THE RESILIENT TRIAL

# 12-Month Results


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**For the RESILIENT Trial Investigators**

# Presenter Disclosure Information

## Name: Stephen R. Ramee, MD

Within the last 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organizations listed below.

Edwards LifeSciences Advisor

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# RESILIENT: Study Device

## LifeStent® NT Self-Expanding Stent

Helically-Designed, Nitinol Self-Expanding Stent

### Sizes Used in the Study

| Diameters | Lengths |
|---|---|
| 6 mm | 40, 60, 80 mm |
| 7 mm | 40, 60, 80 mm |

LifeStent® NT Delivery System


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# RESILIENT: Trial Design

- Lesions: SFA and/or Proximal Popliteal Artery
- Lifestyle-Limiting Claudication: Rutherford Category 1 – 3
- Lesion Length: <150mm
- Test Device: LifeStent® NT Stent & Delivery System

**Control Arm**
**(PTA Only)**
**n=69**

**1:2 Randomization**
206 Patients
24 Study Sites

**Test Arm**
**(PTA + LifeStent®)**
**n=137**


**Primary Endpoint**: TLR and/or TVR at 6 months

**Secondary Endpoints**: Patency; Lesion-, Procedure-, and Clinical-Success

*MACE = Major Adverse Clinical Events

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# RESILIENT: Study Partners

- **Ultrasound Core Lab:**
  - **VasCore (Massachusetts General Hospital)**
  - Evaluated Color Duplex Ultrasound (C-DUS):
    - 30 days, 6 months, and 12 months

- **Angiographic and X-Ray Core Lab:**
  - **Cardiovascular Research Foundation (CRF)**
  - Evaluated baseline and procedural angiographic images
  - Evaluated X-ray images:
    - 6 months, 12 months, and 18 months

# RESILIENT: Clinical Sites & Enrollment*

| | |
|---|---|
| Leipzig, Germany | 41 |
| Philadelphia, PA | 19 |
| Vienna, Austria | 16 |
| La Jolla, CA | 14 |
| Springfield, IL | 14 |
| Harrisburg, PA | 14 |
| Washington, DC | 13 |
| New Orleans, LA | 13 |
| Columbus, OH | 10 |
| Chapel Hill, NC | 8 |
| Atlanta, GA | 7 |
| Boston, MA | 7 |

| | |
|---|---|
| Mountain View, CA | 7 |
| Buffalo, NY | 6 |
| Pittsburgh, PA | 5 |
| Miami, FL | 5 |
| Rochester, NY | 5 |
| Atlanta, GA | 5 |
| Lafayette, LA | 5 |
| Dayton, OH | 4 |
| Tulsa, OK | 3 |
| Phoenix, AZ | 2 |
| Annapolis, MD | 2 |
| Pittsburgh, PA | 1 |

*24 Sites enrolled 20 roll-in and 206 randomized patients

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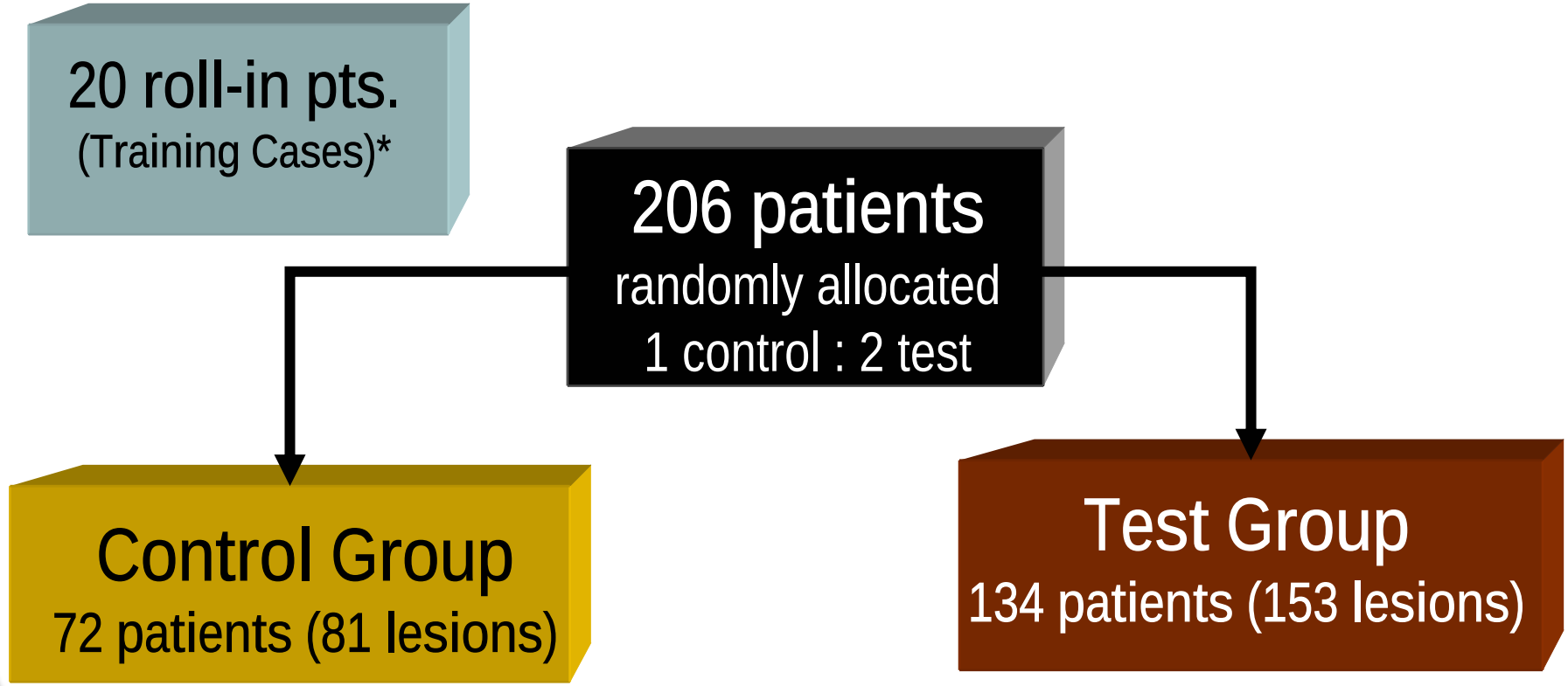
# RESILIENT: Patient Enrollment




*Each new study site was allowed 1 LifeStent® training case

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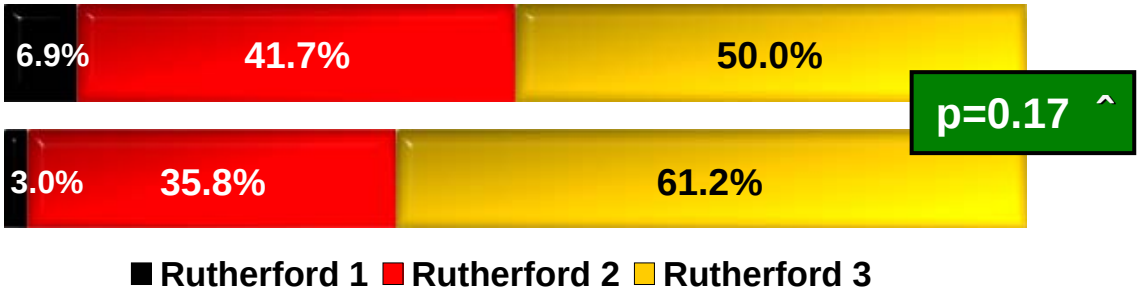
# RESILIENT: Baseline Demographics

| | Control Group (Pts. =72) | Test Group (Pts. =134) | p-value |
|---|---|---|---|
| Male / Female | 66.7% / 33.3% | 70.9% / 29.1% | 0.53 ^ |
| Age, (years) μ ± S.D. | 66.1 ± 9.2 | 68.4 ± 9.9 | 0.11 + |
| Hypertension | 91.7% | 83.6% | 0.14 # |
| Hypercholesterolemia | 73.6% | 78.4% | 0.49 # |
| Smoker (current / quit past 6 mo) | 83.3% | 71.6% | 0.09 # |
| Coronary Artery Disease | 54.2% | 56.0% | 0.88 # |
| Diabetes | 38.9% | 38.1% | 1.00 # |




^ = Chi Square Test
+ = t-test for Equality of Means
# = Fisher´s Exact Test

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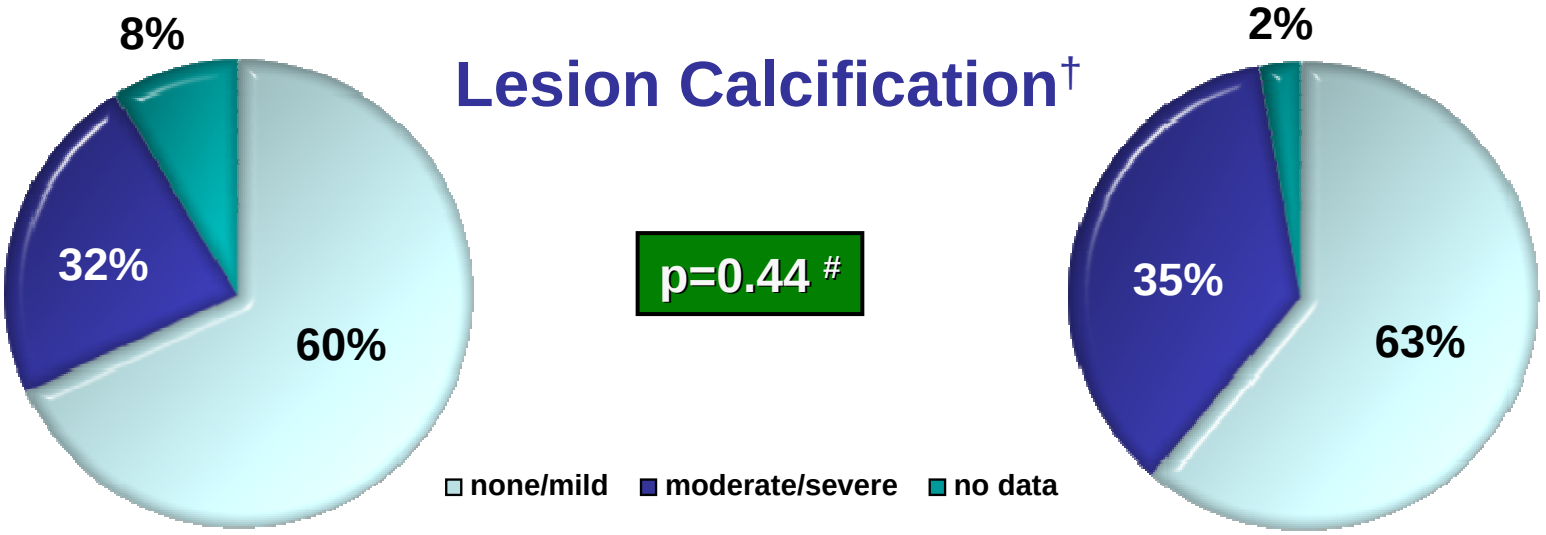
# Baseline Lesion Characteristics

| Characteristics† (mean ± S.D.)# | Control Group (Lesions=81) | Test Group (Lesions=153) | p-value+ |
|---|---|---|---|
| Target Vessel RVD | 5.1 mm ± 0.7 | 5.2 mm ± 0.8 | 0.64 |
| Lesion % Diameter Stenosis | 74.5% ± 18.2 | 72.7% ± 17.6 | 0.49 |

## Lesion Calcification†




Control Group

Test Group

† = Core Lab Analysis
+ = t-test for Equality of Means
# = Fisher´s Exact Test

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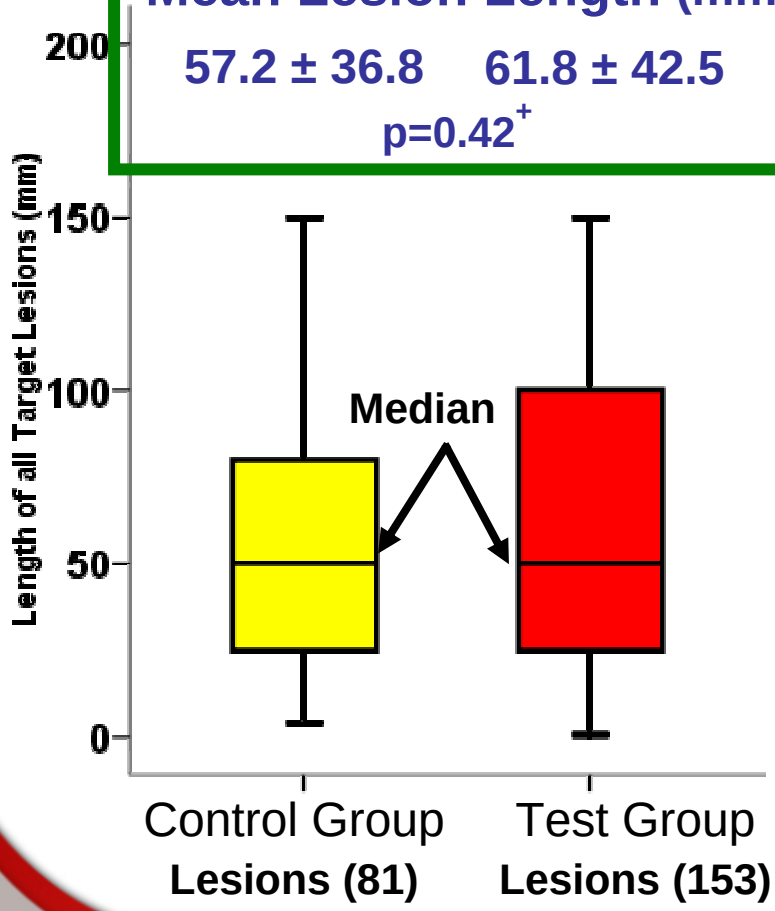
# Baseline Lesion Characteristics*

**Mean Lesion Length (mm)**

**57.2 ± 36.8  61.8 ± 42.5**

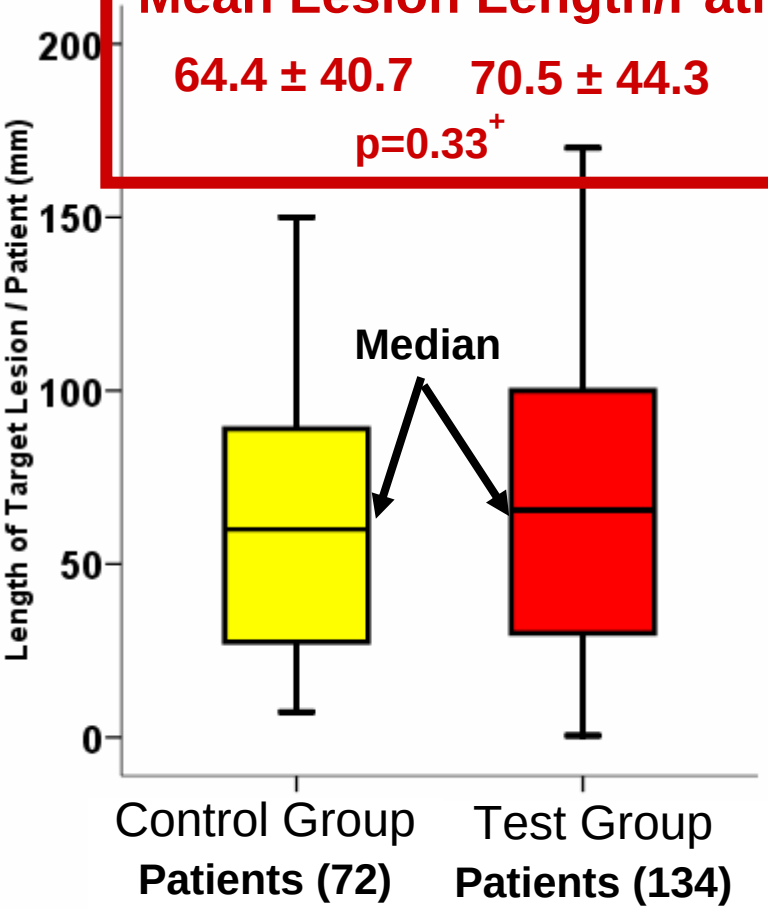
**p=0.42+**




**Mean Lesion Length/Patient**

**64.4 ± 40.7  70.5 ± 44.3**

**p=0.33+**




* = Site Reported

\+ = t-test for Equality of Means

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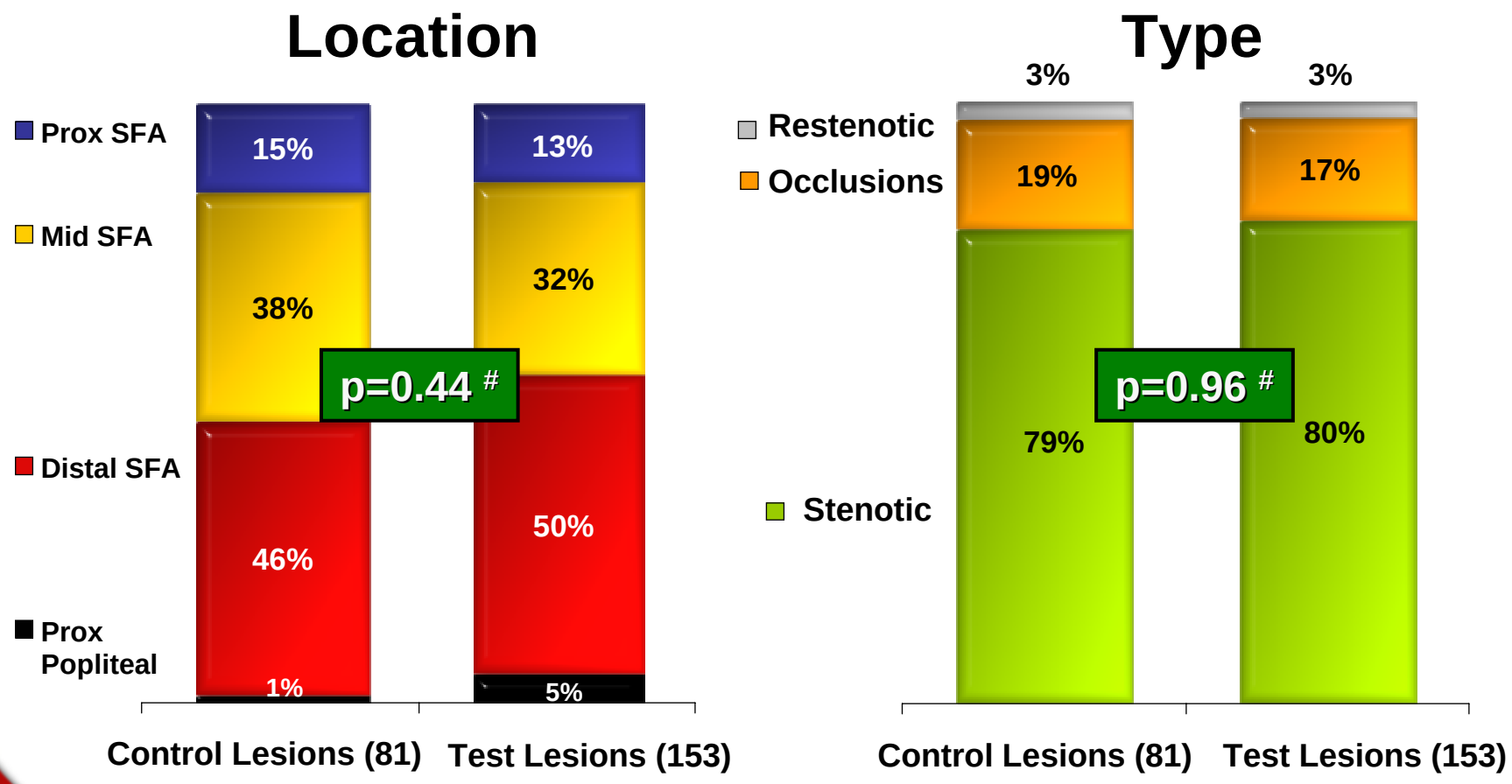
# Baseline Lesion Characteristics*

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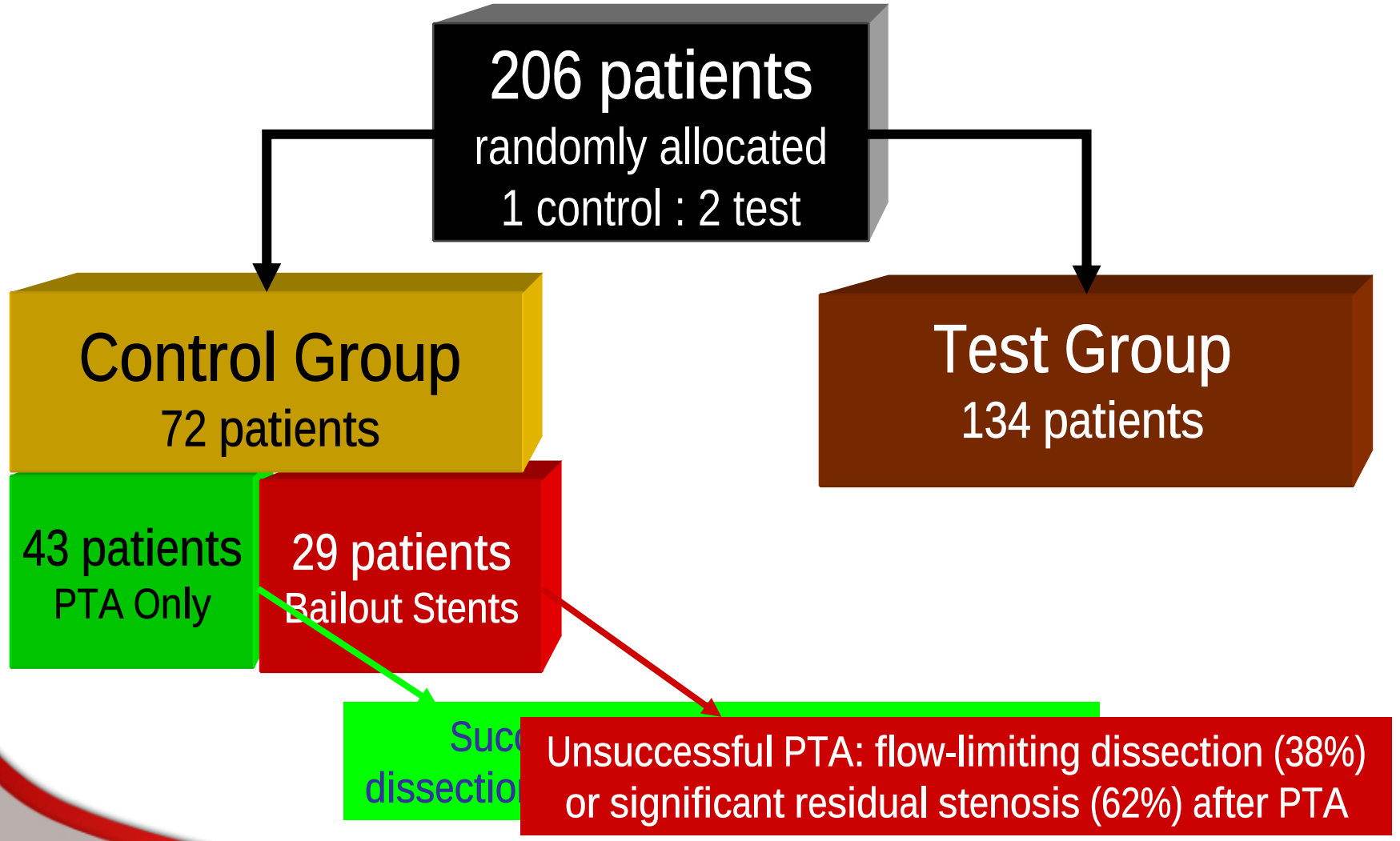
* = Site Reported
# = Chi Square Test

# Patient Enrollment: Bailout Stenting

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# Bailout Stenting

- Data from the bailout stenting cases were included in the Control Arm (as randomized)
- Bailout stenting was considered a target lesion revascularization (TLR) & patency failure:
  - Immediate need for additional intervention, and
  - Loss of flow
- The need for bailout stenting was confirmed by:
  - Angiographic core lab and clinical events committee (93%), or
  - Study site documentation in two patients (7%)

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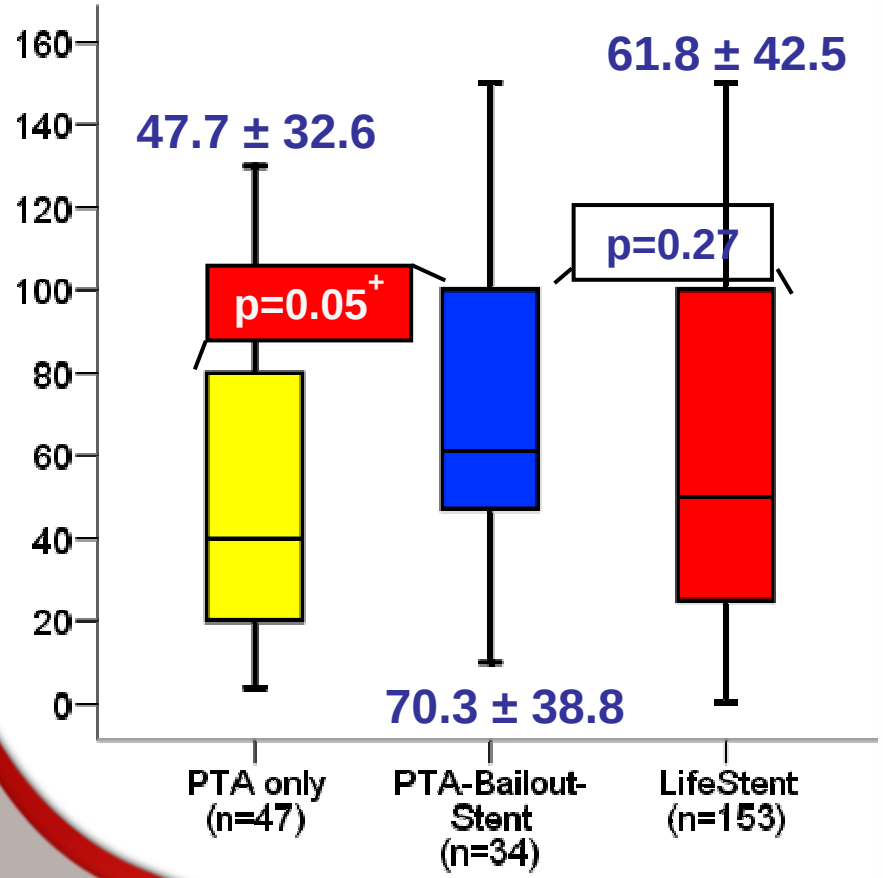
* = Visual Estimate

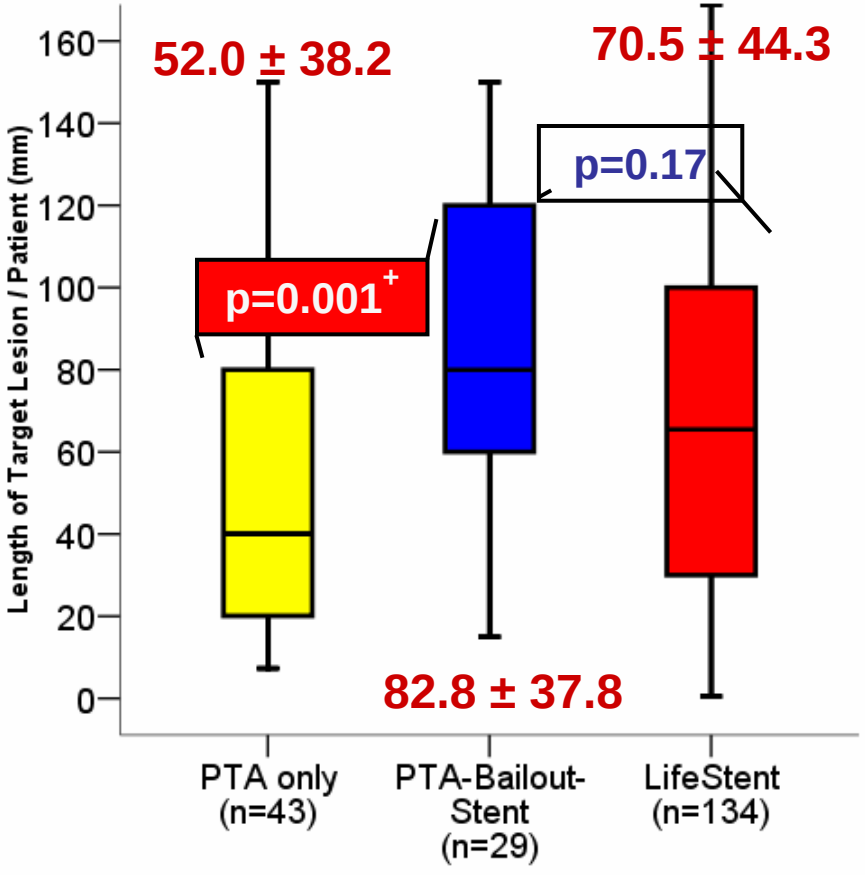
# Bailout Lesion Characteristics*

**Bailout lesions were significantly longer than the PTA-only lesions**

## Mean Lesion Length (mm).




## Mean Lesion Length / Patient (mm)




* = Site Reported

**+ =Statistically Significant**

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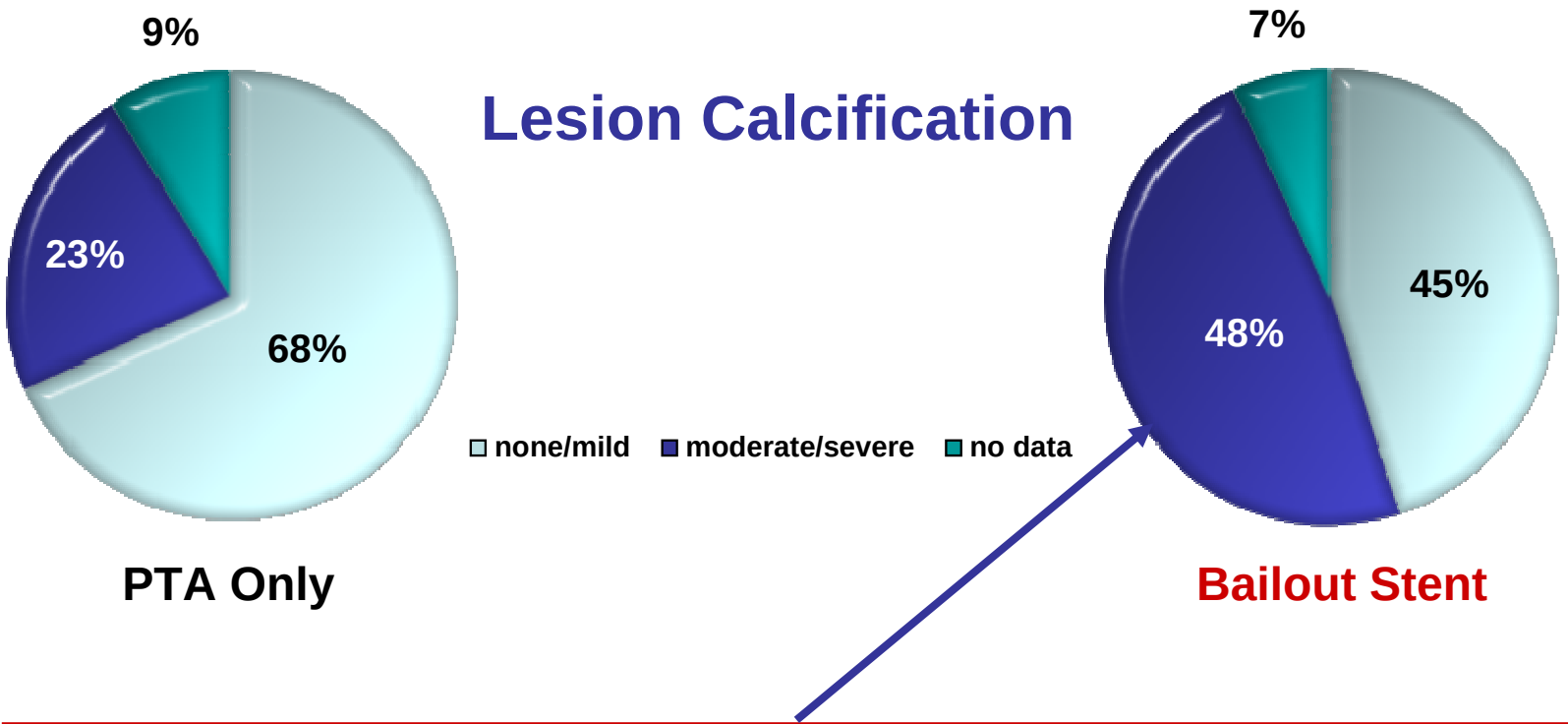
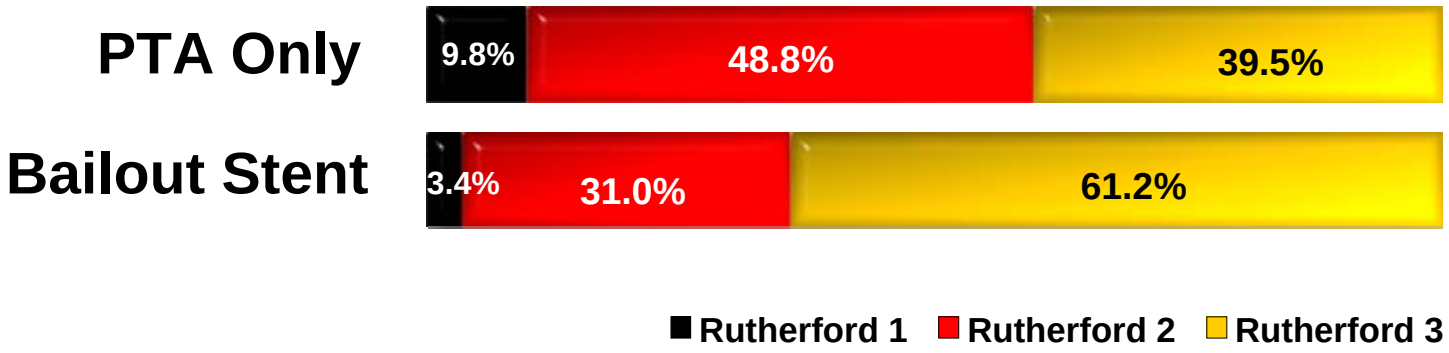
# Bailout Lesion Characteristics




**Bailout lesions tended to be more heavily calcified than the PTA-only lesions**

# Bailout Patient Characteristics

## Rutherford Classification




**Bailout stenting patients tended to have more severe claudication than the PTA-only patients**

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# RESILIENT: Peri-Procedural Results

| Measure (per lesion) | Control Group | Test Group | p-value |
|---|---|---|---|
| **Lesion Success**†(n)<br>residual stenosis < 30% | **71.6%** (58/68) | **85.6%** (131/136) | **0.01**# |

| Measure (per patient) | Control Group | Test Group | p-value |
|---|---|---|---|
| **Procedure Success**†(n)<br>residual stenosis < 30% and<br>no peri-procedural complications | **70.8%** (51/59) | **85.1%** (114/119) | **0.02**# |

† = Core Lab Analysis
# = Fisher´s Exact Test

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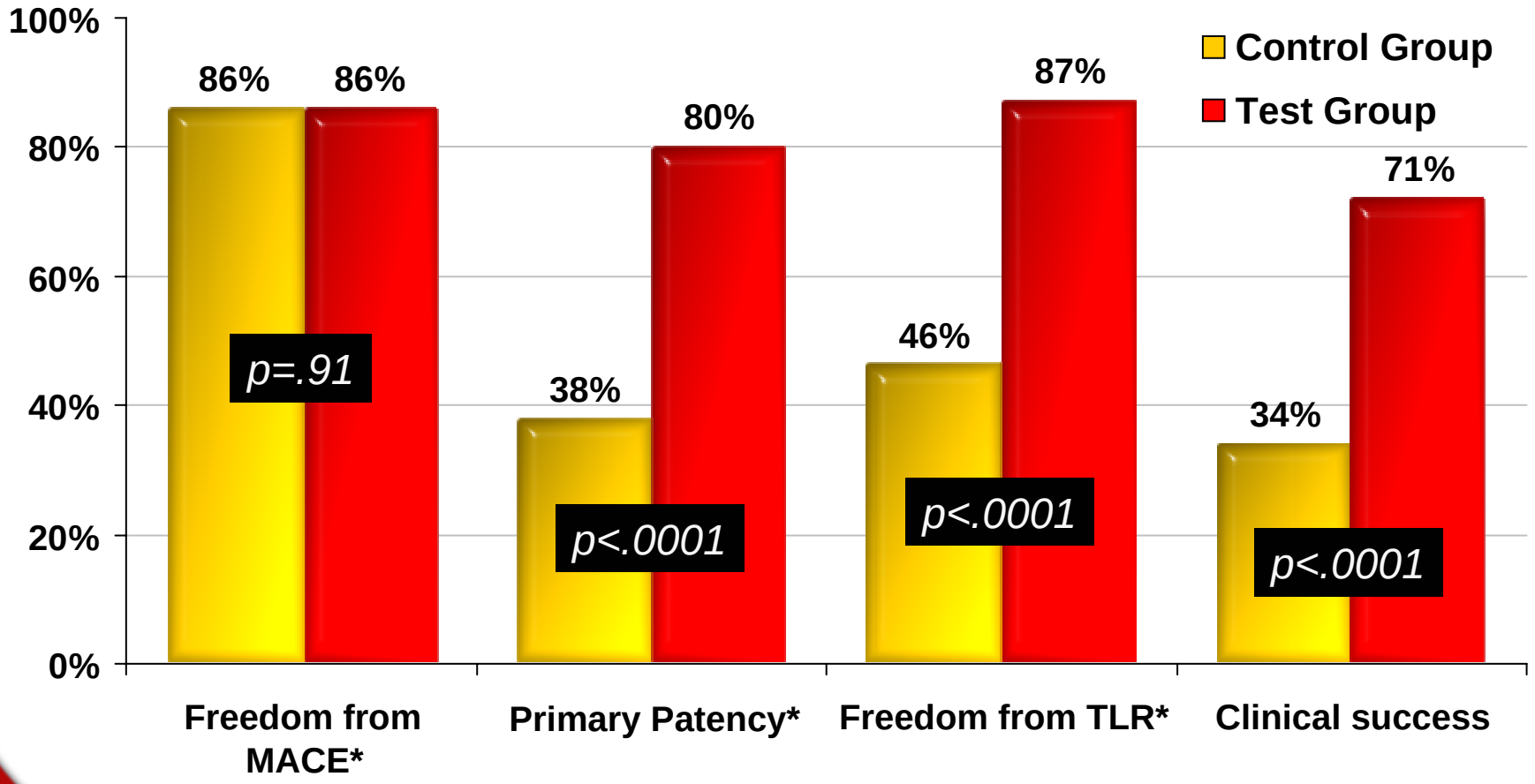
# RESILIENT: Outcome Definitions

- **MACE (Major Adverse Clinical Events)**
  - Death, stroke, MI, significant distal embolization, emergent surgical revascularization of the limb, thrombosis, and Rutherford category worsening post-procedure.
- **Patency**
  - A failure of primary patency is any TLR or binary restenosis greater than 50%. DUS Peak Systolic Velocity (PSV) ratio < 2.5 is considered patent.
- **Target Lesion Revascularization (TLR)**
  - "Clinically-driven" repeat intervention of the target lesion
- **Clinical Success**
  - An improvement of baseline symptoms by at least one Rutherford category as a result of the test or control procedure and sustained through follow-up (with no additional intervention).

# RESILIENT: 12-Month Results




*Data from Kaplan-Meier Survival Analysis

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# RESILIENT: Study Summary

- 206 Patients (claudicants) were enrolled at 24 sites:
  - SFA and proximal popliteal lesions < 150 mm
  - Randomly allocated to “PTA only” or “PTA + LifeStent®”
- Baseline characteristics were similar for both groups.
- Mean stented length (Test Group): **99 mm ± 50 mm**

## RESILIENT : 12-Month Results

| | Control Group | Test Group |
|---|---|---|
| Primary Patency | 38% | 80% |
| Freedom from TLR | 46% | 87% |

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# RESILIENT: Stent Fracture Observations

| Fracture Type | Total 0-12 months | 2 or more overlapping stents | Stent Elongation at deployment | Locations* | Lesion Moderate - Severe Calcification |
|---|---|---|---|---|---|
| Type I | 4 | 1 of 4 | 1 of 4 | MMMD | 2 of 4 |
| Type II | - | - | - | - | - |
| Type III | - | - | - | - | - |
| Type IV | 5 | 4 of 5 | **5 of 5** | MMMMP | 3 of 5 |

| Period 0 – 12 months | TOTAL |
|---|---|
| Fractured Stents | **9** |
| Fracture Rate[#] | **3.2%** |

[#] 9 stent fractures / 280 stents evaluated by the angiographic core lab

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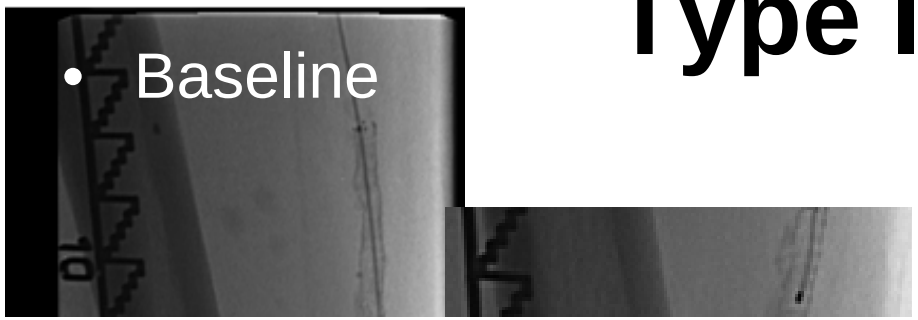
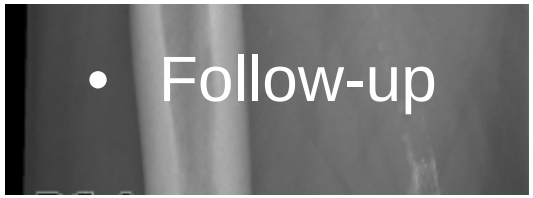
***** Per Core Lab Analysis:
M=Mid SFA; D=Distal SFA; P=Popliteal

# RESILIENT: Stent Fracture Type IV

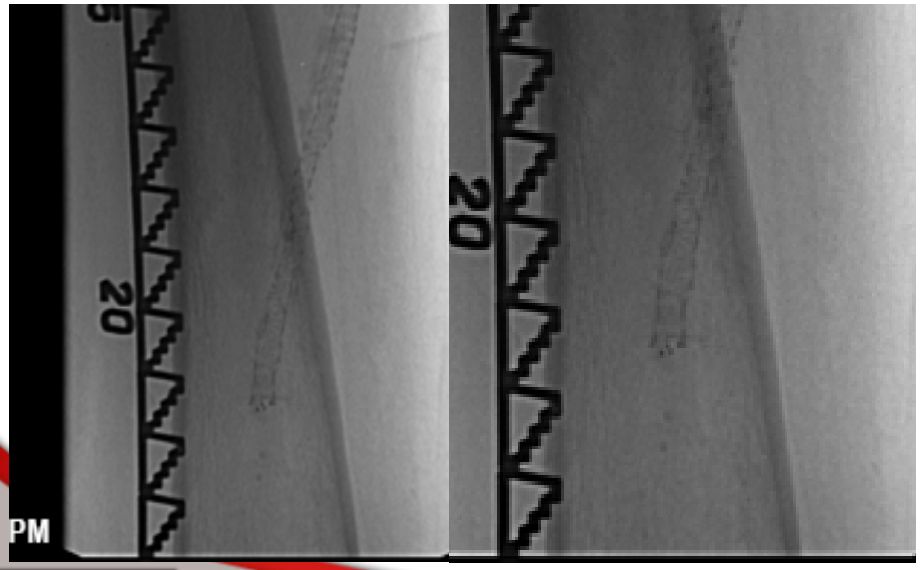
- Baseline

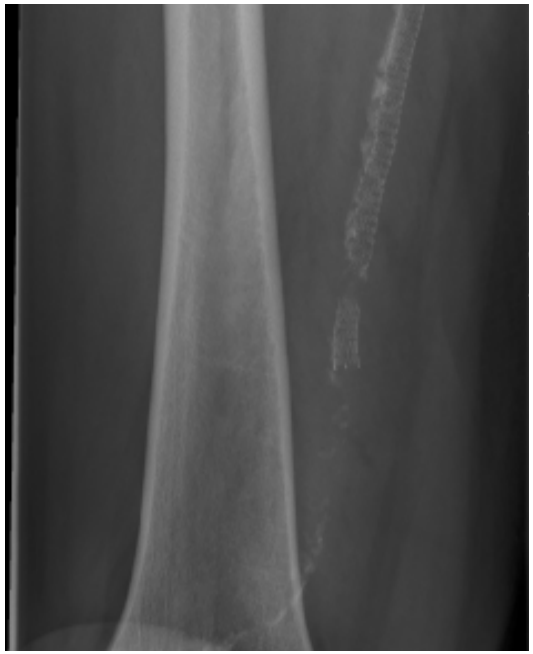


- Follow-up



None of the Stent Fractures were associated with restenosis at 12 months





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# RESILIENT: Study Observations

- "Longer" and/or "more calcified" lesions did not respond sufficiently to a PTA-only strategy:
  - The bailout stenting rate in the Control Group was 40.2%

- A low fracture rate:
  - Observed fractures may be partially explained by elongation of the stent at deployment.
  - A "One Stent" strategy is recommended when possible.

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# RESILIENT: Study Conclusions

## RESILIENT's Level 1 evidence illustrated:

- In claudicants with SFA/ proximal popliteal lesions shorter than 150 mm, a **primary stenting strategy with the LifeStent® was superior to a PTA-only strategy** …
  - **Peri-procedurally** – as evidenced by lesion success and procedure success; and at
  - **One year** – as evidenced by primary patency, freedom from TLR, and clinical success
- A PTA-only strategy has a role in patients with less complex lesions (i.e., shorter, less heavily calcified)
- Use of the LifeStent® did **not** lead to a higher rate of "Major Adverse Clinical Events" than PTA alone

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