Implementing new surgical instruments in minimally invasive surgery

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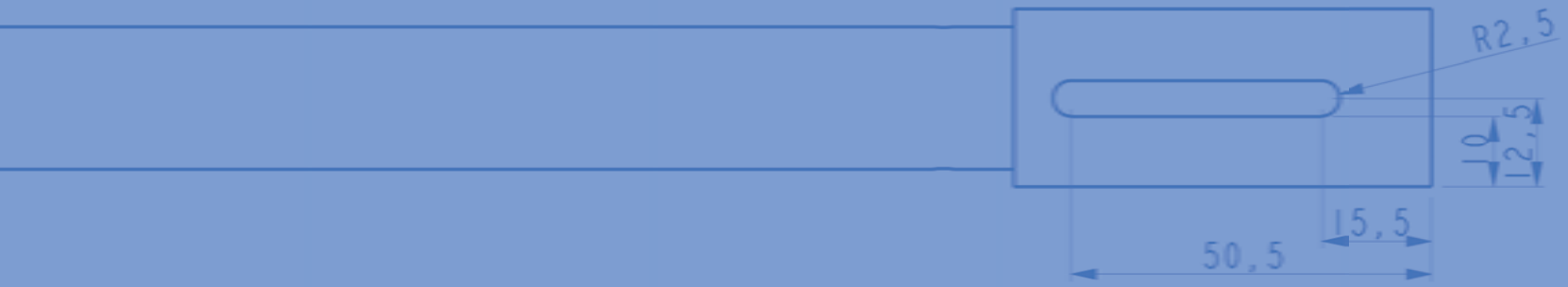
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Assessing basic 'Physiology' of the Morcellation Process and Tissue Spread: A Time Action Analysis

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Abstract

Study Objective: To assess the basic morcellation process in laparoscopic supracervical hysterectomy (LSH). Proper understanding of this process may help enhance future efficacy of morcellation regarding prevention of tissue scatter.

Design: Time Action Analysis was performed based on video imaging of the procedures (Canadian Task Force classification II-2)

Setting: Procedures were performed at Leiden University Medical Centre (LUMC) and St. Lucas Andreas Hospital (SLAZ), Amsterdam.

Patients: Women undergoing LSH for benign conditions.

Interventions: Power morcellation of uterine tissue.

Measurements and Main Results: The morcellation process was divided into 4 stages: tissue manipulation, tissue cutting, tissue depositing and cleaning. Stages were timed and perioperative data were gathered. Data were analysed as a whole, and after subdivision into three groups according to uterine weight: <350g, 350-750g, >750g. A cut-off point was found at uterine weight of 350g, after which an increase in uterine weight did not affect the cleaning stage. Tissue strip cutting time was used as a measure for tissue strip length. With progression of the morcellation process, the tissue strip cutting time decreases. The majority of cutting time is of short duration, 60% of the cutting lasts 5 seconds or less, and these occur later on in the morcellation process.

Conclusion: With the current power morcellators, the amount of tissue spread peaks and is independent of uterine weight after a certain cut-off point (in this study 350g). There is a relative inefficiency in the rotational mechanism because mostly small tissue strips are created. These small tissue strips occur increasingly later on in the procedure. Because small tissue strips are inherently more prone to scatter by the rotational mechanism of the morcellator, the risk of tissue spread is highest at the end of the morcellation procedure. This means that LSH and laparoscopic myomectomy procedures may be at higher risk for tissue scatter than TLH. Finally, engineers should evaluate how to create only large tissue strips or assess alternatives to the rotational mechanism.

Introduction

Morcellation has allowed laparoscopic surgeons to remove large uteri and myoma, thereby offering more women the benefits of a minimally invasive approach to their surgery. Yet the United States Food and Drug Administration (FDA) has recently discouraged the use of uterine power morcellation in laparoscopic hysterectomy and myomectomy because of serious safety concerns after the accidental use of this technique in women with occult uterine sarcoma (e.g. leiomyosarcoma). Patient outcome with respect to morbidity and mortality may be negatively influenced due to morcellation. [1,2] Unfortunately, the diagnosis of uterine sarcoma is complex since methods to rule out this condition with certainty do not exist. Furthermore, although considered difficult due to a paucity of studies with large series of patients, it was estimated by the FDA that 1 in 350 women undergoing hysterectomy or myomectomy for fibroids will have an unsuspected uterine sarcoma.[3] To prevent the unintentional morcellation of a uterine malignancy, it is proposed to stop using a power morcellator and return to traditional methods such as abdominal laparotomy or vaginal incision to remove the uterus or myoma. Methods to avoid tissue spread such as in-bag morcellation are under investigation. [4-8] In theory contact between tissue and abdominal wall and cavity is avoided, however studies in Urology and Gastroenterology have, in fact, demonstrated port-site metastases after contained morcellation. [9-12] Although these occurrences have been rare and additional risk factors other than morcellation have been proposed, they stress the importance of larger studies to confirm the efficacy of in-bag morcellation in gynaecology. Moreover, before any alternative can be proposed, it is essential to understand the actual problem at hand. Without solid knowledge of the process of morcellation, tissue spread and tumour seeding, it is unlikely that a sustainable solution will be discovered. The aim of our study was to assess the occurrence and amount of tissue spread in the morcellation procedure, and to identify any factors that influence the tissue spread. This study intends to contribute to the development of a more effective morcellation technique. Understanding the pattern of tissue spread may help us find a solution to a serious problem, so that in the future the benefits of minimally invasive surgery will not be lost for women with larger uteri.

Methods & Materials

A prospective observational study was performed from January 2011 till May 2013 at the Leiden University Medical Centre (LUMC) and the St Lucas Andreas Hospital (SLAZ) in Amsterdam. The morcellation procedure in Total Laparoscopic Hysterectomy (TLH) procedures and Laparoscopic Supracervical Hysterectomy (LSH) procedures

were timed and basic procedure and patient characteristics were gathered. Seperately, LSH procedures were recorded for a Time Action Analysis (TAA). All procedures were performed by 4 experts in minimally invasive gynaecologic surgery, except for the procedures in the TAA which were performed by 1 expert. The Gynecare Morcellex (Ethicon, Inc., Somerville, NJ) and LiNA Xcise (LiNA medical, Glostrup, Denmark) were used during the procedures. No distinction was made in the data between the type of used morcellator since the Morcellex and LiNA Xcise rely on the same 'motor peeling' working principle, have by approximation a similar instrument diameter, blade rotation speed, weight, and are disposable.[13] Intra-operative data and basic patient characteristics were gathered. To accurately analyse the morcellation procedure, this procedure was divided into 4 stages: Stage 1 or Tissue manipulation: grasping and manipulation of the uterine tissue toward the cutting blade of the morcellator. Stage 2 or Tissue cutting: morcellation instrument actively cutting tissue, and tissue being pulled through the morcellation tube. Stage 3 or Tissue depositing: morcellation instrument inactive, tissue strip being deposited in a retainer outside the patient, and reinsertion of the grasper through the morcellator. Stage 1 to 3 were used to calculate the total morcellation time. Stage 4 or Cleaning stage: inspection of the abdomen to detect and remove residual uterine tissue pieces, and irrigation of the abdominal area. Tissue spread is determined by counting the number of visually detectable tissue pieces removed during stage 4 through grasping, suction and rinsing. In addition, the duration of stage 4 was used as to further estimate the amount of tissue spread. Morcellation rate is calculated in grams per minute as the weight of the excised tissue divided by the morcellation time. Statistical analysis using the 2-tailed *t* test under assumption of homogeneity of variance was performed for the LSH and TLH groups separately with respect to the TAA group. For the TAA group, procedures were divided into 3 groups according to uterine weight (A: <350g, B: 350-750g, C: >750g). A 2-tailed *t* test was used for identifying significant differences between groups. Standard linear regression analysis was performed to assess the interdependence between recorded variables. A p-value of .05 was considered statistically significant. All patients consented to participate in this study.

Results

A combined total of 52 TLH and LSH procedures were analysed, of which 23 LSH procedures were analysed by TAA. Table 1 shows that no statistical differences were observed in patient characteristics and morcellation related parameters between the procedures that were timed and the procedures that were analysed through TAA. The average operation time was 152 min and 158 min respectively and the morcellation procedure comprises 13% and 15% respectively of total operation time.

Table 1: Patient characteristics and morcellation procedure parameters; comparison between Time Action Analysis Group and remaining group. Data provided as mean (Standard deviation; range)

	TAA group (n=23)		TLH & LSH without TAA (n=29)		p
Age	47	(6,5; 36-68)	45,8	(5,9; 31-57)	.5
Parity	1,1	(1,1; 0-3)	1,6	(1,4; 0-4)	.2
BMI*	24,5	(3,0; 21-32)	27,3	(5,7; 18-40)	.1
Indication for surgery					
- Uterine myoma	18 (78,3 %)		24 (82,8 %)		
- menorrhagia	4 (17,4 %)		4 (13,8 %)		
- dysmenorrhea	-		1 (3,4 %)		
- unavailable	1 (4,3 %)		-		
Total operation time [min]	158	(47; 78-245)	152	(45; 90-332)	.7
Uterine weight [g]	425	(341; 29,5-1260)	377	(237; 75-1265)	.5
Morcellation stage time [min]	24	(19; 3,4-245)	20	(15; 3-74)	.4
Morcellated weight [g]	421	(337; 29,5-1260)	302	(237; 75-1265)	.1
Morcellation rate [g/min]	17,8	(8,0; 8,1-33,9)	17,8	(9,7; 4,5-46,7)	1
Number of excised tissue strips	48,5	(40,7; 2-131)	37.7	(29,8; 9-146)	.3
Average weight per strip	9,7	(4,0; 5,1-19,8)	8.8	(3,5; 4,2-19,3)	.4
Bloodloss [ml]	200	(186; 0-800)	270	(328; 0-1600)	.4

* Data missing from 6 patients in TAA group and 3 in remaining group.

The results from the TAA are provided in table 2. Morcellation conditions were similar in all 3 groups because no significant differences were found in morcellation rate and weight per removed tissue strip. Figure 1 is a graphic representation of the time division of the separate morcellation stages. It shows the stage percentages (stages 1-3) and total morcellation time as compared with the cleaning stage time (stage 4). A large proportion of time is spent on manipulating tissue and depositing tissue, and only a limited amount on cutting the tissue. With increasing uterine weight, the total morcellation time also increased. Analysis of the different stages of total morcellation time showed similar increase for stages 1, 2 and 3, but not for stage 4 (i.e. the cleaning stage). No significant difference was found in the cleaning stage between weight group B (350g-750g) and group C (>750g). No significant difference was found in the number of scattered tissue pieces between groups B and C.

To further analyse the cutting process, the tissue cutting time throughout the morcellation procedure was analysed. The length of every single removed tissue strip was approximated by the time spent cutting that tissue strip in the TAA, thereby

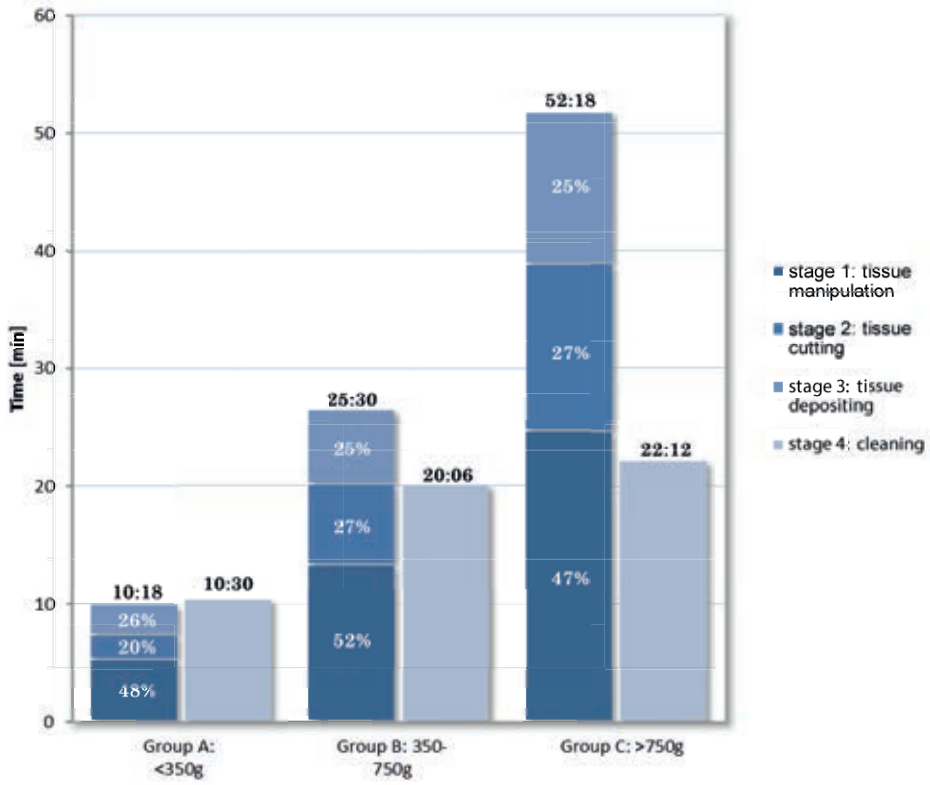

Figure 1: Chart providing the division of morcellation stages in percentages and the morcellation stage and cleaning stage time of groups A, B and C. Note that the presented percentages do not exactly add up to 100% because the percentages are calculated for every separate procedure and the mean is calculated afterwards over the population size.

allowing an evaluation of the change in length of the removed tissue strip during the morcellation process. This resulted in Figure 2, which shows the mean tissue cutting time per tissue strip for all patients combined, as a function of morcellation completion (in percentage). The morcellation completion percentage was calculated as 100 times the n-th tissue strip cutting action divided by the total number of cutting actions required to remove the full mass. The mean tissue cutting time over all patients was calculated for every 2% of morcellation completion. Linear regression analysis through the mean data shows a negative Pearson's correlation coefficient of r = -.,81 (p<.001). This means that the length of tissue strips appears to decrease with progression of the morcellation completion.

Table 2: Patient characteristics and procedure data of Laparoscopic Supracervical Hysterectomy (LSH) group evaluated with Time Action Analysis (TAA), subdivided into categories based on uterine weight. Data presented as mean (Standard deviation; range). Significance calculated with two-tailed t-test under assumption of homogeneity of variance.

Variable	Total (n=23)		Uterine weight:						P Values		
			Group A: <350g (n=11)		Group B: 350g-750g (n=7)		Group C: >750g (n=5)		P_{A-B}	P_{B-C}	P_{A-C}
Total operation time [min]	158	(47; 78-245)	127	(35; 78-182)	178	(44;121-245)	198	(31;165-244)	<.05	-	<.05
Morcellation stage time [min]	24,1	(18,9; 3,4-68,4)	10,3	(4,4; 3,4-16,8)	25,5	(10,6;16,4-47,7)	52,3	(15,2;32,0-68,4)	<.001	<.05	<.001
- **Stage 1: tissue manipulation [min]**	12,0	(9,3; 1,4-36,9)	5,4	(2,8; 1,4-11,4)	13,4	(6,0;6,8-24,8)	24,7	(8,9;13,8-36,9)	<.05	<.05	<.001
- **Stage 2: tissue cutting [min]**	6,1	(5,6; 0,7-19,8)	2,0	(0,7; 0,7-3,0)	6,8	(2,8;2,3-10,9)	14,2	(5,3;6,1-19,8)	<.001	<.05	<.001
- **Stage 3: tissue depositing [min]**	6,0	(4,6; 0,8-15,8)	2,7	(1,5; 0,8-6,2)	6,4	(2,9;4,6-12,0)	12,9	(3,0;9,6-15,8)	<.05	<.05	<.001
- **Stage 4: cleaning [min]**	16,0	(7,3; 3,5-28,8)	10,5	(4,0; 3,5-17,9)	20,1	(6,3;7,5-25,2)	22,2	(5,7;13,5-28,8)	<.001	-	<.001
Weight of excised tissue [g]	421	(337; 29,5-1260)	144	(65; 29,5-238)	499	(138;350-680)	922	(224;680-1260)	<.001	<.05	<.001
Morcellation Rate [1] [g/min]	17,8	(8,0; 8,1-33,9)	15,3	(8,8; 8,1-33,9)	21,5	(8,0;10,4-30,9)	18,3	(4,3;14,6-24,3)	-	-	-
Number of excised tissue strips [-]	48,5	(40,7; 2-131)	16,7	(9,0; 2-38)	55,9	(24,9;23-98)	108,2	(25,2;72-131)	<.001	<.05	<.001
Average weight per strip [g]	9,7	(4,0; 5,1-19,8)	9,8	(4,6; 5,3-19,8)	10,1	(3,9;5,1-16,8)	8,9	(3,0;6,8-13,9)	-	-	-
Tissue scatter pieces [-]	12,8	(9,2; 1-37)	6,7	(5,1; 1-15)	15,1	(7,5;7-29)	22,8	(8,9;14-37)	<.05	-	<.001
Intraoperative blood loss [mL]	200	(186; 0-800)	128	(88; 0-300)	314	(269;50-800)	182	(141;10-400)	-	-	-

[1] Morcellation Rate calculated as Morcellated tissue weight divided by morcellation stage time.

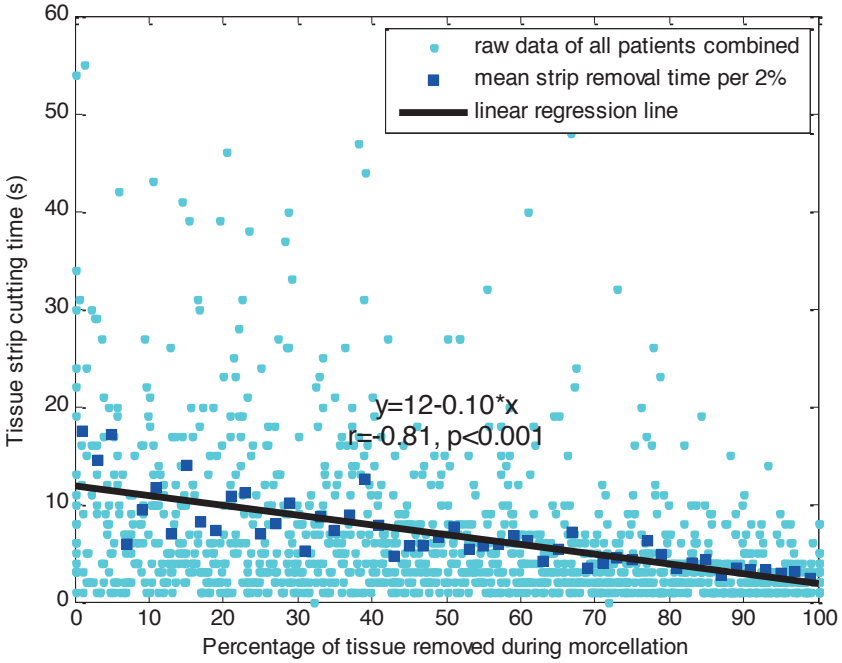

Figure 2: Linear regression analysis for tissue strip cutting time as function of the percentage of removed tissue during morcellation. The percentage of tissue removed is approximated as 100 times the nth tissue cutting action divided by the total number of cutting actions required to remove the tissue mass. Raw data from all patients is used to obtain a mean strip removal time for every 2%. Linear regression analysis is performed on the mean data.

Discussion & Conclusion

This study was performed to provide insight into the 'physiology' of the morcellation process. The complete morcellation process has 4 stages. Overall morcellation time amounts to 15% of the total procedure time on average, showing that morcellation does not account for a large extension of the total operation time. Manipulation of tissue (stage 1) comprises 50% of the morcellation procedure, whereas only 25% of the time is spent on the actual cutting of tissue (stage 2). As expected, the duration of tissue handling, tissue cutting and tissue depositing (stages 1 to 3) increases with larger uteri. In contrast, duration of the cleaning stage (stage 4) did not demonstrate the same linearity. Compared to uteri <350g, more time was spent on cleaning in cases with uteri weighing between 350g-750g. Interestingly, no further increase of stage 4 was noticed when uteri over 750g were compared to uteri weighing 350-750g. The same can be said for the number of scattered tissue pieces during stage 4. Apparently, there seems to be a cut-off point. If the amount of tissue scatter is estimated by the

duration of the cleaning stage (meaning that a longer cleaning stage indicates more tissue scatter), then it implies that tissue scatter increases significantly after this cut-off point, and furthermore that after this point tissue scatter remains constant regardless of uterine weight. It can be cautiously concluded that the amount of tissue scatter is not related to uterine weight, but correlates with a certain cut-off point. To limit the amount of tissue spread with the current technology, power morcellation may only be used until a certain uterine weight. In this study, the cut-off point was found at 350g.

Linear regression analysis of the mean tissue cutting time per tissue strip showed that cutting time decreases as the morcellation process progresses. Using the tissue cutting time to estimate the length of the tissue strips, it can be concluded that at the start of the morcellation process the tissue strips are larger and tissue strips become shorter with progression of the morcellation process. Furthermore, although the range of the raw data is large, 82%, of the tissue cutting action has a duration of less than 10 seconds, and 60% under 5 seconds, both occurring more frequently later on in the procedure. This implies a certain inefficiency in the morcellation procedure, because apparently large pieces of tissue strips are only created at the very beginning of the cutting process. In this light, the rotational mechanism of the current power morcellators should be reconsidered, given that smaller tissue strips are inherently more prone to scatter by the rotating blade of the power morcellator. This rotational mechanism may be an important focus for enhancing the efficacy of the morcellation process regarding tissue spread. A solution may be to enhance the creation of large tissue strips or to assess an alternative for the rotational mechanism. One alternative for this mechanism already exists. The PKS PlasmaSORD (Solid Organ Removal Device) is manufactured by Olympus and it uses bipolar cutting instead of a rotating blade. Unfortunately, it causes smoke and it has been hypothesised that other mechanisms such as the CO_2 pneumoperitoneum, raised abdominal pressure and smoke may contribute to tissue spread.[9] Another important finding of our study is the moment of the morcellation process which is at greatest risk of tissue spread. As stated, over 60% of morcellation time is under 5 seconds, meaning that these tissue strips are small, therefore possibly at risk for spreading. In addition, our study demonstrated these small tissue strips occur increasingly towards the end of the morcellation process, meaning that the risk of tissue spread is highest at the end of the morcellation process. From this it may be concluded that LSH and laparoscopic myomectomy procedures, that do not have a vaginal access, are more prone to tissue scatter since all tissue needs morcellation, compared to TLH procedures in which only part of the uterus is morcellated to the point where the uterine remnant fits through the vagina. A solution to this problem in LSH en LM procedures could be to only use morcellation to the point where the uterine corpus or myoma can be removed vaginally after performing a colpotomy.

Although several studies have been published regarding power morcellators, relatively few comparative or clinical studies exist and some morcellators have been introduced in clinical practice without any (published) studies altogether. [13,14] The main focus of these studies appear to have been technical characteristics such as morcellation rate. It is questionable if upon introduction of power morcellators tissue spread was considered to be a severe side effect of the morcellation process. Gradually reports were published on the iatrogenic spread of benign uterine tissue. It is only afterwards, that information regarding the unintentional morcellation of malignant tissue became available. Naturally power morcellators were never intended for use in case of a malignancy and moreover, any fragmentation of malignant tissue is usually contraindicated in the principles of oncologic surgery.

The weakness of our study is that tissue spread was not evaluated on a cellular level. Instead, the number of macroscopically detectable scattered tissue pieces and the and duration of the cleaning stage were used to determine the amount of tissue spread. Although the complete abdominal cavity and peritoneum were carefully and meticulously searched for tissue spread, it is possible that small tissue fragments were overlooked. Furthermore, the tissue strip cutting time was considered to be representative for the length of the tissue strips. Therefore, any conclusion regarding tissue scatter and tissue strip length should be interpreted with relativism. It was attempted to define the cut-off point of the uterine weight more precisely. A cut-off point calculated on raw data (instead of by comparing the 3 groups according to uterine weight) could not be found due to relatively limited sample size of 23 patients. For the same reason, a confidence interval in which the cut-off point lies could not be calculated. Lastly, the outcome of our study may not be applicable to power morcellators with other technical specifications such as a difference in diameter.

To solve these shortcomings, a TAA of the morcellation process in a larger population is needed to verify the results of this study. Microscopic evaluation of tissue spread and the pattern of tissue spread may be an interesting addition to future studies. Notwithstanding these limitations, this study offers valuable knowledge regarding the basic 'physiology' of the morcellation procedure and tissue spread. Based on the results, the current rotational mechanism of the power morcellators should be reconsidered due to their relative inefficiency with respect to tissue scatter. Furthermore, the partial morcellation of uterine tissue seems less at risk to cause tissue spread compared to complete morcellation. For LSH and LH procedures this means that only part of the uterine tissue should be morcellated after which the remnant tissue can be removed vaginally through colpotomy. In TLH this is already standard procedure.

Finally, solutions that allow morcellation without spread are being investigated and focus mainly on in-bag morcellation. Although in-bag morcellation may be a proper solution for now, it treats a "symptom" rather than the underlying condition. To come to a sustainable solution to the current problem of tissue spread, it is most important that the underlying mechanism is addressed. This study suggests the rotational mechanism as an important factor. It is time for the engineer to further evaluate and enhance the technology of power morcellators.

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