

## AVE GFX Stent의 초기결과

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### Immediate Results of AVE GFX<sup>®</sup> Stent

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#### ABSTRACT

**Background :** The AVE GFX<sup>®</sup> coronary stent, a corrugated ring-type premounted stainless-steel stent, is designed for improved flexibility and trackability with increased vessel support when compared to the current Micro-II stent. We report the immediate results of our experience with the GFX stent. The purpose of this study was to assess the feasibility, safety and efficacy of deployment of the premounted GFX stent in patients with complex coronary anatomy as well as their clinical outcomes within the first month. **Methods :** Between April 1997 and August 1997, fifty-two GFX stents were deployed in the coronary arteries of forty-nine patients (male 71.4%, mean age 60 ± 8 years) with 52 lesions. Thirty-two patients had unstable angina pectoris, five had stable angina, and twelve had acute myocardial infarctions. **Results :** 1) The frequency of the used stents diameter was 3.0 mm in 23 (44.2%) patients, 3.5 mm in 22 (42.3%) patients, and 4.0 mm in 7 (13.5%) patients. The lengths of used stents were 18 mm (33 cases, 63.6%), 24 mm (17 cases, 32.7%) and 30 mm (2 cases, 3.8%). 2) Single stent implantation was achieved in 47 (92.1%) lesions ; multiple stents were deployed in 4 (7.9%) lesions (a case with 2nd GFX stent and 3 lesions overlapped with other kinds of stents). 3) Successful deployment was achieved in 51/52 stents (98.1%) with one case of stent passing failure. Adjuvant high pressure balloon dilatations (over 12 atm) were needed in 14 cases (26.9%) to achieve optimal result. 4) No major adverse cardiac events (MI, repeat PTCA, CABG, death) occurred in this series of 49 consecutive patients within 4 weeks after procedure. Stents were deployed successfully in complex lesions including calcified and angulated (>45°) lesions or in lesions with proximal tortuosity ; B2 (57.7%), C (28.8%) (procedural success rates and angiographic success rates were both 100%). 5) No subacute stent thrombosis occurred during hospital stay. Persistent dissections were performed in 2 cases distal-to-stent without significant compromise of blood flow. Of the 8 lesions with side branches, 1 side branch was occluded after stent deployment. 6) Mean lumen diameter of target lesion was increased from 0.79 ± 0.41 mm to 3.19 ± 0.41 mm (P < 0.001) after stent implantation. Percent of diameter stenosis was decreased from 75.6 ± 12.0% to 4.6 ± 12.9% (P < 0.001) after stent implantation. Mean diameter of reference artery was 3.20 ± 0.54 mm. **Conclusion :** GFX stent implantation can be achieved with high procedural success rate. With several favorable characteristics, good trackability, flexibility, and good vessel support, this new stent was deployed successfully in complex lesions for percutaneous coronary intervention. Follow-up data is needed to assess

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long term patency of this stent. (**Korean Circulation J 1998;28(4):568-575**)

**KEY WORDS** : Stent · Coronary artery disease · Intravascular ultrasound.

서 론

radial force가 Micro - II stent  
AVE GFX<sup>®</sup>stent (flexibility) vessel support 가

1986 가 1) 49

가 가 2,3)

대상 및 방법

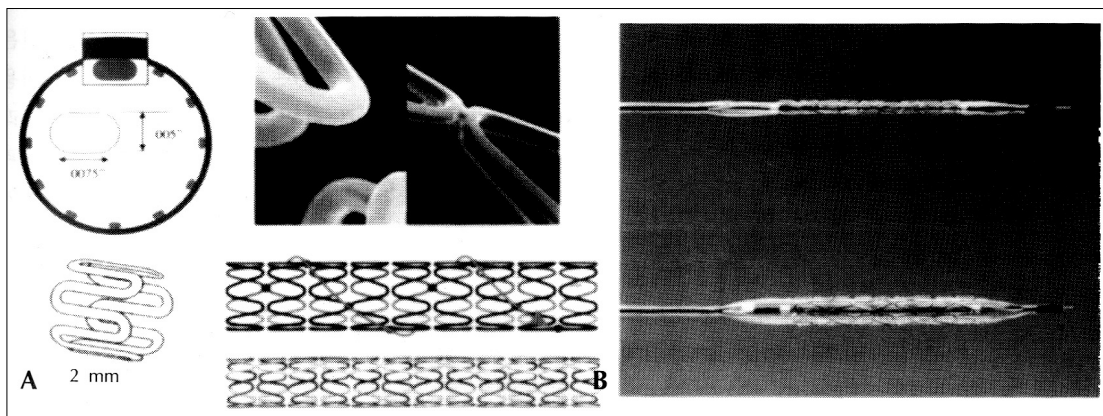
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4) 가 GFX<sup>®</sup> 49 (52 profile )

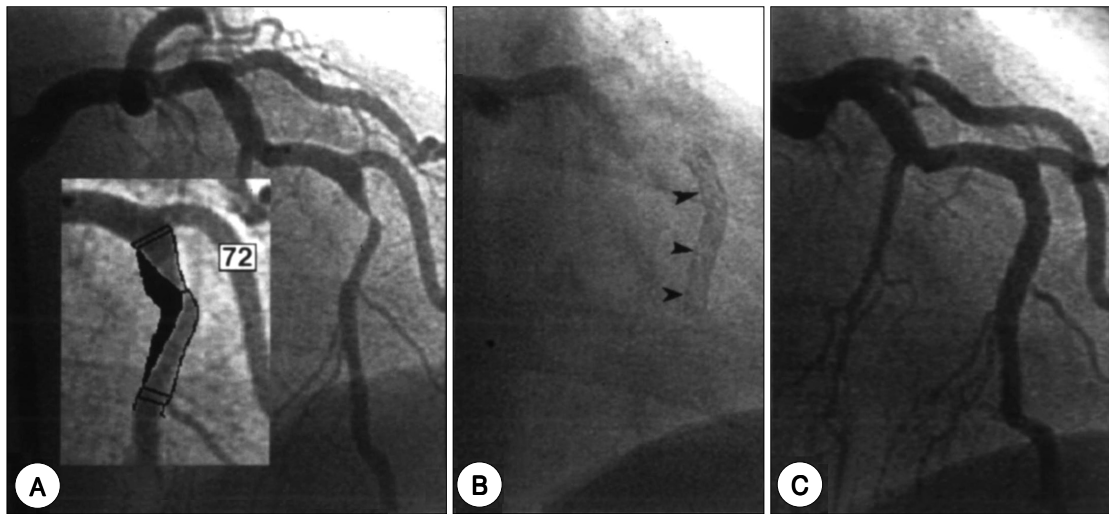
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Corrugated ring type AVE GFX<sup>®</sup>stent 가  
coil type Gianturco - Roubin stent가



**Fig. 1.** GFX stent design. Ellipt-rectangular struts with 6-crown design provides good vessel support and uniform stent expansion. 2 mm sinusoidal elements are helically fused to provide enhanced flexibility (A). Pre-mounted sheathless and low profile design for ease of use (B).



**Fig. 2.** An angulated lesion of distal LAD artery treated with a GFX stent. Initial coronary angiogram revealed tubular angulated lesion at distal LAD artery (A). The percent stenosis was measured as 72% by digital caliper (intersect). After deployment of a GFX stent of 3.5-24 mm size, angiogram showed moderate radiopacity (arrow heads) of expanded stent (B). The angulated vascular geometry of the lesion was well preserved after stent deployment (C).

스텐트 시술	8F	7F	175 cm	0.014
GFX stent(Arterial Vascular Engineering, Santa Rosa, CA)	inch		가	
stainless steel balloon - expandable				
rapid - exchange delivery system	direct PTCA	aspirin(100 mg po qd)	ticlopidine(250 mg po bid)	2 3
(segment)			ticlopidine	
0.005 inch (0.005 x 0.075)inch	aspirin		heparin 10,000	
ellipto - rectangular			activated clotting time	300
12 axial struts (6 crown)(Fig. 1). 3.5 mm			가	
non - expanded crossing profile		24	heparin	
0.060 inch surface area coverage		activated prothrombin time		2
20% recoil 4% (foreshortening)				
2% (foreshortening)	자료의 분석 및 통계			
semic - compliant balloon catheter mount	1997 5 8		GFX <sup>®</sup>	
good apposition			AHA/ACC	
GFX <sup>®</sup> 3.0, 3.5, 4.0 mm	empty catheter		electric caliper	
12, 18, 24, 30, 40 mm				
가 18, 24, 30 mm				
AVE	±			
	Student t - test		p	0.05

## 결 과

### 대상환자

49 (51 )  
 35 (71.4%), 14 (28.6%)  
 60 ± 8  
 12 (24.5%), 32 (65.3%),  
 5 (10.2%)

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

	Number (%)
Sex (male/female)	35 (71.4) / 14 (28.6)
Age (years, mean ± SD)	60 ± 8
Risk factors	
Smoking	28 (57.1)
Hypertension	19 (38.8)
Diabetes mellitus	14 (28.6)
Hypercholesterolemia (>240mg%)	9 (18.4)
Clinical diagnosis	
Stable angina pectoris	5 (10.2)
Unstable angina pectoris	32 (65.3)
Acute myocardial infarction	12 (24.5)
Angiographic diagnosis	
Single vessel disease	18 (36.7)
Multiple vessel disease	31 (63.3)

**Table 2.** Angiographic characteristics of the lesions

	Number (%)
Target lesion vessel	
LAD	17 (32.7%)
LCX	12 (23.1%)
RCA	21 (40.4%)
Intermediate branch	1 ( 1.9%)
Lesion type (ACC / AHA classification)	
A	1 ( 1.9%)
B1	6 (11.5%)
B2	30 (57.7%)
C	15 (28.8%)
Angulation (> 45 °)	12 (23.1%)
Tortuosity*	8 (15.4%)
Side branch	8 (15.4%)
Calcification	17 (32.7%)
Total occlusion	4 ( 7.7%)

\* ; Moderate tortuosity : lesion is distal to two bands >75 °  
 Severe tortuosity: lesion is distal to three bands >75 °  
 or two bands >90 °

18 (36.7%), 31  
 (63.3%) (Tabel 1).

### Characteristic of the lesions

17  
 (32.7%), 12(23.1%) , 21  
 (40.4%), (intermediate branch) 1 (1.9%)  
 . AHA/ACC B2  
 30 (57.7%), C 15 (28.8%), A B1  
 1.9%, 11.5% . 47 (90.4%) ec -  
 centric 17  
 (32.7%) 가 8 (15.4%)  
 . 4 (Table 2).

### 시술결과

51 52 가 . 1  
 2 GFX st -  
 ent(GR - II, NIR) overlap 3  
 1 cover . 14  
 12 optimal result  
 . 3.0  
 mm 23 (44.2%), 3.5 mm 22 (42.3%), 4.0 mm 7  
 (13.5%) 18 mm 33 (63.6%), 24  
 mm 17 (32.7%), 30 mm 2 (3.8%) 3.5 mm  
 18 mm 가 가 (14 ,  
 26.9%)(Table 3).  
 75.6 ± 12.0% - .6 ± 12.9%

**Table 3.** Stent size and number

	Number (%)
Diameter (mm)	
3.0	23 (44.2)
3.5	22 (42.3)
4.0	7 (13.5)
Length(mm)	
18	33 (63.6)
24	17 (32.7)
30	2 ( 3.8)
NO. of stents by lesion vessel	
Single stent	47/51 (92.1)
Overlapping with GFX stent	1/51 ( 2.0)
with other stent	3/51 ( 5.9)

**Table 4.** Angiographic result

Reference diameter (mm)	3.20 ± 0.54
MLD (mm)	
pre-stent	0.79 ± 0.40
post-stent	3.19 ± 0.41*
Percent diameter stenosis (%)	
pre-stent	75.6 ± 12.0
post-stent	-0.6 ± 12.9*
Peri-stent dissection	2 (3.9%)
proximal to stent	0
distal to stent	2
proximal and distal to stent	0
Compromised side branch	1/8 (12.5%)
Angiographic success	51/52 (98.1%)
Mean ± S.D.	

\*pre-stent vs post-stent : p < 0.001

**Table 5.** Procedure related complications

	Number (%)
Stenting failure	1 (1.9)
Failure to cross the lesion	1
Stenting success	51 (98.1)
Q-myocardial infarction	0 (0%)
Bleeding requiring transfusion	0 (0%)
Acute and subacute closure	0 (0%)

(minimal luminal diameter, MLD) 0.79 ± 0.40 mm 3.19 ± 0.41 mm  
 가 . Stent persistent dissection 2 (3.9%)  
 가 stent distal edge .  
 Stenting 1.5 mm aque) fluoroscope 가  
 side branch 8 stenting compromise .  
 1 (12.5%) . Angiographic success rate 98.1%  
 1 (Table 4). 3.5  
 mm 24 mm pr - 98.1%  
 edilation 가  
 가 2 . 100% . 61 81 GFX  
 Stenting 4 98.7% Joseph  
 , , (Table 5).  
 .<sup>9)</sup> 20% 2  
 Joseph 3  
 1 2  
 stent  
 STRESS study,<sup>2)</sup> BENESTENT<sup>3)</sup> BENESTENT (GR - II, NIR) overlap 3

II<sup>5)</sup> 가  
 가 가 . Colombo  
 ticlopidine  
 7)  
 flexible 가  
 tracking  
 shortening metal coverage가  
 radial force가  
 side branch가 jail side branch  
 PTCA가 radiopacity 가 fluo -  
 roscope .<sup>8)</sup>  
 GFX<sup>®</sup> stent corrugated ring type segment가  
 welded Micro II stent  
 . Micro II  
 3 mm segment GFX<sup>®</sup> 2 mm  
 crossing profile 0.6 inch  
 6 Fr 가  
 segment corrugated fold Micro II  
 4 6 가 12 strut가  
 . Strut  
 ellipt - rectangular  
 strut wire가 가  
 premount  
 (moderate radiop -  
 aque) fluoroscope 가  
 .  
 30%  
 procedural success rate  
 4 ,  
 98.1%  
 ,  
 61 81 GFX  
 98.7% Joseph  
 .<sup>9)</sup> 20% 2  
 Joseph 3  
 1 2  
 stent  
 GFX  
 (GR - II, NIR) overlap 3

cover . . . . .<sup>17)</sup>  
minimal luminal diameter(MLD) 3.19±0.41 10%<sup>18)19)</sup>  
mm Joseph 3.5±0.4 mm 20 40%  
3 mm 가 23 AVE Micro - II stent  
MLD 3.39±0.32 (persistent)<sup>20)</sup>  
mm . stent 가 ,  
thrombosis 가 ,  
Acute thrombosis 1% angulation  
1<sup>10)</sup> suba -<sup>21)</sup>  
cute thrombosis 3 21%<sup>4)6)11-14)</sup> oversizing balloon  
foreign body reaction, dead . 17  
space,  
Colombo Palmaz - Schatz stent 가  
<sup>8)</sup> 2 (3.9%) persistent di -  
dead space ssection Micro - II stent  
subacute thr - 14%<sup>20)</sup> Dissection  
ombosis<sup>7)</sup> angulated lesion 24 mm  
GFX<sup>®</sup> stent premount balloon catheter stent stent  
12 가 stent distal edge  
12 optimal result type A TIMI3 가  
Joseph GFX<sup>®</sup> stent  
15 thro - Side branch  
mbosis가<sup>9)</sup> 14 side branch occlusion side bra -  
(26.9%) 12 nch  
thrombosis coil stent가<sup>8)22)</sup> Stenting  
stent apposition st - 1.5 mm side branch 8  
ent occlusion<sup>7)15)</sup> 1 (12.5%).  
stent acute result longterm result G - R stent 7%,<sup>22)</sup> P - S stent<sup>1,23)</sup> NIR stent  
9.6%<sup>21)</sup>  
AVE Micro - II stent side branch occlusion 50%  
<sup>16)</sup> oversizing balloon side branch가 1 70%  
<sup>17)</sup>  
thrombosis tortuosity  
good apposition<sup>8)21)</sup> 가  
<sup>8)</sup> tortuosity 8 (15.4%) ,  
subacute  
thrombosis가 good ap - GFX Micro - II stent flexibility  
position 30 mm  
가 .

edge  
 flexibility  
 vascular geometry  
 stent가

stent  
 good trackability, flexibility, good vessel support, less traumaticity  
 , angulated lesion, calcified lesion

가  
 12 45

요 약

lesion  
 radial force  
 MLD  
 calcification  
 )

연구배경 :  
 GFX corrugated ring type  
 Micro - II flexibility vessel support  
 GFX stent  
 angioplasty stent safety feasibility

radial force  
 stent apposition  
 )  
 0.579).  
 GFX<sup>®</sup> stent  
 stent apposition

방 법 :  
 1997 4 8  
 49 ( 71.4%,  
 60 ± 9 ), 51 52 AVE GFX<sup>®</sup> stent

coil stent  
 welding  
 unit 가 bare area  
 )  
 Micro - II stent가 45  
 .<sup>16)</sup> Segment strut  
 GFX stent  
 good metal coverage

결 과 :  
 1) 3.0 mm 23 (44.2%), 3.5 mm 22 (42.3%), 4.0 mm 7 (13.5%)  
 18 mm 33 (63.6%), 24 mm 17 (32.7%), 30 mm 2 (3.8%)  
 2) GFX stent 94.1%  
 GFX stent overlapping 2.0%, overlapping 5.9%

inal diameter(MLD)  
 가

3) Angiographic success rate 98.1%  
 4  
 . Calcified 45 °  
 , proximal tortuosity  
 angiographic success rate 100%  
 4) subacute closure

GFX<sup>®</sup> stent  
 Micro - II stent

가 2  
 . 1.5 mm 가 8

1 가 occlusion  
 5) MLD 0.79 ± 0.41 mm  
 3.19 ± 0.41 mm 가 (P < 0.001)  
 75.6 ± 12.0%  
 - 0.6 ± 12.9% (P < 0.001)  
 3.20 ± 0.54 mm  
 6) 1 (1.9%)  
 결론 :  
 GFX stent Micro-II stent  
 good trackability, flexibility, less traumaticity, good  
 vessel support  
 , angulated lesion, calcified lesion  
 . stent long term pat-  
 ency  
 중심 단어 : . GFX .

#### REFERENCES

- 1) Sigwart U, Puel J, Mirkovitch V, Joffre F, Kappenberger L. *Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty.* *N Eng J Med* 1987;316:701-6.
- 2) Fischman DL, Leon MB, Baim DS, et al. *A randomized comparison of coronary stent placement and balloon angioplasty in the treatment of coronary artery disease.* *N Engl J Med* 1994;331:496-501.
- 3) Serruys PW, De Jaegere PP, Kiemeneij F, et al. *A comparison of balloon expandable stent implantation with balloon angioplasty in patients with coronary artery disease.* *N Engl J Med* 1994;331:489-95.
- 4) Suttton JM, Ellis SG, Roubin GS, et al. *Major clinical events after coronary stenting: The multicenter registry of acute and elective Gianturco-Roubin stent placement.* *Circulation* 1994;89:1126-37.
- 5) BENESTENT II study group. *Heparin-coated Palmaz-Schatz stents in human coronary arteries. The European Society of Cardiology Meeting (Stockholm, Sweden), August;1997.*
- 6) Colombo A, Hall P, Nakamura S, Aalmagor Y, Maiello L, Martini G, Saglione A, Goldberg SL, Tobias JM. *Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance.* *Circulation* 1995;91:1676-88.
- 7) Jang YS. *Ideal stent selection and design.* *Korean Circulation J* 1997;27:1055-60.
- 8) Joseph T, Cassaguan B, Fajadet J, Jordan C, Laborde JC, Laurent IP, Marco I, Marco J. *Initial experience with the new GFX coronary stent. Eighth complex coronary angioplasty course:283-291, Paris, May 20-23, 1997.*
- 9) Ueda Y, Nanto S, Komamura K, Kodama K. *Neointimal coverage of stents in human coronary arteries observed by angiography.* *J Am Coll Cardiol* 1994;23:341-6.
- 10) Barragan P, Sainsous J, Silvestri M, Bouvier JL, Comet B, Simeoni JB, Charmasson C, Bremond M. *Ticlopidine and subcutaneous heparin as an alternative regimen following coronary stenting.* *Cathet Cardiovasc Diagn* 1994;32:133-8.
- 11) Muller DWM, Shamir KJ, Ellis SG, Topol EJ. *Peripheral vascular complications after conventional and complex percutaneous coronary intervention procedures.* *Am J Cardiol* 1992;69:63-8.
- 12) Herrmann HC, Buchbinder M, Clemen MW, Fischman D, Goldberg S, Leon M, Schatz RA, Tierstein P, Walker CM, Hirschfield JW. *Emergency use of balloon expandable coronary artery stenting for failed percutaneous transluminal coronary angioplasty.* *Circulation* 1992;86:812-9.
- 13) Haude M, Erbel R, Issa H, Straub U, Rupprecht HJ, Treese N, Heyer J. *Subacute thrombotic complications after intracoronary implantation of Palmaz-Schatz stents.* *Am Heart J* 1993;126:15-22.
- 14) Sheath S, Litvach F, Dev V, et al. *Subacute thrombosis and vascular injury resulting from the slotted-tube nitinol and stainless steel stents in a rabbit carotid artery model.* *Circulation* 1996;94:1733-40.
- 15) Choi DH, Jang YS, Hong BK, Lee NH, Kim TY, Ha JW, et al. *AVE Micro-II stent: 6-months follow up result.* *Korean Circulation J* 1997;27:1280-8.
- 16) Lee NH, Jang YS, Hong BK, Choi D, Ha JW, Rim SJ, et al. *Coronary Less shortening wallstent in the long lesion of coronary artery disease: 6 months follow-up results.* *Korean Circulation J* 1997;27:1249-57.
- 17) Mehta S, Popma J, Margolis J, et al. *Angiographic complications after new device angioplasty in native coronary arteries: A NACI Angiographic Core Laboratory Report. The proceedings of TCT Meeting (Washington DC), February;1995.*
- 18) Bailey S, Ricci D, Kiesz S, et al. *Incidence and clinical impact of dissections after PTCA and stent placement: Results from the Randomized Stent REStenosis Study. The proceedings of TCT Meeting (Washington DC), February; 1995.*
- 19) Ryu JC, Jang YS, Kim KY, Lee SH, Kim JH, Chun DW, et al. *Immediate results of AVE Micro-II stent.* *Korean Circulation J* 1997;27:532-40.
- 20) Kim TY, Lee DI, Hong BK, Choi D, Rim SJ, Kim DS, et al. *Immediate results of manually crimped NIR stent.* *Korean Circulation J* 1998:(in press).
- 21) Mazur W, Grinstead WC, Hakim AH, Dabaghi SF, Abukhalil JM, Ali NM, Joseph J, French BA, Raizner AE. *Fate of side branches after intracoronary implantation of the Gianturco-Roubin flex-stents for acute or threatened closure after percutaneous transluminal coronary angioplasty.* *Am J Cardiol* 1994;74:1207-10.
- 22) Fischman DL, Savage MP, Leon MB, Schatz RA, Ellis S, Clemen MW, Hirschfeld JW, Tierstein P, Baley S, Walker CM, Goldberg S. *Fate of lesion related side branches after coronary artery stenting.* *J Am Coll Cardiol* 1993;22:1641-6.
- 23) Hong MK, Chuang YC, Prunka N, Salter LF. *Predictors of early and late cardiac events in patients undergoing saphenous vein graft angioplasty with PTCA and new device modalities.* *Circulation* 1993;88:1-601.
- 24) Tamura T, Kimura T, Nosaka H, Nobuyoshi M. *Predi-*



- ctors of restenosis after Palmaz-Schatz stent implantation. Circulation 1994;90:1-324.*
- 25) Rau T, Txhiruer BI, Mathey DG, Schofer J. *Comparison of restenosis rates after placement of Palmaz-Schatz stents and AVE Micro stents (abstr): Eur Heart J (Suppl) 1996;17:179.*
- 26) Colombo A. *Coronary stenting: Stent indications. The vascular stent summit. Milano, May 29-31, 1997*