

**Virtual Reality for Pain Management in Orthopaedic Trauma
Patients: A Prospective Study**

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Virtual Reality for Pain Management in Orthopaedic Patients: A Prospective Randomized Control Study

Data Plan-

Data Collection:

Study data were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS). REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. Computer-generated randomization through REDCap was utilized.

Research staff thoroughly explained the study and its objective. If research staff were working remotely and called the patients on their hospital room phone or cell phone, they also e-mailed an electronic version of the consent form via a REDCap survey for the patient to review. The consent form was also available to download on this link. Subjects were given time to weigh the risks and benefits of participation in the study. After all questions from the subject were answered by the research staff or the clinician investigator, written consent was obtained from the subject. If an experienced research assistant/coordinator obtained consent, they offered that a physician investigator could answer any additional questions posed by the patient, if preferred. If a research staff worked remotely, they obtained consent via e-signature on REDCap. This signed e-consent form was then sent back to the patient for their records once it had been signed by the research staff via secure e-mail.

Data Acquisition:

Data collection took place in two phases. Phase one took place at the time of enrollment where basic demographic data, fracture characteristics, and AO classification was recorded in a REDCap database. The enrollment questionnaire also included questions about recent narcotic use. Patients filled out a baseline PROMIS pain intensity questionnaire at time of enrollment and were given a packet of pain intensity questionnaires to be filled out daily during the hospitalization. Phase two took place after discharge. Data was tallied from the PROMIS questionnaires and also collected from the electronic medical record.

Data gathered encompass three broad categories: Demographic data, hospitalization data, and PROMIS data. Basic demographic data include, DOB, DOS, age at surgery (calculated), sex, height, weight, BMI (calculated), ASA classification (anesthesia note), and race. Hospitalization data include AO fracture classification, narcotic type, dose, total MME (morphine milligram equivalents), and hospital LOS. PROMIS pain (v 1.0 short form 3a) questionnaires were collected daily.

Assuming patients take an average of 45 mg of morphine equivalents daily, a robust randomized controlled trial would be powered at 90% to detect a 10% decrease in opioid use amongst the experimental arm. The goal of the study was to enroll 200 patients.