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Comparison of two anastomosis techniques in terms of postoperative pancreatic fistula development: A retrospective cohort study

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Ethics Committee Approval
The study was approved by Haydarpasa Numune Training and Research Hospital Ethics Committee approved the study protocol (Date: 05.03.2021, Number: HNEAH KAEK 2021/KK/49). All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Postoperative pancreatic fistula (POPF) development is a common complication after pancreaticoduodenectomy. Various surgical anastomosis techniques have been proposed to mitigate this risk. This study compares two techniques: the two-layer duct-to-mucosa pancreaticojejunostomy (TLPJ) and the modified layer-to-layer end-to-side duct-to-mucosa pancreaticojejunostomy with jejunal serosa resection (MLLPJ).

Methods: A retrospective cohort study was conducted on patients who underwent pancreaticoduodenectomy between January 2012 and December 2020. The primary outcome was the rate of biochemical leak and clinically relevant POPF (grades B and C POPFs).

Results: The rate of biochemical leak was significantly higher in the TLPJ group than in the MLLPJ group (54.5% vs. 4.0%, $P<0.001$). Clinically relevant POPFs developed in 5.2% of all patients, with rates of 6.1% in the TLPJ group and 4.0% in the MLLPJ group. Patients with longer surgery durations, increased bleeding, and a soft pancreas texture had significantly higher risk of developing clinically relevant POPFs ($P=0.009$, $P=0.039$, and $P=0.022$, respectively).

Conclusion: The MLLPJ anastomosis technique demonstrated a significant reduction in biochemical leak rates. However, the choice between TLPJ and MLLPJ did not significantly impact the rates of clinically relevant POPFs. Other factors, such as surgery duration, bleeding volume, and pancreas texture, were identified as significant risk factors for the development of these fistulas.

Keywords: pancreaticoduodenectomy, pancreaticojejunostomy, pancreatic fistula, postoperative complications, jejunum, serosa

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Introduction

Pancreatic cancer is the fourth leading cause of cancer-related deaths in developed countries [1]. Surgical resection is the primary treatment method in operable pancreatic cancer patients. The operative mortality related to pancreaticoduodenectomy (PD) has been reduced to below 3% as a result of improved surgical techniques, new technologies, and increased surgical experience [2]. Nevertheless, the rate of patients who develop a postoperative pancreatic fistula (POPF) after PD is still above 10%. Up to 40% mortality rates have been reported, depending on the severity of POPF [2,3].

According to the International Study Group of Pancreatic Fistula (ISGPF), three times more drain amylase levels than serum amylase levels on the third postoperative day [4] indicate POPF. POPF, graded as A in the older version of the ISGPF guidelines, has been redefined as a biochemical leak in the updated guidelines. Thus, POPFs are currently categorized as either Grade B or C. The incidence of POPF reported in the literature varies considerably based on the different definitions of POPF [3,4]. Therefore, the incidence rate of clinically relevant POPFs needs to be revised.

Narrow pancreatic duct (<3 mm) and soft pancreatic tissue, which are among the risk factors for the development of POPF, have been studied extensively [5,6]. It has been speculated that technical modifications, including external stenting of the pancreatic duct, pancreatico-jejunal or pancreatico-gastric anastomosis, and reinforcement of the anastomosis via several materials, might reduce POPF rates compared to the use of only two-layer end-to-side duct-to-mucosal pancreaticojejunostomy (TLPJ) [7,8]. Nevertheless, the use of techniques or modifications, such as the Blumgart method with one to six transpancreatic jejunal seromuscular U-sutures, modified Kakita anastomosis with two to eight nonabsorbable interrupted penetrating sutures between the pancreatic stump and jejunal seromuscular layer, two-layer duct-to-mucosa anastomosis with resection of jejunal serosa (layer-to-layer PJ), and modified layer-to-layer PJ (MLLPJ), resulted in controversial outcomes [7,9–14]. Several studies have proposed that MLLPJ might be an effective way to reduce the rates of POPF [10,12].

In light of the preceding evidence, this study aimed to compare the efficacies of TLPJ and MLLPJ in terms of the rate of POPF after PD and determine the risk factors associated with the development of clinically relevant POPFs.

Materials and methods

Population and sample

The population of this retrospective cohort study consisted of 186 patients who underwent PD with the diagnosis of a benign or malignant pancreatic tumor at Haydarpaşa Numune Training and Research Hospital between January 2012 and December 2020. Patients with neoadjuvant chemoradiotherapy (n=20) and incomplete medical data (n=108) were excluded from the study. In the end, 58 patients were included in the study sample. The patients were divided into two groups based on the type of PF anastomosis technique, i.e., TLPJ or MLLPJ, performed by two different surgical teams. Accordingly, 33 (56.9%) and 25 (43.1%) patients who were operated on using the TLPJ and MLLPJ techniques constituted TLPJ and MLLPJ groups, respectively.

The Haydarpasa Numune Training and Research Hospital Ethics Committee approved the study protocol (date: 05.03.2021; number: HNEAH KAEK 2021/KK/49). The study was performed in accordance with the principles set forth in the Declaration of Helsinki. Written informed consent could not be acquired from the patients due to the study's retrospective design and the data's anonymity.

Data collection

Patients' demographic characteristics, intraoperative findings, pathological diagnoses, postoperative morbidities, including biochemical leak, Grades B and C POPFs, intra-abdominal abscess, intra-abdominal bleeding, and delayed gastric emptying, and 90-day mortality rates were obtained from the medical files of the patients and the hospital information system.

We diagnosed biochemical leak, Grades B and C POPFs, based on the 2016 ISGPF criteria [4].

The pancreatic duct size was measured using images from preoperative radiological examinations. The hardness of the pancreatic tissue, which is categorized as either hard or soft, was determined intraoperatively.

Patients with high total bilirubin values received preoperative drainage with endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography (PTC), as well as biliary stenting, where necessary.

Surgical procedure

In Group TLPJ, the jejunal serosa and pancreatic capsule were sutured intermittently with 4/0 polydioxanone (PDS) without resection of the serosa, and duct-to-mucosa anastomosis was performed with 4/0 PDS [8]. Conversely, in Group MLLPJ, a segment of the jejunal serosa smaller than the surface of the pancreas was excised using a scalpel, allowing the pancreas to invaginate into the small intestine, with surgeons taking care not to open the mucosa. After the posterior wall was sutured with 4/0 PDS, the jejunal mucosa was opened from the section corresponding to the level of the duct. A duct-to-mucosa anastomosis was performed with four to six individual sutures with 4/0 PDS. The anastomosis was completed by ensuring that the jejunum serosa and pancreatic capsule were more inverted, employing intermittent sutures with 4/0 PDS on the anterior side [10].

In both anastomosis groups, a silicone internal stent was placed in the pancreatic duct. Choledochojejunostomy and gastrojejunostomy were performed to conduct Roux-Y anastomosis as described previously [8,10].

Postoperative follow-up

A standard follow-up procedure was applied to all patients. Feeding was started early in patients who did not have gastric emptying problems. Somatostatin was started in patients with a narrow pancreatic duct (<3 mm), soft pancreatic tissue, or high drain amylase levels. A lasting need for nasogastric decompression by the tenth postoperative day or the inability to tolerate oral intake was considered a delay in gastric emptying [15].

Postoperative complications were classified according to the Clavien-Dindo staging system [16]. In order to follow the development of POPF, serum amylase levels on the first and third postoperative days and drain amylase levels on the third postoperative day were checked.

Statistical analysis

The study's primary outcome was the incidence of the biochemical leak and Grade B and Grade C POPFs, whereas the study's secondary outcome was the risk factors with an impact on the development of clinically relevant POPFs (Grades B and C).

For descriptive statistics, mean (standard deviation) was used to present continuous data with normal distribution. Median with minimum-maximum values was applied for continuous variables without normal distribution. Numbers and percentages were used for categorical variables. The Shapiro-Wilk, Kolmogorov-Smirnov, and Anderson-Darling tests analyzed the normal distribution of the numerical variables.

The Independent Samples t-test compared two independent groups in which numerical variables had a normal distribution. For the variables without normal distribution, the Mann-Whitney U test was used to compare two independent groups. The Pearson Chi-Square and Fisher's Exact tests were used to compare the differences between categorical variables in 2x2 tables. The Fisher-Freeman-Halton test was used in RxC tables.

For statistical analysis, Jamovi (Version 2.2.5.0) and JASP (Version 0.16.1) were used. The significance level (*P*-value) was determined at 0.05 in all statistical analyses.

Results

The age and gender distribution of the patients in Groups TLPJ and MLLPW were similar (*P*=0.986 and *P*=0.279, respectively). The comparison of preoperative and postoperative clinical findings revealed no significant difference between the groups (*P*>0.05 for all comparisons) (Table 1). The median duration of surgery was 315 and 300 min in Groups TLPJ and MLLPJ, respectively (*P*=0.641). The pancreatic duct width and the proportion of patients with soft pancreas were similar between the groups (*P*=0.879 and *P*=0.287, respectively). Adenocarcinoma was the most common diagnosis in both groups (75.8% in Group TLPJ and 76.0% in Group MLLPJ). There was no significant difference between the groups in the frequencies of the pathological diagnoses (*P*=0.287). Other characteristics of the patients are summarized in Table 1.

There was a significant difference between the groups in the rates of patients with a biochemical leak and different POPF grades (*P*<0.001). The rate of patients with biochemical leak was 54.5% in Group TLPJ and 4.0% in Group MLLPJ. There was one (3.0%) patient with Grade B POPF in Group TLPJ and one with Grade C POPF in each group (3.0% in Group TLPF and 4.0% in Group MLLPJ). The rate of patients who developed clinically relevant POPFs, either Grade B or C, was 6.1% and 4.0% in Groups TLPJ and MLLPJ, respectively (*P*=0.999). The distribution of other postoperative complications, except for gastric paresis, was similar between the groups (*P*>0.05 for all comparisons). The incidence of gastric paresis was significantly higher in Group TLPJ than in Group MLLPJ (*P*=0.022). There was a significant difference between the groups in terms of grades of surgical complications as determined by the Clavien-Dindo classification system (*P*=0.008). The length of hospitalization was significantly shorter in Group MLLPJ than in Group TLPJ (*P*=0.002). The 30-day and 90-day mortality rates were similar between the groups (*P*=0.999 and *P*=0.687, respectively) (Table 2).

Table 1: Distribution of demographic and clinical characteristics by the anastomosis technique.

	Groups		
	TLPJ (n=33)	**MLLPJ (n=25)**	***P*-value**
Sex †			
Female	15 (45.5)	7 (28)	0.279[c]
Male	18 (54.5)	18 (72)	
Age (year) ‡	62.8 (14.2)	62.9 (12.0)	0.986[a]
BMI (kg/m^2) ‡	28.9 (6.2)	30.7 (5.1)	0.228[a]
Comorbidities †	24 (72.7)	18 (72.0)	0.999[c]
ASA stages †			
1	2 (6.1)	3 (12)	0.698[c]
2	23 (69.7)	14 (56)	
3	6 (18.2)	6 (24)	
4	2 (6.1)	2 (8)	
Biliary drainage method †			
ERCP	6 (28.6)	8 (57.1)	0.181[c]
PTC	15 (71.4)	6 (42.9)	
Biliary stenting †	6 (18.2)	8 (34.8)	0.272[c]
Duration of surgery (min) §	315 (180–540)	300 (235–480)	0.641[b]
Amount of bleeding (ml) §	600 (50–1600)	450 (200–2000)	0.819[b]
Pancreatic duct width (mm) §	4 (2–10)	4 (2–15)	0.879[b]
Structure of pancreatic tissue †			
Soft	12 (36.4)	5 (20)	0.287[c]
Hard	21 (63.6)	20 (80)	
Pathological diagnosis †			
Adenocarcinoma	25 (75.8)	19 (76.0)	0.287[c]
Neuroendocrine tumor	3 (9.1)	3 (12.0)	
Chronic Pancreatitis	0 (0)	3 (12.0)	
Other	5 (15.2)	0 (0)	
TNM Stage †			
1B	3 (10.7)	3 (13.6)	0.752[c]
2A	4 (14.3)	5 (22.7)	
2B	18 (64.3)	11 (50)	
3	3 (10.7)	3 (13.6)	

†: n (%), ‡: mean (standard deviation), §: median (min-max), [a] Independent Samples T-Test, [b] Mann-Whitney U test, [c] Pearson Chi-Square/Fisher's Exact test/Fisher Freeman Halton test, TLPJ: two-layered end-to-side duct-to-mucosal pancreaticojejunostomy, MLLPJ: modified layer-to-layer pancreaticojejunostomy, BMI: body mass index, ASA: American Society of Anesthesiologists, ERCP: endoscopic retrograde cholangiopancreatography, PTC: percutaneous cholangiopancreatography.

Table 2: Distribution of postoperative findings in the groups based on the anastomosis technique.

	Groups		
	TLPJ (n=33)	**MLLPJ (n=25)**	***P*-value**
Postoperative third day drain amylase level (IU/mL) §	558 (5–32865)	29 (4–15748)	0.001[b]
POPF Grades †			
Biochemical leak	18 (54.5)	1 (4.0)	<0.001[c]
POPF Grade B	1 (3.0)	0 (0)	
POPF Grade C	1 (3.0)	1 (4.0)	
Patients with clinically relevant POPF	2 (6.1)	1 (4.0)	0.999[c]
Biliary fistula †	3 (9.1)	0 (0)	0.251[c]
Gastric paresis †	16 (48.5)	4 (16.0)	0.022[c]
Intraabdominal abscess †	3 (9.1)	1 (4.0)	0.627[c]
Bleeding †	3 (9.1	1 (4.0)	0.627[c]
Wound infection †	11 (33.3)	8 (32.0)	0.999[c]
Clavien-Dindo grades †			
1	3 (12)	7 (63.6)	0.008[c]
2	16 (64)	2 (18.2)	
3	4 (16)	1 (9.1)	
5	2 (8)	1 (9.1)	
Length of hospital stay §	16 (8–60)	11 (7–20)	0.002[b]
30-day mortality †	2 (6.1)	2 (8.0)	0.999[c]
90-day mortality †	5 (15.2)	2 (8.0)	0.687[c]

†: n (%), §: median (min-max), [b] Mann-Whitney U test, [c] Pearson Chi-Square/Fisher's Exact test/Fisher Freeman Halton test, TLPJ: two-layered end-to-side duct-to-mucosal pancreaticojejunostomy, MLLPJ: modified layer-to-layer pancreaticojejunostomy, POPF: postoperative pancreatic fistula.

There were three (5.2%) patients with clinically relevant POPFs in the entire study group. There was no significant difference between the groups in terms of the demographic and preoperative clinical characteristics of the patients with clinically relevant POPFs (*P*>0.05 for all comparisons) (Table 3). The patients with clinically relevant POPFs had a significantly longer

duration of surgery and a significantly higher amount of bleeding (P=0.009 and P=0.039, respectively). All three patients with clinically relevant POPFs had soft pancreas (P=0.022). There was no significant difference between the groups in other intraoperative and postoperative characteristics (P>0.05 for all comparisons) (Table 3).

Table 3: Distribution of demographic and clinical characteristics in patients with and without clinically relevant fistula.

	Patients		
	Without POPF (n=55)	**With POPF (n=3)**	***P*-value**
Sex †			
Female	20 (36.4)	2 (66.7)	0.551[c]
Male	35 (63.6)	1 (33.3)	
Age (year) ‡	62 (31–93)	67 (59–78)	0.493[b]
BMI (kg/m²) ‡	29.0 (17.5–45.0)	29.6 (28.2–33.0)	0.686[b]
Comorbidities †	39 (70.9)	3 (100.0)	0.554[c]
ASA stages †			
1	5 (9.1)	0 (0.0)	0.999[c]
2	35 (63.6)	2 (66.7)	
3	11 (20.0)	1 (33.3)	
4	4 (7.3)	0 (0.0)	
Biliary drainage method †			
ERCP	13 (39.4)	1 (50.0)	0.999[c]
PTC	20 (60.6)	1 (50.0)	
Biliary stenting †	13 (24.5)	1 (33.3)	0.999[c]
Duration of surgery (min) §	300 (180–540)	480 (420–480)	0.009[b]
Amount of bleeding (ml) §	450 (50–2000)	1050.0 (800–1700)	0.039[b]
Pancreatic duct width (mm) §	4 (2–150)	3 (3-3)	0.333[b]
Structure of pancreatic tissue †			
Soft	14 (25.5)	3 (100)	0.022[c]
Hard	41 (74.5)	0 (0)	
Anastomosis type			
TLPJ	31 (56.4)	2 (66.7)	0.999[c]
MLLPJ	24 (43.6)	1 (33.3)	
Pathological diagnosis †			
Adenocarcinoma	42 (76.4)	2 (66.7)	0.571[c]
Neuroendocrine tumor	5 (9.1)	1 (33.3)	
Chronic Pancreatitis	3 (5.5)	0 (0)	
Other	5 (15.2)	0 (0)	
TNM Stage †			
1B	5 (10.6)	1 (33.3)	0.619[c]
2A	9 (19.1)	0 (0.0)	
2B	27 (57.4)	2 (66.7)	
3	6 (12.8)	0 (0.0)	

†: n (%), ‡: mean standard deviation, §: median (min-max), b Mann-Whitney U test, c Pearson Chi-Square/Fisher's Exact test/Fisher Freeman Halton test, POPF: postoperative pancreatic fistula, BMI: body mass index, ASA: American Society of Anesthesiologists, ERCP: endoscopic retrograde cholangiopancreatography, PTC: percutaneous cholangiopancreatography, TLPJ: two-layered end-to-side duct-to-mucosal pancreaticojejunostomy, MLLPJ: modified layer-to-layer pancreaticojejunostomy.

In addition, there were significant differences between the groups in the postoperative clinical findings of the patients with clinically relevant POPFs. Accordingly, the rates of gastric paresis, intra-abdominal abscess, and wound infection were significantly higher in patients with POPF than those without POPF (P<0.05 for all comparisons) (Table 4). There were significant differences between the patients with and without POPF in the grades of surgical complications graded according to the Clavien-Dindo classification system, the length of hospital stay, and the 90-day mortality (Table 4).

Table 4: Distribution of postoperative clinical characteristics in patients with and without clinically relevant fistula.

	Patients		
	Without POPF (n=55)	**With POPF (n=3)**	***P*-value**
Biliary fistula †	2 (3.6)	1 (33.3)	0.150[c]
Gastric paresis †	17 (30.9)	3 (100.0)	0.037[c]
Intraabdominal abscess †	2 (3.6)	2 (66.7)	0.011[c]
Bleeding †	3 (5.5)	1 (33.3)	0.196[c]
Wound infection †	16 (29.1)	3 (100.0)	0.031[c]
Clavien-Dindo grades †			
1	10 (30.3)	0 (0.0)	0.012[c]
2	18 (54.5)	0 (0.0)	
3	3 (9.1)	2 (66.7)	
5	2 (6.1)	1 (33.3)	
Length of hospital stay §	14 (7–60)	35 (18–38)	0.025[b]
30-day mortality †	3 (5.5)	1 (33.3)	0.196[c]
90-day mortality †	5 (9.1)	2 (66.7)	0.036[c]

†: n (%), §: median (min-max), [b] Mann-Whitney U test, [c] Pearson Chi-Square/Fisher's Exact test/Fisher Freeman Halton test, POPF: postoperative pancreatic fistula

Discussion

The study findings indicated that the MLLPJ anastomosis technique significantly prevented the development of biochemical leaks. In addition, it was determined that the length of surgery, the amount of bleeding, and the texture of the pancreas were significant risk factors for clinically relevant POPFs. On the other hand, the anastomosis type used—TLPJ or MLLPF—had no impact on the development of clinically relevant POPFs. Therefore, intraoperative findings and pancreatic tissue characteristics seem to have a higher prognostic value in predicting POPF than the technical variances.

Reconstruction in relation to the PD procedure and the effects of reconstruction on the development of POPF are still a matter of debate. Invagination PJ and duct-to-mucosa PJ continue to be the most popular reconstruction procedures. Although each procedure has some advantages and disadvantages, several systematic reviews and meta-analyses failed to show the superiority of either technique [17–19]. In the Pancreatic Anastomosis Audit (PARANOIA) study, the authors reported that invagination PJ, compared to the duct-to-mucosa technique, was associated with reduced rates of all POPF, including biochemical leaks and clinically relevant fistula types [17]. The most recent version of the Cochrane review did not find any significant difference between duct-to-mucosa and invagination PJs in terms of the development of Grade B or C POPFs [18]. Although several studies have reported that the modified Blumgart technique was associated with significantly lower POPF rates [7,9], the Cochrane review reported that the evidence on the superiority of duct-to-mucosa PJ using the modified Blumgart technique was inconclusive [18]. Another study that compared six-stitch PJ and standard PJ determined that six-stitch PJ reduced POPF development by 81.7% and that pancreatic tissue hardness, pancreatic duct size, and anastomosis technique were important risk factors for the development of POPF [20]. Kone et al. [21] compared invagination PJ and duct-to-mucosa PJ techniques and reported that multivariate logistic regression and propensity score analyses did not reveal any significant difference between the two techniques in terms of POPF development rate. Thus, it is still unclear which anastomosis technique has the lowest rate of developing clinically relevant POPFs after PD.

Hayashibe et al. [14], in 2005, were the first researchers to perform the duct-to-mucosa PJ with resection of jejunal serosa (layer-to-layer PJ). This technique did not result in any leakage after PD in any of their consecutive studies [12–14]. They suggested that promoting the vascularization and enhancement of the anastomotic healing process could be possible via the resection of the serosa. This new duct-to-mucosa PJ technique with resection of the jejunal serosa (layer-to-layer PJ) is regarded as a safe, reliable, and favorable anastomosis technique after PD. In 2006, Ibrahim et al. [22] added a new anastomotic layer (triple-layer duct-to-mucosa PJ) to the technique previously described by Hayashibe et al. [14] and found that 1.96% of patients operated on with this modified technique developed POPF. Su et al. [10] abbreviated this modified technique as MLLPJ in an article published in 2014. They performed triple-layer duct-to-mucosa PJ with jejunal serosal resection and found that a significantly higher rate of patients with soft pancreatic

tissue and pancreatic duct diameter <3 mm and patients in whom anastomosis with the TLPJ technique was used developed POPF. Accordingly, they speculated that the partial invagination achieved in the MLLPJ technique reduced the tension over the anastomosis, as there be no dead space around the anastomosis, and that the alignment of the pancreatic stump and the jejunal mucosa might have resulted in better healing. In contrast, the findings of this study did not reveal any significant relationship between the anastomosis type and the development of clinically relevant POPFs. Although the MLLPJ technique resulted in significantly lower rates of biochemical leak compared to the TLPJ technique, this significant difference did not translate into a clinical benefit. Therefore, a definitive conclusion on the superiority of MLLPJ in reducing POPF after PD could not be made.

POPF can lead to severe complications such as delayed gastric emptying, intra-abdominal abscess, and intra-abdominal bleeding [23]. Delayed gastric emptying, which is reported in 19% to 57% of the patients with POPF, is a non-life-threatening morbidity that decreases the quality of life and prolongs hospitalization. It has been reported that delayed gastric emptying can predict complications such as POPF or intra-abdominal abscess [24, 25]. In fact, the incidence of gastric paresis was significantly higher in patients who developed POPF in this study.

Limitations

The most important limitations of this study were its retrospective nature and relatively small sample size. Additionally, the fact that the two surgical techniques investigated within the scope of this study were performed by two different teams might have impacted the results, given the differences between the teams in surgical experience. The size and heterogeneity of the sample and lack of control might have prevented significant differences. The performance of each technique by two different teams might be regarded as a strength of the study, considering the standardized surgical experience. Future large-scale studies are needed to obtain more evident outcomes for the optimum anastomotic technique for pancreaticojejunostomy.

Conclusion

In conclusion, the findings of this study indicated that the use of the MLLPJ anastomosis technique might have prevented the occurrence of biochemical leaks following PD. The length of surgery, the amount of bleeding, and the texture of the pancreas were significant risk factors for the development of clinically relevant POPFs. However, further studies are needed to shed light on the debate about the optimum PJ technique.

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