Evaluating the Impact of Surgical Theater's Patient Engagement 360VR Platform on Spinal Surgery Patient Expectations and Experiences

NCT05334212

08/2019

Objectives

To evaluate usefulness of Surgical Theater's Patient Engagement 360VR platform in helping align patient expectations and improve patient satisfaction and understanding in spinal surgery consults.

Background

Surgical Theater is a company that has developed a platform which can be used to describe and explain spinal surgery to patient before they undergo the procedure. The platform specifically implements data from the patient's own MRI and CT scans, creating a 3d reconstruction that can be seen through a virtual reality lens. This technology was developed to help clarify any concerns patient's may have before surgery, and help them better appreciate what will occur in the OR. Surgical theater has FDA clearance for patient interaction and engagement. Our study is to take surgical theater into our clinics and, after a patient is defined as a surgical candidate, use surgical theater to provide spatial learning and comprehension through modeling so they better understand their surgical plan. Only the SRP system will be used for this study (Surgical Planner). The intervention is showing surgical theater to patients identified for surgery in clinic routinely. Surgical theater will be offered to all patients offered surgery. No other changes in practice will be done.

Inclusion and Exclusion Criteria for Experimental Group

Inclusion

1. Age range: 18-89
2. Patients undergoing elective lumbar or cervical spine surgeries
3. Those who are receiving Surgical Theater consultation as part of their clinical care

Exclusion

1. Age <18 years
2. Nonelective surgery due to emergency, trauma
3. Patients undergoing correction for spinal deformities

Inclusion and Exclusion Criteria for Countrol Group

Inclusion

1. Age range: 18-89
2. Patients undergoing elective lumbar or cervical spine surgeries
3. Patients who do not have a previous CT scan and thus are unable to undergo Surgical Theater Consultation

Exclusion

1. Age <18 years
2. Nonelective surgery due to emergency, trauma
3. Patients undergoing correction for spinal deformities

Number of Research Participants

We will enroll 90 subjects at UHCMC. 30 subjects will receive surgical theater consulation. 60 patients will not receive surgical theater consulation, and will their survey resposnes will thus serve as a "control".

Recruitment Methods

Patients will be consented and offered surgery as normally performed in clinical practice in the office setting. The patient will then be offered a simulation of their surgery on Surgical Theater's Virtual Reality Rehearsal Platform. Subjects will be approached in person at the end of their appointment with PI. Treating physician will be on the study team.

Setting

1) Southwest General Health Center – Patients will be given survey and offered 360VR consult
2) Southwest General Health Center – Patients at this institution will be approached
3) Southwest General Health Center – 360VR platform is at this institution

All study procedures will take place at Southwest General

Consent Process

The consent process will take place at the end of patient's consult with PI. The consent process will take place in a private location. Steps will be taken to review the concept of three dimensional modeling and spatial learning. We will emphasize that modeling and simulation do not account for complications or adverse events during surgery. We will clarify that modeling and simulation display the optimal technique and approach to their disease. We will also discuss with the patient the rationale of showing them a different approach to learning more about their surgery. The patient will then be offered a simulation of their surgery on Surgical Theater's Virtual Reality Rehearsal Platform and sign consent if they agree to use surgical theater platform

Sharing of Results with Research Participants

☒ Results will not be shared with research participants
☒ Results will not be shared with research participants' doctors

Study Design

This study is a non-randomized, survey

Study Procedures

We will review their imaging in person and discuss the virtual reality software. There is no risk in showing the 3-D reconstruction of their surgery. Surgical Theater 360VR Platform will be used, it has been approved for patient education purposes. No medical, educational records will be used to collect data. The surgical theater platform will be explained as a virtual reality device that will display the patient's radiological imaging in 3d.

Survey assessing patient's understanding, anxiety, and satisfaction (Surgical Theater Survey, attached to Smart Form) will be given immediately before and after 360VR session is completed Surgical theater appointment and review will take 24 minutes. QOL surveys (EQ-5D-5L, NDI, Oswestry, RAPT, VR-12) will also be given before 360-VR,6 week post-op, 3 month post op, and 6 month post op. All survey's will be administered by giving the patient a physical paper form that they will fill out. Time commitment for each survey is 2 minutes.

A control group will be chosen, which will consist of patients who are scheduled to undergo elective spinal surgery but will not receive a 360VR appointment. This control group will consist of patients who do not have a CT scan prior to surgery.

Survey assessing control group patients' understanding, anxiety, and satisfaction (Control Group Survey, attached to Smart Form) will be given immediately after presurgical consult with Dr. Smith and will take 5 minutes. QOL surveys (EQ-5D-5L, NDI, Oswestry, RAPT, VR-12) will also be given 6 week post-op, 3 month post op, and 6 month post op. All surveys will be administered by giving the patient a physical paper form that they will fill out. Time commitment for each survey is 2 minutes.

Study Timeline

	Screening	Visit 1	Visit 2	Visit 3	Visit 4
Estimated time requirement of visit	0	54 minutes	10 minutes	10 minutes	10 minutes
360VR Consult	0	24	0	0	0
QOL Survey	0	10	10	10	10
Surgical Theater Survey	0	10	0	0	0
Consent Procedures	0	10	0	0	0

Data to be Collected for your study (AFTER consent and HIPAA Authorization have been obtained)

- Outcome measures
  - ♣ Patient-reported health status outcomes
    - EQ-5D Health-Related Quality of Life
      - o Reports on 5 dimensions of health: Mobility, Self-care, Usual activities, Pain/Discomfort, Anxiety/Depression
        - ♣ Each score from 1-3
      - o 0 .0(death) to 1.0 (perfect health),
    - Pain Disability Questionnaire (PDQ)
      - o 0-10 scale to assess how pain affects the ability to function across 15 categories.
      - o 0 (optimal function) to 150 (total disability)
  - ♣ Patient satisfaction and understanding with HCHAPS
    - Understanding – before and after consult
    - Anxiety level – before and after consult
    - Satisfaction with consult
    - HCAHPS – Overall rating of hospital

- o Satisfied = 9 or 10 rating
- ♣ Surgical conversion rate
- ♣ Consult time including time spent with VR
  - • Time points
  1. Before 360VR consult (Visit 1)
  2. Immediately after 360VR consult (Visit 1)
  3. Post-op 6 weeks (Visit 2)
  4. Post op 3 months (Visit 3)
  5. Post op 6 month (Visit 4)

Data Analysis Plan

Descriptive statistics summarizing patient population and surgical characteristics will be compared using chi-square for categorical variables and Students t-tests for continuous variables.

Associations of patient-reported satisfaction and understanding with changes in each patientreported health measure will be estimated using linear regression analysis as well as multivariable linear regression models, adjusting for potential confounders.

Risks to Research Participants

Possible motion sickness with 360VR goggles. May feel uncomfortable with some QOL questions regarding depression and anxiety. To mitigate this, patients will be told to skip any questions they fell uncomfortable with and the presence of such questions will be outlined during consent process. There is a risk of breach of confidentiality which means that someone who is not listed in this form might view your data either by accident or from malicious actions they take to hack the data. We are protecting against this by using a Password-protected locked drawer in a locked office at Southwest General Hospital to store data.

Provisions to Protect the Privacy Interests of Research Participants

All study procedures will be done in a private room where no other patients will be present. Data will be protected via RedCap

Password-protected locked drawer in a locked office at Southwest General Hospital to store data. Drawer will be Dr. Smith's Room on Floor 3 Suite 305. Only Dr. Smith will have access to the drawer. Data will be monitored weekly by Dr. Gabriel Smith

Potential Benefit to Research Participants

This study aims to provide helpful information on the impact of implementing VR into spinal surgery consults. By providing quantitative evidence on how personalized VR can improve patient's experiences, this study could lay the ground-work needed for drastic developments in patient education. Additionally, the patients themselves may benefit by receiving a different perspective regarding their condition and its treatment.

Withdrawal of Research Participants

Subjects may withdraw at any time, or refuse to answer any survey questions.

Some surveys ask questions about depression and anxiety. For mitigation, a medical professional will be available to speak with patient if they feel uncomfortable at any point during the study. In the instance patient experiences suicidal ideation, the study team will assess the acuity of the complaint and address that complaint in 2 possible ways:

1) Referral to the closet emergency room if we feel from the history that there is a high probability of self-harm, or

2) Referral to a psychiatrist if the threat is not immediate.

Alternatives to Participation

The alternative to participation is to have the surgery described in the usual manner without the use of the VR device

Costs to Research Participants

N/A

Research Participant Compensation

N/A

Provisions to Monitor the Data to Ensure the Safety of Research Participants

Data accuracy and completion will be reviewed and monitored by the study's data coordinator and PI on a weekly basis. There will be no Data and Safety Monitoring Board or Committee for this study.

References

1.https://www.sciencedirect.com/science/article/abs/pii/S0967586819307957
2. https://academic.oup.com/neurosurgery/article-abstract/73/suppl_1/S122/2417519
3.https://journals.lww.com/retinajournal/Abstract/2018/09001/THE_INTEGRATIVE_SURGICAL_THEATER__Combining.13.aspx