Long Term Outcome of Subintimal Angioplasty in Femoropopliteal Artery Occlusions

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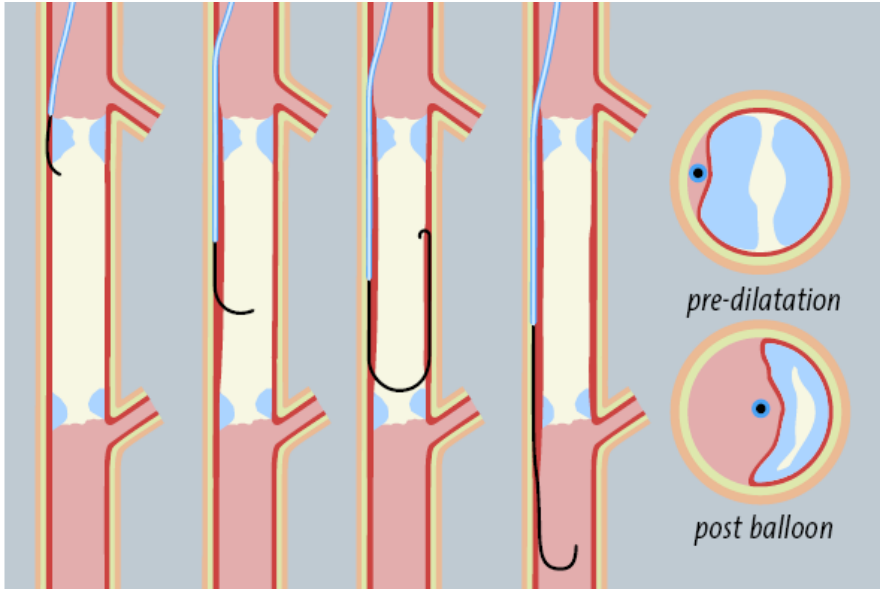
Theoretical Advantages of SIA

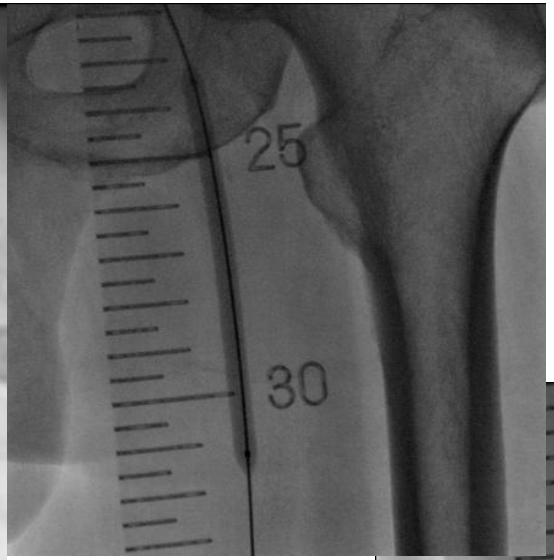


- Relatively high success rate
- Less time consuming
- Less exposure to radiation
- Less use of contrast dye
- Less need for devices (esp. wires)
- Complications are generally manageable.

SFA CTO

035” Terumo wire & 5F multipurpose catheter


65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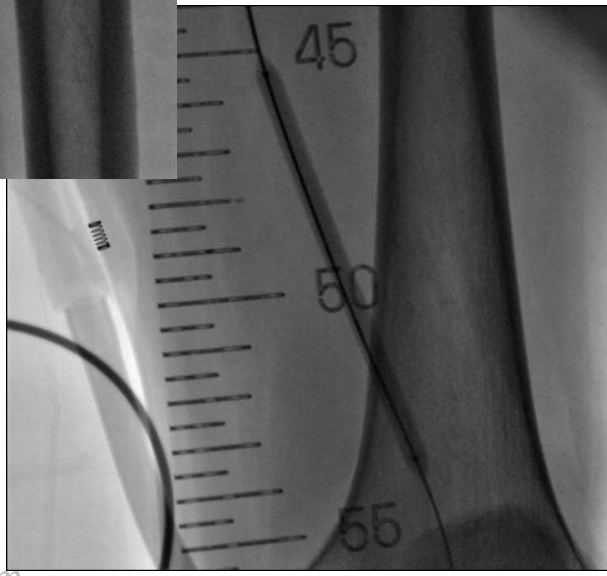
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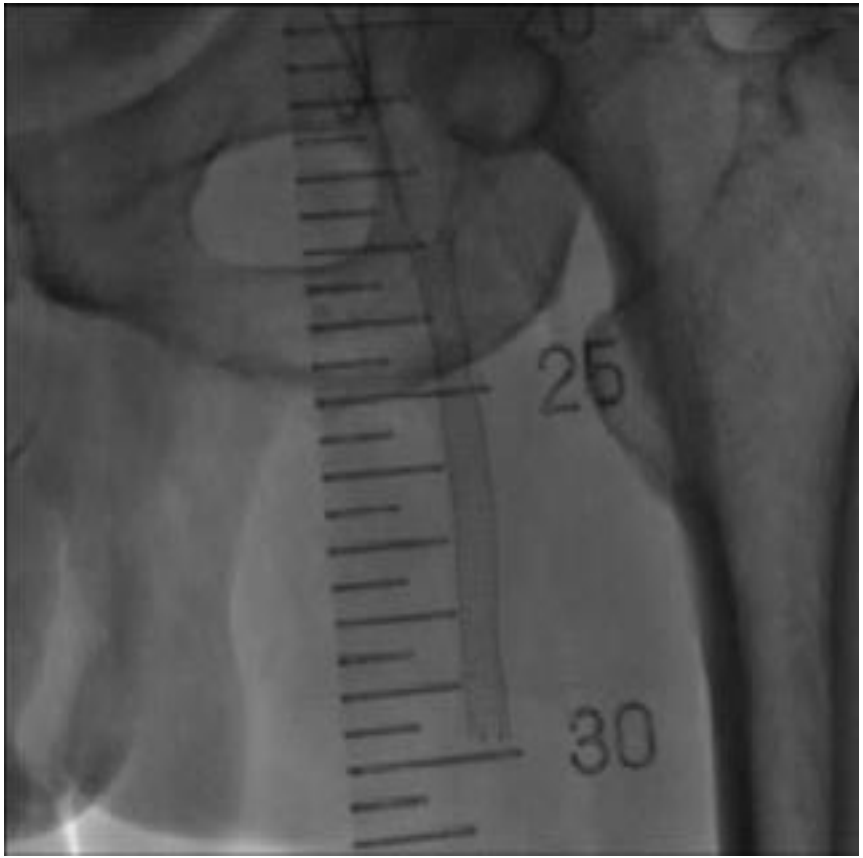
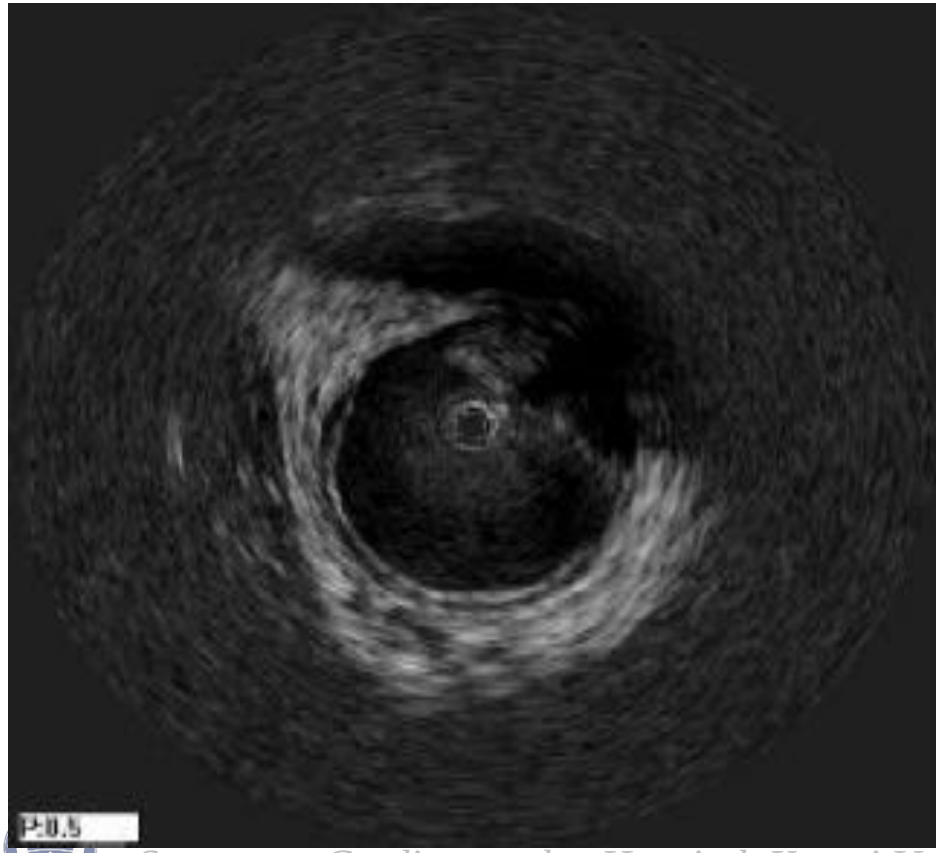
50
55

Implantation of Self-expandable Nitinol Stent

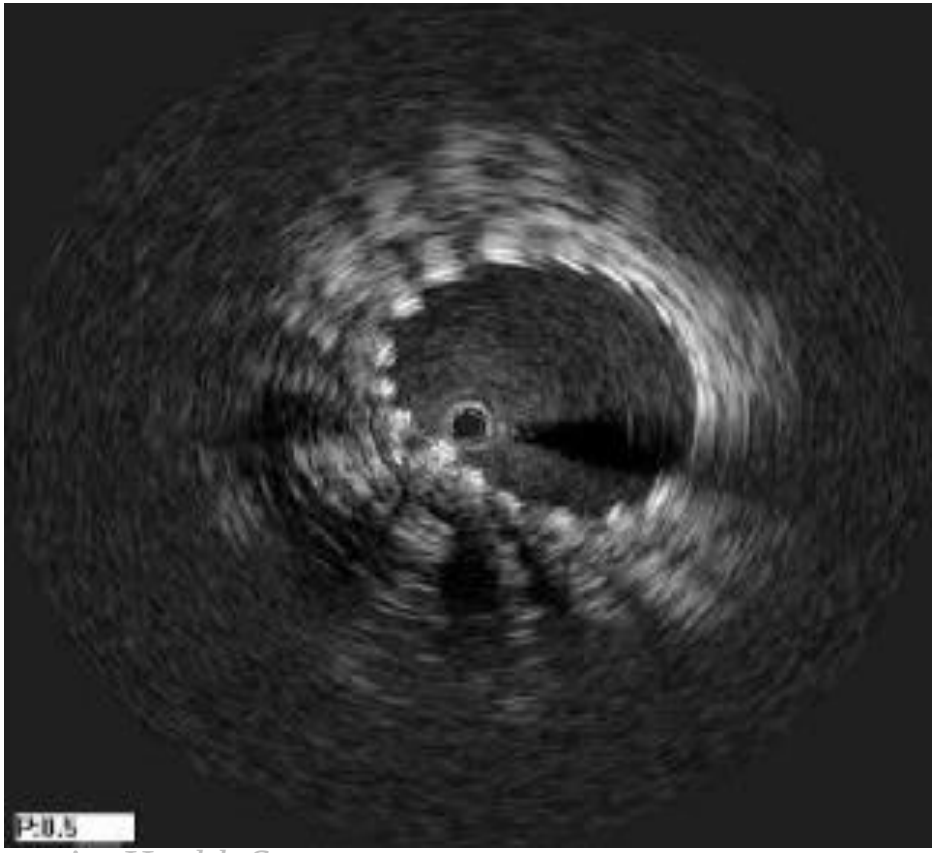


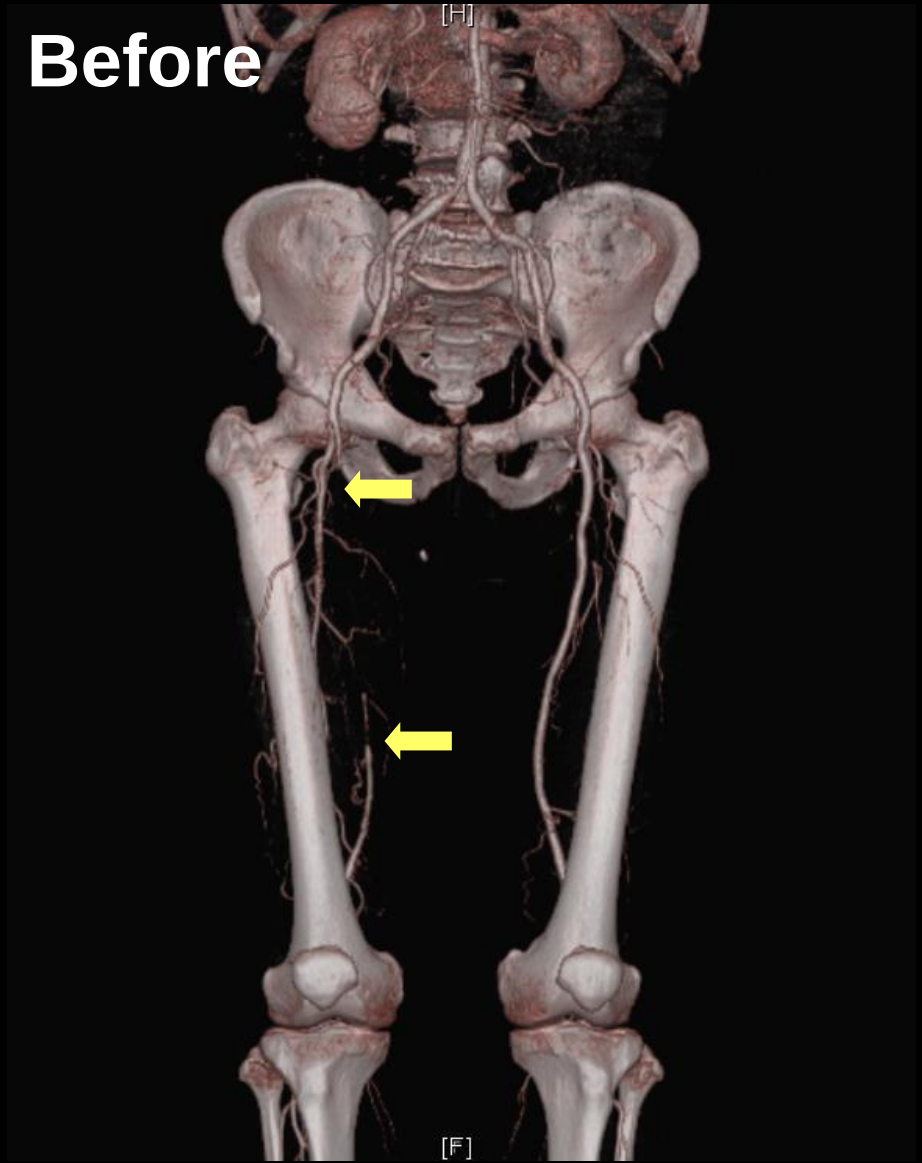
IVUS

Post balloon dilation



Post stent deployment




Before
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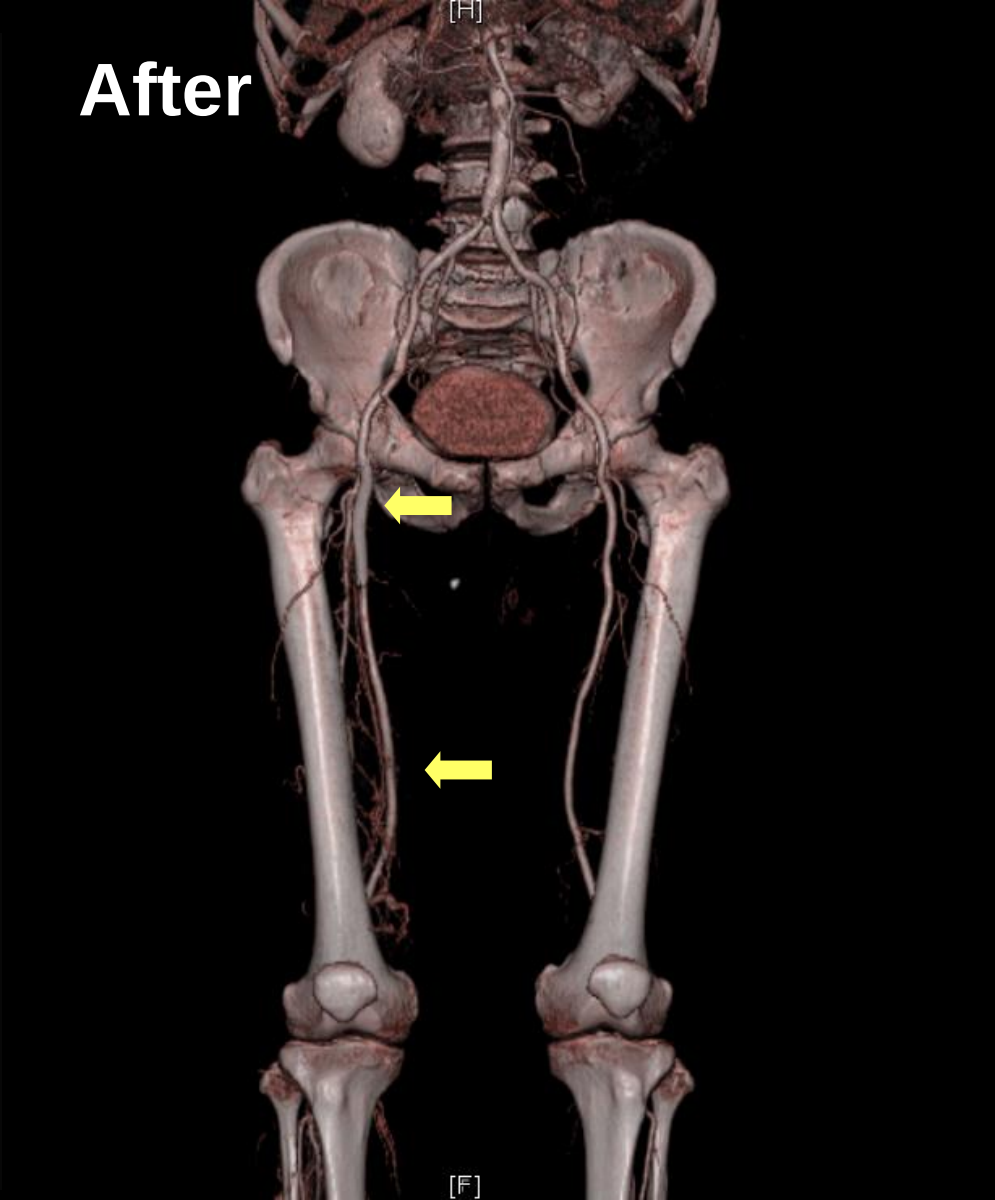
After
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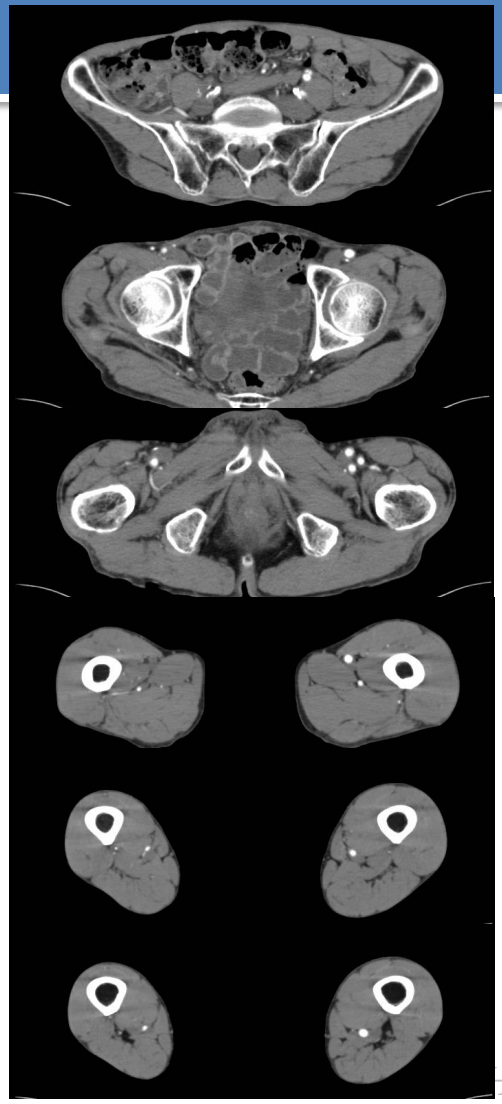
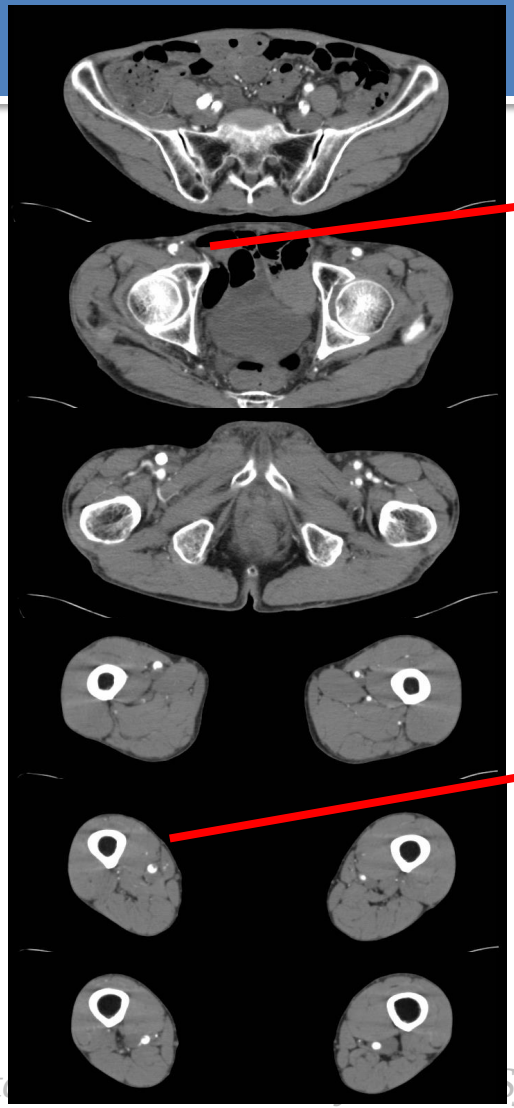
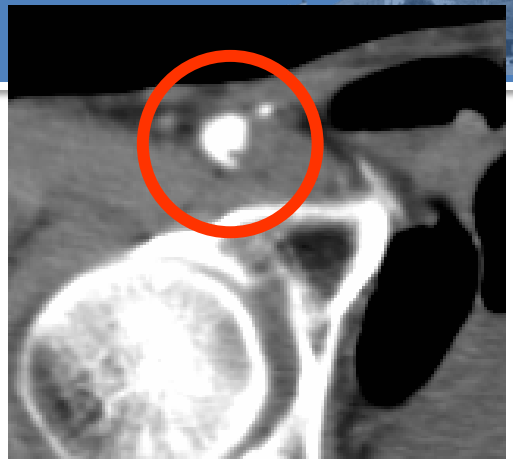
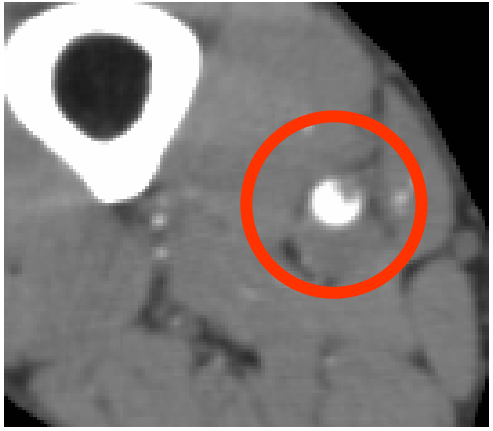
Before

After

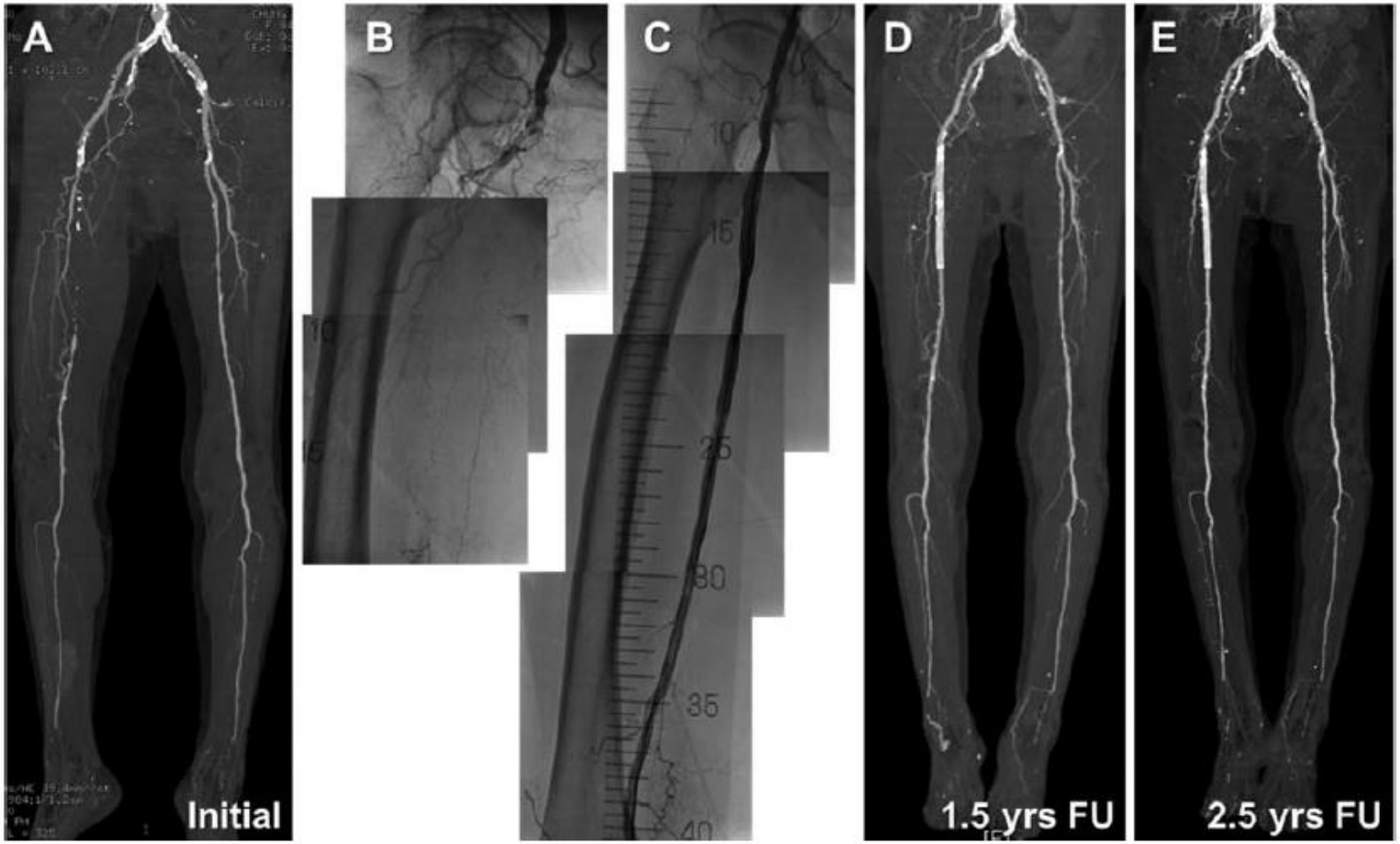






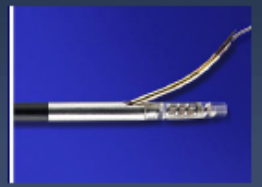


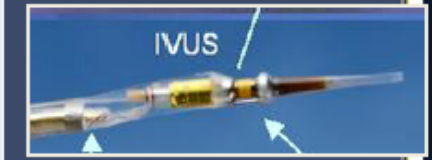
M/85, SFA CTO Treated by SIA

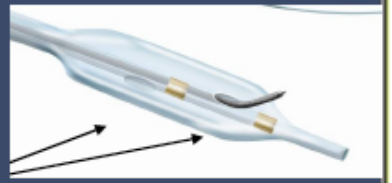


Re-Entry Devices

Catheter	Co.	Features
Outback	Cordis	Premounted needle on a 6Fr catheter with fluoroscopic orientation
Pioneer	Medtronic	IVUS guided, premounted needle, orient needle to 12 o'clock, color flow in true lumen
Enteer	Covidien	Flat balloon orients itself in subintimal space and points needle toward true lumen, 0.018 compatible
Offroad	Boston Sci	Conical balloon 5.4mm, when inflated points toward true lumen, microcatheter lancet







Improved Technical Success and Midterm Patency With Subintimal Angioplasty Compared to Intraluminal Angioplasty in Long Femoropopliteal Occlusions

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Purpose: To compare the efficacy of subintimal angioplasty combined with primary stenting to intraluminal angioplasty with stenting for revascularization of long (>10 cm) femoropopliteal arterial occlusions.

Methods: Baseline characteristics and outcomes of 52 patients (40 men; mean age 65.6±9.7 years) with superficial femoral artery (SFA) occlusions in 61 limbs (mean occlusion length 22.7±9.9 cm) treated with subintimal angioplasty and primary stenting were compared with a 54-patient control group (46 men; mean age 64.8±8.2 years) from our registry database who had intraluminal angioplasty with stenting in 60 limbs (mean occlusion length 22.0±8.5 cm).

Results: All baseline clinical and angiographic characteristics showed no differences. In all patients, at least 1 self-expanding nitinol stent was implanted. Subintimal angioplasty was successful in 58 (95.1%) of 61 limbs, whereas technical success for the conventional approach was 86.7% (52/60 limbs; p=0.11). In both groups, there were no major complications requiring surgery. Primary patency at 12 months for successful cases was 76.4% for subintimal angioplasty and 59.2% for conventional angioplasty (p=0.06); on an intention-to-treat basis, including technical failures, the rates were 72.4% and 50.9%, respectively (p=0.02).

Conclusion: Subintimal angioplasty combined with stenting was feasible, with a high technical success rate and better short and midterm results for revascularization of long femoropopliteal occlusions than the conventional intraluminal approach.

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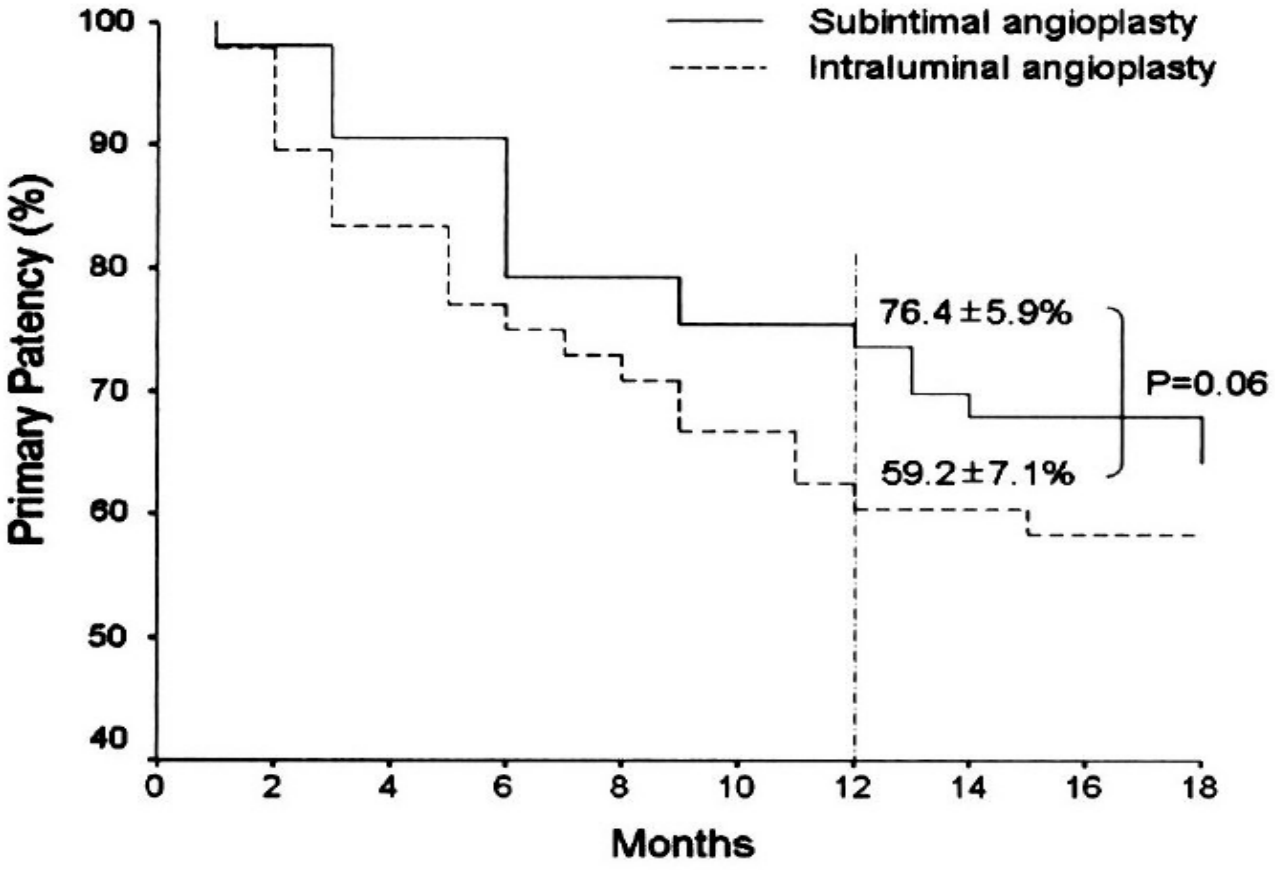
Baseline Characteristics

	Subintimal	Intraluminal	p
Patients	54	53	
Limbs	62	60	
Age, years	65.7±9.1	65.1±8.9	ns
Male, n (%)	40 (74.1)	42 (79.2)	ns
DM, n (%)	35 (64.8)	35 (66.0)	ns
HTN, n (%)	38 (70.3)	39 (73.6)	ns
Smoking, n (%)	26 (48.1)	24 (45.3)	ns
CAD, n (%)	34 (63.0)	32 (60.4)	ns

Procedural Outcome

	Subintimal	Intraluminal	p
Occlusion length (cm)	22.5 ± 6.5	20.8 ± 11.3	ns
Technical success	95.2%	86.7%	ns
GW passage Failure (n)	3	5	
Major complications*	0	0	ns
No. of stents	1.08 ± 0.27	1.22 ± 0.49	ns
Stent diameter (mm)	8.0 ± 1.1	7.8 ± 1.3	ns
Stent length (mm)	76.5 ± 6.7	80.4 ± 12.3	ns
Post-PTA ABI	0.79 ± 0.21	0.81 ± 0.19	ns

Primary Patency



Midterm Outcomes of Subintimal Angioplasty Supported by Primary Proximal Stenting for Chronic Total Occlusion of the Superficial Femoral Artery

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Purpose: To investigate the midterm outcomes of subintimal angioplasty in occluded superficial femoral arteries (SFA) and evaluate the clinical and procedural factors affecting these results.

Methods: Between April 2004 and April 2012, 150 patients (122 men; mean age 69±10 years) with chronic total occlusions in the SFA underwent subintimal angioplasty with primary stenting in 172 limbs. The average lesion length was 22.6±8.5 cm. Stents were routinely implanted at the proximal entry into the subintimal channel. The primary endpoint was binary restenosis.

Results: Technical success was achieved in 161 (94%) limbs; there were no procedure-related deaths or complications requiring surgery, but distal embolization and arterial perforation occurred in 2 and 4 limbs, respectively. The cumulative freedom from binary restenosis rates at 1 and 3 years were 77% and 59%, respectively, in the entire study group. Patients without CLI (n=96) had significantly higher patency rates at 1 and 3 years (84% and 66%, respectively) than the 54 patients with CLI (66% and 43%, respectively; p=0.011). Based on multivariate analysis, a larger number of stents, lower post-procedure ankle-brachial index, and lower body mass index were each independent predictors of binary restenosis.

Conclusions: Subintimal angioplasty with routine stenting at the proximal stump is safe and effective for the treatment of chronic total SFA occlusions.

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Key words: subintimal angioplasty, peripheral occlusive disease, superficial femoral artery, chronic total occlusion, critical limb ischemia, stent, primary stenting, intimal flap, restenosis, target lesion revascularization

Baseline Clinical Data

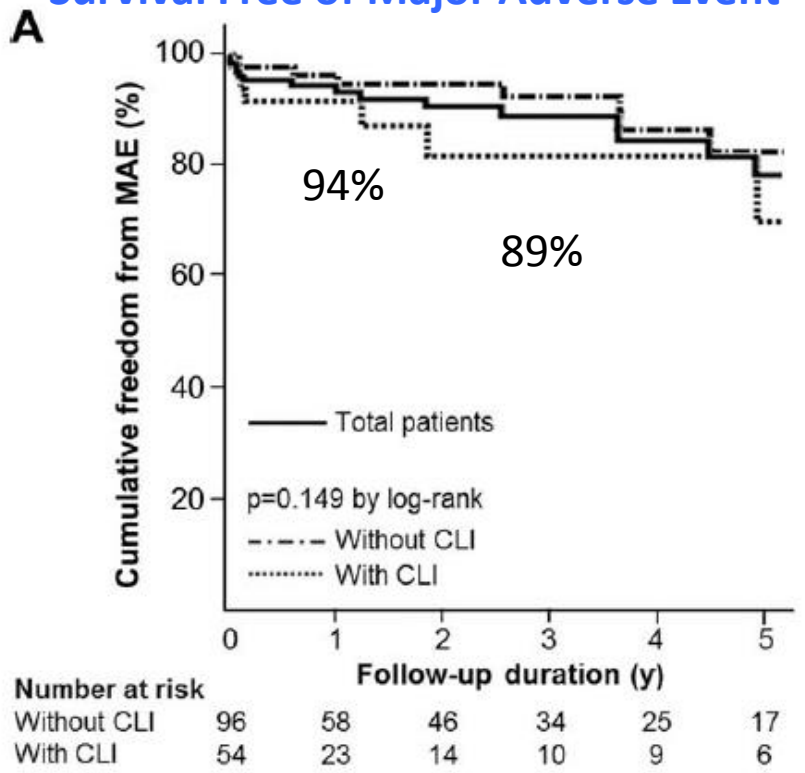
Variables	Total patients 150 patients 172 limbs	No CLI 96 patients 110 limbs	CLI 54 patients 62 limbs	p
Age (years)	69 ± 10	69 ± 10	70 ± 11	0.425
Male	122 (81%)	81 (84%)	41 (76%)	0.202
Body mass index (kg/m^2)	22.6 ± 3.3	22.7 ± 2.8	21.3 ± 3.2	0.025
Risk factors				
Hypertension	105 (70%)	65 (68%)	40 (74%)	0.414
Diabetes mellitus	70 (47%)	40 (42%)	30 (56%)	0.102
Coronary artery disease	95 (63%)	65 (68%)	40 (74%)	0.414
History of smoking	72 (48%)	53 (55%)	19 (35%)	0.018
Dyslipidemia	46 (31%)	33 (34%)	13 (24%)	0.189
Chronic kidney disease	25 (17%)	12 (13%)	14 (26%)	0.037
Clinical stage of PAD				<0.001
Rutherford 2	14 (8%)	14 (13%)	0	
Rutherford 3	96 (56%)	96 (88%)	0	
Rutherford 4	24 (14%)	0	24 (33%)	
Rutherford 5	36 (21%)	0	36 (50%)	
Rutherford 6	2 (1%)	0	2 (3%)	

Lesion & Procedure Data

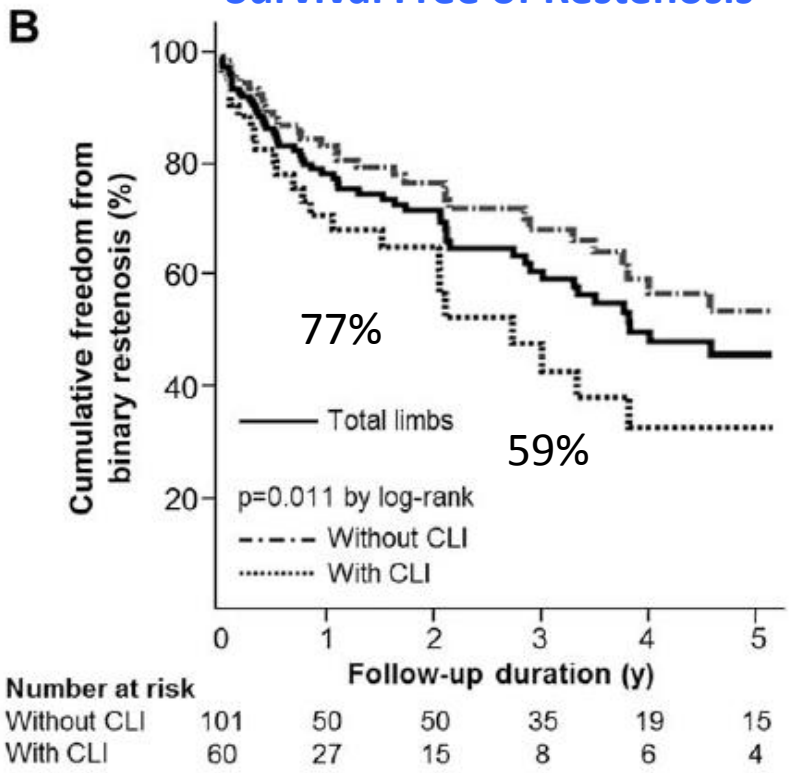
	Total limbs (172 limbs)	No CLI (110 limbs)	CLI (62 limbs)	p
Mean lesion length (cm)	22.6 ± 8.5	21.7 ± 8.6	24.0 ± 8.3	0.089
Level of lesion				0.130
Proximal SFA	128(74%)	77 (70%)	51 (82%)	
Middle SFA	35 (20%)	25 (23%)	10 (16%)	
Distal SFA	9 (5%)	8 (7%)	1 (2%)	
Lesion type (TASC II)				0.093
B	19 (11%)	16 (15%)	3 (5%)	
C	32 (19%)	22 (20%)	10 (16%)	
D	121 (70%)	72 (66%)	49 (79%)	
Side				0.691
Right	77 (45%)	48 (44%)	29 (47%)	
Left	95 (55%)	62 (56%)	33 (53%)	
Number of run-off vessels				<0.001
0 or 1	59 (34%)	23 (21%)	35 (57%)	
2	46 (27%)	30 (27%)	17 (27%)	
3	67 (39%)	57 (52%)	10 (16%)	
Ankle-brachial index				
Pre-procedure	0.47 ± 0.16	0.50 ± 0.16	0.40 ± 0.15	<0.001
Post-procedure	0.81 ± 0.20	0.84 ± 0.17	0.73 ± 0.23	0.004
Number of stents				0.306

Results: MAE & Restenosis

Survival Free of Major Adverse Event*



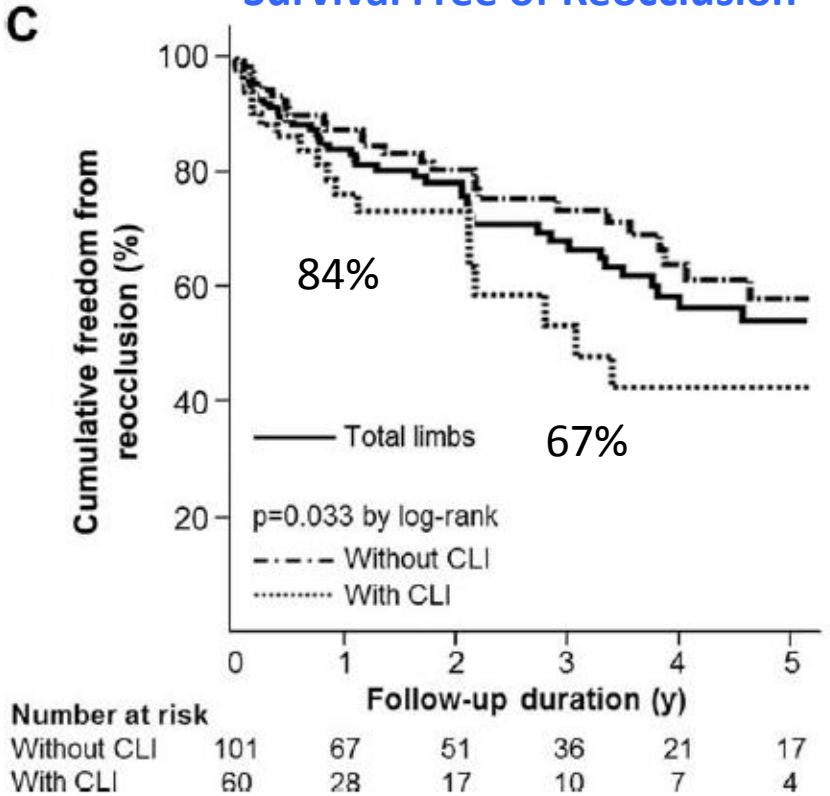
Survival Free of Restenosis



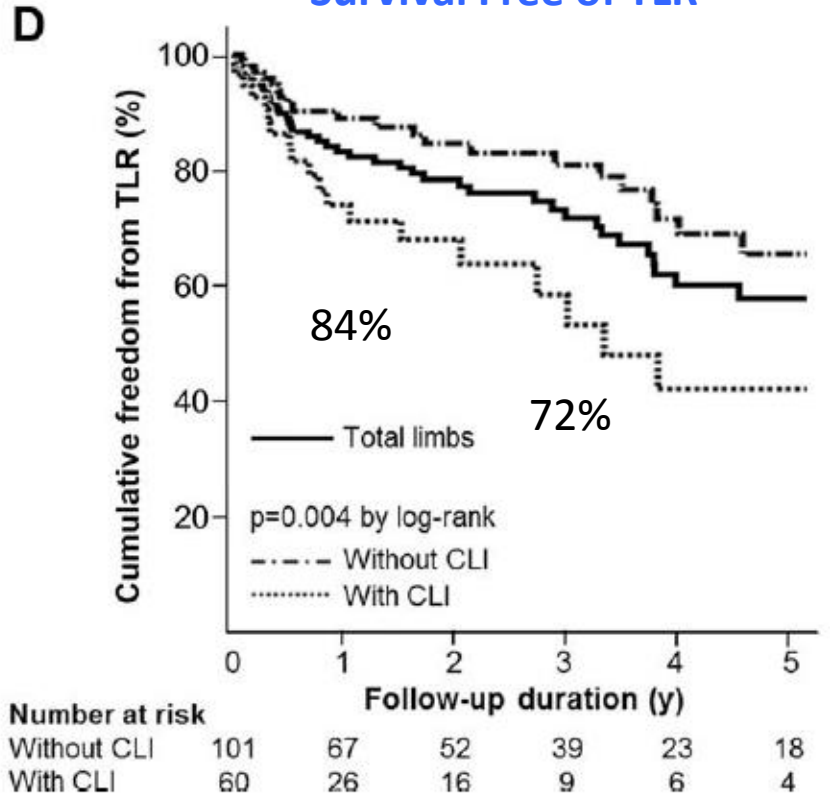
*Defined as a composite of all death and major amputation

Results: Reocclusion & TLR

Survival Free of Reocclusion



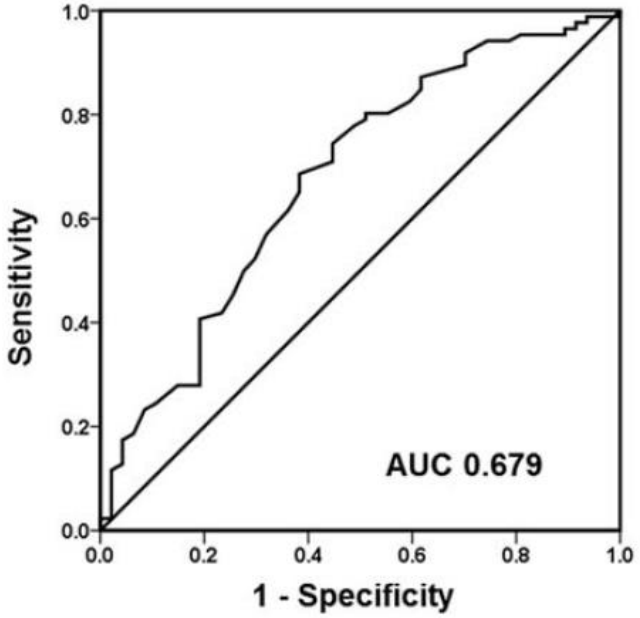
Survival Free of TLR

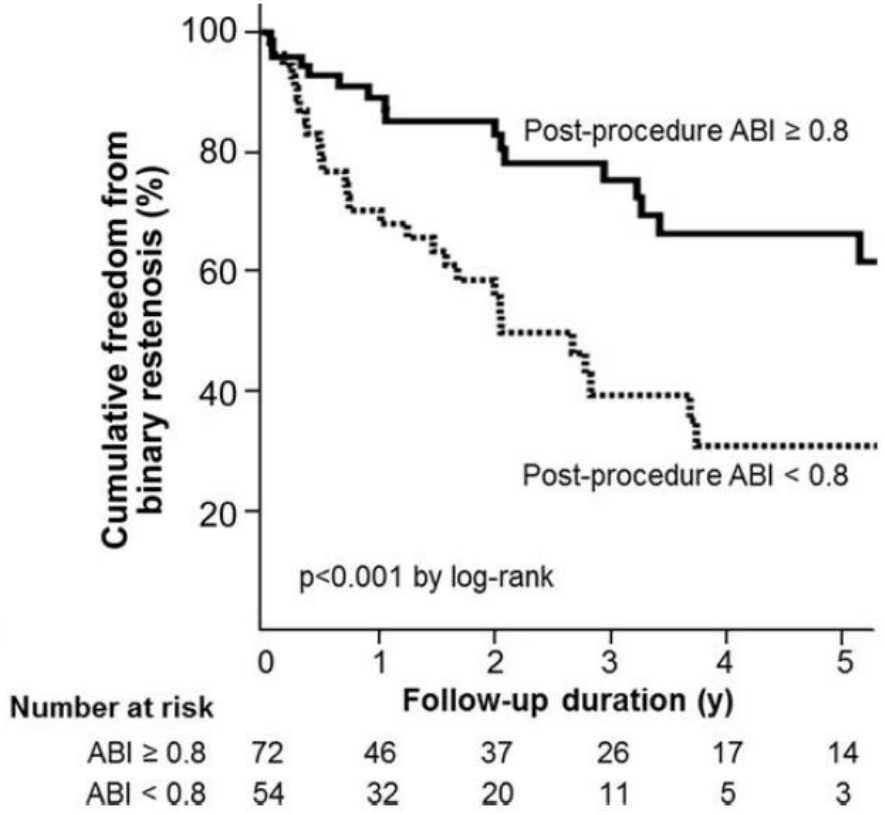


Multivariate Analysis of Binary Restenosis

	Univariate	Multivariate
Age	1.04, 1.01 to 1.08 (0.018)	1.01, 0.97 to 1.04 (0.764)
Female gender	1.49, 0.79 to 2.82 (0.221)	1.76, 0.77 to 4.03 (0.177)
Body mass index	0.91, 0.84 to 0.99 (0.022)	0.90, 0.81 to 1.00 (0.041)
Diabetes	0.97, 0.58 to 1.64 (0.921)	
Hypertension	0.98, 0.57 to 1.70 (0.946)	
Chronic kidney disease	1.62, 0.82 to 3.18 (0.166)	
Smoking	1.10, 0.66 to 1.87 (0.699)	
Critical limb ischemia	1.97, 1.16 to 3.36 (0.013)	1.30, 0.66 to 2.57 (0.449)
Post-procedure ABI	0.05, 0.01 to 0.20 (<0.001)	0.15, 0.03 to 0.75 (0.020)
Lesion length	1.00, 1.00 to 1.01 (0.156)	
Runoff vessels ≤1	2.36, 1.39 to 3.99 (0.001)	1.92, 0.94 to 3.92 (0.072)
Number of stents ≥2	2.50, 1.39 to 4.50 (0.002)	2.44, 1.19 to 5.03 (0.015)
Stent diameter	0.79, 0.53 to 1.17 (0.240)	

Survival Free of Restenosis According to Post-procedural ABI

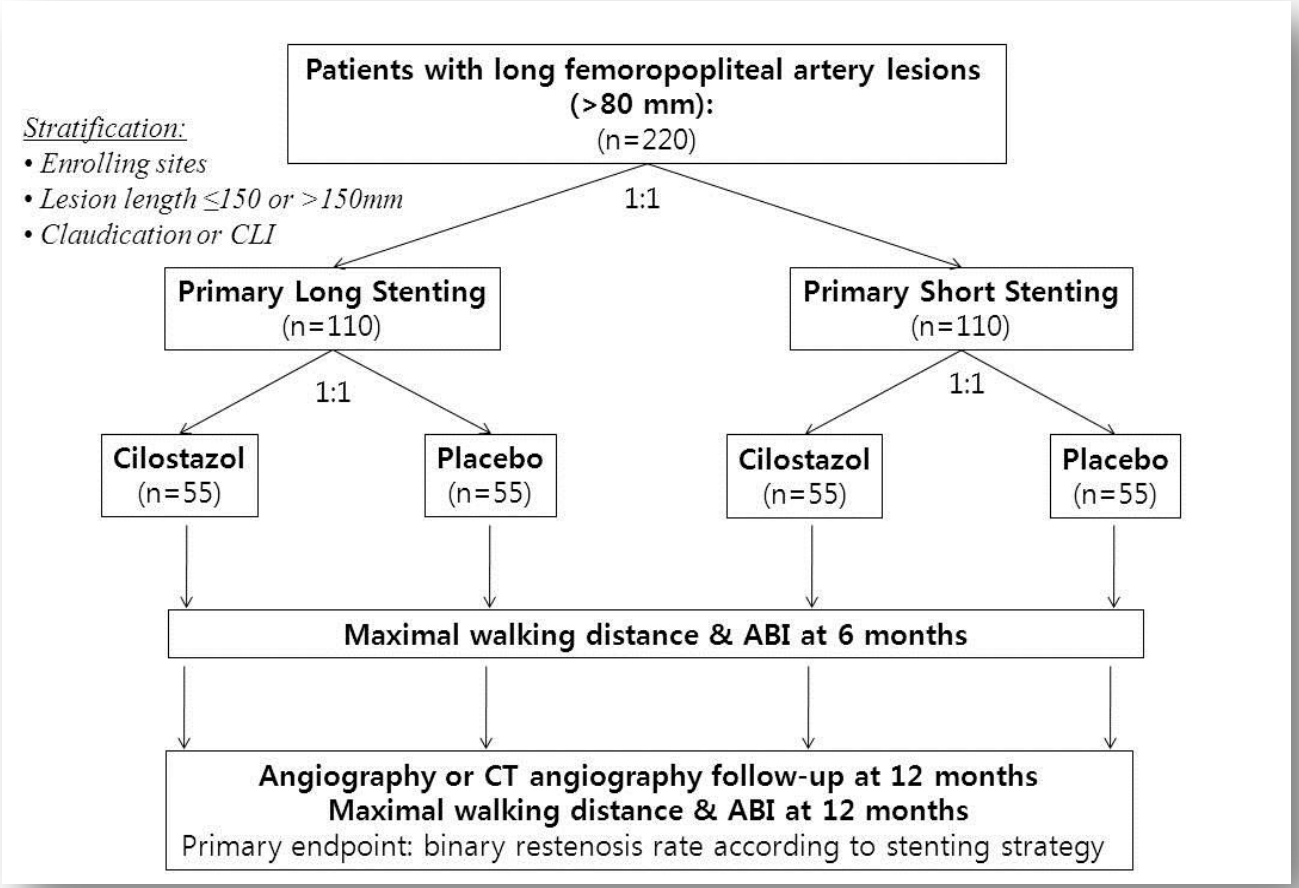




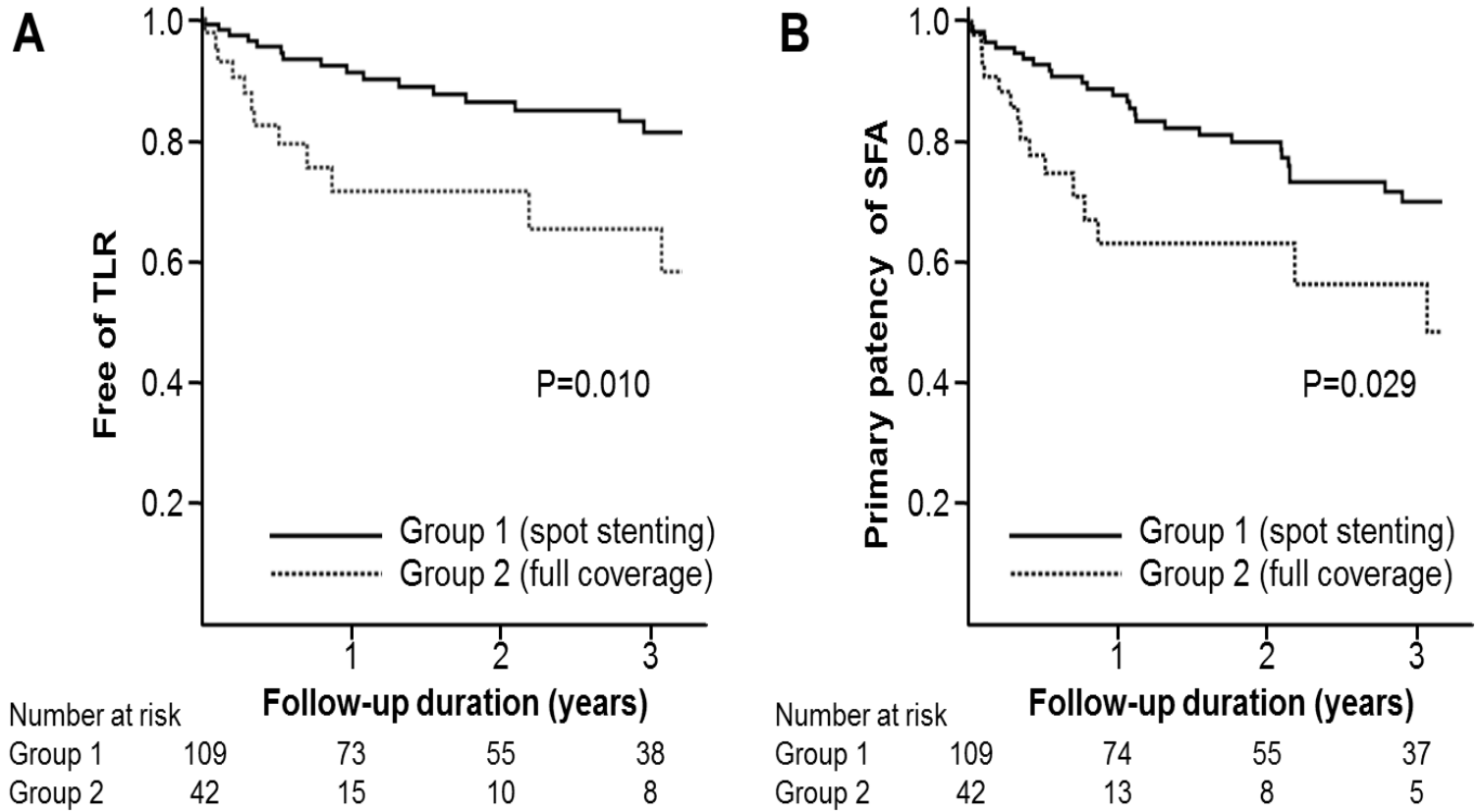
Number at risk						
ABI ≥ 0.8	72	46	37	26	17	14
ABI < 0.8	54	32	20	11	5	3

PARADE: Study Design

Registered at
www.clinicalTrials.gov
NCT 01359423

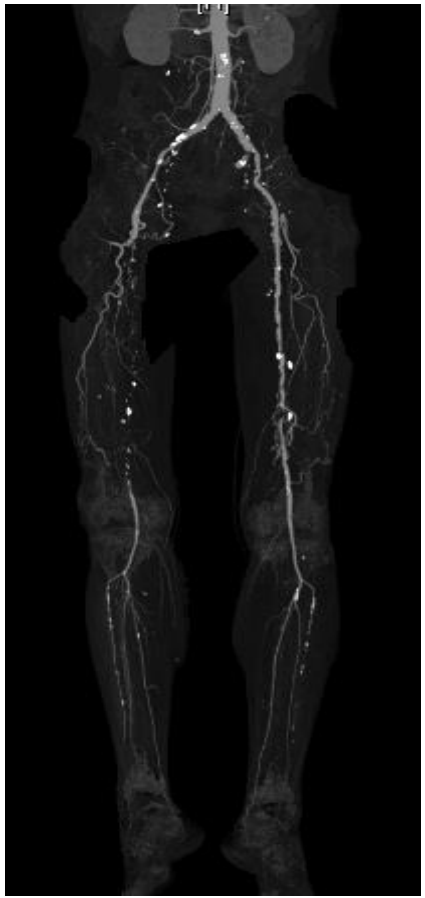


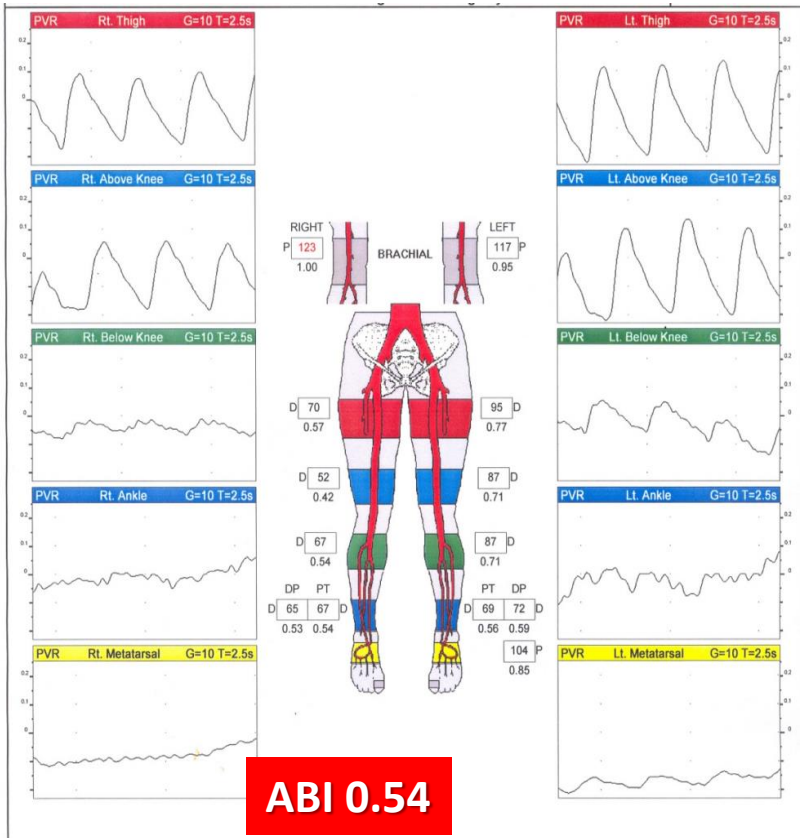
Long vs. Spot Stenting after SIA



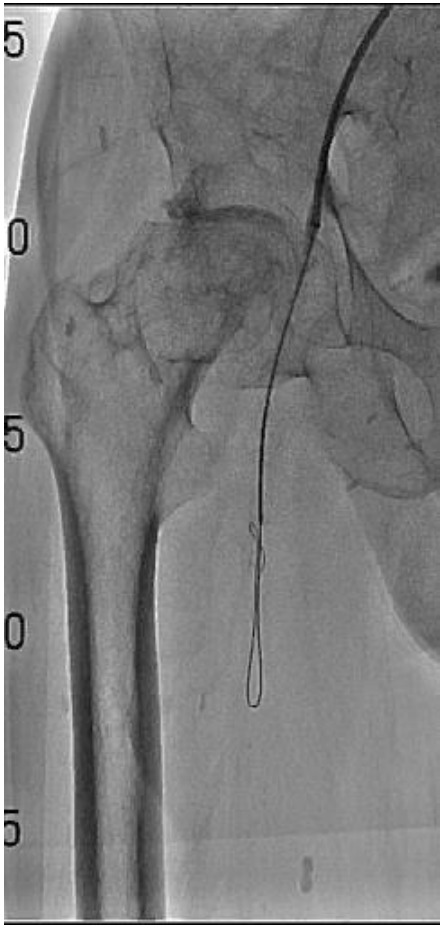
M/77, CIG #2093303

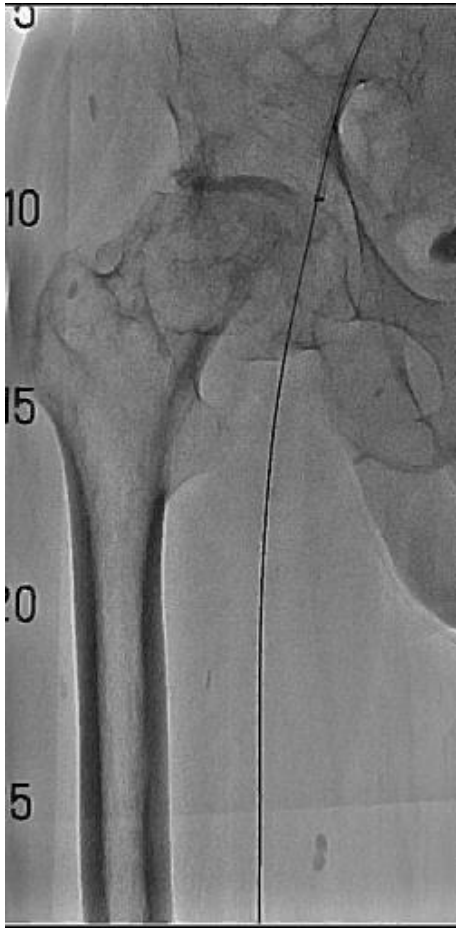
- Sx: Claudication Rt > Lt (Rutherford 3)
- Risk factors: smoker

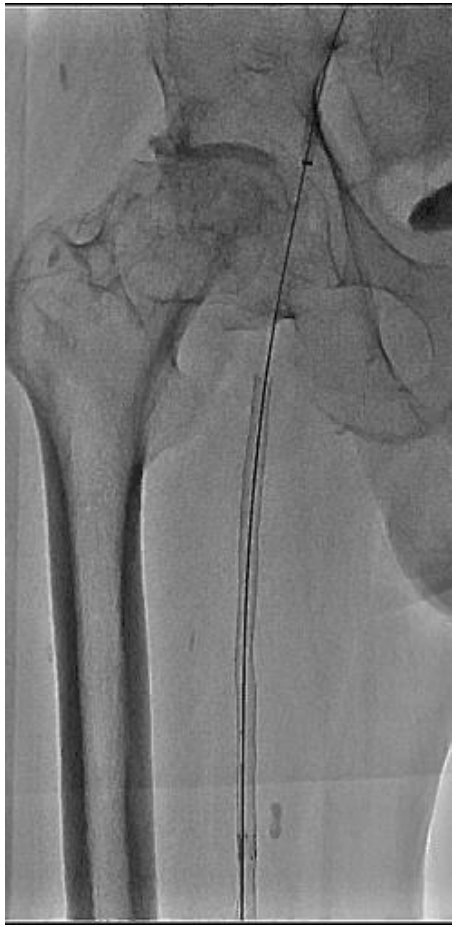




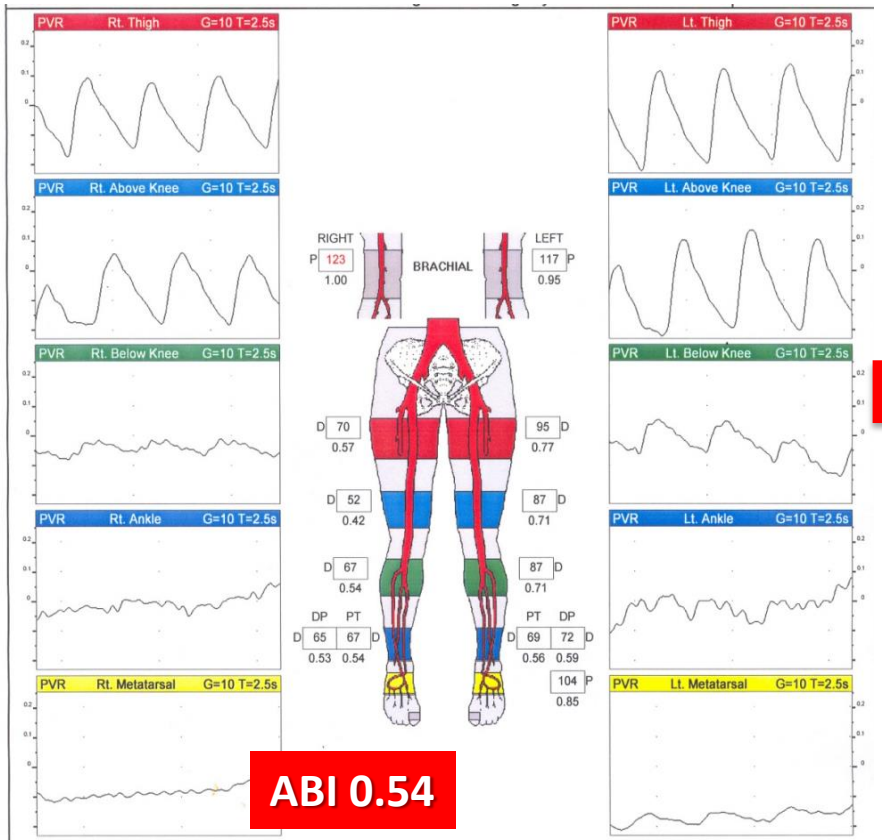
Long Stenting after SIA

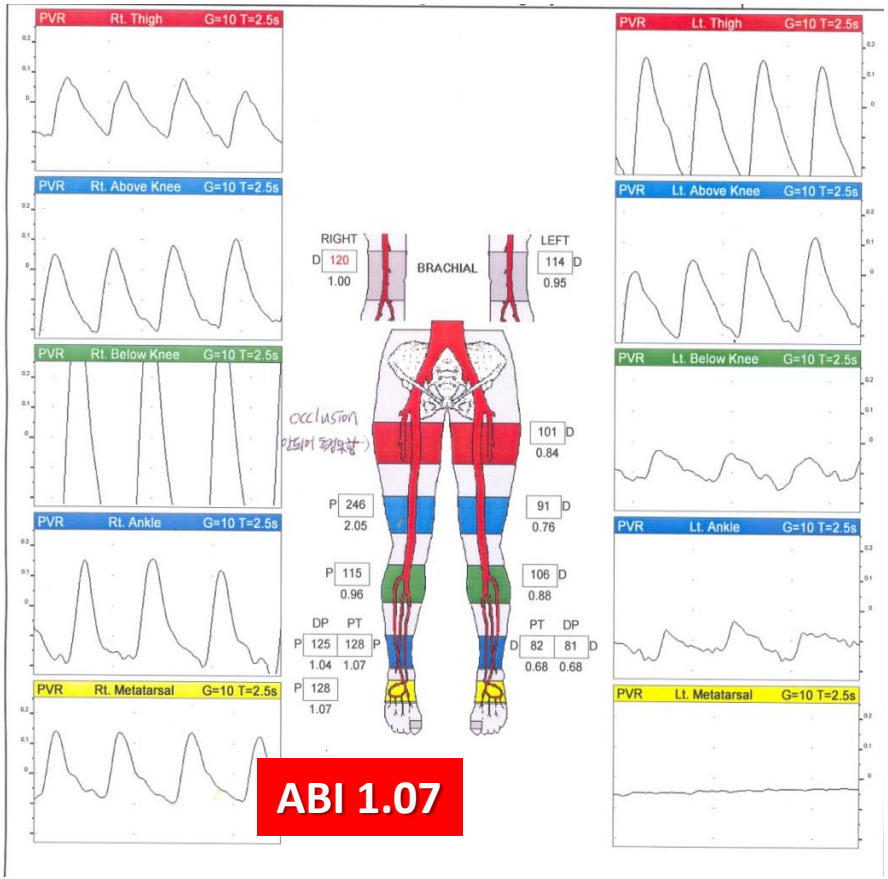




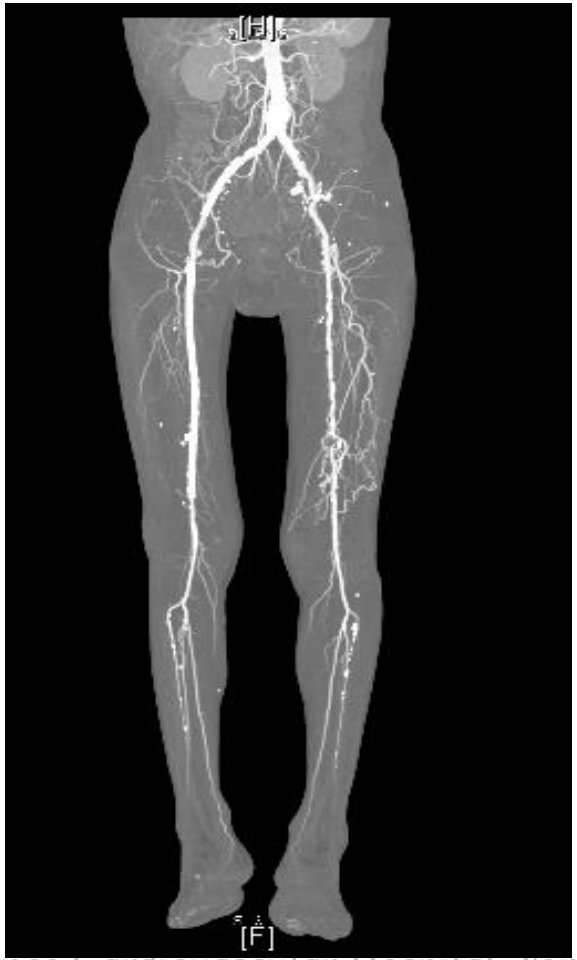


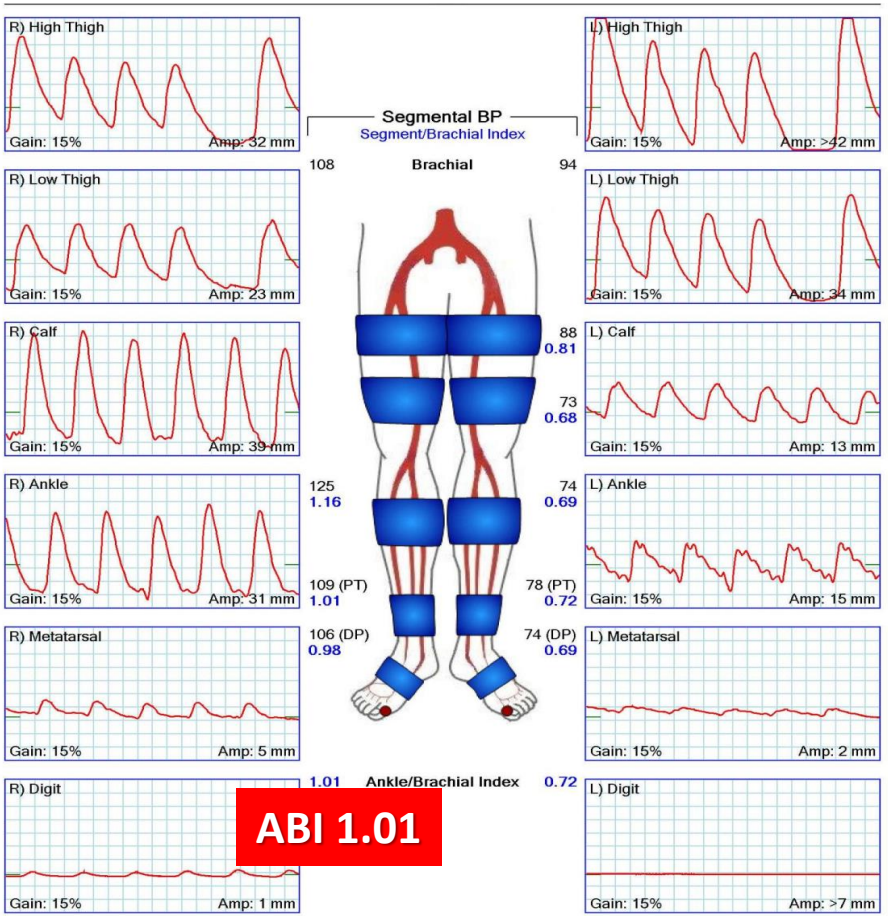
Improved ABI at FU PVR





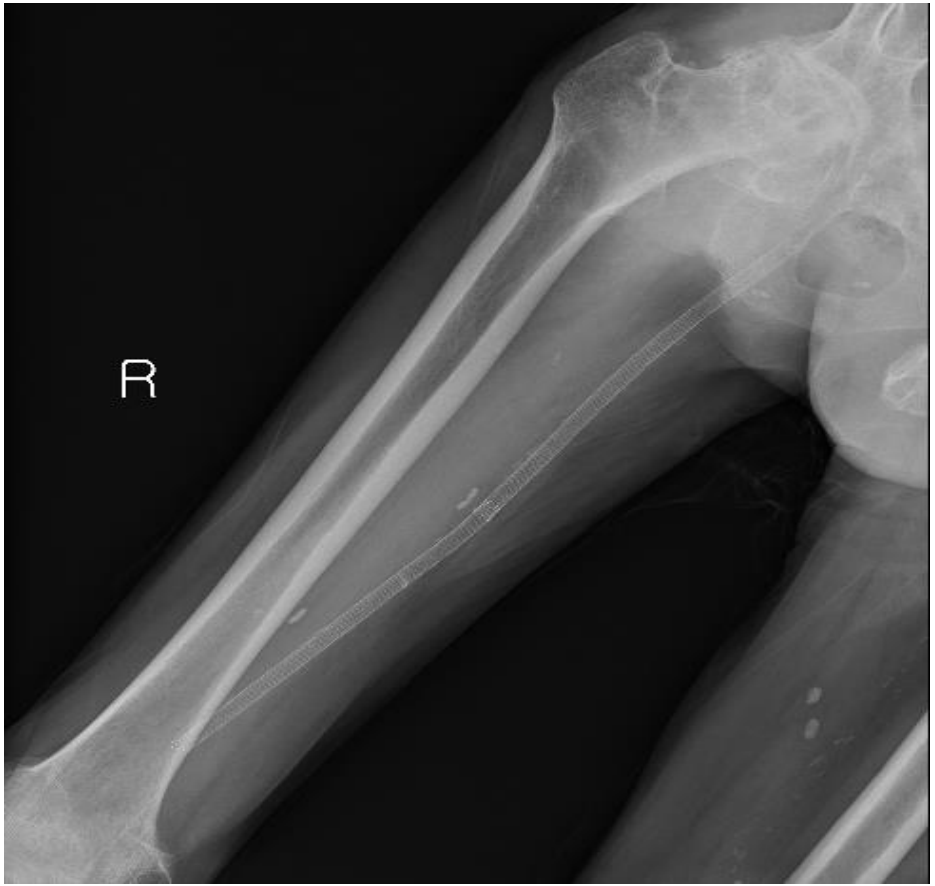
Follow-up at 12 months





ABI 1.01

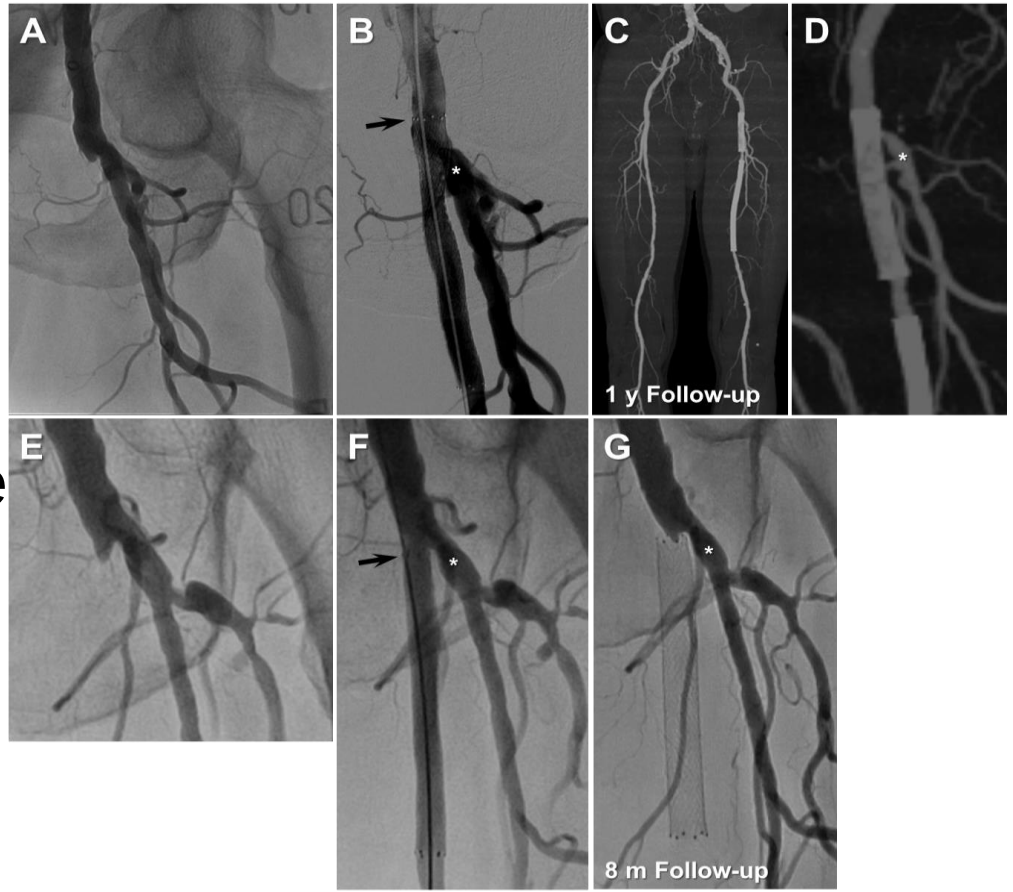
Nitinol Stents at 12-month Follow-up



Treatment of Femoral Bifurcation

Ostial stenting
with coverage of DFA

Stenting without coverage
of SFA ostium & DFA



Baseline Clinical Data

	Overall limbs (N=171)	Group 1 (N=101)	Group 2 (N=70)	p-value
Age (y)	70±8	69±8	70±9	0.475
Male	140 (82%)	81 (80%)	59 (84%)	0.495
Body mass index (kg/m^2)	22.7±3.3	22.8±3.4	22.5±3.2	0.629
Risk factors				
Hypertension	131 (77%)	74 (73%)	57 (81%)	0.215
Diabetes mellitus	95 (56%)	55 (55%)	40 (57%)	0.728
Coronary artery disease	121 (71%)	72 (71%)	49 (70%)	0.856
History of smoking	74 (43%)	44 (44%)	30 (43%)	0.927
Dyslipidemia	56 (33%)	32 (32%)	24 (34%)	0.721
Chronic kidney disease	34 (20%)	18 (18%)	16 (23%)	0.417
Clinical stage of PAD				0.452
Rutherford 2	46 (27%)	26 (26%)	20 (29%)	
Rutherford 3	64 (37%)	43 (43%)	21 (30%)	
Rutherford 4	36 (21%)	19 (19%)	17 (24%)	
Rutherford 5	19 (11%)	9 (9%)	10 (14%)	
Rutherford 6	6 (4%)	4 (4%)	2 (3%)	

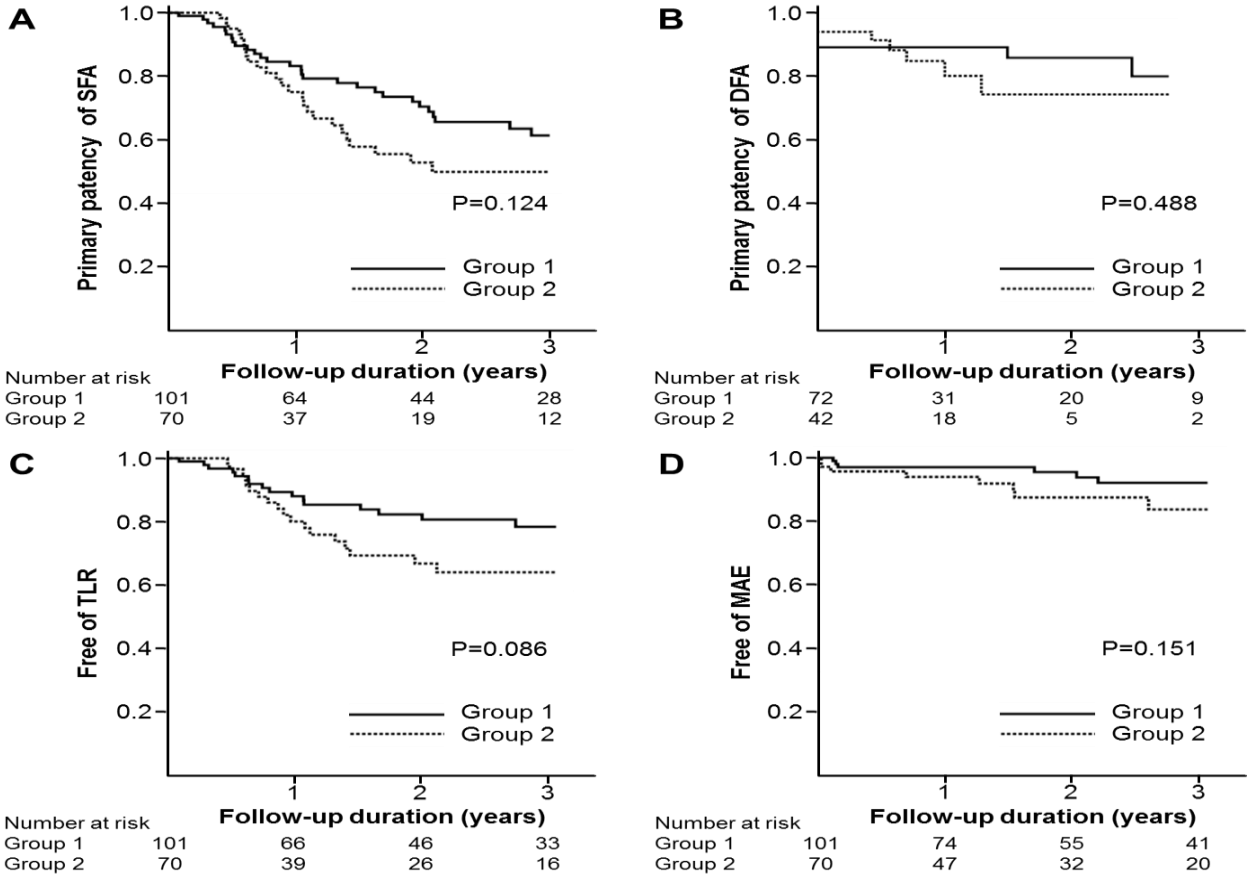
Procedural Data

	Overall limbs (N=171)	Group 1 (N=101)	Group 2 (N=70)	p-value
Mean lesion length (cm)	22.5±8.4	22.6±9.0	22.5±7.4	0.914
Medina (CFA-SFA-DFA)				0.187
0-1-0	106 (62%)	56 (55%)	50 (71%)	
0-1-1	33 (19%)	23 (23%)	10 (14%)	
1-1-0	20 (12%)	13 (13%)	7 (10%)	
1-1-1	12 (7%)	9 (9%)	3 (4%)	
Lesion type (TASC II)				0.591
B	15 (9%)	11 (11%)	4 (6%)	
C	29 (17%)	15 (15%)	14 (20%)	
D	122 (71%)	72 (71%)	50 (71%)	
CTO of SFA ostium	133 (78%)	81 (80%)	52 (74%)	0.360
Side				0.211
Left	88 (52%)	56 (55%)	32 (46%)	
Right	83 (49%)	45 (45%)	38 (54%)	
Pre-procedural ABI	0.48±0.18	0.45±0.18	0.51±0.17	0.046
Procedures				0.481
Intraluminal approach	54 (32%)	34 (34%)	20 (29%)	
Subintimal approach	117 (68%)	67 (66%)	50 (71%)	
Number of stents				0.399
1	124 (71%)	76 (75%)	46 (66%)	
2	45 (26%)	23 (23%)	22 (31%)	
3	4 (2%)	2 (2%)	2 (3%)	
Average number of stents	1.3±0.5	1.3±0.5	1.4±0.5	0.201

Results

	Overall limbs (N=171)	Group 1 (N=101)	Group 2 (N=70)	p-value
Post-procedural ABI	0.83±0.19	0.84±0.17	0.83±0.21	0.781
Complications				
Procedure-related deaths	0	0	0	1.000
Embolization to distal SFA	9 (5%)	4 (4%)	5 (7%)	0.282
Arterial perforation	2 (1%)	1 (1%)	1 (1%)	1.000
Flow limitation of DFA	13 (8%)	9 (9%)	4 (6%)	0.320
Post-procedural distal run-off				0.352
0 or 1	49 (29%)	33 (33%)	16 (23%)	
2	43 (25%)	23 (23%)	20 (29%)	
3	79 (46%)	45 (45%)	34 (49%)	

Outcomes


A
Primary patency of SFA
1.0
0.8
0.6
0.4
0.2
P=0.124
Group 1
Group 2
1
2
3
Follow-up duration (years)
Number at risk
Group 1 101 64 44 28
Group 2 70 37 19 12
B
Primary patency of DFA
P=0.488
Group 1
Group 2
Follow-up duration (years)
Number at risk
Group 1 72 31 20 9
Group 2 42 18 5 2
C
Free of TLR
P=0.086
Group 1
Group 2
Follow-up duration (years)
Number at risk
Group 1 101 66 46 33
Group 2 70 39 26 16
D
Free of MAE
P=0.151
Group 1
Group 2
Follow-up duration (years)
Number at risk
Group 1 101 74 55 41
Group 2 70 47 32 20

Conclusions

- Intentional SA with primary stent implantation is effective for the treatment of chronic total SFA occlusions, with a high technical success rate and few complications.
- SA with primary stenting provided not only a high short-term freedom from binary restenosis but also satisfactory midterm outcomes.
- However, additional stenting beyond the proximal stump is related to higher binary restenosis rates.
- Lower postprocedure ABI and lower BMI were independent predictors for binary restenosis.


Thank you
for your attention!