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DESIGN AND DEVELOPMENT OF A NOVEL ASSISTIVE DEVICE FOR LAPAROSCOPIC SURGERY USING GRANULAR JAMMING

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ABSTRACT

Laparoscopic surgery has a notably high learning curve, hindering typical approaches to training. Due to unique challenges that are not present in open surgery (the hinge effect, small field of view (FoV), lack of depth perception, and small workspace), a surgical resident may be delayed in participating in laparoscopic surgery until later in residency. Having a narrow window to complete highly specialized training can lead to graduates feeling under-prepared for solo practice. Additionally, delayed introduction may expose trainees to fewer than 200 laparoscopic cases. Therefore, there is a need for surgical residents to increase both their caseload and training window without compromising patient safety. This project aims to develop and test a proof-of-concept prototype that uses granular jamming technology to controllably vary the force required to move a laparoscopic tool. By increasing tool resistance, the device helps prevents accidental injury to important nearby anatomical structures such as urinary tract, vasculature, and/or bowel. Increasing the safety of laparoscopic surgery would allow residents to begin their training earlier, gaining exposure and confidence. A device to adjust tool resistance has benefits to the experienced surgeon as well – surgeries require continuous tool adjustment and tension, resulting in fatigue. Increasing tool resistance can assist surgeons in situations requiring continuous tension and can also provide safety against sudden movements. This investigational device was prototyped using SolidWorks CAD software, then 3D printed and assessed with a laparoscopic box trainer.

Keywords: laparoscopic surgery, medical education, surgical training, Halstedian model, 3D printing, additive manufacturing, granular jamming.

1. INTRODUCTION

At the turn of the 20th century, Dr. William Halsted introduced a new method of surgical training. The Halstedian model was based on a standardized system of increasing responsibility year after year [1]. Since its introduction, the Halstedian model has been successful, consistently producing high-quality surgeons in the 20th and 21st centuries. However, the increasing complexity of surgical procedures and instruments puts evermore pressure on trainees to learn and master more material [1]. Additionally, with emphasis on resident well-being, trainees are expected to master more material in even less time [2]. Thus, training programs have turned to surgical simulators to begin the training process prior to the operating room (OR) [3]. Simulated practice is an attractive option, as many procedures can be replicated on cadaver, animal, and computer models. Simulations have a comparable learning curve to real surgery, without any patient risk. Although simulations provide an important step for training surgeons, there are limitations. One example is haptic feedback on grip strength. Trainees often over-grip tissue in the OR, and existing research aims to address this issue [4]. Thus, the final location of surgical training remains in the OR.

Supervised procedures in the OR are the final step of training for the surgeon. This crucial period builds the competence and confidence required for performing procedures after graduation. Limitations in training during this period, such as caseload, can hinder the performance of graduates [5]. Minimally invasive laparoscopic surgery is particularly sensitive to increasing complexity and decreasing caseload. Due to the counterintuitive nature of laparoscopic surgery, less prepared trainees have a significant chance of causing patient harm. Since the quality of patient care is paramount, programs may delay the supervised training period for laparoscopic surgeries to the 5th or 6th year. Older residents with more training are thus more competent to handle a procedure [6]. However, it may take between 150 to 200 cases to produce a graduate with moderate to high proficiency [5]. Limiting training to within two years further reduces caseload prior to graduation and negatively impacting surgeons' feelings of comfort and readiness [5].

Laparoscopic surgery involves insertion of cannulas, a hollow port, in the abdominal wall so that surgical tools can be inserted into the abdominal cavity. To make the incision that introduces the cannula, a cylindrical cutting device called a trocar is threaded within the cannula and brings the cannula into position as a circular cut is made. Variations in trocar/cannula size allow different tools to be introduced, the largest often being a laparoscope (camera). Pneumoperitoneum is the inflation of the abdominal cavity with carbon dioxide to separate the organs from the abdominal wall [7]. Pneumoperitoneum can be introduced before or after trocar/cannula insertion. Establishing pneumoperitoneum with a Veress needle before trocar insertion is generally safer, as the initial pneumoperitoneum moves organs away from the abdominal wall [8].

The technical challenges of laparoscopic surgery include the hinge effect, small FoV, lack of depth perception, and small workspace [9]. These unique challenges, paired with navigation around important anatomical structures, result in intraoperative complications including bowel perforation, urinary tract injury, and/or neurovascular injury [10-12]. Further complicating the situation is the hinge effect causing tool tips to move variable distances depending on its depth. Excess motion can swing tools outside of the camera's FoV and some maneuvers naturally do the same. Since the laparoscope's visual input is essential, regularly moving outside its FoV increases risk. Indeed, accidental movement that damages surrounding tissues is a major concern. In typical clinical practice, the addition of this device can reduce the risk of accidental injury, through compensation of the hinge effect and preventing tool excursions outside the FoV of the laparoscope.

The goal of this study is to design a device that can adjust the force and motion of laparoscopic tools to user-set tolerances. Introducing a user-controlled supporting force to laparoscopic tools alleviates many challenges, including the hinge effect, small FoV, and small workspace. The assistive device would provide a stabilizing force to a fixed radius only in the pitch and yaw angles (i.e., tilt forward/backward and left/right). The tool retains all degrees of freedom but be limited in maximum pitch and yaw deflections.

For the surgeon-in-training, a fixed workspace produced by this device can allow trainees to gain experience with the unique properties of laparoscopic surgery while maintaining patient safety. For routine laparoscopic surgery, this device can alleviate fatigue associated with operating the laparoscope or retracting tissues with graspers. These maneuvers can require extended periods of static support, which would benefit from extra support.

2. MATERIALS AND METHODS

Prototypes were designed using SolidWorks 2019 3D CAD software (Dassault Systèmes SolidWorks Corp., MA) and printed using a MakerBot Replicator+ 3D printer (MakerBot Industries, LLC., NY). Prototypes were printed with polylactic acid (PLA) plastic. Large latex balloons were used as bladders which contained either coffee grounds or granulated sugar. Vacuum forces were generated using a 100mL plastic syringe and plastic medical tubing. Standard Luer-lock connectors and 3-way stopcocks were used to join tubing to the 100mL syringe.

Granule bladders were assembled by first inflating the latex balloons with air to increase their volume and compliance. A bicycle pump was used to minimize moisture in the balloons and prevent granules from clumping. The pre-stretched balloons were filled with a plastic funnel with approximately 40 grams of granulated sugar or 30 grams of coarse ground coffee.

Surgical tubing was covered with a single layer of cotton cloth to prevent aspirating granules. The cloth was held in place by wrapping a cotton thread 1 cm from the opening of the tube, approximately 15 times. The tubing with cloth was inserted into the end of the balloon and secured with thread again. This time, the thread was wrapped around the neck of the balloon, with the cloth-covered tubing inserted approximately 5cm into the balloon.

Both bladder-tubing assemblies were threaded into the side ports of the device, with the bladders placed within the cup of the device. The free ends of tubing were joined to a 3-way stopcock via Luer-locks and tubing adapters. Finally, the 100mL syringe was attached to the stopcock. Granular jamming was actuated by pulling suction with the 100mL syringe.

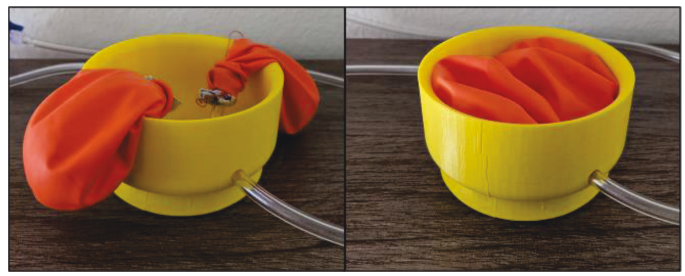

FIGURE 1: The final prototype showing a 3-D printed PLA cup with two latex balloons. Each balloon holds 40 g of granulated sugar and is attached to a 100 mL plastic syringe (not shown) by surgical tubing.

To test the ability of the device to restrict motion, deflection angles were measured with a laparoscopic grasper inserted approximately 10-12 cm into the cannula. A small piece of painter's tape was used to prevent the tool from sliding at higher angles. The device was implemented in a stepwise fashion, with deflection angles measured with each additional component. Deflection angles were measured once using a photograph and ImageJ (an image processing program developed by NIH) for no device, device with granular jamming removed, device with granular jamming disengaged, and fully implemented device with granular jamming engaged.

3. RESULTS

The goal of this study was to create a device that would offer increased safety during laparoscopic procedures. The device has two components: a stiff, cylindrical cup and a granular jamming system. The cylindrical cup is intended to not only hold the granular jamming system in place, but to also provide a limit on maximum tool deflection. When the shaft of the laparoscopic tool encounters the rim of the cup, additional deflection is prevented. The granular jamming system is placed within the cup and is in contact with both the shaft of the laparoscopic tool and the cannula. When disengaged, the granules slide out of and fill in the path traced by the tool. When suction is applied to engage the jamming system, the jammed granules prevent motion of the tool and cannula.

The application of the device on a laparoscopic trainer allowed simple evaluation of its function and helped troubleshoot potential pitfalls. Deflection angles were measured with stepwise application of device components. At each step of device application, the cone of possible tool motion shrank.

Without the device, the tool has a possible deflection of approximately 64˚ from baseline (i.e., approximately perpendicular to entry surface). Assuming the ports are symmetric, the tool has a total possible deflection of 128˚ from horizontal. Adding the cup only results in a deflection of 18˚ from horizontal and 47˚ from baseline, resulting in a 94˚ total. Similarly, adding the granular jamming system, but disengaged results in a 72˚ total deflection. Utilizing the entire system results in a 36˚ total deflection.

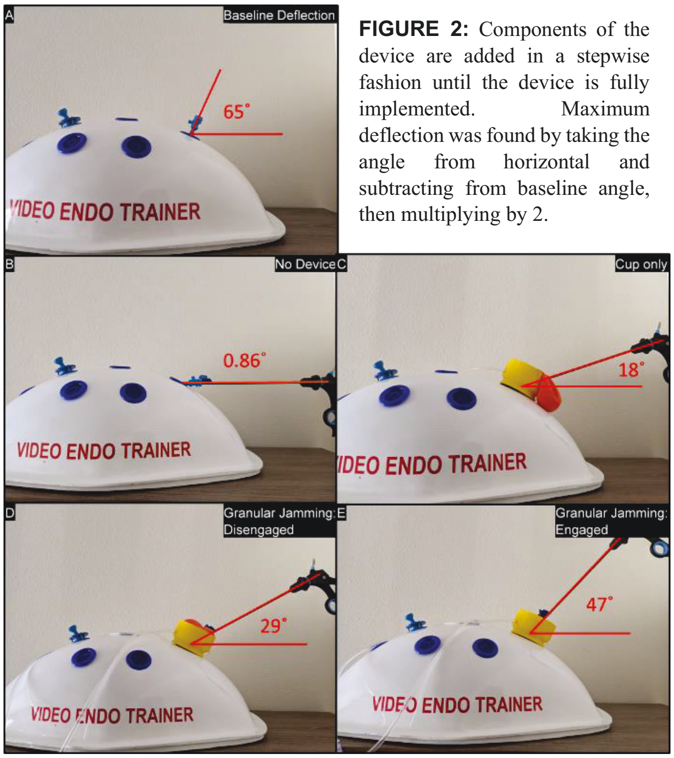

FIGURE 2: Components of the device are added in a stepwise fashion until the device is fully implemented. Maximum deflection was found by taking the angle from horizontal and subtracting from baseline angle, then multiplying by 2.

	ΔHorizontal (˚)	ΔBaseline (˚)	Total Deflection (˚)
No device	0.86	64	128
Cup only	18	47	94
Jamming disengaged	29	36	72
Jamming engaged	47	18	36

TABLE 1: Tabulated deflection angles from stepwise implementation of the granular jamming device.

4. DISCUSSION

Granular jamming has been previously applied to the medical field, but commonly as a multi-articulated grasper or flexible laparoscope [13, 14]. Other applications include surgical training, with granular jamming used as modifiable textures in organ palpation in medical training [15]. Granular jamming's application as an assistive device for use in laparoscopic surgery has not been published thus far.

One key outcome evident with the current granular jamming design is that, although disengaged, the granules apply unintended resistance near the rim of the cup due to partial jamming. High resistance near maximum deflection hinders smooth operation. Factors that hinder smooth operation include cup geometry, granule type, bladder material, and bladder geometry.

Initial iterations of the device were funnel-shaped so that, at maximum deflection, the entire conical surface would be in contact with the cannula and tool at maximum deflection. However, that design left little volume for the granular jamming system, so a more cylindrical design was adopted. The extra volume in the cylindrical version increases contact area between the tool and granules, offering better support when jamming is engaged. Extending this concept further, bowing the walls of the cylinder such that there is even more space for granules to flow could reduced unintended resistance.

Using granule material optimized for flow over jamming properties is one way to address the problem of granule redistribution. Typically, granular jamming systems require coarse granules with rigid jamming to maximize holding power. However, in this application, granule flow should be maximized to achieve smooth operation. Adequate holding power necessitates balancing granule flow and jamming characteristics. For example, sugar was used in the final prototype because of its superior flow properties, providing lower resistance when disengaged. Qualitatively, granulated sugar had a smaller average particle size and higher density than ground coffee, both factors that contributed to its better flow characteristics. Additional materials with varying flow and jamming characteristics that can be tested include salt, silica powder, and polystyrene beads.

An aspect of the granular jamming system that was not addressed is bladder material and geometry. The two latex balloons used in the prototype were partially filled to ensure allow room for granule flow. If the balloons were fully filled, the elasticity of the latex caused the granules to jam without any suction applied. Polymers with varying mechanical properties may enhance the performance of future prototypes via optimizing membrane properties[14]. In this application, a material with a low stress-strain ratio may be ideal. High compliance and easy deformability are key aspects for optimal granule redistribution. Much of the supporting force to a laparoscopic tool comes from the edges of the device cup, so the bladder membrane may not require high stiffness.

Bladder geometry was simplified to two spherical bladders. This design introduces varying granule densities and thus anisotropic supporting force. In a future iteration, bladder geometry can be further optimized as donut shaped, producing isotropic supporting force and facilitating granule flow. Additionally, increasing unfilled bladder volume results in reduced improved flow and decreased resistance when jamming is disengaged.

Implementation and adoption of an assistive device for laparoscopic surgery depends ultimately on the usability of the device. It must accomplish its engineering goals while remaining invisible to the surgeon. Baseline resistance of the disengaged device prevents smooth operation and presents a significant barrier to adoption. However, through granule and bladder optimization, future iterations have the potential to be implemented seamlessly. This device has measurable safety and training benefits, but adoption will be hindered if there is any impediment to the natural flow of surgery.

The current design of this device requires the trocar and cannula to be inserted coaxially. The current method of device application hinders access during emergencies, so a break-away system will be incorporated into future iterations. A clasp-based hinge system can allow ease of implementation and removal during emergencies.

4. CONCLUSION

This study describes the first time granular jamming has been used within an assistive device for laparoscopic surgery. The prototype developed in this study can effectively reduce the cone of tool motion and is tunable between 36˚ and 72˚. Granule redistribution is a significant challenge to smooth operation and effective stabilization when jamming is engaged.

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REFERENCES

[1] Polavarapu, H., Kulaylat, A., Sun, S., and Hamed, O., July 1, 2013, "100 years of surgical education: The past, present, and future," bulletin.facs.org/2013/07/100-years-of-surgical-education/.

[2] Gozen, A. S., and Akin, Y., 2015, "Are structured curriculums for laparoscopic training useful? A review of current literature," Curr. Opin. Urol., 25(2), pp. 163-167.

[3] Badash, I., Burtt, K., Solorzano, C. A., and Carey, J. N., 2016, "Innovations in surgery simulation: a review of past, current and future techniques," Ann Transl Med, 4(23), p. 453.

[4] Ulhaq, N., Wadi, H., Amlee, T., Diesen, D., and Fey, A. M., 2018, "Design and Evaluation of Haptic Constraints for Laparoscopic Instrument Handling," Conference proceedings : ... Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual Conference, 2018, pp. 961-964.

[5] Naveiro-Fuentes, M., Rodríguez-Oliver, A., Fernández-Parra, J., González-Paredes, A., Aguilar-Romero, T., and Mozas-Moreno, J., 2018, "Effect of surgeon's experience on complications from laparoscopic hysterectomy," J Gynecol Obstet Hum Reprod, 47(2), pp. 63-67.

[6] Nijhof, H. W., Silvis, R., Vuylsteke, R. C. L. M., Oosterling, S. J., Rijna, H., and Stockmann, H. B. A. C., 2017, "Training residents in laparoscopic colorectal surgery: is supervised surgery safe?," Surg. Endosc., 31(6), pp. 2602-2606.

[7] Perrin, M., and Fletcher, A., 2004, "Laparoscopic abdominal surgery," Continuing Education in Anaesthesia Critical Care & Pain, 4(4), pp. 107-110.

[8] Thepsuwan, J., Huang, K.-G., Wilamarta, M., Adlan, A.-S., Manvelyan, V., and Lee, C.-L., 2013, "Principles of safe abdominal entry in laparoscopic gynecologic surgery," Gynecology and Minimally Invasive Therapy, 2(4), pp. 105-109.

[9] Gould, J., Ponsky, T. A., and Blatnik, J., "Instruments and devices used in laparoscopic surgery," UpToDate, J. Marks, and T. Falcone, eds.UpToDate, Waltham, MA.

[10] Cassaro, S., 2015, "Delayed manifestations of laparoscopic bowel injury," Am. Surg., 81(5), pp. 478-482.

[11] Elbiss, H. M., and Abu-Zidan, F. M., 2017, "Bowel injury following gynecological laparoscopic surgery," Afr. Health Sci., 17(4), pp. 1237-1245.

[12] Adelman, M. R., Bardsley, T. R., and Sharp, H. T., 2014, "Urinary tract injuries in laparoscopic hysterectomy: a systematic review," J. Minim. Invasive Gynecol., 21(4), pp. 558-566.

[13] Jiang, A., Ataollahi, A., Althoefer, K., Dasgupta, P., and Nanayakkara, T., "A variable stiffness joint by granular jamming," Proc. International Design Engineering Technical Conferences and Computers and Information in Engineering Conference, American Society of Mechanical Engineers, pp. 267-275.

[14] Jiang, A., Ranzani, T., Gerboni, G., Lekstutyte, L., Althoefer, K., Dasgupta, P., and Nanayakkara, T., 2014, "Robotic granular jamming: Does the membrane matter?," Soft Robotics, 1(3), pp. 192-201.

[15] He, L., Herzig, N., de Lusignan, S., and Nanayakkara, T., "Granular jamming based controllable organ design for abdominal palpation," Proc. 2018 40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), IEEE, pp. 2154-2157.