FX MiniRAIL™ Catheter Usage for Treatment of De Novo Complex Coronary Lesions: Results from the "OFFAR"

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***Introduction**: Gradual prolonged balloon angioplasty may cause less arterial trauma, higher success rates, and fewer complications than conventional angioplasty (POBA). The OFFAR aimed to determine the safety and effectiveness of the FX MiniRAIL™ (FX) catheter, used with a slow, stepwise inflation protocol.*
***Methods and Results:** From June to December 2003, 181 consecutive patients (age 61.9 ± 10.6 years) with de novo coronary artery lesions (n = 217) were treated by FX and stent implantation in 11 European centers. Fifty-one patients (28.2%) had diabetes, and 70 (38.7%) had prior MI; 73 patients (40.3%) presented with stable angina and 85 (47.0%) with unstable angina. Fifty-five lesions (25.3%) were in small vessels (<2.5 mm), 40 (18.6%) were highly calcific, and 133 (62%) were long lesions (>18 mm). Stenosis resolution pressure was 7.17 ± 4.2 atm; inflation time was 116.5 ± 54.6 seconds. FX technical success (residual stenosis <50% post-FX) was obtained in 191 lesions (88.0%), and FX optimal success (residual stenosis <20% post-FX) in 117 (54.9%). Dissection was observed in 34 lesions (15.9%), 27 (79.3%) of which were type A or B. No coronary ruptures occurred. Nine (5.0%) in-hospital events occurred, all non-Q-wave MI. During 6-month follow-up, major adverse clinical events occurred in 14.4% of cases (n = 26; 3 cardiac deaths, 1 Q-wave MI, 2 non-Q-wave MI, 3 CABG, and 17 re-PTCA).*
***Conclusion**: The results of the OFFAR suggest that FX utilization for treatment of de novo complex coronary lesions is safe and effective.*(J Interven Cardiol 2006;19:250–257)

Introduction

Complex lesion characteristics represent a critical risk factor for an adverse outcome after both conventional balloon angioplasty (POBA) and stenting.[1,2] During percutaneous coronary angioplasty, balloon expansion disrupts the coronary vessel wall, which may become dissected. The consequences vary according to the severity of the dissection, and in some cases may cause myocardial infarction (MI) or may even be a life-threatening event.[3–5] In addition, coronary stent studies have reported that stents are often inadequately expanded when deployed as recommended by the respective manufacturers.[6,7] The use of high pressure postdilatation may however increase vessel trauma, and thus contribute to in-stent restenosis.[8]

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The use of focused force angioplasty techniques or devices, such as the "buddy wire," cutting balloon, eccentric balloon, and gradual prolonged balloon angioplasty, have been reported to cause less arterial trauma and fewer in-hospital complications than POBA.[9–12]

The FX MiniRAIL™ (FX) is a novel coronary dilation catheter that incorporates a balloon with a double integrated guidewire system. During balloon inflation, the FX MiniRAIL™ creates longitudinal expansion planes, thus allowing for a controlled dilation and stability.[13] The aim of the Optimal Focused Force Angioplasty Registry (OFFAR) was to determine if the use of the FX MiniRAIL™, in a technique using a slow, stepwise inflation protocol, can improve the acute and long-term outcome of the interventional procedure.

Materials and Methods

Population. Patients with either single or multiple vessel coronary artery disease, who were scheduled to undergo percutaneous coronary intervention because of symptoms of stable or unstable angina pectoris, were included. Patients had at least one de novo lesion in native coronary arteries. Reference vessel diameter (RVD) was between 2.0 mm and 4.0 mm. All lesions requiring intervention were to be considered treatable with the FX MiniRAIL™ coronary dilatation catheter as the first interventional device. Exclusion criteria were patients under 21 years of age; patients not available for 180-day follow-up; patients with contraindications to coronary artery bypass graft (CABG); patients with contraindications to antiplatelet and/or anticoagulant therapy; pregnant women; patients participating in another study with an investigational percutaneous interventional device; patients with totally obstructed coronary arteries and thrombolysis in myocardial infarction (TIMI) flow 0; patients with coronary spasm in the absence of a significant stenosis; patients with lesions within stent borders (in-stent restenosis).

This study was conducted in full accordance with the principles of the "Declaration of Helsinki," and with the laws and regulations of the country in which the research was conducted. The protocol was approved by the institutional review boards at all institutions and all patients included in the study signed an informed consent form.

Device Description. The unique design of the FX MiniRAIL™ features an integral wire positioned external to a dilating balloon, and a short, 12-mm guidewire lumen distal to the balloon. When the device is threaded over the guidewire, the steerable guidewire remains outside of the balloon. The balloon inflates against the external wires to prevent slippage, and to introduce high focal stresses longitudinally along the luminal surface of the lesion at low inflation pressures. Results from an initial, small, single-center investigation of the FX MiniRAIL™ suggested that the device may improve the outcome of a percutaneous coronary intervention. In this study, a slow stepwise inflation protocol was used. A subset analysis in the study indicated that, when stents are to be used, optimal predilatation of the lesion with the FX MiniRAIL™ may allow full-stent expansion at nominal deployment pressures.[13,14]

Angioplasty Procedure. All patients received medications in accordance with the investigators' standard practice for a percutaneous coronary intervention procedure. Patients were prepared according to the normal routine of each participating site. The FX MiniRAIL™ was the first interventional device used. Step-up inflation procedure: the balloon was inflated to 2 atm, and the same pressure was held for 15 seconds; the inflation pressure was then increased in a step-up procedure at a rate of 1 atm every 15 seconds until the fluoroscopically visible indentation in the stenosis disappeared (stenosis resolution pressure [SRP] was achieved); SRP was held for 10 seconds and documented by cine; the inflation pressure was increased at the rate of 1 atm every 10 seconds until the target balloon diameter was achieved by fluoroscopic assessment; final pressure was held for 10 seconds. When step-up balloon inflation as detailed above resulted in patient discomfort or ST segment changes, the investigator modified the inflation protocol as follows: the balloon was deflated and ischemia was allowed to resolve; the inflation protocol was resumed starting at the highest pressure achieved during the previous inflation (a rate of 1 atm/2 seconds was used to inflate the balloon from zero pressure to the new starting pressure). After the target balloon diameter was achieved, additional inflation was performed at the discretion of the investigator, at the rate of 1 atm/10 seconds. Following use of the FX miniRAIL™ catheter, the investigator waited for 2 minutes and performed angiography. Post-FX minimum lumen diameter (MLD), percentage diameter stenosis (% DS), TIMI flow, and dissections and complications were assessed and recorded in the case report form. Additional interventional procedures (FX MiniRAIL™ catheter, conventional percutaneous transluminal coronary angioplasty (PTCA),

atherectomy, stent implantation, etc.) in accordance with standard protocol (excluding any other investigational devices, procedures, or drugs) were performed if deemed necessary. Where stents were deployed, efforts were made to standardize the stenting protocol. Such "standardization" included choice of one or two stent designs, and the use of stent lengths that were greater than the length of the FX balloon used. Types of procedure(s)/device(s) were recorded in the case report form. MLD, % DS, TIMI flow, dissections, and complications were measured and recorded in the case report form.

Coronary Angiography. Three coronary angiograms were performed in each patient: baseline, one after FX MiniRAIL™ usage, and one after the end of the procedure. At least two orthogonal projections of the coronary segment scheduled for coronary intervention were filmed before the intervention. The same projections were repeated at angiography after the intervention. Angiograms were preceded by intracoronary injection of nitrates (100–200 μg nitroglycerin or 1–3 mg isosorbide dinitrate). The angiographic findings of dissection were recorded and analyzed.

Quantitative Coronary Angiography. Reference diameter, MLD, % DS, and lesion length were measured for each lesion from single view showing the most severe stenosis by the use of a computer-assisted automated edge-detection algorithm (QCA-CMS version 5.1, Medis, The Netherlands).

Intravascular Ultrasound. Intravascular ultrasound (IVUS) was used in a subset of cases to form a consecutive group of patients for IVUS substudy analysis. IVUS was performed preprocedure, post-FX MiniRAIL™ use, and postprocedure to evaluate stent expansion characteristics after FX MiniRAIL™ usage. All IVUS procedures were performed after intracoronary administration of 200 μg of nitroglycerin, with an automated pullback at a rate of 0.5 mm/s. IVUS procedures were recorded on VHS videotapes and sent to a core lab (Mediolanum Cardio Research, Milan, Italy) for review. Quantitative analysis was performed using commercially available planimetry software (Tape Measure/Echo Plaque, Indec Systems, Mountain View, California) according to previously validated protocols. All IVUS measurements were performed according to the "ACC Clinical Expert Consensus Document on Standards for Acquisition, Measurement and Reporting of Intravascular Ultrasound Studies."[15] Patients enrolled in the IVUS substudy were pooled with the overall population in the study. Postintervention procedures were performed in accordance with standard practice.

Optimal stent expansion was defined when stents met all three criteria defined by the Multicenter Ultrasound Stenting in Coronaries Study (MUSIC study).[16]

Study Endpoints. Primary endpoints were: FX technical success, defined as residual stenosis $<50\%$ post-FX; FX optimal success, defined as residual stenosis $\leq 20\%$ post-FX; procedural success, defined as residual stenosis $<50\%$ in the target lesion postprocedure; optimal procedural success, defined as residual stenosis $\leq 20\%$ in the target lesion postprocedure; in-hospital major adverse cardiac events (MACE), defined as death; MI, defined as new Q-waves in two or more continuous leads on the 12-lead surface ECG (Q-wave MI) or an increase in total CK >3 times upper the limit of normality, with elevated CK-MB fraction, according to local laboratory (non-Q-wave MI) or target lesion revascularization (TLR). Additional parameters that were measured were: SRP; maximum inflation pressure; inflation time; frequency of obtaining FX optimal success (residual stenosis $\leq 20\%$); frequency of obtaining optimal procedural success; frequency and severity of dissection; post-FX MLD, % DS, post-FX acute gain; final MLD, % DS, final acute gain. For stented lesions, we also assessed the ratio of measured to manufacturers' predicted diameter (area for IVUS) and the frequency of balloon slippage . At 6-month follow-up, freedom from MACE, TLR, TVR, restenosis ($>50\%$ DS at angiographic follow-up), MLD, % DS, late loss, % AS were assessed. Intimal hyperplasia area was also measured in the IVUS subgroup. Subset analyses were performed for small vessels, long lesions, and heavily calcified lesions.

Statistical Analysis. Continuous variables were reported as mean and standard deviation, and categorical variables as contingency tables. Analysis on patient subgroups were performed according to Student's *t*-test for continuous parameters, and according to Fisher's exact test and χ^2 statistics for discrete variables. All analyses were performed with BMDP Statistical Software version 7.0 (Statistical Solutions, Saugus, Massachusetts).

Results

From March to December 2003, 181 consecutive patients presenting with de novo native coronary artery lesions (n = 217) were treated with the FX MiniRAIL™

Table 1. Baseline Clinical Characteristics

	Patients (n = 181)
Age	61.9 ± 10.6
Male	145 (80.1%)
Diabetes	51 (28.2%)
Prior MI	70 (38.7%)
Prior CABG	23 (12.7%)
LVEF	56.3 ± 11.0
Clinical presentation	
Stable angina	73 (40.3%)
Unstable angina	85 (47.0%)
Other	23 (12.7%)

MI = myocardial infarction; CABG = coronary artery bypass graft; LVEF = left ventricular ejection fraction.

catheter at 11 European centers. Baseline clinical and angiographic characteristics are summarized in Tables 1 and 2. In the study population, 85 patients (47.0%) underwent coronary intervention for unstable angina, and 51 (28.2%) were affected by diabetes mellitus. A rate of 1.18 lesions per patient was treated. According to the ACC/AHA morphological classification, 133 lesions (62.1%) were type B2 or C. Fifty-five lesions (25.3%) were sited in small vessels (RVD < 2.5 mm), 40 (18.6%) were in moderately to severely calcified vessels according to the operator, and 133 (62.1%) were long lesions (lesion length ≥10 mm) according to quantitative coronary analysis. Angioplasty

Table 2. Baseline Angiographic Characteristics

	Lesions (n = 217)
Number of treated lesions per patient	1.18
Vessel distribution	
LM	2 (0.9%)
LAD	80 (36.9%)
LCX	62 (28.6%)
RCA	73 (33.6%)
ACC/AHA lesion type B2 or C	133 (62 %)
Small vessel (<2.5 mm)	55 (25.3%)
Calcified	40 (18.6%)
Long lesions (≥10 mm)	133 (62%)
RVD (mm)	2.60 ± 0.55
MLD (mm)	0.80 ± 0.35
% stenosis	69.5 ± 11.1
Lesion length (mm)	12.39 ± 6.8

LM = left main coronary artery; LAD = left anterior descending artery; LCX = left circumflex artery; RCA = right coronary artery; RVD = reference vessel diameter; MLD = minimal luminal diameter.

Table 3. Results

Lesions (n = 217)	Post-FX	Final
RVD	2.61 ± 0.51	2.90 ± 0.56
MLD	1.67 ± 0.47	2.47 ± 0.57
% stenosis	37.4 ± 15.0	15.11 ± 11.11
Stenosis resolution pressure (atm)	7.17 ± 4.2	
Maximum inflation pressure (atm)	8.4 ± 3.4	
Inflation time (seconds)	116.5 ± 54.6	
Technical success	191 (88.0%)	207 (99.5%)
Optimal success	117 (54.9%)	207 (99.5%)

RVD = reference vessel diameter; MLD = minimal luminal diameter; technical success = stenosis <50%; optimal success = stenosis <20%.

with FX MiniRAIL™ was followed by stenting in 87% of lesions.

Results and clinical outcome are summarized in Tables 3 and 4. After FX MiniRAIL™ usage, FX technical success (residual stenosis <50%) was obtained in 127 lesions (59.3%), and FX optimal success (residual stenosis <20%) was obtained in 25 lesions (11.6 %). Final procedural success was obtained in 207 lesions (99.5%) and optimal procedural success in 207 (99.5%). These success rates were obtained at a mean SRP of 7.17 ± 4.2 atm, a maximum inflation pressure of 8.4 ± 3.4 atm, and an inflation time of 116.5 ± 54.6 seconds. Subgroup analyses with results in small vessels (≤2.5 mm RVD), moderately to heavily calcified lesions, and long lesions (≥10 mm lesion length) are

Table 4. Adverse Events Rate in the Study Groups

	Patients (n = 181)
In-hospital MACE	9 (5.0%)
Death	0 (0%)
Q-wave MI	0 (0%)
Non-Q-wave MI	9 (5.0%)
Re-PTCA	0 (0%)
Emergency CABG	0 (0%)
6-month MACE	26 (14.4%)
Death	3 (1.7%)
Q-wave MI	1 (0.6%)
Non-Q-wave MI	2(1.1%)
Target lesion Re-PTCA	17 (9.4%)
CABG	3 (1.6 %)
6-Month severe adverse events	
Target vessel PTCA	22 (12.1%)
Cerebrovascular accident	2 (1.1%)

MACE = major adverse cardiovascular events MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass graft.

Table 5. Subgroup Analyses

	Small Vessels (n = 89*)	Calcified Lesions (n = 33§)	Long Lesions (n = 117†)
Fx technical success	53 (80.3%)	25 (92.6%)	65 (73.0%)
Fx optimal success	13 (19.7%)	3 (11.1%)	9 (10.1%)
Procedural success	87 (97.8%)	33 (100%)	116 (99.1%)
Optimal procedural success	64 (71.9%)	24 (72.7%)	78 (66.7%)

Success is defined according to operator's visual estimate. *For Fx technical and optimal success, 66 lesions were counted; §for Fx technical and optimal success, 27 lesions were counted; †for Fx technical and optimal success, 89 lesions were counted.

reported in Table 5. The lower rate of FX technical success and FX optimal success that we observed in small vessels and long lesions was caused by the inability to reach adequate residual lumen diameter due to lesion recoil.

Intravascular ultrasound analysis was performed at baseline after FX MiniRAIL™ usage and after stent implantation in a subgroup of 38 patients. IVUS data are summarized in Table 6.

The safety profile of the FX MiniRAIL™ was acceptable. Dissection after FX occurred in 34 lesions overall (15.9%). Most dissections were type A, 11 cases (32.3% of all dissections) or B, 16 cases (47% of all dissections). Type C dissections were seen in four cases (11.7% of all dissections) and type F in one (2.9% of all dissections). No coronary ruptures occurred. All dissections except one (type C) were resolved after stent placement. In-hospital MACE occurred in nine patients (5.0%); all were non-Q-wave MI. No death, emergency percutaneous coronary intervention , CABG, or Q-wave MI occurred.

Follow-up angiography was symptom-driven. At 6 months, global MACE rate was 14.4% (26 patients). Three patients had died (1.7%), one patient had a Q-wave MI (0.6%), two patients had non-Q-wave MI (1.1%), three patients (1.7%) underwent CABG. The remaining events were two cerebrovascular accidents (1 TIA and 1 stroke), 17 target lesion percutaneous revascularization procedures (9.6%), and 22 target vessel percutaneous revascularization procedures (12.1%).

Discussion

This prospective registry, evaluating the FX MiniRAIL™ angioplasty catheter used at a slow stepwise inflation protocol, confirms the findings of a previous pilot study, at a larger scale. FX MiniRAIL™ was effective in resolving coronary stenosis, at low SRP and maximum inflation pressure. Procedural success rates and optimal procedural rates were elevated, and in many cases success was obtained with FX alone. Regarding the safety profile of FX, dissection occurred in a low percentage of lesions, and most dissections were type A or B. The in-hospital MACE rate was only 5.0%. All in-hospital MACE were non-Q-wave MI. These results were obtained despite the relatively high-risk lesion subset enrolled in the study.

Limitations of POBA are the decreasing success rates with high-risk lesion subsets. According to the ACC/AHA guidelines for PTCA, type B lesions have reported success rates of 60–85% and a moderate risk of events, and type C lesions have a reported success rate <60%, with high risk of complications.[2,17] In our registry, the procedural success rate with FX in complex lesion subsets was 97.8% for small vessels, 100% for calcified lesions, and 99.1% for long lesions. The

Table 6. Intravascular Ultrasound Analysis

	Baseline (n = 31)	Post-FX (n = 28)	Post-Stent (n = 27)	P
Vessel area (mm^2)	14.32 ± 4.99	14.0 ± 4.8	14.16 ± 5.15	ns
Lumen area (mm^2)*	2.51 ± 1.25	4.03 ± 1.71	6.55 ± 2.09	<0.001 both
Plaque area (mm^2)*	11.81 ± 4.77	9.97 ± 4.01	7.61 ± 3.82	0.004 e 0.001
Calcium arch (degrees)	99.6 ± 25.2	86.6 ± 37.0		ns
Stent area (mm^2)			7.44 ± 2.46	
Optimal stent expansion (%)			81.5	
Lumen eccentricity§	0.33 ± 0.22	0.32 ± 0.21	0.17 ± 0.08	ns e 0.014

*P < 0.01 for comparisons between baseline versus post-FX and post-FX versus post-stent; §P < 0.01 for comparison between post-FX versus post-stent.

global rate of angiographic complications was low and was easily managed, and the clinical event rate was accordingly low.

One potential advantage of FX MiniRAIL™ used at a slow stepwise inflation protocol over POBA is the high rate of technical and optimal success with FX alone, obtained at relatively low SRP, a low stress on the vessel wall, and thus low complication rate. With POBA, the pressure that is exerted by the balloon is distributed evenly on the arterial wall, and high press res are often required to optimally resolve stenosis. This frequently leads to irregular rips and tears on the vessel wall, with disruption of the intima and media.[18–20] An autoptic study by Potkin et al.[20] showed a prevalence of plaque tear in 25 of 26 patients who had undergone PTCA. Plaque tear extended to the media and caused dissection in 24 of 28 PTCA sites. Hemorrhage into plaque was present in 19 of 28 PTCA sites. Vascular injury induces an inflammatory reaction, with vascular thrombus formation and neointimal growth.[21] Histological analyses show that focused force devices concentrate their force on a given spot, thus causing less disruption of the endothelium and media, and "surgical cuts" along the focused force lines. Prior animal studies[22] suggest that the scoring of the wire may be seen with IVUS. However, in the present study, during IVUS interrogation of the lesion, no wire marks have been noted among the cases.

Increasing vessel damage is also associated to increased neointimal growth after stent placement. A study by Farb et al.[8] demonstrated increased neointimal growth at or near the sites of medial damage, thus suggesting the avoidance of techniques that cause severe arterial damage during PCI, and the use of devices that do not require high inflation pressures to achieve adequate stent deployment and apposition to the arterial wall. In the REDUCE III trial, presented at TCT 2003, authors showed how cutting balloon angioplasty prior to stenting may be achieved with a lower maximum inflation pressure compared to POBA (respectively 7.5 vs 8.8 atm; $P = 0.001$). This was associated to a relative reduction in the restenosis rate by 38.2% (from 19.1% to 11.8%; $P = 0.03$) at 6-month angiographic follow-up.

High rates of procedural and optimal procedural success were achieved with low SRP (7.17 ± 4.2 atm) in our study. We did not compare lesion resistance with POBA. To our knowledge only one study,[23] by Chenu et al., has assessed lesion resistance during balloon angioplasty. The authors found a mean SRP of 4.4 ± 2.3 atm. Stable angina pectoris ($P < 10^{-6}$), calcifications ($P = 0.016$), occurrence of vessel wall dissection ($P = 0.005$), and the absence of a side branch arising from the stenosis ($P = 0.047$) were factors related to an increasing SRP. Apparently the SRP was lower than what we found with FX MiniRAIL™. However, the case series are certainly not matched.

Studies with drug-eluting stents have underscored the importance of achieving an adequate expansion of the stent. Sonoda et al.[24] demonstrated that minimal stent cross-sectional areas <5.0 mm^2 are predictive of restenosis at angiographic follow-up in sirolimus-eluting stents. Studies have shown that stents are often inadequately expanded when deployed as recommended by the manufacturers.[6,7,25] Adequate stent expansion may be more easily obtained with focused force devices than with conventional balloon alone, even when high pre- or postdilatation pressures are used. The IVUS subanalysis of this study shows that 81.5% of stents were optimally expanded according to MUSIC criteria.[16] Rizik et al. have demonstrated that cutting balloon can be used in lesion preparation before stent placement. Significant gains in minimal stent cross-sectional areas may be attained at relatively low pressures.[26]

An additional potential advantage of the FX Minirail™ over POBA is the higher friction of the device, and thus lesser balloon slippage during inflation. This makes it a useful device in the treatment of in-stent restenosis. In a matched lesion comparison,[27] Doven et al. showed that in-stent restenotic lesions treated with the FX MiniRAIL™ had significantly higher acute gain, MLD at follow-up, and net gain compared to POBA. Recurrent in-stent restenosis was significantly lower (19.6 vs 39.1%), and the pattern of recurrence was more benign with focal pattern occurring in 50% vs 22.2%, respectively, in FX MiniRAIL™ versus balloon angioplasty groups. It is clear that an increase in friction will potentially decrease the watermelon seeding effect usually observed during treatment of in-stent restenosis. However, such types of lesions were not included in our study, and a definitive answer cannot be drawn from our results.

The ease of use of the FX MiniRAIL™, which is similar to conventional balloon, should make it a preferred choice over other devices used in lesion preparation, such as rotational and directional atherotomy devices, which are costly, often bulky, have a reportedly higher rate of complications[28,29] than POBA, and are less diffusely available.

The findings of this study demonstrate the effectiveness and safety of FX MiniRAIL™ use in percutaneous coronary intervention. This novel device shows promise in particular in complex lesion subsets, where it achieves a satisfying resolution of stenosis at low pressure. Further studies specifically tailored to assess the possible beneficial effect of optimal lesion preparation associated to FX MiniRAIL™ usage before stenting are necessary in the near future. In particular, a randomized controlled comparison with angiographic follow-up of FX MiniRAIL™ versus balloon angioplasty before stent implantation should address the intriguing issues of lesion resistance, stent expansion (by IVUS), and, most importantly, in-stent restenosis.

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