WHITE PAPER
Single-use flexible cystoscope

CLINICAL PERFORMANCE OF THE SINGLE-USE CYSTOSCOPE aScope™ 4 Cysto

An evaluation based on initial perceptions from urologists worldwide

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Purpose
To evaluate the performance of the Ambu® aScope™ 4 Cysto and Ambu® aView™ 2 Advance Displaying Unit by collecting feedback from urologists on the perceived performance of this system during urology procedures.

Materials and methods
A user evaluation form was completed by urologists in Europe, Australia and Hong Kong, after finalising a clinical procedure with the aScope™ 4 Cysto system. Descriptive statistics and 95% confidence intervals (CI) were calculated in Microsoft Excel.

Results
A total of 380 urologists replied using the evaluation form. The majority (96.4%; 95% CI: 95%-98%) were able to complete the planned procedure using only the aScope™ 4 Cysto visualisation system and reported an average performance rating from 4.38 ± 0.67 to 4.55 ± 0.61 on a 5-point Likert scale (1=”very poor” to 5=”very good”).

Conclusions
The results indicate satisfaction with the aScope™ 4 Cysto system on the most important performance parameters such as image quality, bending capabilities and navigation. Based on these results, the single-use cystoscope aScope™ 4 Cysto is a highly useful device for daily urology practices, with uncompromised quality with every use.

INTRODUCTION

Cystoscopy is a common procedure within urology. Both rigid and flexible cystoscopes can be used for most cystoscopy procedures. The flexible cystoscope is a valuable tool when diagnosing, treating and controlling both malignant and benign disorders in the lower urinary tract, and its performance has improved significantly since the introduction of the first flexible cystoscope[1]. Within the field of urology, single-use flexible ureteroscopes are widely used, while single-use cystoscopes are still rare.

Recently Ambu® launched its first single-use cystoscope – the Ambu® aScope™ 4 Cysto – and introduced this technology to urologists globally. The aScope™ 4 Cysto can be used together with the full-HD Ambu® aView™ 2 Advance Displaying Unit (together referred to as the aScope™ 4 Cysto system). The image quality, bending capability and overall performance of a cystoscope are essential elements when deciding to convert to single-use cystoscopes. This is the first international investigation to evaluate the performance of the aScope™ 4 Cysto system by collecting feedback from urologists on the perceived performance of this system during urology procedures.

METHODS

Evaluation design

The user evaluation aimed to perform subjective quality assessments of the aScope™ 4 Cysto system during cystoscopy procedures, by collecting observational data in a non-controlled, non-interventional setting. The investigation period lasted for one day and was collected over a three-month period from December 2020 to March 2021. A user evaluation form was completed by practising urologists of varying levels of experience in Australia, Belgium, Denmark, Finland, France, Germany, Hong Kong, Italy, Norway, Spain, Sweden and the UK. Patients were not asked to consent to participate in this study, as no data from human subjects were obtained.

Data collection

Respondents were recruited by local sales representatives. The sales representatives were trained through work instructions to include only urologists qualified to perform flexible cystoscopy, and to ensure that the products were handled in accordance with instructions for use. During regular practice within the urology department, where a cystoscopy was planned or requested for an adult patient, the treating urologist would decide which cystoscope (type/model) should be used for the procedure. If the aScope™ 4 Cysto system was chosen, the evaluation form was completed after finalising the clinical procedure. Respondents were asked to rate the overall performance of the aScope™ 4 Cysto system, as well as the navigation, manoeuvrability, image quality, and bending capability with and without a tool in the working channel on a 5-point Likert scale (from "very poor" (1) to "very good" (5) or "very difficult" (1) to "very easy" (5)). The respondents were also asked to categorize the indication for the procedure, which tools they used, and if they could complete the procedure using only the aScope™ 4 Cysto visualisation system.

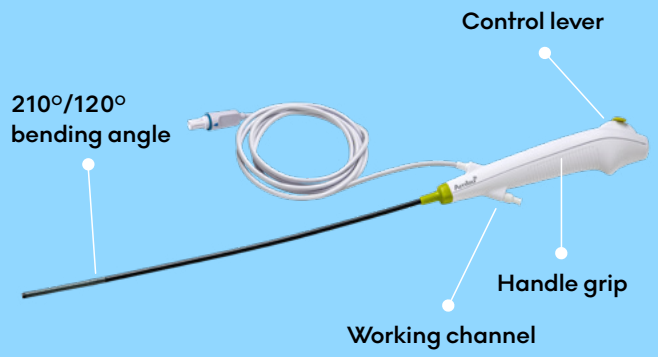
The data was collected in paper form or by using the online survey tool QuestionPro®. Data entry from paper forms was manually imported to Excel by two clinical research specialists from Ambu A/S. Double data entry was performed by validating 10% of the manually entered evaluation forms for correctness.

Statistical methods

Descriptive statistics were used to analyse sub-groups of data where applicable, such as indications and experience of the urologist performing the evaluation. 95% CI were calculated for the estimate on the ability to complete the procedure using only the aScope™ 4 Cysto visualisation system. For the performance estimates, standard deviations of the mean were calculated. All statistical analyses were performed in Microsoft Excel by external statistical consultant.

Ambu aScope 4 Cysto

The Ambu® aScope™ 4 Cysto is a single-use flexible endoscope that is always available and portable. The aScope 4 Cysto was CE-marked in November 2020 and is intended to be used for endoscopic access and examination of the lower urinary tract. The bending angles of 210°/120° enable the physician to manoeuvre and navigate smoothly in the urethra and bladder, while relying on clear, sharp images. The sterile aScope 4 Cysto eliminates the need for reprocessing and costly repairs, and the risk of cross-contamination. As a result, the aScope 4 Cysto simplifies workflow, frees up resources, and makes it easy for the physician to manage the day.



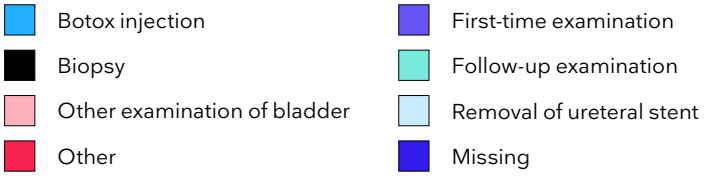
RESULTS

A total of 380 urologists filled in the evaluation form, of whom 152 (40.0%) were from Northern Europe, 102 (26.8%) were from Western Europe, 91 (23.9%) were from Southern Europe, 32 (8.4%) were from Australia and 3 (0.8%) were from Hong Kong (see Table 1).

Country	Number (%) of respondents
Northern Europe	
Denmark	18 (4.7%)
Finland	10 (2.6%)
Norway	26 (6.8%)
Sweden	10 (2.6%)
Western Europe	
Belgium	24 (6.3%)
France	54 (14.2%)
Germany	24 (6.3%)
United Kingdom	88 (23.2%)
Southern Europe	
Italy	43 (11.3%)
Spain	48 (12.6%)
Rest of the World	
Hong Kong	3 (0.8%)
Australia	32 (8.4%)

Table 1: Location for procedure

Of all the respondents, 287 (75.5%) informed about how many years of experience they had performing cystoscopy procedures. According to this information, 30 (10.5%) had 1-5 years of experience, 147 (51.2%) had 6-20 years of experience and 110 (38.3%) had >20 years of experience performing such procedures. The urologists were asked to categorize the main indication for the procedure and if any endoscopic tools were used during the procedure. Most of the procedures were performed to do a first-time (48.9%) bladder examination, a follow-up bladder examination (31.1%) or the removal of ureteral stent (9%) (see Figure 1).



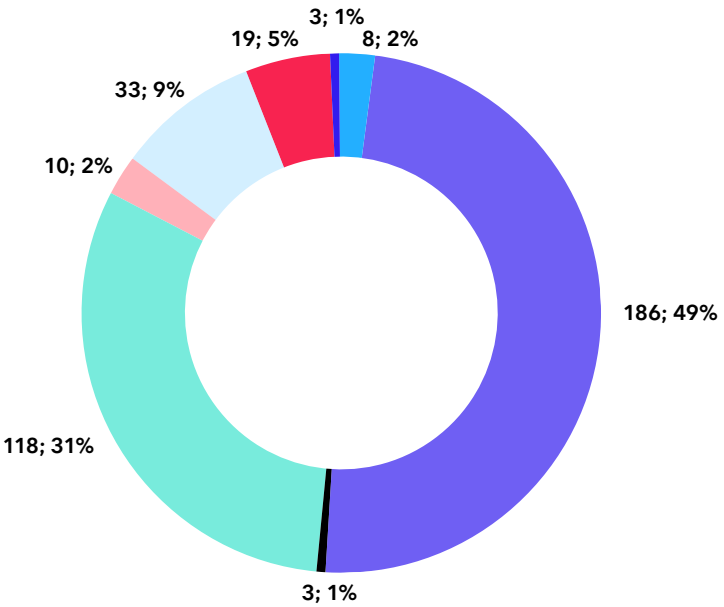
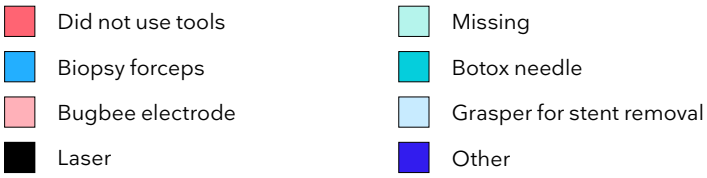


Figure 1: Main indication for the procedure (N, %)

The majority (366, 96.3%) provided information on the use of endoscopic tools during the procedure. Most of the procedures (278, 73.2%) were performed without the use of any endoscopic tool. However, for the 88 procedures where a tool was used, the most commonly used endoscopic tool was a grasper for stent removal (45, 51.1%) (see Figure 2).



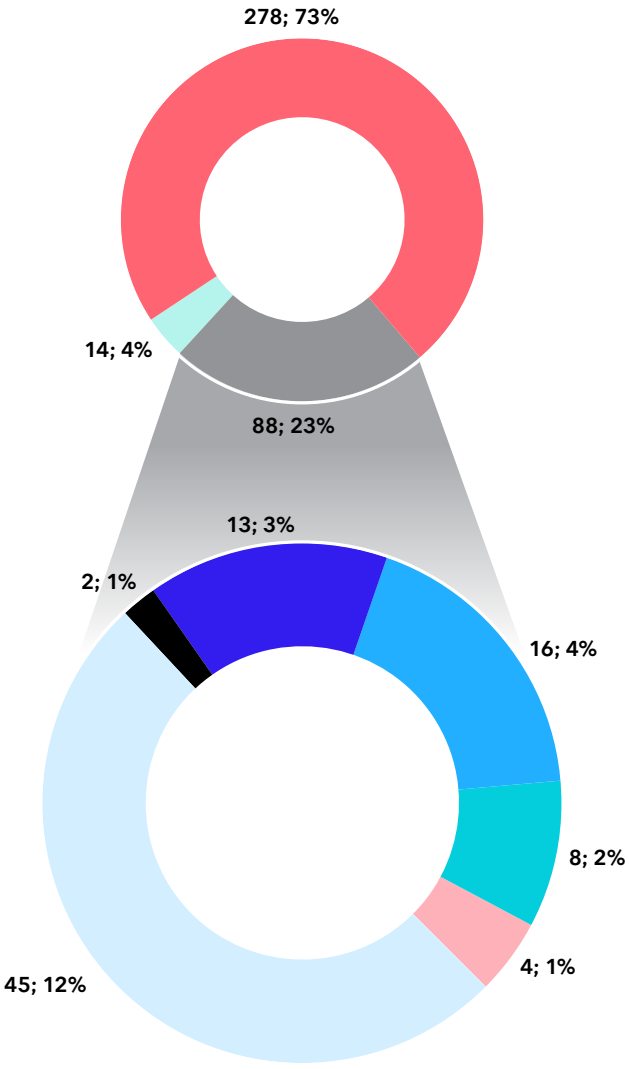


Figure 2: Use of endoscopic tools during the procedure (N, %)

The majority (368, 96.8%) of the urologists informed about whether they were able to complete the procedure. To this question, 355 (96.4%; 95% CI: 95%-98%) replied that they were able to complete the procedure using only the aScope™ 4 Cysto visualisation system. Hence, in 13 cases another cystoscope was needed to complete the procedure. This was due to several causes, where "missing NBI" (2, 15.4%), "difficulty inserting forceps" (2, 15.4%) and "device malfunction" (2, 15.4%) were the most frequently experienced.

The urologists rated the performance of the aScope™ 4 Cysto on parameters concerning image quality, bending capability (with and without tool) and navigation. Finally, they were asked to rate separately the overall performance of the aScope™ 4 Cysto and aView™ 2 Advance Displaying Unit. All the ratings were based on a 5-point Likert scale from either "very good" to "very poor" or "very difficult" to "very easy". For performance parameters concerning image quality, bending (with and without tool) and overall performance (of the aScope™ 4 Cysto as well as the aView™ 2 Advance Displaying Unit), more than 90% reported "very good" or "good" performance. For ratings on navigation, 93.6% reported "very easy" or "easy" navigation. When comparing the average performance ratings (mean ± SD), the highest average performance rating (4.55 ± 0.61) and the lowest average performance rating (4.38 ± 0.67) were given for bending capability without tool and with tool, respectively (see Figure 3).

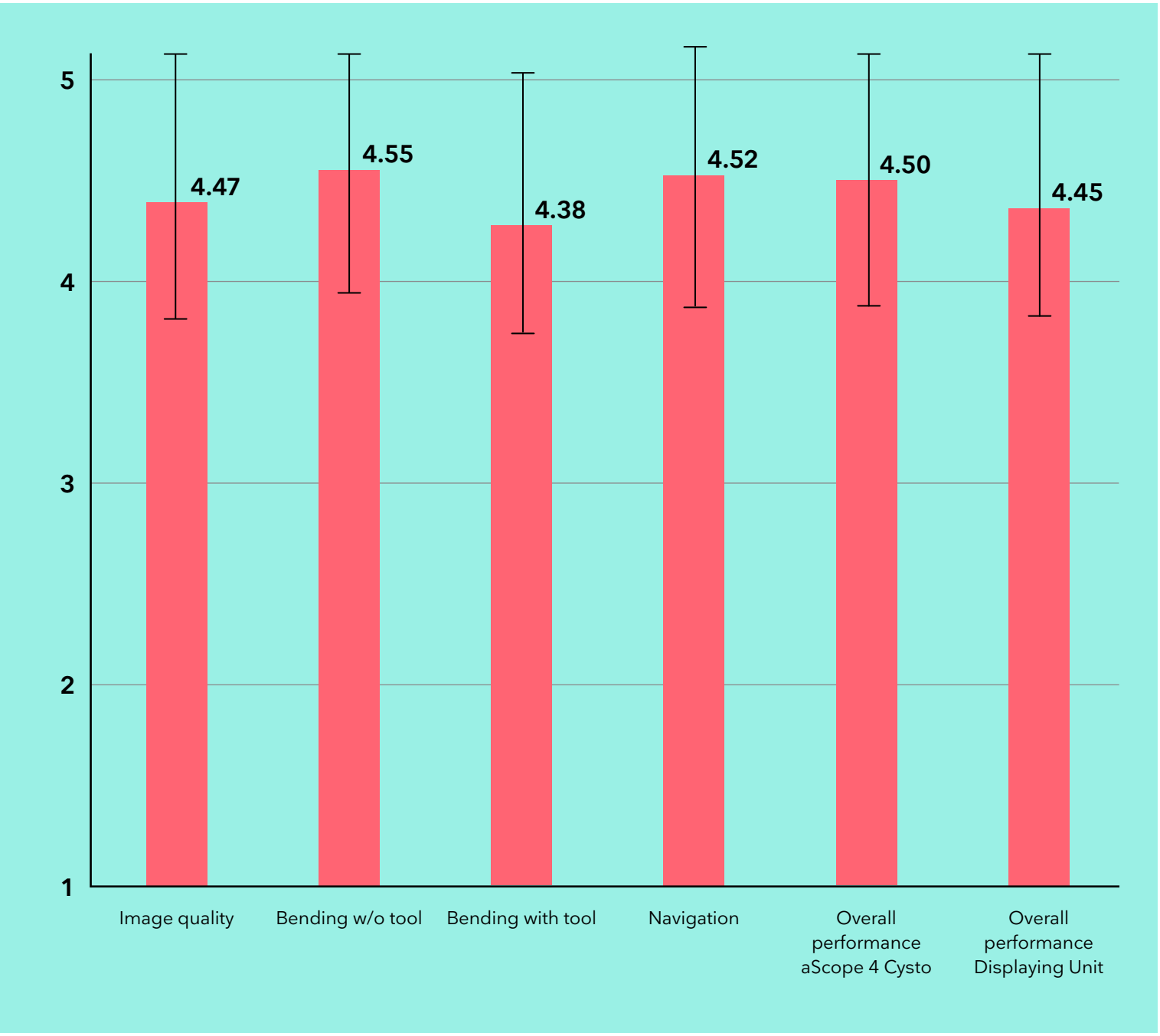


Figure 3: Average rating of performance (mean ± SD) on a 5-point Likert scale.

DISCUSSION

One of the most important aspects of a flexible cystoscope is the performance and quality of the device, and whether procedures can be carried out successfully. Besides the benefits of a more simplified workflow, as well as availability and portability, the performance of the single-use cystoscope aScope™ 4 Cysto is a vital element to consider before implementing the device into urology practice. This is the first international investigation of the performance of the aScope™ 4 Cysto system based on evaluation forms filled out by urologists. Due to the limitations associated with the research design, this investigation should merely be used as an early assessment of the performance of the aScope™ 4 Cysto system. Hence, further studies, comparing the clinical performance of the aScope 4 Cysto system with relevant counterparts, are needed.

A previous investigation on the performance of the aScope™ 4 Cysto system has been carried out in the US, including a total of 62 evaluation forms from 12 sites. In this investigation urologists assessed the aScope™ 4 Cysto system on performance parameters concerning image quality, bending (with and without tool) and overall performance (of the aScope™ 4 Cysto and the aView™ 2 Advance Displaying Unit). To these parameters, >90% of the urologists reported "very good" or "good" performance. The results of this investigation are described in a whitepaper by Ambu A/S, available at the website www.ambu.com[2].

In health care systems with limited resources, cost is an important issue with implications for value and efficiency. A recently published study by Wong et al. (2021) compared the cost of maintaining and reprocessing reusable cystoscopes with the cost of the aScope™ 4 Cysto at a hospital in the UK[3]. The study revealed a cost of £135.23 per procedure using the aScope™ 4 Cysto, and £166.33 per procedure using a reusable flexible cystoscope. Besides costs, the authors also assessed patient preferences and found that, given the option, 95% of their patients preferred the aScope™ 4 Cysto to a reusable cystoscope.

The sterile single-use aScope™ 4 Cysto eliminates the risk of cross-contamination. Even though the risk of cross-contamination of reusable cystoscopes is considered to be low, several outbreaks of cross-contamination have been documented following cystoscopy procedures[4–7]. Moreover, the U.S. Food and Drug Administration recently announced an investigation into patient infections and other possible contamination issues associated with reprocessing urological endoscopes, after receiving 450 medical device reports describing post-procedure patient infections or other possible contamination issues[8]. In situations where there is a heightened concern about infection, single-use cystoscopes may serve as a suitable alternative, with no risk of cystoscope-related cross-contamination.

Environmental impact should be considered when implementing new disposable devices. So far, only two studies have investigated the environmental impact associated with single-use endoscopes[9,10]. Davis et al. (2018) conducted a comparative study of single-use and reusable ureteroscopes and found a comparable carbon footprint per cycle of 4.43 kg of CO_2 for single-use and 4.47 kg of CO_2 for reusable ureteroscopes. The authors found that electricity use of the automated endoscope reprocessors alone accounted for 88% of the total carbon footprint and consumed 82.5 l of water per cycle in addition to the 4.47 kg of CO_2 for reusable ureteroscopes. Given the limited amount of evidence available, further studies are needed to assess the environmental impact of single-use vs reusable cystoscopes.

With no need for reprocessing or repair, the single-use cystoscope offers a more simplified workflow, while always having cystoscopes available. Baston et al. (2018) investigated the impact single-use cystoscopes had on procedure cancellation rates and hospital readmissions[11]. The study found that the single-use setup reduced readmission and cancellation rates in their department. Phan et al. (2018) also experienced fewer cancellations of procedures after implementing single-use cystoscopes[12]. According to the study, the department had experienced having to cancel procedures when the reusable cystoscopes were out of service, causing unnecessary disappointment and anxiety among patients. After implementing single-use cystoscopes, they always had cystoscopes available when needed, which meant that they were no longer forced to cancel or postpone procedures due to a lack of cystoscopes.

CONCLUSION

This study evaluated the performance of the aScope™ 4 Cysto system by collecting feedback from urologists on the perceived performance of the aScope™ 4 Cysto and the aView™ 2 Advance Displaying Unit during urology procedures. The investigation was based on 380 procedures that varied in terms of indication for procedure and the use of different endoscopic tools. The large majority (96.4%) were able to complete the procedure using only the aScope™ 4 Cysto visualisation system. The results indicate significant satisfaction with the aScope™ 4 Cysto on the most important performance parameters such as image quality, bending capabilities and navigation, with average performance ratings from 4.38 ± 0.67 to 4.55 ± 0.61 on a 5-point Likert scale. Based on these results, the single-use cystoscope aScope™ 4 Cysto is a highly useful device for daily urology practices, with uncompromised quality with every use.

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