

## Robotic Colonoscopy

Felice Cosentino<sup>1</sup>, Emanuele Tumino<sup>2</sup>, Giovanni Rubis Passoni<sup>3</sup>,  
Antonella Rigante<sup>1</sup>, Roberta Barbera<sup>1</sup>,  
Antonella Tauro<sup>1</sup> and Philipp Emanuel Cosentino<sup>4</sup>

<sup>1</sup>San Giuseppe Hospital, Milan

<sup>2</sup>Pisana University Hospital, Pisa

<sup>3</sup>San Carlo Borromeo Hospital

<sup>4</sup>Veterinary Medicine,

University of Milan

Italy

### 1. Introduction

This chapter is focused on emerging robotic techniques for improving conventional colonoscopy.

Video-colonoscopy is considered the gold-standard for the diagnosis of colonic diseases, and it is included as first line choice in colon-rectum cancer screening program in high-risk populations. However, this diagnostic technique shows some technical limitations, such as invasiveness and patient discomfort, which limit the adherence to the procedure.

To facilitate the conventional colonoscopy procedure, robotic colonoscopy solutions have been proposed. State of the art of robotic colonoscopy has been thus summarized. In details, Endotics System and Invendoscope are presented.

The *Endotics System* is composed of a disposable probe and a workstation. The probe has a steerable tip, a flexible body and a thin tail. The head hosts both a vision system and channels for water jet and air in order to provide rinsing and suction/insufflation, respectively. The workstation allows the endoscopist to fully control the disposable probe by means of a hand-held console and to visualize on a screen real time images. The operator can steer the head of the robotic colonoscope in every direction, elongate the body of the probe in order to move it forward following the shape of the intestine, and control rinsing, insufflation and suction. This technology thanks its extremely flexible and disposable probe is highly safe and painless (Cosentino et Al, 2009).

The *Invendoscope*, a single-use, combines a flexible endoscope and the proprietary “inverted sleeve” technology that enables a potentially safe and sedationless colonoscopy. The instrument is steered by a hand-held device and propelled by a motorized drive unit.

Limitations and advantages of the two devices are reported compared to conventional colonoscopy. In the last part of the chapter are presented data of pilot studies both in healthy volunteers and patients in terms of technical aspects (cecal intubation, pain score, sedation) and clinical results (lesions detection).

## 2. Why and how robotic systems in colonoscopy?

The first colonoscopy procedures go back to the 1960's, when in Japan a device for the examination of the left colon was developed (Niwa et Al, 1969). In the 1970's further progresses were made, and colonoscopy devices able to explore the whole colon were available (Classen et Al., 2010).

Since then, research efforts were focused towards improvements of the vision system, of the degrees of flexibility and of the localization systems. Nevertheless, the main characteristics of the devices, based on a CCD camera or a fiber optic camera on a flexible tube passed through the anus, remained unchanged till the 1990's. In those years, robotic technologies grew up enough to allow an increasing number of robots to be realized and used in various fields of medicine. The main reasons for including colonoscopy were to try to overcome the existing limitations of the standard devices, quite rigid, requiring high experience of the doctor to perform difficult maneuvers to proceed along the tortuous colon walls, and constructed of materials that could be damaged by heat, pressure, and moisture used during the decontamination processes. (Sturges & Laowattana, 1993) The stated above limitations made, and still make, standard colonoscopy a quite invasive technique, with risks related to perforation, sedation and cross-infections, far for being accepted by massive percentages of patients as needed in colorectal cancer screening programs. Screening as a matter of fact can find non-cancerous colorectal polyps and remove them before they become cancerous. If colorectal cancer does occur, early detection and treatment dramatically increase chances of survival. The relative 5-year survival rate for colorectal cancer when diagnosed at an early stage before it has spread is about 90%, but since screening rates are low, less than 40% of colorectal cancers are found early. Once the cancer has spread to nearby organs or lymph nodes, the 5-year relative survival rate goes down, and if cancer has spread to distant organs (like the liver or lung) the rate is about 11%, and as many as 60% of deaths from colorectal cancer could be prevented if everyone age 50 and older were screened regularly.

Moreover, painless colonoscopy, besides being a remarkable achievement for the patient, and avoiding any risk related to sedation, has major fallout in terms of prevention. As matter of fact, colonoscopy could be largely used for screening purposes of healthy and asymptomatic patients, less willing to feel pain because of an invasive procedure. Nowadays, colonoscopy is used as screening test just in first-level demonstrative studies and pilot projects. One of the main limitations to use this survey as primary screening, besides the feasibility related to allocation of facilities and complications rates, is the acceptance of the procedure. Participation in the first-level FOB (faecal occult blood) screening test is always above 50% (Faivre et Al., 2004), while the few available data in literature about compliance to colonoscopy as primary screening is in a range from 15% to 90% (Swaroop et Al., 2002). Compliance for second level screening programs, which in principle should be very high since this second examination takes place after positive results of the first one, is in a range from 30 to 60%, as reported in a study of from AIGO - Oncology Group Study.

For the above listed reasons, it appears clear how big can be the impact, in terms of survival rate, of new devices able to perform painless and safe diagnostic colonoscopic procedures. Thus robotics, as a science that tries to find and develop methodologies that enable machines to perform specific tasks, could make the difference in developing endoscopes that pulled themselves, with no risk for stretching the colonic wall outward and causing painful

cramps. The main challenge to building such devices involved clutching onto the slippery walls of the colon in a way that did not damage them. The new endoscopes had to be disposable, highly flexible, with a particularly suited internal locomotion, and with a direct vision of the colon tissue, to solve acceptance problems and maintain quality of gold standard.

### 2.1 Robotic colonoscopy: state of the art

As for robotic colonoscopy, first studies go back to 1995, with the locomotion system "inchworm". Subsequently, a lot of research work was carried out aiming at devising several robotic colonoscopes based on different types of locomotion such as "snake", "earthworm", "continuum" and "caterpillar", or other different concepts.

The Inchworm robots were inspired to the caterpillar Geometridae, whose mode of locomotion is to firmly attach the rear portion of its body to a surface via its foot pads, extending the remainder of its body forward, attaching it to the surface and bridging the rear part of its body to meet the forward part. On this principle is based the Endotics system. (Slatkin et AL., 1995)

The **Endotics System** is composed of a sterile, disposable probe and a workstation. The probe has a head, a steerable tip and a flexible body. The head hosts both a vision system and channels for water jet and air. The locomotion is achieved by two clampers that are located in the proximal and distal part of the probe. The proximal clamber adheres to the mucosa and the central part of the body is elongated; the distal clamber adheres to the mucosa and the proximal clamber is released; the central part of the body is contracted so that the proximal clamber may adhere to the mucosa; and finally, the distal clamp is released. The sequence is repeated several times allowing the probe to move in a worm-like fashion. (Perri et AL., 2010)



Fig. 1. Endotics Workstation and disposable probe

The Snake robots took inspiration from the sinuous movement of the snake, based on the temporal shifting of positions and angles of subsequent parts of its body. Movements starts from the head that, bending and moving forward, is able to avoid obstacles. In robotics, this is translated in devices with a finite number of independent segments where, during the progress, the position and the angle of the distal part is encoded by an algorithm and then associated with the next segment. All segments are associated with the same geometrical parameters of the previous segment. NES, the NeoGuide System is based on this principle of functioning.

The **NeoGuide Endoscopy System** (NES) has many features in common with standard colonoscopes. In addition to these, there is a “tip position sensor” that continually records the tip-steering commands of the endoscopist, and an external position sensor placed at the anus that records the insertion depth of the colonoscope. The scope also contains additional control elements in multiple segments following the tip of the scope. Each segment is the same basic length as the tip segment itself, and the orientation of each segment is separately controlled by the system’s computer. The NES combines data on the depth of insertion of the scope and the orientation of the tip at each depth, to actively articulate each segment so that the scope follows the natural shape of the colon. The insertion tube is advanced manually into the colon and has a conventional CCD for visualization. The device includes a handle air insufflation/suction and rinsing systems similar to conventional scopes. (Eickhoff et Al. 2006)



Fig. 2. NeoGuide Endoscopic device

Peristalsis motion like an earthworm has attracted attention because the movement is useful to progress in small spaces (Saito et Al., 2009). The Earthworm robots were based on the earthworm’s locomotion, thus moving not only changing length, but also changing thickness (Zuo et Al., 2005). The Continuum robots worked according to the moving principle of the elephant trunk or the tongue, i.e. structures without rigid constraints able to perform complex movements (Hu et Al., 2009). Finally, the Caterpillar robots were characterized by wheels and caterpillar tracks and their locomotion was similar to a tank.

Other technique of locomotion not based on bio-mimicking, but having relations with robotics in terms of sensors or automated movements have been developed (Swain, 2009).

The **Aer-O-Scope system**, is a disposable, self-propelling, self-navigating, endoscope incorporating a CMOS camera with “omni-directional viewing system”.

A rectal introducer, consisting of a hollow tube with a stationary balloon attached to its outer surface, is inserted through the anus and, when the stationary balloon is inflated, seals the orifice. An electro-optical capsule is embedded in the front of a lightweight balloon vehicle, while low pressure colon insufflation with CO<sub>2</sub>, between stationary and vehicle balloon, propels the vehicle balloon, causing it to glide along the ‘slippery’ colon walls. Computer controlled pressure management, coupled with sensors in the workstation, adjust balloon size and shape to changing bowel anatomy, thus allowing the pressure-propelled balloon to find its path. The Aer-O-Scope visual system provides simultaneous 360 degree viewing of the colon mucosal surface. (Pfeffer et Al., 2006)

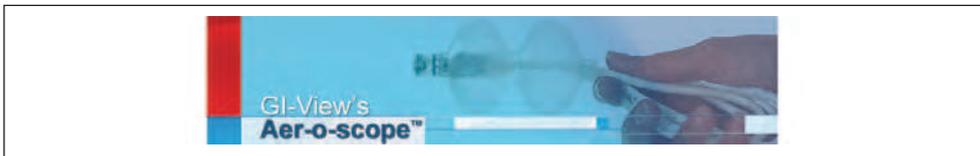


Fig. 3. Aer-O-scope disposable device

The **ColonoSight system** uses air pressure assisted pull technology to pull the scope into the colon. A disposable device consisting of a plastic sleeve, wrapped on a loader, is unfolded gradually through insufflation of air. The forward force of the device is generated by a pneumatic mechanism just below the tip of the scope. This force draws the scope in, and the operator then navigates with the handles, drastically reducing the need to push from the back. Aside from making the procedure safer, it also reduces the amount of local anesthetic required. (Shike et Al. 2005)

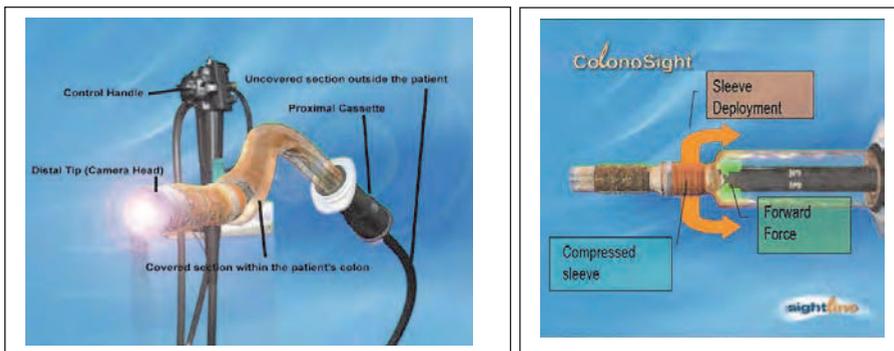


Fig. 4. The ColonoSight system and scheme of working principle

The **InvendoScope system** is a single-use, hand-held controlled computer-assisted colonoscope. A sleeve is pulled over this inner sheath, inverted at each of the respective ends, and attached to a propulsion connector. The outer wall of the sheath is motionless and the intubation is achieved by the eversion of an inner portion of the sleeve which carries the

optical system and the instrument channel. The physician controls the device by activating the “Forward drive” and the “Backward drive” keys on the handheld control unit. By manipulating the joystick of the hand control unit the physician can electro-hydraulically deflect the endoscope tip, steering the colonoscope during the drive through the colon (Waye et AL., 2009).



Fig. 4. Invendoscope workstation and disposable probe

The above stated overview of the state of the art of robotic devices developed for colonoscopy procedures shows that the main priority was to realize a system with an internal locomotion action, able to advance in a hostile environment. The movement of the device is always under computer control by means of mechanical, electrical, or computer-algorithm based sensors. Moreover, the robotic colonoscopes generally include the following sub-systems:

- A probe, with at least a disposable part (the one in contact with the colonic mucosa);
- A vision system located at the tip of the device;
- A PC-based workstation or a hand-held unit which controls the propulsion of the probe in the colon.

Some of the characteristics of the above listed sub-systems, as well as other aspects related to personnel and sedation during the procedures have of course an impact on the cost saving issue. Moreover, also the related timings have to be considered, including e.g. the preparation which non-disposable devices have to undergo to prevent from cross-infections, the duration of the procedures themselves, the gaining of time in the turn-over of patients and the recovery time for the patients to go back to work.

Even if several robotic colonoscopes have been tested in vitro and seemed to be ready to be used in pilot studies on human beings, very few completed the engineering phase and went through the certification steps, and only one became available off-the-shelf as a real product. In particular, in the following further details will be presented on the Endotics System, whose core component is a disposable probe with inchworm locomotion, currently used in clinical practice in a few hospitals, and on the Invendoscope, based on inverted sleeve technology, not yet commercially available, but with most recent news than others.

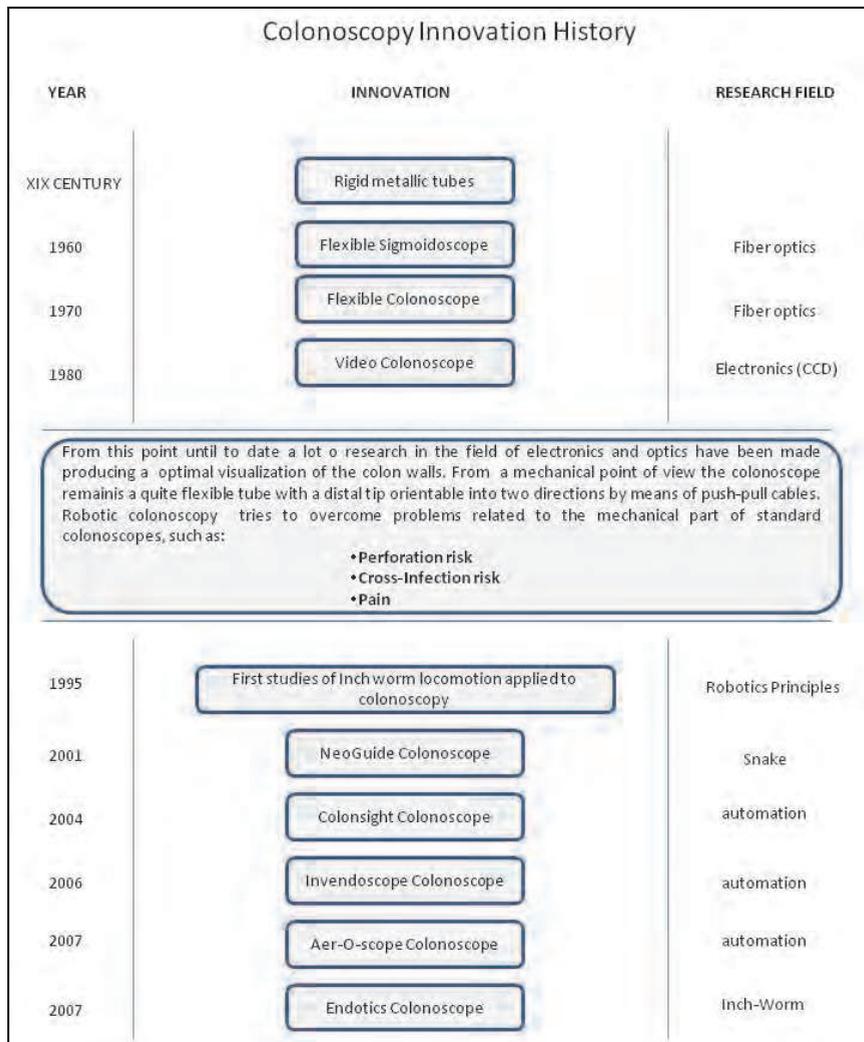


Fig. 5. Colonoscopy innovation history diagram

PRODUCT NAME	LATEST PUBLICATION	LATEST EVENT	COMMERCIALY AVAILABLE
Neoguide	2006	Transformed in laparoscopic device	No
Aer-o-Scope	2007	DDW 2007	No
Colonsight	2007	Closed business 2008	No
Endotics	2011	Fismad 2011	Yes
Invendoscope	2011	-	No

Table 1. Publication & event blatancy

PRODUCT NAME	DEVELOPER/ COMPANY NAME	NATIONALITY	DEVELOPMENT STATUS	INITIAL COMMERCIAL FOCUS
Neoguide	NeoGuide Systems Inc	USA	Abandoned *	n.a
Aer-o-Scope	GI View Ltd	Israel	Almost abandoned *	n.a.
Colonosight	Sightline Technologies Ltd	Israel	Almost abandoned *	n.a.
Endotics	Era Endoscopy Srl	Italy	Off the shelf product	Europe
Invendoscope	invendo medical GmbH	Germany	Filed 510(K) notice submission with the FDA (08/03/2010)	USA

Table 2. Commercial information \* (Eli, 2008)

## 2.2 The endotics system

The excessive stretching of bowel and mesenteries and the air insufflation are the main reasons of the pain felt by the patient during this uncomfortable procedure. In order to avoid perforation risks, addressed both to pushing action exerted by the endoscopist during the intubation phase and to the rigidity in the pushing direction of the traditional colonoscope, it is essential to realize a system with an internal locomotion action, able to advance in a hostile environment. The ideal screening investigation should be as non invasive as possible and safe while maintaining a high diagnostic accuracy. Thus, a device extremely flexible and soft, which gently deforms just locally the colon tissue, represents the optimal solution.

The innovative systems require a lower amount of insufflations and do not stress on mesenteries resulting in a real painless colonoscopy. Moreover, infective risks, due to sterilization procedure's limits, are definitively eliminated by disposable endoscopes.

From a technical point of view, the simplest inchworm device consists of two clampers at the ends, used to adhere securely onto the "terrain", and one extensor as its midsection that brings about a positive displacement. The device of the robot was focused towards a disposable device, totally pneumatically driven, and very soft and flexible, able to adapt its shape to the configuration of the bowel. The probe is composed of two main parts: an active one, including the head, the steering and the flexible extensible body, and the passive components of the devise including the tail and the tank containing eventual body fluids, and the connector used to fix the disposable probe to the workstation. The overall dimensions of the active part are: a diameter of 17 mm and a variable length from 24 to 40 cm, considering the inchworm movements. The head hosts both a vision system, including a CMOS camera and LED light sources, and channels for water jet and air in order to provide rinsing and suction/insufflations, respectively. As the Endotics system requires air insufflations only in the immediate proximity of the head lens, an accurate automatic insufflations-suction balance prevents painful bowel stretching.

The passive component, a very thin and extremely flexible plastic tail, has a diameter of 7,5 mm and a length of 180 cm. The workstation allows the endoscopist to easily and fully control the disposable probe by means of a hand-held console and to visualize on a screen

real time images. Thanks to the electro-pneumatic steerable tip, the operator can steer the head of the robotic colonoscope of 180° in every direction, elongate the soft body of the probe in order to move it forward and backward following the shape of the intestine, and control rising, insufflations and suction.

The locomotion phase begins with the automatic adherence of the proximal clamber of the probe to the colon walls. The next phases can be described as follows:

1. the midsection is elongated under control of the operator;
2. the distal clamber adheres to the colon walls (automatic);
3. the proximal clamber is released (automatic);
4. the midsection is contracted (automatic);
5. the proximal clamber adheres to the colon walls (automatic);
6. the distal clamp is released (automatic).

The purposely developed patented clamping system allows to hold the colonic tissue by means of a combined vacuum-mechanical action. The clamping mechanism does not create neither lesions in the bowel wall, nor mucosal lacerations.

Diagnostic accuracy and patient acceptance of robotic colonoscopy have been evaluated in a first pilot multicentre study, in 40 consecutive volunteers (27 men and 13 women) who underwent standard colonoscopy also. This pilot study showed that the Endotics System has a diagnostic accuracy equivalent to the one achievable through the standard colonoscope. Moreover, the Endotics System was able to visualize two small polyps (sized below 2 mm), in two different cases, not seen using standard colonoscopy. This probably due to the fact that during standard colonoscopy a bigger amount of air was insufflated causing a flattening of the small polyps. Considering the patient acceptance issue, the Endotics colonoscopy was unanimously rated strongly better than conventional colonoscopy: in a scale from 0 to 10 for pain and discomfort the procedure performed by means of the Endotics System scored on average 0.9 and 1.1 (mode 0 for both), compared to 6.9 and 6.8 (mode 9 and 8) of the standard colonoscopy, respectively. (Cosentino et Al., 2009)



Fig. 6. Workstation and disposable probe Endotics

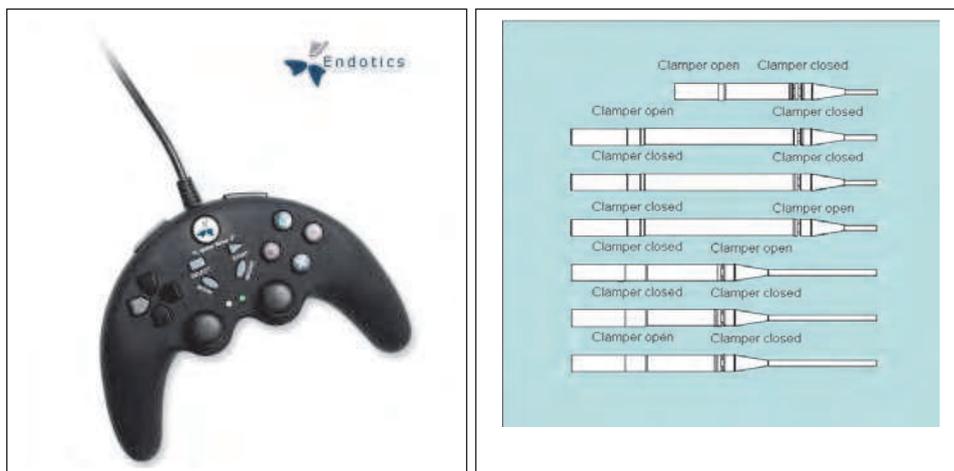


Fig. 7. Hand-Held device and locomotion sequence of Endotics probe

In a second pilot study which involved 71 patients (40 men and 31 women), diagnostic accuracy and enhanced patient acceptance of Endotics system compared with standard colonoscopy, was confirmed showing a sensitivity equal to 93,3% (95% C.I.:68.0-99.0), a specificity equal to 100% (95% C.I.:88.0-99.9), a predictive positive and negative values, PPV and NPV respectively, equal to 100% and 97.7%. No patients requested sedation during the Endotics procedure, while 14 subjects (19.7%) requested the administration of midazolam and meperidine during standard colonoscopy. In this study has been used a slightly different Endotics probe version from the one used in the previous pilot study (25 cm length in the contracted form and 43 cm in the elongated form, with respect to 23 and 37 cm, respectively, of the previous version) (Tumino et Al., 2010)

In a third study 12 patients with inflammatory bowel diseases were enrolled in order to compare the diagnostic performance and tolerability of the Endotics System with standard colonoscopy for the staging of ulcerative colitis. Mean pain/discomfort on a 0-10 scale was 2.08 (SD 1.67) for Endotics system and 4.17 (SD 1.74) for standard colonoscopy, with a statistically significant difference ( $p = 0.066$ ) favoring Endotics system.

In conclusion, the Endotics System is a diagnostic instrument comparable to the gold standard and highly suitable for screening purposes due to the extremely high level of patients acceptance. (Pallotta et Al., 2011)

### 2.3 The invendoscope

This computer-assisted colonoscope is based on inverted sleeve technology, where the outer side of the inverted sleeve stays in position, and the inner side is pulled forward below the distal tip, moving the colonoscope into the colon by 10 cm each time. Wheels are rolled on the inner side of an inverted sleeve, so that the sleeve is rolled inside out, drawing the colonoscope deeper into the colon. With this mechanism there is no relative movement to the colon wall, and in combination with the small bending diameter minimizes the forces on the colon walls and prevents looping, minimizing pain and discomfort for the patient. The device is equipped with a centralized 3.2 mm working channel with the support of the deflectable electrohydraulic tip; therefore it can be also used for routine therapeutic procedures such as

polypectomy. Both the vision capabilities and the working channels are similar to those of conventional colonoscopes. All endoscopic activities are controlled by a hand-held unit. First pilot study (Roesch et Al, 2007) was focused on capability of the device of reaching cecum measuring time needed and pain/discomfort rate. Were enrolled 24 patients reaching cecum in 79% of cases, with a mean time 26 minutes. Participants rated the examination on an overall score (1.77 points; range, 1-3), using a self assessed pain scale (pain scale range was from 1 = no discomfort to 6 = severe pain).

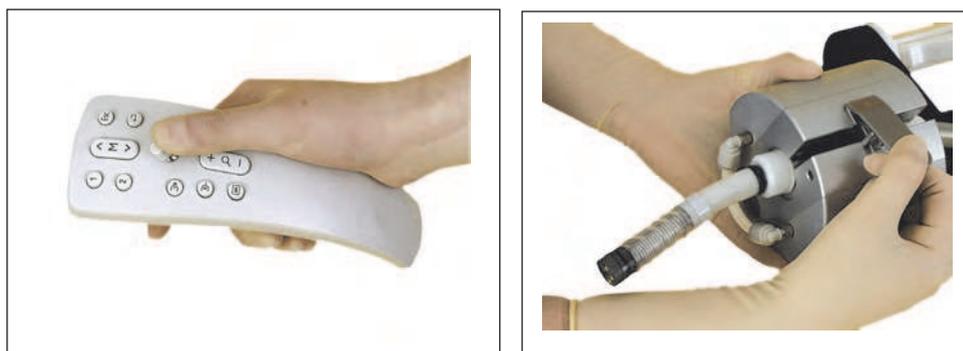


Fig. 8. Hand-Held device and the instrument tip in the driving unit.



Fig. 9. Disposable probe and scheme of working principle of Invendoscope system.

A second single-arm, pilot study (Invendoscope 1<sup>st</sup>) on 39 paid healthy volunteers was carried out. Again, cecum reaching rate and time were the focus of study, with some attention towards the patient acceptance. The cecal intubation rate was of 82% (95% C.I., 66-92). Two incomplete colonoscopies had to be stopped at the sigmoid colon because of pain, and in other four volunteers the procedure was terminated at the hepatic flexure. Bloating was reported in four volunteers after that an endoscopy intravenous administration of 20 to 40 mg of hyoscine butylbromide was allowed to facilitate endoscope passage. It should be noted that only limited time was spent on inspection of the mucosa while withdrawing the instrument. The volunteer rating showed a mean score of 1.96 (range 1-6; 1 = no discomfort). Study was divided into two phases. On the basis of experience during phase 1, the instrument was made longer (from 170 to 180 or 200 cm) and a few other modifications (e.g., stiffening below the endoscope tip, improved coating) were also made to achieve better performance in the right colon, however, a comparison between the two instruments was

not the main aim of the pilot study. To date, no data concerning diagnostic accuracy and comparison with conventional colonoscopy are available.

Moreover, a third prospective single-arm study (Invendoscope 2<sup>nd</sup>) on 61 paid healthy volunteers was conducted. There were 34 men and 27 women with a mean age of 57.5 years (range 50 - 70) and a mean body mass index of 26.3 kg/ m<sup>2</sup> (19.5 - 36.8). Main outcome parameters were safety, as measured by the frequency and severity of device related adverse events, and device effectiveness, as shown by cecal intubation rate. Secondary outcome parameters were utility of the device in the documentation and biopsy of pathological findings, and pathological findings. Pain/discomfort rating and introduction/withdrawal timing were also recorded. Comparison with standard colonoscopy was not included in the parameters of the study. Cecal intubation was reached in 60 volunteers (98,4%): introduction mean time was 16.4 min as also withdrawal mean time. Abdominal compression and/or position change were used in approximately two-thirds (66%) of the patients, to help in further advancing the scope. Sedation was used in three participants (4.9%); the Propofol doses used were 120, 130, and 180 mg. The mean ratings from the screenees, immediately after colonoscopy, for overall assessment and pain/discomfort were 1.6 (range 1- 3) and 2.3 (range 1- 6). A rating of 6 was automatically given immediately after the procedure in cases where sedation was used. CO<sub>2</sub> was used for insufflation in all cases. Water immersion, administered via a foot pump, was used during insertion at the discretion of the endoscopist. Follow-up at 24 h and 7 days was complete for all the study participants. The mean overall ratings at 24 h and at 7 days were 1.4 and 1.3 (range 1-5). The mean pain/discomfort ratings at 24 h and at 7 days were 1.5 and 1.3 (range 1-6). Only three screenees had previous colonoscopy. (Groth et Al., 2011)

#### **2.4 Endotics Vs Invendoscope: a data comparison coming from published results**

Before to compare the two technologies it is mandatory to uniform data recovered from studies:

- In the calculation of cecum reaching rate Endotics included procedures where device had technical problems, while Invendoscope not. For the calculation, procedures with technical failures are excluded also for Endotics.
- Both systems presented two models, where the second one was intended as a ameliorative system. For the calculation of caecum reaching rate and time for both devices is considered the second device
- According to observational studies (Rex et Al., 2002 - a) and as reported in guidelines (National Guidelines Clearinghouse-NGC 4969, 2006) , cases in which procedures are aborted because of poor preparation or severe colitis need not be counted in determining cecal intubation rates. Thus, such procedure are not counted in the presented data. Moreover, because of the protocol of third study afferent Endotics system is focused on the assessment of ulcerative colitis endoscopic activity with Endotics system, related data are not included in the comparison.
- Pain score is calculated on the basis of different ranges, from 0 to 10 for Endotics and from 1 to 6 for Invendoscope. Pain score is indicated in the following table as percentage of maximum value of the respective range. Moreover, should be noted that Endotics system used air for insufflation, while Invendoscope, in the last paper, described the use of advanced reduction discomfort techniques, such as CO<sub>2</sub> insufflation instead of air and water immersion during insertion.

- For all devices, comprising standard colonoscope, “time to cecum” does not include the time spent to carefully analyze the colonic mucosa with diagnostic purposes, except for Endotics, that, due to its working principle, makes observations useful for diagnosis while proceeding towards cecum. Thus, to make a consistent comparison, data related to colonoscopy completion timing should be taken into account. As regards the Endotics system, time to cecum and time to complete diagnosis is slightly different, while for other colonoscopes that make diagnosis during withdrawal is substantially different. According to ASGE guideline, physicians performing a colonoscopy should have an average withdrawal time of six minutes or more for a thorough exam (ASGE-Media Backgrounder, 2010). Moreover, colonoscopist with a low miss rate of lesions have a mean withdrawal time of about nine minutes (Rex et Al., 2000) (Simmons et Al, 2006) (Barclay et Al., 2006) (Overholt et Al, 2010)

	Endotics	Invendoscope	
Disposable	Yes	Yes	
Tool channel	No	Yes	
# Studies	3	3	
# Patients enrolled	123	124	
<i>For the following data comparison, Tumino, Roesch and Groth papers are considered</i>			
	Endotics	Invendoscope 1 <sup>st</sup>	Invendoscope 2 <sup>nd</sup>
Comparison with Standard Colonoscopy	Yes	No	No
Asymptomatic volunteers	No	Yes	Yes
Paid volunteers	No	Yes	Yes
Mean Age	51.9	49.7	57.5
One to One procedure*	Yes	No	No
Sedation (Propofol)	0%	0%	4.9%
Antispasmodic given	0%	79%	Not mentioned
Insufflation of CO <sub>2</sub>	No	No	Yes
Water immersion technique	No	No	Yes
Pain range	9% fs	32.6% fs	26.6% f.s.
Discomfort range	11% f.s.	Not mentioned	38.3% f.s.
Abdominal compression	0%	Occasionally	66%
Sensitivity	93.3%	n.a.**	n.a.**
Specificity	100%	n.a.**	n.a.**
NPV	97.7%	n.a.**	n.a.**
PPV	100%	n.a.**	n.a.**
Cecal intubation rate	93,6%	90%	98.4 %
Mean time to cecum (min)	n.a.	23	16.4
Mean completion time procedure (min)	45,3	n.a.	32.8

\* One to one procedure is intended procedure conducted without any additional personnel  
 \*\* Data are not applicable because they require a comparison with standard colonoscopy

Table 3. Data comparison: Endotics Vs Invendoscope

- Moreover it has to be considered that studies carried out with Endotics have eligibility criteria that include mainly people with prior diagnosis of colorectal diseases (about 70% of patients in the second study) thus procedures' timing should be compared with a similar study population where completion of the procedure is reached in a mean time of 33 min (range 10-80) (Rex. et Al. 2002 - b).

The problem with studies reporting a very high completion rate is that they are screening endoscopies in asymptomatic individuals. These populations are different from normal daily practice. Patients undergo colonoscopy for all kinds of clinical indications (Loffeld et Al., 2009). For this reason it is very important, in order to fully understand carry out an exhaustive comparative analysis a comparison between different clinical trials, to study also eligibility and exclusion criteria adopted. The Endotics and Invendoscope systems are described and compared with parameters advocated to predict a difficulty colonoscopic procedure. Parameters are listed in table 3 (Anderson et Al., 2001). Sometimes difficulty's parameters could be described in different ways, e.g. *"previously failed colonoscopies can usually be characterized as an angulated sigmoid colon or redundant colon"* (Rex, 2008). In people with high BMI, percentage of redundant colon is much higher than people with lower BMI, whereas people with low BMI has probably very angulated bends.

Difficulty's parameters	Exclusion Criteria		
	Endotics	Invendoscope 1 <sup>st</sup>	Invendoscope 2 <sup>nd</sup>
Age > 50	No	Not described	No
History of abdominal surgery	No	Not described	Yes
History of pelvic surgery	No	Not described	Yes
History of diverticular disease	No	Not described	Yes
Body mass index	No	Not described	Yes
Inflammatory bowel disease	Yes	Not described	Yes

Table 4. Difficulty's parameters and exclusion criteria

### 3. Conclusion

In this chapter main reasons for including robotic colonoscopy in common practice of colonoscopy screening have been considered. Standard devices are quite rigid, require high experience of the doctor to perform difficult maneuvers to proceed along the tortuous colon walls, and are constructed of materials that could be damaged by heat, pressure, and moisture used during the decontamination processes. The stated above limitations, that could be overcome with robotic colonoscopies, made, and still make, standard colonoscopy a quite invasive technique, with risks related to perforation, sedation and cross-infections, far from being accepted by massive percentages of patients as needed in colorectal cancer screening programs. Nowadays, colonoscopy is used as a matter of fact as screening test just in first-level demonstrative studies and pilot projects. Participation in the first-level FOB (fecal occult blood) screening test is above 50%, and compliance for second level screening

programs, is very low compared to expected values, since it is in a range from 30 to 60%. Other important issues that have to be taken into account are related to timing and personnel. As a matter of fact, timing affects all the procedure phases, starting from the preparation which not-disposable devices have to undergo to prevent from cross-infections, and including the duration of the procedures themselves, the gaining of time in the turn-over of patients and the recovery time for the patients to go back to work. As for the personnel, both the number of operators needed and their specific competences.

A state of the art related to working principles of robotic devices have been described as well as main robotic devices proposed for pilot studies. Among these devices two robotic colonoscopes are deeply described and compared: Endotics System and Invendoscope. The comparison included:

- If the device is disposable or not
- Age of the patients and if they are asymptomatic and/or paid
- Presence of tool channel
- Number of studies, with related number of patients enrolled
- Comparison with standard colonoscopy, in terms of pain range, sensitivity, specificity, NPV and PPV
- Sedation or antispasmodic administration
- Procedure details, such as cecal intubation rate and timing, abdominal compression maneuvers

An additional table related to the difficulty's parameters in colonoscopy and exclusion criteria adopted in clinical trials has been filled. In this table parameters related to the age of patients, their surgical and/or colonic disease history, and their BMI are considered.

Endotics system appears to be a promising diagnostic instrument comparable to the gold standard and highly suitable for screening purposes due to the extremely high level of patients' acceptance even without the adoption of advanced discomfort reducing techniques like CO<sub>2</sub> insufflation and water immersion during insertion.

The introduction of this diagnostic instrument in clinical practice could facilitate the adoption of colonoscopy as first-level screening, with a further reduction in the incidence of the colon cancer, estimated in the order of 76-90%. In conclusion a painless colonoscopy, besides being a remarkable achievement for the patient and avoiding any risk related to sedation, has major fallout in terms of prevention.

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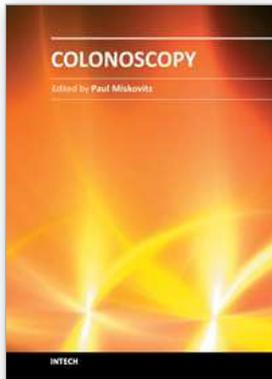
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To publish a book on colonoscopy suitable for an international medical audience, drawing upon the expertise and talents of many outstanding world-wide clinicians, is a daunting task. New developments in videocolonoscopy instruments, procedural technique, patient selection and preparation, and moderate sedation and monitoring are being made and reported daily in both the medical and the lay press. Just as over the last several decades colonoscopy has largely supplanted the use of barium enema x-ray study of the colon, new developments in gastrointestinal imaging such as computerized tomographic colonography and video transmitted capsule study of the colonic lumen and new discoveries in cellular and molecular biology that may facilitate the early detection of colon cancer, colon polyps and other gastrointestinal pathology threaten to relegate the role of screening colonoscopy to the side lines of medical practice. This book draws on the talents of renowned physicians who convey a sense of the history, the present state-of-the art and ongoing confronting issues, and the predicted future of this discipline.

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Phone: +86-21-62489820  
Fax: +86-21-62489821

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