Original Article

Single-use flexible bronchoscope evaluation for bronchoalveolar lavage

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Background: Since their initial release in 2009, single-use flexible bronchoscopes (SUFBs) have significantly evolved from simple tools largely used for airway inspection with limited functionality to highly advanced instruments with the same capabilities as reusable flexible bronchoscopes (RFBs). Despite this, scrutiny still exists. The purpose of this study was to better understand the performance and preference of six industry leading SUFBs.

Methods: Thirty-one physicians who regularly use bronchoscopes performed two simulated bronchoalveolar lavages (BALs) on low fidelity lung models with six SUFBs: Ambu aScope 4 and 5 (with integrated sampler system), Boston Scientific Exalt Model B, Olympus H-SteriScope, and Verathon B-Flex and B-Flex 2 (all with a Lukens trap). After completing BALs with each scope, physicians answered an 18-question survey with a five-point rating system where 1 indicated unacceptable, 3 indicated satisfactory, and 5 indicated excellent.

Results: The Ambu aScope 5 Broncho HD rated highest in each of the 18 evaluated categories with an overall average performance score of 4.47 and sampling score of 4.40. A two-sample *t*-test found that the average score of the Ambu aScope 5 HD was significantly higher than the other SUFBs for both performance and sampling.

Conclusions: All six SUFBs included in the study scored above "satisfactory" in both the performance and sampling metrics measured. Of the six, the aScope 5 Broncho HD with an integrated sampling system had the highest average rating for both performance and sampling metrics, followed by the Exalt Model B for performance and the aScope 4 Broncho for sampling. As the annual volume of procedures continues to increase, SUFBs that combine safety, superb performance, and convenience will help further evolve bronchoscopy.

Keywords: Single-use; disposable; bronchoscopes; bronchoalveolar lavage

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Introduction

The first commercially available flexible bronchoscope was brought to market in 1968 when Shigeto Ikeda finalized the design of a fiberoptic scope and ushered in the "second revolution" in bronchoscopy (1). Nearly two decades later in 1987, Pentax, with the help of Ikeda, released the first video bronchoscope (1). As a result, flexible bronchoscopy has become one of the most important components of respiratory care, allowing physicians to perform both diagnostic and therapeutic airway and parenchymal procedures. Although considered one of the simpler bronchoscopic procedures, bronchoalveolar lavages (BALs) quickly became one of the most important and frequently performed diagnostic pulmonary procedures.

BALs are a widely performed diagnostic procedure used to collect alveolar fluid samples with over 110,000 reported in the United States in 2022 in the outpatient setting (2). During the procedure, a bronchoscope is wedged in a pulmonary subsegment, saline is instilled into the target lung, and the fluid is suctioned back into a collection container such as a syringe or Lukens trap (3). This sample is then sent for cellular, microbiologic, and/or cytologic evaluation to provide insights into pathology to develop an appropriate course of treatment (3). BALs may provide valuable information for infection as well as numerous noninfectious conditions such as alveolar hemorrhage, interstitial lung disease, and malignancy (3).

Despite progress in the design and functionality of bronchoscopes over 50 years, it wasn't until 2009 that the first single-use flexible bronchoscope (SUFB) became commercially available. The single-use nature of these scopes ensures they will only be used on one patient, eliminating the risk of bronchoscope-related cross-contamination and infections and subsequently providing physicians and patients with peace of mind unattainable with reusable flexible bronchoscopes (RFBs). This is of extreme importance since recent literature has found that over 28% of reprocessed RFBs may be positive for microbial cultures, with an attributable infection rate of 2.8% (4,5). The issue of bronchoscope-related infections has become such a concern the Food and Drug Administration (FDA) issued a safety communication recommending that healthcare providers "consider using a single-use bronchoscope in situations where there is an increased risk of spreading infection (multidrug resistant microorganisms, immunocompromised patients, or patients with prion disease) or when there is no support for immediate reprocessing of the bronchoscope" (6). Beyond safety, SUFBs may provide users with the added benefit of reliability and availability since they are neither subject to repairs nor reprocessing. This unique characteristic gives physicians and patients rapid access to care whether it be in the ICU, endoscopy suite, or operating room.

Since their initial release in 2009, SUFBs have significantly evolved from simple tools with limited functionality to highly advanced instruments on par with RFBs. Despite this, scrutiny still exists around their overall performance as well as their image quality, maneuverability, and suctioning capabilities. As manufacturers continue to develop new SUFBs, obtaining a better understanding of how hospitals, physicians, and patients can all benefit from their adoption will be paramount. The purpose of this study was to better understand and compare the performance and preference of six industry leading SUFBs.

Highlight box

Key findings

- Of the market leading single-use flexible bronchoscopes, the aScope™ 5 Broncho HD with BronchoSampler™ rated the highest on average for both performance and sampling metrics.

What is known and what is new?

- Since their initial release in 2009, single-use flexible bronchoscopes have significantly evolved from simple tools with limited functionality to highly advanced instruments on par with reusables. Despite this, scrutiny still exists around their overall performance as well as their image quality, maneuverability, and suctioning capabilities.
- Investigating the performance of and preference for certain single-use flexible bronchoscopes will be paramount in understanding of how hospitals, physicians, and patients can all benefit from their adoption.

What is the implication, and what should change now?

- The results from this study provide additional support that single-use flexible bronchoscopes have continued to evolve and improve since their original development.

Methods

From March 2023 to February 2024, 31 physicians in the United States who regularly use bronchoscopes were enrolled in a prospective observational study. Seven were from a meeting of interventional pulmonologists (22.6%), twelve were from a large university hospital in the Midwestern United States (38.7%), and twelve were from a large university hospital in the Southern United States.

Table 1 Technical specifications of tested single-use flexible bronchoscopes

Specification	Ambu® aScope™ 5 Broncho HD (7)	Ambu® aScope™ 4 Broncho (8)	Boston® Scientific Exalt™ Model B (9)	Olympus® H-SteriScope™ (10)	Verathon® B-Flex™ (11)	Verathon® B-Flex™ 2 (12)
Outer diameter (mm)	5.6	5.8	5.8	5.8	5.8	5.8
Working channel diameter (mm)	2.8	2.8	2.6	2.8	3.0	3.0
Field of view (degrees)	120	85	90	110	85	85
Articulation up (degrees)	195	180	180	210	140	190
Articulation down (degrees)	195	160	180	210	135	205

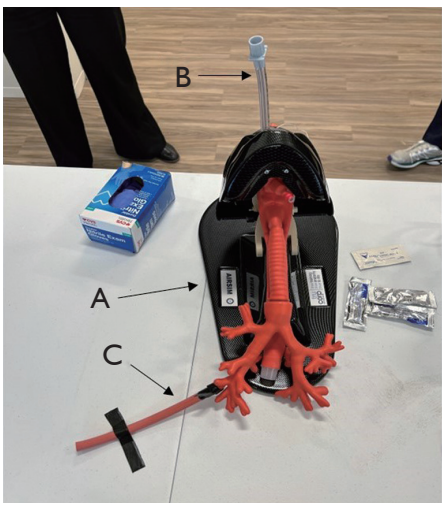

Figure 1 Experimental setup. A: Low-fidelity lung model. B: Endotracheal tube. C: Reservoir.

All physicians performed two simulated BALs on low-fidelity lung models (Trucorp® AirSim®, Lurgan, Northern Ireland, UK) with five SUFBs with comparable outer and working channel diameters: Ambu® aScope™ 4 (5.8 mm/2.8 mm, Ballerup, Denmark), Ambu® aScope™ 5 HD (5.6 mm/2.8 mm), Boston Scientific® Exalt™ Model B (5.8 mm/2.6 mm, Marlborough, MA, USA), Olympus® H-SteriScope™ (5.8 mm/2.8 mm, Tokyo, Japan), and Verathon® B-Flex™ (5.8 mm/3.0 mm, Bothell, WA, USA). Twenty-four (n=24) of the participants also performed simulated lavages with the Verathon® B-Flex™ 2 (5.8 mm/3.0 mm) as it became commercially available during the data collection period. Technical specifications for each SUFB can be found in *Table 1*.

For BAL sample collection, the two Ambu® bronchoscopes utilized an integrated sampling tool, the BronchoSampler™, which comes packaged with the Ambu® scope, while the other bronchoscopes used a standard Lukens trap. The BronchoSampler™ is currently the only integrated sampling tool available for the included scopes.

Data was collected over five days at three locations: one day at a meeting of interventional pulmonologists, two days at a large university hospital in the Southern United States, and two days at a large university hospital in the Midwestern United States. New SUFBs were used for each day of the study to ensure optimal performance of each scope.

Each bronchoscope was connected to its accompanying visualization monitor and attached to a vacuum pump set (7305 Series® DeVilbiss® Suction Unit, Port Washington, NY, USA) to the same pounds per square inch (PSI) prior to each trial. A member of the study staff was on standby to assist with the procedure upon request. Fourteen of the participants had the suction tubing connected to a vacuum for them prior to sampling while 17 of the participants connected their own tubing. The participants navigated the low-fidelity lung model with each bronchoscope until they became familiar with the scope and could gauge its performance. When comfortable, each participant then navigated the bronchoscope into the target lobe of the lung model where they performed two BALs by instilling 20–60 mL of water into an attached reservoir made of vacuum tubing (*Figure 1*). These steps were repeated for each bronchoscope on separate lung models.

After all bronchoscopes were trialed, each participant completed an 18-question survey on how each scope performed during general use and during the two BALs. The survey employed a five-point Likert scale where 1 indicated unacceptable, 3 indicated satisfactory, and 5 indicated excellent. Participants were allowed to revisit each bronchoscope while answering the survey questions.

Additionally, the survey collected background data on each physician such as where they regularly perform their procedures in their facility, years of experience, title, and exposure history with each scope given the novelty of SUFBs. The participants were blinded to the study sponsors to avoid any potential bias in responses. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. Informed consent was taken from all the participants.

Statistical analysis

Averages and relevant statistical tests for each survey variable were calculated to compare each SUFB. The results of the study were stratified by years of experience to help understand if this impacted the average score. An ordinal logistic regression model was run on the overall sampling and performance scores to further understand the influence of the background variables. Akaike information criterion (AIC) values and the Hosmer and Lemeshow test for goodness of fit were used to calculate the models' fit. Microsoft® Excel® Version 2302 and RStudio® 2024.04.0+735 for Windows® were used to organize and analyze the data.

Results

Thirty-one physicians completed the simulated procedures and completed the assessment survey for the Ambu® aScope™ 4 (5.8 mm/2.8 mm), Ambu® aScope™ 5 HD (5.6 mm/2.8 mm), Boston Scientific® Exalt™ Model B (5.8 mm/2.6 mm), Olympus® H-SteriScope™ (5.8 mm/2.8 mm), and Verathon® B-Flex™ (5.8 mm/3.0 mm). Twenty-four of the 31 physicians also completed the simulated procedures and filled out the assessment survey for the Verathon® B-Flex™ 2 (5.8 mm/3.0 mm).

Twenty participants stated they regularly performed their bronchoscopies in the endoscopy/bronchoscopy suite (64.5%), twenty-three in the operating room (74.2%), and two in the ICU/bedside (6.5%). Seven of the participants were certified interventional pulmonologists (22.6%), 14 were critical care fellows (45.2%), eight were pulmonary/critical care attending/faculty/physicians (25.8%), and two were identified as other (6.5%). Eight of the study participants had 0–1 years of experience performing bronchoscopies (25.8%), 12 had 1 to 5 years of experience (38.7%), and 11 had over 5 years of experience (35.5%). The full background results can be found in Table S1.

Each SUFB had a plurality of physicians who had never encountered the scope prior to the experiment. The aScope™ 4 Broncho had the most physician use in procedures prior to the study (67.7%), followed by the Exalt™ Model B (58.1%), B-Flex™ (45.2%), aScope™ 5 Broncho HD (41.9%), B-Flex™ 2 (22.6%), and H-SteriScope™ (3.2%). The full experience data for each scope can be found in Table S2.

The aScope™ 5 Broncho HD scored significantly higher than the other five bronchoscopes in overall performance with an average score of 4.47 out of 5. The second highest rated scope was the Exalt™ B with a score of 4.11 (P=0.004), followed by the H-SteriScope™ (3.95, P=0.001), aScope™ 4 Broncho (3.89, P<0.001), B-Flex™ 2 (3.59, P<0.001), and B-Flex™ (3.27, P<0.001). The aScope™ 5 Broncho HD also scored the highest in each of the nine performance questions asked. For the sampling-based questions, the aScope™ 5 Broncho HD with the BronchoSampler™ scored significantly higher than the other five scopes with an average score of 4.40 out of 5. The second highest rated scope was the aScope™ 4 Broncho with BronchoSampler™ (4.12, P=0.049), followed by the Exalt™ Model B (3.97, P=0.005), H-SteriScope™ (3.90, P=0.005), B-Flex™ 2 (3.52, P=0.03), and B-Flex™ (3.07, P<0.001), all with a Lukens trap. The aScope™ 5 Broncho HD scored the highest and the B-Flex™ scored the lowest in each of the nine sampling questions asked. The average scores (sd) of the survey can be found in *Table 2*. When stratifying by years of experience, the aScope™ 5 Broncho HD remained the highest scoring scope for overall performance with a score of 4.50, 4.36, and 4.58 for the 0 to 1, 1 to 5, and 5+ years of experience groups, respectively. For sampling, the H-SteriScope™ with Lukens trap rated highest for both the 0 to 1 and 1 to 5 years of experience groups while the aScope™ 5 Broncho HD rated highest for the 5+ years of experience group. The stratified results can be found in Table S3.

Table 3 shows the average overall performance and sampling ratings for each scope. For both, the aScope™ 5 Broncho HD was rated significantly higher than the other five SUFBs in the study. For overall performance scores, the Exalt™ Model B was the second highest rated scope (3.97), followed by the aScope™ 4 Broncho (3.84), H-SteriScope™ (3.74), B-Flex™ 2 (3.42), and B-Flex™ (2.90). For sampling scores, the aScope™ 4 Broncho was the second highest rated scope (4.10), Exalt™ Model B (3.94), H-SteriScope™ (3.90), B-Flex™ 2 (3.38), and B-Flex™ (2.81).

The ordinal logistic regression model indicated that none of the collected background variables were

Table 2 Summary statistics of performance and sampling

Metric	aScope™ 5 Broncho HD (n=31)	aScope™ 4 Broncho (n=31)	Exalt™ Model B (n=31)	H-SteriScope™ (n=31)	B-Flex™ (n=31)	B-Flex™ 2 (n=24)
Performance						
Overall comfort/ergonomics	4.45 (0.68)	3.90 (0.70)	4.03 (0.66)	3.84 (1.16)	2.90 (1.04)	3.33 (1.09)
Overall ease of use	4.45 (0.68)	3.90 (0.70)	4.03 (0.60)	3.97 (0.95)	3.06 (1.06)	3.50 (0.83)
Ease of reaching the suction button	4.61 (0.56)	4.26 (0.77)	4.35 (0.71)	4.29 (0.78)	3.71 (1.13)	3.75 (1.07)
Image quality, field of view	4.52 (0.63)	3.81 (0.79)	4.23 (0.76)	3.74 (1.09)	3.68 (0.70)	3.79 (0.72)
Image quality, depth of field	4.55 (0.62)	3.84 (0.82)	4.03 (1.02)	3.74 (1.03)	3.68 (0.75)	3.83 (0.76)
Maneuverability during airway inspection	4.45 (0.68)	3.90 (0.70)	4.13 (0.67)	4.10 (0.83)	3.10 (0.91)	3.54 (0.88)
Maneuverability into difficult segmental airways	4.13 (0.88)	3.68 (0.79)	4.03 (0.75)	4.10 (0.87)	3.13 (1.15)	3.46 (0.83)
Perception of efficacy	4.52 (0.63)	3.87 (0.67)	4.16 (0.64)	4.06 (0.81)	3.23 (0.96)	3.71 (0.81)
Overall performance assessment/score	4.58 (0.50)	3.84 (0.69)	3.97 (0.66)	3.74 (1.06)	2.90 (0.91)	3.42 (0.93)
Performance average (*sd*)	*4.47* (*0.55*)	*3.89* (*0.58*)	*4.11* (*0.52*)	*3.95* (*0.77*)	*3.27* (*0.72*)	*3.59* (*0.74*)
Performance P value	–	*<0.001*	*0.004*	*0.001*	*<0.001*	*<0.001*
Sampling						
Overall comfort/ergonomics during sampling	4.29 (0.86)	3.97 (0.80)	4.00 (0.82)	3.94 (1.06)	2.81 (1.14)	3.25 (0.85)
Overall ease of use (start to finish)	4.42 (0.81)	4.03 (0.75)	3.94 (0.77)	3.94 (0.89)	2.81 (0.95)	3.33 (0.82)
Overall ease of set up (connections)	4.00 (1.13)	3.77 (1.02)	3.77 (0.84)	3.77 (0.88)	2.94 (0.96)	3.63 (0.77)
Comfort of sampling without assistance	4.61 (0.88)	4.26 (0.86)	3.94 (0.93)	3.90 (1.05)	3.26 (1.19)	3.58 (0.93)
Comfort of sampling with assistance	4.35 (0.69)	4.16 (0.71)	3.74 (0.73)	3.68 (0.88)	2.84 (1.02)	3.50 (0.90)
Perceived safety of sampling	4.48 (0.68)	4.31 (0.71)	4.21 (0.78)	4.07 (0.91)	3.45 (1.09)	3.64 (0.90)
Satisfaction of sampling	4.55 (0.76)	4.35 (0.75)	4.16 (0.75)	4.10 (0.90)	3.58 (0.98)	3.88 (0.93)
Overall of ease of sample collection	4.42 (0.62)	4.10 (0.77)	4.03 (0.77)	3.84 (0.83)	3.10 (1.09)	3.50 (0.83)
Overall sampling assessment/score	4.45 (0.77)	4.10 (0.75)	3.94 (0.77)	3.90 (0.94)	2.81 (0.83)	3.38 (0.77)
Sampling average	*4.40* (*0.67*)	*4.12* (*0.64*)	*3.97* (*0.60*)	*3.90* (*0.79*)	*3.07* (*0.78*)	*3.52* (*0.69*)
Sampling P value	–	*0.049*	*0.005*	*0.005*	*<0.001*	*0.03*

Data are presented as mean (standard deviation).

Table 3 Overall performance and sampling assessment comparison

SUFBs	Overall performance assessment		Overall sampling assessment	
	Score	P value	Score	P value
aScope™ 5 Broncho HD (n=31)	4.58	–	4.45	–
aScope™ 4 Broncho (n=31)	3.84	<0.001	4.1	0.03
Exalt™ Model B (n=31)	3.97	<0.001	3.94	0.005
H-SteriScope™ (n=31)	3.74	0.001	3.9	0.001
B-Flex™ (n=31)	2.9	<0.001	2.81	<0.001
B-Flex™ 2 (n=24)	3.42	<0.001	3.38	<0.001

SUFBs, single-use flexible bronchoscopes.

significantly associated with the overall performance score of the aScope™ 5 Broncho HD. The regression model for the overall sampling score for the aScope™ 5 Broncho HD indicated that the location of the simulated procedures was the only predictor that significantly contributed to the model. The output indicates that participants who completed the experiment at either the Midwestern or Southern hospital had significantly higher odds of rating the aScope™ 5 Broncho HD lower in overall sampling than someone who completed it at the meeting of interventional pulmonologists. However, a subgroup analysis excluding individuals from the meeting of interventional pulmonologists resulted in the aScope™ 5 Broncho HD remaining the highest scoring SUFB in this category, but is no longer significant. The regression model output and subgroup analysis can be found in Tables S4,S5.

Discussion

The results of this study help further highlight the changing attitude towards and growing satisfaction with SUFBs and their ability to achieve high levels of performance. A 2022 article from Ho *et al.* outlined how the SUFBs available at the time were limited in function and capable only of certain simple procedures such as airway inspections, washings, peripheral nodule sampling, and mediastinal sampling (13). The authors concluded that SUFB adoption for more complex interventional procedures would occur with improvements to maneuverability, channel sizes, angle tip deflection, sturdiness, and image quality (13).

In recent years, manufacturers have made progress towards addressing these concerns and limitations in their newest generation of SUFBs. When compared to RFBs, some new SUFBs have equivalent or even better technical specifications. Beyond comparisons to RFBs, SUFBs have received significant sturdiness improvements which further expanded the list of capable procedures such as cryotherapy, thermal ablation, and foreign body retrieval and made it compatible with accessories such as high-frequency electrosurgical equipment. As a result of these improvements to imaging, tool compatibility, and articulation, the Centers of Medicare and Medicaid Services (CMS) awarded advanced SUFBs Transitional Pass-Through (TPT) Payment status since they demonstrated "a substantial clinical improvement over currently available treatment options in the clinical setting" (14).

Despite the limitations listed by Ho *et al.* (13), all six SUFBs scored on average better than 3 out of 5 (satisfactory) for the performance metrics, with two scoring above a 4 out of 5 (good). Similar trends held true when considering image quality and maneuverability, two characteristics of SUFBs commonly critiqued. All six of the examined scopes scored above a 3 out of 5 for image quality, with two scoring above a 4 out of 5. As for maneuverability, all six scored above a 3 out of 5 with three scoring above a 4 out of 5. These results further support SUFB's evolution towards becoming acceptable alternatives for procedures previously reserved for RFBs.

One important factor that should be further examined is the BronchoSampler's impact on sampling scores. Given that the aScope™ 4 and 5 Broncho's were the only two SUFBs to average above a 4 out of 5, the BronchoSampler may improve the ability to collect samples. If true, this could indicate that the use of an integrated sampling system with a SUFB may provide physicians additional benefits such as increased confidence, safety, efficiency, and comfort during sampling.

As SUFB performance continues to improve with new models, their appeal to all users and care settings should continue to grow. When they were first released in 2009, patient safety and sterility were the motivating forces behind their creation given the ever-present cross-contamination and transmission issues that RFBs face. As they quickly evolved, other benefits to healthcare facilities became evident such as improving ease of access during out-of-hours and emergent cases, avoiding costly repairs and reprocessing, and even increasing patient throughput and serving as a teaching aid that can reduce the amount of subsequent damage to RFBs (15). In addition, the manufacturing of single-use products allows for improvements and changes to be integrated more rapidly than reusable counterparts. This is evident in endoscopy, where new and improved single-use versions are released more frequently than reusables.

This study has limitations that must be addressed. First, the study did not include any RFBs for comparison. While the goal of the study was to compare the current market leading SUFBs, including an RFB would have provided valuable insight into how they compare head-to-head and evaluate whether SUFBs are considered an appropriate alternative to RFBs in many aspects. Despite this, the rating system used still provides information into this given that the participants were not asked to rank the SUFBs, but to score them where a value of 3 (satisfactory) was only achieved by a scope that performed just as well as RFBs. Another limitation is that a lung model is not a

perfect analog for a patient. While they may serve as an acceptable tool for training or educational purposes, they do not exactly imitate the normal conditions encountered in real life procedures. Finally, the study did not include a viscous material to suction during the BAL. By including a material to imitate lung secretions or a mucus plug, metrics such as image quality, perceived safety, and/or satisfaction of sampling could be affected.

Conclusions

On average, all six SUFBs included in the study scored above "satisfactory" in both performance and sampling metrics measured. Of the six, the aScope™ 5 Broncho HD with the BronchoSampler™ rated the highest on average for both performance and sampling metrics, followed by the Exalt™ Model B for performance and the aScope™ 4 Broncho for sampling. The results from this study provide additional support that SUFBs have continued to evolve and improve since their original development. Studies that assess user satisfaction of various aspects of SUFBs, as well as performance characteristics with a basic pulmonary procedure such as a BAL, provide useful information which will allow for the design and evaluation of these metrics for more advanced pulmonary procedures. SUFBs that combine safety, superb performance, and convenience will help further establish a third revolution in bronchoscopy.

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None.

Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki and its subsequent amendments. Informed consent was taken from all the participants.

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