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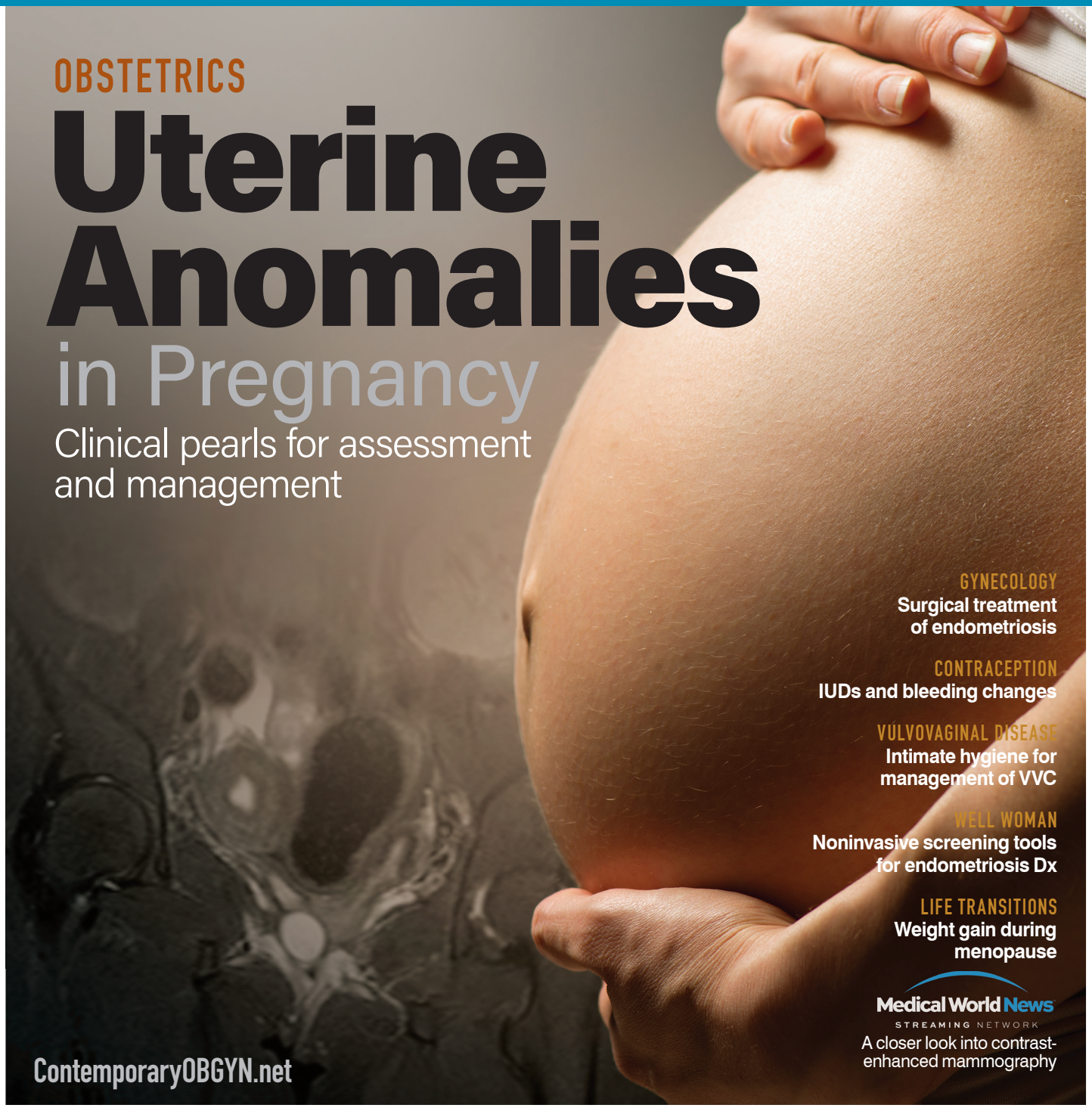

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Utilizing AbGrab® to Lift the Abdominal Wall with Suction

Multi-Phase, Multi-Site Clinical Study Evaluating the Performance of a Novel Abdominal Lifting Device on Human Subjects

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Study Sponsor: Lapovations – Fayetteville, AR

Background

With ~ 10 million procedures performed annually, laparoscopy is one of the most common surgeries performed in the United States.[1] Benefits include faster recovery times, less pain and blood loss, less scarring, and reduced risk of infection when compared to open procedures.[2] Although these benefits are well established, laparoscopy does pose a unique life-threatening risk: laparoscopic abdominal entry.[2] Entry related complications include perforation of the bowel or bladder, vascular injury, solid organ injury, and nerve injury. Though underreporting is suspected,[3] life-threatening gastrointestinal and vascular injury complications during laparoscopic entry are estimated to occur in 0.6 cases per 1,000,[4] with non-life threatening venous or arterial injury rates occurring in up to 6.4 cases per 1,000.[5] Despite this relatively low occurrence rate, laparoscopic abdominal entry accounts for approximately 50% of serious laparoscopic complications and medico-legal litigations related to laparoscopy.[6]

Laparoscopic abdominal entry can be achieved using open (Hasson) or closed techniques (Direct Trocar, Veress Needle, or Direct Trocar Under Vision). To reduce the risk of entry related injuries with closed insertion techniques, most surgeons lift the abdominal tissue as they insert the initial trocar or Veress needle. Two lifting techniques are commonly used—manual grasp (Fig 1) and perforating towel clips (Fig 2) – but both have significant drawbacks.

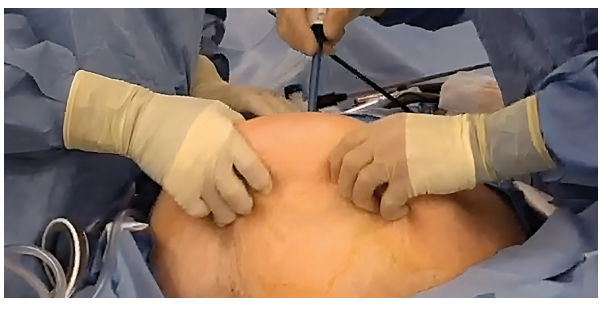

Figure 1 – Manual Grasp

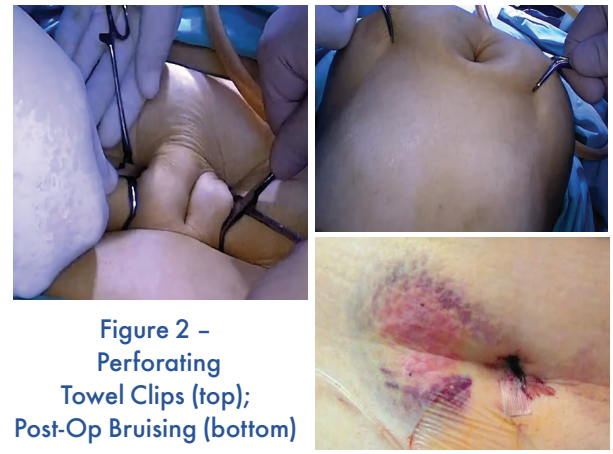

Figure 2 – Perforating Towel Clips (top); Post-Op Bruising (bottom)

With manual grasp, it is difficult to maintain grip and proper elevation, especially with lean or obese patients, or for surgeons with small hands or a weak grip, and the potential for losing grip introduces unnecessary risk. Perforating towel clips invasively pierce the tissue to provide a handle by which to lift the abdominal wall. Although this results in a more secure grip, the resulting perforations can be a significant source of post-op pain and bruising after what is intended to be a minimally invasive procedure.

AbGrab® (Fig 3) is a novel device that utilizes suction to lift the abdominal wall during laparoscopic entry and may provide a more reliable, less invasive way to lift the abdominal wall.

At the start of the procedure, two AbGrab® devices are connected to the hospital or portable vacuum system via medical tubing. After the vacuum system has been turned on and the lip of the AbGrab® cups placed against the patient abdomen ~ 3 cm lateral of each

Figure 3 - AbGrab®

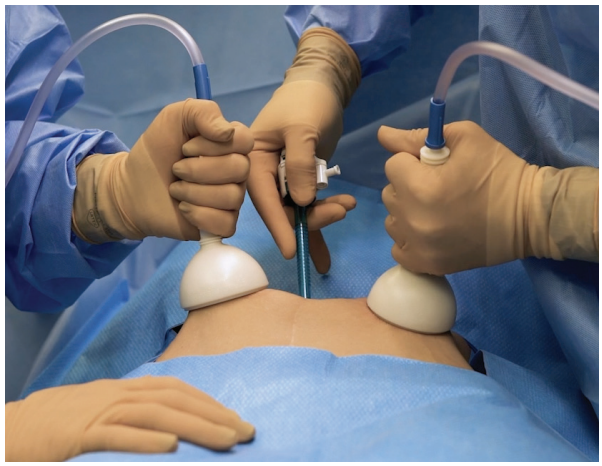

Figure 4 - AbGrab® Lifting Abdominal Wall

side of the umbilicus (Fig 4), a negative pressure is created between the device and the skin. When coupled with manual lifting, AbGrab® will lift the abdominal wall, allowing for surgeon directed trocar or Veress needle insertion. After laparoscopic entry is complete, AbGrab® can be lowered, then detached from the abdomen by removing the medical tubing from AbGrab® or removing the tubing from the vacuum system ports.

A three-phase, multi-site, IRB-approved, human trial was conducted to determine the study device's ability to maintain a vacuum seal while lifting the abdomen, and to identify which, if any, participant specific variables correlated to the device popping off. Eight potential device designs were tested during Phase I and II, with the best performing design being manufactured and further tested in Phase III. The primary objective of Phase III was to evaluate the device's ability to perform reliably during an abdominal lift simulating that required for laparoscopic abdominal entry. The secondary objective was to determine which participant specific variables correlated with pop-off.

Methods

Sites: participants were tested at one of three sites – University of Arkansas for Medical Sciences in Little Rock, AR, Taylor Surgical Arts in Harrison, AR, and the University of Arkansas Genesis Technology Incubator in Fayetteville, AR. Female volunteers 18 years of age and older were recruited to participate in the clinical study and compensated with a $25 gift card. This study focused on female subjects because OBGYNs are likely early adopters of the device.

Participant Measurements: variables collected included body mass index (BMI), waist size, abdominal firmness, and degree of skin laxity. Abdominal firmness was tested using an analog Type OO durometer with a Shore OO range of 0 – 100 (Fig 5). Durometer readings were taken at three abdominal locations and averaged. Higher durometer readings indicate firmer skin.

Figure 5 - Rex Gauge 1600 Type OO Durometer

Skin laxity was measured using a modified 3-inch diameter, 2.5-inch height cupping cup (Fig 6). The cup was modified by removing the check valve. It was then graduated at 1, 1.25, and 1.5 inches from the base. Anything below the 1-inch line was rated as 1, between the 1-inch line and 1.25-inch line was rated as 2, between the 1.25 and 1.5-inch line was rated 2.5, and above the 1.5-inch line was rated 3. The higher the rating, the laxer the skin. The laxity test was carried out by attaching the cup to a vacuum source with standard medical tubing, placing the cup on the abdomen ~ 3 cm lateral of the umbilicus, and applying 30 kPa of negative pressure. This level of negative pressure was chosen because it allowed for a measurable difference in skin laxity between participants. Laxity was then recorded as the height of the skin inside the cup (Fig 7).

Figure 6 - Skin Laxity Measurement Cup

AbGrab® Lift Testing: reliability was measured using a pop-off test. AbGrab® was attached to a vacuum source with standard medical tubing then placed on the abdomen ~ 3 cm lateral of the umbilicus.

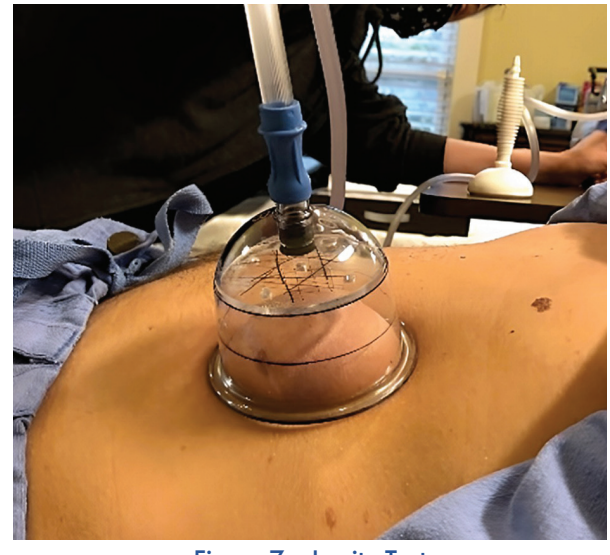

Figure 7 – Laxity Test

The vacuum source was turned on and a negative pressure of 50 kPa was used to create a vacuum seal betweeh AbGrab® and the abdomen (Fig 8). While the recommended negative pressure for AbGrab® in laparoscopy is 60 kPa – 97 kPa, 50 kPa was used for this trial since participants were awake during testing and 50 kPa is more comfortable. After the vacuum seal was created by placing AbGrab® on the abdomen, the handle was grasped and manually lifted at a force ≥ 40 N (9 lbs.) then held for 30 seconds. This force and duration simulates that used to lift the abdominal wall at the start of laparoscopy[7].

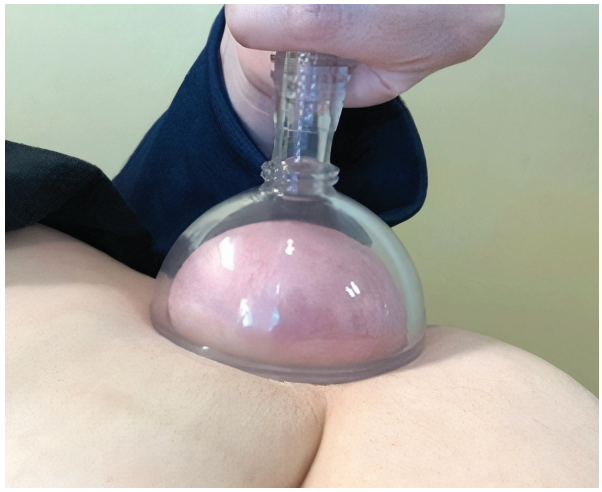

Figure 8 – AbGrab® Lift Test

Results

Demographics (Table 1): There were 76 participants in Phase III. Ages ranged from 18 - 72 (μ = 43), weight from 96 - 256 lbs. (μ = 158.8), BMI from 18 - 41 kg/m^2 (μ = 27), waist circumference from 26 - 49 inches (μ = 35), durometer reading from 2.0 - 18.7 (μ = 11.0), and skin laxity from 1.0 - 3.0 (μ = 2.3).

Lift Test Results: 75 of 76 (98.7%) test subjects had successful lifts using AbGrab®. The one subject who experienced a popoff was a 20-year-old weighing 147 lbs. with BMI 24.46 kg/m^2 and a 28 in. waist, all well below the mean. Her skin laxity of 2.5 and durometer reading of 13 were both above the mean. Based on the previous experience of the research technician, none of her measured predictive variables indicated an elevated potential for pop-off. However, one notable observation potentially warranting further research was her skin appeared thicker than other participants with a similar BMI. This may be due to a thicker hypodermis and/or dermis layer, but this variable was not measured in the study.

Discussion

The study results (98.7% of subjects experienced a successful lift) validates that AbGrab® performs reliably during a simulation of the lift performed for laparoscopic abdominal entry. The 76 participants included a wide variety of skin types, including high BMIs, deep stretch marks, and loose/lax skin. The single pop-off occurred with a young, thin, narrow-waisted test subject. When narrow-waisted individuals with minimal subcutaneous fat are supine, there is a natural concave contour that presents between the edge of the abdominal muscle and the hip bone that creates an uneven surface. The narrow torso also reduces the surface area available for AbGrab® to attach. Positioning the device closer to the lateral abdominal area may also increase the risk of pop-off due to a steeper contact angle with the skin and the

Table 1 – Patient Demographics and Skin Characteristics

Variable	Mean	Median	Max	Min	Std Dev
Age (years)	43.0	42.5	72.0	18.0	14.25
Height (in.)	64.2	64.5	69.0	56.0	2.74
Weight (lbs.)	158.8	150.5	256.0	96.0	35.00
BMI (kg/m^2)	27.1	26.1	41.3	18.1	5.37
Waist (in.)	35.0	35.0	49.0	26.0	5.47
Durometer (Skin Firmness)	11.0	11.2	18.7	2.0	2.86
Skin Laxity	2.3	2.5	3.0	1.0	0.53

device. Additionally, young skin is usually more taut than older skin, making it more difficult for the skin to be pulled up into the suction cup. It is suspected that the combination of taut skin and a narrow waist generated suboptimal conditions for creating a reliable vacuum seal. Ideally, enough skin can be pulled into the cup so a secure seal can form along the entire inner rim of the cup (as shown in Figure 8). Further research may be needed to determine which of these factors contributed to the pop-off. However, it's also important to note that AbGrab® performed reliably for several other thin, young subjects. It's also important to note that thin, young patients are not the primary demographic for laparoscopy. A 2014 study showed the mean BMI of patients undergoing laparoscopic hysterectomy was 30 kg/m^2, with 41.5% of patients being obese (BMI > 30kg/m^2) [8]. A 2018 study found that 42% of patients undergoing laparoscopic surgery for gynecological cancers were obese or morbidly obese (BMI > 30kg/m^2),[9] so thin, young patients likely represent a small minority of laparoscopic patients.

Conclusion

The primary objective of this study was to demonstrate the reliability of AbGrab® on a diverse group of 76 adult female test subjects while lifting the abdominal wall in a method simulating the lift required for laparoscopic abdominal entry. AbGrab® was 98.7% effective in this group. It is therefore reasonable to conclude AbGrab® will provide a reliable, yet non-invasive way to lift the abdominal wall at the start of laparoscopy.

The secondary objective was to determine if BMI, waist size, abdominal firmness, and/or degree of skin laxity could be used as indicators of increased risk of pop-off, where the device failed to maintain a vacuum seal during lifting. With only one pop-off data point, no conclusion can be drawn at this time regarding these participant specific variables. However, observations made from the one pop-off participant indicate that, for future studies, body fat content measured with skinfold calipers may provide further insight.

Recommendations

When compared to manual grasp, AbGrab® may provide a more reliable lift because it can be used on a wide variety of patient sizes and skin types. Also, surgeon hand size and grip strength do not impact the ability for the vacuum seal to be maintained, therefore AbGrab® may prove more reliable for surgeons with small hands or weak grip strength. AbGrab® provides a non-invasive alternative to perforating towel clips, a tool that can lead to unnecessary post-operative bruising and pain for patients. Reducing risk during the most dangerous part of laparoscopy continues to be a priority for surgeons and hospitals alike, as decreasing laparoscopic entry related injuries translates to better patient outcomes and lower litigation risk. A more reliable, less invasive suction-based alternative to current lifting techniques may be a solution worth consideration.

References available at
www.lapovations.com/white-paper-references

Dr. Amy Hester is the Chairwoman and CEO of HD Nursing, a leading provider of patient safety solutions. She previously served as the Director of Nursing Research and Innovation at the University of Arkansas for Medical Sciences before retiring after 26 years of service. Dr. Hester continues to serve as adjunct faculty for the UAMS College of Nursing and as clinician in residence for Health Tech Arkansas where she helps young startups get a footing in healthcare.

Scan the QR code to watch AbGrab® in use in the Operating Room