

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

**A user evaluation based on initial perceptions from
Urologists in the UK and Ireland**

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Purpose

To evaluate the clinical performance of the Ambu® aScope™ 4 Cysto and Ambu® aView™ 2 Advance Display Unit by collecting feedback from Urologists on the initial perceived performance of this system during flexible cystoscopy procedures.

Materials and methods

A user evaluation form was completed by Urologists in the UK and Ireland after finalising a clinical procedure with the aScope™ 4 Cysto system. Clinical performance measures were assessed on a 5-point Likert scale. The primary endpoint was procedural success using only the aScope™ 4 Cysto system. Descriptive statistics were calculated in Microsoft Excel.

Results

A total of 111 user evaluation responses were collected from Urologists. 98% of Urologists were able to complete the flexible cystoscopy procedure using only the aScope™ 4 Cysto visualisation system and reported an average performance rating from 4.51 ± 0.72 to 4.68 ± 0.51 . The highest performance rating was for the overall performance of the aScope™ 4 Cysto.

Conclusion

Based on Urologists' initial perceptions of the aScope™ 4 Cysto system, this evaluation indicates highly favourable clinical performance ratings on critical performance parameters such as image quality, bending capabilities, and navigation. The single-use aScope™ 4 Cysto is a highly useful device for Urological endoscopic practice, offering consistent quality with every use.

INTRODUCTION

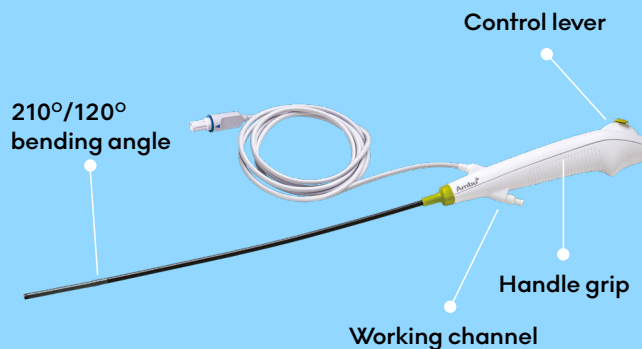
Flexible cystoscopy is a low-risk endoscopic procedure that plays an essential role in managing both diagnostic and therapeutic activities. The use of a flexible cystoscope is a commonly used valuable diagnostic tool used for a range of indications including haematuria, urinary tract infections, and bladder incontinence. Treatments such as removing bladder stones, insertion or removal of a JJ stent, or injecting Botulinum toxin type A (Botox®) can be performed conveniently during the same procedure in the out-patient clinic.

Flexible cystoscopy serves as the gold standard for the diagnosis and surveillance of malignant/benign bladder tumours and allows the Urologist to take biopsy specimens and resect papillary tumours during the same patient visit.

Since the inception of the first flexible cystoscope in 1973 by Tsuchida & Sugawara, clinical performance has improved significantly.¹ The modern landscape in flexible cystoscopy has shifted to the use of single-use flexible cystoscopes with the aim to provide a cost-efficient, portable solution and simplify workflow through eliminating reprocessing.²

Ambu® aScope™ 4 Cysto

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 Ambu® aView™ 2 Advance Display Unit (together referred to as the aScope™ 4 Cysto system). The image quality, bending capability and overall performance of a cystoscope are fundamental when deciding to convert to single-use cystoscopes. The first global survey, evaluating the performance of the aScope™ 4 Cysto system from 380 flexible cystoscopy procedures performed in Europe, Australia and Hong Kong, showed significant satisfaction on important performance parameters such as image quality, bending capabilities and navigation³. The current investigation forms part of the previous global evaluation and assesses the initial user perception of the aScope™ 4 Cysto system from Urologists in the UK and Ireland.



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METHODS

Evaluation design

This survey aimed to perform initial quality assessments of the aScope™ 4 Cysto system during cystoscopy procedures by collecting user evaluation forms. The Ambu® aScope™ 4 Cysto was used and evaluated during flexible cystoscopy procedures in adult patients clinically indicated for a diagnostic and/or therapeutic flexible cystoscopy procedure. Evaluation forms were collected over a four-month period from December 2020 to April 2021 by practising Urologists of varying experience levels.

Data collection

Experienced Urologists performing flexible cystoscopies were recruited from hospitals within the UK and Ireland. All users were trained to use the Ambu® aScope™ 4 Cysto system in accordance with the instructions for use. The evaluation was conducted according to the standard patient pathway within the Urology department. For scheduled or emergency cystoscopies, the flexible cystoscope make/model was chosen by the Urologist. Following the initial use of the aScope™ 4 Cysto system, a user evaluation was completed after 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 primary endpoint of procedural success was defined by the ability to complete all aspects of the procedure without the use of a secondary scope. The data was collected in paper form and manually imported to Microsoft Excel.

Statistical methods

All statistical analyses were performed in Microsoft Excel. Descriptive statistics were used to analyse sub-groups of data where applicable. All values are shown as the % mean; for performance estimates mean ± standard deviation (sd) of the mean was calculated.

RESULTS

This user evaluation focused on the Urologist’s initial perception following their use of the aScope™ 4 Cysto. A total of 111 Urologists from the UK and Ireland participated in the survey, of which 88 respondents formed part of the Global aScope™ 4 Cysto User Evaluation.³ 76.2% of evaluations were collected from National Health Service/Health Service Executive hospitals, and the remaining 23.8% were from private hospitals. Of the respondents, 76 (68.4%) provided information on the years of experience they had performing cystoscopy procedures; 54% had 6-20 years or >20 years experience (Figure 1).

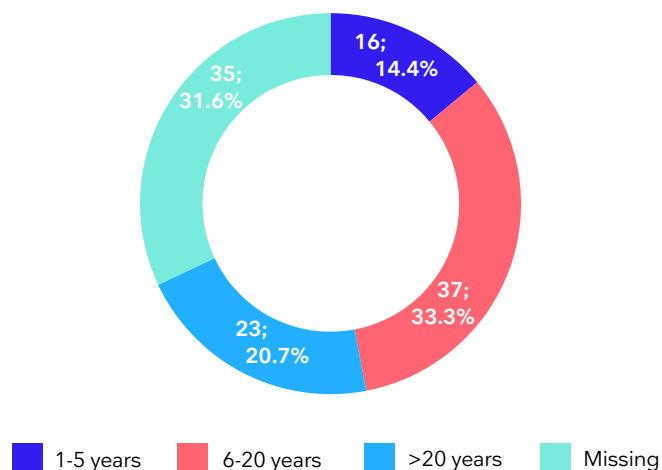


Figure 1. Years of experience performing cystoscopy procedures (N,%)

108 Urologists (97%) provided information on the indication(s) for the flexible cystoscopy procedure and whether endoscopic tools were used. Most of the procedures were performed to do a first-time bladder examination (54%), a follow-up bladder examination (26%), and/or the removal of a ureteral stent (7%) (Figure 2).

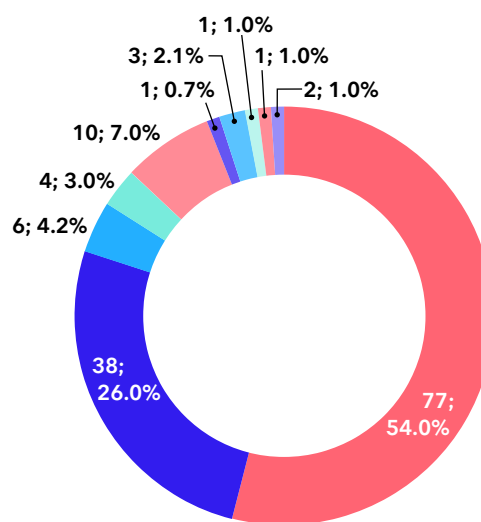


Figure 2. Indications for using the aScope™ 4 Cysto (N,%)

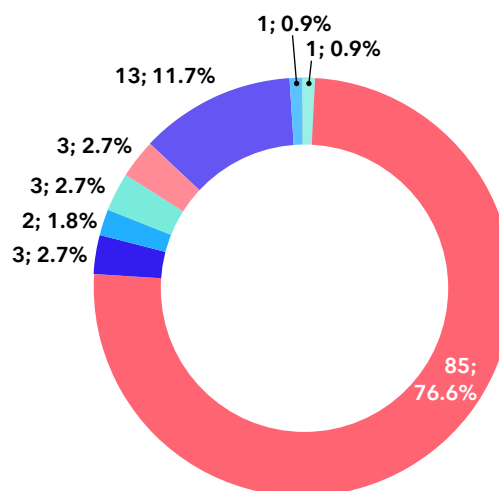
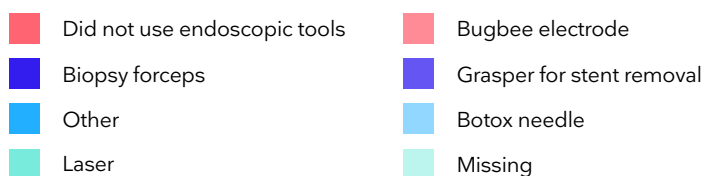


Figure 3. Use of endoscopic tools during the procedure (N,%)

Most of the procedures (85, 76.6%) were performed without the use of an endoscopic tool. For the 23 procedures where an endoscopic tool was used, the most commonly used was a grasper for a JJ stent removal (13, 11.7%) (Figure 3).

The majority (104, 93.7%) of Urologists specified whether they were able to complete the flexible cystoscopy procedure. 102 respondents (98%) replied that they were able to complete the procedure using only the aScope™ 4 Cysto visualisation system. For the remaining 2 cases, another cystoscope was required to complete the procedure; however, the respondents provided no further explanation.

Clinical performance measures including the image quality, bending capability, and overall performance of a cystoscope are essential when deciding to convert to single-use cystoscopes. In this evaluation, more than 95% of Urologists rated the image quality, bending capability (with/without tool), and overall performance of the aScope™ 4 Cysto and the aView™ 2 Advance Displaying Unit as “very good” or “good”. The navigation of the aScope™ 4 Cysto was perceived as “easy” or “very easy” in 91% of respondents. When comparing the average performance ratings, the highest average performance rating (4.68 ± 0.51) and the lowest average performance rating (4.51 ± 0.72) were given for the overall performance of the aScope™ 4 Cysto and navigation, respectively (Figure 4).

AVERAGE RATING OF CLINICAL PERFORMANCE

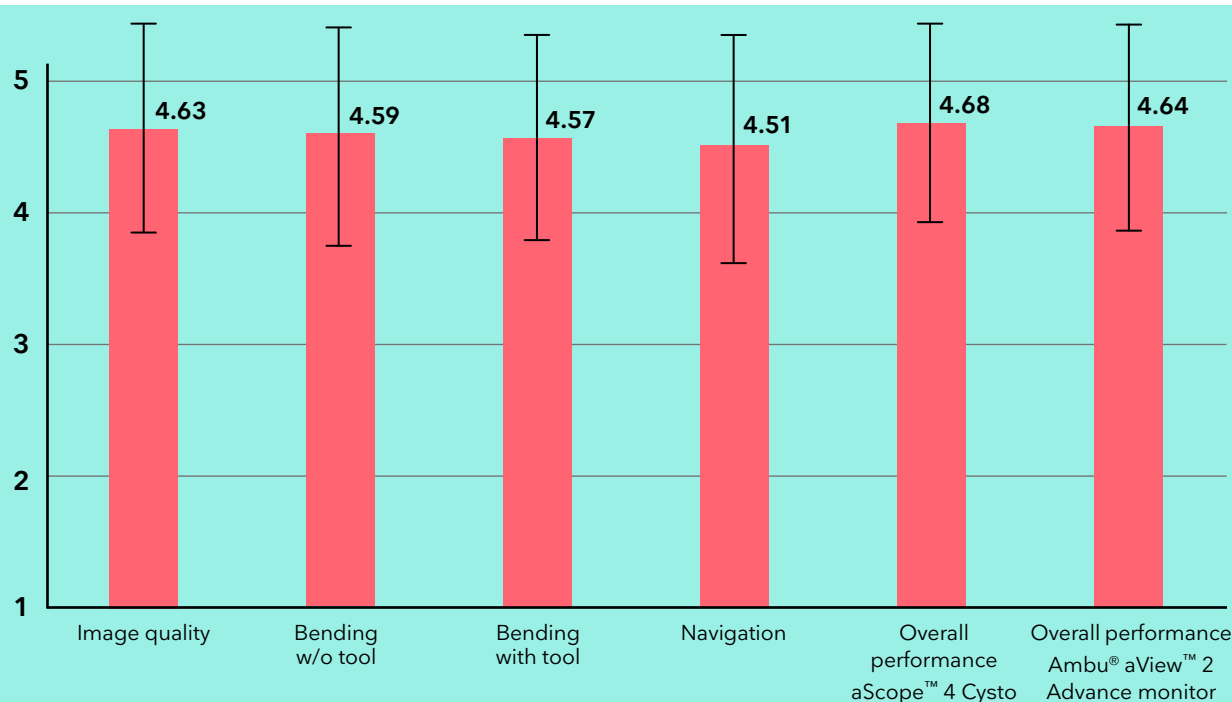


Figure 4. Average rating of clinical performance. All the ratings were based on a 5-point Likert scale: “very poor” (1) to “very good” (5) or “very easy” (5) to “very difficult” (1). Values are shown as mean±sd

DISCUSSION

Single-use flexible cystoscopes offer several key benefits over reusable cystoscopes. These include a more simplified workflow, straightforward procedure, consistent quality for each cystoscopy procedure, availability and portability, guaranteed sterility, no risk of wear and tear or damage and eliminating the cost associated with reprocessing. In addition to these key benefits, the performance and ability to carry out procedures successfully with a single-use cystoscope is imperative to consider prior to adopting the device for use in clinical Urological practice.

A previous investigation on the clinical performance of the aScope™ 4 Cysto system has been performed with 380 user evaluations worldwide.³ The findings showed that most Urologists (96.4%) were able to complete the cystoscopy procedure using only the aScope™ 4 Cysto visualisation system. The results of the global evaluation show satisfaction with the aScope™ 4 Cysto on essential performance parameters such as image quality, bending capabilities, and navigation, with average performance ratings from 4.38 ± 0.67 to 4.55 ± 0.61 (by means of the same 5-point Likert scale).

The current investigation assessed the initial perceived performance of the aScope™ 4 Cysto system from Urologists in the UK and Ireland, and formed part of the global user evaluation with 23 additional responses. In the current evaluation, the average performance ratings for the aScope™ 4 Cysto are higher (4.51 ± 0.72 to 4.68 ± 0.51). Furthermore, the overall performance of the Ambu® aScope™ 4 Cysto was rated as the highest clinical performance measure by Urologists, which from a UK and Ireland standpoint is encouraging.

Both evaluations form only an early assessment of the performance of the aScope™ 4 Cysto system, and large-scale randomised studies are warranted to thoroughly understand the comparative performance of single-use versus reusable cystoscopes for a broader range of interventional procedures. Whelan et al. performed the first published benchtop and initial clinical assessment of aScope™ 4 Cysto, demonstrating there was no need to switch to a reusable cystoscope for any procedure, no reported complications relating to any scopes and a higher flexion in aScope™ 4 Cysto compared to a reusable, flexible cystoscope.⁴

Guaranteed sterility with the aScope™ 4 Cysto

Several cross contaminations and infection outbreaks have been documented following Urological endoscopic procedures.⁵⁻⁹ The U.S. Food and Drug Administration (FDA) is investigating >450 Medical Device Reports describing post-procedure patient infections and other possible contamination issues possibly associated with reprocessed Urological endoscopes.¹⁰ The sterile single-use aScope™ 4 Cysto eliminates the risk of cystoscopy related cross-contamination with a brand-new scope used for every patient procedure.

aScope™ 4 Cysto eliminates costs associated with reusable cystoscopes

Economic evaluation is a key-aspect in the decision-making process when implementing new medical devices at a hospital. Therefore, a cost-analysis of single-use cystoscopes compared to traditional reusable cystoscopes is essential to assess when adopting single-use flexible cystoscopes into clinical practice. Based on cost evidence from three published UK studies, the aScope™ 4 Cysto is expected to lead to a cost saving of £71 per procedure, compared to reusable cystoscopes.^{2, 11, 12}

Patient satisfaction with the single-use aScope™ 4 Cysto

In addition to cost, patient satisfaction is also fundamental when considering a new cystoscope into Urological practice. Out of service reusable cystoscopes lead to procedure cancellations, causing unnecessary disappointment and anxiety among patients.¹² A recent patient preference study revealed there was a statistical significance between the patient experience using the aScope™ 4 Cysto compared with traditional reusable flexible cystoscopes. Moreover, 95% of patients also preferred the aScope™ 4 Cysto system over reusable cystoscopes, given the choice.²

Single-use cystoscopes are always available and portable

The portability of single-use cystoscopes allows the clinician to perform procedures in less resourceful intensive settings such as the outpatient clinic, thereby reducing the organisational pressure on endoscopy related diagnostic

procedures.¹¹ In addition, the availability of single-use cystoscopes helps minimise the risk for procedure delays and cancellations. After implementing single-use cystoscopes in a UK hospital, Urologists were no longer forced to cancel or postpone cystoscopy procedures previously attributed to a lack of reusable cystoscopes.¹²

Environmental impact

Ambu is leading the way with environmentally focused single-use solutions, including the aScope™ 4 Cysto. Ambu focuses on sustainability through initiatives, including our commitment to the United Nations Sustainable Development Goals, partnership with Plastic Bank® (to offset the environmental impact of aScope in Europe and Latin America), and Operation Clean Sweep® (to prevent plastic pellets from ending in bodies of water). Ambu's recent sustainability report includes a detailed summary of our sustainability approach and performance highlights.¹³

OUR SUSTAINABILITY TARGETS



100% **phthalate-free** products by 2020

COMPLETED



95% of new products released during and after 2025 to be **PVC-free**

ON TRACK



100% **recyclable, reusable or compostable** packaging applied by 2025*

*if solutions and/or technology exist

ON TRACK



We are working towards a 50% reduction of our **carbon emissions** by 2025, compared to 2019 baseline

ON TRACK

Find out more on the Ambu® Environmental standpoint



CONCLUSION

This user evaluation investigated the clinical performance of the aScope™ 4 Cysto system by collecting feedback from Urologists in the UK and Ireland. Findings showed a significant satisfaction with the aScope™ 4 Cysto on the most critical performance parameters such as image quality, bending capabilities, and navigation, with high average performance ratings from 4.51 ± 0.72 to 4.68 ± 0.51 . The highest performance rating was for the overall performance of the aScope™ 4 Cysto. Based on this user evaluation, the single-use aScope™ 4 Cysto is highly effective and reliable for clinical practice, and offers consistent quality with every use. The positive initial perceptions of aScope™ 4 Cysto combined with rapid adoption rates suggest the aScope™ 4 Cysto system as a suitable alternative to reusable cystoscopes in Urological endoscopic practice.

Rapid adoption of the aScope™ 4 Cysto

The complete Ambu® aScope™ 4 Cysto solution, including the single-use aScope™ 4 Cysto and aView™ 2 Advance is adopted in 176 accounts (including the top three hospitals in the UK) since its launch in the UK and Ireland in Oct 2020. Over 30,000 single-use cystoscopes have been sold for flexible cystoscopies performed in outpatient, inpatient care and emergency A&E/ICU settings.

This rapid adoption suggests a strong potential for shifting practice patterns, eliminating reusable cystoscope reprocessing and improving patient pathways/optimising workflows to enable the faster diagnosis and treatment for patients.

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