Study code: ERGOROB

Study title:

The ERGOROB Project (ERGOnomics in surgical ROBotics)

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PROTOCOL SIGNATURE PAGE

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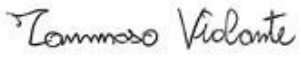
30/08/2025

(Author *1*) Matteo Rottoli signature date



29/08/2025

(Author *2*) Tommaso Violante signature date

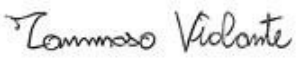
INVESTIGATOR'S STATEMENT:

Study code: ERGOROB

I declare that I have read the protocol and agree to conduct this clinical study in accordance with all the requirements of the protocol, the Good Clinical Practice guidelines and the Declaration of Helsinki principles.

30/08/2025

(Principal Investigator) Matteo Rottoli	signature	date



(Co-Principal Investigator) Tommaso Violante	signature	date

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1 LIST OF ABBREVIATIONS

ERGOROB	ERGOnomics in surgical ROBotics
RAS	Robotic Assisted Surgery
sEMG	Surface Electromyography
HRV	Heart Rate Variability
ECG	Electrocardiogram
ISO	International Organization for Standardization
GCP	Good Clinical Practice
CRF	Case Report Form
CND	Classificazione Unica Nazionale (dei dispositivi medici)
IVD	In Vitro Diagnostic medical device
IFU	Instructions For Use
PI	Principal Investigator
EC	Ethics Committee
SAP	Statistical Analysis Plan
DPIA	Data Protection Impact

2 Introduction

2.1 Background and study rationale

Surgery is a profession that demands both exceptional cognitive skills and remarkable physical resilience. Surgeons must possess intricate knowledge, honed through years of dedicated training, and the stamina to perform complex procedures that can extend for several hours. While a surgeon's expertise and judgment typically improve with experience, the cumulative physical burden of operating can have a significant impact on their health and well-being. Musculoskeletal disorders are a common concern, often arising from awkward postures, repetitive movements, and prolonged periods of standing. These disorders can potentially lead to premature career cessation, resulting in a loss of valuable surgical expertise.

The evolution of surgical techniques has sought to minimize patient trauma and improve outcomes. Laparoscopy revolutionized surgery by replacing large incisions with small keyhole incisions. However, this technique introduced new ergonomic challenges for surgeons, who often find themselves in awkward positions with limited freedom of movement and reduced tactile feedback while manipulating long instruments through small incisions. These factors can contribute to muscle fatigue and strain.

Robotic surgery represents the next step in minimally invasive surgery, offering the potential to overcome some of the limitations of laparoscopy. With robotic systems, surgeons control robotic arms from a console, providing enhanced dexterity, greater precision, and magnified 3D visualization. This technology allows for a more ergonomic working posture, potentially reducing physical strain and improving surgeon comfort. Early research suggests that robotic surgery may indeed offer significant ergonomic advantages over traditional laparoscopy.

Based on these considerations, this research project will pursue two distinct but related studies:

The first study will examine the differential physical demands placed on colorectal surgeons when performing the same surgical procedure using both laparoscopic and robotic (Hugo RAS) approaches.

The second study will evaluate the differential physical demands placed on surgeons when performing the same surgical procedure using the two most common robotic surgical platforms: the Hugo RAS (Medtronics) and the Da Vinci Xi system (Intuitive).

These studies are classified as observational studies and are not considered post-market medical device investigations. None of the data collected will be used for regulatory purposes; all data will serve exclusively for a comparative evaluation of the ergonomics in different surgical approaches.

2.2 Importance of the study and its clinical relevance

This research aims to provide valuable insights into the ergonomic implications of different surgical approaches and contribute to the optimization of surgeon well-being and performance in the operating room. Understanding the physical demands can lead to improved surgical system design, better training protocols, and strategies to mitigate work-related musculoskeletal disorders among surgeons, ultimately preserving valuable surgical expertise and enhancing patient care.

WHAT IS ALREADY KNOWN ON THIS TOPIC	● Musculoskeletal disorders are common among surgeons due to awkward postures and repetitive movements in traditional and laparoscopic surgery ● Robotic surgery generally offers improved ergonomics over laparoscopy ● Laparoscopy presents ergonomic challenges such as limited movement and reduced tactile feedback ● Different robotic systems exist, but direct, comprehensive ergonomic comparisons are limited.
WHAT THE STUDY COULD ADD	● Detailed, objective, comparative data on the specific physical demands and ergonomic differences between laparoscopic surgery and the Hugo RAS system for Low Anterior Resection of the Rectum ● A direct comparison of the physical demands and ergonomic characteristics of two leading robotic platforms (Hugo RAS and Da Vinci Xi) during Radical Prostatectomy procedures, using a comprehensive suite of objective measures ● Quantification of these challenges using advanced motion capture and physiological sensors during colorectal surgery, compared directly to a robotic alternative ● Insights into the manipulation forces required by each robotic system (Hugo RAS vs. Da Vinci Xi) using specialized sensorized gloves

2.3 Is the study included in the research areas of IRCCS AOU Bologna?

Oncology ☐

Transplants and severe organ deficiencies ☐

COVID-19 ☐

Other research area ☒

3 Aims and endpoints of the study

3.1 Primary aim(s)

- **Study 1:** To conduct a comprehensive assessment of the physical demands and ergonomic implications of performing Low Anterior Resection of the Rectum using both laparoscopic and robotic (Hugo RAS) surgical approaches. The research hypothesis is that the robotic (Hugo RAS) approach will impose lower physical demands and offer superior ergonomic conditions for the operating surgeon compared to the standard laparoscopic approach for this procedure.
- **Study 2:** To conduct a detailed comparison of the physical demands and ergonomic characteristics of two leading robotic surgical platforms – the Hugo RAS (Medtronics) and the Da Vinci Xi system (Intuitive) – in the context of Radical Prostatectomy procedures. The research hypothesis is that there will be measurable differences in physical demands and ergonomic characteristics between the Hugo RAS and Da Vinci Xi systems, which could have implications for surgeon comfort and strain during Radical Prostatectomy.

3.2 Secondary aim(s)

- To identify specific surgical tasks or phases within Low Anterior Resection of the Rectum and Radical Prostatectomy that are associated with the highest physical and ergonomic loads for surgeons across the different platforms.
- For Study 2, to compare the manipulation forces required by the Hugo RAS and Da Vinci Xi systems during Radical Prostatectomy.

3.3 Endpoints

The aim of the study should not be repeated, but rather the specific measure that will be evaluated or calculated should be stated; on the basis of the results obtained for this measure it will be established if the results expected from the study have been achieved or not.

Primary endpoint

Primary endpoint	How it will be measured	When it will be evaluated
• Posture (deviations) • Range of motion (upper limbs) • Repetitive movements (upper limbs)	• Trunk flexion and lateral bending angles calculated from Xsens Motion Capture Suit data • Shoulder and elbow range of motion quantified from Xsens Motion Capture Suit data	Throughout each surgical procedure for all primary endpoints (all the measurements will be acquired in real time)

● Muscle activity levels ● Muscle fatigue ● Muscle strain indicators ● Physical exertion ● Manipulation forces (Study 2 only)	● Frequency and amplitude of repetitive movements analyzed from Xsens Motion Capture Suit data ● Root mean square (RMS) values of sEMG signals from trapezius, erector spinae, biceps brachii, and forearm extensor muscles using WaveX sensors ● Median frequency and spectral analysis of sEMG signals from WaveX sensors ● Periods of sustained muscle activation and high levels of co-contraction identified from sEMG signals using WaveX sensors ● Peak forces, average forces, and force variability measured by sensorized gloves	

Secondary endpoints

Secondary endpoints	How it will be measured	When it will be evaluated
Identification of high-demand surgical tasks/phases	Correlation of specific tasks (identified from video recordings) with peaks in kinematic (Xsens) and physiological (sEMG,) data.	Post-procedure analysis of synchronized data.
Surgeon's interactions with surgical instruments/robotic console and workflow	Qualitative and quantitative analysis of high-resolution video recordings.	Post-procedure analysis of video data.
Detailed measurements of robotic platforms (Study 2 only)	Physical measurements of surgeon's seat and interactive components of the robotic platforms.	During data acquisition setup for Study 2.

4 Study plan

4.1 Type of study

RCT	☐
Non-randomized controlled study	☐
Experimental study, uncontrolled	☐
Cross-sectional study	☐
Retrospective Case-control study	☐
Retrospective cohort study	☐
Prospective cohort study	☒
Retrospective and prospective cohort study	☐

4.2 Mono- or multicentric study

Monocentric	☒
National Multicentric	☐
International Multicentric	☐

4.3 Study design

This research project comprises two related studies, both employing a within-subjects experimental design where each participating surgeon acts as their own control.

- **Study 1 (Comparative Analysis of Laparoscopic and Robotic Approaches in Colorectal Surgery):** This study will compare the physical demands on surgeons performing Low Anterior Resection of the Rectum. Each of the 5 participating colorectal surgeons will perform the procedure 5 times using a standard laparoscopic approach and 5 times using the Hugo RAS robotic system. Data on posture, movement, muscle activity will be collected during each procedure. The order of procedures (laparoscopic vs. robotic) may be counterbalanced if feasible to minimize order effects.
- **Study 2 (Comparative Analysis of Two Robotic Platforms in Urological Surgery):** This study will compare the physical demands on surgeons performing Radical Prostatectomy. Each of the 5 participating urological surgeons will perform the procedure 5 times using the Hugo RAS robotic system and 5 times using the Da Vinci Xi robotic system. Similar data as in Study 1 will be collected, with the addition of hand force measurements using sensorized gloves. The order of procedures (Hugo RAS vs. Da Vinci Xi) may be counterbalanced.

For both studies, surgical procedures will be standardized to ensure comparability. Data collection will involve equipping surgeons with a suite of wireless sensors and recording the procedures with high-resolution video. An interim analysis will be conducted after 3 cases per

surgeon per approach in each study (30 total procedures per study) to assess data variability and re-evaluate the required number of procedures.

4.4 Study population

The study population consists of experienced surgeons from two different specialties.

- **Study 1:**
  - Participants: 5 experienced general surgeons with (aged 40-55 years) specializing in colorectal surgery.
  - Enrollment period: March - December 2026 (as per project timeline for patient recruitment and data acquisition).
  - UO/strutture di riferimento: Specific surgical units within IRCCS - Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi where eligible surgeons operate and where the specified procedures (Low Anterior Resection of the Rectum) are performed using both laparoscopic and Hugo RAS techniques. *(Institution inferred based on template context)*.
  - Modalità di arruolamento: Eligible surgeons meeting inclusion criteria within the institution will be identified and invited to participate.
- **Study 2:**
  - Participants: 5 experienced urological surgeons (aged 40-50 years) with expertise in robotic-assisted Radical Prostatectomy using both the Hugo RAS and Da Vinci Xi systems.
  - Enrollment period: March - December 2026 (as per project timeline for patient recruitment and data acquisition).
  - UO/strutture di riferimento: Specific surgical units within IRCCS - Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi where eligible surgeons operate and where Radical Prostatectomy is performed using both Hugo RAS and Da Vinci Xi systems. *(Institution inferred based on template context)*.
  - Modalità di arruolamento: Eligible surgeons meeting inclusion criteria within the institution will be identified and invited to participate

4.4.1 Inclusion criteria

Study 1:

- Experienced general surgeons specializing in colorectal surgery.
- Age between 40-55 years.
- Proficient in performing Low Anterior Resection of the Rectum using both standard laparoscopic techniques and the Hugo RAS robotic system (over 30 robotic and laparoscopic procedures completed).
- Willingness to undergo extensive data collection during surgical procedures.
- Provide written informed consent.

Study 2:

- Experienced urological surgeons.
- Age between 40-50 years.
- Expertise in robotic-assisted Radical Prostatectomy using both the Hugo RAS and Da Vinci Xi systems(over 20 radical prostatectomies performed on both platforms)
- Willingness to undergo extensive data collection during surgical procedures.

- Provide written informed consent.

4.4.2 Exclusion criteria

Not applicable

4.4.3 Study population size and statistical power

Study 1:

- Total number of participating surgeons: 5. Each surgeon will perform 10 procedures (5 laparoscopic, 5 Hugo RAS), for a total of 50 surgical procedures.
- Considerations: The number of surgeons proficient in both laparoscopy and the relatively new Hugo RAS system for colorectal surgery is limited. 5 potential participants meeting inclusion criteria have been identified within the institution. The study involves a significant time commitment from surgeons. Statistical power is enhanced by a comprehensive data collection methodology and a within-subjects design, where each surgeon acts as their own control, increasing sensitivity to detect differences. The focus is on detecting clinically meaningful differences. An interim analysis will be conducted after 3 cases per surgeon per approach (30 total) to assess data variability and re-evaluate the required number of procedures; if needed, data from additional procedures will be collected.

Study 2:

- Total number of participating surgeons: 5. Each surgeon will perform 10 procedures (5 Hugo RAS, 5 Da Vinci Xi), for a total of 50 surgical procedures.
- Considerations: The pool of urological surgeons experienced with both Hugo RAS and Da Vinci Xi systems is limited. 5 potential participants meeting inclusion criteria have been identified within the institution. The study involves a significant time commitment. Similar to Study 1, rigorous methodology, comprehensive data collection, and a within-subjects design are expected to provide meaningful results with this sample size. The focus is on clinically meaningful differences. An interim analysis will be conducted after 3 cases per surgeon per approach (30 total) to assess data variability and re-evaluate the required number of procedures; if needed, data from additional procedures will be collected.

4.5 Intervention/treatment under investigation

This study investigates the ergonomic impact on surgeons using different surgical systems/approaches, which are considered the "interventions" from the perspective of surgeon ergonomics.

Study 1 Intervention: Hugo RAS (Robotic Assisted Surgery) System

- The Hugo RAS system (Medtronics) is a robotic surgical platform used for minimally invasive procedures. Surgeons operate from a console to control robotic arms that manipulate surgical instruments.
    - Hugo™ RAS system
    - Medtronic

        - Medtronic
        - REF: *142239*
        - *SN: C22CAF0110*
    - **Risk class** *(*IIb according to Directive (EU) 2017/745 (MDR))
    - The console and robotic arms are multi-use; specific instruments and accessories may be single-use.
    - The full robotic system including surgeon console, vision cart, and robotic arms is required.
    - The Hugo RAS system is stated as being used for comparison, implying it is available/in use or will be made available. Compatibility with institutional infrastructure (power, space, network if applicable) is already available
    - For use in minimally invasive surgical procedures, including colorectal surgery (Low Anterior Resection of the Rectum for this study).
    - **:** As per manufacturer's Instructions For Use (IFU). Standard operating room environment.
    - Surgeons require specific training and experience on the Hugo RAS system. Participating surgeons are proficient.
    - The system is managed by surgical and hospital staff.
    - System is already in use

Study 2 Interventions: Hugo RAS System and Da Vinci Xi System

1. Hugo RAS System (Medtronics) * Details as described above for Study 1, with the intended use including urological procedures (Radical Prostatectomy for this study). Participating surgeons have expertise with this system for the specified procedure.

2. Da Vinci Xi System (Intuitive)

- The Da Vinci Xi system (Intuitive) is a robotic surgical platform used for minimally invasive procedures. Similar to other robotic systems, surgeons operate from a console to control robotic arms.
        - da Vinci® Xi Surgical System
        - DAVINCI XI IS 4000 HD
        - Intuitive Surgical, Inc.
        - Intuitive Surgical, Inc.
        - REF: 129537
        - SN: 375738
    - **Numero di repertorio:** *(To be specified)*
    - **Risk Class:** *(*IIb according to Directive (EU) 2017/745 (MDR))
    - The console and robotic arms are multi-use; specific instruments and accessories may be single use.
    - Yes, the full robotic system including surgeon console, vision cart, and robotic arms is required.
    - The Da Vinci Xi system is stated as being used for comparison, implying it is use. Compatibility si already confirmed.
    - use in minimally invasive surgical procedures, including urological surgery (Radical Prostatectomy for this study).
    - As per manufacturer's Instructions For Use (IFU). Standard operating room environment.
    - Yes, surgeons require specific training and experience on the Da Vinci Xi system. Participating surgeons have this expertise.

- Not applicable to the surgeon as the study subject. The system is managed by surgical and hospital staff.
- is currently already in use at the institution

Sensors used for ergonomic assessment (considered investigational tools for the purpose of this study on surgeons):

- **Xsens Motion Capture Suit (www.movella.com):** Full-body suit with 17 inertial measurement units for 3D movement data.
- **WaveX Sensors (www.btsbioengineering.com):** Wireless surface electromyography sensors.
- **GRIP VERSATEK(www.tekscan.com):** Sensorized glove for measuring hand/finger force.

For both studies the sensors have already been tested in a simulated environment to determine that none of the used equipment that will be employed in this study will affect the surgeon's dexterity and comfort during the surgical procedures.

It is currently already in use at IRCCS AOUBO	☒
It will be provided on a free loan for use (multi-use DM)	☐
It will be provided free of charge by a third-party lender (single-use DM)	☐

4.6 Possible intervention/treatment control/comparison

Study 1: The control/comparison is the standard Laparoscopic Surgical Approach for Low Anterior Resection of the Rectum. This involves surgeons manipulating long instruments through small incisions without robotic assistance, often leading to awkward postures and reduced tactile feedback. The specific laparoscopic instruments used will be those standardly employed by the participating surgeons for this procedure.

Study 2: The two robotic platforms, Hugo RAS System and Da Vinci Xi System, are being directly compared against each other. Both are described in section 4.5.

4.7 Study duration

- **Total project duration:** 2 years.
- **Estimated timeline for the phases:**
  1. Acquisition of equipment, setting organization, pilot data acquisition: October 2025 - March 2026 (approx. 7 months).

2. Enrollment/selection of surgeons and data acquisition (during patient procedures): March - December 2026 (approx. 10 months). (This involves observing surgeons during surgical procedures, so "treatment phase" applies to the actual patients undergoing surgery, while data is collected on surgeons.)
3. Follow-up required for outcome assessment: Not applicable in the traditional sense for surgeons; data is collected per procedure.
4. Data analysis and publication: January - May 2027 (approx. 5 months).

The enrollment/selection of participants (surgeons) will begin subsequent to the study's approval by the Ethics Committee (expected September 2025) and the issuance of clearance by the General Director of the IRCCS.

Estimated start and end dates of the study:

- Presumed Start (Ethics approval): September 2025
- Presumed Start (Equipment/Pilot): September 2025
- Presumed Start (Surgeon Data Acquisition): March 2026
- Presumed End (Publication): May 2027

Phase of the study	Time (months/years)
Ethics committee submission & approval	**June 2025 - September 2025 (4 months)**
Acquisition of equipment, organization, pilot data	**September 2025 - March 2026 (7 months)**
Enrollment/selection of surgeons & data acquisition during procedures	**March 2026 - December 2026 (10 months)**
Data analysis and publication	**January 2027 - May 2027 (5 months)**
overall study duration	**2 years (approx.)**

4.8 Treatments, monitoring and evaluations

During each surgical procedure included in the study, participating surgeons will be equipped with an integrated system of wireless sensors for comprehensive ergonomic assessment. High-resolution video recordings will also be made.

4.8.1 First visit evaluations

Clinical history/current therapy	☐
Previous therapies	☐
Overall assessment	☐
Laboratory tests	☐
Outpatient visits and/or specialized examinations	☐
Administration of questionnaires	☐
Administration of scales	☐
Other	☒

(specify)

(Evaluations are per-procedure, not per-visit in the traditional sense. The first procedure observed for each surgeon/approach combination will serve as their initial data point for that condition.) The following will be collected for each surgeon during each observed surgical procedure:

- **3D Movement Data:** Using Xsens Motion Capture Suit (position, orientation, acceleration).
- **Muscle Activity (sEMG):** Using WaveX sensors on trapezius, erector spinae, biceps brachii, and forearm extensor muscles.
- **Hand/Finger Forces (Study 2 only):** Using grip versatek.
- **Video Recording:** High-resolution video of the surgeon's movements, interactions, and workflow.

4.8.2 Evaluations at follow-up visits and timing

Laboratory tests	☐
Outpatient visits and/or specialized examinations	☐
Administration of questionnaires	☐
Administration of scales	☐
Other……..	☒

(specify)

Data collection as listed in 4.8.1 will occur during *each* of the 10 surgical procedures performed by each participating surgeon (5 procedures per approach/platform). These are not follow-up visits for the surgeons in a clinical sense, but rather repeated observation sessions during their standard surgical work under the specified conditions. The frequency of "visits" (i.e., observed surgical procedures) is 10 per surgeon, divided

between the two compared approaches/platforms. The evaluations are continuous throughout each surgical procedure.

Type of evaluation	Description	Time of evaluation (days/months/years)	Is it within normal clinical practice or is it study-specific?	If already in clinical practice, is the timing different?
Xsens Motion Capture	Full-body 3D movement data (posture, range of motion, repetitive movements).	During each of the 10 surgical procedures per surgeon.	Study-specific	N/A
WaveX sEMG	Muscle activity, fatigue, and strain indicators from key muscle groups.	During each of the 10 surgical procedures per surgeon.	Study-specific	N/A
Grip Versatek (Study 2 only)	Hand and finger forces during manipulation.	During each of the 10 surgical procedures per surgeon (Study 2).	Study-specific	N/A
High-Resolution Video Recording	Documentation of surgeon's movements, interactions, workflow.	During each of the 10 surgical procedures per surgeon.	Study-specific	N/A
Measurements of Robotic Platforms (Study 2)	Detailed measurements of surgeon's seat and interactive components.	Once per platform during setup.	Study-specific	N/A

4.8.3 Patient drop-out from the study

Surgeons may withdraw from the study at any time without prejudice. Conditions that might cause premature exit include:

- Voluntary withdrawal by the surgeon.
- Unforeseen changes in the surgeon's clinical duties or availability that prevent completion of the required number of procedures.
- Technical difficulties with data acquisition equipment that cannot be resolved in a timely manner. If a surgeon drops out, efforts will be made to recruit a replacement if feasible and if the dropout occurs early in the data collection phase. Data collected from surgeons who do not complete the full set of procedures may be included in a modified analysis if appropriate or excluded from the primary per-protocol analysis. The interim analyses will help assess the impact of any dropouts on statistical power. Expected drop-out is minimal due to the small, selected cohort of highly motivated participants. A drop-out rate exceeding 20% (i.e., more than 1 surgeon per study) would trigger a re-evaluation of recruitment feasibility and sample size.

4.9 Funding

Is funding provided for the study?

No	☐
Yes, from internal funds	☐
Yes, from institutional third parties	☐
Yes, from private third parties	☒

4.9.1 Funding parties

 Medtronic (for the overall project or a significant part, including General Surgery and Urology budget allocation)

- Goal of the funding: To support research into the ergonomic aspects of surgical robotics, specifically involving the Hugo RAS system.

4.10 Data Management

The clinical data required by the protocol will be collected in pseudonymized form by personnel designated by the Principal Investigator in an electronic Data Collection Form (CRF) and will be managed through the REDCap platform. The eCRF in REDCap will be requested and implemented according to the procedure described in the "Corporate Operational Instruction for the Management and Use of the REDCap Platform" (IOA119). The Principal Investigator must indicate the names of personnel delegated to data management by specifying their relative functions within the study in the *Delegation log*.

Data from sensors (Xsens, FREEEMG, Sensorized Gloves) will be processed using dedicated software for each system and then exported for integrated analysis. Video recordings will be stored securely.

4.11 Statistical Analysis Plan (SAP)

4.11.1 Methodology of analysis

A comparative analysis of the sensor data and video recordings will be performed to evaluate key ergonomic parameters for each study.

- **Study 1:** Comparison between laparoscopic approach and Hugo RAS system for Low Anterior Resection of the Rectum.
- **Study 2:** Comparison between Hugo RAS system and Da Vinci Xi system for Radical Prostatectomy.

The analysis will involve:

- **Kinematic data (Xsens):** Statistical comparison (e.g., paired t-tests or non-parametric equivalents, ANOVA/ANCOVA for repeated measures) of posture angles (trunk flexion, lateral bending), range of motion (shoulder, elbow), and frequency/amplitude of repetitive movements between the compared conditions.
- **sEMG data (WaveX):** Comparison of RMS values (muscle activation), median frequency changes (fatigue), and duration of sustained activation/co-contraction (strain) across different surgical phases and overall procedure between conditions.
- **Force data (Grip Versatek Gloves - Study 2 only):** Comparison of peak forces, average forces, and force variability between the Hugo RAS and Da Vinci Xi systems.
- **Video data:** Qualitative analysis of workflow, surgeon movements, and interactions. Quantitative analysis where applicable (e.g., task duration, frequency of specific movements or instrument exchanges).
- Synchronized analysis of sensor and video data will be performed to link objective ergonomic measures to specific surgical tasks and phases.
- For Study 2, the analysis will reference recognized scientific and technical standards, such as ISO 6385 (Ergonomic principles in the design of work systems), to provide an objective assessment.
- An interim analysis will be conducted after 3 cases per surgeon per approach (30 total per study) to assess variability and inform if additional procedures are needed.
- Methods to manage missing data will be considered (e.g., imputation if appropriate and limited, or complete case analysis). Sensitivity analyses may be conducted to assess the robustness of findings to different assumptions or analytical choices.

4.11.2 Risk factors, confounders and effect modifiers

 Potential Confounders/Effect Modifiers:

- Surgeon experience (though controlled by inclusion criteria requiring proficiency and within-subjects design).
- Case complexity (procedures will be standardized as much as possible).
- Duration of surgery.
- Order of surgical approach/platform (will be counterbalanced if feasible).
- Individual surgeon anthropometry and baseline physical condition.

 Data Sources: Surgeon demographic data (age, years of experience – collected at baseline), procedure logs (duration, specific events), sensor data itself.

 The within-subjects design, where each surgeon acts as their own control, is the primary method to control for inter-individual variability.

4.11.3 Selection and matching criteria for controls

Not applicable, as this is not a case-control study. Each surgeon serves as their own control.

4.11.4 Policy for sharing data with other researchers/research groups (data sharing)

Upon completion of the study and publication of primary results, anonymized datasets (primarily processed ergonomic and physiological parameters, not raw sensor feeds or identifiable video) may be made available to other researchers upon reasonable request to the Principal Investigator and subject to a data sharing agreement.

5 Administrative procedures and statements

5.1 Informed consent and consent to the processing of personal data

The study protocol, any amendments to the protocol, informed consent, consent to the processing of personal data and any other information for patients must be approved by the Ethics Committee.

To be included in the study, each surgeon must provide written informed consent as well as consent to the processing of his or her personal data.

5.1.1 Modalities for acquiring informed consent and consent to the processing of personal data

The Principal Investigator or a delegated co-investigator (e.g., experienced research staff familiar with the protocol and ethical considerations) will be responsible for acquiring informed consent from the participating surgeons. This process will take place within the IRCCS AOU Bologna, likely in a private office or meeting room within the relevant surgical departments, prior to any study-specific procedures or data collection. Surgeons will be given adequate time to read the information sheet, ask questions, and consider participation.

5.1.2 Study phase during which consents will be obtained

Screening	☒
Baseline	☐
First follow-up visit	☐

5.1.3 Cases for which the acquisition of consent to the processing of personal data is not required

Not applicable for this study, as all participants (surgeons) will be prospectively enrolled and will provide consent for the collection and processing of their ergonomic and physiological data. This study does not involve retrospective data collection from individuals unable to consent

5.2 Specific study Insurance

Due to the observational nature of the study, no study-specific insurance is stipulated.

5.3 Amendments to the protocol and changes in the conduction of the study

Any changes to the protocol will be made through an amendment, which will be submitted to the Ethics Committee. No other mode of amendment to the protocol is allowed during the study period. Any unexpected changes in the conduct of the study will be recorded in the "Clinical Study Report."

5.4 Publication of results

The investigator commits to:

- notify the conclusion of the study
- submit the study for publication to a peer-reviewed journal within 12 months of study completion and regardless of the nature of its results

- use the correct affiliation of our research institution (*IRCCS Azienda Ospedaliero-Universitaria di Bologna*) in the scientific publications that will be submitted,

For this purpose, the study will be registered on an Open Science platform (for example: osf.io, clinicaltrials.gov). Any formal submission or publication of data derived from this study shall be considered as a publication on behalf of the Investigator.

5.4.1 Strategies for the dissemination of results and for the reproducibility of research

Strategies for the dissemination of results include:

- Publication in high-impact, peer-reviewed scientific journals relevant to surgery, ergonomics, and medical technology.
- Presentations at national and international scientific conferences and congresses.
- Internal dissemination within IRCCS AOU Bologna to relevant departments and stakeholders.
- Potentially, results could inform training programs for surgeons or guidelines for ergonomic best practices in surgery. Reproducibility will be supported by detailed methodology in publications, adherence to reporting guidelines, and the data sharing policy outlined in section 4.11.4.

5.4.2 Criteria for the order of authors in publications

Authorship will be determined based on the International Committee of Medical Journal Editors (ICMJE) criteria. The order of authors will be decided by mutual agreement among the research team, reflecting the relative contributions to study design, data acquisition, analysis, interpretation, and manuscript preparation. The Principal Investigator will typically be the senior author.

5.5 Storage of Documentation

The Investigator is responsible for the storage and preservation of the essential documents of the study, before, during the course of, and after the completion or interruption of the study, in accordance with the requirements of current regulations and GCP and corresponding timelines.

The data collected in the CRF will be in strictly pseudonymous form and the subject will only be identified with a number/code.

The Investigator shall keep the original patient data and the signed informed consent in a safe place to ensure that confidentiality and privacy are maintained.

5.6 Inspections/Audits

If a Regulatory Authority requests an inspection, the Investigator is required to inform the Ethics Committee immediately.

5.7 Contact Persons

The telephone numbers and e-mail addresses of the contact persons for the conduction of the study are listed in the Investigator Folder at the center.

6 Bibliography

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