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Use of a new device for gasless endosurgery in a laparoscopic diaphragmatic hernia repair ex vivo canine model: A pre-clinical study

Maurício V. Brun[1,2] | Juan A. Sánchez-Margallo[3] | Marco A. Machado-Silva[4] | Francisco M. Sánchez-Margallo[3]

[1] Department of Small Animal Clinics (DCPA), Santa Maria, RS - Federal University of Santa Maria (UFSM), Santa Maria, Brazil

[2] Medicine Veterinary Post-Graduation Program (PPGMV) - UFSM, National Council for Scientific and Technological Development (CNPq), Federal District, Brazil

[3] Jesús Usón Minimally Invasive Surgery Centre (CCMIJU), Cáceres, Spain

[4] Federal University of Goias (UFG), Goiânia, Brazil

Correspondence
Maurício V. Brun, Researcher of CNPq/Brazil (308019/2015-6; 200346/2017-2; 305876/2018-0), DVM. Cx Postal 1005, Avenida Roraima 1000, Bairro Camobi, Santa Maria, RS, Brazil.
Email: mauriciovelosobrun@hotmail.com

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Abstract

Objectives: To test the feasibility of a new device for gasless laparoscopy in providing working space for diaphragmatic hernia repair in an ex vivo canine model as a pre-clinical study.

Study design: Technical feasibility study.

Animal: Eight beagles and two greyhound cadavers (not client-owned).

Methods: The new device was used for abdominal traction in gasless laparoscopic reconstruction of diaphragmatic hernias produced in dog cadavers. It consists of three main parts (vertical and horizontal rods, a three-piece structure, and a 3D-printed unit that incorporates slots for haemostatic forceps). Composite hernias (two incisions of about 4 cm) were closed by an intra-corporeal suture [suture group (GS), $n = 5$] or by a central suture and a polypropylene mesh [mesh group (GM), $n = 5$]. Surgical steps were T1 (primary port access up to third port placement), T2 (defect development), and T3 (diaphragmatic reconstruction). Total surgical time (TT) was also recorded.

Results: The defect was successfully developed and reconstructed in all cadavers. To close the defect, 7.0 ± 0.7 crossed mattress sutures were required in the GS, and 15.2 ± 1.9 hernia staples and one intra-corporal suture were used in the GM. T3 was longer ($p = 0.0076$) in GS (50.00 ± 16.46 min) than in GM (23.24 ± 5.25 min). TT was 87.22 ± 19.23 min in GS and 66.45 ± 6.38 min in GM ($p = 0.0547$).

Conclusions: Gasless laparoscopic diaphragmatic hernia repair using the developed device is feasible in the canine cadaver model. Both suture and mesh graft techniques for experimental diaphragmatic herniorrhaphy can be performed using this new device in this pre-clinical model.

Clinical significance: This new device for gasless laparoscopy allows diaphragmatic herniorrhaphy by intra-corporeal suture or mesh implantation in ex vivo canine model. The device demonstrates potential for future use in clinical cases.

KEYWORDS
gasless surgery, lift laparoscopy, surgical device, videosurgery, minimally invasive surgery (MIS)

1 | INTRODUCTION

Diaphragmatic hernia is a common surgical condition in dogs, with varying morbidity and mortality rates. Diaphragmatic hernia may be either a congenital or acquired defect. Most congenital conditions are pleuroperitoneal or peritoniopericardial hernias. However, rupture is the most frequent acquired diaphragmatic hernia etiopathology in small animals. Traditional diaphragmatic hernia repair in small animals is approached by celiotomy and thoracotomy, which are traumatic and lead to additional blood loss (Fossum, 2019; Hunt & Johnson, 2012).

Laparoscopic diaphragmatic hernia repair has been described in small animals (Monnet & Fransson, 2015), including cases with extensive and chronic defects and large numbers of abdominal organs displaced into the pleural space (Brun, 2017; Brun et al., 2010; Copat et al., 2017). It is believed that the benefits of laparoscopy, such as reduced tissue trauma and less pain than conventional approaches, can be expected for diaphragmatic hernia repair. However, no studies were found comparing minimally invasive surgery (MIS) with conventional approaches for diaphragmatic herniorrhaphy in small animals. Diaphragmatic hernia can be an incidental finding during laparoscopy for other purposes (Fransson & Ragle, 2011). In this case, one possibility is to treat this disease by MIS.

Canine MIS diaphragmatic hernia repair may be approached either through the thorax [thoracoscopy or video-assisted thoracoscopic surgery (VATS)] or abdomen (laparoscopy or laparoscopic-assisted). The pure laparoscopic approach provides better working space than thoracoscopy, which is an important consideration regarding extensive defects. Moreover, the laparoscopic approach is more suitable than thoracoscopy for bilateral repair (Beck et al., 2004). Thoracoscopic herniorrhaphy usually require one-lung ventilation or pneumothorax with CO_2 at reduced intra-thoracic positive pressure. Maximum thoracic insufflation pressures should not exceed 5 mmHg. In healthy cats, 3 mmHg intra-thoracic pressure is associated with less acidosis, better cardiac index, less cardiac oxygen consumption, and a similar amount of working space than 5 mmHg (Mayhew et al., 2019). In small dogs and cats, thoracoscopic repair may be challenging or impractical due to the small working space.

During conventional laparoscopic diaphragmatic hernia repair, the insufflation pressure recommended creating optimal working space will cause tension pneumothorax. Thus, intra-abdominal pressure should be decreased when compared with other laparoscopic surgeries in which the diaphragm is normal. Otherwise, the repair of chronic and large defects might be impractical in the reduced workspace, especially if intra-corporeal suturing is to be used.

The establishment and maintenance of capnoperitoneum during laparoscopy may cause hypercapnia, acidosis, reduction in cardiac output, decreased pulmonary compliance, hypothermia, and post-operative pain (Scott et al., 2020), as well as accidental bowel injury by Veress needle or trocar insertion (Anderson & Fransson, 2019). Moreover, CO_2 insufflation may trigger clinically relevant neurohumoral responses. Thus, gasless laparoscopy (or lift laparoscopy) was developed to reduce pneumoperitoneum-related changes. In gasless laparoscopy, working space could be created by lifting the abdominal wall with specific devices (Brun et al., 2019; Fransson & Ragle, 2011; Fransson et al., 2015; Scott et al., 2020).

Due to potential complications related to CO_2 pneumoperitoneum, gasless surgery is a promising alternative for diaphragmatic hernia repair in small animals, as it was seen in human patients with large diaphragmatic defects (Orita et al., 1997; Yu et al., 2016). Gasless laparoscopic approaches have been described for several procedures in dogs and cats (Fransson & Ragle, 2011; Fransson et al., 2015), including ovariohysterectomy (OVH), multiple gastrointestinal tract biopsy, gastropexy, cystotomy, hepatic biopsy, cryptorchidectomy, and jejunostomy and tube placement. In a randomized, controlled, and blinded study, OVH by lift laparoscopy provided similar pain, less frequency of hypercapnia, and required less anaesthetic gas, as well as similar surgical time than conventional OVH (Fransson et al., 2015).

Several patents of devices[1] and tools for gasless laparoscopic surgery have been reported (Adler, 1996; Chin, 1996; Corden & Augustine, 2013; Moll et al., 1996, 2004; Ortiz & Steckel, 1995; Volz et al., 1999; Warner et al., 1998). Most of them were specially designed for use with humans, and thus are not suitable for small animals due to their anatomical and physiological particularities. Some instruments have been designed to be placed inside the abdominal cavity after a celiotomy (Adler, 1996; Chin, 1996; Moll et al., 1996; Ortiz & Steckel, 1995; Volz et al., 1999; Warner et al., 1998). Therefore, at the end of the procedure, that additional surgical access requires careful wound closure. In addition, intra-peritoneal lifting devices may occupy considerable intra-peritoneal space, which could drastically reduce working space during laparoscopic approaches in small animals. Other gasless laparoscopy devices expand to lift the abdominal wall after its insertion into the abdominal cavity (Corden & Augustine, 2013; Moll et al., 2004), causing visceral compression. In the authors' opinion, these expanding devices could hamper intra-corporal suturing in cases of large diaphragmatic defects.

The purpose of this study was to test the feasibility of a new device for gasless laparoscopy in providing working space for diaphragmatic hernia repair using two techniques (intra-corporeal suture or by a central suture and a polypropylene mesh) in an ex vivo canine model as a pre-clinical study.

2 | MATERIALS AND METHODS

The gasless device was developed in a partnership project involving Federal University of Santa Maria (UFSM), Jesús Usón Minimally Invasive Surgery Centre (CCMIJU) and the National Council for Scientific and Technological Development (CNPq). The device consists of three main parts (Figures 1 and 2). The first part [Figures 1 (blue) and 2a] is a movable base consisting of a clamp for attachment to the surgical table and a vertical and a horizontal rod. The rods are articulated by a piece with two clamps and by an articulated arm with ball joints at its end.

[1] US005398671A, (Ortiz & Steckel, 1995) US005501653A, (Chin, 1996) US005514075A, (Moll et al., 1996) US005573495A, (Adler, 1996) US005976079A, (Volz et al., 1999) US005716327A, (Warner et al., 1998) US20040097792A1 (Moll et al., 2004), and GB2495522 (Corden & Augustine, 2013).

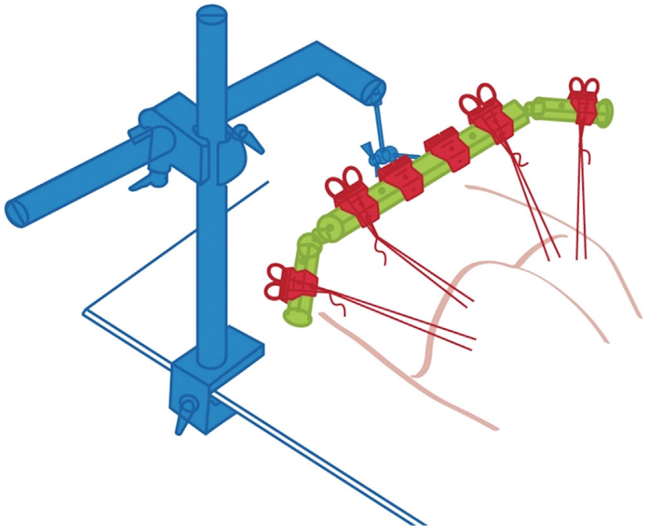

FIGURE 1 The multi-directional traction device is composed of three parts. The first part (blue) is a movable base attached to the surgical table. The second part (green) is an articulated structure of three pieces: one central and two lateral. The third component (red) is a 3D-printed piece to hold the haemostatic forceps that support the tacking sutures

The second part [Figures 1 (green) and 2b] is a three-piece structure: one central and two lateral. These pieces are connected by ball joints that allow their articulation.

The third component [Figures 1 (red) and 2b] is a 3D-printed piece that incorporates slots for haemostatic forceps, which are used to hold the tacking sutures applied to the abdominal wall.

The developed device was tested in the laparoscopic diaphragmatic reconstruction of 10 defrosted dog cadavers (eight Beagles and two Greyhounds) in ambient temperature. The animals used in this study were reused from previous training or research studies (not involving thoracic or abdominal cavity) that were approved by the Ethical Committee and Institutional Animal Care of the Jesús Usón Minimally Invasive Surgery Centre (CCMIJU).

The study was organized into two groups of animals, suture group (GS) and mesh group (GM). In the GS group, the diaphragmatic hernia was closed using intra-corporeal sutures. In the GM group, the defect was repaired using a polypropylene mesh and laparoscopic hernia staples after the placement of a single central suture to approximate the margins of the defect.

After an extensive thoracic and abdominal clipping, the eight defrosted Beagle cadavers were randomly distributed in the two groups of an identical number (GS and GM). The two Greyhounds were distributed into the two study groups. In both groups, the Greyhounds were the last cadavers to be operated on.

Ports were placed in triangulation. The first (camera) port (12 mm) was set on the midline, at the umbilical area (slightly cranial, caudal, or exactly at the umbilicus, according to the dog' individual anatomical variations), using the open approach (Hasson-modified technique). A 10-mm and 0-degree telescope coupled to a video system (Karl Storz, Image1 HD; Karl Storz SE & Co. KG, Tuttlingen, Germany) was used. The working ports, a 5-mm and an 11-mm trocar, were placed to the right and left side of the camera port, respectively (Figure 3). The working ports were placed either cranially or caudally to the first port, according to the anatomical distance between the umbilical scar and diaphragm. An 11-mm working port was established for the surgeon's right (dominant) hand for insertion of the needle holder, hernia stapler, and the polypropylene mesh.

Following insertion of the first port, the abdominal wall was lifted by four parietal suspension sutures attached to the lifting device. Sutures are placed more and less parallel to the xiphoid process and both costal arches, at the maximum depth of the muscle fascia and not penetrating the abdominal cavity. They were lifted until clear visualization of the diaphragmatic defect was achieved. Four USP 0 silk sutures (Silk 0

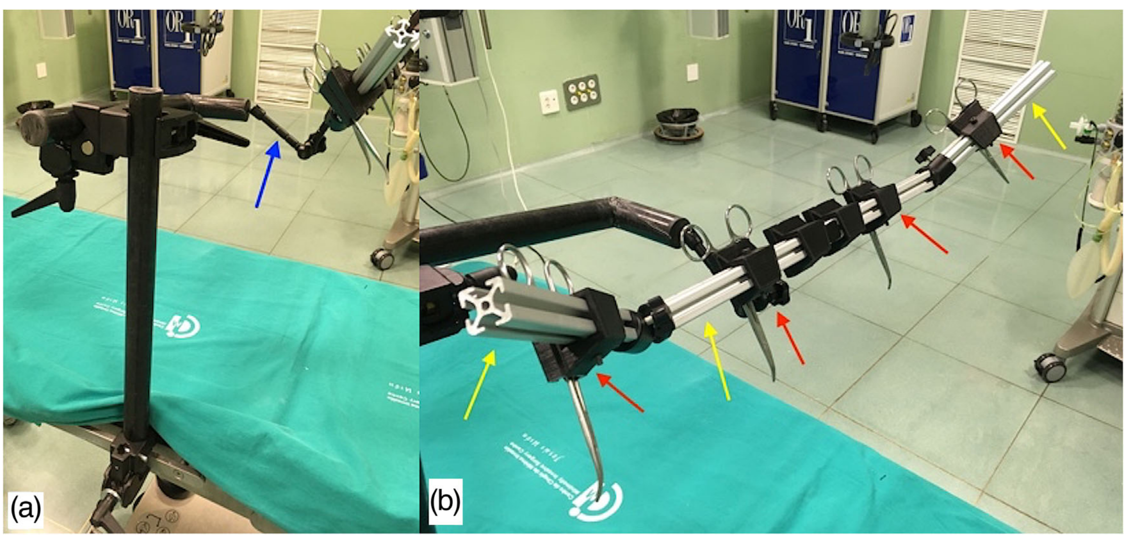

FIGURE 2 Assembled multi-directional traction device. (a) Part 1, with two rods (vertical and horizontal) and an articulated arm (blue arrow). (b) Part 2 (yellow arrows) and part 3 (red arrows)

FIGURE 3 Position of video system tower, surgeon, multi-directional traction device, and ports during gasless laparoscopic diaphragmatic hernia repair in an ex vivo canine model

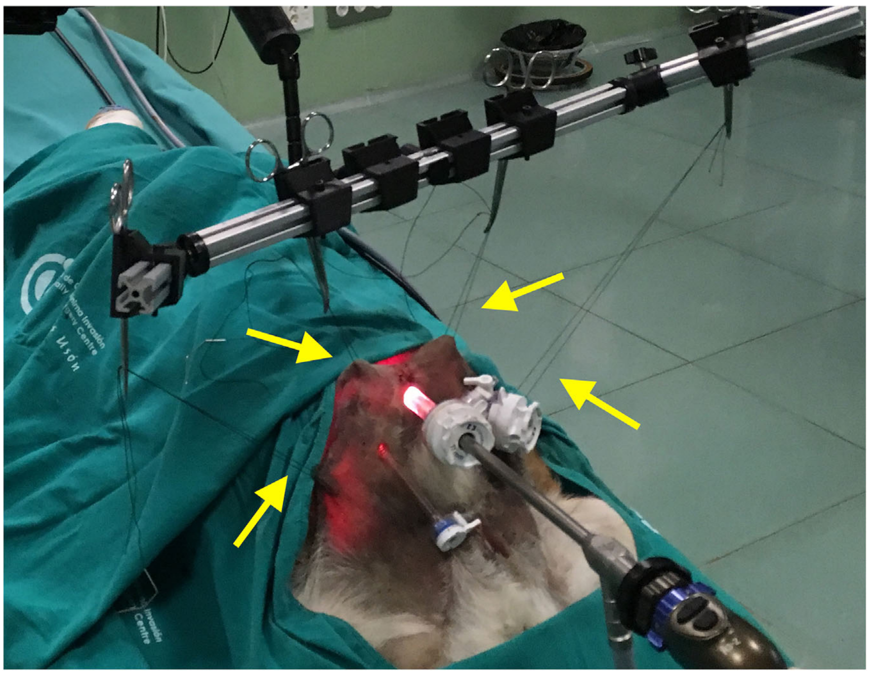

FIGURE 4 Position of transparietal silk tacking sutures (yellow arrows), strategically placed cranial to the ports for suspension of the abdominal wall and creation of the working space, for diaphragmatic hernia repair in an ex vivo canine model

TR60; Laboratorio Aragó, Barcelona, Spain) were strategically applied cranially to the ports (Figure 4). The animals were positioned in Trendelenburg reverse (20°).

In both groups, a diaphragmatic defect formed by a circumcostal, and a radial incision was created (composed hernia). A 4-cm cotton stripe was used as a template for the defect production, as described previously (Beck et al., 2004). The incision was performed in the muscular part and phrenic centre using Metzenbaum scissors, besides the stripe, to produce a radial defect. The circumcostal defect was carried out by extending the radial incision laterally in a ventrodorsal direction, close to the subxiphoid area.

In the GS group, the defect was closed using crossed mattress sutures, as previously reported (Brun, 2017, 2010), using USP 2-0 polyglactin 910 thread (Novosyn HR26; B. Braun, Barcelona, Spain). In the GM group, the defect was covered by either an 8 × 8-cm ($n = 1$) or a 10 × 10-cm ($n = 4$) polypropylene mesh using hernia staples (Figure 5). In this group, a single approximation crossed mattress suture was also applied at the defect's edges prior to mesh fixation. Additionally, the

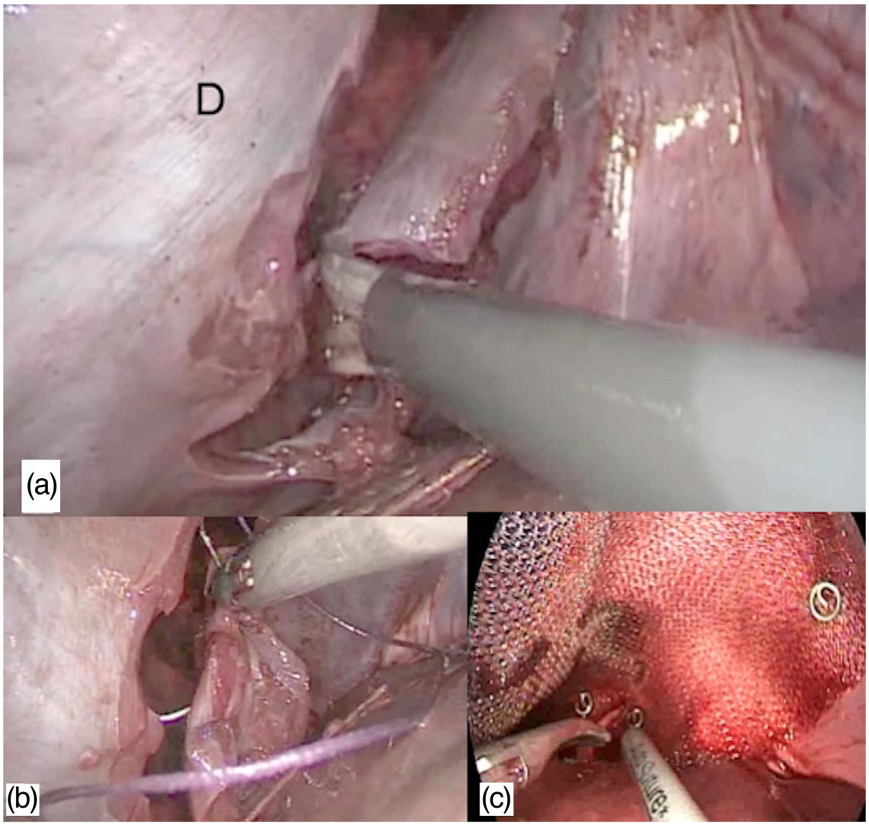

FIGURE 5 Creation and repair of the diaphragmatic defect in an ex vivo canine model. Intra-abdominal images were taken after establishing the working space using the multi-directional lifting device. (a) Creation of the composite defect using Metzenbaum scissors. (b) Intra-corporeal suturing to approximate the midpoint of the defect's edges. (c) Fixation of the polypropylene mesh using helicoidal hernia staples

omentum was attached to the mesh using hernia staples. Port incisions were closed using crossed mattress sutures, and the skin was closed with simple interrupted sutures.

Technical feasibility and viability, technical issues, complications, and time of the surgical stages (steps), as well as overall surgical time (TT), were assessed in both groups. All data were tested for normality using the Shapiro–Wilk test. Surgical stages were divided into T1 (from primary port entry to third port placement), T2 (defect creation) and T3 - diaphragmatic repair with (GM) or without (GS) omentopexy. Variables TT, T1, T2, T3, and dogs' body weight were compared between groups using the unpaired *t* test with a bicaudal *p*-value. For all tests, $p < 0.05$ was considered statistically significant.

3 | RESULTS

The gasless laparoscopy device presented and tested in this study allows fine adjustment to various anatomical conditions and different abdominal entry sites. After this study, it was registered as a utility model (Brun et al., 2019).[2] It was effective for gasless laparoscopic diaphragmatic hernia repair in all dog cadavers, with proper creation of working space for surgery of the cranial abdomen. Capnoperitoneum was not required to create working space.

Bodyweight (GS = 18.90 ± 3.42 and GM = 18.00 ± 2.40) did not differ significantly between groups ($p = 0.6049$). Overall surgical time did not differ ($p = 0.0547$) between the GS (86.8 ± 19.2 min, range 68.1–119.24 min) and GM (66.4 ± 6.4 min, range 56.1–72.5 min) groups (Table 1).

Regarding intra-operative moments, T1 ($p = 0.5360$) and T2 ($p = 0.2599$) did not differ between groups, while T3 was significantly higher ($p = 0.0076$) for the GS group than for the GM group.

In the GS group, 7.0 ± 0.7 sutures (range 6–8) were required to occlude the defect, while 15.2 ± 1.9 (range 13–18) spiral staples were used to repair the diaphragmatic tear in the GM group, following a single intra-corporeal crossed mattress approximation suture (Table 1).

Reviewing the videos of the surgical procedures, in cadaver No. 10 of the GS group, one of the seven sutures was not performed as a crossed mattress suture since the needle was not properly passed through the diaphragm muscularis. However, the defect was effectively closed with an adequate approximation of the wound edges. Thus, that suture was not replaced. In another cadaver (No. 7) from the GS group, a triple inverted surgeon's knot was required for approximation of the midpoint of the defect, as the conventional surgeon's knot was slipping. In cadaver No. 9 from the GM group, one of the staples was attached to the diaphragm at two points. Thus, the most distal fixation point was released by gentle traction using grasping forceps. Also, in the same cadaver, a small superficial tear to the liver capsule was reported as a minor complication due to accidental contact with the tip of the stapler.

[2] The device was registered as a utility model by the Spanish Patent and Trademark Office (Oficina Española de Patentes y Marcas) (ES201800465U). Subsequently, it was registered as a patent by the Brazilian National Institute of Industrial Property (Instituto Nacional da Propriedade Intelectual – INPI) (BR102019013473A2) (Brun et al., 2019). The device is already licensed for production by the Bhiosupply Company (Brazil).

TABLE 1 Distribution of animals (dog cadavers) by groups. The number of staples (GM) and sutures (GS) used during surgery, overall surgical time (TT), and partial intra-operative times (T1-T3) are indicated

Id	Hernia repair		Surgical times			
	Number of sutures	Number of staples	TT	T1	T2	T3
GS						
2	6	–	68.10	10.28	6.28	36.51
4	7	–	84.26	10.51	11.55	44.32
7	7	–	79.12	7.33	7.19	43.30
8	8	–	83.37	7.13	8.54	47.31
10	7	–	119.24	8.42	11.56	78.58
Mean	**7**	–	86.82	8.73	9.02	50.00^{A}
SD	0.71	–	19.23	1.60	2.45	16.46
GM						
1*	1	13	56.07	8.49	9.23	14.51
3	1	16	69.3	9.32	11.28	26.17
5	1	15	72.54	12.36	8.29	24.00
6	1	14	69.25	10.02	11.54	26.25
9	1	18	65.09	7.12	13.35	23.25
Mean	–	15.20	66.45	9.46	10.74	22.84^{B}
SD	–	1.92	6.38	1.95	2.00	4.84

Note: TT, total surgical time; T1, time from primary port access up to third port placement; T2, time of the defect creation; T3, diaphragmatic reconstruction. Different capital letters in the same column mean significant difference ($p = 0.0076$).
Abbreviations: GM, mesh group; GS, suture group.
*One of the staples was applied slightly close to the vena cava. However, there was no vascular involvement confirmed by necropsy.

In the first cadaver from the GM group (cadaver No. 1), one of the staples was applied slightly close to the vena cava. In that case, a necropsy was performed to investigate possible vascular invasion, which did not occur (Figure 6). In all other cases, there was no doubt regarding the proper fixation of the mesh or other surgical issues, and no necropsy was required.

The position of the surgical ports was changed due to anatomical variation of the animals and the observations done during the study (Table 2). In most cadavers (6/10), the first port was placed slightly cranial to the umbilicus. In the remaining cadavers (4/10), it was placed slightly caudal to the umbilicus. In a cadaver (No. 5) from the GM group, the skin incision for the first port was made away from the midline. Thus, a new skin incision was made at the umbilicus, and the first one was discarded. In that case, surgical time was considered from the second skin incision.

4 | DISCUSSION

Intra-corporal suturing of wide defects is challenging even for experienced laparoscopic surgeons (Fu et al., 2019; Moorthy et al., 2004; Sánchez-Margallo et al., 2017). However, the abdominal wall lifting by this device provides appropriated space for laparoscopic diaphragmatic hernia repair in an ex vivo canine model by intra-corporeal sutures. The results are promising and indicate the need for live animals trials using the gasless device for complex clinical conditions, including laparoscopic diaphragmatic hernia repair.

The degree of freedom for positioning the lifting sutures in this device is due to different aspects. Multiple joints, consisting of a central bar and two sidearms and support for up to six lifting sutures, simultaneously provide a wide range of movements for the creation of the intra-corporeal working space. In addition, if necessary, the support for the lifting sutures allows for fine adjustment to improve the abdominal wall lifting at specific sites during the procedure. Unlike what other authors bring (Adler, 1996; Chin, 1996; Fransson & Ragle, 2011; Fransson et al., 2015; Moll et al., 1996; Ortiz & Steckel, 1995; Volz et al., 1999; Warner et al., 1998), no intra-abdominal device was used to create working space in this study, which could considerably affect intracorporal suturing during diaphragmatic reconstruction.

We believe that the wide working space was obtained through the simultaneous traction of multiple abdominal lifting sutures, providing a broad range of adjustable directions and angles. This allows a homogeneous distribution of the forces applied to the abdominal wall circumference in its ventral and lateral areas. According to previous studies (Fransson & Ragle, 2011; Watkins et al., 2013), the exploration of the lateral aspects of the abdominal cavity by lift laparoscopy was harder when using internal traction from a retractor positioned on the ventral midline, due to the tenting effect. This effect can be considerably reduced with the present device by applying traction sutures close to the costal edge on the approached flank.

TABLE 2 Distribution of animals (dog cadavers) by groups. The port position is indicated for each animal

Id	First umbilical, second and third caudal	First umbilical, second and third cranial	First pre-umbilical, second and third caudal	First post-umbilical, second and third caudal	First post-umbilical, second and third cranial
GS					
2	X				
4			X		
7				X	
8			X		
10			X		
GM					
1			X		
3					X
5		X			
6				X	
9	X				
Total	2	1	4	2	1

Abbreviations: GM, mesh group; GS, suture group.

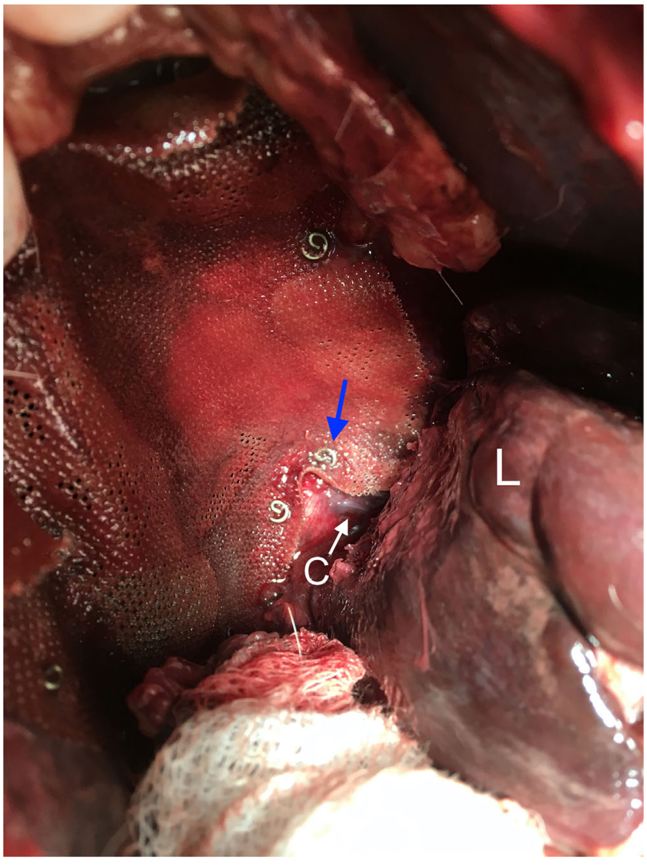

FIGURE 6 Necropsy image of dog 1 (Id 1) from the mesh group (GM) group to check the position of the hernial clip (blue arrow), which was inserted close to the vena cava (C) during surgery. The vena cava was not punctured by the clip. Abbreviation: L, liver

Additionally, the shape of the thorax in dogs facilitates the creation of a working space wide enough to access the diaphragm at the cranial abdomen. This fact was seen in all dog cadavers, especially in both Greyhounds. However, intra-corporeal suturing was considered technically more challenging in those two cases than in the Beagle cadavers. Although only two greyhounds were used, they show greater depth of the thorax in relation to beagles. The deeper chest tends to reduce the working space obtained with external abdominal traction.

The use of three access ports for laparoscopic reconstruction of diaphragmatic hernias has been previously described (Beck et al., 2004; Brun, 2017, 2010; Monnet & Fransson, 2015; Souza et al., 2015). In this study, three portal accesses in five configurations were used for laparoscopic hernia repair. All of them were considered appropriate for diaphragmatic reconstruction. However, in most cadavers, the camera port was placed slightly cranial to the umbilicus, and the working ports were inserted caudally. From the surgeon's point of view, this configuration seems to provide a wider working field since it allows the two suspension sutures to be passed closer to the linea alba, more caudally to the camera port at the level of or slightly cranial to the umbilicus. Moreover, establishing the second and third ports caudally to the camera port provide proper triangulation, which is more distant from the diaphragm than other port configurations. Thus, a broader range of motion was obtained compared to the second and third ports inserted cranially to the camera port.

The optimal position of working ports should be based on the patient's body conformation and the site of the diaphragmatic defect. Furthermore, the surgical ports should be placed, taking into account the position of the lifting sutures so that the thread of those sutures does not affect the laparoscopic handling and suturing. Although not assessed in this study, we observed that the placement of lifting sutures and ports for diaphragmatic hernia repair also provided appropriated access to the liver. The superficial tearing of the liver capsule in one of the cadavers occurred due to inadvertent movement during the fixation of the polypropylene mesh, not due to the reduced working space.

The time required for laparoscopic diaphragm reconstruction was similar (Beck et al., 2004; Brun et al., 2010) or longer (Souza et al., 2015) than described in previous studies; however, it is not possible to directly compare these results due to the visible methodological differences between the models, including the type of diaphragm defect, access, and reconstruction techniques used. Hernia repair (step T3) was longer in the GS group than in the mesh group. This was to be expected since intra-corporal suturing is more challenging than fixing a mesh over the defect using a helicoidal clip applier. Nonetheless, hernia repair was considered appropriate in the GS group, considering the defect size, the number of sutures required, and the working space.

A central intra-corporal suture was performed in all cadavers, regardless of the group, in order to approximate the margins at the centre of the defect. This manoeuvre was based on our previous experience on the diaphragmatic repair of large composite hernias (Brun, 2017, 2010). In those cases, sutures placed strategically at the centre of the defect or slightly close to it may not provide proper contact of the defect margins. However, this approximation of the margins favours the placement of subsequent appositional sutures for complete closure of the defect. In the GM group, this technique allowed the diaphragmatic muscle flap to provide additional support to the mesh, preventing mobility at its central area.

During hernia repair in the GM group, we observed an interesting possibility for use in clinical cases, which consists of applying a hernia clip to join the muscle flap with the mesh for better coverage of the diaphragm. Nevertheless, in larger defects, the mesh should preferably be fixed dorsally and laterally to the tendinous centre and to the diaphragm muscle before it is unfolded. If the mesh is completely unfolded before this fixation, it can lead to a considerable loss of working space. On the other hand, the initial fixation of the flap might influence the fine adjustment of the mesh position at the repair site.

Another important stage for those types of reconstruction concerns the closure of defects slightly close to the caval foramen (Brun, 2017) in cases of radial or composite hernias. This presentation is not uncommon in the clinical setting. It is crucial to verify the correct placement of the clip or suture since vascular damage would be potentially lethal (Brun, 2017). That complication did not occur in this study. In animal 1 of the GM group, the clip was applied too close to the vena cava. The suspicion of vascular damage was dismissed during necropsy in that case.

Omentalization was carried out only in the GM group. In the clinical setting, polypropylene mesh frequently causes intra-peritoneal adhesions, especially to the surface of the liver, as reported in a dog that underwent laparoscopic repair of a pleuroperitoneal hernia (Hartmann et al., 2015). Omentalization added surgical time to the GM group compared to the GS group, as the placement of absorbable sutures is less likely to cause severe adhesions. Therefore, both groups did not differ in terms of total surgical time, although statistical differences were seen in T3.

One disadvantage of this prototype is the impossibility of sterilizing in its current formulation since it was produced with some materials that are not autoclavable. This disadvantage will be overcome when this device is produced for clinical use using autoclaving resistant materials. Other more important limitations of this study are associated with the use of a new technique in the ex vivo dog model. This model does not allow simulating haemorrhages, the possible complications associated with the application of traction sutures in the muscle wall, and physiological respiratory movements, among other conditions. Thus, we believe that the present proposal is of importance as a pre-clinical study, with potential for future application in living animals with diaphragmatic hernia. Therefore, an in vivo study will be necessary before using this device and technology in an actual clinical setting.

5 | CONCLUSIONS

The device presented in this study is feasible for gasless laparoscopy, providing an appropriate intra-abdominal space for diaphragmatic hernia repair in an ex vivo canine model. Both suture and mesh graft techniques for diaphragmatic hernia repair can be performed in this model using this new device. This gasless device presents the potential for further investigation in clinical cases.

CONFLICT OF INTEREST

Maurício V. Brun, Juan A. Sánchez-Margallo, and Francisco M. Sánchez-Margallo declare that they are the inventors of the gasless device used in this research. They also declare that this did not introduce bias into the report. Marco A. Machado-Silva declares no conflict of interest.

AUTHOR CONTRIBUTIONS

Maurício V. Brun conceived the gasless new platform, co-created the gasless prototype, co-conceived study, performed all surgical procedures, manuscript writing, and manuscript review & editing. Juan A. Sánchez-Margallo co-created the gasless prototype, co-conceived study, and manuscript review & editing. Marco A. Machado-Silva co-conceived study and manuscript review & editing. Francisco M. Sánchez-Margallo co-created the gasless prototype, co-conceived study, manuscript review & editing, resources, and supervision.

PEER REVIEW

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ORCID

Maurício V. Brun https://orcid.org/0000-0001-9252-8512

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