

aScope™ 4 RhinoLaryngo Slim



Assessing the performance of a
single-use flexible **rhinolaryngoscope**

The aScope 4
RhinoLaryngo Slim
was successfully used for
more than 97%
of flexible ENT
endoscopy procedures

A recent study including 117 otorhinolaryngologists from eight different countries found that a newly developed single-use endoscope yielded **satisfactory results in more than 97% of the 270 endoscopic procedures performed.**

The doctors expressed positive opinions regarding the maneuverability and image quality of the scope, which could eliminate potential problems regarding availability, the need for post processing, and the risk of cross-contamination.





BACKGROUND

Flexible pharyngolaryngoscopy (FPL) enables the diagnosis of a broad range of acute and chronic diseases¹, and a study from the United States found that it was the most frequently performed procedure by otorhinolaryngologists². Flexible endoscopes, which are needed to perform the procedures, have evolved during the past 50 years from fiber optic endoscopes³ to very slim videoscopes with a small chip-camera at the tip⁴. All endoscopes are classified as semi-critical devices requiring special cleaning equipment and trained support staff to ensure that a clean scope is available for every procedure^{5,6}.

Furthermore, frequent costly and time-consuming repairs of the delicate instruments can threaten availability⁷. Single-use scopes could offer a solution by ensuring that the endoscopist always has a clean and functioning scope at hand when needed. Single-use bronchoscopes have proven to be equivalent in performance to traditional bronchoscopes⁸, and a dedicated single-use endoscope was recently developed for ENT procedures (Ambu® aScope™ 4 RhinoLaryngo Slim [©Ambu A/S, Ballerup, Denmark]) with an outer diameter of 3.0 mm).

AIM

The aim of the current study was to systematically assess the maneuverability and image quality of the single-use endoscope to ensure that it fulfills the requirements of otolaryngologists.

METHODS

International otorhinolaryngologists were invited to use the single-use scope on patients already scheduled for any endoscopic ENT procedure, including nasal endoscopy, laryngoscopy, and pharyngoscopy. Immediately following the procedure, the participants filled out a form regarding the performance and usability of the single-use scope. Items such as maneuverability, image quality, and overall perception of quality and functionality were rated on three, four, or five-point scales according to personal preferences. Finally, participants were asked if they thought that the single-use scope could replace their existing reusable scope for the procedure performed and if (and why) they had to change scopes during the procedure. All forms were collected centrally, and all data was entered into a statistics program (©IBM SPSS Statistics, ver. 22.0). The three, four, and five-point scales were normalized into 0 to 100 scores to allow for addition and direct comparison. Descriptive statistics were used to report the findings.

RESULTS

A total of 270 procedures were performed in eight different countries; Table 1 shows the countries and the distribution of procedures in each country. A total of 117 doctors from 60 different hospitals performed between 1 and 16 procedures each; median 1. The doctors came from the UK (n=36), Germany (n=26), France (n=24), the United States (n=14), Sweden (n=6), Italy (n=5), Australia (n=4), and Denmark (n=2).

Five doctors from the UK and one from Italy found it necessary to change to their traditional reusable scope in one of the procedures performed. One doctor from Germany performed two procedures and changed scope both times. A total of 262 procedures (>97%) were performed satisfactorily with the single-use scope, and in eight procedures (<3%), the doctor needed to revert to their usual reusable scope. Two reasons were given for changing scopes: Perceived lack of image quality (n=6; 2.2% of total procedures) and patient intolerance of the single-use scope (n=2; 0.7% of total procedures). The doctors found that the single-use scope could replace the reusable scope for the majority of the procedures performed – 172 out of the 248 procedures (69.4%) where this question was assessed. There were considerable national differences with regard to the possibility of replacement: from 90% and 100% in Denmark and Italy to 63% in France (Table 2). The overall perception of the quality and functionality of the single-use scope was positive: 75 points on a scale from 0 to 100 where 50 indicated neutral (neither bad nor good). Specific issues regarding image quality and maneuverability (the ability to navigate to the desired areas) were also assessed as good with scores of 70 points and 68 points, respectively.



DISCUSSION

Developers should continue to strive to supply the doctors with the best possible scopes. "The ideal scope" must be able to navigate to the desired locations and to deliver images that enable the performing specialists to make the right diagnostic decisions. It should also facilitate the optimal education of trainees and improve the patients' understanding of their conditions. Finally, "the ideal scope" should be available 24/7, be guaranteed clean and safe, and allow the procedure to be performed at a reasonable price.



Maneuverability and image quality

The new single-use scope received an average score of 68 out of 100 for maneuverability, which is positive (50 points equal a neutral perception of the scope), and none of the procedures had to be aborted due to an inability to navigate to the desired position. The mean assessment of image quality was also positive (70 out of 100 points). At the same time, seven of the doctors reverted to their usual reusable scope in 2.2 percent of the procedures due to perceived doubt regarding the image quality of the single-use scope. Some doctors preferred the new single-use scope while others were more comfortable with the scope they were used to. A randomized controlled trial using patient-specific outcome parameters would be necessary for objective comparison of the different endoscopes.

Patient and trainees' education

Several doctors commented that the videoscope had advantages compared to their traditional scopes. For example, the monitor view allowed their patients to visualize and understand the diagnosis and made it possible for trainees to follow the procedure with better educational outcome.

Risk of cross-contamination

Endoscopes are classified as 'semi-critical' devices because they come into contact with non-intact skin, mucous membranes, saliva, and potentially with blood), and they can therefore be a source for transmissible infections^{5,6}. In fact, cross-contamination from reusable flexible endoscopes has been a "Top 10 Health Technology Hazard" for the last 13 years according to an annual report published by the ECRI Institute¹⁰.

Meticulous cleaning procedures should be performed by specially trained personnel, and records on the usage of reusable scopes should be kept in order to enable tracking of patients subjected to contaminated scopes¹¹.

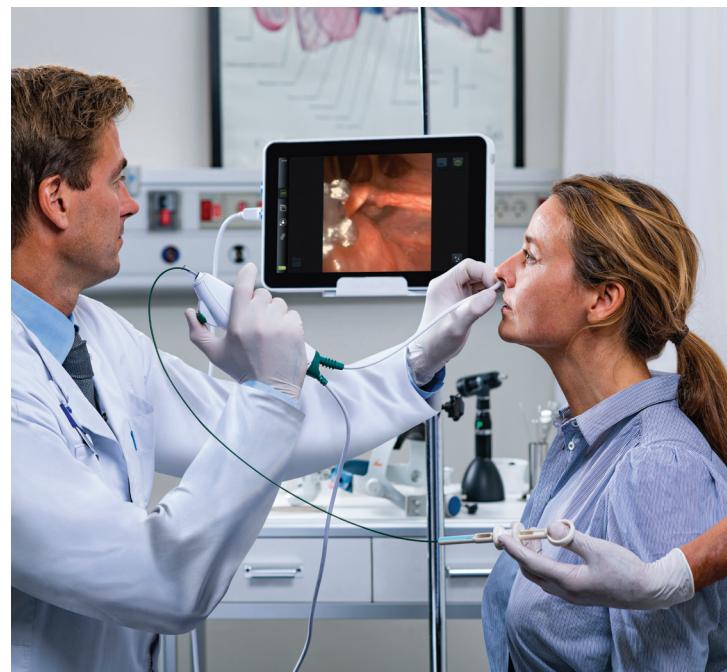
These guidelines can be challenging to adhere to in a busy outpatient clinic with a high endoscope turnover, and access to properly cleaned scopes can also be a problem in acute, out-of-hours situations. A study from the UK found that busy junior doctors without formal training in cleaning techniques were often responsible for cleaning and keeping track of used endoscopes while on duty, and the authors concluded that "Hospitals are therefore subjecting emergency patients to risk, and the institutions themselves are exposed to medico-legal vulnerability."¹² Single-use scopes, on the other hand, can be available 24/7 without any risk of cross-contamination or need for cleaning or record keeping.

Procedure costs

The procedure cost should be reasonable compared to the reusable scope but parameters such as scope price, support staff salaries, and repair costs vary hugely globally and were not explored in this initial examination in eight different countries.

Strengths and limitations

The international multicenter design is a major strength that adds credibility to the study and helps ensure the generalizability of the findings. Selection bias was avoided by including all scheduled procedures in a consecutive fashion and by inviting more than 100 unselected otorhinolaryngologists to participate in the study. Administration of the survey directly following the procedure ensured a very high response rate and served to minimize recall bias.



However, this approach made blinding the answers from each doctor unfeasible, which might introduce a bias even though data regarding the individual doctors was not collected on the forms. A randomized controlled trial would be better suited to directly compare single-use and reusable scopes and future studies should consider supplementing the subjective opinions of the doctors with important objective parameters, such as waiting time, contamination, procedure cost, and patient related outcomes.

CONCLUSION

International otorhinolaryngologists were generally positive towards different properties of a single-use video-endoscope specifically developed to target their needs. More than 97% of unselected endoscopic ENT procedures could be performed using the scope, which could eliminate potential problems regarding availability, the need for post processing, and the risk of cross-contamination.

TABLES

Table 1: Country

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|------------------|-----------|---------|---------------|--------------------|
| Valid | | | | |
| UK | 152 | 56,3 | 56,3 | 56,3 |
| Sweden | 13 | 4,8 | 4,8 | 61,1 |
| Denmark | 10 | 3,7 | 3,7 | 64,8 |
| Italy | 5 | 1,9 | 1,9 | 66,7 |
| Germany | 41 | 15,2 | 15,2 | 81,9 |
| France | 30 | 11,1 | 11,1 | 93,0 |
| USA | 15 | 5,6 | 5,6 | 98,5 |
| Australia | 4 | 1,5 | 1,5 | 100,0 |
| Total | 270 | 100,0 | 100,0 | |

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