Current Methods of Tissue Extraction in Minimally Invasive Surgical Treatment of Uterine Fibroids

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ABSTRACT

Background and Objectives: Since the 2014 Food and Drug Administration communication regarding the use of power morcellation, gynecologists have adopted alternative tissue extraction strategies. The objective of this study is to investigate the current techniques used by gynecologic surgeons for tissue extraction following minimally invasive hysterectomy or myomectomy for fibroids.

Methods: An online survey was distributed to all AAGL members and responses were collected between March 26, 2019 and April 17, 2019.

Results: Four hundred thirty-six respondents completed the survey. For hysterectomy, the most common methods of tissue extraction were manual morcellation through the colpotomy (72.4%) or minilaparotomy (66.9%). Nearly one-third (31.7%) endorsed using power morcellation. For myomectomy, manual morcellation via minilaparotomy (71.9%) was the most common approach, followed by power morcellation (35.7%). Use of containment bags was common. Minilaparotomy incisions were typically three cm and most often at the umbilicus.

Geographic differences were detected, particularly with power morcellation. During hysterectomy, 18.4% of US-based surgeons reported its use, compared to 56.9% of non-US-based surgeons. During myomectomy, 20.5% of US-based surgeons reported its use compared to 67.5% of their international counterparts. Age, years in practice, fellowship training, and practice location were all significantly associated with power morcellator use.

Conclusion: A large majority of practitioners are performing manual morcellation through the colpotomy or minilaparotomy. Use of containment bags is common with all routes of tissue removal. Power morcellation use is less common in the United States than in other countries.

Key Words: Leiomyoma, Morcellation, Survey, Tissue extraction.

INTRODUCTION

In April 2014 the U.S. Food and Drug Administration (FDA) issued a communication discouraging the use of power morcellation at the time of surgical treatment for fibroids due to the risk of occult malignancy.1-2 Concerns about morcellation include the risk of malignant tissue dissemination in cases of undiagnosed uterine leiomyosarcoma, which could result in worsened prognosis.3-6

Academic and regulatory focus on this topic has driven a notable shift in the surgical approach to tissue extraction, and in some settings, the utilization of minimally invasive modes of hysterectomy and myomectomy have decreased.7-10 This change in practice occurred despite prediction models demonstrating that the risk of complications and costs associated with abdominal surgery outweighed the benefit of avoiding morcellation in many cases.11,12 However, there is evidence that in high-volume surgical centers, outcomes did not worsen during this transition period.7
In order to perform surgery for uterine fibroids without the use of power morcellation, it may be necessary to create a minilaparotomy for tissue extraction. Additionally, the use of containment systems has been studied both with manual and power morcellation techniques. Though gynecologists have adopted alternative approaches for tissue extraction in the five years since the initial FDA communication, little is known about the specifics of current practice patterns and variations. These changes could have wide implications, including but not limited to relevant surgical complications, such as wound infections of hernias associated with minilaparotomy, technique refinement and development of novel medical devices.

The objective of this study is to investigate the techniques currently employed by gynecologic surgeons for tissue extraction following minimally invasive myomectomy and hysterectomy for fibroids.

**METHODOLOGY**

A survey was developed to assess current practices in tissue extraction for laparoscopic or robotic hysterectomy or myomectomy for the primary indication of fibroids in which the specimen is too large for intact removal through the colpotomy or existing port site. The survey specifically asked about the use of manual or power morcellation, containment bags and minilaparotomy. Minilaparotomy was defined as an incision between two to five centimeters. Questions were asked with respect to hysterectomies and myomectomies separately, and some questions were adaptive based on prior answers. There were also two questions addressing whether power morcellation was permitted at the participant’s hospital, and if so, whether there were restrictions on its use. Finally, demographic data was collected. The survey was pilot tested with multiple gynecologic surgeons of various subspecialties who regularly perform these procedures to maximize readability and validity. All survey data were collected and managed using REDCap hosted through Partners Healthcare, a secure, web-based application designed for research. The final survey instrument is included in Appendix. The survey was only available in English. Approval for the study was provided by the Partners Human Research Committee.

The survey was distributed to all AAGL members on March 26, 2019, with two additional reminders sent over one-week intervals to those who had not yet opened the email. There were no incentives, the survey was voluntary, and consent was indicated by participation. Responses were accepted through April 17, 2019 and all were kept anonymous. The sole exclusion criterion was if laparoscopic hysterectomy or myomectomy for the primary indication of fibroids was not within a participant’s current scope of practice. Respondents were allowed to review or change answers prior to final submission. Descriptive statistics, univariate, and multivariate logistic regression analyses comparing various demographic characteristics with power morcellator use were performed using STATA 15.0.

**RESULTS**

A unique survey link was distributed to all 7450 current AAGL members. Three thousand eight hundred thirty-one members opened the email, and 567 opened the survey link. Of these, 436 participants endorsed performing either hysterectomies and/or myomectomies for fibroids and completed the survey for a response rate of 11.4%. Demographic information of survey respondents is included in Table 1. The participants reflected a wide range of geographic locations, ages, training backgrounds, years in practice, and practice settings. The median participant age was 46 and there was an even distribution of ages represented. The median number of years in practice was 12, with 35.3% of respondents reporting 20 years or more. Of note, survey options for methods of tissue extraction were not mutually exclusive, and thus the percentages may add up to greater than 100%.

**Hysterectomy**

Four hundred twenty-nine respondents endorsed performing hysterectomy for fibroids; of these, six were excluded due to uninterpretable responses leaving 423 complete responses. Figure 1 demonstrates the distribution of various modes of tissue extraction. The most common approaches to tissue extraction at time of hysterectomy were manual morcellation through the colpotomy (72.3%) and minilaparotomy (66.2%). Other reported methods included power morcellation or intact removal through a laparotomy. Near one third (31.7%) of all participants endorsed the use of power morcellation. Intact specimen removal through a laparotomy was reported by 9.9% of respondents. Other methods of tissue extraction, such as intra-abdominal manual morcellation with a laparoscopic scalpel, were reported by 1.4%. Only 30.4% reported using one method exclusively, whereas most respondents reported using more than one method.

Use of containment bags, summarized in Figure 2, demonstrate heterogeneity with respect to their use with...
various morcellation sites. Containment bag usage was reported by 42.9% of respondents at the time of vaginal morcellation through the colpotomy. Whereas 84.2% of respondents endorsed containment bag use at the time of manual morcellation through a minilaparotomy, and 56.0% during power morcellation. Minilaparotomies were a median of 3 cm and most commonly located at the umbilicus.

Geographic differences were seen with respect to power morcellation, with 18.4% of US-based surgeons reporting its use compared to 57.2% of international surgeons, as shown in Figure 3. Sixty-six percent of US surgeons reported using a containment bag for power morcellation, compared to 50.6% of their international colleagues, as shown in Figure 5. Differences were also seen with

| Table 1. Continued | N  | %  |
|--------------------|----|----|
| Gynecologic Oncology | 21 | 4.8|
| Reproductive Endocrinology and Infertility | 22 | 5.0 |
| Other | 20 | 4.6 |
| Area of practice (if not fellowship trained) | | |
| General Obstetrics/Gynecology | 137 | 31.4 |
| Gynecology only | 76 | 17.4 |
| Other/unknown | 1 | 0.2 |

Table 1. Continued

| Demographic Characteristics of Survey Participants |
|---------------------------------------------------|
| N | %  |
| Age |
| ≤ 35 | 77 | 17.7 |
| 36 – 45 | 137 | 31.4 |
| 46 – 55 | 102 | 23.4 |
| ≥ 56 | 116 | 26.6 |
| Unknown | 4 | 0.9 |
| Sex |
| Female | 179 | 41.1 |
| Male | 256 | 58.7 |
| Prefer not to specify | 1 | 0.2 |
| Country/Region |
| United States | 262 | 60.1 |
| International | 143 | 32.8 |
| Africa | 2 | 0.5 |
| Asia | 34 | 7.8 |
| Australia/New Zealand | 7 | 1.6 |
| Canada | 20 | 4.6 |
| Central/South America | 30 | 6.9 |
| Europe | 34 | 7.8 |
| Middle East | 16 | 3.7 |
| Unknown | 31 | 7.1 |
| Years in practice |
| 0 – 9 | 186 | 42.7 |
| 10 – 19 | 86 | 19.7 |
| 20 – 29 | 88 | 20.2 |
| ≥ 30 | 66 | 15.1 |
| Unknown | 10 | 2.3 |
| Practice setting |
| Academic hospital | 147 | 33.7 |
| Private/Community hospital | 167 | 38.3 |
| Both academic and private hospital | 106 | 24.3 |
| Other/unknown | 16 | 3.7 |
| Fellowship trained |
| Yes | 215 | 49.3 |
| No | 214 | 49.1 |
| Unknown | 7 | 1.6 |
| Fellowship background |
| Minimally Invasive Gynecologic Surgery | 179 | 41.1 |
| Urogynecology/ Female Pelvic Medicine and Reconstructive Surgery | 24 | 5.5 |

Figure 1. Modes of tissue extraction for hysterectomy and myomectomy.

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respect to minilaparotomy, with 81.2% of US-based surgeons reporting the use of minilaparotomy, compared to 39.1% of their international counterparts. Rates of intact specimen retrieval through a laparotomy were comparable between US and international surgeons, at 9.4% and 10.9%, respectively.

Myomectomy

Three hundred ninety-two participants reported performing laparoscopic or robotic myomectomy for fibroids; however, eight responses were excluded due to missing data, resulting in 385 complete responses. Figure 1 demonstrates the distribution of various modes of tissue extraction. The most common for myomectomies was manual morcellation via minilaparotomy, which was reported by 71.9% of respondents. Of these respondents, 82.6% reported using this method exclusively or as a first choice. Other methods included power morcellation (35.7%), manual morcellation through the posterior cul-de-sac (12.8%), and intact removal through a laparotomy (7.6%). Three (0.8%) respondents reported “other” without further clarification.

Practice patterns with respect to containment bags were assessed. Of those performing manual morcellation through the posterior cul-de-sac, approximately half (48.0%) endorsed using a containment bag. In the setting of manual morcellation through a minilaparotomy, 84.8% of all respondents reported using a containment bag. These values, as well as differences seen between US-based and international surgeons, are demonstrated in Figure 2. A slight majority (54.0%) of those using power morcellation reported using a containment bag.

Regarding minilaparotomy, the median incision length was 3 cm. The most common location was at the umbilicus (68.8%). However, survey participants also reported using suprapubic incisions (39.9%), extension of a lateral port site (9.8%), and supraumbilical incisions (2.2%).

There were geographic differences noted with respect to myomectomy as well. A large majority (87.8%) of US-based surgeons reported utilizing manual morcellation via minilaparotomy compared to a minority (39.8%) of international surgeons. With power morcellation, only 20.5% of US-based surgeons reported its use compared to 67.5% of international respondents, as shown in Figure 4. US surgeons were also more likely to use a containment system during power morcellation, as demonstrated in Figure 5. A majority (74.8%) of international participants reported intact specimen retrieval through a laparotomy compared to 5.3% of American participants.

Power Morcellation

Overall, 51.8% of respondents stated that power morcellation was permitted at their hospital, 40.6% stated that it was not. An additional 8.7% did not know, and one individual reported that though power morcellation was allowed, there was no actual device available within the hospital.
facility. Notable geographic differences emerged, with only 37.4% of US-based participants reporting that power morcellation was allowed at their institution compared to 78.3% of international participants. Univariate analyses revealed significant regional differences within the US with regard to the use of power morcellation. In comparison with surgeons in the Northeast, those in the Midwest (odds ratio [OR] 7.1, confidence interval [CI] 1.9–26.9) and West (OR 9.4, CI 2.6–33.9) report using power morcellation more often. There was no significant difference between those in the Northeast and Southeast (Table 2).

Figure 5. Overall use of power morcellation for hysterectomy and myomectomy by practice region, with proportion using a containment bag.

Table 2 also describes other demographic characteristics that were significantly associated with power morcellator use, including country of practice outside of the US, increasing age, years in practice, and fellowship training. Odds of power morcellator use increased by 2.5% (1.01–1.04, p = 0.004) with each year of surgeon age and by 1.6% (1.0–1.03, p = 0.044) with each year in practice. Gender and practice setting (i.e., academic or private) showed no significant association. An international practice setting was by far the strongest predictor of power morcellator use after controlling for age, years in practice, and fellowship background.

DISCUSSION/CONCLUSIONS

A variety of tissue extraction techniques are currently being employed across the country and the globe. There is marked heterogeneity among strategies employed for removal of large uteri; however, the most common appear to be manual morcellation through the colpotomy or a minilaparotomy. For myomectomies, manual morcellation via minilaparotomy was the most common and often exclusive method of tissue extraction. These data demonstrate that there are many ways in which gynecologists are able to continue providing a minimally invasive option to patients while avoiding the morbidity of open surgery.

Other surveys have been conducted studying the changes in rates of and attitudes surrounding power morcellator use and have found increased rates of laparotomy;
however, none of these have investigated any alternative minimally invasive methods of tissue extraction.\textsuperscript{17–19} Our data is most comparable to that of Desai and colleagues, who surveyed 46 AAGL Fellowship in Minimally Invasive Gynecologic Surgery program directors, and found that 81\% had changed their practice in response to the FDA warnings in November 2014. Consistent with our results, these changes included the adoption of minilaparotomy and/or containment bags, as well as alternative routes of hysterectomy.\textsuperscript{9} However, our study is unique in the larger sample size and diversity of practice backgrounds, which included many surgeons who operate in private or community hospital settings, as well as those who are not fellowship trained.

Power morcellation restrictions are far more common among US hospitals than international ones, which corresponded to disparate rates of use. Lum and colleagues reported that 60.8\% of their respondents, all of whom were US-based, had stopped using power morcellation entirely after the warnings were issued.\textsuperscript{8} This is comparable to our data and suggests that though three years have passed since that survey, rates of power morcellator use remain low among US surgeons. Within the US, some of the regional differences in power morcellator use may be explained by the ripple effect of the highly publicized report of disseminated leiomyosarcoma occurring in the Northeast.

There are many providers who use a containment bag for tissue extraction for manual morcellation through a minilaparotomy, but not through a colpotomy. Multiple studies have demonstrated that tumor morcellation during initial surgery for presumed leiomyoma was associated with a decrease in both disease-free and overall survival.\textsuperscript{5–6} Despite some data suggesting that, in the context of vaginal hysterectomy, patient outcomes are not worsened by uncontained morcellation,\textsuperscript{20} two large reviews have found that morcellation or tumor disruption by any route is associated with worsened survival outcomes.\textsuperscript{21, 22} Therefore, the theoretical risks associated with uncontained tissue morcellation should apply for any intra-abdominal site of morcellation, and thus the authors deem it contradictory to use a containment bag with a minilaparotomy but not with a colpotomy.

Further research is necessary to confirm the value of containment bag use at the time of tissue extraction, particularly with regard to microspillage of tissue. Future studies may also investigate complication rates in relation to routes of tissue extraction, such as risk of incisional hernia or wound infection with minilaparotomy versus colpotomy.

Limitations of this study include the low response rate; however, a large majority of respondents who actually opened the invitation email completed the survey in its entirety. The low response rates are a known limitation of all large society survey studies and was similar to that of Lum and colleagues among their AAGL respondents.\textsuperscript{8} Though demographics of our respondents reflect AAGL members as a whole in terms of international representation, age, and variety of practice types, they may not be representative of all gynecologists managing fibroids operatively. The survey also may not have captured responses from the most high-volume surgeons, further limiting the generalizability of the results. Another limitation of this study is that despite a relatively large international constituency within AAGL, the survey was only available in English. Finally, the survey did not track unique site visitors so it is possible that the same participant could have completed the survey more than once.

Strengths of this study include representation of a variety of practice settings, including academic and community hospitals, as well as geographic location. There was a wide diversity of training backgrounds including fellowships in all gynecologic subspecialties such as minimally invasive gynecologic surgery, gynecologic oncology, reproductive endocrinology and infertility, and urogynecology, as well as generalist practice. The short window of survey availability is also a strength of this study in that surgeons are unlikely to make large practice changes within this timeframe, and thus the results represent a cross-sectional overview.

In conclusion, there is a wide variety of tissue extraction techniques that are being employed for the laparoscopic hysterectomy and myomectomy for the primary indication of fibroids. These data demonstrate the various alternatives to power morcellation that are currently in practice among surgeons that continue to provide patients with the benefits of minimally invasive surgery. This information may be used to direct future studies on surgical complications related to specific methods of tissue extraction, and may also be helpful for directing development of novel strategies or surgical devices that can make these techniques safer and more efficient.

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APPENDIX

Current methods of tissue extraction in minimally invasive surgical treatment of uterine fibroids

A research team at Brigham and Women’s Hospital is conducting a study among minimally invasive gynecologic procedures across the country about current practices in tissue extraction for uterine fibroids.

In April 2014 the Food and Drug Administration (FDA) issued a report discouraging the use of power morcellation during hysterectomy and myomectomy for fibroids due to the concern for occult malignancy. This has led to a notable shift in practice, however little is known about alternative methods of tissue extraction. We are interested to assess the prevalence of various techniques, such as use of containment bags or mini-laparotomy.

If you wish to participate, please fill out this survey which should take approximately 5 minutes. Your responses will be completely anonymous. The results will be used for research purposes only. Being in this study is optional and your participation will serve as consent.

Please contact Renkia Kim, RGY’3 at rkim@partners.org or the PI, Dr. Sarah Cohen at scohen2@hms.harvard.edu with questions or concerns about this study. This study has been approved by the Partners Institutional Review Board (IRB).

We thank you in advance for your participation.

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Do you perform laparoscopic or robotic surgery for fibroids as part of your current practice?  
☐ Yes  ☐ No

Which of the following laparoscopic or robotic surgeries for fibroids do you perform?  
☐ Hysterectomy only  ☐ Myomectomy only  ☐ Both

First, we would like to ask you about your practices regarding minimally invasive Hysterectomies performed for the primary indication of fibroids.

Which mode(s) of tissue extraction do you employ during a laparoscopic or robotic hysterectomy?  
☐ Manual morcellation through the colpotomy site (vaginal)  ☐ Manual morcellation through a mini-laparotomy (small incision ranging from 2.5cm)  ☐ Power morcellation  ☐ Intact specimen removal through a laparotomy (5cm) without morcellation  ☐ Other (please specify below)  (Check all that apply)

Please estimate what percentage of the time you perform each of the selected methods (Answers should add up to 100).

| Method                                             | Percentage |
|----------------------------------------------------|------------|
| Manual morcellation through the colpotomy site     | 56% 130%  |
| Manual morcellation through a mini-laparotomy      | 56% 130%  |
| Power morcellation                                 | 56% 130%  |
| Intact specimen removal through a laparotomy       | 56% 130%  |
| The method specified in “Other”                    | 56% 130%  |

Sum of all responses  (Must equal 100)

This section refers to manual morcellation through the vagina (posterior cul de sac or posterior fornix) for myomectomy.

Do you use a containment bag during manual morcellation through the posterior fornix?  
☐ Yes  ☐ No

The following questions refer to manual morcellation through a Mini-Laparotomy during myomectomy.

Do you use a containment bag while performing manual morcellation through a mini-laparotomy?  
☐ Yes  ☐ No

What is the average size of the mini-laparotomy?  (Length in centimeters)

Where do you create the mini-laparotomy incision?  
☐ Limbus  ☐ Supracervical  ☐ Transcervical  ☐ Other (please specify below)  (Choose all that apply)

The following questions refer to use of POWER MORCELLATION during myomectomy.

Do you use a containment bag while performing power morcellation?  
☐ Yes  ☐ No

(continued)
The following section includes questions regarding the use of power morcellation in general.

Is power morcellation currently permitted at your hospital?

- Yes
- No
- Don’t know
- Other (please describe below)

Are there any restrictions on the use of power morcellation?

- Yes
- No

Are there any restrictions on power morcellation in terms of case type or equipment? Please explain.

The final section of the survey includes basic demographic information.

What is your current gender identity?

- Female
- Male
- Prefer to self-describe (please specify below)
- Prefer not to answer

What is your current age?

In which country do you practice?

- United States of America
- Albania
- Algeria
- Andorra
- Angola
- Argentina
- Armenia
- Australia
- Austria
- Azerbaijan
- The Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bhutan
- Botswana
- Bosnia and Herzegovina
- Bhutan
- Brazil
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Central African Republic
- Chad
- China
- Colombia
- Comoros
- Congo, Democratic Republic of the
- Congo, Republic of the
- Costa Rica
- Côte d’Ivoire
- Croatia
- Cuba
- Cyprus
- Czech Republic
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- East Timor (Timor-Leste)
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia
- Fiji
- Finland
- France
- Gabon
- The Gambia
- Georgia
- Germany
- Ghana
- Greece
- Grenada
- Guatemala

(continued)
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#### In which state do you currently practice?

- [ ] Alabama
- [ ] Alaska
- [ ] Arizona
- [ ] Arkansas
- [ ] California
- [ ] Colorado
- [ ] Connecticut
- [ ] Delaware
- [ ] Florida
- [ ] Georgia
- [ ] Hawaii
- [ ] Idaho
- [ ] Illinois
- [ ] Indiana
- [ ] Iowa
- [ ] Kansas
- [ ] Kentucky
- [ ] Louisiana
- [ ] Maine
- [ ] Maryland
- [ ] Massachusetts
- [ ] Michigan
- [ ] Minnesota
- [ ] Mississippi
- [ ] Missouri
- [ ] Montana
- [ ] Nebraska
- [ ] Nevada
- [ ] New Hampshire
- [ ] New Jersey
- [ ] New Mexico
- [ ] New York
- [ ] North Carolina
- [ ] North Dakota
- [ ] Ohio
- [ ] Oklahoma
- [ ] Oregon
- [ ] Pennsylvania
- [ ] Rhode Island
- [ ] South Carolina
- [ ] South Dakota
- [ ] Tennessee
- [ ] Texas
- [ ] Utah
- [ ] Vermont
- [ ] Virginia
- [ ] Washington
- [ ] West Virginia
- [ ] Wisconsin
- [ ] Wyoming

(Primary practice location)

#### Did you complete a subspecialty fellowship after residency training?

- [ ] Yes
- [ ] No

#### Which one?

- [ ] Minimally invasive gynecologic surgery
- [ ] Reproductive endocrinology and infertility
- [ ] Urogynecology
- [ ] Gynecologic oncology
- [ ] Family planning
- [ ] Material fetal medicine
- [ ] Pediatric and Adolescent gynecology
- [ ] Other (please specify below)

#### What is your primary clinical focus?

- [ ] General obstetrics and gynecology
- [ ] Gynecology only practice
- [ ] Other (please specify below)

#### In what year did you complete your training?

(YYYY)

#### Which option best describes your current practice setting?

- [ ] Academic hospital
- [ ] Private/community hospital
- [ ] Both academic and private
- [ ] Other (please specify below)