SURGICAL & RADIOLOGICAL ENDOVASCULAR SYMPOSIUM
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*Nouveautés*

# Comment traiter les lésions calcifiées des artères de jambe?

**Drs Bogdan BRICIU, Philippe CHAMMAS, Louis DELMAS, Gilles GOYAULT, Olivier STEINBERGER, Bernard WOERLY**

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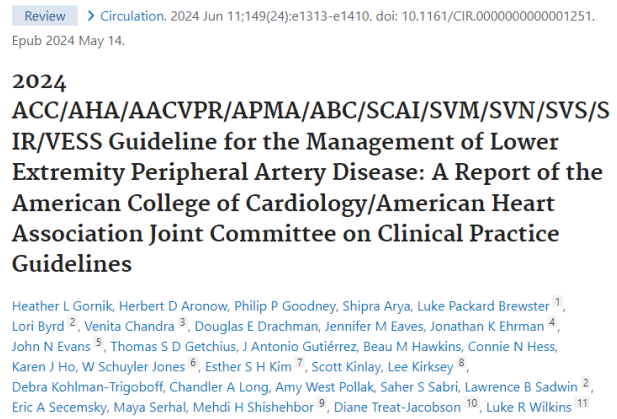
Rhëna
CLINIQUE DE STRASBOURG

ics
Institut Cardiovasculaire de Strasbourg

# Angioplastie des artères de jambe

- Patients en ischémie critique
  - *Douleurs de repos*
  - *Troubles trophiques*
- 50% d'amputation à 2 ans – mortalité de 20% à 1 an après amputation
- Patients âgés, fragiles et souvent diabétiques++
- Lésions calcifiées et diffuses
- Revascularisation rapide et efficace indispensable



Review > Circulation. 2024 Jun 11;149(24):e1313-e1410. doi: 10.1161/CIR.0000000000001251. Epub 2024 May 14.

**2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines**

Heather L Gornik, Herbert D Aronow, Philip P Goodney, Shipra Arya, Luke Packard Brewster [1], Lori Byrd [2], Venita Chandra [3], Douglas E Drachman, Jennifer M Eaves, Jonathan K Ehrman [4], John N Evans [5], Thomas S D Getchius, J Antonio Gutiérrez, Beau M Hawkins, Connie N Hess, Karen J Ho, W Schuyler Jones [6], Esther S H Kim [7], Scott Kinlay, Lee Kirksey [8], Debra Kohlman-Trigoboff, Chandler A Long, Amy West Pollak, Saher S Sabri, Lawrence B Sadwin [2], Eric A Secemsky, Maya Serhal, Mehdi H Shishehbor [9], Diane Treat-Jacobson [10], Luke R Wilkins [11]

# Problématique de l'angioplastie au ballon simple

Eur J Vasc Endovasc Surg. 2012 Oct;44(4):425-31. doi: 10.1016/j.ejvs.2012.07.017. Epub 2012 Aug 28.

**Angiographic restenosis and its clinical impact after infrapopliteal angioplasty.**

Iida O, Soga Y, Kawasaki D, Hirano K, Yamaoka T, Suzuki K, Miyashita Y, Yokoi H, Takahara M, Uematsu M.

**RESULTS:** 95% of cases had 3-month angiography; **restenosis** rate was 73%: 40% **restenosis** and 33% re-occlusion. Twelve-month follow-up angiography was conducted for the patients without 3-month **angiographic restenosis**, and **restenosis** rate at 12 months was 82%. Non-administration of cilostazol and statin, and chronic total occlusion were 3-month **angiographic restenosis** predictors. Three- and 12-month mortality was 5% and 12%, respectively. Despite no patients having undergone amputation, 15% had persistent ischemic symptoms, and 48% of limbs underwent reintervention within 12 months. During the same study period, ambulatory status and limbs with complete healing were more frequently observed in the non-**restenosis** group than in the **restenosis** group. In the tissue loss group, time to wound healing in the **restenosis** group was longer than in the non-**restenosis** group (127 days vs. 66 days, p = 0.02).

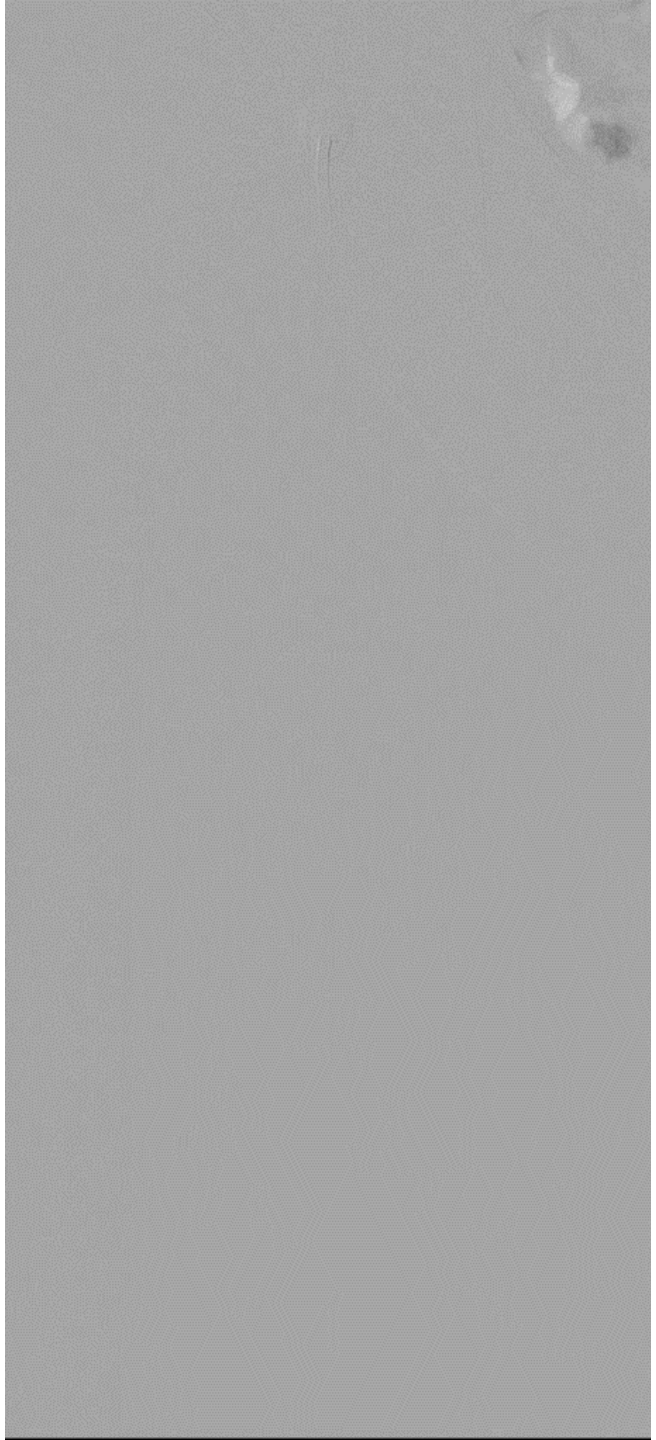
Réinterventions ↗ coût et ↘ QoI des patients

# Étapes du traitement endovasculaire

- Accès
- Franchissement
- Préparation du vaisseau
- Traitement de la lésion

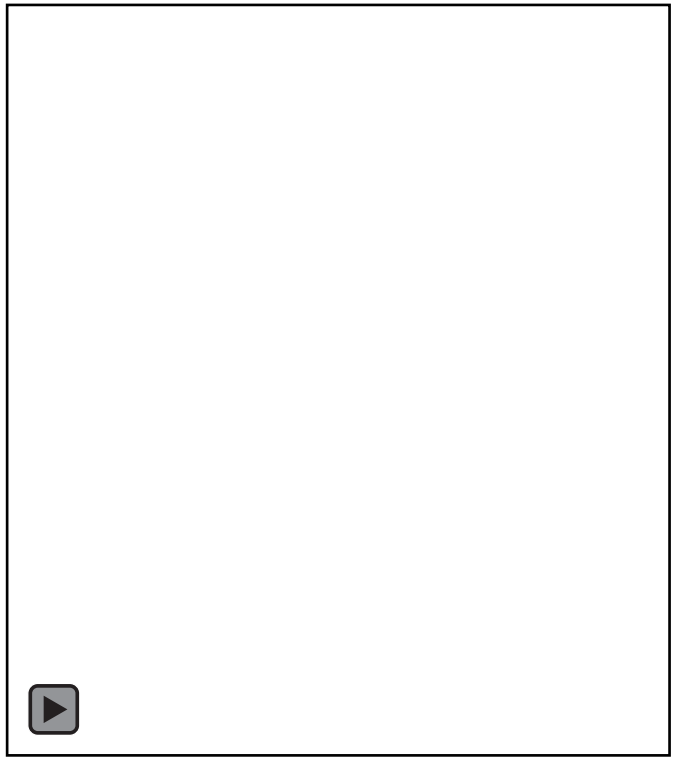
# Étapes du traitement endovasculaire

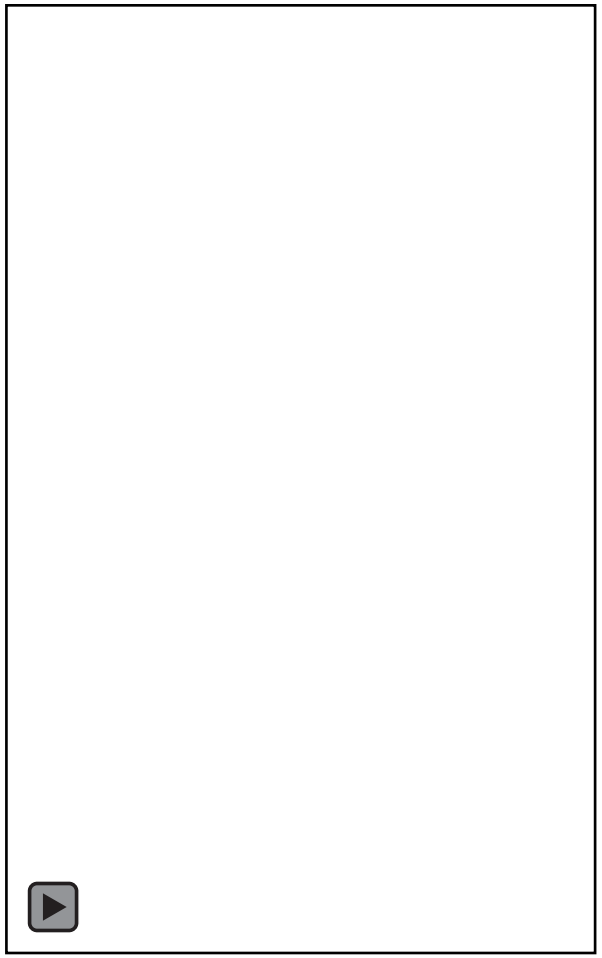
- **Accès**
  - *Antégrade*
- Franchissement
- Préparation du vaisseau
- Traitement de la lésion



# Étapes du traitement endovasculaire

- Accès : antégrade
- **Franchissement :**
  - *Intraluminal*
  - *Sous-intimal*
  - *Rétrograde*
  - *Réentrée*
- Préparation du vaisseau
- Traitement de la lésion





# Étapes du traitement endovasculaire

- Accès
- Franchissement
- **Préparation du vaisseau**
  - *Réduire le volume de la plaque*
  - *Modifier la compliance du vaisseau*
- Traitement de la lésion

Diminuer dissection, recoil, sténose résiduelle

+/- Améliorer la pénétration de la drogue

# Dispositifs de préparation du vaisseau actuellement disponibles

| | PTA | Ballons spécialisés | Athérectomie rotationnelle | | | Athérectomie orbitale | IVL | Athérectomie directionnelle | Athérectomie Laser |
|---|---|---|---|---|---|---|---|---|---|
| | | | Jetstream | Phoenix | Rotarex | | | | |
| **Intro** | From 4Fr | From 5Fr | 7Fr | 5 to 7Fr | 6 - 8Fr | 6Fr | 6 - 7Fr | 6 - 7Fr | 4 to 8Fr |
| **Intraluminal** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| **Sous-intimal** | ✓ | ✓ | | | | | ✓ | | |
| **Réduction plaque** | | | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ |
| **$CA^{++}$** | ± | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |
| **Aspiration** | | | ✓ | | ✓ | | | | |
| **Filtre distal** | | | ± | ± | | | | ✓ | |
| **Occlusion** | ✓ | ✓ | ✓ | ✓ | ✓ | ± | ± | | |
| **RIS/thrombose** | ± | ± | ✓ | | ✓ | | | | ✓ |
| **BTK** | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |

# Dispositifs de préparation du vaisseau actuellement disponibles

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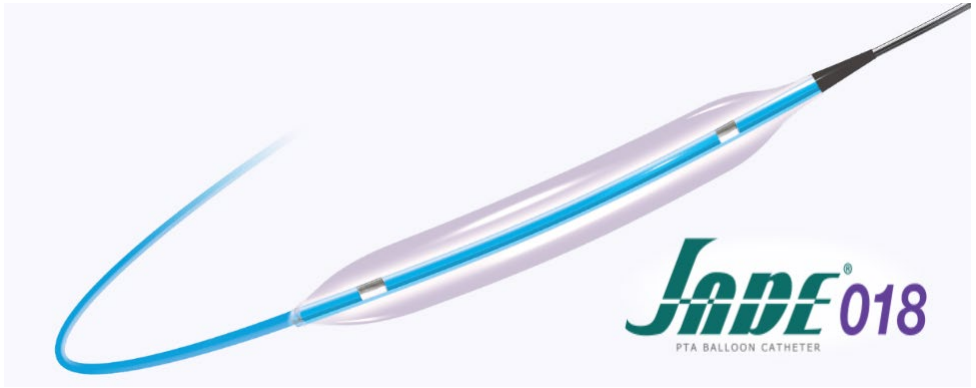
| **RIS/thrombose** | ± | ± | ✓ | | ✓ | | | | ✓ |
| **BTK** | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |

# Ballons spécialisés

- **Ballons non compliants**



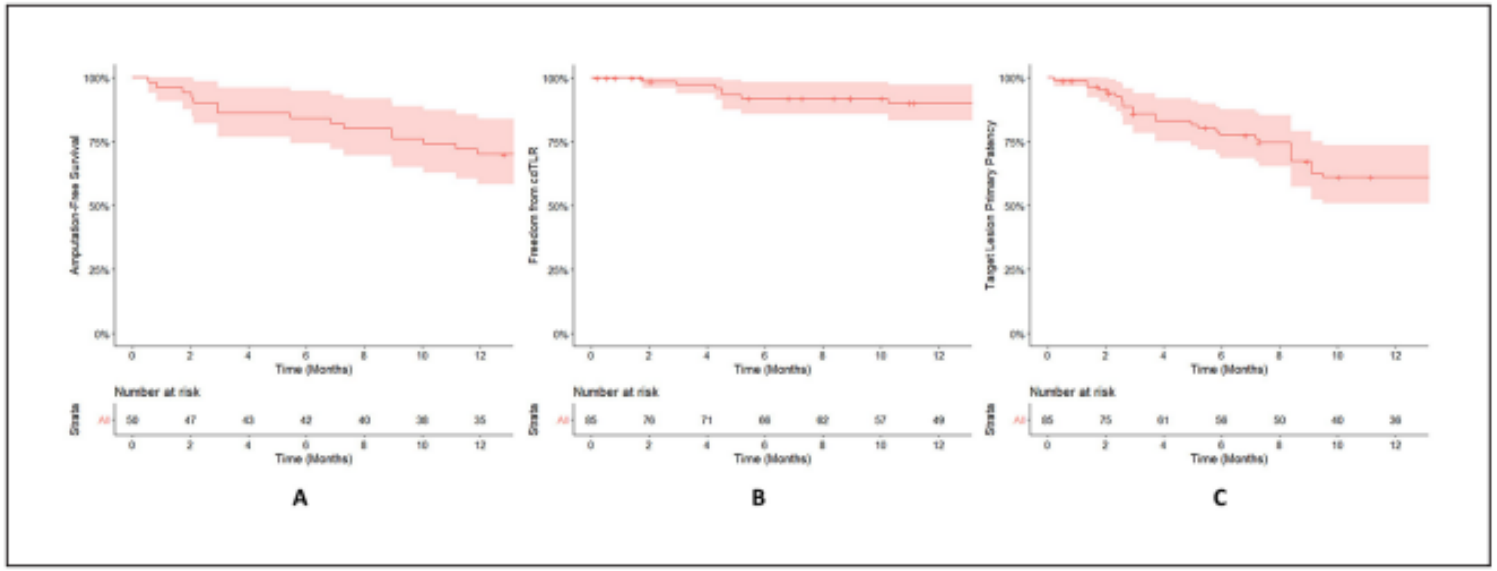




**Figure 1.** Amputation -Free Survival rate (A), Freedom from Clinically Driven Targent Lesion Revascularization rate (B) and Target Lesion Primary Patency rate (C) at 12 months calculated by Kaplan-Meier analysis were 70% (95% CI, 58.4 – 83.9%), 90.1% (95% CI, 83.4 – 97.4%) and 61.1% (95% CI, 50.7 – 73.6%) respectively.

Prospective monocentrique

50 patients – 85 lésions

Rutherford 5-6

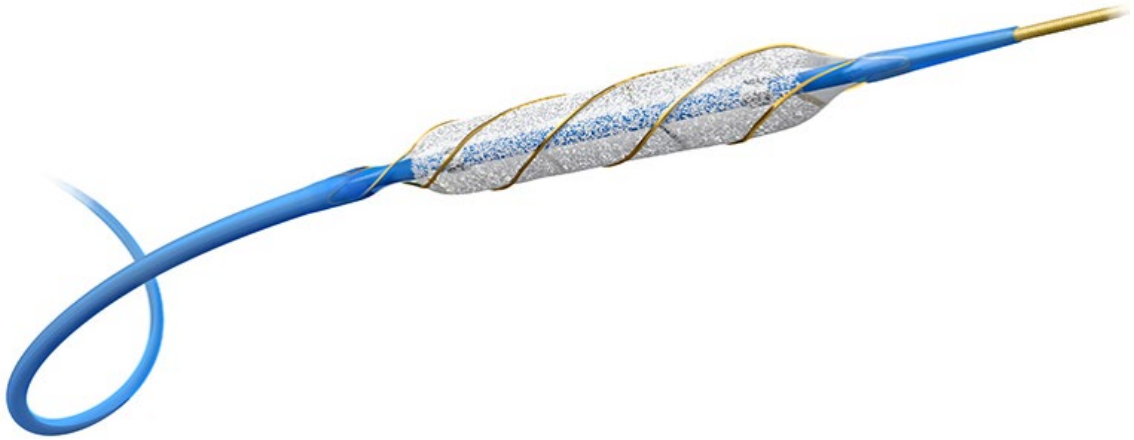
Ballon non compliant seul

J Endovasc Ther. 2024 Aug 10:15266028241268828. doi: 10.1177/15266028241268828. Online ahead of print.

## Outcomes of Noncompliant Balloons in the Treatment of Lower Extremity Chronic Limb Threatening Ischemia: A Prospective Study

Hao Yun Yap [1], Tjun Yip Tang [2], Charyl Yap [1], Sze Ling Chan [3], Tze Tec Chong [1]

# Ballons spécialisés



- Ballons non compliants
- **Scoring balloons**
  - ***Angiosculpt (Philips)***
  - Scoreflex (OrbusNeich)
  - Naviscore (iVascular)
  - Ultrascore (BD)
  - Cutting balloon (BSc)
  - Serrenator (Cagent Vascular)
  - Spur (Reflow Medical)

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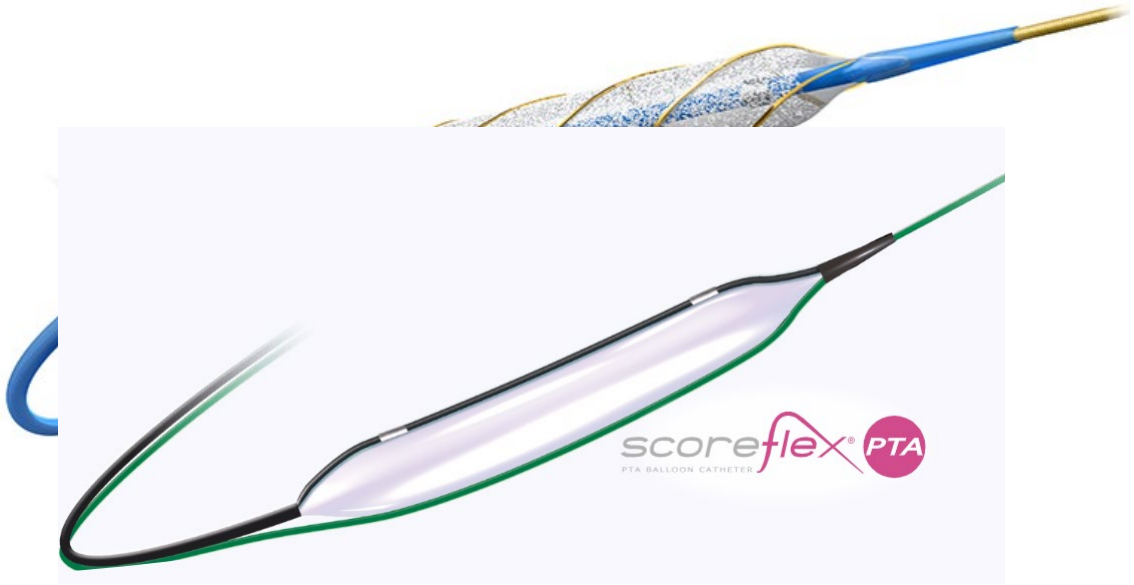

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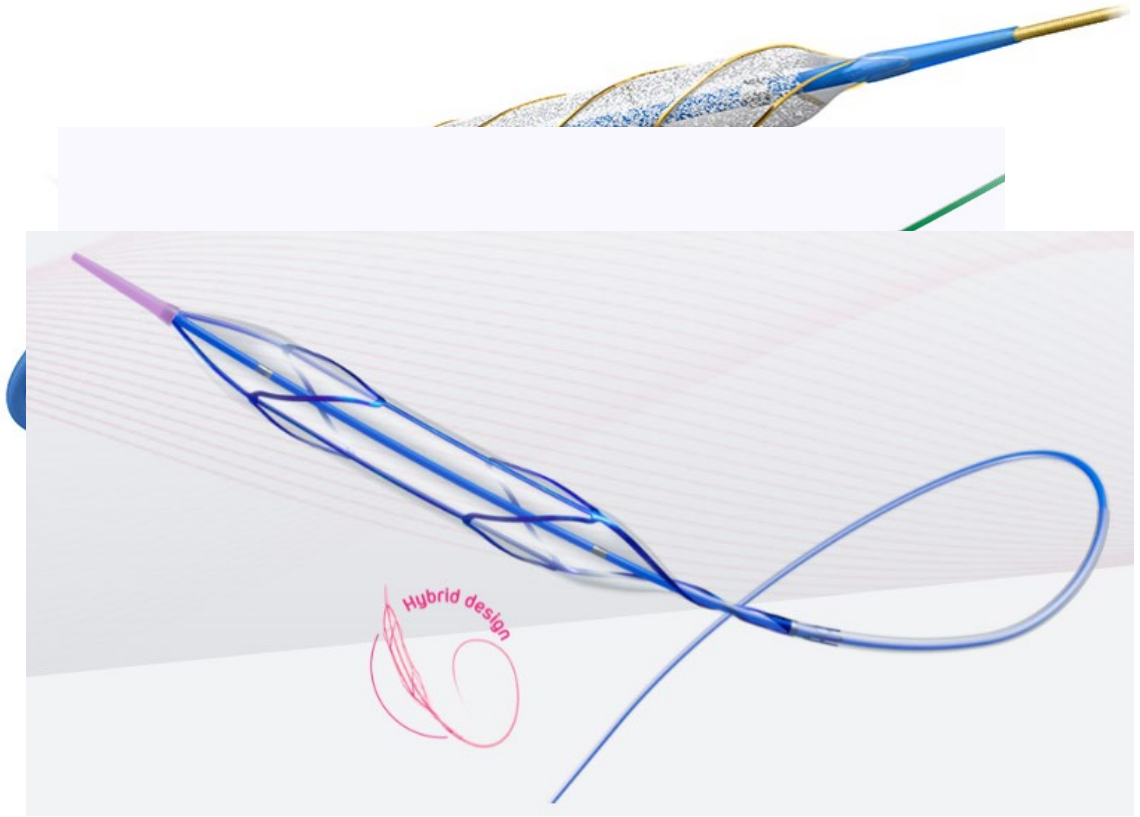

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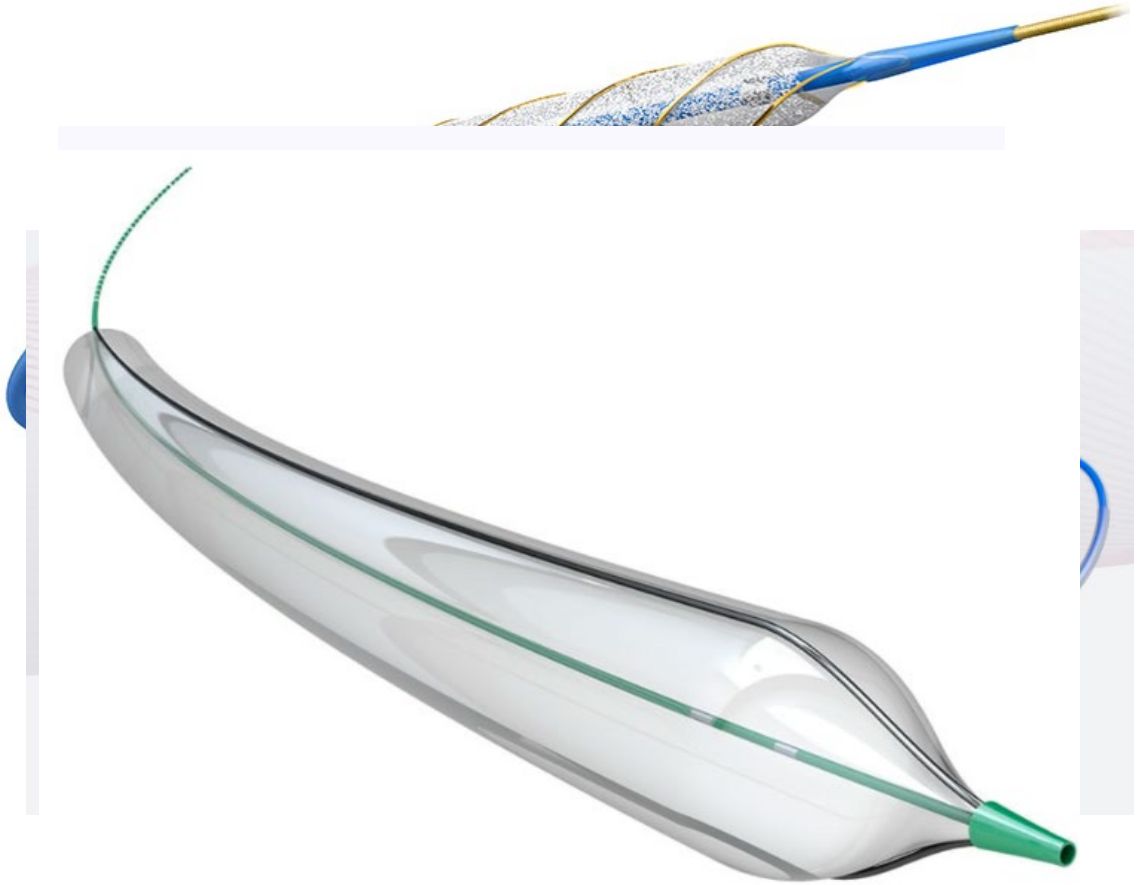

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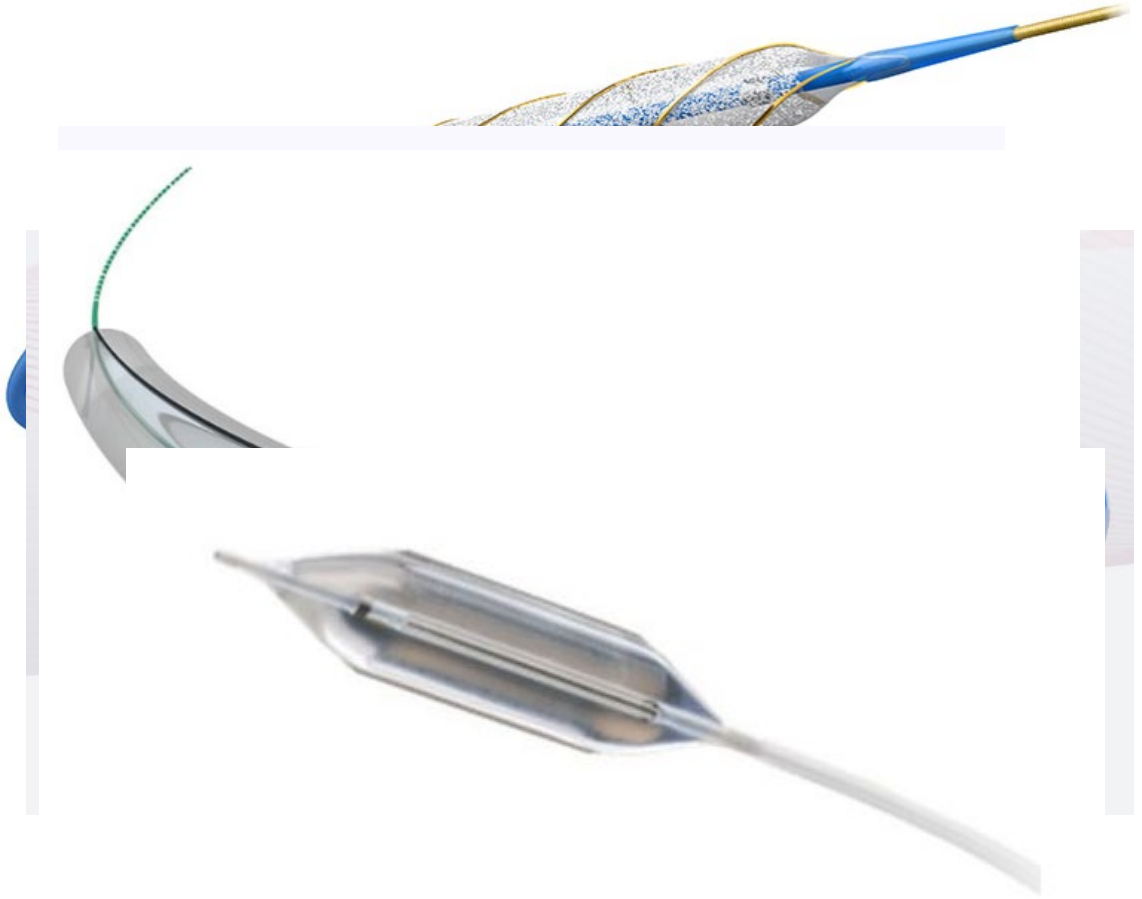
  - Ultrascore (BD)
  - ***Cutting balloon (BSc)***
  - Serrenator (Cagent Vascular)
  - Spur (Reflow Medical)



# Ballons spécialisés

- Ballons non compliants
- **Scoring balloons**
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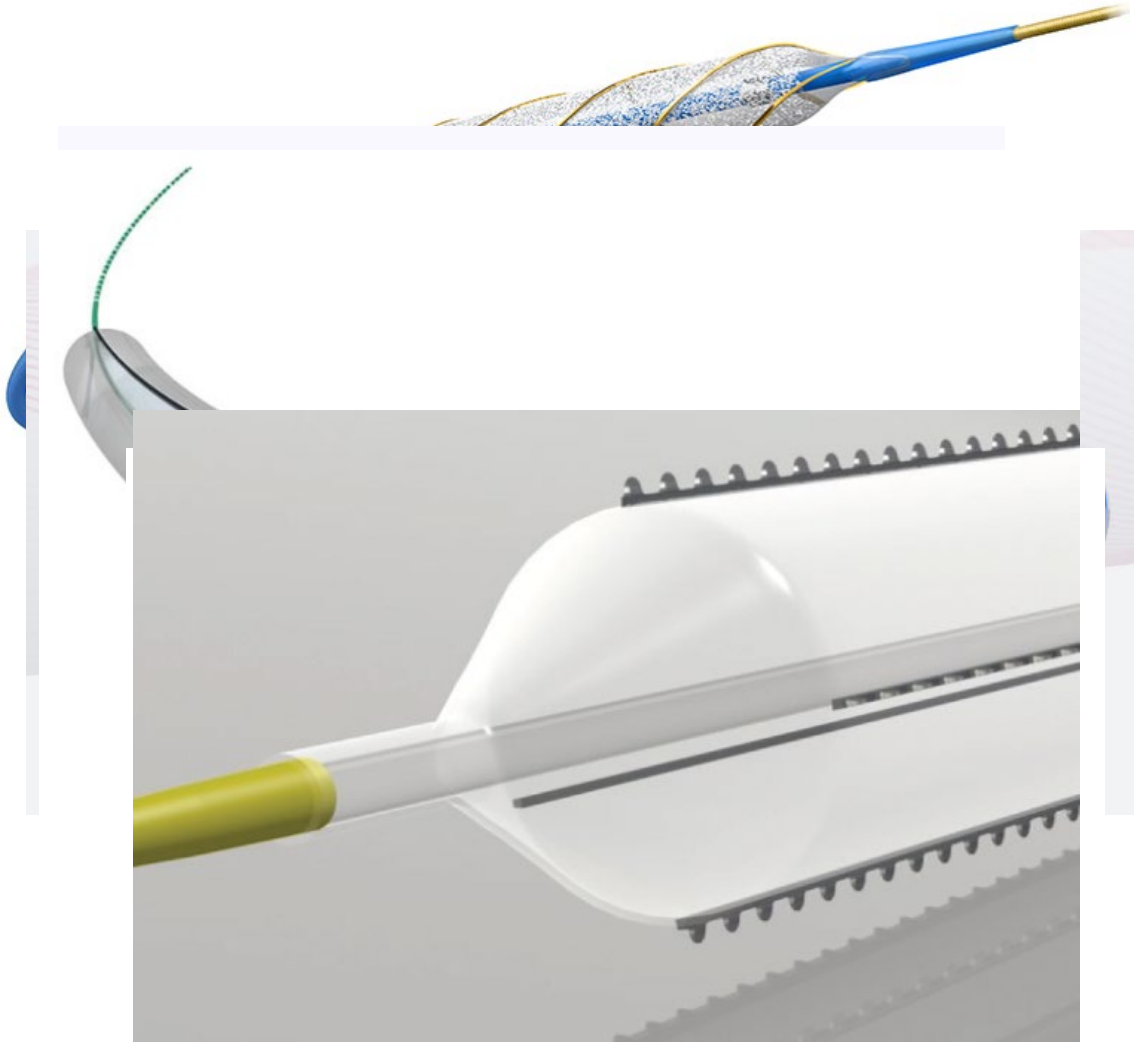

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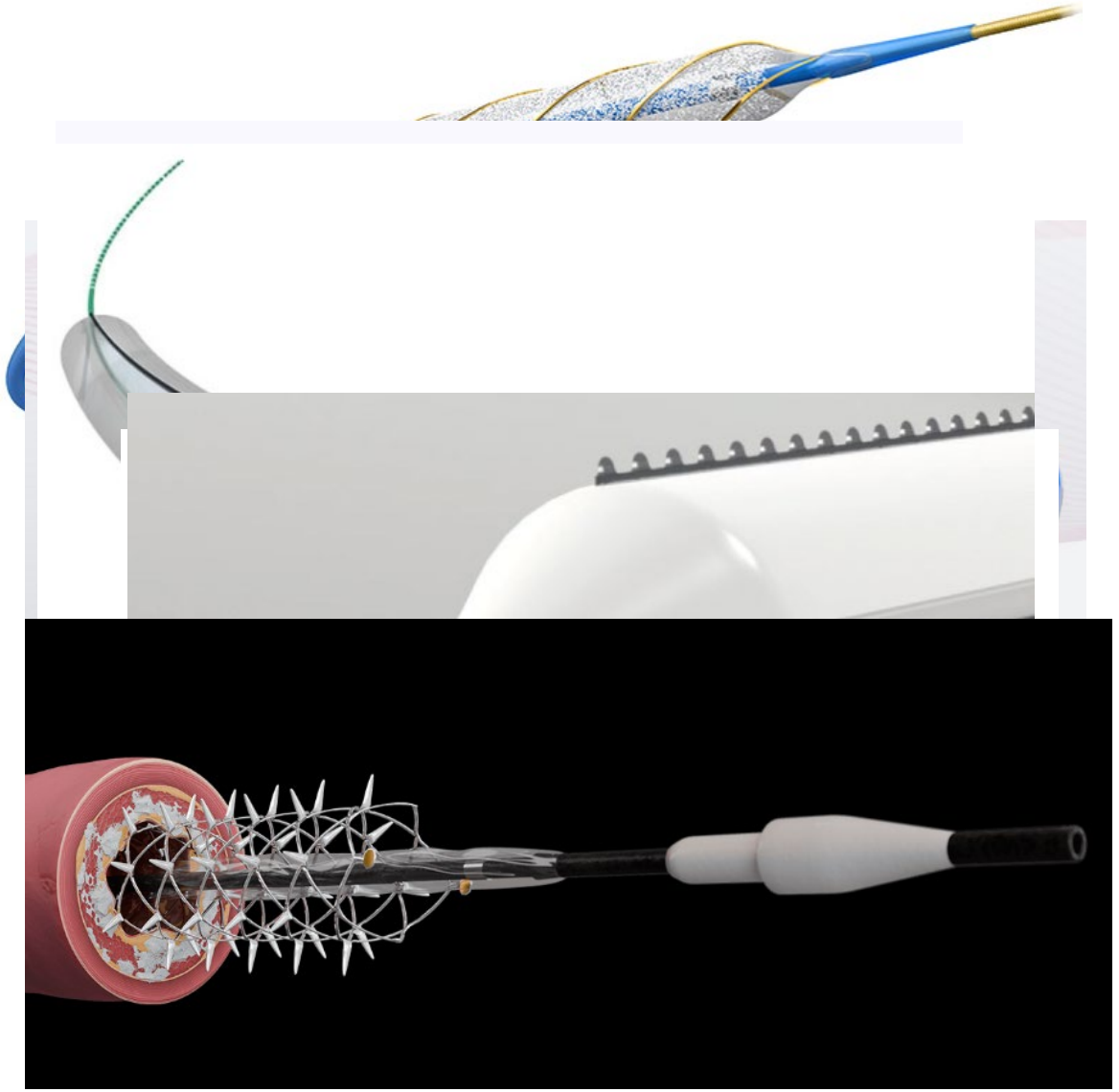


## DEEPER OUS

Prospective, multicenter, single-arm, performance goal comparator

### 12-MONTH RESULTS[1]

74.4% — PATENCY OF LESIONS (DUS)

98.9% — FREEDOM FROM MALE

89.5% — FREEDOM FROM CD-TLR

**RUTHERFORD SCORE IMPROVEMENT**
**58.4%**
improvement in mean Rutherford score from the baseline

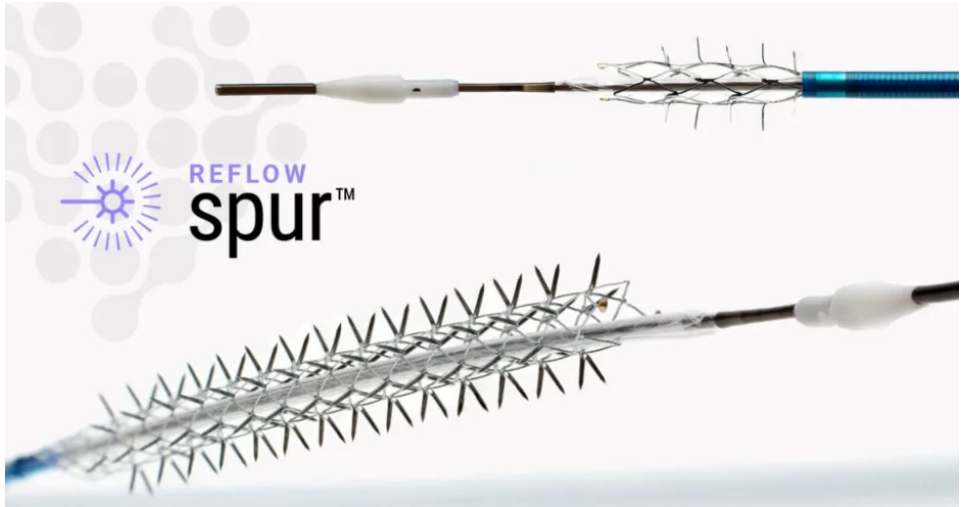
**WOUND SIZE REDUCTION**
**63.1%**
Reduction

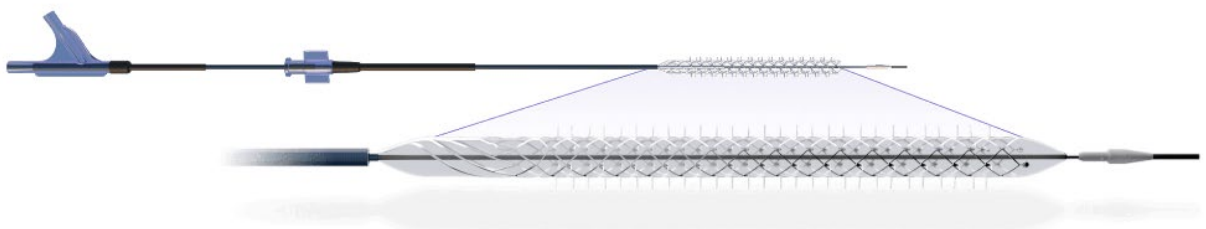
**STUDY DEVICES**
Spur + paclitaxel-coated DCB*

**STUDY SIZE**
107 patients enrolled
10 centers (EU + NZ)

**BASELINE LESION CHARACTERISTICS**
21% total occlusions
21% moderately/severely calcified lesions

**92.7mm (60-240mm)**
mean Spur-treated length (range)



## DEEPER LIMUS

Prospective, single-center, pilot, single arm

### 12-MONTH RESULTS[2]

89.5% — PATENCY OF LESIONS (DUS)

95.5% — FREEDOM FROM MALE

95.2% — FREEDOM FROM CD-TLR

**RUTHERFORD SCORE IMPROVEMENT**
**68.2%**
subjects improved to Rutherford classification 0

**WOUND SIZE REDUCTION**
**54.0%**
Reduction

**STUDY DEVICES**
Spur + sirolimus-coated DCB**

**STUDY SIZE**
26 patients enrolled
1 center (Austria)

**BASELINE LESION CHARACTERISTICS**
37% total occlusions

**97mm (60-210mm)**
mean Spur-treated length (range)

# Dispositifs de préparation du vaisseau actuellement disponibles

| | PTA | Ballons spécialisés | Athérectomie rotationnelle | | | Athérectomie orbitale | IVL | Athérectomie directionnelle | Athérectomie Laser |
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| **Intraluminal** | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| **Sous-intimal** | ✓ | ✓ | | | | | ✓ | | |
| **Réduction plaque** | | | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ |
| **$CA^{++}$** | ± | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |
| **Aspiration** | | | ✓ | | ✓ | | | | |
| **Filtre distal** | | | ± | ± | | | | ✓ | |
| **Occlusion** | ✓ | ✓ | ✓ | ✓ | ✓ | ± | ± | | |
| **RIS/thrombose** | ± | ± | ✓ | | ✓ | | | | ✓ |
| **BTK** | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |

# Lithotripsie intra-vasculaire (IVL)


Clinical Trial > J Endovasc Ther. 2018 Aug;25(4):499-503. doi: 10.1177/1526602818783989. Epub 2018 Jun 18.

## Safety and Feasibility of Intravascular Lithotripsy for Treatment of Below-the-Knee Arterial Stenoses

Marianne Brodmann [1], Andrew Holden [2], Thomas Zeller [3]

Observational Study > J Endovasc Ther. 2022 Feb;29(1):76-83. doi: 10.1177/15266028211032953. Epub 2021 Aug 12.

## Intravascular Lithotripsy for Treatment of Calcified Infrapopliteal Lesions: Results from the Disrupt PAD III Observational Study

George Adams [1], Peter A Soukas [2], Anderson Mehrle [3], Barry Bertolet [4], Ehrin J Armstrong [5]

# Dispositifs de préparation du vaisseau actuellement disponibles

| | PTA | Ballons spécialisés | Athérectomie rotationnelle | | | Athérectomie orbitale | IVL | Athérectomie directionnelle | Athérectomie Laser |
|---|---|---|---|---|---|---|---|---|---|
| | | | Jetstream | Phoenix | Rotarex | | | | |
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| **Sous-intimal** | ✓ | ✓ | | | | | ✓ | | |
| **Réduction plaque** | | | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ |
| **$CA^{++}$** | ± | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |
| **Aspiration** | | | ✓ | | ✓ | | | | |
| **Filtre distal** | | | ± | ± | | | | ✓ | |
| **Occlusion** | ✓ | ✓ | ✓ | ✓ | ✓ | ± | ± | | |
| **RIS/thrombose** | ± | ± | ✓ | | ✓ | | | | ✓ |
| **BTK** | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ |

# Que penser des dispositifs de préparation du vaisseau?

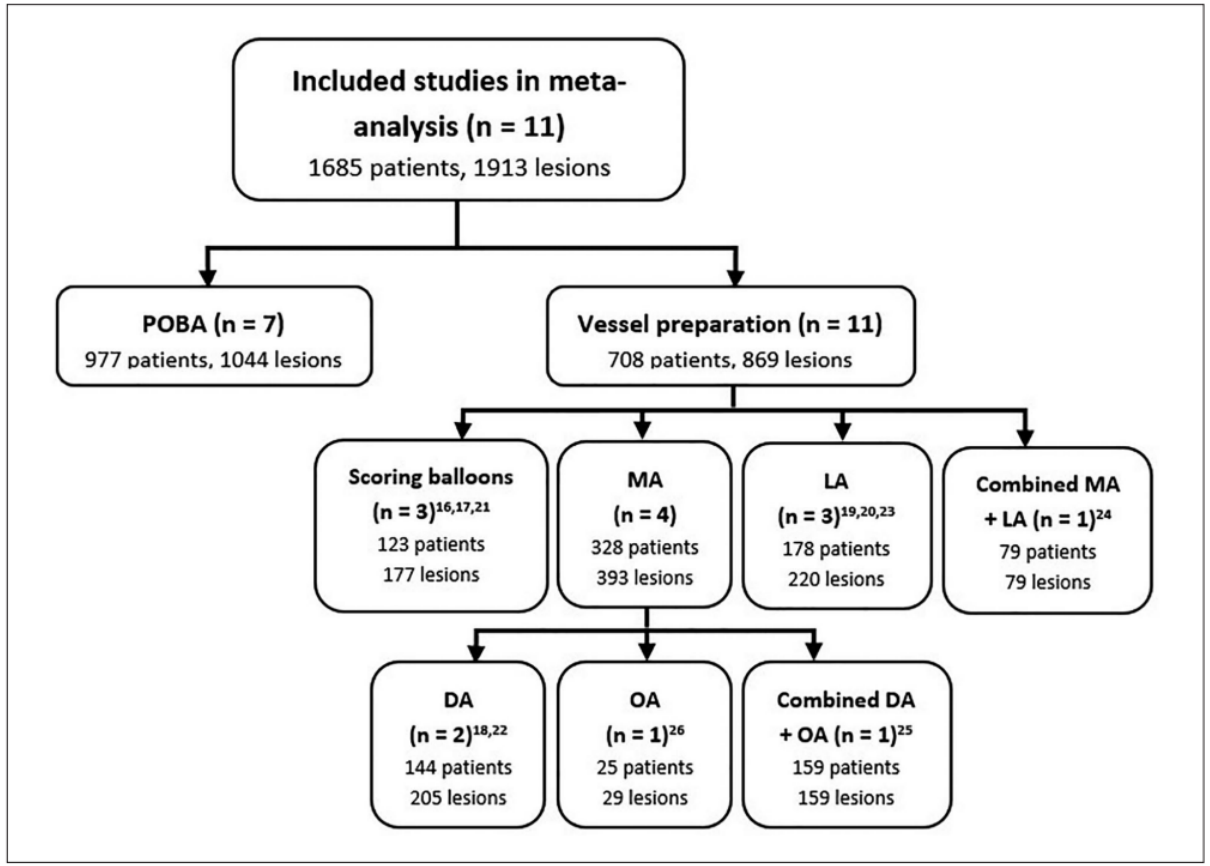



**Figure 2.** Patient distribution per endovascular technique in this meta-analysis. DA, directional atherectomy; LA, laser atherectomy; MA, mechanical atherectomy; OA, orbital atherectomy; POBA, plain old balloon angioplasty.

Different forms of adjunctive vessel preparation demonstrate similar 12-month outcomes compared to POBA or DCB angioplasty alone in infrapopliteal disease, with the exception of improved 12-month limb salvage in scoring balloons and MA. However, this finding should be interpreted with great caution, since the included studies were heterogeneous and assessed as poor to moderate quality on the MINORS score. Therefore, selection bias may have played an important role. Main conclusion is that this systematic review found no additional value of standard use of vessel preparation.

Review > J Endovasc Ther. 2024 Apr;31(2):191-202. doi: 10.1177/15266028221120752. Epub 2022 Sep 4.

**Vessel Preparation in Infrapopliteal Arterial Disease: A Systematic Review and Meta-Analysis**

Michael J Nugteren [1 2], Rutger H A Welling [3], Olaf J Bakker [3], Çağdaş Ünlü [1], Constantijn E V B Hazenberg [2]

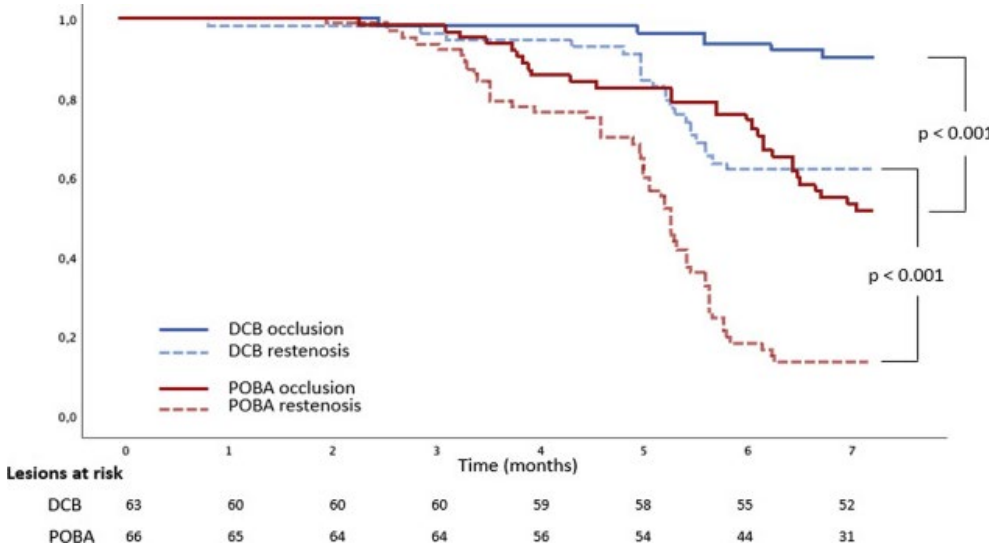
# Étapes du traitement endovasculaire

- Accès
- Franchissement
- Préparation du vaisseau
- **Traitement de la lésion**
  - *Amélioration de la PP*
  - *Diminution du taux de réintervention*
  - *Diminution du taux d'amputation*

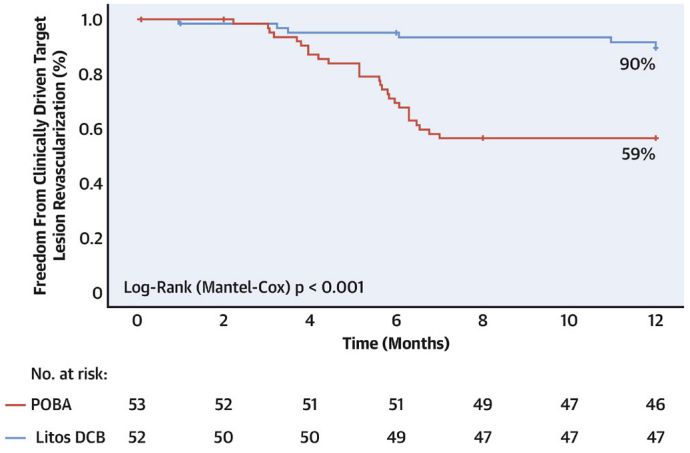
# Dispositifs de traitement actuellement disponibles

- POBA ?
- Ballons coatés (DCB)
- Stents nus
- Stents actifs (limus)
- Stents biorésorbables

# AcoArt-BTK I et II : RCT DCB vs POBA




**CENTRAL ILLUSTRATION: Freedom From 12-Month Clinically Driven Target Lesion Revascularization**




Liistro, F. et al. J Am Coll Cardiol Intv. 2020;13(19):2277-86.

***Signaux en faveur du DCB vs POBA***

***Suivis à 6 mois seulement***

***Effectifs 120 patients dans chaque***

Randomized Controlled Trial › JACC Cardiovasc Interv. 2020 Oct 12;13(19):2277-2286.
doi: 10.1016/j.jcin.2020.06.045. Epub 2020 Sep 16.

**Randomized Controlled Trial of Acotec Drug-Eluting Balloon Versus Plain Balloon for Below-the-Knee Angioplasty**

Francesco Liistro [1], Paolo Angioli [2], Giorgio Ventoruzzo [2], Kenneth Ducci [2], Matteo Rocco Reccia [2], Lucia Ricci [2], Giovanni Falsini [2], Alessia Scatena [2], Maurizio Pieroni [2], Leonardo Bolognese [2]

Randomized Controlled Trial › J Endovasc Ther. 2021 Apr;28(2):215-221.
doi: 10.1177/1526602820969681. Epub 2020 Oct 29.

**Drug-Coated Balloon Angioplasty Compared With Uncoated Balloons in the Treatment of Infrapopliteal Artery Lesions (AcoArt II-BTK)**

Xin Jia [1], Baixi Zhuang [2], Feng Wang [3], Yongquan Gu [4], Jiwei Zhang [5], Xinwu Lu [6], Xiangchen Dai [7], Zhaoyu Liu [8], Wei Bi [9], Changwei Liu [10], Shenming Wang [11], Francesco Liistro [12], Wei Guo [1]

# Les stents biorésorbables

Review > Rev Cardiovasc Med. 2024 Apr 3;25(4):133. doi: 10.31083/j.rcm2504133. eCollection 2024 Apr.

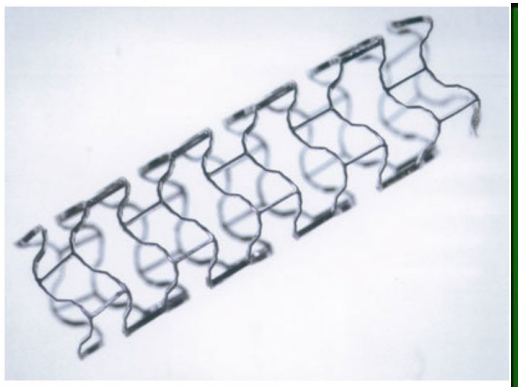
## Bioresorbable Scaffolds for Below-the-Knee Arterial Disease: A Literature Review of New Developments

Hong-Jie Cui [1], Ying-Feng Wu [2]

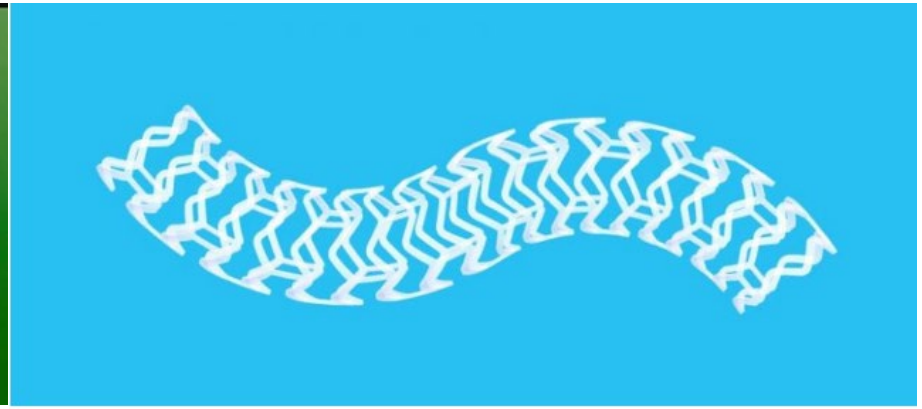
**Table 1. Stent characteristics of three bioresorbable scaffolds.**

| Characteristics | AMS-1 | Absorb GT 1 | MOTIV |
|---|---|---|---|
| Scaffold material | Magnesium alloy | PLLA | Tyrocore |
| Drug coating | None | Everolimus+PDLLA | Sirolimus+Tyrocore |
| Strut thickness | 3.0 mm, 165 µm<br>3.5 mm, 165 µm | 2.5 mm, 150 µm<br>3.0 mm, 150 µm<br>3.5 mm, 150 µm | 2.5 mm, 95 µm<br>3.0 mm, 105 µm<br>3.5 mm, 115 µm |
| Crossing profile | 1.5 mm | 1.44 mm | 1.3 mm |
| Delivery | Single-step inflation | Muti-step inflation | Single-step inflation |
| Radial strength | 0.17 N/mm | 0.14 N/mm | 0.22 N/mm |
| Recoil | <8% | 2.3% | 2.0% |
| Max expansion over nominal | 0.6 mm | 0.5 mm | 0.75 mm, 2.5–3.0 mm<br>0.5 mm, 3.5 mm |
| Resorption profile | At least 4 months | Loss of mechanical support in 18 months<br>Resorption in 36 months | Vessel uncaged in 12 months<br>Resorption in 48 months |

AMS, absorbable metal stent; PLLA, poly L-lactic acid; PDLLA, poly D, L-lactic acid.



Absorbable Metal Stent (Magic 3.0/10, Biotronik) fully dilated.

*Motiv bioresorbable scaffold (Reva Medical,*

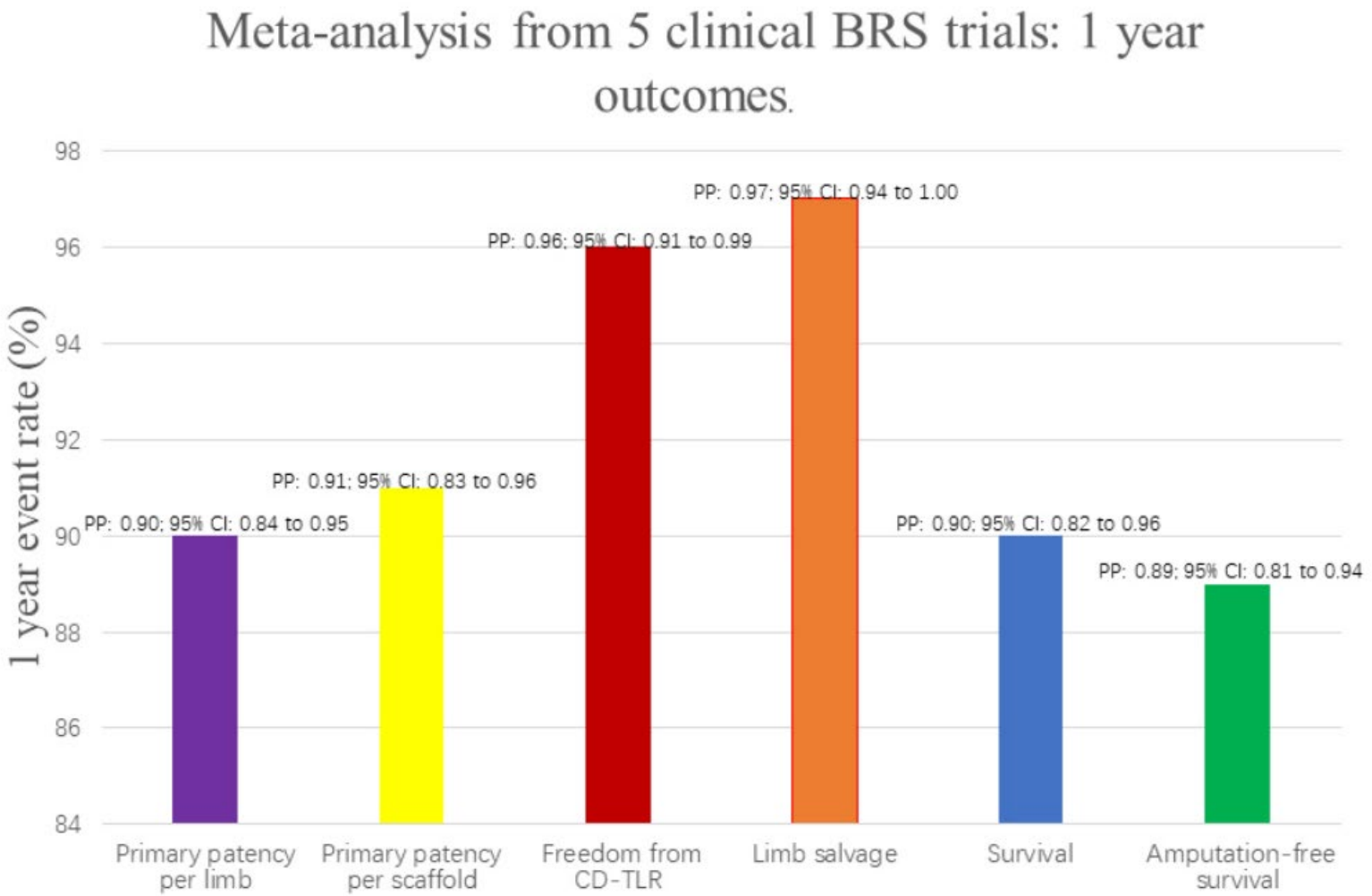



**Fig. 3. Summary of 1-year pooled results from a meta-analysis of five clinical studies.** BRS, bioresorbable scaffold; CI, confidence interval; CD-TLR, clinical-driven target lesion revascularization; PP, proportion.

***Excellents résultats <u>mais</u> :***

***- lésions courtes (20-30mm)***

***- moindre force radiale et mailles plus épaisses que DES = risque supérieur de thrombose***

***Résultats > DCB et =DES***

Review › Rev Cardiovasc Med. 2024 Apr 3;25(4):133. doi: 10.31083/j.rcm2504133. eCollection 2024 Apr.

**Bioresorbable Scaffolds for Below-the-Knee Arterial Disease: A Literature Review of New Developments**

Hong-Jie Cui [1], Ying-Feng Wu [2]

# Conclusion

- POBA reste le traitement de première intention…mais résultats très insuffisants
- De + en + de signaux en faveur de l'intérêt d'une préparation du vaisseau plus agressive sur les lésions calcifiées avec les ballons spécialisés et les systèmes d'athérectomie
- Résultats prometteurs de certains DCB et des plateformes biorésorbables (mais lésions courtes…)
- Besoins d'essais randomisés multicentriques+++

# Pourquoi ne pas faire fondre le calcium?

› Catheter Cardiovasc Interv. 2024 May;103(6):972-981. doi: 10.1002/ccd.31052. Epub 2024 Apr 12.

## Effect of EDTA with porous balloon on calcified lesion: An atherosclerotic cadaver study

Kenji Kawai [1], Anna Madra [1], Rika Kawakami [1], Yu Sato [1], Takao Konishi [1], Tatsuya Shiraki [1], Teruo Sekimoto [1], Takamasa Tanaka [1], Renu Virmani [1], Aloke V Finn [1 2]

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# Comment traiter les lésions calcifiées des artères de jambe?

**Drs Bogdan BRICIU, Philippe CHAMMAS, Louis DELMAS, Gilles GOYAULT, Olivier STEINBERGER, Bernard WOERLY**

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