

# Robotically Assisted Gastric Resections Using the hinotori™: A Cadaveric Feasibility Study

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## Keywords

Robotic procedure · Gastric resections · Feasibility study · Extended flexibility · Single setup

## Abstract

**Introduction:** In this first preclinical evaluation study of the hinotori™ system in gastric resection procedure, its capabilities to perform distal and total gastrectomy while using human cadaver models were evaluated. **Methods:** Three robotic distal gastrectomies (RADGs) and one total gastrectomy were performed in human cadavers using the same setup. A delta-shaped anastomosis in the RADG procedures were performed with a manual stapler. **Results:** The mean operative time for three distal gastrectomies was 118 min, while the total gastrectomy procedure focused on the resection only. The dissection could be made up to pulmonary veins, while the entire setup was kept. The procedures were done safely according to the surgical standards with smooth instrument and overall performance without any complications seen. An ergonomic surgeon cockpit and head rest supported the outcome. **Conclusion:** Docking-free

design and human arm-like movement with a high degree of operation arm mobility showed a wide range of motion of the wristed robotic instruments. This could be beneficial for multiquadrant procedures resulting in potential shorter procedures times with smoother performance, which should be evaluated in further studies.

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## Introduction

Gastric cancer remains one of the fifth most common cancers worldwide with high incidence and mortality rates, resulting in one million new cases per annum with a global difference in distribution, showing the highest incidence in Asia making up to 70% of the cases worldwide [1, 2]. The differentiated approach in treatment of gastric cancer has been extensively described including different perioperative and adjuvant chemotherapies being the standard of care in advanced stages followed by the surgical treatment [3–5]. For stage I gastric cancer, Katai et al. [6] have shown in a

non-inferiority RCT with 921 patients a similar relapse-free and overall survival in a 5-year follow-up after laparoscopic distal gastrectomy versus open distal gastrectomy. Kim et al. [7] have proven equivalent overall and cancer-specific survival rates in 5-year interval for laparoscopic distal gastrectomy and open distal gastrectomy with 1,416 patients enrolled. In the era of robotic surgery, distal gastrectomy (RADG) for localized and total gastrectomy (RATG) for gastric cancer have shown its superiority to open surgery. Faster recovery, less blood loss, and a higher number of retrieved lymph nodes has been shown, including a faster oral intake, in comparison to the laparoscopic approach [7–12]. After the first robotic surgical system was developed by Intuitive Inc. (Sunnyvale, CA, USA) in 1999, many different robotic systems have shown the feasibility of RAS systems multiple times, including its capabilities of performing remote surgery procedures [13–16]. The new hinotori<sup>TM</sup> developed by Mediaroid Inc. (Kobe, Japan) is a robotic master slave system with a bedside chart including an adjustable boom with 4 eight-axis arms. The 3D-4K vision is supported by the Rubina<sup>®</sup> technology from Karl Storz. After receiving approval from the Japanese Pharmaceuticals and Medical Devices Agency initially for urology at the end of 2020, till date more than 8,500 procedures in urology, gynecology, general and thoracic surgery were performed while CE approval is pending [14, 17, 18]. Inoue et al. [19] published the first experience of robotic total gastrectomy with laparoscopic support using an external energy device that proved the hinotori<sup>TM</sup> system to be safe during the first 24 clinical procedures in Japan. The main objective of this first in Europe study with the hinotori system in the upper abdomen was to evaluate the feasibility of the hinotori system by performing distal and total gastrectomy, showing the capabilities of the system. By performing these indicator procedures, we hypothesize the capabilities, safety, and efficacy of the hinotori<sup>TM</sup> system could be confirmed.

## Methods

This preclinical cadaveric feasibility study was performed following stage 0 of the IDEAL-D framework focusing on the technical feasibility of the system performing gastric resections [20, 21]. Three human male cadavers with BMIs of 23.0, 24.0, and 29.8, respectively, were used to conduct the study in a certified research institute. All procedures were performed by two experienced robotic surgeons in accordance with the standards of Cadaver Dissection in Education and Research as well as the Declaration of Helsinki. The hinotori<sup>TM</sup> is a single

adjustable boom 4-arm system with a fully adjustable surgeon cockpit including the head rest containing the 3D viewer (shown in Fig. 1). A monitor chart from Karl Storz contains the camera unit (TIPCAM<sup>®</sup> Rubina 0° and 30°, 2D/3D-Monitor) and the electrical surgical unit Autocon III 400<sup>®</sup>. Each arm has 8 joints while the 10 mm ICG providing camera is mounted onto one of the inner two operation unit arms using a customized scope holder. The 8-mm wristed instruments that were used, being versatile grasper, a bipolar fenestrated forceps, a monopolar curved scissor, and a clip applicator (large) with Teleflex<sup>®</sup> polymer clips, are from the hinotori<sup>TM</sup> feather portfolio having 7 degrees of freedom (shown in Fig. 2). Providing a docking-free technology, the fulcrum point of the instruments is calibrated prior to a procedure once for each arm using a blunt instrument, a so-called pivot pointer, after that the software keeps the fulcrum point steady throughout the procedure [22]. The pneumoperitoneum was ensured by AirSeal<sup>®</sup> i.F.S. (Intelligent Flow System, ConMed, USA), while the assistant trocar was a 12-mm AirSeal<sup>®</sup> trocar. Lacking a robotic stapler, a manual ECHELON FLEX<sup>TM</sup> articulating Endoscopic Linear Cutter 60 mm (Ethicon Inc., Cincinnati, OH, USA) with red cartridges via the assistant trocar was used. The cadavers were placed in a supine position with a reverse Trendelenburg (10°). The trocars were placed in a U-shaped line (shown in Fig. 3). During the first RADG performed, the camera was mounted onto the second left operation arm. During the other procedures, the camera was mounted onto the second right arm. The assistant trocar was placed between the trocars for arm number 1 and 2 in the first procedure and in the following between the trocars for arm number 3 and 4. Three distal gastrectomies with delta-shaped anastomosis and one total gastrectomy, focusing on the resection only, including an exploration of the lower mediastinum were done. The distal gastrectomy included the dissection of the greater omentum, clipping of the right gastroepiploic artery and vein, D2 lymphadenectomy (lymph node stations 1, 3, 4sb, 4d, 5, 6, 7, 8a, 9, 11p, and 12a), clipping of the right and left gastric artery and vein, transection of the duodenum and distal part of the stomach using the manual stapler. A robotically assisted anastomosis in a delta-shaped manner using the stapler finished the procedure. The completion to a total gastrectomy involved dissection of the left gastroepiploic artery and vein including the short gastric vessels, dissection of the hiatus including mobilization of the distal esophagus. During the mobilization of the distal esophagus, an exploration of the lower mediastinum was done, and the systems capabilities were tested to reach as high up as technically possible into the mediastinum. The transection of the esophagus was



**Fig. 1.** Shown is the hinotori™ system consisting of the operation unit with an adjustable arm base and the surgeon cockpit, which is fully adjustable including the headrest containing the 3D viewer.

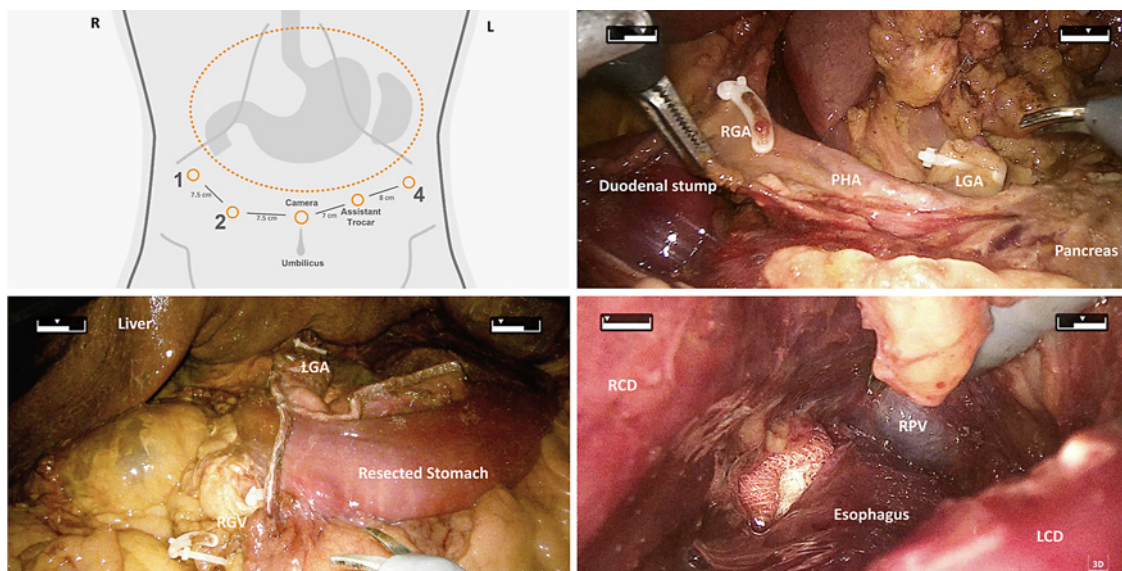


**Fig. 2.** Instruments used during the procedures. From left to right: monopolar curved scissor, bipolar fenestrated forceps, Groce grasping forceps, clip applicator (size L). As well, the pivot pointer is shown with its blunt tip.

performed using the manual stapler. The focus of this study was to test the limits of the range of motion of the instruments and the system performance, which was demonstrated with the procedures above mentioned. Hence, an esophago-jejunal anastomosis was not deemed necessary and omitted because of its location within the surgical anatomical area where the dissection was successfully done.

## Results

Three RADGs with D2 lymphadenectomy were successfully completed. The trocar placement and positioning of the robot system was done in accordance with the setup guide with no changes needed. The transection in the distal third of the stomach was done with the stapler without



**Fig. 3.** Top left: trocar placement in a U-shaped line. The camera was placed supraumbilical, the assistant trocar in the left upper quadrant between camera and arm 4. The instruments inserted were right to left: 1 arm: Groce grasping forceps, 2 arm: bipolar fenestrated forceps, 4 arm: monopolar curved scissor. After the

transection of the right gastric vessels (RGV), left gastric artery (LGA) with the D2 lymphadenectomy done. Bottom left: situs after the delta-shaped anastomosis. Bottom right: view onto the right pulmonary vein (RPV), left and right crus of diaphragm (LCD, RCD).

interference of the robot maneuvers. In the following, the delta-shaped anastomosis was performed with the endostapler while robotic assistance facilitated the stapling via the assistant trocar, which was done without any interference or complications. The mean surgeon cockpit time was 118 min while the mean entire setup time of the system until starting the procedure was 9 min. The total gastrectomy was performed after the last RADG without changing the trocar setting or cadaver position. Included was the dissection of the esophagus in the mediastinum reaching up to the pulmonary veins (shown in Fig. 3). With the manual stapler, the transection of the esophagus was done in the following without any changes in trocar positioning or robot setup. The two different setups using two instrument arms left or right of the camera did not change the procedure and both setups were stated as equal in use for the surgeons and performance of the system, reaching the same precision. No complications occurred, and the procedures were completed using the system only without conversion to laparoscopic or open surgery. No vessel or other organ injuries were seen. The handling of the instruments including the clip applicator were smooth and sufficient while a visual indication bar seen at the cockpit screen supported the handling, indicating the range of the rotation of the instruments. The procedures were performed according to surgical standards and the daily practice setup in robotic surgery was successfully mimicked.

## Discussion

This feasibility study is the first performed for gastric resections in Europe with the hinotori™, and it showed a short console time, precise operative procedure step performance, and the reachability of the entire upper abdomen following just one single setup. This setup permitted the completion of all the procedures, including a mediastinal dissection of the esophagus up to pulmonary veins, without issues or the need for repositioning the trocars, the cadaver, or the robot.

However, this study presents limitations. First, related to the selection of the model, a cadaveric specimen provides high anatomical accuracy, but it lacks tissue realism and physiological response of a live model (e.g., porcine). Second, the sample size and number of procedures performed is limited. Furthermore, the RATG was performed focusing on the maneuverability of the instruments. Consequently, only the resection was performed and the esophago-jejunal anastomosis was omitted.

In relation to the system, while performing the procedures, all participants highlighted that the hinotori™ presents a sharp 3D vision which, in combination with the adjustable ergonomic viewer and surgeon cockpit, allowed for a comfortable and precise lymph node dissection, preparation, and resection throughout the

procedures. All the procedures were performed utilizing the same recommended trocar placement but testing the 4th instrument mounted both on the left and the right of the camera, confirming equality in performance and highlighting a high adaptability to surgical procedural preferences without impacting the setup and flow.

Moreover, the human arm-like movements showed an advantage for the increased reachability and clashes avoidance, allowing the system to easily have a multi-quadrant approach RAS using only a single setup for different procedures, as shown in this study. Perhaps, this approach is supported and feasible because the hinotori™ uses a docking-free technology, which differentiates it from the existing robotic 4-arm platforms.

In fact, the hinotori™ instruments are not fixed to the physical trocar and require the system to be taught the fulcrum point with the pivot pointer at the beginning of the procedure. However, this technology offers both advantages and disadvantages. On the one hand, the docking-free function may allow for a greater overall length of the instruments with potential added clinical benefits, such as reduced skin trauma, quicker procedures with reduced perioperative morbidity and pain. On the other hand, the process of setting the pivot point require an initial learning curve and could cause potential minor extensions of the total operative times, specifically if the patient needs intraoperative repositioning. Nevertheless, further studies would be required. Moreover, the instrument portfolio lacks options for advanced energy and stapling, relevant for the current practice in complex general surgery cases.

While a direct comparison with the literature is not possible due to the limitations of this study, the total operative time of RADG performed with the hinotori™ was a mean of 118 min, while the data provided by Sung et al. [23] show a mean of 150 min with the Da Vinci System (Intuitive Inc.). The reduced operative time can be influenced by the combination of performing a delta-shaped anastomosis and the ability to perform the procedure without repositioning the robotic system or trocars [24].

Concomitantly in Japan, Inoue et al. [19] published the first 23 clinical cases of RADG and one total RATG, confirming the system usability. Further confirmation comes from Tsuji et al. [25], where the first 12 RATG procedures performed present similar perioperative outcomes in comparison to the DaVinci. Moreover, its use in esophagectomies was already tested in a preclinical study by Lozanovski et al. [22], which showed sufficiency.

In conclusion, this study confirmed the capabilities of the hinotori™ in performing gastric resections. The non-docking technique and fluid movements show potential

advantages in the reach and maneuverability of the system, positively impacting the overall procedure time. Further studies should investigate the full capabilities of the entire system, focusing on aspects like the potential advantage of the docking-free design, repositioning avoidance, multi-quadrant approach, and their impact on the operative time and patient's outcome. As well, more studies following the IDEAL-D framework are needed to explore different procedures and confirm the system capabilities in more complex and challenging scenarios.

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## Statement of Ethics

The study was performed at the ORSI Academy (Melle, Ghent, Belgium) being a certified wet laboratory facility with approval for human cadaver studies. All procedures were performed in human cadavers; written informed consent from donors was obtained.

## Conflict of Interest Statement

Christoph Wandh fer is employed by Medicaroid Europe GmbH. Peter P. Grimminger is proctor for Medicaroid Europe GmbH. Suzanne S. Gisbertz was a member of the journal's Editorial Board at the time of submission. All other authors declare no conflicts of interest.

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## Author Contributions

C.W. wrote the manuscript. C.W., S.S.G., and F.R. participated in conceptualization, methodology, supervision, and original and final draft preparation. V.J.L., E.T., H.L., and P.P.G. reviewed the manuscript. All authors have read and agreed to the published version of the manuscript.

## Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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