

First-In-Human Clinical Trial of a New Robot-Assisted Surgical System For Use in Minimal Access Cholecystectomy Procedures

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OBJECTIVE

- To perform an interim safety analysis of the first-in-human clinical trial of a new robotic surgical system, Versius, when performing cholecystectomy procedures.

BACKGROUND

- Versius is a new tele-operated robotic surgical system designed to assist surgeons in performing minimal access surgery (MAS) (**Figure 1**).¹
- The surgical system has been developed to meet an unmet need in the provision of MAS. For example, it was designed with surgeons to ensure enhanced ergonomics, instruments mimic the articulation of the human wrist and the bedside units support the maximum maneuverability.¹⁻⁵
- The clinical development program is broadly in line with recommendations from the IDEAL-D (Idea, Development, Exploration, Assessment, Long-term study) collaboration for surgical research.^{6,7} This recognizes the difficulty in introducing a complex surgical system to clinical practice.
- Versius is currently undergoing a first-in-human, prospective, cohort, clinical trial to confirm the safety and effectiveness of the device when performing MAS procedures.
- This study reports on the first 15 cholecystectomy procedures, in alignment with IDEAL-D Stage 2a: Development. This builds on the previous preclinical work performed in developing the system.

METHODS

Ethical Board Review Statement

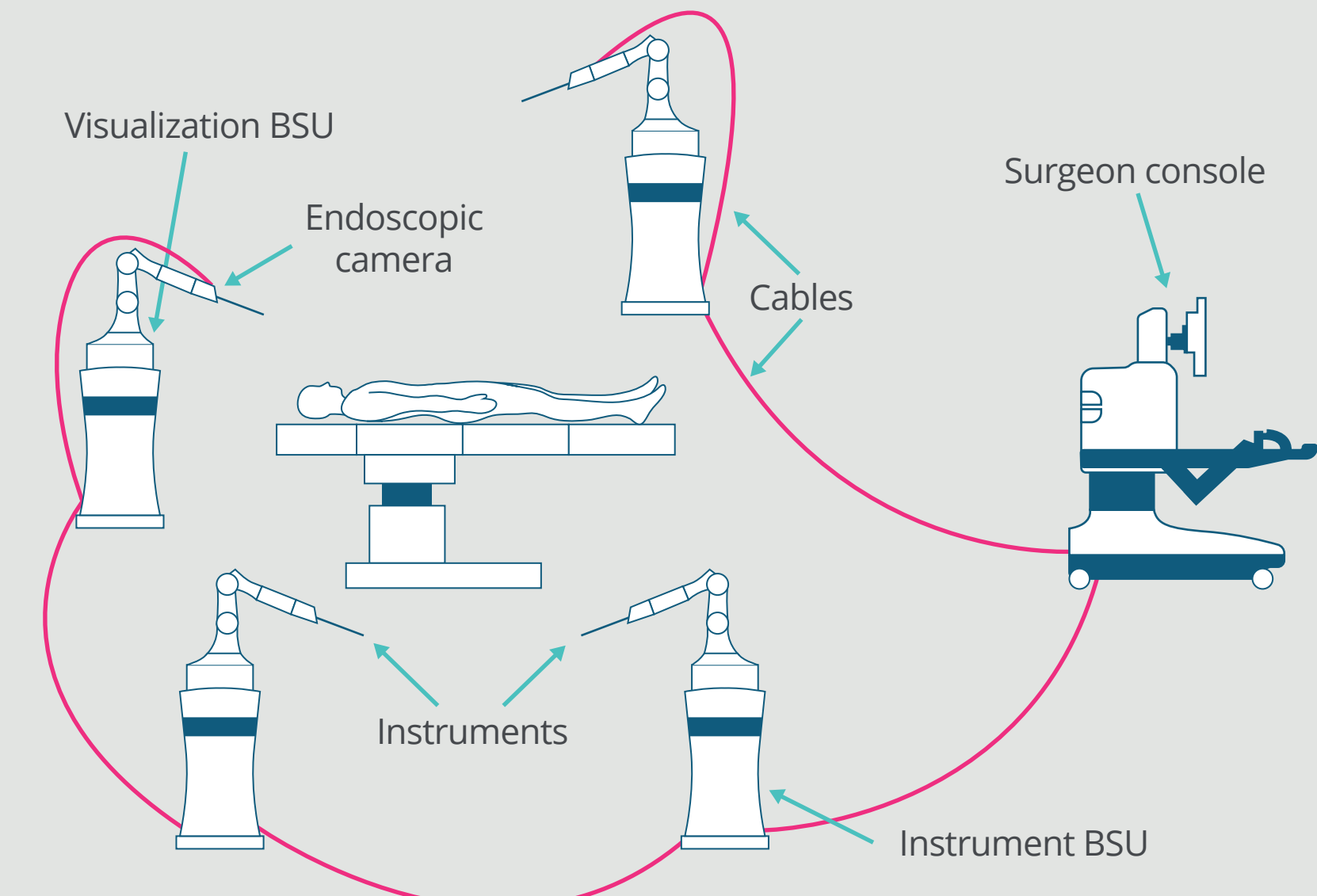
- Procedures were completed at the Deenanath Mangeshkar Hospital and Research Center, Erandawne, Pune, Maharashtra 411004, India, between March 8 and April 19, 2019.
- This study was reviewed and approved by the Institutional Ethics Committee, Deenanath Mangeshkar Hospital and Research Center (DGC registration no.: ECR/15/Inst/Maha/2013/RR-16; CTRI/2019/02/017872).

Surgical Team

- All members of the surgical team completed and passed the structured training schedule, including online training and a validated 3.5-day Versius training program (VT training), immediately prior to the start of the study. They also had additional experience in cadaveric cases.
- Lead surgeons were accredited, practicing, high-volume minimal access surgeons, as defined by >50 cholecystectomy cases/year.
- Potential patients were identified from Deenanath Mangeshkar Hospital surgical lists and approached directly by their surgeon or clinical team.
- Patients provided written and audio-visual consent. Patients were also asked for confirmation of consent immediately before the start of surgery.
- Following patient screening, hospitalization and discharge, patients had

Figure 1. Overview of the Versius Surgical System

A. Schematic representation of the setup of Versius



B. Demonstration of Versius in use



BSU: bedside unit.

a follow-up clinical visit or telephone call at 30 ($\pm$ 7 days) and 90 ($\pm$ 7 days) days post-operation (**Figure 2**).

- The primary endpoint was the rate of unplanned conversion of procedures to other MAS or open surgery.
- Secondary endpoints included:
 - Intra-operative complications
 - Complications occurring during hospital stay or within 90 days after discharge
 - Intra-operative blood transfusion
 - Estimated intra-operative blood loss
 - Return to the operating room within 24 hours and up to 30 days
 - Readmission to hospital within 30 and 90 days
 - Operative time (from incision to skin closure)
 - Length of hospital stay
 - 90-day mortality

Figure 2. Study Design



Figure 3. Patient outcome data

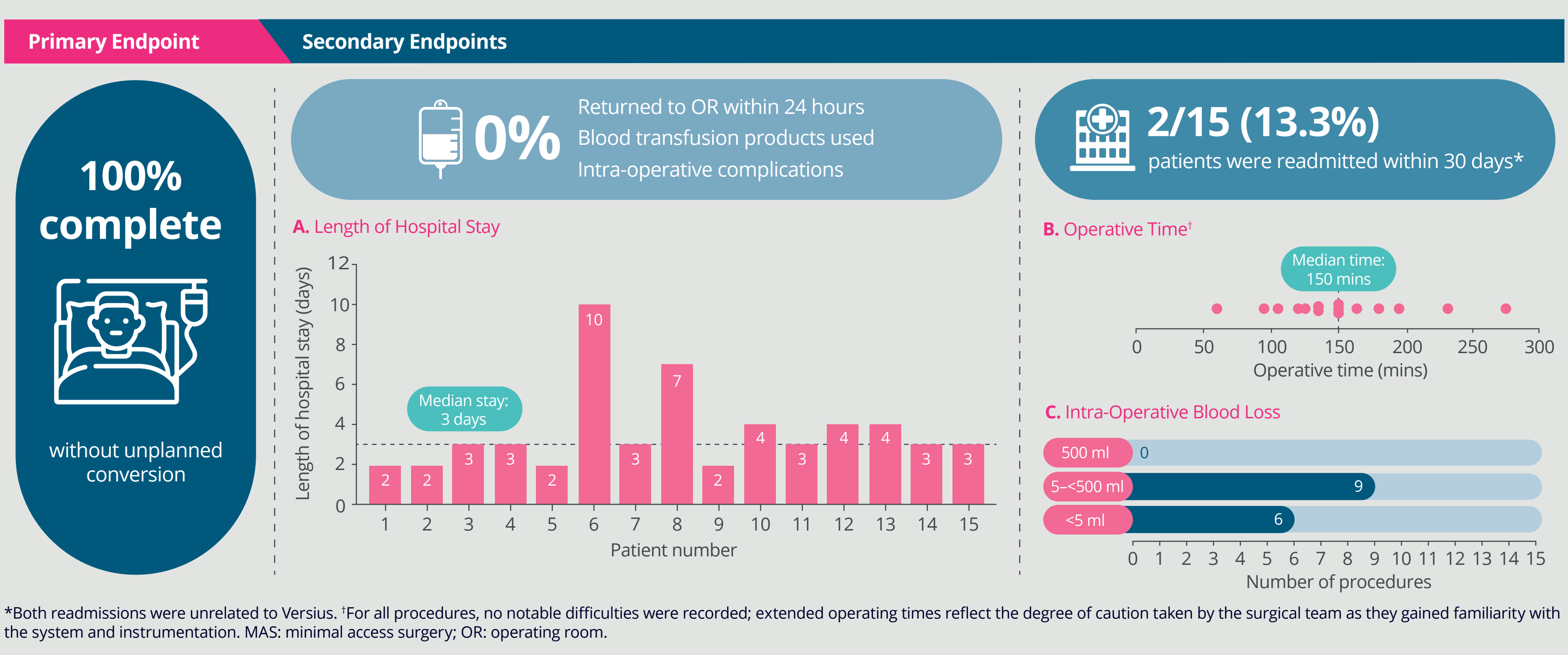


Table 1. Patient demographics and primary diagnoses

Case	Gender	Age (years)	BMI (kg/m ²)	Previous surgery?*	Primary diagnosis
1	Female	40	27.0	N	Cholelithiasis
2	Female	41	33.4	N	Cholelithiasis
3	Male	53	23.8	N	Cholelithiasis
4	Female	33	27.4	N	Cholelithiasis
5	Female	46	24.0	N	Cholelithiasis
6	Male	38	28.3	N	Cholelithiasis
7	Female	39	39.8	Y; not within the last year	Cholelithiasis
8	Male	64	22.6	N	Pancreatitis with cholelithiasis
9	Female	42	32.6	Y; not within the last year	Cholelithiasis
10	Female	52	41.5	N	Cholelithiasis
11	Female	27	29.6	N	Cholelithiasis
12	Male	33	29.9	N	Cholelithiasis
13	Female	56	25.8	N	Cholelithiasis
14	Female	28	26.8	N	Cholelithiasis
15	Female	34	23.2	N	Cholelithiasis

*Pelvic/abdominal surgery. BMI: body mass index; N: no; Y: yes.

RESULTS

Patient Demographics

- The first 15 cholecystectomy procedures performed using Versius were included for analysis. Patient demographics and primary diagnoses are presented in **Table 1**.
- Patients were aged 27–64 years (median: 40 years) and represented a wide range of body mass indices (BMIs), 22.6–41.5 kg/m² (median: 27.4 kg/m²). 73.3% (11/15) patients were female.

Patient Outcome Data

- All procedures were completed as planned and without recorded complications (**Figure 3**).
- Median stay in hospital was 3 days (range: 2–10 days), operating time ranged between 60–275 mins (median: 150 mins) and all patients had an estimated blood loss <500 ml (**Figure 3**).
- Two patients were readmitted within 30 days following surgery with acute gastroenteritis. Both were unrelated to Versius and made a full recovery; all patients completed the study.
- For video feed captured via the endoscopic camera during a procedure, please scan the QR code at the bottom of the poster.

CONCLUSIONS

- Surgeons and surgical teams were able to successfully complete robot-assisted cholecystectomies using the Versius system without experiencing any device-related difficulties.
- The first-in-human cases presented here justify continued patient recruitment onto the Versius clinical trial.
- Additional recruitment and analysis will ensure continued alignment with the IDEAL-D Framework Stage 2b: Exploration.

References

1. Hares L, *et al.* BMJ Surg Interv Health Technologies 2019;1:e000019; 2. Haig F, *et al.* BMJ Surg Interv Health Technologies 2020;2:e000028; 3. Carey M, *et al.* Gynecol Surg 2020;17; 4. Morton J, *et al.* Surgical Endoscopy 2020; 5. Thomas BC, *et al.* Eur Urol Focus 2020;5:2405-4569; 6. McCulloch P. Lancet 2009;374:1105-12; 7. Sedrakyan A, *et al.* BMJ 2016;353:i2372.

Author Contributions

Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: DK, MB, GG, UK, ED, LS; drafting of the publication, or revising it critically for important intellectual content: DK, MB, GG, UK, ED, LS; final approval of the publication: DK, MB, GG, UK, ED, LS.

Author Disclosures

DK, MB, GG and UK have none to declare; ED and LS received consultancy fees from CMR Surgical.

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