Randomized clinical trial

Randomized trial of two types of gastrojejunostomy after pancreatoduodenectomy and risk of delayed gastric emptying (PAUDA trial)

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Background: Delayed gastric emptying (DGE) is the most important cause of an extended hospital stay after pancreatoduodenectomy. Reports suggest that a Roux-en-Y gastroenteric anastomosis may have lower incidence of DGE than a Billroth II reconstruction. The primary aim of this RCT was to compare Billroth II (single loop) and Roux-en-Y (double loop) after pancreatoduodenectomy to determine whether Roux-en-Y reconstruction is associated with a lower incidence of DGE. Secondary endpoints were postoperative complications.

Methods: This was a randomized unblinded single-centre trial without masked evaluation of the main outcome. Patients undergoing pancreatoduodenectomy between 2013 and 2015 were randomized to undergo one of two types of gastroenteric anastomosis for reconstruction.

Results: A total of 80 patients were randomized, 40 in each group. The incidence of DGE was the same in patients undergoing Billroth II or Roux-en-Y gastroenteric anastomosis (both 18 of 40 patients; P = 1.000). The grade of DGE was also similar in the Billroth II and Roux-en-Y groups (grade A, both 10 of 40; grade B, 5 of 40 versus 6 of 40; grade C, 3 of 40 versus 2 of 40; P = 0.962). The mortality rate was 3 per cent, with no significant difference between the two groups. There were no differences in the overall rate of postoperative morbidity, relaparotomy rate or duration of hospital stay.

Conclusion: The incidence and severity of DGE does not differ between single- or double-loop gastroenteric anastomosis performed after pancreatoduodenectomy. Registration number: NCT00915863 (http://www.clinicaltrials.gov).

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Introduction

Delayed gastric emptying (DGE) continues to be one of the most frequent complications after pancreateoduodenectomy, with rates varying from 13.5 per cent to more than 40 per cent1–4. Technical approaches in the resection phase of pancreatoduodenectomy, such as the performance of standard Whipple versus pylorus-preserving pancreateoduodenectomy5, extension of lymphadenectomy6 or division of the left gastric vein7, have been investigated as putative risk factors for DGE. Likewise, several modifications to the surgical procedure in the reconstruction phase have been proposed to reduce DGE after pancreatoduodenectomy. These include an antecolic route of gastroenteric anastomosis8,9, Billroth I reconstruction for the gastroenteric anastomosis10, Braun enterenterostomy11 and the use of staples12. Furthermore, Roux-en-Y (double-loop) reconstruction has been proposed to isolate the pancreateojunostomy13,14 and the gastroenteric anastomosis15–17. In theory, this could help to decrease the severity of pancreatic leakage as well as DGE. However, only one RCT18 has compared Billroth II with Roux-en-Y reconstruction of the gastroenteric anastomosis after pancreatoduodenectomy. This study showed that the DGE rate was higher with the use of Roux-en-Y reconstruction18. A meta-analysis19 of the use of Roux-en-Y reconstruction, based on only three studies of either pancreateojunostomy13,14 or a gastroenteric anastomosis18 after pancreateoduodenectomy, was confusing.
Type of gastrojejunostomy after pancreatoduodenectomy and risk of delayed gastric emptying

Fig. 1 Schematic diagram of Billroth II reconstruction after pancreatoduodenectomy. The three anastomoses were made in the same loop, beginning with pancreatojejunostomy, followed by hepaticojejunostomy and ending with gastroenteric anastomosis. The distance between the hepaticojejunostomy and gastroenteric anastomosis was 60 cm.

Fig. 2 Schematic diagram of Roux-en-Y reconstruction after pancreatoduodenectomy. The pancreatojejunostomy and the hepaticojejunostomy were made in the same loop. A second loop was made to perform the gastroenteric anastomosis. The distance between the hepaticojejunostomy and enteroenteric anastomosis was 60 cm, and that between the gastroenteric anastomosis and enteroenteric anastomosis was 30 cm.

Some have suggested that reconstruction with a double-loop Roux-en-Y could favour digestive transit by separating the pancreatic and gastric sutures. Thus, the delay in starting an oral diet in patients with a pancreatic fistula and Roux-en-Y reconstruction could, in theory, be prevented.

The authors decided to compare Billroth II with Roux-en-Y reconstruction after pancreatoduodenectomy (Figs 1 and 2). The primary aim of this RCT was to determine whether Roux-en-Y reconstruction is associated with a lower incidence and severity of DGE. Secondary endpoints were postoperative complications, postoperative mortality and duration of hospital stay.

Methods

The study protocol was approved by the Ethical Scientific Research Committee (PR135/12BIS), is registered in the ClinicalTrials.gov international registry (PAUDA Trial; NCT02246205), complies with the principles of the Declaration of Helsinki, and is reported according to the CONSORT guidelines.

Study design and inclusion criteria

This was a single-centre, unblinded RCT. The main hypothesis of the study was that Roux-en-Y reconstruction of the gastroenteric anastomosis after pancreatoduodenectomy reduces the incidence of DGE.

The study included patients who underwent surgical resection of the head of the pancreas at the Hospital Universitari de Bellvitge from March 2013 to March 2015. Adults of either sex aged over 18 years were included. The exclusion criteria were: associated resections of other organs, except for the portal or superior mesenteric vein; total pancreatectomy; previous gastrectomy; neoadjuvant treatment; and liver cirrhosis.
Randomization

Patients were selected by the surgical team and provided informed consent to participate in the study. Patients were assigned randomly to one of two groups according to the gastroenteric anastomosis approach used. The control group included patients undergoing pancreateoduodenectomy with single-loop reconstruction or Billroth II, whereas the study group included patients undergoing pancreateoduodenectomy and double-loop reconstruction or Roux-en-Y.

A computer-generated randomization list was developed by a statistical consultant (Bellvitge Biomedical Research Institute) using simple randomization and a 1:1 randomization ratio. The surgical approach was assigned by the opening of a sealed, opaque sequentially numbered envelope by a blinded assistant. This was done after pancreatic head resection and just before starting reconstruction, as described in another study. The timing of randomization was selected to diminish other bias. The number of patients with an uncompleted pancreateoduodenectomy because of intraoperative findings such as liver metastasis was reduced. Other intraoperative findings may require a change in the previous surgical plan and the need for total pancreatectomy owing to an affected margin. In this way, concealment of the sequence was maintained.

Blinding

This was an unblinded study in which the patient and the surgeon knew which type of reconstruction the patient received. A blinded third-party evaluation of the primary endpoint was not done.

Surgical technique

The resection technique has been described previously. All patients underwent resection with curative intent, comprising pancreateoduodenectomy with standard lymphadenectomy and antrectomy.

In all patients, a duct-to-mucosa pancreatojejunostomy was the first choice. Patients in the control group underwent Billroth II reconstruction. Pancreatic, biliary and gastric anastomoses were performed in the same intestinal loop. The gastroenteric anastomosis was created 30 cm from the gastroenteric anastomosis to the foot of the loop, and a distance of 60 cm from the hepaticojejunal anastomosis to the foot of the loop (Fig. 2). In both groups, two drains were placed close to the pancreateojunal suture and one posterior to the hepaticojejunal suture (Bellovac, Wellspect, Health Care, Möndal, Sweden).

Surgical team

All interventions were undertaken by a team of surgeons with experience in hepatobiliary and pancreatic surgery who perform about 80 pancreatic resections annually. The six authors are surgeons, and all contributed to the trial. Five are staff surgeons with special dedication to hepatobiliary surgery and liver transplantation, and three have more than 15 years of experience. At least one of the latter three was always present at the interventions.

Postoperative management

Antiemetic treatment during the hospital stay included intravenous ondansetron (4 mg per 8 h) and intravenous metoclopramide (10 mg per 8 h) in patients who developed nausea. The decision to administer one or two antiemetic drugs was made by the anaesthetist during the first 24 h after surgery and the surgical team thereafter, depending on the symptoms in each patient. The nasogastric tube was clamped 24 h after surgery, and withdrawn at 48 h in the absence of nausea or vomiting. The introduction and progression of oral diet were individualized for each patient. Analgesia during the first 48 h included intravenous metamizole (2 g per 8 h) and intravenous paracetamol (1 g per 8 h). Rescue analgesia comprised subcutaneous or intravenous morphine by means of patient-controlled analgesia (PCA), at a dose of 0.5 mg per bolus with a 5-min lock-out to a maximum dose of 24 mg in 4 h. If nausea was difficult to control, doses of dexketoprofen were administered promptly. After 48 h, the standard analgesic schedule following PCA withdrawal included metamizole (2 g per 8 h) and paracetamol (1 g per 8 h), both intravenously. Patients who required rescue analgesia received 10 mg subcutaneous morphine. The antiemetic and analgesic schedules were identical in both groups.

Follow-up

Clinical follow-up of all patients was carried out by the same team of surgeons. No diagnostic test was scheduled routinely during the postoperative period, but a radiological or endoscopic study was performed in the event of grade B or C DGE. Amylase in the drain fluid was determined.
on the first and third days after operation. The drains were removed when amylase levels were less than threefold those in blood. None of the patients received erythromycin or somatostatin.\textsuperscript{23,24}

Follow-up comprised scheduled outpatient visits to the operating surgeon in the perioperative period. All patients visited twice during the first 90 days: in the first week after discharge and in the second or third month. Readmissions and morbidity at 90 days after surgery were recorded.

**Study endpoints and definitions**

The primary endpoint was the incidence and severity of DGE. Secondary endpoints were postoperative morbidity and mortality, and length of hospital stay. The emergence of DGE and other postoperative complications was identified by consensus by the surgical team after the daily visit.

DGE was defined by intolerance of oral diet from the seventh day after operation and the persistent need for a nasogastric tube on day 4 or later, according to the International Study Group of Pancreatic Surgery (ISGPS) criteria.\textsuperscript{1,2} The grade of DGE was defined as A, B or C, depending on the day of oral diet initiation or withdrawal of the nasogastric tube.

A narrow pancreatic duct was defined as that with a diameter of less than or equal to 3 mm. A pancreatic fistula was defined by outflow of amylase-rich drainage fluid from the third postoperative day, and classified according to the International Study Group for Pancreatic Fistula.\textsuperscript{25}

Postoperative morbidity encompassed the appearance of any complication during the hospital stay. Postoperative complications and postoperative mortality were defined according to the Clavien–Dindo classification.\textsuperscript{26}

Perioperative mortality was defined as death during the same hospital admission or within 90 days after surgery if the patient was discharged earlier. Readmissions during the first 90 days after surgery were registered.

**Statistical analysis**

A randomized pilot study comparing two reconstruction techniques was proposed, taking into account the uncertainty of estimating the incidence of DGE with the use of Roux-en-Y reconstruction within the setting of a randomized study with a population similar to the present one. The sample size calculation was based on the incidence
Table 1 Preoperative demographic and characteristics of the patients

<table>
<thead>
<tr>
<th></th>
<th>All patients (n = 80)</th>
<th>Billroth II (n = 40)</th>
<th>Roux-en-Y (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)*</td>
<td>66 (11-3)</td>
<td>65 (10-9)</td>
<td>68 (11-7)</td>
</tr>
<tr>
<td>Sex ratio (M:F)</td>
<td>48:32</td>
<td>24:16</td>
<td>24:16</td>
</tr>
<tr>
<td>BMI (kg/m²)*</td>
<td>26 (5-6)</td>
<td>26 (5-6)</td>
<td>26 (4-6)</td>
</tr>
<tr>
<td>Co-morbidity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>16 (20)</td>
<td>7 (18)</td>
<td>9 (23)</td>
</tr>
<tr>
<td>Arterial hypertension</td>
<td>37 (46)</td>
<td>14 (35)</td>
<td>23 (58)</td>
</tr>
<tr>
<td>Dyslipidaemia</td>
<td>26 (33)</td>
<td>11 (28)</td>
<td>15 (38)</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>12 (15)</td>
<td>7 (18)</td>
<td>5 (13)</td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>9 (11)</td>
<td>5 (13)</td>
<td>4 (10)</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>3 (4)</td>
<td>1 (3)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Cause of obstructive jaundice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pancreatic ductal adenocarcinoma</td>
<td>51 (64)</td>
<td>27 (68)</td>
<td>24 (60)</td>
</tr>
<tr>
<td>Distal bile duct carcinoma</td>
<td>8 (10)</td>
<td>3 (8)</td>
<td>5 (13)</td>
</tr>
<tr>
<td>Ampullary adenocarcinoma</td>
<td>15 (19)</td>
<td>9 (23)</td>
<td>6 (15)</td>
</tr>
<tr>
<td>Duodenal adenocarcinoma</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Intraductal papillary mucinous neoplasm</td>
<td>3 (4)</td>
<td>0 (0)</td>
<td>3 (8)</td>
</tr>
<tr>
<td>Pancreatic neuroendocrine tumour</td>
<td>2 (3)</td>
<td>1 (3)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Biochemical values</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Preoperative albumin (g/l)*</td>
<td>36 (4-5-3)</td>
<td>36 (4-4-1)</td>
<td>36 (4-6-4)</td>
</tr>
<tr>
<td>Preoperative bilirubin (μmol/l)*</td>
<td>116 (131)</td>
<td>113 (117)</td>
<td>119 (146)</td>
</tr>
<tr>
<td>Preoperative creatinine (μmol/l)*</td>
<td>73 (21)</td>
<td>71 (18)</td>
<td>75 (23)</td>
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<tr>
<td>Preoperative haemoglobin (g/l)*</td>
<td>12 (3-7)</td>
<td>12 (1-1-4)</td>
<td>12-7 (5-2)</td>
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<tr>
<td>Preoperative CA19.9 (kunits/l)*</td>
<td>522 (1158)</td>
<td>339 (689)</td>
<td>701 (1467)</td>
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<tr>
<td>Perioperative values</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perioperative transfusion (within 48 h)</td>
<td>26 (33)</td>
<td>10 (25)</td>
<td>16 (40)</td>
</tr>
<tr>
<td>Venous resection</td>
<td>9 (11)</td>
<td>3 (8)</td>
<td>6 (15)</td>
</tr>
<tr>
<td>Wirsung diameter &lt; 3 mm</td>
<td>32 (40)</td>
<td>15 (38)</td>
<td>17 (43)</td>
</tr>
<tr>
<td>Duct-to-mucosa pancreatojejunostomy</td>
<td>78 (98)</td>
<td>40 (100)</td>
<td>38 (95)</td>
</tr>
<tr>
<td>Intraoperative hypotension arterial pressure &lt; 60 mmHg</td>
<td>4 (5)</td>
<td>3 (8)</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Duration of operation (min)*</td>
<td>419 (87)</td>
<td>405 (88)</td>
<td>431 (85)</td>
</tr>
</tbody>
</table>

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). Percentages may not add up owing to rounding. CA, carbohydrate antigen.

of DGE after pancreatoduodenectomy. Based on previous studies3, the incidence of DGE after single-loop reconstruction was taken as 0.39. An analysis of unpublished data carried out before the present study showed the incidence of DGE in the authors’ setting to be 0.40. Based on other series4,7 and according to feasibility criteria, an incidence of DGE of 0.1 was sought in the Roux-en-Y group. To detect a reduction in the incidence of DGE of 0.29 in the Roux-en-Y group, based on a two-sided test with an α error of 0.05 and a statistical power of 0.80, and allowing for a dropout of 20 percent, it was calculated that 40 patients would be required in each group.

Data were encrypted and stored in a database created with Microsoft Access® (Microsoft, Redmond, Washington, USA). Continuous variables are reported as mean(s.d.). Data were analysed according to intention to treat. The χ² test or Fisher’s exact test was used for analysis of categorical variables and the Mann–Whitney U test for continuous variables. P < 0.050 was considered statistically significant. Statistical analyses were performed using SPSS® software version 18 (IBM, Armonk, New York, USA).

Results

The flow chart for the trial is shown in Fig. 3. Follow-up was closed in April 2015, 2 months after the discharge of the last patient included in the study. One patient in the Roux-en-Y group developed cardiogenic shock and intraoperative haemodynamic instability after randomization, requiring completion of the intervention with Billroth II reconstruction. This patient was analysed in the Roux-en-Y group, according to the intention-to-treat principle. Clinical data for patients included in the study are summarized in Table 1. With regard to surgery, perioperative transfusion was performed in one-third of the patients, and the duration of operation was approximately 7 h.

Delayed gastric emptying and postoperative outcomes

The overall incidence and grades of DGE were similar in the two groups (Table 2). Postoperative analgesia included metamizole and paracetamol with rescue PCA.
in 55 per cent of the patients. Dexketoprofen was added to this schedule in 40 per cent of patients, whereas 5 per cent did not receive PCA during the first few postoperative days. There were no differences in analgesic schedules between the study groups. A total of 56 patients (70 per cent) developed complications, and 23 per cent had complications of Clavien grade IIIa or higher. There was no difference in overall morbidity between groups. Five patients (6 per cent) were reoperated, three in the Billroth II group and two in the Roux-en-Y group. The postoperative mortality rate was 3 per cent (2 deaths in the Roux-en-Y group). One death was due to sudden massive intestinal ischaemia during the first week after reintervention, with no evidence of anastomotic dehiscence or intra-abdominal infection; this patient remained with a nasogastric tube throughout the postoperative period, and was considered to have DGE. The other patient died from respiratory superinfection 3 months after surgery without any severe intra-abdominal complications. Four patients (2 in each group) were readmitted before day 90 after surgery. Reasons for readmission were intra-abdominal abscess in three patients and colitis in one.

Factors related to delayed gastric emptying

Hypoalbuminaemia (albumin level less than 35 g/l) and hyperbilirubinaemia (bilirubin level over 200 μmol/l) were more frequent in patients who developed DGE: 18 of 36 versus 11 of 44 (P = 0.036) and 14 of 36 versus eight of 44 (P = 0.039) respectively. Table S1 (supporting information) shows the differences between patients with and without DGE.

Discussion

In this randomized trial, the type of gastrojejunostomy reconstruction after pancreatoduodenectomy did not influence the frequency of DGE or any other postoperative complications.

One of the most frequent complications after pancreatoduodenectomy is DGE. The aetiopathogenesis of this complication has been studied extensively, but no single cause has been identified. Numerous technical modifications have been proposed to reduce DGE, based on the magnitude of gastroduodenal resection, such as...
pancreatoduodenectomy with pyloric preservation\textsuperscript{29}, pancreatectoduodenectomy with pyloric ring resection\textsuperscript{17,30}, and pancreatectoduodenectomy with subtotal gastric preservation\textsuperscript{11}. Despite the proposed technical modifications, none has demonstrated clear superiority in reducing DGE after pancreatectoduodenectomy. The most commonly used technique is a single-loop reconstruction, or procedure in which the pancreatojejunostomy anastomosis, hepaticojejunostomy anastomosis and, finally, the gastroenteric anastomosis with a Billroth II reconstruction are performed sequentially\textsuperscript{32–34}. Numerous studies have described modifications in the reconstruction to reduce the incidence of DGE. Some favour a terminal–terminal gastroenteric anastomosis to Billroth I\textsuperscript{10,11,35}. Others incorporate an enteroenteric anastomosis to the omega of Braun\textsuperscript{11}. However, these studies were performed with few patients or had poor methodology. Others propose the preparation of an isolated Roux-en-Y loop for the pancreatojejunostomy\textsuperscript{36}. Some even suggest reconstructing the intestine in a single loop but starting with the gastric anastomosis, followed by the pancreatic anastomosis and ending with the biliary anastomosis\textsuperscript{35}. Thus, the reconstruction approach following pancreatectoduodenectomy remains controversial among pancreatic surgeons.

Recently, it has been proposed that preparation of the gastroenteric anastomosis with Roux-en-Y following pancreatectoduodenectomy should be done separately from the pancreatojejunostomy\textsuperscript{12,18,37}. According to some authors\textsuperscript{12,15,17,18}, a Roux-en-Y gastroenteric anastomosis contributes to a lower incidence of DGE. In a review of previous reports, Murakami and colleagues\textsuperscript{15} compared Billroth I with Roux-en-Y reconstruction after pancreatectoduodenectomy, and multivariable analysis demonstrated a lower rate of DGE after Roux-en-Y reconstruction. However, they used pancreatogastrostomy as the pancreatic anastomosis, making it difficult to compare their results with those of the present study. On multivariable analysis, Sakamoto and colleagues\textsuperscript{12,16} demonstrated less DGE in the Roux-en-Y group with use of mechanical sutures. However, these authors described three different ways of doing the gastroenteric anastomosis, with the addition of Braun enteroenterostomy in the reconstruction. Barakat et al.\textsuperscript{17} also reported a lower incidence of DGE for Roux-en-Y compared with Billroth II reconstruction (10 \textit{versus} 57 per cent respectively). However, the two groups may not have been well matched because the Roux-en-Y group received erythromycin more frequently during the postoperative course and the gastric resection was not the same in both groups; antrectomy was performed in the Billroth II group and pyloric ring resection in the Roux-en-Y group.

Only one previous randomized study\textsuperscript{18} compared Roux-en-Y with Billroth II reconstruction after pancreatectoduodenectomy, with preservation of most of the stomach. The patients were randomized to undergo Billroth II (52 patients) or Roux-en-Y (49) reconstruction. The nasogastric tube was retained for 5–7 days after surgery, and all patients underwent an upper gastrointestinal imaging series from postoperative days 5 to 7. According to the definition proposed by the ISGPS in 2007, grade A DGE is defined by the need for a nasogastric tube for 4 days or more, or nasogastric tube reinsertion on day 3 after surgery, or the inability to tolerate a solid diet by postoperative day 7. Because routine institutional policy at the time of the study was to leave the nasogastric tube in place for at least 5 days after surgery, it is probable that no patients were diagnosed with grade A DGE, and the incidence of DGE in both groups is therefore likely to have been underestimated. Shimoda and colleagues\textsuperscript{18} showed a higher rate of DGE in the group undergoing Roux-en-Y compared with Billroth II reconstruction (20.4 \textit{versus} 5.7 per cent respectively), and the Roux-en-Y group also had a longer hospital stay (41.1 \textit{versus} 31.6 days).

Another difference between the present study and that of Shimoda et al.\textsuperscript{18} is the use of antrectomy here, whereas the Japanese investigators performed a subtotal stomach-preserving pancreatectoduodenectomy, including division of the stomach 2 cm proximal to the pyloric ring. To date, no randomized trial has compared pancreatectoduodenectomy with antrectomy for the two reconstruction techniques used in the present study. As in the Shimoda study\textsuperscript{18}, there was no improvement with Roux-en-Y reconstruction after pancreatectoduodenectomy in the present trial. The rate of DGE was not lower and nor were there fewer postoperative complications. In addition, the postoperative stay was similar in the two groups.

The most relevant limitation of this study was that the surgeons were also responsible for postoperative management of the patients. Masking was not possible because the researchers knew the group into which each patient had been randomized. In view of the results of this study, it does not seem necessary to modify the usual reconstruction performed after pancreatectoduodenectomy because the Roux-en-Y procedure does not provide any added benefit. Evaluation of the effect of biliary reflux on long-term quality of life in patients with single-loop reconstruction after pancreatectoduodenectomy was not done, and may be a further endpoint pursued in future studies.
Disclosure

The authors declare no conflict of interest.

References


Supporting information
Additional supporting information can be found online in the Supporting Information section at the end of the article.