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Validation of a High-Fidelity Ventral Hernia Model

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Abstract

Introduction

Robotic ventral hernia repair is increasing worldwide. Few robotic ventral hernia simulation models are commercially available. There is a need for high-fidelity simulation models within this domain. We aimed to evaluate the validity of a IMRA Surgical hydrogel model currently in use as part of the national postgraduate residency training programme in Ireland.

Methods

A mixed-methods study was performed. Twenty participants drawn from a convenience sample were randomly assigned to perform a robotic transabdominal preperitoneal ventral hernia repair on a minimum of two robotic platforms: Versius™ (CMR Surgical, United Kingdom), Hugo™ robotic-assisted surgery (RAS) system (Medtronic, Dublin, Ireland), and Da Vinci X/Xi™ (Intuitive, Sunnyvale, CA, USA). Recorded procedures were assessed quantitatively for performance independently by a minimum of three blinded expert assessors using GEARS and RACE scores. Participant views and examiner responses were gathered from subjective feedback. Analysis and validity evidence were interpreted using Messick's Framework.

Results

Twenty participants completed forty-six robotic ventral hernia repairs using the IMRA Surgical simulated hydrogel model. Most experts (75%) agreed that the model appropriately simulated realistic human anatomy and tissue handling. Each procedural micro-component (and defined psychomotor skill) was described by participants as being more realistic using the hydrogel models compared to other simulation models they had used. GEARS (early resident 16 vs senior resident 16.71 vs attending 18.5, p-value 0.0051) and RACE scores (early resident 18.75 vs senior resident 19.92 vs attending 21.67, p-value 0.0078) were persistently higher and proportionate to the grade of individual operative experience.

Conclusion

We have shown that IMRA Surgical hydrogel ventral hernia models have collated substantial validity evidence, including face, content and construct validity. Whether the skills acquired on this model can translate into improved in-vivo operative performance remains to be elucidated.

Terms of Reference (1, 2)

Ventral Hernia	Any abnormal protrusion of intra-abdominal contents through a weakness or defect in the abdominal wall
Content Validity	Test items are representative of the construct of interest
Construct Validity	The simulator can accurately differentiate candidates based on relative surgical skill; this represents the ability of a simulator to be used as an assessment tool
Face Validity	The impression of how realistic a simulation feels (“haptic”) and looks; this concept includes the acceptability of a simulator to the trainee
Response process	Evidence of data integrity, including clear test instructions, rater training, methods for scoring, and data entry
Internal structure	Psychometric properties including score reliability, examination difficulty, and inter-item correlations that help to assess factor structure
Relations with other variables	Convergent and discriminant evidence, including correlations to other variables that would be expected based on theory
Consequences	Impact on learners, instructors, and the system in which the assessment is made

Introduction

Ventral hernias can arise spontaneously or secondary to the failure of a previous incision closure after any primary abdominal surgery. (3) Contemporary practice has increasingly availed of innovative robotic surgical approaches for treating ventral hernia. (3, 4) These include rTAPP (robotic ventral transabdominal pre-peritoneal repair), TARUP (robotic transabdominal retromuscular umbilical prosthetic hernia repair), eTEP (robotic enhanced view totally extraperitoneal), and rTAR (robotic transversus abdominus release) techniques. Due to the steep learning curve associated with these novel approaches, undertaking them without appropriate governance or adequate training can result in significant complications for patients. (5–7)

For surgical trainees, robotic hernia training is hindered by limited exposure volume. (8) A requirement to attain minimum proficiency thresholds using simulation prior to in-vivo operating is the current best practice. (9) Deliberative practice of deconstructed tasks using defined key components of operations enables entrustment of discrete steps to trainees. (10–14) Simulation-based education can facilitate deliberative repeated supervised practice in a safe environment and expedite an accelerated learning curve of trainees. In fact, it has been incorporated into core robotics skills curricula. (10, 14–16)

Although advanced virtual reality simulators have been developed, they still lack realistic tissue handling and the consequences of haptic and psychomotor tele-manipulation. (17) In contrast, animal and cadaver models provide for high-fidelity training. Unlike in other general surgery procedures (e.g. anterior resection, colectomy, parenchymal sparing liver resection), these models lack the requisite pathology for a training procedure, i.e. a ventral hernia. Furthermore, cost and ethical considerations limit their use. (17) More recently, three-dimensional hydrogel models have been described as a viable alternative to

cadavers and animal models. (15) IMRA Surgical (International Medical Robotics Academy, Melbourne, Australia) has developed hydrogel models that provide opportunities for realistic dissection. (18–20) These have been used by the Royal College of Surgeons in Ireland (RCSI, Dublin, Ireland) as an adjunct to the delivery of their postgraduate national residency training curriculum. (21)

The aim of this study was to assess the validity of the IMRA Surgical hydrogel model as part of an ongoing review and reform of the robotic curriculum at RCSI, Dublin, Ireland. This study is a component of the groups research on assessing skill transferability across multiple clinically relevant robotic surgical platforms. (22, 23)

Methods

Hydrogel ventral hernia model

IMRA Surgical produces a range of products consisting of anatomically accurate synthetic simulation organs. All are manufactured without the use of animal products or biological materials, allowing training in a simulation laboratory or operating theatre setting without risk of biological cross-contamination (Fig. 1). (19) Suturing, electro-cautery, and stapling are facilitated. The 'Abdome' is an anterior and lateral abdominal wall dome trainer covered in a silicone polymer – Skinthetic™. (20) An interlocking lid held in place by four locking bolts can be interchanged with separate single use ventral hernia models. Robotic ports can be introduced from all directions, enabling a suprapubic or lateral approach, as required. The ventral hernia model manufactured by IMRA Surgical is a composite hydrogel, relying on different material formulations and processing techniques to create distinct physical properties and textures.

To aid pre-operative planning, intra-operative teaching, and post-operative records a revised nomenclature has been proposed for the descriptions of ventral hernia and associated plane of mesh placement. (24) Following this, training models for ventral hernia should provide opportunities for completing a ventral hernia repair in at least one of these planes (Fig. 2). (24) IMRA's ventral hernia hydrogel model replicates a paraumbilical hernia with a discontinuous fascial layer in the linea alba and has a layer of peritoneum covering this fascial defect. (18) In addition, the model reproduces the rectus muscles, anterior and posterior rectus sheath, subcutaneous fat, and skin layers. (18) It provides an opportunity to perform a rTAPP or TARUP in the preperitoneal and retrorectus planes, respectively (Fig. 3).

Recruitment of participants and assessors

Recruitment for this arm of our study was conducted via an independent gatekeeper by email invitation as part of a larger study investigating technical skill transferability across robotic platforms amongst robotic experts (completed a minimum of 50 robotic cases post approved fellowship / industry training) and novices. (22, 25) Attendings who are independently practicing as robotic surgeons constituted the

robotic expert cohort. Novices consisted of senior residents, at least in their fourth postgraduate year of training (completed internship and a minimum of two residency years), who had procedural competence in open and laparoscopic ventral hernia repair. This was confirmed by an assessment of electronic operative logbooks.

An order effect occurs when participants' performances are affected by the order of assessment. (26) To avoid an order effect, each participant were randomly assigned to a predetermined sequence of robotic platforms which included the Da Vinci X/Xi™ robotic platform (Intuitive Surgical, Sunnyvale, CA, USA), the Versius™ robotic platform (CMR Surgical, Cambridge, United Kingdom), and the Hugo™ robotic-assisted surgery (RAS) system (Medtronic, Dublin, Ireland).

Prior to undertaking the recorded operative procedure each participant underwent a two-hour proctored orientation session on consoles and practiced operative skills using both virtual reality simulation exercises and a separate hydrogel model. They then proceeded to complete a robotic ventral hernia rTAPP repair using prescriptive predefined operative steps as agreed by consensus from internationally recognised high-volume experts. (4) This removed the potential confounder of unfamiliarity with a novel console or simulation model negatively impacting on the ability to use and evaluate the hydrogel model.

Each recorded procedure was submitted anonymously to independent assessors, who are competent open, laparoscopic, and robotic surgeons with extensive clinical experience (FA, MA, FB, JDM, HE, AH, MLC, BM, ROC, CS, DS, YT). Standard setting for consistency and inter-rater reliability were conducted. Prior to video appraisal each assessor undertook training in video analysis. Instructions for benchmarking expert performance, as demonstrated by a consultant robotic surgeon, were outlined. To reduce potential bias, they were blinded to participant demographics, including grade (resident / attending). Each recording was appraised using validated assessment tools, namely a modified Global Evaluative Assessment of Robotic Skills (GEARS) (27) and Robotic Anastomosis Competency Evaluation (RACE) (28) score.

Data analysis and validity frameworks

Data were determined eligible for analysis once enrolled participants had completed at least one component of the study, i.e., at least one recorded and assessed ventral hernia repair. After a participant had completed at least one procedure, they were invited to complete an online anonymised survey eliciting their views on the model. Further semi-structured interviews were carried out at the end of the study. Generated transcripts were analysed using an iterative constructivist approach, with open and axial coding using NVIVO™ software. (29, 30)

Messick's framework was used to evaluate the model's validity evidence. In this structure, 'content' refers to the traditional analysis of items and format, and if they constitute a relevant and representative sample of the domain of tasks. (31) Within this domain several subcategories exist, based on historical validation conceptualisations, including content and face validity. Content validity reflects whether an

assessment of a skill is appropriate and correct, i.e., whether the content is suitable to measure the performance of the desired skill. (32) Face validity involves an expert reviewing a simulation and assessing if it measures what it intends to. (32) These phenomena were sought through the participant survey responses.

'Internal structure evidence' evaluates the relationships of individual assessment items with each other and the overarching construct. (31) Pearson's co-efficient was used to assess inter-rater reliability of examiners using RACE and GEARS scores. Anonymised GEARS and RACE scores were used to inform expert-novice comparisons to establish 'relationships with other variables evidence'. (31)

'Consequences evidence' looks at the impact of the assessment itself and the decisions and actions that result from it, while 'response process' outlines the overlay between the construct and the performance, and includes quality control, assessment security, and analysis of examinees' thoughts or actions during the assessment. (31)

Statistical analysis

Analysis of quantitative data was conducted using the R platform (Version 4.5.2, R Foundation, Vienna, Austria). For continuous variables, median and interquartile range (IQR) were reported. Categorical variables were recorded using percentage and count/frequency. Pearson's coefficient and Pearson's test were used to assess the correlation of assessments, and if this was statistically significant. Kruskal-Wallis and Mann-Whitney U tests were used for non-parametric continuous variables, while students-t test was used for parametric continuous data, and Fisher's exact test was used for paired categorical variables.

Results

Demographics

Twenty participants (Table 1) were recruited and completed a total of forty six procedures across the three described platforms in the following order: (Group I) Da Vinci, Versius, +/- HUGO, or (Group II) Versius, +/- HUGO, Da Vinci (**Supplementary Material I – Video of rTAPP**). Sixteen of the twenty (80%) responded to the online survey, this included four experts and twelve procedurally competent minimally invasive residents who were robotic novices. Six respondents were in Group I, and the remaining ten were part of Group II. All sixteen completed the semi-structured interviews.

Experts described their most commonly performed robotic operations as anterior resections, colectomies, exenterations, rectopexies, and inguinal hernias. All described a minimally invasive approach as their usual choice for ventral hernia repair.

Content validity

Most participants agreed that the ventral hernia model has sufficient anatomical fidelity to the procedure (75% of experts and 92% of novices). When asked if the ventral hernia model replicates handling of human tissue, 75% of experts and 83% of novices agreed. All experts felt the model was adequately realistic to dissect and excise the hernial sac, close the fascial defect, and insert the mesh. Three experts (75%) felt that the incision and closure of the peritoneum was simulated realistically on this model, and that the model is sufficient to simulate the core components of a ventral hernia repair. One expert (25%) responded neutrally to these statements (Table 2). All experts, and 92% of residents (n = 11) reported the model to be useful to improve resident robotic surgical skills, and to act as a useful tool for preparation for a resident before their first robotic case in vivo. All robotically naïve participants reported improved confidence in performing robotic ventral hernia surgery following use of the model (n = 12, 100%). The majority (≥ 81%) felt that simulation using the hydrogel model was superior to virtual reality simulation for the following tasks: cutting (n = 14, 88%), suturing (n = 13, 81%), grasping objects (n = 13, 81%), and camera movement (n = 14, 88%) (Table 2).

Experts perceived that anatomical and procedural content and face validity could be improved by modifying the realism of the tissue, and by increasing the difficulty of the 'cross-over' at the linea alba procedural micro-component, corresponding to clinical challenges of maintaining the correct dissection plane in traversing the linea alba.

Response process and consequences

The current study demonstrates the model's usability. It is fit for purpose requiring minimal effort for set up and use (average of 90 seconds). The model is readily portable using a flight case and was adaptable to multiple training environments.

Performance was assessed using RACE (28) and GEARS (27) scores. Additionally, safety metrics including instrument clashes, instrument time out of view, dropped or broken sutures were recorded, as well as expert rated metrics based on the appearance of the repair (e.g mesh exposure).

Internal structure / relationships with other variables

The internal structure of the hernia model is described using Pearson's co-efficient, with a R^2 value of 0.4201 and 0.7028 for GEARS and RACE scores respectively (p-value < 0.0001 for both). The mean difference in values of assessments between raters was 1.8 and 2 for GEARS and RACE scores separately. Cronbach's alpha for GEARS was 0.64, and for RACE scores was 0.78.

GEARS (early resident 16, senior resident 16.71, attending 18.5, p-value 0.0051) and RACE (early resident 18.75, senior resident 19.92, attending 21.67, p-value 0.0078) scores were higher and proportionate to extent of operative experience and grade of participant, (Table 3).

Discussion

This study provides validity evidence for IMRA Surgical hydrogel ventral hernia model as an ideal simulation tool for robotic training. It constitutes a relevant and representative sample of the domain of tasks, replicating tissue dissection and allowing for realistic imitation of technical procedural steps. (31) Using GEARS and RACE scores, performance could be differentiated in line with operative experience. These findings support the use of hydrogel models within a postgraduate surgical training programme. (21)

Hydrogel ventral hernia models can be used to guide coaching and deliberative repeated practice of residents, identifying specific areas for development, e.g. needle handling or dexterity, through the RACE and GEARS rubrics. Indeed, potential exists to incorporate their use into routine formative assessments, delivering 'just-in-time' feedback to strengthen cognitive schema formation and the accelerated acquisition of automated psychomotor skills. (11, 33)

The results of this study inform the expected benchmark ranges of skill, as measured by GEARS and RACE scores for the IMRA Surgical hydrogel ventral hernia model. The model's ability to differentiate performance grades suggests that it could be used in resident assessment as a component of robotic credentialling. (16, 34–36)

Simulation fidelity refers to how closely learner experiences during a simulation imitate reality. Animal models and human cadavers possess realistic characteristics of tissue handling and planes of dissection. (8, 32, 37) Hernia surgery training poses unique challenges for these otherwise high-fidelity models, as abnormal abdominal wall anatomy is required to replicate procedural steps. This is not routinely available in cadaveric and animal models, given the prevalence of ventral hernias in the general population. Hydrogel synthetic models overcome this barrier allowing residents to engage in full length procedural practice. (38) However, barriers to the routine use of hydrogel models for robotic practice by residents at all levels exist. Limited reusability and prohibitive cost for healthcare systems may encourage judicious allocation of these resources for senior residents. (38) Innovative ways to teach the breadth of the robotic skills curriculum by reusing models for more junior residents for basic docking, targeting, instruments exchanges and suturing skills could increase sustainability.

Given the model's demonstrable utility in selected resident and attending training, these models possess several characteristics that can be further developed to enhance accelerated skill acquisition. The models are readily amenable to quality control. Recording of each simulated procedure can enhance individualised debriefs post-simulated operations and be used to critique and constructively deliver feedback about modifications for future performance. In addition, quality control of raters' assessments can be determined to ensure that inter-rater and intra-rater reliability is maintained, and ongoing rater training can be conducted to ensure benchmark uniformity. Cognitive task analysis of examinee's thoughts or actions during the assessment (e.g. think-aloud protocol) could be added to the response process to further supplement assessments and feedback.

Table 3
Differentiation of technical competence as measured using GEARS and RACE scores based on construct of grade

Measured domain	ST3-6	ST7-8	Consultant	p-value
GEARS – Total	16 (15.25-17)	16.71 (15.31–19.26)	18.5 (17.42–21.5)	**0.0051**
GEARS – Depth perception	4 (3.5–4.5)	4 (3.62–4.5)	4 (4-4.75)	0.1240
GEARS – Bimanual skill	3.5 (3-3.5)	3.75 (3.5–4.5)	4 (3.5–4.75)	**0.0410**
GEARS – Efficiency	3 (2.5–3.5)	3.5 (3-3.88)	3.5 (3.5–4.5)	**0.0208**
GEARS – Force sensitivity	3 (2.5–3.5)	4 (3.5–4.5)	4.5 (3.75-5)	**0.0020**
GEARS – Robotic control	4 (3-4.5)	4.25 (3.62–4.5)	4.5 (4.25–4.75)	0.0591
GEARS – Peritoneal incision	16 (15.5–18)	17.75 (17–20)	19 (18-20.75)	**0.0088**
GEARS – Dissection of preperitoneal space / reduction of hernia sac	16 (15–18)	20 (16.5-21.25)	20 (18.5–21.5)	**0.0071**
GEARS – Fascial defect closure	18.5 (14.5–20)	19.25 (15.75–20.38)	19.5 (18.75–22.8)	0.1170
GEARS – Insertion of mesh	16.5 (14.5–21)	19.5 (17.75–20.38)	20 (18.75–22.8)	0.1340
GEARS – Mesh fixation	16.5 (15–19)	18.75 (15-21.25)	19 (18.5-21.75)	0.0618
GEARS – Peritoneal closure	17.5 (14.5–18.5)	18.25 (16.12–21.38)	19.5 (19-22.25)	**0.0103**
RACE – Total	18.75 (17.3-19.33)	19.92 (16.25–23.12)	21.67 (20.4-24.62)	**0.0078**
RACE – Needle positioning	3.5 (3–4)	3.5 (3-4.38)	4 (4-4.75)	**0.0059**
RACE – Needle entry	3.5 (3–4)	3.5 (3–4)	4 (3.5–4.75)	0.0958

Measured domain	ST3-6	ST7-8	Consultant	p-value
RACE – Needle driving and tissue trauma	3.5 (3–4)	3.5 (3–4)	3.5 (3.5–4.5)	0.1220
RACE – Suture placement	3 (2.5-3)	3.5 (2.5–4.38)	3.5 (3.5-4)	**0.0131**
RACE – Tissue approximation	3 (3-3.5)	3.5 (2.62–4.5)	3.5 (3-4.5)	0.1660
RACE – Knot tying	3.5 (3–4)	3.5 (2.62–4.5)	4 (3.5–4.75)	0.0855
RACE – Fascial defect	18 (15.5–19.5)	19.25 (16–21)	19 (16.75–22.5)	0.3500
RACE – Mesh fixation	13.5 (12–16)	15.25 (14.25–17.88)	17 (15.25–18.8)	**0.0411**
RACE – Peritoneal closure	16.5 (13.5–18)	17 (14.12–20.62)	20 (17.5-22.75)	**0.0210**

Limitations

Arguably the most important component of Messick's validation framework, the 'Consequences evidence' for the model, remains to be determined. This looks at the impact of the assessment itself and the decisions and actions that result from it, i.e. the impact on examinee performance (e.g. downstream effects, clinical performance, patient safety, graduation rates) and other examinee effects (e.g. test preparation, length of training, stress, anxiety). (16) These aspects require further evaluation.

As the recruited experts were robotically competent general surgeons who perform hernia surgeries, rather than specialist robotic abdominal wall hernia surgeons, some interpretation of the findings may be limited, particularly regarding procedural knowledge and contextual content. We have shown that these models are feasible to deliver high quality focused postgraduate training to surgical trainees, however, the use of the modified GEARS assessment, removing the autonomy component and instead utilising prescriptive steps has potential implications on the results validity evidence.

Conclusion

IMRA Surgical's hydrogel hernia models are an excellent fit for purpose simulation tool, exhibiting high validity across many domains. However, their use may be reserved for individuals who have already attained the basic technical robotic skills and cognitive schemata, such that the cost and potential limited reusability are offset.

Declarations

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Table 1 and 2

Table 1 and 2 are available in the Supplementary Files section.

Figures



Figure 1

IMRA Surgical ventral hernia model in use in clinical and laboratory environments (clockwise from left to right); (i) Da Vinci Xi robotic platform (Intuitive Surgical, Sunnyvale, CA, USA), (ii) Versius robotic platform (Cambridge Medical Robotics, Cambridge, United Kingdom), and (iii) HUGO RAS robotic platform (Medtronic, Dublin, Ireland).

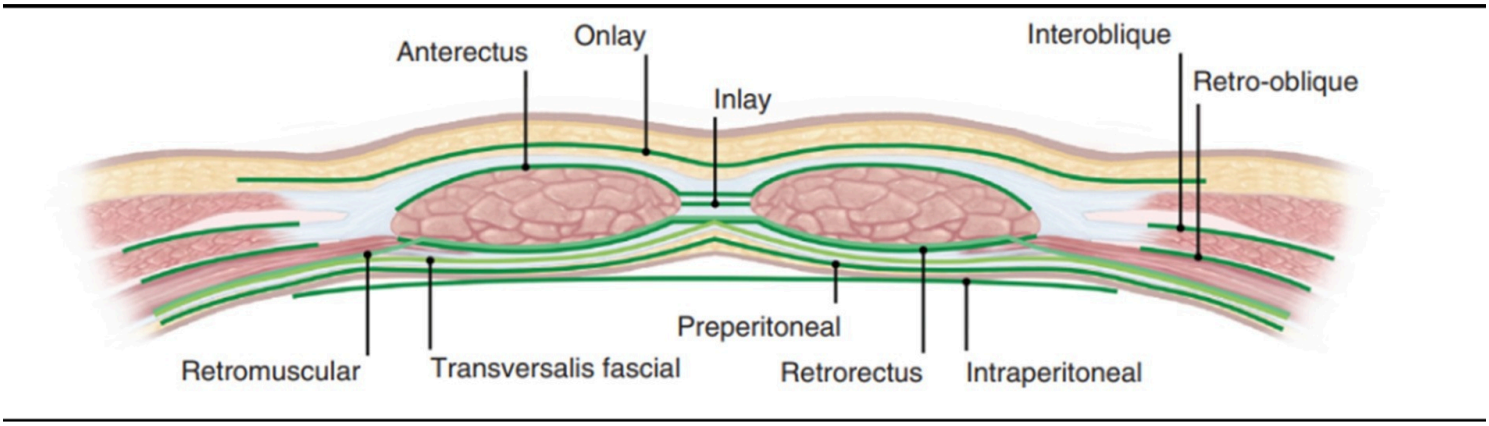


Figure 2

Classification of abdominal wall planes for ventral hernia repair. *Reproduced with permission from Parker et al - International classification of abdominal wall planes (ICAP) to describe mesh insertion for ventral hernia repair. Br J Surg. 2020 Feb;107(3):209-217.* (24)

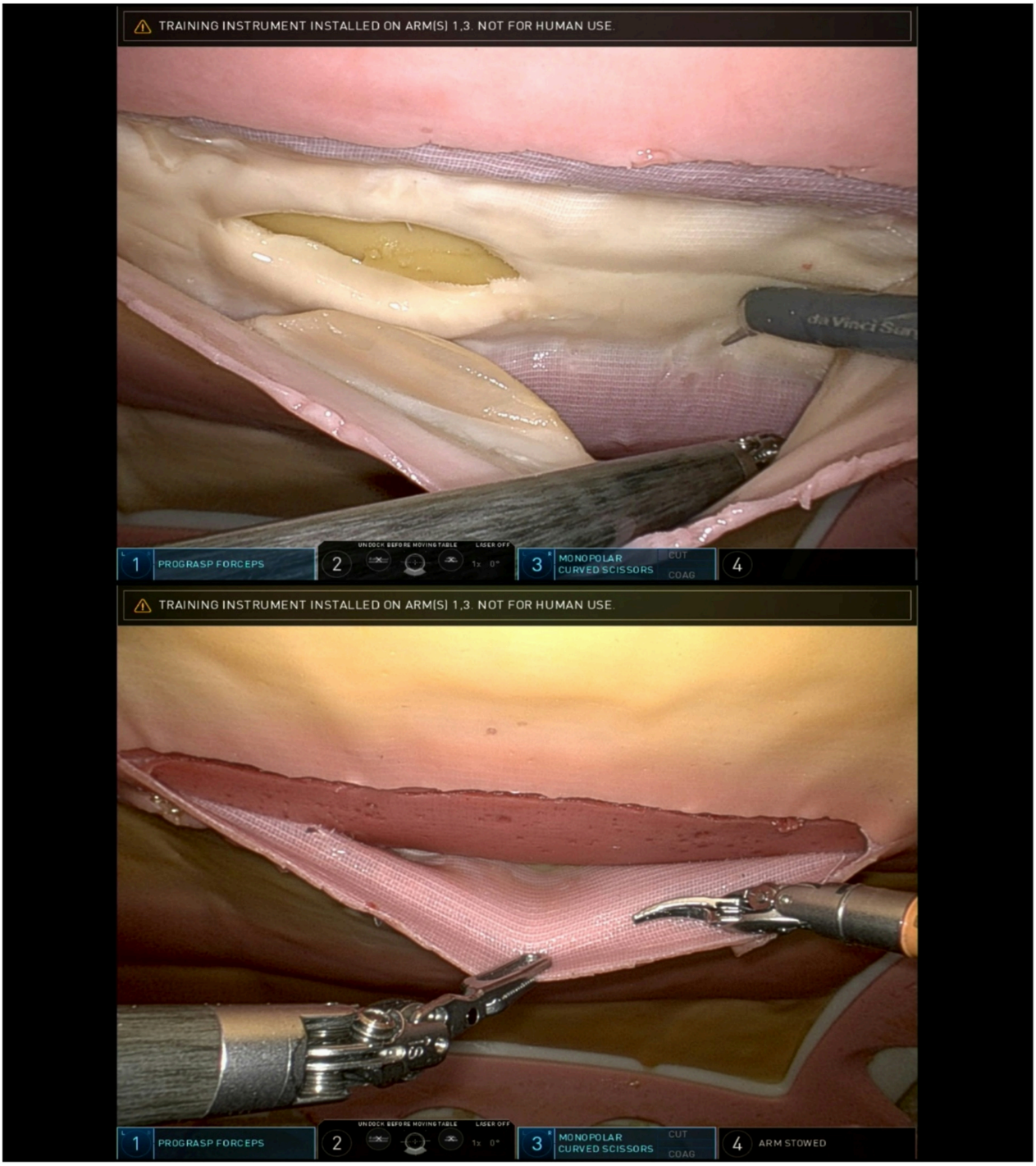


Figure 3

(a) Preperitoneal and (b) retrorectus layers of ventral hernia hydrogel model.

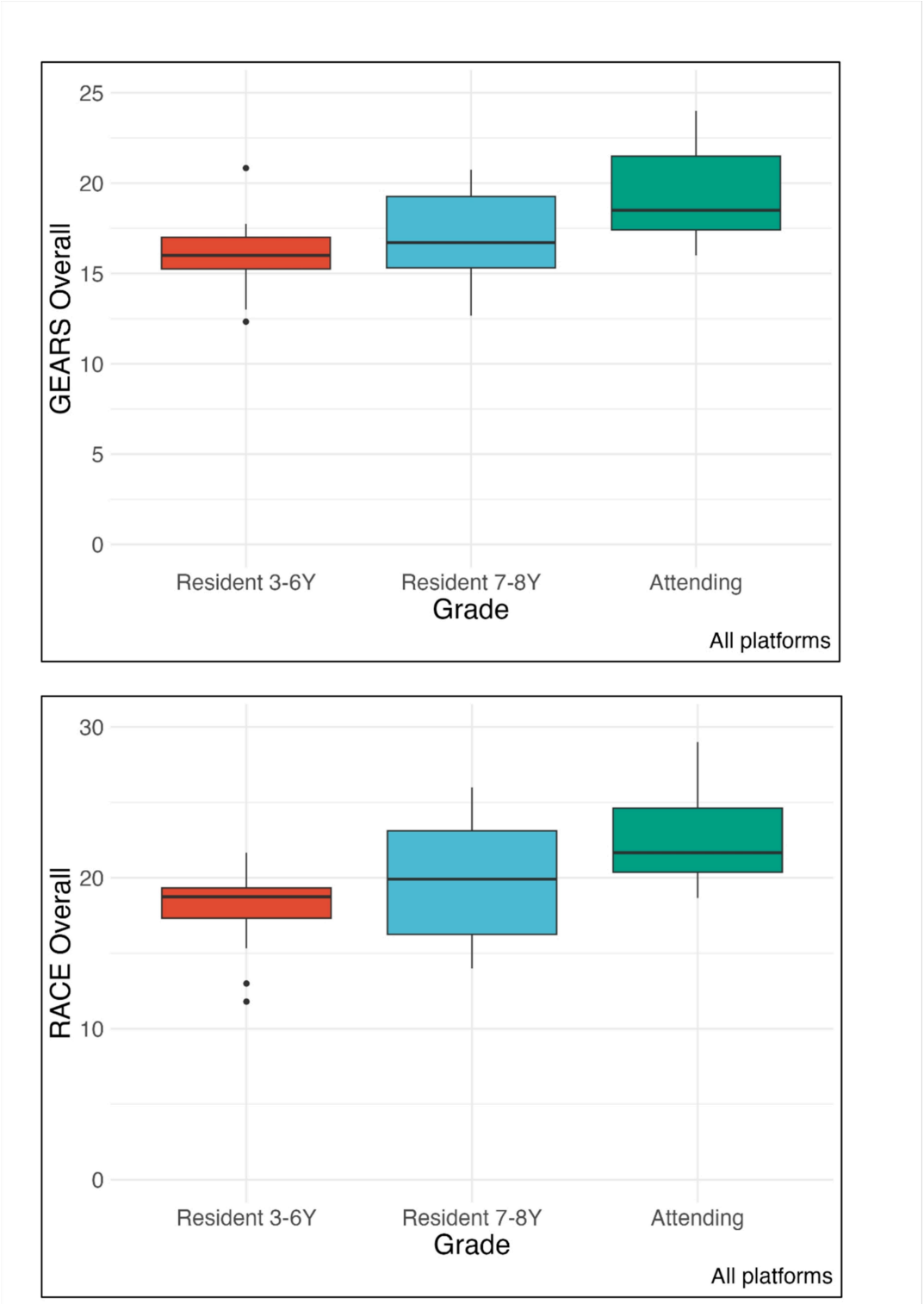


Figure 4

Demonstration of construct validity with differentiation of performance proportionate to grade of participant using (a) GEARS scores, and (b) RACE scores

Supplementary Files

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- Table.docx