

Micro-Ⅱ Stent의 초기결과

류종철 · 장양수 · 김건영 · 이승환 · 김종현 · 전동운 · 심원흠 · 조승연

조 홍 근

= Abstract =

Immediate Results of AVE Micro-Ⅱ Stent

Jong Cheol Ryu, M.D., Yangsoo Jang, M.D., Keun Young Kim, M.D.,
Seung Hwan Lee, M.D., Jong Huyn Kim, M.D., Dong Woon Jeon, M.D.,
Won-Heum Shim, M.D., Seung-Yun Cho, M.D.

Cardiology Division, Yonsei Cardiovascular Center, College of Medicine, Yonsei University,
Seoul, Korea

Hongkeun Cho, M.D.

Department of Cardiology, College of Medicine, Ewha Womans University, Seoul, Korea

Background : Several kinds of stents have shown their safety and efficacy to treat acute or subacute closure after balloon angioplasty as well as to reduce restenosis rate. However, one of the limitations of stents is difficult to deploy especially in tortuous vessels, lesions at a bend, and distal to previously deployed stents. The Micro stent, which was one of the most recently developed stents, is a rapid-exchange balloon expandable stainless steel stent with a zigzag design connected with a continuous single weld in each 3mm segments. It scores over excellent trackability and optimum radio-opacity. Therefore, it is easy to operate and feasible in tortuous, distal lesions and variety of lesion lengths. We report our experiences with Micro-Ⅱ stent implantation in the first 76 patients at Yonsei cardiovascular center to assess its safety and efficacy in patients with complex coronary anatomy and clinical results in the first months.

Methods : Between January 1996 and July 1996, eighty-six Micro-Ⅱ stent were implanted in the coronary arteries of 76 patients (male 65.8%, age 59 ± 10 years). Forty-five patients had unstable angina, the others had stable angina (17 pts), acute myocardial infarction (14 pts).

Results :

- 1) Indication of stenting was de novo 51 (59.3%), suboptimal result 25 (29.1%), restenosis 1 (1.2%) and 9 (10.4%) of lesions were stented in bail out situation.
- 2) Single stent were implanted in 76 (88.4%) lesions, overlapping stent in 10 (11.6%) lesions. Among overlapping stents, the second stent with Micro-Ⅱ stent and with another kind of stent were 4.6%, 7.0%, respectively.
- 3) Procedure related complication including a subacute closure was occurred in 1 (1.2%) patient

who had distal dissection and 45% residual stenosis. In 12(14%) lesions, peristent dissection has been noticed after stent implantation.

4) Angiographic success(defined as a residual stenosis of <30% without major dissection) was achieved in 82 of 86 attempts(95.3%). The procedural success rate(defined as a residual stenosis of <30% without occurrence of major clinical events within 4 weeks after procedure) was 96.1%(73/76 patients). Angiographic success and procedural success rate in calcified lesion were 100% and 100%, respectively. Angiographic success and procedural success rate in tortuous lesion were 100% and 100%, respectively. Angiographic success and procedural success rate in more than 45 ° angulated lesion were 97% and 100%, respectively.

5) The mean minimal luminal diameter of the target lesions was increased from $0.42 \pm 0.40\text{mm}$ before stent implantation to $2.93 \pm 0.50\text{mm}$ ($p < 0.001$). The percentage of diameter stenosis was reduced from $86.49 \pm 13.04\%$ to $1.40 \pm 7.11\%$ ($p < 0.001$) after stent implantation.

Conclusion : Coronary stenting with AVE Micro- stent can be safely performed and is particularly beneficial in tortuous and calcified arteries. There was a high tendency for peristent dissection which need to special consideration to avoid. Follow-up data is needed to assess mid and long term patency.

KEY WORDS : Coronary artery disease · AVE Micro- stent · Immediate results.

서론		, stent	
stent		방 법	
1986 ¹⁾	,	1. 대 상	
first-choice treatment	.	1996 1	1996 7
stent			stent
	2,3)	223	Micro - stent가 76
Palmaz - Schatz stent, Gianturco - Roubin st-			PTCA
ent	stent profile ,		가
	가 , radio -		(antegrade flow)가 TIMI(Thrombolysis in Myo -
opacity가 stent			cardial Infarction) 1, 2
가	.	가 (TIMI 0)	(abrupt
	stent가 ,	vessel closure) 50%	
	stent Micro -	, TIMI 3	
stent 가 , radio - opacity		가 (threatened closure)	
가 ,	,		
side branch가	,		
rapid - exchange delivery system		2. Stent 시술 및 약물요법	
가		Micro - stent(Applied Vascular Engineering,	
		Santa Rosa, CA) radio - opacity	
		stainless steel balloon expandable stent , rapid -	
		exchange balloon delivery system	
Micro - stent Migration			
Micro - stent 76			

stent 3mm segment가 single weld 가 mg po bid) 2 3 stent
zigzag , 2 ticlopidine , aspirin
segment 가 0.008 (0.21mm) 8 heparin 10,000
axial struts , , 가
(Fig. 1). 3.5mm none -
xpened profile 0.065 (1.67mm) , 3.5mm 24 heparin 1,
metallic surface area 000 .
8.4% , foreshortening 2%
stent recoil
balloon expansion 8.7% . Micro -
stent 2.5, 3.0, 3.5, 4.0, 4.5mm balloon
catheter mounted , 6, 9, 12, 18,
24, 30, 36, 39mm . 3.0 4.0mm
18, 30mm stent . Stent
balloon compliant nominal 9 ,
12 3mm stent 3.25mm ,
3.5mm 3.75mm 8.3%, 7.1% 가
가 가 .
Micro - stent AVE
, 8F 175cm
, stent
Stent
aspirin(100mg po qd), ticlopidine(250

3. 자료의 분석 및 통계
1996 1 7 Micro - stent
AHA/
ACC ,
empty catheter caliper
±
Student t - test p 0.05
결 과
1. 대상환자
76 86 Micro - stent가
50 (65.8%),
26 (34.2%) , 59 ± 10
14 (18.4%),

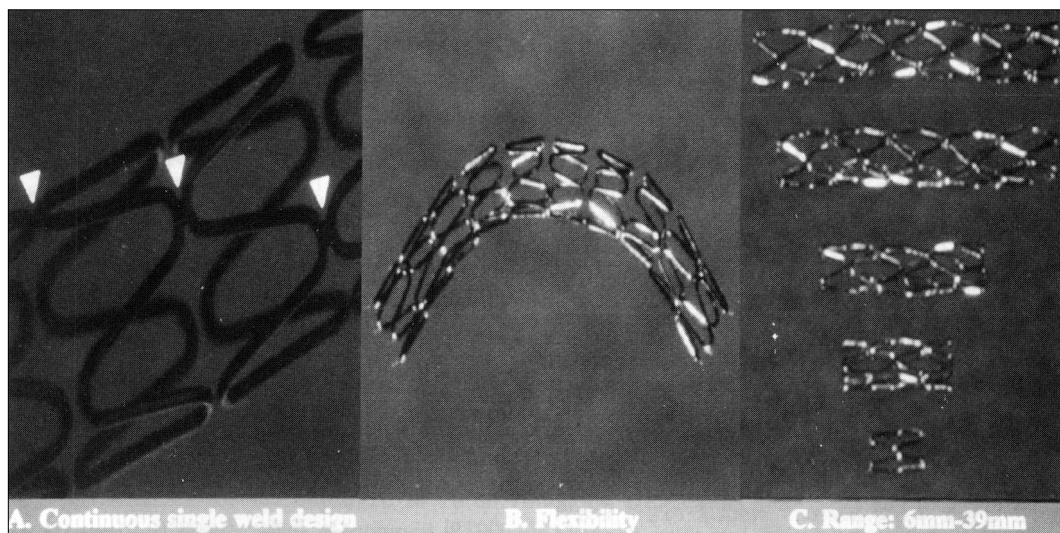


Fig. 1. The AVE Micro- stent consists of continuously connected stent segments in various lengths from 6mm to 39mm. Flexibility is enhanced utilizing a unique single weld connection between each 3mm segments.

Table 1. Clinical characteristics of the patients

	Number(%)
Sex(male/female)	50(65.8)/26(34.2)
Age	59 ± 10
Risk factors	
Diabetes mellitus	20(26.3)
Hypertension	39(51.3)
Hypercholesterolemia(>240mg%)	15(19.7)
Smoking	47(61.8)
Clinical diagnosis	
Stable angina	17(22.4)
Unstable angina	45(59.2)
Acute MI	14(18.4)
Angiographic diagnosis	
One vessel disease	32(42.2)
Two vessel disease	22(28.9)
Triple vessel disease	22(28.9)

45 (59.2%), 17 (22.4%)
 . 32 (42.2%),
 44 (57.8%) (Table 1).

2. Characteristics of the lesions

44 ,
 16 , 24 . AHA/
 ACC B2 53(61.
 6%), C 20(23.3%), A B1 5.
 8%, 9.3% . 10 (11.6%) ,
 45 °
 35 (40.7%) . 75 ° 2
 12 (14%)
 . Stent de novo
 51 (59.3%), suboptimal result 25 (29.1%),
 Bail - out 9 (10.4%), 1 (1.2%)
 . Single stent 76 (88.4%)
 , multiple stent 10 (11.6%)
 (Table 2).

3. 시술결과

stent 3.0mm(70.
 9%), 3.5mm(19.8%), 4.0mm(9.3%) , 18
 mm(79.1%), 30mm(20.9%) (Table 3).
 86.49 ± 13.04%

Table 2. Angiographic characteristics of the lesions

	Number(%)
Location	
LAD	44(51.2)
LCX	16(18.6)
RCA	24(27.9)
Graft vessels	2(2.3)
Lesion type(AHA/ACC classification)	
A	5(5.8)
B1	8(9.3)
B2	53(61.6)
C	20(23.3)
Angulation > 45 °	35(40.7)
Tortuosity*	12(14.0)
Calcification	10(11.6)
Indications	
De novo lesion	51(59.3)
Suboptimal result	25(29.1)
Bailout lesion	9(10.4)
Restenotic lesion	1(1.2)
No. Of stents by lesion vessel	
Single stent	76(88.4)
Overlapping	10(11.6)

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

Table 3. Stent size

	Number(%)
Diameter(mm)	
3.0	61(70.9)
3.5	17(19.8)
4.0	8(9.3)
Length(mm)	
18	68(79.1)
30	18(20.9)

1.40 ± 10.22%(p<0.001)
 , minimal luminal diameter 0.42 ± 0.40
 mm 2.93 ± 0.50mm(p<0.001)
 가 , 3.13 ± 0.41mm
 (Fig. 2). Stent 39 (45.4%)
 9 , 10 (11.6%) 12 , 37 (43.0%)
 14
 Micro - stent

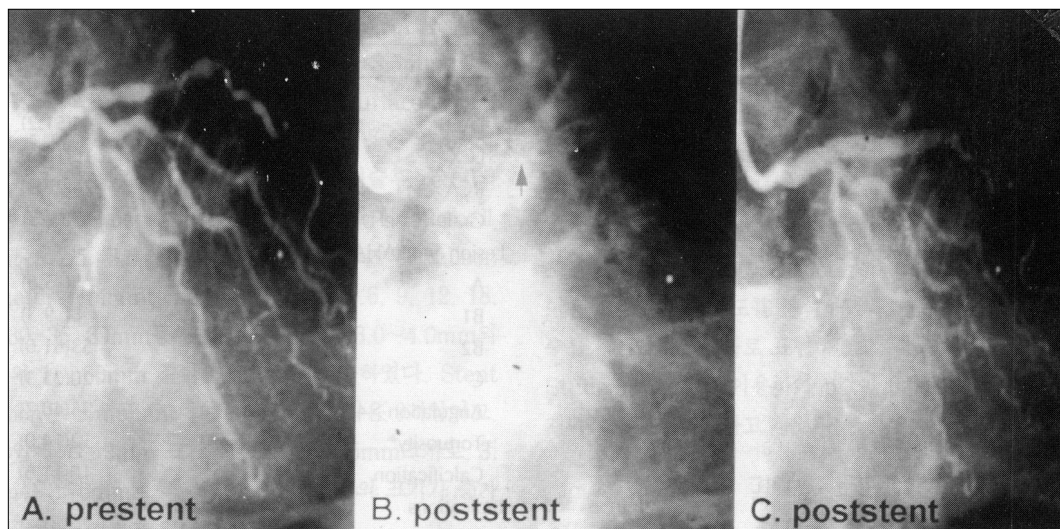


Fig. 2. An angulated, calcified lesion of proximal LAD artery treated by implantation of AVE Micro- stent.

Table 4. Angiographic result

Reference diameter(mm)	3.13 ± 0.42
MLD(mm)	
pre-stent	0.42 ± 0.40
post-stent	2.93 ± 0.50*
Percentage of diameter stenosis	
pre-stent	86.49 ± 13.04
post-stent	1.40 ± 10.22*
Lesion length(mm)	16.27 ± 7.11
Peristent dissection	12(14%)
proximal to stent	2
distal to stent	8
proximal & distal	2

Mean ± S.D.

* : Pre vs Post-stent ; p<0.001

Table 5. Procedure related complications

	Number(%)
Subacute closure*	1(1.2)
Acute closure	0
Stent migration	0
Q-myocardial infarction	0
Emergency CABG	0
Bleeding requiring transfusion	0

* : one case who had distal dissection and 45% residual stenosis

peristent dissection 12 (14%)

(Table 4).

sure가 1

(Table 5).

subacute clo -

95.3%, 16%)

1

96.1%

고 안

stent

(stent

50%)

Micro -

stent

stent

95%

30%

stent

, 95.3%(82/86)

30%

, 1

major clinical events가

proc -

edural success rate

cro - stent procedural success rate 96.1%

(73/76) . Major clinical event

(1 , 1)

2 , subacute stent thrombosis가 1

(1.2%)

stent 가

, 1

stent neointimal

coverage가

stent thrombosis

가

4).

5),

(10

2,3,6,7).

Colombo 8)

Palmaz - Schatz stents
 sub -
 acute thrombosis
 stent thrombosis
 3 21%
 3,5,6,9 - 11)
 3 5 가 , 2
 12). Stent thrombosis
 , stent
 stent 50%
 , stent 3mm , stent
 (residual filling defect), multiple stents
 , 가 1 2 가
 stent thrombosis
 5.6% 9.4%, 16.7% 가 11,13).
 subacute closure 1
 가 stenting 가
 가
 distal dissection 45%
 3mm
 가 . Colombo 8)
 subacute closures
 stent
 (intravascular ultrasound)
 stent apposition
 minimal luminal diameter(MLD)
 MLD 가 ,
 Micro - stent 14,15). Wong
 16) stent Micro - stent 30
 (migration) Micro - stent
 3
 . Wong Micro - stent (migration)
 stent 가 stent
 stent strut가 cross - se - 가
 ction profile 가 0.008 가 stent

가 occlusion , 6 3

가

, 2) 가 1.5mm side branch 17 (19%)

가 , 3) , Micro - stent side branch oc -

4) stent predilatation clusion .

가 Micro - stent ,

. Micro - stent stent , stent

predilatation , , stent

가 가 Micro - stent

stent .

balloon ,

stent

가 ^{24,25)} , stenting

가

PTCA Rotablator

²⁶⁾ .

balloon

stent stent

, stent thrombosis

10

(11.6%)

Proximal tortuosity 14%(12/86

) 100% . 45 °

(angulated lesions) 40.7%(35/

86) , 1 가

30%

97%(34/35) .

angulated lesion 가 45 ° 60 ° , 6

0 ° angulated lesion Micro - st -

ent stent 가

가 .

23 Micro - stent가 76

Stent Side branch occlusion

Tresukosol ¹⁴⁾ Micro stent

side branch occlusion 2%

, Mazur ²⁷⁾

100 6 , G/R stent

가 1

. Fischman ²⁸⁾ 167 6

, P/S stent 3 side branch

3)

요 약

연구배경 :

Palmaz - Schatz stent, Gianturco - Roubin stent

stent profile ,

radio - opacity가

, 가

stent

가 , stent가 .

stent Micro - stent

가 , radio - opacity가

, side branch

가 가 , Monorail system

stent delivery가 가

76

86 Micro - stent , stent

방 법 :

1996 1 1996 7

stent 2

23 Micro - stent가 76

결 과 :

1) Stent de novo 51 (59.3%), su -

boptimal result 25 (29.1%), 1 (1.2%)

, bail out 9 (10.4%) .

2) stent single stent가 76 (88.

4%), overlapping stent가 10 (11.6%) .

3) subacute closure

가 1 (1.2%) , stent
45%
4) Peristent dissection 12 (14%)
, stent (distal to stent)
5) (30%) 95.3%
, 1 (3
0% , 1 major clinical ev-
ent가) 96.1% .
proximal tortuosity
1 10
0% . 45 °
97%, 100% .
6) MLD 0.42 ± 0.40mm
2.93 ± 0.50mm(p<0.001)
가 , 86.49 ±
13.04% 1.40 ± 10.22%(p<0.001)
3.13 ±
0.41mm .
결 론 :
Micro - stent radio - opacity
, 가 , Monorail system
stent
가
Micro - stent peristent disse -
ction , stent

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* 316 : 701-6, 1987
- 2) 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* 331 : 489-495, 1994
- 3) 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 Eng J Med* 331 : 496-501, 1994
- 4) Ueda Y, Nanto S, Komamura K, Kodama K : *Neointimal coverage of stents in human coronary arteries observed by angioscopy*. *J Am Coll Cardiol* 23 : 341-346, 1994
- 5) 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* 32 : 133-138, 1994
- 6) Muller DWM, Shamir KJ, Ellis SG, Topol EJ : *Peripheral vascular complications after conventional and complex percutaneous coronary intervention procedures*. *Am J Cardiol* 69 : 63-68, 1992
- 7) Carrozza JP Jr, Kuntz RE, Levine MJ, et al : *Angiographic and clinical outcome of intracoronary stenting : Immediate and long term results from a large single-center experience*. *J Am Coll Cardiol* 20 : 328-337, 1992
- 8) Colombo A, Hall P, Nakamura S, Almagor Y, Maiello L, Martini G, Saglione A, Goldberg SL, Tobias JM : *Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance*. *Circulation* 91 : 1676-1688, 1995
- 9) 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* 86 : 812-819, 1992
- 10) Sutton 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* 89 : 1126-1137, 1994
- 11) 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* 126 : 15-22, 1993
- 12) Holmes D, Garratt K, Schwartz R : *Timing of stent occlusion/thrombosis after stent placement*. *J Am Coll Cardiol* 23 : 70A, 1994
- 13) Liu MW, Voohees W, Agrawal S, Dean L, Roubin G : *Stratification of the risk of thrombosis after intracoronary stenting for threatened or acute closure complicating coronary balloon angioplasty : A Cook registry study*. *Am Heart J* 130 : 8-13, 1995
- 14) Tresukosol D, Schalij MJ, Savalle LH, Jukema JW, Buis B, Reiber JHC, Bruschke AVG : *Micro stent, quantitative coronary angiography, and procedural results*. *Cathet Cardiovasc Diagn* 38 : 135-143, 1996
- 15) Ozaki Y, Keane D, Ruygrok P, Feyter PD, Stertz S, Serruys PW : *Acute clinical and angiographic results with the new AVE Micro coronary stent in bailout management*. *Am J Cardiol* 76 : 112-116, 1995
- 16) Wong P, Leung WH, Wong CM : *Migration of the AVE Micro coronary stent*. *Cathe Cardiovasc Diagn* 38 : 267-273, 1996
- 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) Tan K, Sulke N, Taub N, Sowton E : *Clinical and lesion morphologic determinants of coronary angioplasty success and complications : Current experience. J Am Coll Cardiol 25 : 855-65, 1995*
 - 20) Hermans WR, Foley DP, Rensing BJ, Rutsch W : *Usefulness of quantitative and qualitative angiographic lesion morphology, and clinical characteristics in predicting major adverse cardiac events during and after native coronary balloon angioplasty. Am J Cardiol 72 : 14-20, 1993*
 - 21) Hermans WR, Rensing BJ, Foley DP, Deckers JW : *Therapeutic dissection after successful coronary balloon angioplasty : No influence on restenosis or on clinical outcome in 693 patients. J Am Coll Cardiol 20 : 767-780, 1992*
 - 22) Sharma SK, Israel DH, Kamean JL, Bodian CA : *Clinical, angiographic, and procedural determinants of major and minor coronary dissection during angioplasty. Am Heart J 126 : 39-47, 1993*
 - 23) Chandra P, Jain BL, Agarwal P, Prakash O, et al : *Intracoronary stenting with AVE Micro stent-single center experience. The proceedings of TCT meeting, J Invasive Cardiol 8 : 41, 1996*
 - 24) Hong MK, Chuang YC, Prunka N, Satler LF : *Predictors of early and late cardiac events in patients undergoing saphenous vein graft angioplasty with PTCA and new device modalities. Circulation 88 : I-601, 1993*
 - 25) Tamura T, Kimura T, Nosaka H, Nobuyoshi M : *Predictors of restenosis after Palmaz-Schatz stent implantation. Circulation 90 : I-324, 1994*
 - 26) Mintz GS, Dusaillant GR, Wong SC, Pichard AD, et al : *Rotational atherectomy followed by adjunct stents : The preferred therapy for calcified lesions in large vessels ? Circulation 92 : I-329, 1995*
 - 27) 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 angiography. Am J Cardiol 74 : 1207-1210, 1994*
 - 28) Fischman DL, Savage MP, Leon MB, Schatz RA, Ellis S, Cleman MW, Hirshfeld JW, Teirstein P, Baley S, Walker CM, Goldberg S : *Fate of lesion-related side branches after coronary artery stenting. J Am Coll Cardiol 22 : 164-6, 1993*