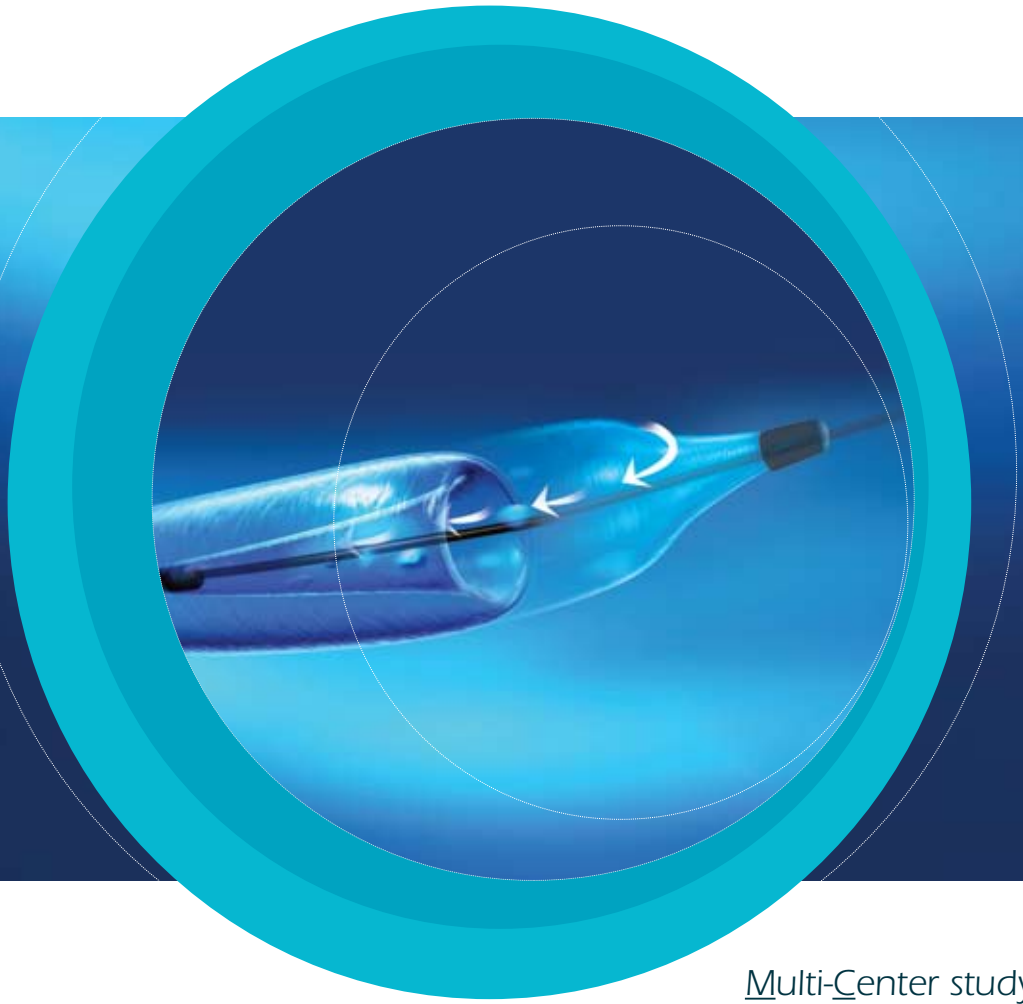
Angioslide
The New Angioplasty Standard

Clinical Compendium



MC-LEADER
Trial Summary

Multi-Center study for Lower Extremity Angioplasty with DEbris Removal (MC-LEADER) to Demonstrate Safety and Efficacy of the Angioslide eXtra™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Study Overview

The Multi-Center Study for Lower Extremity Angioplasty with Debris Removal (MC-LEADER) clinical trial was performed to evaluate and assess the safety and efficacy of the eXtra™ balloon catheter during lower limb Percutaneous Transluminal Angioplasty (PTA).

The eXtra balloon catheter has the same physical and behavioral characteristics as a standard angioplasty or stent deployment balloon catheter, such as inflation time, deflation time, pushability and crossing profile, but with the added feature of embolic material containment and removal. This additional function is achieved in one step:

Angioslide's balloon is folded inwards after inflation, creating a natural negative pressure, which drives embolic particles into the eXtra balloon lumen. The eXtra balloon catheter is then deflated and the device containing the captured debris is retrieved via the sheath.

The MC-LEADER trial was designed as a prospective, non-randomized, single arm study conducted at three centers in Germany:

- Leipzig Heart Center Hospital
- Bad Krozingen Heart Center Hospital
- Eberhard Karls University of Tübingen

At each study center an independent ethics committee approved the study protocol. The Lead Investigator was Dierk Scheinert, M.D. and the Principal Investigators were Thomas Zeller, M.D. and Gunnar Tepe, M.D.

The MC-LEADER clinical trial was initiated on July 7th, 2008. The trial was closed on October 11th, 2008.

Study Design

The trial was designed as a prospective, multi-center, nonrandomized, single arm registry clinical trial.

Patients were scheduled for angiography for assessment of the lower extremity arterial anatomy and nature of the lesion, and then revascularization was performed according to standard clinical procedure. Utilization of the Angioslide eXtra Balloon Catheter was according to clinical discretion of the physician.

MC-LEADER Objectives

Primary Efficacy Objectives:

To evaluate the performance of the Angioslide eXtra Balloon Catheter as an Embolic Protection Device (EPD) during lower extremity transluminal angioplasty and/or stenting and/or post-stent dilatation of a balloon-expandable stent.

The performance was evaluated with the following:

- Technical device success
- Particle analysis (quantitative and qualitative)

Secondary Efficacy Objectives:

To evaluate the performance of the Angioslide eXtra Balloon Catheter as an angioplasty device during lower extremity transluminal angioplasty and/or stening and/or post-stent dilatation of a balloon-expandable stent. This was achieved by:

- Procedural Success scored dichotomously as success or failure of achievement of < 50% residual stenosis immediately after angioplasty +/- stent deployment, measured by post procedure angiography, without occurrence of in-hospital MAE.
- Clinical Success at 30 days scored dichotomously as success or failure of improvement of Rutherford/Becker clinical improvement scale by at least one category from baseline to 30 days and Improvement in ABI from baseline to 30 days.

Safety Objective

To demonstrate the safety of the Angioslide eXtra Balloon Catheter during the following:

- Lower extremity transluminal angioplasty and/or Stenting and/or post-stent dilatation of a balloon-expandable stent
- Embolic protection functions (collection, retraction, deflation and removal)

This was accomplished by determining whether serious adverse events (SAE's) and adverse events (AE's) that were reported and documented during the study were related or not related, to treatment with the Angioslide device.

Materials and Methods

Interventional procedure

Antegrade puncture, either ipsilateral or contralateral, was used to access the lesions in all patients. Either a 6F or 7F sheath was placed. Diagnostic angioplasty was performed during each intervention. Selective stent placement was performed at the discretion of the physician.

Histopathology

Immediately following retrieval from the patient the distal portion of the balloon catheter was cut and placed in a vial containing 10% neutral buffered formalin. A filter at the base of the vial collected particles that detached from the balloon and sank to the bottom of the vial. The samples were then sent to American Preclinical Services (Minneapolis, MN, USA) for quantitative and qualitative analysis by two pathologists.

Clinical Events Committee (CEC)

An independent Clinical Events Committee reviewed all reported SAEs & AEs.

Study Results:

Study Population

Table 1. Subjects Demographics

Subjects Demographics & Baseline Characteristics	Mean (SD)	Range
Age (years)	68.3 (10.5)	44 – 89
Male	61%	
Female	39%	
Body Mass Index (BMI)	27.5 (4.3)	19.0 – 40.9
Subject Risk Factors	**% Study Population**	
Hypertension	82%	
Diabetes	43%	
Hyperlipidemia	78%	
Tobacco use	41%	
Obesity	48%	

Table 2. Rutherford Becker Scale at Baseline

Category	Clinical Description	% of study population (N=78)
0	Asymptomatic	0%
1	Mild claudication	0%
2	Moderate claudication	32%
3	Severe claudication	56%
4	Ischemic rest pain	11%
5	Minor tissue loss	1%
6	Major tissue loss-extending transmetatarsally	0%

Table 3. Ankle Brachial Index at Baseline

Ankle Brachial Index (Diseased Limb)	%	Mean (SD)
Non-compressible	5	1.3 (0.05)
Normal	14	0.99 (0.09)
Mild	24	0.75 (0.06)
Moderate	45	0.54 (0.08)
Severe	12	0.23 (0.10)

Primary Efficacy Results

1. **Technical Success**

Device technical success was assessed per each individual deployment of the eXtra balloon catheter dichotomously as either a success or failure. Technical device success was achieved in 144 out of 148 devices used in this clinical study resulting in a 97% device success rate.

Table 4. Device Technical Success Summary

Site	# of Devices	# of Successes	Success Percent
Leipzig	57	57	100
Bad-Krozingen	77	74	96
Tubingen	14	13	93
Overall	148	144	97

2. **Histology Analysis**

Quantitative Particle Analysis

Particle Count

For 79 subjects a total of 147 specimens were processed. Histopathology analysis identified particulate debris in all 147 eXtra balloon catheters. The number of particles counted in each balloon catheter ranged from 47 particles to 3849 particles. More than eighty-five percent of balloon catheters used extracted over 100 particles.

The distribution of the particle counts per specimen is illustrated in Figure 1.

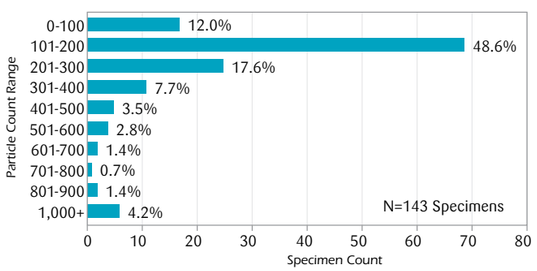


Figure 1. Particle Count per Balloon Catheter

Particle Size

The longest axis of each particle in each balloon catheter was measured. The particle with the longest axis in each balloon catheter was then tabulated. Maximum major axis ranged from 300.6µm to 8353.3µm. The median maximum major axis is 826.71µm (see Figure 3).

Figure 2. Macroscopic debris removed from the proximal SFA

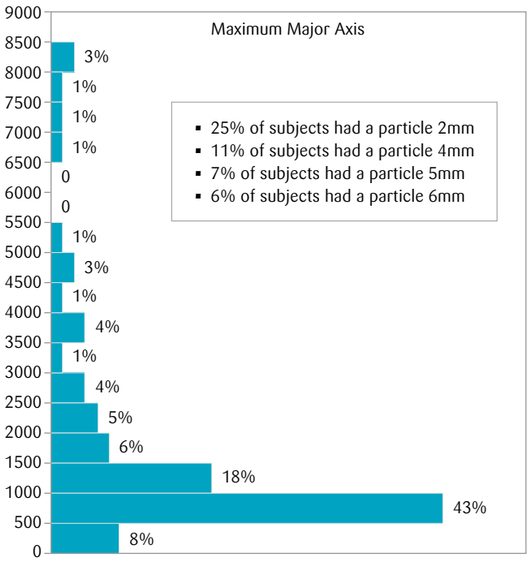


Figure 3. Particle Maximum Major Axis per Subject

Qualitative Particle Analysis

Cell types captured included atherosclerotic plaque debris such as foam cells, fibrous plaque caps, and calcified material in addition to chronic thrombus (see Figures 4, 5).

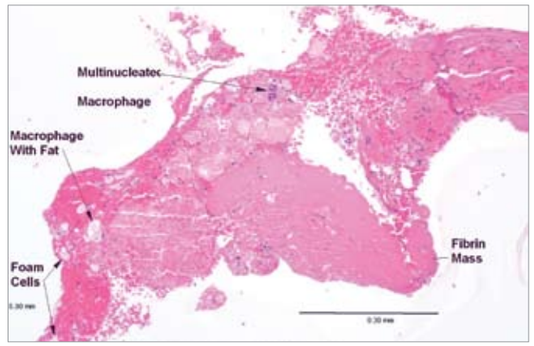


Figure 4. Chronic thrombus with multinucleated macrophage giant cells,macrophages with fat in the cytoplasm and foam cells.

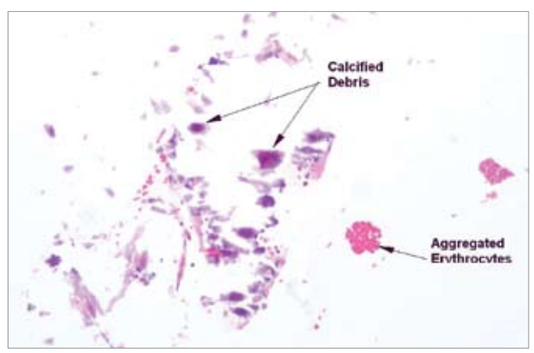


Figure 5. Calcified debris removed from the distal SFA

Study Results:

Study Conclusions:

Notes

Secondary Efficacy Analysis

1. Procedural Success

Acute procedure success was achieved in 79 out of 79 procedures during which the eXtra balloon catheter was used. This was measured by device success to achieve < 50% residual stenosis immediately after angioplasty as measured by post procedure angiography.

2. Clinical Success

Rutherford-Becker Improvement Score

The secondary efficacy assessment of clinical improvement was made using the Rutherford Becker Clinical Improvement Scale at 30 days. As seen in Figure 5 88% of subjects were moderately or markedly improved at 30 days.

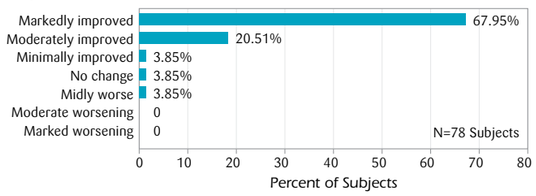


Figure 5. Rutherford - Becker clinical improvement scale at 30 days follow-up visit

Ankle-Brachial Index

Based on treated limbs, 76% (61/80) show a clinical improvement at 30 days over the baseline scores.

Safety Analysis

Four Serious Adverse Events (SAEs) and seventeen Adverse Events (AEs) were recorded during the MC-LEADER clinical study. All AEs and SAEs with full original documentation were presented to the independent Clinical Events Committee (CEC).

The CEC reviewed all SAEs/AEs and documented their relatedness to the eXtra balloon catheter. In summary there were no SAEs related to the eXtra device and six AEs were related to the eXtra device (vessel dissections and device malfunctions).

- The eXtra balloon performs and behaves as a standard PTA balloon catheter
- Retrieves clinically relevant particle sizes and quantities
- Valid alternative to embolic material containment and removal by means of a standard balloon catheter
- Can be used for all applications:
  - Pre/post dilatation
  - In stent restenosis
  - Post athrectomy
  - Balloon mounted stents
  - CTO

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