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INNOVATION

A novel haemostatic powder delivery device applicable in minimally invasive surgery

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Abstract

Haemostatic powder is an effective solution commonly used in various open surgeries. However, there is no specific intra-abdominal delivery device for application of haemostatic powder at the bleeding site during minimally invasive surgery (MIS). In this study, design, construction and test of a novel powder delivery device were carried out. The device uses pressurized gas to deliver the haemostatic powder to the bleeding point. The effect of the gas pressure and the spraying distance on the geometry of the powder dispersion surface area was investigated and found to be significant. The findings indicate that the driving gas pressure range of 60–80 mmHg and the spraying distance range of 2–5 cm achieve the most concentrated powder dispersion surface area. Additionally, *in vivo* experiments confirmed the effectiveness of the device in live tissue.

Keywords

Haemostasis, haemostatic powder, powder delivery device, minimally invasive surgery

History

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1. Introduction

Minimally Invasive Surgery (MIS) is increasingly used as an alternative to traditional open surgery. Advances in video imaging, endoscope technology and instrumentation have led to conversion of many open surgical procedures, in various surgical specialties, to minimally invasive ones [1,2]. MIS has many valuable advantages over open surgery, such as less tissue trauma, fewer post-operative complications, less pain and faster patient recovery [3]. In contrast with these valuable benefits, MIS suffers from some drawbacks including lack of direct access to the surgery site, more difficult surgical techniques and possibly longer surgery duration [3,4]. In this regard, uncontrollable bleeding is one of the most considerable risks brought on from indirect access to the surgery operation site [5]. Even a minor jet bleeding during MIS may cover the lens and distort the vision while it may cause significant laparoscope light absorption and darken the surgical area [6]. In some cases, conversion of laparoscopy to laparotomy could be essential to achieve adequate haemostasis [5,7].

Considering the difficulty of managing bleeding during MIS, a variety of open surgical techniques and instruments has been modified to achieve this purpose. Suturing techniques, clip appliers, staplers and electrocauteries are various choices developed to overcome uncontrollable bleeding in MIS [8–11]. In this regard, haemostatic powder is one of the solutions currently used efficiently in open surgery [12–17]. Haemostatic powder is absorbent and, in contact with the bleeding site, absorbs the blood serum and accelerates clot formation. Despite the advantages of haemostatic powder and adaptations made for its use in MIS, there is no specific intra-abdominal delivery device to apply it at the bleeding site during MIS.

Delivery mechanisms of haemostatic powder have been the subject of only a few investigations. In addition, the proposed devices have limited application for specific procedures. In a research study conducted in 2009, the efficacy of using a haemostatic powder, Microporous Polysaccharide Hemospheres, after endoscopic sinus surgery was examined by applying a powder delivery device consisting of a plastic container and an applicator tube [18,19]. In another study done in 2011, the effectiveness of spraying a haemostatic powder, Hemospray™, was evaluated during endoscopic therapy of active peptic ulcer [20,21]. These devices have a single powder container and the delivery system acts continuously. As a result, the amount of haemostatic powder delivered to the target site could not be accurately controlled and too little or too much powder may be delivered inadvertently.

In this regard, a powder delivery device is required to deliver a controlled amount of haemostatic powder at the bleeding site. At the same time, the device should be able to deliver the powder accurately at the target site while working safe and efficiently in intra-abdominal pressure during laparoscopic surgery. This research presents the design, construction, and test of a novel powder delivery

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device capable of delivering haemostatic powder in a controlled amount to the target during laparoscopic surgery.

2. Materials and methods

2.1. Problem definition

Haemostatic powders are used to control bleeding, particularly blood oozing. They are currently used during open surgeries by means of simple applicators [6,22,23]. However, many challenging technical steps are required to make a laparoscopic applicator suitable for delivering haemostatic powder during minimally invasive surgeries. Lack of an appropriate delivery device hampers the application of haemostatic powders during laparoscopic surgery. Therefore, design and construction of a laparoscopic powder delivery device capable of applying haemostatic powder directly and precisely onto the internal bleeding site were carried out in the present study.

2.2. Mechanism of the new laparoscopic powder delivery device

The device was designed as a hand-held laparoscopic instrument using pressurized gas for delivering haemostatic powder. Powder is stored in a cartridge and, by activating the device, a flow of pressurized gas from the gas reservoir propels the powder through an application tube. The mechanism of delivering haemostatic powder results in a non-contact method, which is very important in bleeding control.

The powder delivery device consists of a powder reservoir for storing haemostatic powder, a non-contact powder delivery tube that applies haemostatic powder on the bleeding site, a handle with an operation switch, and a gas channel that connects the device to the gas reservoir.

The powder reservoir has multiple chambers, where a definite dose of haemostatic powder is stored in each chamber. This ensures delivery of an exact amount of haemostatic powder to be applied to the bleeding site with each fire.

2.3. Construction of the new laparoscopic powder delivery device

Medical grade steel, a biocompatible material, was used to construct the present prototype. The delivery tube has an outer diameter of 8 mm, inner diameter of 6 mm, and length of 300 mm. Figure 1 shows the constructed prototype of the haemostatic powder delivery device.

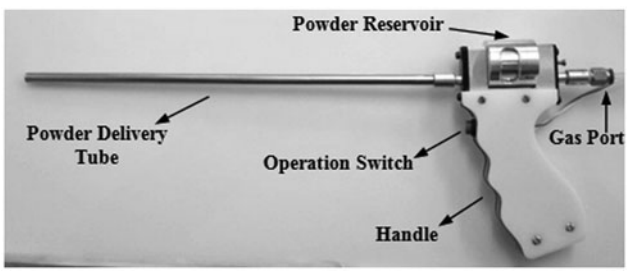

Figure 1. Constructed prototype of the haemostatic powder delivery device.

Carbon dioxide is the driving gas due to its advantages such as high solubility, quick absorbability and availability. Carbon dioxide can be readily absorbed and excreted through the lungs. Additionally, it is utilized as the insufflation gas during laparoscopic surgery to inflate the abdomen and, therefore, is available in the laparoscopic surgery suite [24].

2.4. The experimental procedure

In order to evaluate the performance of the device and investigate the effect of physical parameters on the spraying process an experimental set-up was designed. A pressurized CO_2 cylinder was used to provide pneumatic powder conveying. An additional high precision pressure regulator was used to down-level the pressure to that required for activation of the device. A pressure gauge was installed to monitor the carbon dioxide pressure. A flow meter was used to monitor the delivered gas flow rate and a flow control valve was used to control the amount of the gas flow entering the device. An operation switch activated an electric valve that controlled the gas flow. The designed experimental set-up is shown in Figure 2.

In this study, ChitoHem®, a topical haemostatic powder, was used. ChitoHem® is a superabsorbent topical haemostatic powder, mainly composed of micro-spherical oxidized regenerated cellulose [14,23]. ChitoHem® is widely used in vascular diagnostic and surgical procedures and the minimum amount of powder required to achieve efficient haemostasis is determined at 100 mg.

The constructed powder delivery device was tested on two mix breed rabbits, *in vivo*, to evaluate its performance. The tests were carried out at the department of surgery in a veterinary faculty. The Ethics Committee of the faculty issued ethical approval for the study. The rabbits were food deprived overnight. An intramuscular injection, a mixture of 20 mg kg^{-1} Rampun and 15 mg kg^{-1} Ketamine anaesthetized them. In one rabbit the bleeding site was on the ear and in the other one the bleeding site was on the liver.

Additionally, the constructed device was tested on a sheep liver, *ex vivo*, to study the effect of the driving gas pressure and the spraying distance on the geometry of powder dispersion surface area. In this regard, the haemostatic powder was sprayed on a sheep liver, *ex vivo*, under different driving gas pressures and spraying distances. The liver was located in a laparoscopic simulation box with atmospheric

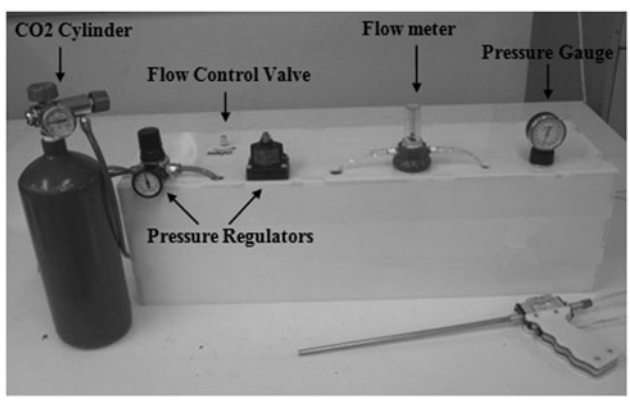

Figure 2. The experimental set-up.

pressure and the device was inserted in the box through a trocar. In all sprays, the device made an elevation angle of ~45° with the liver. Every spray carried 100 mg of powder to the target. All the sprayings on the sheep liver were repeated 3-times to ensure a good repeatability of the results.

2.5. Statistical analysis

Statistical analysis was performed using a two-way analysis of variance (ANOVA). The independent variables were the driving gas pressure and the spraying distance. The geometry of the powder dispersion surface area (ratio of length to diameter of the surface) was chosen as the measured or dependent variable. Student *t*-test was also used to determine significant differences between two groups. A probability value of less than 0.05 was taken as significant. Statistical analysis was applied to determine whether the changes in the driving gas pressure and the spraying distance change the geometry of the surface area covered with the sprayed powder. All the data are presented as mean value and error bars represent standard deviation (SD) of the means.

3. Results and discussion

3.1. Step 1: Evaluating the performance of the device

In order to evaluate the performance of the powder delivery device, it was tested on a mix breed rabbit. The protocol is mentioned in section 2.4. The central ear artery of the rabbit was perforated by a needle. Then, the haemostatic powder was sprayed on the bleeding site by the device (Figure 3). The powder covered the bleeding site uniformly and concentrated on the source of bleeding. No trauma was detected on the target tissue. The haemostasis was obtained in 45 s, while it would be achieved within 2–5 min by gauze compression alone.

3.2. Step 2: Obtaining the proper driving gas pressure and spraying distance

In this step, the spraying distance (distance between the device tip and the bleeding target) and the driving gas pressure variables were studied as two major effective factors on the spraying process. In this regard, the haemostatic powder was delivered to a sheep liver at three different spraying distances, 2, 5 and 8 cm, and under different relative driving gas pressures, 20, 40, 60 and 80 mmHg.

During laparoscopic surgery, intra-abdominal pressure is raised to 12–15 mmHg [25,26] to elevate the abdominal wall and allow the surgical instruments move easily in the operation field. Consequently, the driving gas pressure of the device during laparoscopy is set at a pressure higher than the intra-abdominal pressure to avoid backflow of gas into the device.

To increase the effectiveness of haemostasis, it is required to spray the haemostatic powder accurately and centralized on the bleeding point. The device delivers an exact amount of haemostatic powder in each fire and, so, less dispersion of powder results in a more concentrated delivery. In other words, the bleeding can be controlled more precisely by localizing the sprayed haemostatic powder in a circular surface area.

As shown in Figure 4, geometry of the powder dispersion surface area changes with different driving gas pressures and spraying distances. In order to investigate this relationship, the surface area effectively coated with the haemostatic powder was estimated by a circle. The diameter of this circle (D) and the length of the powder dispersion surface area (L) were measured in each spraying. In all sprayings, variation of D was found to be ~9.08 (SD = 1.27) mm. However, the parameter (L) showed more changes with variations in driving gas pressure and spraying distance. The effect of the mentioned factors on the ratio of L to D was studied. Figure 5 demonstrates the variations of the parameter L/D for various driving gas pressures at different spraying distances.

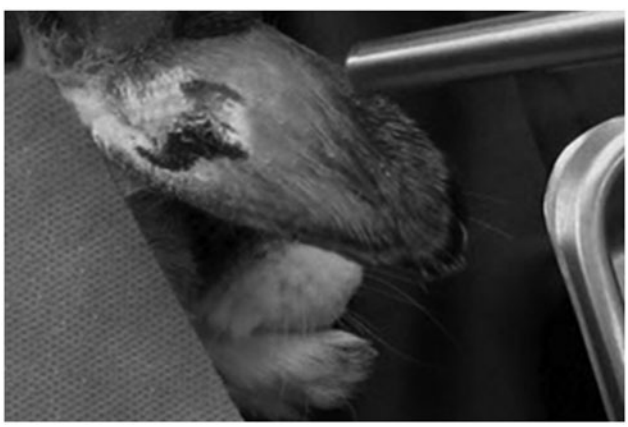

Figure 3. Applying haemostatic powder on the bleeding ear of the rabbit by using the constructed device.

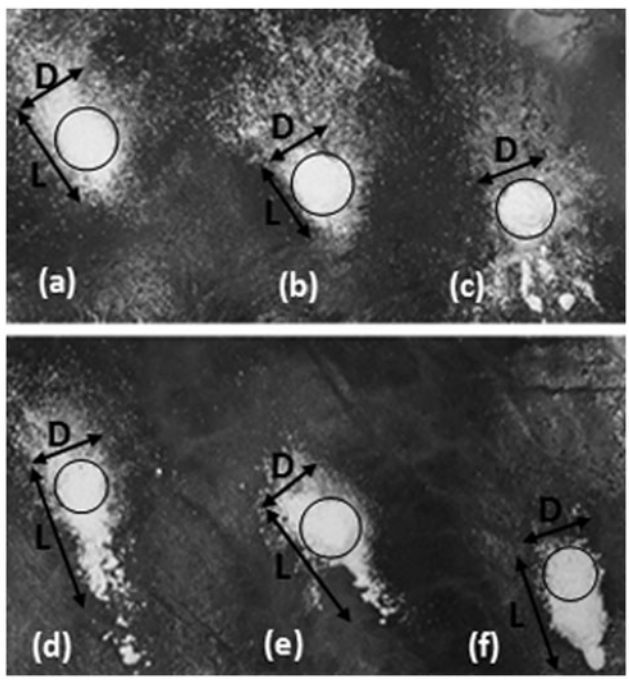

Figure 4. Haemostatic powder sprayed on the sheep liver under two different driving gas pressures (P) and three spraying distances (d). (a) P = 80 mmHg, d = 8 cm, (b) P = 80 mmHg, d = 5 cm, (c) P = 80 mmHg, d = 2 cm, (d) P = 40 mmHg, d = 8 cm, (e) P = 40 mmHg, d = 5 cm, (f) P = 40 mmHg, d = 2 cm.

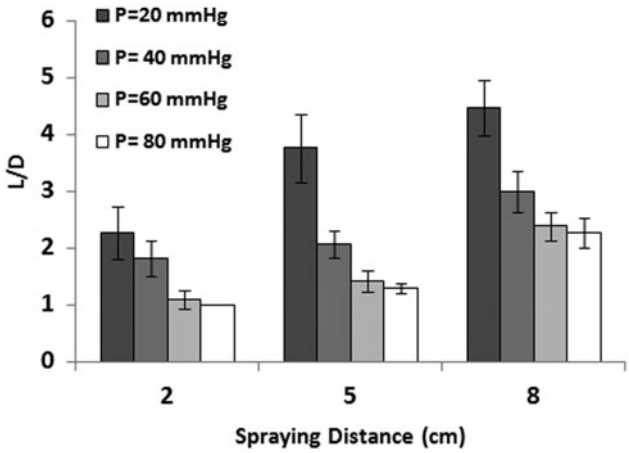

Figure 5. Variations of the parameter L/D for various driving gas pressures (P) at different spraying distances (d).

As shown in Figure 5, at every constant spraying distance, the parameter L/D decreases with increasing driving gas pressure while, at every constant driving gas pressure, the parameter L/D increases with increasing spraying distance.

The two-way ANOVA statistical analysis test revealed a significant ($p < 0.0001$) relation between changes in the driving gas pressure and the spraying distance on the parameter L/D. In addition, test results illustrated a significant interaction effect between these two variables ($p = 0.027$). That is, the gas pressure and the spraying distance interact in their effect on the parameter L/D.

Therefore, by changing the spraying distance and adjusting the driving gas pressure, the surgeon can approximate the parameter L/D to 1 and provide a more effective haemostasis.

As shown in Figure 5, in spraying distance of 8 cm from tissue, the parameter L/D is much more than 1 for all studied gas pressures. That is, it is not recommended to hold the device far from the tissue (more than 5 cm) in the range of studied pressures.

As the spraying distance cannot be determined accurately during laparoscopy, a distance between 2–5 cm is preferable for holding the device tip. As illustrated in Figure 5, at these two spraying distances, the parameter L/D is close to 1 for driving gas pressures of 60 and 80 mmHg. At all three tests with spraying distance of 2 cm and driving gas pressure of 80 mmHg, the parameter L/D is 1. However, the Student *t*-test indicated no significant difference between the results in gas pressure of 60 and 80 mmHg at all spraying distances ($p > 0.05$).

Consequently, the findings of this study recommend the driving gas pressure to be in the range of 60–80 mmHg and the spraying distance to be in the range of 2–5 cm.

3.3. Step 3: Testing the device with gas pressure and spraying distance findings in Step 2

In order to verify the results, the powder delivery device was tested on a second mix breed rabbit. The protocol is mentioned in section 2.4. The rabbit underwent partial hepatectomy. At first, gauze compression was applied on the resected surface of the liver to control bleeding, which took ~12 min to achieve effective haemostasis. This was taken as control. Then a similar partial resection of hepatic tissue was performed and the haemostatic powder was applied on the resected surface by using the constructed device (Figure 6). The amount of haemostatic powder in each powder chamber was 100 mg and seven shots of powder were required to deliver the appropriate amount of haemostatic powder to the resection surface. The driving gas pressure was set to 80 mmHg and the spraying distance was ~2 cm. Haemostasis was obtained in almost 5 min and no trauma was detected in the tissue.

Figure 6. Applying haemostatic powder on the bleeding liver of the rabbit by using the constructed device.

4. Conclusion

The proposed device is an effective powder delivery system capable of delivering a controlled amount of haemostatic powder accurately at the bleeding site during laparoscopic surgery. The device is reliable, safe, non-contact and easy to use. The surgeon can centralize the powder on the bleeding point by adjusting the driving gas pressure and spraying distance. The device can also be employed to deliver other medical powders to the target site efficiently.

The next step will be studying the device *in vivo*, during a real laparoscopic surgery. This will await achieving the minimum safety precautions required for human application.

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Declaration of interest

The third author is a faculty member of Biomedical Engineering at Amirkabir University of Technology, as well as the Managing Director of ChitoTech Company. ChitoTech has provided the hemostatic powder ''ChitoHem®'' to perform the experimental tests.

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