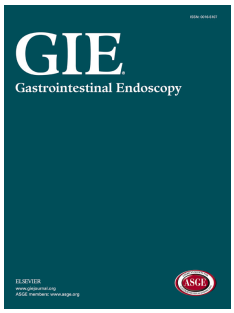

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Disposable versus reusable gastroscope:

a prospective randomized non-inferiority trial

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Background and Aims: Disposable gastroscopes have recently been developed to eliminate the risk of infection transmission from contaminated reusable gastroscopes. We compared the performances of disposable and reusable gastroscopes in patients undergoing gastroscopy.

Methods: Patients requiring gastroscopy were randomized to either the disposable or reusable digital gastroscope group. The primary endpoint was the success rate of photographing customary anatomical sites, with a noninferiority margin of -8%. Secondary endpoints included technical performance factors such as gastroscope imaging quality, maneuverability, gastroscopy completion rate, the device failure/defect rate, operating time, and safety. The data were analyzed using the Newcombe-Wilson score method and Fisher's exact two-tailed t-test.

Results: A total of 110 patients were treated using disposable (n = 55) or reusable (n = 55) gastroscopes. The success rate for capturing images of customary anatomical sites was 100% in both groups. The average imaging quality score was significantly lower (37.02 ± 3.09 vs. 39.47 ± 1.92, $p < 0.001$) and the operating time was significantly longer ($p < 0.001$) in the disposable endoscope group. No significant difference in maneuverability, gastroscopy completion rate, device failure/defect rate, operating time, or safety was found between the two groups.

Conclusions: Given the overall safety profile and similar technical performance, disposable gastroscopes represent an alternative to reusable gastroscopes for routine examination, bedside first aid and some certain circumstances.

Keywords: disposable gastroscope, reusable gastroscope, prospective randomized non-inferiority trial

Introduction

Gastrointestinal endoscopy is widely used in the diagnostic and therapeutic procedures of patients with gastrointestinal diseases. It was estimated that approximately 60,000,000 gastrointestinal endoscopic procedures are performed in China annually which is accompanied by significant costs related to the purchase, ongoing maintenance, reprocessing and disinfection of the endoscopes.

Ordinarily endoscopes are reprocessed according to infection control guidelines/recommendations to minimize iatrogenic transmission risk. However, reprocessing procedures are tedious and time consuming. It has been found that reprocessing may be ineffective because of a combination of factors, including complex structures, improper cleaning, systemic monitoring of contamination, and repair issues. [1] Although most studies to date have focused on the elevator channel endoscopes (duodenoscopes and linear-array echoendoscopes), gastroscope-induced infection has also attracted attention. [2] Thus, endoscope-induced infection remains an evident risk.[3]

The benefits of single-use flexible bronchoscopes and single-use flexible ureterorenoscopes have already been outlined, especially during the COVID-19 pandemic. In August 2019, the U.S. Food and Drug Administration (FDA) recommended that “health care facilities and manufacturers begin transitioning to duodenoscopes with disposable components to reduce risk of patient infection.” Subsequently, the single-use duodenoscope was cleared by FDA in December 2019 and the published data indicate that they provide the same performance as reusable duodenoscopes. [4,5]

The disposable electronic gastroscope – XZING-W200B (Huizhou Xianzan Technology Co., Ltd., China) with an electronic endoscope image processor (XZING-S2, serial number: S22003003, S22003004) has been recently developed. And the U.S. FDA and Conformite Europeenne (CE) have already approved this device for use in examination/treatment of the upper gastrointestinal tract in September 2020.

This study was designed to evaluate the image quality, operability, operating time, and safety of the disposable gastroscopes.

Methods

1. Subjects: A total of 110 patients (calculated by PASS 11 according to the primary endpoint with a noninferiority margin of -8%) who visited Beijing Friendship Hospital affiliated with Capital Medical University or Tianjin Medical University General Hospital from June 12, 2020 to December 16, 2020, were enrolled in this study. The inclusion criteria were as follows: (1) 18 to 75 years of age, male or female; (2) needs of gastroscopy for upper gastrointestinal symptoms or screening gastroscopy; and (3) willingness to participate and provide written informed consent. The exclusion criteria were as follows: (1) contraindications to gastroscopy: ① thoracic-abdominal aortic aneurysm; ② severe spinal malformations; ③ severe cardiovascular or cerebrovascular diseases; ④ severe cardiopulmonary insufficiency and thus an inability to tolerate gastroscopy; ⑤ giant upper gastrointestinal diverticulum; ⑥ acute upper gastrointestinal inflammation (corrosive ingestion); ⑦ systemic bleeding disorders or coagulation abnormalities with bleeding tendencies; and ⑧ mental illness or severe intellectual disability with an inability to cooperate; (2) pregnant or nursing women; (3) emergency endoscopy or related treatment; (4) a history of upper gastrointestinal surgery; (5) participation in another clinical trial within 1 month of screening; (6) other gastrointestinal endoscopic examination and/or treatment on the same day; (7) a history of allergies to anesthetics; or (8) unsuitability for this trial based on the opinion of the investigator.

This study was approved by the Ethics Committee of Beijing Friendship Hospital affiliated with Capital Medical University on February 21, 2020 and General Hospital affiliated with Tianjin Medical University on March 31, 2020.

2. Devices: The following devices were used: the – XZING-W200B disposable gastroscope (Huizhou Xianzan Technology Co., Ltd., China) with an imaging processor (XZING-S2, serial number: S22003003, S22003004); and reusable gastroscopes (GIF-HQ290, GIF-H290, Olympus Medical Systems, specifications can be found at http://olympusmedical.com.hk/products/gastroenterology/gastroscopy/index.html) with an imaging processor (CV-290), and light source (CLV-290SL), and a water pump (OFP-2). (Table 1)

3. Procedures: The eligible subjects were randomized using a central randomization system (interactive web-based response system, IWRS). On the day of the procedure, when the subject was ready for gastroscopy, the investigator logged into the electronic data capture (EDC) system (Version: 2.0; Version Date: March 27, 2020) to randomize the subject to the experimental group or the control group.

Each subject was instructed to fast (no food or water) for at least 6 hours. Each subject was placed in the left lateral position. After intravenous sufentanil and propofol anesthesia induction,

an experienced endoscopist performed the procedure to observe the esophagus, cardia, gastric body, gastric antrum, pylorus, and duodenum. At the end of the procedure, the endoscope was withdrawn along the duodenum, gastric antrum, gastric angle, gastric body, gastric fundus, cardia, and esophagus. Images of each site were captured, and the entire procedure was recorded. If any lesion was observed, its nature, scope, and location were identified and recorded, followed by endoscopic biopsy if needed. Blood pressure, pulse, and blood oxygen saturation were monitored during the procedure, and each subject was monitored for any signs or symptoms after the procedure.

4. Evaluation measures:

4.1 Effectiveness measures

4.1.1 Primary measure

(1) Acceptable image quality

Evaluation method: The entire procedure was recorded, and images of anatomical landmarks and abnormal findings were accurately captured. Gastroscopy should cover the upper esophagus to the descending duodenum and successfully reach at least 10 anatomical markers: the proximal esophagus, the distal esophagus, the dentate line, the gastric cardia and fundus, the lesser curvature of the gastric body, the greater curvature of the gastric body, the gastric angle, the gastric antrum, the duodenal bulb, and the descending duodenum.[6] All sites were photographed and recorded, with one or more representative images for each site. In addition, all abnormalities were photographed and recorded in the gastroscopy report. A clear image of each of these 10 sites was used for the evaluation. The images were evaluated independently by two researchers; that is, two researchers independently evaluated the gastroscopic images of the subjects enrolled at their hospitals. Any discrepancy was resolved by a third researcher.

Evaluation criterion: Image quality was considered acceptable if at least one representative image of each of the 10 anatomical markers was obtained; otherwise, the image quality was unacceptable.

Acceptable image quality (%) = the number of subjects in each group with acceptable image quality (n) ÷ the number of subjects in each group × 100%.

4.1.2 Secondary measures

(1) Image quality score

Image quality was rated on a scale ranging from 0 to 4, where 0 represented missing sites or unclear images; 1 represented no missing sites, with slightly unclear images; 2 represented no missing sites, with relatively clear images; 3 represented no missing sites, with clear images; and 4 represented no missing sites, with very clear images.[7] Image quality was rated independently by two researchers; that is, two researchers evaluated each gastroscopic image of the subjects enrolled at their hospitals. Any discrepancy was resolved by a third researcher. A total score (up to 40) was calculated by summing the scores for all 10 sites for each subject.

Image quality score (mean) = the total score of all the subjects in each group ÷ the number of subjects in each group.

(2) Gastroscopy completion rate

Gastroscopy was considered completed if the gastroscopic tip reached the descending duodenum.[8]

Gastroscopy completion rate = the number of subjects in each group with completed gastroscopy ÷ the number of subjects in each group × 100%.

(3) Acceptable clinical operability

Evaluation method: The operator evaluated operability and image quality. Operability included flexibility, auxiliary features, therapeutic maneuvers, and operating time. Image quality included image conditions; brightness, contrast, and sharpness; and optical staining techniques. To evaluate image quality, the entire procedure was recorded, and key sites were archived and photographed.

Evaluation criteria: Each item was rated as A (high), B (fair), or C (low). Clinical operability was considered acceptable if both operability and image quality were rated A or B; otherwise, clinical operability was unacceptable.

(4) Device failure/malfunction rate

Device failure, such as image interruption and water jet malfunction, was recorded if it occurred during the procedure.

(5) Operating time

A research assistant recorded the time from insertion (from the esophagus to the descending duodenum) to withdrawal (from the descending duodenum to complete withdrawal) and the total operating time (the time for insertion and withdrawal) with an electronic stopwatch.

The time for insertion was rated as A (< 5 minutes), B (5 to 10 minutes), C (10 to 20 minutes), or D (> 20 minutes).

The time for withdrawal was rated as A (< 10 minutes), B (10 to 20 minutes), C (20 to 30 minutes), or D (> 30 minutes).

4.2 Safety measures

4.2.1 Description of safety measures

(1) In-procedure stability was defined as the stability of the subject's blood pressure and heart rate. Detailed data were recorded to calculate the stability rate.

(2) The incidence of device-related adverse events.

4.2.2 Methods and time points for evaluating, recording, and analyzing safety measures

(1) In-procedure stability was evaluated based on the percentage of subjects whose blood pressure and heart rate changed more than 20% from baseline.[9] Systolic blood pressure was recorded as normal, between 140 and 160 mmHg, > 160 mmHg, or shock; heart rate was recorded as normal, > 100 bpm, < 60 bpm, or arrhythmia. After anesthesia, each subject was placed in the supine position to record blood pressure and heart rate before, during (until the gastroscopic tip reached the gastric body), and 10 ± 5 minutes and 1 hour ± 15 minutes after the procedure to calculate the percentage of subjects whose blood pressure and heart rate changed more than 20% from baseline.

(2) The incidence of adverse events was defined as the percentage of subjects who experienced any adverse event during or within 1 hour after the screening, diagnostic, or therapeutic procedure with an electronic gastroscope. Adverse events included nausea, vomiting, respiratory depression, shock/hypotension, myocardial infarction, gastrointestinal perforation, gastrointestinal hemorrhage, asphyxia, gastrointestinal constriction, fistula, or sinus formation.

5. Statistical analysis: SAS 9.4 was used for statistical analysis. Measurement data were analyzed with the t-test or Wilcoxon rank sum test for intergroup comparisons and the paired t-test or signed rank sum test for intragroup comparisons; count data were analyzed with the chi-squared test or Fisher's exact test for intergroup comparisons; and multivariate or categorical data were analyzed with the Cochran–Mantel–Haenszel (CMH) test. The primary/major effectiveness measures were analyzed with the CMH test, logistic regression analysis, or covariance analysis to

consider hospital-related factors or other stratification factors. $P < 0.05$ was considered statistically significant.

Results

1. General information

No significant between-group differences were observed for sex or age. (Table 2)

2. Effectiveness evaluation

(1) Primary measure – acceptable image quality

The rate of acceptable image quality was 100.0% (55/55; 95% confidence interval (CI): 0.9347, 1.0000) in both groups. The between-group difference was 0.0000, and the lower limit of the 95% CI (-6.5285%, 6.5285%) was greater than -8%, which was the non-inferiority threshold, indicating that image quality in the experimental group was noninferior to that in the control group (Table 3).

(2) Secondary measures

① Image quality score

The mean scores were 37.02 ± 3.09 (95% CI: 36.18, 37.85) in the experimental group and 39.47 ± 1.92 (95% CI: 38.95, 39.99) in the control group. The difference was statistically significant ($P < 0.001$).

For site scores, in the experimental group, the dentate line was rated as 1 in one subject, the gastric cardia and fundus (reverse view) were rated as 1 in one subject, and all other sites were rated as 2 or above; in the control group, the dentate line was rated as 2 in one subject, and all other sites were rated as 3 or above (Table 4).

② Endoscopy completion rate

FAS (full analysis set)/ PP (per protocol): The completion rate was 100.0% (55/55; 95% CI: 0.9347, 1.0000) in both groups.

③ Acceptable clinical operability

FAS/PP: The rate of acceptable (rating: A or B) clinical operability was 100.0% (55/55; 95% CI: 0.9347, 1.0000) in both groups.

The acceptable rates (rating: A or B) of the following were 100% in both groups: flexibility (body rigidity, knob operation, and sharp angle adaptability); auxiliary features (air supply, water supply, and suction); diagnostic biopsy; operating time (lesion biopsy); image conditions (image acquisition and image quality); brightness, contrast, and sharpness (identification of the nature of lesions, cavities, and small vessels during the procedure); and optical staining techniques (identification of the glandular opening and vessel morphology).

For the rating (A, B, or C) of operability, no significant between-group difference was observed for air supply, an auxiliary feature; however, significant between-group differences were observed for flexibility (body rigidity, knob operation, and sharp angle adaptability), certain auxiliary features (water supply and suction), diagnostic biopsy (lesion access and biopsy), and operating time (lesion biopsy). Nevertheless, the rating was A or B in the experimental group and met clinical needs.

For the rating (A, B, or C) of image quality, no significant between-group difference was observed in cavity identification, which is a feature of brightness, contrast, and sharpness; however, significant between-group differences were observed for the following: image conditions (image acquisition and image quality); certain features of brightness, contrast, and sharpness (identification of the nature of lesions and small vessels during the procedure); and optical staining techniques (identification of the glandular opening and vessel morphology). Nevertheless, the rating was A or B in the experimental group and met clinical needs. See Table 5 for details.

④ Device failure/malfunction rate

FAS/PP: The device failure/malfunction rate was 0.0% (0/55; 95% CI: 0.0000, 0.0653) in both groups.

⑤ Operating time

The total operating time, insertion time and withdrawal time were longer in the experimental group and the differences were statistically significant ($P < 0.001$).

The differences of ratings for the insertion time and withdrawal time were not statistically significant between the two groups. See Table 6 for details.

3. Safety evaluation

No adverse events were observed in the experimental or control group.

① Before the procedure: The rates of systolic blood pressure stability, diastolic blood pressure stability, and heart rate stability were 76.4%, 81.8%, and 85.5% in the experimental group, respectively, and 92.5%, 83.0%, and 86.8% in the control group; only the difference in systolic blood pressure was statistically significant ($P = 0.022$, $P = 0.870$, and $P = 0.841$).

② During the procedure, the rates of systolic blood pressure stability, diastolic blood pressure stability, and heart rate stability were 83.6%, 74.5%, and 83.6% in the experimental group, respectively, and 77.8%, 74.1%, and 83.3% in the control group; none of the differences were statistically significant ($P = 0.438$, $P = 0.955$, and $P = 0.966$, respectively).

③ At 10 ± 5 minutes after the procedure, the rates of systolic blood pressure stability, diastolic blood pressure stability, and heart rate stability were 87.3%, 87.3%, and 78.2% in the experimental group, respectively, and 78.2%, 74.5%, and 74.5% in the control group; none of the differences were statistically significant ($P = 0.207$, $P = 0.089$, and $P = 0.654$).

④ At 1 hour ± 15 minutes after the procedure, the rates of systolic blood pressure stability, diastolic blood pressure stability, and heart rate stability were 100.0%, 94.5%, and 83.6% in the experimental group, respectively, and 90.9%, 94.5%, and 72.7% in the control group; none of the differences were statistically significant ($P = 0.057$, $P = 1.000$, and $P = 0.166$).

Discussion

This study is the first to compare disposable and reusable gastroscopes. In this randomized, controlled, noninferiority clinical trial, we evaluated the efficacy, effectiveness and safety of disposable gastroscopes. Additionally, we evaluated whether these devices will function equivalently to reusable endoscopes in current practice. Although the image quality score was

slightly lower in the experimental group than in the control group, the image quality met clinical needs, especially considering the acceptable image quality rate.

Regarding maneuverability, the acceptable flexibility (body rigidity, knob operation, and sharp angle adaptability) rate was 100% in both groups, indicating good flexibility and operability. The acceptable auxiliary feature (air supply, water supply, and suction) rate was 100% in both groups, suggesting good water supply, air supply, and suction, consequently, good scope cleaning (self-cleaning) and liquid or food residue removal from the site (site cleaning), which ensures successful gastroscopic examination or treatment. The acceptable diagnostic biopsy and operating time (lesion biopsy) rates were 100%, indicating successful endoscopic treatment in both groups. The acceptable image condition (image acquisition and image quality) rates and acceptable image brightness, contrast, and sharpness (identification of the nature of lesions, cavities, and small vessels during the procedure) rates were 100%, which are consistent with the primary effectiveness measure. The acceptable optical staining technique (identification of the glandular openings and vessel morphology) rate was 100% in both groups, suggesting that the smart wavelength imaging (SWI) used in the experimental group was equivalent to the narrow band imaging (NBI) used in the control group.

The total operating time, time for insertion, and time for withdrawal were all shorter in the control group than in the experimental group, which might be related to the investigators' familiarity with the reusable endoscopes. It is also possible that the investigators spent more time observing and evaluating the disposable gastroscope's performance at the beginning of trial, as evidenced by decreased time in the mid-late stage of the clinical trial as the investigators became assured of the viability of using the disposable gastroscope.

In this study, none of the 110 subjects experienced any adverse events, indicating a good safety profile in both groups and suggesting that gastroscopy does not cause immediate or delayed harm.

Gastroscopy was well-tolerated in both groups, without significant fluctuations in blood pressure or heart rate before, during, or after the procedure, indirectly demonstrating good operational stability of the gastroscopes used in this study.

The disposable gastroscope proved effective in terms of insertion, handling, and visualization of the upper gastrointestinal tract, and its diagnostic accuracy was not inferior to that of conventional endoscopes.

Gastrointestinal endoscopy is playing an increasingly important role in the routine examination and diagnosis/treatment of gastrointestinal diseases. Endoscope-transmitted infection may be a rare event, but even a rare rate of endoscopic cross-contamination could affect the health of individuals. A disposable gastroscope may be an important option for minimizing and eventually eliminating the risk of endoscopically transmitted infections.

Despite advancements over the years, the gastrointestinal endoscope remains a delicate instrument and requires careful maintenance. The endoscope could be damaged as a result of the improper operation of endoscopic injection needles or tissue adhesive injection. Accordingly, disposable gastroscopes may provide a satisfactory solution.

Patients with signs of gastrointestinal bleeding and hemodynamic instability should be offered urgent endoscopy. These patients stay in the emergency room (ER) or intensive care unit (ICU) because of critical illness. Hospital transfer to the endoscopy suite has both opportunity and associated risk. Bedside endoscopy is an optimal solution in this situation. It is not impractical to equip each department of the hospital with endoscopes and imaging systems. Disposable endoscopes with smaller occupied space and lighter weight have the advantage over reusable endoscopes and represent an alternative to reusable endoscopes.

In addition to the possible contamination and high cost for maintenance and repair for conventional gastroscopes, disposable gastroscopes are an acceptable bedside tool with an important role not only in the ER and ICU but also in certain circumstances, e.g., for patients with severe immune deficiency disorder and hypoimmunity, on warships, and in disaster areas, remote regions, field hospitals, mobile hospitals and infectious disease wards, especially during the COVID-19 pandemic. The application of the disposable gastroscope in a COVID-19 patient with gastrointestinal bleeding was reported by Xu et al. [10] Currently, a clinical trial to evaluate the performance and safety of disposable gastroscopes at the emergency bedside and intraoperative diagnosis and treatment is ongoing at another institution.

Of particular note is that this is a non-inferiority trial and the performance of the disposable gastroscope was not quite as good as that of the reusable gastroscope. However, improvements can be made to the image quality and maneuverability in the future. Once the efficacy and reliability of disposable gastroscopes was no longer in question, cost would become the main concern. Although disposable endoscopes are currently expensive (provisional price $800-1200), the cost would decrease over time as production scales up. Furthermore, the potential environmental impact of disposable gastroscopes remains unknown but should not be ignored. However, cost-effectiveness analyses should be performed considering all aspects related to economic value and health effects.

A study focused on the cost efficiency of a hybrid flexible ureteroscopy program (reusable flexible ureterorenoscopes/single use flexible ureterorenoscopes) indicated that a hybrid system may be a feasible cost-efficient alternative to a reusable flexible ureterorenoscope-only program.[11] Hence, a hybrid scope system (reusable scope supplemented by a disposable scope in special circumstances) might be an alternative for digestive endoscopic centers.

In conclusion, disposable gastroscopes are effective, operable, and safe, and are a favorable option in certain circumstances.

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Table 1 Specifications of the endoscope and the imaging processor

Disposable Endoscope (XZING-W200B)		
Optical System	Field of view	110°
	Direction of view	Forward viewing
	Depth of field	Normal focus mode 3 - 100 mm (without near focus mode)
Insertion Section	Distal end outer diameter	11 mm
	Insertion tube outer diameter	11 mm
	Working length	1300 mm
	Water Jet (auxiliary water channel)	Yes
Instrument Channel	Channel inner diameter	3 mm
Bending Section	Angulation range	Up 180°
		Down 160°
		Right 160°
		Left 160°
Total Length		1,645 mm
Imaging Processor (XZING-S2, serial number: S22003003, S22003004)		
Type of Imaging System	Complementary Metal Oxide Semiconductor (CMOS)	
Optical-Digital Observation	Smart wavelength imaging (SWI)*	
Read Only Memory (ROM)	1GB	
Signal Output	Digital Visual Interface (DVI)(1080P)	

***** SWI works by extracting specific wavelengths of light using a specialized software.

Table 2 Characteristics of the patients

	Disposable (N = 55)	**Reusable (N = 55)**	**P value**
Age	36.58 (40.30 ± 13.30)	38.76 (43.13 ± 14.22)	0.392
Sex, n (%)			0.841
Male	20 (36.4%)	18 (3 2.7%)	
Female	35 (63.6%%)	37 (6 7.3%)	
Medical history, n (%)			0.672
Yes	14 (25.5)	17 (30.9)	
No	41 (74.5)	38 (69.1)	
Previous anesthesia allergy, n (%)			NS
Yes	0 (0.0%)	0 (0.0%)	
No	55 (100.0%)	55 (100.0%)	
Previous upper gastrointestinal surgery, n (%)			NS
Yes	0 (0.0%)	0 (0.0%)	
No	55 (100.0%)	55 (100.0%)	

Table 3 The success rate of photographing iconic anatomical sites in the two groups

Group	Success rate	Difference	Difference 95% CI[#]	Noninferiority margin
Disposable (n = 55)	100%	0%	(-6.5285%, 6.5285%)	-8%
Reusable (n = 55)	100%			

[#] Newcombe-Wilson score method

Table 4 Comparison of the image quality of anatomical sites between disposable gastroscopes (experimental group) reusable gastroscopes (control group)

Site	Score	Experimental Group (n = 55)	Control Group (n = 55)	P value
Proximal esophagus	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	
	2: no missing site, with relatively clear images	0 (0.0)	0 (0.0)	
	3: no missing site, with clear images	5 (9.1)	3 (5.5)	0.716
	4: no missing site, with very clear images	50 (90.9)	52 (94.5)	
	Total	55 (100.0)	55 (100.0)	
Distal esophagus	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	
	2: no missing site, with relatively clear images	1 (1.8)	0 (0.0)	0.527
	3: no missing site, with clear images	6 (10.9)	4 (7.3)	
	4: no missing site, with very clear images	48 (87.3)	51 (92.7)	
	Total	55 (100.0)	55 (100.0)	
Dentate line	1: no missing site, with slightly unclear images	1 (1.8)	0 (0.0)	0.005
	2: no missing site, with relatively clear images	0 (0.0)	1 (1.8)	
	3: no missing site, with clear images	14 (25.5)	3 (5.5)	
	4: no missing site, with very clear images	40 (72.7)	51 (92.7)	
	Total	55 (100.0)	55 (100.0)	
Cardia and fundus (reverse view)	1: no missing site, with slightly unclear images	1 (1.8)	0 (0.0)	0.000
	2: no missing site, with relatively clear images	3 (5.5)	0 (0.0)	
	3: no missing site, with clear images	28 (50.9)	2 (3.6)	

	4: no missing site, with very clear images	23 (41.8)	53 (96.4)	
	Total	55 (100.0)	55 (100.0)	
Gastric body, including the lesser curvature (front view)	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	0.000
	2: no missing site, with relatively clear images	3 (5.5)	0 (0.0)	
	3: no missing site, with clear images	21 (38.2)	3 (5.5)	
	4: no missing site, with very clear images	31 (56.4)	52 (94.5)	
	Total	55 (100.0)	55 (100.0)	
Gastric body, including the greater curvature (reverse view)	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	0.005
	2: no missing site, with relatively clear images	2 (3.6)	0 (0.0)	
	3: no missing site, with clear images	16 (29.1)	5 (9.1)	
	4: no missing site, with very clear images	37 (67.3)	50 (90.9)	
	Total	55 (100.0)	55 (100.0)	
Gastric angle (partial reverse view)	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	0.000
	2: no missing site, with relatively clear images	0 (0.0)	0 (0.0)	
	3: no missing site, with clear images	14 (25.5)	1 (1.8)	
	4: no missing site, with very clear images	41 (74.5)	54 (98.2)	
	Total	55 (100.0)	55 (100.0)	
Gastric antrum	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	0.009
	2: no missing site, with relatively clear images	2 (3.6)	0 (0.0)	
	3: no missing site, with clear images	10 (18.2)	2 (3.6)	
	4: no missing site, with very clear images	43 (78.2)	53 (96.4)	

	Total	55 (100.0)	55 (100.0)	
Duodenal bulb	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	0.093
	2: no missing site, with relatively clear images	1 (1.8)	0 (0.0)	
	3: no missing site, with clear images	7 (12.7)	2 (3.6)	
	4: no missing site, with very clear images	47 (85.5)	53 (96.4)	
	Total	55 (100.0)	55 (100.0)	
Descending duodenum	1: no missing site, with slightly unclear images	0 (0.0)	0 (0.0)	0.002
	2: no missing site, with relatively clear images	0 (0.0)	0 (0.0)	
	3: no missing site, with clear images	13 (23.6)	2 (3.6)	
	4: no missing site, with very clear images	42 (76.4)	53 (96.4)	
	Total	55 (100.0)	55 (100.0)	

Table 5 Comparison of the operability between disposable gastroscopes (experimental group) and reusable gastroscopes (control group)

	Experimental Group (n = 55)	**Control Group (n = 55)**	**Statistics**	**P value**
6.1 Operability				
6.1.1 Flexibility				
Body rigidity			24.444	0.000
A: Moderate rigidity, good operability	35 (63.6)	55 (100.0)		
B: Too rigid or flexible, fair operability	20 (36.4)	0 (0.0)		
Total	55 (100.0)	55 (100.0)		
Knob operation			18.723	0.000
A: Flexible	39 (70.9)	55 (100.0)		
B: Fair, with certain resistance	16 (29.1)	0 (0.0)		
Total	55 (100.0)	55 (100.0)		
Sharp angle adaptability			21.522	0.000
A: Good, the tip of the scope is easy to pass	37 (67.3)	55 (100.0)		
B. Fair, the tip of the scope can pass	18 (32.7)	0 (0.0)		
Total	55 (100.0)	55 (100.0)		
6.1 Operability				
6.1.2 Auxiliary features				
Air supply			Fisher	0.495
A: Operation is sensitive, with moderate air supply	53 (96.4)	55 (100.0)		

B: Operation is relatively sensitive, with more or less air supply	2 (3.6)	0 (0.0)		
Total	55 (100.0)	55 (100.0)		
Water supply			9.340	0.002
A: Operation is sensitive and can effectively clean the scope	42 (76.4)	53 (96.4)		
B: Operation is relatively sensitive and can clean the scope	13 (23.6)	2 (3.6)		
Total	55 (100.0)	55 (100.0)		
Suction			Fisher	0.013
A: Operation is sensitive, with a moderate suction volume	48 (87.3)	55 (100.0)		
B: Operation is relatively sensitive, with more or less suction volume	7 (12.7)	0 (0.0)		
Total	55 (100.0)	55 (100.0)		
6.1 Operability				
6.1.3 Diagnostic biopsy				
Lesion biopsy			Fisher	0.000
A: Good	9 (16.4)	24 (43.6)		
B: Fair	9 (16.4)	0 (0.0)		
N/A	37 (67.3)	31 (56.4)		
Total	55 (100.0)	55 (100.0)		
Lesion access			1.591	0.207
A: Easy to operate, the operating time is shorter than or as usual	7 (12.7)	12 (21.8)		
N/A	48 (87.3)	43 (78.2)		

Total	55 (100.0)	55 (100.0)		
6.1 Operability				
6.1.4 Operating time				
Lesion biopsy			Fisher	0.000
A: Easy to operate, the operating time is shorter than or as usual	9 (16.4)	24 (43.6)		
B: Relatively easy to operate, the operating time is longer than usual	9 (16.4)	0 (0.0)		
N/A	37 (67.3)	31 (56.4)		
Total	55 (100.0)	55 (100.0)		
6.2 Image quality				
6.2.1 Image conditions				
Image acquisition			12.222	0.000
A: Good quality, the images can be used in scientific research and education	44 (80.0)	55 (100.0)		
B: Relatively good quality, the images may be used in scientific research and education	11 (20.0)	0 (0.0)		
Total	55 (100.0)	55 (100.0)		
Image quality			20.651	0.000
A: Good brightness, contrast, and sharpness. The nature of lesions can be identified in real time	30 (54.5)	51 (92.7)		
B: Relatively good brightness, contrast, and sharpness. The nature of the lesion can be identified with close observation	25 (45.5)	4 (7.3)		

Total	55 (100.0)	55 (100.0)		
6.2 Image quality				
6.2.2 Brightness, contrast, and sharpness				
Identification of the nature of lesions			10.555	0.000
A: Good brightness, contrast, and sharpness. The nature of lesions can be identified in real time	43 (78.2)	54 (98.2)		
B: Relatively good brightness, contrast, and sharpness. The nature of lesions can be identified with close observation	12 (21.8)	1 (1.8)		
Total	55 (100.0)	55 (100.0)		
Identification of cavities			Fisher	0.113
A: Good brightness, contrast, and sharpness. Cavities can be accurately identified to facilitate scope insertion	49 (89.1)	54 (98.2)		
B: Relatively good brightness, contrast, and sharpness. Cavities can be identified to facilitate scope insertion	6 (10.9)	1 (1.8)		
Total	55 (100.0)	55 (100.0)		
Identification of small vessels during the procedure			22.736	0.000
A: Good brightness, contrast, and sharpness. Small vessels can be accurately identified during the procedure to prevent bleeding	34 (61.8)	54 (98.2)		
B. Relatively good brightness, contrast, and sharpness. Small vessels can be identified	20 (36.4)	1 (1.8)		

during the procedure to prevent bleeding				
N/A	1 (1.8)	0 (0.0)		
Total	55 (100.0)	55 (100.0)		
6.2 Image quality				
6.2.3 Optical staining techniques				
Identification of the glandular opening			34.605	0.000
Missing	10 (18.2)	1 (1.8)		
A: The gland can be accurately identified, and the type of glandular opening can be effectively identified	25 (45.5)	53 (96.4)		
B: The gland and the type of glandular opening can be identified	20 (36.4)	1 (1.8)		
Total	55 (100.0)	55 (100.0)		
Identification of vessel morphology			34.468	0.000
Missing	10 (18.2)	1 (1.8)		
A: The vessel can be accurately identified, and the type of vessel opening can be effectively identified	24 (43.6)	53 (96.4)		
B: The vessel and the type of vessel opening can be identified	21 (38.2)	1 (1.8)		
Total	55 (100.0)	55 (100.0)		

Table 6 Comparison of the operating time between disposable gastroscopes (experimental group) and reusable gastroscopes (control group)

Operating time			
	Experimental Group (n = 55)	**Control Group (n = 55)**	**P value**
Total operating time (min)	7.73 ± 3.88	4.89 ± 1.56	0.000
Insertion time (min)	3.93 ± 2.91	2.37 ± 1.33	0.000
Withdrawal time (min)	3.79 ± 1.95	2.53 ± 0.89	0.000
Rating for insertion time			0.238
A: < 5 min	50 (90.9%)	54 (98.2%)	
B: 5-10 min	3 (5.5%)	0 (0.0%)	
C: 10-20 min	2 (3.6%)	1 (1.8%)	
D: > 20 min	0 (0.0%)	0 (0.0%)	
Rating for withdrawal time			1.000
A: < 5 min	54 (98.2%)	55 (100.0%)	
B: 5-10 min	1 (1.8%)	0 (0.0%)	
C: 10-20 min	0 (0.0%)	0 (0.0%)	
D: > 20 min	0 (0.0%)	0 (0.0%)	

Figure 1 Disposable endoscope (XZING-W200B) and imaging processor (XZING-S2, serial number: S22003003, S22003004)

Clinical trial registry website： http://www.chictr.org.cn/searchprojen.aspx

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Authors' contributions

Peng Li contributed to the conception, design, revision and final approval of the article.

Xiaoya Luo contributed to the operation, data collection, data analysis and interpretation and the manuscript writing.

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Ming Ji, Shutian Zhang and Bangmao Wang contributed to the conception.

All authors read and approved the final manuscript.

Abbreviations

FDA	Food and Drug Administration
CE	Conformite Europeenne
IWRS	interactive web-based response system
EDC	electronic data capture
CMH test	Cochran–Mantel–Haenszel test
CI	confidence interval
FAS/PP	full analysis set/per protocol
SWI	smart wavelength imaging
NBI	narrow band imaging
ER	emergency room
ICU	intensive care unit
CMOS	Complementary Metal Oxide Semiconductor
ROM	Read Only Memory
DVI	Digital Visual Interface