The magnetic stoma device: a continent colostomy.

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The Magnetic Stoma Device:

A Continent Colostomy*

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The magnetic ring device implanted in an attempt at achieving continence in the colonic stoma, consists of a subcutaneous ring and a removable magnetic cap with a charcoal filter. Fourteen patients were selected from a potential number of 58 candidates. Fifty per cent of the patients have had good results. No complications were attributable to the implanted device. There was no incidence of parastomal hernia. [Key words: Colostomy(ies); Magnetic stoma device; Stoma closure, magnetic]

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THE AESTHETIC DISADVANTAGE of the colostomy is compounded by the necessity of having to wear an appliance, however sophisticated. Over the years, much ingenuity has been demonstrated in attempts at achieving continence in the stomas, but none have succeeded in eliminating the use of an external reservoir pouch over the colostomy. With the natural evacuation technique encouraged by the British surgeons,[1] only 50 to 70 per cent of the patients have to wear a colostomy bag. In this country colostomy irrigation is more frequently practiced. Mazier *et al.*[2] surveyed 105 patients who irrigated their colostomies; nine patients (8.6 per cent) wore their bag at all times, while 59 patients (55 per cent) wore a bag when going out socially.

Feustel and Hennig,[3] at the University of Erlangen, Germany, first worked with a magnetic ring system in 1974. Following several modifications, they have now performed over 180 operations with encouraging results. In September 1977, Bauer *et al.*[4] reported on experimental results in animals and concluded that low metallic toxicity resulted from the use of the cobalt magnet implanted without its coating material. Since then, limited studies are being carried out in a few centers in this country. The manufacturer is to be commended for the restraint shown in not marketing the device prematurely.

A magnetic ring is implanted subcutaneously in the abdominal wall overlying the fascial aponeurosis, and through it the sigmoid colon is brought out as a stoma. This magnetic ring is composed of samarium cobalt encapsulated in titanium and weighs 64 g. An external cap contains a ring magnet in the top of the cap and a core magnet in the center pin. The material used for the undercoating of the cap is polyoxymethylene (POM), and this cap's overcoating is polyurethane or nylon depending on the size. The weight of the caps ranges from 36 to 106 g while the length of the pin ranges from 21 to 54 mm. The interposition of a disposable charcoal filter applied to the undersurface of the disc allows for the egress of malodorous gases (Figs. 1 and 2).

The central pin of the cap provides an average retaining force of five to six newtons over its working distance. The ring device may either be implanted primarily during the performance of the major resective procedure or secondarily in a pre-existing colonic stoma.

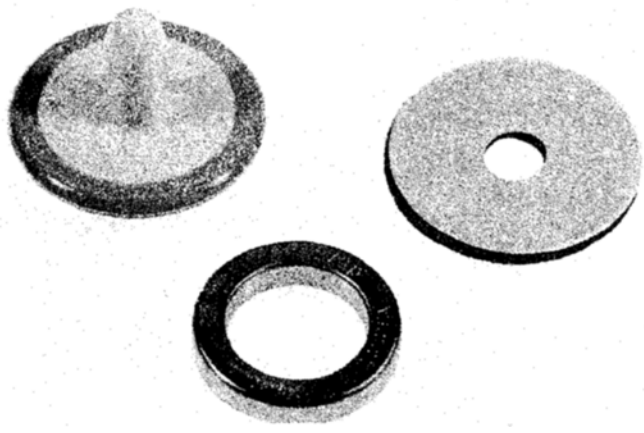

FIG. 1. Magnetic ring, cap and disposable charcoal filter.

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Technique

The location of the stoma is of paramount importance. The site is previously marked by the surgeon and/or the enterostomatherapist after the patient is checked in various positions. As a rule, the stoma site is higher than the conventional, and overlies the rectus abdominis muscle (Fig. 3).

It is our practice to have the enterostomatherapist penetrate the full thickness of the abdominal wall with a needle and establish a perpendicular tract with dye (methylene blue), in order to help orient later dissection. The abdominal cavity is entered through a right paramedian incision, and mobilization of the left colon and the rectum is carried out in the customary fashion.

Before dividing the bowel, the stoma site is created by excising a disc of skin about 2.5 cm in diameter with a minimal amount of underlying adispose tissue. An incision is made in the subcutaneous tissue followed by a cruciate incision in the fascia. The rectus abdominis muscle is split and the peritoneum is opened. Starting at the edge of the main incision, a pouch is created between the fascial layer and the subcutaneous tissue (Figs. 4 and 5). The ring is inserted with its center in alignment with the opening in the abdominal wall and is anchored to the fascia by placing four 3-0 Prolene® sutures (Fig. 6). The medial surface of the ring is then isolated from the later emerging bowel by several interrupted 3-0 Dexon® sutures placed between the edges of the fascia divided by the cruciate incision and Scarpa's fascia, avoiding dimpling of the overlying skin (Figs. 7 and 8). The medial edge of the fascia at the main incision is then sewn to the medial edge of the subcutaneous tissue with running 3-0 chromic catgut suture, thereby isolating the ring completely from the peritoneal cavity (Fig. 9).

The bowel is transsected at the proposed site (the authors prefer the use of the GIA stapler device for this purpose), and the proximal end is covered with a condom. The colon is withdrawn through the opening in the abdominal wall and through the ring (Fig. 10).

The redundant bowel is amputated at the completion of the procedure, and the colostomy is matured using interupted 3-0 chromic catgut sutures between the dermis and the bowel excluding the mucosa. A temporary colostomy appliance is avoided to prevent the creation of a moist chamber.

The cap is inserted four to six weeks postoperatively (Figs. 11 and 12). The patient is taught to regulate the colostomy with irrigation and gradually learns to empty the colonic contents in a disposable appliance or a kidney dish when he feels the urge.

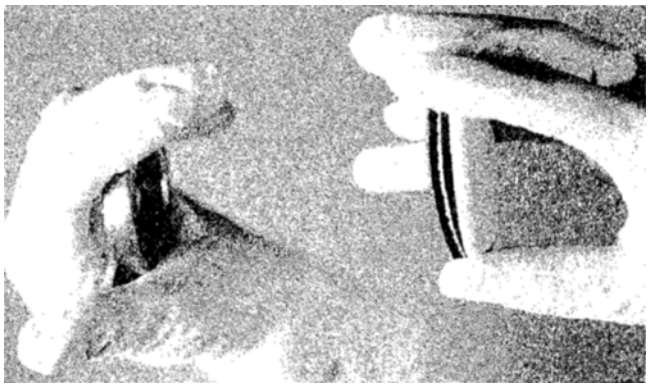

FIG 2. The system with charcoal filter applied to the cap.

The use of a temporary appliance overlying the magnetic cap is recommended during the early training (Table 1).

Results

During the study period of September 1977 through December 1979, 58 sigmoid colostomies

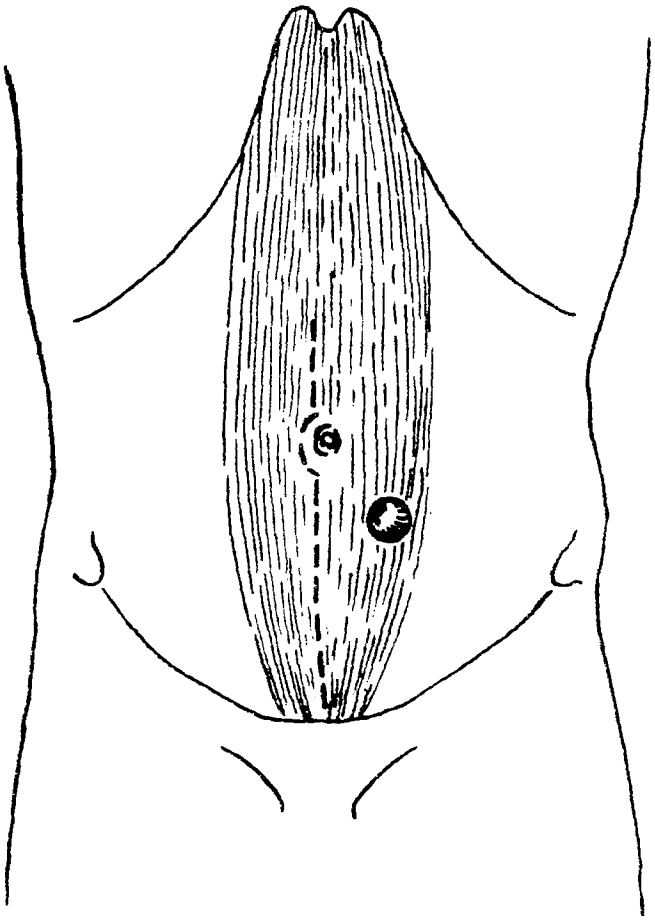

FIG. 3. Diagram showing right paramedian incision and site of stoma.

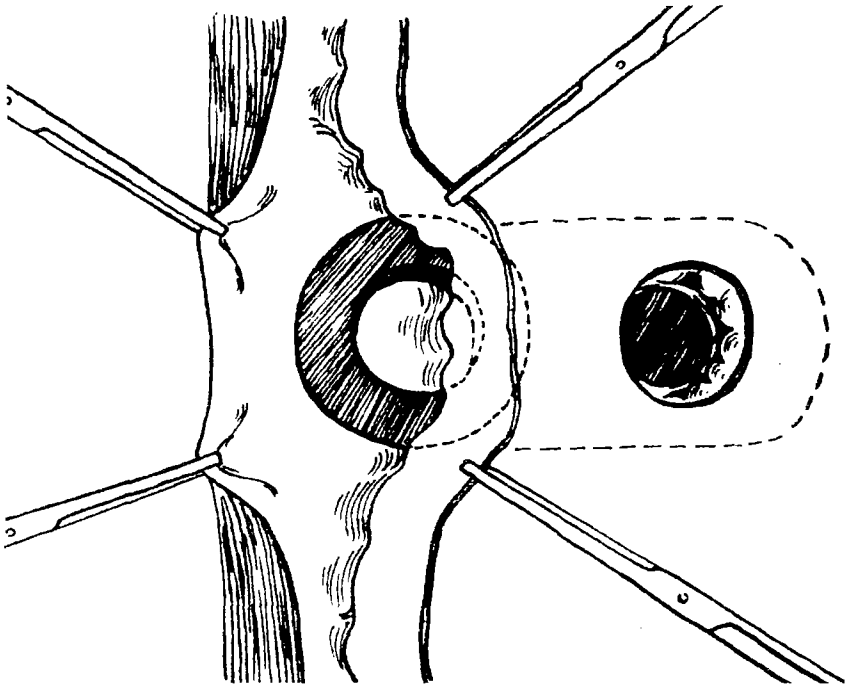

FIG. 4. Development of subcutaneous pouch in front of the aponeurosis.

were performed. All patients were referred to the enterostomatherapist for evaluation. Stringent criteria, established for patient selection, are detailed in Table 2. Fourteen patients were deemed suitable for the magnetic ring. Their ages ranged from 27 to 86 years. There were nine men and seven women. Twelve patients were operated upon for adenocarcinoma of the rectum and two for squamous-cell carcinoma of the anal canal. One patient refused to wear the cap for cosmetic reasons and objected to the weight of the appliance. All patients available for evaluation were categorized according to criteria summarized in Table 3.

FIG. 5. Development of subcutaneous pouch in front of the aponeurosis.

Four patients were deemed as having had excellent results, three of whom irrigated their colostomies on a regular basis. One patient had a good result. None were classified as satisfactory. Five were categorized as poor. Four patients fell into the fifth category.

Four patients needed minor corrective surgery for mucosal prolapse in one quadrant which prevented adequate magnetic contact. There was no morbidity directly attributable to insertion of the ring, and there was no incident of wound infection.

Discussion

For any innovation the following considerations are all important:

1. Safety of the procedure.
2. Lack of serious side effects.
3. Efficacy in aiding the patient to return to normal or near normal life.

Implanting the magnetic ring system has proven, in our hands, to be a safe procedure. Some key points to

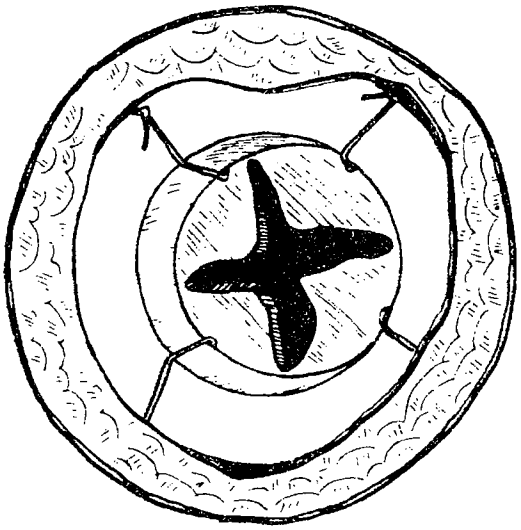

FIG. 6. The ring anchored to the fascia with four 3-0 Prolene® sutures.

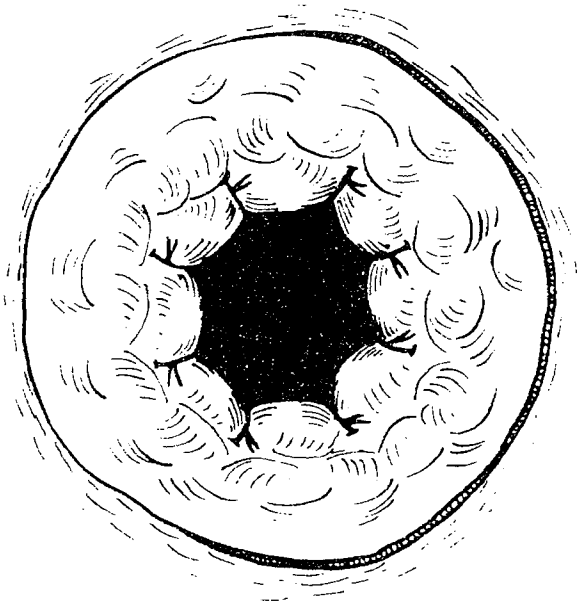

FIG. 8. Ring shown isolated completely by sutures between the fascia and subcutaneous tissue.

avoid complications are as follows: meticulous attention to surgical technique to avoid wound contamination, constructing the colostomy tract through the abdominal wall in a strict perpendicular manner, careful maturation of the stoma constructed without mucosal eversion. The selection of patients with subcutaneous adipose tissue not exceeding 5 cm is important; in this regard the preoperative measurement by CAT scanner was not found to be helpful. Actual measurement at the operating table is recorded. Excluded are patients with an abdominal wall unsuitable for a flat area to bear the disc (Table 4).

When successful, this procedure constructs a continent stoma with obvious advantages. However, when the system fails, the patient is saddled with a heavy implanted magnetic device which is not only non-

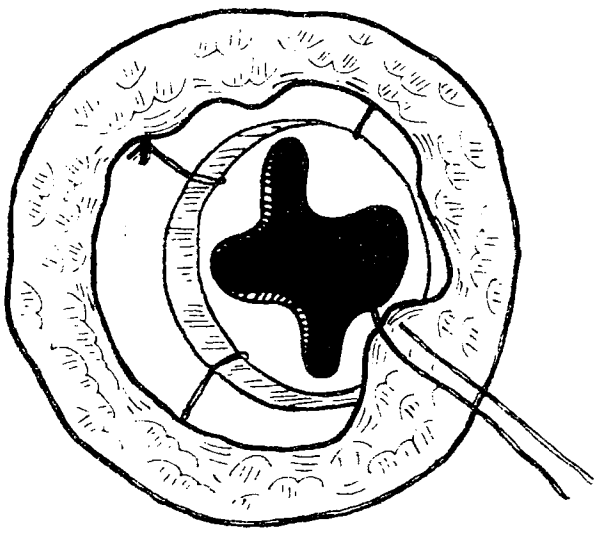

FIG. 7. 3-0 Dexon® suture placed between the fascia inside the medial edge of the ring and Scarpa's fascia.

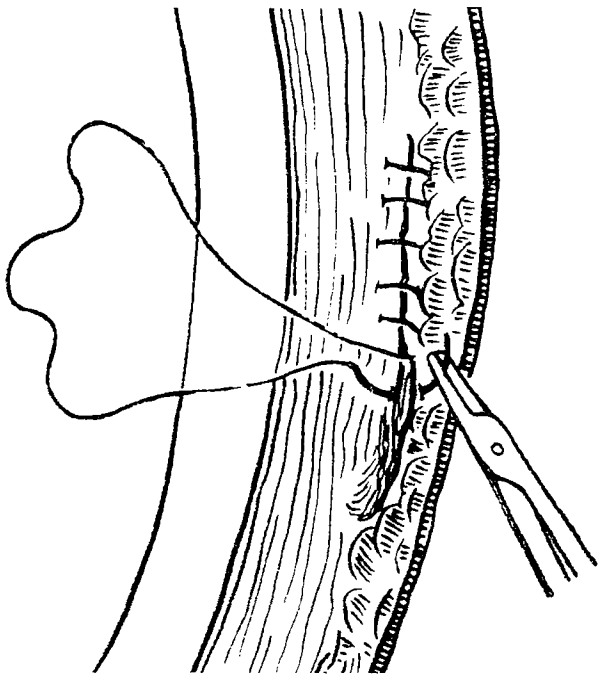

FIG. 9. 3-0 Chromic catgut suture between the medial edge of the fascia in the main incision and the subcutaneous tissue.

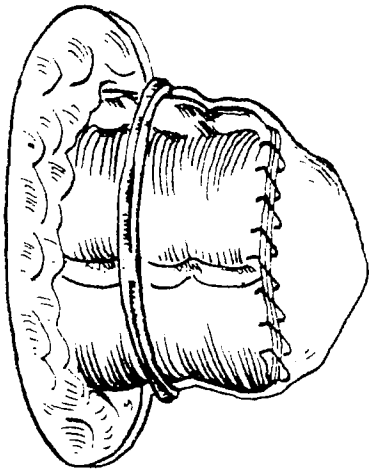

FIG. 10. Proximal end of sigmoid colon, covered with a condom, withdrawn through the opening in the abdominal wall.

functional but may trigger the security monitors at the airports, create disturbances when sitting close to a television set, and cause malfunction of a wristwatch worn on the left wrist (Table 5).

Reinforcement of the abdominal wall with the ring appears to prevent the formation of a paracolostomy hernia. Patients prefer to wear the cap under a bathing suit. Socially, it affords security by eliminating flatus with its accompanying sound and odor.

Further design modification by the manufacturer, providing a longer stem for a thicker abdominal wall, has increased the scope of the device. An optional custom angle stem has made some patients suitable candidates for the apparatus who would otherwise have been excluded. More recently the cap has been redesigned with a softer exterior and also eliminating the bevel. The titanium coating permits autoclaving at a temperature not exceeding 150°C. However, until the system is further perfected, limited study with a careful follow-up should be continued.

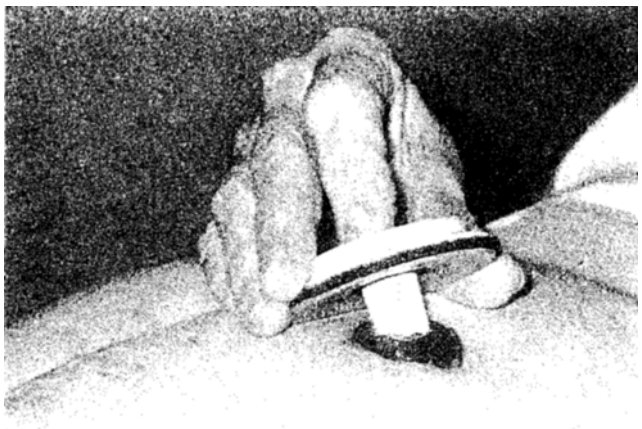

FIG. 11. The cap shown being inserted by the patient.

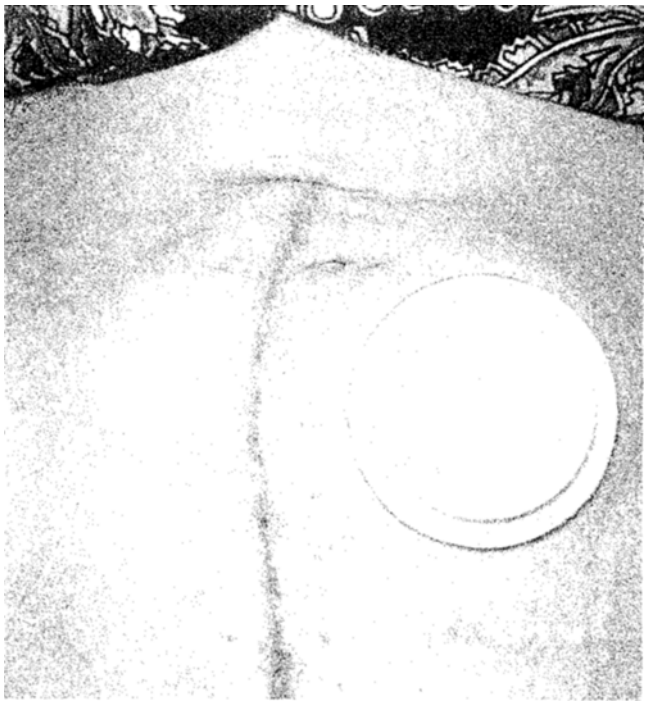

FIG. 12. The cap in place.

Hager *et al.*[5] reported in May 1976 on their follow-up study on 113 magnetic systems implanted in 105 colostomy patients and eight ileostomy patients.

TABLE 1. *Procedure for Instructing Patient How To Use Magnetic Cap*

The first day the cap is worn for three hours.
Wearing time is increased daily by two hours until the cap is being worn for at least nine hours.
The patient may then wear the cap during the sleeping hours plus the daytime hours.
Each morning the cap is removed to allow the bowel to evacuate. The bowel is allowed to evacuate in whatever manner the patient feels most comfortable: 1. directly into the toilet 2. into a small plastic basin 3. into a pouch 4. into an irrigation sleeve
If at any time during the day a sensation of fullness is experienced, the patient is instructed to remove the cap as soon as possible to allow for evacuation.
If the stoma becomes uncomfortable while the cap is being worn, the cap is to be removed and replaced with another covering—pouch or security patch.
Use of a 3" disposable pouch over the magnetic cap is encouraged until the patient feels confident with the magnetic cap alone.
The patients meet in a group every three months with the surgeon and enterostomatherapist to discuss progress with cap.

TABLE 2. *Magnetic Stoma Device Patient Selection Criteria*

Must require a permanent sigmoid colostomy.
Should present no evidence of advanced metastatic disease.
Must be physically and mentally able to cope with the use of the magnetic device.
Must be motivated enough to want to use the device.
Must have more than 1.0 cm of subcutaneous fat but less than 5.0 cm.
Must have a flat, smooth abdominal surface as a suitable site for the device. Site must be determined with the patient in lying, sitting, and standing positions prior to surgery.
Must not have any signs of intra-abdominal infection, and there should be no contamination of the wound.

Sixty-four of the colostomy magnetic systems were implanted primarily and 41 secondarily. Twenty rings had to be removed because of infection and/or necrosis. Of the 74 patients available for follow-up, only 17 (23 per cent) were fully continent. Eighteen patients (14 per cent) were partially continent, and 39 (53 per cent) were incontinent. With improved technique and careful selection of subjects, the continence rate improved to 76 per cent. Their later report[6] included all patients from January 1974 to January 1977; a success rate of 61 per cent was achieved in 91 primary colostomy implantations and 60 per cent in five primary ileostomy operations. Of 55 patients with secondary colostomy implantations and seven patients with secondary ileostomy implantations, 80 and 53.5 per cent, respectively, were reported to be successful. In this later series, however, the criteria of "success" were not rigorously drawn and appeared to include all patients wearing the cap from six to 24 hours daily.

Goligher *et al.*[7] analyzed experience with 22 patients in 1977. One operative death followed necrosis of the colonic stump. Three minor complications occurred—temporary cyanosis of colonic mucosa in two and minimal wound infection in one. Nine of the 22 patients were not wearing the cap for a variety of reasons. Of the 13 remaining patients, only three or possibly four were considered to have achieved "worthwhile continence."

In our series, a more stringent patient selection in consultation with a conscientious enterostomatherapist undoubtedly occurred. This is supported by the fact that only 14 of 58 possible patients were selected for the device and probably accounts for the better results in our series then for others reported in the literature. Certainly the primary implantation in patients who had regular bowel habits before surgery augurs well for the best results. Patients with irregularity of bowel habits seem to do well with irrigation of their colostomies every second or third day; while patients undergoing chemotherapy with the resultant diarrhea are also advised to irrigate their stomas.

Even with a rigid selection process, it would appear that achieving better than 50 per cent good results will be difficult. However, the study is being continued with cautious optimism. All patients in the study group are still regularly interviewed in the office by the surgeon and the enterostomatherapist; the feedback has generally been positive.

TABLE 3. *Results*

Group	Grade	Number of Patients	Criteria
I	Excellent	4	Able to wear the cap . . . during the day, through the night, during social events.
II	Good	1	Able to wear the cap as above but sometimes wears an overlying appliance for further protection.
III	Satisfactory	0	Able to wear the cap at work and at night but wears an appliance during social events.
IV	Poor	5	Unable to wear the cap for more than six hours continuously.
V	Ambivalent	4	This category was necessary for patients who could be made continent when the colostomy was irrigated. However, patients usually preferred to wear a conventional colostomy appliance rather than irrigate the colostomy.

TABLE 4. *Care in Stoma Construction Factors*

Excised skin disc 2.5 cm in diameter with minimal excision of underlying fat.
Dissection in subjacent layers at right angles.
Care in suturing the rectus sheath to Scarpa's fascia.
Care in preventing wound contamination when bringing the bowel through.
Care in suturing the skin to the bowel during maturation of the colostomy.
Placement of the ring with the "up" notation facing the skin side.

TABLE 5. *Potential Problem Effects of Magnetic Device on Patient Environment*

Cap adheres to any metal that patient comes in contact with; for example, kitchen sink, metal buckle or belt, hemostat. Magnetic pull can be felt at about 2" distance.
Color TV becomes difficult if not impossible to tune. Magnet distorts picture. (This could be a factor to consider if the prospective patient is a TV repairman!)
Watch worn on the left wrist lost time. However, watch ran perfectly when worn on the right wrist.
Magnet will set off alarm on metal detector at the airport. (All patients carry an identification card that is provided by the manufacturer of the cap.)

Summary

The magnetic ring device is implanted subcutaneously in the abdominal wall, and the colonic stoma is brought out through it. An external magnetic cap helps achieve continence by mechanically preventing the expulsion of fecal material. A disposable charcoal filter disc applied to the undersurface of the cap permits the egress of malodorous gases. Fourteen patients were selected for the procedure from a group of 58 potential patients. Four patients had excellent results, and one other a good result. There were no complications attributable to insertion of the device. There was no incidence of parastomal hernia. Careful selection of patients and cooperation with the enterostomatherapist are emphasized.

Addendum

Seven more devices have been implanted since this article was prepared. None can be categorized as Group I (excellent) or Group II (good).

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