

# Gastric Bypass Using a Surgical Robot with Table-Mounted Arms: First-in-Human Clinical Trial Results with the OTTAVA Robotic Surgical System

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## Research Article

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# Abstract

## Background

Clinical evaluation is necessary to determine that novel robotic surgical systems can safely support complex procedures. This first-in-human study assessed the safety and performance of the OTTAVA™ Robotic Surgical System (Johnson & Johnson MedTech, Santa Clara, CA, USA), which incorporates table-mounted arms, in patients undergoing Roux-en-Y gastric bypass (RYGB).

## Methods

The FORTE study was a prospective, single-arm, multicenter clinical investigation conducted across six centers. The primary effectiveness endpoint was completion of RYGB using OTTAVA without conversion to open or laparoscopic surgery. Primary safety endpoints were occurrence of device- or procedure-related complications within 30 days. Secondary endpoints included operative and perioperative outcomes.

## Results

Thirty patients underwent robotic-assisted RYGB with 30-day follow-up. The median age was 42.0 years (range 26–64), and median body mass index was 46.7 kg/m<sup>2</sup> (range 33.4–69.0). All procedures (100%) were completed robotically without conversion to open or laparoscopic surgery, meeting the primary effectiveness endpoint. Device- or procedure-related complications occurred in 5 patients (16.7%), below the prespecified performance goal of 27.8%. Complications consisted of manageable intraoperative and postoperative events, none resulting in reoperation, anastomotic leak, stricture, or mortality.

## Conclusions

In this prospective multicenter study, a robotic system with table-mounted arms was successfully used to complete RYGB without conversion to open or laparoscopic surgery. All predefined primary and secondary performance goals were achieved. These findings support the safety and performance of the system in a technically challenging upper abdominal procedure.

ClinicalTrials.gov Registration NCT06709261

# Introduction

Robotic surgical systems were developed to address constraints with laparoscopic surgery by providing improved visualization, wristed instrumentation, and enhanced surgeon control[1–3]. Published data suggest that perioperative outcomes for robotic and laparoscopic RYGB are largely comparable, including complication rates, length of stay, and conversion to open surgery [4–6]. Additionally, longer operative times and higher costs associated with robotic-assisted surgery remain a significant barrier to broader adoption [4, 6–9]. For more than two decades, the robotic surgery market has been largely defined by the dominance of the da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA), resulting in limited competition compared with other areas of surgical technology [10]. Recently, however, multiple robotic platforms have emerged with differing architectures, console designs, and

workflow strategies, signaling a transition toward a more competitive robotic surgery ecosystem [11–14]. In this context, the introduction of a novel robotic platform requires careful clinical evaluation to determine not only whether outcomes are acceptable, but whether the system can reliably support completion of a complex procedure such as Roux-en-Y gastric bypass (RYGB) across different surgeons and institutions.

Successful completion without conversion to open or laparoscopic surgery provides an important measure of whether a novel surgical platform can support the intended procedure. Conversion events may provide insight into limitations related to device performance or workflow integration. As such, early clinical experience must establish that essential procedural steps, such as dissection, reconstruction, and anastomosis, can be performed consistently using the investigational system.

Recent advances in robotic system design have focused on delivering a more seamlessly integrated operating room experience [15]. One such approach is integrating robotic arms into the surgical table. This design is intended to reduce the system footprint, simplify workflow, and reduce procedural disruptions through synchronized table motion, which enables patient repositioning to access anatomy across multiple quadrants without the need to undock the robotic system.

The present study reports the results of a prospective, multicenter clinical evaluation of the OTTAVA Robotic Surgical System (RSS) (Johnson & Johnson MedTech, Santa Clara, CA, USA) with table-mounted arms (Fig. 1) in patients undergoing RYGB. The primary objectives of this study were to assess the ability of the system to support successful completion of the procedure without conversion to open or laparoscopic surgery, and occurrence of intraoperative and postoperative device- or procedure-related complications. Secondary objectives included evaluation of perioperative outcomes. Through this analysis, we sought to characterize early clinical performance and define factors associated with effective implementation of a novel robotic platform.

## **Materials and Methods**

### **Study Design and Setting**

The FORTE study was a prospective, multicenter, single-arm clinical investigation designed to evaluate the safety and performance of an RSS in patients undergoing RYGB. The study was conducted under an Investigational Device Exemption across six institutions in the United States and received institutional review board approval at each participating site. All subjects provided written informed consent prior to enrollment. Participating institutions represented a range of clinical environments with surgeons of varying levels of prior robotic experience, allowing for evaluation of system performance across heterogeneous operating room settings. The study was prospectively registered at ClinicalTrials.gov (NCT06709261) and conducted in accordance with the Declaration of Helsinki.

### **Patient Selection**

Adult patients undergoing elective primary RYGB for treatment of obesity were eligible for inclusion. Enrollment was limited to individuals who met established clinical indications for bariatric surgery and were considered appropriate candidates for minimally invasive surgery. Detailed inclusion and exclusion criteria are provided in the Supplementary Material. Subjects were consecutively screened to reduce selection bias and were required to satisfy predefined inclusion and exclusion criteria. All enrolled patients were followed through 30 days postoperatively for outcome assessment.

## Study Procedure

Roux-en-Y gastric bypass (RYGB) was selected as the index procedure because it represented a technically complex minimally invasive operation requiring tissue dissection, intracorporeal suturing, gastrointestinal reconstruction, and work across multiple abdominal quadrants. Successful completion of RYGB therefore provided a thorough assessment of the ability of the robotic surgical system to support advanced abdominal surgery.

## Surgeon Experience and Training

All procedures were performed by surgeons with prior experience in laparoscopic and robotic bariatric surgery. To assess system performance across a spectrum of robotic experience, surgeons were stratified according to recent robotic surgical volume.

High-volume surgeons were defined as those having performed more than 200 robotic procedures within the preceding two years, whereas mid to low-volume surgeons had performed no more than 200 cases over the same period. The study design required participation from both groups to ensure representation of varying levels of familiarity with robotic systems and to evaluate generalizability of performance. Eleven surgeons, seven high-volume and four mid- to low-volume surgeons, across six sites participated in the trial. All surgeons completed between two and four procedures using the investigational device. All surgeons and operating room staff completed standardized system-specific training prior to performing study procedures. No procedures performed with the investigational system were excluded from analysis; all clinical cases beginning with each surgeon's first use of the platform were included in the study.

## Robotic System and Operative Setup

The investigational robotic system incorporated multiple robotic arms integrated into the surgical table, enabling coordinated instrument control and patient positioning without the need for an external cart-based configuration. The system was controlled from a surgeon console and was designed to facilitate visualization, tissue manipulation, dissection, and suturing during minimally invasive procedures.

Procedures were performed using institutional standards of care, with the use of commercially available adjunct instruments, including laparoscopic staplers and energy devices, at the discretion of the surgical team. Representative intraoperative images demonstrating port placement, robotic suturing, and surgeon console operation are shown in Figure 2.

## Surgical Procedure

All patients underwent robotic-assisted RYGB using a standardized operative approach. Stapling was performed by the bedside assistant using laparoscopic handheld staplers with staple reloads of varying thickness as per surgeon preference. Following abdominal access and port placement, surgeons performed the core procedural steps including:

- Creation of a gastric pouch
- Division of the greater omentum
- Development of the biliopancreatic limb
- Formation of the gastrojejunal anastomosis
- Measurement and development of the roux (alimentary) limb
- Construction of the jejunojejunal anastomosis

Tasks were performed in a different order, modified, or omitted based on surgeon preference or anatomical presentation. Concomitant procedures permitted by the protocol included repair of hiatal hernias  $\leq 5$  cm. Essential components of the procedure, including visualization, grasping and manipulating tissue, orienting tissue for stapling, dissection, cutting, and hemostasis, were expected to be completed using a robotic approach. Consistent with common practice in robotic-assisted RYGB, non-investigational devices used during the procedures included accessory trocars, sutures, buttress, and wound closure.

## Study Endpoints

The primary effectiveness endpoint was defined as successful completion of the RYGB procedure without conversion to an alternative operative approach, including laparoscopy or open surgery. Conversion to open or laparoscopic surgery was defined as the unplanned use of non-robotic techniques for essential procedural steps, reflecting inability of the system to support completion of the operation as intended. The primary safety endpoint was the occurrence of intraoperative or postoperative device- or procedure-related complications within 30 days of surgery. Secondary endpoints included operative time, estimated blood loss, length of hospital stay, hospital readmission, reoperation, and postoperative complications such as anastomotic leak or stricture. Complications were categorized using the Clavien-Dindo classification system. Device deficiencies and intraoperative events were also recorded to assess system reliability and integration into operative workflow. Performance goals for the primary and

secondary endpoints were established prior to study initiation based on a systematic review of the published RYGB literature.

## Statistical Analysis

Statistical analyses were performed according to a prespecified statistical analysis plan. The full analysis set, defined as all subjects who underwent robotic-assisted RYGB with the OTTAVA RSS, was used for analysis of primary and secondary endpoints. Safety outcomes were evaluated through 30-day follow-up. Continuous variables are presented as median and range, while categorical variables are summarized as frequencies and percentages. Exact 95% confidence intervals (CIs) were calculated for categorical endpoints using the Clopper-Pearson method. All analyses were performed using the SAS v9.4 (SAS Institute Inc., Cary, NC) statistical program.

## Results

### Study Population and Procedural Completion

A total of 32 subjects were enrolled across six investigational centers. Two subjects were withdrawn prior to surgery due to determination as non-surgical candidates, and 30 subjects underwent robotic-assisted RYGB. All 30 subjects (100%) who underwent the procedure completed the 30-day follow-up (Figure 3).

The median age of the cohort was 42 years (range 26 to 64 years). There were 22 females (73%) and 8 males (27%). Race and ethnicity included 10 (33%) who identified as Black or African American, 7 (23%) who identified as Hispanic or Latino, and 13 (43%) who identified as White. The median body mass index (BMI) was 46.7 kg/m<sup>2</sup>, with a range of 33.4 to 69.0 kg/m<sup>2</sup> (Table 1).

| Table 1: Demographics and Clinical Characteristics                                                                                        |                   |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Patient Characteristics                                                                                                                   | (N = 30 patients) |
| Age (years)                                                                                                                               |                   |
| Mean (SD)                                                                                                                                 | 41.8 (9.2)        |
| Median                                                                                                                                    | 42.0              |
| Min, Max                                                                                                                                  | 26, 64            |
| Sex, % (n/N)                                                                                                                              |                   |
| Male                                                                                                                                      | 26.7% (8/30)      |
| Female                                                                                                                                    | 73.3% (22/30)     |
| Weight (kg)                                                                                                                               |                   |
| Mean (SD)                                                                                                                                 | 134.3 (29.1)      |
| Median                                                                                                                                    | 129.2             |
| Min, Max                                                                                                                                  | 87.7, 188.0       |
| Height (cm)                                                                                                                               |                   |
| Mean (SD)                                                                                                                                 | 168.0 (8.2)       |
| Median                                                                                                                                    | 166.4             |
| Min, Max                                                                                                                                  | 149.9, 185.4      |
| BMI (kg/m <sup>2</sup> )                                                                                                                  |                   |
| Mean (SD)                                                                                                                                 | 47.4 (9.2)        |
| Median                                                                                                                                    | 46.7              |
| Min, Max                                                                                                                                  | 33.4, 69.0        |
| ASA Physical Status Classification, % (n/N)                                                                                               |                   |
| ASA I—A normal healthy patient                                                                                                            | 0.0% (0/30)       |
| ASA II—A patient with mild systemic disease                                                                                               | 6.7% (2/30)       |
| ASA III—A patient with severe systemic disease                                                                                            | 93.3% (28/30)     |
| SD standard deviation; kg kilogram; cm centimeter; kg/m <sup>2</sup> kilogram per meter squared; ASA American Society of Anesthesiologist |                   |

All 30 procedures were completed with the OTTAVA Robotic Surgical System without conversion to laparoscopic or open surgery.

## Primary Safety Outcomes and Adverse Events

Device- or procedure-related complications occurred in 5 of 30 subjects (16.7%; 95% CI: 5.6–34.7%). Complication severity was classified according to Clavien-Dindo criteria, with four subjects experiencing grade III or higher complications. A total of 99 adverse events were reported among all 30 subjects. The majority were expected postoperative findings. Gastrointestinal adverse events were most common, including abdominal pain in 28 of 30 subjects (93%) and nausea in 17 of 30 subjects (57%).

Four subjects (13%) experienced at least one major complication. This included two device-related adverse events: a mechanical serosal injury, managed with sutured repair during the index procedure (grade IIIb) and a superficial thermal injury to bowel serosa managed with prophylactic imbricating suture placement (grade IIIb). There were two adverse events that were determined not to be device-related, consisting of an intestinal perforation occurring during laparoscopic abdominal access (grade IIIb) and a postoperative sterile fluid collection requiring readmission and managed with percutaneous drainage, yielding sterile fluid (grade IIIa). The intestinal perforation occurred during initial abdominal access under laparoscopic vision with a non-robotic optical trocar and occurred before robotic docking. The injury was repaired laparoscopically before initiation of the robotic phase, after which RYGB was completed robotically without conversion. Two minor complications (grade I) were reported, consisting of transient endotracheal tube malposition (endobronchial intubation) and postoperative vomiting. The airway complication and intestinal perforation occurred in the same subject. There were no unanticipated adverse device effects. All adverse events resolved without long-term sequelae, no device-related event required intervention beyond that described, and there were no reoperations, anastomotic leaks, anastomotic strictures, or mortality within 30 days.

## Secondary Outcomes and Operative Metrics

Median operative time was 154 minutes (range 75–264). Operative workflow and time components, including setup, docking, console, and disassembly intervals, are illustrated in Figure 4. Median estimated blood loss was 20.0 mL (range 2-50). No subjects required intraoperative or postoperative blood transfusion. The median length of stay was 1.5 days (range 1-5). All primary and secondary performance goals specified in the study statistical analysis plan were achieved (Table 2).

| Table 2: Primary and Secondary Objectives of the Study                                                                                                                                                                                                                                                                                                                                                              |              |                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-------------------------------|
| Primary endpoints                                                                                                                                                                                                                                                                                                                                                                                                   | % (n/N)      | Performance Goal <sup>a</sup> |
| Rate of device and procedure related complications (through 30 Days)                                                                                                                                                                                                                                                                                                                                                | 16.7% (5/30) | ≤ 27.8% [16]                  |
| CD class number of complications <sup>b</sup>                                                                                                                                                                                                                                                                                                                                                                       | 13.3% (4/30) |                               |
| Major complications (CD ≥ III)                                                                                                                                                                                                                                                                                                                                                                                      | 6.7% (2/30)  |                               |
| Minor complications (CD I-II)                                                                                                                                                                                                                                                                                                                                                                                       |              |                               |
| Rate of conversions to open or laparoscopic surgery                                                                                                                                                                                                                                                                                                                                                                 | 0.0% (0/30)  | ≤ 10.0%                       |
| Secondary endpoints                                                                                                                                                                                                                                                                                                                                                                                                 | Mean (SD)    | Performance Goal <sup>a</sup> |
| Procedure time (minutes)                                                                                                                                                                                                                                                                                                                                                                                            | 156.2 (47.9) | ≤ 300 [17]                    |
| Estimated blood loss (n=29, mL)                                                                                                                                                                                                                                                                                                                                                                                     | 19.9 (12.8)  | ≤ 60 [18]                     |
| Length of stay (days)                                                                                                                                                                                                                                                                                                                                                                                               | 1.7 (1.0)    | ≤ 4                           |
| Secondary objective endpoints                                                                                                                                                                                                                                                                                                                                                                                       | % (n/N)      | Performance Goal <sup>a</sup> |
| Occurrence of Blood Transfusion                                                                                                                                                                                                                                                                                                                                                                                     | 0.0% (0/30)  | ≤ 5.0% [19]                   |
| Readmission rate (through 30 Days)                                                                                                                                                                                                                                                                                                                                                                                  | 3.3% (1/30)  | ≤ 13.5% [20]                  |
| Reoperation rate (through 30 Days)                                                                                                                                                                                                                                                                                                                                                                                  | 0.0% (0/30)  | ≤ 9.0% [21]                   |
| Anastomotic leak rate (through 30 Days)                                                                                                                                                                                                                                                                                                                                                                             | 0.0% (0/30)  | ≤ 6.8% [22]                   |
| Anastomotic stricture rate (through 30 Days)                                                                                                                                                                                                                                                                                                                                                                        | 0.0% (0/30)  | ≤ 18.0% [23]                  |
| Mortality rate (through 30 Days)                                                                                                                                                                                                                                                                                                                                                                                    | 0.0% (0/30)  | 0.0%                          |
| <i>SD</i> standard deviation; <i>CD</i> Clavien-Dindo; <i>mL</i> milliliter<br>a. Performance goals were prospectively established from a systematic review of the RYGB literature. Corresponding source references are provided in the bibliography [9, 17-37].<br>b. 1 subject experienced both a Major and Minor complication and is counted in both categories here, but once in the primary endpoint category. |              |                               |

## Procedural Performance and Task Completion

All visualization while using robotic instruments, grasping and manipulating tissue, orienting tissue for stapling, dissection, and monopolar/bipolar energy for cutting and hemostasis were performed robotically in all 30 cases (100%). All essential procedural steps, including gastric pouch creation, gastrojejunal anastomosis, and jejunajejunal anastomosis, were completed robotically in all 30 cases (100%), with bedside stapling. Measurement of the roux limb was performed laparoscopically in 3 cases

(10%) based on surgeon preference; all other procedural steps were performed using the robotic system.

Intraoperative findings prompted concomitant procedures in 3 of 30 patients (10%). Robotic hiatal hernia repair was performed in 2 patients (7%), both involving defects measuring 2–5 cm. One patient (3%) additionally underwent robotic repair of a paraduodenal hernia identified intraoperatively; because this procedure was not specified in the study protocol, it was recorded as a protocol deviation. Laparoscopic stapling was performed using Ethicon (Johnson & Johnson MedTech, Cincinnati, OH, USA) staplers in 17 cases (57%) and Covidien (Medtronic, Dublin, Ireland) staplers in 13 cases (43%), according to surgeon preference and institutional practice.

## Surgeon Experience and Site Variability

Procedures were performed by both high-volume and mid-volume to low-volume robotic surgeons. Nineteen procedures (63%) were performed by high-volume surgeons and 11 procedures (37%) by mid- to low-volume surgeons. Procedures were successfully performed across all six clinical sites, including operating rooms with varying configurations and prior robotic experience. All procedures performed with the investigational system, beginning with each surgeon's first clinical use of the platform, were included in the analysis.

## Discussion

This prospective multicenter clinical study demonstrates that a novel RSS with table-mounted arms can be safely and effectively used to perform RYGB. There were no conversions to open or laparoscopic approaches, reflecting the ability of the investigational system to perform all essential components of a complex bariatric procedure. The study cohort had a median body mass index of 46.7 kg/m<sup>2</sup> and demographic characteristics consistent with patients undergoing bariatric surgery (Table 2) [38–40]. These features provide important context for interpretation of procedural performance.

In addition to procedural completion, the study met its primary safety endpoint. Adverse events were evaluated using predefined protocol criteria and adjudicated according to study-specific safety definitions. Device- and procedure-related complications occurred in 16.7% of patients, below the prespecified performance goal of 27.8% established with systematic review of the RYGB literature [9, 17–37]. No procedures required conversion to open or laparoscopic surgery, compared with a performance goal of ≤ 10%. Similarly, operative time, estimated blood loss, length of stay, readmission, reoperation, anastomotic leak, and anastomotic stricture rates all met predefined performance goals. These findings provide additional context for interpretation of the clinical outcomes and indicate that system performance was consistent with established expectations for RYGB.

The clinical significance of reported complications is best understood in the context of event severity and management. Although four subjects experienced CD grade III complications, these consisted

largely of intraoperative events that were recognized immediately and managed during the index procedure. The most severe event, an intestinal perforation, occurred during laparoscopic abdominal access prior to robotic docking and was unrelated to the investigational device. Two gastrointestinal injuries were repaired intraoperatively without conversion or long-term sequelae, and a postoperative incidental sterile fluid collection was successfully managed with percutaneous drainage. Two events were adjudicated as device related: a superficial thermal injury and a serosal tear that were managed intraoperatively without alteration of postoperative recovery. No complication resulted in anastomotic leak, stricture, reoperation, or mortality. These findings indicate that adverse events, when encountered, were resolved with standard intervention within the context of robotic-assisted surgery [4, 6, 41].

Secondary outcomes further characterize system performance. Operative time, estimated blood loss, and length of stay were consistent with previously reported ranges for bariatric surgery [4, 6, 41]. These findings are also consistent with contemporary Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) analyses of robotic bariatric surgery. Importantly, no procedures were excluded as pre-study learning-phase cases, and all cases beginning with each surgeon's first clinical use of the investigational platform were included in the analysis. Median operative time was 154 minutes, and mean operative time was 156 minutes in the first 30 RYGB procedures performed using the investigational RSS across 11 surgeons with varying levels of robotic experience. For comparison, a recent MBSAQIP analysis reported yearly mean operative durations for robotic RYGB ranging from 152 to 160 minutes across the United States and Canada [7]. The similarity of these operative times is notable given that the present study evaluated an entirely new robotic platform during its earliest clinical use and across multiple institutions and surgeons. National database studies have reported low rates of mortality, leak, reoperation, and major perioperative morbidity following robotic RYGB, while demonstrating that robotic approaches can be performed safely across diverse practice settings. Additionally, MBSAQIP analyses have shown that robotic bariatric surgery has become increasingly utilized in the United States, reflecting growing clinical adoption of robotic platforms for complex bariatric procedures [42, 43]. The outcomes observed in the present study are therefore consistent with expectations derived from contemporary robotic bariatric practice, despite representing an early clinical experience with a novel robotic architecture. While this study was not designed for comparative analysis, these findings demonstrate that procedural success was achieved without evidence of unusual perioperative morbidity.

A notable observation from this study is the consistency of procedural completion across multiple surgeons, institutions, and patient size. Procedures were performed across six clinical sites, including environments with varying operating room configurations, by 11 surgeons of variable robotic expertise, and on patients with wide-ranging BMIs (33 to 69 kg/m<sup>2</sup>). The ability to achieve uniform completion without conversion across all sites supports the reproducibility of system performance in early clinical use.

The significance of these findings extends beyond procedural outcomes alone and should also be considered within the context of a rapidly evolving robotic surgery landscape. For many years, clinical

robotic surgery was largely dominated by a single platform, resulting in relatively limited opportunities for comparative evaluation of alternative robotic system designs [10]. More recently, several new robotic platforms have entered clinical development and early clinical use, introducing distinct approaches to surgeon ergonomics, operating room integration, instrument architecture, and procedural workflow [11–14, 44]. The present study contributes to this growing body of evidence by providing prospective multicenter clinical data evaluating a robotic system with table-mounted arms in a complex bariatric procedure. Unlike conventional cart- or boom-based robotic systems, the investigational platform incorporates robotic arms directly into the operating table, representing a distinct architectural approach that warrants independent clinical evaluation.

Beyond its clinical findings, this study has regulatory significance. Prospective multicenter clinical evaluation was conducted to support regulatory assessment of the investigational robotic system in the United States. The results demonstrated successful completion of all procedures without conversion to open or laparoscopic surgery, achievement of all predefined primary and secondary performance goals, and acceptable perioperative safety outcomes. These clinical data contributed to subsequent U.S. Food and Drug Administration (FDA) De Novo authorization of the system for the studied indication.

### Limitations

Several limitations should be considered. This was a single-arm study without a comparator group, limiting direct comparison to existing robotic systems. The sample size was modest, and outcomes were evaluated using descriptive analyses without formal hypothesis testing. The follow up interval for enrolled patients was 30 days, limiting sensitivity for late-presenting complications, such as chronic stricture or incisional hernia. The study was also not designed to assess performance across different patient subgroups or to identify predictors of outcomes. Despite these limitations, this study provides early clinical evidence supporting the ability of a novel robotic system to perform RYGB.

## Conclusions

In this prospective multicenter clinical study, a robotic surgical system with table-mounted arms demonstrated the ability to support completion of RYGB without conversion to open or laparoscopic surgery, with all 30 procedures successfully completed robotically. The achievement of procedural completion, combined with acceptable safety outcomes and consistent performance across sites, supports the feasibility of this system for use in minimally invasive bariatric surgery. Device- and procedure-related complications were observed but were managed without significant interruption of robotic workflow, and no reoperations, anastomotic complications, or mortality occurred within 30 days. Secondary outcomes, including operative time, blood loss, and length of stay, were consistent with expected perioperative findings.

All primary and secondary performance goals established prospectively from a systematic review of the RYGB literature were achieved, and the resulting clinical evidence contributed to FDA De Novo authorization of the system in the United States. Together, these findings support the feasibility of

alternative robotic system architectures as the robotic surgery market transitions toward a more competitive landscape.

## **Declarations**

## **Disclosures**

Johnson & Johnson Medtech provided funding for the study. Authors Dr. Wilson, Dr. Teixeira, Dr. Sudan, Dr. Brathwaite, Dr. DuCoin, Dr. Olavarria, Dr. Abich, Dr. Yuce, Dr. Felinski, Dr. Eckhouse, and Dr. Stefanidis received compensation for research from Johnson & Johnson MedTech. Dr. Davidow is a surgical research fellow and receives salary support from Johnson & Johnson MedTech. Karst, Schwiers, Dr. Benz and Dr. Fryrear disclose employment by Johnson & Johnson MedTech.

## **Competing Interests**

Johnson & Johnson Medtech provided funding for the study. Authors Dr. Wilson, Dr. Teixeira, Dr. Sudan, Dr. Brathwaite, Dr. DuCoin, Dr. Olavarria, Dr. Abich, Dr. Yuce, Dr. Felinski, Dr. Eckhouse, and Dr. Stefanidis received compensation for research from Johnson & Johnson MedTech. Dr. Davidow is a surgical research fellow and receives salary support from Johnson & Johnson MedTech. Karst, Schwiers, Dr. Benz and Dr. Fryrear disclose employment by Johnson & Johnson MedTech.

## **Author Contribution**

E.B.W., A.F.T., R.S., C.E.M.B., C.D., and D.S. served as the primary investigators at their respective sites and made substantial contributions to study design and conduct, surgical procedures, data acquisition and interpretation, and critical manuscript development. O.O.O., E.A., T.Y., M.F., and S.R.E. performed study procedures and contributed to data acquisition and interpretation. M.S. performed the data analysis, with assistance from Y.D. Y.D. led manuscript drafting and table development and contributed to data interpretation. E.K. served as the clinical lead and contributed to study oversight, data interpretation, and table development. H.B. and M.S. contributed to data review, interpretation, and table development. R.S.F. contributed to critical manuscript revision. All authors contributed to manuscript development, critically reviewed the manuscript for important intellectual content, approved the final version for publication, and agreed to be accountable for the integrity and accuracy of the work.

## **Data Availability**

The data supporting the findings of this clinical trial (ClinicalTrials.gov identifier NCT06709261) are not publicly available because they contain sensitive participant-level clinical information and are subject to participant-consent, privacy, and sponsor-controlled-access restrictions. Data are maintained in secure,

controlled-access storage by the study sponsor. Requests for access to appropriately de-identified data may be submitted to the corresponding author and will be considered on a case-by-case basis for scientifically valid purposes, subject to applicable consent provisions, institutional and sponsor review, execution of any required data-use agreement, and all relevant legal and regulatory requirements.

## References

1. Jung M, Morel P, Buehler L, Buchs NC, Hagen ME. Robotic general surgery: current practice, evidence, and perspective. *Langenbecks Arch Surg*. 2015;400(3):283-9210.1007/s00423-015-1278-y.
2. Hazey JW, Melvin WS. Robot-assisted general surgery. *Semin Laparosc Surg*. 2004;11(2):107-1210.1177/107155170401100207.
3. Morris B. Robotic surgery: applications, limitations, and impact on surgical education. *MedGenMed*. 2005;7(3):72
4. Economopoulos KP, Theocharidis V, McKenzie TJ, Sergentanis TN, Psaltopoulou T. Robotic vs. Laparoscopic Roux-En-Y Gastric Bypass: a Systematic Review and Meta-Analysis. *Obes Surg*. 2015;25(11):2180-910.1007/s11695-015-1870-9.
5. Aiolfi A, Tornese S, Bonitta G, Rausa E, Micheletto G, Bona D. Roux-en-Y gastric bypass: systematic review and Bayesian network meta-analysis comparing open, laparoscopic, and robotic approach. *Surg Obes Relat Dis*. 2019;15(6):985-9410.1016/j.soard.2019.03.006.
6. Li K, Zou J, Tang J, Di J, Han X, Zhang P. Robotic Versus Laparoscopic Bariatric Surgery: a Systematic Review and Meta-Analysis. *Obes Surg*. 2016;26(12):3031-4410.1007/s11695-016-2408-5.
7. Sharma G, Strong AT, Tu C, Brethauer SA, Schauer PR, Aminian A. Robotic platform for gastric bypass is associated with more resource utilization: an analysis of MBSAQIP dataset. *Surg Obes Relat Dis*. 2018;14(3):304-1010.1016/j.soard.2017.11.018.
8. Curet MJ. Comparison of hospital charges between robotic, laparoscopic stapled, and laparoscopic handsewn Roux-en-Y gastric bypass. *Journal of Robotic Surgery*. 2009;3(3):199
9. Lyn-Sue JR, Winder JS, Kotch S, Colello J, Docimo S. Laparoscopic gastric bypass to robotic gastric bypass: time and cost commitment involved in training and transitioning an academic surgical practice. *J Robot Surg*. 2016;10(2):111-510.1007/s11701-016-0567-y.
10. Rao PP. Robotic surgery: new robots and finally some real competition! *World J Urol*. 2018;36(4):537-4110.1007/s00345-018-2213-y.
11. Brassetti A, Ragusa A, Tedesco F, Prata F, Cacciatore L, Iannuzzi A, et al. Robotic Surgery in Urology: History from PROBOT((R)) to HUGO(TM). *Sensors (Basel)*. 2023;23(16):710410.3390/s23167104.
12. Farinha R, Puliatti S, Mazzone E, Amato M, Rosiello G, Yadav S, et al. Potential Contenders for the Leadership in Robotic Surgery. *J Endourol*. 2022;36(3):317-2610.1089/end.2021.0321.

13. Picozzi P, Nocco U, Labate C, Gambini I, Puleo G, Silvi F, et al. Advances in Robotic Surgery: A Review of New Surgical Platforms. *Electronics*. 2024;13(23):4675ARTN 4675 10.3390/electronics13234675.
14. Sarin A, Samreen S, Moffett JM, Inga-Zapata E, Bianco F, Alkhamesi NA, et al. Upcoming multi-visceral robotic surgery systems: a SAGES review. *Surg Endosc*. 2024;38(12):6987-701010.1007/s00464-024-11384-8.
15. Kanji F, Cohen T, Alfred M, Caron A, Lawton S, Savage S, et al. Room Size Influences Flow in Robotic-Assisted Surgery. *Int J Environ Res Public Health*. 2021;18(15):798410.3390/ijerph18157984.
16. Buchs NC. Roux-en-Y gastric bypass for super obese patients: what approach? *International Journal of Medical Robotics*. 2016;12(2):276-82
17. Hagen ME, Pugin F, Chassot G, Huber O, Buchs N, Iranmanesh P, et al. Reducing cost of surgery by avoiding complications: the model of robotic Roux-en-Y gastric bypass. *Obes Surg*. 2012;22(1):52-6110.1007/s11695-011-0422-1.
18. Stefanidis D, Bailey SB, Kuwada T, Simms C, Gersin K. Robotic gastric bypass may lead to fewer complications compared with laparoscopy. *Surg Endosc*. 2018;32(2):610-610.1007/s00464-017-5710-y.
19. Myers SR, McGuirl J, Wang J. Robot-assisted versus laparoscopic gastric bypass: comparison of short-term outcomes. *Obes Surg*. 2013;23(4):467-7310.1007/s11695-012-0848-0.
20. Dudash M, Saeed K, Wang S, Johns A, Colonie R, Falvo A, et al. A comparative evaluation of robotic and laparoscopic Roux-en-Y gastric bypass: a critical evaluation on the impact of postoperative pain and opioid requirements. *Surg Endosc*. 2022;36(10):7700-810.1007/s00464-022-09124-x.
21. Benizri EI, Renaud M, Reibel N, Germain A, Ziegler O, Zarnegar R, et al. Perioperative outcomes after totally robotic gastric bypass: a prospective nonrandomized controlled study. *Am J Surg*. 2013;206(2):145-5110.1016/j.amjsurg.2012.07.049.
22. Ugliono E, Rebecchi F, Vicentini C, Salzano A, Morino M. Cost-effectiveness analysis of revisional Roux-en-Y gastric bypass: laparoscopic vs. robot assisted. *Updates Surg*. 2023;75(1):189-9610.1007/s13304-022-01425-z.
23. Soon DSC. Australian experience with robot-assisted Roux-en-Y gastric bypass with comparison to a conventional laparoscopic series. *Surgical Endoscopy*. 2022;36:4025-31
24. Ahmad A, Carleton JD, Ahmad ZF, Agarwala A. Laparoscopic versus robotic-assisted Roux-en-Y gastric bypass: a retrospective, single-center study of early perioperative outcomes at a community hospital. *Surgical Endoscopy and Other Interventional Techniques*. 2016;30(9):3792-610.1007/s00464-015-4675-y.
25. Ayloo S, Roh Y, Choudhury N. Laparoscopic, hybrid, and totally robotic Roux-en-Y gastric bypass. *J Robot Surg*. 2016;10(1):41-710.1007/s11701-016-0559-y.
26. Barros F, Fonseca ABM, Kiss ASB, Braga CF, FR DA-S, Regonati YH. Robotic Versus Laparoscopic Roux-En-Y-Gastric Bypass: A Retrospective Study in a Single Center. *Arq Bras Cir Dig*. 2023;36:e175610.1590/0102-672020230038e1756.

27. Beckmann JH, Bernsmeier A, Kersebaum JN, Mehdorn AS, von Schonfels W, Taivankhuu T, et al. The Impact of Robotics in Learning Roux-en-Y Gastric Bypass: a Retrospective Analysis of 214 Laparoscopic and Robotic Procedures : Robotic Vs. Laparoscopic RYGB. *Obes Surg*. 2020;30(6):2403-1010.1007/s11695-020-04508-1.
28. Buchs NC, Morel P, Azagury DE, Jung M, Chassot G, Huber O, et al. Laparoscopic versus robotic Roux-en-Y gastric bypass: lessons and long-term follow-up learned from a large prospective monocentric study. *Obes Surg*. 2014;24(12):2031-910.1007/s11695-014-1335-6.
29. Cahais J. Less Morbidity with Robot-Assisted Gastric Bypass Surgery than with Laparoscopic Surgery? *Obesity Surgery*. 2019;29:519-25
30. Hilt L, Sherman B, Tan WH, Lak K, Gould JC, Kindel TL, et al. Bariatric Surgeon Ergonomics: A Comparison of Laparoscopy and Robotics. *J Surg Res*. 2024;295:864-7310.1016/j.jss.2023.08.045.
31. Lainas P, Kassir R, Benois M, Derienne J, Debs T, Safieddine M, et al. Comparative analysis of robotic versus laparoscopic Roux-en-Y gastric bypass in severely obese patients. *J Robot Surg*. 2021;15(6):891-810.1007/s11701-020-01181-5.
32. Marincola G, Procopio PF, Pennestri F, Gallucci P, Voloudakis N, Ciccoritti L, et al. Robot-assisted vs laparoscopic bariatric procedures in super-obese patients: clinical and economic outcomes. *J Robot Surg*. 2024;18(1):3410.1007/s11701-023-01748-y.
33. Rogula T. Does Robotic Roux-en-Y Gastric Bypass Provide Outcome Advantages over Standard Laparoscopic Approaches? *Obesity Surgery*. 2018;28(9):2589-96
34. Senellart P, Saint-Jalmes G, Mfam WS, Abou-Mrad A. Laparoscopic versus full robotic Roux-en-Y gastric bypass: retrospective, single-center study of the feasibility and short-term results. *J Robot Surg*. 2020;14(2):291-610.1007/s11701-019-00976-5.
35. Smeenk RM, van 't Hof G, Elsten E, Feskens PG. The Results of 100 Robotic Versus 100 Laparoscopic Gastric Bypass Procedures: a Single High Volume Centre Experience. *Obes Surg*. 2016;26(6):1266-7310.1007/s11695-015-1933-y.
36. Vilallonga R. Laparoscopic Versus Robot-Assisted Roux-en-Y Gastric Bypass: A Center of Excellence for the EAC-BC Experience. *J Laparoendosc Adv Surg Tech*. 2022;32:32-9
37. Wood MH, Kroll JJ, Garretson B. A comparison of outcomes between the traditional laparoscopic and totally robotic Roux-en-Y gastric bypass procedures. *J Robot Surg*. 2014;8(1):29-3410.1007/s11701-013-0416-1.
38. Eisenberg D, Shikora SA, Aarts E, Aminian A, Angrisani L, Cohen RV, et al. 2022 American Society of Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) Indications for Metabolic and Bariatric Surgery. *Obes Surg*. 2023;33(1):3-1410.1007/s11695-022-06332-1.
39. Salminen P, Helmio M, Ovaska J, Juuti A, Leivonen M, Peromaa-Haavisto P, et al. Effect of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Roux-en-Y Gastric Bypass on Weight Loss at 5 Years Among Patients With Morbid Obesity: The SLEEVEPASS Randomized Clinical Trial. *JAMA*. 2018;319(3):241-5410.1001/jama.2017.20313.

40. Peterli R, Wolnerhanssen BK, Peters T, Vetter D, Kroll D, Borbely Y, et al. Effect of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Roux-en-Y Gastric Bypass on Weight Loss in Patients With Morbid Obesity: The SM-BOSS Randomized Clinical Trial. *JAMA*. 2018;319(3):255-6510.1001/jama.2017.20897.
41. Lundberg PW, Wolfe S, Seaone J, Stoltzfus J, Claros L, El Chaar M. Robotic gastric bypass is getting better: first results from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program. *Surg Obes Relat Dis*. 2018;14(9):1240-510.1016/j.soard.2018.05.022.
42. Morales-Marroquin E, Khatiwada S, Xie L, de la Cruz-Munoz N, Kukreja S, Schneider B, et al. Five Year Trends in the Utilization of Robotic Bariatric Surgery Procedures, United States 2015-2019. *Obes Surg*. 2022;32(5):1539-4510.1007/s11695-022-05964-7.
43. Hope W, Gourash W, Ruppert K, Ramanathan R. Robotic-Assisted Bariatric Surgery Compared to Standard Laparoscopy-Utilization Trends, Outcomes, and Operative Times: MBSAQIP Data from 2018 to 2021. *Obes Surg*. 2026;36(1):61-7010.1007/s11695-025-08308-3.
44. Katsimperis S, Tzelvels L, Feretzakis G, Bellos T, Triantafyllou P, Arseniou P, et al. Beyond Da Vinci: Comparative Review of Next-Generation Robotic Platforms in Urologic Surgery. *J Clin Med*. 2025;14(19):677510.3390/jcm14196775.

## Figures



**Figure 1**

OTTAVA Robotic Surgical System with table-mounted arms.

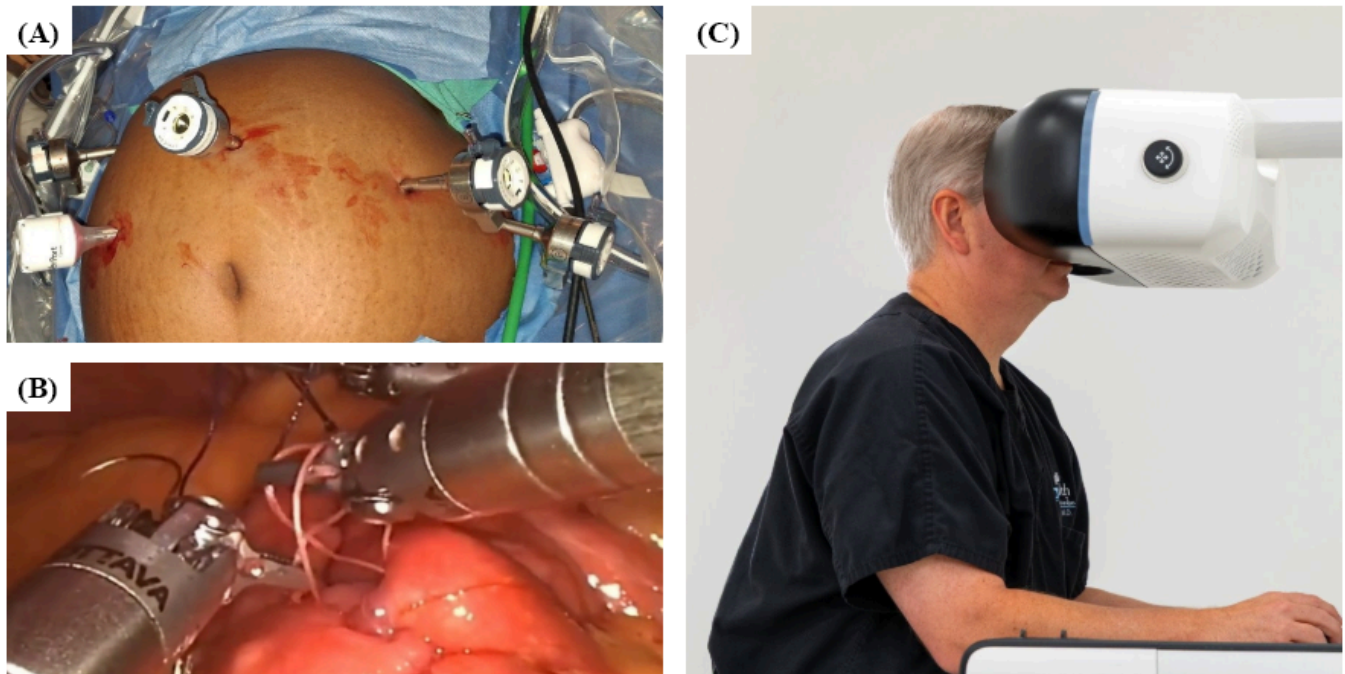


**Figure 2**

(A) RYGB Port Positioning. (B) Intraoperative image exhibiting robotic suturing. (C) OTTAVA Surgeon Console.

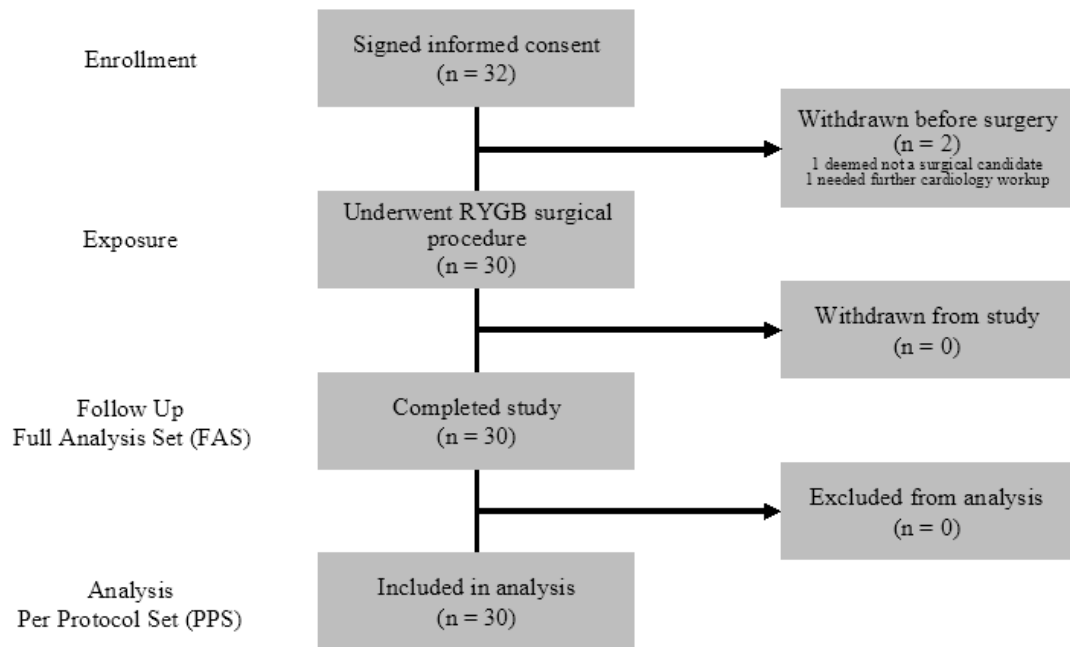
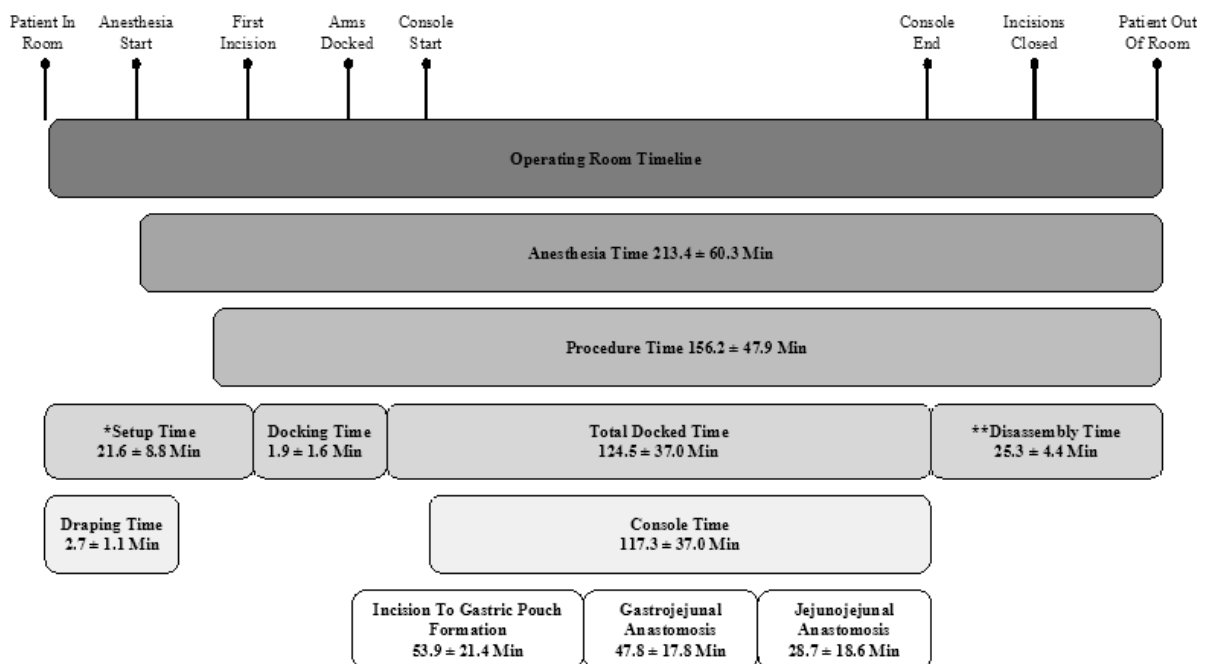


**Figure 3**

Participant flow diagram.



Procedure time: Mean ± standard deviation

\*Setup time included draping arms, preparing the sterile field, and placing ports.

\*\*Disassembly time included removing ports, closing incisions, and stowing arms.

## Figure 4

Operative workflow and procedural time components during robotic Roux-en-Y gastric bypass

## Supplementary Files

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