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Posted Date: 25 February 2025

doi: 10.20944/preprints202502.1983.v1

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Article

New Concept of Colonoscopy Assisted by a Microwave-Based Accessory Device: First Clinical Experience

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Simple Summary: Colorectal cancer is one of the leading causes of cancer-related deaths world-wide, and its early detection is crucial for improving patient outcomes. Colonoscopy is the most effective screening tool but still misses 22% of polyps or cancer precursors. This paper presents, for the first time, the safety and feasibility of a pioneering MiWEndo microwave endoscopy system. The MiWEndo System, a colonoscopy accessory, uses microwave signals to analyze tissue dielectric properties and identify polyps without modifying clinical practice. The sensitivity and specificity results (86.9% and 72%, respectively) position microwave endoscopy as a potential tool to complement and assist colonoscopy in detecting low-optical-contrast polyps, such as flat or most subtle lesions. Additionally, MiWEndo could provide valuable support in real-time clinical decision-making due to the negative predictive value of 97.3% for detecting adenomas.

Abstract: Background/Objectives: Microwave imaging can obtain anatomical and functional images of the colon and has demonstrated to detect polyps based on their dielectric properties. This study aims to evaluate the feasibility, safety and performance of microwave-based colonoscopy for diagnosis of polyps in humans. Methods: single-center, prospective, observational study. Patients referred for elective outpatient diagnostic colonoscopy were included. A device provided with microwave antennas was attached to the tip of a conventional colonoscope. The primary outcomes were rate of cecal intubation, adverse events, mural injuries and performance metrics for detection of polyps. Secondary outcomes were: patients' subjective feedback, procedural time and perception of difficulty by the endoscopist. Results: 15 patients were enrolled. Cecal intubation rate was 100% with a mean time of 12.7±4.9 min (range 4-22). Use of the device did not affect the endoscopic image and polypectomy was successfully performed in all cases. In a scale from 0 (not difficult) to 4 (very difficult), the maneuverability during the insertion was considered ≤2 in the 86.7% (13/15) of colonoscopies. Only 16 incidents were reported in 14 patients: 11 (67%) superficial hematomas, 2 minor rectal bleedings, 1 anal fissure, 1 rhinorrhea and 1 headache. Most of the patients (94%) referred no discomfort or minimal discomfort before discharge (Gloucester score 1 and 2, respectively). In the six patients with 23 polyps used for the performance analysis, the sensitivity and specificity were 86.9% and 72.0%, respectively. Conclusions: microwave-based colonoscopy is safe and feasible and has the potential of detecting polyps.

Keywords: colonoscopy; microwaves; polyp miss-rate; colorectal cancer prevention

1. Introduction



Colorectal cancer (CRC) is the third most common cancer worldwide and the second leading cause of death in men and women [1]. Colonoscopy has demonstrated to prevent CRC by detection and resection of precursor lesions [2]. Nevertheless, it is not a perfect technique and post-colonoscopy CRC, defined as colorectal cancer diagnosed after a colonoscopy in which no cancer was detected and before the next recommended exam, remains a main issue [3]. Post-colonoscopy CRC may arise from possible missed lesions on index procedure, accounting for 70-80% of post colonoscopy CRC [4,5]. This inefficiency of colonoscopy can be partially explained by human limitations such as distractions, fatigue, shorter withdrawal time, incomplete colonoscopy or inadequate inspection technique, but also by visual limitations due to the fact that some lesions are beyond the endoscope field of vision (<180°) mainly due to angulations, folds, heterogeneous illumination and poor bowel cleansing.

To overcome these limitations, several devices have been developed to improve image definition, retrovision capability or mucosal flattening [6]. However, they do not allow a total exposure of colonic mucosa. Microwave imaging (MWI) is a promising technology that allows a 360° view of the mucosa reducing these visual limitations. MWI is based on the detection of changes in the dielectric properties of biological tissues, properties that are determined by the water content of the tissues [7]. MiWEndo is a microwave-based device intended to be used for assistance to conventional colonoscopes for polyp detection. The principle of functionality of MiWEndo device is based on the fact that adenomatous polyps and cancer have an increased vascularization due to neo angiogenesis and, therefore, greater water content that translates into higher dielectric properties in comparison with healthy colonic mucosa [8]. So far, this technology has demonstrated its diagnostic capability in previous preclinical studies with phantoms [9], ex-vivo human colon samples [7]) and in-vivo studies with porcine tissues [10].

In this single center pilot study, we aimed to investigate for the first time the feasibility, safety and performance of colonoscopy assisted by a microwave-based accessory device. Secondary objectives were to assess the perception of difficulty by the endoscopist and the patient's comfort.

2. Materials and Methods

Patient Selection and Study Design

Prospective, observational, single center non comparative study performed at a tertiary center (Hospital Clinic Barcelona). The study protocol was approved by the local ethical committee (HCB/2022/0690) and Spanish competent authority (1023/22/EC-R) and registered in clinical trials (NCT05477836) before the initiation of inclusion.

Eligible participants were patients who met the following inclusion criteria: a) age ≥50 years referred for a diagnostic colonoscopy for symptoms (anemia, hemotochezia/rectorrhagia, abdominal pain, diarrhea, constipation) and/or post-polypectomy surveillance and b) written informed consent. Exclusion criteria were patients in whom the possibility of performing a complete colonoscopy was reduced due to known colonic strictures, recent acute diverticulitis episode, inflammatory bowel disease; suspected or proven lower gastrointestinal bleeding; non-correctable coagulopathy; ASA IV patients and urgent colonoscopy.

Microwave Imaging Description

MiWendo system consists of (a) a disposable part (the **Acquisitor**) with a cylindrical ring-shaped head with 30 mm in length and 20 mm in diameter that can be attached to the tip of the colonoscope and (b) an external unit with a microwave transceiver and a processing unit (the **Analyzer**) [7]. The Acquisitor contains two switched arrays of eight antennas organized in two rings, one containing the transmitters and the other the receivers that are encapsulated and is connected via cables protected with a plastic sleeve to the Analyzer (Figure 1).

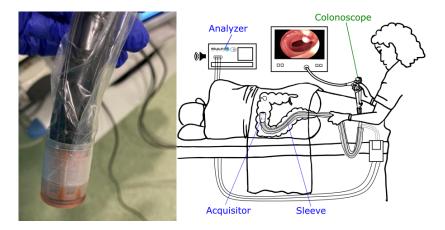


Figure 1. The MiWEndo system comprises two main components: a cylindrical ring-shaped acquisition device (Acquisitor) that is attached to the colonoscope's tip (A) and an external unit (Analyzer) that is connected to the acquisition device via cables (B). The external unit contains a microwave transceiver and a processing unit.

MWI is based on illuminating the colon with microwaves emanating from several antennas that work at 7.5 GHz and cover the full perimeter of the colon and collecting the waves produced by the interaction with the colon as described elsewhere [7]. The total received field is measured at the receiving antenna adjacent to the active transmitting antenna and with the two closest diagonal antennas. The received field contains information of the spatial changes of the dielectric properties of the tissues. By processing the total field with an imaging algorithm, the dielectric property contrast of the colorectal tissues can be retrieved. The information obtained represents a cross-sectional slice of the colon or rectum, which we call a frame. As the colonoscope moves, the acquisition device is continuously scanning frames at a rate of 5 frames/s, thus covering all colorectal lumen surface. These frames are analyzed by adding the magnitude of all their pixels to form an image of the change in dielectric properties as a function of time where regions with brighter pixels correspond to the areas with a high likelihood of containing a polyp.

Endoscopic Procedures

Anterograde cleansing was done according to our center protocol. All patients were encouraged to undertake a diet low in fiber and fat for the 3 days before the procedure.

The procedures were performed with patients under sedation with propofol and remifentanil in perfusion administered by anesthesiologists. Bowel cleansing was considered adequate if the Boston score was ≥ 6 points (≥ 2 by colonic segment).

High definition (HD) colonoscopes (Olympus CF-HQ190L) were used in the study and colonoscopies were performed by two experienced endoscopists previously trained on the use of the device. MiWEndo device was attached to the tip of the scope and inserted through the colon. Carbon dioxide insufflation was used in all colonoscopies and the resection of all detected lesions were performed during the withdrawal. Cecal intubation was recognized through usual landmarks (triradiate cecal folds, appendix orifice and ileocecal valve). After reaching the caecum and before starting withdrawal the MiWEndo system was turned on. Therefore, during the withdrawal, each colonic segment was inspected with HD-white light and MWI. Insertion time, withdrawal time excluding procedures and total procedure time were recorded with a stopwatch.

When a polyp was detected, features such as size in millimeters morphology according to Paris classification [11] and location based on colonic segments (cecal, ascendant colon, hepatic flexure, transverse, splenic flexure, descendent colon, sigmoid, rectum) were collected. (Resection techniques were employed at the discretion of the endoscopist. Resected lesions were retrieved in separated flasks and evaluated by expert pathologist.

Patients were discharged shortly after the colonoscopy. A telephonic visit was performed two weeks after the procedure to collect symptoms related to possible complications. Patients were asked in a direct form about symptoms and if they required additional medications or medical consultation.

Performance Assessment

The optical video from colonoscopy was carefully examined and temporally segmented into sets of consecutive and homogeneous frames. A total of 73 sections were identified, with an average duration of 55 seconds (45 minutes 21 seconds in total), corresponding to approximately 13,600 frames. Of these sections, 23 (31.5%) contained a polyp, 19 (26%) water, 2 (2.7%) angulations, 1 (1.4%) debris and 28 (38.4%) were classified as healthy and clean colon sections.

The same temporal segmentation was performed in the reconstructed synthetic image of the dielectric contrast profile to facilitate the identification of features. Using frames containing endoscopic images of polyps as the ground truth, the segments of the synthetic image reconstruction were carefully examined and the detections were classified as true positives (TP), true negatives (TN), false positives (FP) and false negatives (FN).

Adverse Events

Adverse events (AE) were defined following the ASGE lexicon [12] as an event that prevents completion of the planned procedure (does not include failure of completion because of technical failure or interference by poor preparation or disturbed anatomy or disease or surgery) and/or results in hospital admission, prolongation of existing hospital stay, another procedure (needing sedation/anaesthesia), or subsequent medical consultation. Unplanned events that did not interfere with completion of the planned procedure or change the plan of care were considered as incidents.

Adverse device effects not included on ASGE lexicon but commonly monitored on clinical investigation of devices such as broken or compromised parts, loose or detach parts, usability deficiencies were also collected and analyzed.

A subjective perception of difficulty of MiWEndo-assisted colonoscopy procedure was made by the endoscopist based on a 5-points Likert scale (very easy to very difficult) including variables such as maneuverability during insertion and retrieval and difficulties in polyp resection [13].

Outcomes

The primary outcomes were rate of cecal intubation, number of incidents and AE, mural injuries and performance metrics for detection of polyps. Secondary outcomes were: patients' subjective feedback related to the procedure, insertion and procedural time and perception of difficulty by the endoscopist.

Statistical Analysis

Continuous data were described using means with standard deviation (SD), minimum and maximum. Categorical data were shown as frequencies and percentages. Comparison of continuous data was done using the Mann-Withney U test. Performance characteristics for detection of polyps were calculated using the standard formulas. A two-sided significance level of 5% will be used for confidence intervals. SAS® 9.4 version was used to analyze the data.

3. Results

Fifteen patients were enrolled (9 men, 6 women; mean age 59.5 years, range 51-73). 2/15 (13.3%) had a previous abdominal surgery. Patient preparation was adequate (good or excellent) in all cases. Diverticula were present in 4/15 (26.7%) and all of them were restricted to the sigmoid colon. Adenoma detection rate was 87% (13/15) with a total of 44 polyps (mean 2.9±2.4, range 0-7) with a mean maximum diameter of 4.3±2.7 mm (2-12). Characteristics of the patients are described in Table 1.

Table 1. Patients characteristics and colonoscopy data.

	′N=15
Gender, n (%)	
Men	9 (60%)
Women	6 (40%)
Age, mean <u>+</u> SD (range), years	59.5 <u>+</u> 6.7 (51-73)
Indication for colonoscopy, n (%)	
Surveillance after polypectomy	9 (69.2%)
Abdominal pain	3 (23.1%)
Lower GI bleeding	1 (7.7%)
Boston scale, mean <u>+</u> SD (range)	7.9 <u>+</u> 1.3 (6-9)
Cecal intubation rate, n (%)	15 (100%)
Time to cecum, mean <u>+</u> SD (range), minutes	12.7 <u>+</u> 4.9 (4-22)
Withdrawal time, mean±SD (range), minutes	8.4±3.1 min (5-16)
Total procedure time, mean±SD (range), minutes	26.6+6.7 (16-40)
Adenoma detection rate, n (%)	13 (87%)
Total polyps per patient, mean <u>+</u> SD (range), n	2.9 <u>+</u> 2.4 (range 0-7)
Histology	
Adenoma with LGD, n (%)	28 (60.9%)
Hyperplastic, n (%)	10 (21.7%)
SSL, n (%)	1 (2.2%)
Not retrieved	7 (15.2%)

ASA, American Society of Anesthesiologists. SSL, serrated sessile lesion.

3.1. Feasibility Results

The cecal intubation rate was 100% (Table 1). The mean time to reach the cecum was longer in women than in men (total: 12.7 ± 4.9 min, range 4-22; women: 15.7 ± 4.3 min, 10-22; men: 10.7 ± 4.4 min, 4-18; p=0.048), with mean total procedure time 26.6 ± 6.7 min (range 16-40) and mean withdrawal time 8.4 ± 3.1 min (range 5-16). Figure 2 shows the insertion time of each colonoscopy separated by the two endoscopists.

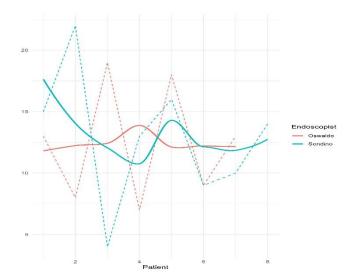


Figure 2. Insertion time of each colonoscopy separated by the endoscopist.

Use of the device did not affect the quality of the colonoscope's high-definition image or its handling characteristics. Specifically, there was no restriction of mobility, tip deflection or retroflexion. Polypectomy was successfully performed in all cases and 39/44 (88.6%) polyps were retrieved for pathological analysis. No dislocation of the device occurred in any of the examinations.

In a scale from 0 (not difficult) to 4 (very difficult), endoscopists considered that the maneuverability during the insertion was \leq 2 in the 86.7% (13/15) of colonoscopies. Two cases had a score of 3 and the difficulty was attributed to a loose sigmoid colon.

3.2. Safety

No immediate or delayed adverse events were recorded. Sixteen incidents were reported in 14 patients: 11 (67%) superficial hematomas, mainly located at rectosigmoid junction, 2 minor auto limited rectal bleedings, 1 anal fissure, 1 rhinorrhea and 1 headache (Table 2). The patients' mean overall discomfort score before discharge was 1.4+0.6 (range 1-3), and 14 patients (94%) referred no discomfort or minimal discomfort (Gloucester score 1 and 2, respectively) (Figure 3).

Table 2. Incidents and adverse events in study of the feasibility and safety of colonoscopy assisted by microwave imaging.

Incidents	Frequency	Related to MiWendo
Mucosal abrasions, n (%)	11 (73.3%)	Yes
Bleeding, n (%)	2 (13.3%)	Yes
Anal fissure, n (%)	1 (6.7%)	Yes
Headache, n (%)	1 (6.7%)	No
Rhinorrhea, n (%)	1 (6.7%)	No

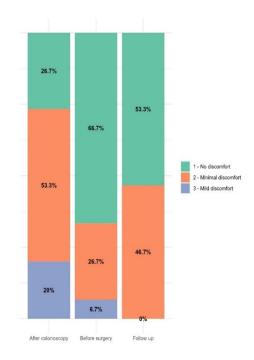


Figure 3. The patients' mean overall discomfort score.

3.3. Performance

Six patients with 23 polyps were used for the performance analysis. Processing and analysis were not possible in the other patients due to hardware issues (cable disconnections and loss of watertightness) in 4 patients, lack of video or pathology analysis for ground truth extraction in 2 patients, and the absence of polyps in 3 patients. Table 3 shows the main characteristics of each processed patient and polyps. Of these, 16 (69.6%) were adenomas with LGD, 6 (26.1%) were hyperplastic, and 1 (4.3%) was a serrated sessile polyp.

Table 3. Characteristics of the processed patients and polyps detether detected with the MiWEndo system.

Patie nt	Number of polyps	Size (mm)	Morphology	Histology	Location	Detected	
1	1	4	0-IIa	SSL	SF	Yes	
	6	0-IIa	Adenoma	AC	Yes		
		2	0-IIa	Adenoma	AC	Yes	
		2	0-IIa	Hyperplastic	TC	No	
2	8	3	0-IIa	Adenoma	TC	Yes	
2 8	0	2	0-IIa	Hyperplastic	TC	Yes	
		4	0-IIa	Adenoma	DC	Yes	
		3	0-IIa	Adenoma	DC	Yes	
	10	0-IIa	Hyperplastic	SC	Yes		
3 5	3	0-Is	Adenoma	AC	Yes		
		4	0-IIa	Adenoma	AC	Yes	
	5	8	0-Is	Adenoma	HF	No	
		12	0-IIa	Adenoma	TC	Yes	
		2	0-IIa	Adenoma	TC	Yes	
		10	0-IIb	Adenoma	С	Yes	
4	4	8	0-IIa	Adenoma	TC	Yes	
4	4	4	5	0-IIa	Adenoma	SC	Yes
		2	0-IIa	Adenoma	SC	Yes	
5	1	3	0-IIa	Hyperplastic	TC	Yes	
	4	2	0-IIa	Hyperplastic	AC	Yes	
		2	0-IIa	Hyperplastic	HF	No	
6		3	0-IIa	Adenoma	TC	Yes	
		4	0-IIa	Adenoma	SC	Yes	

SSL, serrated sessile lesion. SF, splenic flexure; AC, ascending colon; TC, transvers colon; DC, descending colon; HF, hepatic flexure; C, cecum; SC, sigmoid colon.

The sensitivity and specificity for polyp detection were 86.9% and 72.0%, respectively (Table 4). When including only adenomatous polyps, sensitivity increased to 93.7%. A total of 14 false positives were recorded, the majority (78.6%) caused by the presence of water accumulations or debris, while the remaining cases were due to deep angulations. Regarding false negatives, three polyps were not detected by MiWEndo system: two 2-mm slightly elevated hyperplastic polyps and one 8-mm sessile adenoma located within two folds.

Table 4. Performance metrics of polyps' detection with MiWEndo System.

	All polyps N=23	Adenomas N=16
True positives	20	15
False positives	14	14
True negatives	36	36
False negatives	3	1
Sensitivity	86.9%	93.7%
Specificity	72%	72%
PPV	58.8%	51.7%
NPV	92.3%	97.3%

Figure 4 shows a reconstructed synthetic dielectric contrast image of a colonoscopy containing four adenomatous polyps.

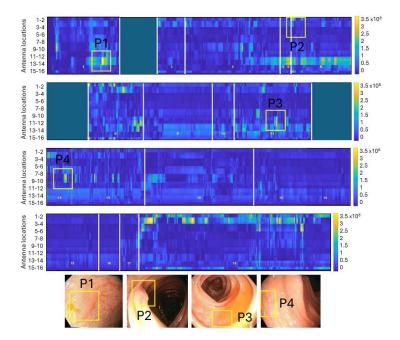


Figure 4. Reconstructed synthetic dielectric contrast image composed of 18 sections with a total duration of 16 minutes. The image displays low-contrast areas in blue, corresponding to healthy tissue, and high-contrast areas in yellow, which are identified as positive detections. In this trajectory, four adenomatous polyps measuring 10, 8, 5, and 2 mm were correctly detected, with no false negatives.

4. Discussion

This study reports the first clinical experience with a new concept of colonoscopy based on microwave imaging for polyp detection and shows that it is feasible and safe and has a good performance. MiWEndo System is the only clinically validated microwave endoscopy system that seamlessly integrates into standard colonoscopy without altering clinical practice. It employs low-power radio-frequency signals to examine patient's colon, without causing discomfort to the patient or hindering or distracting the endoscopist. So far, this technology has demonstrated its diagnostic capability in phantoms and in-vivo animals [7,9]

Other accessory devices have been developed to increase the endoscopes' field of view [13–15]. Artificial Intelligence (AI) is also being explored as a tool for automatic polyp detection in colonoscopy, utilizing machine learning and deep learning algorithms that analyze the optical colonoscopy video feed in real time, identifying variations in texture, shape, and color associated with different types of lesions. While AI has demonstrated an increase in the Adenoma Detection Rate (ADR) in most of the studies [16], its effectiveness is inherently limited to the polyps visible within the optical camera's field of view. Contrarily to other technologies that cannot see what is not captured in the image, our microwave-based colonoscopy can differentiate between healthy mucosa and neoplastic lesions based on the changes in their dielectric properties, thereby, complementing the endoscopic image [8].

The system has been designed to be compatible with colonoscopy, ensure a 360° coverage and produce minimal changes to the current clinical practice. The dimensions and shape of the device ensure non-obstruction of the front tip of the colonoscope and avoid hindering the maneuverability of the colonoscope, even during therapeutic procedures as polypectomy. In this trial, we found a cecal intubation rate of 100%, indicating a high effectiveness of microwave-colonoscopy in terms of completeness of examination, even in patients with diverticula and previous abdominal surgeries. However, these results must be interpreted with caution because of the non-randomized design with a small sample size. Moreover, all the colonoscopies were performed at a highly specialized endoscopic center after a specific training.

The cecal intubation time was longer compared to standard colonoscopy and colonoscopy with other accessory devices [13,14]. This is more likely because of the sleeve and the transmitter cables than the size of the cap. Moreover, during early testing, endoscopists were not as familiar with the device and there was a tendency to apply less pressure during insertion. As they gained confidence, the pressure exerted also increased, although this did not translate into a higher insertion speed, most likely due to patients's anatomical differences and the small sample size. In the two patients in whom the intubation was very difficult, it was due to a "loose sigmoid" and the opinion of the endoscopist was that the colonoscopy would have been as difficult even without the use of the accessory.

Notably, the system achieved a high sensitivity of 86.9% for polyp detection when considering all polyp types. Even more interestingly, sensitivity increased to 93.7% when only adenomas were included. This occurs because hyperplastic polyps are generally small and have no dielectric contrast with healthy colon tissue, making them very difficult to detect using microwaves. From a clinical perspective, this is particularly relevant because small hyperplastic polyps in the sigmoid and rectum can be left untreated without requiring resection following the 'diagnose and leave' strategy. According to the thresholds set by the American Society for Gastrointestinal Endoscopy (ASGE), a NPV of more than 90% for adenomatous histology is recommended to support it [16]. Since the NPV for MiWEndo System was 97.3%, it suggests that it could potentially support this approach by providing additional diagnostic information beyond standard optical imaging.

Regarding specificity, the majority of false positives were caused by water accumulation due to the high dielectric contrast between water and healthy colon tissue, that is even greater than the contrast between healthy colon tissue and polyps or cancer [8]. The effect of water on the microwave image has a different signature compared to polyp detection: while a polyp presents a short-duration detection, water causes a much more prolonged effect and always appears in front of the same antenna combination. Therefore, the automatic detection algorithm should be better trained to filter it out.

The potential of microwave-based colonoscopy is especially relevant in small flat adenomas which constitute the majority of missed lesions. In a previous study, we showed that the dielectric properties correlate with the malignancy and grade of dysplasia of colorectal polyps, and we did not find significant differences in dielectric properties due to the shape of the polyps [8]. Polyps behind mucosa folds also constitute a large percentage of missed lesions due to the limited field of view of current endoscopes. Therefore, a device capable of scanning the mucosa along 360° could help to overcome this problem. Although not used in this experiment, our intention is to emit an acoustic signal when the dielectric contrast is higher than a predefined threshold. Hence, the endoscopist can focus and concentrate on the standard endoscopic image but receive and acoustic signal as soon as the acquisitor device detects a polyp. This makes a big difference with other existing devices that use artificial intelligence which depict boxes in the screen [17] or side-viewing endoscopes that display the image in one or two accessory screens.

The main concern regarding the use of an accessory device that not only increases the size of the endoscope but also its stiffness due to the presence of connecting cables and the sleeve is an anticipated higher perforation rate as happens with long overtubes [18]. In this trial, no adverse events were recorded. Among the incidents, in all patients except two, superficial hematomas located at the rectosigmoid level and/or rectum were seen at the end of endoscopy without any clinical symptoms. These lesions were anticipated and were most probably attributable to the friction of the sleeve with the cables inside. However, comparable lesions are also seen in standard colonoscopy procedures. Because of the larger caliber of the tip of the colonoscope compared to standard colonoscopes, anticipated strictures might be a contraindication for microwave-assisted colonoscopy.

The main limitation of this study is the low number of patients and polyps. However, for the evaluation of surgical operations, invasive medical devices and other complex therapeutic interventions there is an initial stage that includes low number of patients as stated by the IDEAL Framework and Recommendations [19]. Another limitation is that all the procedures were performed

with patients in deep sedation following our clinical practice. Interpretation of the data in terms of patient comfort is therefore limited. However, patients rated overall satisfaction at a high mean level.

5. Conclusions

In summary, microwave-based colonoscopy is safe and feasible and has the potential of detecting polyps. The use of this technology should be investigated in larger prospective studies to evaluate the efficacy for detecting polyps and prove the safety and the true benefit in different settings.

Author Contributions: Conceptualization, M.G. and G.F-E.; methodology, A.G., L.M.N, M.G. and G.F-E.; software, A.G. and L.M.N.; validation, M.G. and G.F-E.; formal analysis, A.G, L.M.N., M.G. and G.F-E.; investigation, O.O., O.S., S.R., J.S., P.S., A.G., L.M.N., M.G. and G.F-E.; resources, M.G. and G.F-E.; data curation, A.G., L.M.N., M.G. and G.F-E.; writing—original draft preparation, M.G. and G.F-E.; writing—review and editing, O.O., A.G., L.M.N., M.G. and G.F-E.; visualization, A.G. and M.G.; supervision, G.F-E.; project administration, M.G.; funding acquisition, M.G. and G.F-E. All authors have read and agreed to the published version of the manuscript.

Funding: This work was supported by the CERCA Programme/Generalitat de Catalunya. Glòria Fernández-Esparrach had a personal grant from Instituto de Salud Carlos III (PI17/00894). Alejandra Garrido acknowledges the financial support from DIN2019-010857 / AEI / 10.13039/501100011033. Marta Guardiola acknowledges the financial support from the European Union's Horizon 2020 research and innovation programme under grant agreement No 960251.

Institutional Review Board Statement: The studies were approved by the local ethical committee (HCB/2022/0690) and Spanish competent authority (1023/22/EC-R).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The authors provide no restriction on the availability of the methods, protocols, instrumentation, and data utilized in this article. Data are available from the corresponding author upon reasonable request.

Conflicts of Interest: M.G. and G.F-E. are shareholders of MiWendo Solutions. O.O., O.S., S.R., A.G., L.M.N., J.S. and P.S. do not have any conflicts of interest related to the study. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

Abbreviations

The following abbreviations are used in this manuscript:

CRC Colorectal cancer MWI Microwave imaging TP True positives TNTrue negatives FP False positives FN False negatives ΑE Adverse events ΑI Artificial intelligence **ADR** Adenoma detection rate

ASGE American Society for Gastrointestinal Endoscopy

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