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

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Jerusalem, Israel

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 interventionist 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 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.

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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.
tuous vessels and preservation of arterial contour will necessi-
tate 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 consid-
erations 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 myo-
cardial 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 was ≥3.0 and ≤5.0 mm in diameter. Patients
with unprotected left main coronary artery disease, bifurcation
lesions, degenerated saphenous vein grafts, suspected intralu-
minal 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 gastroin-
testinal 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, predilatation 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 quantita-
tive coronary angiography. Predilatation was considered satisfac-
tory 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 coro-
nary 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 angiog-
ographic appearance of the target lesion was suboptimal, inves-
tigators were permitted to use further balloon inflation or
additional stent deployment with or without intravascular
ultrasound guidance, as deemed necessary. Heparin was dis-
continued 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 proce-
dural 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 compli-
cation 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 compli-
cation, as previously described, within 6 months of the proce-
dure. Independent monitors were dispatched to each investi-
gational site to ensure the quality of clinical data.

Angiographic analysis and end points. Coronary angiogra-
phy 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 (Cardiology,
Rotterdam, The Netherlands) and analyzed by the Cardiovas-
cular 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.

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 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, IIB) | 65 (25%)    |
| Postinfarction (IC, IIC, IIC) | 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.
reduction in average percent diameter stenosis from 61 to 13% after intervention. Mean maximal balloon inflation pressure for stent expansion was 13 atm (range 4.0 to 24.0).  

Table 2. Baseline Angiographic Characteristics*

<table>
<thead>
<tr>
<th>No. of lesions stented</th>
<th>306</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of lesions stented/patient (mean)</td>
<td>1.3</td>
</tr>
<tr>
<td>1</td>
<td>185 (77%)</td>
</tr>
<tr>
<td>2</td>
<td>42 (18%)</td>
</tr>
<tr>
<td>3</td>
<td>11 (5%)</td>
</tr>
<tr>
<td>4</td>
<td>1 (&lt;1%)</td>
</tr>
<tr>
<td>Vessel size (mm)</td>
<td>2.83 ± 0.61</td>
</tr>
<tr>
<td>Range</td>
<td>1.64–6.11</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>8.68 ± 3.69</td>
</tr>
<tr>
<td>Range</td>
<td>1.91–30.84</td>
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<tr>
<td>MLD (mm)</td>
<td>1.09 ± 0.43</td>
</tr>
<tr>
<td>Range</td>
<td>0.0–3.02</td>
</tr>
<tr>
<td>% diameter stenosis</td>
<td>61 ± 13</td>
</tr>
<tr>
<td>Range</td>
<td>25–100</td>
</tr>
</tbody>
</table>

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 IA: 4 (1%)
- Eccentric type IB: 3 (1%)
- Multiple irregularities: 46 (16%)
- Tandem lesion: 9 (3%)
- Total occlusion: 12 (4%)

Lesion classification‡

- Type A: 6 (2%)
- Type B1: 80 (26%)
- 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.

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 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).

Table 3. Procedural Characteristics and Outcome

<table>
<thead>
<tr>
<th>Stent inventory</th>
<th>457</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of stents used</td>
<td>9 mm, 66 (14.4%)</td>
</tr>
<tr>
<td></td>
<td>16 mm, 272 (59.5%)</td>
</tr>
<tr>
<td></td>
<td>32 mm, 119 (26.0%)</td>
</tr>
<tr>
<td>No. of stents/patient (mean)</td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td>0, 6 (2.4%)</td>
</tr>
<tr>
<td></td>
<td>1, 128 (50.2%)</td>
</tr>
<tr>
<td></td>
<td>2, 74 (29%)</td>
</tr>
<tr>
<td></td>
<td>3, 29 (11.4%)</td>
</tr>
<tr>
<td></td>
<td>&lt;3, 18 (7.1%)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>No. of lesions</th>
<th>306</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref vessel diameter (mm)</td>
<td>Before procedure, 2.83 ± 0.61</td>
</tr>
<tr>
<td></td>
<td>After procedure, 3.15 ± 0.51*</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>Before procedure, 1.09 ± 0.43</td>
</tr>
<tr>
<td></td>
<td>After procedure, 2.60 ± 0.50†</td>
</tr>
<tr>
<td>Acute gain (mm)</td>
<td>Before procedure, 1.51 ± 0.51</td>
</tr>
<tr>
<td>% DS (%)</td>
<td>Before procedure, 61 ± 13</td>
</tr>
<tr>
<td></td>
<td>After procedure, 17 ± 7†</td>
</tr>
</tbody>
</table>

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.
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 of suspected acute or subacute stent thrombosis. Creatine kinase and CK-MB fraction were measured after intervention. 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 intravascular ultrasound measurements have provided predictable

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

*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.
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
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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