First Clinical Trial Results of a Robotic Surgical System with Table-Mounted Arms

Erik B. Wilson, MD, FACS, Andre F. Teixeira, MD, Ranjan Sudan, MD, Collin E.M. Brathwaite, MD, Christopher DuCoin, MD, Oscar O. Olavarria, MD, Estela Abich, MD, Tarik Yuce, MD, Shaina Eckhouse, MD, Melissa Felinski, DO, Edward Karst, MS, Heather Benz, PhD, Michael Schwiers, MS, Raymond S. Fryrear II, MD, Dimitrios Stephanidis, MD, PhD

MIST
MINIMALLY INVASIVE SURGEONS OF TEXAS

UTHealth
The University of Texas Health Science Center at Houston
McGovern Medical School

Disclosures

Dr. Erik Wilson, Dr. Andre F. Teixeira, Dr. Ranjan Sudan, Dr. Collin E.M. Brathwaite, Dr. Christopher DuCoin, Dr. Oscar Olavarria, Dr. Hany Takla, Dr. Melissa Felinski, Dr. Tarik Yuce, and Dr. Dimitrios Stefanidis have engaged in consulting and conducted research with support from Johnson & Johnson MedTech.

OTTAVA Robotic Surgical System

- Immersive console
- Table with four integrated robotic arms
- Tower with touchscreen GUI

Today’s presentation contains results of a clinical trial. We will not be covering details on system design and instrumentation in this talk.

J&J MedTech

Study Design

Objective	Evaluate safety and performance of Roux-en-Y gastric bypass (RYGB) using OTTAVA, through 30 days post-op
Study Design	Prospective, multi-center, single-arm clinical trial 30 RYGB procedures, at least 10 by mid-to-low-volume surgeons *≤200 robotic cases in past 2 years* 8 hours of surgeon training, no roll-in cases
Primary Endpoints	Safety: Subjects with device- or procedure-related complications Effectiveness: Procedure completion without conversion
Key Secondary Endpoints	Procedure time, estimated blood loss, length of stay, anastomotic leak, anastomotic stricture, mortality

Key Eligibility Criteria

Inclusion Criteria

- Adult patients scheduled to undergo primary elective RYGB surgery
- ASA class I, II, or III
- BMI at least 35, or obesity with health risk meeting ASMBS/IFSO guidelines for bariatric surgery

Exclusion Criteria

- Medical condition that makes robotic surgery risky, including intraoperative finding before ports placed
- Concomitant procedure, other than repair of hiatal hernia up to 5 cm and adhesiolysis
- Enrolled in another study that may confound results

Methods

Baseline Visit

Informed consent before any data collection

Demographics

Medical/surgical history

Physical examination

Procedure Visit

Investigational robot installed in OR

Patient admitted morning of surgery

Roux-en-Y gastric bypass procedure using standard technique

Procedure detail and any adverse events recorded during case

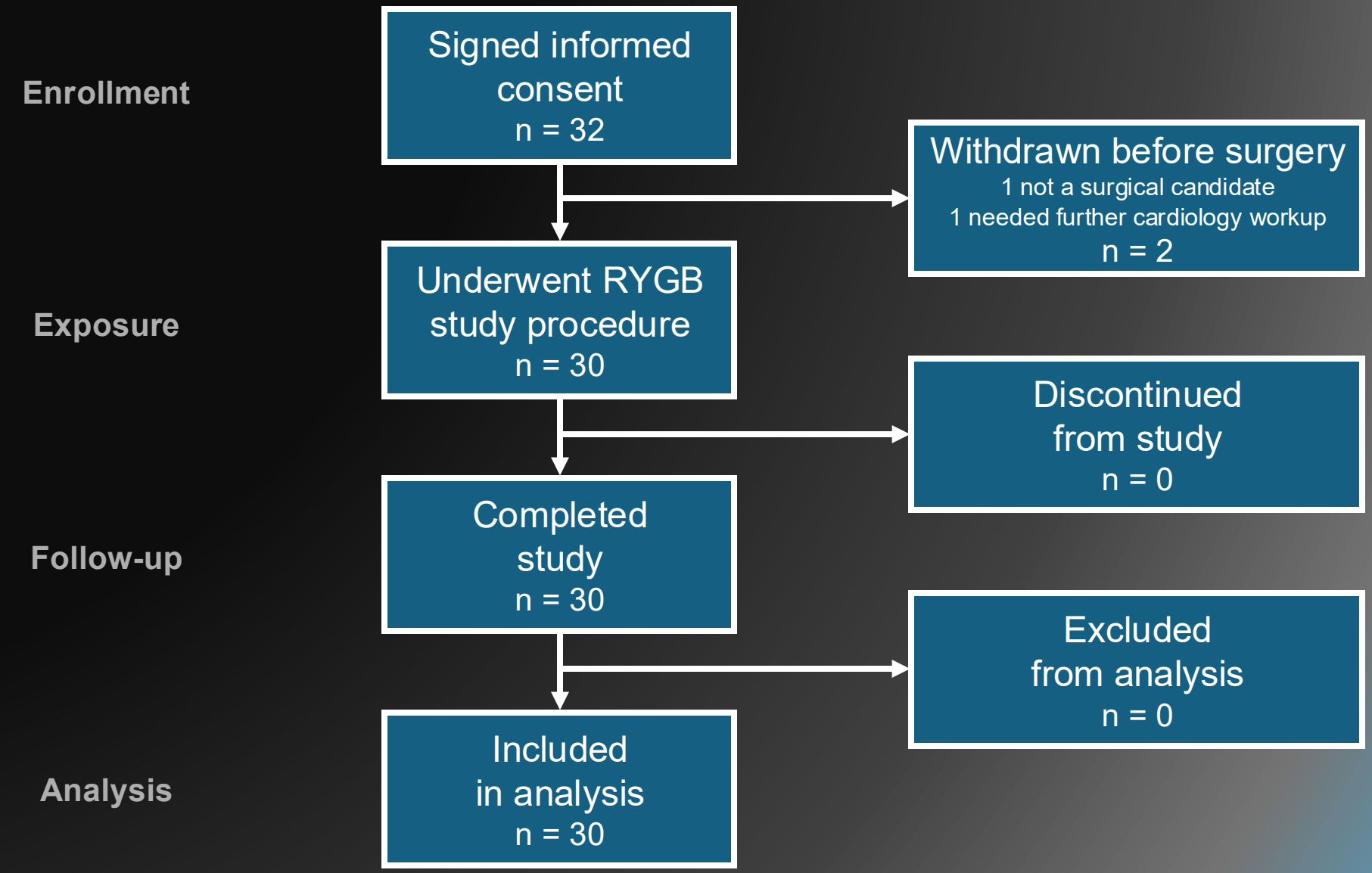
Follow-up Visit

30 ± 7 days after surgery

All adverse events recorded, followed until resolved or stabilized

Safety data adjudicated by Safety Management Team with two surgeons

Consort Diagram



Baseline Characteristics (N = 30)

Demographics

Age	41.8 ± 9.2 years
Female	22 (73.3%)
Black or African American Hispanic or Latino White	10 (33.3%) 7 (23.3%) 13 (43.3%)

Physical Examination

Height	168.0 ± 8.2 cm
Weight	134.3 ± 29.1 kg
BMI	47.4 ± 9.2 kg/m^2
Blood Pressure Systolic Diastolic	134.8 ± 12.8 mm Hg 83.5 ± 8.5 mm Hg
Heart Rate	82.4 ± 13.2 bpm
Oxygen Saturation	97.0 ± 2.2 %
ASA Classification II III	2 (6.7%) 28 (93.3%)

Comorbidities

Metabolic	Hyperlipidemia	9 (30.0%)
	Impaired fasting glucose	9 (30.0%)
	Diabetes mellitus	5 (16.7%)
	Nutrient deficiency	3 (10.0%)
Vascular	Hypertension	17 (56.7%)
	Deep vein thrombosis	2 (6.7%)
Respiratory	Obstructive sleep apnea	8 (26.7%)
	Asthma	7 (23.3%)
	Dyspnea	2 (6.7%)
Psychiatric	Depression	11 (36.7%)
	Anxiety	9 (30.0%)
	ADHD	4 (13.3%)
Gastrointestinal	GERD	9 (30.0%)
	Constipation	2 (6.7%)

Procedure Details

Table positioned in reverse Trendelenburg (13.3 ± 4.6°, range 7-30°)

- Adjusted intraoperatively in 8/30 (tilt 6, trend 4, translation 3, height 1)

Adhesions in 13/30 (upper abdominal 10, mid-abdominal 3, pelvic 1)

- Taken down robotically in 3, manual lap in 8, both in 1

2 robotic hiatal hernia repairs also performed

Hand-sewn gastrojejunal anastomosis in 24/30, stapling with suture closure in 6/30

Jejunojejunal anastomosis used stapling with suture closure in 17/30, fully stapled in 13/30

Leak test using gas endoscopy in 19/30, methylene blue in 11/30

- No clinically significant leaks detected

Port Placement

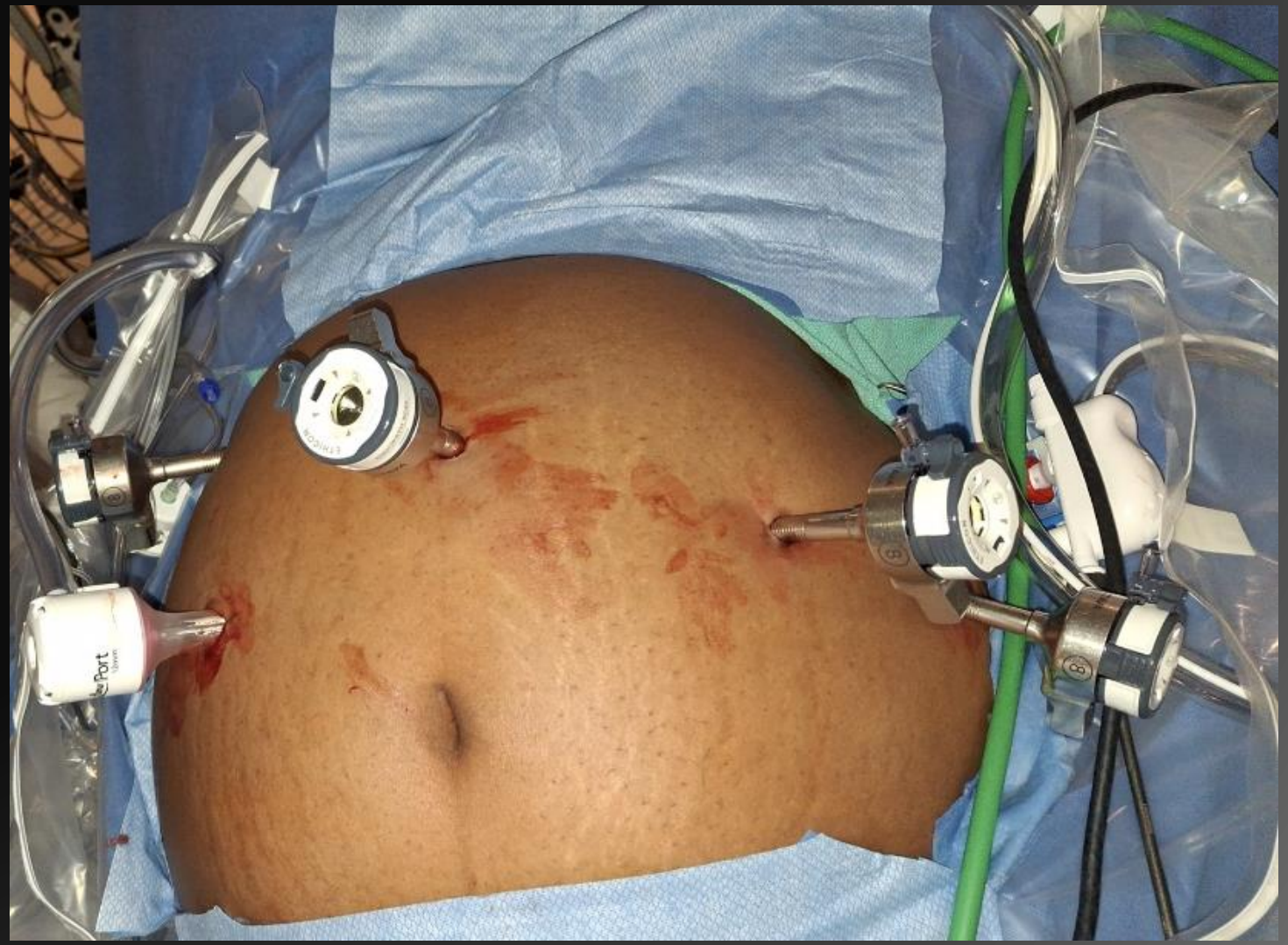
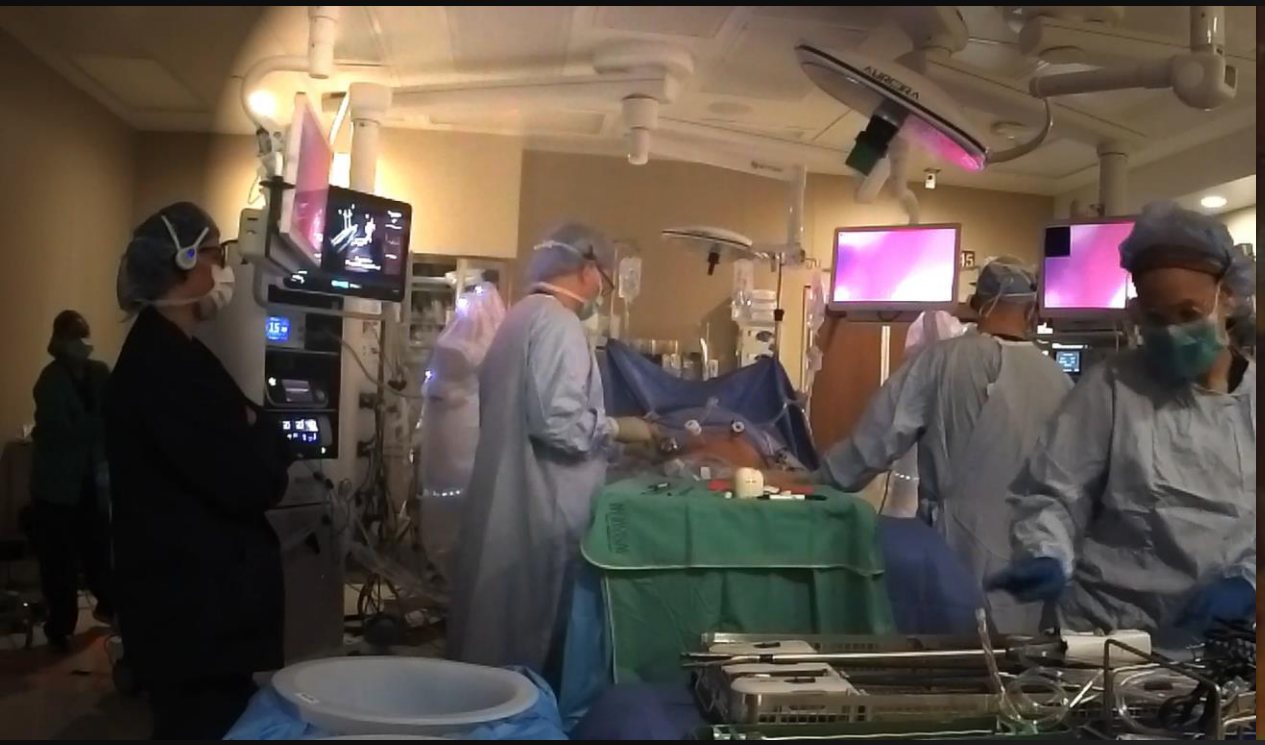
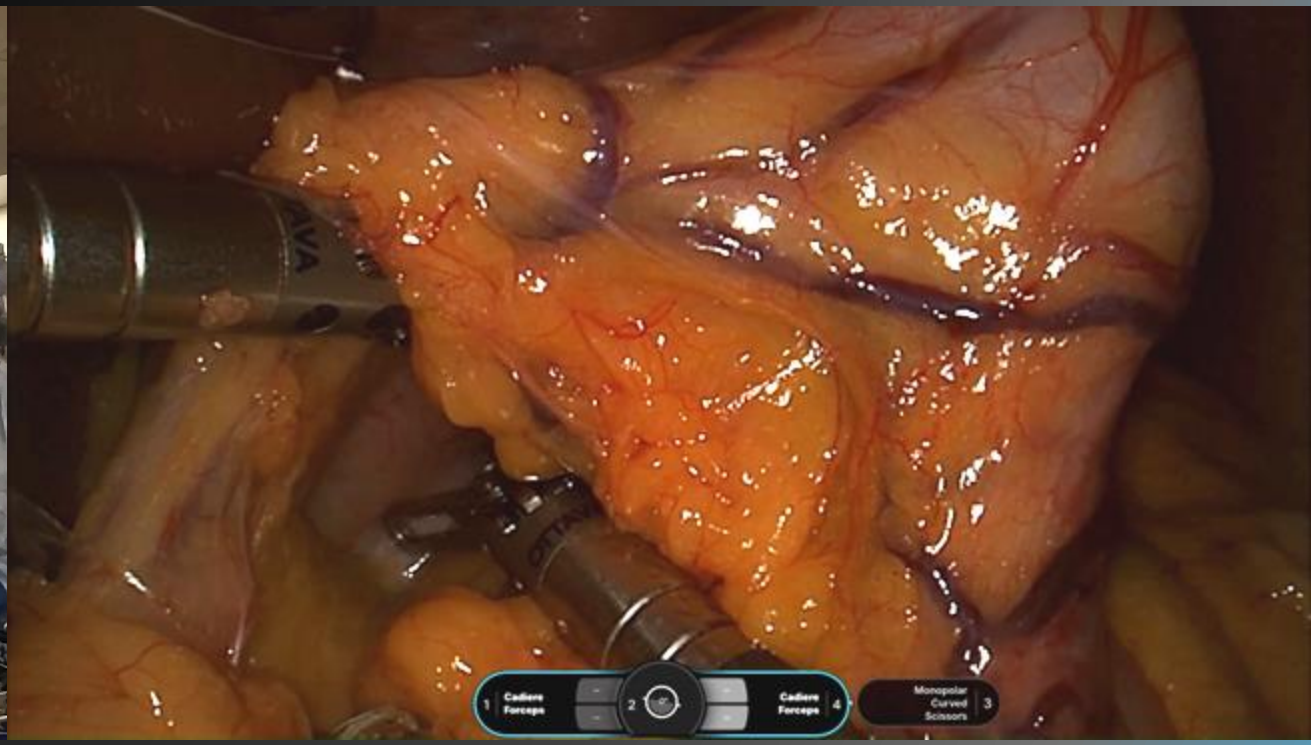
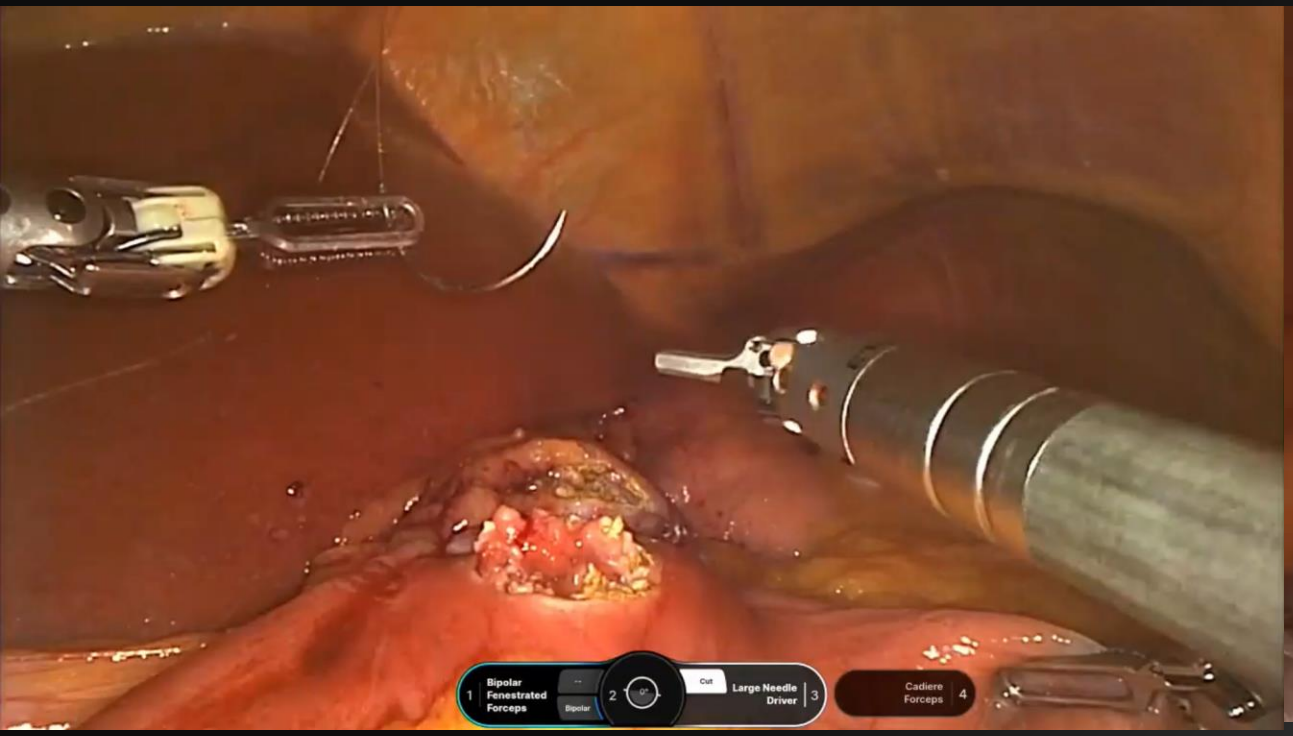


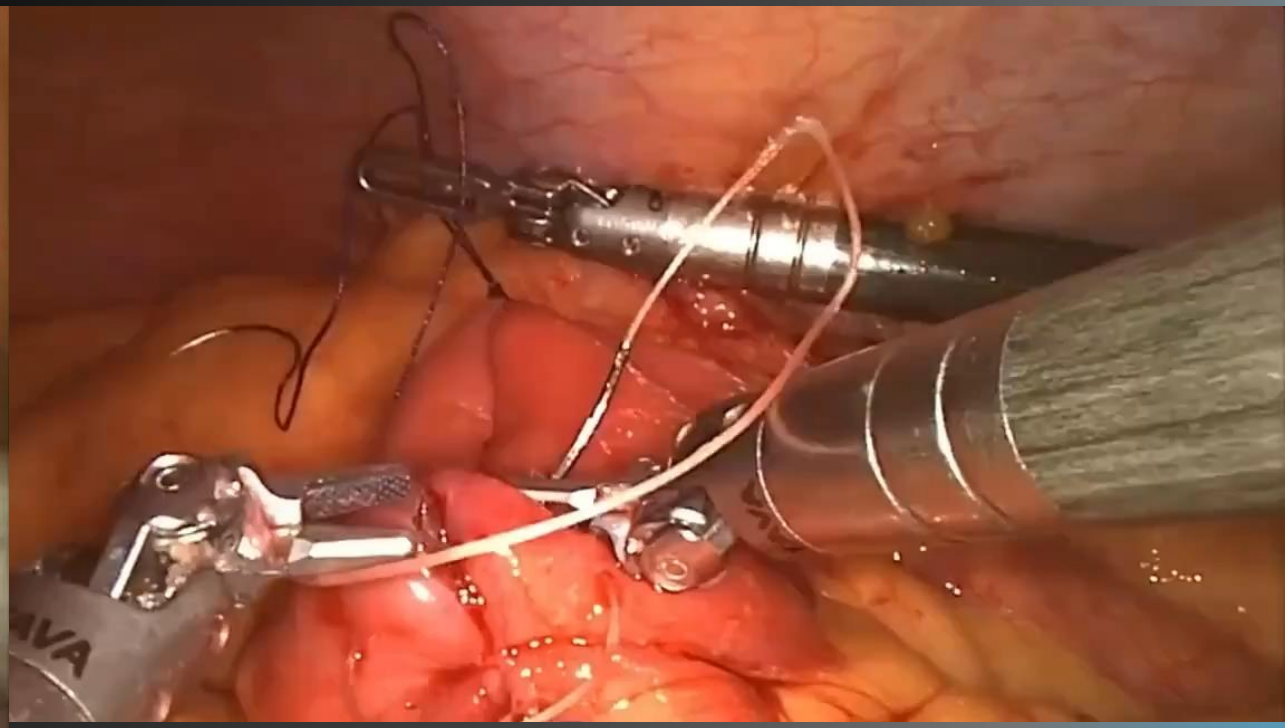
Table and Endoscopic View





Endoscope Video: Suturing

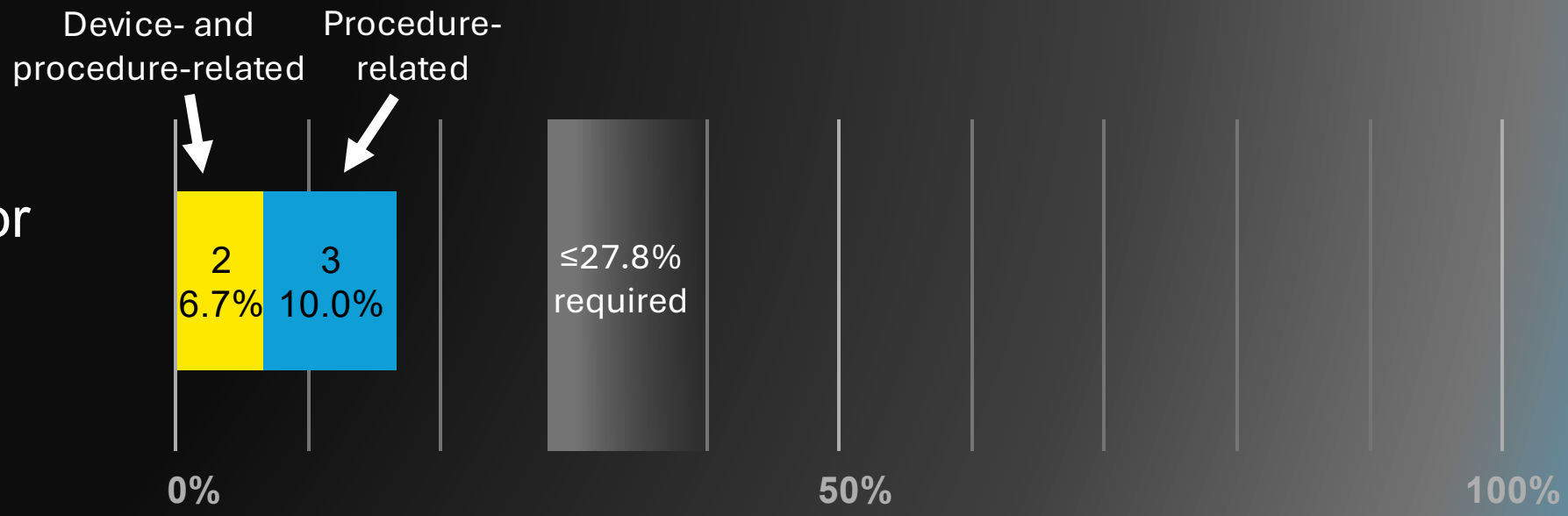




Results: Primary Endpoints

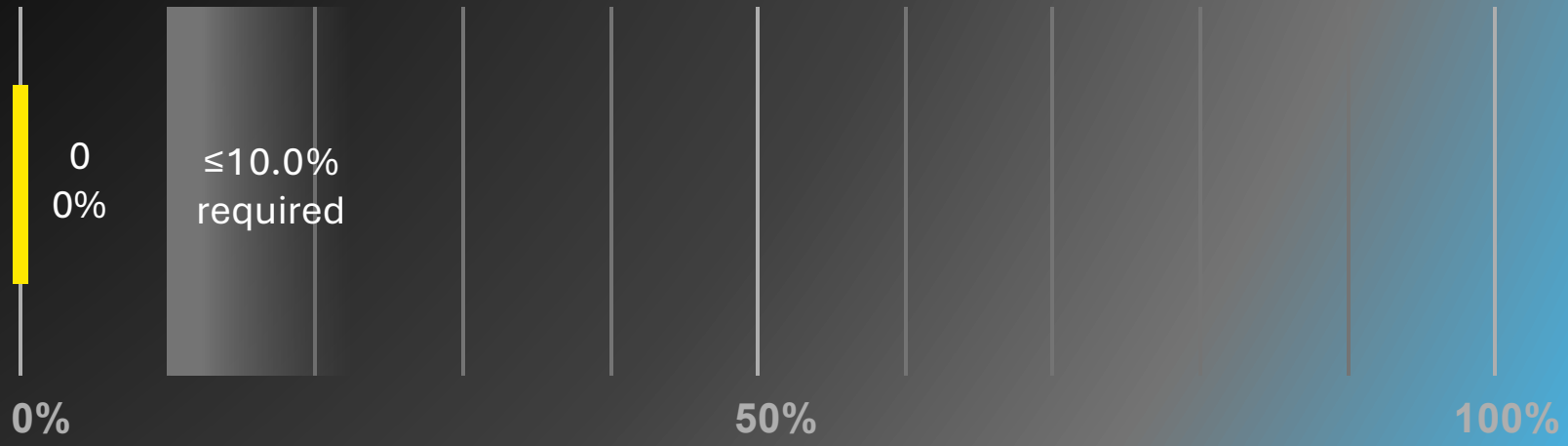
Primary Safety Endpoint

Subjects with device- or procedure-related complications

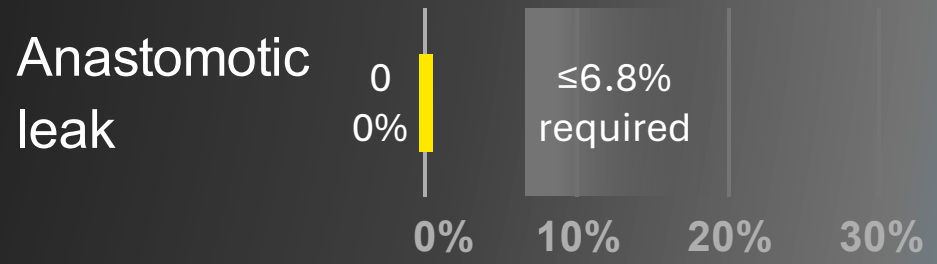


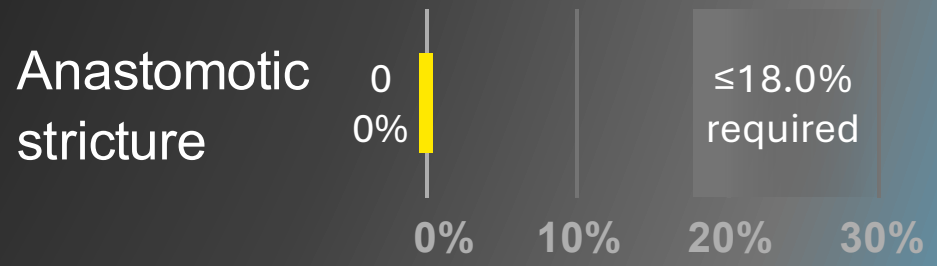
Primary Effectiveness Endpoint

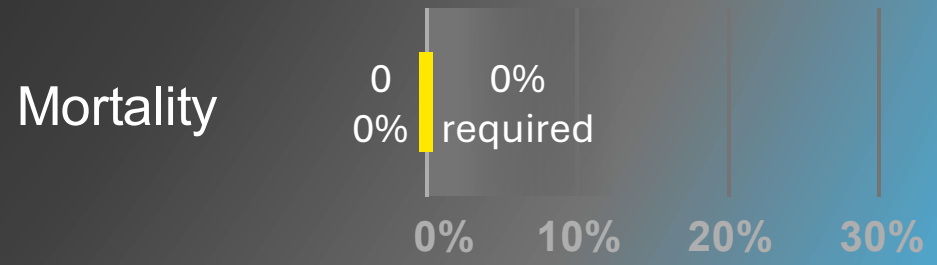
Procedure completion without conversion



Results: Secondary Endpoints







Results: Safety Data

5 Serious Adverse Events (SAEs):

Device- and procedure-related

Serosal tear while grasping tissue, repaired with suture

Tissue burn from unintentional energy delivery, repaired with suture

3 intraop SAEs
Clavien-Dindo 3b

Procedure-related

Bowel perforation during initial optical port placement, repaired with suture

Vomiting which led to 5-day stay in hospital

Clavien-Dindo 1

Intra-abdominal fluid collection drained, serous, straw color, negative culture

Clavien-Dindo 3a

Non-serious AEs included:

Abdominal pain in 28 of 30 patients

Nausea in 17 patients

Vomiting in 7 patients

Constipation in 5 patients

Tachycardia in 3 patients

Implications of Early Experience

OTTAVA was installed in a non-robotic OR in our hospital

We mostly performed 1 study procedure per day, sometimes 2 procedures/day

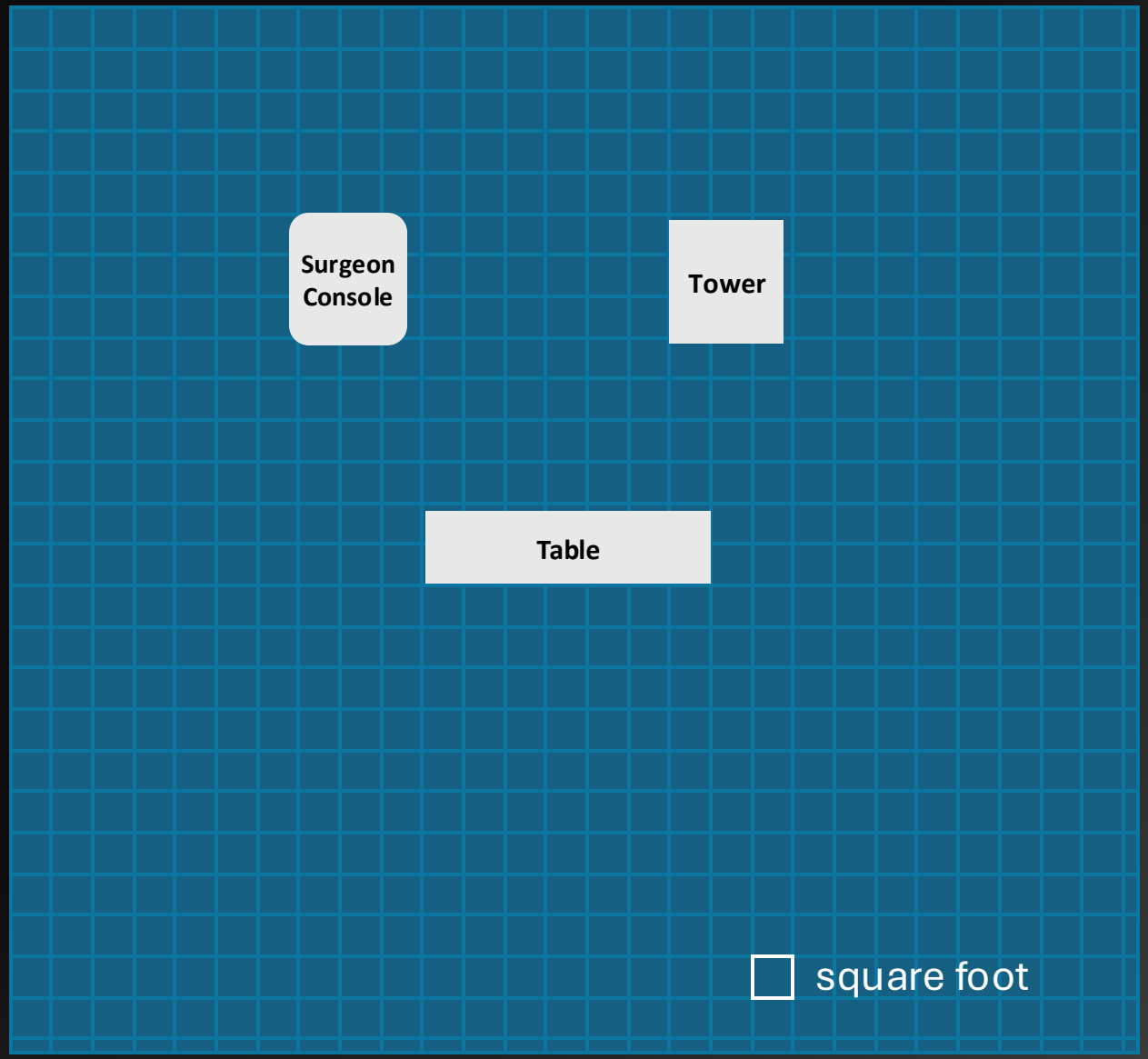
- Engineers did system check and data download after each procedure

We had surgeons at various points in their career, including a recent fellow

Rotating surgical staff, including some who were very experienced and others newer to robotic surgery

Imagining a mixed fleet of surgical robots

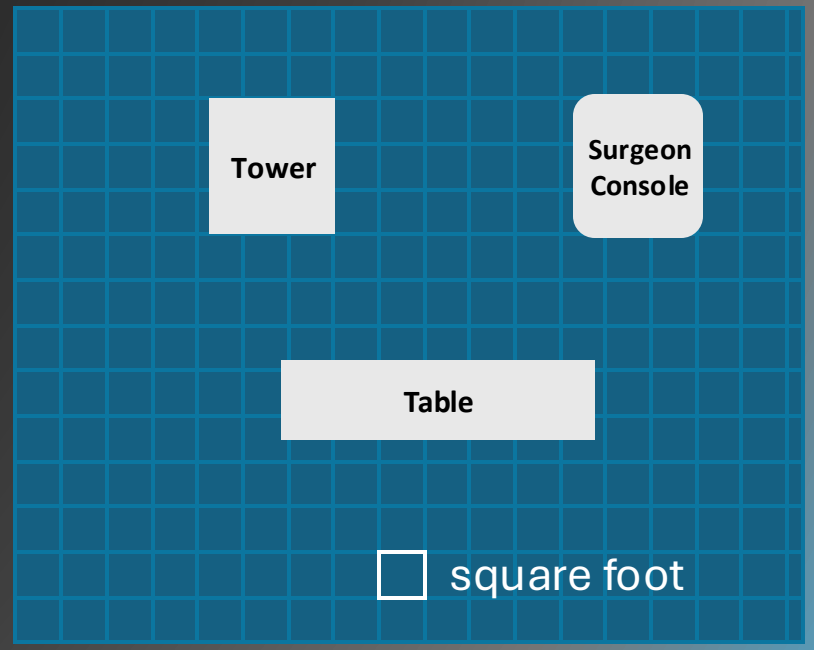
Footprint in Operating Room



5 of 6 sites used non-robotic ORs for study procedures

Largest OR:
694 sq. ft. (64.5 m^2)

Smallest OR:
243 sq. ft. (22.5 m^2)



Conclusions

First clinical use of OTTAVA Robotic Surgical System

5 of 6 sites used non-robotic ORs

All endpoints met pre-established success criteria

Procedure completed in all 30 subjects; no conversions or unexpected use of manual laparoscopy

Two adverse events related to the investigational device, both resolved by placing a suture and continuing the procedure

First clinical trial of OTTAVA evaluated ability to complete the RYGB procedure, and all endpoints met pre-established success criteria

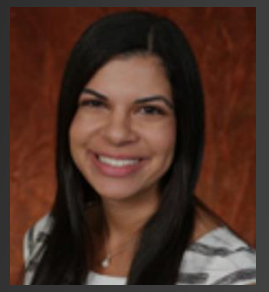
Thanks to Our Team!

Erik B. Wilson, MD

Oscar O. Olavarria, MD

Melissa Felinski, DO

Andre F. Teixeira, MD

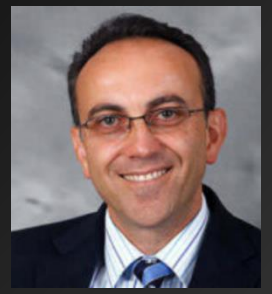


Estela Abich, MD

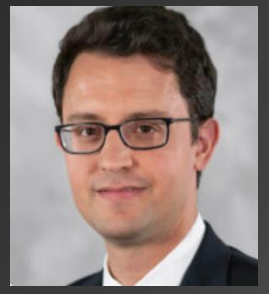
Collin E.M. Brathwaite, MD

Ranjan Sudan, MD

Shaina Eckhouse, MD



Dimitrios Stefanidis, MD



Tarik Yuce, MD

Christopher DuCoin, MD

MEMORIAL HERMANN Texas Medical Center

Duke Regional Hospital

Indiana University Health North Hospital

Orlando Regional Medical Center

TGH Tampa General Hospital

NYU Langone Health Long Island