***Title*:**
Effectiveness of Immersive Virtual Reality Training Compared to Instructional Technical Surgical Video: A Randomized Controlled Trial

Study Protocol
Version 3.0
Date February 6, 2020

Clinical Trials NCT 04404010

Principal Investigator
Name: *Danny P. Goel*
Title: *Clinical Associate Professor*
Clinical Program: *UBC Orthopaedics*
Department: *Orthopedics*
CEO, Co-Founder: PrecisionOS Technology

Co-Investigator(s)
Name: *J Pollock*
Title: Clinical Associate Professor
Program: Surgery
Department: Orthopedics

Name: *Aaron Bois*
Title: Clinical Associate Professor
Program: Surgery
Department: Orthopedics

Name: *George Athwal*
Title: Clinical Associate Professor
Program: Surgery
Department: Orthopedics

Name: *Ryan Lohre*
Title: *Resident PGY 4*
Program*: UBC Orthopaedics*
Department*: Orthopaedics*

INTRODUCTION AND BACKGROUND

Medical education is changing secondary to expectation of flexible work-load, financial and time constraints.[1–4] The effect of this on surgical training potentially predisposes trainees to reduced operative exposure and experience.[5,6] A recent study highlights the majority of general surgery residents lacking confidence to begin independent surgical practice following graduation and that most are less likely to perform core procedures in the latter years of their training.[5] We have also noted a similar finding in orthopedic residents at a large Canadian teaching center on commonly observed fracture cases (Hunter et al unpublished data). Volume-outcome relationships have been previously demonstrated in orthopaedic surgery, as has time-action analysis for improved patient outcomes and efficiency, respectively.[7–16] Of particular interest is shoulder arthroplasty, demonstrating well-defined volume-outcome relationship on post-operative outcomes and associated cost given the technical complexity.[17–25] Reverse shoulder arthroplasty is a complex procedure requiring familiarity and confidence in surgical exposure, component insertion and positioning. Exposure of the glenoid and soft tissue management are crucial for stable prostheses and functional patient outcomes.[22–25] Surgical simulators have been produced to combat low volume technical tasks and to provide concrete reproducible experience, however the majority of these simulators currently lack fidelity, generalizability, as well as demonstrated validity and reliability despite consensus recommendations.[5,6,34–36,26–33]

Virtual Reality (VR), first coined in 1986 by Jaron Lanier, has expanded from the entertainment industry to clinical medicine in the preceding decades. This is based on its unique ability to replicate scenarios and environments while teaching skills in a potentially cost-effective manner. Simulator training is currently advocated by numerous surgical organizations, including the American Academy of Orthopaedic Surgeons (AAOS) however recent systematic reviews reveal the paucity of literature available for VR training in orthopaedic surgery.[37,38] Despite this, a recent study highlights the limited interaction of orthopaedic surgeons with VR or simulation experience, though the majority recognizing the role and benefit in practicing procedures and spatial orientation.[39] VR utilizes a combination of equipment including a three-dimensional (3D) rendering capable computer, head mounted display (HMD) and controllers with position trackers. Increasingly common is the addition of haptic feedback to VR to recreate sense of touch, vibration and motion.[38,40] In the field of orthopaedics, VR has demonstrated greatest potential in application for education secondary to the modification in the training environment.[28] VR systems provide continuous uninterrupted availability with available mentorship provided through immediate metrics, the ability for repetition, and outcome measures for task completion.

Training a single surgeon in the operating room has been estimated to cost roughly $48000 in the US. This is partly associated with increased operating room time with surgical trainees present, accounting for approximately 11 184 minutes of operating room time lost per trainee over four years.[30] Complications in improper surgical technique, reduction, or implant positioning in orthopaedic trauma surgery has additionally been previously demonstrated. The financial implications are also relevant where surgical inefficiency in Canada ranges from $621.60 to $2288.94 CAD per hour in a study incorporating multiple Canadian Hospitals.[10,41]

We have previously completed a randomized controlled trial of senior (PGY4 and PGY5) orthopaedic residents at the Canadian Shoulder and Elbow Society (CSES) 2019 resident training course. Residents from across Canada were randomized to training using an immersive VR simulator (PrecisionOS Technology, Vancouver, BC, Canada) versus a didactic technical journal article (representing traditional training methods) outlining steps to complex glenoid exposure. In this study, residents trained on VR demonstrated a 570% reduction in training time with equivalent knowledge scores on verbal and written testing, and 150% improvement in cadaveric dissection time with improved instrument handling scores measured by validated Objective Structured Assessment of Technical Skills (OSATS) metrics. This simulator was validated in all domains including transfer of skill and represented the first study of its kind in orthopaedic education (pending publication). This study laid the groundwork for subsequent examinations of transfer of learned skill. Resident education in orthopaedics utilizes multiple media sources for education. Technical surgical videos pertaining to specific implants are frequently read and used by residents and consultant orthopaedic surgeons. Surgical video online resources provide these videos to aid surgeons in developing knowledge of implant specific use. The use of these videos is

pervasive in programs across Canada and the world. We wish to further address the transfer of skill through VR training by comparing it to the well-established use of technical surgical videos in learning implant specific reverse shoulder arthroplasty. Additionally, the efficiency of learning using VR or traditional media systems should be evaluated using validated methods such as transfer of training (ToT) or transfer effectiveness ratios (TER).

PURPOSE AND JUSTIFICATION

Production of an immersive VR suite with haptic and user metric feedback would be an advance over current bench top simulator technology, allowing for greater immersion and interaction, leading to better understanding of surgical planning and implementation. The development of this technology could provide trainees with immersive levels of training not previously seen, with improved learning of technical skills over media such as manufacturer technical documents. The effectiveness of training and efficiency of training of the novel immersive VR training systems need to be evaluated as they are increasingly incorporated into competency based, contemporary residency education.

Research Question: Can immersive VR improve the efficiency and competency of technical skill acquisition in senior orthopaedic surgery residents over technical surgical instructional video in learning reverse shoulder arthroplasty?

Research Objective(s):

Primary: To determine if immersive VR is superior to technical surgical instructional video teaching in acquisition of technical skills in learning reverse shoulder arthroplasty

> Technical skill outcomes will be determined by Objective Structured Assessment of Technical Skills (OSATS), a Global Ratings Scale (GRS), and competency assessment (pass/fail) by fellowship trained subspecialty shoulder surgeons

Secondary: (1) To determine the efficiency of learning of immersive VR compared to manufacturer specific technical instructional document training of senior residents in learning reverse shoulder arthroplasty.

1. Efficiency will be determined by transfer of training (ToT) and transfer effectiveness ratio (TER)
2. To validate a created VR scoring system with real-world performance (this will include the use of CT scans of cadaveric specimens)

METHODS

Study Design:

A randomized, blinded intervention-control trial directly comparing immersive VR versus technical surgical instructional video training for teaching of reverse shoulder arthroplasty to senior orthopaedic surgery residents will be conducted.
Residents attending the Canadian Orthopaedic Association (COA), Canadian Shoulder and Elbow Society (CSES) resident training course in Ottawa will be consented for participation. Once consented, residents will be randomized to one of two groups using a computerized blocked protocol based on year of study (R4 and R5) to assure equal level of training between control (technical surgical instructional video) and intervention (immersive VR) groups. Every participant will complete a demographic questionnaire to determine age, handedness, visual correction (eyeglasses), familiarity with shoulder surgery, number of previous courses attended, and familiarity with simulation training and VR. Within the demographic questionnaire will be six questions regarding confidence of performing a reverse shoulder arthroplasty using a modified confidence scale (CS). The demographic questionnaire format will be of Likert-scale responses.
The control group will receive training on completion of a reverse shoulder arthroplasty using a technical surgical instructional video. The control group will be provided as much time as they require to watch the video, including repetition if desired during which they will be timed for completion.

The intervention (VR) group will receive training on completion of a reverse shoulder arthroplasty using an immersive VR simulator (PrecisionOS Technology, Vancouver, BC, Canada). The VR simulator utilizes an HMD producing 3D visuals with haptic controllers for an immersive operating room experience. The module produced consists of the key steps in performing a reverse shoulder arthroplasty using virtual versions of the equipment used in the real procedure. Prior to initiation, participants will be provided with a safety and training demonstration on the use of the VR module by study personnel. The intervention group will similarly be provided as much time as they desire with available repetition as they see fit. The VR group will be timed to task completion as the control group for comparison.
The VR module will provide users with a score based on time to completion of key steps, and performance of key steps such as guide-pin insertion, and overall glenoid baseplate orientation. These positioning scores will be based on clinically relevant cut-off values seen to affect implant longevity. These scores will be subsequently compared to GRS and OSATS scores provided by the assessors for validation purposes.
Both groups will then be taken to a technical skills laboratory where they will be paired with an assessor (fellowship trained, consultant shoulder surgeon and member of CSES). The assessors will be blinded to the training received by the participant. The participants from both groups will then complete a reverse total shoulder arthroplasty using the same equipment used in either the control (technical surgical instructional video) or intervention (VR) learning activity while being assessed on fresh frozen cadavers (scapula to hand). The assessor will use an OSATS, GRS, and overall competency assessment for the resident during the procedure and for evaluation of the finished product. The assessor will also time the resident for time to task completion, which will be determined by the resident when they explicitly express that they are satisfied with final implantation. Following this, participants will complete a survey assessing their enjoyment of learning activity, perceived benefit to continued use in learning orthopaedic skills, and a re-assessment of their confidence following training modality using the modified confidence scale (CS). The post-cadaveric questionnaire format will be of Likert-scale responses.
As part of the procedure, both the assessor and participant will determine implant parameters once the reverse shoulder arthroplasty is complete. The cadaveric specimens with inserted glenoid baseplates will be CT scanned to provide 2D and 3D reformats. This will allow for determination of the implant orientation parameters including version, inclination, rotation, and offset. These parameters will be compared to the VR scores to determine correlation between the VR training and real-world task completion.

Sampling Design and Subject Selection:

Subjects will be recruited from attendance at the Canadian Shoulder and Elbow Society (CSES) annual meeting by volunteering to participate. Subjects recruited will be in their PGY4 or PGY5 years of orthopaedic residency training and will be from multiple Canadian institutions. Once participants are recruited, study personnel will randomize groups to intervention (VR) or control (technical surgical instructional video) groups via a blocked randomization process in statistical computing software R (R Foundation for Statistical Computing, Vienna, Austria).
A recent systematic review comparing validity assessments of surgical orthopaedic simulators demonstrates a breadth of cohort variability, with 17.7% to upwards of 50% differences in reported outcome measures between novice/intermediate and expert groupings. TER ratios have seen variations from 7-42% in early VR simulators for novice surgeons. These studies predominantly focus on VR simulators lacking the immersion of contemporary VR, particularly the system from PrecisionOS. Similarly, the majority of VR simulator research in orthopaedics pertains to arthroscopic surgery which utilizes different global ratings scale outcome measures. The authors of this proposal have recently completed a similar randomized controlled trial at the 2019 CSES meeting (REB approval obtained from the University of Calgary) comparing senior resident VR training to traditional didactic scientific journal training. This resulted in a significant difference in cadaveric task completion time with n=8 in both groups. This study is presently pending publication and in review. As such, for power determination of comparison of VR trained to control group of novice surgeons utilizing a 2-sided test at 5% significance (alpha = 0.05) and to achieve 80% statistical power (beta = 0.02), considering a representative estimated difference of 25% (which we have seen in our previous study, and is conservative regarding similar literature) in combined outcome measures, six subjects will be required for each cohort.

Inclusion Criteria:

1. Individuals registered in licensed post-graduate orthopaedic residency programs attending the CSES resident course and consenting to participation.

Informed Consent:

There will be no direct patient interaction, therapeutic intervention, or other diagnostic or therapeutic intervention related to patient care. Participants will be provided with a consent form outlining the study. Information gathered on participants will not include direct identifiers aside from demographics of age, gender, and training experience. Questionnaires collected will be de-identified using study codes.
The research demonstrates minimal risk to subjects involved as per TCPS2 Chapter 2, and Chapter 10, as the proposed study is observational, does not allow for direct identification of patients, is not staged, and is non-intrusive.

Study Procedures

Randomization: Subjects will be blocked randomized based on year of study (R4 or R5) using computer software.

Intervention: Study participants will voluntarily complete three questionnaires as well as an activity session utilizing either a technical surgical instructional video or VR to learn reverse shoulder arthroplasty followed by a cadaveric activity in the surgical skills laboratory.

Study Visits: Participants will voluntarily complete study requirements at a single visit during the CSES meeting of which they are electively attending.

Follow-up Visits: No follow-up visits of participating subjects.

Data Collection:
Data collection is prospective following randomization of study participants and blinding of expert raters. Data will be collected in a single setting. Voluntary participants will complete a pre-activity questionnaire identifying age, and gender as well as responses to a number of other questions regarding familiarity with shoulder arthroplasty and surgical simulation/VR as seen in appendix. Post-questionnaire data collected will include questions relating to realism and applicability in learning of the compared modalities and confidence. Questionnaires will be performed during the CSES course on paper/hard copy documents. PrecisionOS, the Lead Researcher, and Co-Researchers will have access to this de-identified data. Hardcopy questionnaires will be retained by the Lead Researcher and kept with PrecisionOS, in a locked and secure office. The hardcopy data will be retained for a period of 10 years. Only designated research personnel will have access to the key to participant de-identified study codes and this will be retained in their locked and secure office. Data will be tabulated to digital format, which will be collected, encrypted and stored on computers owned by the Lead Researcher. This data will then be stored on a secure server. Data will not be transferred out of Canada as per FIPPA. The study will take place once ethics approval is obtained and conclude at the end of the CSES course.

Measures:

Participant specific measures to be collected will include demographics, questionnaire responses, and task completion in an anonymous fashion.
Primary outcome of comparison of VR to technical surgical instructional video teaching will be assessed by OSATS, GRS, and competency grade provided by evaluators during the sawbone session. Secondary outcomes will be determined using the ToT and TER, overall time difference of task completion between groups, and CER. The cadaveric scapula will be assessed for implant version, inclination, rotation, and offset in the glenoid and recorded for each participant using a CT scan.
Data collection sheet including measures assessed can be seen in appendix.

Analytical Plan

Normality testing will be performed via Shapiro-Wilk test with subsequent mean comparative statistics to determine difference between VR and control groups. Descriptive statistics will be conducted. Likert questionnaire responses will be treated as Likert-scale and Likert-type data using descriptive statistics. Reliability testing for outcome scales in determining internal consistency will be assessed by Cronbach's alpha.

Ethical considerations

Potential Benefits: Study participants will receive expert instructional information regarding shoulder arthroplasty by participating. No remuneration for participation will occur. Longitudinal benefits could include improved technical skills in reverse shoulder arthroplasty.

Potential Risks: No direct risks to study participants involved. Subject recruitment is free of coercion, and only de-identified demographic data used with adherence to FIPPA and TCPS2 guidelines for data handling and storage.

Subject Safety Provisions: No direct risks to study participants. Occasionally use of immersive VR can produce feelings of nausea. This will be dictated to study participants prior to commencing the study, and participants are free to withdraw at any time. Safety provisions include data handling and transfer of patient information with adherence to FIPPA and TCPS2 guidelines and all attempts to store and utilize de-identified data.

Ethics Approval: Fraser Health Research Ethics Board (REB); Calgary REB

Plans for Publication and conference presentations:
Publication and conference presentations will be conducted following satisfaction of primary outcome and hypothesis testing. Specific editorial has not been determined, though likely conferences will include the Canadian Orthopaedic Association annual meeting, Orthopaedic Trauma Association annual meeting, American Academy of Orthopedic Surgeons and BC Orthopaedic Association Ortho update annual meeting.

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