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# Device malfunctions with use of EUS–guided fine-needle biopsy devices: Analysis of the MAUDE database

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## ABSTRACT

**Background:** The safety of endoscopic ultrasound–guided tissue acquisition through fine-needle biopsy devices is well-established in clinical trials. The real-world experience of using these devices is not known. The authors analyzed the postmarketing surveillance data from the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database to answer this question.

**Methods:** The Food and Drug Administration MAUDE database from January 2012 to June 2022 was accessed to evaluate for device malfunctions and patient-related adverse consequences of these malfunctions.

**Results:** There were 344 device-related issues. Most issues were due to detachment or breakage of the device ($n$ = 185 [53.7%]). Seventy-six of the breakages (40.8%) occurred during the procedure, whereas 89 cases (47.8%) occurred while removing the needle from the endoscope. The most common site of tissue biopsy at the time of needle breakage was the pancreas (44 [23.8%]).
The common patient-related adverse events were retained foreign body ($n$ = 50 [14.5%]) followed by bleeding (16, 4.6%). Six patients (3.4%) required a second intervention for removal of the retained foreign bodies including surgery in 2 cases. The device breakage damaged the endoscope in 3 cases (1.7%), and there was 1 case of needlestick injury to the nurse.

**Conclusion:** The fine-needle biopsy devices can be associated with needle breakage and bending; these adverse events were not previously reported. Needle breakages can result in a retained foreign body that may require additional procedures including surgery. These real-world findings from the MAUDE database may inform clinical decisions and help improve clinical outcomes.

**Key words:** Fine-needle biopsy; Endoscopic ultrasound; Procedure related adverse events; Biopsy needles

## INTRODUCTION

EUS is an invaluable tool for evaluation of luminal as well as extraluminal structures of the gastrointestinal tract.[1,2] The initial EUS devices used for tissue acquisition had a simple beveled tip for fine-needle aspiration (FNA). Although highly effective, the utility of FNA is limited in diagnosing diseases that require intact tissue architecture such as autoimmune pancreatitis and to subtype lymphomas. This paved the way for development of fine-needle biopsy (FNB) devices with different tip designs.[3] The specialized EUS-FNB needles have a higher diagnostic accuracy, require fewer passes, and can reduce or even eliminate the need for Rapid On-Site Evaluation as compared with EUS-FNA needles.[4–6]

All EUS-FNB device needles can be classified based on the cutting tip design into 3 broad categories: beveled needles, Franseen tip needles, and fork-tip needles.[7] The commonly used EUS-FNB devices are the ProCore device (Cook Medical, Inc, Bloomington, Indiana) with a beveled tip, the Acquire device (Boston Scientific, Marlborough, Massachusetts), and SonoTip TopGain (MediGlobe, Rohrdorf, Germany) with a Franseen tip, that is, 3 symmetrically edged cutting surfaces, and the SharkCore device (Medtronic Corp, Minneapolis, Minnesota) that has 6 asymmetrically edged cutting surfaces (fork-tip).[8] The Cook ProCore comes in 2 different designs—one with a forward bevel and one with a reverse bevel.

Although the clinical utility of EUS-FNB devices has been evaluated in multiple randomized controlled trials and prospective studies, real-world device malfunctions and patient consequences of device malfunctions have not been evaluated. The authors used the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database to analyze reported device malfunctions to gain insight into the present real-world experiences of using these needle devices.

## METHODS

The MAUDE database is a publicly accessible database maintained by the US FDA. It passively monitors device-related issues including patient-related adverse events that were sent to the FDA by various users. Device manufacturers and importers are obligated to report

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**Table 1**

**Device related adverse events reported according to the type of devices.**

| | Cook ProCore ($n$ = 314), $n$ (%) | Boston Acquire ($n$ = 15),* $n$ (%) | Covidien SharkCore ($n$ = 15),† $n$ (%) |
|---|---|---|---|
| Breakage/detachment | 174 (55.4) | 5 (33.3) | 6 (40) |
| Advancement issues | 43 (13.7) | 4 (26.6) | 8 (53.3) |
| Retraction problems | 92 (29.3) | 1 (6.6) | 0 |
| Bent needle | 75 (23.8) | 0 | 0 |
| Safety lock dysfunction | 0 | 1 (6.6) | 0 |
| Contaminated needle | 0 | 2 (13.3) | 0 |

*There was 1 reported issue of device malfunction, but the details are not available, 1 report of misassembled device.

†One report of defective suction syringe.

directly to the FDA any instances of device malfunction and/or issues in which the device is thought to have contributed to a patient-related adverse event or death. Facilities are obliged to report issues involving death directly to the FDA, whereas serious adverse events need to be reported to the manufacturer, who in turn reports it to the FDA. The database is in the public domain and freely accessible online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

The database can be searched online based on product problem, product class, event type, device manufacturer, model number of the device, brand name of the device, product code, or date range. The retrievable data contain individual reports (identifiable by a unique report number) pertaining to date of the event, date of the report, event type, device problems, patient problems, number of events, and a description of the event (in a free-text area), in addition to the details of the manufacturer, brand name, model number, and product code.

The authors accessed data from the MAUDE database and searched by manufacturer and brand name for reports containing information regarding each of the 4 FDA-approved EUS-FNB needle devices (ProCore, Acquire, SonoTip TopGain, and SharkCore) from January 2012 to June 2022. The Quick-Core needle device (Cook Medical, Inc, Bloomington, Indiana) was not available and was not evaluated.[1,7] Data pertaining to device malfunctions were retrieved, downloaded to an Excel spreadsheet (Microsoft Corp, Redmond, Washington), and filtered to include only EUS-FNB devices. Reports with no identified device malfunctions were excluded, and adverse events from research studies that were also reported to the database were excluded. The authors classified each device problem according to the type of dysfunction and analyzed if any of the problems were directly attributable to specific patient-related adverse events. Device breakage was defined as a complete detachment of part of the device or splitting of the needles. A breakage site was considered in the needle body if the report mentioned the site of breakage in any part between the device handle and the needle tip.

## RESULTS

### *Device-related issues*

Between January 2012 and June 2022, there were 344 device-related issues. The Cook ProCore needle device had 314 reported issues (91.2%), and the Medtronic SharkCore needle device had 15 issues (4.3%), whereas there were 15 reported issues (4.3%) with the Boston Scientific Acquire needle device, and there were no reported issue with the MediGlobe SonoTip TopGain needle device.

### *Device malfunctions*

Of the 344 device malfunctions, most were due to detachment or breakage of the device ($n$ = 185 [53.7%]), difficulty in advancing the tip ($n$ = 55 [15.9%]), and difficulty in withdrawal of the needle ($n$ = 95 [27.6%]) (Table 1). There were 75 reports of "bent needle without breakage" (21.8%) reported exclusively with the Cook ProCore device. The common reported sites of breakage were at the tip ($n$ = 73 [39.4%]), followed by breakage in the body of the needle (43 [23.2%]), whereas it was not reported in 38 cases (20.5%) (Table 2). The target organ during the procedure was reported only in 65 of 185 reports (35.1%) related to device breakage. The pancreas was the target organ in 44 of the 65 reports (67.7%). In the 27 reports of device breakage (14.6%), there was associated difficulty in retracting the needle into the endoscope. Also, there were 10 reports of device breakage (5.4%) that had an associated difficulty in advancing the FNB devices.

Also, there were reports of contamination in the form of black remnants noticed while flushing the needle before usage in 2 cases that utilized the Boston Acquire device. There was one report of safety lock dysfunction with the Boston Acquire device that was noticed before the device was used for biopsy. The lock could not keep the needle inside the sheath. It was returned to the manufacturer for further evaluation.

### *Consequences of device malfunctions*

Of the 185 reports of device breakages, 75 of the breakages (40.5%) occurred during the procedure, and 90 events (48.6%) occurred while removing the needle from the endoscope, whereas

**Table 2**

**The site of device breakage according to the type of devices.**

| Site of breakage | Cook ProCore ($n$ = 174) | Covidien SharkCore ($n$ = 6) | Boston Acquire ($n$ = 5) |
|---|---|---|---|
| Tip | 68 | 1 | 4 |
| Handle | 10 | 3 | 0 |
| Sheath | 8 | 0 | 0 |
| Needle body | 43 | 0 | 0 |
| Stylet | 3 | 1 | 0 |
| Beacon system | 0 | 1 | 0 |
| Luer lock | 1 | 0 | 0 |
| Adjuster | 1 | 0 | 0 |
| Piston | 1 | 0 | 0 |
| Unknown | 39 | 0 | 1 |

information was not available in the remaining 21 reports (11.3%). Among the 75 intraprocedure breakages, the remnant needle resulted in a foreign body in 50 patients (66.6%). It was successfully removed in 23 patients (46%) during the same endoscopy session. A repeat procedure was required in 6 patients (12.0%) including surgery in 2 patients (4.0%), whereas the details were not available in 3 patients. In the remaining 18 patients (36%), the foreign body was left behind as it could not be retrieved endoscopically. All of these breakages were at the needle tip. Seven of the lesions (14.8%) were lodged in the pancreas, 2 tips (4.2%) were lodged in the duodenum, and 2 (4.2%) were lodged in the stomach, whereas the location of the tip was not described in 6 reports (12.7%). On follow-up, a patient who underwent EUS-guided FNB for a pancreatic tail lesion developed severe abdominal pain after the procedure; computed tomography of the abdomen revealed an abscess in the pancreas tail around the mass lesion, and the tip was embedded in the lesion. No further details were available. There were 3 reports of damaged endoscope channels due to device breakages. Two of these breakages occurred with an associated retraction problem, whereas in the third one, there was a concomitant problem in advancing the scope. Also, 174 of the breakages (93.5%) were reported with the Cook ProCore device, whereas there were no reports of breakage issues with the MediGlobe TopGain device.

Of the 174 patients who had detachment or breakage of the Cook ProCore needle device, 48 patients (27.5%) had a residual foreign body after the procedure (Table 3). In one report of breakage associated with the SharkCore needle, the residual foreign body could not be retrieved. The patient experienced melena after discharge and was admitted to another hospital for blood transfusion and further evaluation. There were no reported lodged foreign bodies with the Boston Acquire device. Bleeding was noted in 16 patients (4.6%) following the biopsy.

## DISCUSSION

To the authors' best knowledge, this is the largest study evaluating real-world data evaluating FNB device–related malfunctions and their clinical consequences. In their analysis of the MAUDE database, device breakages comprised 53.7% of all EUS-FNB device–related malfunctions. Device breakages resulted in remnant foreign bodies lodged in the target organ or adjoining areas in 27% patients. Of concern, 36% of these foreign bodies could not be retrieved, and a patient developed an abscess around the impacted foreign body. In addition, 12% of patients required repeat interventions to treat problems arising from retained foreign bodies, including surgery in 2 patients. Device breakages also damaged the endoscopes in 3 reports.

The current literature on device malfunctions of EUS-FNB devices is sparse, especially with regard to breakage of FNB devices. Breakage of these devices has only been reported in case reports before.[9–12] No patient-related adverse event was reported in these cases.

In a patient with prior pancreaticoduodenectomy who presented for pancreaticojejunal anastomotic stricture, the broken needle fragment could not be retrieved endoscopically, and it was removed during planned surgery.[9] In another case report, it was not realized during the procedure that the tip has fractured and the tip remained lodged in the duodenal wall following the procedure. It was inadvertently discovered on computed tomography of the chest after 6 months. The tip migrated to the aortic bifurcation on follow-up imaging. The needle was removed endovascularly using a snare under fluoroscopy guidance.[12] In the remaining 2 cases, the broken fragment was retrieved endoscopically during the same session.[10,11]

Most of the present studies evaluating the safety of EUS-FNB devices have not reported any instances of device breakage. In a recent systematic review including 51 studies comprising 5530 patients, the pooled adverse event rate for EUS-guided FNB was 0.59% (95% confidence interval, 0.29%–1.0%).[13] Although the most common adverse event was acute pancreatitis, there was no mention of device malfunctions or breakage in the study. Similarly, a network systematic review of 16 randomized controlled trials comparing various types of EUS-FNB devices found that the reported incidence rates of adverse events were 2.7% with the Franseen tip needles, 2% with the fork-tip needle, and 1.9% with the FNA needles.[14] This study's results from the postmarketing surveillance data capture these instances of device malfunctions in real-world settings.

The mechanisms for device breakages could be multifactorial. In this study, there was an associated difficulty in advancing or retracting the needles in 20% of the reported breakages. Also, 94% of the breakages were reported with the use of ProCore devices. This could be due to reporting bias, and also ProCore devices are among the first approved EUS-FNB devices. Approximately 40% of these breakages were at the tip of the needle. The ProCore devices could be more vulnerable because of its beveled needle design. The needle is thinnest at the bevel site, just proximal to the tip, at the "core trap." Fine-needle biopsy needles are also vulnerable to break during use of the elevator, as well as due to excessive elevator actuation ("fanning") and as the reverse bevel can become anchored within lesions during withdrawal.[12] Endoscopists should be cognizant of these complications while performing EUS-FNB procedures and would benefit from inspecting the needles before and after their usage—something rarely performed in clinical practice.

**Table 3**

**Patient-related adverse events reported according to the type of devices.**

| | Cook ProCore (*n* = 314), *n* (%) | Boston Acquire (*n* = 15), *n* (%) | Covidien SharkCore (*n* = 15), *n* (%) |
|---|---|---|---|
| Bleeding | 3 (0.9) | 0 | 13 (86.6) |
| Foreign body | 48 (15.3) | 0 | 2 (13.3) |
| Inflammation/pancreatitis | 1 (0.3) | 0 | 0 |
| Perforation | 4 (1.3) | 0 | 0 |
| Pain | 2 (0.6) | 0 | 0 |
| Abscess | 1 (0.3) | 0 | 0 |

The pancreas was the target organ for device breakages in 67.7% of reports. EUS–FNB is more utilized for pancreatic lesions than in other parts of the gastrointestinal tract. Similarly, manufacturers may consider revising their instructions to include these complications and explore design-related reasons for breakage/bending of the needles during biopsy.

The limitations of this study are inherent to any study that is performed using the MAUDE database. The reporting in this database can be inconsistent, and certain complications may be underreported. The rate of adverse events cannot be calculated as the details of the number of devices used during the period are not available. Also, certain reports lack sufficient details to allow exploration of the underlying reasons for the device malfunctions. Similarly, confounding factors such as operator errors and interaction with other devices cannot be explored from these reports. These limits can be found in all MAUDE studies in the literature, of which there are more than 500 at this time. Despite these limitations, the MAUDE database provides information to physicians and researchers that is simply not available anywhere else. The strength of this article is that it includes a large number of real-world experiences of using EUS-FNB devices. To the authors' best knowledge, device malfunctions, especially breakages based on the various types of EUS-FNB devices have not been studied in this manner before.

Future research should focus on the various reasons including device, procedural, and patient-/lesion-specific risk factors for such complications of device breakage/bending and assess methods that can minimize such complications.

## CONCLUSIONS

The present study found that intraprocedure device breakages are commonly reported malfunctions of EUS-FNB devices. These malfunctions can result in severe patient-related adverse events, injure health care personnel, and damage the echoendoscope. Fine-needle biopsy needles should ideally be inspected before initiation of the procedure and after withdrawal. The endoscopists, patients, and device manufacturers should be cognizant of these risks.

## Compliance With Ethical Standards

This type of study does not involve active human participants and/or animals; therefore, a formal consent, informed consent, institutional review board approval, and ethical approval are not applicable and/or not required.

## Conflicts of Interest

D.G.A. is a consultant to Boston Scientific. The authors declare that they have no financial conflict of interest with regard to the content of this report. Douglas G. Adler is a Co-Editor-in-Chief of the journal. This article was subject to the journal's standard procedures, with peer review handled independently of the editor and his research group.

## Author Contributions

A.S.: data collection, analysis, interpretation of results, and drafting of the article. D.M.: concept, design, interpretation of results, and drafting of the article. All authors: critical revision of the article for important intellectual content and final approval of the article.

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