Performance evaluation of endoscopic ultrasonography needles: Experimental study ▶

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ABSTRACT

Background and study aims The relative procedural performance of needles for endoscopic ultrasound-guided fine-needle aspiration/biopsy (EUS-FNA/B) is unclear. The present study therefore compared six types of 22-gauge FNA/B needles using a bench simulator.

Methods Resistance forces during needle puncture and removal, needle tip damage before and after procedure, leakage after puncture of mucinous cyst models, the shape of the puncture surface at the puncture site, amounts of samples extracted, ranges of needle deflection angles, and needle deformation after multiple procedures were compared using six types of needles.
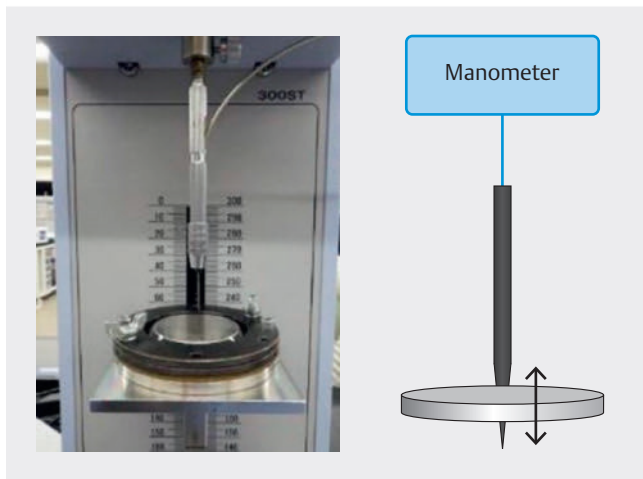
Results Maximum resistance forces during puncture and removal were highest for ProCore needles and lowest for Expect needles. None of the needles had damage after puncturing. SharkCore needles showed the highest amount of leakage, whereas FNA needles showed no leakage. The puncture tracts of FNA needles remained in the form of a flap at the puncture site, whereas FNB needles broke off the target material creating a hole. The target material removed was supplemented within the puncture needle. Top-Gain needles produced significantly larger samples than ProCore, EZShot3 Plus, and Expect needles. FNB needles produced larger and more core samples than FNA needles. EZShot3 Plus needles had the highest range of needle deflection angle using an elevator device and the lowest needle deformation after 20 punctures at full endoscopic angle and a full elevator.

Conclusions The performance of the six needles differed in various ways. Understanding the characteristics of each needle may allow for selection of the appropriate needle for each situation.

Introduction

Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) is a minimally invasive method of obtaining tissue for diagnosis of pancreatobiliary, hepatic, and gastrointestinal tract diseases [1, 2, 3, 4, 5]. This procedure involves insertion of an echoendoscope and a fine needle, which can be guided to the targeted area under real-time EUS guidance. A meta-analysis of 33 studies involving 4984 patients showed that EUS-FNA had a pooled sensitivity of 85% (95% confidence interval [CI], 84%–86%) and a pooled specificity of 98% (95% CI, 97%–99%) for diagnosis of pancreatic cancer [6]. Despite the high diagnostic performance of EUS-FNA, several factors, such as endoscope position and angle, use of an elevator, and tumor hard-

► **Fig. 1** Measurement of resistance forces during needle puncture and removal. Each needle was advanced toward a 0.3-mm thick polyvinyl chloride board at a speed of 500 mm/min. The maximum resistance of each needle during puncture through the polyvinyl chloride board was measured using a rheometer (IMADA CO., LTD, Aichi, Japan).

► **Fig. 2** Measurement of leakage after puncture of a mucinous cyst model. A mucinous cyst model was composed of a pressure vessel filled with echo gels, to which was attached a 2-mm thick silicone sponge rubber. The needles were used to puncture the silicone sponge rubber, and the volume of fluid that leaked from the inside to the outside of the cyst model was measured.

ness, can affect tissue sampling. Moreover, cytological aspiration by EUS-FNA has potential limitations, including an inability to determine histologic architecture, and quantitative samples that are too small for additional immunohistochemical assays. EUS-guided fine-needle biopsy (EUS-FNB), with its larger core biopsy needle, was designed to overcome these potential limitations. The need to obtain larger tissue specimens for precision medicine has favored use of EUS-FNB. A meta-analysis of 18 studies including EUS-FNB (n = 993) and EUS-FNA (n = 1017) showed that pooled diagnostic accuracy and tissue core rate were significantly higher for EUS-FNB (87% and 80%) than for EUS-FNA (80% and 62%). EUS-FNB also required significantly fewer passes for diagnosis [7]. For differentiation of mucinous pancreatic cystic lesions, the network ranking of the superiority index for EUS-guided needle-based confocal laser endomicroscopy and EUS-guided through-the-needle biopsy were significantly better than for other techniques in a meta-analysis of 40 studies including 3,641 patients [8]. Concerns have arisen about peritoneal seeding after EUS-FNA of mucinous pancreatic cystic lesions. In a meta-analysis of 10 studies, the pooled rate of peritoneal seeding was 0.4% in patients with solid masses and 0.3% in patients with pancreatic cystic lesions. Moreover, there was no difference between patients who underwent EUS-FNA/FNB and non-sampled patients (odds ratio 1.02, 0.72–1.46; $P = 0.31$) in terms of metachronous peritoneal dissemination [9]. It is important to assess whether fluid leakage occurs after EUS-FNA/B puncture of cystic lesions.

The relative procedural performance of needles used for EUS-FNA/B puncture of cystic lesions is unclear. The present study compared the performance of six types of 22-gauge EUS-FNA/B needles using a bench simulator designed to provide standardized, reproducible, and comparative performance data.
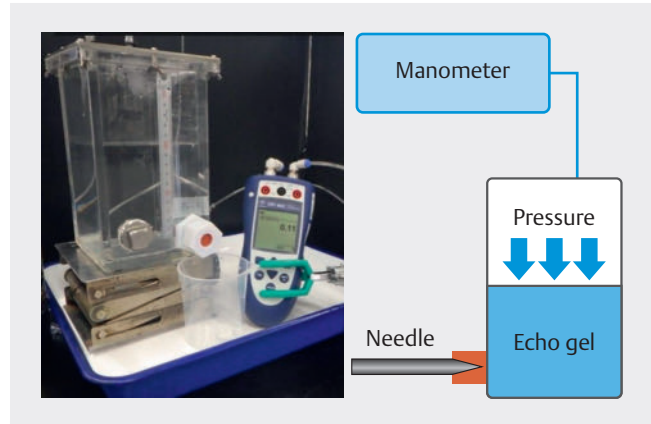
Methods

Needle and echoendoscope

The performances of six commercially available 22-gauge FNA/B needles were compared: (1) EZShot3 Plus (Olympus Medical Systems, Tokyo, Japan), (2) Expect (Boston Scientific, Marlborough, Massachusetts, United States), (3) ProCore (Cook Medical, Bloomington Indiana, United States), (4) Acquire (Boston Scientific, Marlborough, Massachusetts, United States), (5) SharkCore (Covidien, Japan Inc.), and (6) TopGain (Medi-Globe, Achenmuhle, Germany). Each experiment tested five needles of each type. EUS was performed with an EG-580UT echoendoscope (Fujifilm, Tokyo, Japan).

Bench simulation

Measurement of resistance forces during puncture and removal

Each needle was moved toward a 0.3-mm thick polyvinyl chloride board at a speed of 500 mm/min. Maximum resistance of each needle during puncture through the polyvinyl chloride was measured using a rheometer (IMADA CO., LTD, Aichi, Japan) (► **Fig. 1**). Maximum needle resistance during removal from the polyvinyl chloride board was also measured.

Needle tip abrasion damage before and after puncture

The geometry of each needle was evaluated by three investigators (Y.Y., H.Y., and C.G.) before and after puncture. Needle shape was checked prior to puncture. The needle was inserted into and retracted from a polyvinyl chloride board at a speed of 500 mm/min. This procedure was performed 100 times while altering the site of insertion into the board. Abrasion damage to the needle tip was subsequently evaluated using a microscope.
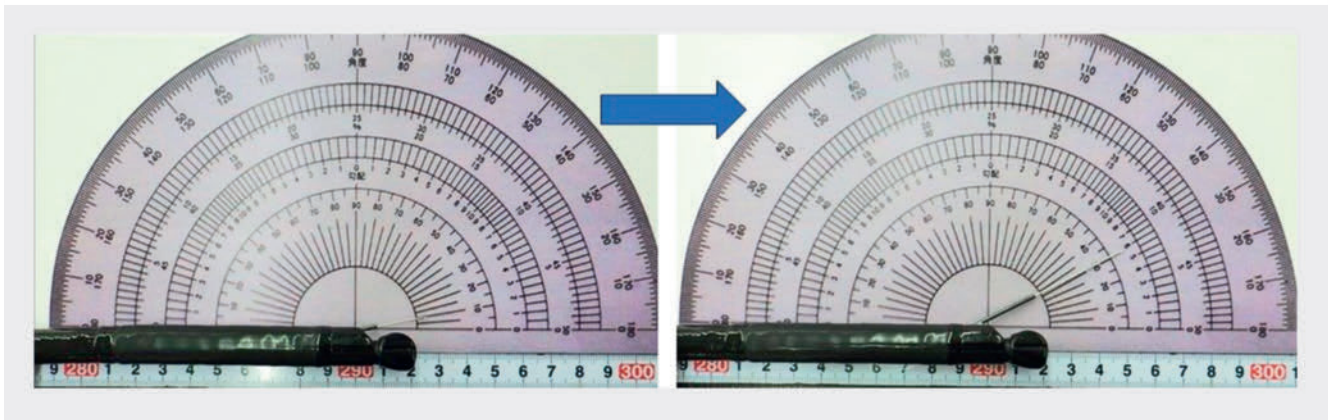
▶ **Fig. 3** Ranges of needle deflection angles using an elevator device. Each puncture needle was attached to the EUS, and the ranges of needle deflection angles were evaluated with an elevator device.
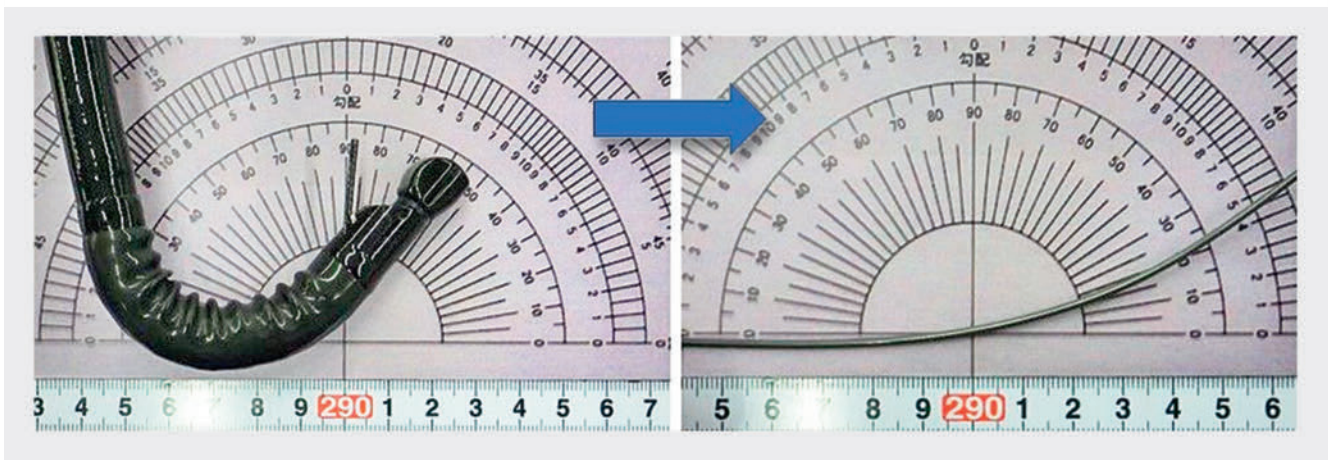
▶ **Fig. 4** Measurement of durability with deformation angle of the needle after 20 punctures at full endoscopic angle and full elevator. Each puncture needle was attached to the EUS and raised to full endoscopic angle and full elevator. The maximum angle of each puncture needle was measured, and the deformation of the needle was evaluated after 20 punctures.

Measurement of leakage after puncture of a mucinous cyst model

A mucinous cyst model was composed of a pressure vessel filled with echo gels, to which was attached a 2-mm thick silicone sponge rubber. The needles were used to puncture the silicone sponge rubber, and the volume of fluid that leaked from the inside to the outside of the cyst model was measured. The pressure in the vessel can be artificially raised from 0 to 50 Kpa. The silicone sponge was punctured, and the volumes of fluid leaking from the inside to the outside of the cyst model at pressures of 5 and 10 Kpa per minute were measured (▶ **Fig. 2**). The pressure at which the liquid leaks out was also determined by gradually increasing the pressure from 0 to 50 Kpa.

Evaluation of puncture surface during and after puncture

The form of the puncture tract (i.e., a hole or flap) was evaluated using a tissue model composed of polyimide. Penetration during puncture was evaluated by examining video recordings.

Amounts and histology of porcine liver tissue samples

Porcine livers in ex vivo were punctured 20 times with each needle and the sample amounts were measured. Each tissue sample was removed from the needle and deposited on a filter paper. The weights were then measured using an electronic weighing instrument (AS ONE CO., LTD, Osaka, Japan). Samples were also examined histologically to determine the presence of core samples.

Ranges of needle deflection angle using an elevator device

Each puncture needle was attached to the EUS and the ranges (from minimal to maximum) of needle deflection angles using an elevator device from no elevation to maximum elevation were measured (▶ **Fig. 3**).

Measurement of durability with deformation angle of the needle after 20 punctures at full endoscopic angle and full elevator.

Needle durability was measured with deformation angle of the needle after 20 punctures at full endoscopic angle and full elevator. Needle deformation was evaluated by measuring its bending angle after puncture (►Fig. 4).

Statistical analysis

Resistance, leakage, and sample amounts were expressed as mean ± standard deviation. Continuous variables in the two groups were compared by Mann-Whitney U tests. All statistical analyses were performed using JMP Pro version 14 (SAS Institute Inc., Cary, North Carolina, United States), with $P < 0.05$ considered statistically significant.

Results

Measurement of resistance forces during puncture and removal

Expect needles had the lowest and ProCore needles had the highest maximum resistance forces during puncture. FNB needles had significantly higher maximum resistance forces during puncture than FNA needles (2.16 ± 0.4 N vs. 1.71 ± 0.48 N, $P = 0.028$). Of the FNB needles, TopGain and SharkCore needles had significantly lower maximum resistance forces during puncture than ProCore and Acquire needles (►Table 1).

ProCore needles had the highest maximum resistance force during removal. There was no significant difference between the maximum resistance of FNB (0.95 ± 0.25 N) needled and those of FNA needles (0.86 ± 0.19 N) in maximum resistance forces during removal (►Table 1).

Needle tip abrasion damage before and after puncture

Before puncture, the tips of Acquire needles were blunter than the tips of TopGain needles, and the needle slits at the tips were longer in Acquire than TopGain needles. Procore needles had reverse bevels. None of the FNA/B needles experienced abrasion damage after puncturing. Visibility markers for ProCore/EZShot3 Plus and SharkCore needles were the dimple points and sandblasting, respectively. Visibility marker shapes of Acquire and Expect Plus needles were the circle slit. A coil sheath was used to visualize EZShot3 Plus needle only (►Fig. 5).

Measurement of leakage after puncture in a mucinous cyst model.

Puncture of the cyst model with any of the FNA needles tested showed no leakage occurred at either 5 or 10 Kpa per minute pressure. In contrast, leakage was observed with all FNB needles. Leakage following puncture with ProCore, Acquire, SharkCore, and TopGain needles (FNB needles) started to occur at pressures of 10.6 ± 14.0 Kpa, 0 Kpa, 0.2 ± 0.45 Kpa, and 0 Kpa, respectively. By contrast, no leakage following puncture by EZShot3 Plus and Expect needles (FNA needles) was observed when the pressure was raised from 0 to 50 Kpa per minute (►Table 1).

Evaluation of puncture surface during and after puncture

Puncture surface was most deformed during puncture by ProCore needles (►Fig. 6 and ►Video 1). Evaluation of puncture surfaces showed that puncture sites of the FNA needles, EZShot3 Plus (100% [5/5]) and Expect (100% [5/5]) remained in the form of a flap, whereas the puncture sites of the FNB needles – Acquire (100% [5/5]), TopGain (100% [5/5]), SharkCore (100% [5/5]), and ProCore (60% [3/5]) – were broken off, with holes remaining in the puncture sites (►Table 1) (►Fig. 7). These holes were supplemented within the puncture needle.

Amounts and histology of porcine liver tissue samples

The amounts of samples obtained with FNB needles (0.026 ± 0.008 mg) were significantly greater than those obtained with FNA needles (0.018 ± 0.009 mg) ($P = 0.03$). The amounts of samples obtained with TopGain needles were significantly larger than those obtained with ProCore, EZShot3 Plus, and Expect needles. The amounts of samples obtained with Acquire needles were significantly larger than those obtained with ProCore and EZShot3 Plus needles (►Table 1). However, there were no significant differences between Franseen and Fork-tip needles. Histological examination showed that core samples were obtained with ProCore, Acquire, TopGain, and SharkCore needles (FNB needles), but not with Expect and EZShot3 Plus needles (FNA needles) (►Fig. 8).

Range of needle deflection angle using an elevator device

The ranges of needle motion increased from minimum to maximum in the following order: EZShot3 Plus, Expect, ProCore, and Acquire/SharkCore/TopGain needle (►Table 1).

Measurement of durability with deformation angle of the needle after 20 punctures at full endoscopic angle and full elevator.

Deformation angle of needles after puncture at full endoscopic angle and full elevator decreased in the following order: EZShot3 Plus, Acquire, Expect, SharkCore, TopGain, and ProCore (►Table 1).

Discussion

EUS-FNA/B is widely used in diagnosis of digestive diseases, with many types of needles available in clinical practice. Choice of needle depends on the preference of individual operators. Few reports to date have utilized experimental methods to objectively evaluate needle performance [10, 11, 12]. The present experimental study objectively evaluated performance of six types of needles under the same objective conditions.

Evaluation of maximum resistance forces during puncture showed that Expect needles had significantly lower resistance, whereas ProCore needles had the highest resistance. Among FNB needles, SharkCore and TopGain had significantly lower maximum resistance forces during puncture than ProCore and

▶ **Table 1** Summary of results of needle evaluation with ranking of superiority.

	EZShot3 Plus	Expect	ProCore	Acquire	SharkCore	TopGain
Resistance during puncture (N) (ranking in order of excellence)	2.16±0.16 (4)	1.26±0.03 (1)	2.53±0.10 (6)	2.40± 0.11 (5)	1.79±0.15 (3)	1.65±0.04 (2)
Resistance during removal (ranking in order of excellence) (N)	1.03±0.12 (5)	0.70±0.04 (1)	1.33±0.04 (6)	0.70±0.08 (2)	0.97±0.02 (3)	0.82±0.03 (4)
Puncture tract (shape)	Flap	Flap	Whole	Whole	Whole	Whole
Amount of tissue sampling (ranking in order of excellence) (mg)	0.018±0.009 (4)	0.018±0.010 (5)	0.017±0.008 (6)	0.030±0.006 (2)	0.025±0.050 (3)	0.032±0.008 (1)
Range of needle deflection (from minimum to maximum) (ranking in order of excellence)	10–45° (1)	10–40° (2)	10–30° (4)	10–30° (4)	10–30° (4)	10–35° (3)
Needle deformation angle (ranking in order of excellence)	1° (1)	16° (3)	32° (6)	8° (2)	28° (4)	31° (5)
Leakage volume at 5Kpa (ranking in order of excellence) (mL)	0 (1)	0 (1)	0.15±0.25 (3)	1.14±0.65 (5)	1.78±1.16 (6)	0.35±0.29 (4)
Leakage volume at 10Kpa (ranking in order of excellence) (mL)	0 (1)	0 (1)	0.3±0.19 (3)	1.49±1.05 (5)	2.04±1.41 (6)	0.73±0.49 (4)
Pressure at the beginning of leak out (KPa)	–	–	10.6±14.0	0	0.2±0.45	0

| Acquire	SharkCore	TopGain	ProCore	EZShot3Plus	Expect
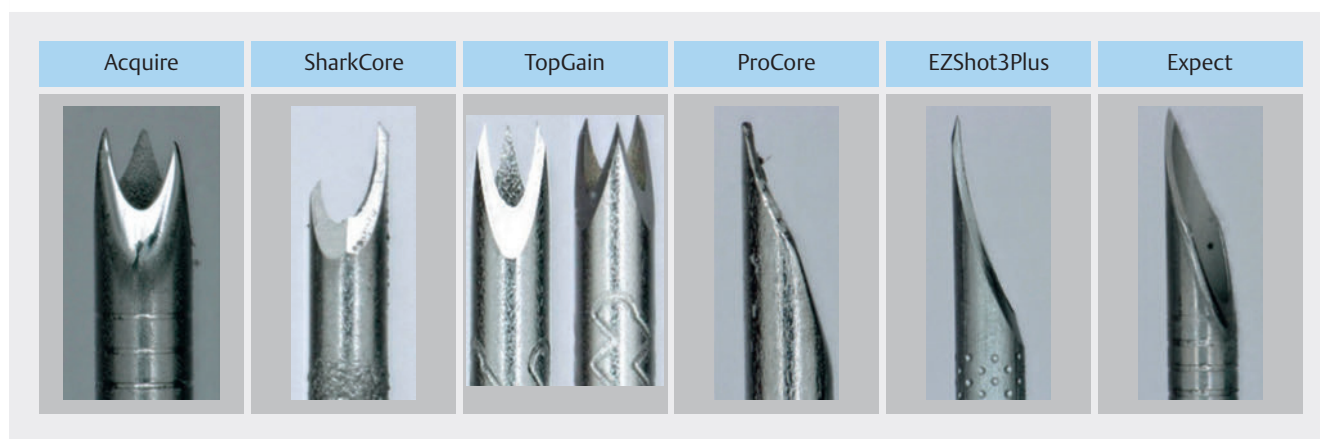
▶ **Fig. 5** Photographs showing the tip shapes of the six needles. **a** Acquire needle, made of cobalt-chromium with a circle slit visibility marker and a crown-shaped tip with three symmetric prongs. **b** SharkCore needle, made of stainless steel with a sandblasting visibility marker, and having a bevel tip incorporating two sharp prongs of different lengths. **c** TopGain needle, made of stainless steel with a unique visibility marker and a crown-shaped tip with three symmetric prongs. **d** ProCore needle, made of stainless steel with dimple points as a visibility marker and a reverse bevel. **e** EZShot3 Plus needle, made of nitinol with a dimple points visibility marker and coil sheath. **f** Expect needle, made of cobalt-chromium with a circle slit visibility marker.

Acquire needles. Therefore, if another needle cannot penetrate a tumor or be advanced into a tumor due to its deep position, Expect needles, with the lowest maximum resistance force during puncture, or SharkCore or TopGain needles, with the lowest maximum resistance forces during puncture among FNB needles, may be selected. A comparison of Franseen needles showed that Acquire needles had significantly higher maximum resistance forces during puncture than TopGain needles. These differences in resistance forces during puncture may be due to differences in the degree of polishing of the tip (sharpness) and/or the length of the needle slit. The reverse bevel of ProCore needles provided more resistance.

Evaluation of maximum resistance forces during needle removal showed that ProCore needles had the highest and Acquire/Expect needles had the lowest resistance. These differences may be due to differences in visibility markers. The visibility markers for the two needles with the highest resistance during removal were dimple points, whereas those for two needles with the lowest resistance were circle slits. ProCore needles had the highest resistance during removal because the combination of reverse bevels and dimple points increased resistance.
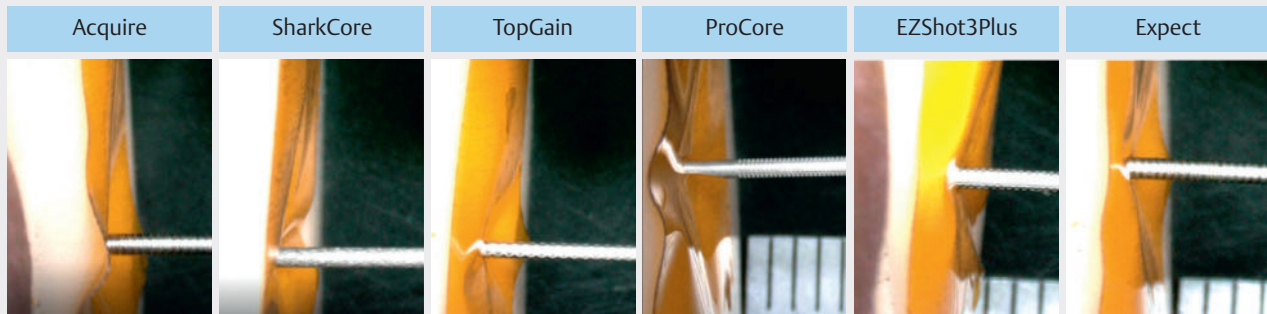
▶ **Fig. 6** Evaluation of needle puncture tracts. Examination of needle puncture tracts, showing that ProCore needles resulted in the most deformed tracts.
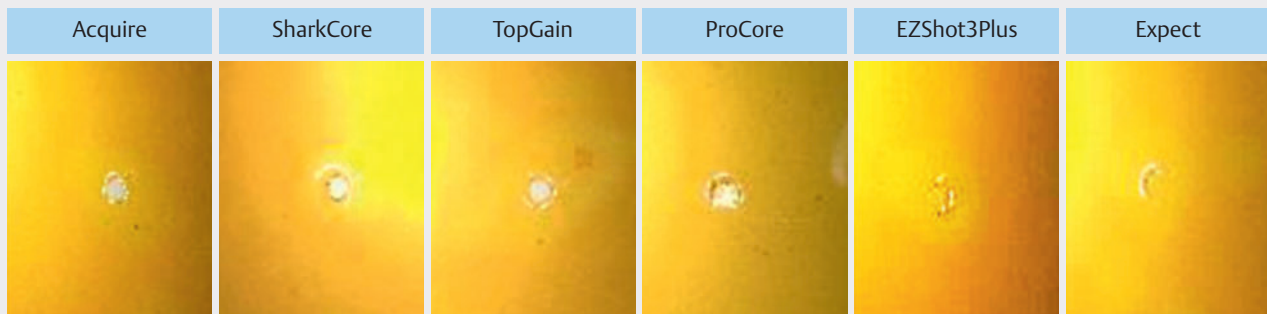
▶ **Fig. 7** Evaluation and deformation of needle puncture surfaces. The puncture sites of EZShot3 Plus and Expect needles appeared as flaps, whereas the puncture sites of Acquire, TopGain, SharkCore, and ProCore needles were broken off, with holes remaining at each puncture site.

▶ **VIDEO**

▶ **Video 1** Evaluation of deformation in needle puncture tracts. Examination of deformation in needle puncture tracts, showing that ProCore needles resulted in more deformed tracts than Expect needles.

Expect and Acquire needles, therefore, should be selected when mobility within a tumor is poor.

FNA needles showed no leakage of fluid, perhaps because a flap remained at the puncture site after needle removal. By contrast, all FNB needles tested showed leakage because their puncture sites were broken off and holes remained at these sites. FNA needles should be used to puncture cystic lesions for diagnosis and treatment, because these needles prevented leakage of cystic fluid. Because the holes remaining after puncture with FNB needles were filled by the collected tissue, FNB needles are recommended for collecting tissue samples from solid lesions.

Regarding puncture surface, puncture sites of the FNA needles remained in the form of a flap after needle removal, whereas puncture sites of the FNB needles were broken off and a hole remained in the puncture site. In fact, FNB needles allowed more and larger core samples compared with FNA needles. In tissue sampling, FNB needles were superior to FNA needles. Yousri M et al. reported that FNB needles were better at obtaining adequate tissue cores than FNA needles [13]. Moreover, Kovacevic B et al. reported that mean total tissue and mean diagnostic tissue areas for FNB needles were 6-fold larger than those for FNA needles [14]. In terms of FNB needles, the Franseen needle was superior to the reverse bevel needle. However, there was no significant difference between Franseen and Fork-tip needles. Therefore, Franseen and Fork-tip needles are recommended when a large amount of tissue samples is required for gene panel testing.
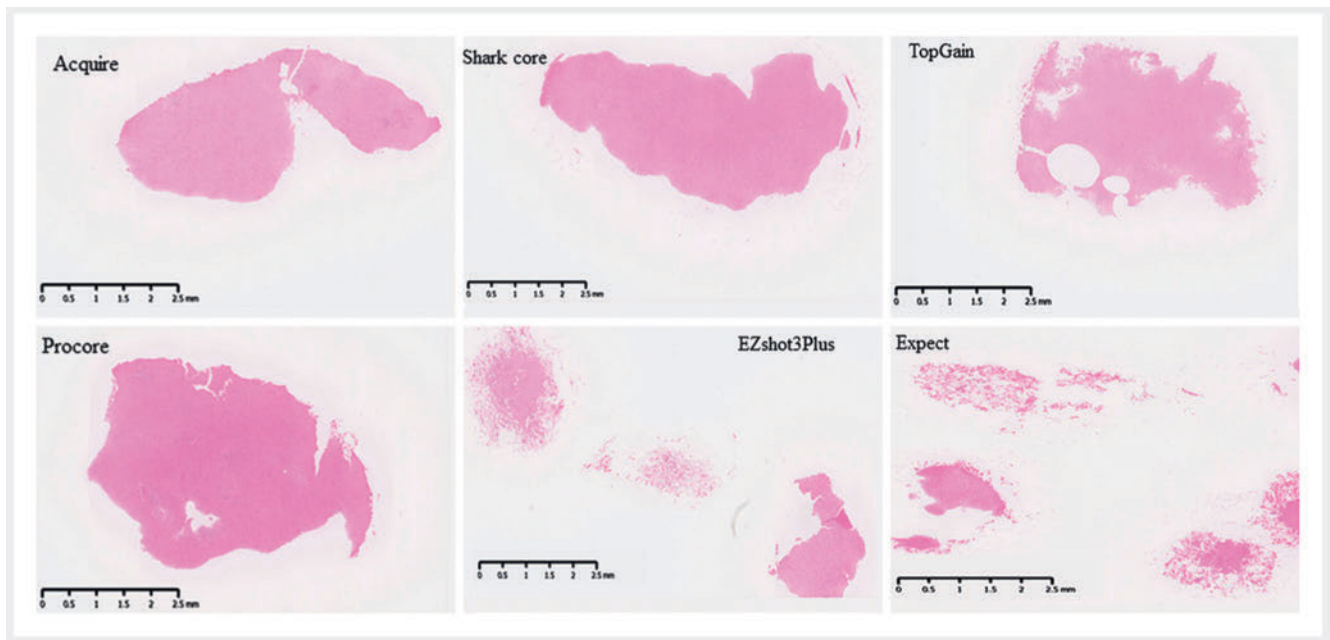
▶ **Fig. 8** Histologic assessment of porcine liver tissue samples. Histological examination showed that ProCore, Acquire, TopGain, and SharkCore needles acquired core samples, whereas Expect and EZShot3 Plus needles did not.

Assessments of performance during puncture showed that EZShot3 Plus needles had the largest range of needle deflection using an elevator device and the lowest durability in terms of deformation angle of the needle after 20 punctures at full endoscopic angle and full elevator. These differences may be ascribable to the material from which these needles are made. EZShot3 Plus needles are composed of nitinol and Acquire and Expect needles of cobalt-chromium, whereas ProCore, Shark-Core, and TopGain needles are composed of stainless steel. These findings suggest that needles made of nitinol have the highest durability and lowest degree of deformation.

EZShot3 Plus needles, which contain coil sheaths, had the largest range of deflection angle ranges using an elevator device and superior mobility. Therefore, interventional EUS with EZShot3 Plus needles may be better for drainage and small lesions because their puncture performance is superior, including lower deflection angles and degree of deformation.

This study had several limitations. First, it was experimental with a small sample size. In addition, the experimental setting may be different from ordinary clinical practice. However, it is difficult to compare performance of needles under the same objective conditions. Experimental comparisons as in the present study enable determination of objective differences in standardized settings.

Concusions

In conclusion, the present study found that the performances of the six needles differed in various aspects. Understanding the characteristics of individual needles may allow for selection of a needle appropriate for each situation

Conflict of Interest

The author M.K. has received honoraria from Olympus Corporation for lectures at conferences and grants from Medico's Hirata Inc. The remaining authors have no conflicts of interest to declare.

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