Surgical Loupes at 5.0× Magnification and the VIO Soft-coagulation System Can Prevent Postoperative Pancreatic Fistula in Duct-to-Mucosa Pancreaticojejunostomy

YO-ICHI YAMASHITA[1,2], YOSHIHIRO YOSHIDA[1], TAKESHI KURIHARA[1], EIJI TSUJITA[2], KAZUKI TAKEISHI[1], TERUYOSHI ISHIDA[2], TETSUO IKEDA[1], YOSHINARI FURUKAWA[3], KEN SHIRABE[1] and YOSHIHIKO MAEHARA[1]

[1]Department of Surgery and Science, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan; Departments of [2]Surgery and [3]Gastroenterology, Hiroshima Red Cross Hospital and Atomic Bomb Survivors Hospital, Hiroshima, Japan

Abstract. *Background/Aim: Postoperative pancreatic fistula (POPF) remains a major complication after pancreaticoduodenectomy (PD). In this study, we examined whether our new method using surgical loupes at 5.0× magnification and the VIO soft coagulation system (SC) for duct-to-mucosa pancreaticojejunostomy (PJ) can prevent POPF. Patients and Methods: A retrospective cohort study was performed in 81 consecutive patients who underwent PD and duct-to-mucosa PJ for periampullary tumors by a single surgeon during a recent 5-year period from 2008 to 2012. These patients were divided into two groups according to the nature of the PJ; the conventional group (n=46) and the 5.0× loupes+SC group (n=35). Short-term surgical results including POPF were compared and an independent risk factor for POPF was identified using the stepwise logistic regression analysis in our series. Results: The rate of Grade B/C POPF was significantly decreased in the 5.0× loupes+SC group (2.9%) compared to that of the conventional group (9.9%, p=0.04). The absence of 5.0× loupes+SC for PJ was identified as the independent risk factor for Grade B/C POPF (odds ratio, 5.23; p-value, 0.03). Conclusion: 5.0× surgical loupes+SC for duct-to-mucosa PJ could be used as a novel technique for preventing POPF after PD.*

Correspondence to: Yo-ichi Yamashita, MD, Ph.D., Department of Surgery and Science, Graduate School of Medical Sciences, Kyushu University, 3-1-1 Maidashi, Higashi-ku, Fukuoka 812-8582, Japan. Tel: +81 926425469, Fax: +81 926425482, e-mail: yamashi@surg2.med.kyushu-u.ac.jp

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Pancreaticoduodenectomy (PD) is a complex procedure but it is the only curative treatment for patients with a localized periampullary tumor. In 1945, Whipple *et al*. reported that PD had a mortality rate over 30% (1). With advances in the surgical management of PD, the recent mortality rate for PD has been reported to be less than 5% (2-4). Despite marked reductions in mortality rates, postoperative pancreatic fistula (POPF) remains one of the most common causes of morbidity occurring in 5%-40% of PD cases, even in the high-volume referral center (4-6). Effective strategies to reduce POPF should, thus, be identified (7).

POPFs occur not only from the leakages from the main pancreatic duct (MPD) but also from branches of the pancreatic ducts (BPDs). To prevent the leakage from the MPD in PD, a duct-to-mucosa anastomosis is recommended (8). In hepatobiliary pancreatic surgery, surgical loupes at 2.5× magnification are most commonly used. However, it has been contended that this magnification does not provide sufficient vision, especially for small MPD, and that better vision would allow for more precise operative techniques (9, 10). Micro-surgery at 12.5× magnification for duct-to-mucosa anastomosis for tiny pancreatic duct (≤3 mm) in PD could reduce the POPF after pancreaticojejunostomy (PJ) (9, 10).

In addition, to prevent leakage from BPDs from the resected pancreatic stump, the application of an electrosurgical device (VIO 300 D; ERBE Elektromedizin, Tübingen, Germany) containing the VIO soft coagulation system (SC) was reported to be effective (11, 12). In this SC, only Joule heat is emitted and the voltage is limited to 200 V, which prevents the development of sparks, carbonization and adhesion of surrounding tissue to the electrode, resulting in a greater degree of coagulation compared to that obtained with conventional electro-surgical coagulation system. In dog experiments, the application of a SC to the pancreatic stump

Table I. *Background characteristics*

Variables	Conventional (n=46)	5.0x loupes and SC (n=35)	*p*-value
Age	66±12	70±9	0.11
Male/Female	21/26	12/23	0.36
Height (cm)	156.4±8.3	155.6±7.2	0.68
Weight (kg)	54.1±10.6	52.2±6.2	0.42
Body mass index	22.0±3.1	21.6±2.7	0.60
Comorbidity (%)	23 (50%)	25 (71%)	0.11
Hypertention (%)	19 (41%)	22 (63%)	0.06
Diabetes mellitus (%)	14 (28%)	6 (8%)	0.86
Cardiac disease (%)	5 (11%)	8 (23%)	0.15
Pulmonary disease (%)	2 (4%)	4 (11%)	0.23
Malignant tumor (%)	41 (89%)	27 (77%)	0.19
Pancreatic cancer (%)	25 (54%)	18 (51%)	0.88

Table II. *Surgical factors*

Variables	Conventional (n=46)	5.0x loupes and SC (n=35)	*p*-value
PD/PPPD/SSPPD	15/14/17	7/8/20	0.15
Diameter of pancreatic duct (mm)	4±2	3±4	0.30
Soft pancreas (%)	18 (39%)	16 (46%)	0.53
Resection of the portal vein (%)	5 (11%)	6 (17%)	0.38
External drainage/ Internal stent for PJ	30/16	20/15	0.46
Operation time (min)	492±90	507±87	0.49
Intraoperative blood loss (g)	951±746	1042±1063	0.67
Transfusion (%)	9 (20%)	8 (23%)	0.90

PD; Pancreaticoduodenectomy, PPPD; pylorus-preserving PD, SSPPD; substomach-preserving PD, PJ; panccreaticojejunostomy.

Table III. *Short-term surgical results*.

Variables	Conventional (n=46)	5.0x loupes and SC(n=35)	*p*-value
Mortality (%)	1 (2.2%)	1 (2.9%)	0.58
Morbidity (%)	12 (26%)	4 (11%)	0.09
Grade B/C POPF (%)	7 (15%)	1 (3%)	0.04
Grade B/C Bile leakage (%)	0 (0%)	0 (0%)	0.99
Grade B/C DGE (%)	3 (7%)	1 (3%)	0.44
SSI (%)	7 (15%)	2 (6%)	0.16
Drain amylase level at 3POD (IU/L)	443±962	226±734	0.16
Duration of hospital stay (days)	27±25	19±13	0.03

POPF; Postoperative pancreatic fistula, DGE; delayed gastric empting, SSI; surgical site infection, POD; postoperative day.

Table IV. *Independent risk factors for Grade B/C POPF*.

Variables	Coefficient/SE	Odds ratio	p-value
5.0xloupes and SC (-)	2.57	5.23	0.03
Soft pancreas	1.26	2.14	0.21
Body mass index≥25	0.76	1.92	0.45
Diameter of pancreatic duct≤3 mm	0.63	1.68	0.57
Intraoperative blood loss≥1000 ml	0.43	1.35	0.97

SE; Standard error.

was able to seal an MPD (diameter 500 μm) and microscopic BPDs in histological examination (11). We recently applied a new method using surgical loupes at 5.0× magnification and a SC for resected pancreatic stump in duct-to-mucosa PJ.

We herein report a series of consecutive patients who underwent PD and duct-to-mucosa PJ for periampullary tumors by a single surgeon. We examined the preventative effect of our new method using 5.0× loupes and a SC for the prevention of POPF in cases of duct-to-mucosa PJ.

Patients and Methods

Patients. From January 2008 to December 2012, 81 PDs for periampullary tumors were performed by a single surgeon (Y.Y.) at the Department of Surgery and Science, Graduate School of Medical Sciences, Kyushu University or at the Department of Surgery, Hiroshima Red Cross and Atomic Bomb Survivors Hospital. All patients undergoing PD had the Eastern Cooperative Oncology Group Performance status 0-2.

Surgical techniques. *En block* conventional PD, pylorus-preserving PD (PPPD) and substomach-preserving PD (SSPPD) with lymph node dissection were performed at the discretion of the surgeon (13-15). PD and SSPPD patients underwent the modified Child reconstruction, while PPPD patients underwent the Traverso reconstruction (16). All PJs were performed by duct-to-mucosa, end-to-side anastomosis with internal or external stent drainage for the pancreatic duct. In 46 patients during a previous period until 2009, surgical loupes at 2.5× magnification (Surgical Telescopes, Looks 2500; Xenosys, Incheon, Korea; Figure 1A) were used during all procedures in PD. Arterial bleeding points from the pancreatic stump, if any, were sealed by Z suturing using 5-0 Proline® (Ethicon, Somerville, NJ, USA) sutures, whereas oozing points, if any, were coagulated with a conventional electrosurgical device.

In 35 patients during a period from around 2010, surgical loupes at 5.0x magnification (Looks 5000; Figure 1B) were used during all procedures in PD. In all cases, a portable surgical light (LED light system, L2S09; Xenosys; Figure 1A, B) was attached to the surgical loupes and used. The whole pancreatic stump was coagulated by gently rubbing an electrode with dropping saline (Monopolar Products DS3.5; Medtronic Advanced Energy, Portsmouth, NH, USA) using a SC (Effect 7 and the maximum output at 80 W;

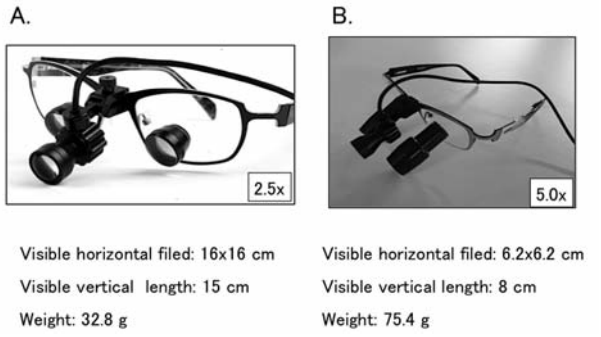

Figure 1. *Surgical loupes at 2.5× magnification (A) and* 5.0× *magnification (B) with a portable surgical light are demonstrated. For the 2.5× magnification versus the* 5.0× *magnification, the visible horizontal fields was 16×16 cm vs. 6.2×6.2 cm, the visible vertical length was 15 cm vs. 8 cm and weight was 32.8 g vs. 75.4 g.*

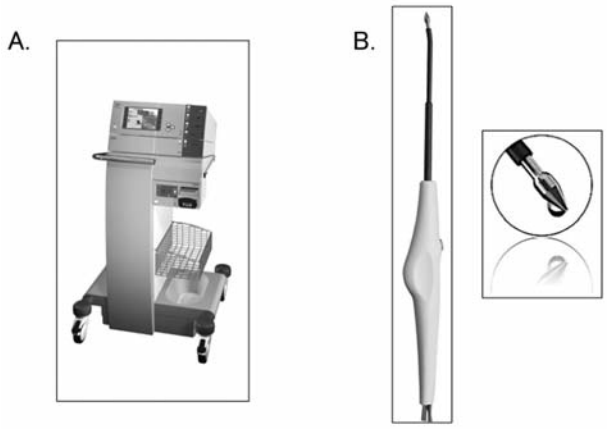

Figure 2. *The electrosurgical device (VIO 300 D) (A) is shown. This device contains the soft coagulation system (SC). The electrode with dropping saline (Monopolar Products DS3.5) (B) is depicted. The electrode in the SC is applied to the stump of the pancreatic parenchyma.*

Figure 2) back and forth on the surface until the entire cut surface turned white. Heavy arterial bleeding was arrested by Z suturing using 5-0 Proline sutures. External suture rows for PJ were created as single- or two layer- sutures between the remnant pancreatic parenchyma and jejunal seromuscular tissue using interrupted sutures with 3-0 Proline® (Ethicon, Somerville, NJ, USA). Internal suture rows for the PJ, duct-to-mucosa, were performed between the pancreatic duct and jejunal mucosa by 8-12 interrupted sutures with 5-0 PDS-II® (Ethicon, Somerville, NJ, USA).

A 4-8 Fr (French gauge) polyvinyl catheter with multiple side holes (MD-41515 pancreatic duct tube; Sumitomo Bakelite, Tokyo, Japan) was inserted as an external drainage stent tube or a internal stent tube in all patients. Then, end-to-side hepaticojejunostomy was performed by 1-layer anastomosis using continuous or interrupted sutures with 5-0 or 6-0 PDS-II at 10 to 15 cm distal from the PJ site. Duodenojejunostomy in PPPD or gastrojejunostomy in PD or SSPPD was performed by 2-layer anastomosis with 4-0 PDS-II and 3-0 silk via the antecolic route at 35 to 45 cm distal from the hepaticojejunostomy site. Thereafter, polyethylene glycolic acid felt (Neoveil® 50×50 mm; Gunze, Kyoto, Japan) and fibrin glue (Bolheal®, The Chemo-Sero-Therapeutic Research Institute, Kumamoto, Japan) were applied to the PJ site. Two 15- or 19-Fr closed drains (J-VAC Suction Reservoir; Johnson and Johnson, Somerville, NJ, USA) were routinely inserted into the Winslow foramen and anterior part of the PJ site.

A 16-Fr nasogastric catheter was inserted intraoperatively and removed from all patients on postoperative day 1. All patients received a proton-pump inhibitor intravenously for postoperative day 3 and orally from postoperative day 4. Routine prophylactic antibiotics were applied intraoperatively and for 2 days postoperatively. Patients were kept nil *per os* for the first two postoperative days, time after which the diet was gradually resumed if there was no evidence of delayed gastric empting (DGE) or POPF. Total parenteral nutrition was used only in patients who could not tolerate an oral diet after postoperative day 5.

Mortality was defined as in-hospital death or death within 30 days of PD. Morbidity was defined according to the Clavian classification and grade 2 or more illness was considered positive (17). We referred to established criteria, grading the pancreatic fistulas by the International Study Group of Pancreatic Fistula (ISGPF) classification (18), grading bile leakage by the International Study Group of Liver Surgery (ISGLS) classification (19) and grading DGE by the International Study Group of Pancreatic Surgery (ISGPS) classification (20).

Statistical analysis. Patients were divided into two groups according to the manner of duct-to-mucosa PJ; the conventional group (n=46) and the 5.0× loupes+SC group (n=35). We compared the patients' background characteristics, surgical factors and short-term surgical results. Continuous variables are expressed as means±standard deviation (SD) and were compared using the Student's *t*-test. Categorical variables were compared using either the χ^2 test or Fisher's exact test, as appropriate. To identify the independent risk factor for Grade B/C POPF, the stepwise logistic regression analysis was applied using 5 factors according to the previous reports (21, 22); soft pancreas, BMI≥25, diameter of pancreatic duct≤3 mm, intraoperative blood loss≥1,000 ml and the absence 5.0× loupes+SC for PJ. All statistical analyses were performed with JMP® Pro 9.0.2 (SAS Institute Inc., Cary, NC, USA). Values of p less than 0.05 were considered significant.

Results

Comparisons of patients' background characteristics. The comparison of the patients' background characteristics is summarized in Table I. There was no significant difference in any of the background characteristics. The mean age was higher (66 years *vs*. 70 years, p=0.11) and the positive rate of comorbidity was higher (50% *vs*. 71%, p=0.11) in the 5.0× loupes+SC group, although not significantly so.

Comparisons of surgical factors. The comparison of the surgical factors is summarized in Table II. There was no

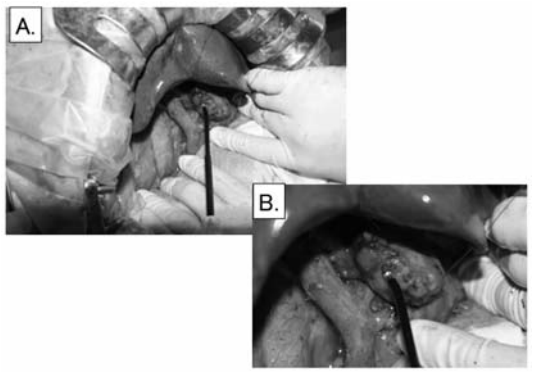

Figure 3. *An actual intraoperative scene applying the SC for the pancreatic stump using an electrode (A, B). The whole pancreatic stump was coagulated by gently rubbing an electrode with dropping saline on it until the cut surface turned white and slightly hard.*

significant difference in any of the surgical factors between the groups. The rate of SSPPD among the performed operations was higher (37% *vs*. 57%, p=0.15) in the 5.0× loupes+SC group, but not statistically so.

Comparisons of short-term surgical results. Our comparison of the short-term surgical results is given in Table III. Surgical mortality occurred in two patients; one due to acute respiratory distress syndrome in the conventional group (2.2%) and one (Child Pugh B liver cirrhosis) due to liver failure in the 5.0× loupes+SC group (2.9%). The rate of mortality did not differ significantly between the two groups (p=0.58). The rate of morbidity-as Clavian grade 2 or more including Grade B/C POPF, bile leakage and DGE and so on-was lower (26% *vs*. 11%) in the 5.0× loupes+SC group, but not significantly so (p=0.09). Grade B/C POPF occurred in 8 patients (9.9%) in our series and 1 patient in the conventional group had a pseudoaneurysm rapture of the stump of gastroduodenal artery requiring trans-arterial embolization of common hepatic artery classified as Grade C. The positive rate of Grade B/C POPF was significantly lower (15% *vs*. 3%, p=0.04) and the mean duration of hospital stay was significantly shortened (27 days *vs*. 19 days, p=0.03) in the 5.0× loupes+SC group.

Independent risk factor for Grade B/C POPF. The results of the stepwise logistic regression analysis are summarized in Table IV. The absence of 5.0× loupes+SC is revealed to be the only independent risk factor for Grade B/C POPF in our series (odds ratio, 5.23; p=0.03).

Discussion

For several decades, dramatic improvements have been observed in the operative results after PD and perioperative mortality has decreased to less than 5% (2-4). However, morbidity remains high at 5%-40% even in high-volume referral centers (4-6). In particular, the development of POPF is a life-threatening complication and a frequent reason for extending the patients' hospital stay. In the current study, we were able to decrease the rate of Grade B/C POPF from 15% to 3% using the 5.0× surgical loupes +SC.

Surgeons have attempted to decrease the development of POPF by devising a variety of techniques, including the type of anastomosis (duct-to-mucosa *vs*. dunking) (23, 24), the site of anastomosis (pancreatico-gastrostomy *vs*. PJ) (25), the administration of somatostatin-like agent octreotide (26), the use of a pancreatic stent (no stent *vs*. internal stent *vs*. external stent) (21, 27, 28) and the application of fibrin glue onto the pancreaticoenteric anastomosis (29). There are many conflicting data and none of these techniques has been clearly effective in reducing POPF.

Better vision would allow for a more precise operative technique and micro-surgery at 12.5× magnification for duct-to-mucosa anastomosis for tiny pancreatic duct (≤3 mm) in PJ was reported to reduce the incidence of POPF (9, 10). The better vision provided by the 5.0× surgical loupes allowed precise techniques for duct-to-mucosa PJ resulting in a significantly lowered incidence of Grade B/C POPF. Of course, the vision provided by 12.5× surgical microscope would be better than that provided by 5.0× surgical loupes but the preparation of the surgical microscope for operative field should be bothersome and time-consuming. In a recent report, hepatic artery reconstruction in living liver transplantation, which was usually done by surgical microscope, could be safely performed by 4.5× surgical loupes with the mean time 10.7 min and the complication rate of hepatic arterial thrombosis as 1.66% (30). Therefore, 5.0x surgical loupes could be an alternative tool for 12.5× surgical microscope against duct-to-mucosa PJ.

Nagakawa *et al*. reported that a SC could seal microscopic pancreatic ducts≤500 μm in a dog model using a burst-pressure test and complete obstructions of pancreatic ducts were confirmed by detailed histological examination (11). In addition, the authors clinically applied a SC for pancreatic stumps in PD for 11 patients and reported that one patient (9.1%) had POPF. One of the serious concerns regarding the application of a SC for pancreatic stumps in PD should be the massive necrosis of the stump of the pancreas parenchyma and this adverse effect would lead to latent POPF (31). Nagakawa *et al*. also reported the uniform coagulation of the stump of pancreatic parenchyma after the application of SC at a depth of approx. 2,000 μm in a dog experiment; regenerative epithelium appeared on the sealed surface on postoperative day 3 and granulation tissue proliferated on postoperative day 5 (11). However, the coagulation area would change according to the status of pancreatic parenchyma, the actual application time and conditions, such as the effect or the maximum output of SC. Therefore, more detailed investigations of the best way to apply a SC for pancreatic parenchyma should be performed using animal experiments.

Berger and colleagues demonstrated the significant differences in the POPF rate after PD between Institutions and surgeons in a randomized controlled trial (24). PDs in our series were performed by a single surgeon during a recent 5-year period and, therefore, confounding biases related to surgical technique might be small compared to other studies. However, our study has two major flaws. First, the patients were not randomized but rather were sequential, consecutive patients. The conventional duct-to- mucosa PJs were performed in the earlier period and 5.0× surgical loupes+SC duct-to- mucosa PJs were performed in the later period. A surgeon gains experience with time and could lower the rate of Grade B/C POPF in accord with the learning curve. This learning curve effect could be one of the possible causes of decreasing Grade B/C POPF in our series.

The results of the present study revealed that the absence of 5.0× loupes+SC is the only independent risk factor for Grade B/C POPF (odds ratio, 5.23; p=0.03). Following the example of previous reports, we included the factors of soft pancreas, BMI≥25, diameter of pancreatic duct≤3 mm and intraoperative blood loss≥1,000 ml in the multivariate analysis in our series (21, 22). The classification of pancreatic texture as soft or hard is relatively subjective and lacks objective criteria. As reported, small pancreatic duct is correlated with soft texture of the pancreas (21). Obesity may affect both the texture of the pancreas and the quality of the PJ because of retroperitoneal peripancreatic visceral fat (32, 33). The difficulty of duct-to-mucosa PJ because of the small pancreatic duct and tears from the sutured site at the pancreatic parenchyma due to soft pancreatic texture would be the major cause of Grade B/C POPF. After the application of the SC for a pancreatic stump in the present study, perhaps due to the coagulation effects, the stump of pancreas became white and relatively hard. This effect would also reduce the pancreas tears of the pancreatic parenchyma from the suture sites.

In conclusion, the use of surgical loupes 5.0× magnification and the application of a SC for the pancreatic stump during duct-to-mucosa PJ should be a novel technique for preventing POPF after PD.

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