

The “Twist-Needle” – a new concept for endoscopic ultrasound-guided fine needle-biopsy



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Bibliography

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ABSTRACT

Background and study aims Endoscopic ultrasound-guided fine-needle biopsy (EUS-FNB) represents a standard method for tissue acquisition of lesions adjacent to the gastrointestinal wall. Needles of 19 gauge acquire more tissue than needles with a smaller diameter, but are often unable to penetrate solid, rigid masses. In this study we evaluated a novel prototype that links forward movement of the needle to rotation of the needle tip.

Materials and methods Two needle-models that generate either a regular axial movement or a combination of axial movement with rotation of the needle tip were compared ex vivo for measurement of pressure needed to penetrate artificial tissue. Furthermore, a standard 19-gauge EUS-FNB needle was compared to a modified model (“Twist Needle”) in an ex vivo model to measure the amount of tissue obtained.

Results Pressure measurements using the rotating needle revealed that significantly less pressure is needed for penetration compared to the regular axial movement (mean ± SEM; 3.7 ± 0.3 N vs. 5.5 ± 0.3 N). Using the modified 19-gauge “Twist Needle” did not diminish tissue acquisition measured by surface amount compared to a standard needle (37 ± 5 mm² vs. 35 ± 6 mm²).

Conclusion The method of rotation of an EUS-FNB needle tip upon forward movement requires less pressure for penetration but does not diminish tissue acquisition. Hence, the concept of our “Twist Needle” may potentially reduce some of the current limitations of standard EUS-FNB.

Introduction

Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) and fine-needle biopsy (FNB) are to date the most important diagnostic procedures to obtain tissue from masses adjacent to the gastrointestinal wall [1]. The sensitivity of those methods depends on the lesion site and factors like needle size and number of passes through the lesion. Although EUS-FNA presents a high sensitivity [2], there are reports of up to 15% of the pathological results that can be indeterminate requiring a second examination with additional biopsies [3, 4]. Technical difficulties may result in inadequate tissue collection. High

technical failure rates are reported especially using a 19-gauge needle for transduodenal FNB [5]. Several attempts have been made to improve material retrieval and lower technical failures. One attempt is to repeat biopsies until an on-site pathologist confirms that there is enough material for diagnosis [6]. Another attempt includes changing the needle tip by adding side holes or changing the needle tip to a fork-like or Franseen shape [7–10]. Also the number of passes through the tissue after insertion helps to improve material acquisition [11]. Still, the sensitivity of this method decreases significantly regarding diseases like chronic calcific pancreatitis with a pancreatic mass and technical success is impaired using 19-gauge needles in

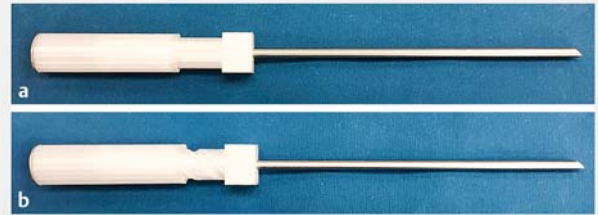
case of lesions that have to be punctured using the transduodenal route [12–15]. One of the main reasons for technical failure is related to the relatively firm needles in case of needle advancement in an angulated position of the endoscope [16]. This is especially true for 19-gauge needles. Consequently conversion to a needle with a smaller diameter has to be performed to successfully acquire material [17]. Although those smaller needles represents the gold standard for the transduodenal route, the amount of obtained tissue suited for a histological analysis is higher with the 19-gauge needles [5]. With the advent of neoadjuvant therapies in pancreatic cancer [18, 19] and recognition of different genetic and molecular subtypes that might lead to a more targeted therapy [20, 21], diagnostic requirements shifted from cytology to histology.

In this work we investigated a new method that allows penetration of target structures more easily to overcome such obstacles. We aimed to develop a mechanism that requires less pressure to penetrate without compromising material acquisition.

Materials and methods

Models used for pressure measurement were composed of a hollow plastic pipe generated by a 3D printer with a steel needle 28 cm long and 5 mm in diameter. The needle bottom was attached to the pipe by a round metal plate (► **Fig. 1**). Two dents were located at the inner surface of the other end of the pipe. The dents fit into preformed tracks of an inner plastic cartridge. Forward sliding of the pipe using a fixed inner cartridge results in either an axial movement of the needle tip or a combination of axial movement and rotation of the needle tip up to 540°, depending on the cartridge used. The combined movement was achieved only by applying slight pressure to the end of the plastic tube as demonstrated using a prototype made only of plastic in ► **Video 1**. A 2-cm thick hard foam plate was used to simulate tissue. Pressure was measured using the PCE-DFG 500 force sensor (PCE, Arnsberg, Germany).

In addition, core biopsies were obtained using a standard nitinol-based 19-gauge EUS-FNB needle (EZ Shot 3 Plus, Olympus GmbH, Hamburg, Germany). For comparison a modified 19-gauge EUS-FNB needle with the middle inner cartridge replaced by one with screw shaped inner tracks was used. The handle of the needle was also modified to slide on the tracks to advance and rotate the needle tip (► **Fig. 2**). Fresh porcine liver was used as tissue for testing. First, the needle sheath was placed 5 mm above the tissue surface. Then the needle was advanced for 3 cm into the tissue. Fanning was applied using suction five times. Then negative suction pressure was stopped and the needle was retracted. Finally, the needle was flushed using saline into a flat bottom tube and an image of the bottom was taken to calculate surface area of the biopsy cores obtained. The area per each core biopsy was determined in random order by an examiner who was blinded regarding the needle type that was used. First, the examiner determined the surface of each fragment visible on the bottom of the tube. The areas were then added to determine the total amount of material obtained during the corresponding biopsy.



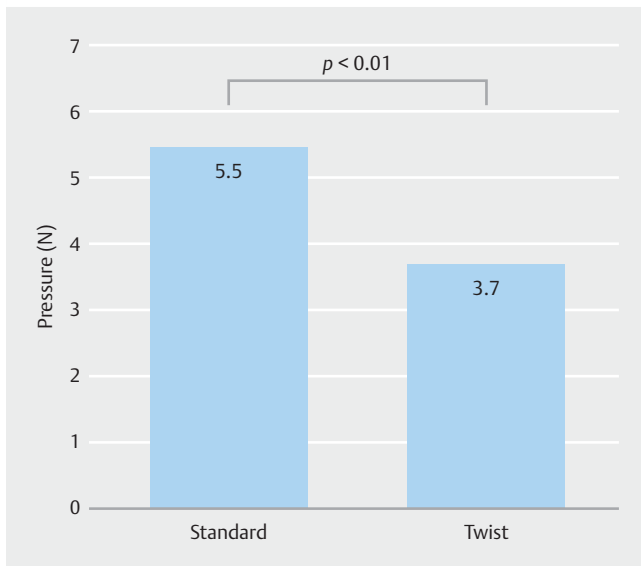
► **Fig. 1** Models used for pressure measurement. Models are composed of a hollow pipe with a needle in their center. The needle bottom is attached to the left end of the pipe by a metal plate. Two dents located at the inner surface of the pipe slide on preformed tracks of an inner cartridge. Forward sliding of the pipe using a fixed inner cartridge results in an axial movement of the needle tip in model **a** and a combination of axial movement and rotation of the needle tip in model **b**.



► **Fig. 2** Fine-needle biopsy (FNB) devices used for core biopsy measurements. The middle inner cartridge of a standard 19-gauge FNB device (**a**) was replaced by an inner cartridge with screw shaped inner tracks (**b**). Two dents on the inner surface of the handle slide on these tracks and allow the rotation of the needle inside the outer sheath.



► **Video 1** Prototype demonstrating the conversion of axial force to axial movement combined with rotation of the needle tip. (representative still image of the video).



► **Fig. 3** Pressure needed to penetrate a hard foam plate simulating tissue. Left bar displays axial movement and right bar a combination of axial movement and rotation of the needle tip.

The hollow pipe and the inner cartridges were designed and produced by 3D printing using polylactid acid. Statistics were performed with IBM SPSS Statistics 24 (IBM Corp, Armonk, New York). Paired student t-test was used to investigate differences between experimental methods. $P < 0.05$ was considered statistically significant.

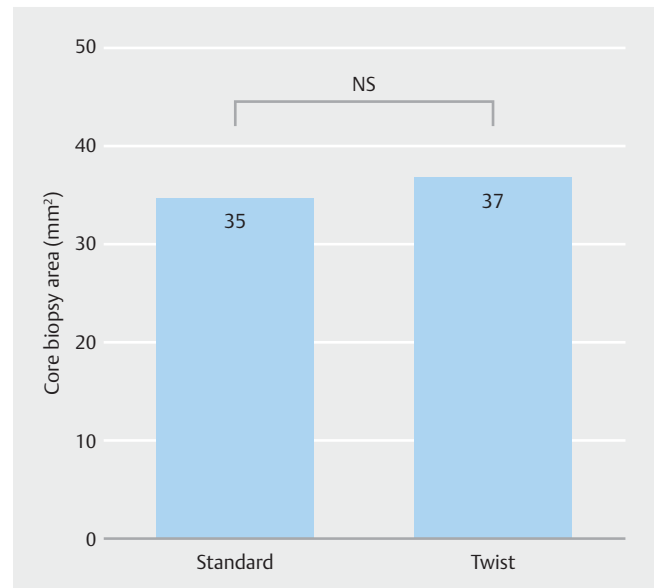
Results

Rotation and axial movement results in less pressure needed to penetrate artificial tissue than axial movement alone

Using the plastic model with the steel needle presented in ► **Fig. 1** we performed 16 biopsies with each movement technique. We were able to show that the pressure needed to penetrate a tissue replica is significantly less when applying axial pressure in combination with rotation of the needle in comparison to axial pressure alone (► **Fig. 3**).

Tissue amount obtained using a “Twist” 19-gauge FNB is comparable to a standard 19-gauge FNB

To apply the twist movement using a more realistic scenario we modified a standard 19-gauge EUS-FNB needle by easily replacing the middle cartridge with our device including the screw like tracks (► **Fig. 2**). This resulted in the twist movement of the EUS-FNB needle upon advancing the needle out of the sheath. The usage is demonstrated in ► **Video 2**. We compared four twist needles with four standard needles. Each needle was used for three punctures resulting in 24 measurements. The comparison of surface of each biopsy core presented no significant difference with a trend in favor of the twist needle (► **Fig. 4**). Hence, using the “Twist” needle did not diminish the amount of tissue obtained.



► **Fig. 4** Amount of core biopsy obtained measured by surface area. Left bar depicts the amount of core biopsy obtained using a standard 19-gauge FNB and right bar using a modified 19-gauge FNB with axial movement and rotation of the needle tip.

Discussion

Since the introduction of EUS-FNA, different devices have been introduced to ease tissue acquisition [22]. Although smaller needles are more flexible and reach structures even in an angulated position of the endoscope in the pancreatic head region, recovery of material suitable for a histological diagnosis is significantly higher using larger 19-gauge-needles [5]. There is a correlation of needle diameter and difficulties in tissue penetration [17]. Furthermore, penetration with larger diameters un-



► **Video 2** Usage of the modified standard 19-gauge FNB device demonstrating that the rotation of the handle translates in rotation of the needle tip. (two representative still images of the video).

der application of considerable force may lead to more trauma of punctured tissue. Conversion to a smaller diameter decreases the pressure needed to penetrate the lesion. For example, a 25-gauge needle allows the examiner to advance the needle with less than 2 N using any position of the endoscope. In contrast use of a 19-gauge needle increases the pressure to advance the needle up to 11 N in an angulated position [16]. Hence, regarding those publications, the precision of obtaining an exact puncture might decrease due to high resistance. Resistance is particularly high during fanning with a 19-gauge needle in an angulated position [16]. Based on our ex-vivo experiments, combining forward with rotational movements reduces the pressure needed to penetrate tissue. This might lower the rate of technical failure. In addition, another disadvantage of larger 19-gauge needles is contamination of blood during biopsy [17]. Less trauma to the tissue due to lower pressure needed using our rotating needle might tackle this problem. Unfortunately, a limitation of our study is that pressure was not measured in the experiment with the modified 19-gauge needles. Further work involving industrial-grade rotational needles might be better suited for pressure measurements using high-precision scales. Histological examination of the obtained specimen in those experiments might be graded for tissue trauma and blood contamination as interesting outcome measurements.

Additional limitations of our experimental model are that we did not simulate different endoscope positions to compare how the new needle performs in an angulated position. There is the theoretical possibility that some grade of angulation of the needle remains after the first pass. This should be diminished by use of a nitinol-based needle. Still, such an angulation might result in a spiral movement of the needle tip during the following passes.

Conclusion

Our work should be regarded as early feasibility data on the use of this new mechanism to obtain material with a modified EUS-FNB needle. Further studies are needed to judge this new method first in an animal model using organs with different attributes regarding stiffness and then in a prospective manner within a clinical trial as soon as such a needle will be available as a medical product. Nevertheless, to the best of our knowledge, this is the first report that introduces a rotating mechanism to an EUS-FNB needle. In summary we conclude that our rotating model needs less pressure to penetrate artificial tissue without decreasing the amount of tissue acquisition using modified 19-gauge EUS-FNB needles.

Competing interests

None

References

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