Safety and Efficacy of Biodegradable Polymer-Coated Sirolimus-Eluting Stents in “Real-World” Practice

18-Month Clinical and 9-Month Angiographic Outcomes

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Objectives This study sought to evaluate the safety and efficacy of a biodegradable polymer-coated sirolimus-eluting stent (Excel, JW Medical System, Weihai, China) with 6-month dual antiplatelet therapy in daily practice.

Background It has been hypothesized that persistent presence of polymer may compromise the safety of drug-eluting stents, and that therefore biodegradable polymer coatings might reduce late adverse events.

Methods Between June and November 2006, 2,077 patients, exclusively treated with Excel stents at 59 centers from 4 countries, were enrolled in this prospective, multicenter registry. Recommended antiplatelet regimen included clopidogrel and aspirin for 6 months followed by chronic aspirin therapy.

Results The average duration of clopidogrel treatment was 199.8 ± 52.7 days and 80.5% of discharged patients discontinued clopidogrel at 6 months. The cumulative rates of major adverse cardiac events were 0.9% at 30 days, 2.7% at 1 year, and 3.1% at 18 months. Overall rate of stent thrombosis was 0.87% at 18 months. The rates of acute, subacute, late, and very late stent thrombosis were 0.1%, 0.38%, 0.34%, and 0.05%, respectively. Angiographic follow-up, performed in 974 (31.6%) lesions from 653 patients (31.7%), revealed a mean in-stent late lumen loss of 0.21 ± 0.39 mm. Binary restenosis rates were 3.8% in-stent and 6.7% in-segment.

Conclusions This multicenter registry documents satisfactory safety and efficacy profiles, as evidenced by low rates of major adverse cardiac events and stent thrombosis up to 18 months, for the Excel biodegradable polymer-based sirolimus-eluting stent when used with 6 months of dual antiplatelet therapy in a “real-world” setting. (Multi-Center Registry Trial of EXCEL Biodegradable Polymer Drug-Eluting Stent [CREATE]; NCT00331578) (J Am Coll Cardiol Intv 2009;2:303–9) © 2009 by the American College of Cardiology Foundation

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Although first-generation drug-eluting stents (DES) were touted as a major breakthrough in interventional cardiology because of their efficacy in reducing in-stent restenosis and target lesion revascularization (TLR) rates compared with bare-metal stents (1–3), the initial enthusiasm has been tempered by concerns about their long-term safety, particularly numerically higher rates of late and very late stent thrombosis, which have been associated with catastrophic consequences (4–7).

The mechanisms of late or very late stent thrombosis after DES implantation have not yet been clarified, but the stent platform design, the toxicity of active drug and the durable polymer coatings are considered potentially relevant to this problem. Several histopathological studies indicated that the durable polymer coatings of DES, which were associated with hypersensitivity reactions directed against the polymer, localized vascular inflammation, apoptosis of smooth muscle cells, and thrombogenic reactions, may play important roles in late or very late stent thrombosis (8–11). Based on this consideration, biodegradable polymer coatings have been used in some new generation DES, including the Excel stent (JW Medical System, Weihai, China). In the present study, we sought to evaluate the long-term safety and efficacy of the Excel stent in the context of 6-month dual antiplatelet therapy for the treatment of coronary lesions in “real-world” practice.

**Abbreviations and Acronyms**

**DES** = drug-eluting stent(s)  
**MACE** = major adverse cardiac event(s)  
**MI** = myocardial infarction  
**PLA** = polyactic acid  
**SES** = sirolimus-eluting stent(s)  
**TLR** = target lesion revascularization

**Methods**

**Patient enrollment.** The CREATE (Multi-Center Registry of Excel Biodegradable Polymer Drug Eluting Stents) registry is a post-marketing surveillance multicenter, prospective study. Between June and November 2006, multiple demographic, clinical, angiographic, and follow-up variables were collected for patients receiving successful Excel stent implantation at 59 medical centers from 4 countries (China, Indonesia, Malaysia, and Thailand). The indications for stenting were left to the operators’ discretion. Patients with device or procedural failure, who received ≥1 stent other than the protocol stent, or had contraindications for dual antiplatelet therapy, heart function worse than New York Heart Association functional class III, or a planned upcoming surgery were excluded. Ethics committees in all participating centers approved the study protocol, and a signed, informed consent was obtained from every enrolled patient.  

**Stent features.** The Excel stent is a sirolimus-eluting stent (SES) that is coated with a biodegradable polyactic acid (PLA) polymer. The stent platform is a laser-cut, 316L stainless steel, open cell design stent with strut thickness of 0.0047 inches. The PLA coating used in the Excel stent is mixed with sirolimus (C_{51}H_{79}NO_{13}, molecular weight 914.2) (North China Pharmaceutical Group Corporation, Shijiazhuang, China) and coated onto the abluminal surfaces of the stent to a thickness of 10 to 15 μm. The coating has been shown in animal studies to have a complete degradation cycle of 6 to 9 months (based on communications with JW Medical System, October, 2007). There is no adhesive surface between the polymer and the stent struts. Total sirolimus dosage varies from 195 to 376 μg per stent according to the stent length.

**Antithrombotic therapy.** Loading doses of aspirin (300 mg) and clopidogrel (300 mg) were given at least 24 h before elective procedures, followed by maintenance dosages of aspirin of 100 mg per day indefinitely and clopidogrel of 75 mg per day for 6 months. Use of low-molecular weight heparin and glycoprotein IIb/IIIa inhibitors during the periprocedure period was left to operators’ discretion.

**Outcomes, definitions, and follow-up.** The predefined primary outcome was rate of major adverse cardiac events (MACE) at 12 months after Excel stent implantation in real-world practice. Secondary outcomes were in-stent late lumen loss and binary restenosis at 9 months, and cumulative thrombotic event rates up to 18 months after the index procedure. We defined MACE as a composite of cardiac death, nonfatal myocardial infarction (MI), and TLR. All deaths were considered to be cardiac unless a noncardiac origin could be clearly established by clinical and/or pathological study. The diagnosis of MI was based on either the development of new pathological Q waves in ≥2 contiguous electrocardiogram leads and/or elevation of creatine kinase-myocardial band isoenzyme level >3 times the upper normal limit after the procedure during index hospitalization, or cardiac enzyme level elevation >2 times the upper normal limit thereafter. We defined TLR as any repeat intervention inside the stent implanted during the index procedure or within 5 mm proximal or distal to the stent. Stent thrombosis was classified as definite, probable, and possible according to definitions proposed by the Academic Research Consortium (12); it was stratified as acute (<24 h), subacute (24 h to 30 days), late (30 days to 1 year), and very late (>1 year). Off-label indications included lesions that did not meet the manufacturer’s instructions for use for the Cypher SES (Cordis Corporation, Miami Lakes, Florida), as well as patients with acute MI or who had lesions in the left main coronary artery or ostial, bifurcated, or totally occluded lesions.
Clinical follow-ups, by office appointment or phone call, were scheduled at 1, 3, and 6 months, and every 6 months thereafter up to 3 years. Angiographic follow-up was performed 6 to 12 months after the index procedure or earlier if clinically indicated. The anticipated angiographic follow-up rate was 35%.

Data collection and management. Clinical data were prospectively collected on case-report forms and submitted to a data coordination center (located at Shenyang Northern Hospital). The consistency and accuracy of the data, including baseline, in-hospital, and follow-up outcomes, were audited by independent study monitors. At least 15% of patients in each center were randomly selected for audit check. If a discrepancy between the case-report form versus source documentation was found, all data from the center was audited. A total of 332 patients from 56 centers were selected for audit check, accounting for 16.0% of all enrolled patients. All adverse clinical events were reviewed and adjudicated by an independent clinical events committee. The overall data accuracy rate was 99.4% (330 of 332), because 2 patients underwent non-TLR that was reported as MACE.

Visual estimation of lesion characteristics in relation to those in the index procedure was performed by the operator and recorded. If a patient underwent angiographic follow-up, coronary angiograms obtained at baseline, procedure completion, and follow-up were submitted to the independent angiographic core laboratory (Catheterization Lab, Cardiovascular Institute and Fu Wai Hospital, Beijing, China). Quantitative coronary angiography was performed with Quantcor QCA (CAAS II) version 5.0 (Pie Medical Imaging, Maastricht, the Netherlands). Binary restenosis was defined as ≥50% diameter stenosis at follow-up and was classified as in-stent if inside of the stent or in-segment if located at the stented segment or up to 5 mm proximal or distal to the stents. Late lumen loss was defined as the difference between the minimal lumen diameter immediately after the procedure and at follow-up.

Statistical analysis. Comparisons between continuous variable data, expressed as mean ± SD, were performed with the t test, while the chi-square or the Fisher exact tests were used for categorical data, expressed as percentages. The MACE-free survival curve was calculated by the Kaplan-Meier method. Statistical analyses were performed with the SPSS 12.0 software (SPSS, Inc., Chicago, Illinois). A p value of <0.05 was considered statistically significant.

Results

Patient sample and baseline characteristics. Data for 2,077 patients in the registry were analyzed, representing 95.1% of 2,183 consecutive patients. We excluded 90 patients (4.1%) because of hybrid stenting with other DES types and 16 (0.7%) patients because of failure to deliver the stent. The mean age of the cohort was 60.6 ± 11.1 years, 73.6% were men, and 21.2% were diabetics. Baseline characteristics are further detailed in Table 1.

Angiographic and procedural characteristics. A total of 3,080 target lesions were treated, including 26 (0.8%) unprotected left main, 667 (21.7%) bifurcation, 76 (2.5%) chronic total occlusion, 69 (2.2%) restenotic, and 1,309 (42.5%) diffusely diseased lesions. Multivessel stenting was performed in 26.9% of patients and 84.5% of enrolled patients had at least 1 off-label indication for DES implantation. A total of 3,748 Excel stents were implanted at index procedure (1.8 stents per patients) with an average diameter and total stent length of 3.05 ± 0.44 mm and a 26.7 ± 13.0 mm, respectively. A total of 52.4% of all stents were implanted without pre-dilation. Major angiographic and procedural characteristics are shown in Table 2.

Antiplatelet therapy. At time of discharge, all surviving patients were being treated with aspirin and clopidogrel except for 1 patient in whom all antiplatelet therapy was discontinued because of thrombocytopenia. Data on dual antiplatelet treatment status from 2,053 discharged patients were obtained. The mean duration of dual antiplatelet therapy was 199.8 ± 52.7 days. Out of 2,053 patients, 1,652 (80.5%) discontinued clopidogrel treatment at 6 months after their index procedures. The other 401 patients (19.5%) had their clopidogrel treatment extended to 7 to 12 months.

Clinical outcomes. Clinical follow-up was completed in 2,077 (100%) patients at 30 days, 2,063 (99.3%) at 1 year, and 2,062 (99.3%) at 18 months, respectively. Primary events developed in 56 patients (2.7%) at 1 year, consisting of 22 (1.1%) cardiac deaths, 8 (0.4%) nonfatal MIs, and 32...
(1.6%) TLRs. At 18-month clinical follow-up, 39 patients (1.8%) had died, including 23 patients (1.1%) who died of cardiac reasons. The rates of MACE, MI, and TLR at 18-month follow-up were 3.1% (64 of 2,062), 0.4% (9 of 2,062), and 1.9% (39 of 2,062), respectively. The 30-day, 1-year, and 18-month adverse clinical events are shown in Table 3. The 18-month MACE-free survival curve is illustrated in Figure 1.

At the 18-month follow-up, stent thromboses had developed in 18 patients (0.87%), including 2 (0.1%) acute, 8 (0.38%) subacute, 7 (0.34%) late, and 1 (0.05%) very late stent thromboses. Another 4 (0.19%) out of 8 late or very late stent thromboses developed at 4, 31, 130, and 198 days after clopidogrel discontinuation, respectively, while the other 4 stent thromboses occurred during treatment with clopidogrel. The occurrence of Academic Research Consortium definite or probable stent thromboses was 0.58% (12 of 2,063). Further details are shown in Table 4.

Univariate analyses showed that male sex (odds ratio [OR]: 2.508, 95% confidence interval [CI]: 1.173 to 5.359; \( p = 0.007 \)), acute MI within 24 h (OR: 1.895, 95% CI: 1.113 to 3.226; \( p = 0.017 \)), \( \geq 2 \) stents implanted (OR: 2.191, 95% CI: 1.252 to 3.836; \( p = 0.005 \)), and multivessel stenting (OR: 2.426, 95% CI: 1.421 to 4.139; \( p = 0.001 \)) were predictors of MACE.

### Angiographic outcomes

Angiographic follow-up was completed in 974 (31.6%) lesions from 653 (31.7%) patients. Quantitative coronary angiography results at baseline, after the procedure, and at follow-up are shown in Table 5. In-stent and -segment late lumen loss were \( 0.21 \pm 0.39 \) mm and \( 0.21 \pm 0.35 \) mm, respectively. Binary restenosis rates were 3.8% in-stent and 6.7% in-segment.

### Discussion

The present study, to our knowledge, is the first post-marketing, multicenter registry of a biodegradable polymer-based SES. The results indicate that, although 80.5% of discharged patients received only 6 months or even shorter periods of dual antiplatelet treatment, the safety profile of this novel DES when used in real-world practice is satisfactory with low rates of MACE, overall stent thrombosis, and late stent thrombosis.

It has been widely accepted that DES can effectively reduce the need for TLR. However, several recent studies have suggested that first-generation DES can delay local

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**Table 2. Angiographic and Procedural Characteristics**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Count (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivessel stenting</td>
<td>558 (26.9)</td>
</tr>
<tr>
<td>Off-label use</td>
<td>1,756 (84.5)</td>
</tr>
<tr>
<td>No. of target vessels</td>
<td>2,717</td>
</tr>
<tr>
<td>No. of target lesions</td>
<td>3,080</td>
</tr>
<tr>
<td>Average reference vessel diameter, mm</td>
<td>3.0 ± 0.46</td>
</tr>
<tr>
<td>Average lesion length, mm</td>
<td>22.3 ± 13.1</td>
</tr>
<tr>
<td>Average diameter stenosis, %</td>
<td>87.0 ± 11.3</td>
</tr>
</tbody>
</table>

**Procedural features**

- Total stent no.                      3,748
- No. of stents per patient            1.8 ± 1.1
- Average stent diameter, mm           3.05 ± 0.44
- Average stent length, mm             26.7 ± 13.0
- Direct stenting                      1,965 (52.4)
- Overlapping stents                   658 (17.5)
- Post-dilation                        496 (13.2)
- Intravascular ultrasound guidance    47 (1.3)

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**Table 3. Clinical Outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Count (n = 2,077)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day outcomes</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>16 (0.77)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>13 (0.63)</td>
</tr>
<tr>
<td>Noncardiac</td>
<td>3 (0.14)</td>
</tr>
<tr>
<td>Nonfatal MI</td>
<td>6 (0.29)</td>
</tr>
<tr>
<td>Urgent TLR</td>
<td>4 (0.19)</td>
</tr>
<tr>
<td>MACE</td>
<td>19 (0.91)</td>
</tr>
<tr>
<td>1-year outcomes</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>35 (1.7)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>22 (1.1)</td>
</tr>
<tr>
<td>Noncardiac</td>
<td>13 (0.6)</td>
</tr>
<tr>
<td>Nonfatal MI</td>
<td>8 (0.4)</td>
</tr>
<tr>
<td>TLR</td>
<td>32 (1.6)</td>
</tr>
<tr>
<td>Percutaneous</td>
<td>31 (1.5)</td>
</tr>
<tr>
<td>Surgical</td>
<td>1 (0.05)</td>
</tr>
<tr>
<td>MACE</td>
<td>56 (2.7)</td>
</tr>
<tr>
<td>Non-TLR target vessel revascularization</td>
<td>2 (0.1)</td>
</tr>
<tr>
<td>18-month outcomes</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>39 (1.9)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>23 (1.1)</td>
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</tr>
<tr>
<td>Percutaneous</td>
<td>38 (1.8)</td>
</tr>
<tr>
<td>Surgical</td>
<td>1 (0.05)</td>
</tr>
<tr>
<td>MACE</td>
<td>64 (3.1)</td>
</tr>
<tr>
<td>Non-TLR target vessel revascularization</td>
<td>4 (0.2)</td>
</tr>
</tbody>
</table>

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**Table 4. Lesion and Procedural Features**

- Lesion features
  - Unprotected left main disease: 26 (0.8%
  - Saphenous vein graft: 1 (0.04)
  - Chronic total occlusions: 76 (2.5)
  - Bifurcations: 667 (21.7)
  - Restenotic lesions: 69 (2.2)
  - Reference diameter <2.5 mm: 180 (5.8)
  - Lesion length >20 mm: 1,309 (42.5)
  - B2/C type: 2,049 (66.5)

- Procedural features
  - Total stent no.: 3,748
  - No. of stents per patient: 1.8 ± 1.1
  - Average stent diameter, mm: 3.05 ± 0.44
  - Average stent length, mm: 26.7 ± 13.0
  - Direct stenting: 1,965 (52.4)
  - Overlapping stents: 658 (17.5)
  - Post-dilation: 496 (13.2)
  - Intravascular ultrasound guidance: 47 (1.3)

Data are expressed as mean ± SD or n (%).
vessel healing and increase the risk of potentially fatal late stent thrombosis (5,13–15), an adverse event that may be attributed to the durable polymer coatings of DES (8–11,15–20). Although prolonged dual antiplatelet therapy for at least 1 year after DES implantation was recommended to address the increased risk of late stent thrombosis (21), long-term dual antiplatelet therapy is associated with increased hemorrhagic events, financial burden, variable patient compliance and responsiveness, and other side effects. Therefore, new generation DES with bioabsorbable polymer coatings or even bioabsorbable stent struts have been recently developed. It is anticipated that those stents will result in comparable neointimal hyperplasia inhibition and fewer late complications compared with first-generation DES.

In accordance with the experience with other SES, in this study the Excel stent has efficiently reduced neointima hyperplasia and in-stent restenosis with an average 0.21 mm in-stent late lumen loss and an in-segment binary restenosis rate of 6.7%. The higher mean late lumen loss in the present study as compared with the 0.12 mm in-stent late lumen loss that we had reported for the Excel stent in a single center pilot registry study (22) was likely due to the fact that angiographic follow-up was not mandatory in the present study, which might have led to an increased proportion of clinically driven angiographic follow-up and thus an over-estimated late loss. In the recently published LEADERS (Limus Eluted from A Durable Versus ERodable Stent Coating) trial, a biolimus-eluting stent with abluminal biodegradable PLA polymer coatings has shown a similar late loss when compared with SES with durable polymer (0.13 mm vs. 0.19 mm) (23). Notably, both the present study and the LEADERS trial had enrolled real-world all-comers including more than 80% off-label indications. Those results suggest that a limus-eluting stent with abluminal coated biodegradable PLA polymer is as effective as SES with durable polymer in reducing restenosis. Thus, the potential differences in pharmacokinetic release of the drug between the 2 kinds of DES have not lead to different effects on restenosis prevention.

It is anticipated that the biodegradable PLA polymer coatings in the Excel stent can be fully absorbed within 6 to 9 months and exert few adverse effects on vascular response and endothelialization. We hypothesized that 6-month dual antiplatelet therapy is enough after Excel stent implantation regardless of baseline characteristics. In the present study, 80.5% of discharged patients discontinued clopidogrel treatment within 6 months and the overall occurrence of stent thrombosis was 0.87%; the rate of Academic Research Consortium definite or probable stent thrombosis, in line with the definition of stent thrombosis in previous studies, was 0.58%, which is similar to that in SES randomized trials (range: between 0% and 2.0%) (1,24–27) as well as that in real-world registries (range: between 0.4% and 1.5%) (28–30). After the discontinuation of clopidogrel, the rate of documented stent thrombosis was 0.19% for the present study, which was substantially lower than that reported in the BASKET-LATE (Late Clinical Events Related to Late Stent Thrombosis After Stopping Clopidogrel) study (2.6%) (5). These encouraging results indicate that the

| Table 4. Stent Thrombotic Events at 18-Month Follow-Up |
|--------------------------------|-----------------|-----------------|------------------|-----------|
| Thrombotic Events               | ARC Definite    | ARC Probable    | ARC Possible     | Total     |
| Acute (≤24 h)                   | 1               | 1               | 0                | 2 (0.10)  |
| Subacute (24 h to 30 days)      | 4               | 4               | 0                | 8 (0.38)  |
| Late (30 days to 1 year)        | 2               | 0               | 5                | 7 (0.34)  |
| Very late (>1 year)             | 0               | 0               | 1                | 1 (0.05)  |
| Total                           | 7 (0.34)        | 5 (0.24)        | 6 (0.29)         | 18 (0.87) |

Data are depicted as n (%).

ARC = Academic Research Consortium.
refinement of DES in coating biocompatibility by use of biodegradable PLA coating, such as that present in the Excel stent, might potentially serve as an appealing alternative to minimize the risk of late stent thrombosis, which requires confirmation with randomized trials.

Several pilot studies had demonstrated the feasibility, safety, and efficacy of biodegradable polymer-based DES in selected patients (31–34). However, the validity of extrapolating those results to daily practice had remained uncertain because the follow-up period of most studies were not long enough to elucidate the consequences after completed degradation of a biodegradable polymer. In the present study, the Excel stent has shown sustained excellent clinical outcomes up to 18 months, which suggests the long-term clinical benefits of biodegradable polymer-based SES. However, issues must be addressed about the very low incidence of MACE and stent thrombosis in the present study. First, patients with device failure, which may influence the long-term prognosis, were excluded in the present study. Second, there are now several reports that suggest that the incidence of stent thrombosis is relatively low in Asian populations (30,35,36). The mechanisms of such phenomenon are unclear, but might be associated with genetic specificity. Third, compared with the multicenter e-Cypher registry, the baseline clinical and angiographic characteristics of the present study were less complex, represented as lower incidences of diabetes, history of MI, prior percutaneous coronary intervention, and fewer B2/C type lesions (29). These distinctions between the 2 studies, although both enrolled all-comers, may reflect the different patient cohort and percutaneous coronary intervention indications between China and other countries, which may result in some differences in clinical outcomes. Finally, in comparison with randomized trials, the rate of TLR was lower in the present study, similar to most of the real-world registries, because the angiographic follow-up was not mandatory and there must be some patients with recurrent ischemia who do not undergo repeat intervention for different reasons.

**Study limitations.** The present study is limited by the fact that it is a single arm, nonrandomized study. A head-to-head comparison with other DES are demanded to confirm the efficacy and safety of biodegradable polymer-based SES. Moreover, post-procedure changes in cardiac biochemical marker levels were not subjected to routine surveillance in some participating centers; therefore, non–Q-wave MI might have been underreported. However, most of the underreported MACEs were asymptomatic events that are usually associated with less clinical significance than symptomatic events, suggesting that underreporting of MACEs in the present study exerts limited impact on the conclusions.

**Conclusions**

The outcomes of the present study demonstrate satisfactory efficacy and safety profiles for the Excel biodegradable polymer-based SES in treating patients in real-world settings, with low rates of MACE and stent thrombosis up to 18 months. The outcomes also suggest that 6 months of dual antiplatelet therapy with clopidogrel and aspirin after Excel stent implantation is safe and feasible.

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REFERENCES


Key Words: drug-eluting stents ▪ sirolimus ▪ biodegradable polymer ▪ coronary heart disease.

APPENDIX

For the list of CREATE investigators and participating institutions, please see the online version of this article.