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The Anal Bag: A Modern Approach to Fecal Incontinence Management

Beniamino Palmieri, MD; Giorgia Benuzzi, BSc; and Nicola Bellini, BSc, PhD

In the past 30 years, colostomy and urostomy bags have dramatically improved the quality of life of ostomy patients. However, the anatomical characteristics and physiological motility of the pelvic floor have hampered the development of suitable disposable containers that can be applied directly to the anus. Use of a recently developed anal bag that insulates the anus and peri-anal area and collects stool was evaluated in two inpatient care settings in Italy from 1994 to 2004. The study included four nurses and eight physicians (four gastroenterologists, two cardiologists, and two gerontologists) involved in the care of 120 patients (65 men, 55 women, ages 45 to 96 years). The study population consisted of patients who were elderly and bedridden (47), had pressure ulcers (15), were affected by fecal incontinence or bedridden in intensive care (10), had coronary problems (10), and were receiving high-dose chemotherapy (10); patients who had undergone anorectal surgery (28) were added to the study to evaluate the anal bag for post-operative use to prevent contamination and contain exudate and fluid. Study participants were divided into groups based on length of anal bag use (3 days, 1 week, or 4 months or more). Objective evaluation at each bag change included skin reactions to the adhesive. Study participants' feelings and perceptions as well as nurse and physician evaluations of the anal bag were assessed using questionnaires and four-point rating scales. No adverse reactions to the product were observed and none of the high-risk patients developed a pressure ulcer. The majority of patients (91, 76%) tolerated the bag well and reported it was not painful to remove or apply (102, 85%). Nurses and physicians all considered the device easy to use and appreciated its potential to prevent contamination and cross-contamination. This device may help improve the management of fecal incontinence and prevent complications.

KEYWORDS: fecal incontinence, bedridden patients, patient hygiene, faecis isolatio, anal bag

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Fecal incontinence is an expensive and potentially dangerous pathologic condition, with severe consequences in terms of contamination, infection, and impending risk of skin ulceration, especially in long-term bedridden patients. Prevalence studies of fecal incontinence in the general population are rare.^{1,2} Among younger age groups (<65 years), the prevalence of fecal incontinence has been estimated at 0.7%³ and 0.9%.⁴ In people 60 years or older, prevalence estimates are higher, ranging between 3.1% and 8.2%, but the sample sizes are not large enough to

draw firm conclusions regarding occurrence rates.⁵⁻⁸ Fecal incontinence has been related to advancing age; institutionalized persons >85 years have been found to be at risk.⁹

Perry and colleagues¹⁰ conducted a cross-sectional postal survey of 15,904 randomly selected adults age 40 years or older (excluding residents of nursing and residential homes) from the Leicestershire Health Authority patient register. Participants were asked to complete a confidential health questionnaire in which major fecal incontinence was defined as clothes soiling

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several times a month or more. From a sample of 10,116 respondents, 1.4% reported major fecal incontinence and 0.7% experienced major fecal incontinence with bowel symptoms that had an impact on quality of life. This condition was more prevalent and more severe in older people with no significant difference between men and women.

Recently, studies have suggested that females are at greater risk of fecal incontinence, primarily related to childbirth¹¹⁻¹³; however, supportive data are inconclusive. General population surveys have either assessed the prevalence of anal incontinence (incontinence of solid or liquid stool or flatulence) or fecal incontinence (incontinence of solid or liquid stools only). Nelson and colleagues³ found that female gender was an independent risk factor for anal incontinence; whereas, Thomas and colleagues⁴ found a preponderance of fecal incontinence in men as opposed to women age 15 to 64 years. According to Johanson and Lafferty,¹⁴ 2.2% of pluriparous women experience fecal incontinence due to obstetric stress-related sphincter weakening. The rate rises to 7% in healthy people over 65 years old.¹⁵ Tobin and Brocklehurst¹⁶ note that 23% of post-stroke patients have fecal incontinence, with incidence increasing throughout follow-up. Thomas⁴ and Lahr¹⁷ found a fecal incontinence prevalence rate of 25% in institutionalized patients; the rate reached 33% when extended to elderly retired people at home or in hospitals.

When anal sphincter dysfunction evolves into chronic disease, it usually is investigated with modern techniques such as anorectal manometry, endosonography, endo-anal magnetic resonance imaging (MRI), and defecography and classified in two main categories: *passive* and *urgent*.¹⁸

Passive fecal incontinence refers to internal sphincter dysfunction and reduced maximum resting anal pressure where the person is unaware of stool discharge. *Urgent fecal incontinence* is a loss of efficient voluntary external sphincter contraction or an increased ejection bowel pressure, with conscious fecal loss perception.

Tuteja et al¹⁹ reviewed many specific tests, treatments, and products used to manage fecal incontinence. They concluded that anorectal physiological tests and anal endosonography help in the evaluation

of functional abnormalities in the assessment of sphincter defects. The results of these tests may guide further management. However, abnormal findings do not predict incontinence severity or response to treatment. Behavioral therapy is successful in most patients and should be offered first; unfortunately, these procedures are not universally available so the creation of a colostomy should be regarded as a viable option. Several experimental approaches (anal sphincter bulking, sacral nerve stimulation, and delivery of radiofrequency through the anal canal) are currently used. Surgical treatment of fecal incontinence improves symptoms but does not definitely cure the condition and the clinical outcome often deteriorates with time.⁷

The psychological and social effects of fecal incontinence on quality of life have been evaluated. Frustration, depression, loss of self-esteem, and isolation affect the patient, especially when the condition is long-term.²⁰ Individual and community costs related to incontinence include pads, medications, skin care, wound healing products, appliances, consultations, medical and paramedical services, examinations and tests to achieve a correct differential diagnosis, and retirement and disability financial support. Ten years ago,²¹ the yearly cost for incontinence appliances in the US was estimated to be \$400 million. Another study found the annual cost of incontinence treatment of each institutionalized patient to be \$9,771.²²

Over the past 10 years, clinicians have been devoted to surgically repairing anal sphincter incompetence and to developing and using medical and surgical devices to control incontinence.

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KEY POINTS

- Skin breakdown, wound infections, and cross-contamination are recurring issues when managing fecal incontinence.
- The authors describe the characteristics, procedures, and outcomes of using an anal bag in the management of 120 patients with fecal incontinence.
- The encouraging results observed suggest that studies examining the relationship between fecal incontinence management procedures, patient comfort, skin breakdown, pressure ulcer healing, and cross-contamination are warranted.

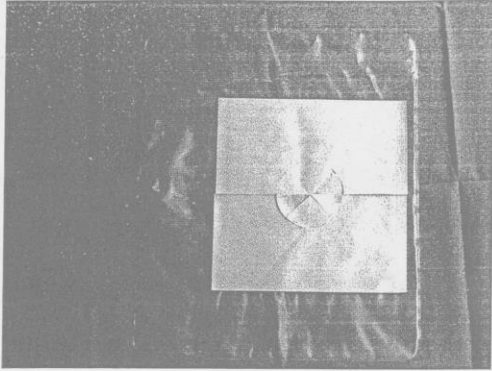


Figure 1.
The anal bag and its adhesive surface.

Within the last 15 years, the authors have been involved in similar endeavors, not only in terms of the successful management of incontinence, but also in the broader arena of perineal area healthcare regarding pressure ulcer prevention and treatment, perineal surgery and hygienic medications, treatment of various types of incontinence and diarrhea, and preventing entero-bacterial hospital environment contamination.

In addition, the perineal problems of the elderly have received growing attention. New operative techniques, biomaterials, and dedicated instrumentation, as well as the risk of contamination and infection, are being examined in order to avoid postsurgical complications. With these concerns in mind, the authors intended to create, manufacture, and evaluate a device suitable for use as a fecal outer reservoir, a

drain for fecal diagnostic evaluation, or a waterproof insulating and protecting "second skin" for the perineum — the anal bag. A prospective, open-label study was conducted to evaluate the safety, efficacy, and potential short- or long-term complications of repeated bag changes.

Materials and Methods

Appliance description. The anal bag²³ is a smooth, rounded or squared high pressure and waterproof PVC envelope. It is manufactured by Tecnoline (Concordia, Modena, Italy). The anal bag has a 700-cc capacity with a flatus discharge valve large enough to fit a small diameter enema tube. One side of the envelope is made of a 20-cm x 20-cm thin adhesive polyurethane layer with a high moisture vapor transmission rate that surrounds the peri-anal and part of the buttocks area and comfortably seals the skin. This layer is centered by a virtual hole resulting from a 7-cm x 7-cm cross incision that severs four square triangles with the apex in the cross center (see Figure 1).

Application. In order to apply the anal bag, the adhesive covering cardboard is withdrawn and with the patient in a supine or lateral position, gentle finger pressure is applied to the center of the cross to open the hole along the incision. The four obtained triangles stick against the anal verge and the perineal conic trunk surface. Wide skin adhesion is carefully completed around the buttocks using hand pressure, avoiding inadvertent folds or irregular stratification (see Figure 2).

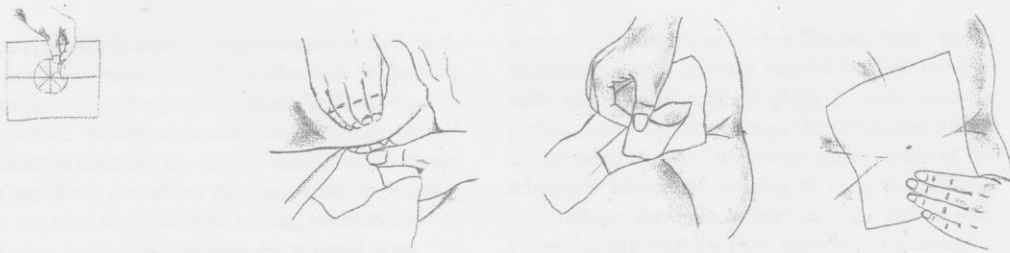


Figure 1.
Anal bag application: The paper triangles in the perianal area are removed in order to expose the adhesive surface. With the patient laying on his side, the center of the bag is placed against the anus. The surrounding squared paper is removed, with anal bag partially inserted, to complete the procedure. Final perineal skin coverage with the adhesive polyurethane surface is achieved: the anal bag in place.

TABLE 1
STUDY PARTICIPANTS PER GROUP: DEMOGRAPHICS AND SELECTED
HEALTH CONDITION/ADMISSION DIAGNOSIS

Group and subgroup (n)	Sex	Age range (years)	Health condition/admission diagnosis (n)
A. Definitely bedridden with fecal and urinary incontinence in nursing homes (62) Without pressure ulcers (47) With pressure ulcers (15)	Male: 38 Female: 24	81-96	Dementia (33) Hemiplegia (11) Tetraplegia (3) Multiple sclerosis (9) Severe respiratory insufficiency (3) Lumbar spine trauma (2) Amyotrophic lateral sclerosis (1)
B. Temporarily bedridden with diarrhea episodes in different hospital wards (n = 30): Intensive care unit (10) Coronary unit (10) Germ-free unit (10)	Male: 6 Female: 24	45-67	Gastrointestinal tract and liver resections (3) Severe ulcerative colitis (2) Polytrauma (2) Acute cerebrovascular disease (2) Lung fibrosis (1) Acute myocardial infarction (7) Severe angina (3) Hematological malignancy and bone marrow transplant (7) Solid tumors and gastrointestinal-tract toxicity of chemotherapy (3)
C. Postoperative; bedridden due to perineal procedures in surgical wards (n = 28)	Male: 10 Female: 18	45-78	Hemorrhoids (11) Rectal prolapse (5) Rectocele (4) Fistulas (3) Cystocele and fecal incontinence (3) Anal cancer (2)

Anal bag application is usually easy but some difficulty has been reported with application on patients restricted to a supine position, especially those placed on a waterbed. To help overcome some of these reported application obstacles, the authors manufactured an anal bag introducer that allows the caregiver to single-handedly complete the procedure, holding the buttocks with the other hand; thus, widening the perianal space. The introducer is a plastic or steel bivalve with a 30-cm x 30-cm plate with a handle that spreads the valves up to 45°. This adaptation frees the bag of the adhesive insulating cardboard and allows it to be folded on the midline

across the distal introducer edge. The bag, folded on the introducer, is then carefully inserted between the buttocks on a sagittal midline plane. Its cross center is pushed against the anus through the protuberant edge of the introducer device; the hollow sacral profile of the introducer allows the caregiver to bring the adhesive polyurethane deeply in contact with the coccyx skin. When this first step has been completed, the caregiver squeezes the introducer's handle, spreading the valves, and the bag surface is extended on a horizontal plane that fits with the perineal area flattened by the pressure to obtain a smooth adhesion of the bag to the skin.

TABLE 2
PATIENT EVALUATION RESULTS (N = 120)

QUESTION	SCORE			
	4	3	2	1
Is the anal bag comfortable for the skin and stool discharge?	Absolutely 92 (77%)	For short periods 16 (14%)	Uncomfortable 8 (7%)	Unbearable 2 (2%)
Is application and removal painful?	Not at all 102 (85%)		Moderately painful 18 (15%)	Very painful 0 (0%)
Is the anal bag better than sanitary napkins?	Yes 90 (75%)	Similar 24 (20%)	Worse 6 (5%)	Very much worse 0 (0%)
Would you recommend anal bag use for a bedridden and incontinent relative or friend?	Yes 81 (68%)	Probably if necessary 26 (22%)	Perhaps in case of doctor prescription 4 (9%)	No 1 (1%)
Overall evaluation of anal bag	Highly approved 91 (76%)	Approved 29 (22%)	Partially approved 2 (2%)	Not approved 0 (0%)

Participants and procedure. After obtaining informed consent, the anal bag was used on 120 patients with a variety of medical conditions. Their ages ranged from 45 to 96 years, 65 were men, 45 were women, and all were admitted to one of two healthcare facilities: City Hospital (Modena) and S. Maria Maddalena Hospital (Rovigo) (see Table 1). Peri-anal skin motility during stool output was assessed in the first 20 bedridden patients to determine how to achieve strong and adequate adherence of the anal bag to avoid soiling.

Group A (n = 92 nursing home residents, bedridden with fecal/urinary incontinence), used the anal bag for 4 weeks or more, having it changed when filled by a substantial amount of stool, usually every 1 to 2 days. Constipated patients were treated with in-bed enemas for rectal toileting; the enema fluid and the discharged bowel contents were collected into the anal bag. Patients who also had a pressure ulcer received daily treatment — wounds were soaked with sterile saline, the ulcer bed dried with dry gauze and covered with non-occlusive medication (Collagenase-Noruxol, Basf Group, Munster, Germany) on a sterile sponge. When the pressure ulcers were close to the anus, the polyurethane sheet of the anal bag kept a dry sponge in place over the wound without stool contamination. Patients were turned every 3 hours, 24 hours a day.

Group B (n = 28 acute care patient temporarily bedridden with diarrhea) used the anal bag for 1 week. Enemas were provided to constipated patients twice during the trial. In patients with diarrhea, the anal bag was changed two or three times a day, according to the cumulative amount of stool discharged.

The C group (n = 45 postsurgical patients) used the anal bag for 3 to 4 days. The product was applied in the operating room at the end of the surgical procedure and changed daily to observe the amount and quality of the drained exudates until the patient was discharged from the hospital.

Patients were asked to rate their experience with the product (comfort, pain during application or removal, comparison with sanitary napkins, willingness to recommend the anal bag to friends) using a four-point scale with responses appropriate to each question (see Table 2). Nurses were instructed about the application procedure and, similar to patients, asked to rate the effectiveness of the anal bag (application and removal, evaluation of discharged material, skin preservation, cleaning time of the peri-anal area during anal bag change, and perceived effectiveness in pressure ulcer prevention and treatment) using a four-point response scale appropriate to each question (see Table 3). Physicians provided responses

TABLE 3
NURSE EVALUATION RESULTS (N = 4)

QUESTION	SCORE			
	4	3	2	1
Application of the anal bag	Easy 92 (77%)	Cumbersome 21 (18%)	Very difficult 6 (5%)	Impossible 0 (0%)
Ability to evaluate discharged material	117 (98%)	2 (2%)	0 (0%)	0 (0%)
Performing a through-anal bag enema	96 (80%)	18 (15%)	6 (5%)	0 (0%)
Anal bag removal	93 (78%)	26 (22%)	0 (0%)	0 (0%)
Perineal skin preservation	Excellent 115 (96%)	Good 0 (0%)	Moderate inflammation 4 (4%)	Damaged 0 (0%)
Difficulty with and cleaning time of perineal area during anal bag change	Short and easy 84 (70%)	Cumbersome 18 (15%)	Soiling 12 (10%)	Massive soiling 6 (5%)
Effectiveness of anal bag in pressure ulcer prevention and treatment	Very effective 96 (80%)	Effective 12 (10%)	Probably effective 6 (5%)	Unpredictable 5%
Overall evaluation of anal bag	Highly approved 90 (75%)	Approved 29 (25%)	Approved in part 0 (0%)	Not approved 0 (0%)

to questions regarding anal bag effectiveness also using a four-point scale (see Table 4). The authors also interviewed physicians and nurses in order to better understand the indications, limits, and difficulties associated with anal bag use.

Results

Patient assessment. All the patients tolerated the anal bag for the wear time required; no adverse reaction to the polyurethane adhesive sheet was reported. At the beginning of the trial, some caregivers expressed concern regarding long-term wear but overall compliance was achieved due to excellent tolerance of the plastic films during the prolonged skin contact (see Table 2). In fact, no specific allergic reactions to the anal bag were detected during the trial.

Of the 120 participants, the majority found the anal bag comfortable (92, 77%), not at all painful

(102, 85%), better than sanitary napkins (114, 75%), and worthy of recommendation (81, 68%), for a "highly approved" rating of 76%. Only 18 (15%) experienced moderate pain on removal and six (5%) preferred sanitary pads. Pain assessment and comfort was not assessed in the surgical group (Group C) because 1) superimposed surgical pain may have created a bias/conflict, 2) the anal bag was worn only for a short period of time (no longer than 3 days), and 3) patients were allowed to walk and move freely, wearing the device under pajamas. Patients had no problem complying with the instructions given by the nurses and appreciated the ability to avoid soiling and wound exudate spillage.

Nurse response. Of the four nurses who participated in the evaluation, two initially expressed some diffidence and anxiety toward the new appliance and voiced three main objections:

TABLE 4
PHYSICIAN EVALUATION RESULTS (N = 8)

QUESTION	SCORE			
	4	3	2	1
Is anal bag use effective in operating room, ICU, and selected departments to prevent soiling and contamination due to incontinence and diarrhea?	Yes, absolutely 72%	Yes, but only in a restricted number of cases 22%	Partially effective 6%	Useless waste of time 0%
Overall evaluation of anal bag	Highly approved 87.5%	Approved 12.5%	Approved in part 0%	Not approved 0%

1. The manual dexterity required for anal bag use would require training and the device was cumbersome compared with the usual method of anal-perineal care.
2. Anal bag application and removal might be painful and require regular trichotomy.
3. Patients would be uncomfortable with the anal bag attached to the peri-anal area for several days.

The other two nurses were looking forward to implementing the new perineal care proposal and appreciated the potential hygienic/preventive quality of the project.

Using a four-point scale, nurses assessed the anal bag as easy with respect to: application (92, 77%), evaluation of discharged material (117, 98%), through-anal-bag enema performance (96, 80%), removal (93, 78%), perineal skin preservation (115, 96%), and perineal cleaning time during anal bag change, (84, 70%). They also perceived the bag as effective in preventing and treating pressure ulcers (96, 80%; group C was excluded because they were not considered to be at high risk for developing pressure ulcers), for a "highly approved" rating of 75%.

Pressure ulcer prevention. Among the 35 high-risk bedridden patients with incontinence (group A without pressure ulcers), no pressure ulcers developed and 96% of the participating nurses judged the product effective in preserving perineal skin integrity (on a skin preservation scale where 1 = damaged, 2 = moderate inflammation, 3 = good (slightly rough but uninjured), 4 = excellent (smooth and soft). The results showed skin condition to be excellent (115, 96%), good (0, 0%), moderately inflamed (4, 4%), and damaged (0, 0%). In fact, the skin surface in the perisacral area was well preserved by the adhesive layer of the polyurethane and no contami-

nation or friction damage was observed during appliance use. In the 10 patients with pressure ulcers (group A), wound healing was obtained in five patients, ulcer diameter was reduced more than 50% in three patients, and moderate improvement (less than 50% reduction and partial effacement and debridement of the ulcer bed) was noted in two patients. The healing process was not compromised by infection. Granulation tissue formation and re-epithelialization occurred under the occlusive polyurethane sheet of the anal bag. In patients with diarrhea and/or constipation from different hospital departments (group B), the anal bag effectively controlled fecal soiling and stool collection. Stools dropped directly into the bag lumen and the adhesive sheet of the bag adequately covered the perineal skin, with minimal soiling just around the anus; thus, dermatitis, burning, and itching due to heavy chemical-microbiological skin contamination were avoided.

Overall assessment. Within the entire study population (n = 120), 91 patients (76%), three out of four nurses (75%) and seven of eight physicians (87.5%) rated the product highly on a scale of 1 to 4, where 1 = not approved, 2 = partially approved, 3 = approved, and 4 = highly approved (see Tables 2, 3, and 4). Of the eight physicians, at least 5 (72%) supported the opportunity to use the anal bag in surgical and medical wards.

Discussion

The results of this study suggest the anal bag can be used safely and effectively in the long-term treatment of home, hospice, or hospitalized bedridden patients with fecal incontinence, or in specific hospital wards or departments where cross-contamination is an important concern. A sterilized anal bag can be used

in the operating room before starting any procedure requiring asepsis or low contamination (eg, plastic, urologic, obstetrics-gynecological, colorectal, and transplant surgery and in immunocompromised hosts) or at the end of anorectal and pelvic operations as a specific tool that allows the qualitative and quantitative evaluation of postoperative discharge. In intensive care units, anal bag use can inhibit the spread of bacteria into the environment and is expected to substantially reduce the risk of developing pressure ulcers or delayed healing of existing ulcers due to repeated pathogenic bacterial exposure.

Fecal contamination of sacral wounds, as well as the mechanical trauma due to the friction of perineal skin against plastic stool containers during in-bed bowel voiding, may cause ulcers or delay healing. Specifically, fecal Gram-negative bacteria with high proteolytic potential disrupt the tissue repair process, often with lethal consequences for the patient.⁷

Alternative devices/treatments. The anal bag is able to seal the anus and peri-anal area using an adherent, well-tolerated and moisture vapor permeable film. The conical trunk of the external anal sphincter skin is not as inert as the abdominal wall in colostomy patients—rather, it is extended and stretched by the sphincter during fecal stream output. Polyurethane film elasticity is required to comply with physiological movements of the perineum. For this reason, existing products such as hydrocolloids and thick adhesive films or peri-anal rings often fail because of their stiffness and poor compliance with skin movement.

An interanal stool bag described by Fujii et al²⁴ is quite different from the anal bag because it features a condom-like inner sac that must be totally introduced into the rectal ampulla and extruded with the stools during defecation. Reported disadvantages of this appliance include invasiveness, flatus barrier, and discomfort. Other products to prevent soiling include balloon inflatable tubes and/or plugs. Use of these items must comply with manufacturer instructions and use should be restricted to insensate patients with anal muscle paralysis with or without diarrhea.²⁵⁻²⁷

Giamundo et al²⁵ report a nonsurgical approach to preventing fecal incontinence using Procon (AnaTech, El Paso, Tex.), a 7-cm, disposable, double-lumen,

cuffed rubber catheter whose distal tip has an infrared photo interruptor sensor and flatus vent holes. The device is intended for self-insertion; bowel movements trigger a beeper connected to the catheter. Kim et al²⁶ discuss another silicone tubular device (Continent Anal Plug [CAP] US Patent No. 5 569 216), used to treat 32 patients (mean age 61 years) with intractable diarrhea, with and without peri-anal dermatitis or pressure ulcers. This device has an occluding balloon and holes for flatus and enema fluid inlet that is inserted into the anus. Fecal matter is drained through to the device's thin collapsible hose situated in the anal canal. The study showed the device to be effective for diarrhea and incontinence control but its invasiveness seemed to be better suited for short-term indications.

Echols et al²⁷ treated 140 burn injured patients using Zassi BMS (Bowel Management System-Zassi Medical Evolutions Inc., Fernandina Beach, FL), another silicon tube-based device. The invasive nature and difficulty of use was disliked by a large number of nurses and patients.

Surgery remains a viable option for treating fecal incontinence, yielding encouraging and improving results.^{28,29}

Conclusion

The anal bag was designed as a simple and effective appliance to collect stool and preserve the peri-anal area from contamination and infection. The results of this study suggest that it also may reduce the risk of skin breakdown related to fecal contamination. In colorectal surgical patients, postoperative use of the anal bag helps avoid suture contamination and wound dehiscence and offers a way to carefully monitor discharged fluids. Clinicians should be instructed in anal bag use and follow-up studies to assess the effect of fecal incontinence-related protocols need to be conducted. - OWM

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