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Implementing new surgical instruments in minimally invasive surgery

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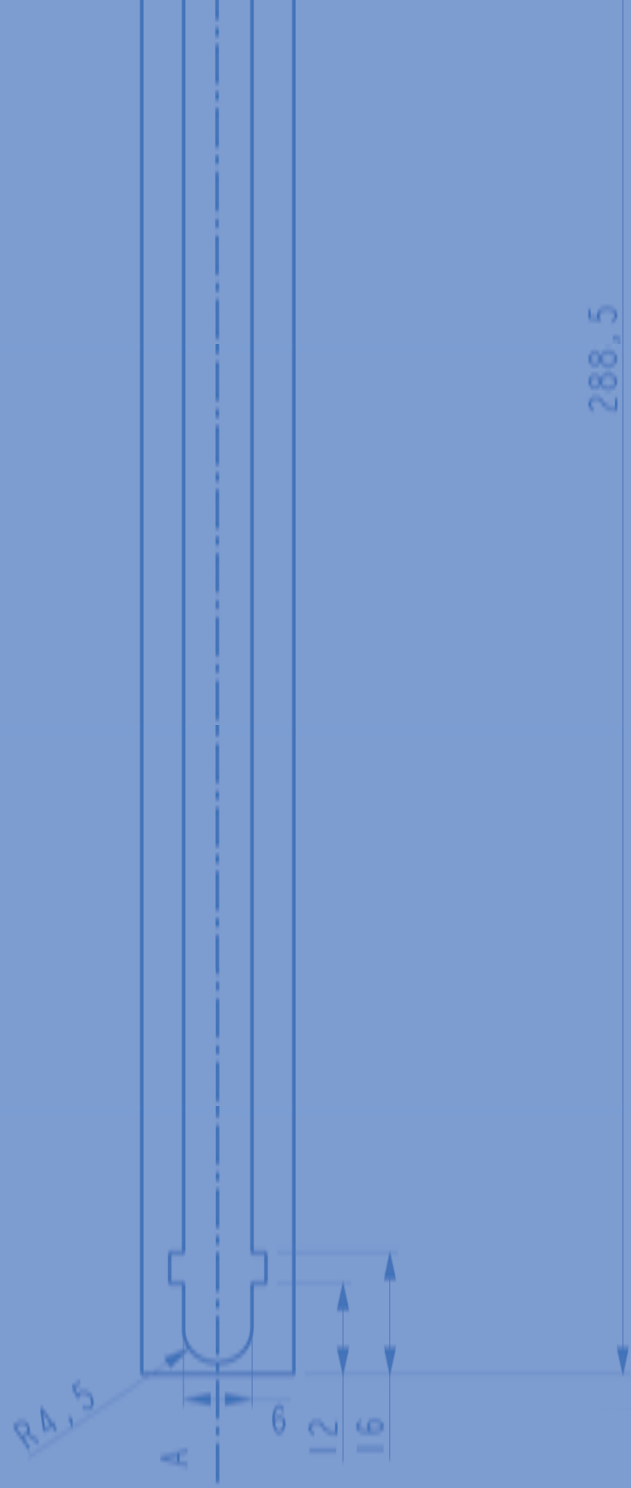


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Power morcellator features affecting tissue spill in gynecological laparoscopy: an in vitro study

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Abstract

Study Objective: To assess features of power morcellators (blade diameter, circular versus oscillating cutting, blade rotation speed, experience level) regarding their effect on the amount of tissue spill. In addition, the amount of tissue spill after the initial two-thirds and final one-third of the morcellated specimen was evaluated.

Design: An in-vitro study (Canadian Task Force classification II-2).

Setting: Laparoscopic skills lab of an academic hospital

Patients: Not applicable

Intervention: Power morcellation of beef tongue specimens

Measurements and main results: Twenty-four trials were performed. Morcellation was performed in 2 phases (phase 1: initial two-thirds of the total tissue, phase 2: last one-third of the tissue). With larger blade diameter a decline was observed in both the weight of the spilled particles (phase 1) and the number of spilled particles (phases 1, 2 and both combined) (weight phase 1= 6.5g vs 6.3gr vs 2.2gr for 12.5mm vs 15mm vs 20mm respectively, $p=.04$; number particles: Phase 1= 10.2 vs 7.2 vs 2.7 $p=.01$, Phase 2= 22.9 vs 19.0 vs 8.9 $p=.02$, Total= 34.7 vs 26.2 vs 11.6 $p=.01$). Also, spinning of the tissue mass due to torque being applied by the rotating blade occurred later when blade size increased, and the size of the spilled particles was larger (weight of morcellated tissue at onset of torque: 136g vs 198g vs 222g $p=.07$ and Size: .6g vs .9g vs .8g $p=.1$). In the oscillation mode, there was less total spill (6.8g/100g versus 21.3g/100g, $p=.01$, for oscillation and circular cutting respectively)

Conclusion: The present study demonstrates that less spill is created by power morcellators with an oscillating blade and / or a large diameter ($\geq 20\text{mm}$). Furthermore, when using a large diameter blade the spilled particles are larger and less morcellation repetitions are needed. By combining these features with currently introduced contained morcellation, the safety of the morcellation process with respect to tissue spill can be further improved.

Introduction

The safety of power morcellators for the laparoscopic removal of large uteri and myoma is seriously questioned after reports of the accidental morcellation of occult uterine malignancies. The occurrence of tissue spread, caused by morcellation, is strongly believed to result in an upstage of the disease.[1] As a result, the U.S. Food and Drug Administration (FDA) decided in 2014 to advise against the further use of these instruments in almost all cases.[2] This poses a challenge for the future of minimally invasive gynecologic surgery, since the FDA statement effectively implies a return to laparotomy for numerous hysterectomy and myomectomy procedures. However, it is questionable if this return to laparotomy is sustainable. In fact, it has been argued that a return to this approach in all cases of hysterectomy and myomectomy will lead to higher morbidity, mortality and costs when compared to laparoscopy, even when including the accidental morcellation of uterine malignancies.[3,4] Based on these studies, the morcellation technique should not be swiftly abandoned. However, it is clear that the safety of power morcellation should be enhanced. Currently, research on this topic focusses mainly on contained morcellation techniques, because in theory this should prevent complications due to tissue spread and may also help to prevent direct organ damage by the morcellation blade. Although the feasibility of in-bag morcellation has been demonstrated in several studies [5-7], long term outcomes do not exist and containment bags are even used off-label. Moreover, contained morcellation does not address the shortcomings of current power morcellators. A recent study, demonstrated that tissue spill increases significantly after a certain weight was morcellated and, in addition, that the efficiency of the current instruments may be improved.[8] The goal of this study is to further explore the technical features of power morcellators and their effect on tissue spill during the morcellation process. By clarifying the details of this process we hope to contribute to the development of more efficient and safe instruments and of surgical techniques with respect to tissue spill.

Methods

The following features and their effect on tissue spill were examined in an in vitro setting (table 1):

First, the effect of different blade diameters was assessed. Diameters of 12.5mm, 15mm and 20mm were used. Speed was set at 400 rotations per minute (rpm) combined with standard circular cutting of the blade; Second, oscillation instead of circular cutting was assessed. In the oscillation mode, the morcellation blade rotates alternately 4 times clockwise and 4 times counter-clockwise; Third, the effect of rotation speed of the morcellation blade was evaluated. For this purpose, the speed was set at 800 rpm and

compared to 400 rpm; Fourth, the effect of experience level was studied, by comparing the results of the expert with a novice (LH, a resident in obstetrics and gynecology), Finally, the point in time (defined as the weight of tissue already morcellated) was evaluated where the tissue cutting action unintentionally shifts to torque being applied to the tissue mass due to friction, and as a result, the tissue mass starts rotating uncontrollably with the blade.

Table 1: experiment design

	12.5 mm	15 mm	20 mm
Diameter ^a	4 trials	4 trials	4 trials
Oscillation ^b		4 trials	
Speed ^c		4 trials	
Novice ^d		4 trials	
Total	24 trials		

^a Standard setting: speed 400 rpm, circular cutting
^b Oscillation mode: 4 rotations clockwise alternated by 4 counter-clockwise. Speed 400 rpm.
^c 800 rpm was compared to 400 rpm.
^d Novice: 2nd level according to the ESGE Standard Laparoscopy

All trials were performed by an expert in minimally invasive gynecologic surgery (FWJ), except for the novice trials. In agreement with other in vitro studies, beef tongue was used to simulate uterine tissue. [5,9,10] Pieces of 400-500 grams were morcellated. To collect all tissue spill, the morcellation specimen was placed in a clear plastic bag in an open laparoscopic box trainer (fig 1).



Figure 1: The test setting in an open laparoscopic box trainer.

The Blue Endo MOREsolution Tissue Morcellation System (Benetec Advanced Medical Systems, Retie, Belgium) power morcellator was used to perform all tests.[11] The system allows the use of 3 different diameters with the same instrument and power settings, thereby ensuring that measured differences can be attributed to diameter alone and not to instrument-specific features. Moreover, the MOREsolution provides circular cutting as well as oscillation, and adjustable blade rotating speed.

All trials consisted of 2 phases. First, the initial two-thirds of the beef tongue specimen was morcellated. The weight of the morcellated tissue was subtracted of the total specimen weight to determine the cut-off point. Next, the remaining one-third of the tissue (minus the spilled particles) was transferred to a new, clean bag and morcellation continued until all tissue was morcellated. The 2 bags were then inspected for macroscopic tissue spill. Spill was defined as any remaining tissue that could be extracted via the morcellator tube without activation of the morcellator. All tissue spill particles were counted and weighed.

The primary outcomes are number and weight of spilled particles (phase 1, phase 2 and both combined), duration of the morcellation procedure, the morcellated tissue weight at the onset of torque, the number of morcellation repetitions (meaning the number of tissue strips removed by the morcellator) and the size per spilled particle (weight per particle). All results (except for time and torque) are standardised for comparison, by calculating the outcome per 100 gram of morcellated tissue. Non-parametric tests (the Mann-Whitney U and Wilcoxon signed-rank test) were used to analyse all data. The Jonckheere-Terpstra test was used to evaluate the presence of trends in the studied diameters. All results are shown as median values, unless otherwise specified. $P \leq .05$ was considered significant.

Results

Twenty-three trials and 1 test trial divided over 6 groups were performed (table 1). For all groups combined, the mean weight of beef tongue was 431 grams (380-504g). During phase 1 and 2, 63% and 30% of the total weight was morcellated respectively. Mean weight and percentage of weight morcellated during phase 1 and 2, did not differ between groups. (table2)

Table 2: Results

	Total weight ^a	Phase 1 (% of procedure)	Phase 2 (% of procedure)	Particles ^b phase 1 (n)	Particles ^b phase 2 (n)	Particles ^b total (n)	Weight ^b phase 1	Weight ^b phase 2	Total weight ^b	Morcellation repetitions(n)	Weight per spill particle ^b	Weight at onset of Torque ^d	Time
12.5mm	400 (385-434)	60 (57-63)	33 (24-35)	10.3 (4.3-15.1)	22.9 (18.9-38.1)	34.7 (23.0-50.0)	6.2 (1.6-11.9)	11.2 (9.2-27.6)	15.9 (13.7-39.5)	13.7 (9.5-18.5)	.6 (.3-.8)	136 (80-184)	18 (14-18)
15mm	458 (391-496)	61 (53-69)	30 (23-39)	7.2 (2.3-8.9)	19.1 (16.8-32.5)	26.2 (21.4-41.3)	6.3 (1.5-9.3)	16.9 (11.3-31.5)	21.3 (17.1-38.2)	10.2 (9.2-11.3)	.9 (.5-1.1)	198 (147-260)	11 (7-18)
20mm	453 (428-504)	65 (62-71)	29 (26-36)	2.7 (1.0-5.9)	8.9 (4.4-19.5)	11.6 (5.4-25.4)	2.2 (.3-3.3)	10.5 (3.9-14.1)	12.7 (4.2-17.4)	4.3 (4.2-4.4)	.8 (.7-1.3)	222 (100-240)	6 (1-6)
Oscillation	386 (380-418)	68 (64-69)	26 (23-29)	6.6 (4.3-8.7)	16.4 (13.9-21.1)	22.7 (18.9-29.8)	ε (1.5-6.7)	ε (11.3-31.5)	6.8 (6.5-7.8)	6.3 (6.0-7.5)	.3 (.3-.4)	232 (161-268)	10 (8-13)
800 rpm	473 (391-496)	62 (53-64)	30 (24-39)	7.4 (2.3-8.8)	22.8 (16.8-32.5)	29.0 (21.4-41.3)	6.3 (1.5-6.7)	16.6 (11.3-31.5)	20.5 (17.6-38.2)	10.2 (9.2-11.3)	.8 (.5-1.1)	198 (147-260)	11 (9-12)
Novice	419 (402-437)	59 (58-63)	34 (33-35)	6.9 (2.8-7.3)	18.2 (16.8-23.5)	25.3 (19.6-30.4)	4.7 (.8-5.5)	11.9 (9.9-13.1)	15.8 (13.0-17.8)	7.0 (5.8-9.7)	.6 (.5-.7)	142 (101-154)	18 (13-26)

Numbers are median (range). ^a All weight in grams, ^b particles and weight per 100grams of morcellated tissue, ^c missing data, ^d onset of torque displayed as the amount of tissue morcellated so far (in grams)

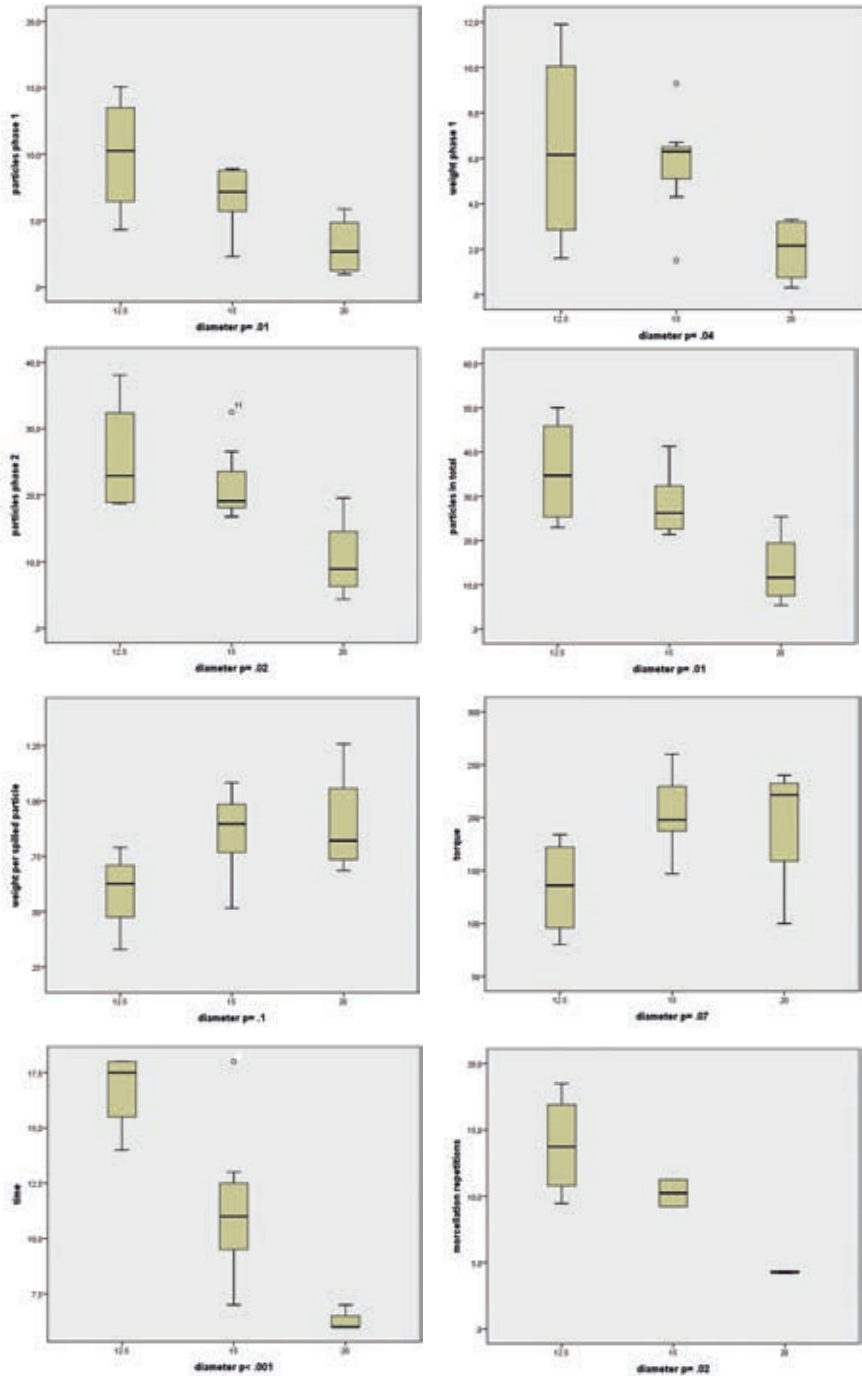


Fig 2 outcome of Jonckheere-Terpstra test. Diameter (mm), weight (g/100g), particles (n/100g), time (min), torque (grams morcellated weight)

With a larger diameter, both the weight of the spilled particles (phase 1) and the number of spilled particles (phase 1, 2 and in total) declined (weight phase 1= 6.5g vs 6.3g vs 2.2g for 12.5mm vs 15mm vs 20mm respectively, $p=.04$; number particles: Phase 1= 10.2 vs 7.2 vs 2.7 $p=.01$, Phase 2= 22.9 vs 19.0 vs 8.9 $p=.02$, Total= 34.7 vs 26.2 vs 11.6 $p=.01$). Also with a larger diameter, morcellation was quicker and less morcellation repetitions were needed (time for total procedure: 18min vs 11min vs 6min $p<.001$ and repetitions: 13.7 vs 10.2 vs 4.3 $p=.02$). Finally, the onset of torque applied to the tissue mass occurred later and the spilled particles were larger (Torque: 136g vs 198g vs 222g $p=.07$ and Size: .6g vs .9g vs .8g $p=.1$). (fig 2), although these differences were not statistically significant.

In the oscillation mode, there was less total spill per 100g (6.8g/100g versus 21.3g/100g, $U=.000$, $p=.01$, for oscillation and circular cutting respectively) and spilled particles were smaller (.3g/particle vs .9g/particle, $U=.000$, $p=.01$).

The novice created smaller spilled particles (.6g/particle vs .9 g/particle, $U=.000$, $p=.02$, for novice and expert respectively) and the onset of torque applied on the tissue mass occurred sooner (after 142g vs 198g, $U=.000$, $p=.02$). Also, morcellation by the novice was significantly slower (18min vs 11min $p=.02$).

No significant differences or trends were observed between rotation speed of 800 rpm and 400 rpm.

Finally, comparing phase 1 and 2 of all diameters of the expert trials with circular cutting, more spillage (particles and weight) occurred in phase 2 (6.0 particles/100g vs 19.0 particles/100g, $T=120$ $p=.001$ and 4.3g/100g vs 13.9g/100g, $T=120$ $p=.001$ for phase 1 and 2 respectively; data not shown).

Discussion

Technical features of power morcellators and the morcellation process are assessed in this study. When a larger diameter morcellation blade was used, tissue spill was significantly reduced, less morcellation repetitions were needed, and the procedure was faster when compared to smaller diameters. Next, our study confirmed our previous finding that more tissue is spilled later in the morcellation process. [8] Additionally, it is strongly suggested that the onset of torque applied to the tissue mass occurs later. This implies that this onset of torque may be prevented when a large diameter blade is used combined with partial instead of complete morcellation. Finally, the spilled tissue particles are larger. This may be advantageous since larger spilled particles are easier to detect and remove and are less likely to escape from containment bags.

Interestingly in the oscillation mode, although no effect was found on the onset of torque to the tissue, less total spill was observed when compared to circular cutting. It appears that less spill is an inherent quality of the oscillation mode. It is questionable if the oscillation mode is optimal in the used morcellator: a cycle of 4 turns clockwise is alternated by the same cycle counterclockwise, still allowing the blade to apply torque on the tissue. In theory, it is expected that reducing the cycle to a 1x1 movement may further delay or even prevent torque being applied to the tissue, however this has to be confirmed in future studies.

The differences in the onset of torque and size of spilled particles as observed in the novices trials underline the technical skills that are needed to morcellate tissue. More “coring” and less “peeling” of tissue occurred in the trials of the novice. Although this study was not powered to evaluate a learning curve, a sharp reduction in the morcellation time was found in the 4 trials of the novice (26min to 13 min). When teaching morcellation to a novice, the “peeling” motion should be emphasized and spillage should be carefully monitored.

In all, the results from our study appear to be in contrast with new developments in minimally invasive surgery with respect to minimizing the size and number of key holes during laparoscopic procedures in vivo. Our results suggest that power morcellators with oscillating blades and a large diameter, of 20mm or perhaps more, are advantageous with respect to the amount of tissue spill. Furthermore, less spill is produced when tissue is only partially morcellated. In case of total laparoscopic hysterectomy (TLH), larger instruments can be readily used by morcellating vaginally. In addition, removal of the larger remnant after partial morcellation should not be difficult via the vagina. However, in case of laparoscopic myomectomy (LMM) or laparoscopic supracervical hysterectomy (LSH), an enlargement of the port-site may be necessary to accommodate larger instruments and to extract the remaining tissue. This can be achieved abdominally, or vaginally by culdotomy.

The current developments in contained morcellation may appear to obviate the need for more efficient power morcellators. However, evidence questions the protective value of contained morcellation in high stage/grade tumors.[12,13] Therefore additional measures should be considered given the often high grade, aggressive characteristics of uterine sarcoma. Furthermore, it has been established that the integrity of morcellation bags can be impaired after use, even when the bags appear intact on gross examination. [14,15] Larger particles are less likely to pass through small puncture holes in the bags, and in case of abdominal spillage, are more easily detected. Finally, less morcellation repetitions decreases the risk of puncture by the device.

Because our experiment was not performed by classical laparoscopy, it may be questioned if our results are clinically applicable and this may be considered a weakness of our study. Our study was intended to examine the technical features of the morcellation instrument and process. By using a box trainer, our results are not affected by laparoscopic skills or the limitations of minimally invasive surgery as such. Furthermore, the use of beef tongue specimens instead of (human) uterine tissue and/or fibroids may be questionable in this context. Although beef tongue has been favorably used in other in vitro studies [5,9,10], its structure may not be completely similar to human fibroid tissue. Fibroids often are inhomogeneous due to calcifications or necrosis, and because of this, the pattern of tissue spread could be different than what we observed. However in our opinion, the inhomogeneity of fibroids may actually cause more tissue spread than the ideal model of beef tongue. Our definition of tissue spill in phase 1 and 2 could be considered artificial. After phase 1, all remaining large tissue particles were transferred to phase 2 and then morcellated. Of course during surgery, morcellation is a continuous process. Moreover, by using the same morcellator for all experiments, the difference in technical features of morcellator was excluded as an influence on the results. As a consequence, however, the outcome from our study may not apply to other commercially available morcellators. Nevertheless, our results are in agreement with previous observations in a clinical setting in which different morcellators were used.[8] Finally, we are aware of the limited sample size of this study. However, large differences were found that were statistically significant even in this sample. Furthermore, it was calculated that, based on our results, only 10-15 trials are necessary to make the trends in torque and particle size significant. Notwithstanding these shortcomings, the results of our study are highly relevant as they finally allow specific recommendations on the morcellator features. Moreover, our recommendations are easy to implement in daily practice and may contribute to safer a morcellation process regarding tissue spill in the very near future. In addition, our study can be used by the health care industry to improve and extend the range of existing power morcellators with oscillating blades and large diameter.

In conclusion, the results from our study demonstrate that tissue spill can be further decreased by using power morcellators with favorable features. Contained morcellation alone has yet to be proven effective, and its shortcomings have been demonstrated. The combined use of in-bag morcellation and more effective power morcellators may well lead to the enhanced safety of this procedure.

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