Vascular Responses at Proximal and Distal Edges of Paclitaxel-Eluting Stents
Serial Intravascular Ultrasound Analysis From the TAXUS II Trial

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Background—On the basis of the brachytherapy experience, edge stenosis has been raised as a potential limitation for drug-eluting stents. We used serial intravascular ultrasound (IVUS) to prospectively analyze vessel responses in adjacent reference segments after implantation of polymer-controlled paclitaxel-eluting stents.

Methods and Results—TAXUS II was a randomized, double-blind trial with 2 consecutive patient cohorts that compared slow-release (SR) and moderate-release (MR) paclitaxel-eluting stents with control bare metal stents (BMS). By protocol, all patients had postprocedure and 6-month follow-up IVUS. Quantitative IVUS analysis was performed by an independent core laboratory, blinded to treatment allocation, in 5-mm vessel segments immediately proximal and distal to the stent. Serial IVUS was available for 106 SR, 107 MR, and 214 BMS patients. For all 3 groups, a significant decrease in proximal-edge lumen area was observed at 6 months. The decrease was comparable (by ANOVA, \( P = 0.194 \)) for patients in the SR (\( -0.54 \pm 2.1 \text{ mm}^2 \)) and MR (\( -0.88 \pm 1.9 \text{ mm}^2 \)) groups compared with the BMS (\( -1.02 \pm 1.9 \text{ mm}^2 \)) group. For the distal edge, a significant decrease in lumen area was only observed with BMS (\( -0.91 \pm 2.0 \text{ mm}^2 \), \( P < 0.001 \)); this decrease was significantly attenuated with SR (0.08 \( \pm 2.0 \text{ mm}^2 \)) and MR (\(-0.19 \pm 1.7 \text{ mm}^2 \)) stents (\( P < 0.0001 \) by ANOVA). Negative vessel remodeling was observed at the proximal (\(-0.48 \pm 2.2 \text{ mm}^2 \), \( P = 0.011 \)) but not the distal edges of BMS and at neither edge of SR or MR stents.

Conclusions—The marked reduction in in-stent restenosis with SR or MR stents is not associated with increased edge stenosis at 6-month follow-up IVUS. In fact, compared with BMS, there is instead a significant reduction in late lumen loss at the distal edge with TAXUS stents. (Circulation. 2004;109:627-633.)

Key Words: angioplasty ■ drugs ■ stents ■ ultrasonics
eluting stents. In the initial trials with sirolimus-eluting stents (SES), the FIM trial and RAVEL (Randomized study with the sirolimus-eluting Bx VELOCITY balloon-expandable stent) trials, no edge effect was reported. In the SIRIUS trial (a multicenter study of the SIRolImUS-eluting Bx-velocity stent in the treatment of patients with de novo coronary artery lesions), which evaluated SES in a more complex population than RAVEL, a higher rate of significant (>50% diameter stenosis) stenosis was observed at the proximal edge of the SES than at either the stented region or its distal edge (M.B. Leon, MD, unpublished data, 2002). These observations have prompted renewed concern regarding the issue of “edge” stenosis with drug-eluting stents.

In the TAXUS I trial, no edge restenosis was seen with a slow-release (SR) paclitaxel formulation; however, this was a feasibility study that included only 61 patients. The TAXUS II trial compared 2 consecutive cohorts (SR and moderate-release [MR] polymer formulations of paclitaxel-eluting stents) with control bare metal stents (BMS) and mandated serial intravascular ultrasound (IVUS) examinations, which provided a unique opportunity to obtain detailed information on the outcome at vessel segments adjacent to paclitaxel-eluting stents.

**Methods**

**Patient Selection**

TAXUS II was a randomized, double-blind, controlled trial conducted in 38 centers. Patients were eligible for inclusion if (1) they had stable or unstable angina pectoris or documented silent ischemia and (2) they were scheduled for treatment of a single significant (>50% stenosis on visual assessment) de novo target lesion in a native coronary artery that could be treated with a single stent (3.0 or 3.5 mm in diameter and 15 mm long). Major exclusion criteria were total vessel occlusion (TIMI grade 0 to 1) before intervention, intervention for evolving myocardial infarction, significant (>50% diameter stenosis) unprotected left main coronary artery stenosis, ostial location of the target lesion, lesion calcification that precluded successful predilation, angiographic evidence of thrombus within the target lesion, left ventricular ejection fraction <30%, or intolerance to aspirin or clopidogrel. The current IVUS substudy included patients who received 1 study stent and underwent serial IVUS examination after the procedure and at 6-month follow-up. The study was reviewed and approved by each participating institution’s Ethics Review Committee, and written informed consent was obtained from all patients.

**TAXUS (Paclitaxel-Eluting) Stent System**

The stent used in the present study was the NIR Conformer stent (Boston Scientific Corporation and Medinol Ltd). The control BMS was an uncoated steel stent (NIRx, Boston Scientific). The TAXUS NIRx stent was coated with proprietary polymer (Translute) designed to control paclitaxel release with an initial burst phase for ~10 days. All TAXUS stents were coated with paclitaxel (total loaded dose of 1.0 μg/mm²). Two paclitaxel-eluting release formulations were evaluated (SR and MR), with an 8-fold higher release rate for the MR formulation in the first 48 hours. All stents were 15 mm long and 3.0 or 3.5 mm in diameter on 20-mm balloon delivery catheters.

**Study Design and Procedure**

To evaluate the safety and performance of the TAXUS NIRx stent, patients in 2 sequential cohorts were randomized (1:1 ratio), after successful predilation, to receive either the TAXUS or a control NIRx BMS. In cohort 1, patients were randomized to SR or BMS. In cohort 2, patients were randomized to MR or BMS.

Stents were deployed at 10 to 16 atm, and postdilation was performed as necessary to achieve a residual stenosis below 20%. Heparin was administered in intravenous boluses to maintain an activated clotting time >250 seconds for the duration of the procedure and was discontinued within 12 hours. Administration of aspirin (at least 100 mg) was begun 12 hours before the procedure and was continued indefinitely. A loading dose of clopidogrel (300 mg) was administered, preferably 48 hours before the procedure, followed by 75 mg once daily for 6 months.

**Quantitative IVUS and Angiographic Analysis**

Serial IVUS (after the procedure and at 6-month follow-up) procedures were performed after administration of 200 μg of intracoronary nitroglycerin, with an automated pullback at 0.5 mm/s. All IVUS procedures were recorded on VHS videotapes, and images were digitized for analysis. A computer-based contour detection was performed with QURAD QCU analysis software (Curad BV, Wijk Bij Duurstede) for 3D reconstruction, as described elsewhere. In the quantitative analysis of the edge segments, the vessel segments beginning 5 mm distal to and extending 5 mm proximal to the stented segment were examined. When calcification with acoustic shadowing or side branches were located in the 5-mm segment proximal or distal to the stent, the external elastic membrane contours were not analyzable, which reduced the length of analysis to <5 mm in these segments.

To clarify the mechanism of possible edge responses to drug elution at different distances from the stent struts, we also performed IVUS analysis for each 1-mm subsegment and for the entire 5-mm edge segments. Therefore, both proximal and distal vessel segments were further divided into 1-mm subsegments and numbered from 1 (nearest the stent) to 5. For each subsegment, vessel, lumen, and plaque areas were calculated from each available cross-sectional slice (up to 50 slices/mm²) obtained after digitization of the videotapes and were expressed as mean values. Area changes (Δ values) for each measurement were calculated as follow-up minus postprocedure value. To eliminate the influence of vessel size, percent change [Δ area/postprocedure area × 100] was also calculated. The quantitative ultrasound and coronary angiographic analyses were performed by an independent core laboratory that remains blind to treatment allocation during follow-up (Cardialysis).

**Statistical Analysis**

The BMS groups of the 2 cohorts were combined because the baseline and 6-month follow-up data showed no significant differences, as described previously. Therefore, 3 groups are reported in the present study: the combined BMS, the TAXUS-SR, and the TAXUS-MR groups. Discrete variables are given as percentages and were tested with Fisher’s exact test. Continuous variables are expressed as mean±SD. Changes for each measurement were calculated as follow-up minus postprocedure values. When the 3 groups were compared, overall probability values were derived from 1-way ANOVA. Comparisons between postprocedure and 6-month follow-up values were performed with a 2-tailed paired t test, whereas comparisons between 2 groups were performed with Fisher’s least significant difference test. A value of P<0.05 was considered statistically significant.

**Results**

Overall, 536 patients, (270 BMS, 135 MR, and 131 SR) were randomized in the TAXUS II trial. IVUS edge analysis could not be performed either in part or in all of the predefined 5-mm edge segments in some patients (n=162) for 1 or more of the following reasons: incomplete image acquisition (23%), inadequate image quality (9%), or the presence of major side branches (68%). Of the 536 patients, 427 with 1 stent and paired IVUS edge analyses (214 BMS, 106 SR, and 107 MR) entered in this substudy. Baseline clinical, demo-
graphic, and angiographic characteristics were similar among BMS, SR, and MR groups (Table 1). Serial IVUS was available for the proximal edge in 161 BMS, 84 SR, and 84 MR patients and for the distal edge in 191 BMS, 97 SR, and 98 MR patients.

Mean Changes Within the Entire 5-mm Section at Proximal and Distal Edges

Mean vessel area, plaque area, and lumen area of the entire 5-mm edge segment (proximal and distal) were comparable, with no statistically significant differences between the 3 groups immediately after the procedure (baseline) or during the 6-month follow-up (Tables 2 and 3). At the proximal edge, only the control group showed significant constrictive vascular remodeling, with a decrease in mean vessel area of the entire proximal edge from baseline to follow-up ($P<0.011$), whereas neither the SR or MR groups showed any differences (SR, $P=0.689$; MR, $P=0.87.82$). With a comparably significant increase in mean plaque area in all 3 groups, this still translated into a significant decrease in mean lumen area in all 3 groups (Figure 1).

At the distal edge, the mean plaque and vessel area remained comparable among all 3 groups. However, the lumen area of the entire distal edge decreased in the control group, whereas it increased in the SR and MR groups. With a comparable increase in mean plaque area in all 3 groups, this translated into a significant decrease in mean lumen area in the control group compared with a stable lumen area in both the SR and MR groups (Figure 1).

Analyses of the vascular response at the proximal or distal edges of the stent in the 3 groups (BMS, MR, and SR) were also performed for patients who underwent postdilation of the stent and for those who exhibited an early or late malapposition of the stent. No level of statistical significance could be detected between groups with and without postdilation, with or without malapposition. Changes in EEM volume and area, lumen volume and area, and plaque volume and area at the proximal and distal edges of the stent were not statistically different between the MR and SR groups.

Subsegmental Analysis of Longitudinal Changes at 5-mm Edge Segment of Proximal and Distal Edges

In a per-segment analysis that analyzed 5 consecutive 1-mm segments adjacent to the stent, vascular remodeling proximal to the SR and MR stents differed within the first 1-mm subsegment. Although vessel area, plaque area, and lumen area did not differ between the different segments and different groups at baseline, positive vascular remodeling, reflected by an increase in vessel area, was more pronounced...
within this first subsegment in the SR and MR groups than in the control group \((P=0.0052; \text{Figure } 2)\). Together with a comparable increase in plaque area in all 3 groups, this resulted in significantly less lumen area loss in the SR and MR groups \((-0.55 \pm 2.1 \text{ and } -0.78 \pm 2.0 \text{ mm}^2\) than in the control group \((-1.42 \pm 2.2 \text{ mm}^2, P=0.0055)\). Beyond the first proximal segment, the change in lumen area, plaque area, and vessel area did not differ significantly between the SR, MR, and control groups (Figure 2).

At the distal edge, the beneficial effect of SR and MR stents on change in lumen area was evident on all 5 1-mm subsegments distal to the stent. The comparable decrease in plaque area in the first 2 subsegments in all 3 groups was balanced in the SR and MR groups by positive vascular remodeling, reflected by an increase in vessel size. This resulted in stable lumen area in all subsegments in both SR and MR patients, whereas the control group exhibited a significant decrease along all 5 subsegments of the distal edge \((P<0.001 \text{ versus SR and MR})\).

### Difference Between Proximal and Distal Edges

There were no significant differences between proximal and distal edges with respect to percentage changes in either vessel or plaque area among groups. However, although there were no significant differences in percent lumen area change between proximal and distal edges with the BMS \((-9.6\% \text{ versus } -8.9\%, \text{ respectively, } P=0.91)\), for TAXUS stents, a significant decrease in lumen area at the proximal compared with the distal edges was seen in both the MR \((-7.6\% \text{ versus } 0.04\%, \text{ respectively, } P=0.01)\) and SR \((-4.4\% \text{ versus } 3.1\%, \text{ respectively, } P=0.03)\) groups.

### Discussion

In the present study, we evaluated the behavior of vessel segments adjacent to polymer-controlled SR and MR paclitaxel-eluting stents (TAXUS) by serial IVUS. The major finding of the study was that the use of TAXUS stents was not associated with a significant increase in edge stenosis compared with BMS. Indeed, the luminal area at the distal edge of

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### TABLE 2. Serial IVUS Results of Proximal Edge

<table>
<thead>
<tr>
<th>Proximal Edge</th>
<th>Control (BMS) ((n=161))</th>
<th>Taxus-SR ((n=82))</th>
<th>Taxus-MR ((n=85))</th>
<th>Overall (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessel area, mm(^2)</td>
<td>16.9±4.3</td>
<td>16.8±4.8</td>
<td>16.6±4.0</td>
<td>0.82</td>
</tr>
<tr>
<td>Postprocedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-Month follow-up</td>
<td>16.4±4.2</td>
<td>16.9±4.5</td>
<td>16.5±4.0</td>
<td>0.70</td>
</tr>
<tr>
<td>(P)</td>
<td>&lt;0.01</td>
<td>0.689</td>
<td>0.782</td>
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<tr>
<td>Plaque area, mm(^2)</td>
<td>7.7±2.9</td>
<td>7.6±2.9</td>
<td>7.5±2.7</td>
<td>0.81</td>
</tr>
<tr>
<td>Postprocedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-Month follow-up</td>
<td>8.2±2.9</td>
<td>8.2±2.9</td>
<td>8.3±2.9</td>
<td>0.97</td>
</tr>
<tr>
<td>(P)</td>
<td>&lt;0.0005</td>
<td>&lt;0.0005</td>
<td>&lt;0.0005</td>
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</tr>
<tr>
<td>Lumen area, mm(^2)</td>
<td>9.2±3.0</td>
<td>9.2±2.9</td>
<td>9.1±2.6</td>
<td>0.93</td>
</tr>
<tr>
<td>Postprocedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-Month follow-up</td>
<td>8.3±2.9</td>
<td>8.7±3.0</td>
<td>8.2±2.4</td>
<td>0.47</td>
</tr>
<tr>
<td>(P)</td>
<td>&lt;0.0001</td>
<td>&lt;0.02</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
</tbody>
</table>

Numbers are mean±SD. \(P=\text{NS for MR vs SR. Overall } P \text{ values are from 1-way ANOVA for continuous variables.}\)

### TABLE 3. Serial IVUS Results of Distal Edge

<table>
<thead>
<tr>
<th>Distal Edge</th>
<th>Control (BMS) ((n=187))</th>
<th>Taxus-SR ((n=94))</th>
<th>Taxus-MR ((n=96))</th>
<th>Overall (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vessel area, mm(^2)</td>
<td>14.7±4.5</td>
<td>14.4±4.3</td>
<td>14.1±4.3</td>
<td>0.54</td>
</tr>
<tr>
<td>Postprocedure</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6-Month follow-up</td>
<td>14.5±4.3</td>
<td>14.8±4.5</td>
<td>14.4±4.1</td>
<td>0.74</td>
</tr>
<tr>
<td>(P)</td>
<td>0.115</td>
<td>0.064</td>
<td>0.103</td>
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</tr>
<tr>
<td>Plaque area, mm(^2)</td>
<td>6.3±3.1</td>
<td>6.1±2.8</td>
<td>5.8±2.7</td>
<td>0.45</td>
</tr>
<tr>
<td>Postprocedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-Month follow-up</td>
<td>6.9±3.0</td>
<td>6.4±2.7</td>
<td>6.3±2.7</td>
<td>0.14</td>
</tr>
<tr>
<td>(P)</td>
<td>&lt;0.0001</td>
<td>0.073</td>
<td>&lt;0.02</td>
<td></td>
</tr>
<tr>
<td>Lumen area, mm(^2)</td>
<td>8.4±2.9</td>
<td>8.4±2.7</td>
<td>8.3±3.0</td>
<td>0.88</td>
</tr>
<tr>
<td>Postprocedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-Month follow-up</td>
<td>7.6±2.8</td>
<td>8.4±2.9</td>
<td>8.0±2.8</td>
<td>0.05</td>
</tr>
<tr>
<td>(P)</td>
<td>&lt;0.0001</td>
<td>0.767</td>
<td>0.190</td>
<td></td>
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</tbody>
</table>

Numbers are mean±SD. \(P=\text{NS for MR vs SR. Overall } P \text{ values are from 1-way ANOVA for continuous variables.}\)
TAXUS stents was significantly greater than that of BMS at follow-up owing to the occurrence of positive vascular remodeling.

**Edge Effects and Restenosis**

The inevitable arterial injury due to balloon deployment of a stent coupled with the presence of a metallic foreign body causes inflammatory and proliferative responses. Animal studies have shown that this results in neointimal hyperplasia not only within the stent but also at the edges, in the adjacent reference segments. In the present study, the correlations between intrastent neointimal area and change in proximal/distal plaque area were investigated separately for all 3 groups. The statistical analysis showed that the intrastent neointimal area was correlated with the distal plaque area in each group and correlated with the proximal plaque area in the MR and control groups but failed to be significant in the SR group. These relationships would suggest that the vascular responses at the proximal and distal edges reflect a global responsiveness of the vessel to the degree of neointimal inhibition induced by the drug with both eluting formulations.

The concerns regarding edge effects with a drug-eluting stent reflect potential similarities between the effects of radioactive stents and those of drug-eluting stents, such as local inhibition of neointimal growth and delayed endothelial healing. In patients treated with radioactive stents, edge stenosis has proved to be an important clinical problem, occurring in 30% of patients. TAXUS II confirmed that no edge effect greater than that found with a BMS occurs with either MR or SR paclitaxel-eluting stents. As reported previously, the term "edge effect" is used to connote an effect greater than would be seen with BMS. In fact, there was a slight but nonsignificant decrease in edge stenosis compared with BMS. Edge stenosis (diameter stenosis >50%) rates for BMS were 3.4% (proximal) and 3.1% (distal), whereas for the SR and MR groups, the rates were 1.6% and 2.3% at the proximal and distal edges, respectively.

In sirolimus-eluting stent trials, no edge stenosis was reported in the FIM and RAVEL trials. However, in the SIRIUS trial, which included patients with more complex lesions than either the RAVEL or TAXUS II trials, edge stenoses, which were more frequently observed at the proximal than at the distal edges and in smaller (<3 mm) vessels, occurred in 5.8% of patients, although the in-stent restenosis rate (3.2%) was similar to that in TAXUS II.

![Figure 1](image.png)

*Figure 1.* Averaged area changes (follow-up minus postprocedure) for entire 5-mm edge segment in lumen, plaque, and vessel at proximal and distal edge segments. *P*<0.05, †*P*<0.0005 by 1-way ANOVA.

![Figure 2](image.png)

*Figure 2.* Every 1-mm mean area change (follow-up minus postprocedure) in lumen, plaque, and vessel at proximal and distal edge subsegments. *P*<0.05, †*P*<0.01 by 1-way ANOVA; ‡*P*=0.0052, BMS vs SR.
Remodeling in Segments Adjacent to the Stent: Insights From IVUS

Previous serial IVUS studies reported that significant lumen loss occurs at the proximal segment after BMS implantation. However, there is controversy as to the mechanism(s) involved. Hoffmann et al2 and Weissman et al20 reported that this luminal loss was predominantly related to negative remodeling, whereas Mudra et al1 suggested that it was related to an increase in plaque burden. In the present study, both BMS and TAXUS stents showed a significant decrease in lumen area in the proximal reference segment at follow-up. Whereas this was due to both negative remodeling and plaque increase in BMS, it was related to plaque increase without significant vessel remodeling in TAXUS stents. Subsegment analysis for BMS demonstrated that in the 2 mm proximal to the stent, lumen loss was exclusively due to plaque increase, whereas more proximally, it reflected both plaque increase and negative remodeling. With TAXUS stents, lumen loss was significantly less than for BMS. This was due to the fact that plaque increase was compensated by positive remodeling. However, there was no statistical argument to suggest the superiority of one eluting formulation over the other.

Previous studies regarding distal edge behavior in BMS have produced conflicting results. Mudra et al1 reported no significant lumen loss or negative remodeling in the 3 mm distal to BMS edges, whereas Weissman et al20 reported discordant results showing significant lumen loss throughout the distal reference segment. In the present study, BMS demonstrated significant lumen loss in the distal reference segment without negative remodeling. In detailed subsegment analyses, we demonstrated that lumen loss in the 2 mm distal to the stent edge was related to plaque increase, in accordance with the results of Weissman et al.20

In contrast to BMS, TAXUS stents were associated with a beneficial effect on the distal reference segment, where no significant lumen narrowing was observed at follow-up. The subsegment analysis showed that this reflects the fact that positive vascular remodeling compensated for the increase in plaque burden in the reference segment immediately (<2 mm) adjacent to the stent. Possible reasons for the beneficial effects of the drug at the distal edge and for the difference between the behavior of proximal and distal edge segments include higher downstream concentrations of the drug or the relatively smaller distal vessel size.

Previous Drug-Eluting Stent Trials

The IVUS findings in TAXUS II are consistent both with the quantitative angiographic results reported in TAXUS I and II (Table 1) and with the results of the sirolimus-eluting stent trials, all of which showed a decrease in lumen loss, compared with BMS, at the distal edge of the stent. Only 2 studies (Honda et al,21 and the ASian Paclitaxel-Eluting Stent Clinical Trial [ASPECT]22) reported serial IVUS edge analysis in small numbers of patients. In the ASPECT study,22 there were no significant changes at either edge, whereas in the study by Honda et al21 there was significant lumen loss at the distal edge. This observation in the latter study is contrary to the findings of the present study. We have recently evaluated edge responses after SES by serial IVUS in a subset of RAVEL and FIM patients and found no significant changes between implantation and follow-up at either proximal or distal edges in any of the parameters studied.

Study Limitations

Patients included in the present study had simple de novo coronary lesion and low-risk profiles, which reflects the inclusion criteria of the TAXUS II trial. The study results cannot be extrapolated to more complex coronary lesions. Furthermore, the follow-up period is relatively short, and no conclusions can be drawn regarding ultimate long-term behavior at the stent edges.

Conclusions

These results suggest that concerns regarding edge stenosis with TAXUS-eluting stents are unfounded. Indeed, compared with BMS, TAXUS stents appear to have a significant protective effect against distal edge “restenosis” compared with BMS. A similar trend was noted for the proximal edge. These effects were observed with both SR and MR formulations.

Acknowledgment

We would like to thank Eugene McFadden, MB, ChB, for his critical review in preparing this manuscript.

References

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Circulation. 2004;109:627-633
doi: 10.1161/01.CIR.0000112566.87022.32
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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