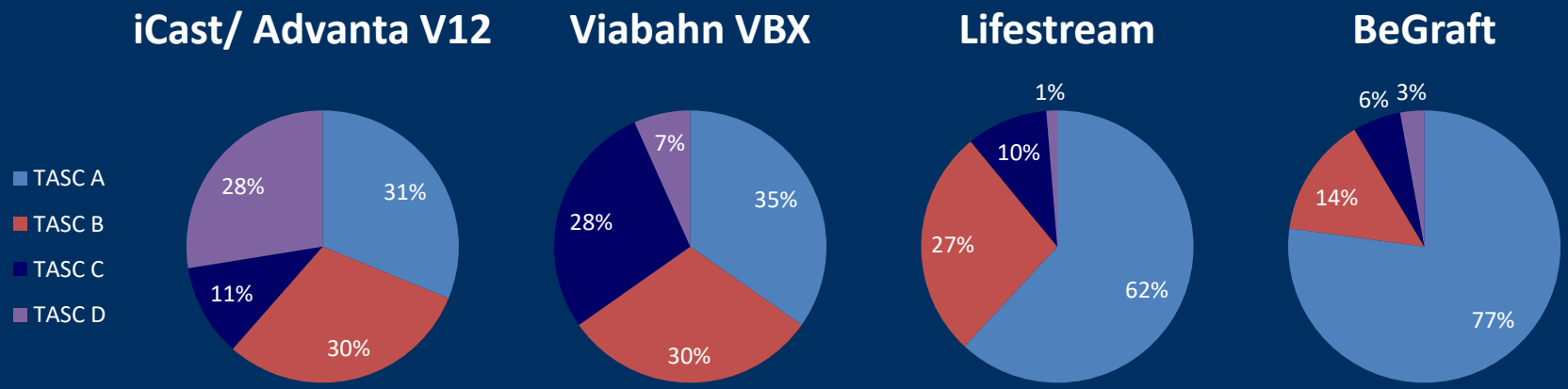
More severe disease in patients from iCAST/Advanta V12 studies than patients with other stents

| Average Lesion Length (mm) | iCast/Advanta V12 | Viabahn VBX | Lifestream | BeGraft |
|---|---|---|---|---|
| Bismuth 2017 | | 26.6 ± 16.3 (n = 209) | | |
| Bosiers 2007 | 42 (n = 91) | | | |
| Deloose 2017 | | | | 34.3 (n = 93) |
| Holden 2017 | | 31.6 (n = 43) | | |
| Humphries 2014 | 42 ± 18 (n = 64) | | | |
| Laird 2019 | 25.4 ± 16.8 (n = 223) | | | |
| Laird 2019 | | | 29.2 ± 17.1 (n = 197) | |

# TASC Classification

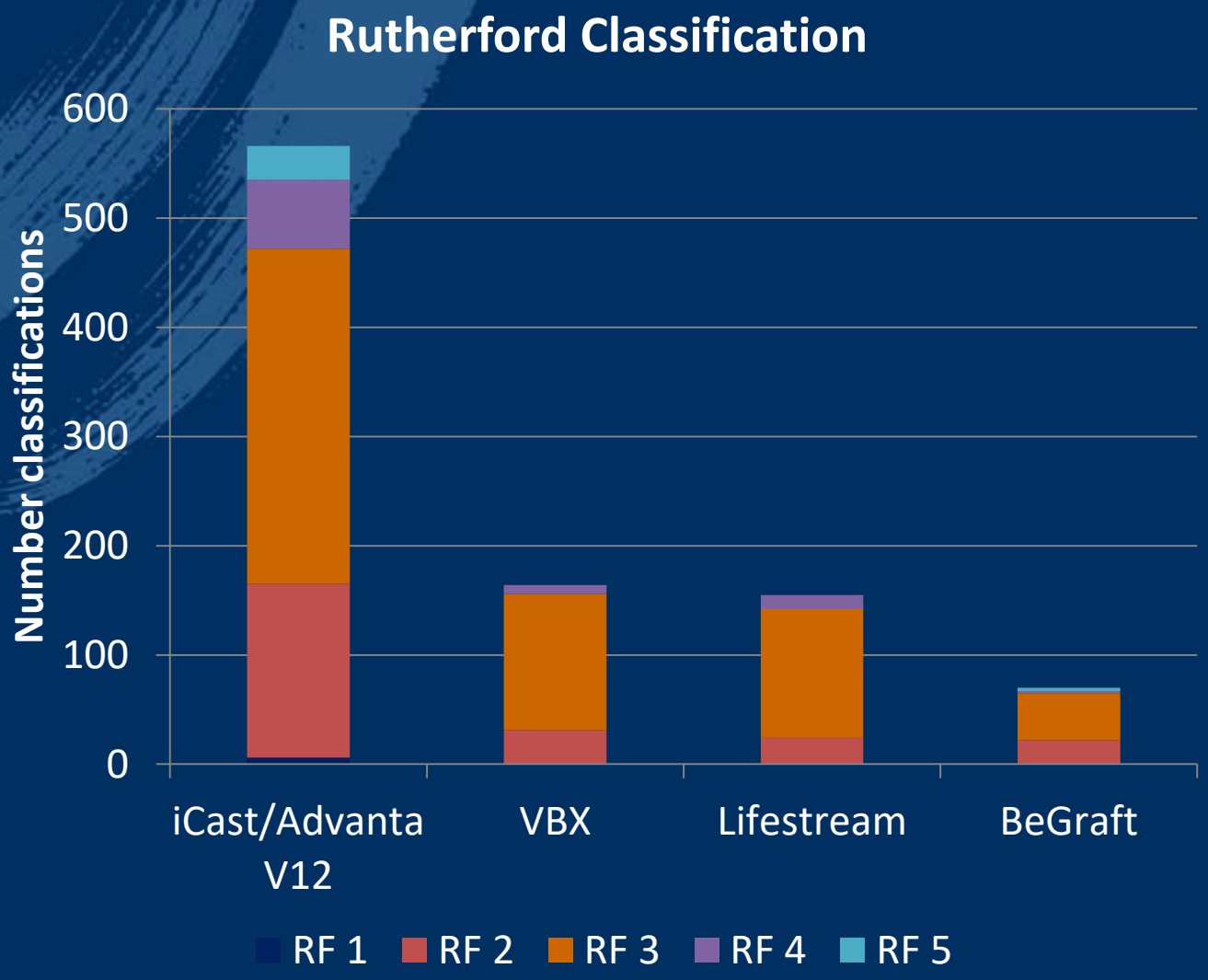
Distribution was comparable in studies evaluating iCAST/Advanta 12 and VBX and included a greater number of TASC C/D lesions than Lifestream or BeGraft studies



# Rutherford Classification

Distribution of Rutherford Classification across studies



# Procedural Complications

**Were comparable and relatively low across all devices**

| | iCast/Advanta V12 | Viabahn VBX | BeGraft | Jostent |
|---|---|---|---|---|
| Procedural Rupture | 0.0 – 1.9% (5 studies) | 0.0% (1 study) | NR | NR |
| Procedural Hematoma | 0.0 – 15.5% (5 studies) | 0.7% (1 study) | | |
| Distal Embolization | 0.0 – 3.8% (5 studies) | 0.0% (1 study) | 0.0% (1 study) | 0.0% (1 study) |

NR, not reported.

** Benchmark Device with long term data

# Primary Patency

*The short-term outcomes are comparable across devices.*
***The Advanta V12/iCAST device is the only device to currently have long-term data****, the interpretation of which is promising*

| | iCast/Advanta V12 | Viabahn VBX | Lifestream | BeGraft | Jostent |
|---|---|---|---|---|---|
| | (9 studies) | (2 studies) | (1 study) | (1 study) | (1 study) |
| Technical success, range | 95.0 – 100% | 100% | 98.3% | 100% | 100% |
| Primary patency, range | | | | | |
| 6 months | 87.2 – 97.0% | 100% | NR | NR | 92% |
| 9 months | 96.4% | 96.7% | 89.1% | | NA |
| 12 months | 83.6 – 96.4% | 96.6% | NA | 94.4% | |
| 18 months | 77.0 – 87.3% | NA | | NA | |
| 24 months | 68.0 – 84.0% | | | | |
| 36 months | 72.0% | | | | |
| 48 months | 63.4 – 79.9% | | | | |
| 60 months | 74.7% | | | | |

NA, not available; NR, not reported.

# Freedom From TLR

*The short-term outcomes are comparable across devices.*
***The Advanta V12/iCAST device is the only device to currently have long-term data****, the interpretation of which is promising*

| | iCast/Advanta V12 | Viabahn VBX | Lifestream | BeGraft | Jostent |
|---|---|---|---|---|---|
| **Freedom from TLR, range** | | | | | |
| **6 months** | 92.4 – 99.3% | 100.0% | 98.1% | NA | NA |
| **9 months** | 97.2% | 97.4% | 96.1% | | |
| **12 months** | 88.2 – 94.3% | 96.6% | NA | 96.7% | |
| **24 months** | 85.6 – 88.3% | NA | | NA | |
| **36 months** | 86.6% | | | | |
| **48 months** | 67.4% | | | | |

NA, not available; NR, not reported.

# CONCLUSIONS: CBES IN AOID

- Covered balloon expandable stents are effective treatment options for AIOD as evidenced by the high rates of technical success and patency at 12 months and up to 5 years (**).
- The Advanta V12/iCAST device is the only balloon expandable covered stent to have long-term, real-world follow-up, the results of which were favorable.
- Further randomized trials and comparative meta-analysis publications are needed to evaluate long-term outcomes for all devices.

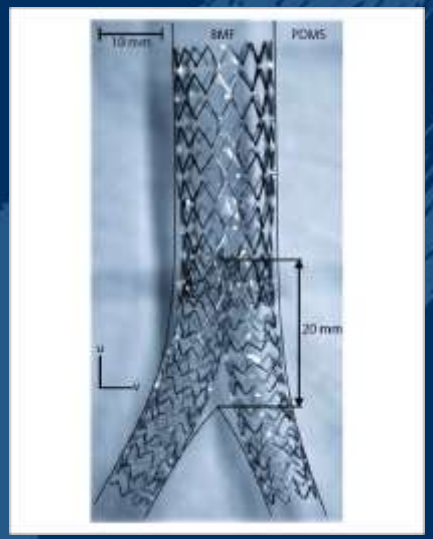
# BEAST STUDY:

GAMECHANGER

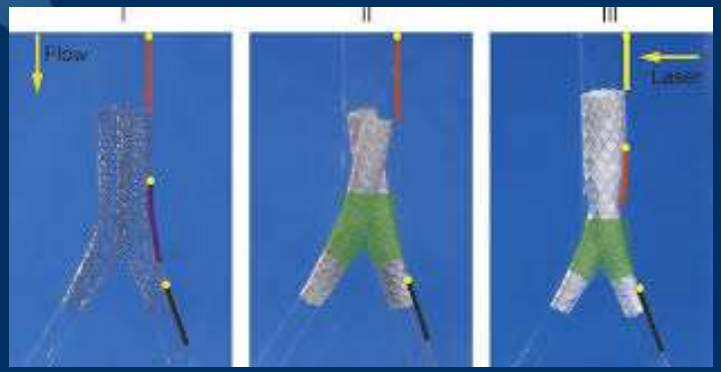
**B**alloon **E**xpandable **A**ortoiliac **S**tenting **T**rial

A prospective analysis comparing the CERAB-technique with parallel aorto-iliac stenting for the treatment of aorto-iliac occlusive disease.

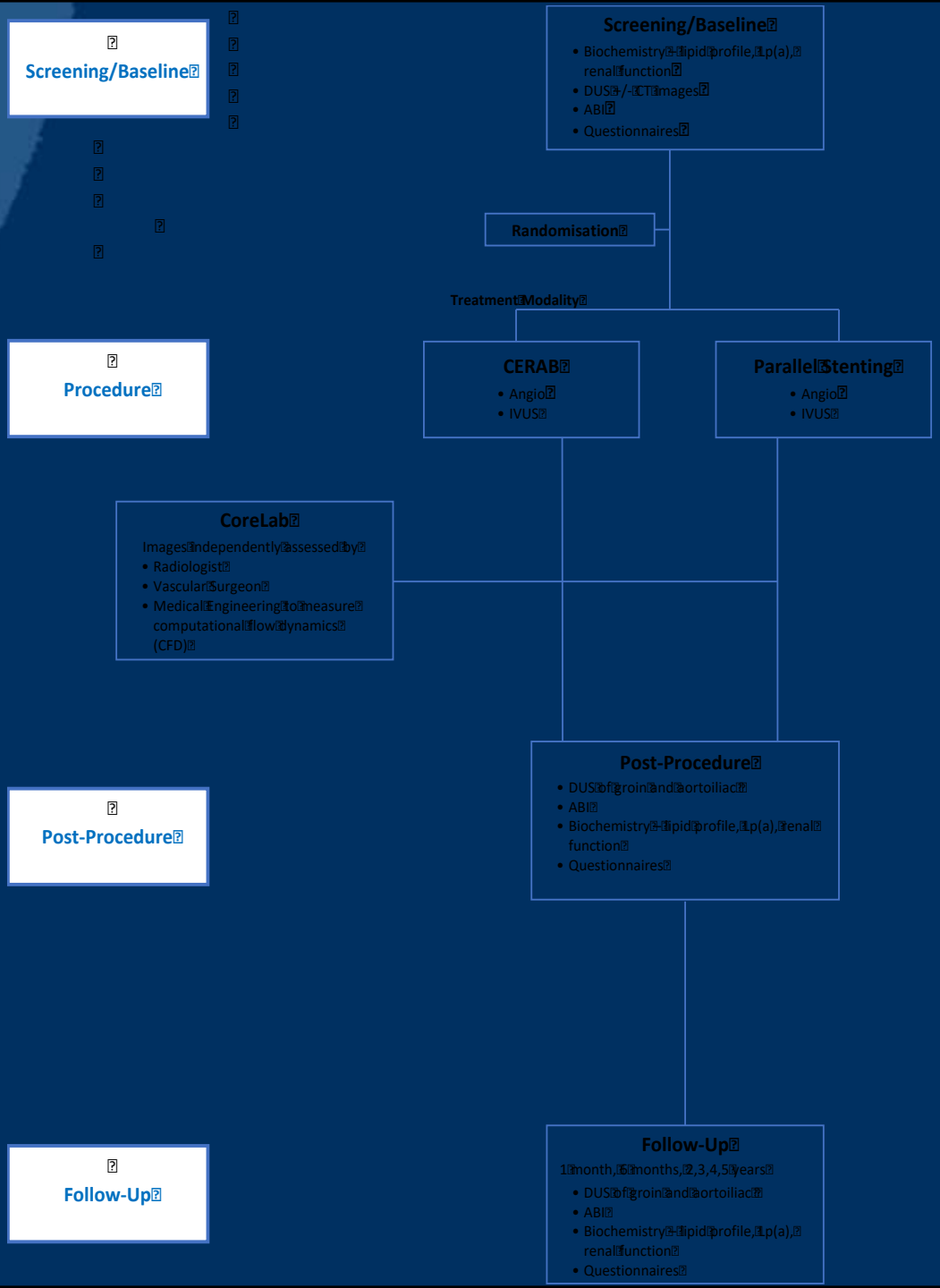
# HYPOTHESIS




Do Patients with TASC C and D lesions with disease extending to the aorta have better results in the short and long terms with the CERAB technique than the Kissing Stent technique?



# FLOW CHART


Screening/Baseline
Screening/Baseline
• Biochemistry (+ lipid profile, Lp(a), renal function)
• DUS (+/- CT images)
• ABI
• Questionnaires
Randomisation
Treatment Modality
Procedure
CERAB
• Angio
• IVUS
Parallel Stenting
• Angio
• IVUS
CoreLab
Images independently assessed by
• Radiologist
• Vascular Surgeon
• Medical Engineering to measure computational flow dynamics (CFD)
Post-Procedure
• DUS of groin and aortoiliac
• ABI
• Biochemistry (+ lipid profile, Lp(a), renal function)
• Questionnaires
Post-Procedure
Follow-Up
1 month, 6 months, 2, 3, 4, 5 years
• DUS of groin and aortoiliac
• ABI
• Biochemistry (+ lipid profile, Lp(a), renal function)
• Questionnaires
Follow-Up

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# THANK YOU

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