

An Incremental Step in Patient Safety: Reducing the Risks of Retained Foreign Bodies by the Use of an Integrated Laparotomy Pad/Retractor

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Retained foreign body is a recognized complication of abdominal, pelvic, and thoracic surgery and a cause of medical malpractice. Efforts to reduce its incidence include safe exposure and the use of fewer laparotomy pads. The EZ DASH is an absorbent 12-thickness laparotomy pad covering a malleable stainless steel mesh, providing both the needed retraction and a reduction in the use of individual pads. EZ DASH has been introduced into clinical use in 183 consecutive cases by specialty surgeons (colorectal, gynecology, and gynecologic oncology services) at multiple medical centers. The retractor may be shaped to the individual needs of an operating field, eg, the pelvis, and the small bowel secured behind the retractor, held in place by the tension of its mesh and the security of the abdominal wall. Positioning has been intuitive and

secure, and the intraoperative use of sponges and of operating time have both been noticeably reduced. Among 183 cases, 91% of uses were felt to reduce OR time by ≤ 5 to ≥ 10 minutes. Ninety-three percent of EZ DASH cases used fewer individual laparotomy pads for small bowel retraction. Ninety-five percent of uses suggested a value added to the case by the operating surgeon with an expressed desire to use the product repeatedly. The EZ DASH is a simple method of obtaining small bowel retraction and laparotomy pad absorption with a reduction in the need for individual pads, providing excellent exposure for the operative field and reducing the risk of retained foreign body.

Keywords: patient safety; retractor; absorbent lap pad; foreign body retention

The risk of a retained foreign body is a well-documented complication of open, abdominal and thoracic surgery. In a nationwide claims-filed report on medical malpractice, it was estimated in the *New England Journal of Medicine* that such occurrences take place in at least 1500 patients per year.¹ Unintentionally retained foreign bodies can cause further complications, leading to severe illness or death. Mortality rates have been reported from 11% to 35%.² In New York state, while there may be mitigating circumstances, a retained foreign body is a reportable event and is considered *prima facie* evidence of medical malpractice.

The goals of obtaining adequate exposure at the operating table include:

- direct targeting of the organ(s) to be dissected or resected, within a highly visible field, and
- retraction of the small bowel, and/or other structures, to avoid injury or interference with the ongoing dissection.

The EZ DASH laparotomy pad/retractor (EZ Surgical Corporation, Hewlett, NY) is designed to accomplish both goals, incrementally increasing patient safety with each operative procedure. The EZ DASH (Disposable Absorbent Secure Hold) laparotomy pad (lap)/retractor combines the advantages of an absorbent lap pad with the security of a flexible, moldable system for dedicated retraction. The device is composed of 2 elements: an outer lap

pad consisting of 12 thicknesses of absorbent cotton, and an inner stainless steel mesh surrounded by a silastic border with rounded edges (to ensure patient safety) providing the matrix for malleable retraction (Figure 1). The device may be molded—even reshaped—intraoperatively to a variety of configurations, each of which may be defined by the circumstances or needs for retraction within the chest, abdomen, or pelvis (Figure 2). It is versatile and easily deployed and may be used in any of the following: colorectal surgery, general surgery, gynecology and gynecologic oncology, thoracic, vascular, and spine-access surgery. EZ DASH comes in sizes varying from 2 × 7 inches, to 4 × 7 inches, to 7 × 11 inches, and the device may also be used in conjunction with many retractor systems.

Methods

During July and August of 2007, we introduced the EZ DASH on 2 specialty services (colorectal and upper GI services), and extended its use to general surgery and gynecologic oncology, thoracic, vascular, and anterior access in spine surgery. Below the diaphragm, the EZ DASH devices were easily adapted to use in 3 locations: the pelvis, various locations in the abdomen, and in the subhepatic space. Typically in the pelvis during hysterectomies, a single 4 × 7-inch or 4 × 11-inch device is folded tightly lengthwise into a double-folded 2 × 7- or 2 × 11-inch form, and then curved to a crescent curve or half-moon. The small bowel is displaced into the upper abdomen and the folded and curved lap/retractor positioned under the abdominal wall and just above the umbilicus, preventing the small bowel from inadvertently finding its way back into the pelvis (Figure 2). The weight of the upper abdominal wall just above the lower midline incision serves to secure the EZ DASH. With the displacement of the

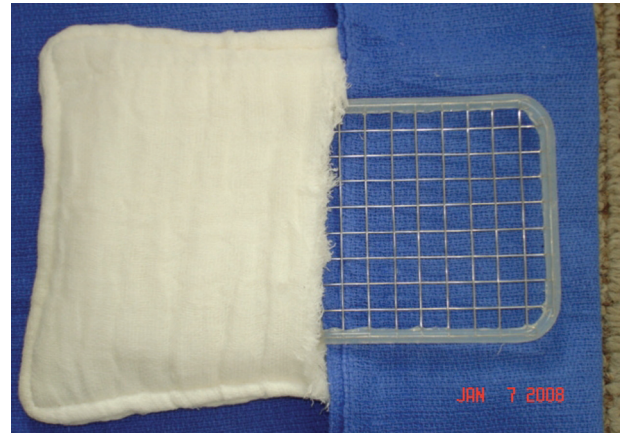


Figure 1. A 4 × 11 EZ DASH retractor composed of an outer, absorbent coat of 12 layers of cotton, and an inner stainless steel mesh protected by a silastic coating and borders.

small bowel, a simple retractor, eg, a Balfour, provides easy access to the pelvis. More sophisticated self-retaining retractors may be used in their traditional manner.

Results

An evaluation period has been carried out at a number of major medical centers. The EZ DASH evaluations have been reported in 183 cases, the initial 17 of which were performed at the Beth Israel Medical Center in New York, New York, 30 at the Cleveland Clinic Florida in Weston, Florida, 14 at St. Mary's Nazareth in Chicago, Illinois, 13 at Barnes Hospital and the affiliated hospitals of Washington University in St. Louis, Missouri, 12 at the Central Mississippi Medical Center in Jackson, Mississippi, along with smaller numbers at other institutions. The product was employed in 72 cases of advanced colon and rectal surgery (including low

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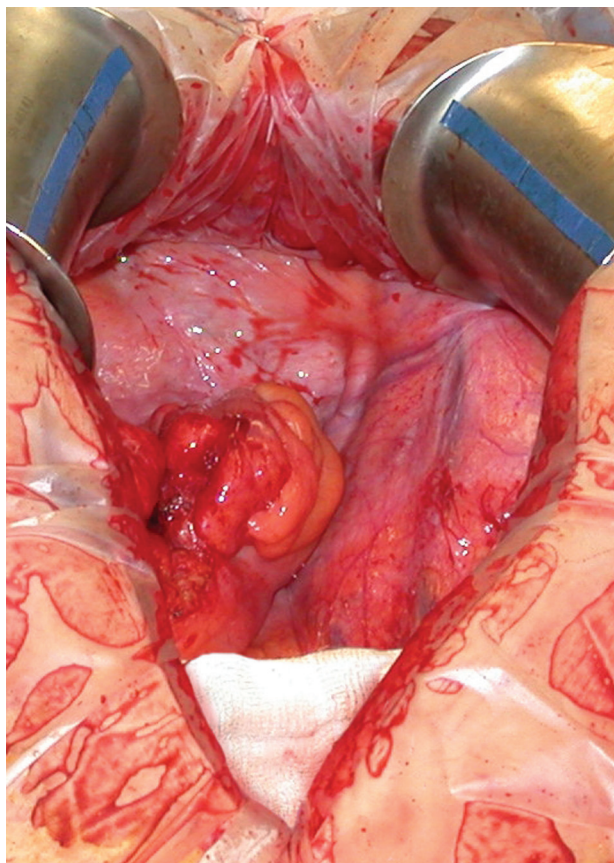


Figure 2. THE EZ DASH in use at the start of a low anterior resection. The patient has had a prior colostomy and preoperative irradiation. The EZ DASH device (white) is tucked up beneath the upper abdominal wall and prevents the small bowel from entering the field.

anterior resections, abdomino-perineal resections, J-pouch revision-reconstructions, etc), 63 total or supracervical hysterectomies, 13 major upper abdominal procedures, ie, Whipple procedures or liver resections, and in 2 cases each of anterior spine access, thoracic and vascular surgery, as well as in assorted other procedures.

The most common sizes used were size 2, (4 × 7) in 98 cases (53.6%) and size 3 (4 × 11) in 84 cases (45.9%). Two or more units were required in only 20 cases (11%), while 163 procedures (87%) were performed using only 1 unit per case. In only 26 cases (17%) performed by 13 surgeons (8.6%) were “sizers” deemed to have even a potential role in choosing the right size unit.

In 125 of the 183 cases (68.3%), the surgeons found the EZ DASH device very easy (grade 1 on a scale of 1-5 degrees of difficulty) to insert properly

into the abdomen. Ease of insertion was given a grade 2 in 45 cases (24.6%), and grade 3 in 13 cases (7.1%). Comments from individual surgeons revealed that often insertion and positioning of the device was deemed “intuitive,” and 170/183 (92%) cases were scored either a level 1 or 2 out of 5 for insertion.

Once in place, the EZ DASH device was held in place securely of its own “integrity” in 117/182 cases (63.9%). In 63 cases (42.6%), the surgeon repositioned the EZ DASH one or more times, but in 55 of those 63 cases (87%), the change of position was prompted by a change in the procedure itself, requiring a change of exposure.

In 166 of 183 cases (90.7%), surgeons felt that operating room (OR) time was saved as a result of using EZ DASH. In 81 cases (49%), surgeons reported saving <5 minutes, in 66 cases (40%) between 5 and 10 minutes, and in 19 cases (11.1%) surgeons reported saving 10 or more minutes. In 170 of 183 (92.9%) of cases, surgeons felt that appreciably fewer laps were required because the EZ DASH was being used. In the interest of patient safety, 1 surgeon (S. D. W.) dramatically reduced the use of lap pads for packing of the small bowel after adopting the use of the EZ DASH lap/retractor.

A sense of the “value added” by the device was requested of the operating surgeon after each use. On a scale of 1 to 5, surgeons in 165 cases (90.1%) felt that the device improved their operating experience and added a high measure of value to each case (a score of 1 or 2). In 10 cases (5.5%), the surgeons felt that there was no value added. Nevertheless, despite any misgivings, when asked whether they want the product in their ORs, 174 of 182 (95%) wanted the EZ DASH product brought in for their continued use.

Discussion

The risk of unintended foreign body retention is real. In 2003, Gawande et al reported on the incidence and the causes of retained foreign body, estimating more than 1500 cases per year.¹ These events occur most commonly during emergency operations, in cases where a change in the intended operation takes place or in patients with a body mass index of more than 25, and they occur despite guidelines for the intraoperative counting of sponges established by the Association of Operating Room Nurses, etc.²

In the majority of such cases, foreign bodies are retained despite normal counts, and, it would stand to reason, that methods that reduce the use of cotton or of other textile foreign bodies would likely reduce this complication. More than half (54%) of the reported foreign bodies were left either in the abdomen or pelvis, areas that are the direct interest of colorectal and general surgeons and to gynecologists and gynecologic oncologists.¹ An additional 7% were retained in the chest.

The consequences of retained foreign body are often serious.³⁻⁵ Complications of the inflammatory or foreign body reaction have included small bowel fistulae, obstruction, visceral perforation, and death. Other factors, namely patient age, the duration or the lateness of an operation, and/or multiple procedures, commonly thought to influence complications were not found to play a role in the actual retention of the foreign body. Where performed, 88% of the cases were associated with a normal lap/sponge count.¹

The incidence of foreign body retention was estimated at 1 case per typical large hospital per year. This figure is likely to be an underestimation, as the study relied on reported malpractice claims and did not take into account either forgiven cases or those that were settled without a lawsuit. Based upon an economic benefit, the authors recommended a routine intraoperative x-ray covering the suspected field in all high-risk patients.¹

Since the report *To Err Is Human* published by the National Academy of Medicine in the late 1990s,⁶ patient safety practices in the OR have been based on the development of strategies to reduce risk and error and on systems that tend to minimize human error. While many risk-inducing factors may affect the operating team (interruptions, anger, fear, time-related pressures, etc)³ other steps may be needed that are directed to the operative field itself.

In 2005, the Joint Commission on Health Care Organizations (JCAHO) made retention of a foreign body a sentinel event requiring a root cause analysis and reporting of the incident.⁷ Also in 2005, the American College of Surgeons created the "Statement on Prevention of Retained Foreign Bodies after Surgery," which may be accessed on the Web at www.facs.org/fellows_info/statements/st-51.html.⁸

Despite the JCAHO and other organizations' efforts to implement systems to ensure correct-site surgery, or of other safety methods such as the "time-out," it remains difficult to perfect fail-safe methods to ensure that all causes of error may be eliminated during surgery.⁷⁻⁹ During the operation itself, exposure

of the entire operating field, adequate retraction, interference of the small bowel with areas such as pelvic dissection may contribute to the retention of a sponge or a lap pad, and in some cases to the retention of instruments. Furthermore, retractors that are neither secure nor easily modified intraoperatively may lead to distractions of the operating team, or may hide potential spaces, ie, the cul-de-sac, the gutters, etc, from regular view or attention. These hidden spaces can easily become the sites of unintended foreign body retention.

A methodical "see and touch" process for reexploring the abdomen, along with radio-opaque markers, has been recommended prior to closure in surgery that involves body cavities.⁸ In addition to the removal of all fascial stitches, these steps should be repeated when the surgeon is informed of an "incorrect" count, and an x-ray should be obtained and read prior to the patient leaving the OR. These steps have been recommended by Gibbs et al⁷ in order to best ensure a policy of "no thing left behind."

But prevention of the complication certainly has to be a better approach than dealing with the events "after the fact." A system or a device that reduces the need for free sponges or lap pads, as well as intraoperative distractions can contribute to the reduction of this complication and may be an incremental step in the promotion of patient safety. EZ DASH provides this incremental step in assuring patient safety. It protects the small bowel behind a safe and secure combination of a disposable 12-thickness lap sponge and a malleable retractor. EZ DASH is a secure retractor on its own merit, and in cases where the surgeon elected to move the EZ DASH during the operation, it was mostly done because of the change in exposure that was needed as a part of an ongoing dissection. In 93% of the cases, surgeons indicated an ease of placing the device securely, and 93% indicated an *a priori* reduced need for laps or sponges. Our surgeons dramatically reduced the use of all separately placed lap pads for packing of the small bowel, in view of the effective retraction and the absorbent nature of the EZ DASH. These 2 elements combined create fewer distractions during the course of the operation, and fewer foreign bodies entering the body cavity being subjected to the surgery, dissection, etc, with their potential loss or retention.

Time saved in the OR may serve both as further safety and economic considerations. Gawande and coworkers¹ did not find that the duration of a case was a significant factor in causing retained foreign body. But in general, most surgeons feel that the

shorter the patient's exposure to anesthesia, the better it is for the patient.

In addition, at modern charges for OR time, any reduction in operating time contributes to reduced OR costs. In both regard, in 91% of cases, surgeons felt that the EZ DASH contributed to a reduction in operating time; in 89% of cases by ≤ 10 minutes, and in 11%, by more than 10 minutes.

Should the suspicion of a retained foreign body arise, the detection of the foreign body becomes the OR team's most critical priority of patient care. Operating room policy normally calls for an x-ray to detect the foreign body, relying on the radio-opaque strip of lap pads or sponges for detection. As demonstrated in Figure 3, the radiologic image of the EZ DASH is on order of magnitude more radio-opaque than the lap pad, let alone a sponge, providing a greater sense of security that, compared to a lap pad or sponge, the EZ DASH will be detectable.

While subjective, stress on the surgeon is an important factor in the overall atmosphere of the OR. In 91% of cases, the surgeons using the EZ DASH felt a "value-added" from the device and, going forward, 96% of the surgeons wanted the device to be routinely stocked and available in their ORs.

Conclusion

EZ DASH is a disposable 12-thickness absorbable lap pad and a stainless steel mesh retractor system combined into a single malleable device. It has been introduced and evaluated, initially among a limited number of surgeons in specialty service settings, and its use extended to multiple surgeons and ORs. It has been well received during the evaluation period (96% of surgeons have asked for the device to remain available) and serves to enhance retraction and to reduce the need for foreign bodies, eg, lap pads or sponges. It is intensely radio-opaque and far more easily detectable on x-ray than either lap pads or sponges. EZ DASH may serve as an incremental step toward assuring patient safety in surgery of the abdomen, pelvis, and chest.

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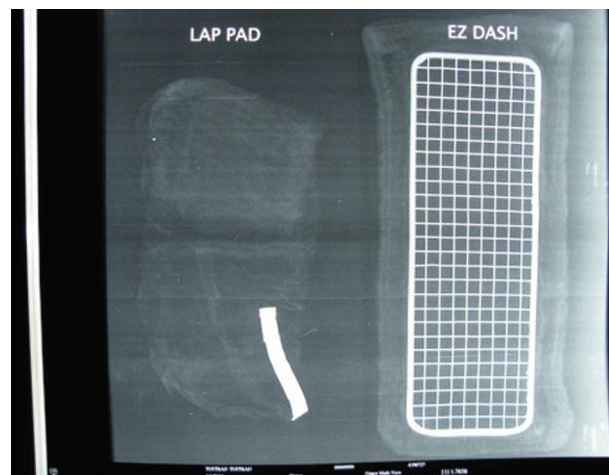


Figure 3. An ex vivo x-ray demonstrates the radio-opacity of a standard lap pad (left) and an EZ DASH lap retractor. The difference in radio-opacity is intense.

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