

Intraoperative Shear Wave Elastography as a Quantitative Predictor of Pancreatic Fibrosis and Exocrine Function

YUSUKE WADA¹, TAKESHI AOKI¹, AKIRA FUJIMORI¹, NOBUYUKI OHIKE²,
TOMOTAKE KOIZUMI¹, TOMOKAZU KUSANO¹, KAZUHIRO MATSUDA¹, KOJI NOGAKI¹,
YOSHIHIKO TASHIRO¹, TOMOKI HAKOZAKI¹, HIDEKI SHIBATA¹, KODAI TOMIOKA¹,
TAKAHITO HIRAI¹, KAZUHIKO SAITO¹, TATSUYA YAMAZAKI¹ and MASAHIKO MURAKAMI¹

¹Department of Surgery, Division of Gastroenterological Surgery and General Surgery,
Showa University, Tokyo, Japan;

²Department of Pathology, Showa University Fujigaoka Hospital, Kanagawa, Japan

Abstract. *Background/Aim:* Soft pancreatic texture is a risk factor for postoperative pancreatic fistula (POPF). However, conventional evaluation of pancreatic texture is largely dependent on subjective assessment and lacks quantitative parameters. The study aimed to use ultrasonic shear wave elastography (SWE) to evaluate pancreatic stiffness to determine if the intraoperative SWE measurement could be a quantitative predictor for POPF. *Patients and Methods:* Fifteen patients scheduled for pancreaticoduodenectomy were included. Both pre- and intra-operative measurement of the pancreatic SWE index (SWEI) were evaluated. Relationships between intraoperative and preoperative SWEI, pathological fibrosis of the resected pancreatic specimen, postoperative exocrine function of the remnant pancreas, and the incidence of POPF were evaluated. *Results:* The intraoperative SWEI was correlated with the preoperative SWEI, pathological fibrosis of pancreatic tissue, and pancreatic exocrine function. *Conclusion:* Intraoperative SWE measurement of pancreatic elasticity may be useful as a quantitative method for evaluating pancreatic fibrosis and exocrine function.

Postoperative pancreatic fistula (POPF) may cause intra-abdominal abscess or massive hemorrhage leading to prolonged hospitalization and life-threatening complications. Estimating individual risks to prevent POPF greatly helps reduce postoperative complications. Among several factors

Correspondence to: Takeshi Aoki, Department of Surgery, Division of Gastroenterological Surgery and General Surgery, Showa University, 1-5-8, Hatanodai, Shinagawa-ku, Tokyo 142-8555, Japan. Tel: +81 337848541, e-mail: takejp@wb4.so-net.ne.jp

Key Words: Pancreatic texture, pancreatic fibrosis, shear wave elastography.

reported as predictive factors of POPF (1-6), soft pancreatic texture, indicating a preserved exocrine pancreatic function of the remaining pancreas, has been suggested as having a large effect on POPF (1-3), whereas a hard pancreatic parenchyma caused by histological fibrosis that decreases exocrine pancreatic function, has been suggested as a low risk factor of POPF. In general, pancreatic texture is simply assessed by the surgeon's tactile sense during surgery to determine the exocrine pancreatic function. However, this conventional evaluation of pancreatic stiffness is largely subjective and may not always accurately indicate the risk of POPF. Therefore, there is a need for objective parameters to evaluate the stiffness of pancreatic parenchyma in patients undergoing pancreatic resection.

Several ultrasonographic techniques have been developed for the noninvasive evaluation of tissue elasticity. Shear wave elastography (SWE) can estimate the elasticity of a target tissue by measuring the speed of shear waves induced by acoustic radiation force impulse (ARFI) through a focused ultrasound beam. Quantitative parameters of tissue elasticity can be achieved by analyzing the particle displacements measured by wave velocity (m/s) or by direct measurement in the region of interest [ROI, kilopascals (kPa)].

In the field of gastroenterology, clinical use of SWE to assess the degree of liver fibrosis has been reported. Many studies have reported a positive correlation between the ultrasonic elastography evaluations and degree of liver fibrosis (7, 8). Thus, SWE is expected to be an alternative method for the evaluation of tissue fibrosis. On the other hand, few studies have reported the assessment of the clinical use of SWE for the pancreas. A recent cohort study reported that preoperative ARFI imaging could be a predictor of pancreatic fibrosis (9). However, preoperative measurement of SWE is not always appropriate for some patients because it can be greatly affected by the amount of gastrointestinal air covering pancreatic surface and/or patient obesity. To improve this

issue, we focused on intraoperative measurement of SWE that can be obtained by attaching the ultrasonic probe directly to the pancreatic parenchyma during surgery.

The study aimed to evaluate the correlation between intraoperative SWE measurement and the pathological degree of pancreatic fibrosis. The relationships between the intraoperative and preoperative SWE values, postoperative external secretion of the pancreas, and incidence of POPF were also evaluated.

Patients and Methods

Patients. Patients who underwent pancreaticoduodenectomy (PD) between March 2015 and July 2019 were included in the study. Of 84 cases, patients in whom ultrasonography was unavailable because of insufficiency in the ultrasonic device were excluded from the study. From 15 patients, all clinical data were collected retrospectively, and the intraoperative ultrasonic shear wave elasticity index (SWEI) of the pancreas was measured and compared with the preoperative SWEI. Pathological findings of the resected pancreatic specimens, postoperative external secretion of the pancreas, and the incidence of POPF were also compared.

This study was conducted in accordance with the Declaration of Helsinki, and was approved by Showa University Clinical Research Review Board (No.2226). Written informed consent was obtained from all individuals included in the study.

Measurement of pancreatic shear wave elasticity index (SWEI). All ultrasonic SWE were measured by using an Aplio™ 500 (CANON MEDICAL SYSTEMS Corp., Tochigi, Japan) in two different periods during surgery. The preoperative SWEI was measured with the patient under general anesthesia in a supine position. Conventional B-mode pancreatic ultrasonic examinations were performed to identify the pancreatic parenchyma. The SWEI was then measured with the examiner maintaining the probe attached to the body surface without manual compression avoiding any movements until image stabilization. Real-time elastograms were first obtained for a qualitative assessment. Quantitative parameters were then measured within a ROI to determine the parameters identified as the shear wave elasticity index (kPa). The ROI was 10 mm in diameter and placed on the pancreatic body anterior to the bifurcation of the splenic and portal veins. To improve accuracy, the ROI was placed distant from the superior mesenteric artery or the pancreatic tumors (Figure 1a, b). After laparotomy, the intraoperative SWE was also measured in the same procedure with the probe attached perpendicularly and directly to the pancreatic parenchyma (Figure 1c, d). For each patient and each period, five measurements were recorded, and the mean SWEI of the median three values was calculated and used in further analyses. To achieve high reproducibility, only two examiners participated in manipulating the ultrasonic examination.

Surgical procedure. The same PD procedures were performed for all patients. The patients were placed in a supine position under general anesthesia. An electrocautery or ultrasonic device (HARMONIC; Ethicon Endosurgery, New Brunswick, NJ, USA) was used to dissect the pancreatic parenchyma with a scalpel to dissect the main pancreatic duct. Intraoperative ultrasonography was used to identify the tumor location and reconfirm the surgical resection margin prior to pancreatic parenchymal dissection. Digestive reconstruction was

performed according to the modified Child method (10). Two Roux limbs, one for biliary-pancreatic anastomoses and the other for gastro-jejunosotomy were created for digestive reconstruction. For pancreaticojejunostomy, duct-to-mucosa end-to-side anastomosis was performed using interrupted 5-0 absorbable monofilament suture with polyethylene internal stent tube that were guided transhepatically via the choledochojejunal anastomosis. Then, the pancreatic stump and jejunal wall were approximated in one layer with interrupted sutures, as described by Kakita *et al.* (11, 12). A closed 15-Fr. diameter suction drain was placed behind the choledochojejunosotomy and pancreaticojejunostomy through the foramen of Winslow. Another 15-Fr. diameter suction drain was placed in front of the pancreaticojejunostomy.

Pathological evaluation of pancreatic fibrosis. Resected specimens, including the tumor, were fixed in buffered formalin and embedded in paraffin. Pathological tissue samples were stained with hematoxylin and eosin. The resected pancreatic stump identical to the area of SWE measurement was histologically evaluated. For the evaluation of pancreatic fibrosis, the degrees of fibrosis were graded into seven categories (0-6) according to Klöppel's report (13). Both perilobular and intralobular fibrotic scores were separately graded and added for the total score (range=0-12). Pancreatic fibrosis was graded into four categories according to the total score: score 0-3, normal; score 4-6, mild fibrosis; score 7-9, moderate fibrosis; and score 10-12, severe fibrosis (Figure 2). The practiced pathologist evaluated the histological fibrotic scores, blinded to any clinical details or postoperative course.

Evaluation of pancreatic exocrine function. The daily output of pancreatic juice from the pancreatic external drainage tube was recorded as a remnant pancreatic exocrine function. The average daily amount from one to seven postoperative days was calculated and used in further analysis.

Postoperative evaluation. POPF were defined according to the International Study Group on Pancreatic Fistula definition (14).

Statistical analysis. Continuous variables are presented as the median. Categorical variables are expressed as percentages. The correlations of the intraoperative SWEI with the preoperative SWEI, and the daily amount of pancreatic juice were evaluated by performing Spearman's rank correlation test. The difference in median values of each pathological fibrotic grading was evaluated by performing Kruskal-Wallis test. Values of $p < 0.05$ were considered to be indicative of statistical significance. All statistical analyses were performed using JMP version 14 (SAS Institute Inc., Cary, NC, USA).

Results

The patients' characteristics and factors reported to have a large influence on the incidence of POPF are shown in Table I. Each SWEI and postoperative outcomes are presented in Table II. Regarding postoperative complications, three patients (two for Grade A, one for Grade B) developed a POPF. Although not significant, the patients with lower intraoperative SWEI tended to have a higher risk of POPF. Intraoperative SWEI was positively correlated with the preoperative SWEI [Spearman's rank correlation test (ρ)=0.8107, $p < 0.001$] (Figure 3). The

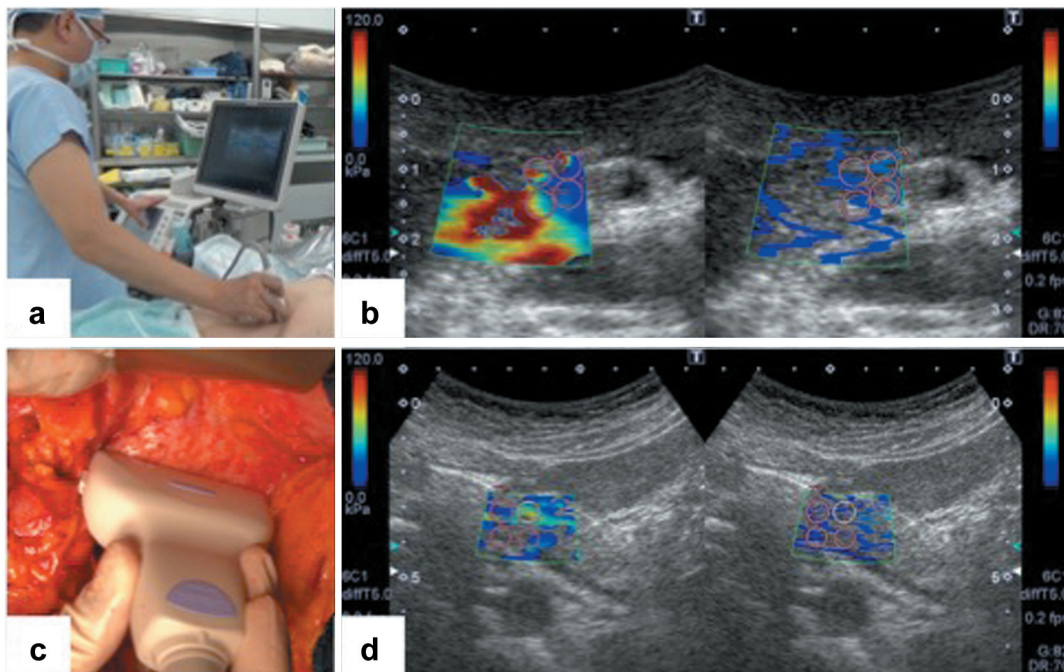


Figure 1. Measurement of pancreatic shear wave elastography (SWE). *a.* Preoperative measurement of SWE from the body surface. *b.* Ultrasonographic findings of preoperative SWE. *c.* Intraoperative measurement of SWE by attaching the probe directly to the pancreatic parenchyma. *d.* Ultrasonographic findings of intraoperative SWE.

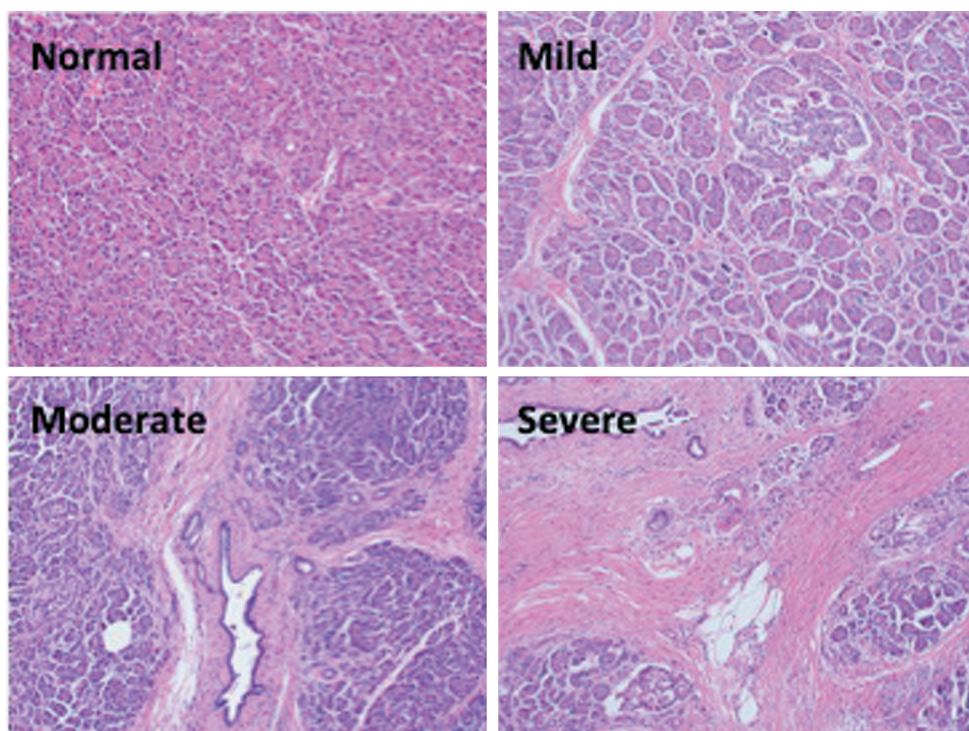


Figure 2. Pathological fibrosis grading of the pancreas according to Klöppel.

Table I. Patient characteristics.

No.	Age (y)	Gender	Primary disease	BMI (kg/m ²)	DM	MPD diameter (mm)
1	65	Male	IPMN	26.8	Present	4
2	35	Male	PDAC	23.1	Absent	6
3	77	Male	CCA	16.6	Absent	2.5
4	71	Female	PDAC	17.1	Absent	6
5	70	Male	PDAC	21.8	Absent	6.5
6	56	Male	IPMN	23.7	Absent	8.5
7	80	Female	CCA	20.3	Absent	3.5
8	76	Female	PA	20.2	Absent	11
9	53	Male	PA	18.1	Absent	1.5
10	69	Female	PDAC	15.6	Present	5.5
11	78	Female	PDAC	21.1	Absent	7.5
12	56	Female	PDAC	17.6	Absent	2.5
13	66	Male	CCA	21.8	Absent	6
14	38	Female	P-NET	29	Absent	3.5
15	72	Male	PDAC	20.8	Absent	1.5

BMI: Body mass index; DM: diabetes mellitus; MPD: main pancreatic duct; IPMN: intra-ductal papillary mucinous neoplasm; PDAC: pancreatic ductal adenocarcinoma; CCA: cholangiocarcinoma; PA: periampullary adenocarcinoma; P-NET: pancreatic neuroendocrine tumor.

Table II. Shear wave elasticity index (SWEI) and postoperative outcome.

No.	Preoperative SWEI (kpa)	Intraoperative SWEI (kpa)	Pathological fibrosis	Pancreatic juice (ml/day)	POPF
1	24.4	26.1	Moderate	214	BL
2	12.8	15	Severe	64	-
3	13.4	10.9	Mild	133.6	-
4	72.5	86	Severe	32.6	-
5	22.6	21	Moderate	81.7	-
6	9.1	10.3	Moderate	120	BL
7	10.5	11.8	Mild	281.7	B
8	5	19.5	Moderate	76.7	-
9	10.3	10.4	Mild	182.4	-
10	17	46.1	Severe	18.7	-
11	19.3	20.6	Severe	48.1	-
12	16.8	25.1	Moderate	56.9	-
13	12.6	17.4	Moderate	125.4	-
14	6.2	8.5	Mild	94.3	-
15	15.3	22.1	Moderate	17.1	-

POPF: Postoperative pancreatic fistula; BL: biochemical leak.

intraoperative SWEI was also correlated with the pathological pancreatic fibrosis grading (Kruskal-Wallis test, $p=0.036$) (Figure 4). The intraoperative SWEI was inversely correlated with the daily output of pancreatic juice [Spearman's rank correlation test (ρ)=-0.5643, $p<0.028$] (Figure 5).

Discussion

Because POPF can be a fatal complication, surgeons must make their best efforts to prevent it from developing. Soft pancreatic texture has been reported as one of the risk factors

of POPF, but no quantitative parameters have been reported. To date, only a few studies have investigated the relationship between the intraoperative SWE and pancreatic fibrosis. Our study demonstrated that the intraoperative SWE was associated with remnant pancreatic exocrine function and pathological fibrosis of pancreatic tissue. The intraoperative SWE was also positively correlated with the preoperative SWE. Although not significant, patients with lower intraoperative SWE tended to have a higher risk of POPF.

A procedure for measuring pancreatic SWE has not yet been established. The advantage of the intraoperative SWE

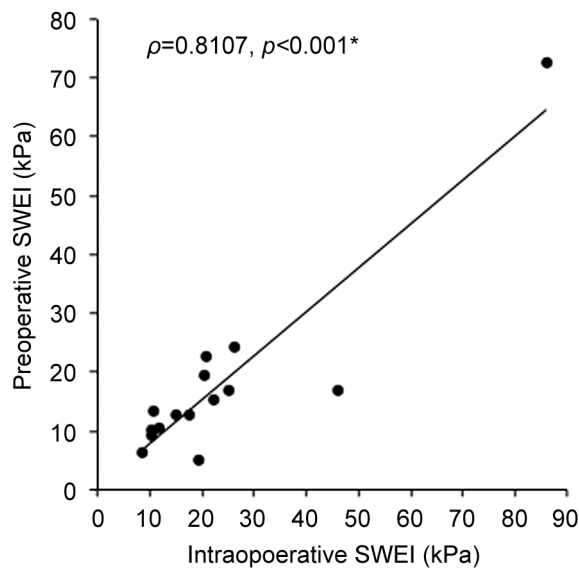


Figure 3. Correlations between preoperative and intraoperative shear wave elasticity index (SWEI). Higher intraoperative SWEI was associated with higher preoperative SWEI [Spearman's rank correlation test (ρ)=0.8107, $p<0.001^*$].

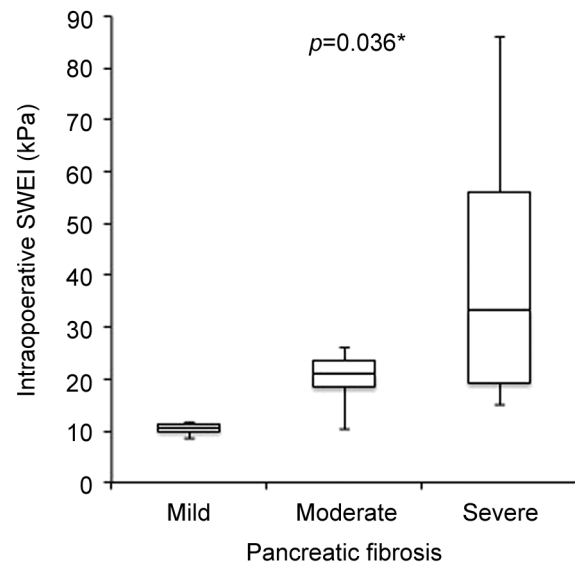


Figure 4. Correlations between shear wave elasticity index (SWEI) of the pancreas and pathologic findings of resected specimens. The higher fibrotic score was associated with higher SWEI (Kruskal-Wallis test, $p=0.036^*$).

measurement is that it may be less affected by interference factors. Although preoperative measurement of SWE is convenient, age, sex, obesity, and increased abdominal wall thickness may decrease measurement accuracy in some cases. A study using ARFI elastography reported that shear wave velocities were significantly different between the surface and deep within the same liver (15). Another study indicated that a deeper ROI was associated with low shear wave velocity in pancreatic measurement (16). Considering the differences in the depth of the pancreas in each patient, the preoperative SWE measurement may lead to larger variations because it is difficult to measure the SWE using the same depths. The intraoperative SWE measurement, however, could alleviate these interference factors by placing the ultrasonic probe directly on the pancreatic parenchyma, which prevents a large variance and provides more reliable data. Intraoperative SWE measurement could be an alternative method when preoperative measurement is difficult or seems insufficient.

Several techniques have been reported for quantitative evaluation of pancreatic stiffness. Previous studies and our own study have demonstrated that SWE correlated well with pathological pancreatic fibrosis and exocrine function, which enables a quantitative measurement of pancreatic stiffness (9). Although various methods, including durometers (17-19) and magnetic resonance elastography (MRE) elastographic methods (20-22), are indicated as useful for measuring tissue stiffness, SWE would be highly valuable because it is complementary to conventional B-mode pancreatic ultrasonic

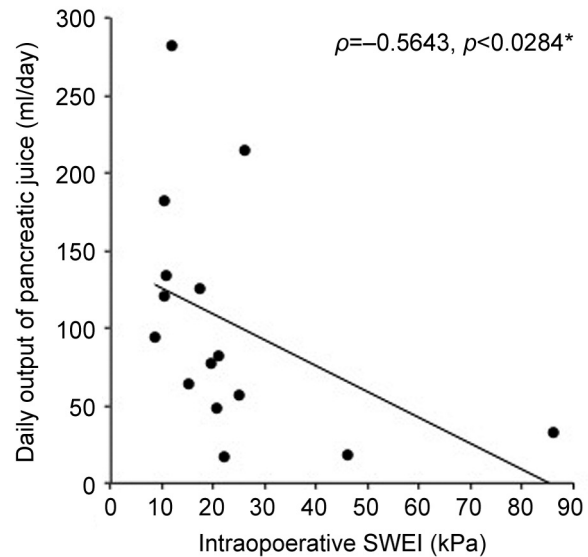


Figure 5. Correlations between shear wave elasticity index (SWEI) of the pancreas and daily output of pancreatic juice. Higher SWEI was associated with a lower level of daily pancreatic juice output [Spearman's rank correlation test (ρ)=-0.5643, $p<0.028^*$].

examinations as a simple, noninvasive, cost-effective, and highly reproducible method.

There are clinical benefits regarding the use of SWE in pancreatic resection. If measured SWE values could be used

as quantitative parameters of pancreatic stiffness, they may help surgeons select more appropriate surgical procedures (e.g. pancreatic parenchyma transection, reconstruction, fistulation of pancreatic juice) and postoperative management to decrease the risk of POPF. A previous study reported that the degree of pancreatic fibrosis could be estimated by the preoperative pancreatic elasticity assessed by ARFI imaging (9). Another preliminary study indicated the potential feasibility of preoperative ARFI elastography in predicting POPF after pancreatic resection (23). Following these studies, we demonstrated in this study that patients with high intraoperative SWE were associated with a lower level of daily pancreatic juice output and higher degree of pathological fibrosis. These results indicate that the measurement of SWE could be a quantitative predictor of pancreatic fibrosis. Although our study failed to show significance in predictive efficiency for POPF because of the small patient sample and lack of patients with grade C POPF, the clinical benefit should still be emphasized as a potential predictor of POPF. Furthermore, demands for a quantitative method in measuring pancreatic stiffness are increasing because laparoscopic pancreatic surgery became more common. Because laparoscopic surgeons cannot use their tactile sense, quantitative measures of pancreatic stiffness would be more informative for selection of surgical procedure and postoperative management to reduce the incidence of POPF in laparoscopic pancreatic surgeries.

Limitations of this study should be acknowledged. As a single-center study, the results may not be applicable to other centers with different ultrasonic devices. Second, the small study sample size may have led to information and selection bias. Finally, these outcomes may have been largely influenced by the skills of each examiner. Additional studies with larger sample sizes are required to ensure high reproducibility, confirm our initial findings, and establish a standard procedure in measuring intraoperative SWE. Intraoperative measurement of pancreatic elasticity by SWE may be useful as a quantitative method for predicting histological fibrosis in pancreatic tissue. This technique can be used to develop alternative and more reliable methods for prediction of POPF in pancreatic resection.

Conflicts of Interest

The Authors declare that they have no conflicts of interest regarding this study.

Authors' Contributions

Drs. Wada, Aoki, Fujimori, Ohike, Koizumi, Kusano, Matsuda, Nogaki, Tashiro, Hakozaiki, Shibata, Tomioka, Hirai, Saito, Yamazaki and Murakami contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

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Received December 13, 2020

Revised January 3, 2021

Accepted January 4, 2021