



Single-site in-bag morcellation achieved via direct puncture of the pneumoperitoneum cap, a cordless electric morcellator, and a 5-mm flexible scope



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ABSTRACT

Objective: To evaluate a modified single-access method of contained power morcellation performed with a single-access laparoscopic device and a new cordless electric morcellator. The study was a preliminary assessment of the feasibility and safety of the new technique.

Study design: A single university hospital observational study involving patients who underwent either laparoscopic myomectomy or laparoscopic hysterectomy. We evaluated the operative results, time required for the contained morcellation, any occurrence of bag leakage, and any complications.

Results: The new contained power morcellation technique was applied in 12 patients (9 undergoing laparoscopic myomectomy and 3 undergoing laparoscopic hysterectomy). The mean bag introduction time was 21.8 min (range, 14–37 min); mean in-bag morcellation time was 11.5 min (range, 1–26 min); and mean total morcellation time was 36.8 min (range, 19–66 min). Visual inspection revealed no bag damage. There were no postoperative complications.

Conclusion: Single-site in-bag morcellation performed with our new technique requires neither bag penetration nor piercing with a trocar and thus may prove beneficial for preventing spillage and dissemination of unwanted cells and tissue.

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Introduction

Electromechanical morcellation was developed near the end of the 20th century for removal of large solid surgical specimens, such as myoma specimens, via small incisions [1], but only as recently as 2014 did the U.S. Food and Drug Administration (FDA) issue a statement recommending against the use of electric morcellators for specimen extraction during laparoscopic gynecologic surgery [2]. This was done to reduce the possibility of upstaging the patient's condition should the surgical specimen harbor an unexpected malignancy that could be dispersed within the peritoneal cavity during power morcellation. In the meantime, the possibility of parasitic leiomyoma developing after the use of an electric morcellator was reported [3]. Since the FDA statement, numerous methods for prevention of the unwanted spread of cells or tissue from the surgical specimen have been devised.

Several of the in-bag morcellation methods proposed to date involve not only placement of the specimen the isolation bag

through the mouth of the bag but also introduction of a trocar into the bag via puncture. However, problems—specimen attachment to the trocar surface and port-site metastasis—have been encountered when the such techniques are used. We recently devised a morcellation technique that features an isolation bag with a drawstring at the mouth of the bag. Our technique appears to have potential to overcome the problems associated with the reliance on bag puncture.

We describe herein our single-site in-bag morcellation method, which includes use of a new cordless electric morcellator and a 5-mm flexible scope. Particular to the method is use of an insufflated isolation bag, which fully prevents the dissemination of tissues and cells from the surgical specimen to the surrounding peritoneal cavity. The method was tested in women undergoing either laparoscopic myomectomy or total laparoscopic hysterectomy at our hospital, and thus we report results of our evaluation.

Patients and methods

Patients

Women included in the study were scheduled to undergo laparoscopic myomectomy or total laparoscopic hysterectomy

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between August 2015 and October 2015. All operations were performed by the same surgeon (Y.A.). The ethics committee of Nihon University School of Medicine approved the morcellation method and our proposed study. All patients provided informed consent for our single-site in-bag morcellation procedure. All also granted permission for anonymized use of their surgical data and photos.

Inclusion criteria for this study were (1) provision of consent for laparoscopic surgery performed with the in-bag morcellation technique practiced by our research group and (2) magnetic resonance imaging (MRI) confirmation that the uterine fundus was caudal to the umbilicus. Exclusion criteria were (1) a contraindication for general anesthesia based on a risk of complications and (2) suspicion of malignancy based on preoperative MRI or endometrial cytology.

For evaluation of our morcellation technique, the following clinical data were obtained: patient age, obstetric history, surgical history, and body mass index (BMI); indications for surgery; additional procedures performed, operation time, weight of the surgical specimen, and estimated blood loss; and variables related to morcellation, i.e., bag introduction time (time from bag insertion to start of abdominal insufflation and morcellation), bag removal time (time to removal of the bag from the body and resumption of intraperitoneal observation), and in-bag morcellation time. Whether or not operative or postoperative complications occurred was also determined.

Values are shown as median and range or mean \pm SD. Descriptive statistics were calculated with Microsoft Office Excel 2007.

The single-site in-bag morcellation technique

The open method was used for port insertion at the umbilicus. A 20-mm incision was made, and a Lap-Protector (Hakko, Nagano, Japan) was inserted into the umbilical incision as a wound retractor and edge protector. An EZ Access port, which is actually a cap designed for single-site surgery and establishment of pneumoperitoneum, was then attached to the Lap-Protector (Hakko). EZ Access is made of silicone rubber and allows direct puncture by 2 or 3 trocars. The outside diameter is 75 mm, and the center section where the trocars are inserted is 30 mm in diameter. Attachment of the cap was followed by puncture with a 12-mm trocar to begin the operation (Fig. 1a) (Video 1). Four trocars were placed, as reported previously [4].

Upon completion of the primary operative procedure, the pneumoperitoneum cap was removed with withdrawal of the specimen. A folded isolation bag (3M Steri-Drape Isolation Bag 1003; 3M Corp, St. Paul, MN) was introduced into the peritoneal cavity (Fig. 1b). The pneumoperitoneum cap was re-attached, and the specimen was placed into the isolation bag under laparoscopic guidance. The mouth of the bag was guided to the umbilicus and then exteriorized. The Lap-Protector was removed and then re-attached, as if to pinch the abdominal wall and the isolation bag (Fig. 1c) (Video 2). The pneumoperitoneum cap, into which a cordless electric morcellator with its 5-mm trocar, the LiNA Xcise (LiNA Medical, Glostrup, Denmark), is inserted by direct puncture, was carefully placed over the Lap-Protector (Fig. 1d) (Video 3). Attachment of the pneumoperitoneum cap requires 2 surgeons. Thus, the morcellator was held by the second assistant. Abdominal insufflation was started via the 5-mm trocar. The abdominal insufflation pressure is usually 12 mmHg, but the bag we use allows for greater inflation and yields an expanded visual field when the pressure is raised to 16–20 mmHg in patients undergoing in-bag morcellation. To secure the visual field, we used a 5-mm flexible scope (Olympus, Tokyo, Japan) to view both the bag and the morcellator (Fig. 1e). After collection of the surgical specimen,

the pneumoperitoneum cap with morcellator and the Lap-Protector were removed, and the isolation bag was retrieved. The isolation bag was rinsed with physiological saline to confirm the absence of leakage and damage (Fig. 1f).

For a final intraperitoneal inspection, a new pneumoperitoneum cap with a 12-mm trocar and wound retractor were attached at the umbilicus. The flexible scope was used only for the in-bag morcellation.

Results

Single-site in-bag morcellation was performed in 9 patients undergoing laparoscopic myomectomy and in 3 patients undergoing total laparoscopic hysterectomy. Median patient age was 36 years (range, 32–47 years), median BMI was 21.3 (range, 19.0–27.4), only 1 patient had delivered a child (gravida 1 para 1), and 2 patients had had at least 1 previous abdominal surgery. The indications for the gynecologic surgery were infertility in 5 patients and dysmenorrhea or hypermenorrhea in 7, with 3 of these 7 patients requiring hysterectomy.

No additional procedures were required in any of the 12 patients, and there were no up-conversions to laparotomy or blood transfusions. Mean operation time was 115.9 min (range, 72–158 min), mean estimated blood loss was 63.5 ml (range, 10–200 ml), mean specimen weight was 232.9 g (range, 35–625 g), mean bag introduction time was 21.8 min (range, 14–37 min), mean in-bag morcellation time was 11.5 min (range, 1–26 min), mean bag removal time was 3.5 min (range, 2–9 min), and mean total morcellation time was 36.8 min (range, 19–66 min). Upon physiological saline testing, no isolation bag leakage was discovered in any case. Neither surgical pathology nor post-surgical histopathologic analysis of the tumor specimens revealed malignancy in any case. All patients were discharged on hospital day 3, per the clinical path we established.

No postoperative complications were noted during follow-up at the outpatient clinic, and no patient required re-operation.

Discussion

In our quest to find a satisfactory in-bag morcellation and retrieval method, we conducted a PubMed search of the literature pertaining to in-bag morcellation. Our search was limited to English-language articles pertaining to laparoscopic surgery and focused particularly on in-bag morcellation for gynecologic procedures. The papers that we found describing use of an abdominal approach for electric morcellation are listed in Table 1.

Einarsson et al. were the first to report an attempt to perform electric morcellation after the FDA statement was issued [5]. In many of the subsequently reported attempts [6–11], an isolation bag with 2 openings was used, with 1 opening being the mouth of the bag and the other a small opening that was created by puncturing the bag with the pointed end of a balloon-tipped trocar. Both openings were shielded. We refer to this method as “double-opening bag morcellation” [5–11]. With this method, leakage from the puncture site is a possibility, and adherence of tumor cells to the surface of the trocar cannot be ruled out at the time of trocar removal. Thus, there is a risk of disease metastasis. An in vitro study was carried out to evaluate the safety of double-opening bag morcellation and revealed that leakage occurred with some types of bags that were used [12]. A subsequent in vivo prospective study disclosed spillage in 7 (9.2%) of 76 cases, leading the authors to conclude that any method that involves creation of a second opening by puncturing the bag with a trocar cannot be viewed as a true containment method [13].

There are also reports describing a method in which contained power morcellation is achieved in a surgical glove. The specimen is

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