

LM stenting - TAXUS

A Pilot Feasibility Study

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TCT Asia, Séoul 30/4/2005



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French Left Main Taxus Registry

Design of the Study

- ✓ May 2003-February 2005
- ✓ Feasibility and Safety Study
- ✓ 3 experienced centers
- ✓ Consecutive patients, informed consent
- ✓ Standardized approach
- ✓ Plavix + Aspirin 1 year



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Design of the Study (cont.)

Follow-up

- ✓ Angiographic recommended at 6 months
- ✓ Clinical at 1 and 6 months, 1, 2, 3 years

Exclusion criteria

- ✓ Acute MI (ST and non ST)
- ✓ Cardiogenic shock



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Clinical Characteristics

Patients (n)	211
Age (years)	69 \pm 11
Male gender (%)	76
Risk factors (%)	
Diabetes	29
Hypertension	61
Hypercholesterolemia	63
Smoker	41
Family history	21



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Clinical Characteristics (cont.)

Previous MI (%)	12
Previous PCI (%)	18
Previous CABG (%)	1.0
Unstable angina (%)	34
Recent MI (%)	7
3 vessel disease (%)	30
EF (%)	61 _± 12



1	Patient factors	
2	Age	78yr
3	Sex	<input checked="" type="checkbox"/> femelle
4	Pulmonary disease	<input type="checkbox"/> Oui
5	Peripheral vascular disease	<input checked="" type="checkbox"/> Oui
6	Neurologic disorder	<input type="checkbox"/> Oui
7	Previous cardiac surgery	<input type="checkbox"/> Oui
8	Creatinine pre surgery > 200 µmol/ L	<input type="checkbox"/> Oui
9	Endocarditis	<input type="checkbox"/> Oui
10	Critical status pre surgery	<input type="checkbox"/> Oui
11	Cardiac factors	
12	Unstable angina	<input checked="" type="checkbox"/> Oui
13	Ejection fraction 30-50%	<input checked="" type="checkbox"/> 30-50%
14	Ejection fraction <30	<input type="checkbox"/> <30%
15	Recent MI	<input type="checkbox"/> Oui
16	sPAP > 60 mmHg	<input type="checkbox"/> Oui
17	Surgical factors	
18	Emergency	<input type="checkbox"/> Oui
19	Associated cardiac surgery	<input type="checkbox"/> Oui
20	Associated thoracic aorta surgery	<input type="checkbox"/> Oui
21	Associated septal rupture treatment	<input type="checkbox"/> Oui
22		
23	Additive EuroSCORE	4.8±3.4
24	Mortality	6.5±11.0
25		
26	For the latest information on EuroSCORE visit http://www.euroscore.org	

Φ	β_i	X_i
4	0,0666354	20
1	0,3304052	VRAI
1	0,4931341	FAUX
2	0,6558917	VRAI
2	0,841626	FAUX
3	1,002625	FAUX
2	0,6521653	FAUX
3	1,101265	FAUX
3	0,9058132	FAUX
2	0,5677075	VRAI
1	0,4191643	VRAI
3	1,094443	FAUX
2	0,5460218	FAUX
2	0,7676924	FAUX
2	0,7127853	FAUX
2	0,5420364	FAUX
3	1,159787	FAUX
4	1,462009	FAUX
Additive euroSCORE = $\sum \Phi$		
Logistic euroSCORE =		
$e^{(-4.789594 + \sum \beta_i X_i)} / 1 + e^{(-4.789594 + \sum \beta_i X_i)}$		

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22		
23	Additive EuroSCORE	≥ 6 36%
24		≥ 10 9%
25		
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Left Main Lesion Location



Ostial-proximal 29 %



Mid-shaft 11 %



Distal 77 %



French Left Main Taxus Registry

Procedural Data

Gp2b3a inhibitors (%)	2.8
Radial approach (%)	56
Guiding size 6 Fr (%)	88
7 Fr (%)	11
8 Fr (%)	1
I ABP (%)	3.8
Other treated vessel (%)	75
Treated vessels (n)	1.2 _± 0.9
Total stent length (mm)	46 _± 17



French Left Main Taxus Registry

Distal left main in 77% of cases

Provisional SB T-stenting (%)	93.8
Systematic T stenting (%)	5.5
V Stenting (%)	0.7
Side branch stented (%)	36
Side branch stent length (mm)	13.3 \pm 4.7
Side branch stent diameter (mm)	3.0 \pm 0.3
Final Kissing (%)	96.8



French Left Main Taxus Registry

In-hospital Outcome (n=211/211)

Angiographic success (%)	99.5
AT (%)	0.5
SAT* (%)	0.5
Non-Q-wave MI (%)	2.4
Q-wave-MI (%)	0
Emergency CABG (%)	0
Stroke (%)	0
Death (%)	0.95
MACCE (%)	3.3



French Left Main Taxus Registry

Discharge to 1-month outcome (n= 208/210)

SAT (%)	0
Non-Q-wave MI (%)	0
Q-wave-Mi (%)	0
Emergency CABG (%)	0
Stroke (%)	0
Death (%)	0.5*
MACCE (%)	0.5



French Left Main Taxus Registry

6 to 7 month F-Up (135/139: 97%)

Reintervention target (%)	4.4
Reintervention non target (%)	12.4
Non Q-wave-MI (%)	3.3
Q-wave MI (%)	0
Stroke (%)	0.7
CABG (%)	0
Total cardiac death (%)	3.0
Total death (%)	5.2



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Cause of death (n=7/135: 5.2%)

Cardiac

- ✓ AT during the procedure 1
- ✓ Severe groin hematoma, day 2 1
- ✓ Sudden death, day 8 1
- ✓ Pulmonary oedema during dialysis, 2 months 1

Non cardiac

- ✓ Pulmonary infection, 4 months 1
- ✓ Hemorrhage during dialysis, 2 months 1
- ✓ Stroke at 5 months 1



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Angiographic F-Up (96/135: 71%)

Delay (months) 6.1 ± 2.5

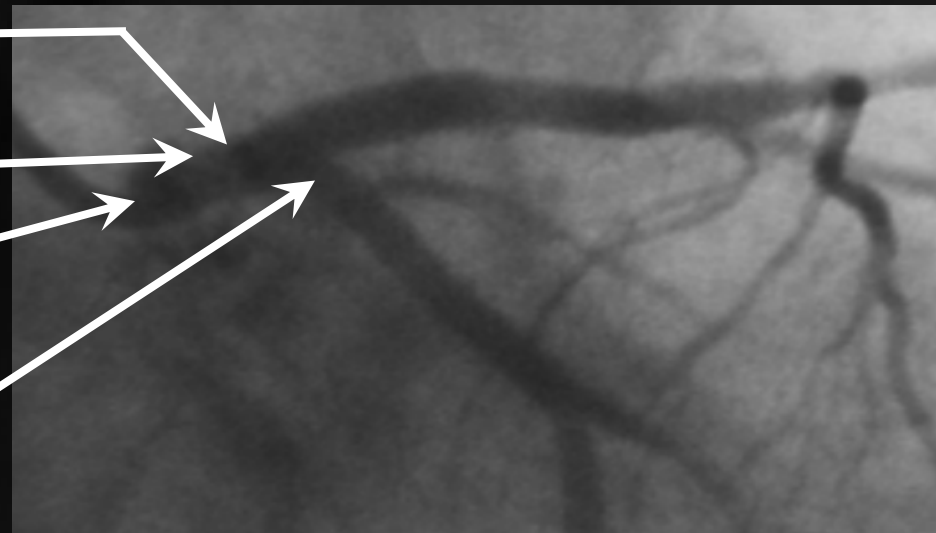
LM restenosis (%) 6.3

Distal to the stent: n=1

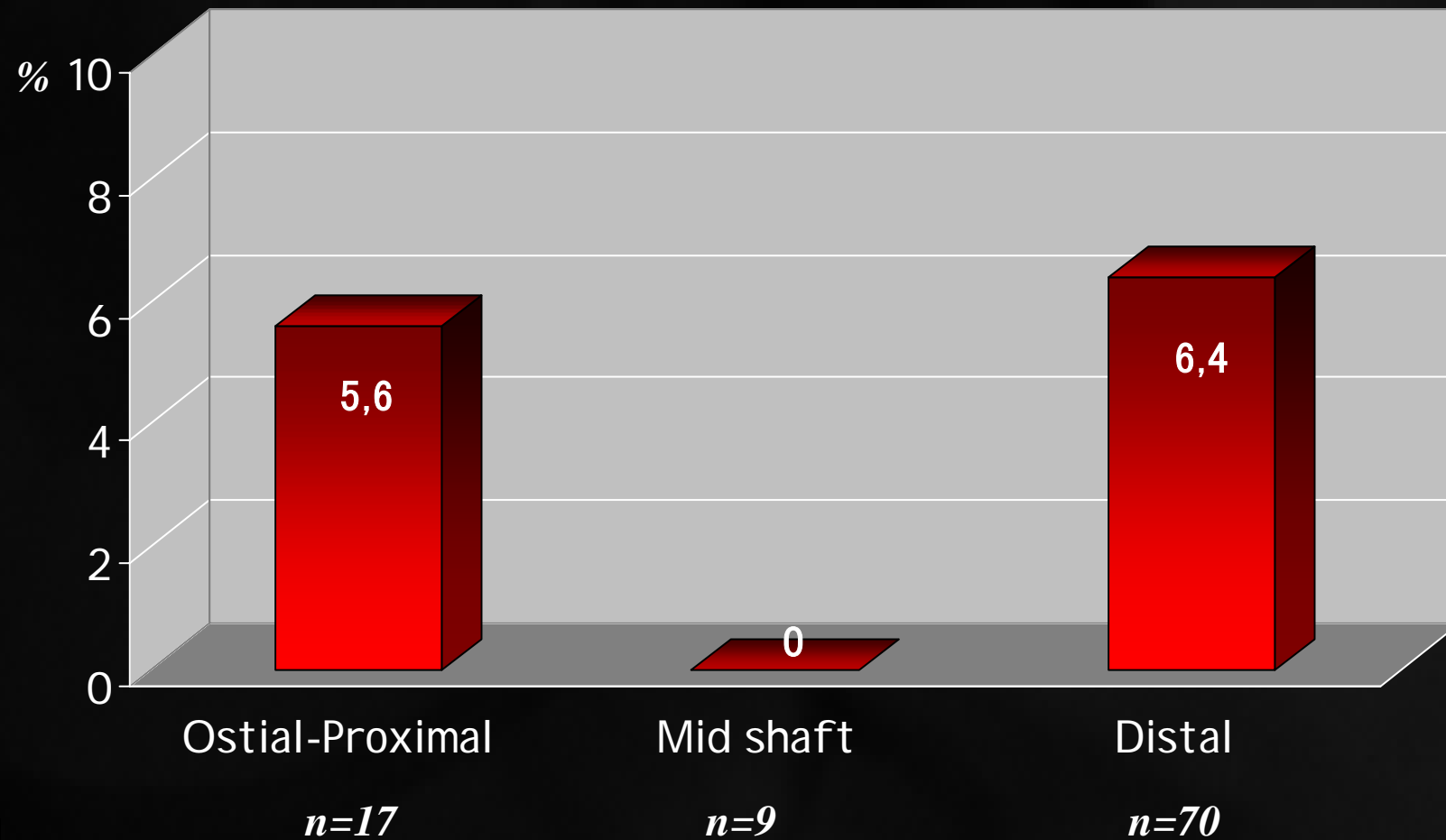
Diffuse In stent : n=1

Ostium unstented: n=3

Side branch unstented: n=1



Restenosis and Lesion Type



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Key Issues

- ✓ Optimal approach for distal left main
- ✓ Optimal ostial stent positioning
- ✓ Optimal anticoagulation during the procedure
- ✓ Optimal antiplatelet treatment



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Conclusion

Preliminary results of this “real world” study using the TAXUS stent for LM PCI are very promising.

Randomized trial necessary (Syntax) to get level of evidence A

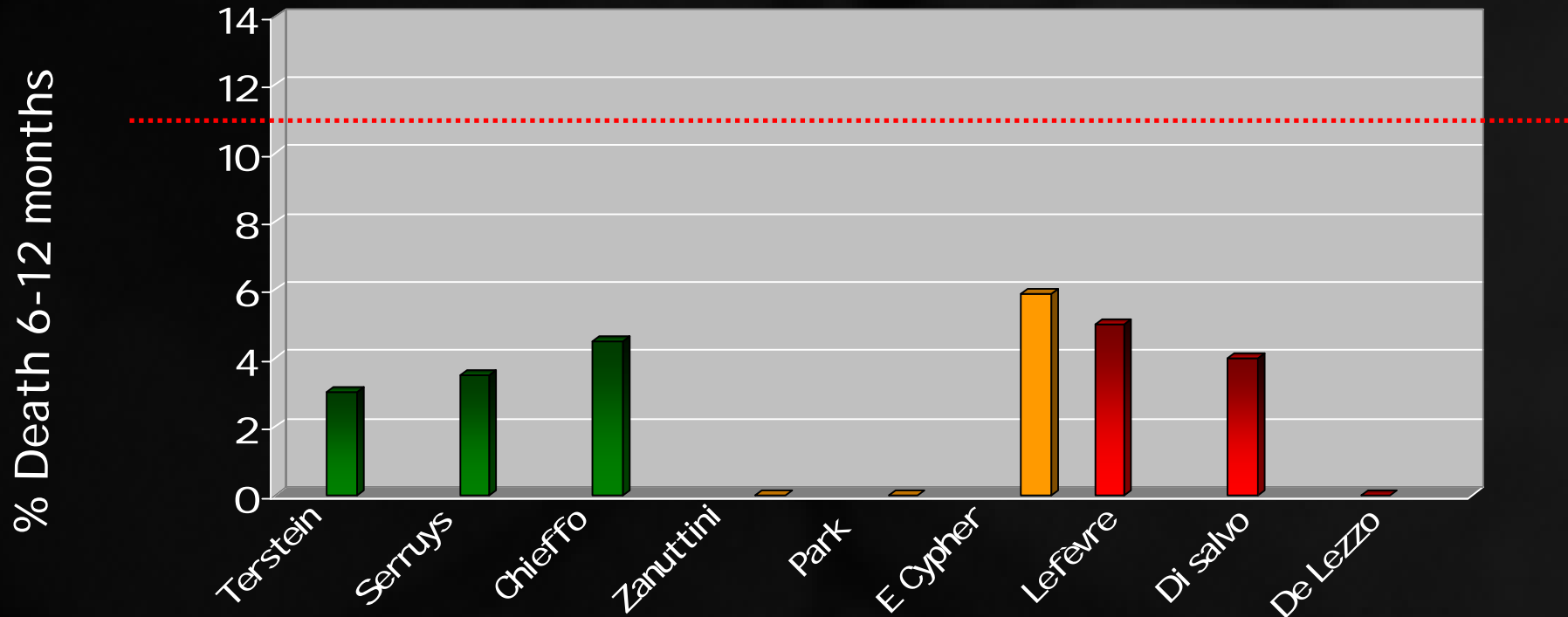


BACK UP SLIDES



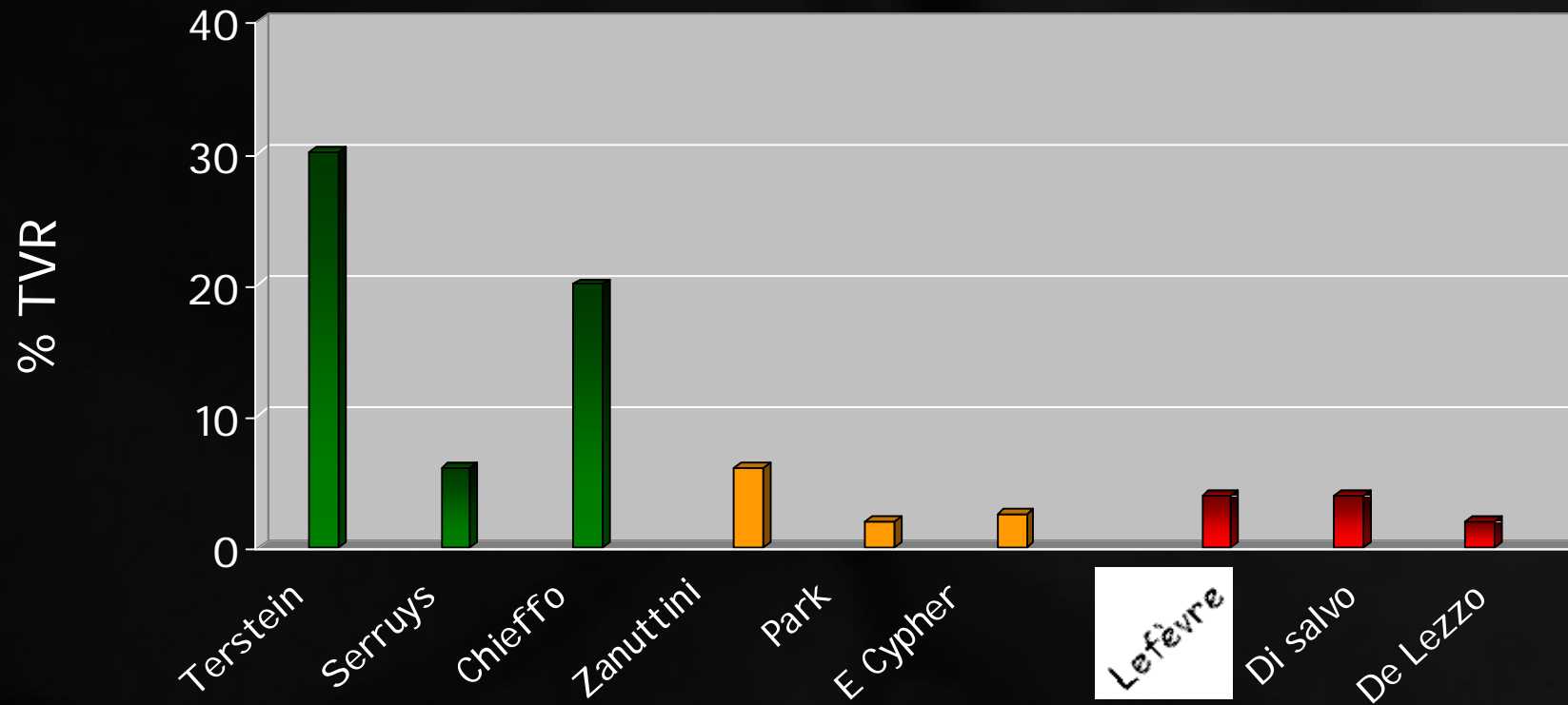
DES for Left Main Stenting

■ Provisional SB stenting ■ Systematic ■ Mix approach

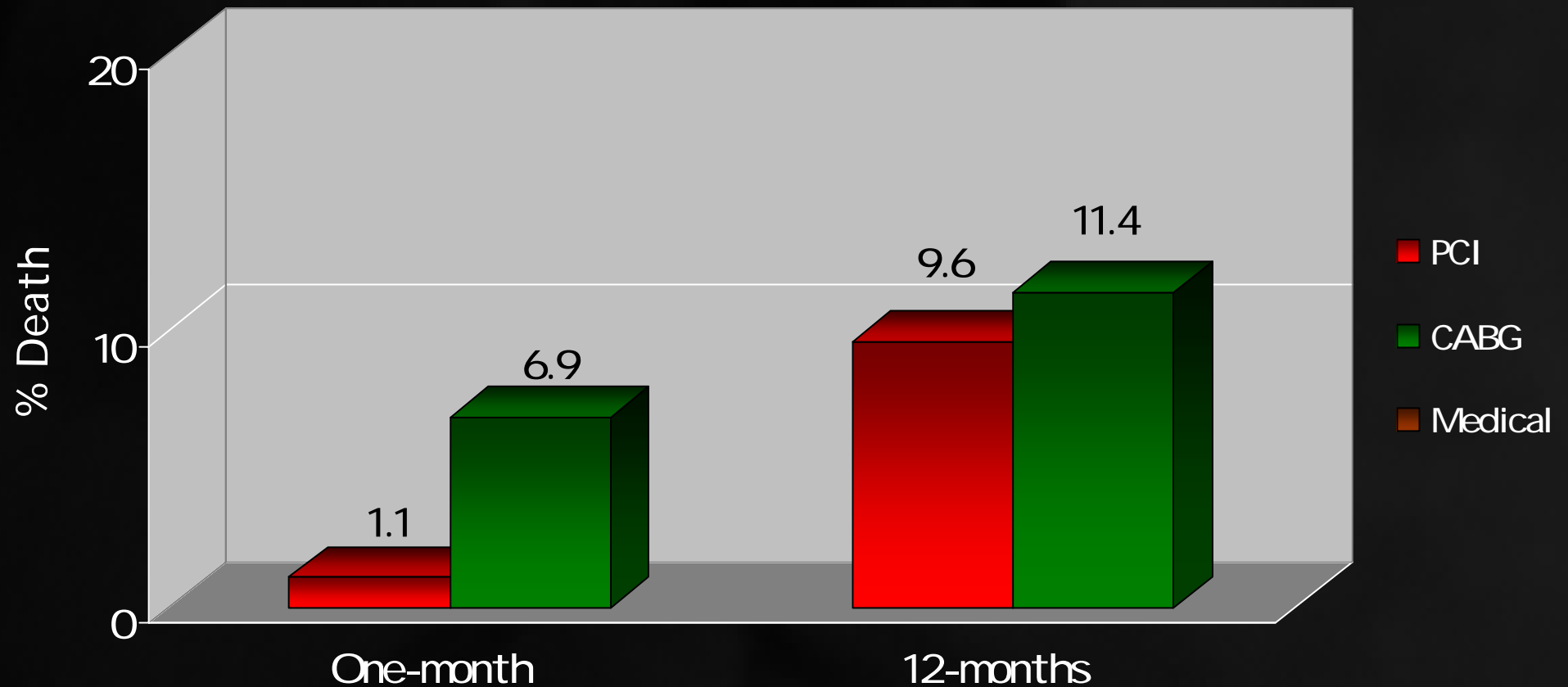


DES for Left Main Stenting

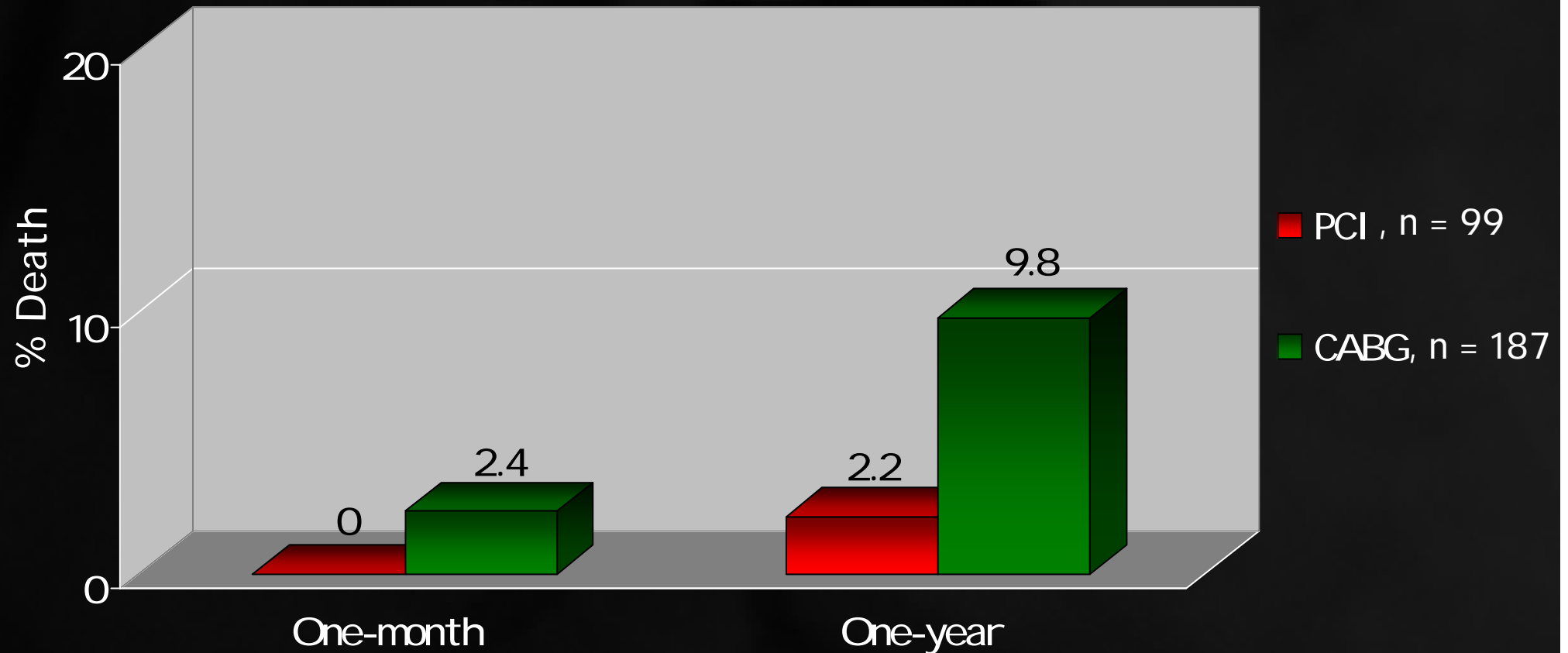
■ Provisional SB stenting ■ Systematic ■ Mix approach



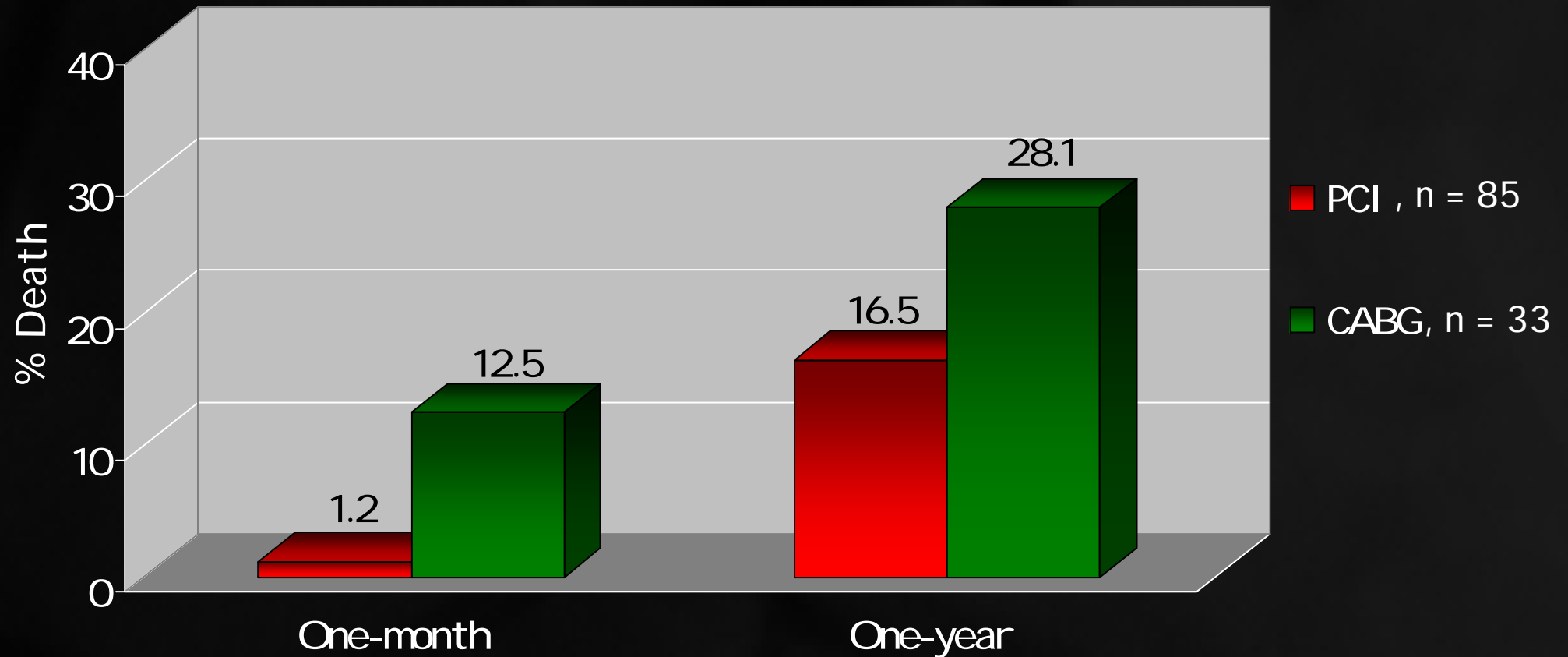
French Left Main Registry



French Left Main Registry (Low Risk)

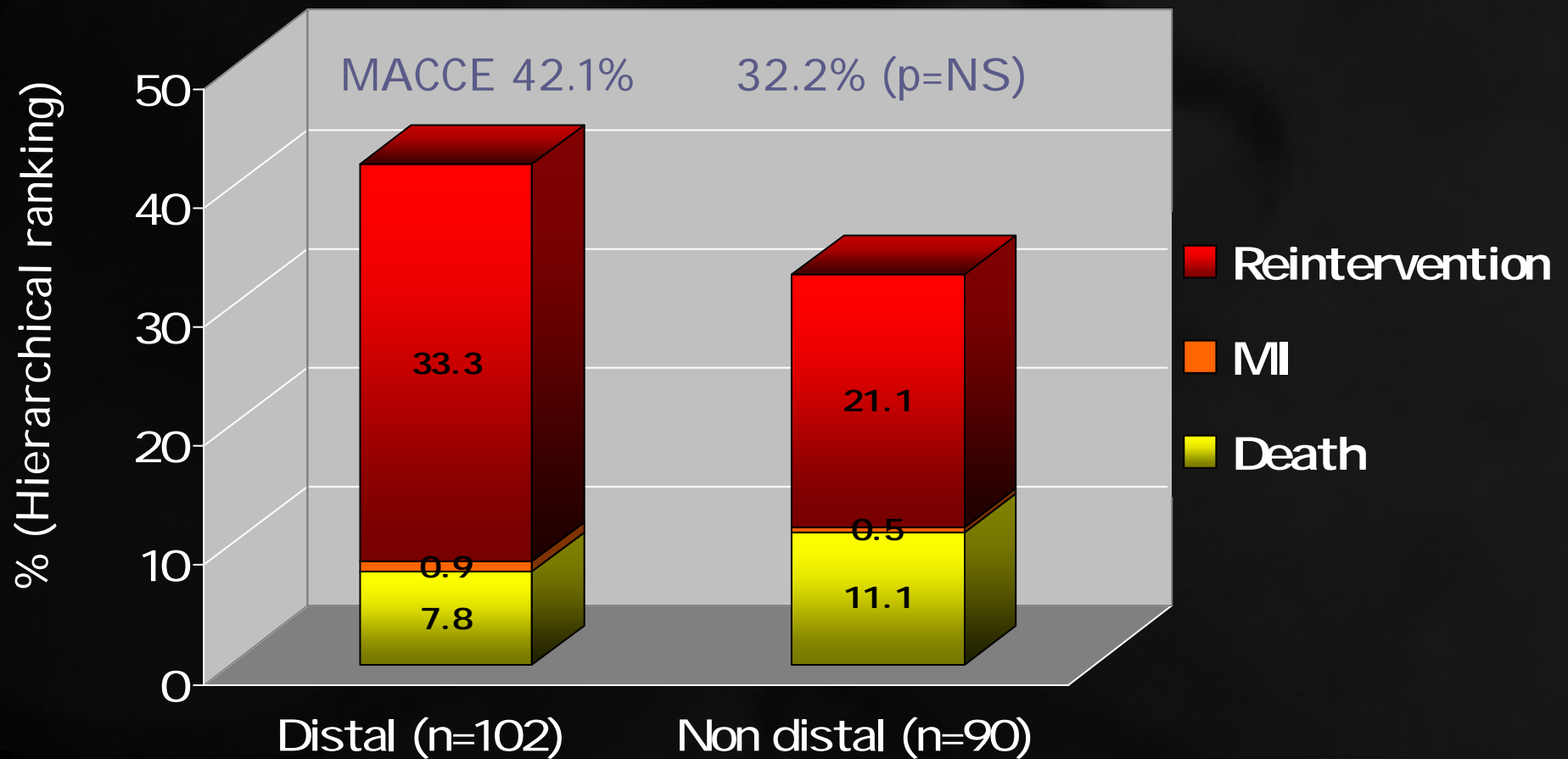


French Left Main Registry (High Risk)

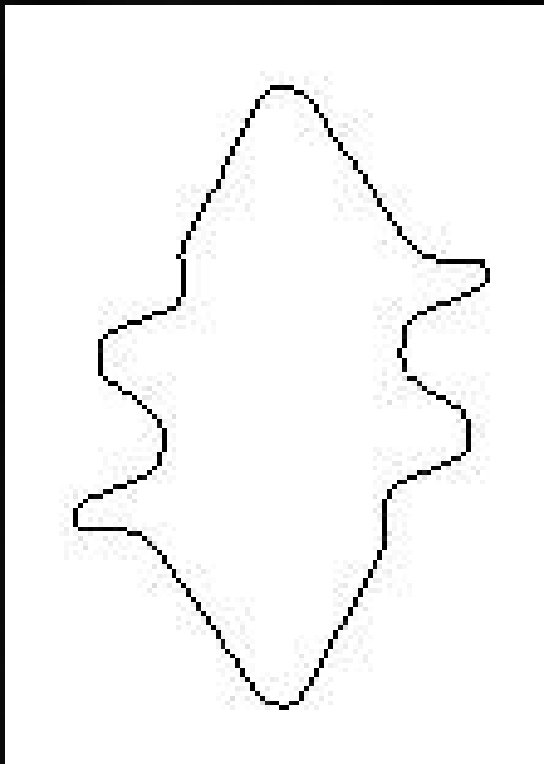


French Left Main Registry

LM Lesion Location and PCI Outcome



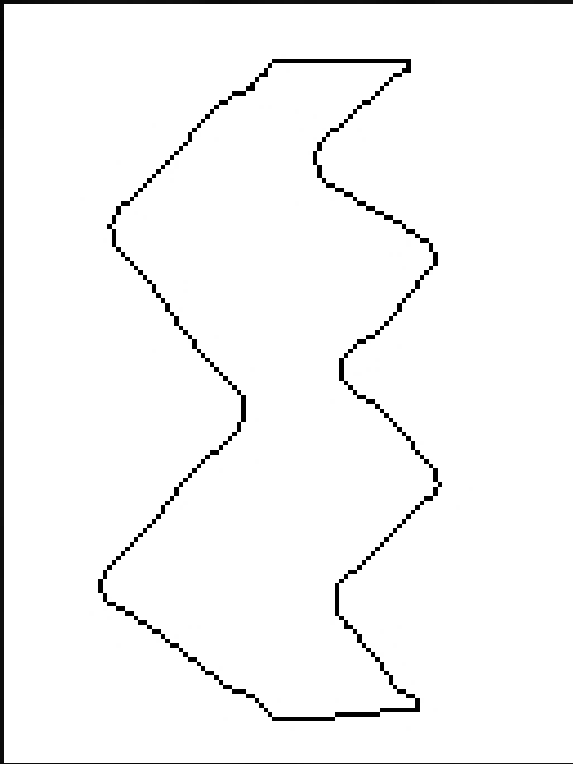
DES for LM Bifurcation Lesions



Cypher 3.5

Max. strut diam. 3.0 mm

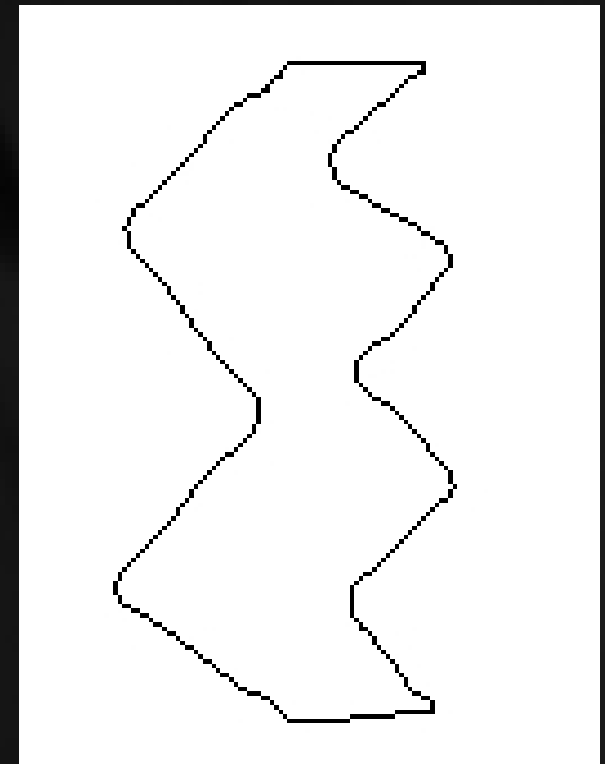
Max. diameter 4.75 mm



Taxus 3.5

Max. strut diam. 3.7 mm

Max. diameter 4.25 mm



Taxus 4.0

Max. strut diam. 3.7 mm

Max. diameter 5.75 mm

