UNM HEALTH SCIENCES CENTER

Applies To: Department: Obstetrics and Gynecology Revised:

Title: **Use of the power morcellator for removal of the uterus or leiomyomata at the time of hysterectomy or myomectomy**	**Policy**

Patient Age Group:	( ) N/A	( ) All Ages	( ) Newborns	( ) Pediatric	(X) Adult

POLICY STATEMENT

Power morcellation of the uterus or leiomyomata in gynecologic surgery has come under recent scrutiny with the FDA releasing a safety communication regarding its use. Power morcellation is sometimes used to facilitate removal of the uterus or leiomyomata. This technique allows the uterus to be removed through small incisions or through the vagina therefore decreasing the morbidity of a surgery by avoiding laparotomy. It is well established that minimally invasive techniques for hysterectomy reduce morbidity and mortality and without power morcellation some patients would need laparotomy. However, power morcellation does carry unique risks. Morcellation of the uterus in the abdomen does have the potential to disseminate an undiagnosed malignancy in the abdominal cavity. This risk is currently best estimated to be 1 in 370 women who undergo power morcellation during a minimally invasive hysterectomy have uterine cancer. In addition, non-malignant pathological processes may also result in seeding of the peritoneum with benign tumors. The risks of intraperitoneal dissemination of undiagnosed cancer must be weighed against the increased morbidity and mortality of more invasive approaches to hysterectomy and myomectomy such as laparotomy. The informed consent process must be comprehensive, documented and include a clear description of the risks of abdominal power morcellation, the benefits of this approach as well as alternatives. The risks and benefits of each individual case is a decision that should be made between a surgeon and his/her patient. Power morcellation is contraindicated in the presence of documented or highly suspected malignancy, may be inadvisable in premalignant conditions or risk-reducing surgery.

PURPOSE:

To describe the consent process for use of the power morcellator at the time of hysterectomy or myomectomy.

APPLICABILITY

This policy applies to women undergoing laparoscopic/robotic hysterectomy or myomectomy where power morcellation may be required

EVIDENCE

Recently, the FDA released a notification regarding the use of the power morcellator for women with leiomyomata that "strongly discouraged" its use because of the risk of intraperitoneal seeding of malignancies including leiomyosarcoma as well as other gynecologic malignancies. In follow-up, ACOG and AAGL have released statements that emphasize the need for clear counseling of the patient undergoing laparoscopic morcellation in women with leiomyomata.

PROCEDURES

The issues listed below should be discussed with the patient and considered by the surgeon when proposing use of the power morcellator.

1) Abdominal power morcellation carries with it the possibility of intraperitoneal seeding of undiagnosed tumors with the peritoneal cavity as well as the risk of the seeding of benign neoplasms. The risk quoted by the FDA is 1/350. It is unknown whether or not this peritoneal seeding significantly changes the prognosis of the tumor. This does not apply to morcellation of the uterus during vaginal hysterectomy, or morcellation that is performed of leiomyomata transcervically during hysteroscopic procedures.

2) While the FDA has suggested that morcellation can be performed in an endoscopic bag, bags currently on the market are not designed for this purpose and the use of the bag may result in the bag tearing or the retention of a foreign body if the bag was accidently caught in the morcellator.

3) Laparotomy carries with it an increased risk of morbidity including but not limited to wound infections, hernias, increased operative time, increased recovery time, blood clots, nerve injury and damage to the bowel or bladder. In addition women who undergo hysterectomy from a laparotomy have 3 times the mortality of women who undergo laparoscopic hysterectomy.

4) When considering morcellation to avoid the morbidity and mortality associated with an open procedure, the patient's age, family history and underlying indication for the hysterectomy should be considered; for example both endometrial carcinoma and leiomyosarcomas increase with increasing age; for leiomyosarcoma the highest incidence is after age 65.

5) Patient consent should include (From ACOG guidelines):
    a. There is a potential risk of undiagnosed gynecologic cancers. The precise incidence of all undiagnosed uterine sarcomas – including leiomyosarcoma – in women undergoing hysterectomy for fibroids in unknown. The risk estimate of 1/350 to 1/500 should be discussed.
    b. If an occult malignancy is present the use of the power morcellator will increase the likelihood of intraperitoneal dissemination. It may worsen the patient's prognosis as well as make a definitive diagnosis more difficult, including cancer staging. This may result in additional surgery, medical management or both.
    c. If the power morcellator is used and fragments of benign tissue are seeded with the peritoneum, there is a possibility that the tissue will be viable and grow. This growing tissue may require additional interventions.
    d. If a bag is used, concerns regarding its use should be discussed including the bag size, bag disruption, and reduced visualization as well as retention of bag fragments if the bag is ruptured.
    e. Alternatives to morcellation include the removal of tissue through laparotomy, colpotomy, total abdominal hysterectomy, vaginal hysterectomy or total laparoscopic hysterectomy.

6) This template language is suggested for the informed consent process and the documentation of the consent process.

    Planned morcellation consent template:

    "Due to the size of her uterus, the size of her fibroid(s) or a plan to perform a supracervical hysterectomy, we discussed the recent concerns raised about in situ morcellation. We discussed the risks and benefits of morcellation versus non-morcellation and that morcellation may allow for a minimally invasive approach reducing her risk of many serious complications. We discussed the potential risks of retention or spreading of endometrial or myometrial tissue that could potentially lead to endometriosis or a pelvic mass causing pain, infection or the need for further surgery. We also discussed the risks of morcellating an undiagnosed endometrial cancer or sarcoma of the uterus. We discussed the prevalence of leiomyosarcoma, and the rate of sarcoma in surgeries for fibroids estimated at 1 per 350 to 1/500

procedures. Morcellation of a sarcoma or cancer could lead to upstaging and this could worsen the prognosis for survival. We discussed that these diseases offer an extremely poor prognosis even when specimens are removed intact. We discussed alternatives and risk to morcellation including laparotomy, mini-laparotomy with morcellation, laparoscopic morcellation in a bag or traditional morcellation. We also discussed that technical difficulties sometimes limit the ability to perform morcellation in a bag.
The patient expressed an understanding of the risks and benefits and expressed a decision to proceed with surgery that included the option of either morcellation within a bag or traditional electromechanical morcellation techniques."

REFERENCES

1. Food and Drug Administration. Quantitative assessment of the prevalence of unsuspected uterine sarcoma in women undergoing treatment of uterine fibroids: summary and key findings. Silver Spring (MD): FDA; 2014. Available at http://www.fda.gov/downloads/medical devices/safety/alerts and notices/UCM393589.pdf. Retrieved May 9, 2014.

2. American College of Obstetricians and Gynecologists. Power morcellation and occult malignancy in gynecologic surgery; a special report. Washington DC: 2014. Available at http://www.acog.org/Resources_And_Publications/Task_Force_and_Work_Group_Reports/Power_Morcellation_and_Occult_Malignancy_in_Gynecologic_Surgery. Retrieved May 27th, 2014.

APPROVAL

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Chair, Department of Obstetrics and Gynecology — Date

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