

Intraoperative localization of colorectal tumors in the early stages using a magnetic marking clip detector system (MMCDS)

T. Ohdaira,¹ H. Nagai,¹ M. Shoji²

¹ Department of Surgery, Jichi Medical School, 3311-1, Yakushiji, Minamikawachi-machi, Kawachi-gun, Tochigi-ken, Japan

² Utsunomiya Social Insurance Hospital of Surgery, Tochigi, Japan

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Abstract

Background: In the laparoscopic surgical treatment of early stage colorectal carcinomas, intraoperative tumor site identification is often difficult. We developed a novel marking method using a magnetic marking clip and a modified magnetometer system.

Methods: We applied magnetic marking clips at the tumor site during preoperative colonoscopy and identified the clip site with a magnetic marking clip detector system (MMCDS) of our design. Eleven patients who underwent laparoscopic colectomy were studied.

Results: In a basic *ex vivo* study, magnetic bodies of more than 300 mT magnetic force were easily detected with a 100% detection ratio. In a clinical study, the marking site was detected in all 11 patients. The mean length between the detected site and clip along the longitudinal bowel axis was 14.1 mm (SD 5.6). The mean detection time was 2.4 min (SD 0.2).

Conclusion: MMCDS accurately identifies tumor sites. This method may be useful for tumor site identification during laparoscopic colectomy.

Key words: Laparoscopic colectomy — Magnetic marking — Marking clip — Detector — Magnetometer

When performing a laparoscopic colectomy for early stage colorectal tumors, intraoperative tumor site localization is important. There are many tumor site marking methods, such as preoperative colonoscopic injection of India ink [6, 8] or a dye solution [5] and the colonoscopic application of clips on the mucosa near the tumor that can be detected by either palpation [2] or x-ray screening during the operation [4]. However, intramural injection of India ink carries intrinsic dangers, such as local infection or ink spillage into the peritoneal cavity [1, 7]. When a dye solution such as methylene blue or indigo-carmin is used, there is also a risk that the dye

may disappear by the time of the surgical operation. Metallic clips applied during preoperative colonoscopy are not always possible to palpate during surgery. When x-ray screening is used to detect the clip site, the surgeon has to wear a heavy x-ray protector, and it is also difficult to identify the clip site on the two-dimensional x-ray monitor. When an ultrasonography system is used, intrabowel air interrupts clip detection [3]. Because of the difficulties that these methods present, some surgeons prefer to perform intraoperative colonoscopy to identify the lesion site. However, a surgeon or colonoscopist must manipulate a colonoscope during the surgical procedure, and it also takes a long time to locate a lesion.

After a basic study of the relationship among magnetic force, the distance from the magnetic body, and the detection ratio, we applied a magnetic marking clip near the tumor during preoperative colonoscopy. The location of the clip was then detected from the serosal side of the colon during laparoscopic surgery by using a magnetic marking clip detector system (MMCDS). There are no other reports of a magnetic marking method for laparoscopic surgery. None of our patients experienced complications from this marking technique. MMCDS was a simple and useful method for identifying the lesion during laparoscopic colectomy.

Basic study

MMCDS unit

MMCDS consists of two units: the magnetic body detection probe and the display unit with a data-processing unit. The probe is a 5-mm-wide, stick-like housing that is inserted through a ϕ 5-mm trocar for laparoscopy, and a micromagnetic sensor is sealed in the top of the probe. The probe handle is made from Food and Drug Administration approved plastic (Fig. 1). The processing unit calculates in real time the magnetic field and the probe direction toward or away from the marking magnetic body. The processing unit calculates a 0–999 mT range with an accuracy of ± 1 mT. The display unit consists of a liquid crystal display (LCD) and an electrical buzzer so that surgeons can recognize the reaction of MMCDS by LCD count or sound (Fig. 2).

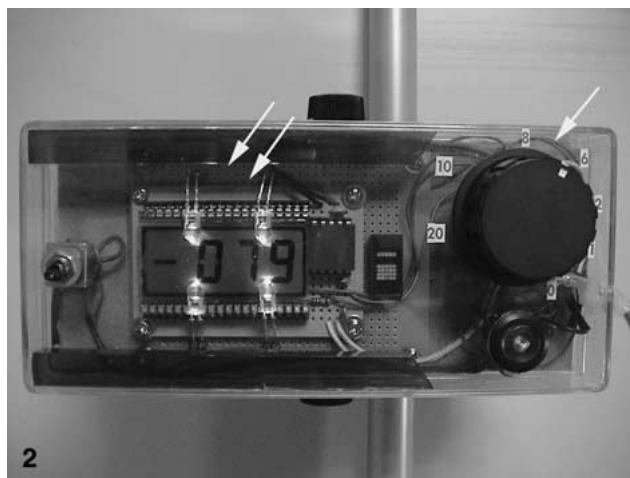


Fig. 1. Magnetic marking clip detector system (MMCDS). Single arrow, sensor in the tip of the probe; double arrows, zero adjusting dial.

Fig. 2. Data processing and display unit. Single arrow, the sensor sensitivity control dial; double arrows, liquid crystal display.

Materials and methods

Using resected colon, we investigated the performance of a novel MMCDS of our design. Two colon specimens, resected from men whose body mass indexes were 22.4 and 24.7, were incised longitudinally on the mesenteric side. The colon thicknesses were approximately 7 mm. The main objective of this study was to determine the optimal magnetic force for marking. We tested six magnetic forces: 25 mT ($\phi 2 \times 4$ mm), 80 mT ($\phi 2 \times 4$ mm), 130 mT ($\phi 2 \times 4$ mm), 320 mT ($\phi 4 \times 2$ mm), 460 mT ($\phi 4 \times 3$ mm), and 640 mT ($\phi 5 \times 3$ mm). The expression of magnetic force (e.g., 320 mT) shows the maximum magnetic force concentration at the surface of the magnetic body.

The basic study protocol was as follows: One person placed a magnetic body randomly under the mucosal side of the incised specimen, irrespective of the tumor location, and another person detected it by MMCDS while maintaining serosal contact. After this procedure was performed 10 times, changing the magnetic body placement each time, another magnetic body was employed using the same protocol. We performed this procedure for each of the six magnetic forces at distances of 0–10 cm from the serosal surface. The detection test was carried out on a double blind basis with one person marking and the other person detecting.

Results

Table 1 shows the relationship among magnetic forces, distances from the magnetic bodies, and detection ratios. When the sensor was in close

Table 1. Detection ratios of MMCDS (%)

Distance from serosa (mm)	Magnetic force (mT)					
	25	80	130	320	460	640
0	0	30	100	100	100	100
10	0	0	20	100	100	100
50	0	0	0	50	100	100
100	0	0	0	0	0	100

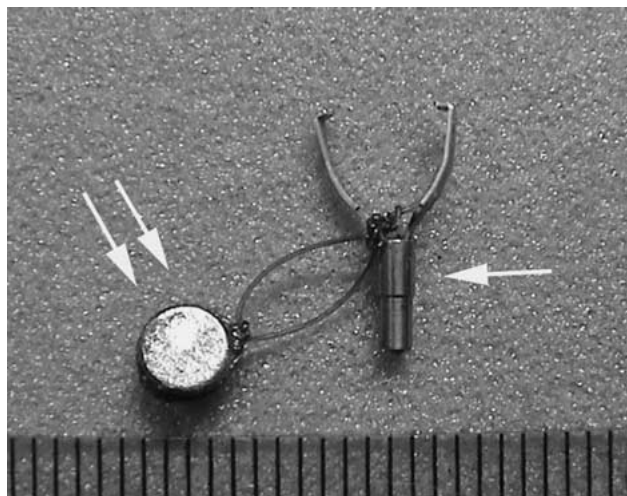


Fig. 3. Marking clip (single arrow) connected with Nylon to the magnetic body of 320 mT (double arrows).

contact with the intestinal serosal surface, 80 mT was the minimum magnetic force for detection by MMCDS. Magnetic bodies of more than 300 mT were easily detected, with 100% of detection ratio by MMCDS when the magnetic body was separated 1 cm from the serosal surface.

Clinical study

Magnetic marking clip for clinical use

Based on results from our basic study, we used a 320-mT ($\phi 4 \times 2$ mm) magnetic body for the clinical study. The magnetic body was fixed to an endoscopic metal marking clip (MD-59, Olympus Optical, Tokyo, Japan) using 3–0 nylon (Ethicon, Chicago, IL, USA) (Fig. 3). To prevent possible adverse effects, such as metal allergy or poisoning, we coated the magnetic body with a 0.5-mm-thick layer of silicon.

Materials and methods

Eleven patients with early colorectal cancer underwent laparoscopic colectomy at the Department of Surgery, Social Insurance Hospital, from October 1999 to April 2002. Table 2 summarizes the tumor locations and operative procedures.

The protocol for using MMCDS was as follows. First, we loaded a marking clip into the clip fixing device (HX-5QR-1, Olympus Optical) which was inserted through the forceps channel of a colonoscope. Then the clip was fixed to the colonic mucosa, approximately 2 cm from the tumor margin, by operating a lever attached to the clip fixing device (Fig. 4). This technique was reported by Hachisu et al. [2] in 1989 and has since been widely used to mark lesion sites. The magnetic marking clip was applied within 5 days before the operation to avoid dislodgment. All patients received bowel preparation using 2 liters of polyethylene glycol electrolyte solution, and none of the clips became dislodged immediately before surgery in any of the patients.

Table 2. Detection results using MMCDS

Patient No.	Sex	Age (years)	BMI	Detection time	Direction gap	Longitudinal Clip		Operation
						Gaps	Portion	
1	Female	67	21.5	1:56 min	51.2	21.3	A	Sigmoidectomy
2	Female	58	27.4	3:04 min	34.9	5.8	P	Right colectomy
3	Male	71	22.2	2:17 min	25.1	16.3	P	Sigmoidectomy
4	Male	83	23.6	4:05 min	45.2	12.7	A	Sigmoidectomy
5	Male	64	19.3	1:57 min	18.4	8.2	A	Anterior resection
6	Female	62	23.3	2:31 min	37.1	25.1	P	Anterior resection
7	Female	79	20.6	2:06 min	24.8	11.2	AA	Anterior resection
8	Male	79	23.8	2:25 min	36.4	17.2	P	Sigmoidectomy
9	Female	63	29.4	2:32 min	22.7	11.9	A	Right colectomy
10	Male	64	25.6	2:16 min	13.8	13.6	A	Sigmoidectomy
11	Female	79	19.4	1:32 min	41.2	12.1	A	Anterior resection
Mean		69.9	23.3	2:25 min	31.9	14.1		
SD		8.7	3.2	0:41 s	11.8	5.6		

A, Antimesenteric side marking; P, postperitoneal marking; AA, antimesenteric side marking with a small intestinal loop adhesion; BMI, body mass index

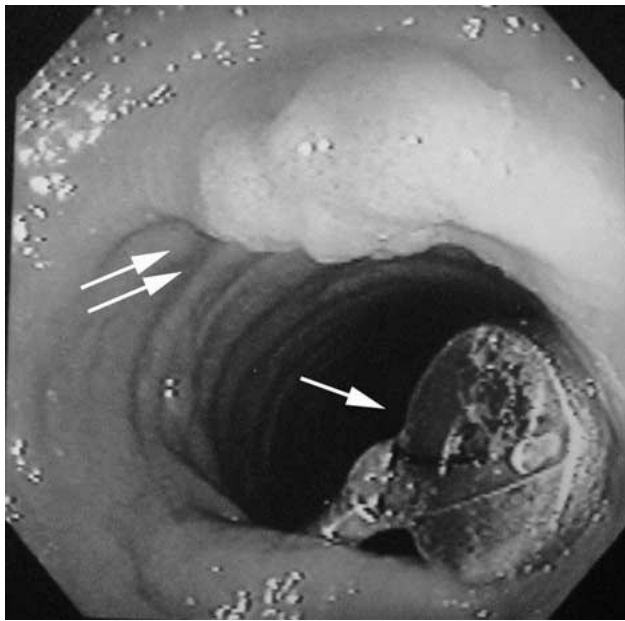


Fig. 4. Colonoscopic view of magnetic marking clip (single arrow) near a tumor (double arrows).

At the beginning of surgery, the probe was placed far from the patient and any magnetic force-emitting material, and the LCD counter was set to zero. Next, MMCDS sensitivity was set at a maximum level. Subsequently, the probe was directed near the control 320-mT magnetic body placed on the tray in front of the scrub nurse to confirm that the magnetic marking detector was working normally. After these preparatory MMCDS adjustments, the MMCDS probe was inserted into the abdominal cavity of the patient through one of the trocars for laparoscopic usage. The probe was brought along a segment of the bowel suspected to have a lesion. The probe was then moved along the longitudinal axis of the colon so that the MMCDS response could be detected (Fig. 5). Once a reaction was obtained, the procedure was repeated at least twice to confirm the reproducibility of the response. The site showing a reaction in the detecting system was then marked on the serosal side using two laparoscopic clips. After the lesion site was detected, laparoscopic procedures, such as bowel dissection and vascular clipping, were carried out. To measure the time for magnetic marking clip detection, we videotaped the procedures. The time for detection was represented by the period from MMCDS probe

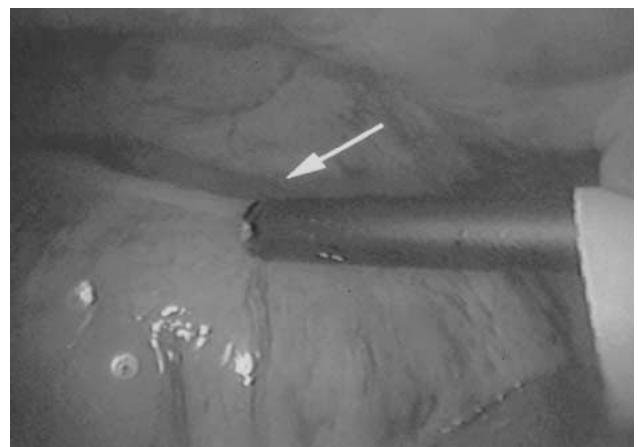


Fig. 5. Laparoscopic view of MMCDS probing the marking site. Single arrow, MMCDS probe head.

insertion through the trocar at the abdominal wall to application of the clip to the site.

Results

Magnetic marking clips were successfully detected in all 11 patients. The time for detection ranged from 1 min, 32 s to 4 min, 5 s (mean, 2 min, 25 s; SD 41 s). The longitudinal axis gap between the magnetic marking clip and the marking point ranged from 5.8 to 25.1 mm (mean, 14.1; SD, 5.6). Six patients were marked at the mucosa on the antimesenteric side and 4 patients on the retroperitoneal side of the colon without surrounding adhesions. The last one was marked at the mucosa on the antimesenteric side of the colon with a small intestinal loop to the serosa of the marking site. No difference was found in detection times, between the serosal side marking (2 min, 18 s; SD, 36 s) and the retroperitoneal side marking (2 min, 30 s; SD 18 s). Even in the patient with adhesions, detection took less than 4 min. There were no complications and no damage to the mucosa of

the marking sites. The magnetic body coating remained intact until the surgical treatment was completed.

Discussion

The success ratio was 100%, with location accuracy within 20 mm along the longitudinal axis. The detection time of approximately 2½ min is clearly shorter than the time necessary for intraoperative colonoscopy and x-ray.

The magnetic force line of our MMCDS can penetrate human organs. Therefore, MMCDS can identify the magnetic body, even when the marking site is covered by tissue or organs. Even on the retroperitoneal side, we can readily detect the site through the opposite bowel wall. MMCDS can identify the marking clip without being influenced by metallic implantations, such as a cardiac pacemaker or artificial joint.

Another feature of our MMCDS is that the detector system functions under Coulomb's law: Force developed between two magnetic poles is inversely proportional to a square of the distance between the poles. In other words, force derived from a magnetic field is inversely proportional to the square of the distance from the magnetic field. Thus, MMCDS has a maximum response at the site of the magnetic body and immediately disappears away from the magnetic body, making it easy to locate the site. These characteristics lend themselves well to the marking procedure.

Since the detector system works through layers of bowels, care should be taken to avoid incorrect detection due to overlapped colon. This error can easily be avoided by stretching the colon along its longitudinal axis.

In this study, the interval between placement of the marking clip and surgery was 4.2 days on average and 5 days at most. In no case were magnetic marking clips

dislodged during these periods. Even with conventional metallic clips, none have ever dislodged within 2 weeks of placement. However, we recommend the interval between setting the magnetic marking clips and the time of surgery to be as close as possible to reduce the possibility of the marking clips being dislodged from the mucosa.

The marking clip detector system was designed and manufactured by us but has not been marketed. After gas sterilization, MMCDS can be reused. The cost of the marking device is as follows: one marking clip (MD-59), \$6.50; magnetic body, \$20; and reusable clip fixing device (HX-5QR-1), \$425.

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