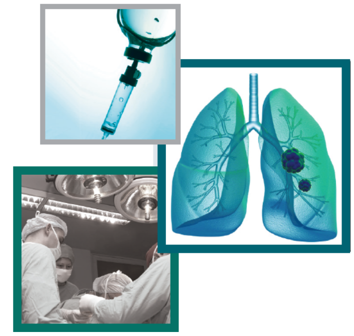
Device Evaluation

Lung Cancer Management



Loss of flexion during bronchoscopy: a physical experiment and case study of commercially available systems

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Practice points

- Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) has advanced bronchoscopic diagnosis and staging of lung cancer and is now a key component in international lung cancer guidelines.
- However current EBUS scopes are larger and less flexible than standard bronchoscopes.
- Reduction in flexibility reduces the yield of EBUS scopes making areas such as the left upper lobe less accessible.
- A case detailing this difficulty and limitation of EBUS-TBNA is presented.
- Two commercially available EBUS scope systems and multiple commercially available EBUS needles were experimentally measured *ex vivo*. It was found that smaller gauge needles allow for better scope angulation and manipulation.
- These data are of significant interest for bronchoscopists planning EBUS-TBNA of difficult to reach areas such as the left upper lobe.

Duringroutine endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) procedures, especially with biopsy of lymph nodes in or around the left upper lobe, frequent reports have noted the loss of ultrasound image and needle angulation leading to an inability to biopsy nodes visualised by EBUS. The aim of this research was to investigate and compare this loss of angulation with commercially available scopes. Bench-top experiments and a clinical case study demonstrated the varying loss of scope angulation, flexibility and manoeuvrability with different scopes and biopsy instruments leading to procedural implications. Improvements in both the EBUS scope and needle characteristics are required to overcome this limitation which has implications in bronchoscope navigation and the diagnostic yield of EBUS-TBNA.

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Flexible bronchoscopes have widely been used as both a diagnostic and therapeutic tool in pulmonology since first presented in 1966 [1]. The endobronchial ultrasound scope (EBUS) contains a curved array ultrasound transducer incorporated into the flexible distal end of the bronchoscope. This curved array transducer facilitates a forward 30° field of vision of the mediastinal vascular structures and lymph nodes adjacent to the airways [2,3]. One technique which has been clinically proven in both the staging and diagnosis of lung cancer is transbronchial needle aspiration (TBNA). TBNA is a minimally invasive endoscopic technique used to sample and diagnose peribronchial masses for lung cancer, infections and diseases, and is often used with real-time ultrasound guidance (EBUS-TBNA) [4,5]. TBNA involves passing an aspiration needle, normally a 21-gauge (Ga) cytology needle or 19-Ga histology needle, through the working channel of a bronchovideoscope and advancing the aspiration needle to the sampling area. The target tissue is pierced with the needle and aspiration begins. Subsequently the needle is withdrawn through the working channel and the sample is analyzed [2,6]. The safety, efficacy and reliability of TBNA and other

Future Medicine

Figure 1. Scopes used during the analysis.
(A) Olympus BF-1T160, **(B)** Pentax EB-1970UK, **(C)** Olympus BF-UC260FW [11–13].

endoscopic techniques that require the insertion of an endoscopic tool through the working channel have been well documented [3,7–10].

However, anecdotal reports suggest that steering a bronchoscope becomes more difficult upon introducing instruments through the working channel. This may be especially evident while attempting to biopsy difficult-to-reach areas such as the nodes surrounding the left upper bronchial lobe. During TBNA, reports suggest that the scope transducer-interface is pushed away from the airway wall on insertion of an aspiration needle, even with the use of an ultrasound balloon. Thus prohibiting the aspiration needle from sampling the target. This not only limits the real time guidance but also the manoeuvrability and navigation of the instrument. Furthermore it has been described that the insertion of a needle into the working channel of a fully flexed endoscope can result in damage to the scope [6].

The aim of this research is to evaluate the loss of flexion of endoscopes during use through both physical experimentation and a clinical case study, and to assess the range of angle loss once instruments are inserted through the working channel of the scope.

Physical experiments materials & methods

A number of experiments were carried out to determine the influence of endoscopic instruments on the manipulation and articulation of bronchoscopes. The experiments comprised of introducing endoscopic instruments of varying cross sectional diameters and measuring the corresponding deflected up and down angles of the bronchoscope. The scopes investigated were the Olympus BF-1T160 bronchovideoscope (n = 1), the Olympus EBUS BF UC260FW (n = 1; Olympus Medical Systems Corp., Tokyo, Japan), and the Pentax EBUS EB-1970UK (n = 2; Pentax Medical Company, NJ, USA) (see Figure 1). The models used in the study were selected due to their prevalence within national health centers and all scopes were confirmed to be in fully working order in advance of the study. The product specifications for all three scopes are listed in Table 1.

Olympus BF-1T160 bronchoscope evaluation

The range of distal deflection was measured by engaging the Olympus BF-1T160 bronchoscope with and without an instrument present in the working channel. The deflections were compared with the manufacturer's specifications (see Table 1). It should be noted that the manufacturing specifications do not include a reduced range of articulation when the working channel is occupied. The biopsy instruments used include two aspiration needles (SmoothShot

Table 1. Product specifications of the three scopes used in the evaluation.

Scope	Distal end diameter (mm)	Instrument channel diameter (mm)	Up angle (°)	Down angle (°)
Olympus BF-1T160	6	2.8	180	130
Olympus BF-UC260FW	6.9	2.2	120	90
Pentax EB-1970UK	6.5	2	120	90

Data taken from [11–13].

NA-411D-1321 *Olympus Medical* and eXcelon™ *Boston Scientific*), and three biopsy forceps (the Radial Jaw™ 4 *Boston Scientific*, Captura® *Cook Medical* and Alligator Jaw-Step FB-211D.S *Olympus Medical*). The deflection of the scope was first measured as a control. Each of the biopsy instruments was inserted in turn through the working channel until their distal end protruded at varying distances beyond the tip of the scope (in increments of 2.5 mm up to 30 mm). The deflected up and down angles at each of these positions were captured using a digital camera (resolution of 1980 × 1080 pixels) positioned directly above, and perpendicular to the scope. Images were subsequently analyzed using computer aided design software (AutoCad® 2014, AutoDesk, CA, USA). A centerline was drawn through the straight distal end of the scope. A second centerline was then drawn parallel to the longitudinal axis of scope shaft. The angle between these two lines measured the deflected angle (see Figure 2). To ensure consistency the scope was retracted and straightened three-times before each test was carried out to account for mechanical lag or stiffness in the system.

EBUS scope manipulation evaluation

Two Olympus EBUS BF UC260FW scopes and one Pentax EBUS EB-1970UK scope, were evaluated by an experienced endoscopist for flexion. Aspiration needles of varying gauge sizes were used in this analysis. For the Pentax scope, a MediGlobe Pro-Flex (22 Ga) and a Cook EchoTip Procore (22 Ga) were used. For the Olympus scope the Olympus NA-201SX-4021 (21 Ga), the Cook EchoTip Procore (22 Ga) and the Cook EchoTip Ultra (25 Ga) were used. The needles were advanced through the working channel in the straight position and were secured to the bronchoscope handle prior to articulation (see Figure 3). Graphical analysis was subsequently carried out to measure the angle of deflection.

Clinical case study

In addition to the physical bench-top experiments, a clinical case study was performed to highlight the limited flexion during use. A 69-year-old male, current smoker, presented with hemoptysis and weight loss. Computed tomography of thorax (CT-th) and subsequent PET-CT identified a 5.2 cm mass in the anterior segment of his left upper lobe with enlarged hilar lymph nodes station 10 L (standardized uptake value = 3.6) and multiple mediastinal nodes in the aortopulmonary (see Figure 4A–D). The case was discussed at multidisciplinary team meeting and then proceeded with a standard bronchoscopy and EBUS-TBNA.

Results

Bronchoscope results

A number of trends were observed during the Olympus BF-1T160 bronchoscope evaluation. There was an immediate reduction in up and down angle deflections on introduction of instruments in the working channel. The control deflection measured an up/down angle of 171°/129° respectively which represents less than 5% deviation from the manufacture's specifications. However, the mean up/down angle with endoscopic instruments measured 113.1°/65.8°, representing a reduction from the control of 33.9%/48.9%, respectively (see Figure 5).

A second trend observed the impact of biopsy instrument diameter and the location of the instrument tip relative to the distal end of the scope. In general it was observed that larger diameter instruments (Captura measuring 2.4 mm) caused further reduction in deflection when compared with the smaller diameter instruments of approximately 1.8 mm OD (Radial Jaw 4). Furthermore the average trend highlights a 5–10% reduction in articulation for instruments extending 0 mm compared with 15 mm beyond the distal tip. Extension beyond 10 mm from the distal appears to tend toward a constant value, which is particularly evident with down angle deflections (see Figure 5).

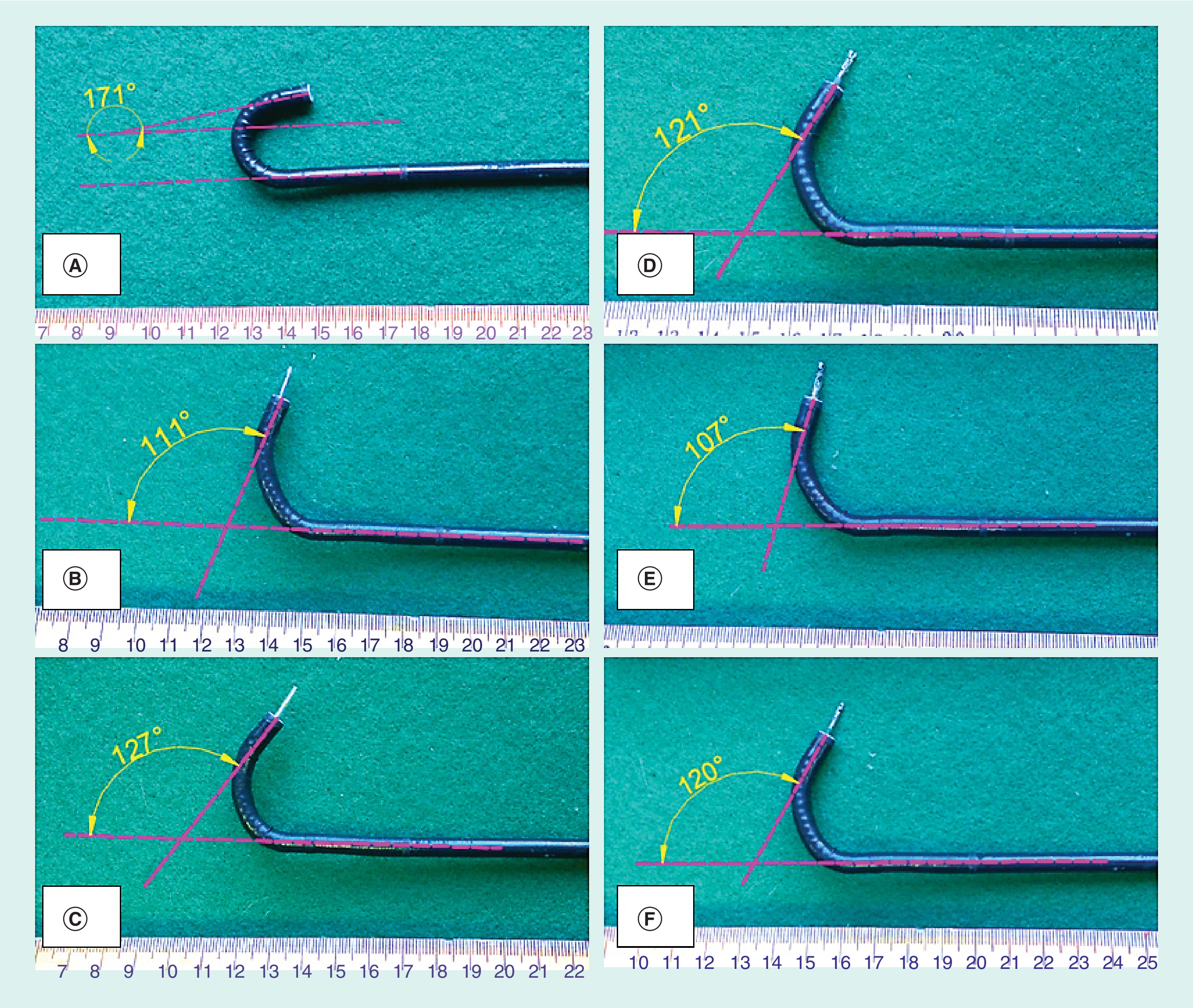

Figure 2. Up angle deflections with 10 mm instrument extensions from distal tip analyzed with AutoCad®. **(A)** No needle, **(B)** SmoothShot, **(C)** eXcelon, **(D)** Radial Jaw 4, **(E)** Captura, and **(F)** Olympus Alligator Jaw.

EBUS scope results

For both the Pentax and Olympus EBUS scopes, the specification indicated by the respective manufacturers for up/down angles is 120°/90° [12,13]. The control deflections measured for the up/down angles on the Pentax and Olympus scopes were 118.33°/86.67° and 113°/85°, respectively (see Tables 2 & 3). These values fall within approximately 5% of the specified angles.

Similar to the Olympus BF-1T160 bronchoscope, a number of trends were observed during EBUS scope manipulation evaluation. As illustrated in Figure 6, the addition of an aspiration needle in the working channel of the bronchoscope greatly reduced the maximum tip deflection. In addition, it was observed that once an aspiration needle was introduced, the curvature at the distal end became more linear and less curved (see Figure 6 B). The maximum deflected up/down angle was reduced by 43%/48% for the Pentax scope and approximately 56%/46% for the Olympus scope with the introduction of a 22 Ga Cook EchoTip Procore needle.

The second trend identified in this study relates to the effect of the needle gauge on scope deflection. Figure 7 compares the Olympus EBUS scope angulation with and without an aspiration needle. The examined needles measured 25, 22 and 21 Ga. Smaller gauge values correspond to larger diameters [14]. The 21 Ga Olympus needle

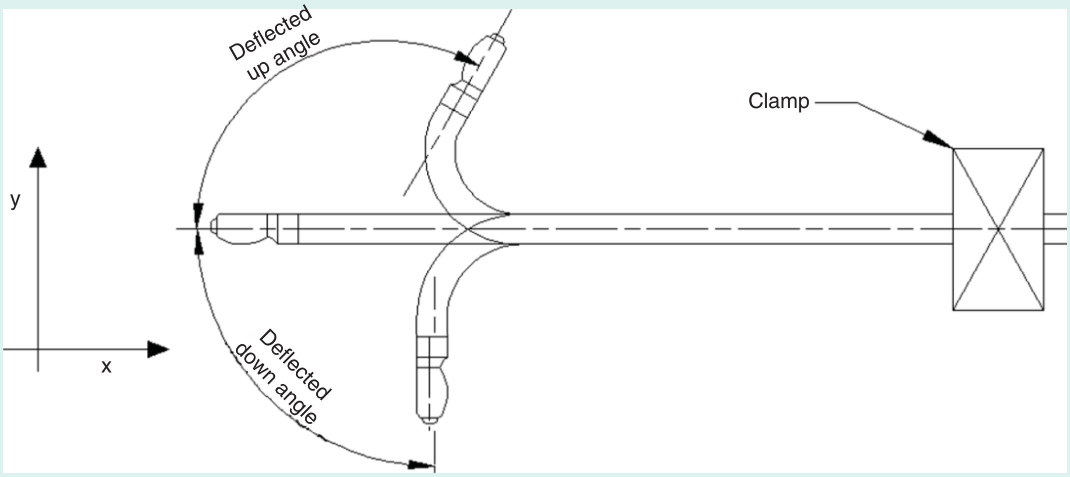

Figure 3. Diagram of endobronchial ultrasound scope manipulation experiment set-up.

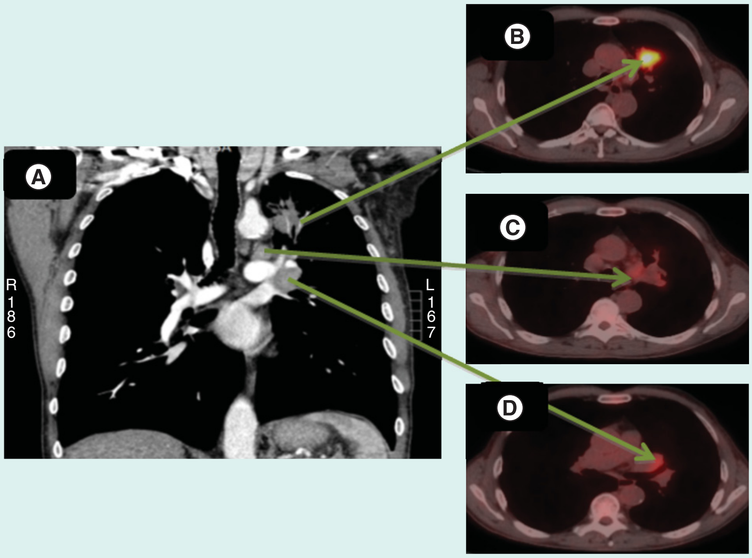

Figure 4. A 69-year-old male with cT3N2M0 non-small-cell lung cancer of his left upper lobe.
(A) Coronal computed tomography (CT) thorax with contrast displays the left upper lobe mass and enlarged mediastinal & hilar lymph nodes. **(B)** Axial fused PET-CT image reveals an fluorodeoxyglucose (FDG) avid 5.2 cm mass in the left upper lobe. **(C & D)** Axial fused PET-CT image identifies low grade FDG avid lymph node station at 4 and 10 L, respectively.

demonstrated the most substantial reduction in tip deflection of 59% with a mean up angle of 46.5° ± 6.5°. However, the aspiration needle with the smallest diameter, the 25 Ga Cook EchoTip Ultra, yielded the maximum mean up angle of 63° ± 6°, a reduction of 44%. This trend was also observed for the down angles (see Tables 2 & 3).

The Cook EchoTip Ultra 25 Ga and the Olympus NA-201SX 21 Ga aspiration needles were also evaluated in the Pentax EBUS bronchoscope, although these needles are not typically used with the Pentax scope. A US FDA MAUDE report published on 10/28/2014 highlighted an adverse event type malfunction whereby the Cook EchoTip Ultra connection with Pentax EBUS was found to be unacceptable [15]. In this report the port of the

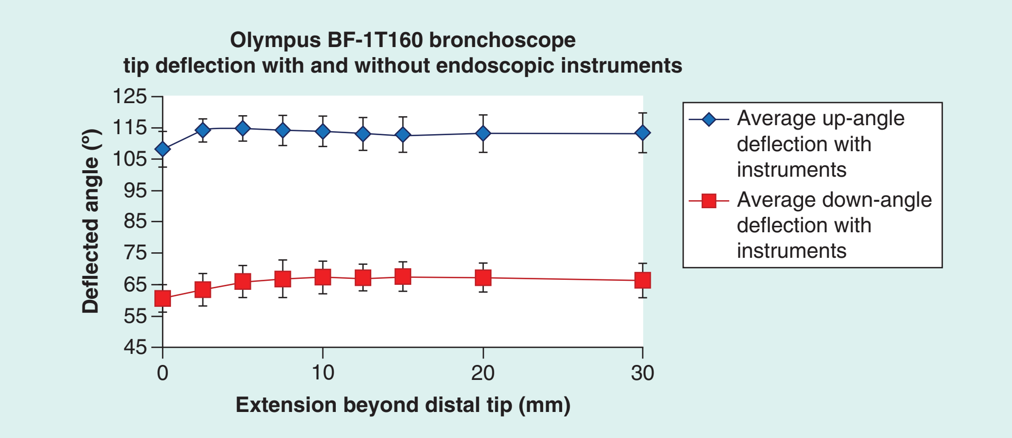

Figure 5. Average Olympus BF-1T160 up and down tip deflection with and without endoscopic instruments present in the working channel.

Table 2. Results of Pentax scope deflection. Pentax

	EBUS EB-1970UK.		
Needle type	**μ(°)**	**σ(°)**	**Angle reduction**
No needle			
Up angle	118.33	3.51	n/a
Down angle	86.67	0.58	n/a
MediGlobe Pro-Flex 22 Ga			
Up angle	80.67	2.89	31.8%
Down angle	49.67	1.15	42.7%
Cook EchoTip Procore 22 Ga			
Up angle	67.67	2.08	42.8%
Down angle	44.67	0.58	48.5%

Table 3. Results of Olympus scope deflection. Olympus EBUS BF UC260FW.

Needle type	μ(°)	σ(°)	Angle reduction
No needle			
Up angle	113.00	9.90	n/a
Down angle	84.50	6.36	n/a
Cook Echotip Ultra 25 Ga			
Up angle	63.00	8.49	44.2%
Down angle	56.00	2.83	33.7%
Cook EchoTip Procore 22 Ga			
Up angle	50.00	8.49	55.8%
Down angle	46.00	2.83	45.6%
Olympus NA-201SX-4021 21 Ga			
Up angle	46.50	9.19	58.8%
Down angle	38.00	1.41	55.0%

EchoTip Ultra did not release the biopsy needle after aspiration and the connection loosens quickly. This resulted in the scope being frequently sent for repair. Despite the unsuitable connection, the Cook 25 Ga needle performed better with an up/down angle of 78°/55°, while the larger 21 Ga Olympus needle only achieved 67°/35°. This result echoes the findings of the Olympus EBUS scope suggesting that smaller diameter needles perform better.

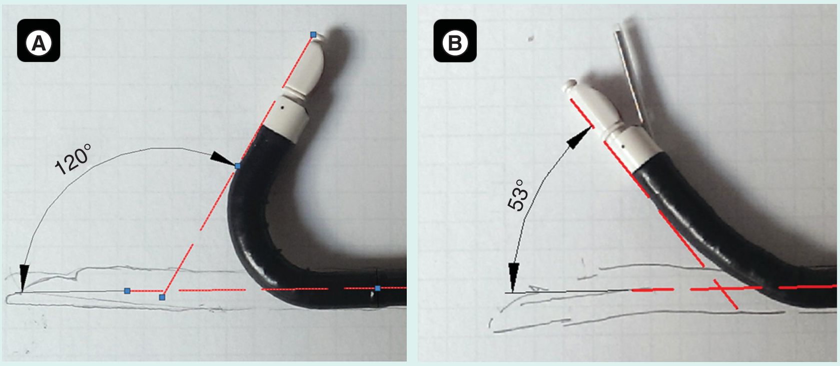

Figure 6. Example of reduced Olympus scope tip deflection.
(A) Up angle with no needle, and **(B)** up angle with 21 Ga Olympus needle positioned in working channel. A 56% reduction can be seen on introduction of the Olympus aspiration needle extended 15 mm beyond the distal tip.
Adapted with permission from [25].

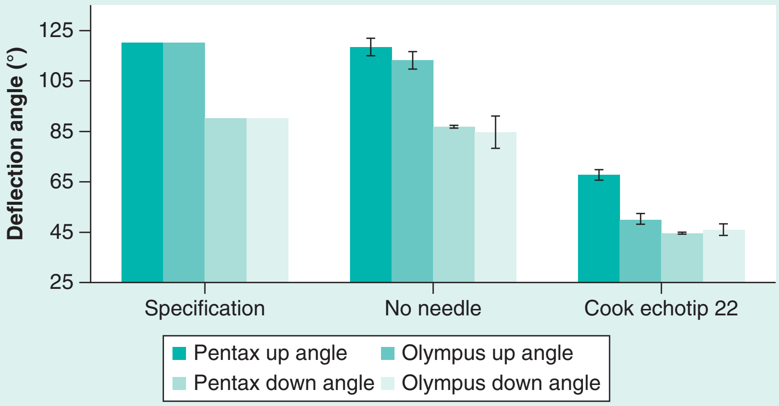

Figure 7. Comparison of reduced tip deflection for the Pentax and Olympus EBUS scope with the manufacturer's specifications (left), a free working channel (middle) and a 22 Ga aspiration needle (right).
Adapted with permission from [25].

Clinical results

Standard bronchoscopy under conscious sedation was normal without any airway lesion. Full evaluation with EBUS identified enlarged lymph nodes at station 4 and 10 L. The lymph node at 4 L measured 8.6 mm and three of four passes provided adequate normal lymphoid tissue by on site evaluation and subsequent cytopathology confirmation. Thereafter station 10 L was identified using EBUS. However, upon passing the sheath and subsequent needle, visualization of the node was inadequate and the scope-needle combination failed to flex into the target lymph node to allow accurate ultrasonic coupling despite multiple attempts leading to two inadequate passes by cytology (Figure 8A & B). It can be appreciated that the tip of the scope needs to bend up to its maximum to access these nodal stations and beyond and thus although we cannot measure this angle *in vivo* – the scope is flexed in a similar position to the lab-based studies.

Thereafter a bronchoalveolar lavage, brush (negative) and 5 'blind' transbronchial biopsies from anterior segment left upper lobe (4/5 alveolated tissue, eosinophilia and fibrotic changes) were negative for a cancer diagnosis. After rediscussion at multidisciplinary team, a CT-guided transthoracic core biopsy of the left upper lobe mass confirmed the diagnosis of squamous cell carcinoma and staging based on PET-CT was finalized as cT3N2M0 NSCLC (4 L positive on PET-CT). The patient was treated with systemic chemotherapy and radiotherapy to the left upper lobe

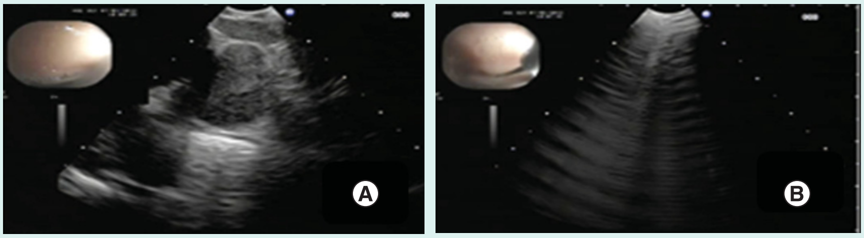

Figure 8. Clinical results demonstrating loss of scope angulation.
(A) 5.2 mm mass located at lymph node station 10 L identified by EBUS, and **(B)** EBUS coupling lost once needle is inserted through working channel.

and mediastinum. Follow-up CT imaging 1 year later was suspicious for disease progression locally. However the patient declined any further therapy due to performance status.

Discussion

This study examined the impact of utilizing endoscopic instruments on the end-user's ability to control and manipulate bronchoscopes. While all endoscopes require the administration of instruments through their working channel to diagnose and treat various ailments, the thin nature of bronchoscopes which is necessary to reach narrow distal pulmonary vessels, seem to be susceptible to reduced mobility with additional instruments in their working channel, and scopes with ultrasound at the distal tip (EBUS) are particularly liable to this influence. In practice, reduced flexion may reduce efficiency and increase difficulty accessing the following lymph node stations, 2 L, 2R, 3P, left sided stations 10 and 11 L [16].

A clear limitation to this open study was the limited number of bronchoscopes (n = 4) investigated. A greater number of instruments whereby the evaluators would be blind to the type of bronchoscope used may have yielded more interesting results. Despite this restriction clear trends were observed. The addition of an endoscopic instrument in the working channel limits the movement when articulating the distal end. For the Olympus BF-1T160, which has a smaller outer diameter, larger working channel and greater deflection range than the EBUS scopes, a reduction in up/down angle of 33.9%/48.9% was observed. The EBUS scopes demonstrated an even more dramatic reduction in deflection measuring 43%/48% for the Pentax EBUS scope and approximately 56%/46% for the Olympus EBUS scope with a 22 Ga Cook EchoTip aspiration needle.

Dedicated EBUS needles in 25, 22 and 21 Ga sizes are currently available. The impact of the needle size (22 vs 21 Ga) on the diagnostic yield of EBUS-TBNA has been studied and the available data have not proven either needle size to be superior to the other [17–20]. However, in terms of manoeuvrability, larger size needles have a disadvantage of making the tip of the bronchoscope stiffer thus decreasing its flexibility. As presented in this research study, smaller gauge TBNA needles (25 Ga) offer improved flexibility and angulation. This may be due to reduced mechanical stiffness as well as reduced friction within the working channel that facilitates increased flexibility at the tip. A limitation to this study is that only one of each type of needle was used during the analysis. Thus the dispersion between comparable needles was not accounted for.

The quality and pliability of the needle material and its sheath also contribute to the resilience of the needle returning to its original shape. Once the TBNA needle is inserted through the working channel of the EBUS scope, the EBUS scope loses contact with the endobronchial surface and requires repositioning for the transbronchial needle aspiration. Balloon inflation with water at the distal end may help to improve ultrasonic coupling. However, in practice has no effect on scope and needle angulation.

In general, segmental lymph node stations are not easily accessible [16] and account for the limitation of the EBUS when compared with postsurgical specimens [21]. It is becoming increasingly important to approach these nodes given the improvements, both in surgical techniques, in particular, segmentectomy versus lobectomy in the selected group of patients and stereotactic radiotherapy techniques, for the treatment of early stage lung cancer which require local nodal sampling to select appropriate patients [21–23]. Therefore, intuitively, a thinner EBUS scope would potentially access the lymph node station 12 and beyond and help in therapeutic decisions making.

However, the reach and accessibility of the thinner scope may be compromised with the needle insertion and pose difficulty in real time tissue acquisition as suggested in our study [24].

There is now an array of EBUS needles and scopes available with different properties. However, one property that is uniform is the loss of scope deflection with insertion of TBNA needle that has implications in reaching certain lymph node stations and needs to be considered when planning EBUS-TBNA procedures. This loss of angulation is not acknowledged in the scope specification manuals.

Both the EBUS scope and the structural components of the needles need improvements to further enhance the efficiency of EBUS-TBNA, which will potentially reduce the procedure time, and ultimately lead to improved access of distal lymph nodes and real time EBUS-guided sampling in the peribronchial region.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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