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Efficacy and safety of a fully covered self-expandable metallic stent equipped with square flare in EUS–guided drainage/anastomosis: A multicenter retrospective study

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ABSTRACT

Background and Objectives: Recent technological advances in interventional EUS have improved EUS-guided drainage/anastomosis (EUS-D/A), yet challenges remain. This study evaluated the safety and feasibility of a square flare fully covered self-expandable metallic stent (SF-FCSEMS) with anti-migration properties for EUS-D/A.

Methods: This retrospective cohort study was performed at 2 academic centers and analyzed patients who underwent SF-FCSEMS placement for EUS-D/A from April 2015 to November 2022. We have used an SF-FCSEMS that has a square flare at both ends that is 4 mm larger in diameter than the stent body, providing an anti-migration effect.

Results: Thirty-six patients (median age: 74 years), 41.6% male, were included. Malignancies accounted for 83.3%. Among the EUS-D/A procedure types, EUS-abscess drainage was performed in 52.8%, EUS-guided gallbladder drainage in 30.6%, and EUS-guided abscess drainage in 16.7%. The technical success rate was 97.2%, and the clinical success rate was 97.1%. The median procedure time was 36 minutes, with puncture tract dilation conducted in all cases. Adverse events occurred in 11.1%; recurrent symptoms were observed in 11.8%, with no migration. SF-FCSEMS removal was performed in 26.5% of patients during the follow-up period, with a median duration of 154 days. The total cost of deploying SF-FCSEMS was approximately 40% less than that of using lumen apposing metal stent.

Conclusions: EUS-D/A with an SF-FCSEMS, which has anti-migration properties, not only was effective and feasible in the present study but also demonstrated a cost advantage.

Key words: EUS-guided drainage/anastomosis; SEMS; Anti-migration system

BACKGROUND

Recent technological advances in interventional EUS (I-EUS) have been remarkable. EUS-guided drainage/anastomosis (EUS-D/A) technique is performed for areas that can be visualized transgastrointestinally. Compared with percutaneous procedures, this technique is better tolerated by patients and less invasive than surgery.[1,2] In EUS-D/A, plastic stents (PS) are often used as transluminal drainage/anastomosis stents (T-DAS) because of their ease of placement; however, PS has a narrow lumen, leading to inadequate drainage.[3] Fully covered self-expandable metallic stents (FCSEMS) and lumen-apposing metallic stents (LAMS) reportedly have better drainage effects because of their larger diameters.[4,5] Using the Hot AXIOS (Boston Scientific, Marlborough, MA), a representative LAMS, drainage can be rapidly and efficiently performed because device exchange is unnecessary. However, a LAMS is more costly than a PS or FCSEMS, and it cannot be used when a gap is present between the gastrointestinal wall and the drainage site; additionally, there are concerns about late adverse events (AEs), such as bleeding and failure to remove the buried LAMS. Moreover, the Hot AXIOS stent can only be used for peripancreatic fluid collection in Japan. An FCSEMS for EUS-guided biliary drainage has a large diameter and is expected to provide efficient drainage with the possibility of preventing leakage. An FCSEMS has various lengths and can thus be placed when a long distance is present between the gastrointestinal wall and the drainage site.[6] However, migration is a major concern when using an FCSEMS as a T-DAS. The ideal FCSEMS has strong anti-migration properties.[7,8] Some reports have described the prevention of stent migration in EUS-hepaticogastrostomy (EUS-HGS), but few such reports have focused on EUS-D/A.[9–12] We have used an FCSEMS (HILZO stent; BCM Co., Ltd., Seoul, Korea) with a square flare at both ends to achieve an anti-migration effect in EUS-guided abscess drainage (EUS-AD), EUS-guided gallbladder drainage (EUS-GBD), and EUS-guided choledochoduodenostomy (EUS-CDS), and

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we believe that this square flare characteristic prevents content leakage and migration.[8,13] This square flare FCSEMS (SF-FCSEMS) has been used in the distal bile duct with good results.[14–16] We retrospectively evaluated the safety and feasibility of using an SF-FCSEMS for EUS-D/A. Although clinical trials of SF-FCSEMSs in EUS-D/A have been performed, the number of cases was small; this is the first large case study.[17]

METHODS

Study design

This retrospective cohort study was performed at 2 academic centers. The study protocol was centrally reviewed and approved by the Ethics Committee of Saitama Medical University (approval number: 2022-101) and subsequently by Juntendo University (approval number: C22-0150). The endoscopists who performed the EUS-D/A procedures in this study were either experts who had performed >100 EUS-D/A procedures or trainees who were supervised by experts. This study is part of a collaborative research project, and there is an overlap of some patients with the study mentioned in Matsubara et al.[17] Specifically, a subset of patients who underwent EUS-AD for ALS were included in both studies.

Patients

This study recruited and analyzed patients who underwent SF-FCSEMS placement for EUS-D/A from April 2015 to November 2022. The EUS-D/A procedures included EUS-AD, EUS-GBD, and EUS-CDS. EUS-AD was performed for afferent loop syndrome (ALS) and liver abscesses. Patients with cholecystitis unsuitable for surgery and patients with abdominal abscesses were usually treated with percutaneous drainage. However, EUS-D/A was performed for patients who were unable or unwilling to undergo a percutaneous procedure.

Procedures

EUS-D/A procedures were performed with the patients under deep sedation using midazolam and pethidine hydrochloride; propofol was used when these agents were ineffective. The echoendoscope used in this study was an oblique-viewing curved linear-array echoendoscope (EG-580UT or EG-740UT; FUJIFILM Medical Corp., Tokyo, Japan). The other devices used in this study were a 19G puncture needle (EZ Shot 3 Plus; Olympus, Tokyo, Japan) and a 0.025-inch guidewire (VisiGlide 2; Olympus; or EndoSelector; Boston Scientific) for initial insertion into the needle. Dilation of the puncture tract was performed with a bougie dilator (ESDilator [Zeon Medical, Tokyo, Japan]; Tornus ES [Olympus]), an electrocautery dilator (6-Fr Cystotome; Endo-Flex GmbH, Voerde, Germany), and a 4-mm balloon dilator (REN; Kaneka Medix, Osaka, Japan). Following tract dilation, an SF-FCSEMS (HILZO stent; BCM Co., Ltd.) was inserted. The HILZO stent, used as a T-DAS in this study, has a square flare at both ends that is 4 mm larger in diameter than the stent body, providing an anti-migration effect [Figure 1]. It is housed in an 8.5-Fr delivery lumen. The length of the SF-FCSEMS was 6 or 8 cm depending on the individual patient, and the diameter of the stent body was 10 mm in all patients. Excluding patients who underwent EUS-CDS, a 7-Fr double-pigtail PS (DPPS) (Zimmon [Cook Medical, Bloomington, IN] or Through & Pass [Gadelius Medical, Tokyo, Japan]) was placed within the lumen of the FCSEMS to prevent contact between the abscess/gallbladder wall and the SF-FCSEMS after the drainage area had shrunk, as well as to prevent migration. Blood testing was performed 2 hours after the procedure and the following day.

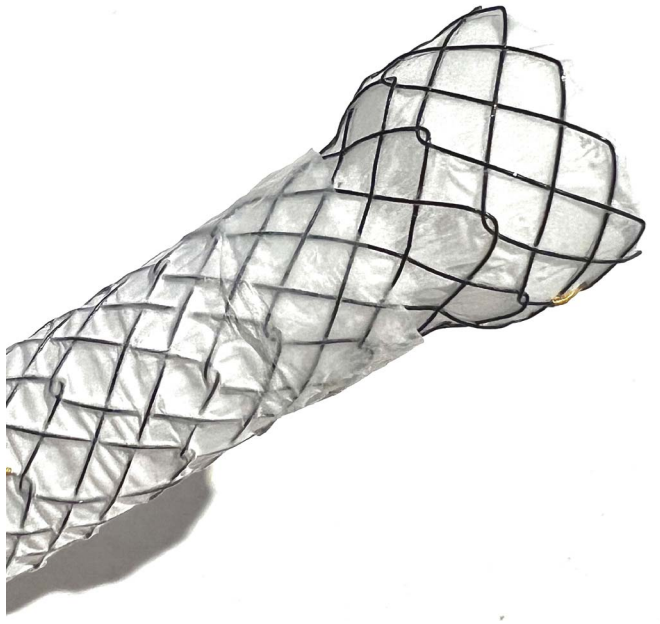

Figure 1. HILZO stent. The HILZO stent is a braided nitinol stent with a hook and cross structure. It has a square flare at both ends that is 4 mm larger in diameter than the stent body. The stent body is covered with polytetrafluoroethylene, both inside and outside, and the flared ends are covered with silicone.

The following morning, plain computed tomography (CT) was performed to assess the effectiveness of the procedure and the occurrence of AEs, such as content leakage or bleeding.[18] SF-FCSEMS removal was not mandatory but was performed when clinical success was achieved and additional procedures such as endoscopic retrograde cholangiopancreatography (ERCP) were performed. When recurrent symptoms associated with occlusion/migration of the T-DAS occurred, the T-DAS was removed and replaced with a DPPS.

Outcome assessment and statistical analysis

The primary outcome was the AE rate (early AEs were defined as those occurring within 14 days, and late AEs were defined as those occurring beyond 14 days). The secondary outcomes were technical success, clinical success, overall survival, the recurrent symptom rate, and recurrent biliary obstruction (RBO) for patients who underwent EUS-CDS. The procedure time was defined as the time from endoscope insertion to stent placement. AEs were described in accordance with a previously published report.[19] All outcomes other than the definitions of AEs were based on the Tokyo criteria 2014 for transpapillary biliary stenting.[20] Technical success was defined as successful stent placement in the intended location. Clinical success was defined as disappearance or decrease of the drained material by CT and improvement of inflammation, as shown by blood testing performed within 1 week. For patients who underwent EUS-CDS, RBO was defined as a composite endpoint of either stent occlusion or symptomatic migration according to the Tokyo criteria. For the remaining patients who underwent EUS-AD/GBD, the rate of recurrent symptoms caused by occlusion/migration of the T-DAS was evaluated. Intentional removal of the stent because of treatment completion or patient death was classified as censored. Patients were followed from initial stent placement until at

Table 1

Patients' characteristics

Number of patients, *n*	36
Sex: male/female, *n*	15/21
Age: median, yr (IQR)	74 (67–82)
Primary disease, *n* (%)	
Malignant	30 (83.3)
Pancreatic carcinoma	17 (56.7)
Biliary tract carcinoma	9 (30.0)
Other carcinoma	4 (13.3)
Benign	6 (16.7)
Procedure type, *n* (%)	
EUS-GBD	11 (30.6)
EUS-AD	19 (52.8)
Liver abscess	10 (52.6)
Afferent loop syndrome	9 (47.4)
EUS-CDS	6 (16.7)

IQR: interquartile range; EUS-GBD: EUS-guided gallbladder drainage; EUS-AD: EUS-guided abscess drainage; EUS-CDS: EUS-guided choledochoduodenostomy.

least 1 year later unless observation discontinuation occurred. The stent follow-up period was defined as the time from stent placement to stent removal, patient death, or the end of observation period. Statistical analysis was performed using SPSS software (version 29.0; IBM Corp., Armonk, NY).

RESULTS

Patient characteristics

Table 1 shows the patients' characteristics. In total, 36 patients (41.6% male) were included. Their median age was 74 years (interquartile range: 67–82 years). Among all primary diseases, malignancies accounted for 30 (83.3%) cases, with pancreatic carcinoma seen in 17 (56.7%), biliary tract carcinoma in 9 (30.0%), and other carcinomas in 4 (16.7%). Among the EUS-D/A procedure types, EUS-AD for liver abscess was performed in 9 (26.5%) patients, EUS-GBD in 11 (30.6%), EUS-AD for ALS in 9 (25.0%), and EUS-CDS in 6 (16.7%) [Figure 2].

Outcomes and AEs

Table 2 shows the patients' outcomes and AEs. The median treatment time was 36.0 minutes (range: 28.8–50.0 minutes). The technical success rate was 97.2% (35/36), and the clinical success rate was 97.1% (34/35). The single case of technical failure occurred in a patient who underwent EUS-GBD. Although the guidewire was successfully inserted after the puncture, the delivery system of the SF-FCSEMS did not pass the gallbladder wall. The single case of clinical failure occurred in a patient with severe gangrenous cholecystitis whose procedure was technically successful but did not improve the clinical condition due to uncontrollable sepsis. In this patient, the focus of infection might be not only within the bile juice but also on the gallbladder wall itself. Puncture tract dilation was performed in all cases using a bougie plus balloon dilator, balloon dilator alone, and electrocautery dilator in 66.6%, 8.3%, and 25.0% of cases, respectively. An SF-CFSEMS was used in all patients, and a DPPS was placed in the lumen of the SF-FCSEMS to prevent migration and perforation in 83.3% of patients (except those who underwent EUS-CDS). In all cases, plain CT was performed on postprocedural day 1 to determine whether AEs had occurred. Four (11.1%) patients were found to have AEs (early in 3, late in 1). The early AEs were graded as mild in 2 patients and fatal in 1; late early AEs was mild in 1. In early AE group, 2 patients were found to have peritonitis with fluid collection as revealed by

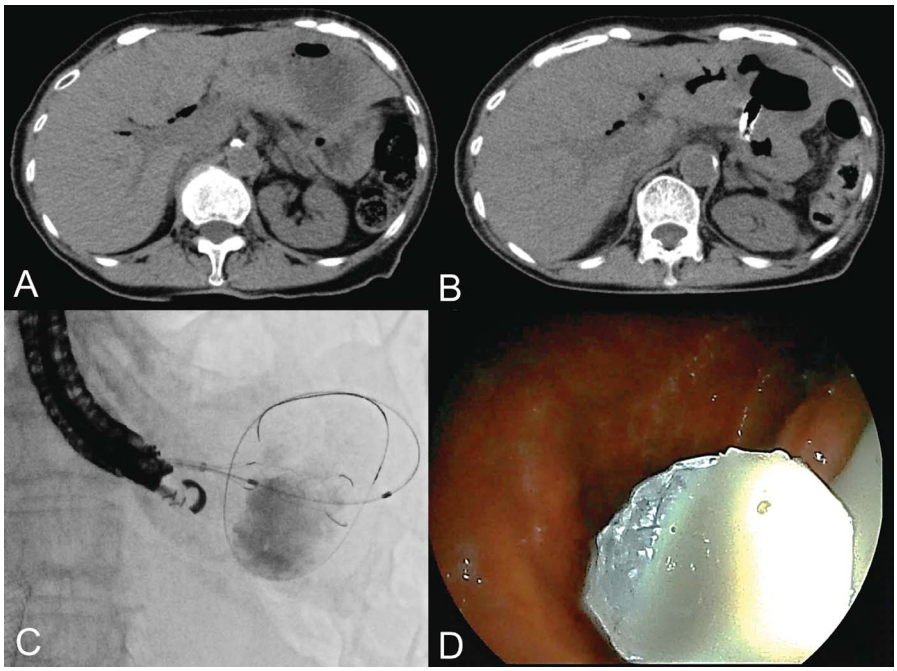

Figure 2. Images of an 82-year-old woman who underwent EUS-AD for a liver abscess. A, CT revealed a liver abscess in the left lobe of the liver. B, On postoperative day 1, CT showed that the liver abscess had been successfully drained by an SF-FCSEMS and PS. C, Deployment of the SF-FCSEMS under fluoroscopy. D, Endoscopic image showing placement of a DPPS in the lumen of the SF-FCSEMS. EUS-AD, EUS-guided abscess drainage; CT, computed tomography; PS, plastic stents; DPPS, double-pigtail plastic stents; SF-FCSEMS, square flare fully covered self-expandable metallic stent.

Table 2

Outcomes and adverse events

Treatment time, median, min (IQR)	36.0 (28.8–50.0)
Technical success, *n* (%)	35 (97.2)
Clinical success, *n* (%)	34 (97.1)
Dilatation of puncture point, *n* (%)	36 (100)
Bougie + balloon dilator	24 (66.6)
Balloon dilator only	3 (8.3)
Electrocautery dilator	9 (25.0)
Deployed fully covered SEMS, *n* (%)	
Type, square flare SEMS	35 (100)
Diameter, 10 mm/12 mm	29 (82.9)/6 (17.1)
Length, 6 cm/8 cm	22 (62.9)/13 (37.1)
Additional PS into the FCSEMS lumen, *n* (%) (except for EUS-CDS)	30 (83.3)
Plain CT postprocedure day 1, *n* (%)	36 (100)
Adverse events, *n* (%)	4 (11.1)
Early adverse events	3
Peritonitis with fluid collection around puncture point	2
Gastrointestinal perforation	1
Late adverse events other than recurrence symptoms	1
Reflux cholangitis	1
Recurrent symptoms in all cases, *n* (%)	4 (11.8)
Occlusion of T-DAS	4
Sludge/food impaction	1/3
Migration of T-DAS	0
RBO in EUS-CDS cases, *n* (%)	1 (16.7)
Food impaction	1
Stent removal, *n* (%)	9 (26.5)
Stent follow-up period, median (IQR), d	117 (53–255)
Patient follow-up period, median (IQR), d	154 (62–342.5)

IQR: interquartile range; FCSEMS: fully covered self-expandable metallic stent; PS: plastic stent; CT: computed tomography; RBO: recurrent biliary obstruction; EUS-CDS: EUS–guided choledochoduodenostomy; T-DAS: transluminal drainage/anastomosis stent.

CT the next day. The patients improved with conservative treatment. One patient who had undergone EUS-GBD was found to have peritonitis with gastrointestinal perforation and died on 14 postoperatively, compounded by a background of terminal-stage pancreatic cancer. In the late AE group, one patient who had undergone EUS-CDS developed reflux cholangitis secondary to duodenal obstruction on day 139; the SF-FCSEMS was removed, and the patient underwent EUS-HGS and duodenal stenting. No cases of stent migration occurred. However, stent occlusion occurred in 4 (11.8%) patients; this was due to biliary sludge in 1 patient (day 15) and food impaction in 3 (days 12, 12, and 54). The longest stent placement period was 561 days. Nine (26.5%) patients underwent SF-FCSEMS removal when stent occlusion occurred or the treatment was completed, and all stents were successfully removed. The median stent follow-up was 117 days (IQR: 53–255 days), and the median patient follow-up was 154 days (IQR: 62–342.5 days).

DISCUSSION

In the present report, the technical and clinical success rates of EUS-D/A with SF-FCSEMS were 97.2% and 97.1%, respectively. Adverse events occurred in 11.1% and were acceptable. Recurrent symptoms were observed in 11.8%, with no migration. This report describes the first large study to evaluate the safety and efficacy of an SF-FCSEMS with anti-migration properties during EUS-D/A.

Although a PS is easy to place, it has the limitations of a narrow lumen, insufficient drainage ability, and short time to RBO. A LAMS is associated with minimal content leakage and reduced migration. However, it has few indications in Japan, cannot be used when a gap is present between the gastrointestinal tract and drainage site, and has a high cost, hindering its widespread use. An FCSEMS combines the properties of both a PS and LAMS in terms of drainage capacity and cost, although migration remains a concern. In EUS-D/A, migration is a severe AE occurring in 1.6%–2.8% of patients undergoing CSEMS placement.[1,21] The anchoring force (ACF), which reflects the resistance force to migration (RFM), is related to factors such as the flare structure, radial force, diameter, and length of the stent body. Among these characteristics, the flare structure is closely related to the RFM. Minaga et al.[13] assessed the RFM of CSEMSs by using a phantom model of biliary SEMS migration. In the 10-mm CSEMS, the RFM increased with a higher taper angle of flare (TAF) (calculated as height of flare/length of flare). Thus, a flare with a sharper rise has a higher RFM. We evaluated the ACF of 4 LAMSs and seven CSEMSs in a phantom model of interventional EUS in which the direction of pull could be changed.[8] The HILZO stent (an SF-FCSEMS) had a higher ACF than the other CSEMSs because of its high TAF. No cases of stent migration occurred in the present study, and we consider that the high ACF due to the high TAF helped to prevent migration. The placement of the DPPS in the lumen of the SF-FCSEMS may also have helped to prevent migration. In a study of EUS-HGS, we reported that a specific partially covered SEMS (Niti-S Spring Stopper Stent; Taewoong Medical, Seoul, Korea), which has a spring-like anchoring function on the gastric side, served as an effective anchor preventing migration.[12] This partially covered SEMS had the strongest ACF among all of the above-described stents, but the anti-migration property is present on only one side (the gastric side); thus, it can only be used in EUS-HGS.[8]

AEs other than migration include peritonitis caused by content leakage. In EUS-D/A, content leakage sometimes occurs after dilation of the anastomosis, necessitating countermeasures to prevent leakage. Because the Hot AXIOS stent equips an electrocautery enhanced delivery system, no device exchange is required. This results in shorter treatment times, and its strong radial force prevents content leakage. FCSEMS and PS placement requires device replacement at each step, which is more time-consuming than LAMS placement; thus, a smooth replacement process is necessary. Although a CSEMS is expected to be associated with less content leakage than a PS, 2 (5.6%) patients in our study developed peritonitis due to content leakage. In one case of EUS-GBD with technical failure, the patient had peritonitis due to content leakage because the stent could not be deployed. FCSEMS, nearly as effective as LAMS, may have the potential to effectively reduce the content leakage post-deployment, owing to their expanding abilities. Another potential AE is bleeding and perforation caused by direct content of the FCSEMS, which can be prevented by inserting a DPPS in the lumen of the FCSEMS; this also helps prevent migration. Some FCSEMSs other than SF-FCSEMSs also have anti-migration properties. A dumbbell-shaped FCSEMS (Bonastent M-Intraductal; Standard Sci-Tech Inc., Seoul, Korea) is used in EUS-AD for ALS and in EUS-CDS.[11,22,23] This FCSEMS has a central saddle portion with a thinner diameter (8 mm) than the proximal and distal portions (12 mm). Although the TAF is lower than that of the SF-FCSEMS, this stent is also useful because of its anti-migration property. Matsubara et al. reported the use of an SF-FCSEMS in 12 patients with malignant ALS.[17] Technical and clinical successes were achieved in all patients. AEs occurred in one (8%) patient with mild peritonitis, and no stent migration was seen. In

drainage for ALS, the anastomoses between intestinal loops allow for a wide range of stent motion, leading to a higher migration risk. In the above study, one case of migration occurred in a patient with a tubular-type FCSEMS, but there were no cases of migration among patients with an SF-FCSEMS.[17] In a report using PSs, FCSEMSs, and LAMSs for walled-off necrosis, migration occurred in no patients with a LAMS but was seen in 5.8% of patients with an FCSEMS.[24] No migration occurred in the present study, an SF-FCSEMS has less potential for migration than an FCSEMS and may be safely used in EUS-D/A.

Another significant advantage associated with the deployment of an FCSEMS is the lower cost. When utilizing an FCSEMS, a range of equipment is necessary, including an SF-FCSEMS (HILZO), puncture needle (EZ Shot 3), guidewire (VisiGlide 2), and dilator (Tornus). By contrast, only the primary unit (Hot AXIOS) is required when using a LAMS. Notable cost efficiency is observed with an FCSEMS, which can be deployed at approximately 60% of the cost compared with a LAMS (approximate prices of $2100 and $3500, respectively). These costs are calculated based on an exchange rate of 1 USD to 140 yen. However, this just represents the cost difference for the device itself and does not examine costs in actual clinical cases.

The main limitation of this study was its retrospective, single-arm design, preventing comparisons with other stents. Although falling under the same category of EUS-D/A, each procedure exhibits unique technical challenges, potential adverse events, and associated risks. Therefore, evaluating the SF-FCSEMS's efficacy and safety across different techniques may not be strictly appropriate. Placing a PS within the lumen might have also enhanced the outcomes. But many reports have discussed the usefulness of LAMSs and PSs for drainage during EUS-D/A, few such reports have focused on SF-FCSEMSs.[17] Therefore, this study may serve as a pilot study leading to future procedure-specific assessments and assessments with and without PS. The present report described the first large study to evaluate the safety and efficacy of an SF-FCSEMS with anti-migration properties during EUS-D/A.

CONCLUSION

EUS-D/A with an SF-FCSEMS, which has anti-migration properties, not only was effective and feasible in the present study but also demonstrated a cost advantage. Future developments of FCSEMSs are anticipated to further enhance these anti-migration properties and maintain cost-effectiveness.

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Informed Consent

Not applicable.

Conflicts of Interest

Author H.I. was supported by research grants from Boston Scientific Japan and FUJIFILM Corporation. The funding source has no role in the design, practice, or analysis of this study. The remaining authors have no conflicts of interest to disclose.

Author Contributions

Conception and design: Hiroyuki Isayama, Toshio Fujisawa, Saburo Matsubara; Writing – original draft: Sho Takahashi; Writing – review & editing: Shigeto Ishii, Sumiko Nagoshi; Acquisition of data: Taito Fukuma, Mako Ushio, Yusuke Takasaki, Takeshi Otsuka, Kentaro Suda; Analysis and interpretation of the data: Akinori Suzuki, Koichi Ito, Ko Tomishima. All authors reviewed and approved the final manuscript.

Data Availability Statement

No additional data is available.

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