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NEW CONCEPT

Magnetic Liver Retraction: an Incision-Less Approach for Less Invasive Bariatric Surgery

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Abstract

Background In bariatric surgery, retraction of the liver is essential to ensure appropriate visualization of the surgical field. Many devices are currently employed for this purpose. Generally, these devices require constant use of a port, or an additional incision. Magnetic technology provides a novel solution, by allowing liver retraction during bariatric procedures that do not require a dedicated port nor an extra incision.

Methods Retrospective review of consecutive patients who underwent magnetic-assisted liver retraction during primary or revisional laparoscopic bariatric surgery at the Duke Center for Metabolic and Weight Loss Surgery between October 2016 and August 2017.

Results The 73 cases were comprised of 29 primary sleeve gastrectomies, 24 gastric bypasses, 10 duodenal switches, 3 gastric band removals, and 7 revisions. All cases were completed laparoscopically. Mean pre-operative BMI was 43.6 kg/m^2 (range 18.3–67.7 kg/m^2). Mean operative times for primary cases were similar to published averages. Two patients experienced minor 30-day morbidities, neither of which were attributed to the device and did not require further interventions. There were no 30-day mortalities. Surgeons described subjective overall surgical exposure as adequate and device utilization as technically simple even for the large livers.

Conclusions Magnetic-assisted retraction is a novel approach that allows a safe, reproducible, incision-less technique for unconstrained, port-less intra-abdominal mobilization. The device successfully permitted optimal liver retraction during laparoscopic bariatric surgery, enhancing surgical exposure while decreasing the number of abdominal incisions.

Keywords Bariatric surgery · Liver retraction · Magnetic-assisted surgery · Incision-less · Laparoscopic

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Introduction

Exposure of the surgical field is an integral part of all surgeries. The need for quality exposure is most pronounced in minimally invasive surgery (MIS) where the goal of limiting invasiveness can impact the surgeon's ability to secure adequate surgical field exposure. Throughout the evolution of MIS, many different techniques have been employed to achieve adequate exposure, while keeping within the boundaries of being less invasive.

In gastric surgery, visualization of the stomach and gastroesophageal junction is essential to properly assess the anatomy. This requires retraction of the left hemi-liver, which often covers most of the stomach and the hiatus. Over the years, many commercial products have been developed to achieve this retraction. These include rigid instruments that are fixed to the operative bed, slings, or hand-held devices [1]. As well, methods such as suturing the liver to the anterior abdominal wall, suctioning the liver lobe [2], fashioning a modified sling [3], or using the non-dominant hand to also elevate the liver have been attempted with good success. While all of these techniques provide good elevation of the left liver lobe, they all either require a dedicated port, a dedicated hand from the surgeon or assistant, or are quite traumatic to the liver.

As there is no perfect liver retraction method, there continues to be room for innovation in this arena. One such area is the use of magnets for intra-abdominal retraction to indirectly elevate the left liver. The magnetic surgical system (Levita Magnetics, San Mateo, CA, USA) is the first magnetic retractor to receive marketing authorization from the FDA; clearance was granted for use in laparoscopic cholecystectomy based on a clinical study of the device in this procedure that was conducted in Chile [4]. Recently, this device was successfully employed during laparoscopic cholecystectomies in the USA [5] and in combination with robot-assisted single incision platforms [6].

Since this retractor does not require a dedicated port, or a dedicated hand, it can allow for even less invasiveness during MIS. As well, it is minimally traumatic to the liver and provides good exposure of the proximal stomach and gastroesophageal junction. The purpose of this study is to present our first experience with this magnetic device for liver retraction in bariatric surgery.

Methods

This study was approved by the Institutional Review Board at the Duke University Health System. The study population comprised consecutive patients who were scheduled for either revisional or primary bariatric surgery. All patients completed a questionnaire (Fig. 1) pre-operatively to ensure that there were no metallic or electronic objects on or in their bodies that would interact with the magnets. All operating room staff who would be handling the magnets completed in-service training to ensure safe and appropriate use of the device.

All procedures were completed laparoscopically. Briefly, pneumoperitoneum was established via Veress needle entry. Four ports were placed in standard foregut fashion, two in the right abdomen and two in the left abdomen. All cases required at least one 12-mm/15-mm port for suturing or stapling.

In all cases, the magnetic system was successfully employed for retraction of the liver. This system is comprised of an internal metallic grasper with a detachable tip that couples with an external magnet controller (Fig. 2). The external magnet is positioned using a standard bedrail mounted arm. Due to its limited size, it can be easily maneuvered across the abdominal wall and does not interfere with traditional port placement. The grasper is introduced through an existing 12- or 15-mm port at the end of a magnetized instrument and clamped to the mid-portion of the left lobe's free edge of the liver (Fig. 3). The external magnet is then placed over the abdominal wall and is coupled to the grasper, and magnetic attraction allows manipulation of the grasper to retract the liver. Once the procedure is completed, the external magnet is decoupled, and the grasper tip is retrieved from the abdominal cavity using the introducer instrument. The data was analyzed retrospectively and reported in means and ranges.

Results

A total of 73 patients successfully completed laparoscopic bariatric surgery using the magnetic surgical system. Fifty-nine patients (81%) were female. Mean age was 43 years (range, 16–70 years). Mean pre-operative body mass index (BMI) was 43.6 kg/m^2 (range 18.3–67.7 kg/m^2) corresponding to a mean total body weight of 121 kg (range 49.9–186.9 kg).

Cases included 63 primary surgeries and ten revisions. Of the primary cases, there were 29 sleeve gastrectomies, 24 Roux-en-Y gastric bypasses, and ten duodenal switches. In addition, there were three adjustable gastric band removals and seven other foregut cases (four gastric bypasses with hiatal hernia repair, two band removals with conversion to sleeve gastrectomy, and one conversion of a sleeve gastrectomy to a gastric bypass). Mean operative times separated by surgery type are described in Table 1.

At a mean follow-up period of 2.2 months (range 0.5–9 months), mean percent excess body weight loss was 31.5% (range − 11.2–101.4%). Two complications occurred within the first 30 days post-operatively. One patient experienced nausea and emesis significant enough to require hospitalization for re-hydration, and one patient suffered a transient ischemic attack (TIA). There were no 30-day mortalities. None of the patients experienced any liver-related

Fig. 1 Patient questionnaire

Patient Label

Magnetic Surgery Screening Checklist
Page 1

Part I

Please answer the following questions:

1. Do you currently have a pacemaker, defibrillator, or other electromedical implants? ☐Yes ☐No
2. Do you currently have one or more ferromagnetic implants? ☐Yes ☐No

If answered "yes" to either of the preceding questions, you are contraindicated from undergoing this surgery with the magnet. Please skip to the end of this questionnaire and sign the form.

Part 2

Please answer the following questions:

1. Have you ever experienced a problem due to metallic objects in a previous procedure? ☐Yes ☐No
2. Have you ever been a welder, grinder or sheet metal worker? ☐Yes ☐No
3. Have you ever had an eye injury involving a metallic object or fragment? ☐Yes ☐No
4. Have you ever been injured by a metallic object or foreign body (nail, bullet, BB, etc.)? ☐Yes ☐No
5. Have you recently ingested anything metallic, including a small camera capsule? ☐Yes ☐No

Please indicate if you currently have any of the following:

Aneurysm clipping	☐Yes ☐No	Medical patch (transdermal)	☐Yes ☐No
Magnetically activated implant	☐Yes ☐No	Any metallic fragment/foreign body	☐Yes ☐No
Neuro or Spinal cord stimulator	☐Yes ☐No	Wire mesh implant	☐Yes ☐No
Bone growth/bone stimulator	☐Yes ☐No	Tissue expander (breast, etc.)	☐Yes ☐No
Internal electrodes or wires	☐Yes ☐No	Surgical staples, clips, metallic suture	☐Yes ☐No
Cochlear, otologic ear implants	☐Yes ☐No	Joint replacement (hip, knee)	☐Yes ☐No
Insulin or other infusion pump	☐Yes ☐No	Bone/joint pin, screw, nail, wire,	
Implanted drug infusion device	☐Yes ☐No	plate, etc.	☐Yes ☐No
Any type of prosthesis	☐Yes ☐No	Intrauterine device (IUD)	☐Yes ☐No
Heart valve prosthesis	☐Yes ☐No	Braces, dentures, or partial plates	☐Yes ☐No
Blood clot filter	☐Yes ☐No	Tattoo or permanent makeup	☐Yes ☐No
Eyelid spring or wire	☐Yes ☐No	Body piercing jewelry	☐Yes ☐No
Artificial or prosthetic limb	☐Yes ☐No	Hair accessories (hairpins, etc.)	☐Yes ☐No
Metallic stent, filter, or coil	☐Yes ☐No	Shunt (spinal or intraventricular)	☐Yes ☐No
Vascular access port/catheter	☐Yes ☐No	Other implant _____	☐Yes ☐No
Radiation seeds or implants	☐Yes ☐No		

complications, and no skin compression damage was observed at the site of placement of the external magnet.

All six surgeons involved in this study cohort observed subjectively that the device was easy to set up, manipulate, and retrieve. The external magnet provided favorable maneuverability without interfering with port placement. After a short learning period, all surgeons were able to set up the device with adequate liver retraction in under 5 min.

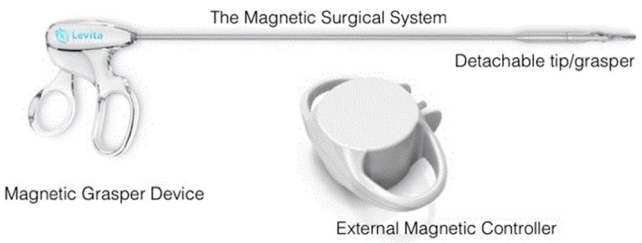

Fig. 2 Magnetic surgical system

Discussion

Minimally invasive foregut surgery requires an advanced skill set, as well as innovative devices, to achieve excellent results. In the bariatric population, this is even more important as the size, weight, and shape of intra-abdominal contents add an extra degree of difficulty. Since obese patients are at higher

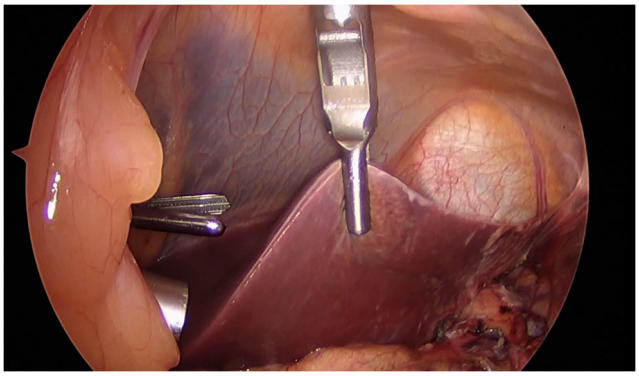

Fig. 3 Metallic grasper coupled to the external magnet controller for liver retraction

risk for post-operative complications, weight loss surgeons are constantly working to improve their ability to manage this patient population via less traumatic approaches.

The ideal liver retraction device should be simple to use, able to be fixed in place but also adjustable, and should not necessitate the use of the hands of the surgeon or the assistant throughout the case. This magnetic device achieves all of these goals. In addition, other types of retraction techniques may contain sharp edges (e.g., hooks, suture needles, and narrow tip) that could potentially cause injury during manipulation.

Early magnetic devices were described in the urology literature over 10 years ago [7–10]. These studies attempted to employ a magnetically manipulated camera to obviate the need for a laparoscope. The initial descriptions were in porcine models, but preliminary human trials have been successfully completed more recently.

The initial clinical trial for the magnetic surgical system was recently described in a cohort of laparoscopic cholecystectomies [4]. Following this, a series of cholecystectomies was performed to describe the technique and record peri-operative outcomes [5, 6]. Our present cohort builds upon this experience to show that this device is not only atraumatic and easy to use but also functions well even in super-obese patients.

A prior study successfully employed an improvised magnetic retractor in colon resections during single site surgery [11]. Multiple studies have demonstrated successful use of improvised magnets in single port laparoscopic cholecystectomy [12]. In these cases, the retractor is used to compensate for the lack of triangulation, which is a major limitation of single port surgery. This is potentially another important application of the device and one that would provide further opportunity to decrease invasiveness during abdominal surgery.

Our present cohort establishes magnetic retraction as a viable option for advanced laparoscopic foregut surgery in the obese and super-obese population with a well-demonstrated proof of concept. The purpose of this case series is to show our first experience using this magnetic device for liver retraction in bariatric surgery. This initial experience will definitely set a base for further studies, which we acknowledge, and should involve a more critical comparison with other existing liver retractors, particularly the Nathanson retractor. A follow-up data analysis is underway to determine the impact of the device on post-operative pain scores, length of stay, and cost as compared to other retraction techniques.

Other direct patient benefits from magnet use beyond simple retraction and visualization should be noted. The cosmetic benefit of one less incision may seem negligible, but is an important aspect of patient preference and discussion that is frequently neglected and undervalued [13, 14]. Fewer incisions intuitively decrease the risk for surgical site infections—the most common hospital-acquired infection for surgical patients and a leading cause of morbidity and financial burden [15, 16]. While the actual risk reduction of one less incision has not been fully elucidated, the advantages to patient comfort and faster healing are in line with the established principles of enhanced recovery after surgery [17].

Setting up the magnetic device for use took up to a maximum of 5 min. All of the involved surgeons in this cohort considered device set-up simple. This time included all the subsequent dynamic adjustments to maneuver the external magnet, which is one of the advantages of this device against the static Nathanson retractor. As with all new technologies, we foresee time to set-up and maneuver the device to decrease as surgeons progress through the learning curve.

The external magnetic controller is reusable and covered in a sterile bag throughout the procedure, which removes the need for sterilization following the case. After the procedure, the external magnetic controller is cleaned with a standard "sani cloth" as suggested by the manufacturer. The introducer and grasper are both made of metal, similar to any other laparoscopic instrument. At this time, both pieces are disposable, in order to decrease the operating room personnel's workload

Table 1 Operative times by surgery type

Surgery type	LSG ($n = 29$)		LRYGB ($n = 24$)		Lap DS ($n = 10$)		LAGB removal ($n = 3$)		Revision ($n = 7$)	
	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
Operative time (min.)	68	44–119	134	95–182	240	152–373	75	61–94	167	106–228

LSG, laparoscopic sleeve gastrectomy; *LRYGB*, laparoscopic Roux-en-Y gastric bypass; *Lap DS*, laparoscopic duodenal switch; *LAGB*, laparoscopic adjustable gastric band

with the need to standardize the sterilization of a new device. Once the device becomes more commonly and widely used, we anticipate it being able to be sterilized and thus completely reusable. Being a new product, we expect the cost per case will depend on the hospital setting in which it is used. However, in our center, a preliminary per-case analysis showed its use was cost-effective to our patients as the cost of the device was offset by the reduction on the length of stay (the reasons for which will be the subject of a further study). We agree that more detailed cost-benefit studies should be performed and it is the intention of our research group to continue exploring in that direction.

As it regards to surgical field exposure, although no specific exposure data were collected, experienced surgeons on the field of bariatric surgery rated it as appropriate. Hiatus and crura visualization (Fig. 4) are of particular interest especially for sleeve gastrectomy cases; in our own experience, the device provides appropriate visualization of the required structures in most of our procedures. However, this device has produced inadequate visualization in larger and more complex hiatal hernias, which is a limitation of the current iteration of the device.

Possible challenging scenarios using this device include patients with large and/or nonalcoholic fat liver disease. The device, when it is clamped to the edge of the liver, has a potential to tear its tissue due to its small surface area. Nevertheless, in this first experience with a large sample of bariatric patients, where NAFLD is more prevalent, we did not experience any significant tear or damage to the liver. Large, floppy livers can potentially be more challenging as well, as they tend to bow at the superior-posterior aspect and cover the hiatus. However, our group believes that in big and friable livers such as those with nonalcoholic fat liver disease (NAFLD), this new device does not add more risk than the conventional liver retractors.

There is a potential impact of the magnet on other metallic intracorporeal implantable devices. The American Heart Association states that magnetic fields in magnetic devices and machinery can inhibit pulse generators for implantable cardioverter defibrillators and pacemakers. During this feasibility and safety series, we provided every patient with a pre-operative questionnaire as part of our pre-operative checklist, which we foresee and recommend being routinely administered before every magnetic-assisted procedure using this device.

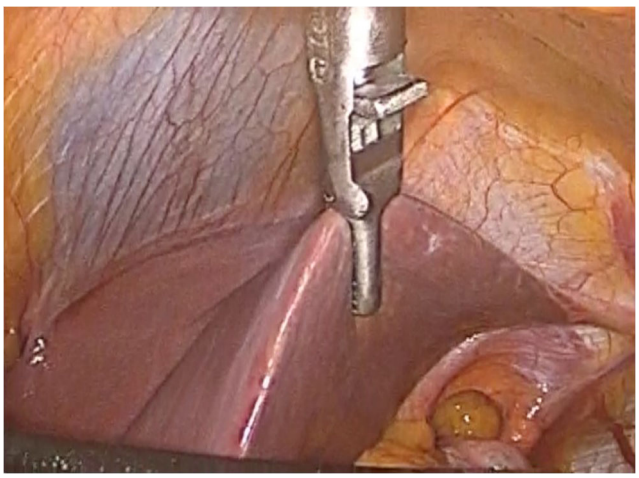

Fig. 4 Magnetic device retracting the liver with appropriate hiatus and crura visualization

Limitations to our study include the retrospective nature of the data, the lack of a control group, and the subjective perception of the surgeons using the device. We believe, however, that with more widespread use of this novel device, there will be an opportunity to accumulate enough data to challenge the more commonly used liver retractors and compare objective clinical outcomes.

Conclusions

The magnetic surgical system is a novel device that permits an incision-less technique for unconstrained, port-less intra-abdominal mobilization. We successfully used the device to obtain optimal liver retraction during laparoscopic bariatric procedures enhancing surgical exposure while decreasing the number of incisions.

Compliance with Ethical Standards

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Conflict of Interest Gerardo Davalos, Camila Ortega, Scott Schimpke, Sugong Chen, Kunoor Jain-Spangler, and Ranjan Sudan have no conflicts of interest. Matthew Davis has no conflicts of interest relevant to this publication, but has received a consultation fee from Medtronic. Jin Yoo has no conflicts of interest relevant to this publication, but is a consultant and speaker for Novadaq, Stryker, and Gore, and is a consultant for Teleflex. Keri Seymour has no conflicts of interest relevant to this publication, but is a speaker for Gore and Medtronic, and is a consultant for Teleflex. Dana Portenier has received an education grant from Levita Magnetics, has received an education grant from Gore, is a consultant, has received a research grant from Medtronic, and is a consultant for Intuitive. Alfredo D Guerron is a consultant for Levita Magnetics and a speaker for Gore and Medtronic.

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