

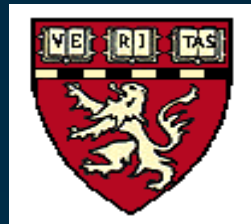
Stent Fractures: Incidence and Clinical Relevance



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Angiographic
Core Laboratory



Conflict of Interest Statement

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Physician Name

Company/Relationship

Jeffrey J. Popma, MD

Research Grants: Cordis, Boston Scientific,
Medtronic, Abbott-Guidant, Biosensors,
Radiant, eV3

Medical Advisory Board: Cordis, Boston
Scientific, Medtronic

Speaker's Bureau: Sanofi, BMS, Boston
Scientific, Pfizer

Original Studies

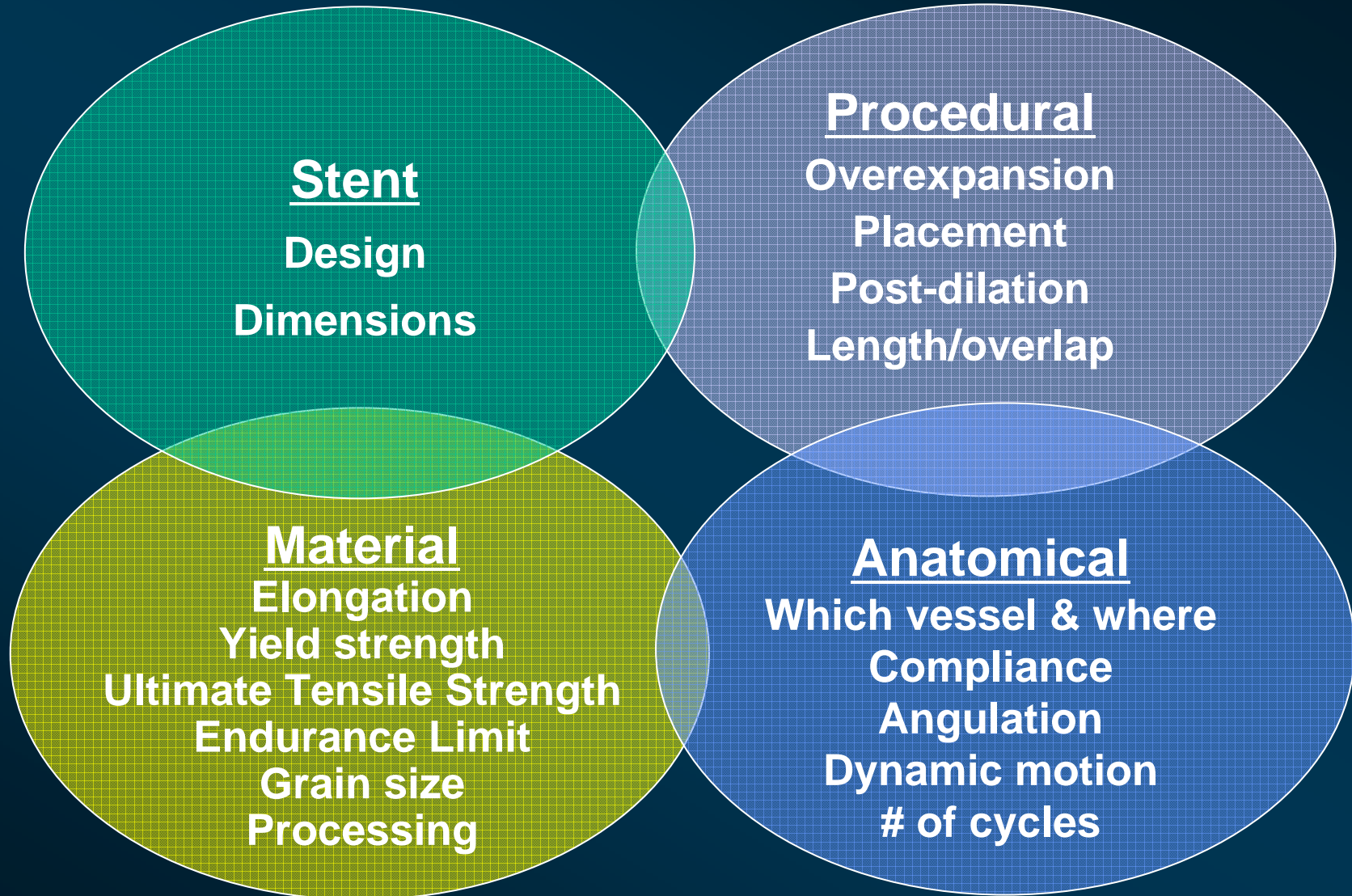
Standardized Evaluation and Reporting of Stent Fractures in Clinical Trials of Noncoronary Devices

Michael Jaff,^{*} Michael Dake, Jeffrey Pompa, Gary Ansel, and Tony Yoder

Standardized
Acquisition
Methodology
Is Needed
To Detect Stent
Fractures
For Peripheral
And Coronary
Studies



Stent Fatigue is Multifactorial



Preclinical Testing: Dynamic Loading

- Dynamic loading in a vessel results in the following deformations:

- Pulsatile (current fatigue test & FEA)

- Bend (static bend modeling in FEA)

- Twist

- Stretch



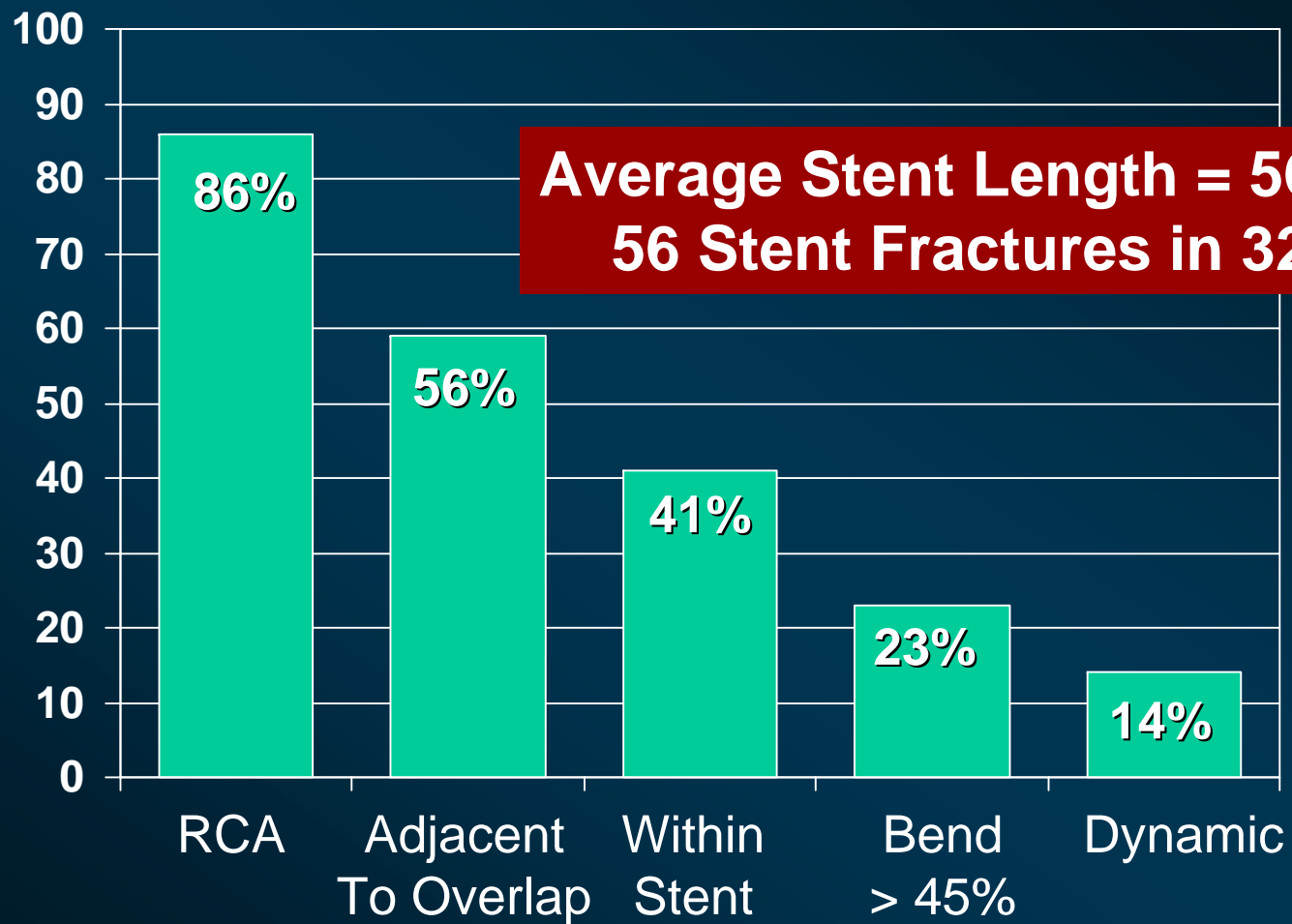
- Above are likely a function of species, vessel (RCA, LAD, LCX) and location (proximal, distal)

SCAIACCI2: Predictors of Stent Fractures

- 1808 pts with 2920 lesions with angiographic FU in 1491 patients with 2357 lesions (80.7%)
- Definition: Obvious separation of stent
- Stent restenosis rate was 11.2%; stent fracture rate was 3.9% and stent fracture with restenosis was 1.1%
- Multivariable predictors for stent fractures with restenosis: aorto-ostial lesions; severe angulation; SVG and overlapping stents
- Coronary artery motion was also an important predictor of stent fracture with restenosis

ACROSS CYPHER for CTO

N=200 Patients



ACROSS CYPHER

Overall Fracture Rate = 16%

	Stent Fracture (N=32)	No Stent Fracture (N=168)	P Value
Stent length, mm	69.9	45.0	< 0.001
Overlapping stents, %	100	89.9	0.06
TLR, %	9.4	5.5	0.42
MACE, %	9.4	6.1	0.45
Stent Thrombosis, %	3.1	0	0.16
In-segment BAR. %	21.9	7.4	0.09

BWH Core Lab Definitions for Stent Fracture

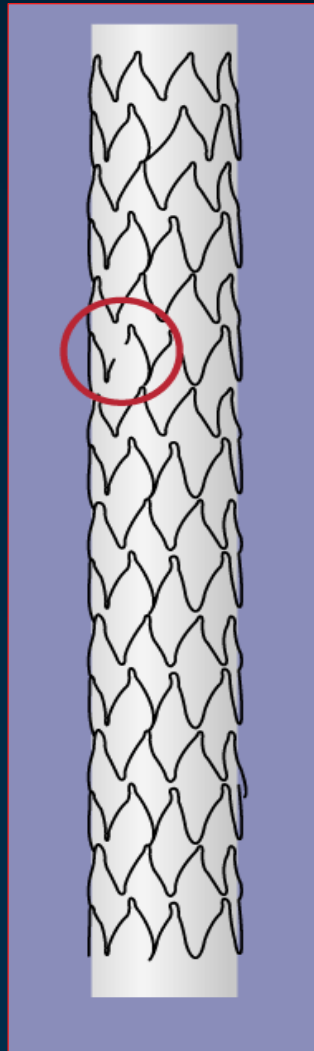
Classification	Current Report	Allie et al ¹	Scheinert et al ²
Type 0	No strut fracture	-	-
Type I	Single strut fracture or gap between struts greater than 2x normal	Single strut fracture only	Minor – single strut fracture
Type II	Multiple strut fractures with V-form division of the stent	Multiple single stent fractures occurring at different sites	Moderate – fracture >1 strut
Type III	Complete transverse stent fracture without displacement of fractured fragments more than 1 mm during the cardiac cycle	Multiple single stent fractures resulting in complete transverse linear fracture but without stent displacement	Severe – complete separation of stent segments
Type IV	Complete transverse stent fracture with abundant movement and displacement of fractured fragments of more than 1 mm during the cardiac cycle	Complete transverse linear type III fracture with stent displacement	-

¹ Allie et al Endovascular Today 2004; July/August: 22-34

² Scheinert et al J Am Coll Cardiol 2005; 45:312-315

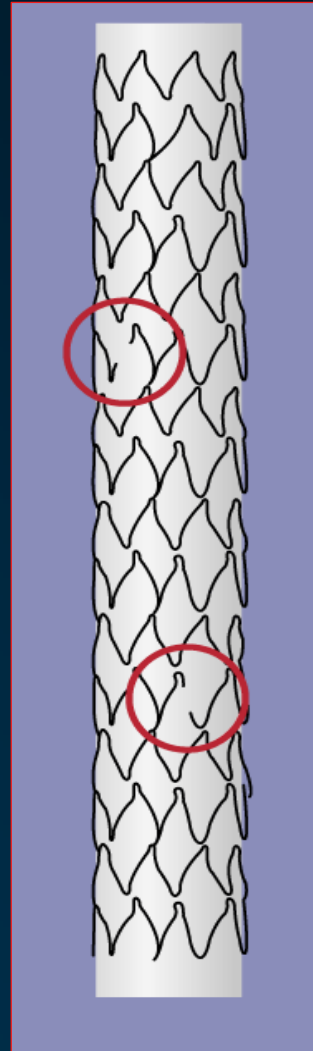
* Type 5 implies spiral fracture of stent

Type I



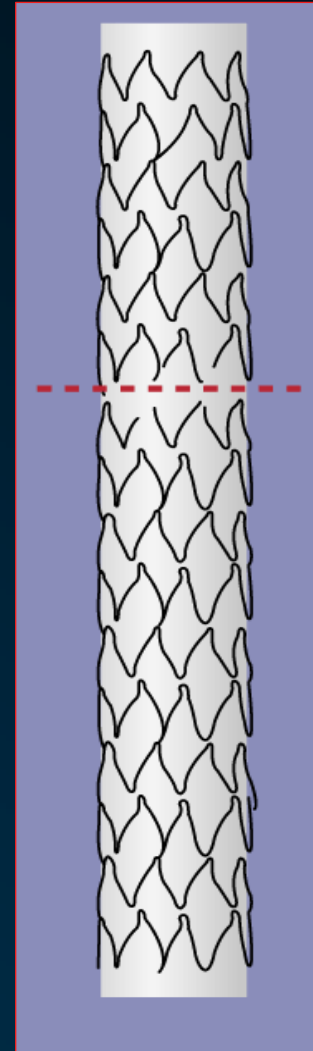
Single strut fracture

Type II



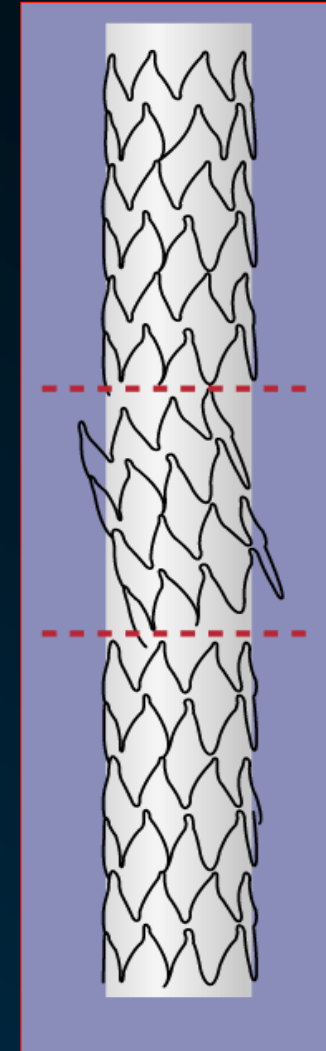
Multiple single
stent fractures;
different sites

Type III



Multiple stent
fractures; complete
transverse linear
fracture

Type IV



Complete transverse
linear Type III fracture
with stent displacement

BWH SIRUS Angiographic Analysis

Did We Miss Something Important?

349 Patients in the CYPHER arm with follow-up in SIRIUS

- 40 Patients with not available CINE films
- 2 patients neither of the follow-up CDs can be opened
- 2 patients all CD missing

305 patients analyzed with 497 follow-up angiograms

4 fractures identified (1.3%),

- 3x Fracture Type 1 (0.98%)
- 1x Fracture Type 2 (0.33%)
- All fractures occurred with multiple stents near the site of overlap, all vessels calcified including one chronic total occlusion.
- 1 ISR at that site with TLR (Type 1 Fracture – tissue growth)

Stent Fracture: Review of Adverse Event Reports

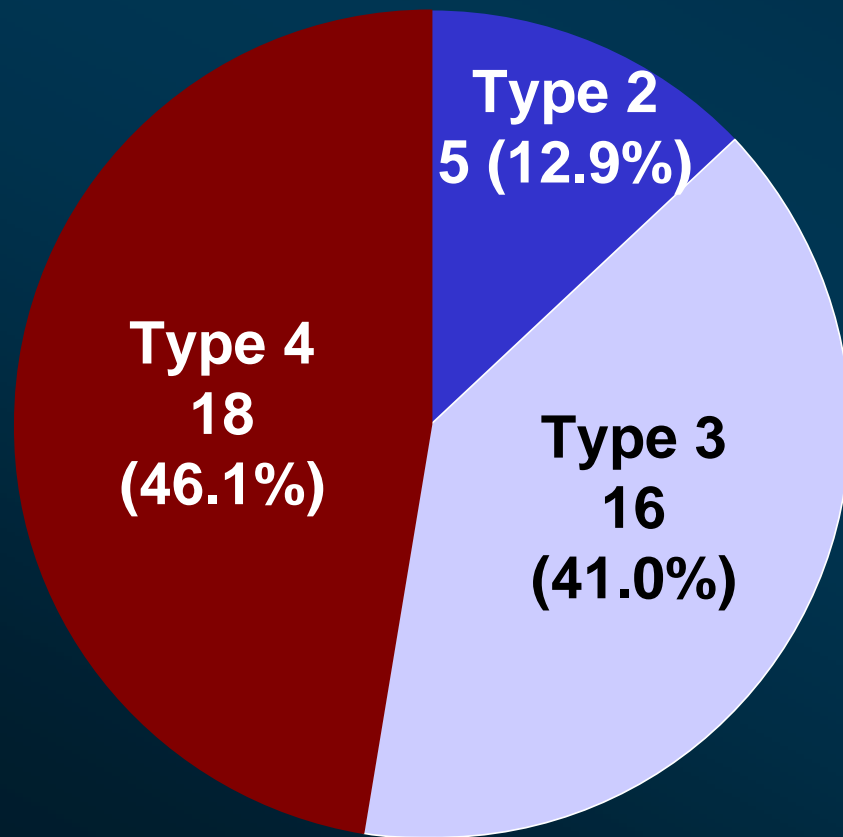
MAUDE cases between August 2003-July 2006

	226 Cases
Coronary Stents:	125
CYPHER	113
TAXUS	12
Peripheral Stents:	101
CYPHER Angiograms Forwarded to Core Lab	51 Cases
No Fracture By Available Paperwork	2
No Stent Fracture Identified	9
Bx Sonic	1
Analysis population	39 Cases
Baseline Angiogram Available	28

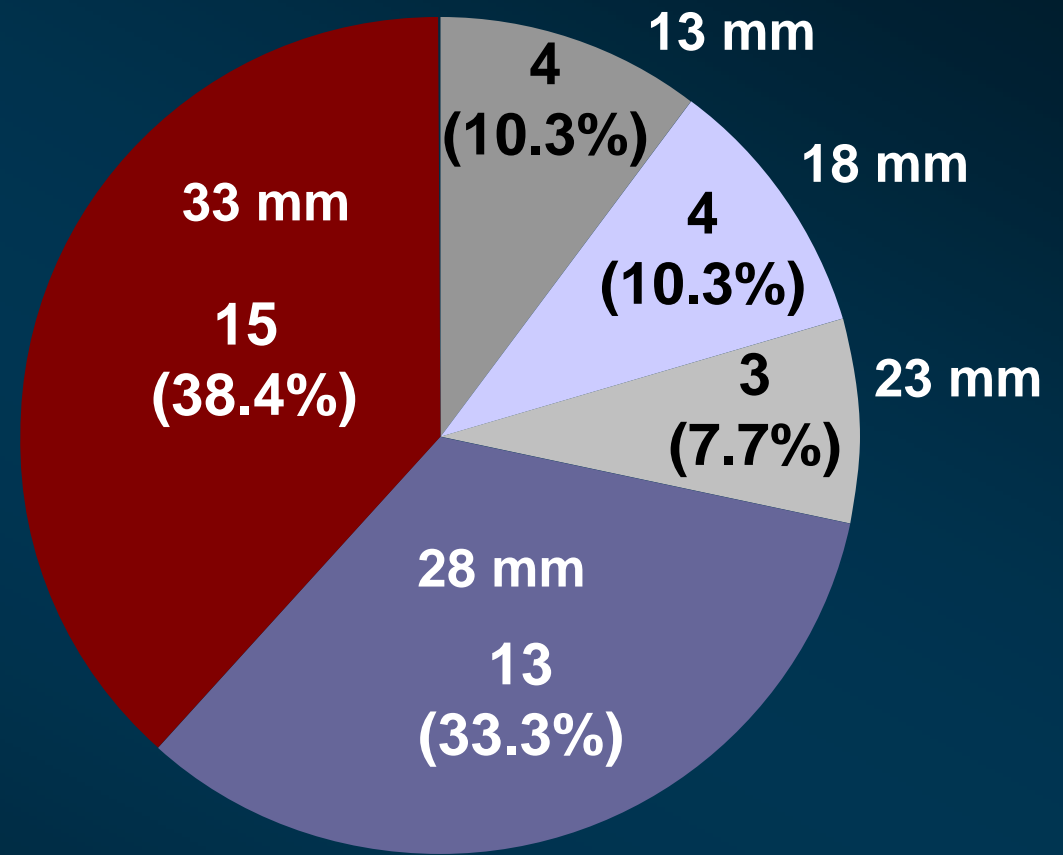
* 45 stent fractures in 39 patients

BWH Angiographic Analysis Adverse Event Reports (N=39)

Fracture Type



Stent Length



Stent Fracture: Baseline Angiographic Findings

Variable	Stent fracture N = 28, (%)	Sirius N = 531, (%)	P Value
Location			
LAD	12 (42.9)	234 (44.1)	0.94
LCx	4 (14.3)	134 (25.2)	0.27
RCA	12 (42.9)	160 (30.1)	0.23
Ostial Location	6 (21.4)	10 (1.9)	<0.001
Lesion Length, mm	22.1±15.9	14.4±5.8	<0.001
0-9.9 mm	7 (25.0)	106 (20.0)	0.66
10-19.9 mm	9 (32.1)	342 (64.6)	0.001
20 or greater	12 (42.9)	82 (15.4)	0.002
Angulations ≥ 45 degrees	13 (46.4)	58 (10.9)	< 0.001
Proximal Tortuosity	7 (25.0)	28 (5.3)	0.002
Calcification present	19 (67.9)	91 (17.1)	<0.001
Total Occlusion	7 (25.0)	17 (3.2)	<0.001

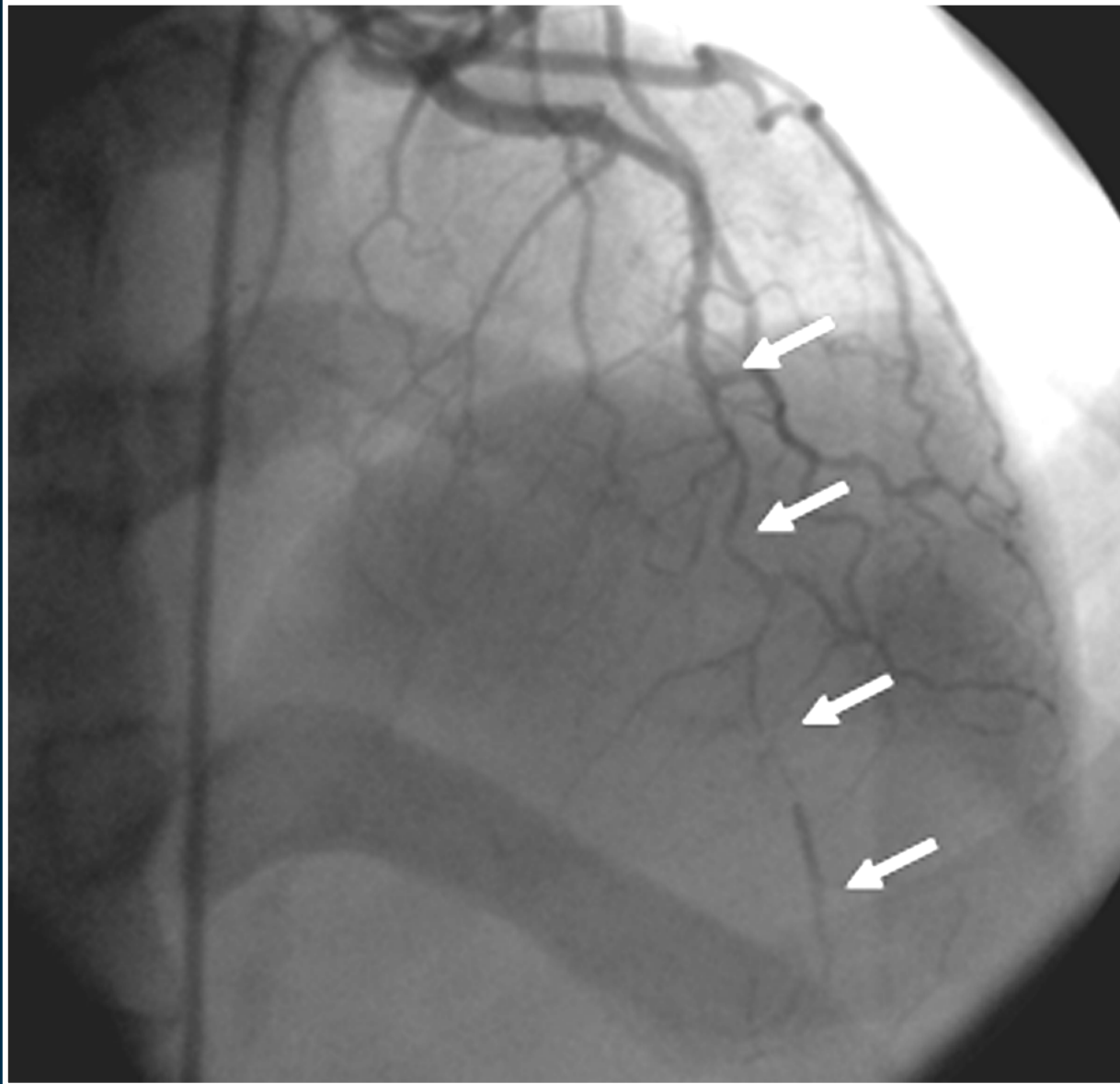
Stent Fracture: Baseline Angiographic Findings

Variable	Stent fracture	Sirius	P Value
Baseline	N = 28	N = 531	
RVD, mm	2.66±0.50	2.79±0.45	0.14
MLD, mm	0.56±0.39	0.97±0.40	<0.001
% Stenosis	77.8±15.3	65.1±12.6	<0.001
Final	N = 28	N = 531	
<i>Within the Segment</i>			
Final MLD	2.06±0.48	2.38±0.42	<0.001
Final % Stenosis	24.6±11.1	16.1±9.7	<0.001
<i>Within the Stent</i>			
Final MLD	2.33±0.49	2.67±0.40	<0.001
Final % Stenosis	14.8±8.9	5.4±8.2	<0.001

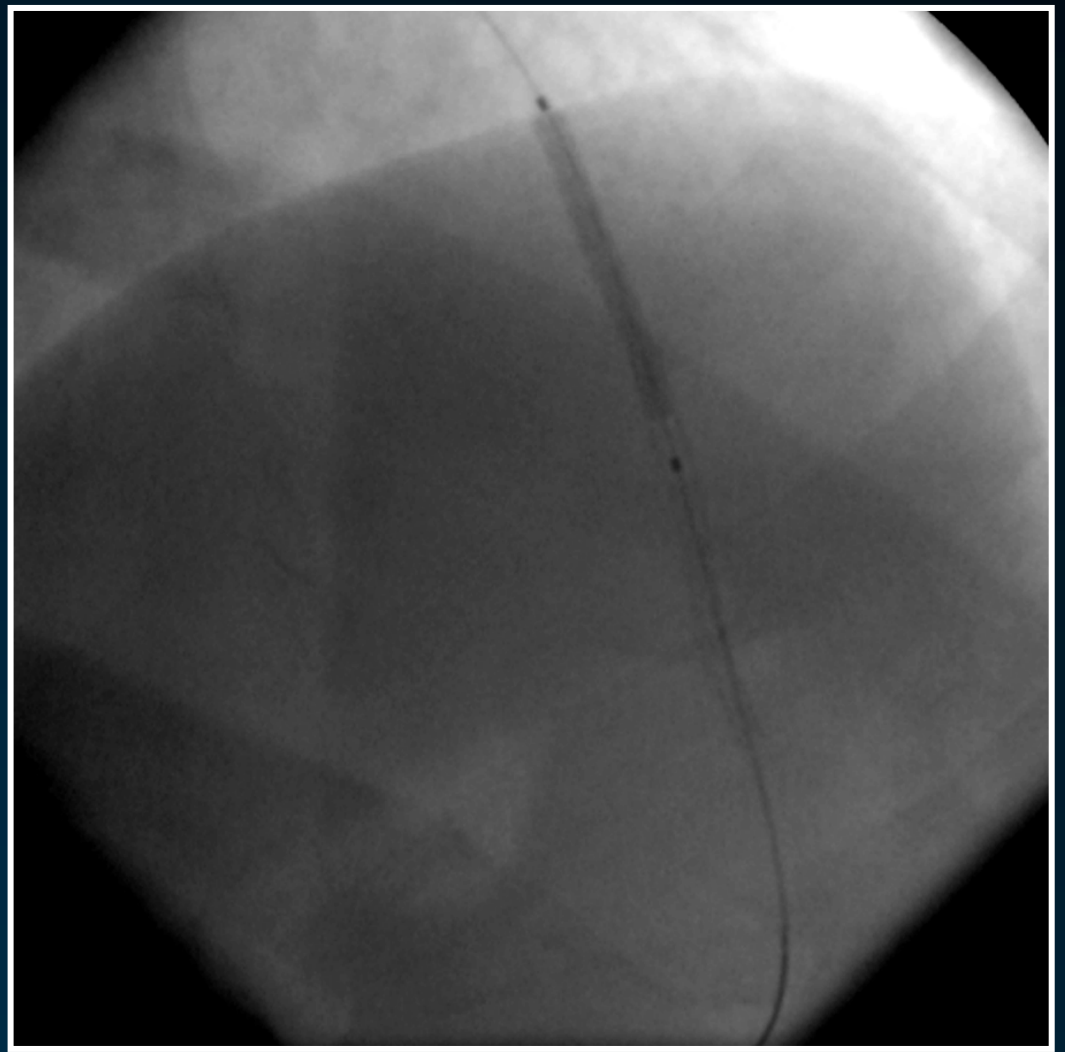
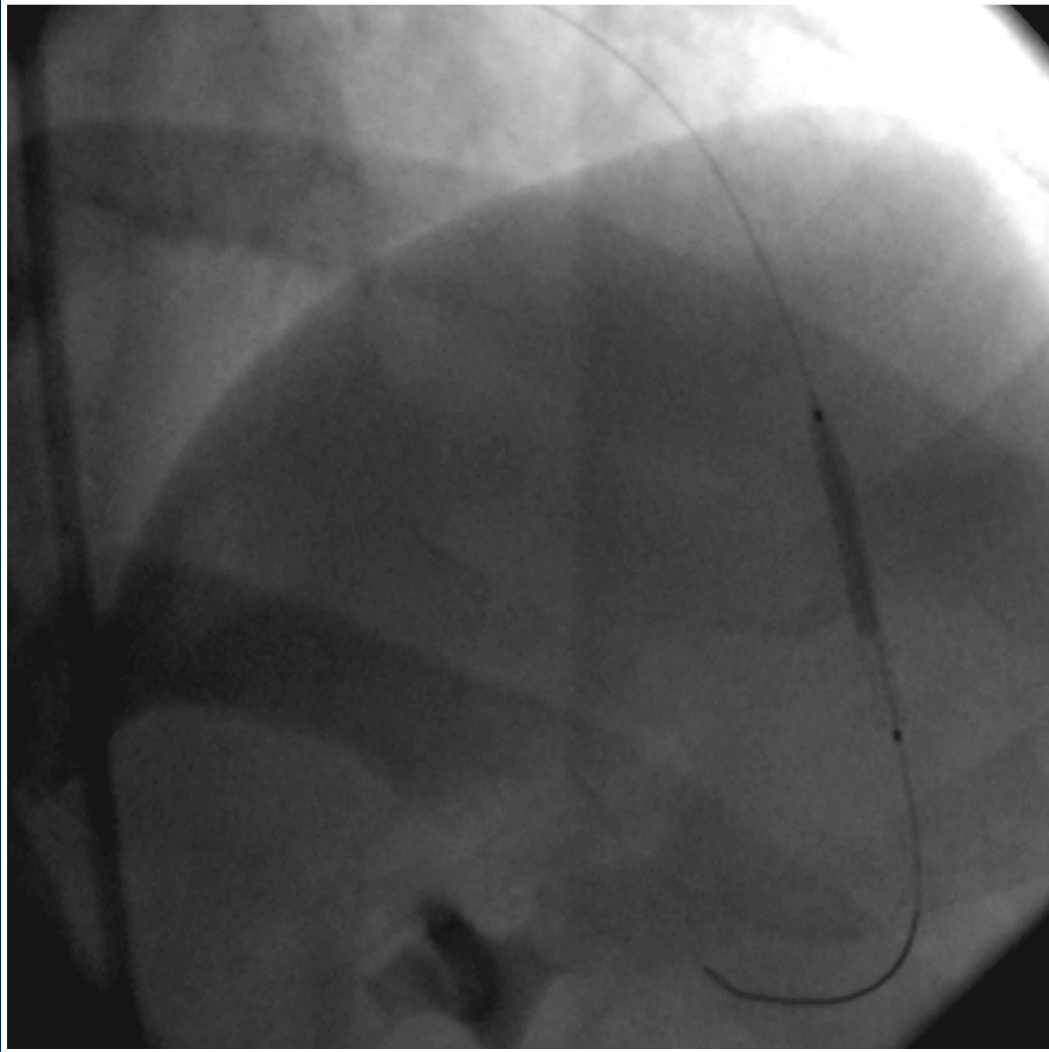
Stent Fracture: Follow-up Findings

Variable	Stent fracture N = 38 (%)	Sirius N = 350 (%)	P Value
RVD, mm	2.72±0.48	2.79±0.42	0.33
<i>Within the Segment</i>			
Follow-up MLD	1.41±0.69	2.15±0.61	<0.001
Late Lumen Loss	0.70±0.66	0.24±0.47	<0.001
Restenosis Rate	18 (47.4)	31 (8.9)	< 0.001
Follow-up % Stenosis	48.6±23.0	23.6±16.4	<0.001
<i>Within the Stent</i>			
Follow-up MLD	1.52±0.82	2.50±0.58	<0.001
Late Lumen Loss	0.96±0.71	0.17±0.44	<0.001
Follow-up % Stenosis	44.1±28.5	10.4±16.5	<0.001
Restenosis Rate	18 (47.4)	11 (3.2)	<0.001
ISR Length, mm	6.55±5.96	9.1±5.8	0.01
Total occlusions	3 (7.9)	2 (0.6)	0.02
Aneurysm	5 (13.2)	2 (0.6)	<0.001

Case 1: Diffuse LAD Disease

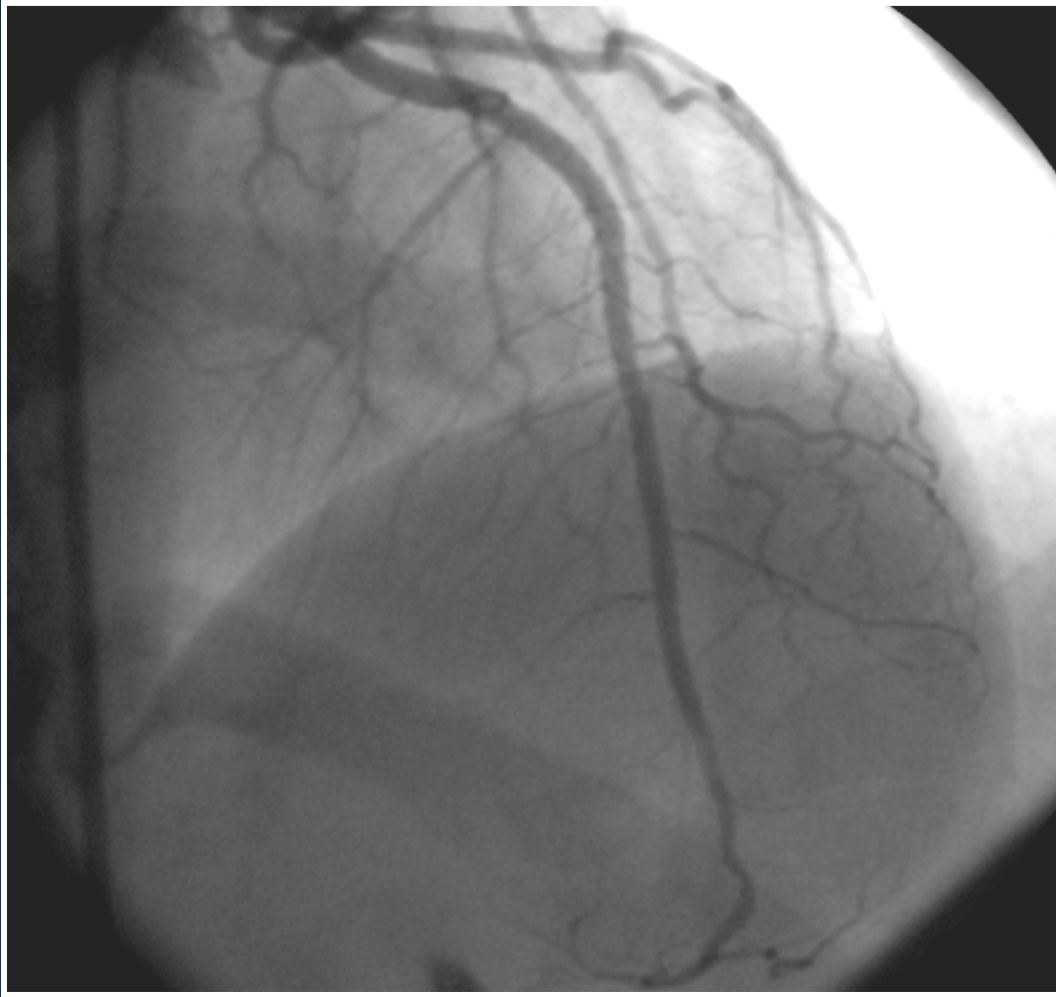


Case 1: Diffuse LAD Disease

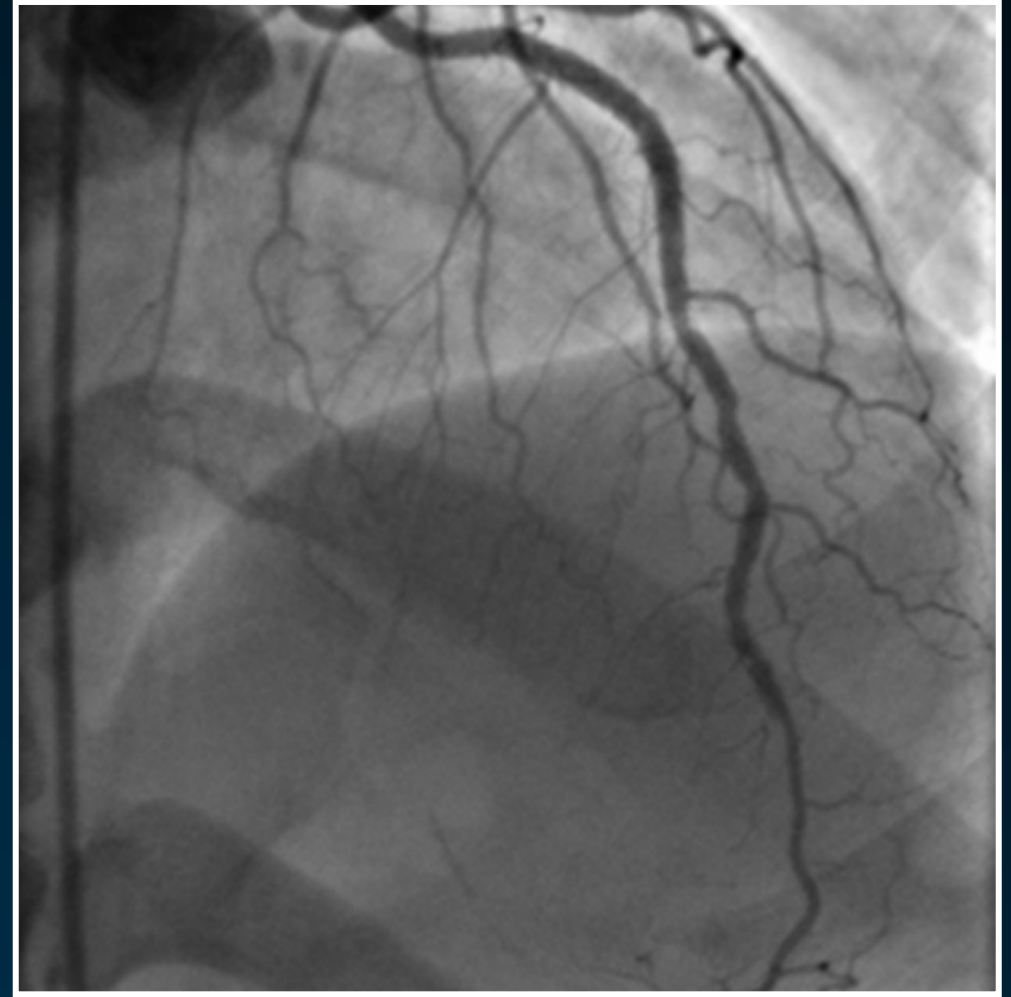


2.5 mm x 23 mm; 2.5 mm x 33 mm; 3.0 x 18 mm CYPHER stents

Case 1: Diffuse LAD Disease

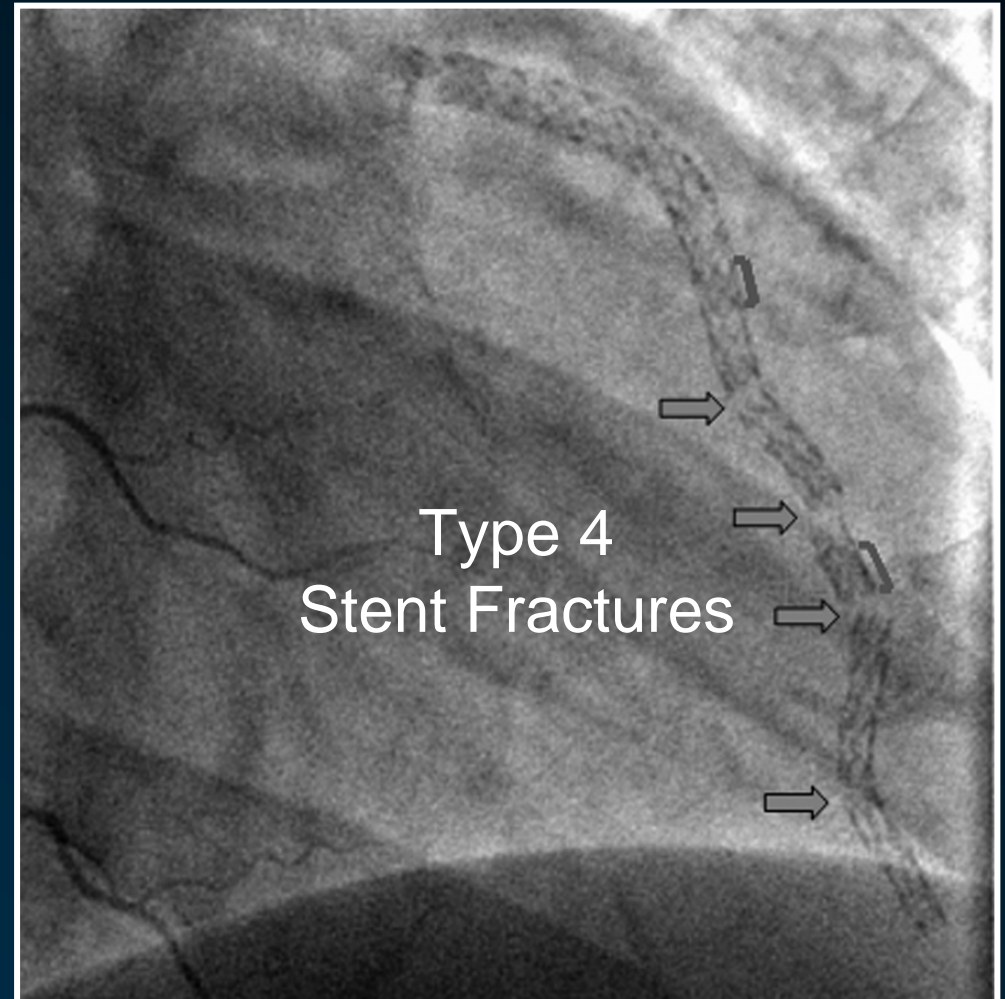
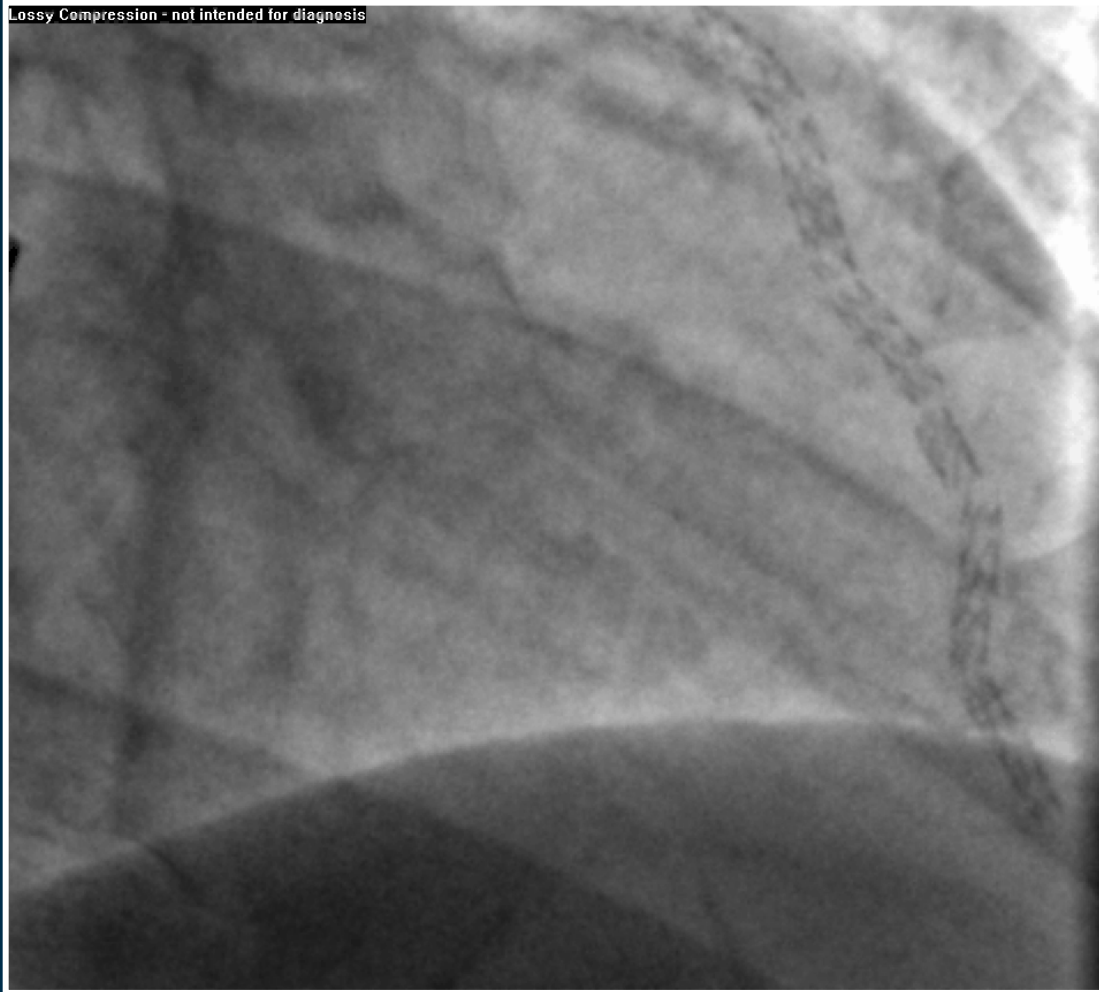


Final Angiographic Result



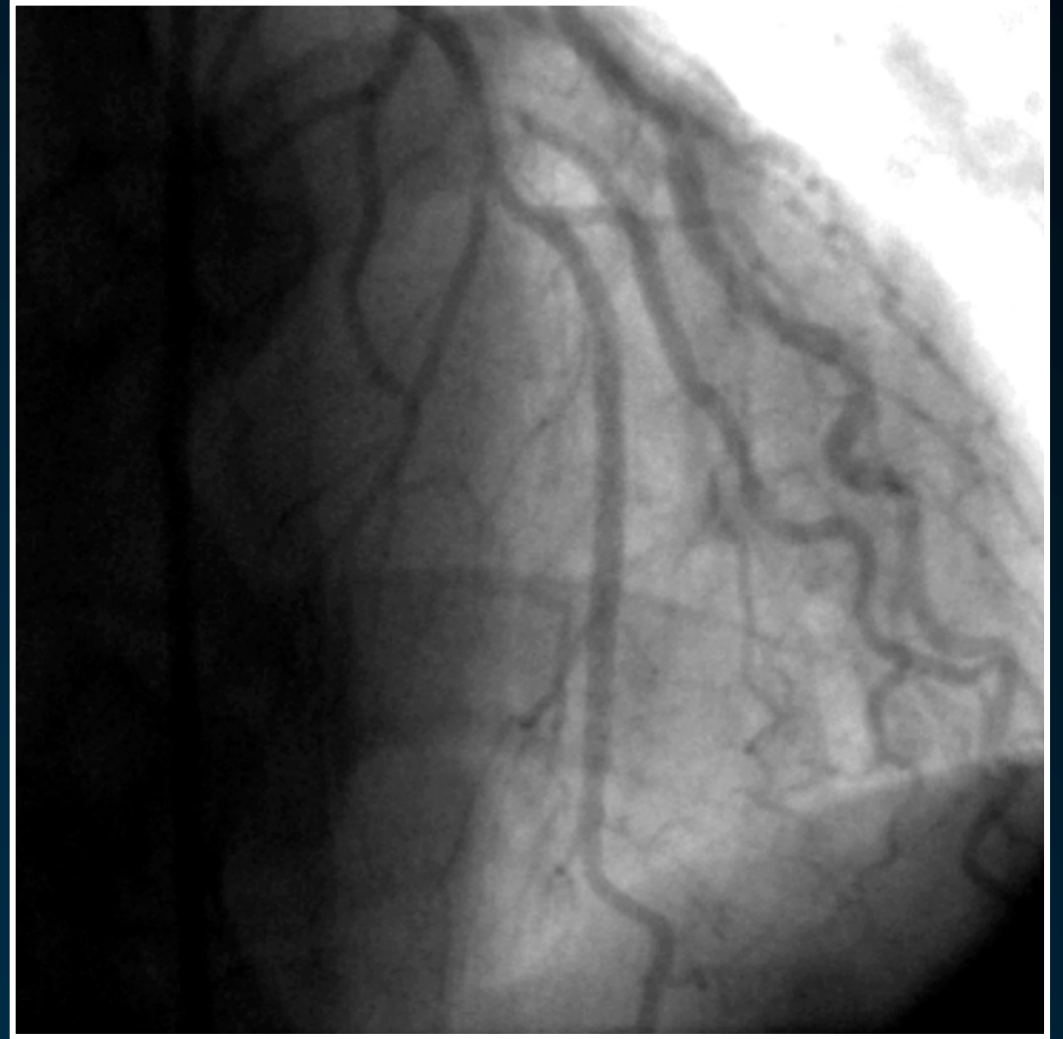
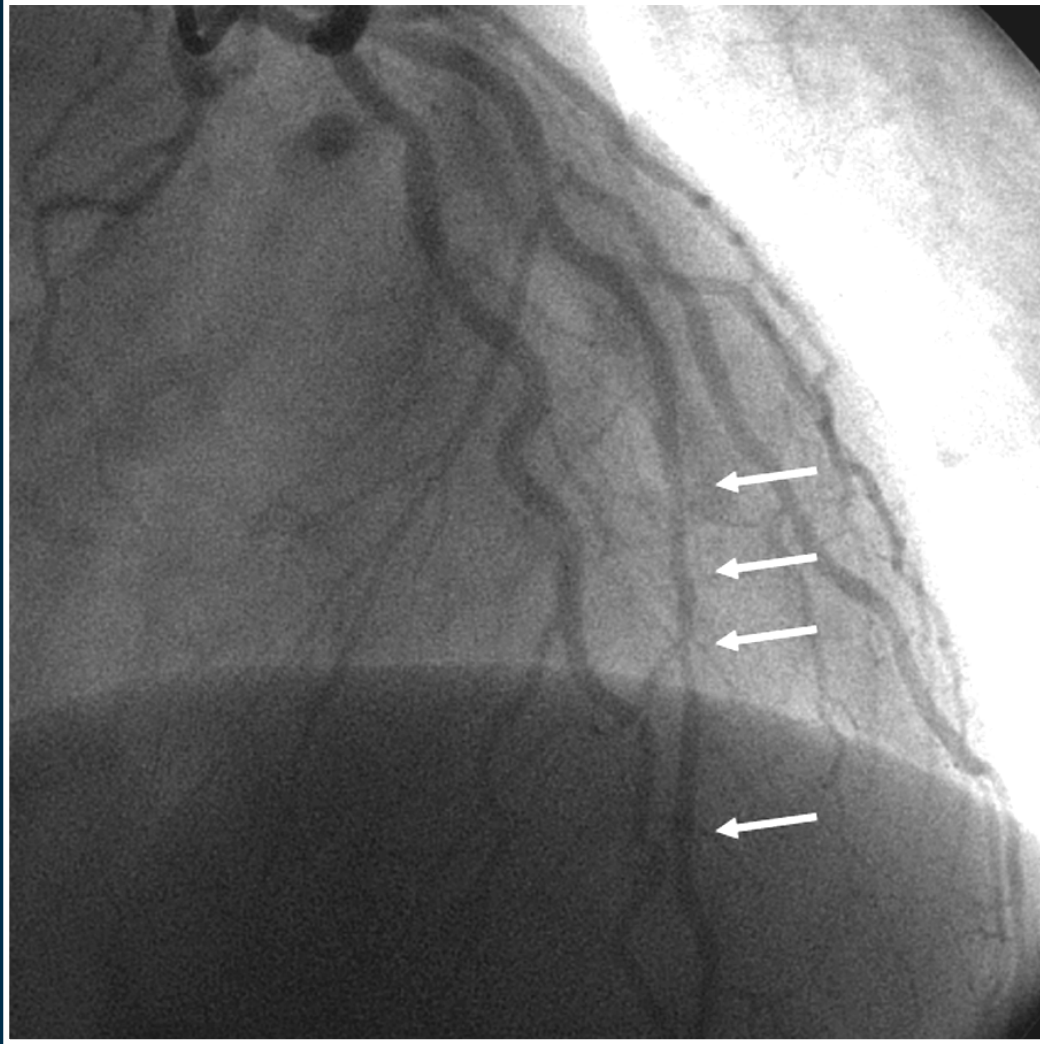
3 Month Angiographic Follow-Up

Case 1: Diffuse LAD Disease



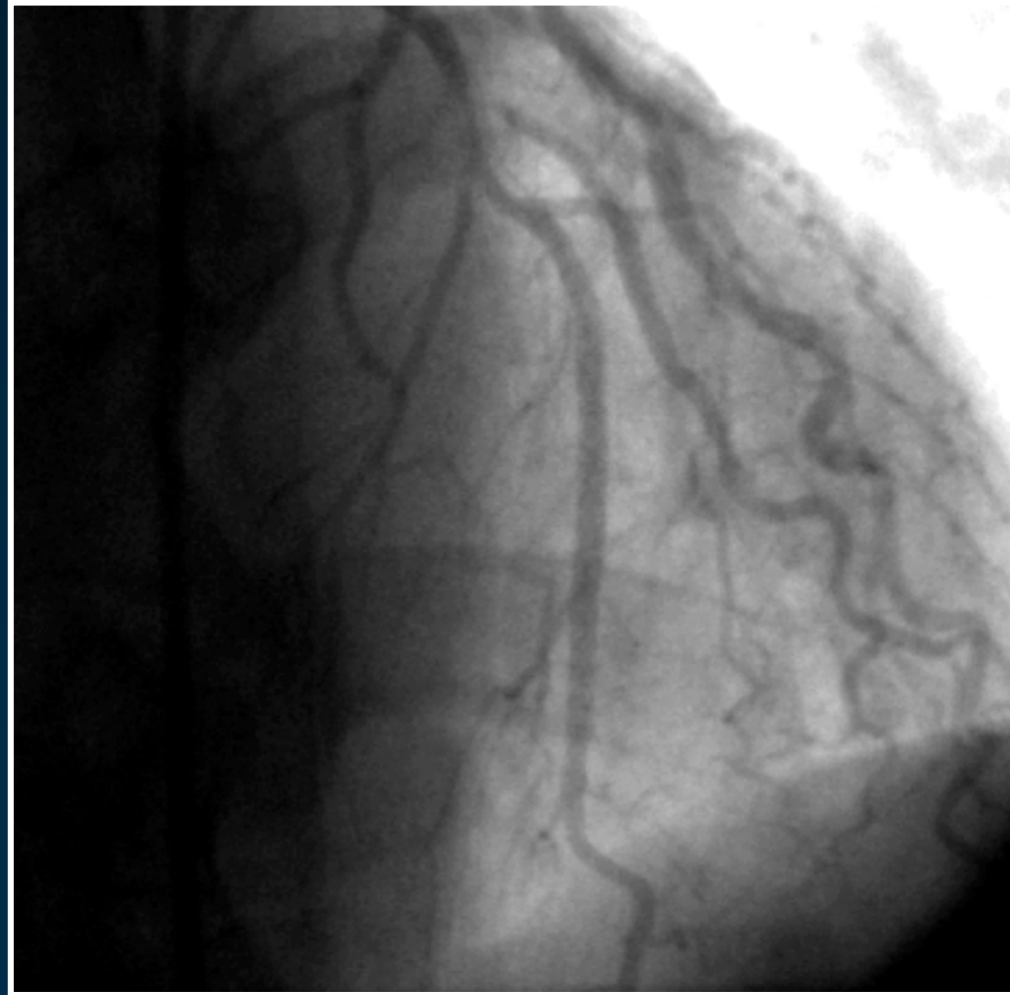
Stent Fracture with 3 mm of Stent Overlap

Case 2: Late Aneurysm Formation



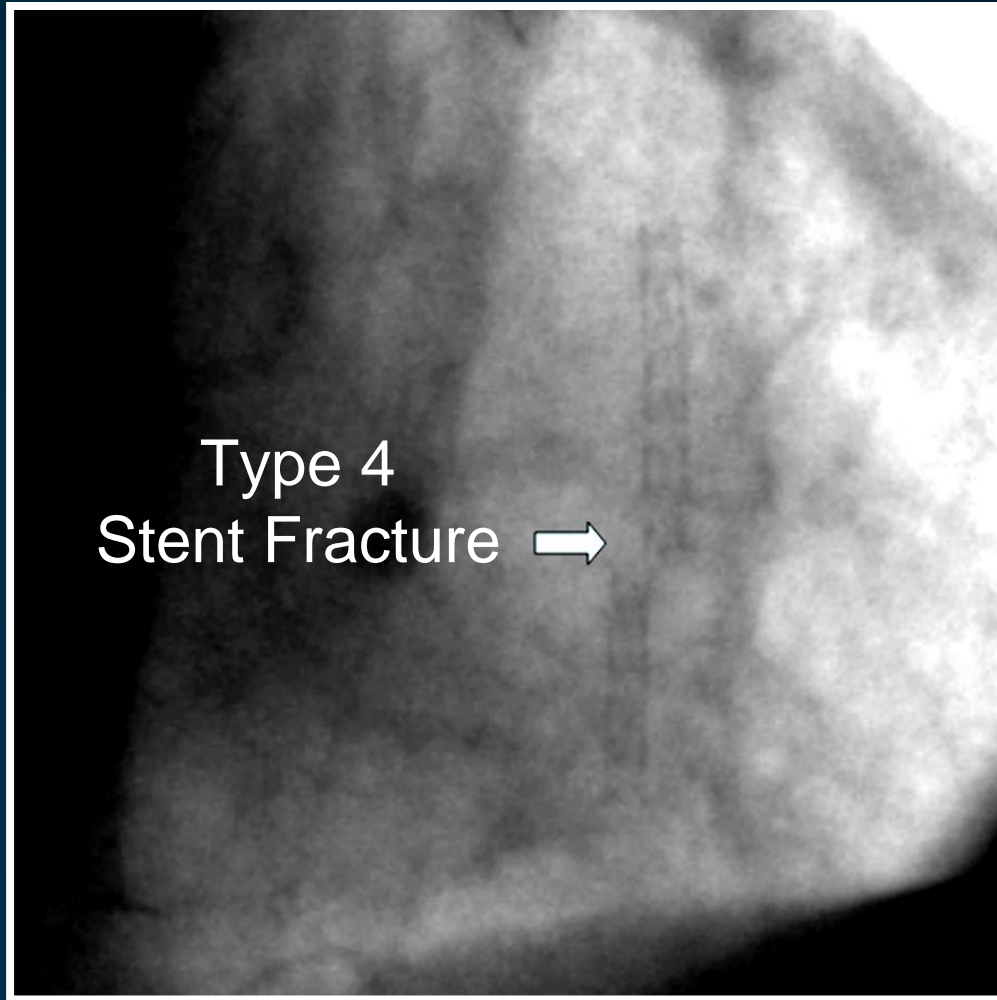
2.5 mm x 23 mm CYPHER

Case 2: Late Aneurysm Formation

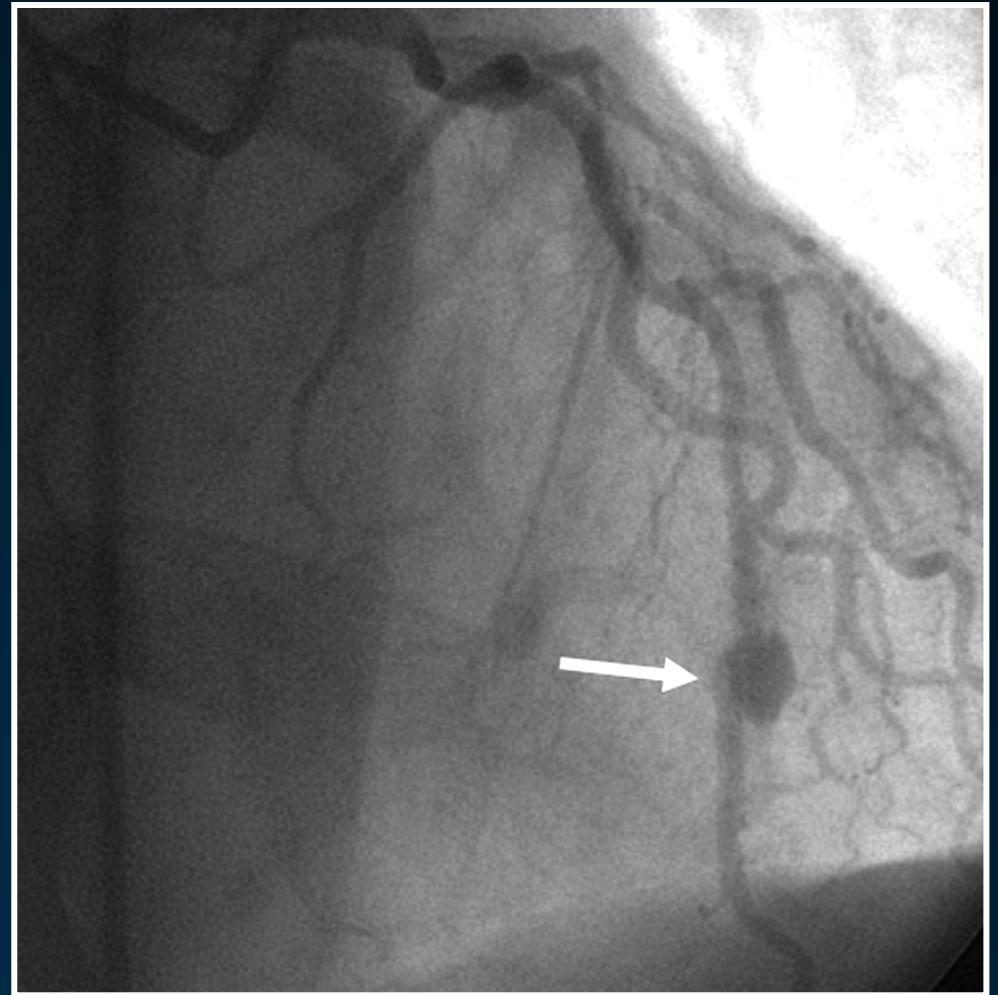


3 Month Follow-up

Case 3: Late Aneurysm Formation



4 Month Follow-up



4 Month Follow-up

TAXUS Analysis

Stent Fracture Evaluated Angiographically in >2,300 Stents

Enrolled (TAXUS+BMS):
3,787 patients
4,509 stents

Patients prospectively assigned to 9-month angiogram:
2,877 patients
3,553 stents

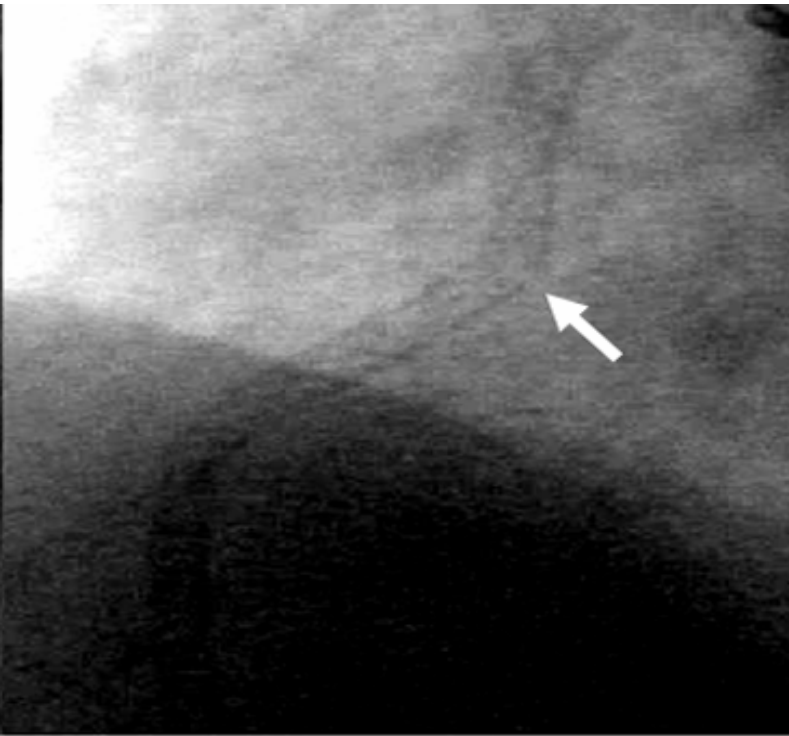
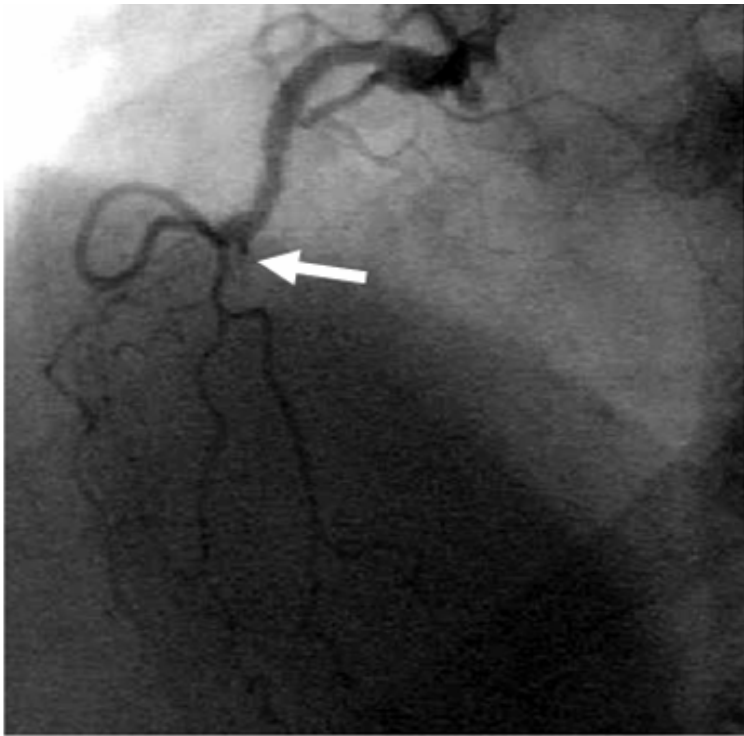
Patients with 9-month angiogram available for analysis:
1,864 patients
2,342 stents

Assess 9-month
fracture
incidence &
predictors

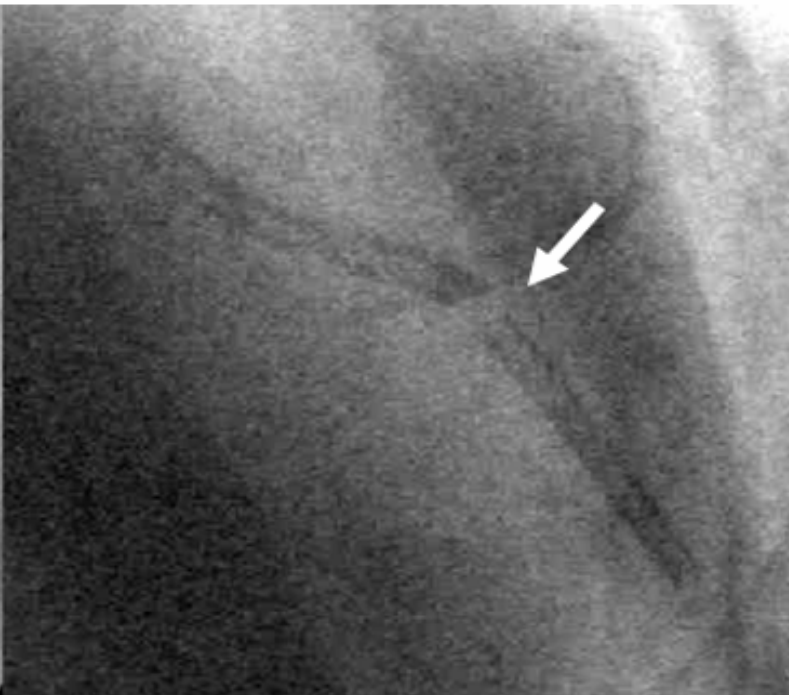
All patients:
2,814 patients
3,060 stents

Assess all clinical
events for association
with fracture





Type II Stent Fracture with strut separation and angulation at the site of total occlusion (arrows) at mandatory angiographic follow-up



Type IV Stent Fracture with stent separation and angulation at the site of total occlusion (arrows) at mandatory angiographic follow-up

TAXUS Analysis

9-Month Incidence of Fracture With Express and Liberté

Per-stent analysis, % (n/N)

Study	Overall	Control*	TAXUS	P value
TAXUS IV	0% (0)	0% (0)	0% (0)	NA
TAXUS V	1.1% (11)	0.4% (2/466)	1.8% (9)	0.07
TAXUS VI	0.4% (2)	0.4% (1)	0.4% (1)	1.00
Pooled IV/V/VI	0.7% (13)	0.3% (3)	1.1% (10)	0.09
TAXUS ATLAS	0.0% (0) [†]	—	0.0% (0)	NA

Among all patients (2,814 patients/3,060 stents; median 1,446 days of follow-up), 4 additional fractures observed beyond 9 months (3 TAXUS Express and 1 TAXUS Liberté)

TAXUS Analysis

Stent Fracture And 9 Month Restenosis

Outcome	Fracture	No fracture	<i>P</i> value
Total patients	11	1853	
In-stent MLD, mm	1.49±0.29	2.00±0.02	0.03
In stent late lumen loss, mm	1.04±0.21	0.60±0.01	0.02
In stent % Diameter Stenosis	48.85±10.16	27.27±0.55	<0.01
In stent binary restenosis, %	40.0% (4/10)	16.4% (292/1776)	0.07

Stent Fracture and Lesion Complexity

Baseline Characteristics in the Angiographic FU Cohort

Characteristic	Fracture	No fracture	<i>P</i> value
Total patients	11	1853	
Previous MI, %	63.6% (7/11)	29.4% (545)	0.02
Lesion type C, %	80.0% (8/10)	37.9% (700)	0.01
Lesion length, mm	23.9±3.7	16.7±0.2	0.01
Proximal tortuosity, %	50.0% (5)	9.83% (181)	<0.01
Study stents implanted	2.27±0.43 (11)	1.32±0.01	0.05

TAXUS Analysis

Stent Fracture and 9 M Outcome

Results in the Angiographic Cohort, All Clinical Follow-up

	Fracture at 9 mo	No fracture at 9 mo	P value
Total patients	11	1853	
TLR	27.3% (3)	11.8% (219)	0.13
MI (total)	18.2% (2)	4.8% (89)	0.10
Q-wave	9.1% (1)	0.8% (15)	0.09
Non-Q-wave	9.1% (1)	4.0% (74)	0.36
All death	0.0% (0)	4.7% (94)	1.00
Cardiac death	0.0% (0)	2.1% (38)	1.00
ARC Def+prob ST	18.2% (2)	0.8% (12/1)	<0.01

Coronary Stent Fractures: Implications

- Stent fracture is not a good thing
- It can be better predicted with appropriate pre-clinical models, particularly with peripheral stents
- Stent fractures tend to occur in patients with ultracomplex disease – calcium, tortuosity, vessel motion
- Rigid stent designs seem more predisposed to stent fracture than more open cell designs
- Movement toward thinner struts and more radiolucent stents will make the detection of stent fracture much more difficult without the use of enhancement