ORIGINAL ARTICLE

CrossMark

Manual morcellation compared to power morcellation during robotic myomectomy

Derrick J. Sanderson[1] · Rohnn Sanderson[2] · Dana Cleason[1] · Catherine Seaman[3] · Ali Ghomi[1]

Abstract

Clinical practice has drastically changed following the 2014 U.S. Food and Drug Administration (FDA) warning statement regarding power morcellation during laparoscopic hysterectomy and myomectomy. Despite investigation into alternative tissue extraction techniques, there remain a paucity of data associated with contained manual morcellation techniques. The goal of this study was to investigate the associated perioperative outcomes of contained manual morcellation compared to power morcellation in women undergoing robotic myomectomy. Performing manual morcellation ($n = 38$) resulted in a 21-min decrease in mean operative time (105.4 ± 42.2 vs 126.1 ± 44.1 min, $p = 0.02$) compared to power morcellation ($n = 62$). Women were younger (33 vs 36 years, $p = 0.03$) in the manual morcellation group, with all other patient demographics being similar. Median specimen weight (82 vs 104 g, $p = 0.13$), number of fibroids removed (2 vs 1, $p = 0.16$), estimated blood loss (10 vs 50 mL, $p = 0.25$), and post-operative morphine equivalents administered (5.57 ± 4.57 vs 5.29 ± 4.39, $p = 0.76$) were similar. The same-day discharge rate was not significantly different between the groups (86 vs 90%, $p = 0.74$). Linear regression modeling identified specimen weight, number of fibroids removed, and use of power morcellation as significant contributors to surgical time. Contained manual morcellation during robotic myomectomy is associated with a significant decrease in surgical time when compared to power morcellation, with similar post-operative narcotic administration and length of stay.

Keywords Robotic myomectomy · Myomectomy · Minimally invasive surgery · Manual morcellation · Power morcellation · Minilaparotomy · Hospital stay

Introduction

Use of intraperitoneal electromechanical power morcellation quickly became routine during endoscopic gynecologic procedures following its introduction to the market in 1993 [1, 2]. Visceral and vascular injuries occurred rarely, and the benefits were believed to outweigh the associated risks

[3]. Over time concerns were raised regarding dissemination of occult malignancy, prompting the U.S. Food and Drug Administration (FDA) to issue a warning statement against the use power morcellation during laparoscopic hysterectomy and myomectomy [4, 5]. The medical-legal fallout had a drastic impact on clinical practice patterns and has all but eliminated the use of electric power morcellators in the United States [6–9].

Investigation into alternative tissue extraction techniques is now well published in the literature. Alternative techniques include contained intraperitoneal power morcellation, vaginal tissue extraction, contained extracorporeal morcellation through an extended midline incision, and use of a minilaparotomy incision [10–15].

There remain a paucity of data associated with contained manual morcellation despite the potential risks of non-contained tissue extraction. The objective of this study is to compare the perioperative outcomes associated with power morcellation to contained manual morcellation in women

undergoing robotic myomectomy, before and after the FDA warning statement.

Materials and methods

After obtaining approval from the Sisters of Charity Hospital Institutional Review Board (IRB) (898290-1), subjects' recruitment began with identification of charts using the current procedure terminology (CPT) codes (CPT 58545 and 58546, for laparoscopic myomectomy, 1–4 myomas, and 5 or more myomas). All procedures were performed between October 2010 and January 2017 at Sisters of Charity Hospital Main Street campus or St. Joseph campus in Buffalo, New York by a single minimally invasive robotic gynecologic surgeon, author AG.

All subjects over the age of 18 who underwent robotic myomectomy for benign indication during the study period were eligible for inclusion. Exclusion criteria included the traditional laparoscopic myomectomy and hysteroscopic myomectomy, as well as any procedures performed for malignancy. Women with contained extracorporeal manual morcellation using surgical scalpel had procedures performed after the 2014 FDA warning statement, while all procedures involving the electric power morcellator occurred prior to the warning statement.

All patients underwent robotic myomectomy using the da Vinci® Surgical System Si (Intuitive Surgical, Sunnyvale, CA, USA) with multilayer myometrial bed closure as previously reported [16].

Manual morcellation technique

Fibroids were placed into a laparoscopic specimen bag (Inzii 12/15 mm Retrieval System, Applied Medical, Rancho Santa Margarita, CA, USA) and brought through the midline 12-mm trocar. Pneumoperitoneum and Trendelenburg positioning were then relieved, and the skin and fascial incisions were then extended cephalad to 4 cm. A small Alexis O Wound Protector/Retractor® (Applied Medical, Rancho Santa Margarita, CA, USA) was then placed and the constant upward traction was applied to the specimen bag. Under direct visualization, the fibroids were grasped with clamps and manual morcellated with a surgical scalpel. Local anesthetic was injected into the subcutaneous, fascia, and peritoneal layers of the incision. The wound retractor was then removed, and the peritoneal and fascial edges were re-approximated with interrupted stitches of 0-0 Ethibond-Excel® (Ethicon US, Cincinnati, OH, USA) and Vicryl® (Ethicon US, Cincinnati, OH, USA) suture.

The remaining incisions were injected with local anesthetic and closed using either 3-0 Vicryl® (Ethicon US, Cincinnati, OH, USA) in a subcuticular fashion or interrupted stitches of 3-0 Prolene® (Ethicon US, Cincinnati, OH, USA). All patients received dose-adjusted intravenous ketorolac prior to leaving the operating room if no contraindications were noted at time of surgery.

Power morcellation technique

All fibroids were morcellated through a 10-mm assistant port using a laparoscopic electric power morcellator (Karl Stroz, Tuttlingen, Germany). Tissue scavenge was then performed, attempting to remove as much debris as possible. The incisions were the injected with local anesthetic and closed using 3-0 Vicryl® (Ethicon US, Cincinnati, OH, USA) in a subcuticular fashion or interrupted stitches of 3-0 Prolene® (Ethicon US, Cincinnati, OH, USA). All patients received dose-adjusted intravenous ketorolac prior to leaving the operating room if no contraindications were noted at time of surgery.

Data collection and analysis

Data were collected from both the electronic medical record (EMR) and paper charts. Demographics collected were age, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, gravidity, parity, and surgical history. Perioperative data extracted included incision-to-closure surgical time in minutes, estimated blood loss (EBL), the number of fibroids removed, specimen weight in grams, the morphine milligram equivalents (MME) administered in the post-anesthesia care unit (PACU), specimen extraction technique, concomitant procedures performed, laparotomic conversion, and length of stay (defined as 0 for a same day discharge and 1 for an overnight stay). The MME was calculated using conversion factors provided by the Center for Disease Control and Prevention (CDC) (https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf).

Parametric and nonparametric tests were performed to compare the groups. Categorical variables are reported as numbers and percentages, with analysis performed using R version 3.2.3 via R Studio [17–20]. Continuous data were analyzed with Welch's t test to accommodate the difference in sample size and variance with a confidence interval (CI) of 95% and $p < 0.05$ considered statistically significant [21]. Categorical data were compared with Chi-square test, Fisher's exact test, or Mann–Whitney U test when appropriate with $p < 0.05$ considered significant [22]. Multivariate regression analysis was performed in a step-wise fashion with a significance level of, $p < 0.05$. The final model was validated using bootstrapping methods with 1000 iterations to overcome potential bias due to the step-wise reduction of variables.

Results

In total, 100 women were identified for inclusion, with 38 women in the manual morcellation group and 62 women had a power morcellation group. There were no significant differences between the groups in BMI, ASA classification, gravidity, parity, or surgical history (Table 1). Women with manual morcellation had an average age of 33.4 ± 7.0 years compared to 36.6 ± 6.9 years, $p = 0.03$.

Perioperative comparisons are tabulated in Table 2. There were no significant differences in the concomitant procedures performed between the groups. Mean surgical time was significantly reduced by 20.7 min ($p = 0.02$) in those with manual morcellation compared to power morcellation (105.39 ± 42.15 [95% CI 91.13, 119.65] vs 126.11 ± 44.06 [95% CI 114.93, 137.30]). Surgical times in the manual morcellation group ranged from 46 to 221 min compared to 57–250 min in the power morcellation group. Median EBL for the manual morcellation group was 10 mL (IQR: 10,150 mL) and 50 mL for the power morcellation group (IQR: 10,100 mL), $p = 0.16$.

Specimen weight was available in the pathology report for 35 (92%) in the manual morcellation group and 53 (85%) in the power morcellation group. The groups were similar in terms of the number of fibroids removed ($p = 0.16$) and weight of specimen extracted ($p = 0.13$). The manual morcellation group had a median of 87 g fibroid(s) removed (IQR: 30, 189 g) with a median of two fibroids removed (IQR: 1, 5) per case, compared to a median weight of 104 g (IQR: 66.7, 254 g) and a median of 1 fibroid removed (IQR: 1, 3). Data regarding fibroid size were not reliably available in the accessible medical record used for this study and was not included in the analysis.

Narcotic administration in the PACU was similar. Women in the manual morcellation group required an average of 5.57 ± 4.57 MME [95% CI 4.302, 7.12] compared to an average of 5.29 ± 4.39 MME [95% CI 4.17, 6.40] for those with power morcellation. The length of hospital stay was not affected by tissue extraction technique, with 33 (87%) of

Table 1 Patient demographics

	Manual morcellation ($n=38$)	Power morcellation ($n=62$)	p value
Mean age, year (SD) [95% CI]	$33.39 \pm (7.02)$ [31.01, 35.76]	$36.56 \pm (6.87)$ [34.82, 38.31]	0.03*
Mean BMI, kg/m^2 (SD) [95% CI]	$32.67 \pm (10.01)$ [29.23, 36.11]	$30.17 \pm (9.40)$ [27.76, 32.57]	0.23*
Median ASA classification	2	2	0.75†
1, n (%)	8 (21.05%)	17 (27.42%)	
2, n (%)	28 (73.68%)	42 (67.74%)	
≥ 3, n (%)	0	2 (3.23%)	
Median gravidity	0	1	0.88‡
0, n (%)	17 (44.74%)	26 (41.94%)	
1, n (%)	7 (18.42%)	15 (24.19%)	
2, n (%)	3 (7.90%)	7 (11.29%)	
≥ 3, n (%)	5 (13.16%)	11 (17.74%)	
Median parity	0	0	0.26‡
0, n (%)	25 (65.79%)	35 (56.45%)	
1, n (%)	4 (10.53%)	16 (25.81%)	
2, n (%)	1 (2.63%)	5 (8.06%)	
≥ 3, n (%)	2 (5.25%)	4 (6.45%)	
Previous cesarean section, n (%)			0.34‡
1	12 (31.58%)	12 (19.35%)	
2	1 (2.63%)	1 (1.61%)	
Previous laparoscopy, n (%)			0.44‡
1	7 (18.42%)	12 (19.35%)	
≥ 2	1 (2.63%)	0	
Previous laparotomy, n (%)			0.53‡
1	5 (13.16%)	5 (8.07%)	
2	0	1 (1.61%)	

ASA American Society of Anesthesia, *BMI* body mass index (kg/m^2)

*p value calculated by unpaired t test

†p value calculated by Mann–Whitney U test

‡p value calculated χ^2

Table 2 Perioperative variables

	Manual morcellation ($n = 38$)	Power morcellation ($n = 62$)	p value
Mean surgical time, min (SD) [95% CI]	105.39 ± (42.15) [91.13, 119.65]	126.11 ± (44.06) [114.93, 137.30]	0.02*
Median EBL, mL [IQR]	10 [10, 150]	50 [10, 100]	0.25[†]
Median # fibroids removed [IQR]	2 [1, 5]	1 [1, 3]	0.16[†]
Median specimen weight (g) [IQR]	87 [30, 189]	104 [66.7, 254]	0.13[†]
Mean MME (SD) [95% CI]	5.57 ± (4.57) [4.02, 7.12]	5.29 ± (4.39) [4.17, 6.40]	0.76*
LOS, n (days)			0.74[‡]
0	33	56	
1	5	6	
Resection of endometriosis, n (%)	4 (10.53%)	8 (12.90%)	1.00[‡]
Enterolysis/LOA, n (%)	4 (10.53%)	4 (6.45%)	0.47[‡]
Ovarian cystectomy, n (%)	1 (2.63%)	2 (3.23%)	1.00[‡]
Tubal surgery, n (%)	2 (5.26%)	2 (3.23%)	0.64[‡]

EBL estimated blood loss, *MME* milligram morphine equivalents, *LOS* length of stay

*p value calculated using unpaired t test

[†]p value calculated using Mann–Whitney U test

[‡]p value calculated using Fisher's exact test

women who had manual morcellation were discharge on the same day compared to 56 (90%) in the power morcellation group; $p = 0.74$.

There were no incisional hernias encountered in either group during the early post-operative (6-week) period, although one subject in the manual morcellation group was readmitted for post-operative ileus.

Multivariate step-wise regression analysis with bootstrap validation was performed and the final model created (Table 3). Manual morcellation decreased surgical time by an average of 28 min per procedure; $p < 0.01$. Surgical time increased by 5 min for every fibroid removed and 7 s were added for every gram of fibroid removed; $p < 0.01$. Although not statistically significant for inclusion in the final

Table 3 Multivariate linear regression analysis for factors impact on surgical time

Variable	Multivariate model[a]		Final multivariant model[b]	
	Coefficient [95% CI]	p value	Coefficient [95% CI]	p value
Intercept	69.20 [24.74, 111.67]	<0.01	65.57 [30.96, 63.15]	<0.01
Power morcellator	27.18 [7.34, 47.01]	0.01	28.01 [39.74, 72.52]	<0.01
Fibroids removed	5.84 [3.02, 8.67]	<0.01	5.75 [4.44, 8.66]	<0.01
Specimen weight (g)	0.13 [0.07, 0.19]	<0.01	0.11 [0.06, 0.16]	<0.01
Ovarian cystectomy	33.21 [−11.04, 77.47]	0.12		
Age > 35	5.47 [−12.11, 23.05]	0.53		
BMI	−0.31 [−1.29, 0.68]	0.53		
ASA class > 2	−6.71 [−61.04 to 47.62]	0.81		
Gravidity > 1	−12.15 [−35.11, 10.81]	0.30		
Parity > 1	21.35 [−13.98, 56.67]	0.22		
EBL	0.03 [−0.05, 0.11]	0.46		
Resection of endometriosis	14.31 [−22.96, 51.59]	0.46		
Enterolysis/LOA	0.34 [−31.91, 32.60]	0.98		
Tubal surgery	12.63 [−45.74, 71.00]	0.67		
Previous cesarean section	3.42 [−15.11, 21.96]	0.75		
Previous laparoscopy	−0.47 [−13.73, 12.80]	0.93		
Previous laparotomy	−12.14 [−40.14, 15.87]	0.40		

BMI body mass index, *ASA* American Society of Anesthesia, *EBL* estimated blood loss

[a]Adjusted $R^2 = 0.39$, $p < 0.05$

[b]Adjusted $R^2 = 0.45$, $p < 0.05$

regression model, performance of concomitant ovarian cystectomy added 33 min of surgical time within the model.

Discussion

Surgical practice has been drastically altered by the 2014 FDA warning statement regarding use of laparoscopic power morcellation [4–8]. The purpose of this study was to analyze the perioperative outcomes associated with contained manual morcellation compared to the traditional intraperitoneal power morcellation.

The technique described was associated with a 21-min decrease in mean surgical time with similarities between the groups noted in the number of fibroids removed, fibroid weight, estimated blood loss, surgical history, and concomitant procedures performed. Regression modeling confirmed the impact that the tissue extraction technique had on surgical efficiency, noting an average decrease in surgical time of 28 min. This difference is due to improved access to the specimen through the enlarged incision and the elimination of technical challenges associated with intraperitoneal power morcellation.

A significant decrease in surgical time, 44 min, was noted by Dubin et al. [23] in 270 women who underwent myomectomy and had fibroids removed through a 3–6-cm minilaparotomy incision compared to 135 myomectomies with power morcellation with a median fibroid weight of 246 g. However, comparison is limited as only 46 of the 270 myomectomies within the minilaparotomy group were performed by a laparoscopic/robotic approach and fibroid weight was missing in 75% of the pathology reports.

Two randomized-controlled trials have compared open power morcellation to contained manual morcellation [14, 15]. Frasca et al. reported a 3-min increase in morcellation time and a 16-min increase in total operative time when using contained manual morcellation [14]. The technique describes extending a 10 mm centrally located trocar site to 20 mm to perform the morcellation and removal of 1.65 fibroids [14]. Venturella et al. [15] also converted a centrally located 10-mm trocar incision to 30 mm for contained manual morcellation. Morcellation (6.77 vs 7.50 min) and total operative (96.96 vs 92.07 min) times were similar for contained manual morcellation compared to the traditional power morcellation, removing an average of 1.37 and 1.43 fibroids in each group [15]. Our results highlight the improved efficiency offered with increased incisional length.

The technique that we present is most similar to the ExCITE technique described by Troung and Advincula [12]. Differences include discontinuation of pneumoperitoneum, during specimen extraction and maintenance of intact linear specimen [12]. However, it is our opinion that maintaining pneumoperitoneum during morcellation is not necessary as

traction placed on the specimen with clamps and the specimen bag allow for a safe morcellation. In addition, ventilation improves with relief of pneumoperitoneum and Trendelenburg position which allows the recovery process to begin.

There were no wound complications noted within the perioperative period in those patients with manual morcellation tissue extraction. A similar finding was noted by Dubin et al. in a sub-analysis comparing wound complications associated with tissue extraction through a minilaparotomy following laparoscopic/robotic myomectomy [21]. There were no cases of post-operative incisional hernias encountered during the early post-operative period in either group. In addition, there was no documentation of post-operative incisional hernia in either the manual morcellation group or power morcellation group during the study period. However, due to the limitations associated with retrospective data collection, we are unable to definitively comment about the incidence incisional hernia in any subject beyond the early post-operative period as follow-up with the surgeon is not routine, subjects may not seek treatment for a non-bothersome hernia, and documentation of an incisional hernia may be present in an unavailable medical record. One subject from the manual morcellation group was readmitted to the hospital for management of post-operative ileus. She was managed with nasogastric tube (NGT) drainage and discharged to home tolerating a diet with bowel function.

Length of stay was similar between the groups, with most patients being discharged on the same day. Same-day discharge and low readmission rates are significant benefits associated with minimally invasive myomectomy [23, 24]. Our findings suggest that the use of an extended midline trocar incision for tissue extraction does not cause a significant change in procedure tolerance, maintaining the benefits of minimally invasive surgery.

Our study does have several limitations. The retrospective design allows for selection bias which cannot be completely overcome by the large sample sizes of each group. The groups were selected based upon the FDA warning statement, not by randomization or patient selections, which may have an unrecognized influence on outcomes. Data collection was limited to the information available within the hospital electronic medical record. A more accurate analysis would be possible with a specifically delineated morcellation time, instead of skin incision-to-closure time. Generalizability of the study may be limited due to the single-surgeon design. The authors tried to limit variations in surgical and tissue extraction technique as analysis was limited to only total operative time. Author AG is a robotic gynecologic surgical specialist, who performs an average of 14 robotic myomectomies per year. All cases performed by AG were included in the analysis, including the cases during the "learning curve" for the manual morcellation technique described. The surgeon was beyond the learning curve for

robotic myomectomy at the start of the study period. These data were not included in the analysis as this experience was obtained at a different institution prior to working at Sisters of Charity Hospital.

The technique described provides safe and efficient tissue extraction which may limit the potential for dissemination for occult malignancy [10–15] and provide an opportunity for improved cosmesis compared to creating an additional 4–6-cm suprapubic minilaparotomy for tissue extraction during robotic myomectomy.

Conclusion

Contained manual morcellation specimen extraction is associated with a significantly decreased surgical time compared to traditional open power morcellation following robot-assisted laparoscopic myomectomy, with no untoward effects caused by an increased incision size.

Compliance with ethical standards

Conflict of interest The authors Derrick J Sanderson, Rohnn Sanderson, Dana Cleason, Catherine Seaman, and Ali Ghomi declare that they have no conflicts of interest.

References

1. Steiner FA, Wight E, Tadir Y, Haller U (1993) Electrical cutting device for laparoscopic removal of tissue from the abdominal cavity. Obstet Gynecol 81:471–474
2. Carter JE, McCarus SD (1997) Laparoscopic myomectomy: time and cost analysis of power vs. manual morcellation. J Reprod Med 42:383–388
3. Moore M, Brown T, Cohen M (2004) Complications of laparoscopic morcellation. J Am Assoc Gynecol Laparosc 11:S80
4. Kho KA, Nezhat CH (2014) Evaluating risks of electric uterine morcellation. JAMA 311(9):905–906
5. U.S. Food and Drug Administration (2014) Laparoscopic uterine power morcellator in hysterectomy and myomectomy: FDA Safety Communication, issued 17 Apr 2014. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm. Accessed 12 Feb 2017
6. Lum DA, Sokol ER, Berek JS, Schulkin J, Chen L, McElwain CA, Wright JD (2016) Impact of 2014 Food and Drug Administration warnings against power morcellation. J Minim Invasive Gynecol 23(4):548–556
7. Barron KI, Richard T, Robinson TS, Lamvu G (2015) Association of the U.S. Food and Drug Administration morcellation warning with rates of minimally invasive hysterectomy and myomectomy. Obstet Gynecol 126(6):1174–1180
8. Harris JA, Swenson CW, Uppal S, Kamdar N, Mahnert N, As-Sanie S, Morgan DM (2016) Practice patterns and postoperative complications before and after US Food and Drug Administration safety communication on power morcellation. Am J Obstet Gynecol 214(1):98.e1–98.e13
9. Po L, Lee PE (2016) The unintended consequences of an FDA warning: the case of power morcellation in myoma surgery. J Minim Invasive Gynecol 23(4):597–602
10. Einarsson JI, Cohen SL, Fuchs N, Wang KC (2014) In-bag morcellation. J Minim Ivasive Gynecol 21(5):951–953
11. Paul PG, Thomas M, Das T, Patil S, Garg R (2015) Contained morcellation for laparoscopic myomectomy within a specially designed bag. J Minim Invasive Gyncol 23(2):257–260
12. Troung MD, Advincula AP (2014) The extracorporeal c-incision tissue extraction (ExCITE) technique. OBG Manag 26(11):56
13. Kho KA, Brown DN (2016) Surgical treatment of uterine fibroids within a containment system and without power morcellation. Clin Obstet Gynecol 59(1):85–92
14. Frasca C, Degli Esposti E, Arena A, Tuzzato G, Moro E, Martelli V, Seracchioli R (2018) Can in-bag manual morcellation represent an alternative to uncontained power morcellation in laparoscopic myomectomy? A randomized controlled trial. Gynecol Obstet Invest 83:52–56
15. Venturella R, Rocca ML, Lico D, La Ferrera N, Cirillo R, Gizzo S, Morelli M, Zupi E, Zullo F (2016) In-bag manual versus uncontained power morcellation for laparoscopic myomectomy: randomized controlled trial. Fertil Steril 105(5):1369–1376
16. Sanderson D, Sanderson R, Ghomi A (2016) Robot-assisted laparoscopic myomectomy: a comparison of techniques. J Gynecol Surg 32(6):329–334
17. R Core Team (2015) R: a language environment for statistical computing. Version 3.2.3. R Foundation for Statistical Computing, Vienna. https://www.r-projection.org/
18. RStudio Team (2015) RStudio: integrated development for R. RStudio, Inc., Boston. http://www.rstudio.com/
19. Canty A, Ripley B (2015) boot: Bootstrap R (S-Plus) functions. R package Version 1:3-17
20. Davison AC, Hinkley DV (1997) Bootstrap methods and their applications. Cambridge University Press, Cambridge (**ISBN 0-521-57391-2**)
21. Ruxton GD (2006) The unequal variance *t*-test is an underused alternative to Student's *t*-test and the Mann–Whitney *U* test. Behav Ecol 17(4):688–690
22. Gaddis GM, Gaddis ML (1990) Introductions to biostatics: part 5, statistical inference techniques for hypothesis testing with non-parametric data. Ann Emerg Med 19(9):1054–1059
23. Dubin AK, Wei JW, Sullivan S, Udaltsova N, Zaritsky E, Yamamoto MP (2017) Minilaparotomy versus laparoscopic myomectomy after cessation of power morcellation: rate of wound complications. JMIG 24(6):946–953
24. Alton K, Sullivan S, Udaltsova N, Yamamoto M, Zaritsky E (2016) Same-day discharge after minimally invasive myomectomy. Obstet Gynecol 127:539–544