

## Freedom TM Stent의 초기결과 및 추적관찰 결과

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## Initial and Follow-up Results of Freedom TM Stent

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## ABSTRACT

**Background :** The Freedom TM stent, which is one of recently developed balloon-expandable coil stents, has advantages of low profile and good trackability and flexibility. We evaluated the initial results and the late restenosis rate of Freedom TM stent in patients with coronary artery disease. **Method :** A total of 40 Freedom stents were implanted in 32 consecutive patients (38 lesions). The clinical diagnosis of the subjects were stable angina in 1 patient, unstable angina in 19, and acute myocardial infarction in 12. The indications of stenting were primary stenting in 11 stents, suboptimal result after PTCA in 26, and bailout procedure in 1. A mean diameter of reference artery was 3.1 mm (SD,  $\pm 0.4$ ) and mean of lesion length was 10.9 mm (SD,  $\pm 5.6$ ). Stents were implanted with a mean maximal balloon pressure of 12.1 atm (SD,  $\pm 2.2$ ). Follow-up angiography was done at least 3 months (mean duration,  $8.7 \pm 3.7$ ) after stenting for 28 lesions of 22 patients. **Results :** All 40 stents were implanted safely except one, which was complicated with side branch occlusion. There was no case of stent thrombosis and clinical success rate was 97% (31/32). Minimal luminal diameter (MLD) was increased from 0.7 (SD,  $\pm 0.4$ ) to 3.0 mm (SD,  $\pm 0.4$ ) and % of diameter stenosis (%DS) was decreased from 78 (SD,  $\pm 13$ ) to 2% (SD,  $\pm 5$ ) immediately after stenting. The overall restenosis rate was 28% (8/28). The restenosis rate was increased in the complex lesions (complex, 38% vs simple, 0%;  $p = 0.05$ ) and lesion of small vessel ( $< 3.0$  mm, 50% vs  $\geq 3.0$  mm, 20%;  $p = 0.11$ ). **Conclusion :** Freedom TM stent is safe and feasible in patients with various morphology of coronary lesions including small and tortuous arteries, and in lesion associated with side branches. But lesions of small vessel and complex morphology are tend to be associated with higher rates of restenosis. (Korean Circulation J 1998;28(6):894-901)

**KEY WORDS :** Coronary stenting · Freedom stent · Restenosis.

## 서 론

(percutaneous transluminal coronary angioplasty, PTCA)

1987 Sigwart<sup>1)</sup>

: 1998 3 11

: 1998 6 25

: , 570 - 711

344 - 2

,<sup>2)3)</sup>

가

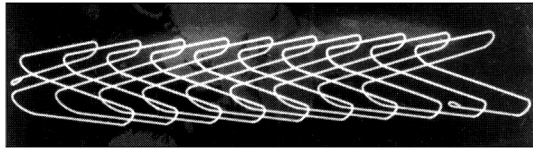
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Freedom

.

-



**Fig. 1.** The Freedom™ coronary stent demonstrating the fishscale design.

(Fig. 1), (fle -  
xibility) (trackability) , 6F  
(guiding catheter) 가 (prof -  
ile) 가 4)  
Freedom  
가

**Table 1.** Clinical characteristics of the subjects

Sex (Men/Women)	22/10
Age (years)	61 ± 9
Clinical Diagnosis	
Stable angina pectoris	1 ( 3%)
Unstable angina pectoris	19 (60%)
Acute myocardial infarction	12 (37%)
Risk factors	
Diabetes Mellitus	4 (13%)
Hypertension	17 (53%)
Hypercholesterolemia ( >240mg/dl)	2 ( 6%)
Smoking	20 (63%)

(guiding catheter) 0.014 inch×185 cm  
(guide wire)

## 연구 및 방법

### 대 상

1996 6 1997 8  
32  
, 38  
40 Freedom  
4 mm  
(ostium) 가  
22 , 10 61  
( 37~75)  
1 , 19 , 12  
(primary  
stenting) 11 , PTCA (sub -  
optimal result)가 26 , PTCA (ba -  
ilout procedure) 1 (Table 1).  
PTCA

4 , 17 , 2 ,  
20  
3 ( 8.7 )  
32 22

### 시술방법 및 약물요법

PTCA 7F

가  
(8~13 )  
20%  
(14~16 )  
20%  
100 mg ticlopidine  
500 mg 2~3  
6 , ticlopidine 1  
8,000~10,000 IU  
aPTT가 1.5  
sheath , 1  
1~2 aPTT  
2  
가  
가 24 sheath

### 관동맥 조영결과 분석

200 µg  
6 2  
(% di -

iameter setenosis, %DS) (mini -  
mal luminal diameter, MLD) ,  
가

2 가 caliper

가 (acute gain)

MLD MLD

가 (relative gain)

임상 및 혈관조영 추적검사

3

1

2

4

20%

1

(CABG)

PTCA

가

3

50%

(late loss)

MLD

MLD

loss)

가 (net gain

index)

MLD

MLD

통계분석

±

paired t - test

unpaired

t - test

uare test

, p

0.05

결 과

시술전 관동맥 조영촬영 소견

, 2

3

20 , 11 , 1

19 ,

8 ,

**Table 2.** Angiographic findings of the 38 coronary ste-  
notic lesions

Number of diseased vessel	
1 - vessel disease	20 (63%)
2 - vessel disease	11 (34%)
3 - vessel disease	1 ( 3%)
Location of the lesions	
Lt anterior descending artery	19 (50%)
Rt coronary artery	11 (29%)
Lt circumflex artery	8 (21%)
Modified ACC/AHA* lesion type	
A	2 ( 5%)
B <sub>1</sub>	7 (19%)
B <sub>2</sub>	19 (50%)
C	10 (26%)
Side branching	24 (63%)
Angulation ( > 45 °)	11 (29%)

\*ACC/AHA : American College of Cardiology / Ame-  
rican Heart Association.

11 , ACC/AHA  
5) A 2 (5%), B<sub>1</sub> 7 (19%), B<sub>2</sub> 19  
(50%), C 10 (26%) . 1  
mm 가 가 24 (63%)  
, 45 ° 11 (29%)  
(Table 2).

시술의 초기결과 결과 분석

38

36

2

3.1 mm( 0.4)

10.9 mm( 5.6),

22.1 mm( 7.9) .

12 ( 2) ,

MLD 0.7 mm(

3.0 mm( 0.40)

가 (p<0.0001), %DS 78%(

13) 2%( 5)

(p<0.0001).

가

2.3 mm( 0.5) ,

가

76%( 14) .

가 1 (3%)

97%(37/38 ), 97% , 8  
(31/32 ) (Table 3, Figs. 2 and 3).

추적 관동맥 조영촬영 결과 분석  
MLD 2.1 mm(  
0.9) %DS 32%(  
0.9 mm( 0.8)  
(69%), 38 28 (74%) 32 22 27) . 29%(  
29),  
가 44%( 30) (Table  
4). 28 8 (28%),

**Table 3.** Immediate angiographic result of stenting for the 38 lesions

	pre-PTCA*	post-stenting
Minimal luminal diameter (mm)	0.7 ± 0.4	3.0 ± 0.4 <sup>†</sup>
Diameter stenosis (%)	78 ± 13	2 ± 5*
Acute gain (mm)		2.3 ± 0.5
Relative gain (%)		76 ± 14
Angiographic success <sup>‡</sup>		37/38 (97%)
Clinical success <sup>‡</sup>		31/32 (97%)

\*PTCA : percutaneous transluminal coronary angioplasty.

<sup>†</sup>p < 0.001.

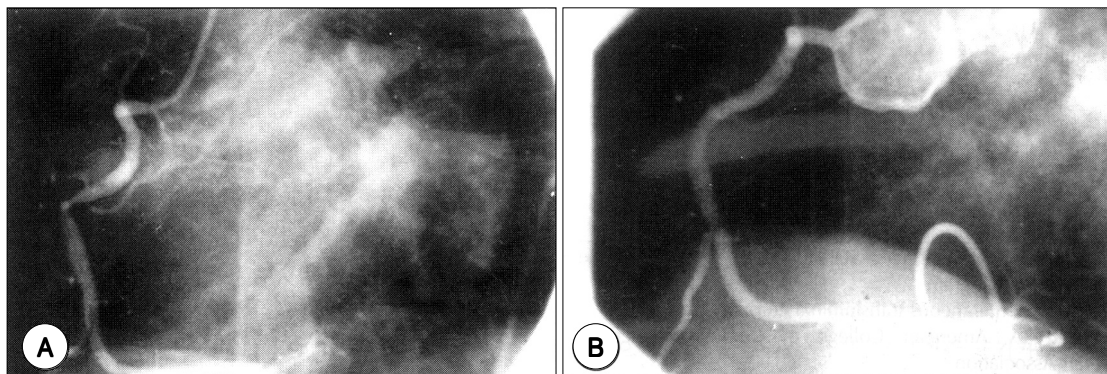
<sup>‡</sup>side branch occlusion in 1 lesion (3%).

**Table 4.** Follow-up angiographic result in the 28 coronary lesions of 22 patients after coronary stenting

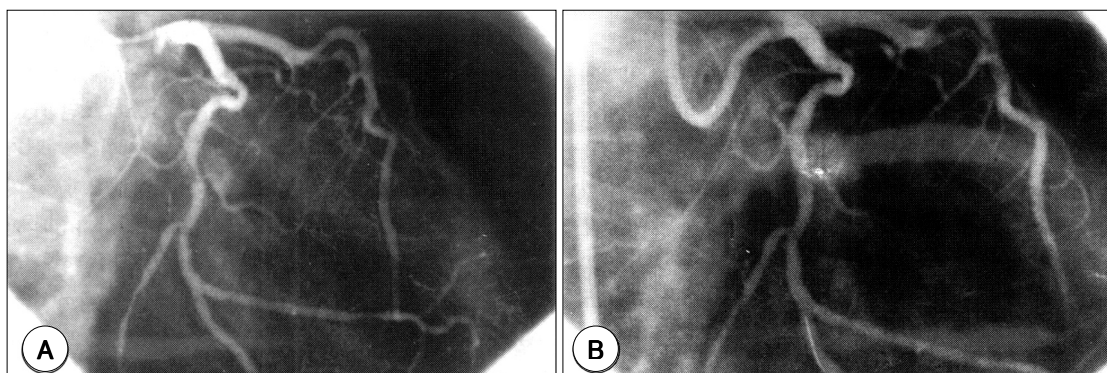
	pre-PTCA*	post-stenting	follow-up
Minimal luminal	0.7 ± 0.4	3.0 ± 0.4	2.1 ± 0.9
Diameter stenosis (%)	76 ± 13	2 ± 5	32 ± 27
Acute gain (mm)		2.3 ± 0.5	
Relative gain (%)		74 ± 14	
Late loss (mm)			0.9 ± 0.8
Relative loss (%)			29 ± 29
Net gain index (%)			44 ± 30

Follow-up duration : 8.7 ± 3.7 months

\*PTCA : percutaneous transluminal coronary angioplasty.



**Fig. 2.** Right coronary angiograms of a 65-year old man with unstable angina. A, before dilation ; B, after stent implantation.



**Fig. 3.** Angiograms of the left circumflex coronary artery in a 43-year old man with acute myocardial infarction. A, before dilation ; B, after stent implantation.

**Table 5.** Restenosis rate of the 28 lesions

Variable	Restenosis rate	p-value
Overall restenosis rate*	8/28 (28%)	
Clinical diagnosis		0.62
Stable angina pectoris	0/ 2 ( 0%)	
Unstable angina pectoris	4/14 (30%)	
Acute myocardial infarction	4/12 (33%)	
Indication of stenting		0.19
Primary stenting	1/ 7 (14%)	
Suboptimal result after PTCA <sup>†</sup>	6/20 (30%)	
Bailout procedure	1/ 1 (100%)	
Location of lesion		0.59
Lt anterior descending artery	5/14 (36%)	
Rt coronary artery	2/ 7 (29%)	
Lt circumflex artery	1/ 7 (14%)	
Modified ACC/AHA <sup>‡</sup> lesion type		0.05
Simple lesion (Type A or B1)	0/ 7 ( 0%)	
Complex lesion (Type B2 or C)	8/21 (38%)	
Reference vessel diameter		0.11
< 3.0mm	4/ 8 (50%)	
3.0mm	4/20 (20%)	
Angulation (> 45°)		0.20
+	4/ 9 (44%)	
-	4/19 (21%)	
Max. balloon pressure		0.88
13atm	6/20 (30%)	
14atm	2/ 8 (25%)	

\*Restenosis : defined as 50% diameter stenosis on the follow-up angiogram.

<sup>†</sup> PTCA : percutaneous transluminal coronary angioplasty.

<sup>‡</sup> ACC/AHA : American College of Cardiology/American Heart Association.

Table 5 .  
(B<sub>2</sub> C ) (A B<sub>1</sub>  
) (38%, 0% ; p=0.05),  
가 3 mm 가 3 mm  
(50%, 20% ; p=0.11), 45°  
(44%, 21% ; p =  
0.20).  
, , ,  
, , 가 가  
가 .

8 3 2  
CABG PTCA 1  
, 5 .  
고 찰  
PTCA  
가 6)  
20 가 .  
, ACC/AHA C  
, 가 A ,  
,  
7)  
, 4 mm  
Freedom 97%  
Palmaz - Schatz  
가  
STRESS 2) BENESTENT 3)  
99%, 97% .  
가  
Freedom De Sche -  
erder 4) 96%  
Freedom ,  
Fischman 8)  
maz - Schatz 5% Pal -  
가  
50%  
가 3  
Mazur 9)  
Gianturco - Roubin 0.8%

가

Freedom

De Scheerder <sup>4)</sup> 24 1 (4%)

PTCA 22~32% <sup>2)3)</sup>

PTCA (neointimal hyperplasia) (vascular re-modeling) (elastic recoil) <sup>18-20)</sup>

Freedom (11~15%)

PTCA

28% , Fr -

Freedom

De Sc -

heerder <sup>4)</sup> 21.3%

가

Palma - Schatz

STRESS <sup>2)</sup> BENESTENT

31.6% 22%

De Scheerder <sup>3)</sup> <sup>4)</sup>

Freedom 가 Palma - Schatz

warfarin

Serruys <sup>12)</sup>

39%

3.5%

<sup>2)3)</sup>

<sup>13)</sup> 가

<sup>14)</sup>

<sup>15)16)</sup>

Freedom

3.0 mm 20%

3 mm 50%

De Scheerder <sup>4)</sup> 가 3.0 mm

13%, 2.5 mm 3.0 mm 24%, 2.5 mm

mm 39% 가

ticlopidine

가

가

Freedom

De

Scheerder <sup>4)</sup> 0.6%

Gianturco - Roubin 0.9%, <sup>17)</sup>

Palma - Schatz 1.6% <sup>14)</sup>

Freedom

가

3 mm , 45 °

Freedom 가

요약

연구배경 : 가 Freedom

대상 및 방법 : 1996 6 1997 8 32 ( / : 22/10, : 37~75 ) 38 40 Freedom 1 , 19 , 12 11 , PTCA 26 , 1 가 (8~13 ) 100 mg ticlopidine 500 mg 2~3 1 . 8.7 22 28

결과 : 1) 19 , 8 , 11 , ACC/AHA (Type A or B<sub>1</sub>) 9 , (Type B<sub>2</sub> or C) 29 , 24 , 45 ° 11 . 2) 3.1 mm( 0.4) , 12.1 ( , 2.2) . MLD 0.7 mm( 0.4) 3.0 mm( 0.4) 가 , %DS 78%( 13) 2%(

5) . 3) 1 (3%) 97%(37/38), 97%(31/32) . 4) 28 8 28% , ( , 38% ; , 0%) 가 (<3.0 mm, 50% ; 3.0 mm, 20%)

결론 : Freedom , , 가 ,

3 mm 가 ,

중심 단어 : Freedom

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