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# Can maneuverability in the robot assisted laparoscopic stapler during ileoileal anastomosis compensate for shorter stapler length? – A randomized experimental porcine study

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## ABSTRACT

**Background:** Ileal anastomosis is imperative in patients given a urinary diversion during radical cystectomy. Proper handling and staplers with a certain length are important to prevent stenosis of the bowel. The study aim was to compare the circumference and diameter of ileoileal anastomoses using the Endo GIA tri-stapler 45 mm and 60 mm iDrive systems compared to the RAL Endowrist DaVinci 45 mm. This was to investigate if the better maneuverability of the robotic stapler would compensate for the shorter stapler length in the RAL Endowrist DaVinci 45.

**Materials and methods:** Twenty ileoileal anastomoses were performed in a total of three pigs after randomization according to the type of anastomosis technique used (depending on stapler and robotic system) allocated to four groups (each with five anastomoses): (1) iDrive 45 mm, (2) iDrive 60 mm, (3) RAL DaVinci 45 mm (Si-system), and (4) RAL DaVinci 45 mm (Xi-system). Diameter (mm) and circumference (mm) were measured and compared.

**Results:** Diameters and circumferences in Group 1 were significantly smaller compared to all the other groups, which did not differ from each other, except in Group 2 where anastomoses had a significantly higher circumference than Group 4.

**Conclusion:** The iDrive 60 mm makes the anastomoses with the widest diameter and highest circumference compared to the iDrive 45 mm. With the RAL DaVinci 45 mm, the diameter and circumference were comparable to the iDrive 60 mm and significantly better than the iDrive 45 mm. An explanation may be the better maneuverability and surgeon control of the RAL DaVinci stapler.

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## KEYWORDS

Cystectomy; ileoileal anastomoses; stapler length; comparison; maneuverability; robotics

## Introduction

Re-establishment of bowel continuity is imperative when constructing urinary diversion in patients given an ileal conduit or neobladder after radical cystectomy. The risks of complications and sequelae following radical cystectomy are considerable whether you use the open or robot assisted laparoscopic approach [1,2]. Although rare, anastomotic dehiscence is one of the most serious complications [3]. However, a less recognized but most likely a more common problem is relative stenosis of the bowel anastomosis if construction of the lumen is too small. This can lead to prolonged ileus in the postoperative phase and long-term bowel problems. The construction of intestinal anastomosis has evolved remarkably over the years, from hand sewn to stapled anastomoses and from open to robotic assisted laparoscopic (RAL) technique. Nowadays, the intestinal anastomosis is performed with minimal morbidity and mortality [4]. Construction of a stapled side-to-side anastomosis allows for a faster and better anastomosis according to leak rates and a faster learning curve compared to a hand sewn end-to-end anastomosis [5–8]. Thus, side-to-side anastomosis allows for

the creation of a large diameter of anastomosis. However, proper handling of the bowel and staplers with a certain length are important in order to prevent strictures of the bowel [5].

For surgical stapling many different stapler devices have been created. In general, the principle of stapling and potential integrated cutting is uniform. Staplers are available in a manual or mechanical version, where the stapler is delivered and fired through a laparoscopic trocar. They come in multiple lengths (45, 60, 75 or 80 mm) and different stapler heights (2.5, 3.8 or 4.8 mm) that can help match the level of compression to the thickness of tissues.

The majority of comparative studies on different stapler devices has been conducted within the field of abdominal surgery and only very few within urology [8–11]. New technologies are constantly being introduced into the market. The principles are the same, but are invented to improve patient outcome and ensure consistency in movements of the device. New technology has costs, but has the potential to improve outcomes and must constantly be evaluated and compared to current used products.

A comparison between the Endo GIA tri-stapler system and the RAL DaVinci 45 in small bowel reconstruction has to our knowledge never been performed. The aim of this study was to compare the circumference and diameter of ileoileal anastomoses using the Endo GIA tri-stapler 45 mm and 60 mm iDrive systems compared to the RAL Endowrist DaVinci 45 mm in a porcine model. Our hypothesis was that the largest diameter and circumference would be generated by using the Endo GIA 60 mm but given the fact that the surgeon had the entire maneuverability of the instrument, contrary the Endo GIA, would compensate for the shorter stapler length in the RAL DaVinci 45.

## Materials and methods

### Experimental design

Twenty ileoileal anastomoses were performed in a total of three female pigs with an age of ~ 11 weeks and with a weight of 25 kg. Performance of the ileal anastomoses were randomized and assigned to four groups depending on stapler and robotic system used.

- Group 1 = five anastomoses with iDrive 45 mm;
- Group 2 = five anastomoses with iDrive 60 mm;
- Group 3 = five anastomoses with RAL DaVinci 45 mm (Si-system); and
- Group 4 = five anastomoses with RAL DaVinci 45 mm (Xi-system).

In each of the three pigs, three different types of anastomoses allocated to Groups 1, 2 and either 3 or 4 were performed.

The present study was conducted in accordance with the French National guidelines for handling and care of animals and general practices and principles at IRCAD, France (L'Institut de Recherche contre les Cancers de l'Appareil Digestif) (license no.: APAFIS#2981-2015120212324587). Reporting of the study followed the ARRIVE guidelines.

### Anesthesia

All pigs were fasted for 12 h before surgery with free access to water. The pigs were premedicated with intramuscular (im.) ketamine (20 mg/kg) (7 mL Ketalar<sup>TM</sup> (50 mg/ml), Mylan<sup>®</sup>, France) and Azaperone (4 mg/kg) (3 mL Stresnil<sup>TM</sup> (40 mg/ml), Janssen-Cilag, Lillyvet, France). Anesthesia was induced with intravenous (iv) Propofol (2.5 mg/kg) (10 mL Diprivan (10 mg/ml), AstraZeneca, France) and Rocuronium Bromide (0.6 mg/kg) (3 ml Esmeron<sup>®</sup> (10 mg/ml), MSD, France). Maintenance anesthesia was kept with inhalation Isoflurane aiming to have a mean minimum alveolar concentration value of 1.1–1.4. Pigs were intubated and mechanically ventilated on a Dräger, Primus<sup>®</sup> infinity<sup>®</sup> ventilator system (Dräger Médical France SAS, Antony France). Respiratory rate was adjusted to maintain an end-tidal Carbondioxid (EtCO<sub>2</sub>) of 4.0–5.0 kPa. Pigs were monitored by pulse oximetry. All procedures were performed under sterile

conditions and by two surgeons, with equal experience in robotic surgery. A 12Fr Foley catheter was placed in the bladder during surgery. After the procedure, euthanasia was achieved by injecting a solution of potassium chloride according to the institutional protocol.

### Surgical procedures

Pigs were placed in supine position and a five-trocar approach was employed. Using the Si-system, a 12-mm disposable auto-suture camera trocar was placed 2–3 cm superior to the umbilicus (Figure 1(a)) and for the Xi-system a robotic 10 mm camera port was used (Figure 1(b)). For placement of both camera trocars, the open Hasson technique was used. CO<sub>2</sub>-Pneumoperitoneum was established and fixed at 10 mmHg. All remaining trocars were placed under direct vision. During surgery insufflation was maintained through the Airseal<sup>®</sup> i.F.S (intelligent flow system) (CONMED corporation, France).

Once trocars were placed, the animal was brought to a 30° Trendelenburg position and the robot docked (Da Vinci<sup>®</sup> Si<sup>TM</sup> and Xi<sup>TM</sup> Robot, Intuitive Surgical, Sunny valley, CA). A 0° camera lens was used for the entire procedure. All procedures were performed by two experienced bladder cancer surgeons who both had vast experience in robotic cystectomy with intracorporeal diversion and in handling a laparoscopic stapler (both surgeons with over 10 years of experience in robotic surgery). The surgeons assisted each other during the procedures, including performance of the laparoscopic stapling.

### Si-model for the iDrive 45 mm and 60 mm tri-stapler magazine

An appropriate ileal segment was after identification grasped and held by two Endowrist Small ProGrasp<sup>TM</sup> Forceps. With the use of either one 45-mm or one 60-mm Endo-GIA articulating tri-stapler magazine (Medtronic, Minneapolis, USA) the ileal segment was divided. The ileoileal continuity was restored intracorporeally with a standard side-to-side Endo GIA stapled anastomosis with the use of two 45-mm or 60-mm tri-stapler magazines with one magazine doing the side-to-side anastomosis and the other closing the end of the bowel segments together (Figure 2(a–d)). The assistant handled the Endo-GIA.

### Xi- and Si-model for the RAL DaVinci 45 mm magazine

After identifying an appropriate ileal segment the surgeon grasped the segment with two Endowrist Small ProGrasp<sup>TM</sup> Forceps and divided the ileal segment by the use of an RAL DaVinci 45 mm magazine. Two additional RAL DaVinci 45 mm magazines were used to make the side-to-side anastomosis (one magazine) and close the bowel segments together (one magazine), as described for the laparoscopic technique.

The time from start of first stapling to the completion of each anastomoses were registered.

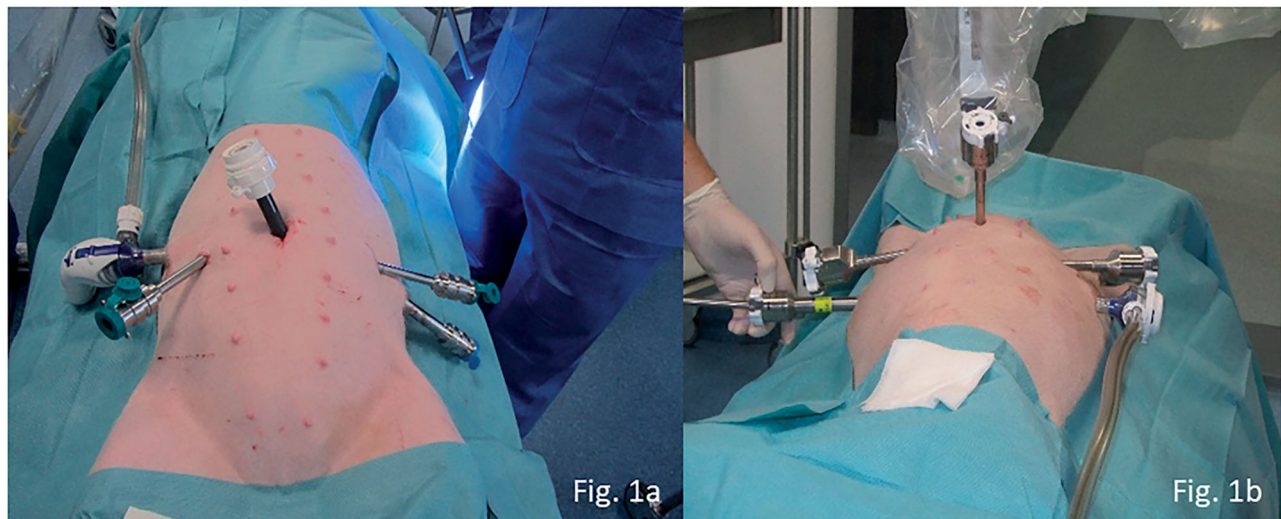


Figure 1. Trocar placement (a) Si-system and (b) Xi-system.

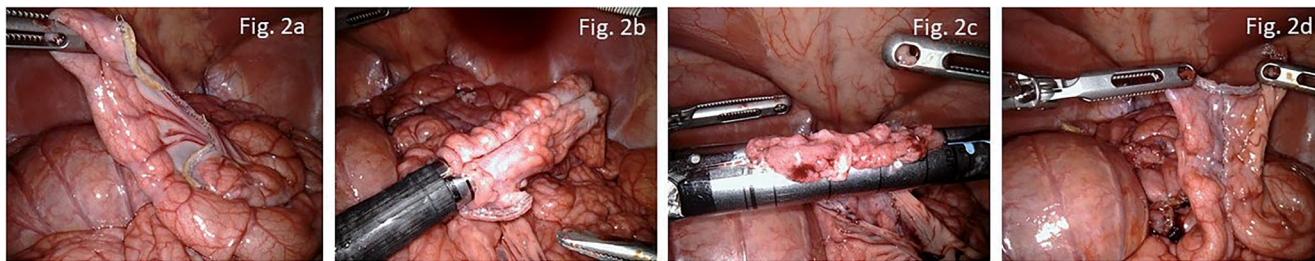


Figure 2. (a) Dividing the bowel, (b) Side-to-side anastomosis, (c) Closing the anastomosis, (d) Finale result.

After performing five, seven, and eight anastomoses in animal 1, 2, and 3, respectively, all anastomoses were taken out by open technique. Anastomoses were checked to ensure they were sufficient and without leakage by visual inspection and water pressure test. At the stapler-line, the diameter (mm) was measured. Thereafter the anastomoses were opened in order to measure the entire length of the stapler-line, which corresponded to the circumference (mm) (Figure 3(a–d)).

### Statistical analysis

Statistical analysis was performed using SPSS software v. 26.0 (IBM, Armonk, NY, USA). Continuous variables were compared using One-way ANOVA. Tests were used to evaluate associations between diameter and circumference (mm) between the groups according to the ileoileal anastomoses with an  $\alpha$  of 0.05.

### Results

All anastomoses were sufficient and without leakage. Diameters in Group 1 (mean 26 mm) were significantly smaller compared to all other groups, whereas no significant differences were found comparing diameters in Groups 2 (37 mm), 3 (34 mm) and 4 (35 mm). The circumference in Group 1 (mean 55 mm) was also significantly different from Group 2 (81 mm), Group 3 (74 mm) and Group 4 (67 mm) ( $p < 0.0117$ ). Group 2 had a significantly higher circumference

than Group 4 (67 mm) ( $p = 0.005$ ). No significant differences were found when comparing circumferences in Group 3 with Groups 2 and 4 ( $p > 0.113$ ) (Table 1; Figure 4).

It took significantly longer time to perform the anastomoses using the Xi robot compared to the other groups ( $p < 0.028$ ).

### Discussion

Minimal invasive surgery has, with great success, been applied to virtually every organ. Technical equipment in surgery is rapidly developed and produced in order to create safe and secure procedures. Regarding bowel anastomosis, the side-to-side anastomosis is increasingly preferred as it takes less operative time and staplers create equal or even better results compared with hand sewn technique [7,12]. One of the most common postoperative complications within cystectomy regardless of the recently implemented ERAS (enhanced recovery after surgery) protocols is ileus either mechanical or paralytic [13]. Among factors that can influence morbidity after RC is the operative time [14]. In a study by Chang et al., stapling devices helped decrease blood loss significantly compared to the traditional suturing technique and in addition reduced the operative time [15]. A study by Tzortzis et al. [8] showed that stapling devices seem to make RC safer and faster in surgeons with different surgical volumes, with the greatest benefit in low-volume surgeons. This favors the stapled technique within radical cystectomy when performed endoscopically, which is why

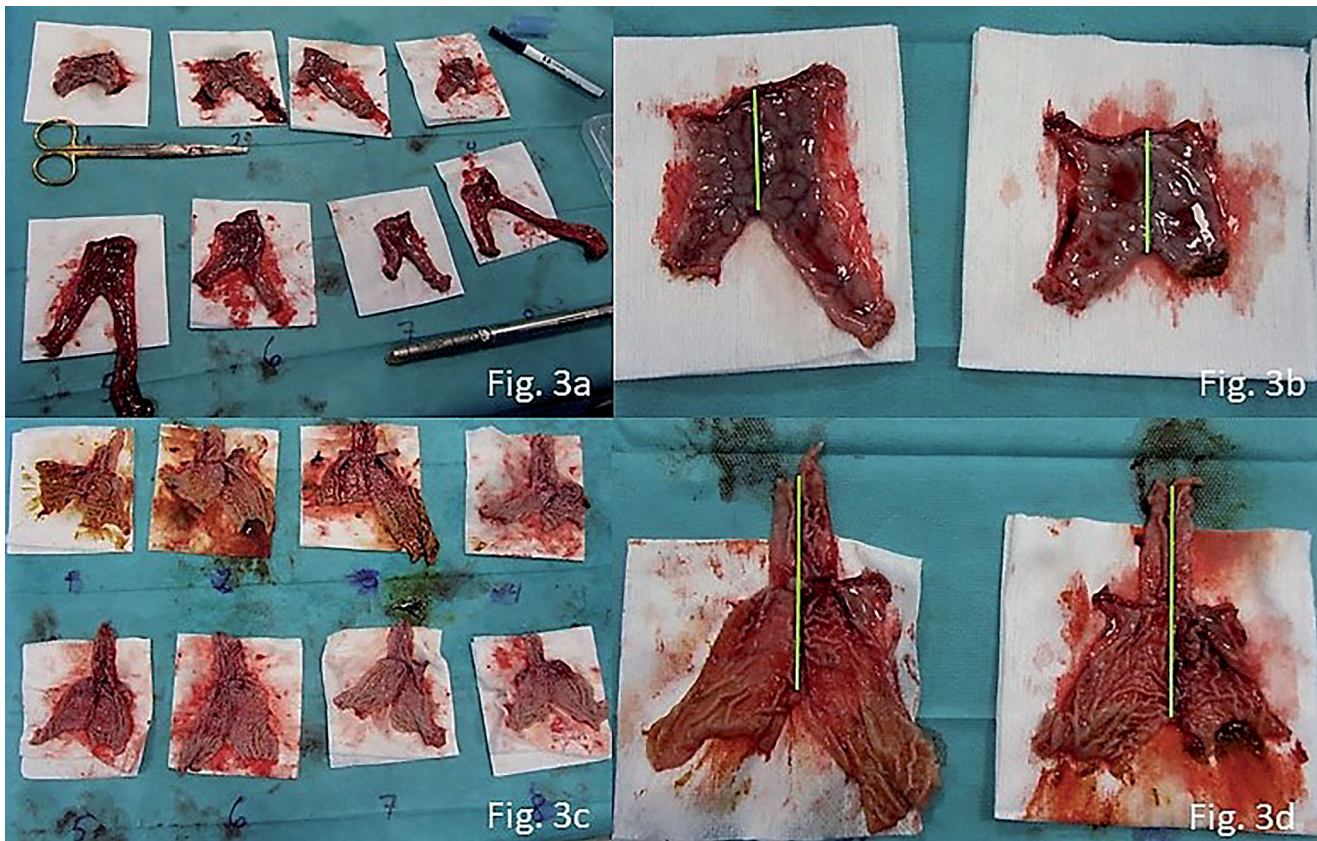


Figure 3. (a and b) Measuring the diameter (mm); (c and d) Measuring the circumference (mm).

Table 1. Measurement on ileoileal anastomoses in the groups.

Group Variable	Gr. 1 iDrive – 45 mm	Gr. 2 iDrive – 60 mm	Gr.3 Si – 45 mm	Gr. 4 Xi – 45 mm	Total mean (± SD)
Mean Diameter /mm (SD)	26.00 (2.83)	36.20 (4.39)	34.20 (2.68)	35.20 (5.85)	33.00 (5.64)
Mean Circumference /mm (SD)	55.60 (3.85)	80.80 (4.32)	74.20 (7.19)	67.00 (9.97)	69.40 (11.44)
Time /sec. (SD)	293.60 (30.74)	298.00 (47.09)	377.20 (24.47)	436.40 (47.69)	351.30 (70.55)

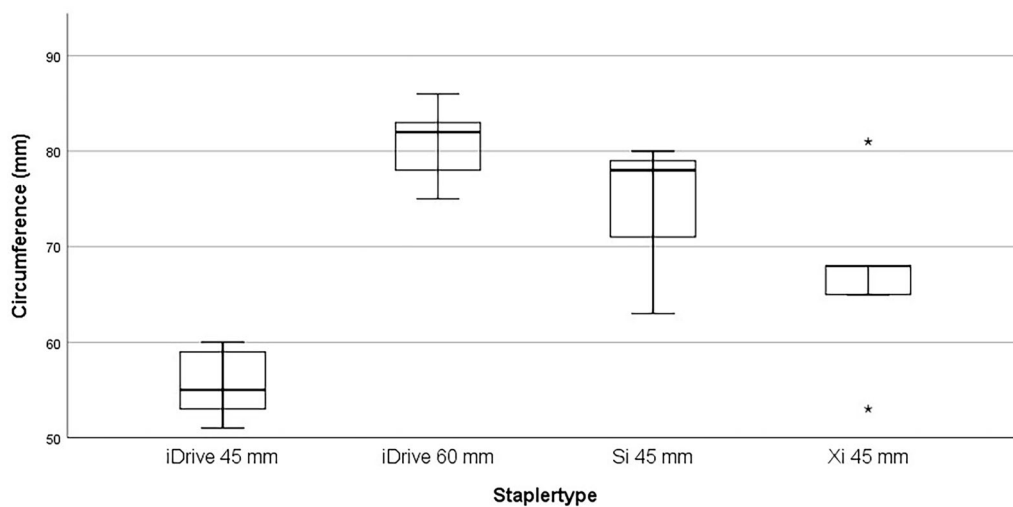


Figure 4. Circumference (mm) stratified by Stapler type.

we choose to do so in our clinical practice. However, whether you use the hand-sewn or stapled technique the lumen within the anastomoses are of real importance in order to decrease the time to bowel movement and prevent

Stapler-line failure owing to excessive intraluminal pressure. In a study by Ghanaat et al. [16], they investigated the size of the stapled intestinal anastomoses using the Endo GIA 80 mm versus the Endo GIA-60 mm stapler and its

relationship to ileus rate following radical cystectomy. They found similar rates and severity of postoperative ileus when comparing patients operated on by the two different stapler lengths. This could be due to the large stapler devices used in both groups which, by definition, when handled correctly, gives a reasonably large lumen when performing the intestinal anastomosis.

Different stapler devices have been developed and the most commonly used in urology is the Endo-Gia Tri-stapler device as this device has been reported to have the best stapler-line strength [17]. The use of the Endo-Gia Tri-stapler is dependent of the presence of an assistant and preferably an experienced one in order not to delay and complicate matters during the operation. A study by Aljabery et al. [18] compared the Endo-Gia Tri-stapler with hand sewn intracorporeal ileoileal anastomosis in cystectomized patients. They did not find any significant difference between the two groups concerning robotic operation time; despite the fact, robotic hand sewn anastomoses can be time consuming. An explanation could be the lack of surgeon control of the stapler device and the need of an assistant to handle the stapler. With the development of the RAL Endowrist DaVinci, it gives the surgeon the opportunity to be fully in charge of the stapler device with the possibility of easier placing the stapler correctly and faster without the use of an assistant who might be untrained. For the Si DaVinci model only the 45 mm stapler has been developed which might lead to a smaller lumen than with the use of a 60 mm stapler length provided by the Endo-Gia Tri-stapler.

In this study, we found a comparable diameter of the side-to-side anastomoses and with no significant differences between the 60 mm iDrive and the 45 mm Si and Xi stapler groups. This indicates that the better maneuverability of the RAL stapler device could compensate for the smaller length of the stapler. In a study by Holzmacher et al. [19], the robotic 45 mm stapler was compared to the most commonly used laparoscopic 45 mm stapler devices within minimally invasive Colon and Rectal Surgery. This study confirmed that better maneuverability of the robotic stapler leads to a significantly lower number of firings per patient compared to the laparoscopic stapler group. This leads to less cost per patient in the robotic group.

Even though the diameter in Group 3 (Si-system) and Group 4 (Xi-system) were essentially the same, the circumference in Group 4 were somewhat smaller. A reason for this could be that sometimes when closing the side-to-side anastomosis during the last firing the two sides of the anastomosis are not entirely aligned, making the longitudinal stapler lines a little shifted relative to each other. When it is not possible to achieve an accurate longitudinal stapler alignment, the transverse stapler line is perceived as part of a functional diameter. This is not the case when an exact alignment is accomplished, but this can be clinically challenging to achieve.

Furthermore, results in this study inspired us to use two 45 mm stapler magazines in continuation of each other instead of using one when performing the side-to-side anastomoses, thus providing us with a larger lumen. This was

tested in an experimental pilot study at IRCAD, Belgium and showed an excellent safety profile and supported the evaluation for a study in human subjects (clinicalTrials.gov: EGIAES study, identifier no: NCT03385798). The results from this study are expected to be reported at the end of 2021.

Even though this study provides us with the unique possibility to take out the anastomoses and measure the exact lumen of the anastomoses, which is not possible in humans, there are some limitations. First, despite the fact that the anatomy of the gastrointestinal tract of the porcine resembles that of humans with a comparable diameter of the ileum of 2.5 cm in both species [20,21], the intestinal wall in the pig is thinner than in humans. This makes it easier to perform the anastomoses and additionally may provide us with a broader lumen. Second, we did not perform an exact measure of the anastomotic strength of the stapler line, we only tested the solidity of the anastomosis by water leakage, so we do not know which anastomosis is the strongest. Third, unfortunately the trocar in the Xi robot fell out when the stapler was inserted, which delayed the procedure remarkably using the Xi model. This makes it difficult to draw any reliable conclusions of the operative time, when comparing the Si- and Xi- model. But even though the time of the stapling was significantly different between the Si and Xi model, the mean time difference in this study was only a little less than 1 minute, which in a clinical setting, with an operative time between 3 and 4 hours, is of no clinical relevance to the postoperative outcome.

Despite the mentioned limitations, this experimental study is the first study to date to compare the Endo GIA tri-stapler 45 mm and 60 mm iDrive systems to the RAL Endowrist DaVinci 45 mm in a porcine model and we believe this study provides useful information for the appropriate usage of the available stapling devices.

## Conclusions

In this study, the iDrive 60 mm, to no surprise, makes the anastomoses with the widest diameter and highest circumference. However, the RAL Endowrist 45 mm staplers appear to be associated with anastomoses with an almost comparable diameter and circumference to the iDrive 60 mm, while being significantly better than anastomoses made with the iDrive 45 mm. An explanation to this may be the better maneuverability and surgeon control.

## Ethics approval

The present study was conducted in accordance with the French National guidelines for handling and care of animals and general practices and principles at IRCAD, France (L'Institut de Recherche contre les Cancers de l'Appareil Digestif) (license no.: APAFIS#2981-2015120212324587). Reporting of the study followed the ARRIVE guidelines.

## Authors' contributions

The first author wrote the first draft. The other authors critically revised the paper for important intellectual content. All authors have

contributed to the work and agreed on the final version. This manuscript is not being considered by any other journal.

## Disclosure statement

Jørgen Bjerggaard Jensen is proctor for Intuitive Surgery. The authors reported no other potential conflicts of interest.

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