# Protocol

## Comparing the variation in Laparoscopic skills Acquisition in obstetrics & Gynaecology and General Surgical trainees (LAGGS)

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## Background and Rationale

Laparoscopic surgery (LS) is currently the gold standard for many operative procedures in general surgery and obstetrics and gynaecology (O&G). However, the psychomotor skills of laparoscopic surgery can be difficult to develop and trainees pursuing a laparoscopic surgical career often face a steep learning curve. Whilst simulation-based training can lead to a demonstrable acquisition of transferrable laparoscopic skills,[1] they must be considered an adjunct rather than a substitute for in-theatre operating.

In both specialties, obtaining adequate exposure to operative work is a multifaceted challenge for the trainees as well as those involved in designing and delivering surgical training. Amongst other factors, NHS pressures driving service provision, European Working Time Directive (EWTD), loss of firm structures and the cost of training to the trainees themselves have been identified as factors affecting the quality of surgical training in the UK.[2,3] This is reflected in annual training surveys highlighting concerns over loss of practical training and experience across both specialties.[4,5,6]

Within O&G, at Certificate of Completion of Training (CCT), there is concern that trainees lack the confidence and skills to perform the same breadth of procedures as the previous generation.[3] An intra deanery survey showed that 67% of O&G trainees felt inadequately prepared for CCT[8]. In 2012, analysis of 155 successful applications for CCT in general surgery (GS) revealed that only 67% of the cohort had achieved the logbook requirement of 1600 cases and around 73% had the necessary experience in index procedures.[9] There is currently no literature to highlight expectations and opinions of consultants or programme directors of trainees' skills within GS or O&G in the UK, which we believe to be one of the indicator of training standards.

Whilst the requirements for CCT for general operative skills in open and laparoscopic surgery are comparable in both specialties, the training pathways defer significantly. GS training is 8 years in duration (CT1, CT2, ST3-ST8), whereas O&G consists of 7 years of specialty training (ST1–ST7). The ST1-ST5 years in O&G is mainly devoted to obstetrics and only those trainees pursuing a gynaecological training pathway undertake an intensive period of surgical training in the last two years of their training. We believe there is also earlier exposure to laparoscopy in GS training with a greater volume of laparoscopic work in comparison to O&G training. To our knowledge, there is no direct comparison of O&G and GS training pathways and outcomes in laparoscopic skills.

It is known that greater exposure to laparoscopic training is associated with "muscle memory" and may contribute to reducing physical and mental stress of the surgeon. It is not known whether the existing training is sufficient to meet the demands of a laparoscopic gynaecological or GS consultant or whether the differences in training affects the development of fundamental laparoscopic skills (FLS). These FLS include spatial awareness, hand eye co-ordination, bimanual dexterity and laparoscopic suturing. We would expect trainees to be better at FLS with more laparoscopic surgery exposure. The measurement of muscular and cognitive

fatigue can be regarded as a surrogate marker of exposure to laparoscopy giving further insights into the quality of laparoscopic training between the two training programs.

## Hypothesis

We postulate that there is a difference in acquisition of fundamental laparoscopic skills (FLS) between general surgical and O&G trainees. This is likely to be demonstrated as a difference in musculoskeletal and cognitive fatigue between the specialties.

Within both specialties, there is likely to be a discrepancy in the expectations of consultants and trainees on skills perceived to be important at CCT.

## Overall Aim

To compare and evaluate the training programmes in O&G and GS in order to identify areas for improvement in the training pathway contributing to the acquisition of FLS in both specialties.

## Objectives

1) To compare FLS in O&G and GS trainees at ST3/4/5 and those in their final 2 years [ST7/8(GS) and ST6/7 (O&G)]
2) To compare the musculoskeletal and cognitive fatigue experienced by O&G and GS trainees in performing FLS as a marker of their competence.
3) To compare the standards of laparoscopic ability expected from trainees by experienced GS and gynaecological consultants.

## Research Strategy

### Study Design

This is a prospective comparative study and we will recruit participants from professional membership bodies and the North West health education formerly known as the North West deanery. The study is divided in two parts. In part 1, Consultants and trainees from O&G and GS specialties will be contacted electronically through professional membership bodies (O&G consultants through RCOG/BSGE, GS consultants through ASGBI, O&G trainees through RCOG/BSGE and GS trainees through ASiT). In addition to above communication methods we will consider the use of social media and direct emails to increase survey response rate. The consultants and trainees will be requested to fill out an online short questionnaire designed to assess their perceptions of FLS required at CCT (Appendix 1& 2). These surveys will not include any personal details and will be returned anonymously to us via the survey monkey platform. In the second part we will recruit trainees from the two specialties via the North West deanery by sending out a centralised email requesting them to volunteer for the

FLS tasks. In addition to above recruitment methods we will consider the use of social media and direct emails to increase trainee recruitment for the study. Trainees will be able to volunteer their help by replying to a secure email address. Those trainees who respond and meet the inclusion criteria will subsequently be invited to attend a study day to perform four FLS tasks with a choice of 6 days across 3 possible weekends. On the day, they will be asked to fill out another short questionnaire to gather some demographic information and account for potential confounding variables. Personal details from these questionnaires will be separated and a study number will be randomly allocated to both parts of questionnaires and this number will be written on the trainee's badge which will be used for filling out the task evaluation sheets. A single sheet of paper will allow us to recognise the study number against the relevant trainee in case we need to contact them at some point. This form will be securely stored in a locked cabinet in an NHS locked office accessible only to the research team. A sub selection of trainees will be randomly chosen to have electromyography (EMG) and electroencephalography (EEG) monitoring whilst performing the tasks.

The email accompanying the questionnaires will contain a brief introduction to the study, a participant information sheet and consent form as attachments. Trainees will be able to self select if they meet the inclusion criteria and volunteer their participation for the FLS tasks. At this point they will be asked to provide us with contact details so that we can contact them to verify their suitability for the study prior to attendance and go through the different dates for them to choose a convenient slot.

**Study Population**

Trainees (Inclusion Criteria):

We will recruit 20 trainees from GS and 20 trainees from O&G in the north west deanery in the following proportions:

| Obstetrics and Gynaecology (O&G) | General Surgery (GS) |
|---|---|
| ST3/ST4/ST5* (n=10) | ST3/ST4/ST5* (n=10) |
| ST6/ST7 (n=10)** | ST7/ST8 (n=10) |

* ST5 trainees with limited experience at this grade and are functionally at grade ST4. This include ST5 trainees who have less than 3 months of experience at this grade or its equivalent for part time trainees.

**As OG training covers both obstetrics and gynaecology curriculums, we will recruit trainees in their final two years of training, with gynaecology special interest, who are undertaking at least one gynaecology Advanced Training Skills Modules (ATSM). These include advanced laparoscopic training, open and laparoscopic benign abdomen, urogynaecology, gynaecology-oncology and reproductive medicine. These ATSMs involve core laparoscopic skills such as laparoscopic suturing as an essential component of their curriculum.

Trainees (Exclusion Criteria)

Those trainees who have had substantial pre-training experience in laparoscopic surgery such as those who have completed another surgical speciality training, have worked as clinical fellows or speciality doctor with substantial exposure to laparoscopic work will be excluded. Those trainees who are currently out of program/training and not doing regular clinical work or those trainees outside the North West deanery will also be excluded. For the safety of others anybody with positive Covid-19 test, symptoms or contact with someone infected with the virus will be excluded.

**Withdrawal**

Participation in this study is voluntary and all participants will be required to provide explicit consent **(Appendix 3 &4)**. Participants can withdraw at any time by contacting a member of the research team.

**Study Protocol**

Part 1 consists of questionnaires sent out to Consultants and trainees.

**Consultant Questionnaire** (Appendix 1)

A questionnaire will be sent to consultants nationally via the RCOG and BSGE (O&G consultants) and ASGBI (GS consultants) to get an idea of their own level of laparoscopic surgical experience and their expectations of laparoscopic competencies required at CCT by trainees. No personal details will be requested in the questionnaires.

The email accompanying the questionnaires email will contain a brief introduction to the study, a participant information sheet **(Appendix 3)** and consent form **(Appendix 4)** as attachments and a link to the online questionnaire. All questionnaires will be returned anonymously via survey monkey service.

**Trainee Questionnaire** (Appendix 2)

A short questionnaire will be sent to trainees nationally via the RCOG and BSGE assessing their perception of self rated laparoscopic ability and skills they rate as important at CCT. No personal details will be requested in the questionnaires.

The email accompanying the questionnaires will contain a brief introduction to the study, a participant information sheet **(Appendix 3)**, consent form **(Appendix 4)** as attachments and a link to the online questionnaire.

The completed questionnaires will be returned to us via 'survey monkey' service.

**Part 2:**

This phase consist of four FLS tasks and EMG/EEG data recording on a randomly selected small subset of trainees.

The relevant trainees (ST3, ST4 , ST5 grades in both specialties, ST6/7 in O&G and ST7/8 in GS) will be identified and approached through north west deanery on our behalf who hold contact details for all trainees in the region. This email will contain a brief introduction to the study and request their help by volunteering with the FLS tasks if they meet the selection criteria. This email will contain a participant information sheet and consent form (Appendix 3 & 5 respectively) as attachments. Trainees will be able to self select from this information if they meet the inclusion criteria and volunteer their help. There will be a secure email address for them to reply to if they wish to volunteer. In addition to above recruitment methods we will consider the use of social media and direct emails to increase trainee recruitment for the study

Volunteering for FLS (part 2) is not contingent on trainees completing the questionnaire in part 1 of study. Trainees can help with both parts of the study or one or the other as they are able.

Trainees volunteering for the FLS tasks will be requested for their preferred contact number or email. This will be used by the research team to verify their inclusion criteria and offer a convenient date from a choice of 6 days over 3 separate weekends for the FLS tasks in part 2. By engaging in this process we are restricting our access to personal details on a strictly 'need to know basis', i.e. only dealing with personal details of trainees interested in volunteering for FLS tasks.

On the day, trainees will be asked to fill out a short questionnaire on demographic details, previous laparoscopic experience, physical fitness and presence of any musculoskeletal symptoms as these are potential confounding variables **(Appendix 6).** A written consent form will be completed at this stage (**Appendix 5).**

Personal details from these questionnaires will be separated and a study number will be allocated to both parts of questionnaires. The same study number will be written on the trainee's badge as this number will be

used for filling out the evaluation sheets. A single sheet of paper will allow us to recognise the study number against relevant trainee in case we need to contact them at a later point. This form will be securely stored in a locked cabinet in an NHS locked office accessible only to the research team.

There are four FLS tasks and they are carried out using validated training models called LASTT (Laparoscopic Skills Training and Testing method) and SUTT-1 (Suturing and knot tying Training and Testing method). LASTT is a wooden model and SUTT-1 is a foam sponge.

A sub selection of trainees will be randomly chosen on the day (with their consent) to have EMG and EEG monitoring whilst performing these tasks.

A summary of the tasks is given below in table 1 below followed by a more detailed explanation later in this section.

Table 1: Summary of FLS tasks.

| Task | Task Aim | Ideal time for completion | Data to be recorded* |
|---|---|---|---|
| 1 | Camera navigation to find 14 targets – repeated 3 times | Ideal time for completion of task 1 is 2 minutes and 30 seconds. For trainees unable to achieve the ideal target time can continue up to a maximum of 5 minutes. | Time taken (min/sec) to find 14 targets if within 5 minutes. If trainee exceeds 5 minutes then we will record last target found. Penalty- subtracting 1 target from the total found targets if ideal time of 2:30 is exceeded. |
| 2 | Transfer 6 objects (repeated 3 times) | Ideal time for completion of task 2 is 3 minutes | Time taken (min/sec) No of objects dropped |
| 3 | Position 6 objects (repeated 3 times) | Ideal time for completion of task 3 is 3 minutes | Time taken (min/sec) No of objects dropped |
| 4 | Perform 4 interrupted sutures and 4 knots. (done once only) | Maximum time allowed is 15 minutes | Time taken (min/sec) Quality of the sutures and knots*** |

***The quality of the sutures and knots will be assessed after the completion of the task by 2 independent assessors using validated tools.[10]

EMG and EEG readings will be recorded on a subsection of trainees whilst performing the laparoscopic tasks - 4 GS trainees at grade ST3/ST4/ST5, 4 trainees at ST7/8 from GS and, likewise, 4 O&G trainees at ST3/ST4/ST5 and 4 trainees at ST6/7 from O&G.

The Laparoscopic Skills Testing and Training (LASTT) model (Figure 1), is a validated model for the assessment of FLS[9] and will be used to perform tasks 1-3. It has the configuration of a female pelvis and consists of 6 wooden panels with 2cm disc shaped holes which are fitted with various inserts. The model is placed in Szabo trainer box (Storz), mounted with relevant inserts for each task.

Task 1 – Laparoscopic Camera Navigation

Laparoscopic camera navigation (LCN) assesses the trainee's ability to navigate a 30 degrees camera using either their dominant hand (DH) or their non-dominant hand (NDH).

The task requires the trainee to insert a 10mm 30 degrees optic through the central port of the Szabo box trainer. 14 targets will be dispersed around the LASTT model. Each target contains a large size character (either a large number or a large alphabet letter) and a small size character (either a number or an alphabet letter). The large character can be seen from a panoramic field but the smaller character requires the trainee to zoom in.

**Figure 1:** A target on LASTT model displaying both the large and small characters. This prompt will be used as a visual aid to ensure trainees understand the instructions properly.


Large character '1' corresponds to the starting character.

Small character 'a' corresponds to the next character to find which will appear as a large character on the next target.

The task will be set up by the facilitator and will give the trainee standardised instructions and a short demo video on how to perform this task **(Appendix 7)**. The task begins when the trainee inserts the camera to find the character on the first target (e.g. **1**), zoom in and identify the small size character (e.g. **a**) located next to it. Before they can proceed to the next target, the facilitator needs to confirm that they are happy with the identification and placement of the small character by saying "next". Trainee can demonstrate this by placing the target in the circle on the screen and reading it out. Trainee can then navigate the camera to find the next target on the LASTT model which in the above example will be large character **'A',** then zoom in to find the small character next to it, put the small character in the circle on the screen and read it out. They can then move on when indicated by faculty as ok to do so. Trainee can then continue until they find the 14th target **"N $_{end}$"** which completes the task. Please see figure 1 for an example. The facilitator will record the trainee's study number (badge number) and time taken to identify 14 targets. A time of 2 minutes and 30 seconds is considered as ideal for completion of this task. If trainee exceed this time then it will incur a penalty. For every

30 seconds they exceed beyond 2 minutes and 30 seconds, 1 target will be subtracted from the total number of targets they have found. The penalty column does not need to be completed at the time of assessment and can be worked out retrospectively. Furthermore maximum time allowed for this task is 5 minutes and if all 14 targets have not been identified within 5 minutes then the trainee is encouraged to move on to the second sequence of this task, i.e. round 2. The assessor will be required to record the last target found on the evaluation sheet if 5 minutes limit is reached and the task is still incomplete. The rationale for the 5 minute cap is t minimise fatigue. This task will be repeated 3 times and above data will be recorded on the evaluation sheet **(Appendix 8)**. To avoid memory effect the sequence of targets will be changed each round so that there are 3 different sequences to find. The same 3 sequences will be used for all trainees throughout the testing phase **(please see the end of appendix 7).**

Task 2 - Hand eye co-ordination (HEC)

To assess HEC, trainees are assessed on their ability to transfer objects as well as navigate the camera. The trainee is expected to use the dominant hand (DH) to hold grasping forceps and non-dominant hand (NDH) to hold the camera. The LASTT model will be used to assess this.

The facilitator will set up the Szabo box trainer for this task. Coloured cylinders will be placed (10 × 4-mm open cylinders) in a circular style in a vertical upright position around the " +he academy…" sign on the LASTT model. There will be 2 cylinders of each colour in case one is dropped out of view. Corresponding coloured targets, i.e. nails (10 ×-1 mm) will be located in easy view on the LASTT model. Facilitator will place 1 lateral port so that the coloured cylinders and LASTT model can be comfortably reached. The facilitator will give standardised instructions and show a standardised demonstration video on how to perform this task **(Appendix 7).**

The trainee is expected to inserts the 10mm 0 degrees camera through the central port of Szabo box trainer. The time starts when the trainee inserts the grasper through the lateral port and the grasper comes into endoscopic view. The trainee is expected to identify a coloured cylinder (e.g. green), grasp it with Maryland forceps using their DH and transfer it to the corresponding coloured nail whilst using NDH to drive the camera. Once the cylinder is correctly placed over the pin, the trainee can proceed to the next coloured cylinder and continue until 3 minutes have elapsed or all the 6 cylinders have been transferred. If a cylinder is dropped the trainee can re grasp it if possible or choose to use the second cylinder of the same colour provided it is still in endoscopic view. All grasped then dropped cylinders will also be recorded. This task will be repeated 3 times and scores for each run will be recorded on the task evaluation sheets **(Appendix 8).** The time taken for the trainee to transfer 6 objects correctly will be recorded (if completed in 3 or less minutes) or if the task in incomplete in 3 minutes, then the total number of cylinders transferred will be counted. To avoid memory effect the colour sequence of targets will be changed each round. The same 3 sequences will be used for all trainees throughout the testing phase **(please see the end of appendix 7).**

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Task 3 - Bimanual co-ordination (BMC)

BMC is assessed by measuring the time taken for a trainee to transfer 6 objects between their DH and NDH and position them correctly on the LASTT model. The Szabo box trainer will be securely fitted with the LASTT model and the facilitator will place the coloured pushpins around the "+he Academy…" sign on the LASTT model. The pins will be laid flat in a circle with pin's tail (metal part) pointing outwards and the pin's head (plastic part) pointing towards the 'Academy' sign on LASTT model. The trainee will be given standardised instructions and shown a standardised demonstration video on how to perform the task **(Appendix 7).**

Facilitator will place 2 lateral ports so that the pins and LASTT model can be comfortably reached. The facilitator will then insert the 10mm 0 degrees camera through the central port and will position all the targets and LASTT model in an optimal view on the centre of the screen. Coloured push pins (10 × 5-mm push pins) and coloured targets (20-mm circles/discs) will be located on the LASTT model. There will be 2 pins of each colour in case one is dropped out of view. The time starts when both graspers are inserted and appear in endoscopic view on screen.

The trainee is expected to identify a coloured pushpin (e.g. red), grasp it by the head with grasping forceps(Johans) using their NDH, then transfer the pin to their DH and grasp the pin by its tail using curved forceps like Maryland. The pushpin then needs to be placed in the corresponding disc of the same colour correctly before moving on to the next coloured pushpin. Correct placement is achieved when the trainee has placed the pushpin (either its head or tail) in the respective disc. Trainee can use both hands to stop the pin from falling out. The trainee will continue until the 3 minutes time limit is reached or all the 6 pins have been correctly placed. If a pin is dropped the trainee can re grasp it if possible or choose to use the second pin of the same colour provided it is still in endoscopic view. Number of dropped pins will be recorded. If 3 minutes have lapsed and the task in incomplete, then the total number of pins positioned will be counted. This task will be repeated 3 times and scores for each run will be recorded on validated evaluation sheets **(Appendix 8).** To avoid memory effect the colour sequence of targets will be changed each round. The same 3 sequences will be used for all trainees throughout the testing phase **(please see the end of appendix 7).**

Task 4 - Suturing and knot placement

All trainees will be shown a video demonstration of laparoscopic suturing and intra corporeal knotting.

A Suturing and knot tying Training and Testing method (SUTT1) foam pad will be used for assessment of suturing and knot placement (Figure 2). This has 5 rows of dots. For this task the top 4 rows are used and the 5$^{th}$ row is disregarded.


Figure 2. SUTT1 foam pad for assessment of suturing and intra corporeal knot tying. It contains 5 rows of large black dots placed about 10mm apart.

The facilitator will set up the SUTT1 model inside a Szabo box trainer and insert 2 lateral ports approximately half way down the box. This is to allow easy access to the foam pad. A 10mm 0 degrees camera will be introduced through the central port and held in an optimal position for this task by the facilitator or according to the trainee's instructions. The trainee will be given standardised instructions and a video demonstration on how to perform this task. **(Appendix 7).**

Trainees will be expected to place interrupted sutures between two dots and perform 4 intra corporeal knots with 3 throws. They will be instructed to place sutures between the two dots along the first 4 rows on the foam pad. The trainee is not expected to use the 5$^{th}$ row at the bottom of the foam pad. A total of 15 minutes will be allowed for this task and the time taken to complete 4 sutures and 4 knots if performed will be recorded. If the trainee runs out of time, then total number of sutures +/- knots performed within the 15 minutes will be recorded. At the completion of the tasks, each foam pad will be labelled with the trainee's study number and collected. The quality of suturing and knot will be assessed after completion of the task using validated SUTT scoring system by two independent assessors **(Appendix 9)**.

**Measurement of EMG and EEG**

Musculoskeletal and cognitive fatigue will be tested using electromyelography (EMG) and electroencephalography (EEG) respectively in a sub set of trainees as described earlier. They will be fitted with EMG and EEG electrodes as per the protocol and this data will be collected for round 2 of tasks 1-3 and throughout the duration of the suturing task 4. As the equipment is wireless, it is anticipated that the trainee's freedom of movement will not be affected by it. EMG will be measured by placing wireless electrodes over arms, neck and upper and lower back muscles **(Appendix 10)** and EEG will be recorded using wireless electrodes over the scalp using a validated protocol **(Appendix 11).**

**Location and timescale for experiments**

We have opted to conduct these tasks in a large seminar/conference room to minimise any potential pressure on performance of another colleague. We are restricting the number of trainees to a maximum number of 6 per each run. We will conduct these tasks over 3 weekends (2 consecutive weekends and one weekend 3 weeks later). The rationale behind this is to increase the chances of recruiting volunteers who may be restricted otherwise by on-call commitments or might be away on leave.

Choice of location will be between Royal Blackburn hospital and Manchester based hospitals.

## Outcome measures

**The primary outcome measure:**

- Task 1 is ideally completed in 2 minutes and 30 seconds, however trainees will not be confined to this time and will be allowed to continue until all 14 targets have been identified or reached 5 minutes. The rationale for putting a time limit of 5 minutes per round is to avoid fatigue. We will record the time taken (in minutes and seconds) to locate the 14 targets and will average this across 3 rounds. If the task is incomplete by 5 minutes, we will record the last found target (small character). Those trainees who are able to complete the task but have taken longer than 2 minutes and 30 seconds will incur a penalty. For every 30 seconds exceeded beyond 2 minutes and 30 seconds we will subtract 1 target from the total number of targets they have found.
- For tasks 2-3, we will record the time taken in minutes and seconds to complete the tasks and use an average of this across 3 rounds. If the tasks are not completed within time (i.e. 3 minutes) then we will record the number of objects handled within 3 minutes and take an average of this across 3 rounds. Where participant shows mixed/inconsistent performance (i.e. completes the task once in time (i.e. 3 minutes) but not on the other two runs then we will use the average number of handled objects over 3 runs and note the performance as mixed/inconsistent. If an object is dropped whilst being handled, the number of drops will be recorded as this indicates inefficient performance.

- For task 4 the number of sutures, correct knots and extent of trauma will be recorded on the evaluation sheet and maximum time allowed will be15 minutes.

**Secondary outcome measures:**

-EMG and EEG signal analysis.

- Qualitative measures such as consultant's perception of trainee's laparoscopic ability and the abilities they regard as important at CCT using a likert scale of 1-5.

## Regulatory issues

### Consent

The research team responsible for conducting the study are trained medical practitioners and are able to assess capacity and take informed consent.

We believe consent is a dynamic process and it will start when we make initial contact with the trainees and consultants via email. They will be provided with participant information sheet including contact details of the research team. In part 2 consent will be confirmed in writing for both the laparoscopic tasks and EMG/EEG recordings. All efforts will be made to communicate appropriately including facilitating access to translational and interpretation services if needed. All our prospective trainees are likely to be fluent in English so we do not anticipate English language barriers.

### Risks, burdens and benefits

The study does not involve any invasive procedures/tasks. It does not raise any issues which may be upsetting to the trainees.

Muscular and cognitive fatigue will be measured using wireless sensors over head, shoulders, arms, upper and lower back. These are painless, discreet and unlikely to impede any freedom of movements.

The researcher responsible for applying these electrodes is a male surgeon. If a female trainee prefers the electrodes to be applied by a female staff then we will respect such wishes. We have trained female members of the research team to be able to undertake this task.

Four laparoscopic tasks are assessed using simulator boxes with inanimate models. Study duration will be kept to a minimum to avoid fatigue and refreshments will be provided throughout.

To minimise pressure on trainees, the study will be conducted over a weekend and away from their workplace. We will try to ensure that there is plenty of physical space for each trainee and their facilitators to minimise performance related pressure on each other. The environment will be kept comfortable and constant to minimise adverse effects on performance. If they want to have a different facilitator because they may know or feel uncomfortable with them then they can discreetly request this from a member of the research team. They don't have to give a reason.

We will try to minimise any burden on trainee by providing the following: Ensuring access to lavatory facilities, refreshments, lunch and in inconvenience allowance aimed at covering their travel and parking costs.

The risk of covid 19 transmission is an on-going issue. We will adhere to local guidelines regarding reducing transmission, wear face covering, maintain a distance and have ample hand sanitising facilities in place. We

will take a register on the day with phone numbers of attendees for the benefit of tracking and tracing if we later find evidence of infection amongst participants or faculty.

**Data storage: security arrangements:**

Questionnaires will be returned electronically via survey monkey (anonymised) and we will not be able to see any individual email addresses for any respondents. We are recruiting volunteers and requesting them to provide us with their preferred contact details. For this reason we are using an NHS email for security. The contact details will be used by the research team primarily for contacting the trainees to verify their suitability for the study and to offer a choice of study days to attend. In phase 2, questionnaires will request personal information which will be detached from the rest of the questionnaire and both will be labelled with a study number. Personal data will be kept in a locked cabinet in an NHS locked office belonging to a named NHS consultant. Electronic files will be stored on encrypted devices.

**Confidentiality**

The research team is trained in confidentiality and aware of the Caldicott principles. We are minimising the collection of personal information by:

- Sending out questionnaires through professional membership organisations.
- Only asking personal contact details of trainees volunteering for phase 2 of the study.
- If any abnormalities are detected on EEG/EMG the trainees will be contacted and requested to see their GP. We will not share that data with a third party unless data is anonymised.
- We are not involving any patients or their care records in the study.
- All personal information is to be kept on NHS computers or encrypted devices for secure storage.

**Conflict of interest**

We don't have any conflicts of interest to declare. The study is supported by Storz and medtronics and BSGE.

**Ethical Approval**

We have been granted ethical approval for the study to proceed from the faculty of Health and Medicine Research Ethics Committee (FHMREC) Lancaster University.

The study is sponsored by East Lancashire Hospital NHS Trust.

**Study timeline**

Permission from school heads- Sep-Dec 2020

Ethics approval- May 2021

Host registration- May 2021

Participant recruitment- part 1/online questionnaires: starting Mid April 2021-ongoing

Data collection- part 2- Sep to Oct 2021

Data analysis- Nov-Dec 2021

Manuscript- Jan-March 2021

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## Appendix

1. **Consultant Questionnaire (Appendix 1)**
2. **Trainee Questionnaire I (Appendix 2)**
3. **Participant information sheet (Appendix 3)**
4. **Consent Form 1 (Appendix 4)**
5. **Consent form 2 (Appendix 5)**
6. **Trainee questionnaire II (Appendix 6)**
7. **Trainee Standardised Task Instructions (Appendix 7)**
8. **Validated Laparoscopic tasks scoring Form (Appendix 8)**
9. **Validated suturing scoring system (Appendix 9)**
10. **EMG will be measured by placing wireless electrodes over arms, neck and back muscles (Appendix 10)**
11. **EEG will be recorded using wireless electrodes over parietal cortex using validated protocols. (Appendix 11)**
12. **Equipment (Appendix 12)**
13. **Assessor Instructions (Appendix 13)**

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**Appendix 1**

# Consultant Questionnaire: Expectations of Fundamental Laparoscopic Skills Required by the end of Higher Specialty Training

**Gender**

| | Mark with 'X' | | Mark with 'X' |
|---|---|---|---|
| Male | | Female | |

**Please state the year you became a consultant.**

**Specialty**

| | Mark with 'X' | | Mark with 'X' |
|---|---|---|---|
| General Surgery – Colorectal/HPB/Upper GI | | Gynaecology only | |
| | | Obstetrics and gynaecology | |

**Where did you complete the majority of your higher surgical Training?**

| | Mark with 'X' |
|---|---|
| UK | |
| EU, not UK | |
| Outside of the EU | |

**What percentage of your work do you perform laparoscopically?**

| | Mark with 'X' |
|---|---|
| **0-25%** | |
| **25-50%** | |
| **50-75%** | |
| **75-100%** | |

**What are your <u>expectations</u> of required laparoscopic abilities of trainees at CCT? For gynaecology consultants please base your answers on a trainee who is undertaking the following ATSM: Advanced laparoscopy, open and laparoscopic benign abdomen, gynae-oncology and other sub specialty trainees involving major laparoscopic work. Please mark your answer with an 'X'**

**Strongly Disagree – 1, Disagree -2, Neither agree nor disagree-3, Agree -4 and Strongly agree – 5.**

| **Laparoscopic ability** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| Proficient in obtaining laparoscopic intra-abdominal access | | | | | |
| Proficient in recognition of anatomy and anatomic tissue planes laparoscopically | | | | | |
| Proficient in safe manipulation of tissue laparoscopically | | | | | |
| Proficient in dissection of tissue planes laparoscopically | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Able to control bleeding laparoscopically using diathermy/energy devices. | | | | | |
| Able to control bleeding laparoscopically using endovascular staplers/haemolocks/endoloops | | | | | |
| Able to control bleeding laparoscopically using haemostatic agents ie Flowseal/surgicel | | | | | |
| Proficient in appropriate use of laparoscopic energy devices | | | | | |
| Proficient in laparoscopic suturing | | | | | |
| Proficient in use of laparoscopic staplers | | | | | |

**What is your <u>experience</u> of laparoscopic abilities of trainees at CCT? For gynaecology consultants please base your answers on a trainee who is undertaking the following ATSM: Advanced laparoscopy, open and laparoscopic benign abdomen, gynae-oncology and other sub specialty trainees involving major laparoscopic work. Please mark your answer with an 'X'**

**Strongly Disagree – 1, Disagree -2, Neither agree nor disagree-3, Agree -4 and Strongly agree – 5.**

| **Laparoscopic ability** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| Proficient in obtaining laparoscopic intra-abdominal access | | | | | |
| Proficient in recognition of anatomy and anatomic tissue planes laparoscopically | | | | | |
| Proficient in safe manipulation of tissue laparoscopically | | | | | |
| Proficient in dissection of tissue planes laparoscopically | | | | | |
| Able to control bleeding laparoscopically using diathermy/energy devices. | | | | | |
| Able to control bleeding laparoscopically using endovascular staplers/haemolocks/endoloops | | | | | |
| Able to control bleeding laparoscopically using haemostatic agents ie Flowseal/surgicel | | | | | |
| Proficient in appropriate use of laparoscopic energy devices | | | | | |
| Proficient in laparoscopic suturing | | | | | |
| Proficient in use of laparoscopic staplers | | | | | |

**How would you rate <u>your own confidence</u> with the listed laparoscopic skills? Please mark your answer with an 'X'**

**Not at all confident -1, Not so confident-2, Somewhat confident -3, Very confident -4, extremely confident-5.**

| **Laparoscopic ability** | **1** | **2** | **3** | **4** | **5** |
|---|---|---|---|---|---|
| Proficient in obtaining laparoscopic intra-abdominal access | | | | | |
| Proficient in recognition of anatomy and anatomic tissue planes laparoscopically | | | | | |
| Proficient in safe manipulation of tissue laparoscopically | | | | | |
| Proficient in dissection of tissue planes laparoscopically | | | | | |
| Able to control bleeding laparoscopically using diathermy/energy devices. | | | | | |
| Able to control bleeding laparoscopically using endovascular staplers/haemolocks/endoloops | | | | | |
| Able to control bleeding laparoscopically using haemostatic agents ie Flowseal/surgicel | | | | | |
| Proficient in appropriate use of laparoscopic energy devices | | | | | |
| Proficient in laparoscopic suturing | | | | | |
| Proficient in use of laparoscopic staplers | | | | | |

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**Appendix 2**

# Trainee Questionnaire: Expectations of Fundamental Laparoscopic Skills Required by the end of Higher Specialty Training and current level of confidence.

**1. Gender**

| | Mark with 'X' | | | Mark with 'X' | | Mark with 'X' |
|---|---|---|---|---|---|---|
| Male (including transgender men) | | Female (including transgender women) | Other | | Prefer not to say | |

**2. Specialty**

| | Mark with 'X' | | Mark with 'X' |
|---|---|---|---|
| General Surgery – Colorectal/HPB/Upper GI | | Other | |
| Obstetrics and gynaecology | | | |

**3. Are you currently enrolled in a specialty training program?**

Yes/ No

**4. Which deanery are you currently enrolled in a training program in? Please mark your answer with an X.**

North East Yorkshire and Humber North west

East midlands West midlands East of England South West

Thames valley Wessex Kent/surrey/Sussex (KSS)

North central and East London North West London

South London.

**5. Which level of training are you currently?**

| **Please mark your answer with an X** | | | | | |
|---|---|---|---|---|---|
| **ST3** | **ST4** | **ST5** | **ST6** | **ST7** | **ST8** |

**6. When did you commence higher surgical training/Obs and Gynae Training? (Year) _____**

**7. Please select the NHS deanery in which you are currently employed in. Please mark your answer with an X.**

North East Yorkshire and Humber North west

East midlands West midlands East of England South West

Thames valley Wessex Kent/surrey/Sussex (KSS)

North central and East London North West London

South London. None of the above.

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**8. What are your *expectations* of required laparoscopic abilities of trainees at CCT? Please mark your answer with an 'X'**

**Strongly Disagree – 1, Disagree -2, Neither agree nor disagree-3, Agree -4 and Strongly agree – 5.**

| Laparoscopic ability | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Proficient in obtaining laparoscopic intra-abdominal access | | | | | |
| Proficient in recognition of anatomy and anatomic tissue planes laparoscopically | | | | | |
| Proficient in safe manipulation of tissue laparoscopically | | | | | |
| Proficient in dissection of tissue planes laparoscopically | | | | | |
| Able to control bleeding laparoscopically using diathermy/energy devices. | | | | | |
| Able to control bleeding laparoscopically using endovascular staplers/haemolocks/endoloops | | | | | |
| Able to control bleeding laparoscopically using haemostatic agents ie Flowseal/surgicel | | | | | |
| Proficient in appropriate use of laparoscopic energy devices | | | | | |
| Proficient in laparoscopic suturing | | | | | |
| Proficient in use of laparoscopic staplers | | | | | |

**How would you rate *your own confidence* with the listed laparoscopic skills? Please mark your answer with an 'X'**

**Not at all confident -1, Not so confident-2, Somewhat confident -3, Very confident -4, extremely confident-5.**

| Laparoscopic ability | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Proficient in obtaining laparoscopic intra-abdominal access | | | | | |
| Proficient in recognition of anatomy and anatomic tissue planes laparoscopically | | | | | |
| Proficient in safe manipulation of tissue laparoscopically | | | | | |
| Proficient in dissection of tissue planes laparoscopically | | | | | |
| Able to control bleeding laparoscopically using diathermy/energy devices. | | | | | |
| Able to control bleeding laparoscopically using endovascular staplers/haemolocks/endoloops | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| Able to control bleeding laparoscopically using haemostatic agents ie Flowseal/surgicel | | | | | |
| Proficient in appropriate use of laparoscopic energy devices | | | | | |
| Proficient in laparoscopic suturing | | | | | |
| Proficient in use of laparoscopic staplers | | | | | |

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**Appendix 3**

**Participant Information Sheet (PIS)**

**Laparoscopic skills acquisition in obstetrics/Gynaecology and General Surgical trainees (LAGGS).**

We would like to invite you to take part in our research study. This is an information sheet detailing why the research is being done and what it would involve for you.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage: www.lancaster.ac.uk/research/data-protection

**What is the study about?**

We are exploring the differences between training programs in Obstetrics & Gynaecology (O&G) and general surgery (GS). We want to see if there is a difference in the acquisition of fundamental laparoscopic skills such as navigating a laparoscopic camera, using both hands, co-ordinating movements and placing sutures and knots in laparoscopic surgery. It is not very clear what laparoscopic skills are expected by experienced consultants at completion of training (CCT) by trainees. We believe this is important as this may indicate training standards. As part of this study we are therefore conducting questionnaires to explore these expectations of both trainees and consultants.

This study is conducted in 2 parts. The first part consists of a brief questionnaire. It asks about your training program type, training grade and how long you have been in training for. The questionnaire then ask you to rate your own laparoscopic skills using a scale of 1-5 followed by your perception of what laparoscopic skills you deem important at completion of training.
The second part of the study is based on performance on four laparoscopic tasks. These tasks involve navigating a laparoscopic camera, handling laparoscopic instruments, co-ordinating movements and placing sutures and knots on a foam pad in a laparoscopic simulator. During these tasks a small number of trainees will be requested to wear electrodes over their head and arms/neck which will measure brain and muscle fatigue. We are using this information as a marker of how much exposure a trainee may have had to laparoscopic surgery.

**Why have I been approached?**
To carry out this study, we need help from trainees on O&G and GS training programs. We are interested in comparing trainees from both specialties across a range of training grades. We are including trainees from the following training grades within the North West deanery:
Ten trainees at ST3, ST4 and ST5 (if experience in ST5 grade is < 3 months or equivalent for part time trainees) in O&G and ten trainees of same grades in GS,
Ten trainees at ST6-7 in O&G,
Ten trainees at ST7-8 in GS,
You have been requested to help if you fall in one of these training grades.

We are asking your help by both completing the questionnaire (national) and by volunteering to take part in the laparoscopic exercises (north west deanery based).

**Do I have to take part?**
No. Participation in this study is completely voluntary. You may decide that you want to help with only one part of the study but not the other which is entirely acceptable. We are grateful for whatever contribution you are able to make.

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**What will I be asked to do if I take part?**

If you decide you would like to take part, you will be asked to fill in a short online questionnaire on your perception of laparoscopic training. This part applies both to consultants and trainees alike.

If you are willing to volunteer for part 2 of the study by undertaking laparoscopic exercises then we will contact you to arrange a suitable day to attend a hospital site of your choice over a weekend day. We will ask you to complete a written consent form and fill out a short questionnaire. This survey takes approximately 5 minutes to complete.

We will then request you to carry out 4 laparoscopic tasks on Storz simulators using inanimate training models. These models and structure of the tasks are very similar to gynaecological endoscopic surgery education and assessment (GESEA) certification and are endorsed by BSGE for O&G trainees wishing to pursue a career in laparoscopic surgery. Some of the trainees will be randomly chosen to have wireless sensors applied over head, neck, arms and lower back. We will record neural activity from the muscles and the brain during the completion of 4 laparoscopic tasks. These sensors are very discreet, painless and will not impede your freedom of movements. These will tell us how quickly fatigue sets in.

**Will my data be Identifiable?**

Your personal data will be kept confidential and separate from your questionnaire and laparoscopic tasks data. You will be allocated a study number to preserve your anonymity. Your study number will be used to link up your data from the research study (questionnaire and laparoscopic tasks data). Your data will therefore be anonymous and you will not be identifiable from the research data.

**Will my data be kept confidential?**

We will follow ethical and legal practice and all information about you will be handled in confidence.

The data collected for this study will be stored securely on Lancaster university secure cloud storage and only the researchers conducting this study will have access to this data.

- Hard copies of questionnaires will be kept in a locked cabinet.
- The files on the computer will be encrypted (that is no-one other than the researchers will be able to access them) and the computer itself is password protected.
- At the end of the study, hard copies of questionnaires will be kept securely in a locked cabinet for ten years. At the end of this period, they will be destroyed.
- All your personal data will be confidential and will be kept for 1-3 years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted).

**What will happen to the results?**

The results will be analysed and reported. The results may be used for presentations at conferences, medical meetings and may be submitted for publication in an academic or professional journal.

**Are there any risks?**

There are no potential risks associated with EMG and EEG recordings. EMG electrodes will be placed on the skin after being prepped with cleansing agent and application of a gel.

Wireless systems will be used so it does not impede your movements during the procedure or cause distractions.

Any incidental musculoskeletal or EEG findings which warrant further investigation will be reported to your GP as per standard protocol and with your consent.

**Are there any benefits to taking part?**

You may find that taking part in this study is interesting and will get the opportunity to use laparoscopic simulator boxes and models. Tasks used in this study are very similar to those used in GESEA courses. GESEA is useful for those interested in pursuing training in gynaecological laparoscopy. We will be offering an Amazon voucher of £30 as an inconvenience allowance.

**What will happen if I don't want to carry on with the study?**
Your participation is voluntary, and you are free to withdraw at any time, without necessarily giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

**Will any blood or genetic tests be done?**
No. For this particular study, only non-invasive data is being collected.

**Who has reviewed the study?**
This study is being submitted for review by the Faculty of Health and Medicine Research Ethics Committee at Lancaster University. This study is sponsored by East Lancashire Hospitals NHS Trust.

If you have any questions, queries or complaints then please contact:
Dr Christopher Gaffney
Lecturer in Integrative Physiology, Lancaster Medical school
Health Innovation One, Sir John Fisher Drive
Lancaster University, LA1 4AT
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Contact details:

| | | | |
|---|---|---|---|
| Research investigators | Zaibun khan<br>ST4, O&G<br>Royal<br>Lancaster infirmary.<br>zaibunkhan@gmail.com | Mrs Donna Shrestha<br>ST6, General surgery<br>Royal Blackburn hospital.<br>Donna.shrestha@elht.nhs.uk | Mr Abdulwarith Shugaba<br>Research fellow<br>Lancaster university.<br>Abdulwarith.shugaba@elht.nhs.uk |
| Research supervisors | Mr Daren Subar<br>Consultant HPB laparoscopic surgeon,<br>East Lancashire hospitals NHS Trust. | Prof Thomas Justin Clark<br>Consultant gynaecologist<br>Birmingham<br>President of BSGE.<br>Birmingham women's hospital. | Dr Chris Gaffney<br>Lecturer in integrative physiology,<br>Lancaster Medical school,<br>Lancaster university. |
| Research supervisors | Dr Elizabeth Haslett<br>Head of School for obstetrics & gynaecology, North West health education. | Miss Karolina Afors<br>Consultant obstetrician & gynaecologist<br>Whittington hospital,<br>London | Research sponsor<br>Michelle Stevens, Research & Development. East Lancashire hospitals NHS Trust (ELHT).<br>michelle.stephens@elht.nhs.uk |

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**Appendix 4.**

**Consent form 1** (For consultant and trainee questionnaires).

By proceeding to the survey you confirm that:

- You have read the information sheet and understand what is expected of you within this study
- You confirm that you understand that any responses/information you give will remain anonymous
- Your participation is voluntary
- You consent for the information you provide to be discussed with my supervisors
- You consent to Lancaster University keeping the anonymised data for a period of 10 years after the study has finished
- By clicking on this link, you consent to **taking part in the current study**.

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**Appendix 5**

**Consent form 2**

**Laparoscopic skills acquisition in obstetrics/Gynaecology and General Surgical trainees (LAGGS).**

We are asking if you would like to take part in a research project exploring the differences in Obstetrics & Gynaecology and General surgery training programs.
Before you consent to participating in the study we ask that you read the participant information sheet and mark each box below with your initials if you agree. If you have any questions or queries before signing the consent form please speak to the principal investigator.

I confirm that I have read the information sheet and fully understand what is expected of me within this study

1. I confirm that I have read the information sheet and fully understand what is expected of me within this study ☐
2. I confirm that I have had the opportunity to ask any questions and to have them answered. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
4. I understand that once my data have been anonymised it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication. ☐
5. I understand that my anonymised data will be pooled with other participants' responses and may be published; all reasonable steps will be taken to protect the anonymity of the participants involved in this project. ☐
6. I understand that the researcher will discuss data with their supervisor as needed. ☐
7. I understand that any information I give will remain confidential and anonymous ☐
8. I consent to Lancaster University storing the anonymised study data for 10 years after the study has finished. ☐

9. I consent to taking part in the above study. ☐
10. I consent to EEG/EMG testing in this study. ☐

Please indicate if you prefer a female member of the team to apply these electrodes for you. This is completely understandable and no trouble for us at all.

**Name of Participant**_____ **Signature**_____ **Date** _____

**Name of Researcher** _____**Signature** _____**Date** _____

**Appendix 6**

Trainee questionnaire II

**ANONYMISED CODE HERE e.g LAP 01 G2**

Name---------- Age----------

Email---------- contact phone number……..

--x---------x----------x----------x----------x----------x----------x----------x---------x----------x-

**Your personal contact details will be stored separately and securely from the remaining questionnaire and scoring sheets.**

**ANONYMISED CODE HERE e.g LAP 01 G2**

Gender----------Deanery……Specialty----------Training grade/Job title ----------

Start of ST3 training (Year)

Weight---------- height---------- BMI----------

Q1.Dominant handedness. Please tick one of the following 3 options.

| I am right handed | I am left handed | I am bi-dexterous |
|---|---|---|

Q2. Do you play video games on average? Please tick 'Yes/No' below. If answering 'Yes' please tick the appropriate frequency of use from the below list.

| | | |
|---|---|---|
| **Yes** | Daily | |
| | Weekly | |
| | Monthly | |
| | Every 3 months | |
| | Yearly or less frequently | |
| **No**- I don't play video games | | |

Q3.Do you use a laparoscopic simulator? Please tick 'Yes/No' below. If answering 'Yes' please tick the appropriate frequency of use from the below list.

| | | |
|---|---|---|
| YES | Daily | |
| | Weekly | |
| | Monthly | |
| | Every 3 months | |
| | Yearly or less frequently | |
| NO- I don't use lap simulator | | |

Q4. Please indicate the type and approximate number of laparoscopic courses have you attended during your current training program? If none attended, please indicate not applicable here.

| Type of courses | Box trainer | Virtual reality | Cadaver based | Animal tissue | Other |
|---|---|---|---|---|---|
| No of courses attended | | | | | |

Q5. Have you done laparoscopic work during 'time out of training' or before starting your current training program?

| Yes | No |
|---|---|

If answering yes to Q4, how frequently were you doing operative laparoscopic work (on average) during this period?

| >2 times per week. | 2 times per week. | Once weekly. | Once fortnightly. | Once monthly. | Less than once monthly. |
|---|---|---|---|---|---|
| | | | | | |

Q6. In which training grade were you **initially** allocated to an operative laparoscopy list?.....

Q7. How regularly are you allocated to a theatre list involving operative laparoscopy? Please tick one of the following statements.

| >2 times per week. | 2 times per week. | Once weekly. | Once fortnightly. | Once monthly. | Less than once monthly. |
|---|---|---|---|---|---|
| | | | | | |

Q8. When allocated to a theatre list involving operative laparoscopy, do you **'Generally'** get the opportunity to perform some or most of the operation in suitable training cases, or are you mostly assigned as an assistant or an observer? Please tick one of the following statements or free text your answer if you are able or want to provide more details.

| I get the opportunity to perform some or most of the operation in cases suitable for training. | I am usually assigned to an assistant's role. | I usually observe the case only. | |
|---|---|---|---|

Space for free text answer.----------

Q9. How frequently were you involved in emergency operative laparoscopy such as lap appendicectomy, cholecystectomy, laparoscopic management bowel obstruction, of ectopic pregnancy and or ovarian torsion? Please tick one of the statements below.

| >2 times per week. | 2 times per week. | Once weekly. | Once fortnightly. | Once monthly. | Less than once monthly. |
|---|---|---|---|---|---|
| | | | | | |

**Physical health and fitness:**

What form of regular exercise do you undertake? E.g. Walking/running/resistance training/yoga etc

……..

How frequently do you undertake the above exercise in a week? Please choose by ticking the appropriate statement from the list below.

### Activity level

| | |
|---|---|
| Inactive (less than 30minutes a week) | |
| Moderately Active (Between 30 and 60 minutes a week) | |
| Active (Between 60 and 150 minutes a week) | |

**Musculoskeletal symptoms**

During the past 12 months have you had any trouble (ache/pain/discomfort/numbness) in any of the following please: (please circle the appropriate response)

| Body system | Yes | No |
|---|---|---|
| Neck | | |
| Right shoulder | | |
| Left shoulder | | |
| Right wrist | | |
| Left wrist | | |
| Right upper back | | |
| Left upper back | | |
| Right lower back | | |
| Left lower back | | |

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**Appendix 7**

**Trainee Instructions for laparoscopic tasks**

**Exercise 1: Camera Handling**

The aim of the first exercise is to navigate the 30° camera to locate all targets in the shortest amount of time.

Each target consists of a large character and a small character. (Numbers and alphabet letters).

The task begins when you insert the camera to find the character on the first target. The small character indicates your next target.

The task ends when all 14 targets have been found.

Your first target is '1a' - Start your search by locating the first target "1a". The figure below is an example of the first target to find and what each target consists of.


Large character '1' corresponds to the starting character.

Small character 'a' corresponds to the next character to find which will appear as a large character on the subsequent target.

Once the small character is found, zoom in and place the small character in the circle on the screen. If facilitator approves your found character then move on to the next one. Now navigate the camera to find 'A' which should appear as a large character from a panoramic field, zoom in and find the small character next to it and place it in the circle on the screen and then move on. Continue until all 14 characters have been found indicated by finding ' **Nend'**. This completes the task.

This task will be repeated 3 times with 3 different target sequences.

**Exercise 2: Hand-eye Coordination**

The aim of this exercise is to test your ability to navigate the camera with your non-dominant hand and to handle the forceps with your dominant hand.

Pick up **one** coloured cylinder from the centre of the wooden model using grasping forceps (Maryland) in your dominant hand and then place this cylinder on its corresponding coloured nail on the wooden model.

If you drop a cylinder, you can use the second cylinder of the same colour or you may re-grasp the fallen one, as long as you can find the cylinder within the endoscopic boundaries. The exercise starts when you insert the 0 degrees camera through the central port.

This task will be repeated 3 times with 3 different colour sequences.

**Exercise 3: Bi-manual Coordination**

The aim of this exercise is to evaluate the ability to handle two forceps simultaneously with your dominant and non-dominant hand. The facilitator will navigate the camera for you in an optimal position or as per your instructions.

Your task is to position **one** pushpin of each colour in the corresponding colour disc.

Grasp the plastic head of the pin with Johan forceps using your non-dominant hand and lift the pin up.

Whilst elevated, pass the pin to the dominant hand by grasping the metal part of the pin with a Maryland grasper.

Place the pin (head or tail) in the corresponding coloured disc and repeat for all colours. Once the pin is positioned in the disc of the same colour, you may move on to the next coloured push pin. It is not necessary to position the entire length of the pushpin in the respective circle. You may use both hands to stop the pin from falling out.

You are only required to place 6 pins in their respective circles, i.e. one of each colour. If the pin is dropped, use the second pin of the same colour or you may re-grasp the fallen pin, as long as you can find the pin within the endoscopic boundaries.

This task will be repeated 3 times with 3 different colour sequences.

**Exercise 4: Suturing and knot tying**

The aim of this task is to perform 4 interrupted stitches using correct needle handling and intra-corporeal knot tying techniques.

Perform 4 interrupted sutures by taking a needle bite through the black dots in a horizontal plane. Please use the first 4 rows for your sutures and leave the 5$^{th}$ row.

Pass the suture by entering and exiting precisely within the black dots.

Perform an intra-corporeal knot with 3 throws. Ensure that the knot is secure.

Cut the excess suture using laparoscopic scissors leaving behind a tail of approx. 1-2cm.

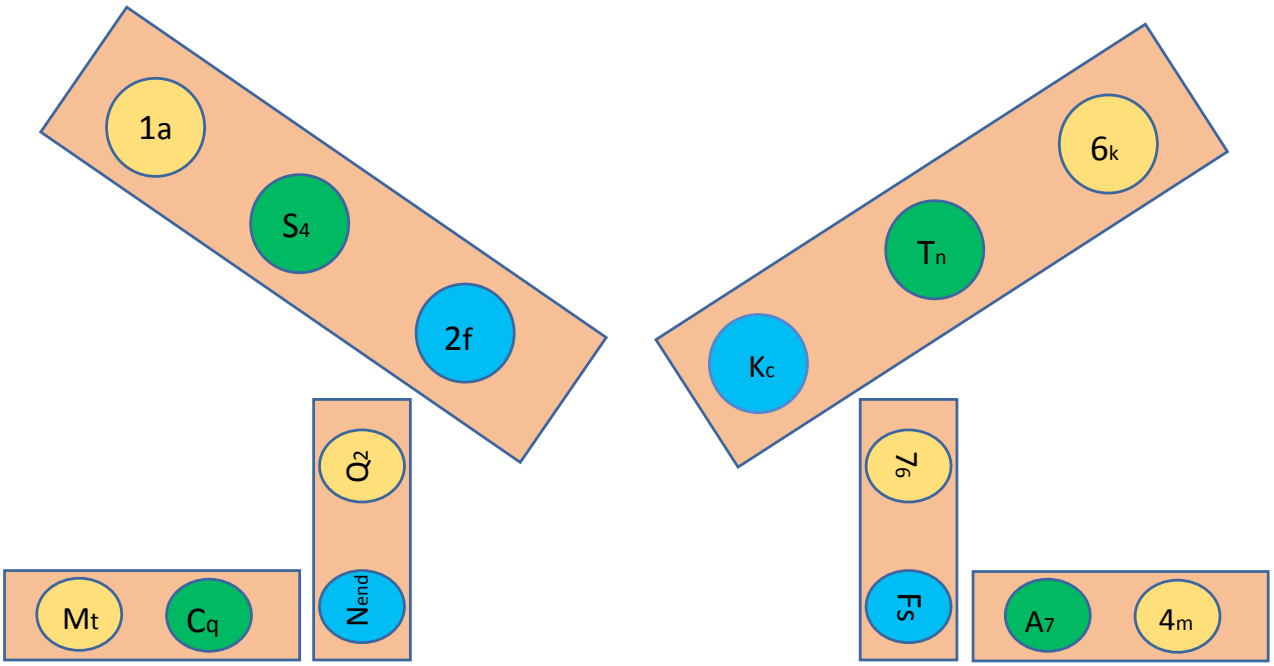
## The link to the video demonstration for tasks 1-3 is:

## https://europeanacademy.org/training-tools/lastt/

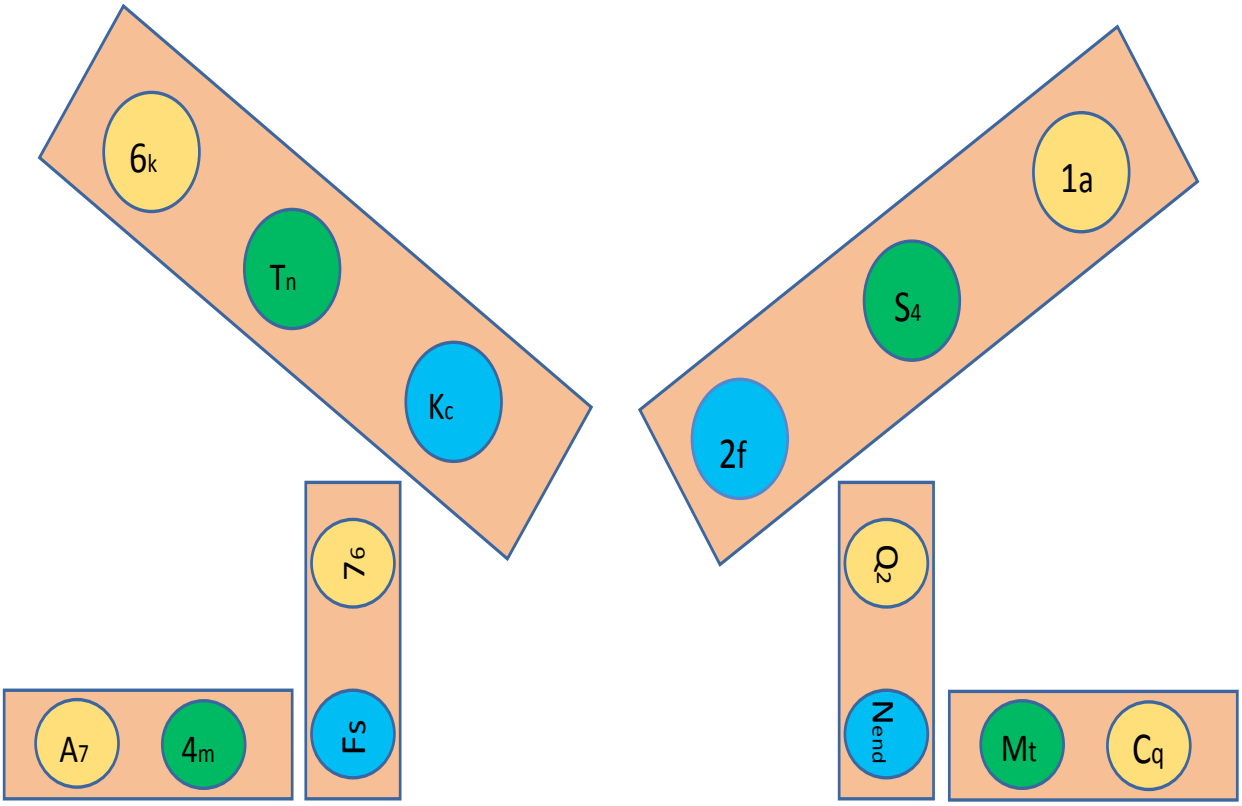
## The link to suturing demonstration video is:

## https://www.youtube.com/watch?v=2qCBvbWBJ64

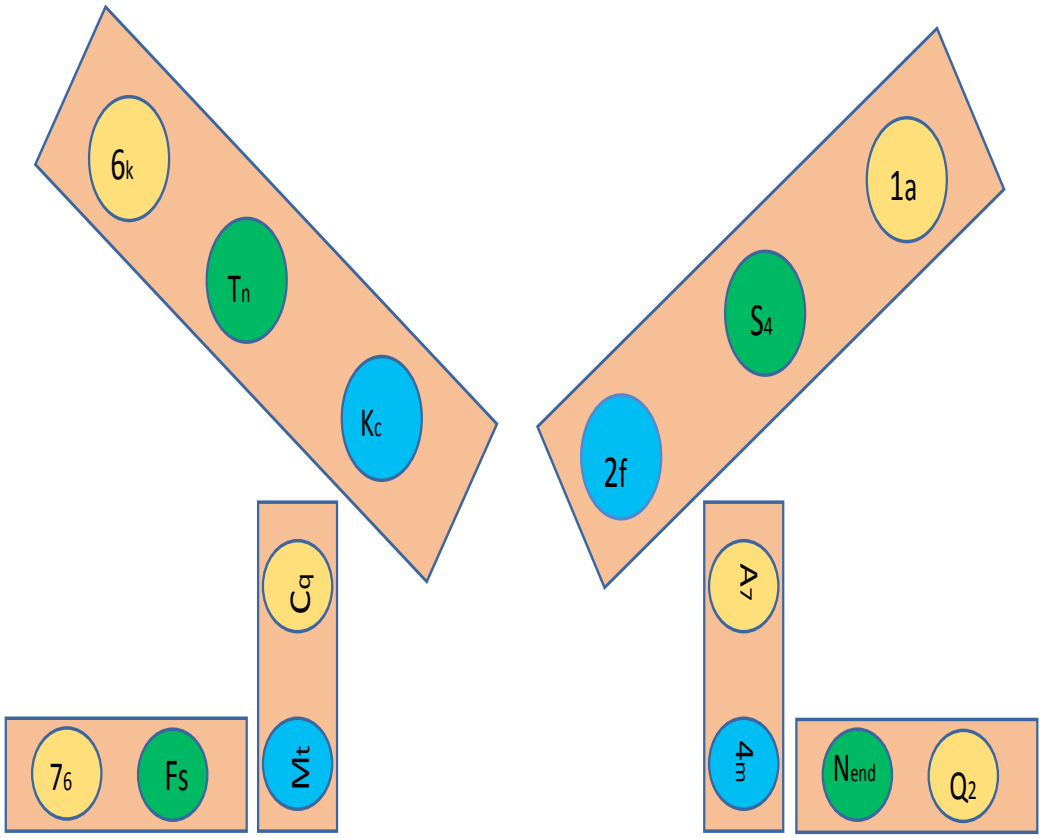
**Below are the 3 different sequences to be used in task 1.**




Sequence 1




Sequence 2




Sequence 3

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**The following are 3 different colour sequences to be used in task 2 and 3.**


**Colour sequence 1 for tasks 2 and 3**

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**Colour sequence 2 for tasks 2 and 3**


**Colour sequence 3 for tasks 2 and 3.**

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**Appendix 8**

**Task evaluation sheets for laparoscopic tasks**

Please indicate the time as you read it on the stopwatch in MM:SS:HH

**Task 1: Laparoscopic Camera Navigation (LCN)**

| **Runs** | Time required for identifying all 14 targets. (If within or up to 5 minutes taken). | If 5 minutes are exceeded, record the last found target (small character). | Penalties. **To be filled after study tasks are completed**. |
|---|---|---|---|
| **1** | : : | | |
| **2** | : : | | |
| **3** | : : | | |

**Task 2: Hand- Eye Co-ordination (HEC)**

| **Runs** | Time required for inserting 6 cylinders OR 3 minutes | No of cylinders placed in 3 minutes | No of dropped objects |
|---|---|---|---|
| **1** | : : | | |
| **2** | : : | | |
| **3** | : : | | |

**Task 3: Bimanual co-ordination (BMC)**

| **Runs** | Time required for positioning 6 pins OR 3 minutes | No of pins placed in 3 minutes | No of dropped objects |
|---|---|---|---|
| **1** | : : | | |
| **2** | : : | | |
| **3** | : : | | |

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**Appendix 9**

**Scoring sheets for laparoscopic suturing and knot quality:**

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# SUT+T1 EVALUATION

| RESULT | | | |
|---|---|---|---|
| TIME: | : : | | max 15 min. |
| DOT: | 0 1 2 3 4 5 6 7 8 9 10 | | |
| CORRECT STITCH: | 0 1 2 3 4 5 | | |
| KNOT: | 0 - 2 | TRAUMA: | 0 1 2 |

## 1) TIME

Time maximum - 15 minutes

## 2) DOT 0-1-2-3-4-5-6-7-8-9-10

To count dots through which the thread is passed correctly.

Dot may be counted when the stitch (thread) is entered in any point of the dot (when the thread is visually in contact with any part of the dot)
Incorrect dot (not to be counted)is considered when the stitch is passed obviously out of the knot


## 3) CORRECT STITCH 0 – 5

The thread is passed correctly through **both dots**

## 4) TRAUMA

The damage of the suturing pad

0 = minimal, no damage | 1 = moderated damage | 2 = heavy damage

## 5) KNOT 0 – 1 - 2

Flat knot and two additional half knot

2 = knot is correct and tied | 0 = all the rest

**Trauma**

0: No damage, up to 4 needle puncture marks, no excavation, or exposed foam irrespective of the size of defect.

1: Between 5 and 8 needle puncture marks, defect in foam pad of less than 5mm or extent of trauma more than grade 0 but less than grade 2.

2: More than 8 needle puncture marks, Underlying foam exposed, defect in foam pad of 5mm or more, excavation and cavity formation.

**Knot quality:**

2: square knot, 3 throws and flat.

0: any of the above absent.

Knot quality should be assessed for each knot. Overall score for this section (knot quality) is the sum of all knots quality scores.

**Appendix 10**

**Electromyography (EMG) protocol**

Participants will be fitted with wireless EMG sensors. The EMG data collection procedures will follow established protocols regarding site preparation and electrode placement, as well as data collection, processing and normalisation. Briefly, the site will be shaved and cleansed with alcohol wipes, with the bipolar electrodes placed on the belly of the muscle and parallel to the muscle's fibres having an inter-electrode distance of 20mm. Electrodes will be placed on muscles of the arm, neck, shoulder and back e.g. flexor carpi radialis muscles, biceps muscle, bilaterally from the trapezius muscles, and bilaterally from the erector spinae muscle. A wireless EMG system has been selected so that it is minimally invasive and does not impede the participants' movement with wires.

Data will be collected and analysed using EMG Works (Delsys Inc., Boston, MA, USA), with recommended normalisation, sampling, filtering and smoothing techniques. EMG recordings in previous data show significant changes during laparoscopic procedures in 70 - 85% of surgeons, mainly in neck, shoulders, hands, lower back, and lower extremities muscles. We will be obtaining recordings from muscles of the arm, neck, shoulder and back. Once the EMG signal has been normalise, basic EMG variables, such as frequency and amplitude, can provide information on how muscle fibre recruitment has changed, both at a single muscle as well across several muscles (activation / recruitment strategies), while a fatigue score can also be calculated. The normalisation process can afford the ability to compare between muscles as well as examine the muscles' activity different time points (i.e. within the same session or after a longer time has elapsed

**Figure:** Example wireless EMG sensor placement

**Appendix 11**

**Electroencephalography (EEG) protocol**

Similar to the EMG data capture, EEG data will also be collected during the surgical task. The skin site on the head will be prepared as previously described before the electrode gel and electrode cap are applied. Electrodes will be placed over the cortex using an 8-channel electrode montage to record ongoing EEG oscillations during surgery. Electrodes will be positioned according to the 10-20 international electrode placement system. The main EEG channels of interest will be positioned over the occipital and parietal cortex, namely electrode locations O1, O2, P3, P4, P7, P8 where maximal alpha activity can be detected. A wireless EEG system has been selected so that it is minimally invasive and does not interfere with movement during the task.

Data will be collected and analysed using Enobio 8 5G (Neuroelectrics, Cambridge, MA, USA) using standard referencing, sampling, filtering and smoothing technique. We will compare peak alpha power, and alpha spindle duration and amplitude between groups. Changes in EEG power spectra, specifically in the alpha frequency band, will be used to monitor alertness. We will also be able to identify how alertness changes over time during surgery through the EEG power spectra.

**Figure:** Example wireless EEG sensor placement

**Appendix 12**

**Equipment**

6 stack systems (monitor, 10mm optic (0 and 30 degrees, light)

Laparoscopic 5mm ports x2, 10mm port x1

Tissue grasping forceps (Johans)

Kelly/Maryland  dissecting forceps

Needle holders (right and left)

Laparoscopic scissors

Vicryl 2.0 sutures each one cut to 20cm in length.

SUTT1 foam pads

Wooden LASTT model with its inserts

Stop-watch

Weighing  scale

Measuring tape for height

**Appendix 13**

**Assessor Information**

An assessor will be allocated to each trainee who will mount the relevant inserts into LASTT model, replace the LASTT model with SUTT suturing pad and set up equipment as in Appendix 9.

They will provide the trainee with standardised instructions before each task and discreetly fill out the scoring sheets. The assessors will not give any performance feedback although they can clarify the instructions as many times as necessary on the trainee's request. They will use the stopwatch and keep the trainee updated with how much time they have used up.

**Task 1:**

The aim of the first exercise is to navigate the 30° camera to locate all targets in the shortest amount of time.

Place the LASTT model in the box such that the top edge of this box is lined up with the second white pin along the side of box trainer. Put the inserts as per sequence 1.

A 10mm and 30 degrees camera is used. It is to be inserted through the most proximal central port on the Szabo box trainer. Request the trainee to read the instructions and then show them the demonstration video.

Check trainee's understanding of the task.

On the LASTT model there are 14 targets. Each target consists of a large character and a small character (numbers and alphabet letters).

The task time begins when the trainee inserts the camera to find the first target. The small character on that target indicates their next target.

The first target is always '1a'. Trainee starts their search by locating the first target "1a". The figure below is an example of what the first target looks like.


Large character '1' corresponds to the starting character.

Small character 'a' corresponds to the next character to find which will appear as a large character on the subsequent target.

Once the small character is found, trainee needs to zoom in and place the small character in the circle on the screen. If you approve that the entirety or boundaries of the small character is placed in the circle on the screen then indicate that they can move on to next target by saying 'next." The trainee should now navigate the camera to find capital 'A' on the next target, then zoom in, find the small character next to it

and place it in the circle on the screen and then move on. The trainee can continue until all 14 characters have been found indicated by finding ' **Nend'**. This completes the task.
Record the time taken to find 14 targets for each round. Ideal time for completing this task is 2 minutes and 30 seconds. However we are allowing a maximum time of 5 minutes for its completion. If trainee is unable to complete the task within 5 minutes, then stop the trainee at that point and record the last target they found; e.g. Mq.

Now change the inserts for round 2 using sequence 2 and repeat above. Record the same data as above before proceeding to round 3 using sequence 3. Once this round is completed, record the above data and move the trainee on to task 2.

**Exercise 2: Hand-eye Coordination**

The aim of this exercise is to test the trainee's ability to navigate the camera with their non-dominant hand and to simultaneously handle the forceps with their dominant hand.

The LASTT model stays in position as per task 1.

Put the coloured inserts as per sequence 1 for task 2 in the LASTT model.

A 10mm and 0 degrees camera is used for this task. The camera is to be inserted through the most proximal central port on the Szabo box trainer. Insert a 5mm lateral port (left or right) half way down the Szabo box trainer.

Place the coloured cylinders in a circular style in a vertical upright position around the " +he academy…" sign on the LASTT model. There will be 2 cylinders of each colour in case one is dropped out of view. Trainee is expected to transfer only one cylinder of each colour to their corresponding nails.

On the LASTT model there are 6 coloured discs (blue, red, yellow, green, black and white) and a pin is located next to each coloured disc.

Request the trainee to read the instructions and then show them the demonstration video.

Check trainee's understanding of the task.

The trainee is expected to pick **one** coloured cylinder using grasping forceps (Maryland) in their dominant hand and then place this cylinder on its corresponding coloured nail on the wooden model.

If they drop a cylinder, they can use the second cylinder of the same colour or could re-grasp the fallen one, as long as it remains in endoscopic view.

The trainee is expected to insert the 0 degrees camera and the timer starts when the grasper is inserted through the lateral port and it can be seen in endoscopic view on the screen.

A total time of 3 minutes is allowed for this task. Record the time taken for trainee to transfer 6 cylinders if task completed within 3 minutes. If 3 minutes are exceeded then record the number of cylinders correctly transferred, i.e. 4 cylinders. Also record the number of time a cylinder is grasped and dropped.

Now change the inserts for round 2 using sequence 2 for this task and repeat above. Record the same data as above before proceeding to round 3 using sequence 3. Once this round is completed, record the above data and move the trainee on to task 3.

This task will be repeated 3 times with 3 different colour sequences.

**Exercise 3: Bi-manual Coordination**

The aim of this exercise is to evaluate trainee's ability to handle two forceps simultaneously with their dominant and non-dominant hands. As the facilitator you will navigate the camera for them and give them an optimal position or as per the trainee's instructions.

The LASTT model stays in position as per task 1 and 2.

Put the coloured inserts as per sequence 1 for task 3 in the LASTT model.

A 10mm and 0 degrees camera is used for this task. The camera is to be inserted through the most proximal central port on the Szabo box trainer. Insert two 5mm lateral ports (left and right) halfway down the Szabo box trainer.

Place the coloured pushpins around the "+he Academy…" sign on the LASTT model. There should be 6 coloured pushpins (blue, red, yellow, green, black and white). The pins will be laid flat in a circle with pin's tail (metal part) pointing outwards and the pin's head (plastic part) pointing towards the 'Academy' sign on LASTT model.

There will be 2 pushpins of each colour in case one is dropped out of view. Trainee is required to transfer only one pushpin to their corresponding coloured disc.

On the LASTT model there are 6 coloured discs (blue, red, yellow, green, black and white).

Request the trainee to read the instructions and then show them the demonstration video.

Check trainee's understanding of the task.

You are expected to insert the 0 degrees camera and start the timer starts when the trainee inserts the graspers and they can be seen in endoscopic view on the screen.

The trainee is expected to identify a coloured pin (e.g. red), grasp it by the head with grasping forceps (Johans) using their NDH, then transfer the pin to their DH and grasp the pin by its tail using curved forceps like Maryland. The pushpin then needs to be placed in the corresponding disc of the same colour correctly before moving on to the next pushpin. Correct placement is achieved when the trainee has placed the pushpin (either its head or tail) in the respective disc. Trainee can use both hands to stop the pin from falling out.

If they drop a pushpin, they can use the second pushpin of the same colour or could re-grasp the fallen one, as long as it remains in endoscopic view.

A total time of 3 minutes is allowed for this task. Record the time taken for trainee to transfer 6 pushpins if task completed within 3 minutes. If 3 minutes are exceeded then record the number of pushpins correctly transferred. Also record the number of time a pushpin is grasped and dropped.

Now change the coloured inserts for round 2 using sequence 2 for task 3 and repeat above. Record the same data as above before proceeding to round 3 using sequence 3. Once this round is completed, record the above data and move the trainee on to task 4.

**Exercise 4: Suturing and knot tying**

The aim of this task is to perform 4 interrupted sutures and knots using correct needle handling and intra-corporeal knot tying techniques.

Remove the LASTT model along with its inserts from the box trainer.

A Suturing and knot tying Training and Testing method (SUTT1) foam pad will be used for assessment of suturing and knot placement (Figure 2). This has 5 rows of dots. For this task the top 4 rows are used and the 5th row is disregarded.


Figure 2. SUTT1 foam pad for assessment of suturing and intra corporeal knot tying. It contains 5 rows of large black dots placed about 10mm apart.

The suturing pad is affixed on an A4 card labelled SUTT-1. This card is to be secured on to a large black foam base. This foam base has 2 raised edges near the top.

Align the top of A4 SUTT-1 card with the top ridge on this foam base and then secure it on to the foam base using 6 pins (3 pins along each long edge of A4 card).

Attach the large foam base to the floor of the Szabo box trainer using 4 Velcro strips at the four corners. The purpose of this is to prevent any potential movements of the suturing pad/base during the suturing task.

Cut 6 Vicryl 2.0 sutures to a length of 20cm.

As the facilitator you are expected to insert the 0 degrees camera through the central port in the middle of the box trainer. Insert two 5mm lateral ports (left and right) halfway down the box.

Request the trainee to read the instructions and then show them the suturing demonstration video.

Check trainee's understanding of the task.

The trainee is required to perform 4 interrupted sutures by taking a needle bite through the black dots in a horizontal plane. Please instruct the trainee to use the first 4 rows on the suturing pad and leave the 5$^{th}$ row.

The trainee is expected to pass the suture by entering and exiting precisely within the black dots and perform intra-corporeal knot with 3 throws. They should then cut the excess suture using laparoscopic scissors leaving behind a tail of approx. 1-2cm. This process can then be repeated along the 4 rows to perform a total of 4 sutures and 4 knots.

A total time of 15 minutes will be allowed for this task. Please record the total time taken to complete 4 sutures and 4 knots if completed within or less than 15 minutes. If the trainee runs out of time (15 minutes are exceeded) then the total number of sutures +/- knots performed within the 15 minutes will be recorded. The suturing task will be assessed by 2 independent assessors retrospectively.