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A new in-bag system to reduce the risk of tissue morcellation: development and experimental evaluation during laparoscopic hysterectomy

Stefan Rimbach[1] · Annette Holzknecht[2] · Constanze Nemes[3] · Felix Offner[3] ·
Marius Craina[4]

Abstract

Introduction Minimal invasive approaches have proven beneficial for patients undergoing myomectomy and hysterectomy, but necessary tissue morcellation carries the risk of cell dissemination in rare cases of inadvertent malignancy. Performing the morcellation process within a contained bag system may prevent spilling and therefore enhance safety of the laparoscopic procedures.

Material and methods The present study describes the development and experimental evaluation of a new bag system in vitro and in vivo in a pig model of laparoscopic supracervical hysterectomies.

Results The main results on $n = 8$ procedures with in-bag morcellation compared to $n = 8$ controls without bag indicate reproducible feasibility and protective effect of the new bag, which is the first published to our knowledge that does not require puncturing in a standard multiport laparoscopy setting. Overall surgery time was significantly prolonged in the bag group by 12.86 min ($P = 0.0052$; 95 % confidence interval 4.64–21.07), but peritoneal washings were negative for muscle cells in all cases with bag use, compared to positive cytology in 5/8 cases without bag ($P = 0.0256$).

Conclusion Clinical trials will now be necessary to investigate the reproducibility of these encouraging data in human application.

Keywords Laparoscopy · Power morcellation · Hysterectomy · Myomectomy · Retrieval bag · In-bag morcellation

✉ Stefan Rimbach
  stefan.rimbach@stgag.ch

1 Kantonsspital Münsterlingen, Spitalcampus 1, Postfach 100, CH-8596 Münsterlingen, Switzerland

2 Department of Obstetrics and Gynecology, Landeskrankenhaus Feldkirch, Carinagasse 47, 6800 Feldkirch, Austria

3 Institute of Pathology, Landeskrankenhaus Feldkirch, Feldkirch, Austria

4 Department of Obstetrics and Gynecology, University of Timisoara, Timisoara, Romania

Introduction

Minimally invasive approaches have proven beneficial for patients undergoing myomectomy as well as hysterectomy in comparison to open techniques, as they reduce significantly the surgery-associated morbidity [1, 2]. To retrieve surgical specimens from the abdomen, however, the minimally invasive concept requires morcellating them intra-abdominally. This applies obviously to enucleated fibroids and supracervically amputated uteri, but may also become necessary during total laparoscopic hysterectomy, if the specimen is too large to pass the vaginal opening [3]. Manual morcellation has been clinical routine long before power-driven morcellators were introduced in 1993 to ease the procedure [4].

Using laparoscopic morcellation for two decades, not only benefits but also potential risks associated with this technique have been reported. Among other, i.e., mainly mechanical, risks [5, 6], the potential of harmful cell spreading from the morcellated tissue throughout the abdominal cavity was reported. When seeding, this may lead to benign conditions such as so-called parasitic leiomyoma or peritoneal adenomyosis [7–11], but may also result in peritoneal dissemination of inadvertently

morcellated malignancy, e.g., uterine sarcoma mistaken for benign leiomyoma [11–13]. Despite controversial discussion [14], evidence suggests that the prognosis of malignant disease may thus be worsened iatrogenically [15–18].

Prevalence data of such unsuspected malignancy at the time of hysterectomy and power morcellation to date derive from retrospective analyses and vary largely. In a cohort of 36,470 patients from a US insurance database, it was determined at 0.27 % [19], while it was found at only 0.13 % of 10,731 morcellated uteri in a German single center series [20]. Estimates from meta-analyses and literature reviews by international gynecological societies range from 0.1 to 0.25 % [21–26].

The risk of inadvertently morcellating and spreading malignant tissue led to strong warnings against the use of power morcellators to treat uterine fibroids by the US Federal Drug Administration (FDA) in April and November 2014 [27, 28], thereby questioning essential aspects of the minimally invasive concept for myomectomy and hysterectomy. On the other hand, it was estimated using a decision analysis model [23, 29] that converting all hysterectomies currently undergoing power morcellation to open procedures would result in a substantial increase in morbidity and mortality from open surgery.

Acknowledging that there will remain a risk of unsuspected malignancy despite all efforts in preoperative differential diagnostics, the question arises how to reduce the risk of tissue morcellation instead of abandoning the benefits of minimally invasive treatment [21–26, 29–31]. Morcellating within an intra-abdominally placed, closed containment system has been suggested for this purpose as a potential method to prevent cell spilling [22, 23, 25, 32, 33].

The aim of the present experimental study was therefore, to develop an innovative bag system for closed power morcellation and pre-clinically evaluate its ability to reduce the risk of fluid or cell spilling during laparoscopic supracervical hysterectomy.

Materials and methods

Bag system

The material was to be compatible for use in human, inflatable, transparent, water and cell tight, not inflammable and not melting under endoscopic light exposure. These clinical requirements were fulfilled by a 50 μm polyurethane film, not allowing molecule migration above 2–5 Å (2–5×10^{-10} m), with stress failure at 60 MPa.

The dimensions were defined according to human anatomy and an average pneumoperitoneum volume with the aim of allowing visualized contained power morcellation using an otherwise unmodified technique in a multiport laparoscopic approach.

Feed sizes of 340 × 250 mm were calculated to allow a pseudo-pneumoperitoneum capacity of 2.5 l, while the bag could still be folded suitably to enter a 12 mm trocar. An opening of 160 mm enables the surgeon to even bring in fibroid or uterine specimens clinically considered as large. This site was well designated for suprapubic morcellator access after pulling the opening outside the abdominal wall. A separate 16 mm-wide tubular opening was created for optic trocar access. This second opening was designed to be pulled out at the umbilical site, giving access to an umbilical optic trocar with usual CO_2 insufflation (Fig. 1). To protect the optic against contamination, keeping it uncontaminated for eventually continuing the surgery after morcellation, a rigid sleeve was additionally designed at 250 mm length and 11 mm diameter with a window at its tip (Fig. 2).

Fig. 1 Bag prototype with large opening (*right side*) for specimen and morcellator access, and small everted opening (*left side*) for optic trocar access (manufacturer: A.M.I., Austria)

Fig. 2 Optic sleeve for protecting the laparoscopy optic against contamination during visualized in-bag morcellation (manufacturer: A.M.I., Austria)
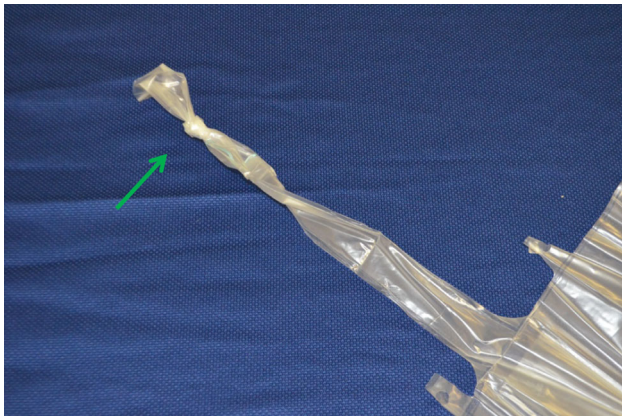
Fig. 3 Knot for bag occlusion at optic trocar opening before removal (two such knots have to be tied beneath each other)

After completing power morcellation, the optic should be withdrawn from the bag with its sleeve, and the possibly contaminated sleeve removed.

To remove the bag, it is pulled through toward the suprapubic side. The bag was designed to prevent contamination also during this phase of the procedure, when the former umbilical opening is to be pulled through the peritoneal cavity. To achieve this goal, the respective tubular opening was designed at a length of 190 mm, not only to suit different anatomies but also to allow everting its outer part. By the eversion, contamination could be prevented during the procedure and optic sleeve removal. The protected, everted part of the tubular opening is unrolled after removing the optic and sleeve, and occluded by tying a double knot (Fig. 3). Thus, the potentially contaminated section of the bag should be securely tight, while the part of the bag, which gets into contact with the peritoneal cavity during the pull-through, should have remained uncontaminated.

Experimental model

The properties of the new bag system (manufacturer: A.M.I. GmbH, Austria) were first tested in vitro, morcellating beef tongues in a laparoscopy training device using standard laparoscopy equipment including a Rotocut

morcellator (KARL STORZ GmbH & Co. KG, Germany). Typical multiport laparoscopy was simulated with an umbilical 11 mm trocar and 10 mm optic, two laterally positioned 6 mm trocars and one suprapubically positioned 12 mm trocar, which served to introduce the bag. Specimens to be morcellated measured $10 \times 6 \times 5$ cm. Three surgical procedures were simulated consecutively in this setting.

As a second step, experimental evaluation was continued in vivo after obtaining ethical committee approval performing laparoscopic supracervical hysterectomy on $n = 16$ PIC-variety farmhouse pigs.

The animals were randomly distributed into two groups: in group A ($n = 8$), power morcellation and tissue extraction were performed using the new containment bag system ("bag group"), and group B ($n = 8$) was operated conventionally without bag ("control group") (Fig. 4).

All operative procedures were performed by the same team of surgeons (SR, AH).

Three different types of power morcellators were used: Morcellex (Gynecare), Lina Xcise (Lina Medical) and Rotocut (Karl Storz). Each type was used in each group in a pre-defined number (Morcellex x3, Lina Xcise x3, Rotocut x2), but in a randomly assigned order.

Animal surgical procedure

The animal was positioned in lithotripsy position. The pneumoperitoneum was established via Veress needle at the umbilical site, an 11 mm trocar inserted transumbilically and the optic (0°) introduced. Under visual control (HD), another 11 mm suprapubic trocar and two 6 mm lateral trocars were positioned and the peritoneal cavity inspected and rinsed with physiologic NaCl. The fluid was extracted by suction for peritoneal cytology. Supracervical hysterectomy started with dividing the adnexa from the uterine horns, followed by dissection of the parametria and cutting the uterine vessels after coagulation and completed by dissecting the uterine corpus from the cervix. The entire procedure was performed using bipolar scissors for preparation and cutting, eventually replaced by bipolar clamps for coagulation in case of bleeding. The tissue was

Fig. 4 In vivo animal experimental evaluation: experimental design
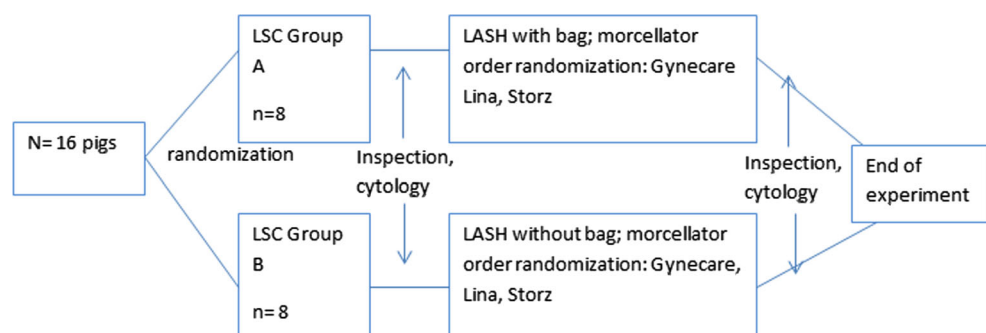
Fig. 5 Experimental in-bag morcellation during laparoscopic supracervical hysterectomy in the pig model

manipulated with a traumatic 5 mm grasping forceps (equipment and instrumentation: Karl Storz, Germany).

In group A, the containment bag was now introduced suprapubically after replacing the 11 mm trocar at this site by a blunt 12 mm introductory trocar. The uterine specimen was put into the bag via its large opening and the same pulled back through the suprapubic port site, while removing the introductory trocar again. Using a traumatic forceps via a lateral trocar, the second, small opening of the bag was then led through the umbilical trocar, while the trocar itself was removed for later use. At this time, both openings of the bag were situated extraperitoneally. Via the small bag opening at the umbilical site, the optic was introduced with its cover sheath, using the blunt introductory trocar now at this site. Pseudo-pneumoperitoneum in the bag was established by inflating the bag via this trocar, maintaining 12 mmHg during the entire procedure. The morcellator was inserted via the large opening suprapubically into the bag, and in-bag morcellation of the uterine specimens performed in the usual manner (Fig. 5). After completion, the morcellator was removed from the bag and the bag instilled with blue dye solution for tightness control. Now, the optic and its cover sheath were withdrawn together with the introductory trocar, the small bag opening closed securely by knotting, and the bag extracted from the peritoneal cavity by pulling it through from its suprapubic part. The original umbilical trocar and the optic (after removing the protective sheath) were re-inserted and the procedure continued by re-establishing the pneumoperitoneum.

In group B, tissue morcellation and extraction were performed in a routine manner via suprapubic access.

In both groups, at this time of the procedure, the peritoneal cavity was rinsed again with physiologic NaCl and the fluid again suctioned to obtain a second, post-morcellation peritoneal cytology. The procedure was ended by removing the pneumoperitoneum and closing the abdominal wall incisions by sutures.

Evaluation parameter and statistical analysis

Bag handling, pseudo-pneumoperitoneum, feasibility of power morcellation and visualization quality were qualitatively registered as described subjectively by the surgeons during both, in vitro and in vivo experiments.

Bag integrity including security of knot occlusion was checked by visual inspection for lesions and blue dye spilling. Additionally, the bags were postoperatively inflated with pressurized air at 20 mbar (15 mmHG) under laboratory conditions.

Regarding the in vivo evaluation, animal weight, initial CO_2 volume of the pneumoperitoneum, weight of morcellated tissue and amount of fluid collected for cytology were registered for baseline characteristics comparison of both groups for possible heterogeneity using unpaired t test.

Time of surgery, time of bag use and overall volume of used CO_2 were measured to analyze the impact of bag use for the duration of surgery. Comparisons between the two groups were analyzed using unpaired t test.

Peritoneal cytology was analyzed for the presence of smooth muscle cells in the bag group (group A) versus the control group (group B) prior and post-morcellation as an indicator for possible cell spilling. Examination was done by two cytologists independently (CN, FO) blinded to the procedures and the experimental groups. The collected fluid specimens were centrifuged, suspended in CytoLyt^R, centrifuged, decanted and resuspended in PeservCyt^R, then processed using ThinPrep^R 5000 automated slide processor (Hologic) and stained with Pap stain using the Tissue Stainer COT 20 (Medite). Positive controls were prepared similarly. Cellularity was first graded semi-quantitatively as none (0), low (1+), moderate (2+) or high (3+). Additional centrifugation steps with resuspension in CytoLyt^R solution were performed for bloody specimens. Cell blocks were then prepared by centrifuging and decanting the residual solution to yield a cell pellet, which was suspended using thrombin and 1 ml citrate and then embedded in paraffin wax, sectioned and stained with hematoxylin and eosin using standard technique. Slides were examined for the presence of mesothelial cells, lymphocytes, granulocytes and spindle cells using the above-described score. Samples scored positive for spindle cells based on morphological criteria were subjected to immunocytochemistry for smooth muscle cell identification. For this purpose, cell block sections were deparaffinized, washed in ethanol and in phosphate-buffered saline, and then incubated with the primary antibodies ActinSMA (DAKO-Clone 1A4 RTU), desmin (DAKO-Clone D33 RTU) and caldesmon (Ventana-Clone E89 RTU). Standard detection technique was performed using ultraView Universal Alkaline Phophatase Red Detection

Kit (Ventana). Slides were counterstained with Bluing Reagent. Differences in smooth muscle cell presence was compared for Group A and B in a contingency table and analyzed using Fisher's exact test for significance.

Results

Feasibility

Handling of the bag system proved intuitively feasible and was successful in all cases, in vitro and in vivo, during all steps of the procedures. The same applies for specimen positioning into the bag. Also in all cases, sufficient pseudo-pneumoperitoneum, subjectively similar to the usual pneumoperitoneum in human procedures, could be established within the bag, using routine pressure-controlled CO_2 insufflation in the same way as in control cases. Visualization was clear and not impaired while using the protection sleeve. Power morcellation proved feasible without the need to modify the technique as compared to the conventionally performed cases. No differences were found between the three morcellator devices as far as in-bag procedure feasibility was concerned. No differences in feasibility were noted between the two surgeons.

Bag integrity

Visual inspection after use did not reveal any lesions of the bags. Fluid tightness was proved in all cases by visual control for eventual blue dye spilling. Bags did not lose blue dye-stained fluid, nor was spilled blue dye found in the peritoneal cavity. All used bags proved also tight during pressurized air inflation.

Baseline characteristics of comparison groups

The analysis of baseline characteristics did not reveal any heterogeneity among both groups (Table 1). The median weight of the animals in group A was 32 kg (minimum 30, maximum 34) and in group B 32.5 kg (minimum 31, maximum 35). The difference was not significant

($P = 0.1450$; 95 % confidence interval of the mean difference −0.389 to 2.389).

Mean volumes of CO_2 at initial pneumoperitoneum were 3.988 ± 0.511 l in group A and 3.913 ± 0.422 l in group B. The mean difference of 0.075 (95 % confidence interval −0.428 to 0.578) l was not statistically significant ($P = 0.7537$).

Mean weights of morcellated tissue were 17.263 ± 8.766 g in group A and 26.575 ± 15.285 g in group B. The mean difference of 9.313 g (95 % confidence interval −22.674 to 4.049) was not statistically significant ($P = 0.1572$).

Time of surgery and CO_2 volume use (Table 2)

The mean overall duration of surgery was 31.86 ± 8.90 min in group A versus 19.00 ± 4.51 min in group B. The mean difference of 12.86 min (95 % confidence interval 4.64–21.07) was highly significant ($P = 0.0052$).

The time of bag use in group A ranged from 10 to 36 min with a median of 13.5 min. The case in which the bag was in place during 36 min was the first in group A and thus the initial bag application. If the time of bag use was calculated without this case, it ranged from 10 to 20 min among the other seven cases with a median of 12 min. The mean time of surgery in group A exclusive bag use time was 18.29 + 6.29 min, not significantly different from the overall time in group B ($P = 0.8112$). The mean difference was 0.71 (95 % confidence interval −7.09 to 5.66).

The mean overall volumes of CO_2 used to maintain pneumoperitoneum during the entire surgery were 79.500 ± 28.597 l in group A and 44.350 ± 21.677 l in group B. The mean difference of 35.150 (95 % confidence interval 7.076–63.224) proved statistically significant ($P = 0.0180$).

Peritoneal cytology

Prior to morcellation, mean fluid amounts collected for peritoneal cytology were 935.63 ± 48.72 ml in group A and 976.63 ± 59.14 ml in group B. The mean difference of

**Table 1** Baseline characteristics of animal experimental groups A and B

	Group A: in-bag morcellation	Group B: conventional morcellation	P value
n	8	8	
Median animal weight (kg)	32 (30–34)	32.5 (31–35)	0.1450 (ns)
Mean CO_2 volume of initial pneumoperitoneum (l)	3.988 ± 0.511	3.913 ± 0.422	0.7537 (ns)
Mean weight of morcellated tissue (g)	17.263 ± 8.766	26.575 ± 15.285	0.1572 (ns)
Mean fluid volume for cytology prior to morcellation (ml)	935.63 ± 48.72	976.63 ± 59.14	0.1524 (ns)
Mean fluid volume for cytology post-morcellation (ml)	1007.25 ± 40.61	992.75 ± 45.47	0.5121 (ns)

ns not significant in unpaired *t* test

Table 2 Comparative results in animal experimental groups A and B: time of surgery and overall CO_2 use to maintain pneumoperitoneum over the entire procedure

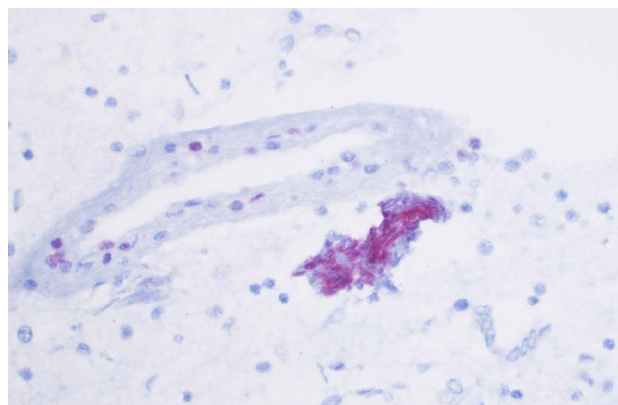|	Group A: in-bag morcellation	Group B: conventional morcellation	Mean difference (95 % confidence interval)	P value
Mean overall time of surgery (min)	31.86 ± 8.90	19.00 ± 4.51	12.86 (4.64 to 21.07)	0.0052 (sign.)
Mean time of surgery exclusive bag use time (min)	18.29 ± 6.29	=Overall time 19.00 + 4.51	0.71 (−7.09 to 5.66)	0.8112 (ns)
Mean overall CO_2 volume (liter)	79.500 ± 28.597	44.350 ± 21.677	35.150 (7.076 to 63.224)	0.0180 (sign.)

sign. significant, *ns* not significant in unpaired *t* test
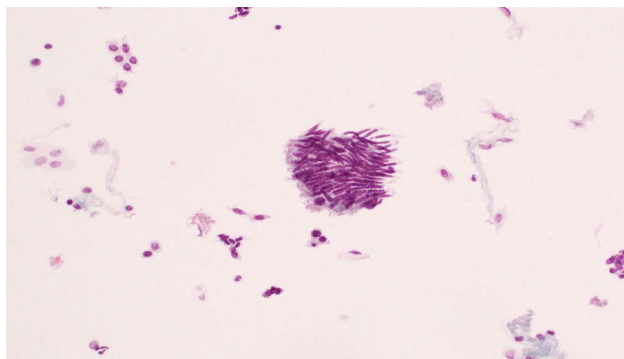
Fig. 6 Spindle cells in peritoneal fluid, detected in a case post-morcellation without bag (cell bloc, HE stain, 40×)

Fig. 7 Immunocytochemical identification of smooth muscle cells by SMA antibody staining: same case as in Fig. 6 post-morcellation without bag (ActinSMA, 20×)

41 ml was not significant ($P = 0.1524$; 95 % confidence interval −99.10 to 17.10). After morcellation, the mean amounts were 1007.25 ± 40.61 and 992.75 ± 45.47 ml with a not significant difference of 14.50 ml ($P = 0.5121$; 95 % confidence interval −31.73 to 60.73) (Table 1).

Cellularity was found positive in all peritoneal fluid specimens prior to morcellation, regardless of the experimental groups (group A: score 3+ $n = 4$, score 2+ $n = 4$; group B: score 3+ $n = 4$, score 2+ $n = 4$). Post-morcellation, the cellularity of the specimens was obtained in 15/16 cases (group A: score 3+ $n = 4$, score 2+ $n = 3$; score 1+ $n = 1$; group B: score 3+ $n = 6$, score 1+ $n = 1$). In one case of group B, the fluid was found to be acellular except for the presence of erythrocytes. Morphologically, the cells found prior to morcellation could all be differentiated into mesothelial cells, lymphocytes or granulocytes, but no spindle cells. Post-morcellation, all specimens in group A and 7/8 in group B as well contained mesothelial cells, lymphocytes or granulocytes, and additionally spindle cells (Fig. 6) were detected in 5 cases of group B versus none of group A. These were identified as smooth muscle cells by immunocytochemical staining in four cases with positive SMA (Fig. 7). In one case SMA was negative, but desmin and caldesmon were positive. The difference between the two groups proved statistically significant ($P = 0.0256$). The results are summarized in Table 3.

Discussion

Tissue morcellation during hysterectomy or myomectomy is consistently considered contraindicated in settings where uterine malignancy is either known or suspected. But despite meticulous preoperative diagnostic workup, there remains a risk of inadvertently morcellating malignancy in presumed benign tissue [21, 22, 25, 26, 31, 34]. Cell spread throughout the peritoneal cavity could potentially be prevented in such circumstances by using a retrieval bag for tissue morcellation and extraction [24–26, 32, 33, 35].

The first attempts date back to 1993 in urology [36]. Then, and during subsequent years, laparoscopic techniques were clinically and experimentally evaluated for nephrectomy in early and low-grade renal cell carcinoma. Morcellation in a bag was intended to prevent iatrogenic dissemination and especially port site metastases. Oncological results were discussed controversially [37–39]. As far as technical aspects are concerned, bags were inserted via a port site and, after positioning the specimen and exteriorization of the bag's mouth, morcellation was performed mechanically or power driven, under direct inspection or with the help of a laparoscopy optic inserted beneath the morcellator into the bag [39–42]. In general surgery, a comparable technique has been reported for

Table 3 Comparative results of peritoneal cytology in animal experimental groups A and B prior and post-morcellation

	Group A: in-bag morcellation	Group B: conventional morcellation	P value
Prior morcellation			
n	8	8	
Cellularity			
Pos	8	8	ns
Neg	0	0	
Spindle cells			
Pos	0	0	ns
ICC	na	na	
Neg	8	8	
Post-morcellation			
Cellularity			
Pos	8	7	ns
Neg	0	1	
Spindle cells			
Pos	0	5	0.0256 (sign.)
ICC: SMA	na	4	
DES	na	3	
CAL	na	5	
Neg	8	3	

ICC immunocytochemistry, *SMA* smooth muscle actin, *DES* desmin, *CAL* caldesmon, *sign.* significant, *ns* not significant in Fisher's exact test)

splenectomy with manual morcellation in an exteriorized bag after laparoscopic preparation [43].

Several approaches have been described in gynecology to date using different ways of bag insertion, morcellation and tissue extraction. These include abdominal port site [44–49] or transvaginal [50] insertion of the bag, open abdominal (mini-laparotomic) [49] or vaginal in-bag morcellation [51–55], each manually under direct vision, and laparoscopic power morcellation within a pseudo-pneumoperitoneum in the bag inside the abdomen [44–50]. The latter technique provides the possibility of containing morcellation, when vaginal access is not suitable.

Bags used for the respective approaches have different sizes and materials, but all have a common geometry consisting of a sac with one mouth. After bag insertion into the peritoneal space, the specimen is positioned in the bag via this mouth and the same exteriorized onto the abdominal wall, thus following the principles of usual retrieval bags [44, 47, 48]. The challenge at this point is to provide safe morcellation which requires access for the morcellator device, enough space and visual control. If direct vision is not an option, because vaginal access is not practicable and laparotomy needs to be avoided, laparoscopic guidance is needed.

In analogy to the vaginal approach, single incision umbilical trocars provide suitable simultaneous access for morcellator and optic, as described by Cohen [44]. Multiport approach requires at least one puncture of the intraperitoneally insufflated bag in all so far published

systems [44–50]. Puncturing the bag, however, carries the risk of leakage and spilling, and thus opposes the intent of contained morcellation [21, 23, 25, 26, 56].

To our knowledge, the bag system reported in the present study is the first providing multiport access without puncturing.

The initial procedure compares to that yet reported with bag insertion into the peritoneal space and specimen positioning into the bag. In contrast to others, our prefolded system fits through a 12 mm suprapubic trocar and intraperitoneal orientation is facilitated by a ring, keeping the bag mouth open to ease the entry of the specimen. Up to this point, the procedure does not differ from usual multiport laparoscopy approach. The bag's mouth, where the specimen has been placed in, is now exteriorized suprapubically and the respective trocar removed. This site will allow morcellator access at its typical position without the necessity of modifying the classical, trained approach.

In contrast to earlier reported systems, the bag here described has a second preformed mouth resembling a tube, designed for optic trocar access. This tube is pulled out transumbilically and replaces the optic trocar. Re-inserting this trocar and the optic now bluntly inside the tube gives visual access to the bag interior in a setting completely comparable to usual multiport laparoscopy. Also pseudo-pneumoperitoneum is established in a trained manner via the umbilical optic trocar.

Systems requiring bag puncture achieve to prevent spilling from the puncture hole by using a balloon tip trocar

[44–50]. Our system provides at this point an intact closed, contained environment for subsequent morcellation.

One aspect of the potential of cell dissemination has not been addressed in earlier concepts to our knowledge. The laparoscopy optic may be contaminated by aerosolized tissue components and dissemination might occur during continuation of the surgical procedure. To overcome this risk, a window-tipped sleeve has been designed to cover the optic, which is eliminated after completing the morcellation-associated part of the procedure. Concerns about impaired visualization did not prove relevant during our experimental evaluation.

Contained power morcellation was feasible without problems in all cases of our experimental series. No differences were noted between the two operating surgeons, or with regard to the morcellator types.

Important prerequisites consist of adequate size and geometry of the bag, allowing tissue handling and correct visualization [21, 23]. Earlier reports used bags at volumes between 1000 and 3100 ml [44, 47–50]. The bag presented here provides a capacity of 2500 ml, which proved suitable to establish a pseudo-pneumoperitoneum totally comparable to clinical routine. Morcellation, therefore, did not differ from routine use either. The experimental model of performing the surgery in pigs proved well selected with regard to the question of space, with average pneumoperitoneum volumes measuring around 3.9 l. Limitations of the experimental model may consist of the smaller tissue sizes and shape of the morcellate, and clinical trials will have to prove equal success in human.

Using the bags takes time. Earlier clinical trials reported 26–30 min additional duration of surgery [46, 49]. In our experimental setting, the time consumed for handling the bags ranged from 10 to 36 min with an average of 12.9 min. Timelines are also reflected in augmented CO_2 consumption for maintaining the pneumoperitoneum. The significant difference in this regard may also be increased by CO_2 loss during bag insertion, removal, and re-establishing the pneumoperitoneum afterward. The rest of the procedure including the morcellation process, however, was not influenced with reference to time measurements, which did not differ statistically.

As claimed before [21–23], the transparency of the bag facilitated simultaneous visualization inside the bag and of the surrounding organs, thus allowing the surgeon to control morcellation in a previously trained routine manner, protecting adjacent tissue from the morcellator blade by keeping adequate distance. As the presented bag system does not require puncture from outside, there is no necessity of obscured instrument action, which had been criticized compared to other techniques [23, 56].

Further dissemination risk exists during bag removal [25]. In approaches with bag puncture, the described strategies to prevent spilling from the hole include grasping at this site as well as suctioning to create negative pressure by keeping aerosols within the bag [44, 47, 48, 50]. The present approach does not have to fear leakage from a puncture, but from the constructive second opening of the bag. This challenge was solved by designing a special method for occlusion. Before the bag is removed by pulling it toward the suprapubic site, the tubular optic trocar opening at the umbilical site is occluded by knotting it twice. Because the inner surface may have been contaminated while withdrawing the optic and its sleeve, the tubular part is originally everted and its uncontaminated part not unrolled until knotting.

In fact, tightness was successfully ensured in all cases. Visual inspection did not reveal any lesion, formally confirmed by the absence of blue dye spilling or gas leakage.

As previously described in vitro by Cohen [57], cytologic analyses of fluid washings searching for muscle cells may indicate possible cell dissemination. Thus, the most important result of the present study consists of the complete absence of disseminated myometrial cells in peritoneal washings after morcellation within bags, while spindle cells were found in five of eight (4 of them smooth muscle actin positive) animals of the control group without bags. Negative findings in all cases of both groups prior to morcellation indicate that this was the most probable source.

Whereas cell dissemination was neither detectable in all cases without bags, the observed difference between the experimental groups with complete absence of spread cells when morcellation took place within the bag suggests a significant protective effect of the evaluated system.

A clinical trial will now be necessary to investigate the reproducibility of these encouraging experimental data in human application.

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