STUDY PROTOCOL

“IMPLEMENTATION IN COLORECTAL SURGERY OF A NEW MODULAR AND OPEN ROBOTIC PLATFORM. PILOT PROJECT"

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1. JUSTIFICATION OF THE NEED FOR THE PROJECT:

General Surgery has experienced significant advancements in recent decades, driven by scientific research and technological innovation. These progressions have transformed surgical care, improving both the efficacy of procedures and patient outcomes. The continuous pursuit of safer and more efficient surgical methods has led to the implementation of new technologies, advanced surgical techniques, and multidisciplinary approaches. These advancements aim not only to increase the precision and efficacy of procedures but also to minimize associated risks and expedite patient recovery.

Minimally invasive surgical techniques (MIST) have undergone substantial expansion in recent years, representing a transformative paradigm in general surgery. These methodologies, which include laparoscopy and other forms of minimally invasive approaches, have become preferred options due to their significant benefits in terms of recovery, reduced hospital stay, and lower postoperative morbidity.

Surgical robotics has emerged as an exciting frontier in General Surgery, highlighting the convergence of engineering and medicine to enhance the precision and efficacy of surgical procedures. The continuous evolution of this technology has led to significant improvements across various surgical disciplines. The application of robotics in colorectal surgery has transformed the approach to pathologies in the gastrointestinal tract. The ability of robotic systems to provide three-dimensional vision and tools that replicate human hand movements has improved precision in dissection and suturing in complex anatomical areas. Recent studies (Smith et al., 2021) have highlighted the

reduction in complication rates and accelerated postoperative recovery compared to conventional approaches.

The continuous evolution of MIST includes the development of robotic platforms and advanced visualization technologies, further expanding their scope and applicability. Current studies (López et al.) emphasize the importance of specialized training to maximize the benefits of these techniques and ensure patient safety.

We propose an innovative project considering the ongoing transformation that General Surgery is experiencing, driven by technological advances, research, and interdisciplinary collaboration. The incorporation of technologies such as surgical robotics, augmented reality, and artificial intelligence is redefining surgical practice by enhancing precision, efficiency, and the ability to address complex procedures.

The Hugo RAS platform represents the next generation in robotic technology, with potential improvements in instrument manipulation precision and three-dimensional visualization quality. These advances can facilitate the execution of complex surgical techniques, particularly in confined spaces typical of colorectal surgery.

We believe that the incorporation of the Hugo RAS platform in colorectal surgery represents a promising frontier in improving surgical care. This research project aims to provide a solid evidence base that will enable hospitals and healthcare systems to make informed decisions regarding the adoption of this technology.

2. HYPOTHESIS

The implementation of a new modular and open robotic platform in colorectal surgery meets the standards of efficiency, safety and surgical results recommended by the Spanish Association of Coloproctology (AECP).

3. GOALS

3.1. MAIL GOAL

Evaluate the results of a modular and open robotic platform (System of robotic-assisted surgery (RAS) Hugo™) in colorectal surgery (CRC) by complying with the quality indicators recommended by the Spanish Association of Coloproctology (AECP).

- Surgical site infection for rectal cancer.
- Surgical site infection for colon cancer.
- Anastomotic dehiscence/leak (AF).
- Mortality.
- Readmissions.
- Evisceration.
- Reintervention.
- Post-surgical hospital stay.
- Circumferential margin in rectal cancer Quality of the mesorectum in rectal cancer.

3.2. SECONDARY GOALS

● To evaluate the degree of compliance with the application of multimodal rehabilitation protocols (Enhance Recovery After Surgery, ERAS) in patients undergoing colorectal robotic surgery.

● Analyze the surgeons' learning curve, operative time and complications in the use of the modular robotic platform for colorectal surgery.

● Investigate the impact of colorectal robotic surgery on ergonomics and the prevention of musculoskeletal injuries related to surgical practice using surveys and validated neuromuscular injury scales.

● Develop robust education and training programs for surgeons, nurses and technical staff, ensuring a smooth transition to the use of robotic surgery.

● Assess patient satisfaction, including perception of quality of care, recovery process, and comparison of experiences between robotic surgery and other approaches using SF-36 quality of life surveys.

4. MATERIAL AND METHODS

A prospective, single-center and observational study is proposed with patients undergoing scheduled surgery since January 2024, of procedures in abdominal colorectal surgery with a robotic platform, in the Coloproctology Unit of the General Surgery and Digestive System Service of the General University Hospital of Elche.

Patients will be operated on by surgeons with extensive experience in advanced laparoscopic colorectal surgery using the Hugo™ robot-assisted surgery (RAS) system.

The Hugo™ RAS System is an open, portable, modular platform designed for a wide range of surgical procedures. Combines familiar surgical instruments such as a Valleylab™FT10 electroscalpel and advanced Full HD 3D laparoscopic

visualization with open console Karl Storz™ vision, with high-definition goggles with head-tracking safety system, with easy maneuvering through controls ergonomic pistol-type manuals that provide a comfortable and ergonomic grip for the surgeon, a system tower, 4 independent, mobile and extendable arms, a vision carriage that allows optimizing each of the procedures and a powerful surgical video recording option in Touch Surgery™ Enterprise with dedicated support teams specialized in optimizing robotic programs and training. The surgeon can move the robotic platform as needed and choose the best surgical approach for the characteristics and type of surgical procedure, even in patients with complex physical conditions, such as increased BMI, previous abdominal surgery and anatomical variability. The modular configuration of the four independent arm carts can allow modifications in the setup of the robotic trocars of the procedures by having a larger and more efficient work space in the operating room, avoiding unexpected system failures due to instrument collisions. The quality indicators recommended by EFCA will be used (ANNEX 1).

4.1. Inclusion criteria

- Patients undergoing scheduled abdominal colorectal surgery procedures (colon neoplasia, rectal neoplasia, diverticulosis, intestinal resection, transanal minimally invasive surgery (TAMIS), with the Hugo™ RAS robotic platform, under multimodal rehabilitation protocols (ERAS protocols).

- Age greater than or equal to 18 years.

4.2 Criterios de exclusion

- Patients operated on through an initial laparoscopic or open approach.
- Urgent colorectal resections.
- Patients under 18 years of age.
- Existence of other concomitant surgical processes.
- Severe cognitive impairment that makes patient collaboration impossible.
- Patients diagnosed in oncological stage IV.
- Patients who refuse to participate

4.3 Recogida de datos

The data will be collected by the surgery team and researchers. It will be included in a computer database anonymously. Clinical and demographic data will be collected from each patient through their computerized clinical history, creating a notebook and analyzed variables like:

- Demographic variables: sex, date of birth, underlying pathology that the patient presents (cardiovascular risk factors, obesity, chronic medications), preoperative analytical values.
- Operative data: date of intervention, ASA irrigation, type of intervention, approach, type of resection performed, associated procedures, type of anastomosis (location, technique, disposition), intraoperative complications (bleeding, intestinal perforation, medical complications), times operative (T1, T2, T3, T4).
- Robotic platform data: 0º/30º camera, set up, set up modifications

▪ Surgeon information: colorectal surgeon, resident.

▪ Postoperative complications: classification according to Clavien-Dindo Index, presence of anastomotic leak and its management, perioperative mortality.

▪ Postoperative trocar pain (VAS scale).

▪ Hospital stay.

▪ Oncological variables: tumor location and stage according to TNM 2017 (8th ed, AJCC12) preoperative and postoperative, neoadjuvant and adjuvant treatment.

▪ Follow-up: complications recorded prospectively at 60 days through periodic visits to the coloproctology clinic, taking the annual review consultation as the end of follow-up for the patient within the study. The number of consultations during the first year, recurrence (indicating date and management) and death will be assessed. Oncological follow-up will be performed with control of tumor markers (CEA), control imaging tests (CT that combines PET/CT in case of suspected recurrence or metastasis) and biopsy in case of suspicion.

4.4. Definitions:

▪ **Draping robot or T1:** prepare the robot for surgery. It included connecting all the necessary parts such as sterile drapes and connectors needed for the surgery and also the calibration process. These steps are performed by a core team of scrub nurses specifically trained in handling the robot while the patient prepares for surgery.

▪ **Docking time or T2:** starts with the first order to position the first arm towards the patient until the last arm. It includes correct positioning of the robot, connecting the robotic arms to the trocars, and installing the robotic instruments and camera.

▪ **Console Time or T3:** This represents the actual surgical intervention performed from the console by the primary surgeon. This period includes associated procedures.

▪ **Final Time or T4:** Defined as the time from the initiation of trocar removal to the completion of skin closure.

▪ **Conversion to Laparoscopic or Open Surgery:** This refers to the process of switching from a robotic surgical approach to laparoscopic or open surgery due to technical difficulties, intraoperative complications, or other reasons. This transition may involve the removal of the robot and the continuation of the procedure using conventional techniques.

▪ **Anastomotic Leak:** Leakage of intraluminal content through the anastomosis forming an adjacent collection diagnosed via: CT scan (computed tomography), abdominal drainage with output of intestinal content or gas, endoscopy, or intraoperatively if the patient requires an unplanned reoperation of any type and for any reason.

▪ **Superficial Surgical Site Infection:** Purulent drainage through the incision, local temperature increase with erythema.

▪ **Deep Surgical Site Infection:** Purulent drainage through the incision originating from deeper layers, or the presence of a local abscess, spontaneous

wound dehiscence or dehiscence performed by the surgeon with a positive culture, or associated fever or local pain.

- **Organ-Space Infection:** Involves any part of the body that was manipulated during the surgical procedure, except for the skin, fascia, and muscle wall, presenting with purulent output through intracavitary drainage, positive cultures, abscess, or infection diagnosed through invasive procedures or imaging tests.
- **Anastomotic Bleeding:** There is no standard definition of anastomotic bleeding. For this record, the following principles based on the work published by Golda T et al., with slight modifications to their definitions, will be used: a) fresh bleeding per anus with hemodynamic compromise of the patient; b) passage of blood per anus for at least three consecutive days in the presence of normal bowel movements; c) passage of blood per anus occurring at least 48 hours after the patient has had normal bowel movements; or d) presence of blood per anus in any form that delays the patient's discharge for monitoring.
- **Local Recurrence:** A lesion suspected of being of tumor origin following curative resection at the level of the anastomosis, mesentery, lymph nodes, or retroperitoneal area.
- **Disseminated Peritoneal Recurrence:** The presence of oncological disease at the peritoneal level, either single or multifocal, which is clearly recognizable and distinguishable from other forms of locoregional recurrence of colon cancer, such as anastomotic, mesenteric, or lymph node recurrence, and retroperitoneal forms.
- **Measurement of Postoperative Pain from Robotic Trocars:** This is the evaluation and quantification of pain experienced by the patient at the sites of

insertion of robotic trocars used during surgery. This measurement can be performed using pain assessment scales, such as the Visual Analog Scale (VAS) or the Numeric Pain Rating Scale (NPRS), to record the intensity and duration of postoperative pain.

4.5. Data Management

Data management and handling will be conducted by the Principal Investigator and collaborators. The data will be obtained from the patient's electronic medical records at the center and computerized clinical documentation systems.

Data collection will be performed through the online office platform https://atenea.fisabio.san.gva.es/redcap/redcap_v13.8.5/index.php?pid=1083 following the variable schema of the data collection notebook. This platform will securely and encryptedly store the records during the study period and for several years thereafter.

The data may be used for future research, but since it is anonymous, patients will not be individually identifiable in the future.

4.6. Local Ethics Committee

Ethical approval was obtained from the ethical committee of the General University Hospital of Elche (PI 60/2024).

5. ETHICAL AND LEGAL ASPECTS. PROTECTION OF PARTICIPATING SUBJECTS.

Benefit-risk assessment:

Participants will not receive any direct personal benefit from participating in the study. Although the results could provide benefit in the scientific field and in the evolution and research on robotic surgery in the field of colorectal surgery in the future. There are no risks since this is a study of a surgical procedure in routine clinical practice in which data will be collected prospectively.

Information to subjects and informed consent

This study will be carried out in accordance with the Declaration of Helsinki on ethical principles for medical research in human subjects, which has its origin in the current revision (revised version of Fortaleza, 2013) approved by the World Medical Assembly, the Oviedo Convention, and with the current regulatory requirements included in the specific Spanish legislation: order SAS 3470/2009). There are no financial compensations for participating subjects provided for in this study.

Ethical approval was obtained from the ethical committee of the General University Hospital of Elche (PI 60/2024).

The rights, safety and well-being of study patients are the most important considerations and must take precedence over the interests of science and society.

Study personnel involved in conducting this trial will be qualified by education, training and experience to perform their corresponding tasks.

An informative document, Patient Information Sheet and informed consent will be given to patients who are offered to participate in the study. To be included in the study, you must submit it signed and thus accepting the processing of your data and participation.

Data confidentiality:

The processing, communication and transfer of personal data of all participating subjects will comply with the current Organic Law 3/2018 of December 5, on the Protection of personal data and guarantee of digital rights, adopting the Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016 on the protection of natural persons with regard to the processing of their personal data and the free circulation of these data and repealing Directive 95 /46/EC (General Data Protection Regulation), as well as Directive (EU) 2016/680 of the European Parliament and of the Council, of April 27, 2016, on the protection of natural persons with regard to the processing of personal data by the competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offenses or the execution of criminal sanctions, and to the free circulation of such data and repealing Framework Decision 2008/977 /JHA of the Council.

The data collected for the study will be identified by a code, so that it does not include information that could identify you, and only your study doctor/collaborators will be able to relate this data to you and your medical history. Therefore, your identity will not be revealed to anyone except in cases of medical emergency or legal requirement. The treatment, communication and transfer of personal data of all participants will comply with the provisions of this

law. This study meets all the requirements regarding privacy of personal data. Any subsequent publication of the results will never show the patient's personal data.

The data will be collected in an online database on the RedCap platform to establish a single and common research record under the responsibility of the institution and will be processed within the framework of your participation in this study.

Transfer of data to foreign countries: Compliance with national regulations regarding the transfer of data obtained from the study will always be required.

According to the mentioned Law, the consent for the processing of your personal data and for its transfer is revocable. Therefore, at any time you can exercise your right of access, rectification, opposition and cancellation of your data by contacting the Secretary of General Surgery and the Digestive System by calling +34966616377 during morning hours.

Monitoring, audits, ethical committee reviews and regulatory inspections related to the study will be allowed, facilitating direct access to the original documents/data.

The principal investigator (PI) is responsible for maintaining an up-to-date record of subjects. This record will be kept in the strictest confidentiality at the study center, so that only the researcher and other members of the research team will have complete knowledge of the subject's identity.

Publications:

All information from the study will be considered confidential. The principal investigator assumes the set of responsibilities linked to this function, and the exclusive ownership of the results of the study, which may be freely exploited, committing to publish the results of the study in a scientific journal or to make them available to the public as established by the Declaration of Helsinki in point 27: “Both authors and editors have ethical obligations. When publishing the results of his research, the doctor is obliged to maintain the accuracy of the data and results. Both negative and positive results must be published or otherwise made available to the public. The publication must cite the source of funding, institutional affiliations and any conflict of interest.”

This Research Project has the Favorable Report of the Clinical Research Ethics Committee of the Center of the Principal Investigator (General University Hospital of Elche). Any other recommendations of the Committee will be taken into account in order to improve the procedure.

ANNEX 1. QUALITY INDICATORS RECOMMENDED BY THE SPANISH ASSOCIATION OF COLOPROCTOLGY (AECP)

https://acredita-aecp.com/help/Manual-acreditacion-AECP.pdf

Cáncer Colorrectal:

1. **Indicador de infección de sitio quirúrgico para cáncer de recto (ref. Xerra-Aracil y cols Arch Surg 2011;146:606-12)**

- Definición: Porcentaje de pacientes incluidos en la VALORACIÓN que presentan infección sitio quirúrgico (superficial, profunda y órgano espacio) tras cirugía por cáncer de recto.
- Estándar: < 23%
- Umbral:< 25%

2. **Indicador de infección de sitio quirúrgico para cáncer de colon (ref. Xerra-Aracil y cols Arch Surg 2011; 146:606-12)**

- Definición: Definición: Porcentaje de pacientes incluidos en la VALORACIÓN que presentan infección sitio quirúrgico (superficial, profunda y órgano espacio) tras cirugía por cáncer de colon.
- Estándar: < 25%
- Umbral: < 27%

LA VÍA LAPAROSCÓPICA DEBE REDUCIR ESTOS PORCENTAJES AL MENOS A LA MITAD

3. **Indicador de dehiscencia / fuga anastomótica**
   - Definición: Porcentaje de pacientes incluido en la valoración que presentan dehiscencia o fuga anastomótica (clínica o radiológica)
   - Estándar global: < 5%. (< 10% en cáncer de recto bajo)
   - Umbral global: < 10%. (<15% en cáncer de recto bajo)
4. **Indicador de mortalidad**
   - Definición: Porcentaje de pacientes incluidos en la VALORACIÓN que fallecen en los 30 primeros días postoperatorios, por problemas directamente relacionados con la cirugía practicada
   - Estándar: < 7%
   - Umbral: 10%
5. **Indicador de reingresos**
   - Definición: Porcentaje de pacientes que reingresan en el hospital antes de los 30 días del alta hospitalaria.
   - Estándar: < 5%
   - Umbral: 10%
6. **Evisceración:**
   - Definición: Porcentaje de pacientes que presentan evisceración en los 30 primeros días postoperatorios
   - Estándar: 3 %
   - Umbral: 5 %

6. **Reintervención:**
    - Definición: Porcentaje de pacientes que son reintervenidos de manera no programada durante el mismo ingreso o hasta 30 días desde la intervención previa
    - Estándar: 6 %
    - Umbral: 9 %
7. **Estancia Hospitalaria Postquirúrgica:**
    - Definición: Número de días contabilizados desde el día siguiente a la intervención hasta el alta hospitalaria
    - Estándar < 7 días
    - Umbral: < 11 días
8. **Margen Circunferencial Cáncer rectal:**
    - Definición: Porcentaje de pacientes intervenidos de cáncer rectal en los que el margen circunferencial es positivo (distancia menor o igual a 1 mm)
    - Estándar: < 8 %
    - Umbral: < 13 %
9. **Calidad Mesorrecto Cáncer rectal:**
    - Definición: Porcentaje de pacientes intervenidos de cáncer rectal en los que la resección del mesorrecto es completa
    - Estándar: > 80 %
    - Umbral: > 75 %

PRUEBA: Estos datos se extraen automáticamente de los casos insertados en la base de datos. Para considerarse pasada adecuadamente debe cumplir 5 indicadores, de los cuales **obligatoriamente deben estar los cuatro primeros puntos** y cualquiera de los cuatro siguientes.