



Medicolegal Issues in Power Morcellation: Cautionary Rules for Gynecologists to Avoid Unfavorable Outcomes

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2 **Medicolegal Issues in Power Morcellation. Cautionary Rules for Gynecologists to Avoid**
3 **Unfavorable Outcomes.**

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21 **Disclosure statement:** The authors declare that they have no conflicts of interest and nothing to
22 disclose.

23 **Precis:** Adequate information must be provided to patients to obtain proper consent, based on
24 awareness of the potential risks involved, such as occult malignancy spread.

25

26

27 **ABSTRACT**

28 Power morcellation in the context of laparoscopic surgery is a technology that enables specialists
29 to carry out minimally invasive procedures such as hysterectomies and myomectomies by cutting
30 the specimen into smaller pieces using a rotating blade and removing it through a laparoscope.
31 Unexpected uterine sarcoma treated by surgery involving tumor disruption could be associated
32 with worse prognosis. The current study aims to shed light on power morcellation from a
33 medicolegal perspective: the procedure has in fact given rise to adverse outcomes, resulting in
34 litigation and substantial compensation for plaintiffs. Studies have been published in various
35 journals cited in PubMed-Medline, Cochrane Library, Embase, GyneWeb between 1995 and 2019.
36 Considering claims following the US Food and Drug Administration (FDA) warnings on
37 morcellation, the current study broadens the scope of research, including search engines, legal
38 databases, and court filings (DeJure, Lexis Nexis, Justia, Superior Court of New Jersey, United
39 States District Court of Minnesota). Trial records show that courts, especially under tort law
40 statutes, often tend to place responsibility for unfavorable outcomes on doctors and facilities
41 (finding malpractice, rather than complications, to have occurred). It is therefore essential to
42 document adherence to safety protocols and specific guidelines, when available. Sound medical
43 practice is tied to guidelines; adverse legal outcomes can be avoided if there are grounds to prove
44 conformity with specific guidelines and the unpredictability of an event. Moreover, grey areas ought
45 to be clarified. Well-defined best practices ought to be outlined, when missing, to defend health
46 care operators from liability when unfavorable clinical outcomes do occur.

47 *Keywords:* Leiomyosarcoma; Liability; Lawsuit; Malignancies

48

50 INTRODUCTION

51 Power morcellation is a practical technology that effectively enables specialists to carry out
52 minimally invasive procedures such as hysterectomies and myomectomies by cutting the
53 specimen into smaller pieces using a rotating blade and removing it through a laparoscope [1]. The
54 ability to extract tissue through small abdominal incisions using morcellators revolutionized
55 minimally invasive gynecologic surgery, which previously required open abdominal incisions to
56 remove large uteri and fibroids [2,3]. In the absence of unsuspected malignancies, performing
57 intracorporeal power morcellation may entail risks such as the dissemination of benign tissues (eg,
58 leiomyoma, endometriosis, and rarely, parasitic fibroids) that may develop from morcellation
59 remnants after laparoscopic myomectomy [4]. Dispersed tissue fragments could implant on
60 abdominal organ surfaces and lead to inflammation, infection, and intestinal obstruction, which
61 may in turn require additional surgery and treatments [5,6]. Power morcellation has nonetheless
62 given rise to additional risks and complications associated with dissemination of benign as well as
63 malignant tissues inside the abdominal cavity, particularly uterine leiomyosarcomas (LMS) a
64 particularly aggressive, however rare, form of cancer. Based on reports of adverse events that led
65 to worsened prognosis and even death, the US Food and Drug Administration (FDA) issued a
66 discouraging statement in April 2014 on the use of power morcellators for the vast majority of
67 patients undergoing hysterectomy or myomectomy, which caused a progressive, sharp decrease
68 in the number of minimally invasive approaches over the following months and an increase of
69 complications associated with open abdominal surgery [7]. Eventually, in February 2017, the
70 Government Accountability Office (GAO) came into play, asserting that the FDA delay in warning
71 the public was owing to research findings dating back to the 1990s (when the first power
72 morcellator was greenlighted in 1991), which discounted the tissue dissemination risks, stating that
73 only 1 in 10,000 women with uterine fibroids had undetected cancer [8]. As a response to these
74 newly-asserted concerns, researchers have developed several containment systems aimed at
75 averting the spread of tissue fragments during the morcellation of specimen (in-bag morcellation
76 methods, however, need further improvement according to the FDA and major scientific societies)

77 [9-11]. Meanwhile, medicolegal implications are manifesting themselves, with individual and class-
78 action lawsuits being filed and expected to grow, given that patients had not been warned prior to
79 the FDA releases of the real risk associated with the use of power morcellation. Further, device
80 makers may be blamed for breach of product liability statutes in the United States, as well as
81 negligence, fraudulent misrepresentation, and failure to warn, test, and eventually recall their
82 products, among other charges. The development of guidelines and new screening procedures to
83 identify low-risk patients who may benefit from morcellation and the provision of thorough
84 information to patients prior to any surgery are of utmost importance and represent the key to
85 avoiding legal repercussions and unfavorable rulings.

86 **OBJECTIVE**

87 By virtue of the numerous lawsuits that have been filed with relation to the practice of
88 morcellation and the restrictions that have been put in place, we have aimed to clarify the grounds
89 upon which morcellation-related lawsuits had been filed. The assumptions that have been
90 evaluated as possible causes of claims are failure to comply with recommendations, disregard of
91 informed consent standards, unorthodox execution of the morcellation procedure, and incorrect
92 indications relative to patient selection.

93 Therefore, the FDA warnings, documentation, official positions, and recommendations from
94 national and international health care and medical societies in the field have been taken into
95 account. Various statements that seem to back up the recommendations of the FDA, among
96 which, the American Association of Gynecologic Laparoscopists, the American College of
97 Obstetricians and Gynecologists, the British Society for Gynaecological Endoscopy, the European
98 Society for Gynaecological Endoscopy, the European Society of Gynecological Oncology, the
99 National Institute For Health And Care Excellence, the Italian Society of Gynecological Endoscopy,
100 the Italian Association of Hospital Obstetricians and Gynecologists, the German Society for
101 Gynecology and Obstetrics, and the Society of Gynecologic Oncology. Moreover, searches in
102 Medline/PubMed and Cochrane Library, Embase, GyneWeb for publications between 1995 and
103 2019 have been conducted using keywords “uterine fibroids”, “morcellation”, “laparoscopy”,

104 “hysterectomy”, “myomectomy”, and “uterine sarcoma.” For medicolegal aspects to be optimally
105 highlighted, major legal databases have been searched: DeJure, Lexis Nexis, Justia, and Court
106 filings have been perused from all available sources (ie, Superior Court of New Jersey, United
107 States District Court of Minnesota), taking into account all relevant cases that saw uncontained
108 power morcellation as the centerpiece of the claims. Professional medical societies and
109 associations are predominantly in favor of keeping power morcellation available, though with
110 caveats, for patients to be able to benefit from the well-documented advantages inherent to
111 minimally invasive procedures, in light of the low incidence of undetected malignancies being
112 spread (Table 1) [12-22].

113 In 2015, the GAO began investigating the FDA and power morcellators at the request of US
114 House Representatives Mike Fitzpatrick, Louise Slaughter, and others over concerns the device
115 could spread uterine cancer. Failures in the reporting system may have played a role as well. The
116 GAO February 7, 2017 report found doctors, hospitals, and individuals did not properly report
117 morcellator problems to the FDA through its adverse event reporting system, causing a delay in its
118 action to warn the public. The GAO report said that the FDA knew power morcellators could
119 spread potentially cancerous tissue in the body as early as 1991, before receiving the first adverse
120 event reports describing the spread of cancerous tissue after the use of a power morcellator to
121 treat uterine fibroids, when it allowed the first morcellator on the market. This awareness was
122 reflected in the labeling of 12 of the 25 devices cleared by the FDA. Yet, the agency believed the
123 threat of spreading cancer was low—between 1 in 500 and 1 in 10,000 [7], as mentioned above. In
124 fact, the labeling for these power morcellators recommended [23] the use of a bag when cutting
125 cancerous (diagnosed or suspected) tissue and any other tissue that may be considered harmful if
126 spread, even though available data regarding the performance, safety, and effectiveness of bags
127 during laparoscopic morcellation of tissue are limited, according to the FDA. To arrive at those
128 conclusions, the GAO looked at 25 power morcellators, nearly all of them indicated for gynecologic
129 surgery, that the FDA approved from 1991 through 2014. There were no clinical trials to assess
130 their safety or efficacy because they were all greenlighted through the FDA 510(k) premarket
131 approval process. Under 510(k), a manufacturer need only demonstrate that the product is

132 substantially the same as one already on the market (called predicate). In the case of the first
133 power morcellator approved in 1991, the predicate product was an electromechanical device for
134 cutting tissue in orthopedic procedures. The 24 morcellators that followed piggy-backed on that
135 previously approved morcellator [23]. Professional societies interviewed by GAO offered guidance
136 to physicians on the proper use of power morcellators, while manufacturers provided instructions
137 and some technical training. It became apparent that currently there are no clearly defined
138 professional standards for use of power morcellators, but some guidance and educational
139 resources are available for surgical procedures to treat uterine fibroids for which the devices may
140 be used. Training activities for physicians using power morcellators routinely take place at
141 hospitals to supply physicians with suitable experience and abilities.

142 Manufacturers provide instructions for use, and some offer technical training relative to the
143 device structural characteristics, functional traits, and its necessary cleaning (Table 2) [7, 9,10, 23].
144 Original studies, meta-analyses and reviews have been looked into: such probes have shown that
145 the prevalence of unsuspected uterine sarcoma in patients undergoing hysterectomy or
146 myomectomy for presumed benign leiomyoma is 1 in 352 and the prevalence of unsuspected
147 uterine LMS is 1 in 498 [24]. The risk ratio of unsuspected uterine sarcoma has been found to be
148 0.14% or 1 in 700 [25]. Differences have been observed with a significant degree of variation (from
149 0.49 %, or 1 in 204 [14], to 0.056 % or 1 in 1,788 [26]). On average, papers that have reported on
150 power morcellators and myomectomy specimens pointed to a lower risk (though by a mere .08%,
151 or 1 in 1,306) compared with those that looked at hysterectomy specimens and found the overall
152 pooled risk to be 0.15%, or 1 in 650. There seems to be an undisputable age correlation in those
153 rates; the risk has been observed to be lower in patients under 45 [27]. Of the 234 sources found,
154 31 were ultimately deemed to be suitable for the paper's objective[1-6, 8, 24-33, 52, 54-64, 67, 68
155]. As for the Court cases herein expounded upon, they have been selected out of a 54-case pool,
156 among which 9 involved morcellation as a determining factor in giving rise to the claim. Court
157 cases where morcellation did occur but was not the determining factor in terms of causing the
158 alleged damage have been disregarded. After the FDA statement, studies showed decreased
159 rates of minimally invasive surgery and increased rates of open abdominal hysterectomy. A

160 retrospective cohort study, published in 2018, included 75,487 patients (mean [SD] age 47.8
161 years)[28] who underwent hysterectomy for benign conditions. The study was based on the
162 National Surgical Quality Improvement Program and that included 603 hospitals. 32,186 (42.6%)
163 patients were treated before the FDA warning regarding power morcellation and 43,301 (57.4%)
164 were treated after the warning. The population included mainly non-Hispanic white women (59.4%)
165 and African American women (15.1%). While the overall rate of major and minor complications
166 remained similar both before and after the FDA warning, in a subgroup of patients undergoing
167 hysterectomy for uterine fibroids (25,571 patients or 33.9% of the total population), the study found
168 a significant increase in major complications following the warning (from 1.9% to 2.4%) as well as
169 a rise in minor complications (from 2.7% to 3.3%). This group reported higher rates of abdominal
170 hysterectomy (from 37.2% to 43.0%) and lower rates of minimally invasive hysterectomy (from
171 56.1% to 49.7%). In light of those findings, it is undeniably of utmost importance to outline a
172 thorough risk-benefit analysis, by which surgeons should appropriately advise patients on both the
173 risks and potential benefits connected to power morcellation during minimally invasive
174 hysterectomy. The decision should be a shared decision between patient and surgeon, and all
175 patients should be adequately informed before surgery. It is of utmost importance to pursue a
176 substantial improvement of these alternative techniques of uterine morcellation and a more
177 effective identification process of patients who can benefit from minimally invasive procedures [29-
178 30].

179 Following the FDA advisory panel concerns regarding a surgical device commonly used in
180 hysterectomies and to remove fibroids, a July 29, 2014 *Journal of the American Medical*
181 *Association* briefing noted “We may have underestimated the risks of morcellation,” on the basis of
182 a study that showed patients with undetected cancer that unintentionally spread [31]. Following the
183 publication, Ethicon (a Johnson & Johnson subsidiary), the manufacturer of nearly three-quarters
184 of laparoscopic power morcellators on the US market, started a voluntary recall of the device [32].
185 Such developments have given rise to far-reaching medicolegal ramifications associated with
186 power morcellation and possible adverse outcomes. Considering that research noting the possible
187 risks of morcellation has been publicly available since 1990 before power morcellators were even

188 released, plaintiffs cite these studies to support their claims that manufacturers should have known
189 about the serious cancer-spreading risks of their products and yet did not take appropriate action
190 [33]. In the US, the first such lawsuit was filed in March 2014 (Burkhart vs. LiNA Medical); since
191 then, more than 300 suits have been filed [34-36] against morcellator manufacturers on the heels
192 of FDA warnings, of which those that were made public are summarized in Table 3 [37-47] .
193 Johnson & Johnson has reportedly paid \$100,000 to \$1 million [48]per case to settle power
194 morcellator lawsuits behind the scenes, and it is expected that the manufacturer will pay millions to
195 settle future claims. According to attorneys, Johnson & Johnson is already in talks to settle more of
196 its morcellator lawsuits, including those in state courts throughout the country, and more cases are
197 expected to be filed [49]. According to court transcripts, plaintiff attorney Sean Tracey said he had
198 “another 40 morcellator cases” ready to be filed. Companies often settle lawsuits confidentially to
199 prevent damaging information from coming to light [50]. The Wall Street Journal reported in March
200 2016 that Johnson & Johnson has settled nearly 70 of the estimated 100 legal claims that the
201 devices harmed patients by spreading undetected cancer. Plaintiffs also state that device makers
202 were aware or should have known of the dangers of morcellators but continued to profit from their
203 sales, disregarding the blatant consumer risk posed by their conducts, and should have stopped
204 selling them because of the potential harm they can cause, but they failed to recall or remove the
205 products from the market [51]. Singh et al reported that Canadian guidelines in 2015 stated that
206 morcellation should be discouraged in patients in menopause or older and in patients with a history
207 of pelvic cancer because their cancer risk is higher [52]. Meanwhile, major insurers in the United
208 States, such as Aetna, UnitedHealth, Highmark, Blue Cross Blue Shield of Massachusetts, and
209 AmeriHealth Caritas are among payers who have ceased coverage of procedures that use a
210 morcellator. Among major insurers, UnitedHealth and Anthem require prior authorization for
211 morcellator use. Vice President of Medical Affairs at the University of Pittsburgh Medical Center
212 said that reimbursement for morcellation procedures was being discontinued to “protect patient
213 safety,” while University of Pittsburgh Medical Center spokeswoman Gloria Kreps called the policy
214 decision “an appropriate and prudent course of action [53].”

215 **CONCLUSION**

216 Informed consent is eminently relevant when it comes to risky surgical practices such as
217 morcellation and should be viewed as a process, not as a mere form, involving ongoing, interactive
218 dialogue between medical staff and prospective patients.

219 In particular, during patient counseling, the surgeon should stress how current scientific
220 evidence reinforces the use of a minimally invasive approach to myomectomy [54]. The surgical
221 approach should be tailored according to the individual characteristics of the patient (such as size,
222 location, and number of fibroids) and to surgeon expertise [55]. All patients undergoing
223 myomectomy should be aware of the low prevalence of malignancy in a presumed fibroid [56].
224 According to the FDA, the overall risk is 1 in 350, seemingly an overestimation. An overall risk of
225 malignancy in a presumed benign uterine fibroid of less than 1 in 500 has been reported, lower in
226 some cohorts (down to 1 in 7,400) [57]. Age is an important factor when considering the risk of
227 inadvertent LMS, with a prevalence in women under 40 years being less than 1 in 1,000 [58].

228 Myomectomy is a surgical procedure usually performed in younger patients who are
229 interested in preserving their fertility [59], in place of hysterectomy. Patients should also clearly
230 understand that it is not possible to completely rule out malignancy through preoperative imaging
231 modalities, although certain morphological characteristics may be highly suspicious [60]. In case of
232 inadvertent LMS during a myomectomy for a presumed fibroid, the non en-bloc dissection
233 performed through the use of morcellation carries a poorer prognosis. In bag morcellation has
234 been proposed to reduce the risk of malignancy spread in case of occult LMS, nonetheless the
235 evidence in its favor is scant. The increased risk of vascular or visceral damage when using such a
236 device has been noted [61]. Consensus and evidence-based guidelines should always be
237 consulted when choosing the best surgical route for the patient and during the selection for
238 appropriate morcellation candidates. A standard preoperative workup that excludes malignancy is
239 important and should include cervical cytology, pelvic imaging, and possibly endometrial
240 assessment [62]. During the selection process, patient age should be evaluated as well as
241 menopausal state, uterine dimensions, rapid growth of the fibroid, treatments (eg, tamoxifen) and
242 genetic conditions (eg, Lynch syndrome) [63].

243 In addition to a thorough informed consent process and proper assessment of risk factors
244 and patient individualities, it is worth considering that a court of law (particularly in tort law) tends to
245 place responsibility and blame on doctors and facilities (finding malpractice, rather than
246 complications, to have occurred) if the informed consent documentation process and patient
247 medical records are lacking in any way; such inconsistencies may contribute to poor outcomes,
248 that can be viewed by a court as stemming from negligence rather than typical complications. In
249 broader terms, any failure to abide by surgical safety protocols or properly produce documentation
250 reflecting adherence to those rules will most commonly lead to unfavorable rulings against health
251 care providers and facilities. It is imperative to standardize clearly-defined best practices to shield
252 health care professionals from arbitrary judicial rulings as well as to protect patients. Adverse legal
253 outcomes can be avoided if conformity specific guidelines can be proven as well as the
254 unforeseeable nature of the mishap. Virtually all litigation that has been singled out and delved into
255 by the authors [37-47] related to morcellation stemmed from the dissemination of unsuspected
256 malignancies in the pelvic cavity. Thus, it is incumbent upon specialists to put in place more
257 reliable selection criteria for patients eligible to undergo these procedure. To reduce the risk of
258 adverse outcomes and legal claims, only patients of fertile age should undergo power morcellation
259 (ie, patients with a small likelihood of having an occult malignancy). The increasing prevalence of
260 LMS with advancing age (menopause or perimenopause status), could warn this patient population
261 to avoid procedures involving morcellation. ~~However, adequate and thorough information must be
262 provided to such patients, to acquire a solidly grounded consent, based on awareness of the risks
263 involved, including those relative to the spreading of occult malignancies.~~

264 Morcellation-targeted consent forms have been developed, such as the one recently
265 released by the Royal College of Obstetricians and Gynecologists [64]. The essential nature of the
266 consent process has been reinforced by the support of the American College of Obstetricians and
267 Gynecologists as well [65]. It is important to note the potential risks associated with power
268 morcellation, even those completed within a containment system [66-68]. ~~It is therefore necessary
269 for patients to be made aware of the fact that by consenting to undergo power morcellation, they
270 will be exposed to a risk, however low, of upstaging unsuspected cancer and resulting in a worse~~

271 ~~prognosis.~~The information may well act as a dissuading factor for patients, even leading them to
272 opt for open surgery instead, which, however, entails no less risk, from the standpoints of surgery
273 and anesthesia. As several studies have shown, awareness of the risks associated with power
274 morcellation will likely lead to a decrease in the rates of minimally invasive surgery overall, since
275 fewer patients are willing to take those chances.

276 Furthermore, medical insurance providers have been pulling out of covering power
277 morcellation in their policies, on account of its controversial nature. A more clearly defined stance
278 by scientific societies and health care organizations worldwide may validate morcellation and its
279 undeniable benefits as a minimally invasive surgical practice, at least in strictly select patients that
280 would make it possible for minimally invasive practices to grow, rather than be abandoned for
281 defensive medicine reasons.

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