Objective evaluation of the resistance forces of 22-gauge EUS-FNA and fine-needle biopsy needles

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ABSTRACT

Background and Objectives: EUS-guided tissue acquisition is routinely performed for the diagnosis of gastrointestinal tract and adjacent organ lesions. Recently, various types of needles have been developed. However, how the shape of the needle tip and echoendoscope tip angle affect puncturability, has not been clarified. The aim of this experimental study was to compare the puncturability of several 22-gauge EUS-FNA and EUS-guided fine-needle biopsy (EUS-FNB) needles, and to evaluate the effects of the needle tip shape and echoendoscope tip angle on tissue puncturability. **Materials and Methods:** The following six major FNA and FNB needles were evaluated: SonoTip® ProControl, EZ Shot 3 Plus, Expect™ Standard Handle, SonoTip® TopGain, Acquire™, and SharkCore™. The mean maximum resistance force against needle advancement was evaluated and compared under several conditions using an echoendoscope. **Results:** The mean maximum resistance force of the needle alone was higher for the FNB needles than for the FNA needles. The mean maximum resistance force of the needle in the echoendoscope with free angle demonstrated that the resistance forces were between 2.10 and 2.34 Newton (N). The mean maximum resistance force increased upon increases in angle of the tip of echoendoscope, particularly in the FNA needles. Among the FNB needles, SharkCore™ had the lowest resistance force (2.23 N). The mean maximum resistance force of the needle alone, the needle in the echoendoscope with free angle, and the needle in the echoendoscope with full-up angle for SonoTip® TopGain were all similar to that of Acquire™. **Conclusion:** SonoTip® TopGain had similar puncturability to Acquire™ in all tested situations. Regarding the puncturability, SharkCore™ is most suitable for insertion into target lesions, when tight echoendoscope tip angle is necessary.

Key words: EUS-FNA, EUS-guided fine-needle biopsy, EUS guided tissue acquisition, fork tip type needle, Franseen type needle, Lancet type needle, puncturability, resistance force of the needle,twenty two gauge

INTRODUCTION

EUS-guided tissue acquisition (TA) is known as a safe and accurate procedure for the diagnosis

Access this article online

Quick Response Code:	Website: www.eusjournal.com
	DOI: 10.4103/EUS-D-22-00059

How to cite this article: Matsunami Y, Itoi T, Tsuchiya T, Ishii K, Tanaka R, Tonozuka R, *et al*. Objective evaluation of the resistance forces of 22-gauge EUS-FNA and fine-needle biopsy needles. Endosc Ultrasound 2023;12:251-8.

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Received: 2022-03-30; **Accepted:** 2022-11-06; **Published online:** 2023-04-28

of gastrointestinal (GI) tract and adjacent organ lesions.[1-3] The first needle developed for EUS-guided TA (EUS-TA) was the Lancet-shaped needle, namely, double-edged conventional FNA needles.[1,4] Since the first report of EUS-FNA, EUS-associated devices have been continuously evolving.[5,6] FNA needles had long been used as the gold standard; however, owing to their limitations, such as their inability to retain stromal and cellular architecture, fine-needle biopsy (FNB) needles were invented.[7-13] The development of needles with innovative tip designs has enabled the acquisition of large tissue samples, resulting in higher diagnostic ability.[14,15] Therefore, at present, many types of FNB needles are available worldwide. The major representative FNB needles include SharkCore™ (Medtronic, Minneapolis, MN, USA) and Acquire™ (Boston Scientific Corporation, Marlborough, MA, USA).[16-19] The needle tip of SharkCore™ is shaped as a fork-tip, with two opposite cutting edges.[20] Acquire™ has three crown-cut cutting edges symmetrically distributed at the needle tip, which is the so-called Franseen-type needle. Recently, another Franseen-type needle, SonoTip® TopGain (Medi-Globe, Achenmuhle, Germany), was established, in which the cutting edges of the spikes have been adjusted slightly.[21] In the clinical setting, it is well known that not only the gauge and characteristics of the needles but also the echoendoscope position and angle of the echoendoscope tip affect sample acquisition. We previously conducted a bench study, in which we compared the resistance force of various FNA needles against needle advancement.[22,23] Our previous study demonstrated that, regarding the size of FNA needles, 22-gauge and 25-gauge rather than 19-gauge needles are suitable for insertion into the target lesions, when tight endoscopic tip angle is used. The resistance force against needle advancement is thought to affect the influences the maneuverability of the needle, and eventually results in differences in the amount of TA, and diagnostic ability. However, to our knowledge, although several reports have been published on the clinical experience of the use of various FNB needles, there are no experimental data, regarding the resistance force of FNB needles. Hence, the aim of this experimental study was to compare the puncturability of the commercially available major 22-gauge FNA and FNB needles, using a bench simulator designed to provide standardized, reproducible, comparative performance data, and to evaluate the effects of differences in needle tip shape and echoendoscope tip angle on needle puncturability.

MATERIALS AND METHODS

Echoendoscope and needles

A curved linear-array echoendoscope (EG-3870UTK Ultrasound Video Endoscope, PENTAX Medical, Tokyo, Japan), with a working channel width of 3.8 mm, working length of 1250 mm, and tip angle of 130° up, and 130° down was used. Three types of FNA and FNB needles were evaluated respectively by bench simulation. Regarding the size of the needles, 22-gauge needles were used in this study owing to the following reasons. First, this is the most commonly used size and representative needle of each manufacturer, and second, our previous bench study already demonstrated that the 19-gauge needle is not useful for procedures using tight scope angulation.[23] The tested needles were SonoTip® ProControl (Medi-Globe) (L1), EZ Shot 3 Plus (Olympus Medical Systems, Tokyo, Japan) (L2), Expect™ Standard Handle (Boston Scientific Corporation) (L3), SonoTip® TopGain (F1), Acquire™ (F2), and SharkCore™ (S1). L1, L2, and L3 are major Lancet-type FNA needles each made by a different manufacturer. F1 and F2 are newly developed and conventional Franseen-type needles, respectively. S1 is a fork-tip-type needle, which is different from both the Franseen and the Lancet types. The characteristics of the needles are shown in Table 1.

Bench simulation

This was a laboratory simulation comparing the resistance force against needle advancement under several conditions. The bench simulator and protocol were designed by one of the investigators (T. I.), and the bench simulation test was conducted at Medico's Hirata Company (Osaka, Japan), which is a vendor of SonoTip® TopGain and SonoTip® ProControl needles. The primary outcome was to clarify the differences in resistance force against needle advancement among FNA and FNB needles. Before the simulation, accurate diameters of all six needles were measured by a digital micrometer caliper, VHX-6000 (KEYENCE, Osaka, Japan) [Figure 1]. The number of each needle tested was set to 2, so that the variability and standard deviation (SD) could be analyzed, and this was the minimum number required to detect individual differences. Puncturability was tested for the needle alone, the needle in the echoendoscope with free angle, and the needle in the echoendoscope with full-up angle.

Puncturability test of the needle alone

The resistance force against needle advancement was measured using Autograph, AGS-X (Shimadzu

Table 1. Needle characteristics

	L1	L2	L3	F1	F2	S1
Product name	SonoTip® ProControl	EZ shot 3 Plus	Expect™ Standard handle	SonoTip® TopGain	Acquire™ EUS-FNB needle	SharkCore™ FNB needle
Needle body	Stainless steel	Nitinol	Cobalt chromium	Stainless steel	Cobalt chromium	Stainless steel
Outer sheath	Synthetic resin	Stainless steel coil	Synthetic resin	Synthetic resin	Polyether ether ketone	Polyester block amide copolymer
Stylet	Nitinol	Nitinol	Nitinol	Nitinol	Nitinol	Nitinol
Manufacturer	Medi-Globe GmbH	Olympus Medical Systems	Boston Scientific Corporation	Medi-Globe GmbH	Boston Scientific Corporation	Medtronic
Product number	GUS-33-18-022	NA-U200H-8022	5001	GUB-33-18-022	M00555540	C-22-05

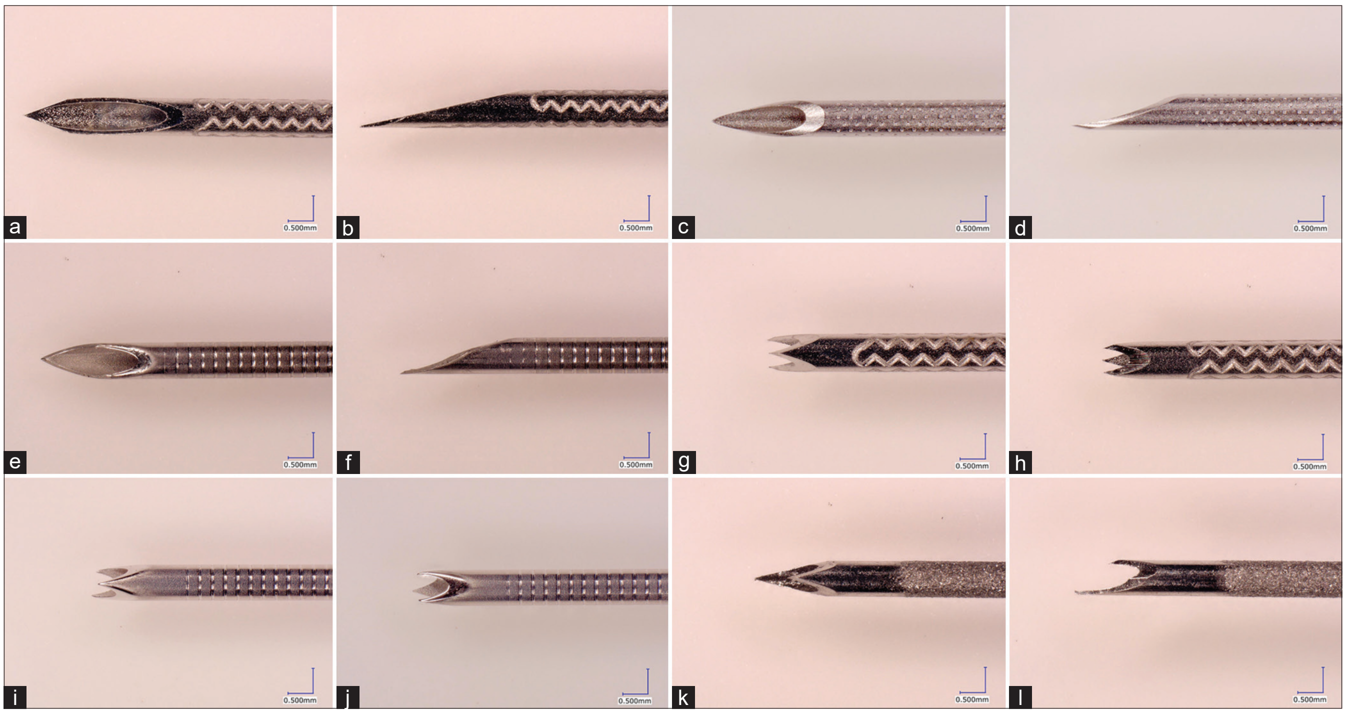

Figure 1. Images of the tip of each type of needles. (a) Top view of SonoTip® ProControl, (b) Side view of SonoTip® ProControl, (c) Top view of EZshot3, (d) Side view of EZshot3, (e) Top view of Expect™, (f) Side view of Expect™, (g) Top view of SonoTip® TopGain, (h) Side view of SonoTip® TopGain, (i) Top view of Acquire™, (j) Side view of Acquire™, (k) Top view of SharkCore™, (l) Side view of SharkCore™

Corporation, Kyoto, Japan), which is a universal tester that has a maximum tolerable pressure of 1000 Newton (N). The stylets of each needle were removed before the test. Each needle tip was fixed to the Autograph, and the resistance force when the puncture target is pierced was measured [Figure 2]. The parameter of the Autograph was set up as follows: load cell, 50 N; the needle advancement speed, 500 mm/min; and the length of the needle insertion, 10 mm. Natural rubber sheet, Amegomu sheet AGS-14 (Waki Industry, Osaka, Japan), was used as the target of needle puncture. Puncture tests were performed three times for two needles each of the six needle types, to confirm the reproducibility, and needle resistance was recorded continuously during insertion under the various experimental conditions. The mean maximum value of the resistance force was used as the measurement value. Data were analyzed by accompanying software.

Puncturability test of the needle in the echoendoscope

The operating portion of the echoendoscope was fixed using a vise, and the inserted portion was fixed at straight (free angle) and angled (full-up angle) endoscope positions using a wooden plate, a vinyl chloride material with U-ring-type stainless saddles [Figure 3]. The lateral angle was set at 0°, and the endoscopic upward angle was fixed at 0° (free angle) or 130° (full-up angle). The elevator mechanism was fixed manually at 45°. Needles were inserted into the scope and fixed, and the handle was pushed in to measure the resistance force when the needle tip pierces the puncture target. Analysis of the resistance force against needle advancement through the endoscope was measured using the Autograph. The Autograph settings were set to the same condition as the puncturability test of needle alone. Puncture tests were performed three times for two needles each of the six needle types, and data were obtained for the endoscope in the free angle and that in the full-up angle. The maximum value of resistance force for each needle was used as the measurement value. Data were analyzed by accompanying software.

RESULTS

The results of the mean maximum resistance force of the needle alone, the needle in the echoendoscope with free angle, and the needle in the echoendoscope with full-up angle are shown in Figures 4-6. The results indicated a high reproducibility and small SD. The mean maximum resistance force of the needle alone was higher for the FNB needles than the FNA needles. Among the FNB needles, SharkCore™ had the lowest resistance force (2.02 N; SD: 0.03) [Figure 4]. The mean maximum resistance force of the needle in the echoendoscope with free angle demonstrated that the resistance forces were between 2.10 and 2.34 N [Figure 5]. The difference in resistance force between the needle alone and the needle in the echoendoscope with free angle was less clear for FNB needles than FNA needles. The mean maximum resistance force of the needles was significantly increased with increases in up angle of echoendoscope, particularly for the FNA needles [Figure 6]. Among the tested needles, SharkCore™ had the lowest resistance force (2.23 N; SD: 0.10), even when the echoendoscope was fully-up angled. The mean maximum resistance force of the needle in the echoendoscope with full-up angle was similar for SonoTip® TopGain (3.22 N) and Acquire™ (3.54 N). All data for all needle types are shown in Figure 7.

DISCUSSION

In recent years, EUS-TA has been established as an accurate and safe method to diagnose lesions within GI

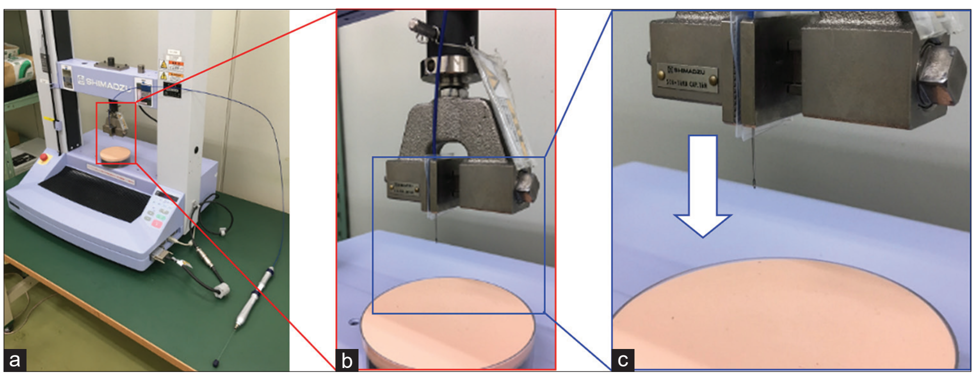

Figure 2. Images of the bench simulator of puncturability test of the needle alone. (a) The Autograph and the tested needle. The needle tip is fixed to the Autograph, (b) The Autograph, needle tip, and the natural rubber sheet, (c) Measuring the resistance force when the needle tip pierces the natural rubber sheet

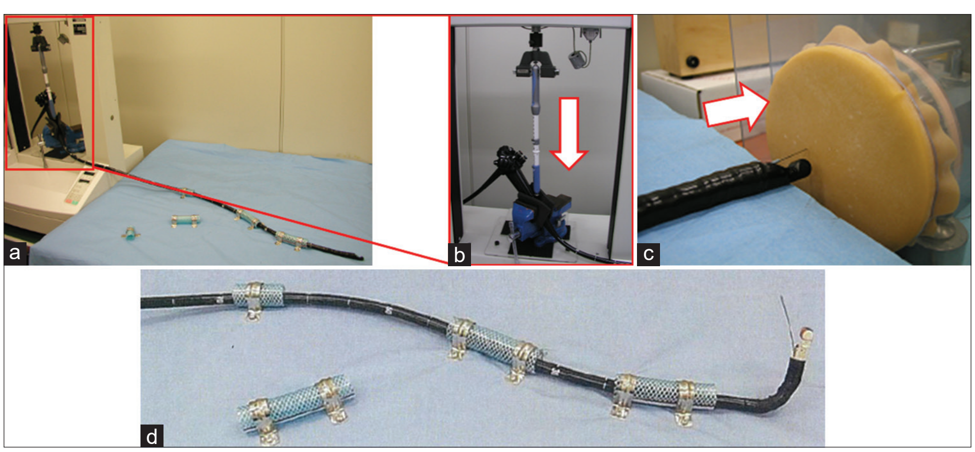

Figure 3. Images of the bench simulator of puncturability test of the needle in the echoendoscope. (a) The Autograph, the echoendoscope, and the tested needle, (b) The Autograph and the handle of needle, (c) Measuring the resistance force when the needle tip pierces the natural rubber sheet. The tip of echoendoscope is straight, (d) The tip of echoendoscope is fully-up angled

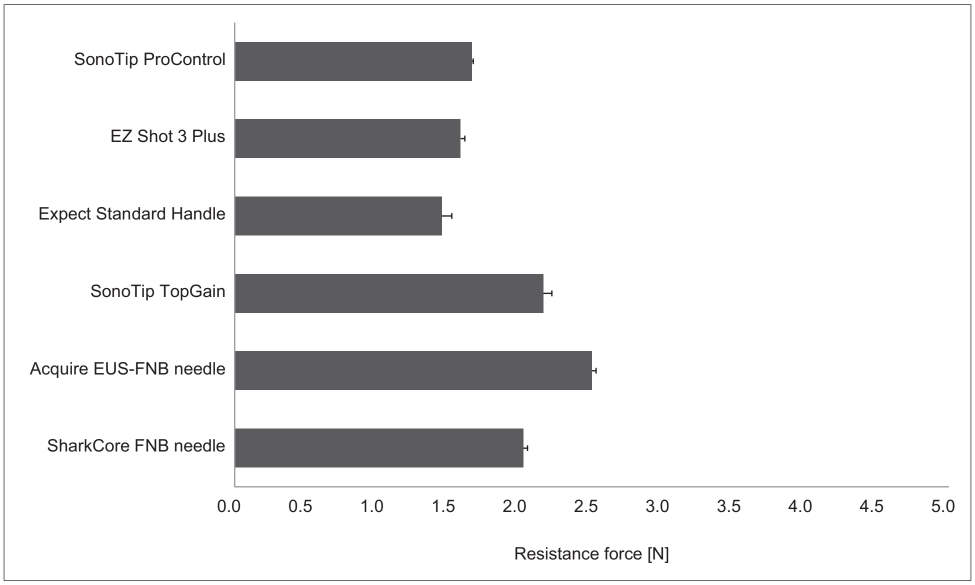

Figure 4. Resistance forces of the needles alone

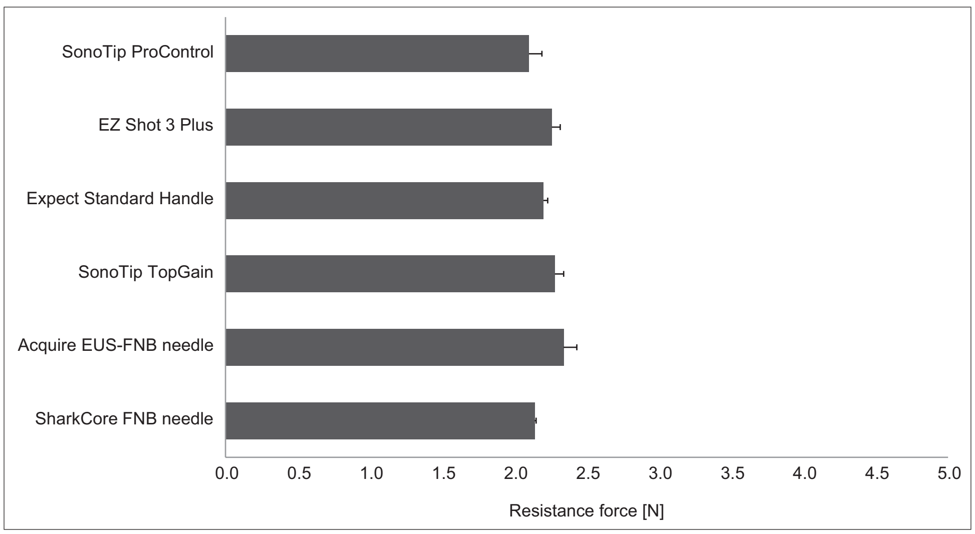

Figure 5. Resistance forces of the needles in the echoendoscope with free angle

tract and/or in organs or lymph nodes located adjacent to the GI tract.[9,12,24,25] The commercially available needles at present have various needle tip shapes and sizes. In general, the choice of the needle is important, and it depends on several patient factors (*i.e.*, lesion size, location, and organ) and physician factors (*i.e.*, preference and experience). Regarding the gauge of the needles, previously, 19-gauge FNA needles were preferably used to obtain a tissue sample of sufficient size; however, there were some concerns, such as the difficulty in passing the needle through the echoendoscope when the tip of the echoendoscope is angulated, owing to the high resistance force, and second, once the needle is inserted through the working channel, the bent section of the endoscope tip becomes less flexible, thereby limiting tip angulation and making it more difficult to visualize and access the lesion.[22] The greater rigidity also restricted the elevator function by a range of motion of 5° to 10°.[26] Some studies have shown no significant differences in diagnostic yield of malignancy between using the 19-gauge needle and using the 22-gauge needle.[5,27,28] On the other hand, 25-gauge needles have a small diameter, and the needle itself is soft, enabling it to easily pass through the echoendoscope, even with a tight angulation. However, the small diameter limits the amount of specimens that can be obtained.[29] Owing to these reasons, puncturing with a 22-gauge needle has become the standard.[3] In the present study, we attempted to analyze the resistance force against needle advancement of six

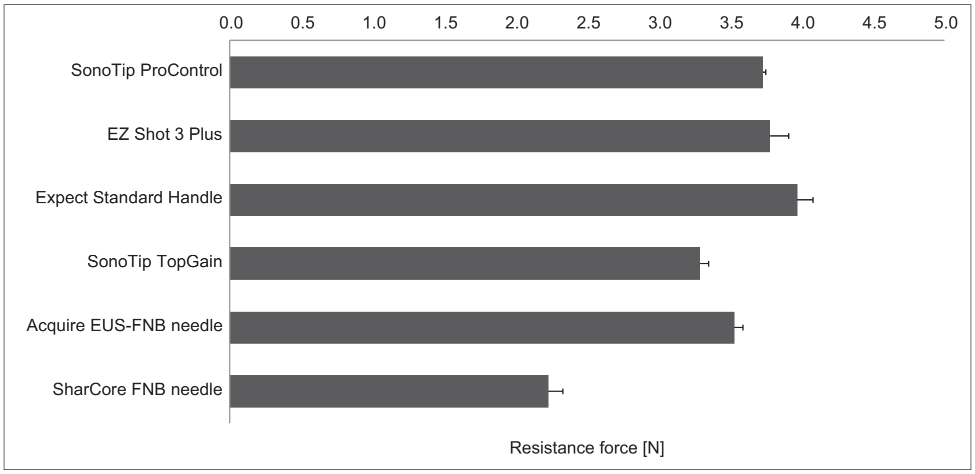

Figure 6. Resistance forces of the needles in the echoendoscope with full-up angle

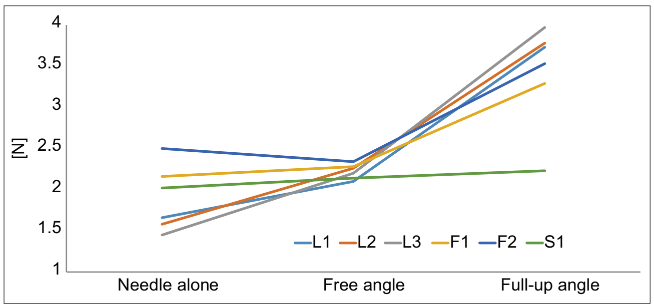

Figure 7. Resistance forces of the needles alone, the needles in the echoendoscope with free angle, and the needles in the echoendoscope with full-up angle

commercially available 22-gauge FNA and FNB needles, in combination with the presence or absence of upward angle of the echoendoscope tip. Endosonographers are aware that there is a difference in resistance force between different needles, which is also influenced by the angle of the echoendoscope tip. Needle-associated mechanical features, such as internal friction, retention, or loss of shape, may contribute to the difference in resistance force.[22] Therefore, in the present study, we established a system to objectively evaluate the insertion characteristics of needles under various conditions. Generally, all needles have four main components: a needle body, a stylet, an outer sheath, and a handle. The resistance force against needle advancement is mainly produced by the material difference of the needle body and outer sheath. Major materials used for the needle body are stainless steel and nitinol, and major materials used for the outer sheath are synthetic resin and steel coil. In the present study, the result that the resistance force of the FNB needle alone is higher than the FNA needle alone is thought to be a result of the difference in shape of the needle tip. FNA needles have low resistance force, owing to their simple sharp edge, and FNB needles have a higher resistance force than FNA needles, owing to the unique shape of the needle tip. However, the difference in resistance force between the needle alone and the needle in the echoendoscope with free angle was less clear for FNB needles than FNA needles. Namely, the body of FNB needles had lower friction to the outer sheath compared with FNA needles in the channel of echoendoscope. The higher puncturability of FNB needles in the channel of echoendoscope is thought to be owing to their smooth puncture with lower friction, as a result of their improved outer sheath and body material. Regarding the resistance force against needle advancement in the echoendoscope with full-up angle, the FNB needles have lower resistance force than FNA needles, and SharkCore™ had the lowest resistance force. Our study indicated that SharkCore™ is most easily inserted into target lesion with the echoendoscope full-up angle. This result was thought to be owing to the low friction and elasticity of the outer sheath and needle body of SharkCore™. The outer sheath of SharkCore™ is made of a polyester block amide copolymer, which is type of the synthetic resin, and it may decrease the friction between the outer sheath and needle body, particularly in full-up angle situation. We think that low friction together with elasticity of the needle body and outer sheath greatly contributes to a needle's low resistance force and high puncturability. It is unclear that how the difference of resistance forces of each needle is clinically problematic. However, it is considered that the needles with high puncturability may be useful in the following clinical settings, for example, small solid pancreatic tumor (SPT), such as small pancreatic ductal adenocarcinoma with strong fibrosis, and small GI subepithelial lesions (SELs) of gastric fornix, in which the needle is slippery. These small lesions are occasionally difficult to puncture by the needle with low puncturability, and hence, the 25-gauge FNA needles had been used instead of FNB needles. Owing to the low resistance force of SharkCore™ when the echoendoscope is fully-up angled, we suggest that in cases in which full-up angle of the echoendoscope is necessary, for example, small SPT, which is punctured from duodenal bulb with the scope push position, and SEL of gastric fornix, SharkCore™ is the most suitable for insertion into the target lesions. Regarding the Franseen-type needles, the mean maximum resistance force of the needle alone, the needle in the echoendoscope with free angle, and the needle in the echoendoscope with full-up angle of SonoTip® TopGain were all similar to Acquire™. These results indicate that regarding puncturability, SonoTip® TopGain, which was released more recently, is comparable to Acquire™. These needle improvements have reduced the opportunity to use 25-gauge needles, and at present, the use of 22-gauge FNB needles seems to be the first choice. However, further development and improvement of needles are required to further increase their diagnostic ability.

There are several limitations to this study. First, this was an *ex vivo* experimental bench study, and may be different from *in vivo* conditions, and clinical validity remains to be determined. Second, some other needles, such as reverse bevel-type needles, were not evaluated, although the six tested needles are the most frequently used. Third, it is unclear whether the same results will be obtained in the setting of 19-gauge or 25-gauge needles. Fourth, this study only focused on and evaluated the resistance force and puncturability of the needles. Needles have numerous other features, for example, needle visibility, echogenicity, the amount of tissue that can be sampled, and texture of the scope handle; however, these factors were not evaluated. In conclusion, in the current bench study, SonoTip® TopGain had similar puncturability to Acquire™ in all tested situations. Regarding the puncturability, SharkCore™ is most suitable for insertion into the target lesions, in which the echoendoscope tip is fully-up angled.

Acknowledgments

All needles and cost were provided by the Tokyo Medical University, research funds. We would like to thank Dr. Helena Akiko Popiel for editing of the manuscript.

Financial support and sponsorship

Nil.

Conflicts of interest

Takao Itoi is an Associate Editor of the journal, and Shuntaro Mukai is an Editorial Board Member. This article was subject to the journal's standard procedures, with peer review handled independently of the editors and their research groups.

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