Study Title: Simulation-based Arthroscopic Surgery Programme

Internal Reference Number / Short title: Simulation-based Arthroscopic Surgery Programme

Ethics Ref: MSD-IDREC-C1-2014-152

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Sponsor:	University of Oxford
Funder:	Royal College of Surgeons of England and NIHR Oxford Musculoskeletal Biomedical Research Unit

Chief Investigator Signature:

The investigators have no potential conflicts of interest.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	'Simulation-based Arthroscopic Surgery Programme' (MSD-IDREC-C1-2014-152)	
Internal ref. no. / short title		
Study Design	Educational observational study	
Study Participants	Healthy Volunteers from junior surgical trainees, and their consultants, working within the Oxford Deanery (Health Education Thames Valley)	
Planned Sample Size	60 per year	
Planned Study Period	5 years (to 2019)	
	Objectives	**Outcome Measures**
Primary	Assess the usefulness to training of the new elbow-attached motion sensors during diagnostic knee arthroscopy as part of routine consultant-supervised training in theatre	Motion data, Global Rating Scales, Surgical logbook data
Secondary	Assess the usefulness to training of the new elbow-attached motion sensors during simulated arthroscopy in the skills lab	Motion data, Surgical logbook data

2. ABBREVIATIONS

CCT	Certificate of Completion of Training
CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
GMC	General Medical Council
GP	General Practitioner
GRS	Global Rating Scale
HETV	Health Education Thames Valley
ICF	Informed Consent Form
MAT	McLaren Applied Technology
NHS	National Health Service
NRES	National Research Ethics Service

OOSEC	Oxford Orthopaedic Simulation and Education Centre
PI	Principal Investigator
PIL	Participant Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SAC	Specialty Advisory Committee
SOP	Standard Operating Procedure

3. BACKGROUND AND RATIONALE

The 'Simulation-based Arthroscopic Surgery Programme' MSD-IDREC-C1-2014-152 aims to gather evidence for simulation training during surgical training. On a background of decreasing working time available, less independent operating, and greater public expectations of the medical profession, simulation is seen as an important support to routine surgical training. However, there is little evidence to show it improves surgical performance, and studies not been based on truly objective measurements. The 'Simulation-based Arthroscopic Surgery Programme' has the primary aim of developing evidence-based simulation training by objectively justifying the use of simulation to improve surgical training.

At the Oxford Orthopaedic Simulation and Education Centre (OOSEC) we are investigating new training methods for our future surgeons and using simulators, cadaver specimens and virtual reality models. To ensure evidenced based training we assess the learning and performance of the trainee groups using these various simulators. These groups mainly compromise surgical trainees, consultants and medical students and NHS ethics is not required, however to ensure best practice and as this work can lead to educational publications, we have ethical approval in place from CUREC (Simulation-based Arthroscopic Surgery Programme; MSD-IDREC-2014-152). In addition, and as part of an educational project, we will assess trainees in the real operating theatre as part of their usual training with their consultants, while patients receive their normal treatment.

Motion analysis is a validated objective measure of technical skill used previously in simulated settings: numbers of hand movements and total path length have been shown to decrease with surgeon experience during simulated tasks. Typically, motion analysis involves wired sensors attached to the wrists that are unsuitable for use in theatre as the position interferes with sterile scrubbing. Our group has developed simple elbow-worn wireless motion sensors: besides using these sensors in the simulated setting it is now possible to also use them in the real operating theatre while trainees under go their normal training and assessments.

Our study has CUREC approval to use surgical trainees as volunteers, and for technical skills assessments to take place in a simulated setting: we are seeking additional Trust approval to use elbow-worn wireless motion sensors during a routine consultant-supervised training list in the real operating theatre as an objective form of educational monitoring in addition to the methods already in use in their training programme curriculum portfolios (e.g. Practice-based Assessments, Directly Observed Procedures, Global Rating Scales). For the purpose of completeness, we also detail the specific features of this study

as part of the Simulation-based Arthroscopy Programme which occur in the simulated setting in the study description below.

The sensors only gather surgical movement data and the trainers and trainees can then review their performance after the case to better understand and improve their training. The sensors themselves are safe to use in a clinical environment. They are securely attached to the surgeon's elbows and do not interfere with thorough surgical scrubbing, nor do they interfere with any theatre equipment. They do not make contact with the patient, and are not attached or implanted in the patient. They do not involve the collection of any patient identifiable data, nor storage of tissue samples. As such, they pose no risk or interruption to standard theatre procedure.

This study aims to investigate the use of a new form of educational monitoring during normal clinical practise, and this does not interfere with the delivery of normal patient care nor usual surgical practise.

Risks: The presence of these sensors in theatre poses no additional risks or interruption to standard theatre procedure.

Benefits: Participants will gain an understanding of their technical dexterity and skill. This may indicate areas of focus for practice, and may benefit patients by improving the learning curve in surgical trainees. They will make further possible the development of national evidenced based guidelines for arthroscopy training.

Population: The participants wearing these sensors will be a mixture of core surgical trainees and specialist registrars on approved surgical training programmes, and their consultant supervisors. Typically these will be young healthy adults.

Generalisable findings: Initially we aim to assess the motion parameters associated with diagnostic knee arthroscopy (a single repeatable arthroscopic tasks), but the concept and techniques of in theatre motion analysis could be generalised to all procedures where technical skills are required. The use of motion analysis intra-operatively means that surgical competence could be defined in terms of motion analysis parameters. Correlation between simulated and intra-operative measurements of these motion analysis parameters could be used to define a proficiency criterion in simulated pre-patient training before performing surgery in theatre, or motion analysis parameter correlation with the number of procedures performed could be used to advise the SAC when defining the indicative numbers of procedures required to achieve CCT.

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective Assess the usefulness of the new elbow-attached motion sensors during diagnostic knee arthroscopy as part of routine, consultant-	Motion analysis parameters during consultant-supervised diagnostic knee arthroscopy Global rating scale during consultant-supervised diagnostic	At 3 months follow up, as part of and during the CUREC-approved 'Simulation-based Arthroscopic Surgery Programme' MSD-IDREC-2014-152

supervised training in theatre	knee arthroscopy	
Secondary Objective Assess the usefulness to training of the new elbow-attached motion sensors during simulated arthroscopy in the skills lab	Motion analysis parameters during simulated arthroscopy in the Skills lab	At baseline and after 3 months,

5. STUDY DESIGN

The 'Simulation-based Arthroscopic Surgery Programme' MSD-IDREC-2014-152 is a CUREC-approved series of studies investigating the effect of new training methods for our future surgeons and using simulators, cadaver specimens and virtual reality models. These studies involve the assessment of trainee groups (including junior surgical trainees, specialist registrars and consultants) in two ways:

1 – on simulators, using metrics such as motion analysis data, global rating scales and participant feedback

2 – in theatre, using metrics such as global rating scales, procedure based assessments and participant feedback.

In this particular sub-study, we are recruiting up to 60 junior surgical trainees in T&O posts as part of their training programme. These will all undergo a baseline assessment on an arthroscopic simulator, after which they will be randomised 50:50 to either a control group (regular training i.e. their T&O post) or an experimental group (additional simulation training approx.. 1 hour per week) for the next three months. At 3 months they will undergo repeat assessment on the arthroscopic simulator, and in theatre.

Participants will use simple elbow-worn wireless motion sensors during simulation assessments and simulation training, and during usual training in theatre under consultant-supervision, while the patients received their normal treatment, to assess their effectiveness at monitoring learning and performance in addition to the usual forms of educational monitoring above. Over the course of the study, surgical logbook/training data will be collected by the participant and linked to their other results anonymously.

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

Healthy volunteers from the deanery training programme at junior surgical trainee and specialist registrar level, plus consultant orthopaedic surgeons

6.2. Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the study.
- Healthy adults, Male or Female, aged 18 years or above.
- Enrolled in Health Education Thames Valley/Oxford Deanery Training Programme in junior surgical training posts; or supervising Orthopaedic Consultant.

6.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Unwilling or unable to provide informed consent

7. STUDY PROCEDURES

7.1. Recruitment

The 'Simulation-based Arthroscopic Surgery Programme' MSD-IDREC-2014-152 recruits junior surgical trainees, specialist registrars, and their supervising consultants from the Oxford Deanery for simulation training using simple elbow-worn wireless motion sensors. Recruitment takes place using emailed adverts sent via clinical and academic departments e.g. newsletters. In this particular sub-study, we are recruiting up to 60 junior surgical trainees in T&O posts as part of their training programme. Those who express an interest to the invite circulated by the Deanery/Trust will be provided with a participant information sheet and have the opportunity to discuss this with an investigator. Those wishing to proceed will be invited to attend a baseline session where eligibility and consent are confirmed in person after the participant has the opportunity to ask any further questions regarding the study or participant information sheet.

7.2. Screening and Eligibility Assessment

The invitation emails will be sent to those who fit the recruitment group by the Deanery and the Trust. Of those responding and expressing an interest, the eligibility criteria (namely employed in a T&O post at a junior surgical level in the OUH Foundation Trust; consenting to take part) will be confirmed before proceeding to arrange any assessments.

7.3. Baseline assessment

The first session will be a baseline meeting where eligibility and consent are confirmed once the participants questions regarding the previously provided information sheet are answered. Baseline simulator performance data using motion analysis will be gathered, plus some basis demographic data and information about surgical experience. They will also be asked to keep a note of all surgical procedures they perform in the coming 3 months. They will also be randomised to the control (usual training) or experimental (additional simulation training) group. This meeting will take about 45-60 minutes.

7.4. Randomisation

At the first meeting after their baseline simulation assessment, they will be randomised by sealed envelopes method to either control or experimental groups. As the participant will be attending simulation training, they cannot be blinded to this, but they will be provided with a unique identifier for use during the motion capture which will allow the data to be recorded anonymously and analysed blindly as to the randomisation.

7.5. Informed Consent

For each study in the 'Simulation-based Arthroscopic Training Programme' the participant must personally sign and date the latest approved version of the Informed Consent form before any study specific procedures are performed. This takes place at the baseline assessment.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; the presence of randomisation in the protocol; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

7.6. Subsequent Sessions

Those randomised to the experimental group will be asked to attend for 1 hour per week over the next 3 months at the Skills lab in the Nuffield Orthopaedic Centre for regular simulation training. Motion data may also be recorded during these sessions.

At 3 month follow up, all participants will repeat a simulated arthroscopy assessment lasting about 30-45 mins, similar to that which occurred at baseline, and an in theatre assessment using the same wireless elbow sensors. We aim to coordinate these two events in the same visit.

Junior surgical trainees perform surgery under consultant supervision as part of their training programme. It is during one of these surgical cases, we will gather objective surgical motion data in addition to the usual forms of educational evaluation which take place as part of training.

Participants will attend a consultant supervised knee arthroscopy list at the Nuffield Orthopaedic Centre. The participant and consultant will have the wireless sensors attached to their elbows by adhesive tape or custom sleeves that fit to the elbow. They are securely attached to the surgeon's elbows and do not interfere with thorough surgical scrubbing, nor do they interfere with any theatre equipment. The participant will scrub for the case with the consultant. The consultant will perform the procedure the patient has been admitted for, and once complete, will demonstrate a diagnostic knee arthroscopy (a

keyhole video examination of all the structures within the knee) to the participant as per standard surgical training practise. The consultant will then supervise the participant performing the same procedure as would normally happen during surgical training. They will provide the same support, and interrupt the procedure as they would in any other supervised surgical case if they feel this is necessary.

Participants motion analysis parameters will be compared to those of the supervising consultant, which will act as a bench-marking process to account for the technical differences between cases (e.g. the weight or size of the leg). This wireless motion data will be recorded to assess the elbow sensors' effectiveness at monitoring learning and performance in addition to the usual forms of educational monitoring e.g. Procedure-base assessments and global rating scales.

7.7. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with treatment regimen or study requirements
- Withdrawal of Consent
- Loss to follow up
- Exclusion from core or higher surgical training programme

The reason for withdrawal, if disclosed, will be recorded in the Case Report Form.

7.8. Definition of End of Study

The CUREC-approved 'Simulation-Based Arthroscopic Surgery Programme' will allow the repeated practice of technical tasks in a safe environment, whilst posing no risk to patient or learner. Our aim is to assess the effectiveness of simulation based arthroscopic training and to see whether it may have a role in surgical training. More specifically, we will assess the usefulness to training of the new elbow-attached motion sensors during routine, consultant-supervised procedures in theatre.

This research programme will take place over a five year period in the "Oxford Orthopaedic Simulation & Education Centre" which is situated within the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Science. This period expires in 2019.

8. STATISTICS AND ANALYSIS

8.1. Description of Statistical Methods

Motion analysis data from the elbow-worn wireless motion sensors produces similar data to the wired sensors our group has used previously.

Number of movements and path length are common to both devices. Data distributions will be assessed for normality. Previous studies show such data are not normally distributed and we would expect to use non-parametric tests, in this case the Mann-Whitney U test or Kruskall-Wallis test, to compare performance between groups during a given task. Mann-Whitney U tests will also be used within a group to compare performance before and after training on a simulator.

Surgical logbook data will be assessed using descriptive statistics, and motion analysis performance will be reported with reference to surgical experience.

Questionnaire data regarding the trainee and consultant perception of the utility of these sensors will be reported as descriptive statistics.

8.2. The Number of Participants

We plan to use these elbow-worn wireless motion sensors during as an additional educational monitoring tool during normal surgical training. We have not set a limit on the participant numbers (although up to 60 participants per year is possible). More participants to the studies within 'Simulation-based Arthroscopic Surgery Programme' at all stages will allow us to monitor their performance and develop performance curves, to show how motion analysis parameters change with surgical experience.

9. DATA MANAGEMENT

9.1. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

OOSEC research team members will have access to raw motion data, and output metrics generated from the raw data. By unique identifiers, this can be matched to other metrics during the Simulation-based Arthroscopic Surgery Programme, but not de-anonymised to reveal participants or patients.

Our collaborator computer at MAT will have access to the raw motion data, and use this to produce algorithms to generate the performance output metrics. They will not require access to any files that matches participants to their unique identifiers, nor to non-motion sensor data generated by participants elsewhere in the study. As such, MAT computer scientists will not be able to link any motion data to participants.

9.2. Data Recording and Record Keeping

Anonymised non-personal raw motion data will be uploaded to secure off-site servers using SSL/TLS using strong cipher suites that support perfect forward secrecy. This prevents decoding of captured data, even if the secret long-term key itself is compromised. Every instance has a built in firewall that is configured using a least privilege basis and will only accept https (port 443) connections from the

internet. The data centres are staffed 24x7 by trained security guards and access is authorised strictly on a least privileged basis.

This data will be remain anonymised regards to the participant, and will contain no information that related to patients. The raw motion data can be queried to generate usable motion analysis metrics (e.g. smoothness, hand movements etc). These are not stored on the server, but generated on request via proprietary algorithms. Pooled anonymised non-personal raw data from participants' motion data is used to generate and refine the algorithms, and as such, as more raw data is acquired by the server, the requested outputs become more accurate. Pooled data cannot extracted to be attributed to any participant.

Usable output motion analysis metrics will be downloaded form the server and stored locally on an Excel spreadsheet (.xlsx). These data may be opened in other programmes or copied to other formats for certain analyses e.g. SPSS data files (.sav). Where study data are generated in a proprietary file type, these will be transposed to Excel format.

The participants will be identified by a unique study specific number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file. All study data files will be kept on password protected hard-drives. Output study data will be kept for a further 3 years following the completion of the study before being destroyed. Anonymised non-personal raw data from the sensors will contribute to the algorithm on the secure server, but will not be extractable or identifiable to any participant.

10. QUALITY ASSURANCE PROCEDURES

The study will be conducted in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures, may be monitored, or audited against these.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

11.3. Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

11.4. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

11.5. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database, with the exception of the CRF, where participant initials may be added. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

11.6. Expenses and Benefits

No payments are intended for the participants. Participants may receive benefit from access to simulation training, and any technical skills development that may result.

11.7. Other Ethical Considerations

The aims of this project are to develop a novel method of educational monitoring: some monitoring will take place in a patient setting (the operating theatre), but does not involve the alteration of patient treatment.

The wireless sensors are safe to use in a clinical environment. They are securely attached to the surgeon's elbows and do not interfere with thorough surgical scrubbing, nor do they interfere with any theatre equipment. They do not make contact with the patient, and are not attached or implanted in the patient. They do not involve the collection of any patient identifiable data, nor storage of tissue samples. As such, they pose no risk or interruption to standard theatre procedure.

The methods of assessing technical skills being investigated by these studies are experimental. As such, these will not be used to draw conclusions about a trainee's performance with regards to the requirements of the training programme, and will not be available to the Deanery for ARCP evaluations.

So as participants randomised to the control group are not disadvantaged in terms of training opportunities, they will be offered the simulation training experience by the experimental group free of charge when they have completed their participation in the study.

12. FINANCE AND INSURANCE

12.1. Funding

Dinwoodie Simulation Research Fellowship funded by Royal College of Surgeons of England

12.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

13. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by Royal College of Surgeons of England Dinwoodie Research Fellowship and NIHR Oxford Musculoskeletal Biomedical Resreach Unit. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by NIHR Oxford Musculoskeletal Biomedical Research Unit. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. The findings will also be used towards a DPhil thesis for Patrick Garfjeld Roberts.

Participants will be alerted to publication of findings via email.

14. APPENDIX C: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.0	26 June 2015	P Garfjeld Roberts	Use of McLaren Server to store anonymous data generated from motion sensors; retain data at end of project
2	1.0	31 July 2015	P Garfjeld Roberts	Elbow sensors added (as technically Class B Invasive, being attached to particpant)
3	1.0	5 Nov 2015	P Garfjeld Roberts	Additional consent for study data in future studies; consent for logbook data; change in population to junior orthopaedic trainees
4	1.0	16 Nov 2015	P Garfjeld Roberts	Clarification of aspects of Simulation Based Arthroscopic Surgery programme relevant to this study (previously only mentioned theatre)