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SURGICAL TECHNIQUES

A Novel Liver Parenchyma Transection Technique Using Locking Straight Rigid Ties. An Experimental Study in Pigs

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ABSTRACT

Introduction: Technological advances have led to the development of many devices used in liver resections. However, no single transection tool is uniformly considered to be better than the others. This study aimed to develop an effective, fast, and cost-efficient technique for hepatic parenchymal transection. *Materials and Methods*: A liver parenchyma compression device in the form of a locking straight rigid tie (LoStRiT) was newly developed. Twelve pigs were distributed into two groups. The control group ($n = 6$) comprised animals that underwent hepatectomy using the standard Kelly-clysis technique. The study group ($n = 6$) comprised animals that underwent hepatectomy using sequential LoStRiT mechanisms. The transection speed, blood loss, and biloma formation were recorded. *Results*: The mean parenchymal transection speed was 1.27 ± 0.27 cm^2/min for the control group and 2.39 ± 0.56 cm^2/min for the LoStRiT group ($p = .003$). The mean blood loss per kilogram of body weight was 9.8 ± 5.2 ml/kg for the control group and 3.9 ± 0.9 ml/kg for the LoStRiT group ($p = .040$). No bilomas were identified. *Conclusion*: LoStRiT hepatectomy appears to be effective, fast, and reproducible in a porcine model of liver resection. Further development of this novel and potentially cost-efficient technique includes construction of the device using absorbable materials.

Keywords: liver resection; hepatectomy; parenchymal transection; technique; experimental; animals

INTRODUCTION

Parenchymal transection is the most crucial step during hepatectomy. Finger fracture and clamp crushing (also known as Kelly-clysis) have been the standard transection techniques for decades [1]. However, in the last 25 years, technological advances and innovations have led to the development of many other devices that are employed in liver resections. These specialized instruments function in one of the following ways: (1) dissection using ultrasonic energy or a high-pressure water jet; (2) dissection, sealing, and division using ultrasonic or bipolar radiofrequency energy; (3) precoagulation using radiofrequency thermocoagulation; and (4) placing staples and division. Dissecting devices include the Cavitron Ultrasonic Surgical Aspirator (CUSA; Tyco Healthcare, Mansfield, MA, USA) [2] and the water-jet dissector ERBEJET 2 (ERBE USA Inc., Marietta, GA, USA) [3]. Sealing devices include the EES Harmonic (Ethicon, Cincinnati, OH, USA) [4], the LigaSure Vessel Sealing System (Covidien, Mansfield, MA, USA) [5], the Gyrus ACMI PlasmaKinetic (Olympus, Tokyo, Japan) [6], the ENSEAL G2 Super Jaw (Ethicon, Cincinnati, OH, USA) [7], and the Salient Dissecting Sealer (Salient Surgical Technologies, Portsmouth, NH, USA) [8]. Precoagulation devices include the Cool-tip RF electrode (Radionics Inc., Burlington, MA, USA) [9] and the Habib 4X (AngioDynamics, Queensbury, NY, USA) [10]. Finally, the most commonly used staplers for parenchymal transection include the Endo

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GIA (Covidien, Mansfield, MA, USA) [11] and the Echelon (Ethicon, Cincinnati, OH, USA) [12].

This large number of devices has been developed because different techniques can be more advantageous in one setting than another, and no single transection tool is accepted by the majority of liver surgeons to be more effective than the others. Furthermore, the recent literature supports the theory that the use of transection devices increases medical costs and does not lead to a clinically important benefit [13].

The aim of this study was to develop a conceptually straightforward, reproducible, fast, and cost-efficient technique for hepatic parenchymal transection that could be applied in most types of liver resection. This technique was based on the observation that bleeding or bile leakage from the liver transection surface stops after gentle compression of the parenchyma near the hepatectomy edge. A new compression device in the form of a locking straight rigid tie (LoStRiT) was newly developed.

METHODS

The design configuration for the LoStRiT was a ratchet mechanism that consisted of a male thread with a continuous series of conical teeth (Figure 1a) engaging against a female system of flexible jaws (Figures 1b and c). The needle end of the male had hole and sulcus features added to facilitate suture insertion (Figure 1d). The outer configurations of both ends were identical and appropriately rounded to efficiently prevent the development of surface stress on tissues, tightly block entry and exit holes, and smoothly accommodate material stresses within the LoStRiT itself. The dimensions of the actual system were approximately 11 × 1.5 cm (Figure 1e). Polyamide (nylon) was chosen for LoStRiT construction due to its known biocompatibility, manufacturability, and ability to be sterilized (ethylene oxide). Because nylons are generally hydroscopic and lose their strength in vivo over time when implanted (water molecules serve as plasticizers that attack the amorphous region), the least hydroscopic polyamide was used as a prototyping material for the LoStRiT (polylaurinlactam, feinpolyamide PA2200). LoStRiT strength tests were executed in the insertion and retraction modes. At a displacement speed of 10 mm/min, insertion and retraction performance characteristics were recorded at a sampling frequency as high as 100 Hz to adequately capture force and displacement. Several insertion tests were conducted. Force and displacement data demonstrated a consistent trend fluctuating approximately every 2 mm, followed by the "click" sound of the locking mechanism. In most cases, a load of 1.5–2.0 N (equivalent to approximately 200 g) was necessary to engage the locking steps (Figure 2a). In addition, several retraction tests were conducted. Force data demonstrated a consistent strength pattern, with failure occurring at a maximum load of 60 N (equivalent to approximately 6000 g) at a random location along the core of the male part (Figure 2b). The locking mechanisms exhibited no failure. A LoStRiT coupled with the insertion polypropylene suture (3/0 Prolene, 8622H, Ethicon, New Brunswick, NJ, USA) is depicted in Figure 3.

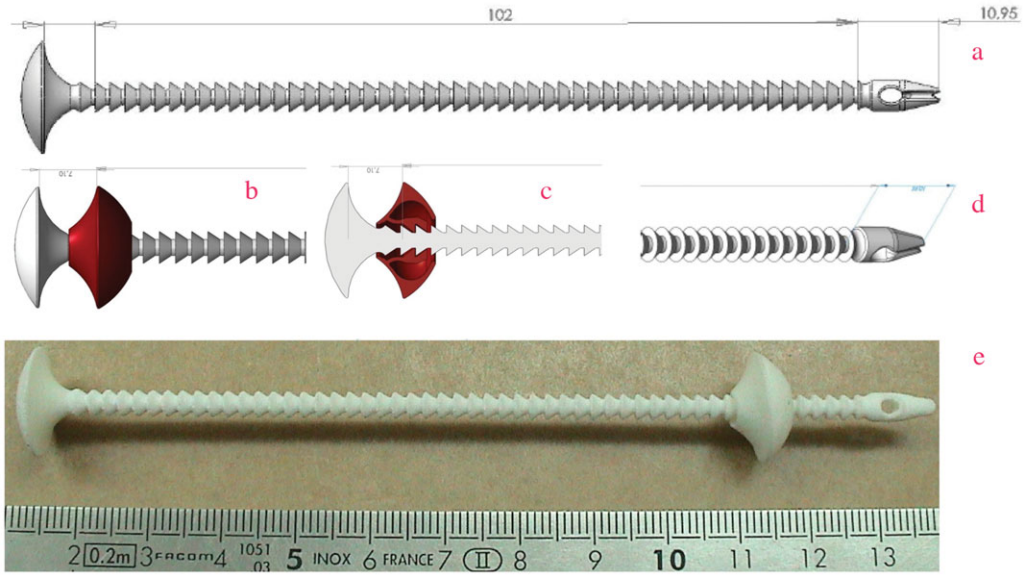

FIGURE 1 LoStRiT is a ratchet mechanism made from nylon that consists of a male thread with a continuous series of conical teeth (a) engaging against a female system (b) of flexible jaws (c). The needle end of the male thread has hole and sulcus features to facilitate suture insertion (d). The core and the outer diameter of the male thread are 2 and 4 mm, respectively. The tooth step is 2 mm. The head and cup diameters are both 15 mm. The length of the entire mechanism is approximately 110 mm (e).

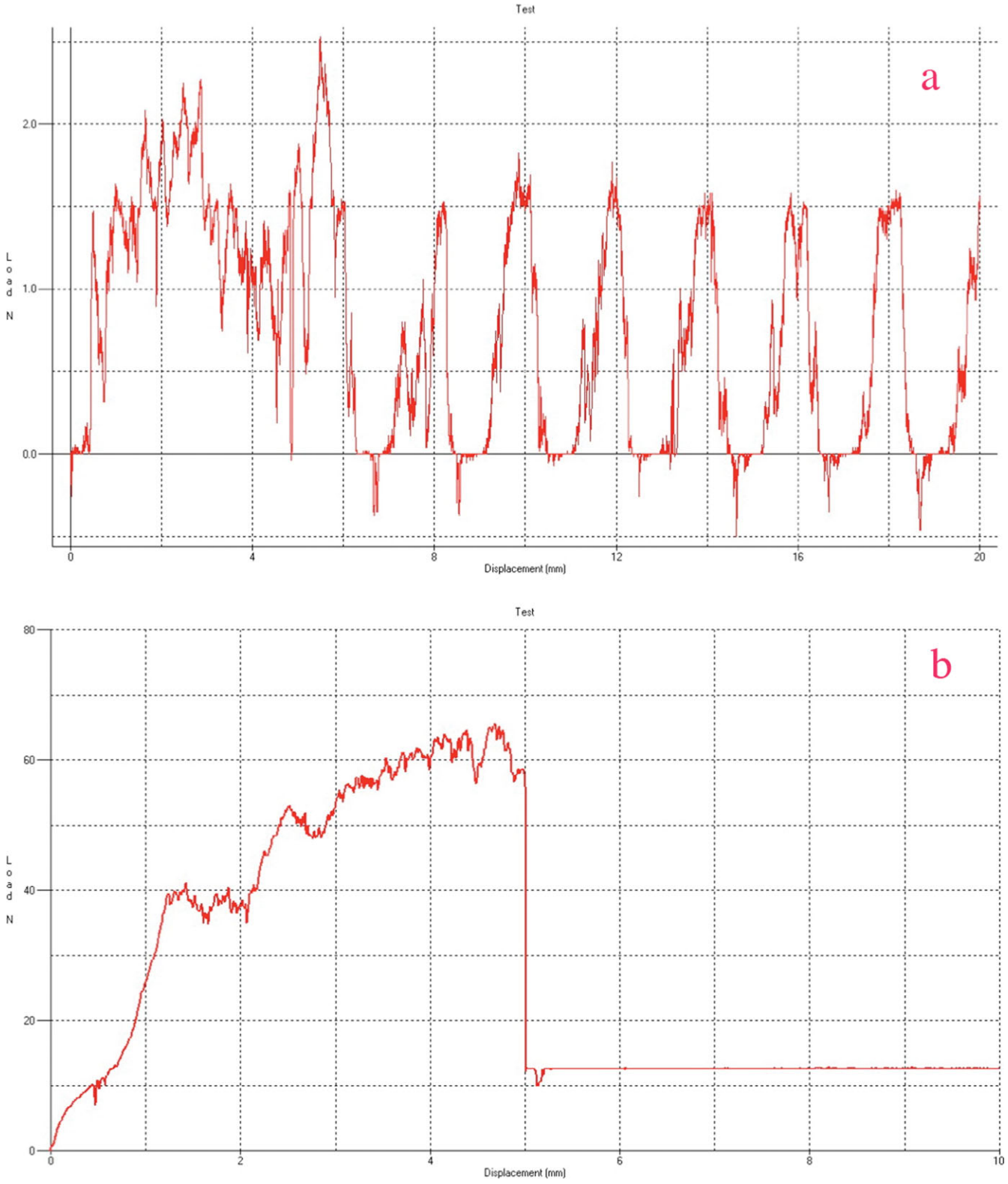

FIGURE 2 Strength tests of the LoStRiT mechanism in the insertion (a) and retraction (b) modes. In the upper graph, each peak of the curve represents the force required to advance the female cup by one step ("click"). In the lower graph, the peak of the curve represents the force required to break the male thread.

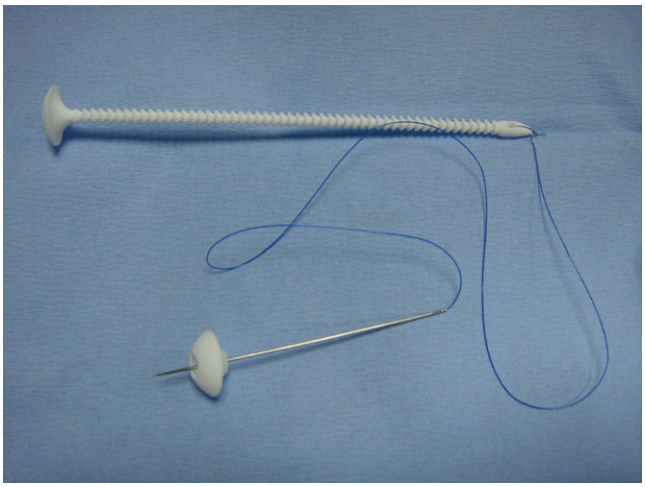

FIGURE 3 The LoStRiT mechanism coupled with the guidance suture that facilitates its insertion. Any commercially available suture would do. Ideally, it should have a straight tapered needle. In this picture, a 3/0 Prolene (8622H) suture made by Ethicon was utilized.

A total of 12 Landrace female pigs with a median weight of 32.2 kg (range 28.1–33.4 kg) were used. The Ethics Committee and Veterinary Authority of East Attica approved the study protocol in accordance with the 86/609 guidelines and act PD 160/May 1991 (10 November, 2010, reference number 3679). The animals were fasted for one day before all of the procedures. Premedication was administered 10 min prior to intubation and consisted of intramuscular 0.5 mg/kg midazolam (Dormicum, Roche, Grenzach, Germany), 15 mg/kg ketamine hydrochloride (Narketan, Vetoquinol, Ittigen, Switzerland), and 0.045 mg/kgr atropine (Atropine, Demo, Athens, Greece). Anesthesia was induced with intravenous 3 mg/kg propofol (Propofol, Fresenius Kabi, Graz, Austria), 0.012 mg/kg fentanyl citrate (Fentanyl, Janssen Cilag, Beerse, Belgium), and 0.5 mg/kgr cisatracurium besylate (Nimbex, GlaxoWellcome, Greenford, UK). Anesthesia was maintained by a cuffed endotracheal tube (0.4 FiO_2, 20 breaths/min) with 1,1,1,3,3,3-hexafluoro-2-(fluoromethoxy)propane (Sevoflurane, Baxter, Deerfield, IL, USA) and intravenous 8 mg/kg/hr propofol (Propofol, Fresenius Kabi, Graz, Austria), 5 mg/kg/hr fentanyl citrate (Fentanyl, Janssen Cilag, Beerse, Belgium), and 25 mg/kg/hr cisatracurium besylate (Nimbex, GlaxoWellcome, Greenford, UK). Before awakening, the animals received intramuscular 0.1 mg/kg neostigmine (Neostigmine, Cooper, Athens, Greece) and 0.4 mg/kg metoclopramide (Primperan, Sanofi Aventis, Frankfurt, Germany). Asepsis was established by washing the skin with a 7.5% povidone–iodine solution (Betadine Surgical Scrub, Lavipharm, Athens, Greece). The skin was then washed twice with a 10% povidone–iodine solution (Betadine, Vianex, Athens, Greece). The animals received 20 mg/kg/12 hr cefaclor (Ceclor, Lilly, Kinsale, Ireland) intramuscularly for antimicrobial prophylaxis for five days. Pain was managed by 4 mg/kg/24 hr carprofen (Rimadyl, Vericore, Dundee, UK) administered intramuscularly for the first three postoperative days (or longer if needed).

The animals were divided into two groups. The control group ($n = 6$) comprised animals that underwent resection of the α' pig liver lobe (corresponding to the third hepatic segment in humans) using the standard Kelly-clysis technique. The LoStRiT group ($n = 6$) comprised animals that underwent resection of the α' pig liver lobe using sequential LoStRiT mechanisms (Figure 4). Briefly, the α' pig liver lobe was accessed through a midline incision. Using guiding sutures, male LoStRiT components (ranging from six to eight) were inserted along the desired line of transection and locked by their female counterparts. Parenchymal transection followed using electrocauterization (cutting current). Bleeding from the transected liver surface was controlled by either increasing the tensile strength of the LoStRiT ratchet mechanism (one or two more "clicks") or adding another male–female combination. The excess of the male LoStRiT components was cut with scissors, and the abdomen was closed. The LoStRiT group was further divided into sub-groups A′ ($n = 3$) and B′ ($n = 3$). The difference between the two sub-groups was that animals in sub-group B′ received noradrenaline (Levophed, Hospira, Lake Forest, IL, USA) during parenchymal transection titrated to a mean blood pressure above 110 mmHg.

Animal demographics and operative vitals were recorded. Total blood loss was recorded by weighing all of the sponges used before and after hepatectomy (no suction or irrigation was used during the procedure). The speed of parenchymal transection was measured in cm^2/s by dividing the cut surface area (as measured by the footprint of the resected specimen on absorptive paper) by the time required to complete it.

Control group animals were immediately euthanized at the end of the hepatectomy with 20 ml of intravenous pentobarbital sodium/benzyl alcohol (Dolethal, Vetoquinol, Buckingham, UK) and exsanguination. LoStRiT group animals underwent a laparotomy at the end of an eight-week follow-up period to evaluate possible biloma formation. Livers were sampled (two specimens per experiment) for histology. The animals were then euthanized with 20 ml of intravenous pentobarbital sodium/benzyl alcohol (Dolethal, Vetoquinol, Buckingham, UK) and exsanguination.

The formalin-fixed, paraffin-embedded liver specimens were stained with hematoxylin and eosin. A histological analysis was performed using light microscopy at X25, X100, and X400 magnifications. For the liver specimens, the levels of periportal or bridging necrosis, hemorrhage, proliferation of cholangioles, fibrosis, regeneration, foreign body reaction, and portal inflammation in the vicinity (less than 1 cm) of

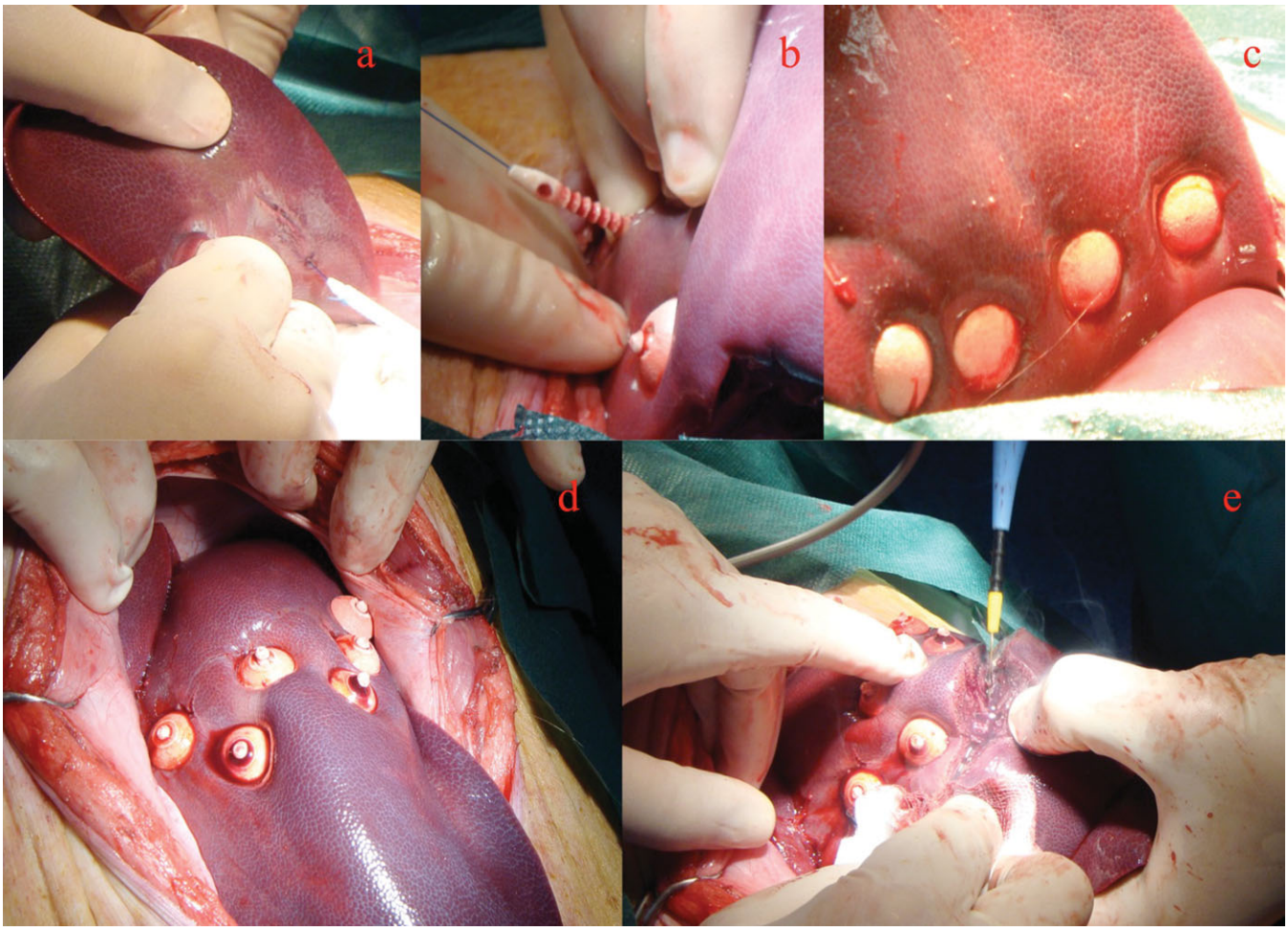

FIGURE 4 The LoStRiT hepatectomy technique. Using the guiding suture, a male thread is inserted into the liver parenchyma along the intended transection line (a). The female system is then lowered over the male thread to the point that the parenchyma is sufficiently compressed. The excess of the male LoStRiT component is then cut with scissors, and the insertion of the next male thread begins (b). Six to eight LoStRiT mechanisms are typically sufficient to resect the α' segment of the pig liver ((c) and (d)). Parenchymal transection is then performed using electrocauterization (e).

the transection line were evaluated on a scale ranging from 0 to 3.

The quantitative data are shown as the median with the range or the mean with the standard deviation. An independent sample *t*-test was used to reveal statistically significant differences between two groups of quantitative data. A one-way ANOVA was used to test for statistically significant differences among three or more groups of quantitative data. Differences of $p \leq .05$ were considered statistically significant. The statistical analyses were performed with SPSS 16.0 for Mac (SPSS Inc., Chicago, IL, USA). The qualitative data are shown as absolute numbers without any statistical analysis.

RESULTS

The mean parenchymal transection surface was 22.8 ± 7.2 cm^2 for the control group and 23.3 ± 3.6 cm^2 for the LoStRiT group ($p = .876$). The mean parenchymal transection time was 17.6 ± 2.2 min for the control group and 10.1 ± 2.1 min for the LoStRiT group ($p = .001$). The mean parenchymal transection speed was 1.27 ± 0.27 cm^2/min for the control group and 2.39 ± 0.56 cm^2/min for the LoStRiT group ($p = .003$). The mean parenchymal transection surface size, time, and speed were not significantly different between LoStRiT sub-groups A′ and B′ (Table 1).

The mean blood loss was 302.5 ± 150.5 ml for the control group and 122.5 ± 24.6 ml for the LoStRiT group ($p = .032$). The mean blood loss per kilogram of body weight was 9.8 ± 5.2 ml/kg for the control group and 3.9 ± 0.9 ml/kg for the LoStRiT group ($p = .040$). The mean blood loss and blood loss per kilogram of body weight were not significantly different between LoStRiT sub-groups A′ and B′ (Table 1).

Four of the LoStRiT group animals underwent re-laparotomy eight weeks post-hepatectomy. The other two had to be euthanized earlier (at 21 and 11 days) due to evisceration. No bilomas were revealed at the eight-week re-laparotomy. Macroscopically, all four livers

TABLE 1 Comparison of hepatectomy technique parameters among the control group ($n = 6$), LoStRiT sub-group A′ ($n = 3$), and LoStRiT sub-group B′ ($n = 3$)

Parameter	Group	Mean	SD	p
Transection surface (cm^2)	Control group	22.8	7.2	.882
	LoStRiT subgroup A′	24.5	5.2	
	LoStRiT subgroup B′	22.1	1.2	
Transection time (min)	Control group	17.6	2.2	.001
	LoStRiT subgroup A′	11.1	2.3	
	LoStRiT subgroup B′	9.0	1.5	
Transection speed (cm^2/min)	Control group	1.27	0.27	.007
	LoStRiT subgroup A′	2.27	0.71	
	LoStRiT subgroup B′	2.51	0.49	
Blood loss (ml)	Control group	302.5	150.5	.062
	LoStRiT subgroup A′	136.6	17.5	
	LoStRiT subgroup B′	108.3	24.6	
Blood loss per kilogram (ml/kg)	Control group	9.8	5.2	.080
	LoStRiT subgroup A′	4.5	0.6	
	LoStRiT subgroup B′	3.3	0.7	

Note. SD: standard deviation.

had completed regeneration and had a normal appearance. The LoStRiT ratchet mechanisms could be easily identified and were unaffected and covered by omentum. Microscopically, minor changes could be identified at a mean distance of 1.21 ± 1.58 mm from the ratchet mechanisms, including some fibrosis and mild lymphocytic infiltration (Figure 5). In addition, mild periportal hemorrhage could be observed in the subgroup B′ specimens. Finally, no foreign body reaction was revealed in any of the specimens (Table 2).

DISCUSSION

Parenchymal division in liver surgery has traditionally been achieved with the Kelly-clysis technique [1]. Technological advances in the last 25 years have led to the development of new instruments for hepatic transection [14]. Even so, none of these innovative devices has gained uniform acceptance by liver surgeons, either because they failed to show a specific clinical advantage [15, 16] or because they increased the cost [13]. However, liver compression, bimanually, by sponge packing or by interlocking stitches, is a well-established method for controlling hemorrhage and bile leakage in both elective hepatic resections [17–19] and trauma cases [20].

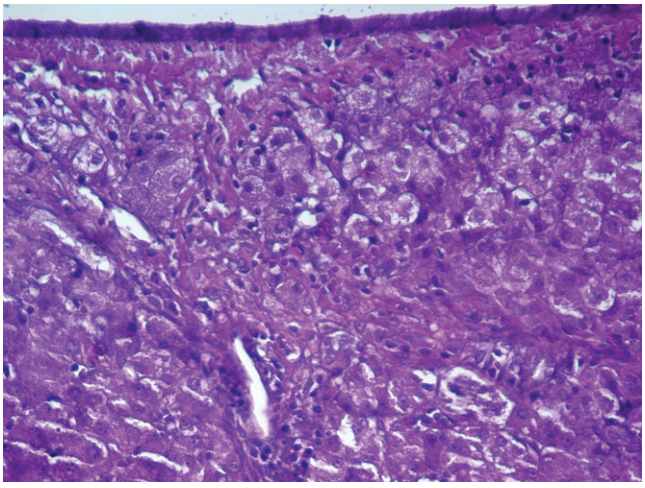

FIGURE 5 The liver specimens presented minimal histological changes consisting of mild lymphocytic infiltration close to the border of the LoStRiT device (upper part of the picture), usually within the first 1–2 mm (hematoxylin & eosin, X100).

The purpose of this study was to use a porcine model to develop and test a simple device that creates and maintains indefinite pressure on the cutting surface of the remnant liver, thus reducing bleeding and bile leakage incidents. This device has the form of a straight locking rigid tie (made from polyamide), hence the name LoStRiT. The device(s) would be applied in the transection plane before parenchymal division to facilitate and increase the speed of the entire process.

The speed of hepatic transection using LoStRiT devices was almost double that of Kelly-clysis. Additionally, the blood loss per kilogram of body weight was more than halved in the LoStRiT group of animals compared to the control group. Blood loss reduction was achieved regardless of the level of systemic blood pressure. LoStRiT utilization did not lead to any incidents of hepatic insufficiency or the development of bilomas. In addition, the microscopic appearance of the liver at the resection surface was nearly normal.

Three important observations were made regarding LoStRiT application in the liver parenchyma. First, the device application required adequate mobilization of the liver, which may be an oncologic compromise according to the principles of the anterior approach if a LoStRiT hepatectomy is performed for tumors [21]. Second, to safely achieve adequate hemostasis and biliostasis, a minimum distance had to be maintained between the cut surface and any critical liver structure

TABLE 2 Liver pathology specimens from LoStRiT group animals sampled at re-laparotomy. Mild periportal hemorrhage was observed in all subgroup B′ animals that received noradrenaline titrated to a mean blood pressure above 110 mmHg. Regeneration was observed in the second subgroup B′ animal, which had to be euthanized on the 11th day after hepatectomy because of evisceration

Specimen subgroup	Sample	Necrosis	Hemorrhage	Cholangiole proliferation	Fibrosis	Regeneration	Giant cells	Lymphocytes	Neutrophils
A′ 1	a	0	0	0	3	0	0	2	0
	b	0	0	0	2	0	0	1	0
A′ 2[f]	a	0	0	0	1	0	0	1	0
	b	0	0	0	0	0	0	0	0
A′ 3	a	0	0	0	3	0	0	2	0
	b	0	0	0	3	0	0	1	0
B′ 1	a	0	1	0	1	0	0	1	0
	b	0	1	0	0	0	0	0	0
B′ 2[§]	a	0	1	1	1	1	0	2	1
	b	0	0	1	1	1	0	1	0
B′ 3	a	0	1	0	3	0	0	2	0
	b	0	1	0	2	0	0	1	0

Notes. *f* denotes the animal that had to be euthanized on the 21st day after hepatectomy because of evisceration; § denotes the animal that had to be euthanized on the 11th day after hepatectomy because of evisceration

(vascular or biliary) that had to be preserved during hepatectomy. This distance was the width of the device, i.e., 1.5 cm. Finally, if post-resection bleeding or bile leakage occurred, it was simply a matter of the insertion of additional LoStRiT devices to control it. LoStRiT could easily be utilized as a rescue method to control bleeding or bile leakage when hepatectomy is performed with any other technique.

Improving the LoStRiT hepatectomy technique could be achieved by combining it with intra-operative ultrasonography. Indeed, inserting the male component of the ratchet mechanism under ultrasound guidance would help to avoid piercing major vascular and biliary structures before compressing them, resulting in even easier and safer LoStRiT placement.

However, there are several limitations to this study that warrant comment. First, these results are derived from a porcine experimentation model. LoStRiT application in humans might be of greater complexity and have less efficacy and safety. Second, the devices were applied in non-cirrhotic livers, and placing LoStRiT mechanisms in cirrhotic parenchyma, with or without concomitant coagulopathy, might be more demanding.

The next step in the development of the LoStRiT hepatectomy is the construction of the device from absorbable material. In addition, producing male components of various lengths would enhance its versatility. Developing a version of the device that could be applied laparoscopically is another potential future step.

In conclusion, LoStRiT hepatectomy appears to be an easily applicable technique for porcine liver transection with very good results. Further development of the device is required, particularly in the form of an absorbable mechanism. Its use in human hepatectomies should follow. If this novel parenchymal transection technique finds its way into clinical practice, it will most likely have a wide variety of applications, including oncologic resections, operative treatment of liver trauma and partial graft procurements. It may also be useful for resections in other parenchymal organs, e.g., splenectomies and nephrectomies. Because no energy source is required, this parenchymal transection technique would be cost-efficient in addition to being effective, safe, fast, and reproducible.

Declaration of interest: The authors report no conflict of interest. The authors alone are responsible for the content and writing of the article.

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