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CLINICAL STUDIES

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First International New Intravascular Rigid-Flex Endovascular Stent Study (FINESS): Clinical and Angiographic Results After Elective and Urgent Stent Implantation

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Objectives. **The purpose of this study was to determine the feasibility, safety and efficacy of elective and urgent deployment of the new intravascular rigid-flex (NIR) stent in patients with coronary artery disease.**

Background. **Stent implantation has been shown to be effective in the treatment of focal, new coronary stenoses and in restoring coronary flow after coronary dissection and abrupt vessel closure. However, currently available stents either lack flexibility, hindering navigation through tortuous arteries, or lack axial strength, resulting in suboptimal scaffolding of the vessel. The unique transforming multicellular design of the NIR stent appears to provide both longitudinal flexibility and radial strength.**

Methods. **NIR stent implantation was attempted in 255 patients (341 lesions) enrolled prospectively in a multicenter international registry from December 1995 through March 1996. Nine-, 16- and 32-mm long NIR stents were manually crimped onto coronary balloons and deployed in native coronary (94%) and saphenous vein graft (6%) lesions. Seventy-four percent of patients underwent elective stenting for primary or restenotic lesions, 21% for a suboptimal angioplasty result and 5% for threatened or abrupt vessel closure. Fifty-two percent of patients presented with unstable angina, 48% had a previous myocardial infarction, and 45% had multivessel disease. Coronary lesions were frequently complex, occurring in relatively small arteries (mean [±SD] reference diameter 2.8 ± 0.6 mm). Patients were followed up for 6 months for the occurrence of major adverse cardiovascular events.**

Results. **Stent deployment was accomplished in 98% of lesions. Mean minimal lumen diameter increased by 1.51 ± 0.51 mm (from 1.09 ± 0.43 mm before to 2.60 ± 0.50 mm after the procedure). Mean percent diameter stenosis decreased from 61 ± 13% before to 17 ± 7% after intervention. A successful interventional procedure with <50% diameter stenosis of all treatment site lesions and no major adverse cardiac events within 30 days occurred in 95% of patients. Event-free survival at 6 months was 82%. Ninety-four percent of surviving patients were either asymptomatic or had mild stable angina at 6 month follow-up.**

Conclusions. **Despite unfavorable clinical and angiographic characteristics of the majority of patients enrolled, the acute angiographic results and early clinical outcome after NIR stent deployment were very promising. A prospective, randomized trial comparing the NIR stent with other currently available stents appears warranted.**

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Improvements in operator technique and equipment have enabled patients with unstable clinical syndromes, multivessel disease and complex lesion morphology to undergo coronary angioplasty or atherectomy with a high degree of procedural success (1–5). Despite improvements in technology, such patients remain at increased risk for acute complications. Stent implantation has proven to be a valuable asset to the interventionalist in the setting of significant coronary dissection or threatened or abrupt vessel closure (6–8). Coronary stenting has also been shown to be an effective modality for reducing the incidence of restenosis and clinical adverse events after elective implantation in patients with new, discrete coronary stenoses (9,10). Access to more difficult, longer lesions in tor-

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tuous vessels and preservation of arterial contour will necessitate improvements in stent design. A number of second-generation stents have recently been introduced with encouraging early results (11,12). The new intravascular rigid-flex (NIR) stent was designed specifically to provide greater longitudinal flexibility and trackability during deployment, while maintaining high radial support and stent conformation to the vessel wall after implantation. These geometric considerations may be of particular importance in patients with complex lesions. We report the initial results of a multicenter, prospective, observational study with the NIR stent, including procedural success and 6-month clinical follow-up.

Methods

Patient selection. Patients with objective evidence of myocardial ischemia scheduled to undergo balloon angioplasty of native coronary arteries or saphenous vein bypass grafts were eligible for inclusion in the study. The target lesion needed to be <32 mm in length to permit a single NIR stent to completely cover the lesion and be located in a vessel whose reference diameter on visual inspection or quantitative arteriography was ≥3.0 and ≤5.0 mm in diameter. Patients with unprotected left main coronary artery disease, bifurcation lesions, degenerated saphenous vein grafts, suspected intraluminal thrombus, heavily calcified lesions that would preclude adequate predilatation, recent myocardial infarction (within 72 h) and severe left ventricular dysfunction (ejection fraction <30%) were excluded. Patients with leukopenia, neutropenia or thrombocytopenia, active peptic ulcer disease or gastrointestinal bleeding in the previous 6 months or an intolerance to therapy with aspirin or ticlopidine were also excluded.

The study was conducted according to the principles of the Declaration of Helsinki, and written informed consent was obtained for all patients.

Stent procedure. Coronary angiography and intervention were performed according to standard clinical practice by the femoral or radial approach. Patients received aspirin (≥100 mg/day) and ticlopidine (250 mg twice daily) beginning the day before elective stent implantation. Ticlopidine was given at the time of catheterization in patients who did not receive the medication on the day before the interventional procedure. During coronary intervention, patients received an initial intravenous bolus of heparin (10,000 U) supplemented as needed to maintain an activated clotting time >300 s. For elective stent deployment, predilation of the target lesion was performed using a balloon of appropriate length that was either undersized or equivalent in size to the reference vessel diameter determined by visual assessment or on-line quantitative coronary angiography. Predilation was considered satisfactory when a sufficient lumen caliber for subsequent unimpeded stent deployment across the lesion site was achieved. A nine-cell NIR stent of sufficient length (9, 16 or 32 mm) to cover the entire lesion and correct diameter, yielding a stent to distal reference diameter ratio ≤1.1:1, was chosen. The NIR stent was manually crimped onto an appropriately sized coronary balloon after removal of the balloon's lubricious coating with an organic solvent. The 9-mm NIR stent was mounted on a 10-mm balloon, the 16-mm NIR stent on a 20-mm balloon and the 32-mm NIR stent on a 36-mm balloon. Intracoronary nitroglycerin (0.2 mg) was administered before and after stent implantation. Stents were deployed at 2 to 4 atm above nominal balloon inflation pressure. After stent deployment, moderately high pressure balloon inflation of 12 to 16 atm with semicompliant or noncompliant coronary balloons was then performed. Angiographic criteria for optimal stent expansion were achieved when the diameter stenosis within the stent was <20% and the mean diameter of the stent was greater than or equal to the reference diameter of the vessel. If the angiographic appearance of the target lesion was suboptimal, investigators were permitted to use further balloon inflation or additional stent deployment with or without intravascular ultrasound guidance, as deemed necessary. Heparin was discontinued on completion of the procedure, and vascular sheaths were removed the same day, according to institutional practice. Patients were treated with ticlopidine (250 mg twice daily for 1 month) and aspirin (≥100 mg/day for at least 6 months). Warfarin sodium (Coumadin) was prescribed at operator discretion on the basis of an unsatisfactory procedural result.

Follow-up and clinical end points. Clinical evaluation was performed before hospital discharge and at 30 days and 6 months after stent implantation. A complete blood count, including differential white blood cell and platelet counts were obtained every 2 weeks while the patient was treated with ticlopidine. A prothrombin time and international normalized ratio were obtained once or twice weekly for patients receiving warfarin. The primary clinical end point was the occurrence of a major adverse cardiac event (death, myocardial infarction or target lesion revascularization) or bleeding or vascular complication necessitating transfusion or operation within 30 days of stent implantation. Myocardial infarction was diagnosed when two of the following criteria were met: 1) a history of chest discomfort of at least 30 min in duration; 2) development of new abnormal Q waves of at least 0.04 s in duration; and 3) enzyme elevation of creatine kinase and CK-MB fraction (when available) to more than twice the upper limit of normal. A secondary clinical end point was the occurrence of a major adverse cardiac event, significant bleeding or vascular complication, as previously described, within 6 months of the procedure. Independent monitors were dispatched to each investigational site to ensure the quality of clinical data.

Angiographic analysis and end points. Coronary angiography was performed in at least two orthogonal projections chosen to optimally assess lesion site morphology. Identical views were obtained before and after coronary intervention after intracoronary administration of nitroglycerin (0.2 mg). All angiograms were sent to the core laboratory (Cardialysis, Rotterdam, The Netherlands) and analyzed by the Cardiovascular Angiography Analysis System. Guidelines to ensure uniform, reproducible data acquisition during angiography of coronary segments before and after intervention have been

described elsewhere (13). Selected end-diastolic cine frames were digitized for off-line quantitative arteriographic analysis. Vessel size, lesion length, minimal lumen diameter and percent diameter stenosis were determined from a computer-generated interpolated reference diameter by using previously validated software for image processing that involves edge detection, contour reconstruction, magnification and pincushion correction and morphologic analysis of the stenosis (14). The primary angiographic end point was the acute gain in minimal lumen diameter of the target vessel stenosis after stent implantation. A secondary end point was initial angiographic success resulting in a reduction in percent diameter stenosis to <50% of the reference diameter of the stented segment measured by off-line quantitative coronary angiography.

Statistical analysis. Results are expressed as mean value ± SD. The unpaired two-tailed Student *t* test was performed for comparative analysis of continuous variables. A p value <0.05 was considered significant.

Results

Baseline characteristics. A total of 255 patients were enrolled at 11 clinical centers from December 1995 through March 1996. All patients were included in the clinical analysis, although many patients did not meet strict angiographic enrollment criteria (stent implantation in small vessels or across significant side branches), which may have influenced outcome. In addition, three patients underwent uncomplicated primary stent implantation in the setting of an acute myocardial infarction. NIR stent implantation was not accomplished in six patients because of inability to dilate the lesion (one patient) and failure to cross the lesion with the NIR stent (five patients). Of these six patients, two were treated with another stent design, and four underwent conventional balloon angioplasty. An additional 10 patients had poor quality imaging or tape loss or damage that precluded quantitative measurements. Quantitative angiographic analysis was available in 239 of the 255 enrolled patients and in 306 of 335 stented lesions.

The baseline clinical and angiographic characteristics are shown in Tables 1 and 2. Overall, the study group represented a high risk cohort. More than half of the patients (52%) presented with unstable angina, 48% had a previous myocardial infarction, and 45% had multivessel coronary artery disease. Nonelective stent implantation was performed in 26% of patients for either abrupt or threatened vessel closure or for a suboptimal angiographic result. Among patients who underwent elective stent implantation, 20% were deployed in restenotic lesions. Seventy percent of stented lesions were either B2 or C lesions according to the American Heart Association/American College of Cardiology classification (18). Reference diameter of the target vessel before intervention determined by off-line quantitative coronary arteriography performed at the core laboratory was <2.75 mm in 48% of stented lesions and <2.5 mm in 31%. Although only 6% of lesions were assessed to be >15 mm in length by quantitative angiography, experienced operators chose a long (32 mm) NIR stent for 26% of the NIR stents that were deployed. This choice may reflect a desire by the interventionalist to more completely cover visible vessel narrowing beyond the area of significant stenosis or to treat consecutive lesions with a single stent. The relatively high incidence (26%) of stent deployment for abrupt closure, dissection or suboptimal result in our series of patients may have also contributed to the use of longer stents for initially discrete stenoses.

Table 1. Baseline Clinical Characteristics of 255 Study Patients

Age (yr)	61 ± 10
Male	215 (84%)
Diabetes	39 (15%)
Insulin treated	7 (3%)
Hypertension	115 (45%)
Hypercholesterolemia	144 (56%)
Family history	89 (35%)
Prior MI	121 (48%)
Prior angioplasty	83 (33%)
Prior CABG	36 (14%)
Prior stroke	6 (2%)
Peripheral vascular disease	18 (7%)
Multivessel disease	115 (45%)
Anginal status	
Unstable*	133 (52%)
Crescendo (IB)	45 (18%)
Rest (IIB, IIIB)	65 (25%)
Postinfarction (IC, IIC, IIIC)	23 (9%)
Stable†	96 (38%)
Class I	15 (6%)
Class II	42 (16%)
Class III	38 (15%)
Class IV	1 (<1%)
Silent ischemia	26 (10%)
Stent indication	
Primary lesion	162 (59%)
Restenotic lesion	40 (15%)
Suboptimal result	57 (21%)
Abrupt/threatened closure	14 (5%)

*Braunwald classification (15). †Canadian Cardiovascular Society classification (16). Data presented are mean value ± SD or number (%) of patients. CABG = coronary artery bypass graft surgery; MI = myocardial infarction.

Procedural outcome. Procedural characteristics and outcomes are shown in Table 3. Twenty-three percent of patients had more than one lesion stented and 47% had more than one stent implanted; 26% of stents used were 32 mm in length. NIR stents were deployed in 335 (98.2%) of 341 lesions attempted. Stent deployment was considered angiographically successful when the percent diameter stenosis assessed by averaging multiple matched views on quantitative coronary angiography performed at the core laboratory was <50% of the reference vessel diameter after stenting. Angiographic success was achieved in 100% of stented lesions. A percent diameter stenosis <20% was achieved in 68% of stented lesions. The intervention was considered successful when the percent diameter stenosis of the stented lesion was <50% of the reference diameter (angiographic success) in the absence of major bleeding or adverse cardiac events during the hospital

Table 2. Baseline Angiographic Characteristics*

No. of lesions stented	306
No. of lesions stented/patient (mean)	1.3
1	185 (77%)
2	42 (18%)
3	11 (5%)
4	1 (<1%)
Vessel size (mm)	2.83 ± 0.61
Range	1.64–6.11
Lesion length (mm)	8.68 ± 3.69
Range	1.91–30.84
MLD (mm)	1.09 ± 0.43
Range	0.0–3.02
% diameter stenosis	61 ± 13
Range	25–100
Target lesion vessel	
LAD	107 (35%)
LCx	69 (23%)
RCA	108 (35%)
LMCA	3 (1%)
SVG	19 (6%)
Lesion characteristics†	
Concentric	13 (4%)
Eccentric type IA	105 (34%)
Eccentric type IB	112 (37%)
Eccentric type IIA	4 (1%)
Eccentric type IIB	3 (1%)
Multiple irregularities	48 (16%)
Tandem lesion	9 (3%)
Total occlusion	12 (4%)
Lesion classification‡	
Type A	6 (2%)
Type B1	86 (28%)
Type B2	197 (64%)
Type C	17 (6%)
Calcification	84 (27%)

*Based on 239 patients with adequate qualitative and quantitative angiographic analysis. †Ambrose score (17). ‡American Heart Association/American College of Cardiology classification (18). Data presented are mean value ± SD or number (%) of patients, unless otherwise indicated. LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LMCA = left main coronary artery; MLD = minimal lumen diameter; RCA = right coronary artery; SVG = saphenous vein graft.

period. Procedural success was achieved in 95% of 306 stented lesions and in 95% of 255 patients on an intention to treat basis. Quantitative and qualitative angiographic results appear in Table 4. Acute gain in minimal lumen diameter of stented lesions averaged 1.51 ± 0.51 mm, accompanied by a significant reduction in average percent diameter stenosis from 61 ± 13% to 17 ± 7% after intervention. Mean maximal balloon inflation pressure for stent expansion was 15.6 ± 3.3 atm (range 4.0 to 24.0).

Clinical events. Twelve patients had major adverse cardiac events in the first month after NIR stent implantation (Table 5). Three patients with multivessel coronary artery disease died during the hospital period or within 1 month of successful NIR stent implantation. The first patient underwent successful NIR stent implantation for lesions in the right coronary, circumflex and obtuse marginal coronary arteries but subsequently died of a massive anterior wall myocardial infarction due to proximal left anterior descending coronary artery occlusion. All stented arteries were patent on angiography performed immediately before death. The second patient with severely compromised left ventricular function and four previous myocardial infarctions had an NIR stent deployed across a bifurcation lesion in a saphenous vein jump bypass graft that supplied the obtuse marginal branch of the circumflex artery and the right posterior descending artery. Major side branch (obtuse marginal) occlusion occurred after stent deployment, ultimately leading to the patient's death. The third patient underwent successful deployment of two NIR stents for two lesions in the left

Table 3. Procedural Characteristics and Outcome

Stent inventory	
No. of stents used	457
9 mm	66 (14.4%)
16 mm	272 (59.5%)
32 mm	119 (26.0%)
No. of stents/patient (mean)	1.8
0	6 (2.4%)
1	128 (50.2%)
2	74 (29%)
3	29 (11.4%)
>3	18 (7.1%)
Procedural outcome*	
Angiographic success	
% DS <20%	207 (67.6%)
% DS <50%	306 (100%)
Procedural success†	
% DS <20%	196 (64.1%)
% DS <50%	290 (94.8%)

*Procedural outcome for 306 stented lesions with adequate quantitative angiographic analysis. †Angiographic success of all lesions with no major adverse cardiovascular events during the hospital period. Data presented are number (%) of patients, unless otherwise indicated. % DS = percent diameter stenosis.

Table 4. Quantitative and Qualitative Angiographic Results

No. of lesions	306
Ref vessel diameter (mm)	
Before procedure	2.83 ± 0.61
After procedure	3.15 ± 0.51*
MLD (mm)	
Before procedure	1.09 ± 0.43
After procedure	2.60 ± 0.50†
Acute gain (mm)	1.51 ± 0.51
% DS (%)	
Before procedure	61 ± 13
After procedure	17 ± 7†
Dissection‡	
Type A	19 (6.2%)
Type B	25 (8.2%)
Type C	2 (<1%)
Thrombus	1 (<1%)

*$p < 0.05$, before versus after procedure. †$p < 0.001$, before versus after procedure. ‡National Heart, Lung, and Blood Institute classification for coronary dissection (19). Data presented are mean value ± SD or number (%) of patients, unless otherwise indicated. Abbreviations as in Tables 2 and 3.

Table 5. Major Adverse Cardiovascular Events and Clinical Follow-Up

	Adverse Events	
	0–30 Days	0–180 Days
No. of pts followed up	255	255
No. of pts with cardiac events	12 (4.7%)	47 (18.4%)
Total cardiac events	18 (7.1%)	60 (23.5%)
Death	3 (1.2%)	8 (3.1%)
MI	11 (4.3%)	15 (5.8%)
Q wave	5 (2.0%)	7 (2.7%)
Non-Q wave	6 (2.4%)	8 (3.1%)
Perc revasc of target vessel	0	24 (9.4%)
CABG	4 (1.6%)	13 (5.1%)
Urgent	2 (0.8%)	2 (0.8%)
Elective	2 (0.8%)	11 (4.3%)
Major bleeding	3 (1.2%)	3 (1.2%)
Anginal status		
No. of pts followed up	238	243
No angina	205 (86.1%)	184 (75.7%)
Unstable angina	0	5 (2.1%)
Stable angina*	32 (13.4%)	47 (19.3%)
Class I	14 (5.9%)	9 (3.7%)
Class II	14 (5.9%)	29 (11.9%)
Class III	4 (1.6%)	8 (3.3%)
Class IV	0	1 (0.4%)
Silent ischemia	1 (0.4%)	7 (2.9%)

*Canadian Cardiovascular Society classification (16). Data presented are number (%) of patients (pts), unless otherwise indicated. Perc revasc = percutaneous revascularization; other abbreviations as in Table 1.

anterior descending artery. Elective angioplasty of a circumflex stenosis was performed in a subsequent procedure, resulting in significant dissection. NIR and Palmaz-Schatz stent deployment was complicated by proximal dissection into the left main coronary artery and cardiovascular collapse. The patient died after emergency coronary artery bypass graft surgery. An additional eight patients experienced an acute myocardial infarction within 1 month of NIR stent implantation. In three of four patients with Q wave infarctions, myocardial infarction appeared to be the result of side branch occlusion (two patients) and distal embolization during bypass graft intervention of a nonstented artery (one patient). There were no cases of suspected acute or subacute stent thrombosis. Creatine kinase and CK-MB fraction were measured after intervention in 91.4% and 38.4% of patients, respectively. Elective surgical revascularization was performed in two patients with a non-Q wave myocardial infarction that followed multivessel intervention, including NIR stent implantation. In both patients, the stented arteries were patent. Emergency bypass surgery was performed in two patients, one of whom died during the hospital period (described earlier). The second patient had two successful NIR stents implanted in the right coronary artery but required urgent surgical intervention after perforation of an occluded left anterior descending coronary artery during attempted angioplasty.

Complete 6-month clinical follow-up was obtained in 243 (98.4%) of 247 surviving patients and is summarized in Table 5. A total of 60 adverse cardiac events were encountered in 47 (18.4%) of enrolled patients after coronary intervention. Hierarchic ranking of all clinical events revealed that eight patients died, 10 experienced a myocardial infarction, and the remaining 29 underwent repeat percutaneous or surgical revascularization of the target vessel. Ninety-four percent of surviving patients were either asymptomatic or had mild stable angina (Canadian Cardiovascular Society class I or II) at their 6-month follow-up visit.

Discussion

Mechanical properties of NIR stent. The NIR stent is a tubular patterned multicellular stainless steel stent available in 9-, 16-, 25- and 32-mm lengths (Fig. 1). The NIR stent is manually crimped onto an appropriately sized balloon that is equal to or slightly larger than the normal reference vessel diameter during high pressure inflation. The expanded diameter of the NIR stent is between 2 and 5 mm. NIR stents containing seven attached cells in circumference are appropriate for implantation in smaller diameter vessels (2 to 3.5 mm), whereas the nine-cell NIR stents are recommended for optimal structural support and expansion of larger (3.5 to 5.0 mm) arteries. When the NIR stent is expanded to 3 mm, the cell diameter of the seven-cell NIR stent is double that of the nine-cell NIR stent (1.2 vs. 0.6 mm), permitting better access to side branches covered by a seven-cell NIR stent. Only nine-cell NIR stents were used in the present trial. The NIR stent is a highly flexible stent with excellent trackability. Most of the struts of the unexpanded NIR stent parallel the insertion direction, without free flare points, permitting unimpeded stent delivery through tortuous, atheromatous vessels to the site of implantation. Once deployed, the NIR stent transforms into a diamond-like mesh of uniform cellular design that provides rigid scaffolding of the vessel wall. Stent expansion results in alignment of horizontal struts that forshorten, with vertical loops that elongate such that the overall stent length is preserved. There are no articulation sites or gaps in the NIR stent, which minimizes tissue prolapse. The cellular structure of the NIR stent was designed to provide differential elongation of the struts (Fig. 2). This unique feature not only facilitates delivery of the unexpanded stent to the lesion site, but also favors stent conformity with the vessel curvature after deployment with minimal deformation of the vessel.

Clinical results. We describe a multicenter experience with this novel balloon-expandable, "transformable" multicellular stent, including initial angiographic results and 6-month clinical follow-up. Stents were deployed in frequently complex lesions (only 2% were classified as type A lesions) occurring in native coronary arteries and saphenous vein grafts. Six-month angiographic evaluation after NIR stent deployment in more uniform lesions that would meet inclusion criteria for enrollment in the Stent Restenosis Study (STRESS) (10) or the Belgium-Netherlands Stent Trial (BENESTENT) (9) will be the subject of a second international trial now in progress. Studies involving serial quantitative angiographic and intracoronary ultrasound measurements have provided predictable

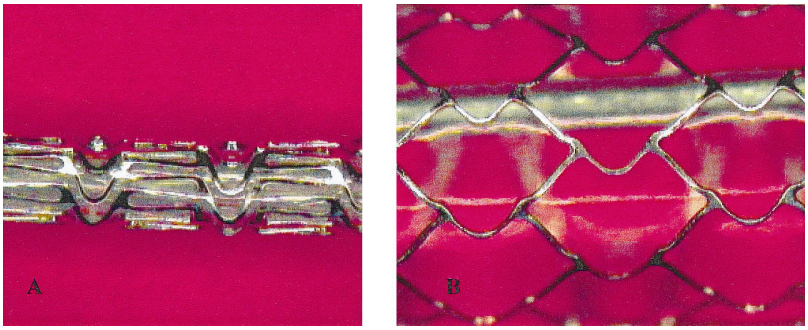

Figure 1. A, Crimped stent shows uniform cellular pattern, each cell containing vertical loops that allow flexibility during insertion. **B,** Expanded stent shows uniform cellular design, with expanded cells having aligned struts constituting the rigidity of the stent after expansion.

relations between "acute gain" after balloon angioplasty or newer device intervention and "late loss" in lumen diameter (20). Furthermore, an improvement in minimal lumen diameter on angiographic follow-up does not necessarily translate into improvement in clinical outcome (21). The combination of acute angiographic results and clinical follow-up for major adverse cardiovascular events should provide a reliable means for determining NIR stent performance and the biologic response of the target lesion to intervention (22,23). A pilot study that involved NIR stent implantation for 64 lesions in 41 consecutive patients reported successful deployment in 97% of lesions and no acute or subacute thrombosis. Unfavorable coronary anatomy or lesion characteristics that may reduce procedural success, such as severe proximal vessel tortuosity, long lesion length (>15 mm) or small-caliber vessels (<2.5 mm diameter) were present in nearly half of the lesions stented (24).

In the present trial, immediate angiographic and procedural success with NIR stent implantation was impressive despite the inclusion of patients with unfavorable clinical or angiographic characteristics that increase the risk of coronary intervention (25,26). Stent deployment was accomplished in 98% of lesions attempted. Stenoses were often complex (70% were type B2 or C), requiring long (32 mm) or multiple stents in 26% and 47% of lesions, respectively. Patients with distal stenoses in tortuous vessels were not excluded. Procedural success was achieved in 95% of stented lesions. The definition of procedural success was similar to that used in previous randomized stent trials (9,10), consisting of <50% residual diameter stenosis after stent deployment in the absence of in-hospital cardiovascular complications.

Residual stenosis after NIR stent implantation was 17% on quantitative analysis. High risk clinical characteristics of the study group included unstable coronary syndromes (52%), multivessel disease (44%) and unplanned stent deployment (26%). Moreover, all patients enrolled in the present trial were included in the statistical analysis, even though some developing complications did not meet entry criteria. This included patients with acute myocardial infarction, severe left ventricular dysfunction and bifurcation lesions involving major side branches. By comparison, Palmaz-Schatz stent deployment was achieved in 94% and 98% of patients with relatively uncomplicated lesions enrolled in the BENESTENT and STRESS trials, with procedural success rates of 93% and 96%, respectively. Postprocedural diameter stenosis was 19% and 22% for patients with stented lesions in the STRESS and BENESTENT trials, respectively, and 18% in Phase 4 of the BENESTENT II trial (27), where high pressure inflation was routinely used in an attempt to optimize stent expansion.

Major early adverse clinical events encountered in the present trial were few, usually occurring in patients with multivessel disease, and frequently unrelated to the procedure involving NIR stent implantation. Eighteen major adverse cardiac events occurred within 1 month of NIR stent implantation in 12 patients (4.7%). This rate compares favorably to the early cardiac event rate encountered in the patients with stent placement enrolled in the STRESS and BENESTENT trials (5.9% and 6.9% of patients, respectively). In these two

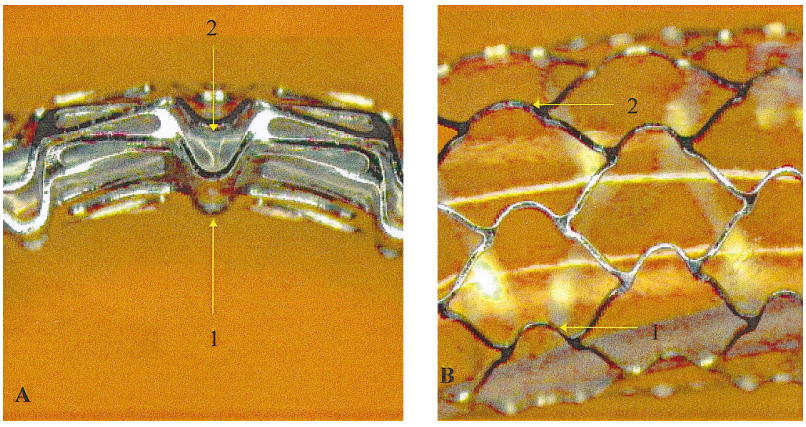

Figure 2. A, Crimped stent is flexible by virtue of differential elongation of vertical loops (note the difference in opening of the vertical loop inside [1] and outside [2] the curve). **B,** Stent expanded in a curve shows conformity to curvature by the same differential elongation (note the difference in length of the loop inside [1] and outside [2] the curve).

randomized trials, there was no in-hospital death in patients assigned to receive a Palmaz-Schatz stent for new, single, discrete, native coronary artery lesions. Three deaths occurred within 1 month of NIR stent implantation in the present trial, yielding a 1.2% early mortality rate. All fatal events followed multivessel intervention for complex lesions in clinically high risk patients. Five additional patients died during follow-up. During the 6 months after coronary intervention, a total of eight patients (3.1%) died, and 18.4% of enrolled patients experienced an adverse cardiac event. The need for repeat target lesion revascularization comprised the majority of late adverse events. Event-free survival 6 months after NIR stent implantation was 81.6% compared with 79.9% in the BENESTENT study and 80.5% in the STRESS trial at 7 and 8 months, respectively.

Limitations of the study. Although nearly 25% of the patients enrolled in the present trial had some degree of angina or silent ischemia during follow-up, restenosis after NIR stent implantation is difficult to estimate on clinical grounds because almost 50% of the patients had multivessel disease. Coronary arteriography was not routinely performed in patients at the time of 6-month follow-up and would have provided important information concerning the incidence of in-stent stenosis.

The acute angiographic results obtained after NIR stent implantation are comparable to those of other stent trials conducted before and after postdeployment high pressure balloon inflation became commonly used (9,10,27). Nonetheless, nearly one-third of patients (32%) had a residual stenosis >20% after high pressure balloon inflation on quantitative analysis performed by the core laboratory. Routine use of intravascular ultrasound probably would have been helpful in ensuring optimal stent deployment in the present study.

Conclusions. In this multicenter registry with broad patient and lesion inclusion criteria, the NIR stent proved highly efficacious in the treatment of complex, obstructive coronary artery disease. Because of its advanced stent design, the NIR stent appears particularly suitable for implantation in complex and difficult to reach lesions. A prospective, consecutive case registry assessing late angiographic results and a multicenter, randomized trial comparing the NIR stent with other currently available stents are in progress. Thus, NIR stent implantation is an effective means of treating patients with symptomatic coronary artery disease and may be particularly useful in patients with unfavorable lesions for percutaneous coronary intervention.

Appendix

*Participating Institutions and Investigators for the FINESS Trial**

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*Principal investigator; numbers in parentheses are number of patients enrolled at each site.

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