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Comparison of the Efficacy and Safety of Paclitaxel-Eluting Coroflex Please Stents and Paclitaxel-Eluting Stents in Patients with Coronary Artery Disease: A Randomized PIPA Trial

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Objectives: To compare the safety and efficacy of the new Coroflex™ Please stents with conventional Taxus™ Liberte stents in patients with coronary artery lesions. Background: The Coroflex™ Please stent is a new version of paclitaxel-eluting stent, and observational cohort studies have reported similar angiographic and clinical outcomes as with the first-generation stents. However, it has not been directly compared with the early generation paclitaxel-eluting stents in a multicenter, prospective, and randomized study. Methods: We randomly assigned 319 patients to receive Coroflex™ Please stents (159 patients; 198 lesions) or Taxus™ Liberte stents (160 patients; 232 lesions). The primary end point was angiographic in-segment late luminal loss at 9 months. Results: Most baseline clinical and angiographic characteristics were similar between these two groups. The Coroflex™ Please and Taxus™ Liberte stents showed similar in-segment late loss (0.40 ± 0.53 mm vs. 0.39 ± 0.52 mm, $P = 0.98$) and rates of in-segment binary restenosis (22.2% vs. 18.8%, $P = 0.48$) at 9 months. After clinical follow-up for 12 months, the two groups had similar rates of death (1.3% vs. 1.3%, $P > 0.99$), myocardial infarction (3.8% vs. 7.5%, $P = 0.22$), stent thrombosis (2.5% vs. 1.9%, $P = 0.72$), and target-lesion revascularization (7.5% vs. 7.5%, $P = 0.99$). Conclusions: The Coroflex™ Please stent resulted in similar angiographic and clinical outcomes as the Taxus™ Liberte stent in patients with coronary artery lesions. © 2012 Wiley Periodicals, Inc.

Key words: paclitaxel; drug-eluting stent; Coroflex™; Please stent; coronary artery disease

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INTRODUCTION

Although the first generation of drug-eluting stents (DESs) have reduced the rates of angiographic restenosis and subsequent revascularization when compared with bare-metal stents [1–3], serious concerns have been raised about the long-term safety of DES due to late-stent thrombosis and increased rates of late-occurring mortality and myocardial infarction (MI) [4,5]. Therefore, a new generation of DES is being developed to improve the efficacy and safety profiles of early generation devices [6,7].

The Coroflex™ Please stent is a new version of the paclitaxel-eluting stent. It is composed of 0.120-mm-thick 316L stainless steel struts covered by a nonresorbable, thermostable polymer, polysulfone®, which prevents coating delamination and web formation, thus reducing the potential risk of stent thrombosis, and a 60 ± 20 nm layer of paclitaxel dosed at 1 $\mu g/mm^2$. The pivotal trial, the Paclitaxel-Eluting Coroflex™ Please Stent Study I (PECOPS I), showed that this stent had similar safety and efficacy as early generation paclitaxel-eluting stents [8,9]. The PECOPS II study showed similar findings for Coroflex™ Please stents in the treatment of longer coronary artery lesions [10]. However, these studies had several important limitations, including their single-arm observational designs, the enrollment of patients with relatively low-risk lesions, and the limited number of patients.

We have designed a multicenter, prospective, and randomized study to concurrently compare new-generation paclitaxel-eluting stents (Coroflex™ Please; B. Braun, Germany) with earlier-generation paclitaxel-eluting stents (Taxus™ Liberte; Boston Scientific, USA). Parameters assessed included clinical efficacy, angiographic outcomes, and safety in the treatment of patients with coronary artery disease, including more complex lesions.

MATERIALS AND METHODS

Study Design and Population

The PIPA (***P***acl***I***taxel-Eluting Coroflex™ Please Stent versus ***P***aclitaxel-Eluting Stent in Patients with Coronary ***A***rtery Disease) trial is a prospective, randomized, single-blind, and controlled study conducted in eight centers throughout Korea between February 2008 and October 2010. The study protocol was approved by the Ethics Committee at each participating center and was conducted according to the principles of the Declaration of Helsinki. All patients provided written informed consent for participation in this trial.

We consecutively enrolled patients aged ≥18 years with symptoms of angina, either stable angina or acute coronary syndromes, or documented myocardial ischemia with at least one coronary lesion (defined as ≥50% stenosis) suitable for stent implantation. There were no limitations on the number of lesions or vessels or on the length of the lesions, reflecting routine clinical practice. Exclusion criteria included acute ST-segment elevation MI necessitating primary percutaneous coronary intervention (PCI); severely compromised left ventricular dysfunction (ejection fraction <25%) or cardiogenic shock; allergy to antiplatelet drugs, heparin, stainless steel, contrast agents, or paclitaxel; left main coronary artery disease (defined as ≥50% diameter stenosis); in-stent restenosis of DES; graft vessel disease; a planned elective surgical procedure that would necessitate interruption of thienopyridines during the first 12 months; impaired renal dysfunction (creatinine >3.0 mg/dL or dialysis); limited life expectancy (<1 year); or participation in another coronary device study or inability to follow the study protocol.

Randomization, Procedures, and Adjunct Drug Therapy

Patients were randomly assigned after diagnostic angiography and before PCI. Eligible patients were randomly assigned with 1:1 to implantation of Coroflex™ Please stents or Taxus™ Liberte stents using sealed envelopes containing a computer-generated randomization sequence. The allocation sequence was stratified according to participating center and blocked with block sizes of 6 and 10 varying randomly. Patients, but not investigators, were unaware of the treatment assignment.

Stents were implanted according to standard techniques. Mixtures of DES were not permitted by the protocol. In patients with multiple lesions, all the lesions were to be treated with the assigned stent, except when the latter could not be inserted, in which case crossover to another device was allowed. Complete lesion coverage was recommended.

Before or during the procedure, all patients received at least 100 mg of aspirin and a 300–600 mg loading dose of clopidogrel. Heparin was administered to maintain an activated clotting time ≥250 sec. Administration of glycoprotein IIb/IIIa inhibitors was at the discretion of the operator. After the procedure, all patients received 100 mg/day of aspirin indefinitely and 75 mg/day clopidogrel for at least 12 months. Use of the standard postintervention care was recommended.

Patient Follow-Up and Data Management

Clinical follow-up visits were scheduled at 1, 4, 9, and 12 months. Each visit included a physical examination, electrocardiogram, and monitoring for major

adverse cardiac events (MACE) and angina recurrence. Repeat coronary angiography was routinely recommended 9 months after PCI or earlier if indicated by clinical symptoms or evidence of myocardial ischemia.

At each participating center, patient data were recorded prospectively on standard case report forms and gathered in the central data management center (Asan Medical Center, Seoul, Korea). All adverse clinical events were centrally adjudicated by an independent events committee blinded to treatment. An independent data and safety monitoring board reviewed the data periodically to identify potential safety issues; however, there were no formal stopping rules.

Quantitative Coronary Angiographic Analysis

Coronary angiograms were obtained before the procedure (baseline), after the procedure, and at follow-up and were assessed offline in the angiographic core analysis center (Asan Medical Center) using an automated edge-detection system (CAAS V, Pie Medical Imaging) by experienced assessors unaware of the allocated stent. Standard qualitative and quantitative analyses and definitions were used for angiographic analysis [11]. Target lesions were measured qualitatively, both the stented segment alone (in-stent), and the region including the stented segment and the margins 5-mm proximal and distal to the stent (in-segment). Measured variables included absolute lesion length, stent length, reference vessel diameter, minimum lumen diameter, percent diameter stenosis, binary restenosis rate, acute gain, late loss, and patterns of restenosis. The reference diameter was determined by interpolation. In-segment late loss was calculated as the difference between the minimal luminal diameter immediately after the procedure and at follow-up. Binary restenosis was defined as $\geq$50% diameter stenosis on follow-up angiography, and patterns of angiographic restenosis were assessed using the Mehran classification [12].

Study End Points and Definitions

The primary end point was angiographic in-segment late loss at 9 months. The secondary end points included death, MI, ischemia-driven target-lesion revascularization (TLR), ischemia-driven target-vessel revascularization (TVR), stent thrombosis, and the composite outcome of death, MI, and ischemia-driven TLR or TVR at 30 days and at 12 months. Other end points included in-stent and in-segment restenosis rates; and in-stent late loss at 9 months.

Deaths were categorized as cardiac or noncardiac. All deaths were considered cardiac unless a noncardiac cause could be unequivocally established. MI was diagnosed based on the presence of new Q waves in at least two contiguous leads or an elevation of creatine kinase or its MB isoenzyme to at least three times the upper limit of the normal range. Revascularization was defined as ischemia-driven if there was either $\geq$50% stenosis of the diameter, as documented by a positive functional study, ischemic changes on an electrocardiogram or ischemic symptoms, or, in the absence of documented ischemia, of $\geq$70% stenosis as assessed by quantitative coronary analysis. Stent thrombosis was defined as definite or probable thrombosis by the Academic Research Consortium definitions [13].

Statistical Analysis

The objective of the current study was to assess whether the outcome of treatment with Coroflex™ Please stent is not inferior to the outcome of treatment with Taxus™ Liberte stent. Despite improved polymer characteristics of the Coroflex™ Please stent, it showed similar, not superior, angiographic and clinical outcomes to the first-generation paclitaxel-eluting stent in the PECOPS I and II trials. Based on these available data, we planned to perform the noninferiority design. Based on the results of the TAXUS IV trial [3], we hypothesized a late luminal loss of 0.39 $\pm$ 0.50 mm in patients treated with Taxus™ Liberte stents. At the time of the PIPA trial, a late luminal loss of Taxus™ Liberte stents has not been well established in several clinical studies. Therefore, we assumed that the expected angiographic outcome of Taxus™ Liberte would be similar to Taxus Express quoted in Taxus IV. Sample size was calculated based on a noninferiority margin for an in-segment late loss of 0.16 mm, a one-sided α-level of 0.05, and 90% power. Based on an expected 25% rate of loss to angiographic follow-up, we estimated a total sample size of 500 patients (250 per group). However, recruitment rate was much slower than expected, and the planned enrollment of 500 patients was not feasible. Consequently, recruitment was closed at 320 patients.

All analyses of primary and secondary end points were performed according to the intention-to-treat principle. Continuous variables are presented as mean $\pm$ SD or median (interquartile range), and categorical variables are presented as numbers or percentages. Between-group differences in categorical variables were assessed using the χ^2 test or Fisher's exact test, with differences in continuous variables assessed using the unpaired *t*-test or Mann-Whitney *U* test. Event-free survival was analyzed using the Kaplan-Meier method, and differences were compared using the log-rank test. Two-tailed *P* values of less than 0.05 were considered statistically significant. All statistical analyses were performed using commercially available software (SPSS 11 for Windows; SPSS, Chicago, IL). Dr. S.-J.

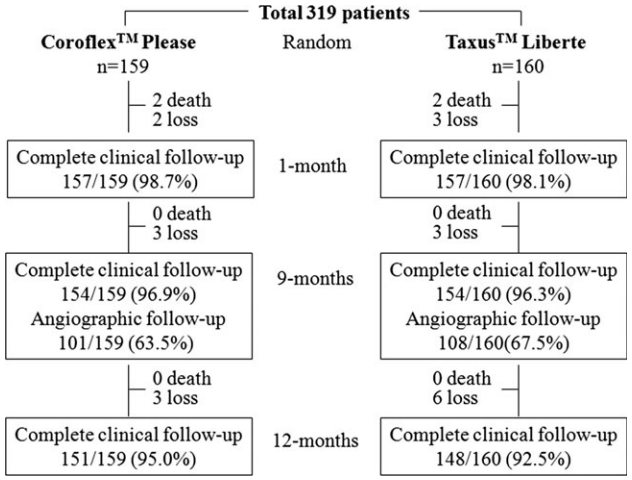

Fig. 1. Flow chart of patients from enrollment through follow-up.

TABLE I. Baseline Clinical Characteristics

Variable	Coroflex™ Please ($N = 159$)	Taxus™ Liberte ($N = 160$)	P value
Age (years)	65.9 ± 10.9	64.6 ± 10.1	0.25
Male gender	94 (59.1%)	104 (65.0%)	0.28
Hypertension	115 (72.3%)	106 (66.3%)	0.24
Total cholesterol ≥200 mg/dL	71 (44.7%)	63 (39.4%)	0.34
Diabetes mellitus	43 (27.0%)	38 (23.8%)	0.50
Current smoker	41 (25.8%)	32 (20.0%)	0.22
Family history of coronary artery disease	9 (5.7%)	8 (5.0%)	0.79
Previous percutaneous coronary intervention	10 (6.3%)	13 (8.1%)	0.53
Clinical indications			0.78
Silent ischemia	5 (3.1%)	7 (4.4%)	
Chronic stable angina	64 (40.3%)	70 (43.8%)	
Unstable angina	73 (45.9%)	65 (40.6%)	
NSTEMI	17 (10.7%)	18 (11.3%)	
Left ventricular ejection fraction (%)	62.1 ± 8.2	59.8 ± 8.9	0.03
Multivessel involvement (≥2 epicardial arteries)	64 (40.3%)	76 (47.5%)	0.19

NSTEMI, non ST-segment elevation myocardial infarction.

Park had full access to the data and vouches for its integrity and analysis.

RESULTS

Baseline and Procedural Characteristics

A total of 319 patients were enrolled in the study and randomly assigned to receive Coroflex™ Please stents (159 patients; 198 lesions) or Taxus™ Liberte stents (160 patients; 232 lesions). However, four patients assigned to the Coroflex™ Please stent group were actually treated with Taxus™ Liberte stents. There were no crossover cases from the Taxus™ Liberte stents group to the Coroflex™ Please stent group. The study profile is depicted in Fig. 1; baseline patient demographic and clinical characteristics are shown in Table I; and lesion and procedural characteristics are shown in Table II. Most clinical, lesion, and procedural characteristics were similar between the two groups.

TABLE II. Baseline Lesion and Procedural Characteristics

Variable	Coroflex™ Please ($N = 198$ lesions)	Taxus™ Liberte ($N = 232$ lesions)	P value
Target lesion location			0.66
Left anterior descending artery	91 (46.0%)	107 (46.1%)	
Left circumflex artery	50 (25.3%)	51 (22.0%)	
Right coronary artery	57 (28.8%)	74 (31.9%)	
TIMI flow grade = 0 or 1	11 (5.6%)	8 (3.4%)	0.29
Thrombus containing	9 (4.5%)	5 (2.2%)	0.18
Moderate to severe tortuosity	13 (6.6%)	7 (3.0%)	0.11
Moderate to severe calcium	25 (12.6%)	28 (12.1%)	0.86
Bifurcation lesion (side branch ≥ 1.5 mm)	59 (29.8%)	51 (22.0%)	0.06
Maximal stent diameter (mm)	3.4 ± 0.5	3.4 ± 0.6	0.63
Maximal inflation pressure (atm)	12.4 ± 3.1	12.8 ± 3.5	0.32
Number of used stents per patient	1.3 ± 0.6	1.5 ± 0.9	0.08

TIMI, thrombolysis in myocardial infarction.

Angiographic Results

The quantitative angiographic results in the two groups at baseline, immediately after the procedure, and at follow-up are given in Table III. Angiographic measurements of lesions before and after the procedure were similar between the two groups; the exceptions were that the mean lesion length and implanted stent length were longer in the Taxus™ Liberte than in the Coroflex™ Please stent group.

A total of 63.5% of the patients in the Coroflex™ Please stent group and 67.5% of those in the Taxus™ Liberte stent underwent follow-up angiography ($P = 0.74$; Fig. 1), at a median 278 days (interquartile range, 256–318 days) and 272 days (interquartile range, 248–300 days), respectively ($P = 0.11$). Patients undergoing angiographic follow-up were significantly younger (63.3 ± 10.0 years vs. 69.1 ± 10.7 years, $P < 0.001$) and significantly more likely to be male (69.4% vs. 48.2%, $P < 0.001$) than those who did not return for angiographic follow-up.

TABLE III. Quantitative Angiographic Measurements

Variable	Coroflex™ Please ($N = 198$ lesions)	Taxus™ Liberte ($N = 232$ lesions)	P value
Before procedure			
Lesion length (mm)	17.0 ± 10.1	19.2 ± 10.8	0.04
Reference diameter (mm)	3.08 ± 0.51	3.09 ± 0.49	0.84
Minimum lumen diameter (mm)	1.13 ± 0.40	1.16 ± 0.41	0.41
Diameter stenosis (%)	62.8 ± 12.5	62.4 ± 11.0	0.70
Immediate after procedure			
Stent length (mm)	22.2 ± 9.2	24.4 ± 11.3	0.03
Minimum lumen diameter (mm)			
In-segment	2.33 ± 0.52	2.35 ± 0.50	0.89
In-stent	2.34 ± 0.52	2.35 ± 0.50	0.89
Diameter stenosis (%)			
In-segment	18.0 ± 9.1	17.6 ± 9.0	0.68
In-stent	11.2 ± 8.0	11.1 ± 7.7	0.87
Acute gain (mm)			
In-segment	1.21 ± 0.59	1.18 ± 0.51	0.61
In-stent	1.49 ± 0.59	1.46 ± 0.47	0.56
Follow-up at 9 months, n (%)	126 (63.6%)	144 (62.1%)	0.74
Minimum lumen diameter (mm)			
In-segment	1.96 ± 0.62	1.96 ± 0.61	0.96
In-stent	2.11 ± 0.67	2.11 ± 0.62	0.99
Diameter stenosis (%)			
In-segment	34.1 ± 18.1	33.7 ± 17.9	0.86
In-stent	29.8 ± 19.4	30.6 ± 17.7	0.72
Late luminal loss (mm)			
In-segment	0.40 ± 0.53	0.39 ± 0.52	0.98
In-stent	0.55 ± 0.53	0.49 ± 0.52	0.40
Binary angiographic restenosis, n (%)			
In-segment	28 (22.2%)	27 (18.8%)	0.48
In-stent	22 (17.5%)	16 (11.1%)	0.13

TABLE IV. Angiographic Patterns of Restenosis[a]

Variable	Coroflex™ Please ($N = 28$ lesions)	Taxus™ Liberte ($N = 27$ lesions)	P value
Focal	17 (60.7%)	20 (74.1%)	0.29
IA (articulation or gap)	0	0	
IB (margin)	9	11	
IC (focal body)	8	7	
ID (multifocal)	0	2	
Diffuse	11 (39.3%)	7 (25.9%)	0.29
II (intrastent)	6	3	
III (proliferative)	4	4	
IV (total occlusion)	1	0	

[a]Classified using the Mehran criteria [12].

The primary study end point, in-segment late luminal loss, was similar in the Coroflex™ Please stent and Taxus™ Liberte stent groups (0.40 ± 0.53 mm vs. 0.39 ± 0.52 mm, $P = 0.98$). We also found that mean in-stent late luminal loss was similar between the two groups (0.55 ± 0.53 mm vs. 0.49 ± 0.52 mm, $P = 0.40$), as were the rates of in-segment binary restenosis (22.2% vs. 18.8%, $P = 0.48$) and in-stent restenosis (17.5% vs. 11.1%, $P = 0.13$). Angiographic patterns of restenosis also did not differ between the two groups (Table IV).

Clinical Outcomes

Complete follow-up clinical data were obtained from 151 patients (95.0%) in the Coroflex™ Please stent group and 148 (92.5%) in the Taxus™ Liberte stent group ($P = 0.36$; Fig. 1). Major clinical events during follow-up are given in Table V. The two groups had similar rates of clinical events at 1 month, and similar rates of individual and composite clinical outcomes at 12 months. Two patients in each group died within 1 month after the procedure, with all of these deaths being of cardiac origin and related to stent thrombosis. The incidence of periprocedural MI was numerically lower in the Coroflex™ Please stent than in the Taxus™ Liberte stent group (3.8% vs. 7.5%, $P = 0.22$), whereas the incidence of definite or probable stent thrombosis at 12 months in these two groups was 2.5% and 1.9%, respectively. Cumulative event-free survival (i.e., free from TLR and MACE, the composite of death, MI, or ischemia-driven driven TLR) is shown in Fig. 2A and B.

DISCUSSION

The major findings of this randomized clinical trial are as follows: (1) when compared with the first-generation

TABLE V. Clinical Outcomes of Follow-Up

Variable	Coroflex™ Please ($N = 159$)	Taxus™ Liberte ($N = 160$)	P value
Follow-up at 30 days			
Death	2 (1.3%)	2 (1.3%)	>0.99
Cardiac	2	2	
Noncardiac	0	0	
MI	6 (3.8%)	12 (7.5%)	0.22
Non-Q	3	9	
Q	3	3	
TLR	3 (1.9%)	2 (1.3%)	0.69
TVR	3 (1.9%)	2 (1.3%)	0.69
Stent thrombosis	4 (2.5%)	3 (1.9%)	0.72
Definite	3 (1.9%)	1 (0.6%)	
Probable	1 (0.6%)	2 (1.3%)	
Composite of death, MI, and TLR	7 (4.4%)	12 (7.5%)	0.24
Composite of death, MI, and TVR	7 (4.4%)	12 (7.5%)	0.24
Follow-up at 12 months			
Death	2 (1.3%)	2 (1.3%)	>0.99
Cardiac	2	2	
Noncardiac	0	0	
MI	6 (3.8%)	12 (7.5%)	0.22
Non-Q	3	9	
Q	3	3	
TLR	12 (7.5%)	12 (7.5%)	0.99
TVR	12 (7.5%)	12 (7.5%)	0.99
Stent thrombosis	4 (2.5%)	3 (1.9%)	0.72
Composite of death, MI, and TLR	15 (9.4%)	22 (13.8%)	0.23
Composite of death, MI, and TVR	15 (9.4%)	22 (13.8%)	0.23

MI, myocardial infarction; TLR, target lesion revascularization; TVR, target vessel revascularization.

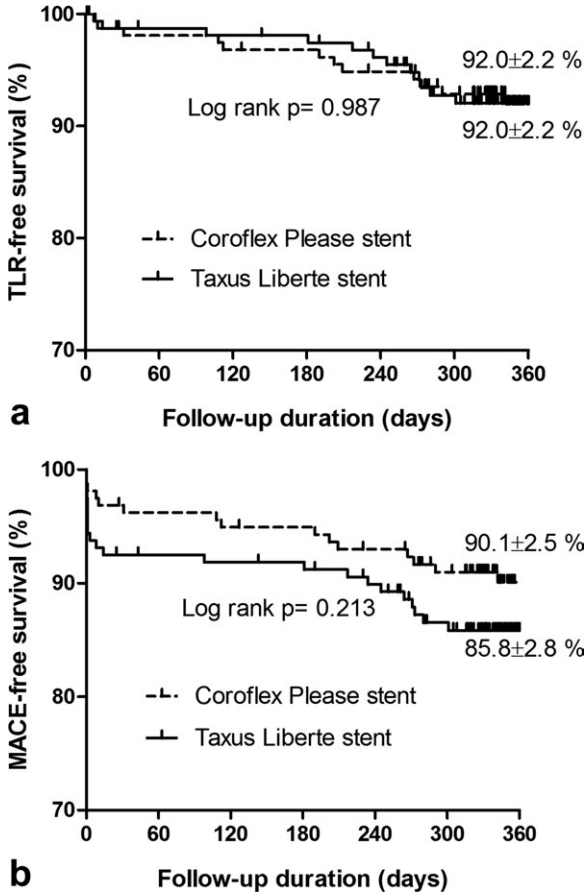

Fig. 2. Kaplan-Meier curves of freedom from (a) ischemia-driven target-lesion revascularization (TLR) and (b) major adverse cardiac events (MACE, defined as a composite of death, myocardial infarction, or ischemia-driven target-lesion revascularization) in patients treated with Coroflex™ Please and Taxus™ Liberte stents.

paclitaxel-eluting Taxus™ Liberte stent, the new-generation paclitaxel-eluting Coroflex™ Please stent showed similar late luminal loss and restenosis rates in the stented and analyzed segments; and (2) the overall rates of clinical events, including death, MI, ischemia-driven TLR, and stent thrombosis, were similar between these two groups for up to 12 months.

The Coroflex™ Please stent is a new version of paclitaxel-eluting stent, and observational cohort studies have reported similar angiographic and clinical outcomes as with the first-generation stents. To our knowledge, this study is the first multicenter, prospective, and randomized trial comparing the efficacy and safety of Coroflex™ Please and Taxus™ Liberte stents in patients with a relatively broad range of clinical and lesion subsets. As a primary result, the in-segment late loss of the two stents was similar; the in-segment late loss was also similar to that reported for the Taxus stent in the Taxus IV trial [3], in which patients had a similar range of clinical and lesion criteria as ours. These findings indicate that the Coroflex™ Please stents have similar efficacy to first-generation paclitaxel-eluting stents in inhibiting neointimal growth.

We found that the in-segment late lumen loss in the Coroflex™ Please stent group was 0.40 ± 0.53 mm, less than that observed in the PEPCOS I trial (0.47 ± 0.60 mm) [8] but more than that observed in the PEPCOS II trial (0.21 ± 0.70 mm) [10]. The rates of in-segment restenosis (22.2%) and TLR (7.5%) at 9 months were higher than those in the PEPCOS trial I (7.8% and 5.7%), but similar to those in the PEPCOS II (16.7% and 14.5%) at 6 months. These discrepancies may be due, at least in part, to differences in lesion characteristics and time of follow-up angiography. Although we found that the angiographic measurements of in-segment late loss and the rates of restenosis and clinically measured TLR were similar for both stent types, these measurements were higher than those previously reported for sirolimus- and everolimus-eluting stents [2,7].

The safety profiles of the Coroflex™ Please stent and Taxus™ Liberte stents were similar, with similar rates of death, MI, and 1-year stent thrombosis (2.5% vs. 2.6%). Our findings were also similar to those previously reported for paclitaxel-eluting stents; a meta-analysis showed that the 30-month probability of thrombosis after paclitaxel stent deployment was 2.6% [14]. The Coroflex™ Please stent struts are covered by new polymer free of delamination and webbing, which potentially reduce the potential risk of stent thrombosis. Following stent deployment in the coronary arteries of pigs, this polymer was found to induce only non-significant increase in vascular inflammatory response when compared with implantation of bare metal devices [15]. Hypersensitivity to the stent's underlying polymer has been regarded as a potential cause of delayed endothelialization and enhanced thrombogenicity [16]. Thus, the polymer polysulfone® may be responsible, at least in part, for reducing the risk of late stent thrombosis. In PECOPS I, stent thromboses occurred within 6 months after the procedure, with none observed subsequently up to 3 years [9]. Because polymers have been accused in the occurrence of stent thrombosis and the polymer on the Coroflex™ Please stent is felt to be superior to that on the Taxus™ Liberte stent, one might have theoretically anticipated a lower rate of stent thrombosis in the patients with Coroflex™ Please stent. In the PIPA study, there was no difference in the occurrence of stent thrombosis between the two groups, and no stent thrombosis was seen in either arm after 30 days. The differences in pharmacokinetics of the drugs and in clinical and anatomic situations could also be responsible for development of thrombosis, not a polymer only. Therefore, the improved polymer characteristics of the Coroflex™ Please stent itself might not seem to be solely translated in important reduction in the occurrence of stent thrombosis over the Taxus™ Liberte stent in real-world practice. This study, however, was not designed to show differences in stent thrombosis and was underpowered to detect meaningful differences in hard clinical end points. Trials in larger populations with follow-up data for more than 3 years may provide more information on the long-term safety and durability of this stent.

Our study had several potential limitations, including its early termination due to delayed enrollment speed and difficulty meeting the initially planned sample size. The numbers in each of the groups were below the statistical power needed for significance. In addition, the rate of angiographic follow-up was unsatisfactory and may have resulted in an underestimation of the occurrence of angiographic restenosis. Furthermore, the angiographic follow-up was biased by a higher proportion of younger patients undergoing angiographic follow-up. The mean lesion and stent length were longer in the Taxus group. This random error limits the possible conclusions that the new paclitaxel-eluting Coroflex™ Please stent showed similar angiographic outcomes as the Taxus™ Liberte stent. Similar angiographic outcomes may not correctly occur. Even with the higher baseline risk of restenosis, longer lesion, and stent lengths in the Taxus group, the Coroflex™ Please stent could not show superiority. This trial, however, was not designed for superiority of this device when compared with Taxus™ Liberte stent. Another limitation of our study was the relatively short follow-up period of 12 months. Durable polymers of early generation DES have been associated with chronic inflammation of the arterial wall with the potential for delayed restenosis. Therefore, long-term comparisons of new and old DES may be needed to confirm the long-term durability of the new devices. Finally, this study assessed angiographic outcomes but was not powered for clinical outcomes. Even though late luminal loss is a good surrogate marker for neointimal growth and subsequent restenosis after DES implantation, angiography is inaccurate in assessing the functional significance of a coronary stenosis severity and need for revascularization [17], suggesting the need for larger clinical outcome studies to focus on equivalency in clinical end points to evaluate the efficacy and safety profiles of a new generation of DES, Coroflex™ Please stent.

CONCLUSIONS

The new paclitaxel-eluting Coroflex™ Please stent showed similar angiographic and clinical efficacy and safety profiles as the conventional first-generation paclitaxel-eluting Taxus™ Liberte stent in patients with coronary artery lesions.

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