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Real-World Tissue Containment Use in Laparoscopic Hysterectomy and Myomectomy: Insights from a Survey of FMIGS Fellows

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ABSTRACT

Objective: *To assess real-world usage patterns, regulatory compliance, and perceived safety concerns related to tissue containment systems (TCSs) and tissue retrieval bags (TRBs) in laparoscopic hysterectomy and myomectomy among first-year fellows in minimally invasive gynecologic surgery (FMIGS).*

Design: *Cross-sectional electronic survey.*

Setting: *U.S.-based academic centers participating in FMIGS.*

Participants: *First-year FMIGS fellows. No patient data was collected.*

Interventions: *None.*

Results: *Of 50 eligible fellows, 31 completed the survey (62% response rate). Abdominal manual morcellation (AMM) was the predominant extraction technique, with 42% using it in over 80% of cases. Transvaginal morcellation (TVM) was used in fewer than 20% of cases by 65%, and power morcellation (PM) was rarely used (3%).*

Although 77% of respondents reported awareness of the regulatory distinction between FDA-cleared containment systems and off-label retrieval bags, 45% usually or always used the latter. The Alexis Contained Extraction System (Applied Medical) was the most frequently used containment device (90%), but 81% of users did not consistently apply the included protective components. Notably, 35% of respondents estimated that punctures occurred in 30% or more of cases, regardless of bag type. Cost was cited more often than regulatory concerns as a barrier to use (61% vs. 29%).

Conclusion: *Laparoscopic procedures involving AMM and the use of containment systems are increasingly common. However, high estimated puncture rates, frequent off-label usage, and incomplete protocol adherence suggest the need for greater regulatory clarity, improved device training, and broader access to purpose-built containment solutions.*

Keywords

Cancer, Minimally invasive gynecologic surgery, Morcellation, Tissue containment, Tissue extraction.

Introduction

Minimally invasive surgery (MIS), including laparoscopic myomectomy and hysterectomy, offers substantial benefits over open surgery, such as reduced blood loss, faster recovery, and lower morbidity [1-3]. For large specimens, morcellation is often required to facilitate removal through small incisions [1]. However, both manual and power morcellation carry the risk of tissue dissemination, which may lead to conditions such as

metastatic disease, parasitic myomas, or endometriosis [4-6].

Following the 2014 FDA safety communication highlighting a 1 in 350 risk of occult malignancy with power morcellation [7], there was a marked decline in its use and a shift toward manual morcellation [8]. The FDA now recommends using power morcellation only with FDA-cleared containment systems, which undergo safety and integrity testing [9,10]. Currently, only tissue containment systems (TCSs) are FDA-cleared for morcellation; tissue retrieval bags (TRBs), although widely used, are not [11-13]. Concerns persist about system integrity, with reported leakage rates as high as 15–32% [14]. In FDA-conducted testing, one commonly used off-label bag showed leakage in 88% of simulations due to material porosity [13].

This study evaluates real-world containment practices among U.S. first-year FMIGS fellows, focusing on use patterns, safety concerns, and barriers to the adoption of approved containment technologies.

Methods

Institutional review board approval was not required as the study did not involve human or animal subjects. We conducted an anonymous electronic survey of first-year fellows in the FMIGS program for academic year 2024-25, which comprises 54 U.S. and 7 international training sites [15]. All first-year fellows were eligible. The survey included 12 questions assessing surgical approach, containment device usage, perceived puncture rates, and barriers to containment use. Question formats included Likert scales, ordinal responses, and open-ended items.

The survey was distributed via Google Forms between December 20, 2024, and January 19, 2025. Participation was voluntary and implied informed consent. A separate link was provided to claim a participation incentive, which was decoupled from the response data to preserve anonymity. Descriptive statistics were calculated using Microsoft Excel.

Results

Of 50 fellows contacted, 31 responded (62%). Abdominal manual morcellation (AMM) was the dominant extraction method, used in over 80% of cases by 42% of fellows. Transvaginal morcellation (TVM) was employed in fewer than 20% of cases by 65%. Power morcellation (PM) was rarely used, with 97% reporting never using it.

Overall, 65% of fellows reported using AMM in at least 60% of procedures, while only 16% reported using TVM in that frequency range. Containment practices varied. 77% of fellows reported awareness of the regulatory distinction between tissue containment systems (TCSs; e.g., Alexis Contained Extraction System [Applied Medical], LapBox [Ark Surgical], Guardenia [Olympus]) and tissue retrieval bags (TRBs; e.g., Endo Catch [Medtronic], Inzii [Applied Medical], Anchor [CONMED], EcoSac [Espiner Medical]) (Figure 1). Nevertheless, 45% reported regular off-label TRB use, and an additional 42% reported use in about half of cases (Figure 2).

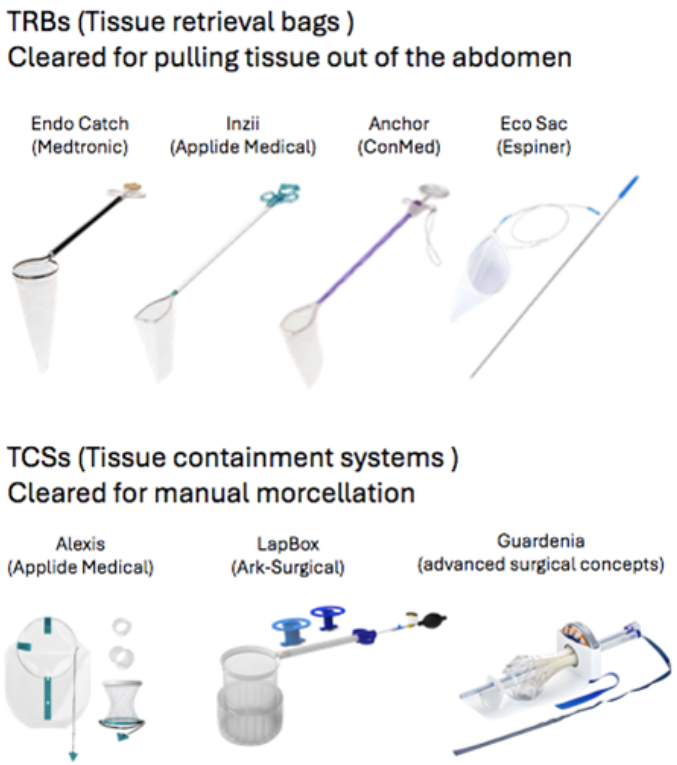


Figure 1: FDA Cleared Tissue Retrieval Bags and Tissue Containment Systems.

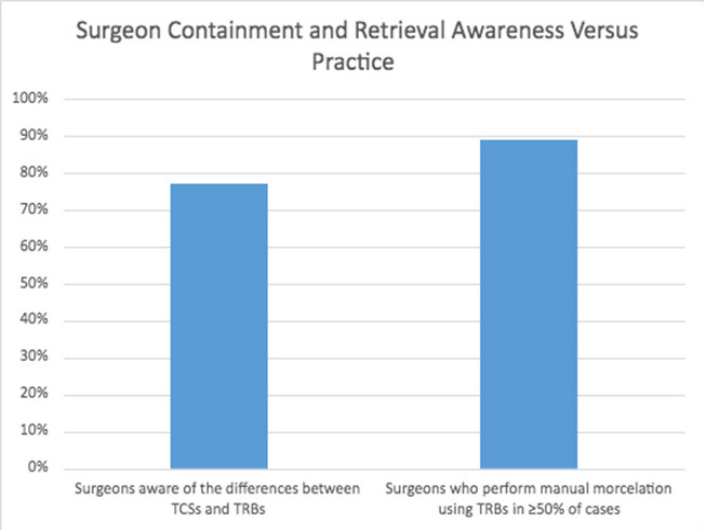
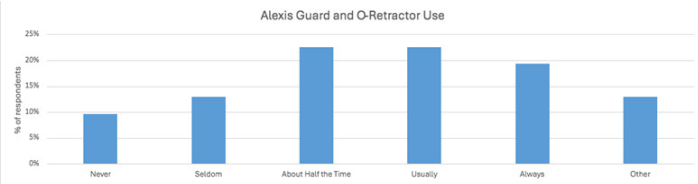


Figure 2: Containment and Retrieval Awareness versus Practice in FMIGS Fellows.

The Alexis system was the most commonly used TCS (90%), but only 19% reported consistent use of both the O-retractor and guard. Nearly one-quarter (23%) seldom or never used these protective

elements (Figure 3).

Figure 3: Alexis Retractor Guard and O-Retractor Use in FMIGS Fellows.



Bag puncture was perceived as common across all bag types, with 35% of fellows estimating puncture rates of 30% or more. Even with an FDA-cleared TCS, more than half of fellows believed that perforation occurs in 5–10% of procedures.

When asked which factors might increase access to containment systems, 29% believed regulatory guidance from AAGL or ACOG would be somewhat or very likely to influence adoption, while 61% reported that reducing the cost of TCSs to the level of TRBs would improve access.

Discussion

Our findings highlight widespread use of AMM and high awareness of containment options among FMIGS fellows. Compared with a 2019 AAGL member survey [8], this study suggests increased use of abdominal extraction and avoidance of PM, with only 3% of our respondents reporting its use—a shift in practice likely influenced by FDA guidance.

While containment is broadly adopted, gaps persist in compliance and standardization. Almost half of fellows reported using TRBs off-label, and over 80% did not consistently follow recommended protocols for FDA-cleared systems like Alexis. These findings reveal a disconnect between device design and real-world applications among MIGS providers in training as well as their attending physicians overseeing the cases.

One-third of participants estimating a puncture rate of 30% or more is concerning. Prior studies have reported leakage in 15–32% of procedures [14]. The fact that FDA-cleared systems are still perceived as vulnerable to perforation suggests a need for improved design, training, or both. Furthermore, the interchangeable use of TRBs and TCSs, despite their regulatory distinction, may reflect the influence of institutional cost constraints over clinical best practices, or other factors such as ease of use not captured by this survey.

Encouragingly, newer containment systems with dual-layer architecture may offer enhanced protection, though further study is needed to confirm improved clinical outcomes. Regardless, broad access to such systems will depend on affordability and integration into routine training.

Limitations of this study include modest sample size and reliance on self-reported recall. The lack of demographic data limits subgroup analyses. Future studies should incorporate objective surgical data (e.g., EHR review or operative video audit) to validate findings.

Conclusion

Abdominal manual morcellation with containment is now standard in many laparoscopic hysterectomies and myomectomies. However, current practices reveal significant variability in device selection, off-label use, and protocol adherence. Clinical guidelines emphasizing consistent use of FDA-cleared containment systems with full component application would mitigate dissemination risks and optimize patient safety. Institutional purchasing decisions should align with safety priorities, and formal training on containment practices should be encouraged.

Without consistent application, containment systems risk offering only a false sense of safety. Coordinated efforts by surgical societies, regulatory bodies, and hospitals are essential to promote safe, standardized use of tissue containment devices.

Source of Funding

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