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Instruments and Techniques

Laparoscopic Morcellator-Related Complications

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ABSTRACT Morcellation at laparoscopy is a commonly used minimally invasive method to extract bulky tissue from the abdomen without extending abdominal incisions. Despite widespread use of morcellation, complications still remain underreported and poorly understood. We performed a systematic review of surgical centers in the United States to identify, collate and update the morcellator-related injuries and near misses associated with powered tissue removal. We searched articles on morcellator-related injuries published from 1993 through June 2013. In addition, all cases reported to MedSun and the FDA device database (MAUDE) were evaluated for inclusion. We used the search terms "morcellation," "morcellator," "parasitic," and "retained" and model name keywords "Morcellex," "MOREsolution," "PlasmaSORD," "Powerplus," "Rotocut," "SAWALHE," "Steiner," and "X-Tract." During the past 15 years, 55 complications were identified. Injuries involved the small and large bowels (n = 31), vascular system (n = 27), kidney (n = 3), ureter (n = 3), bladder (n = 1), and diaphragm (n = 1). Of these injuries, 11 involved more than 1 organ. Complications were identified intraoperatively in most patients (n = 37 [66%]); however, the remainder were not identified until up to 10 days postoperatively. Surgeon inexperience was a contributing factor in most cases in which a cause was ascribed. Six deaths were attributed to morcellator-related complications. Nearly all major complications were identified from the FDA device database and not from the published literature. The laparoscopic morcellator has substantially expanded our ability to complete procedures using minimally invasive techniques. Associated with this opportunity have been increasing reports of major and minor intraoperative complications. These complications are largely unreported, likely because of publication bias associated with catastrophic events. Surgeon experience likely confers some protection against these injuries. Understanding and implementing safe practices associated with the use of the laparoscopic morcellator will reduce these iatrogenic injuries. Journal of Minimally Invasive Gynecology (2014) 21, 486–491 © 2014 AAGL. All rights reserved.

Keywords: Blue Endo; Fibroids; Laparoscopic; Laparoscopy; Leiomyoma; Leiomyomata; Morcellation; Morcellator; Morcellex; MOREsolution; Parasitic; PlasmaSORD; Powerplus; Retained; Rotocut; SAWALHE; Steiner; X-Tract

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Laparoscopic morcellation is an established technique for removing bulky tissue from the abdomen without the need to substantially extend port-site incisions. Initially, morcellation was performed using a hand-activated device that required time-consuming repetitive motions. Other reports of tissue extraction described the introduction of a scalpel directly through an abdominal incision, manually creating tissues samples small enough to extrude through the port site or cul-de-sac. In 1993, the first electronic morcellator was introduced [1]. First applied for uterine extraction, it was later used to remove other organs such as kidney and spleen and lesions such as myomas. Despite 20 years of experience coupled with widespread acceptance of several morcellators in the United States market, reports of complications are lacking.

A report from 2003 summarized the laparoscopic morcellator-related injuries to date [2]. The authors described 1 case and found 14 additional visceral and vascular injuries using the US Food and Drug Association (FDA) database. Since then, several other morcellators

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have been added to the surgical armamentarium, making this a timely reanalysis. We performed a systematic review to identify complications, near misses, and device malfunctions associated with the laparoscopic morcellator.

Materials and Methods

The FDA operates the Medical Device Reporting (MDR) and Manufacturer and User Facility Device Experience (MAUDE) databases. The MDR database enables one to search for information about medical devices that may have malfunctioned or caused a death or serious injury during 1992 through 1996. Searchable data in the MAUDE system provide reports of adverse events involving medical devices. The data consist of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. These voluntary reporting systems can be accessed through the FDA websites http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm (MDR) and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm (MAUDE).

The FDA also provides an adverse event reporting program called MedSun, which is designed to work collaboratively with the clinical community to identify, understand, and solve problems associated with the use of medical devices. This system, launched in 2002, enabled further understanding of device malfunctions associated with powered tissue removal.

In addition, we screened the medical literature published before and after FDA approval of the electric morcellator in 1993. The following key words and search terms for all database and literature were used: "Blue Endo," "LiNA," "Morce," "morcellator," "Morcellex," "Sawalhe," "SORD," "Steiner," and "X-Tract" and keyword combinations of fibroids, laparoscopic, parasitic, and retained. All languages and publication types were included. Bibliographies of pertinent articles and reviews were searched for additional references. Relevant textbooks and foreign-language articles were also reviewed.

Results

Table 1 gives a summary of the morcellators currently available in the United States for each device. The diameter of the morcellator outer sheath ranges from 12 to 20 mm, with speeds up to 1200 revolutions per minute. One morcellator is completely disposable, and another is completely reusable. Most have some reusable and disposable parts. Most use a foot pedal for activation. One device has no moving parts and uses bipolar technology for morcellation.

As morcellators have become more commonplace, morcellator-related injuries have increased. The frequency of morcellator injuries during the past 15 years is shown in Figure 1. From 1992 to 2012, a total of 55 complications were identified (Table 2). Injuries were to the small and large bowels (n = 31), vascular system (n = 27), kidney (n = 3), ureter (n = 3), bladder (n = 1), and diaphragm (n = 1). Of these injuries, 11 involved more than 1 organ. Complications were identified intraoperatively in most patients (n = 37 [66%]); however, the remainder were not identified until up to 10 days postoperatively. Six patients died of morcellator-related complications.

No single manufacturer was solely associated with visceral and vascular injuries (Table 3). The Gynecare products, X-Tract and Morcellex (Ethicon, Inc., Somerville, NJ), were more commonly identified, likely reflecting the market share and length of time that the devices have been available. Similarly, the Blue Endo morcellator (Blue Endo, Lenexa, KS) was not identified in any reported cases, likely because of its recent release.

A range of procedures was associated with morcellator injuries across all surgical specialties, with no type of surgery overly represented (Table 4).

Table 1

Description of morcellator models

Morcellator; manufacturer	Date introduced	Diameter, mm	Revolutions per minute, range	Features
PKS PlasmaSORD; Olympus, Center Valley, PA	May 2008	12	NA	Disposable handpiece, bladeless, bipolar technology
ROTOCUT G1; Karl Storz GmbH & Co., Tuttlingen, Germany	July 2006	12 or 15	0–1200	Disposable blade, Motor in handpiece
Gynecare Morcellex; Ethicon, Inc., Somerville, NJ	July 2006	15	125–1000	Hand or foot activation, disposable handpiece, motor in generator box
Gynecare X-Tract; Ethicon, Inc., Somerville, NJ	February 2000	12	125–1000	Foot activation, disposable handpiece, motor in generator box
Morce Power Plus; Richard Wolf GmbH; Knittlingen, Germany	June 2009	12, 15, or 20	100–1000	Reusable blade, motor in generator box
MOREsolution; Blue Endo, Lenexa, KS	March 2011	12.5, 15, or 20	100–800	Hand or foot activation, motor in generator box
Xcise; LiNA Medical, Norcross, GA	March 2011	15	1000	Cordless, completely disposable, 5-hour battery life, motor in handpiece

NA = not applicable.