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New robotic platform for transoral robotic surgery: an IDEAL stage 0 study

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ABSTRACT

Objectives This study aims to assess the feasibility to perform transoral robotic surgery (TORS) with a new robotic platform, the Versius Surgical System (CMR Surgical, UK) in a preclinical cadaveric setting in accordance to stage 0 of the IDEAL-D framework.

Design IDEAL stage 0 preclinical assessment of the Versius Robotic System in TORS in human cadavers.

Setting All procedures were performed in a simulated operating theatre environment at a UK surgical training centre.

Participants 11 consultant head and neck surgeons from the UK, mainland Europe and the USA took part in TORS procedures on six human cadavers.

Interventions 3 key index procedures were assessed that represent the core surgical workload of TORS: lateral oropharyngectomy, tongue base resection and partial supraglottic laryngectomy.

Main outcome measures The primary outcome was the successful completion of each surgical procedure. Secondary outcomes included the optimisation of system setup, instrumentation and surgeon-reported outcomes for feasibility of each component procedural step.

Results 33 cadaveric procedures were performed and 32 were successfully completed. One supraglottic laryngectomy was not fully completed due to issues dividing the epiglottic cartilage with available instrumentation. Surgeon-reported outcomes met the minimal level of feasibility in all procedures and a consensus that it is feasible to perform TORS with Versius was reached. Available instrumentation was not representative of other robotic platforms used in TORS and further instrument optimisation is recommended before wider dissemination.

Conclusions It is feasible to perform TORS with the Versius Surgical System (CMR Surgical) within a preclinical cadaveric setting. Clinical evaluation is needed and appropriate with the system. Further instrument development and optimisation is desirable.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The Versius Surgical System is a new robotic platform that has not been trialed in transoral surgery before. The system is currently in use in other surgical specialities including gynaecology, urology and general surgery.

⇒ Initial feasibility study of the Versius robotic platform identified issues with instrument stability when applied to the transoral environment.

WHAT THIS STUDY ADDS

⇒ This study identifies that transoral robotic surgery (TORS) is feasible with Versius and prior issues identified during initial feasibility assessment can be overcome through optimisation of system setup. This study concludes that TORS is feasible and clinical stage 1 and 2a studies are appropriate.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study provides a preclinical assessment of the Versius Surgical System in TORS. The system is feasible for transoral applications and clinical assessment is appropriate. This may result in a wider range of robotic systems being available for use in transoral surgery.

INTRODUCTION

Transoral robotic surgery (TORS) was pioneered in 2005 and is now well established in the treatment paradigm of oropharyngeal pathology.[1 2] TORS offers a minimally invasive approach to the oropharynx without the morbidity associated with traditional jaw spitting or maxillary swing open techniques. Robotic-assisted surgery also offers the advantages of high-definition three-dimensional vision, tremor filtration, motion scaling, dextrous instrumentation and en bloc tumour resection that is not offered with other minimally invasive techniques.[1 3]

TORS was first developed for the management of early oropharyngeal malignancy but is expanding beyond this anatomical subsite and has expanding applications, both malignant and benign.[4–7] The clear advantages that robotic-assisted surgery provides are likely to continue to evolve and robotic-assisted surgery within the head and neck will continue to expand.

The current remit of TORS is largely limited by transoral access. The upper aerodigestive tract broadly resembles a funnel with the oral aperture the opening and the subglottis the

apex. As instruments pass distally down this funnel, the working space and surgical access become more limited. Current robotic systems perform well within the upper portion of this funnel, the oropharynx; however, effective surgery becomes more difficult as the anatomical space narrows. This phenomenon has been coined the 'funnel effect' and remains a significant hurdle in the expansion of transoral surgery.[8]

The robotic surgical landscape is rapidly expanding. Rapid technological development has resulted in the development of multiple novel devices and a rapid market expansion. These novel systems offer single port, flexible and modular devices.[9–11] The advent of new technology and surgical systems raises the possibility of overcoming the 'funnel effect'and expanding TORS into the larynx and other previously limited subsites.[12]

The Versius Surgical System is a novel robotic platform by CMR Surgical (Cambridge, UK) designed to overcome some of the challenges and limitations associated with currently available robotic systems. The system uses a novel modular design with multijointed instrument arms and a visualisation arm mounted on individual bedside units (BSU). The system can be setup in multiple configurations tailored to the required task. Each BSU is individually portable and can be transported between theatres and hospital sites. The operating surgeon interacts with the system through an open console, which uses polarised glasses to provide three dimensional high-definition optics. The system is operated through hand controls and the console is adjustable allowing the console surgeon to sit or stand.[13]

The Versius Surgical System has undergone in-human clinical trials for robotic-assisted surgery in gynaecology, general surgery and urology.[13–17] The system has proved to be safe and effective in these applications and is in clinical use in general surgery, urology, gynaecology and thoracic surgery. Initial feasibility of the Versius Surgical System for use in TORS and also robotic access to the nasopharynx and anterior skull base via a combined transorbital and transnasal approach has been previously reported by our group.[5 18]

The initial feasibility work conducted a three cadaver evaluation using two expert TORS surgeons.[18] This study aims to build on initial feasibility work and conduct a preclinical evaluation that evaluates and optimises the Versius surgical system for clinical study in TORS. This is in accordance with the IDEAL-D framework and recommendations for surgical innovation and constitutes an IDEAL-D Stage 0 study.[19 20]

METHODS

Study design

A series of human cadaver studies were performed at the Evelyn Cambridge Surgical Training Centre, UK between April 2021 and March 2022. All cadavers were fresh-frozen torso, head and neck specimens and donated with consent. All procedures were performed using the Versius Surgical System (CMR Surgical, Cambridge, UK) in a replicated operating theatre to reflect true clinical practice. The studies adhered to the IDEAL-D Stage 0 recommendations for pre-clinical studies.

Surgical team

Eleven consultant head and neck surgeons from the UK, France and USA with a wide spread of TORS experience participated in the study. TORS experience varied from newly established TORS practice to >2000 cases.

All procedures were performed by an operating surgeon with a trained bedside assistant surgeon as per recognised TORS practice. The lead surgeon performed all surgical steps of the procedure and evaluated the system in accordance with the study protocol. Bedside surgeon provided bedside assistance, including suction and manual retraction as per lead surgeons' instruction. During each procedure, a professional CMR surgical team provided expert advice at the console.

System familiarisation

All participating surgeons underwent a bedside walk-through and familiarisation of the Versius Surgical System prior to cadaveric assessments. Each surgeon was introduced to the system through the use of the Versius Virtual Trainer simulation programme prior to cadaveric procedures.

Theatre setup

Cadavers were positioned supine on a surgical table with a shoulder roll in place and head extended. The tongue was retracted using a silk suture and a soft rubber dental cheek retractor was used to retract the lips and cheeks. An FK retractor and Boyle-Davis gag with a selection of Doughty blades were available to provide oral retraction.

The Versius Surgical System was set up using two instruments and one endoscope BSU and a single surgical console. The BSUs were placed around the bedside and the instrument arms trained on the target site based on surgeon assessment and established standard technique for TORS. The robotic endoscope was placed through a bespoke endoscope stabilisation device and trained on the target surgical site. The BSUs were iteratively altered if instrument clashing occurred, or surgical access was impeded due to arm positioning. BSU positions were deemed suitable if there was adequate surgical access without instrument clashes and no need to reposition the BSU floor position during the procedure and if this was replicable between cadavers and surgical subsites. Surgical access was assessed through a surgeon-reported visual analogue scale (VAS).

Virtual pivot point

In TORS, the Versius Surgical System is operated without laparoscopic ports and each instrument must be trained around a virtual fulcrum or 'virtual pivot point' around which the instrument arms mobilise. This point is fixed in space and the optimal pivot point must be defined for TORS. Alongside cadaveric studies, a dry lab assessment of

Table 1 Biometrics of cadaveric specimens

Cadaver	Body Mass Index (kg/m^2)	Hyo-mental distance (mm)	Neck circumference (mm)	Mouth opening (mm)
1	27	70	390	45
2	19	65	380	35
3	22	55	405	40
4	22	60	420	45
5	17	65	385	50
6	27	65	355	40

the virtual pivot point (VPP) height range was performed. Each instrument arm was trained on the target anatomical site (lateral oropharyngeal wall, tongue base or supraglottis) and the VVP set. This VPP was adjusted to enable full reach for each anatomical subsite and to limit instrument clashes. The distance of the VPP in relation to the incisors was measured and recorded. Sequential increases in VPP were trialled. This process was repeated in the cadaveric environment. The workable range for VPP was 4–10 cm above the level of the incisors. Following defining the VPP effective range, a port training jig was used to set the VPP of each instrument arm. The port training methods demonstrated to each participating surgeon and then replicated.

Cadaver procedures

Three key index procedures were performed on fresh frozen cadavers: Lateral oropharyngectomy, tongue base resection and partial supraglottic laryngectomy.

Each procedure was divided into component procedural steps and each step was assessed individually.

0° and 30° endoscopes were available and Versius Surgical System Bipolar Maryland Graspers, Fenestrated Graspers, Monopolar Hook and Monopolar Scissors were available for each procedure and surgeons could change instruments on request.

Each surgeon undertook console and bedside roles. Surgeon-reported outcomes were recorded via a 0–10 VAS where clinical feasibility was predefined as 6. Outcomes were collected during the procedures by dedicated data collection personnel and subsequently through an anonymised debriefing questionnaire immediately following the dissection, including if there were any concerns regarding safety of the system (online supplemental appendix 1). Any instrument clashes and the completion of each component surgical step was recorded.

RESULTS

Cadaver biometrics

Six fresh frozen cadavers were used in this study. Table 1 shows cadaver biometrics.

Bedside setup

The Versius Surgical System was set up as per conventional TORS practice with one endoscope and two instrument arms. BSUs were placed around the bedside as directed by prior dry lab assessment. If during the surgical procedure significant instrument clashes occurred or access was not optimal, the BSUs were iteratively moved. Each position was recorded in relation to the head of the surgical bed. Each cadaver study was performed sequentially, and bedside setup carried over from previous studies. Table 2 documents the number of clashes that occurred requiring BSU repositioning per cadaver specimen.

Figure 1 demonstrates the final BSU setup range that was used. This setup with the endoscope BSU offset allows

Table 2 BSUs were positioned around the bedside, if instrument clashing limited surgical performance the BSUs were re-positioned

Cadaver number	Procedure	Number of bedside unit repositions
1	Lateral oropharyngectomy	0
	Tongue base resection	1
	Partial supraglottic laryngectomy	0
2	Lateral oropharyngectomy	1
	Tongue base resection	0
	Partial supraglottic laryngectomy	0
3	Lateral oropharyngectomy	1
	Tongue base resection	0
	Partial supraglottic laryngectomy	0
4	Lateral oropharyngectomy	1
	Tongue base resection	0
	Partial supraglottic laryngectomy	0
5	Lateral oropharyngectomy	1
	Tongue base resection	0
	Partial supraglottic laryngectomy	0
6	Lateral oropharyngectomy	1
	Tongue base resection	1
	Partial supraglottic laryngectomy	0

The number of clashes requiring BSU repositioning is demonstrated.
BSUs, bedside units.

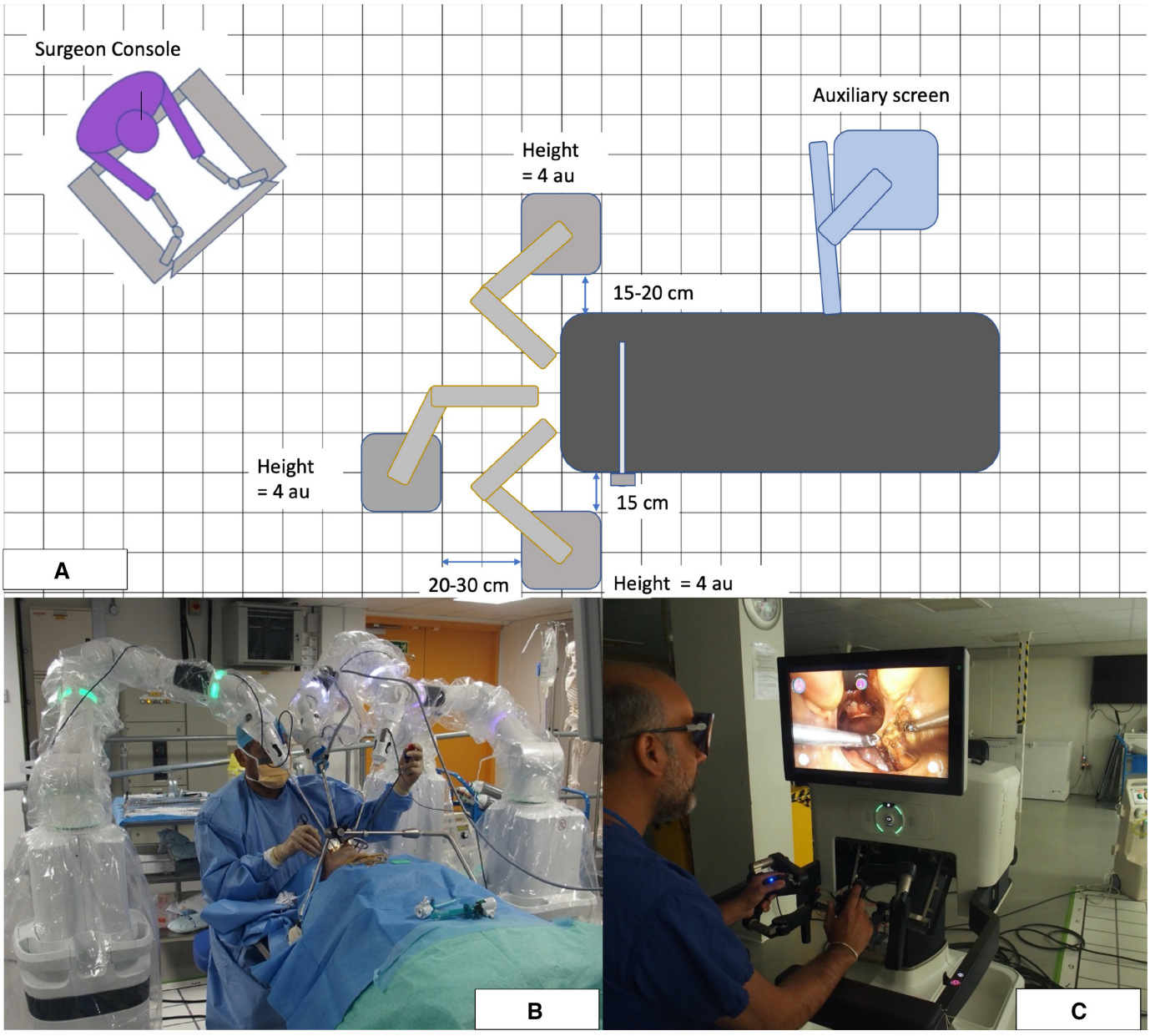

Figure 1 (A) Optimal BSU placement around the bedside to allow bedside surgeon access and provide optimal robotic access with limited instrument clashes. (B) Photograph of Versius (CMR Surgical) beside unit placement and bedside surgeon assisting. This setup maximised bedside surgeon access to the oral cavity without limiting surgical access. (C) The operating surgeon sits at the Versius (CMR Surgical) open console, 3D vision is provided via 3D glasses and the system is controlled through hand controllers. BSU, bedside units.

seating space for the bedside surgeon while maintaining transoral access and minimising instrument clashes.

Instrument stability

During the previously published feasibility cadaver studies, significant tremor of the instrument and endoscope arms was experienced when the operating surgeon activated that arm.[18] Four solutions to address this issue were undertaken. Manual stabilisation, resting instrument arms on the cheek retractor, setup optimisation and a bespoke stabilisation device were trialled. Manual stabilisation was effective at reducing tremor however not optimal as it required constant active input from the bedside surgeon. Resting the instrument shafts on the cheek retractor was found to be effective, however, this applied lateral stress to the instruments when working laterally and was deemed not suitable. Throughout the course of the studies, the Versius Surgical System received updated instrumentation, software and combined with optimisation of port training position was found to effectively reduce instrument tremor without the need for additional stabilisation techniques. It was agreed that the addition of a bespoke stabilisation solution was no longer required. Figure 2 demonstrates VAS of surgeon-reported outcomes on instrument stability prior and post

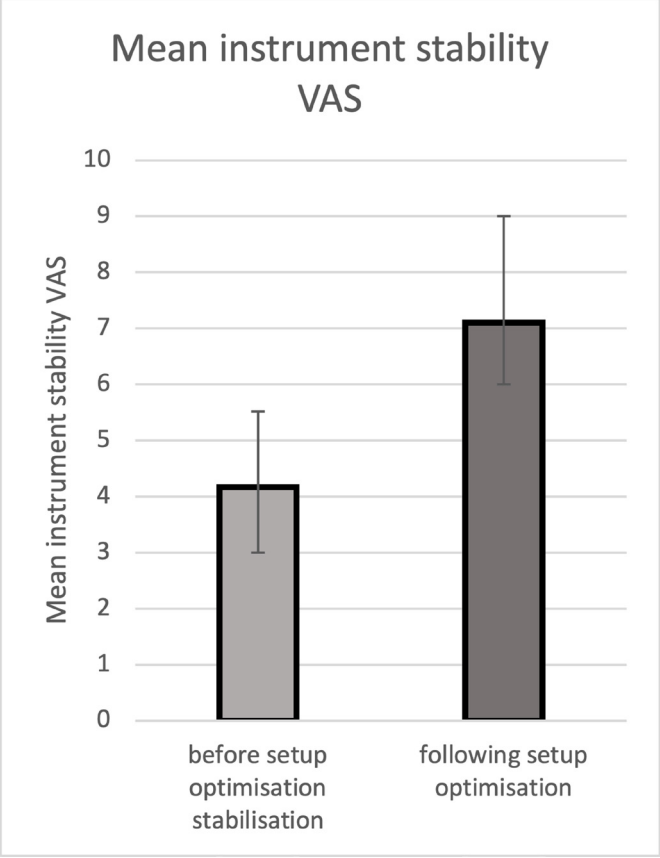

Figure 2 Mean instrument stability VAS prior and post setup optimisation. Each study consists of two surgeon ratings of each index procedure. VAS ranges from 1 (clinical unachievable) to 10 (perfect), 6 was deemed clinically usable prior to the study. Error bars demonstrate range. VAS, visual analogue scale.

setup optimisation. The optimal setup is outlined in the previous BSU and VPP setups.

Completion of procedures

In total 33 transoral robotic procedures were performed on six cadavers. 32 procedures were performed to completion (table 3). One supraglottic laryngectomy was not completed due to inability to divide the cartilaginous epiglottis with monopolar electrocautery. No safety concerns were raised by any participating surgeon. Each surgeon-reported VAS for each component step are reported in figure 3.

Instrumentation

Surgeons preferred to use the 0° endoscope to perform lateral oropharyngectomy and the 30° endoscope angled up for the tongue base and supraglottic procedures. All surgeons used either the Fenestrated Graspers or the Bipolar Maryland Graspers to provide tissue retraction. All 11 surgeons noted that in a clinical setting, the graspers are used to provide haemostasis and require an electrocautery function with bipolar diathermy most highly desired. All surgeons preferred to perform dissection with the monopolar hook with the exception of a single surgeon who preferred monopolar curved scissor as these reflect their clinical practice. All 11 surgeons commented that the monopolar hook was feasible to perform the dissection, however is not clinically representative of their usual practice. Online supplemental appendix 2 is a video recording of a right lateral oropharyngectomy demonstrating the use of Versius in TORS with fenestrated graspers and the monopolar hook.

DISCUSSION

In this series of cadaver evaluations, 33 transoral procedures were performed on six cadaveric specimens. One procedure was not completed due to difficulty dividing the cartilaginous epiglottis with available instrumentation. No significant limitations were found and all surgeon-reported outcomes rated the Versius Surgical System as feasible to perform TORS in all key index procedures. The index procedures evaluated represent the majority of the current TORS workload and the Versius Surgical System has been demonstrated to perform effectively in these domains.

This study builds on the initial feasibility work and performs an IDEAL-D stage 0 evaluation of the system to perform transoral surgery.[18] Development and optimisation of a standard setup of the individual BSU have overcome limitations of the system within TORS identified at the initial feasibility studies. The Versius Surgical System is usually deployed through laparoscopic ports into a visceral cavity. Initial trials suggested that when applied transorally, without laparoscopic ports, the instruments suffered from significant tremor.[18] Optimisation of BSU and VPP placements combined with system developments has reduced the number of instrument arm clashes and addressed this limitation. Surgeon-reported outcomes

Table 3 Summary of procedures completed

Procedure	Number performed	Number completed	Mean setup time (min)	Mean operative time (min) (range)
Lateral oropharyngectomy	12	12	13	36 (22–47)
Unilateral tongue base resection	12	12	10	25 (12–34)
Partial supraglottic laryngectomy European Laryngology Society Type IIa	9	8	22	43 (21–61)
Total	33	32		

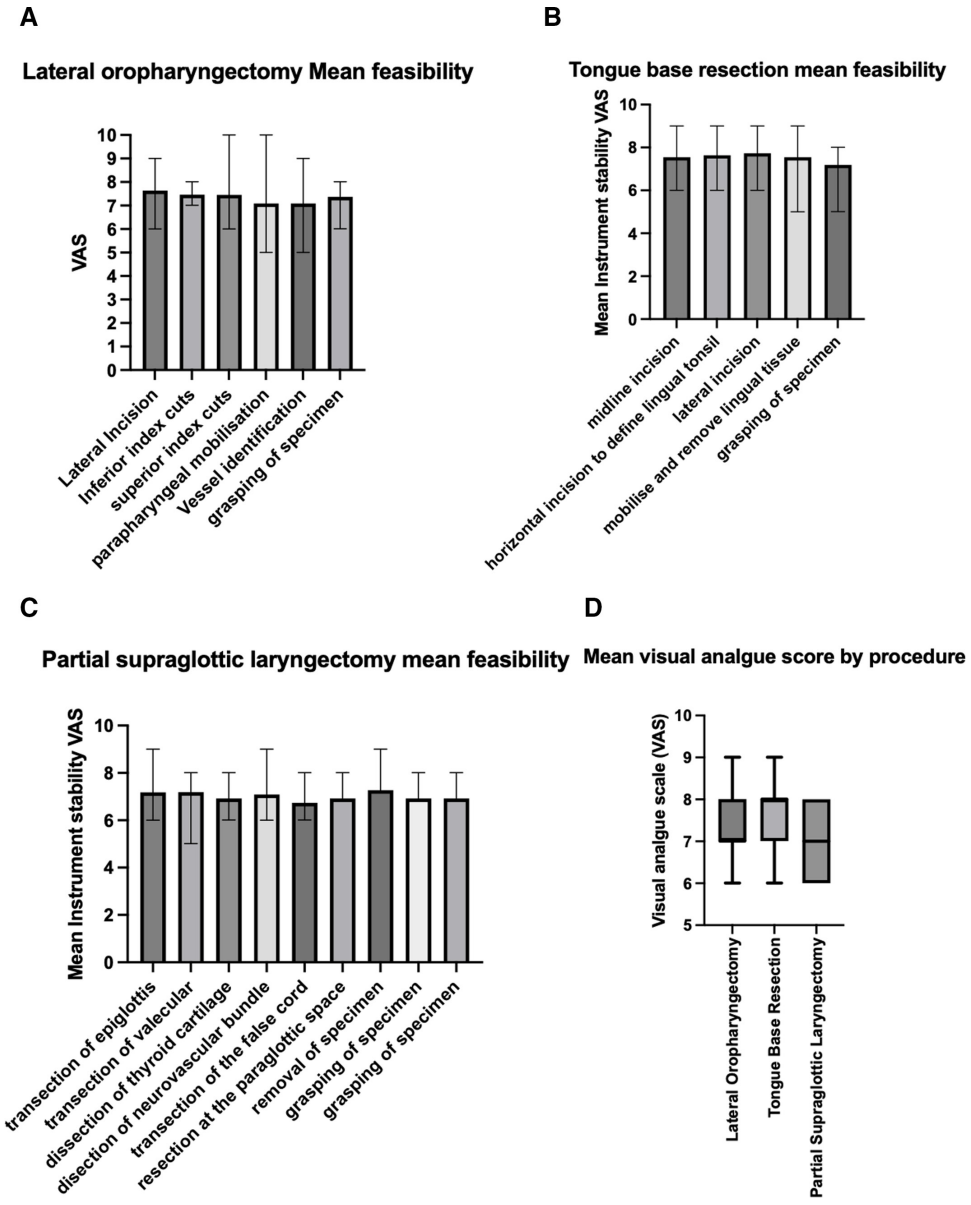

Figure 3 Mean feasibility VAS. For (A) lateral oropharyngectomy, (B) tongue base resection, (C) partial supraglottic laryngectomy and (D) mean for each procedure. VAS ranges from 1 (clinical unachievable) to 10 (perfect), 6 was deemed clinically usable prior to the study. Error bars demonstrate range of VAS. VAS, visual analog scale.

demonstrate that additional instrument stabilisation is no longer required. Endoscope stability remained an issue for some participating surgeons despite setup optimisation. Others commented that camera stabilisation was unnecessary as once positioned in the target area the endoscope was not regularly moved. This is theorised to occur due to the additional mass of the endoscope requiring additional dampening beyond that achievable through setup. This study successfully trialled the use of a stabilisation prototype that provided sufficient stability for effective surgery to be performed. However, the need for additional stabilisation may reduce with formalised training and follow a learning curve as experienced with novel surgical devices and further evaluation of learning curve assessment may be appropriate.

VVP optimisation was undertaken and an optimal VPP range was established. VPP evaluation studies demonstrate that the closer to the oral cavity the more optimal the VPP due to reduced horizontal movement of the instruments at the plane of the pivot point. This reduces instrument clashes and improves access. The Versius Surgical System requires the instrument arms to be inserted 5 cm beyond the VPP before they can be controlled. Due to this inherent feature, the VPP cannot be placed at the level of the entry into the oral cavity as surgical targets, including the tonsils and tongue base lie too close to this 5 cm marker to enable operating by the console. This study demonstrates the closest distance that the VPP could be set and allow full surgical access, which was 4 cm above the incisors. Subsequent development

of the Versius platform to reduce this '5 cm rule' would allow further VPP optimisation.

It has been previously hypothesised that performing procedures distal in the upper aerodigestive tract is surgically more challenging and leads to an increase in instrument clashes. This was not represented in our cohort with all significant clashes requiring system adjustments occurring in the lateral oropharyngectomy or tongue base procedures. Changing to a 30° endoscope was found to increase tongue base access. When performed, procedures were performed sequentially from lateral oropharyngectomy to tongue base resection to supraglottic laryngectomy. In doing so, if clashes occurred and the system setup was changed, it was then further optimised for subsequent procedures, which may have resulted in fewer distal access issues.

All the cadaver studies were performed using currently available Versius Surgical System instruments. The primary cutting device used was a monopolar diathermy hook and the primary grasping devices were either bipolar Maryland graspers or non-powered fenestrated graspers (demonstrated in online supplemental appendix 2—video of lateral oropharyngectomy). This selection of instruments differs from what is conventionally used in TORS, which typically uses bipolar diathermy grasping forceps (typically Maryland or fenestrated forceps) and a monopolar cutting device (typically a monopolar spatula). In these cadaveric studies, intraoperative bleeding could not be replicated and bipolar diathermy for hemostasis was not required. All surgeons reported that all three procedures were feasible with the currently available instrumentation, however, 10 of the 11 participating surgeons noted that they would prefer a spatula that would enable surgery to be performed more in line with established techniques. TORS is feasible with the current instrumentation, however ease of adoption of a new system would likely be enhanced with the addition of a monopolar spatula and bipolar-enabled fenestrated graspers.

All participating surgeons were current substantive head and neck consultants within the UK, France or USA. Experience of TORS was variable between the operating cohort, however, usability of the system and ability to perform surgical procedures was not limited by surgeons' experience. More experienced surgeons encountered fewer instrument clashes and faster operating times and were less limited by endoscope stability, however, experience did not affect the ability to successfully complete the procedures. This suggests that this platform is suitable for adoption by a wide range of surgeons. Further learning curve work should be performed to fully evaluate adoption of TORS competencies, however, this should not limit progression to clinical trials.

The Versius Surgical System was deemed feasible in all three index procedures, however, the system performed most effectively within the oropharynx compared with the supraglottis. This is consistent with other current multiport robotic systems and consistent with limitations associated with the funnel effect.[8] The use of a 30° endoscope and FK retractor for tongue base and supraglottic procedures increased working space and allowed all procedures to be performed, however, access to sites distal to the supraglottic larynx is likely to still be limited by anatomical constraints.

Study limitations

This study addressed the limitations of the prior feasibility study and conducted an IDEAL-D stage 0 preclinical study with multiple participating surgeons in six cadaveric specimens. All procedures were performed in a replicated theater environment and feasibility was demonstrated. Cadaveric studies replicate human anatomy but are limited in the assessment of live tissue handling, dissection and haemostasis. The Versius Surgical System has previously been assessed in porcine studies and is in current clinical use in abdominal and chest applications and, therefore, further living animal studies for TORS where anatomy is not effectively represented is deemed not to be of significant benefit.[17 21]

This study assesses the feasibility of the Versius Surgical System to perform transoral procedures but does not provide a comparison to other robotic platforms or conventional transoral techniques. A direct comparison trial would be of significant value in determining the efficacy of Versius in TORS.

CONCLUSIONS

This study has used the IDEAL-D framework to undertake preclinical evaluation of the Versius Surgical System (CMR Surgical, Cambridge, UK) for TORS in a cadaveric setting. This cadaveric evaluation has helped optimised the Versius system though establishing bedside setup, VVP and addressing prior requirements for instrument and endoscope stability. All three evaluated key index procedures were completed in full without significant limitation. This study demonstrates preclinical feasibility of the Versius Surgical System to perform TORS and concludes that it is appropriate to conduct first in man trials. Further optimisation of instrumentation and port training methods are required prior to further wider dissemination.

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Patient consent for publication Not applicable.

Ethics approval All cadaver studies were conducted at The Evelyn Cambridge Surgical Training Centre, Back Lane, Melbourn, Hertfordshire, SG8 6DP, UK. The Evelyn Centre is certified as Health Tissue Authority (HTA) compliant under licence number: 12 603. All studies conducted by CMR Surgical at The Evelyn Centre met the required HTA, health and safety, and ethical considerations relating to the use of donated cadaveric tissue in dissection, research and development.

Provenance and peer review Not commissioned; externally peer-reviewed.

Data availability statement Data are available upon reasonable request. All data collected are available on request.

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