

**ciw**

**WORLD**

CHALLENGES & INNOVATIONS IN VASCULAR WORLD

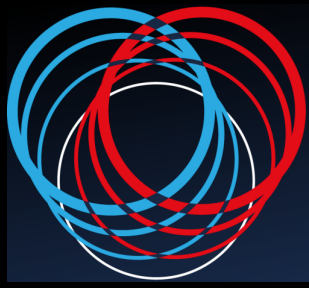
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**31 MARS** **2026**  
**1<sup>ER</sup> AVRIL**

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**MÉRIDIEN ÉTOILE**  
**PARIS**

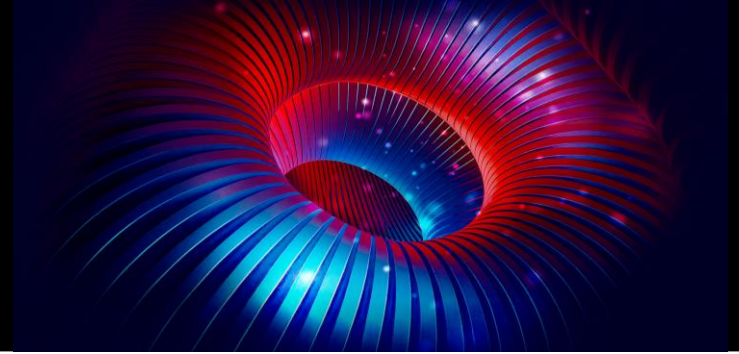
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**CIV**  
**WORLD**  
CHALLENGES & INNOVATIONS IN VASCULAR WORLD

31 MARS  
1<sup>ER</sup> AVRIL **2026**

**MÉRIDIEN ÉTOILE**  
PARIS



# POURQUOI JE PREFERE L'ATHERECTOMIE ROTATIONNELLE?

**F. THAVEAU, MD, PhD, FEBVS**

*Department of Vascular and Endovascular Surgery, University Hospital,*

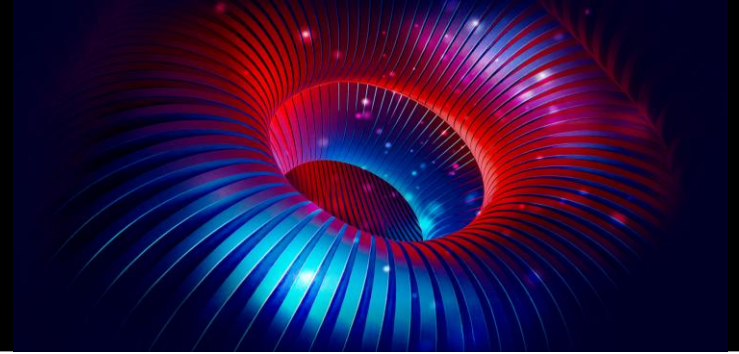
*Pascal Institut, Image Guided Therapy, UMR 6602 CNRS SIGMA UCA*

*CLERMONT-FERRAND, FRANCE*



**UFR DE MÉDECINE  
ET DES PROFESSIONS PARAMÉDICALES**  
Université Clermont Auvergne

# Conflits et liens d'intérêts



J'ai, ou j'ai eu au cours des deux dernières années, une affiliation, des intérêts financiers ou des liens d'intérêts de tout ordre avec les firmes suivantes, ou j'ai reçu des compensations financières ou des honoraires, des bourses de subvention ou de recherche émanant des companies suivantes :

- **BD**
- **Terumo Aortic**
- **Medtronic**
- **Bentley**

# ATHERECTOMIE ROTATIONNELLE ROTAREX<sup>®</sup>



## Dispositif d'athérombectomie

Combine l'athérectomie et la thrombectomie



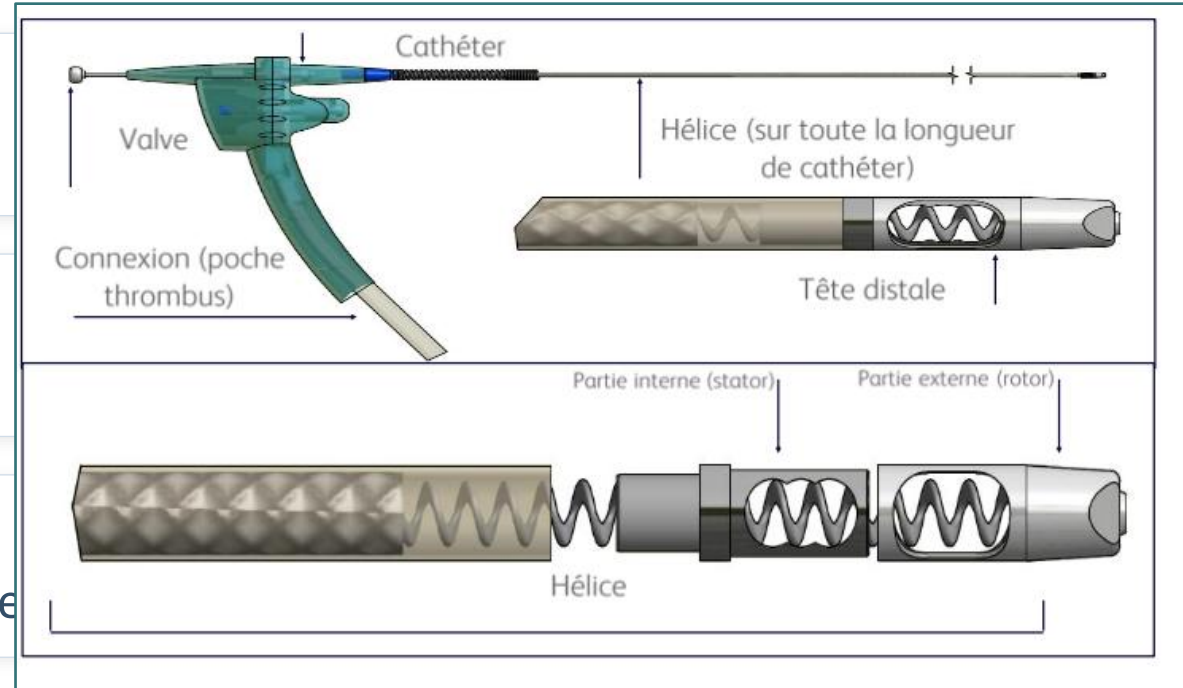
## Traitement des occlusions artérielles

artères natives, stents ou pontages



## Lésions aiguës, subaiguës et chroniques

L'efficacité diminue pour les occlusions très anciennes



# ATHERECTOMIE ROTATIONNELLE ROTAREX<sup>®</sup>

Système de thrombectomie mécanique percutanée

Rotation: debulking intraluminal

Effet de vis Archimède: limite embolisation distale

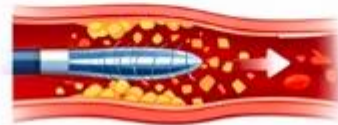


1



Fragmentation

2



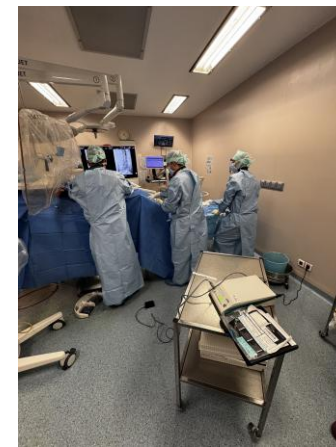
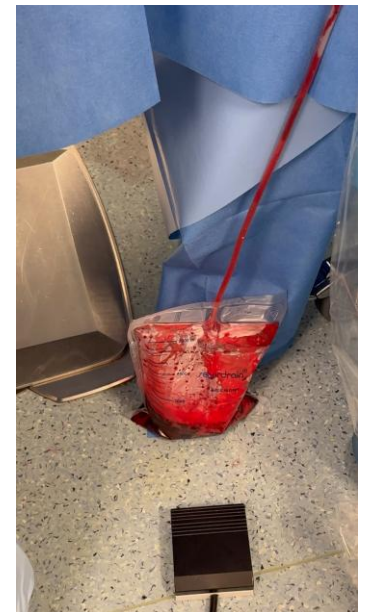
Aspiration

3



Recanalisation

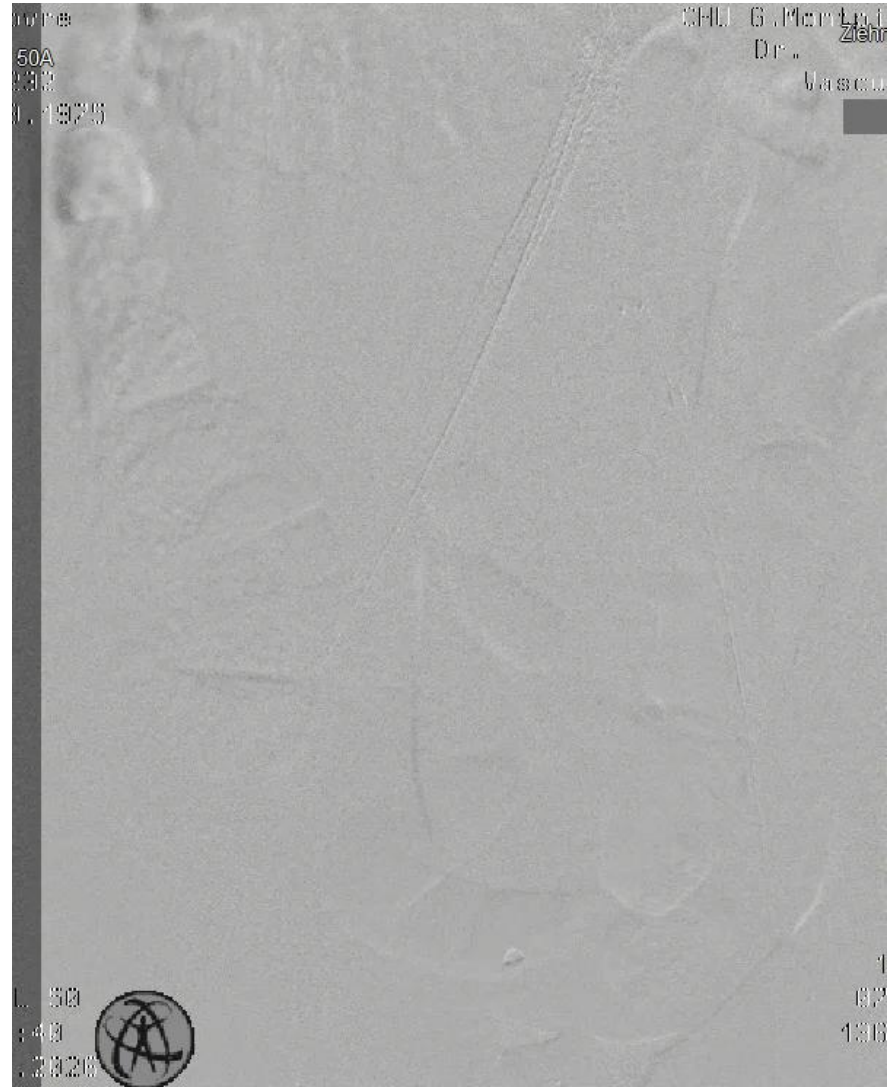
Rotation haute vitesse



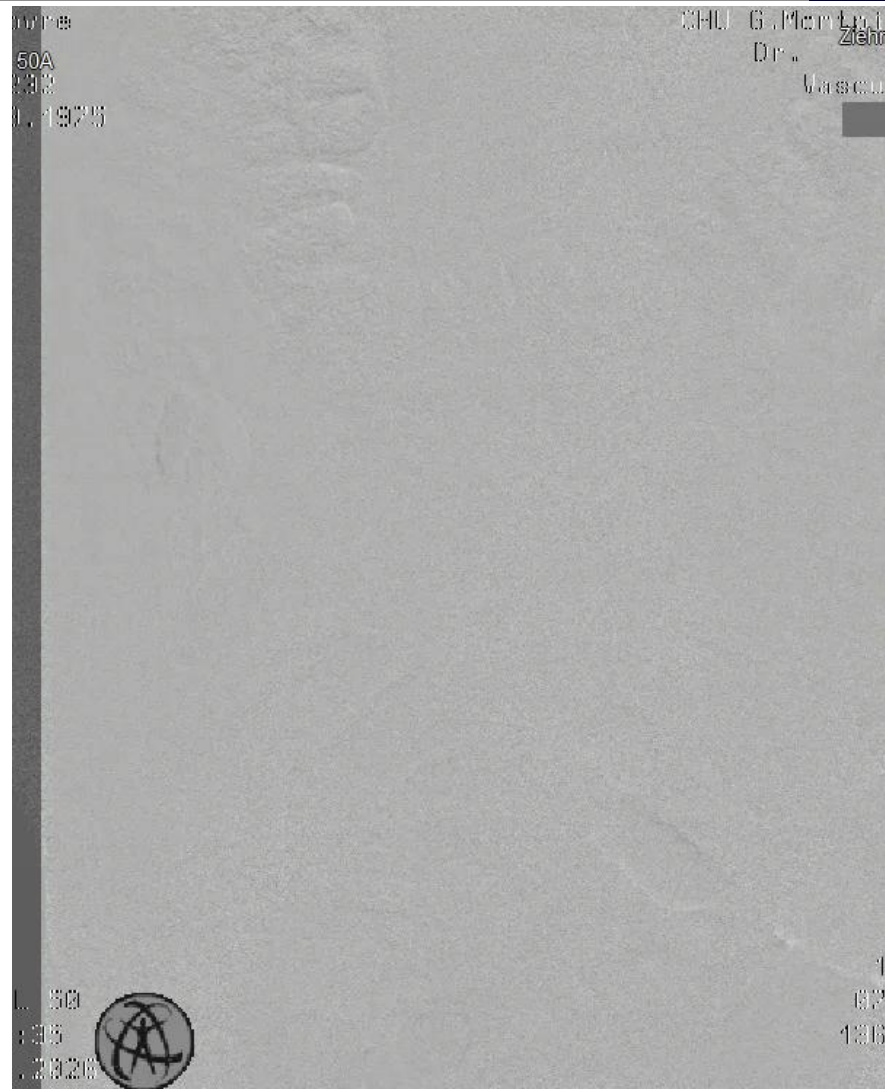
# Mme L. 51 ans, CERAB il y a 3 ans, admise en ischémie aigue bilatérale



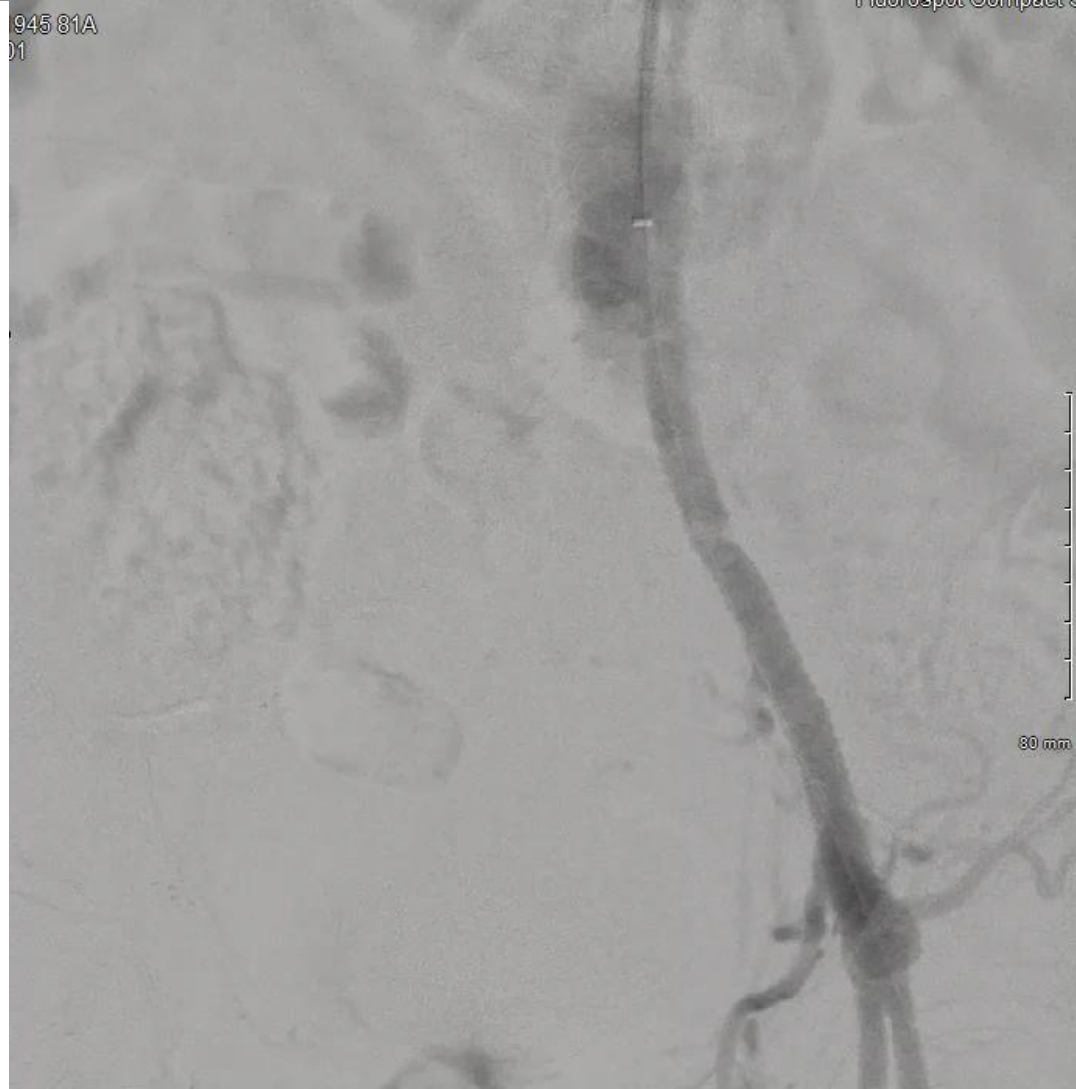
# Ponction bifémorale intro 7 fr, sondes ROTAREX 10 Fr guide 0,025



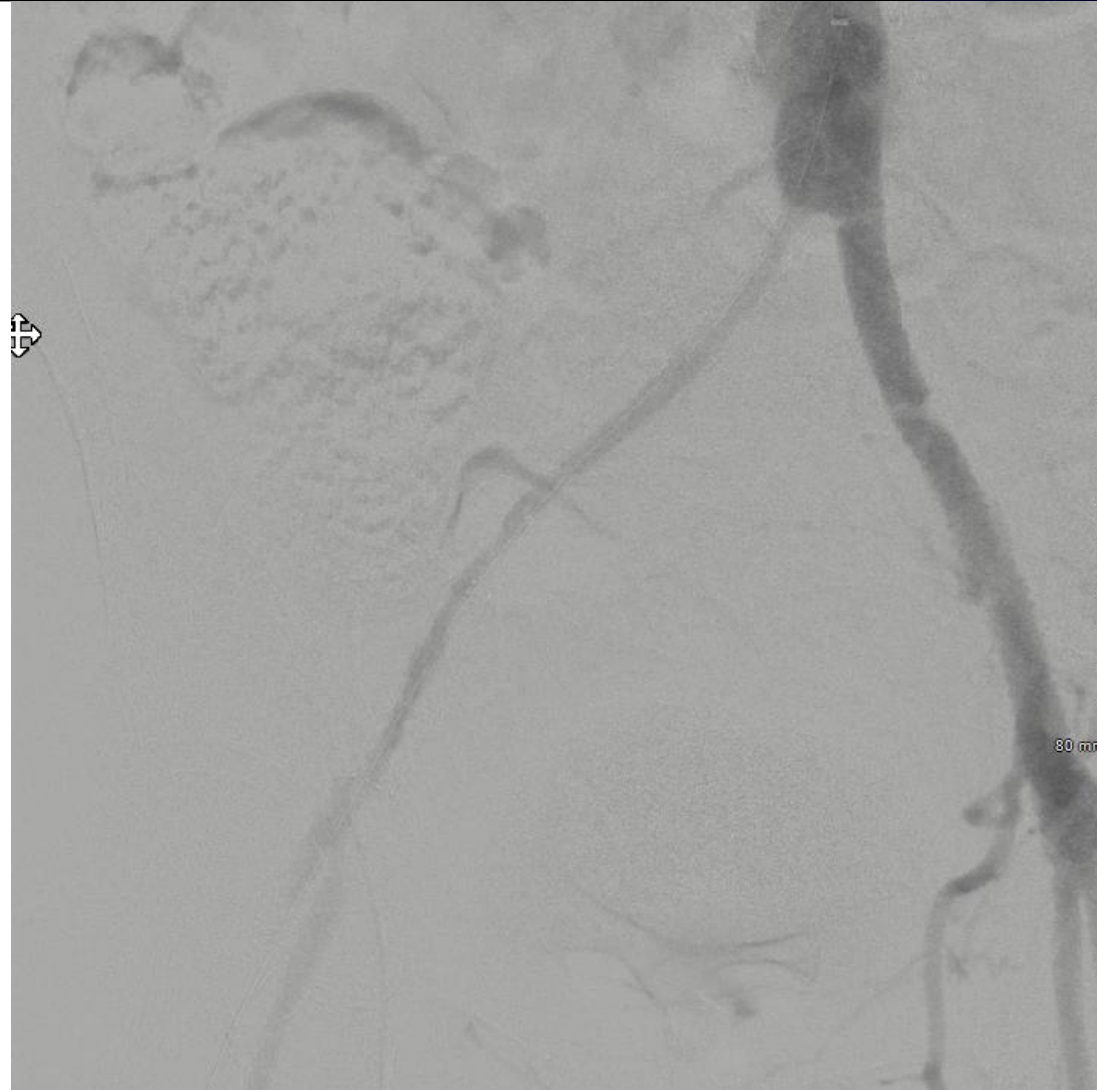
2<sup>ème</sup> « CERAB » = Be Graft Bentley 7x57mm en KB x2 + Viabahn Gore  
7x150mm D + 7x100 mm G



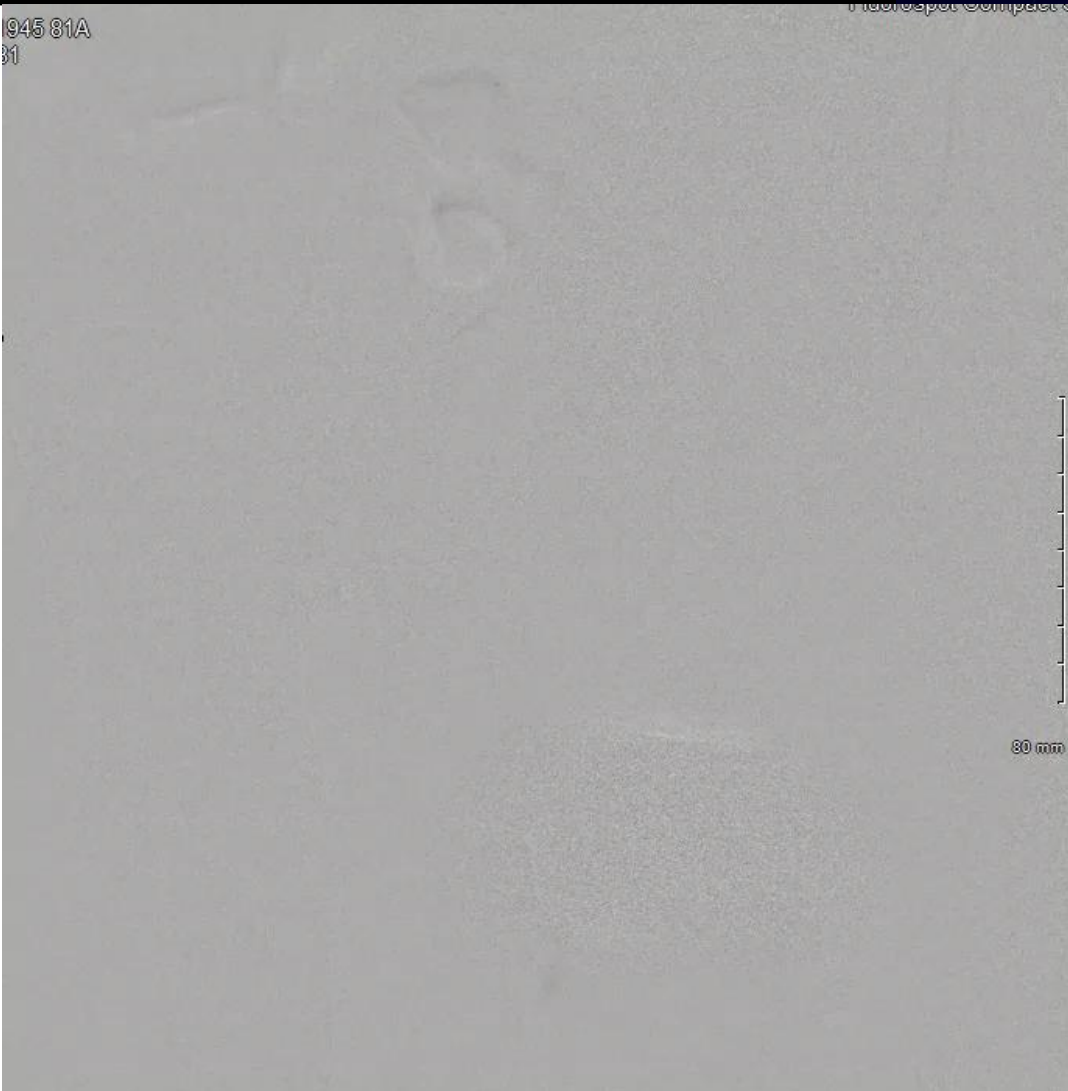
Mr C. 76 ans, PABF il y a 10 ans, admise en ischémie aigue MID sur thrombose aigüe jambage D



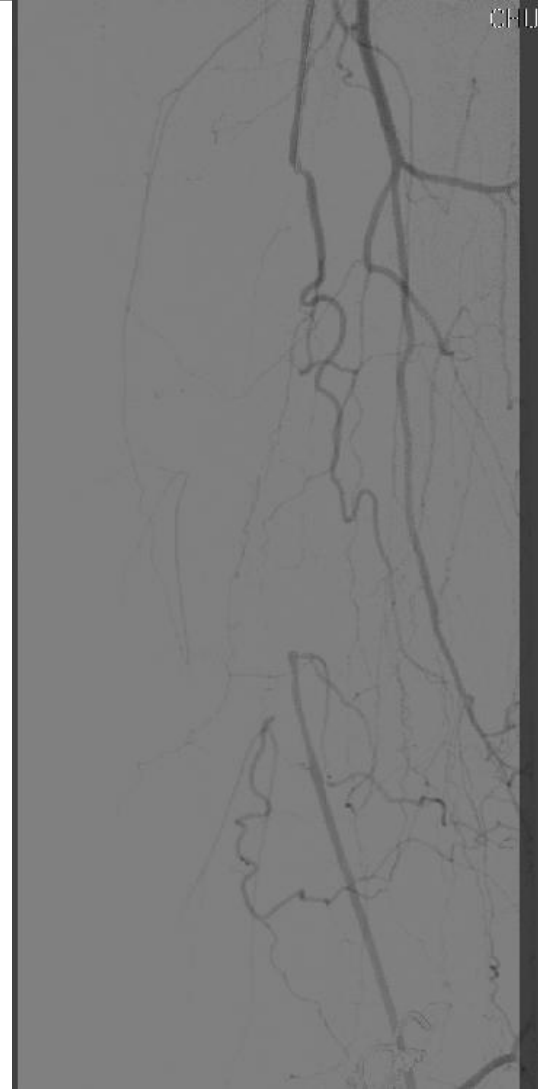
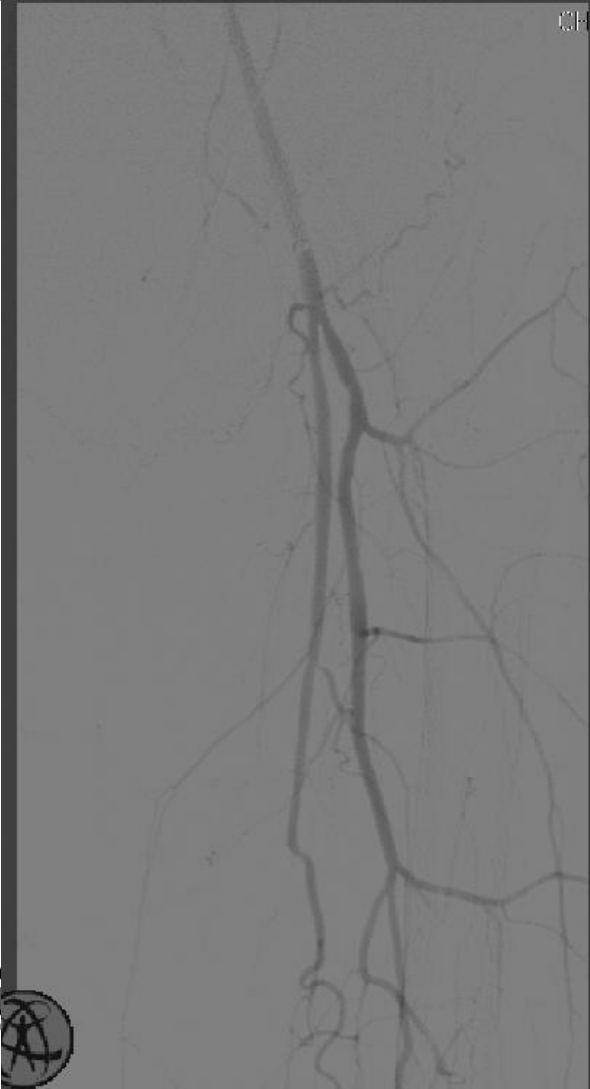
# Voie Humérale G, Cathétérisation Terumo 0,035 puis échange de guide 0,018 pour Rotarex 8 Fr



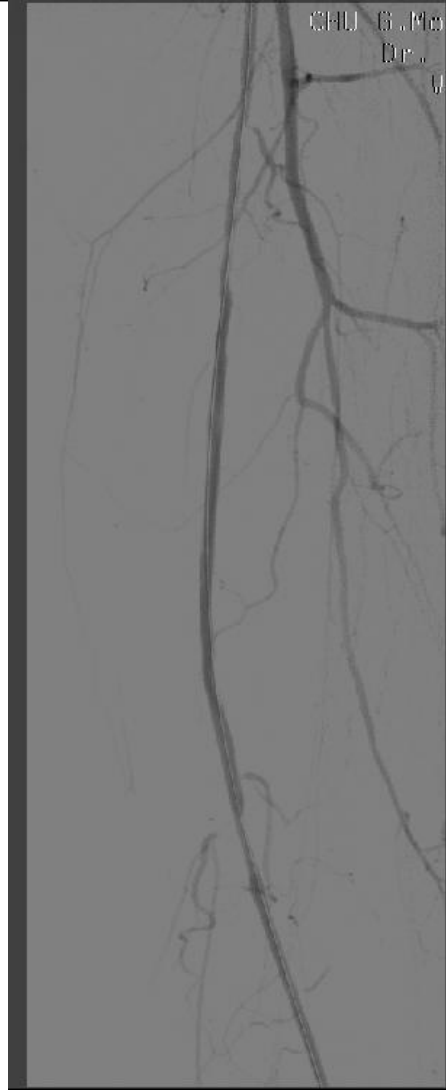
# Be Graft Bentley 8x37mm à la jonction aortoiliaque + Viabahn Gore 8x150mm + 8x50mm



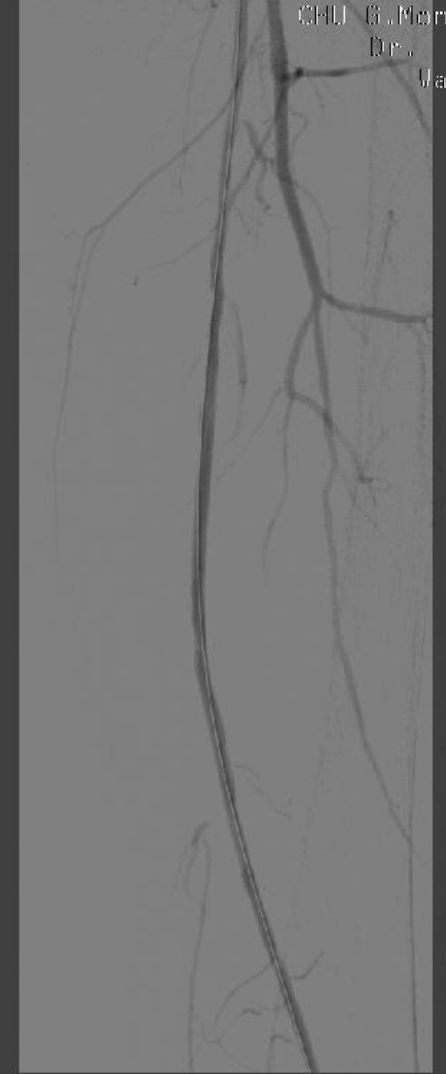
Mme L. 57 ans, ischémie sub-aigue MIG; ED: thrombus frais étendu  
AFS G, reprise vascularisation au Hunter



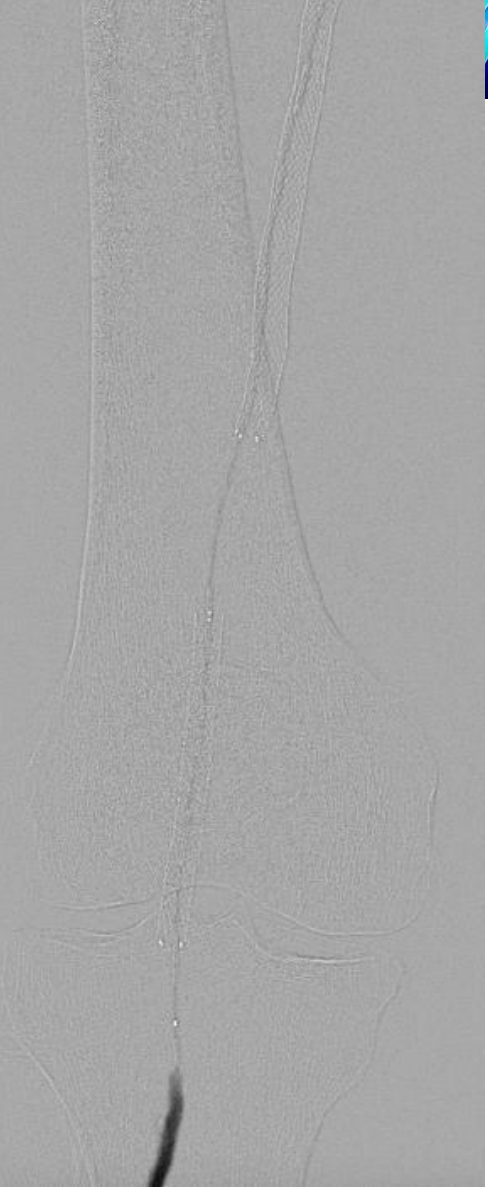
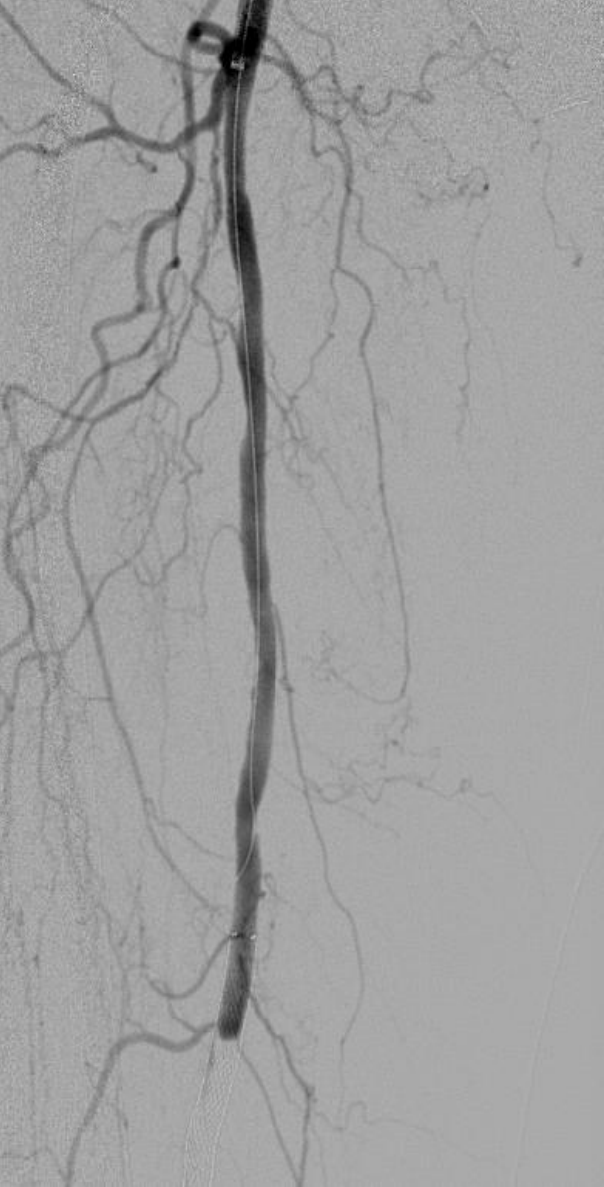
Cathétérisation d'emblée en 0,018 CO ponction fem D, guide  
Advantage + SEEKER 0,018, échange de guide pour Rotarex guide 0,018  
Roiares 6Fr, préparation vaisseau



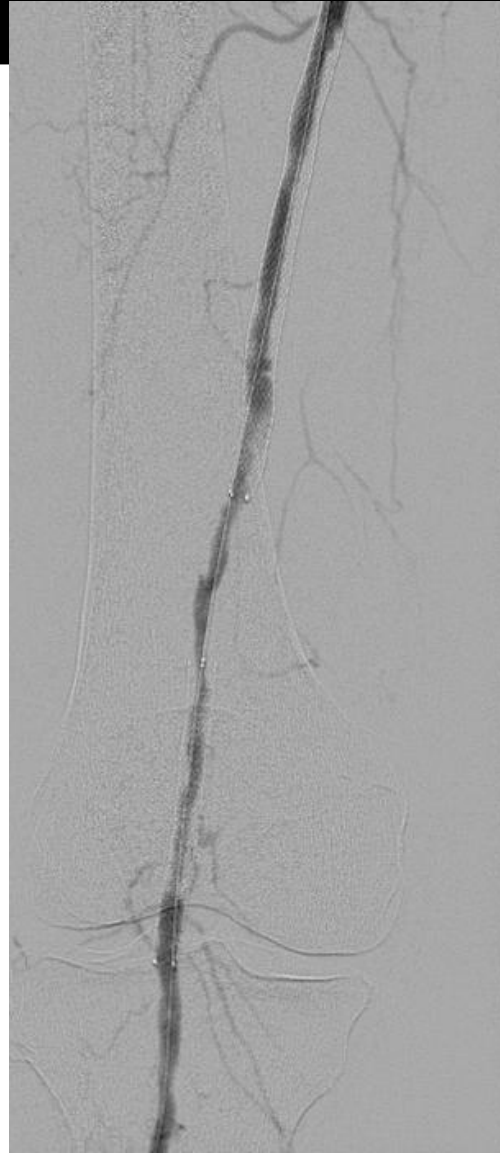
# Ballon actif In Pact Admiral Medtronic 5mmx150mm X 2



Mr D., 67 ans, ischémie sub-aigue MID, thrombose aigë AFS intrastent



Ponction fem G + CO, cathétérisation d'emblée 0,018  
Rotarex 6fr, recanalisation + thrombectomie



# Ballon actif In Pact Admiral Medtronic 6mm x 150mm X 2



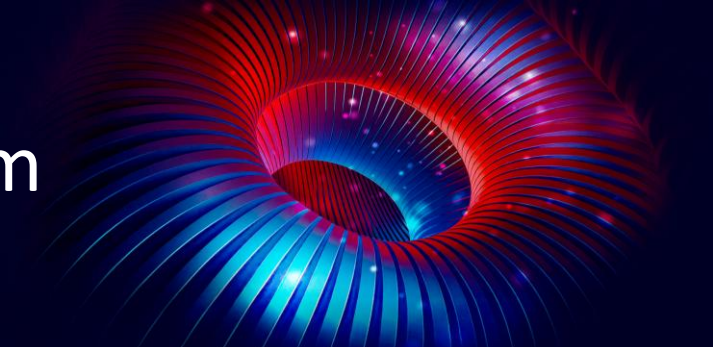
Mr A, 84 ans, ischémie sub-aigue MID; ED: plaque ulcérée + thrombus  
frais AFS/POP



# Cathétérisation d'emblée en 0,018 CO ponction fem G Rotarex 6fr, préparation du vaisseau



# Stenting actif ELUVIA Boston Scientific 6x40mm







# LEÇONS RETENUES DE L'EXPERIENCE OPERATOIRE

## Limitations

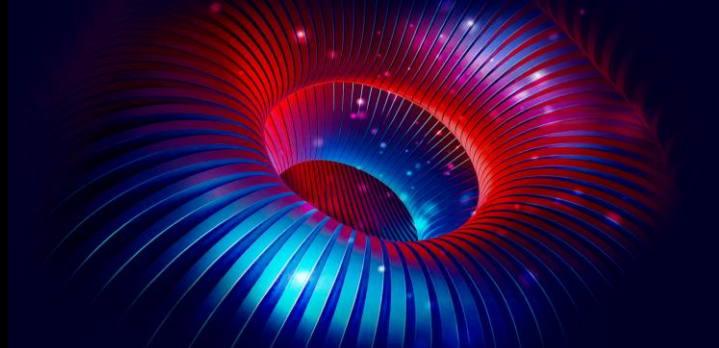
Utilisation intraluminale

Diamètres de vaisseaux < 3 mm

Calcifications importantes

| Type de lésion                         | Efficacité Rotarex   |
|--|--|
| Thrombus pur                           |  Excellente   |
| Lésion mixte (thrombus + plaque molle) |  Bonne        |
| Plaque fibreuse modérée                |  Limitée    |
| Calcification sévère concentrique      |  Non adapté |

# QUE NOUS APPREND LA LITTÉRATURE?



## Percutaneous Rotational Mechanical Atherectomy Plus Thrombectomy Using Rotarex S Device in Patients With Acute and Subacute Lower Limb Ischemia: A Review of Safety, Efficacy, and Outcomes

Romarc Loffroy\*, Nicolas Falvo, Christophe Galland, Léo Fréquier, Frédéric Ledan, Marco Midulla and Olivier Chevallier

IMVA Laboratory-EA 7535, Department of Vascular and Interventional Radiology, Image-Guided Therapy Center, François-Mitterrand University Hospital, Dijon, France

### OPEN ACCESS

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**Specialty section:**  
This article was submitted to  
Cardiovascular Imaging,  
a section of the journal  
Frontiers in Cardiovascular Medicine

**Received:** 30 April 2020  
**Accepted:** 24 September 2020  
**Published:** 22 October 2020

**Citation:**  
Loffroy R, Falvo N, Galland C,  
Fréquier L, Ledan F, Midulla M and  
Chevallier O (2020) Percutaneous  
Rotational Mechanical Atherectomy  
Plus Thrombectomy Using Rotarex S  
Device in Patients With Acute and  
Subacute Lower Limb Ischemia: A  
Review of Safety, Efficacy, and  
Outcomes.  
Front. Cardiovasc. Med. 7:557420.  
doi: 10.3389/fcvm.2020.557420

Acute and subacute ischemia of lower limbs is associated with high risk of amputation and potential severe life-threatening complications. Despite a lack of clear therapeutic recommendations, surgical treatments such as thrombectomy or bypass and/or catheter-directed thrombolysis (CDT) have been first-line procedures in both acute and subacute limb ischemia, but each therapy may lead to significant morbidity. Such situations demand fast restoration of appropriate flow to preclude other complications. Percutaneous mechanical atherectomy plus thrombectomy represents a minimally invasive approach for quickly recanalizing thrombotic lesions whatever the age of thrombus. Indeed, many chronic patients with critical limb ischemia, with thrombus-containing occlusive lesion underlying atherosclerotic disease. MATH offers various advantages over CDT, with lower invasiveness, faster recanalization, and the possibility to treat the underlying lesions, with a lower rate of bleeding complications for intensive care unit stay. Currently, several mechanical thrombectomy offered as an alternative therapy and can be divided into pure rotational and rheolytic thrombectomy devices. The only pure rotational MATH device available on the market is the Rotarex S device. We aimed to review clinical data regarding the safety, efficacy, and outcomes of MATH therapy using Rotarex S catheter in acute and subacute thrombus-containing arterial lesions. Future perspectives of Rotarex S MATH treatment and cost-effectiveness use will be also discussed.

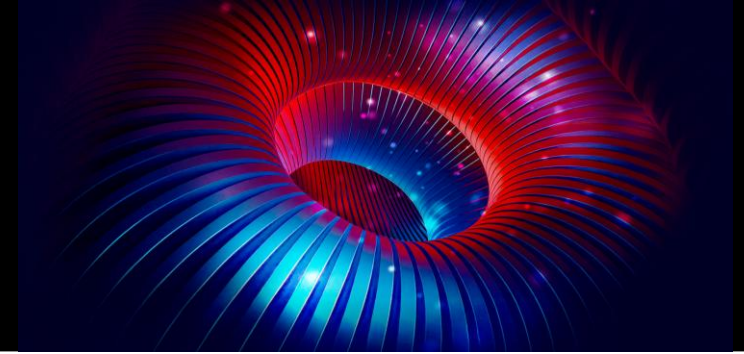
**Keywords:** mechanical thrombectomy, peripheral arterial occlusion, percutaneous transluminal placement, atherectomy

**95%**  
SUCCES TECHNIQUE  
(recanalisation + restauration  
du flux)

**90%**  
Sauvetage de membre  
à 1 an

Revascularisation  
**rapide et en une  
seule procédure**

# Rotarex<sup>®</sup> vs Thrombolyse



## *Essai contrôlé prospectif randomisé*

### 2 groupes : Rotarex vs Thrombolyse

**Randomized Prospective Comparative Study of Mechanical Thrombectomy by Rotarex<sup>®</sup> Device Versus Catheter-Directed Thrombolysis in the Management of Acute Thrombotic Lower Limb Ischemia Without Motor Deficit**

Sherif O Elkerdawi<sup>1</sup>, Mostafa S Abdelbary<sup>2</sup>, Mohamed A Rizk<sup>2</sup>, Hossameldin Ibrahim<sup>1</sup>, Karim El-Awady<sup>2</sup>

## *Etude rétrospective monocentrique*

### 3 groupes : Rotarex / Thrombolyse / Combinaison

**A comparative study on endovascular treatment of (sub)acute critical limb ischemia: mechanical thrombectomy vs thrombolysis**

Mariya Kronlage<sup>1 2</sup>, Ilka Printz<sup>1</sup>, Britta Vogel<sup>1</sup>, Erwin Blessing<sup>3</sup>, Oliver J Müller<sup>1 2</sup>, Hugo A Katus<sup>1 2</sup>, Christian Erbel<sup>1</sup>

# Rotarex® vs Thrombolyse

Randomized Prospective Comparative Study of Mechanical Thrombectomy by Rotarex® Device Versus Catheter-Directed Thrombolysis in the Management of Acute Thrombotic Lower Limb Ischemia Without Motor Deficit

Sherif O Elkerdawi<sup>1</sup>, Mostafa S Abdelbary<sup>2</sup>, Mohamed A Rizk<sup>2</sup>, Hossameldin Ibrahim<sup>1</sup>, Karim El-Awady<sup>2</sup>

**Background:** Acute limb ischemia (ALI) is a serious condition leading to amputation and mortality.

**Patients and methods:** This prospective randomized study included 50 patients with thrombotic ALI treated at 2 hospitals between September 1, 2021, and August 31, 2023. Patients were randomly assigned using a double-blind method into Group A (n = 25), treated with percutaneous mechanical thrombectomy (PMT), and Group B (n = 25), receiving catheter-directed thrombolysis (CDT).

**Results:** The mean (p < .001), though gender was not a risk factor (88% in CDT vs 88% in PMT), smoking (56% in CDT vs 56% in PMT), carotid artery and popliteal artery stenosis (72% and 68% in CDT vs 72% and 68% in PMT), and 56% of Group B patients had no statistical significance. Major complications occurred in 8% of patients in Group A (distal embolization, 2 patients), and 30-day mortality rate was 8% in Group A and 20% in Group B. Patency rates at 1 month were 84% and 62.5% at 1 year, respectively. Resections and amputations, where

**Conclusion:** PMT and CDT offer similar amputation rates, with PMT being statistically significantly superior. PMT may offer some advantages over CDT. This randomized study suggests that PMT using the Rotarex® device may be a safe and effective treatment for patients with acute

ALI. PMT offers a high rate of revascularization in a single session with a tendency toward higher technical success and fewer amputations, while maintaining a safety profile comparable to CDT. By potentially reducing treatment time, bleeding risk, and the need for intensive monitoring, PMT could represent a valuable addition to current endovascular practice. Larger multicenter studies with longer follow-up are warranted to confirm these findings and guide future clinical adoption.

## Succès technique:

PMT = 96% / CDT = 80%

8 % complications perop/groupe

8% mortalité CDT

## PP 1mois + 1 an:

84% + 62,5% PMT

81% + 55,6% CDT

## Taux d'amputation majeures

1 amput PMT

5 amput CDT

Randomisation 1:1 2 centres 2021-23  
Percutaneous Mechanical Thrombectomy (Rotarex) n = 25  
Catheter-Direct Thrombolysis n=25

Tendance non significative  
PMT > CDT  
Réduction temps TT, risque hémorragique et meilleur taux sauvetage de membre



# Rotarex® vs Thrombolyse

## A comparative study on endovascular treatment of (sub)acute critical limb ischemia: mechanical thrombectomy vs thrombolysis

Mariya Kronlage<sup>1,2</sup>, Ilka Printz<sup>1</sup>, Britta Vogel<sup>1</sup>, Erwin Blessing<sup>3</sup>, Oliver J Müller<sup>1,2</sup>, Hugo A Katus<sup>1,2</sup>, Christian Erbel<sup>1</sup>

**Objective:** The aim of this study was to compare different interventional methods for treatment of (sub)acute limb ischemia upon thrombotic occlusions of the lower extremity in terms of their safety and efficacy in a tertiary hospital setting.

**Design:** This is a retrospective, single-center study of non-randomized data.

**Methods:** A total of 202 patients, including 26 critically ill patients, underwent rotational

Single center retrospective study non-randomized data

N = 202

3 groupes: Rotarex + Thrombolyse + (Rotarex + Thrombolyse)

Meilleure PP pour Rotarex, plus safe, moindre DMS, moindre coût

thrombolysis compared to Rotarex<sup>®</sup> ( $P < 0.05$ ).

**Conclusion:** In patients with (sub)acute limb ischemia, Rotarex<sup>®</sup> mechanical thrombectomy represents a safe and effective alternative to thrombolysis and is associated with fewer major bleedings, shorter hospitalization durations, and lower costs.

**Keywords:** acute limb ischemia, thrombolysis, mechanical thrombectomy, Rotarex<sup>®</sup>, major bleeding, thrombosis and embolism, acute artery occlusion

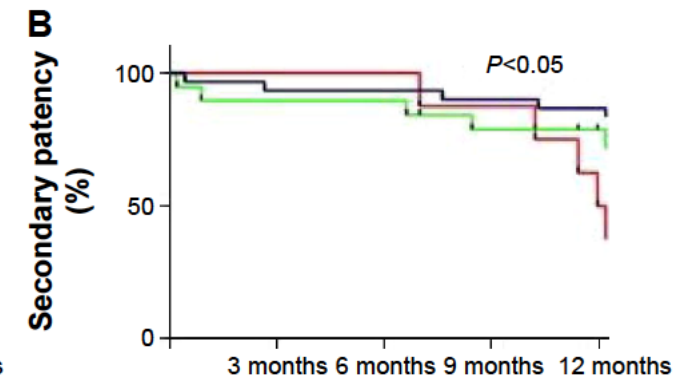
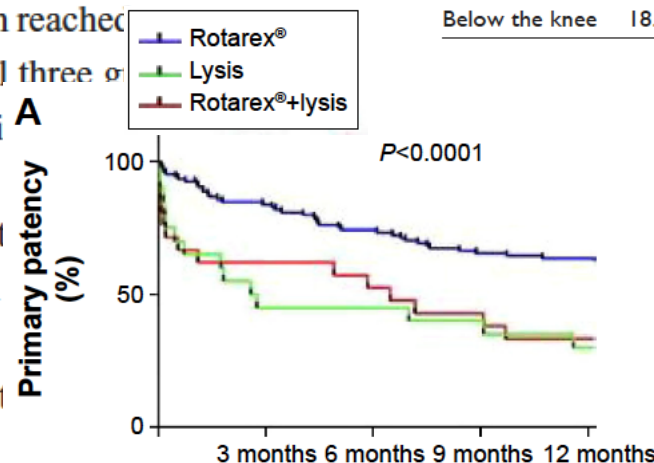
|                          | Rotarex <sup>®</sup> | Lysis         | Rotarex <sup>®</sup> +lysis | P-value                               |
|--------------------------|----------------------|---------------|-----------------------------|---------------------------------------|
| Native vessel            | 68.5% (100/146)      | 78.6% (22/28) | 71.4% (20/28)               | ns                                    |
| Bypass                   | 1.4% (2/146)         | 3.6% (1/28)   | 10.7% (3/28)                | R vs R+L*<br>R vs L ns<br>L vs R+L ns |
| Calcification grade      |                      |               |                             |                                       |
| Low                      | 70.6% (103/146)      | 78.6% (22/28) | 71.4% (20/28)               | ns                                    |
| Moderate-severe          | 29.5% (43/146)       | 21.4% (6/28)  | 28.6% (8/28)                | ns                                    |
| Thrombotic burden        |                      |               |                             |                                       |
| Low                      | 32.3% (50/146)       | 28.6% (8/28)  | 10.7% (3/28)                | R vs R+L*                             |
| Moderate-severe          | 65.8% (96/146)       | 71.7% (20/28) | 89.3% (25/28)               | R vs L ns<br>L vs R+L ns              |
| Length of occlusion (cm) |                      |               |                             |                                       |
| >10                      | 75.3% (110/146)      | 71.4% (20/28) | 85.7% (24/28)               | ns                                    |
| <10                      | 24.7% (36/146)       | 28.6% (8/28)  | 14.3% (4/28)                | ns                                    |
| Stent                    | 55.5% (80/146)       | 46.4% (13/28) | 42.9% (12/28)               | ns                                    |
| PTA                      | 73.9% (108/146)      | 71.4% (20/28) | 78.6% (22/28)               | ns                                    |

|                | Rotarex <sup>®</sup> | Lysis | Rotarex <sup>®</sup> +lysis | P-value                                |
|----------------|----------------------|-------|-----------------------------|--|
| Iliac vessels  | 12.5%                | 28.6% | 16.7%                       | ns                                     |
| SFA            | 69.3%                | 40%   | 52%                         | R vs R+L ns<br>R vs L**<br>L vs R+L ns |
| Below the knee | 18.7%                | 31.4% | 31.3%                       | ns                                     |

...en activator), or  
...e different inter-  
...survival, as well

...% in all groups.  
...al thrombectomy  
...tion of Rotarex<sup>®</sup>

...on reached  
...all three o  
...i



# NOS RESULTATS SUR L'ISCHEMIE AIGUE ET SUBAIGUE

## Design de l'étude

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### TYPE

Étude rétrospective monocentrique

### CENTRE

CHU Clermont-Ferrand

### PÉRIODE

Mars 2024 → Janvier 2026

### EFFECTIF

36 patients · 39 procédures analysées



# FLOWCHART



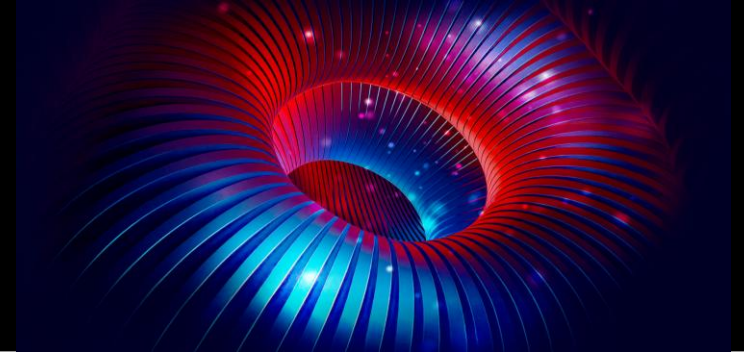
44 sondes Rotarex chez **41 patients**



2 AMS  
1 artère sous clavière  
2 matériovigilances

39 sondes Rotarex chez **36 patients**  
**Ischémie aigüe subaigüe MI**

# OBJECTIFS ETUDE



## CRITÈRE DE JUGEMENT PRINCIPAL (composite)

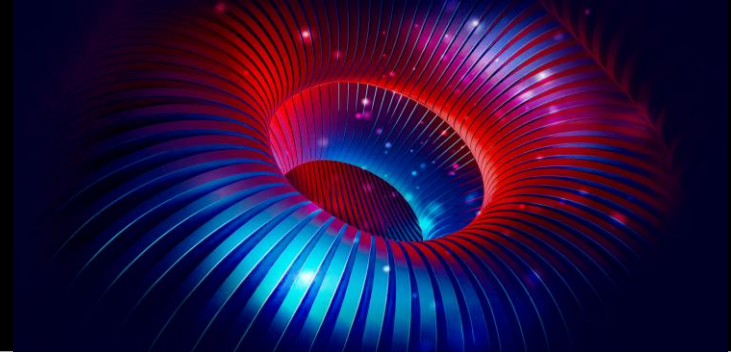
- Succès technique de la revascularisation peropératoire (restauration d'un flux satisfaisant sans conversion)
- Taux de sauvetage de membre

## CRITÈRES DE JUGEMENTS SECONDAIRES

- Perméabilité primaire à 1 mois et 6 mois
- Durée d'hospitalisation
- Morbi-mortalité (embolisation distale, amputation majeure, décès)



# Caractéristiques de population (N=39)



| Caractéristiques        | Valeur      |
|-------------------------|-------------|
| Homme                   | 26 (68%)    |
| Âge                     | 72 ± 11 ans |
| IMC                     | 26,9 ± 9,2  |
| Tabac                   | 31,6%       |
| Maladie rénale          | 7,9%        |
| Cardiopathie ischémique | 26,3%       |
| Diabète                 | 21,1%       |
| AVC                     | 7,9%        |
| Score ASA               | 2,7 ± 0,5   |
| Abord redux             | 34,1%       |



# Classification Clinique ischémie membre inférieur



# Type de lésion / localisation



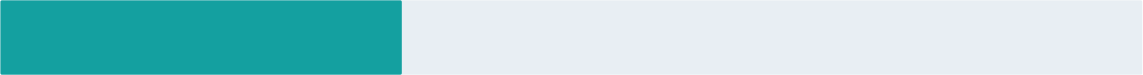
Artère native

35%



Stent

35%



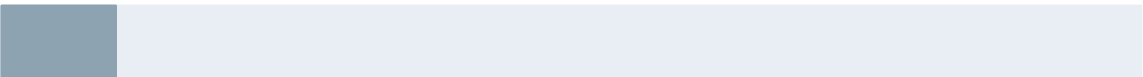
Pontage

20%



Endoprothèse

10%



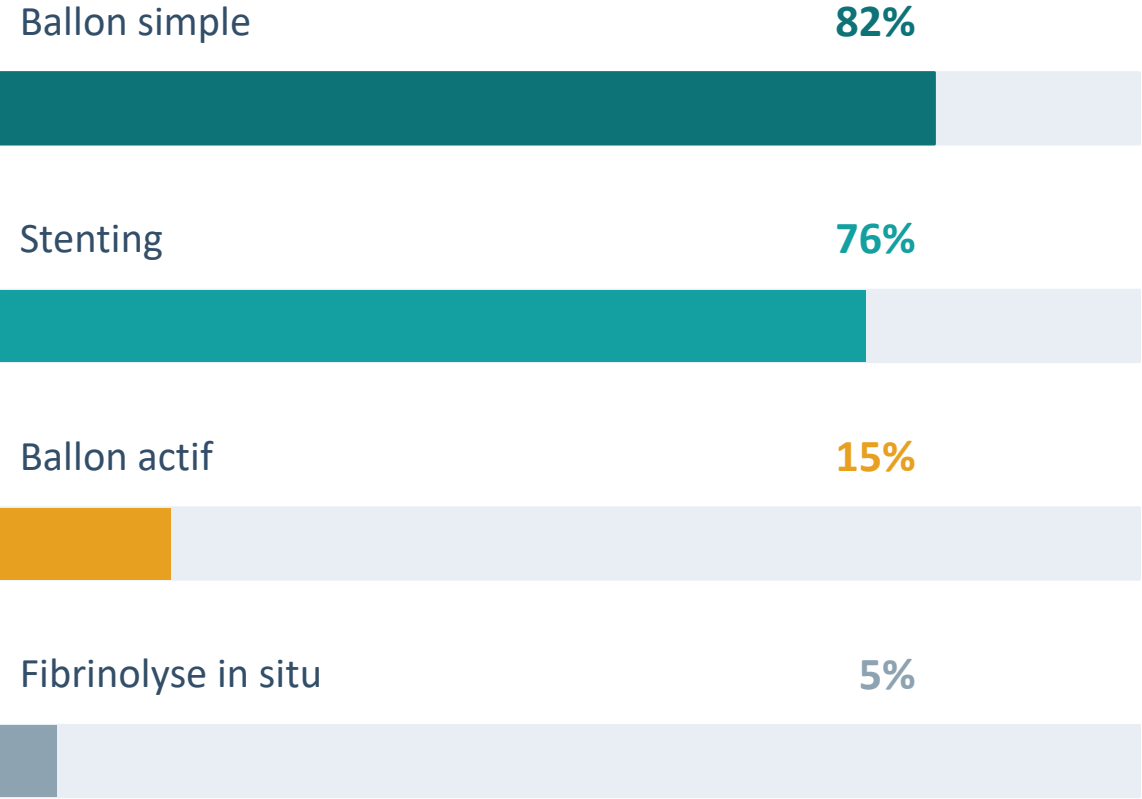
69,3%

Sous-inguinal

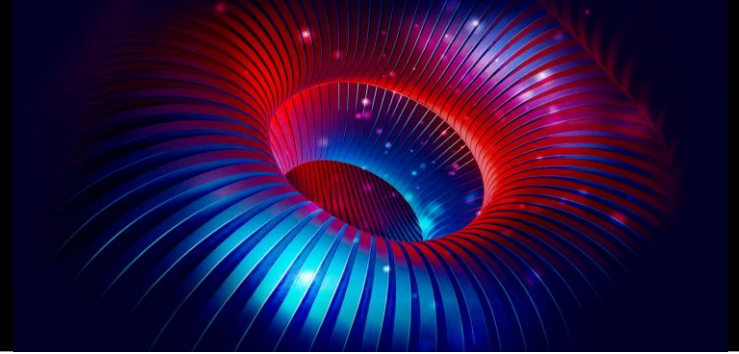
30,7%

Sus-inguinal

# Procédures adjuvantes



# Résultats



**89,7%**

Succès technique  
de la revascularisation

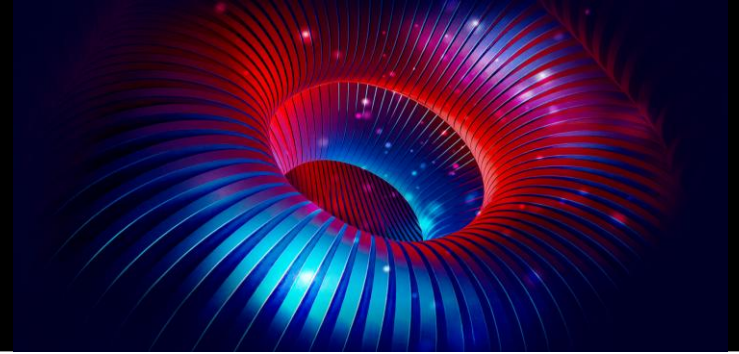
**94,8%**

Sauvetage de membre  
à 1 mois

**91,8%**

Sauvetage de membre  
à 6 mois

# Résultats



PP 1 mois

**80,6%**

PP 6 mois

**56,7%**

Embolisation distale

**2,4% (n=1)**

Durée hospitalisation

**4,4 j**

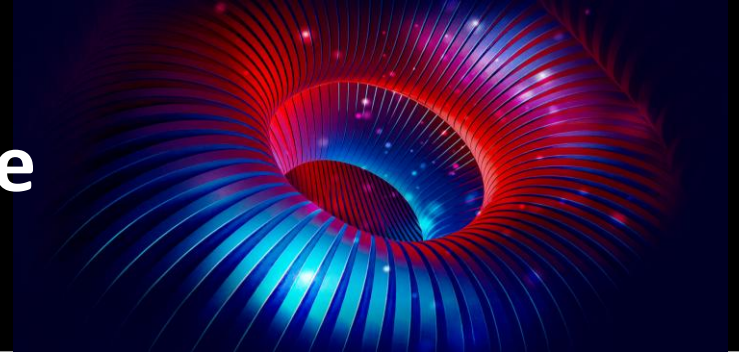
Amputation majeure

**10% (n=4)**

Décès

**10% (n=4)**

# Leçons retenues de notre expérience pratique



## ✓ AVANTAGES

- Revascularisation immédiate
- Diminution du risque hémorragique
- Procédure en 1 temps
- Abord percutané
- Hospitalisation courte
- Pas de surveillance en soins intensifs
- Optimisation des traitements secondaires

## ✗ INCONVÉNIENTS

- Embolisation distale possible
- Spasme artériel
- Risque de dissection / perforation
- Coût élevé
- Courbe d'apprentissage





# Coût: rationnel futur d'une étude médico-économique

**EEAF003** DILATATION INTRALUMINALE D'UNE ARTERE DU MEMBRE INFERIEUR SANS POSE D'ENDOPROTHESE  
**EEJF001** THROMBOASPIRATION D'UNE ARTERE OU DE PONTAGE ARTERIEL DU MEMBRE INFERIEUR, PAR VOIE ARTERIELLE TRANSCUTANEE.  
+ **YYYY300 X 2** (à voir si cela fait changer le GHS?) Supplément pour imagerie pour acte de radiologie interventionnelle, réalisée au bloc opératoire  
**ou**  
**EEAFO06** : DILATATION INTRALUMINALE D'UNE ARTERE DU MEMBRE INFERIEUR AVEC POSE D'ENDOPROTHESE  
+ **YYYY200** : Imagerie pour acte de radiologie interventionnelle ou de cardiologie interventionnelle niveau 11, réalisée en salle d'imagerie

| <b>GHM</b>     | <b>Libellé</b>  | <b>GHS<br/>Rémunération<br/>CHU (€ TTC)</b> |
|----------------|---|---|
| <b>05K251</b>  | Actes thérapeutiques sur les artères par voie vasculaire, âge supérieur à 17 ans, niveau 1  | <b>3037,21</b>                              |
| <b>05K252*</b> | Actes thérapeutiques sur les artères par voie vasculaire, âge supérieur à 17 ans, niveau 2* | <b>5656,97</b>                              |

**\* si 3 nuits d'hospitalisation**

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 EEJF001 THROMBOASPIRATION D'UNE ARTERE OU DE PONTAGE ARTERIEL DU MEMBRE INFERIEUR, PAR VOIE ARTERIELLE TRANSCUTANEE.  
 + YYY pour acte de radiologie interventionnelle, réalisée au bloc opératoire  
 ou  
 EEAF  
 + YYY

**1 cathéter Rotarex = 2390 euros HT**

RIEUR AVEC POSE D'ENDOPROTHESE  
 interventionnelle niveau 11, réalisée en salle d'imagerie

| GH      |   | <b>GHS<br/>Rémunération<br/>CHU (€ TTC)</b> |
|---------|---|---|
| 05K251  | Actes thérapeutiques sur les artères par voie vasculaire, âge supérieur à 17 ans, niveau 1  | <b>3037,21</b>                              |
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\* si 3 nuits d'hospitalisation

**48 h de Thrombolyse = 605 euros TTC**  
**Minimum 48-72h USC / réa**

# Take Home Message: athérectomie rotationnelle

Intérêt clinique

Etude prospectives de plus gros effectifs

Etude médico-économique

Meilleure que la thrombolyse et que la thrombectomie chirurgicale?

UPDATED CLINICAL PRACTICE GUIDELINES

**Editor's Choice – Update of the European Society for Vascular Surgery (ESVS) 2020 Clinical Practice Guidelines on the Management of Acute Limb Ischaemia in Light of the COVID-19 Pandemic, Based on a Scoping Review of the Literature**

Vincent Jongkind <sup>a,\*</sup>, Jonathan J. Earnshaw <sup>b</sup>, Frederico Bastos Gonçalves <sup>c</sup>, Frederic Cochennec <sup>d</sup>, E. Sebastian Debus <sup>e</sup>, Robert Hinchliffe <sup>f</sup>, Gabor Menyhei <sup>g</sup>, Alexei V. Svetlikov <sup>h</sup>, Yamume Tshomba <sup>i</sup>, Jos C. Van Den Berg <sup>j</sup>, Martin Björck <sup>k</sup>

The background features a complex, abstract pattern of wavy, curved lines in shades of red and blue. These lines create a sense of depth and movement, converging towards a central point that forms a tunnel-like structure. The lighting is dramatic, with bright highlights and deep shadows, giving the impression of a glowing, futuristic space. Small, sparkling particles are scattered throughout the scene, adding to the dynamic and ethereal atmosphere.

**MERCI DE VOTRE ATTENTION**