

Intrauterine Pressure During Hysteroscopic Morcellation: A Comparison of Three Commercially-Available Devices

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ABSTRACT

Study objective: Our objective was to compare intrauterine pressures during resection and aspiration modes among three types of commercially-available hysteroscopic morcellators.

Design: This was a benchtop study (Canadian Task Force level II-1). This study cannot feasibly and ethically be done in-vivo, so an ex-vivo study design was chosen.

Setting: A silicone uterine model was attached to a manometer via tubing, with the tip inside the cavity to allow for intracavity pressure measurements. Each hysteroscopic morcellator was then introduced, and intracavity pressures were recorded every one to two seconds in three modes (static, resection, and aspiration) and at three set point pressures (45, 85, and 125 mmHg).

Patients: No human subjects were involved in this study.

Interventions: None.

Measurements and main results: There were a total of 4,872 pressure measurements during this study across the three devices, over the three modes, and at the three set point pressures combined. Using mixed-effects linear regression, the mean observed intracavity pressure was not greater than the set pressure for each of the three devices. This result held true in both aspiration and resection modes. In our statistical models, the coefficient on the terms representing the interaction between device and time were not statistically significant in either resection or aspiration modes. This indicates that, statistically, the change in intracavity pressure over time was not significantly different across the three devices.

Conclusion: In this first of its kind head-to-head benchtop study, we found that all three commercially-available hysteroscopic morcellators appear to be similar to each other in terms of their abilities to maintain intracavity pressure below the set pressure, which is important in avoiding intravasation in-vivo. These findings are important because many gynecologists do not have the ability to choose between the three available devices on the market at their institution.

INTRODUCTION

Hysteroscopy is a commonly-used minimally invasive gynecological procedure, utilized in both clinical and oper-

ating settings. An endoscopic optical lens is inserted through the cervix into the endometrial cavity to directly visualize and treat pathology. Operative hysteroscopy became popular after improvements in endoscopic technology

and instruments in the 1970s and after the introduction of the fluid distension medial in the 1980s. Since that time, the development of new hysteroscopic instruments, fiber optics, and digital video equipment have to provide more

Table I
Descriptions of Symphion™, TruClear™ and MyoSure® hysteroscopic morcellator systems

	Type of energy during resection	Components	Description from manufacturer	
Symphion™ Boston Scientific	Bipolar radiofrequency	Symphion™ controller with integrated fluid management	2 modes: diagnostic and resection.	Figure 1a
		Symphion™ fluid management Accessories, including footswitch and saline pole	Fluid infusion and aspiration of the uterine cavity are controlled by the controller's peristaltic pumps, in conjunction with the disposable fluid management accessories; these components form a closed-loop re-circulating system.	Figure 1a
		Symphion™ resecting device	Disposable hand-held bipolar radiofrequency device.	Figure 1b
		Symphion™ endoscope	0° 6.3 mm rigid scope, with 2 integrated fluid channels (1.5 mm) and 1 working channel (3.7 mm). The fluid channels are used for infusion or distension fluid and direct pressure monitoring of the cavity. The working channel accommodates the Symphion™ resecting device. The working length of the Symphion™ endoscope is 208 mm.	Figure 1c
TruClear™ Medtronic (Smith & Nephew)	Mechanical	TruClear™ fluid management accessories, including footswitch	Minimizes fluid use through proprietary suction control technology. Provides simultaneous cutting and tissue removal, requiring only a single insertion. Provides fewer procedural steps due to single insertion.	Figure 2a
		TruClear™ tissue removal devices	1. TruClear™ INCISOR™ device for soft tissue 2. TruClear™ INCISOR™ Plus device for soft tissue 3. TruClear™ ULTRA Mini device for dense tissue 4. TruClear™ ULTRA Plus device for dense tissue	Figure 2b
		TruClear™ hysteroscope	1. TruClear™ 5C hysteroscope set -Scope is 5 mm in diameter with a 5.7 mm sheath -0° rigid scope 2. TruClear™ 8.0 hysteroscope set -0° rigid scope -For use with larger tissue removal devices (INCISOR™ Plus and ULTRA Plus)	Figure 2c

Table I (continued)
Descriptions of Symphion™, TruClear™ and MyoSure® hysteroscopic morcellator systems

MyoSure® Hologic	Mechanical	MyoSure® hystero- scope	0° direction of view and 80° field of view. Small 6.25 mm outer diameter. Larger scope available that is 7.25mm diameter. Outflow channel is removable.	Figure 3
		Tissue removal devices	<p>MyoSure® LITE: Window length: 10.2 mm Window depth: 1.5 mm</p> <p>MyoSure®: REACH Window length: 14 mm Window depth: 1.8 mm</p> <p>MyoSure® XL Window length: 14 mm Window depth: 2.4 mm</p>	

Symphion figures and description obtained from:
https://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/sites/symphion/pdfs/System_Instructions.pdf.
Truclear figures and description obtained from:
<http://www.premiermedical.ie/wp-content/uploads/2013/09/TRUCLEAR-Brochure.pdf>.
Myosure figures and description obtained from: http://myosure.com/sites/myosure/files/PB-00280-001_Rev_002_MS_Phy_Brochure.pdf.

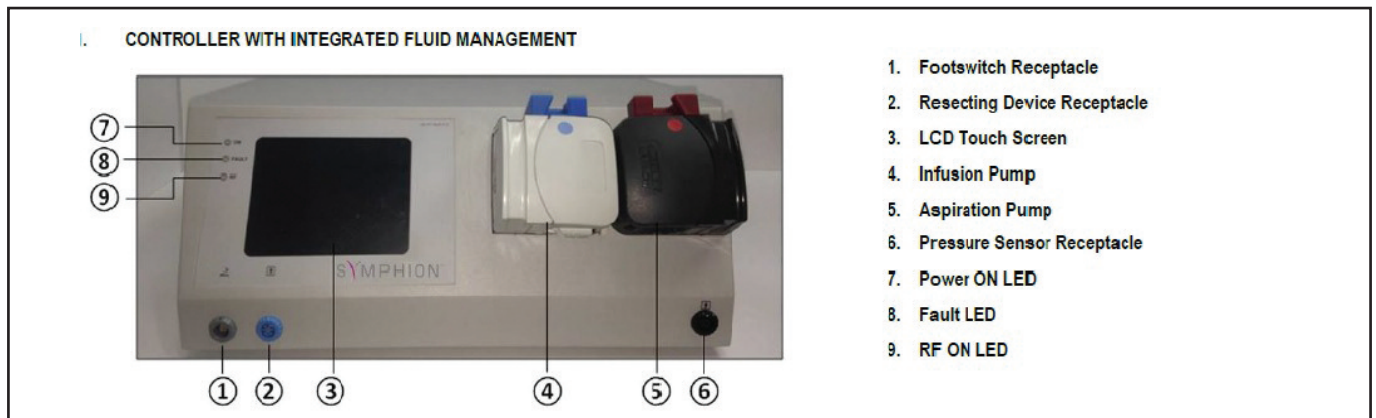


Figure 1a. Symphion™ controller with integrated fluid management.

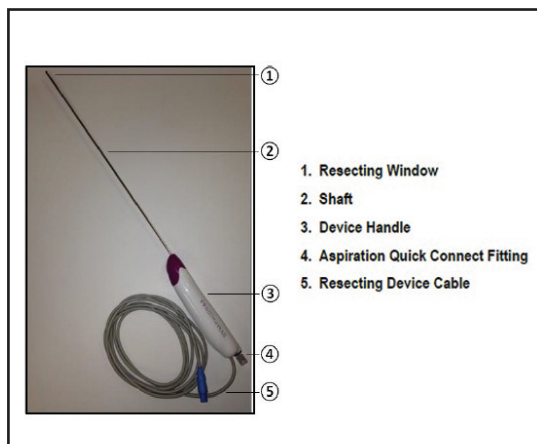


Figure 1b. Symphion™ resecting device.

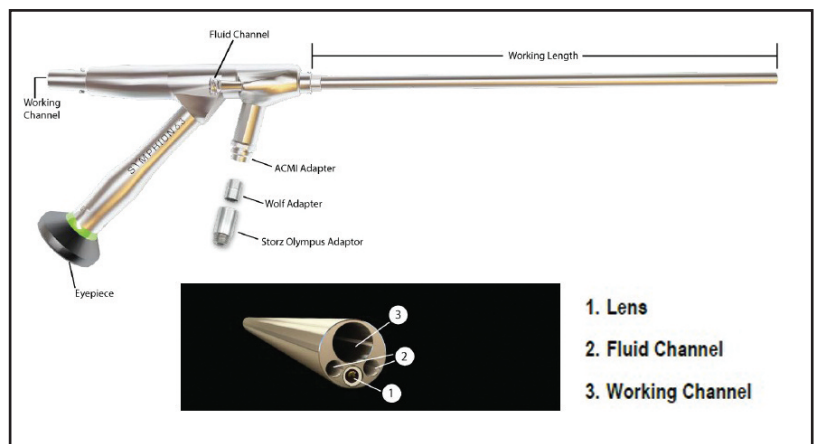


Figure 1c. Symphion™ endoscope.



Figure 2a. TruClear™ fluid management accessories, including footswitch.



Figure 2b. TruClear™ tissue removal devices.



Figure 2c. TruClear™ hysteroscope.

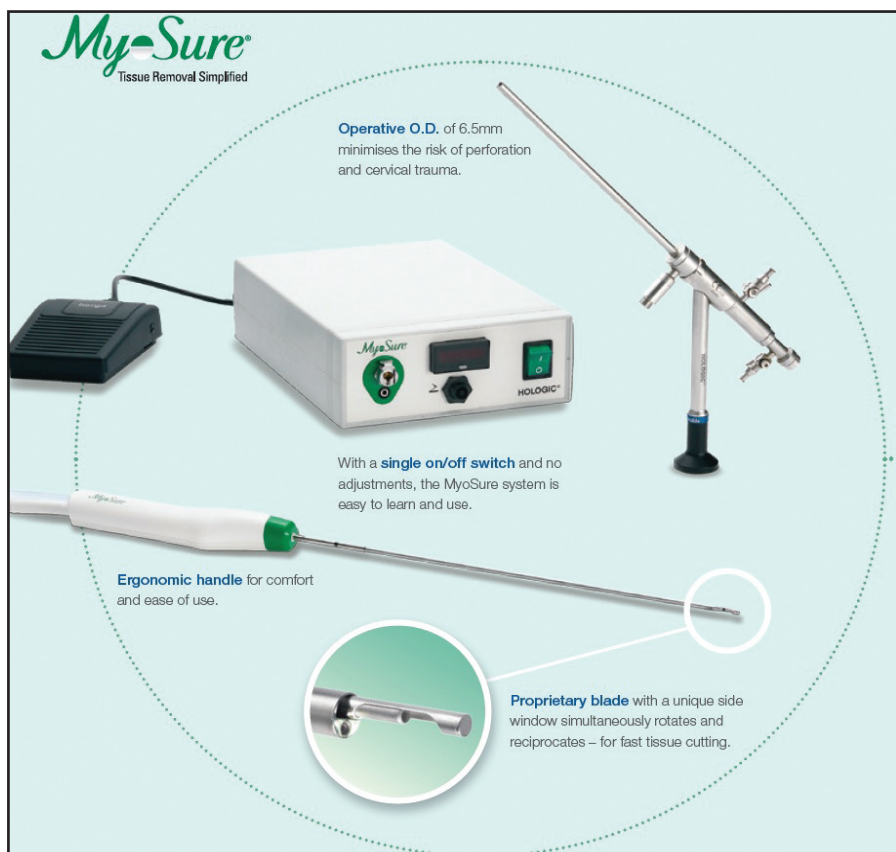


Figure 3. MyoSure® hysteroscope.

varied, efficacious, and less invasive procedures.¹

Operative hysteroscopy is, overall, a safe procedure, resulting in complications in 0.95–3% of cases.^{2,4} The most frequently-observed complications include hemorrhage (2.4%), uterine perforation (1.5%), and cervical laceration (1–11%).⁵ Another rare complication is excessive fluid absorption, with or without resulting hyponatremia (0.2–0.76%).^{3,4,6} Fluid deficits should be carefully managed during hysteroscopy to prevent intravasation. Lower uterine filling pressures have been associated with lower patient pain scores but a higher trend toward inadequate visibility.⁷

The purpose of this non-human benchtop study was to compare intracavity pressures during resection and aspiration modes among three commercially-available hysteroscopic morcellators, using a model to simulate the human uterus. No prior study has compared these three devices in a head-to-head manner using a clinically-relevant outcome measure. Although ex-vivo studies are sometimes limited in generalizability, some studies cannot feasibly or ethically be carried out in-vivo.

There is no feasible way to obtain continuous intrauterine pressure measurements in a live patient. It is, however, very important to attempt to directly compare the three commercially-available hysteroscopic morcellators in terms of their abilities to maintain intrauterine pressure below the set pressure.

MATERIALS AND METHODS

Intrauterine pressure and accuracy was compared utilizing Symphion™ (Boston Scientific Corporation, Marlborough, Massachusetts), MyoSure® (Hologic, Inc., Marlborough, Massachusetts), and TruClear™ (Medtronic plc., Fridley, Minnesota) systems in three modes (static, aspiration, and resection) and at different pressure settings. The study was performed using a silicone uterine model, a manometer to measure intrauterine pressure at one-second intervals, and porcine heart tissue to represent intrauterine fibroid material. Each arm was performed three times (to account for possible variability between individual devices), each time with a new device, and results were averaged. In Table I and Figures 1–3, we provide a detailed description of each of the three devices.

Pressure control setup

First, a 20-gauge dispensing tip (manufactured by Nordson EFD) was used to pierce the thickened section of the simulated uterine cavity model (Fig. 4). Next, the endoscope was introduced into the clear cavity model without the resection device attached. Then, the manometer was connected to the dispensing tip and was connected to a computer using the USB cable provided with the manometer. This allowed for measurement of actual pressure in the cavity model, which was compared to the set pressure on the controller's graphical user interface (GUI). Sper Scientific Data Acquisition Software (Sper Scientific Ltd., Scottsdale, Arizona) was used to measure intrauterine pressure.

Static pressure control

The cavity pressure on the controller was set to 45 mmHg. An infusion pump was run, and cavity pressure was measured after 30 seconds. Cavity pressure was increased in 10 mmHg increments



Figure 4. Twenty-gauge Nordson EFD dispensing tip.

every 30 seconds until 125 mmHg was reached. Pressure was measured at one-second intervals during each step. These steps were performed equally for all three device systems. The primary purpose of this paper was to evaluate the intrauterine pressures observed during aspiration and resection, which are described in the following sections.

Aspiration pressure control

The cavity pressure on the controller was set to 45 mmHg. An infusion pump was run, and aspiration was performed for 10 seconds. Cavity pressure was measured at one-second intervals throughout. This was repeated at cavity pressures of 85 and 125 mmHg for all three device systems.

Resection pressure control

Porcine heart tissue was used to simulate human uterine fibroid tissue. Two 1.5-inch portions of tissue were inserted into the silicone model, and the endoscope with resection device was inserted. Cavity pressure was set to 45 mmHg at the controller. Cut mode was activated for 10 seconds, and cavity pressure was measured at one-second intervals throughout. This was repeated at set cavity pressures of 85 and 125 mmHg for all three device systems.

Statistical methodology

For each device, there were three trials. During each trial, the set point pressure was systematically increased from one predetermined level to another. Intrauterine pressure measurements were repeatedly taken, at every second, for each given set point pressure. Therefore, the data consisted of

“repeated measures” and, as such, multilevel modeling was used to analyze the data.

In constructing our mixed-effects multilevel model, we specified dummy variables representing the device as the fixed effect. Symphion™ was set to be the reference category for each of the two dummy variables representing MyoSure® and TruClear™. In addition to dummy variables representing the device, we also included an interaction term as a covariate, representing the interaction between device and time. The purpose of this interaction term was to be able to assess whether the variation in intrauterine pressure over time was different for the three devices. The stratification variable used was mode. We conducted a separate model for aspiration and resection modes.

The dependent variable in our models was the measured intrauterine pressure. We centered the observed intrauterine pressure reading by subtracting the set point pressure from the obtained value. For example, if the observed intrauterine pressure was 100 mmHg and the set point pressure was 85 mmHg, then the centered pressure would be 15 mmHg (100–85 mmHg). We did this to allow the dependent variable to be continuous, thereby maintaining statistical power and allowing the interpretation of the results from the model to be more clinically meaningful. In our linear mixed models, our main clinical concern was whether the predicted mean intrauterine pressure during use of each device was significantly higher than the set pressure, as this would put the patient at higher risk for intravasation.

Table II
Association between intrauterine pressure and type of device based on mixed effects multi-level regression modeling

	Aspiration		Resection	
	Predicted centered intrauterine pressure ^a	95% CI	Predicted centered intrauterine pressure ^a	95%CI
Device				
Myosure®	-14.2	-30.9, 2.5	-12.4	-23.4, -1.4
Symphion™	-18.4	-20.7, -16.0	-18.3	-23.3, -13.3
TruClear™	-9.4	-17.1, -1.7	-18.9	-23.9, -13.9

^a Obtained from models that were constructed as linear mixed effects multi-level models. Dependent variable was the centered intrauterine pressure in mmHg.

Finally, we used graphical methods to construct two sets of plots. First, we constructed plots of centered intrauterine pressure against time in seconds for each device in each mode. In the second set of plots, we plotted centered

intrauterine pressure against set pressure for each device, irrespective of mode.

We used the mixed command in STATA (StataCorp LLC., College Station, Texas; Version 14) to do the above

models and the lowess command to obtain smoothed plots. Our detailed statistical codes are available upon request.

RESULTS

In Table I and Figures 1–3, we present a descriptive comparison of the three commercially-available hysteroscopic devices. One of the sentinel differences is that one device (Symphion™) uses bipolar energy that allows for coagulation during resection and aspiration, while the other two devices utilize simple mechanical energy.

Mean intrauterine pressure across the three devices

There were a total of 4,872 pressure recordings in this experiment. The predicted mean-centered intracavity pressures obtained from our linear mixed

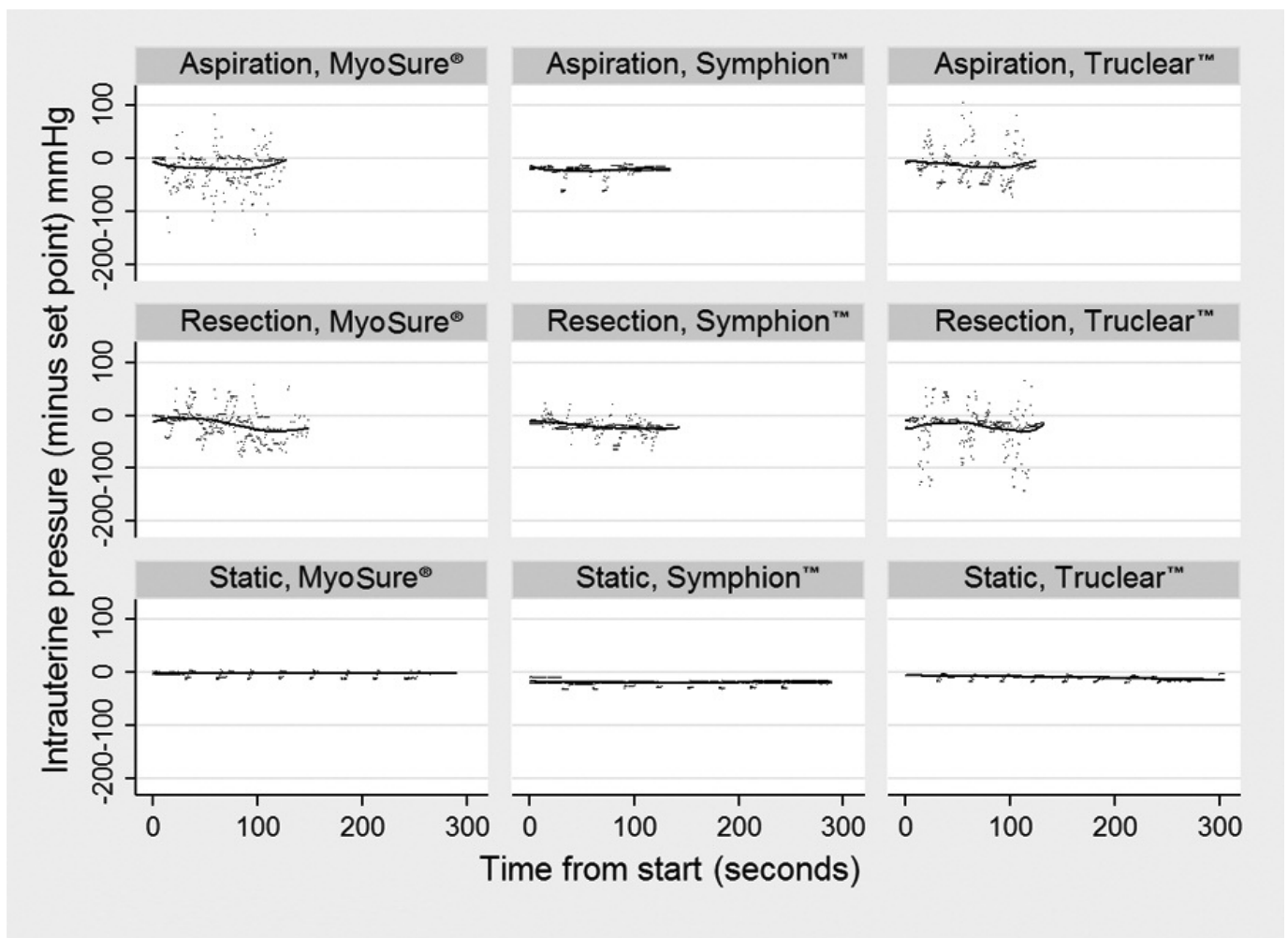


Figure 5. Centered intrauterine pressure versus time in static, resection, and aspiration modes for three hysteroscopic morcellators.

models are shown in Table II. The clinically-meaningful outcome is whether the mean intrauterine pressure is greater than the set pressure. In this scenario, the patient would be at risk for intravasation of fluids. In this study, in aspiration mode, the mean-centered intracavity pressure was never higher than 0, regardless of which device was used. In other words, for each of the three devices, the mean observed intracavity pressure was not greater than the set pressure. The confidence intervals around the mean-centered intracavity pressure for each device all overlap, indicating that the difference between the mean intracavity pressure and the set pressure was not statistically different across the three devices.

In resection mode, the same pattern was observed. The predicted mean-centered intracavity pressure was never greater than 0, regardless of which device was studied. Also, the confidence intervals around the mean-centered

intracavity pressure for each device all overlapped with each other.

It is worth noting that, in both resection and aspiration modes, the confidence interval around the mean intracavity pressure for MyoSure[®] appeared to be much wider than the confidence interval around the mean intrauterine pressure for Symphion[™] and TruClear[™].

Variation of intrauterine pressure over time

In Figure 5, we show the variation in intrauterine pressure over time for each device in each mode. In both aspiration and resection modes, the variation in intrauterine pressure over time graphically appears to be lower for Symphion[™], compared to the other two devices (MyoSure[®] and TruClear[™]). However, in our statistical models, the coefficient on the terms representing the interaction between device and time were not statistically significant in either

resection or aspiration modes. This indicates that, statistically, the change in intrauterine pressure over time was not significantly different across the three devices.

Variation of intrauterine pressure by set pressure

In Figure 6, we show the variation of intrauterine pressure by set pressure (for all modes combined). In aspiration and resection modes, only three set pressures were used (45, 85, and 125 mmHg), so, not surprisingly, more variability was observed at these three set pressures. However, the variation in intrauterine pressures at these three set pressures, graphically speaking, appeared to be lower for Symphion[™], compared to the other two competitor devices (MyoSure[®] and TruClear[™]). We did not formally test whether the variation in the intrauterine pressure at each set pressure was statistically different across the three devices.

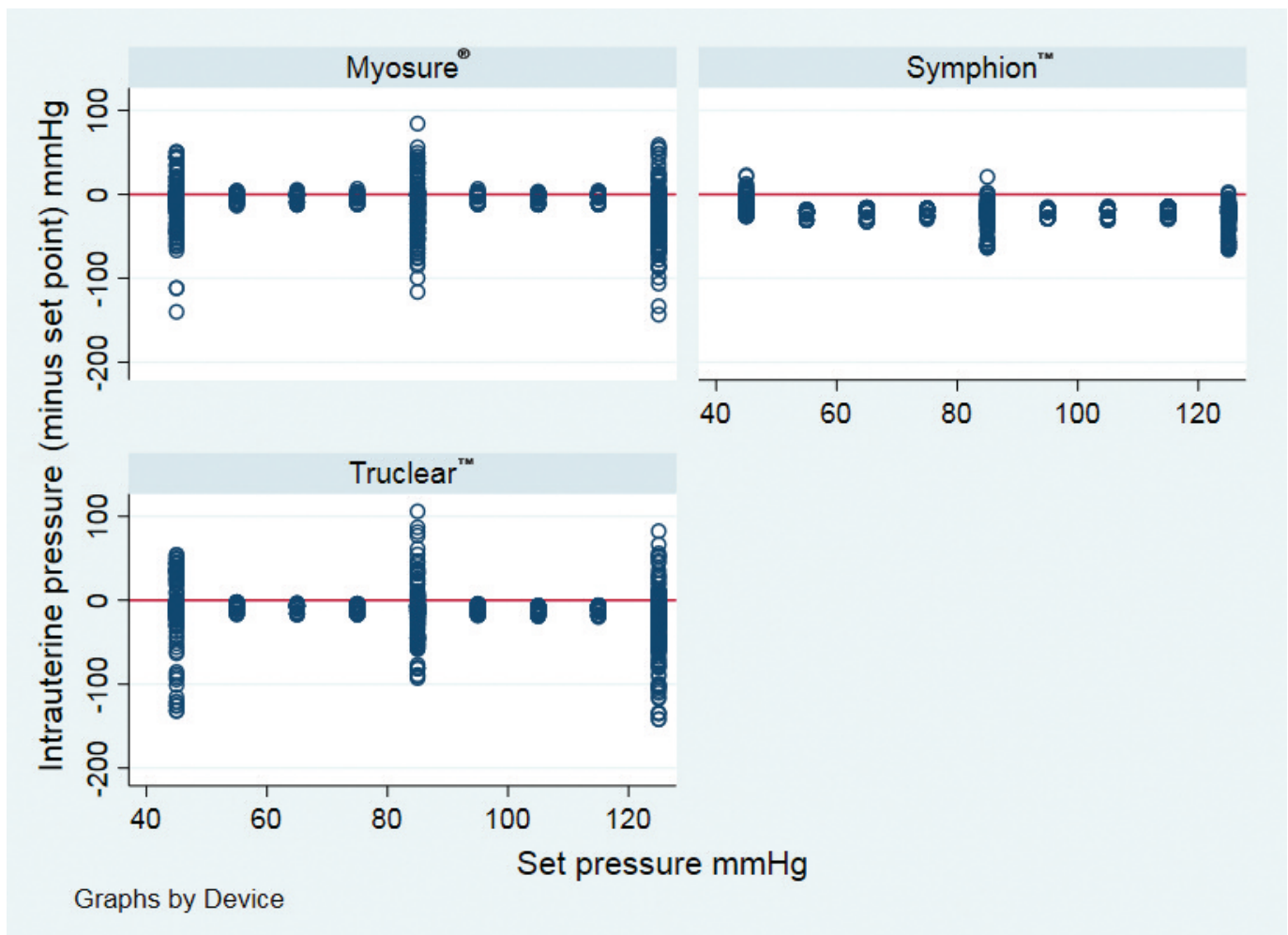


Figure 6. Variation of intrauterine pressure by set pressure for all modes combined for three hysteroscopic morcellators.

DISCUSSION

We present a unique ex-vivo benchtop study of three commercially-available hysteroscopic morcellating devices. For all three devices, regardless of whether the mode was aspiration or resection, the mean measured intracavity pressure was below the set pressure. This provides some support to the basic conclusion that all three devices are equally safe in terms of the risk of intravasation.

This is the first head-to-head benchtop study comparing the three commercially-available hysteroscopic morcellators in the United States. We believe this to be a very well-thought-out experiment with a large number of data points (4,872), and we believe our statistical methods were rigorous.

The main limitation with this study was that it was ex-vivo and not in-vivo. It is unknown how much the results of an experiment conducted using a silicone model to simulate the uterus will translate to a real hysteroscopic procedure on a real patient. However, some experiments are very difficult to execute in-vivo and, consequently, ex-vivo studies such as ours still play an important role in informing clinical practice. It would be extremely technically challenging to conduct an in-vivo study that involves continuous intrauterine pressure measurement while a hysteroscopic procedure is used.

Our main unanswered question is whether variation in intrauterine pressure over time has clinical relevance. Although the change in pressure over time was not statistically different across the three devices, based on statistical models, we noticed that the confidence interval around the mean intrauterine pressure was much wider for MyoSure®, compared to TruClear™

and Symphion™. In aspiration mode, for example, the width of the confidence interval was 33.4 mmHg, whereas for Symphion™, it was only 4.7 mmHg. We believe that future studies should explore whether there is any clinical relevance to variations in intrauterine pressure over time during hysteroscopic morcellation.

Another observation that deserves further exploration is the fact that, in aspiration mode, the entire confidence interval around the mean intrauterine pressure for the Symphion™ device was below the mean intrauterine pressure for the other two devices. Does this indicate a potential tendency for Symphion™ to “under-pressurize” the uterus compared to the other two devices? And, if so, does this have clinical relevance? Further studies are needed to more carefully answer these questions.

CONCLUSION

In conclusion, this detailed, head-to-head benchtop study provides some support to the notion that all three commercially-available hysteroscopic morcellators appear to be non-inferior to each other in terms of the risk of intravasation as a result of the observed intrauterine pressure being greater than the set pressure selected. This is important for clinical practice because many gynecologists do not have a choice as to which device they can use—their choice is dictated by contracts signed between their hospitals and the manufacturers of the devices. **STI**

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AUTHORS' DISCLOSURES

Both Dr. Howard and Dr. Stockwell had full, complete, and unfettered access to the raw data. No employee of Boston Scientific Corporation participated in the writing of the manuscript. Neither author received any compensation from Boston Scientific Corporation.

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7. Karaman E, Kolusari A, Cetin O, et al. What should the optimal intrauterine pressure be during outpatient diagnostic hysteroscopy? A randomized comparative study. *J Obstet Gynecol Res* 2017;43(5):902–8. Figure 2c. TruClear™ hysteroscope.