

Cover Page

Title: Use of the Modified Beef Tongue Model for Teaching Repair of Obstetrical Fourth-Degree Laceration to Residents

Approved by the Human Subjects IRB at UAB

Date of Document: 09/29/2017

This document contains the participant consent form

CONSENT FORM

TITLE OF RESEARCH: Use of the Modified Beef Tongue Model for Teaching Repair of Obstetrical Fourth-Degree Laceration to Residents

IRB PROTOCOL NO.: IRB - 300000074

INVESTIGATOR: Joseph M. Malek, MD

SPONSOR: UAB Department of Ob/Gyn

SUPPORTED BY: UAB School of Medicine Dean's Research Award

Purpose of the Research

We are asking you to take part in a research study. This study will examine two groups for teaching repair of fourth-degree obstetrical lacerations. One group will participate in a workshop using a modified beef tongue model which will illustrate anatomy and repair of a fourth-degree laceration, and the other group will watch a video using the modified beef tongue model to illustrate anatomy and repair of a fourth-degree laceration. We are trying to evaluate differences in skill achievement in the two groups. This study will enroll up to 32 participants who are residents in UAB Department of Obstetrics and Gynecology.

Explanation of Procedures

All participants will complete demographic and baseline data including PGY level, number of fourth-degree lacerations performed, whether they have read a textbook regarding fourth-degree laceration repair, whether they have read a journal article regarding fourth-degree laceration repair, whether they have attended a didactic session in pelvic anatomy, and whether they have attended a didactic session on fourth-degree laceration repair.

Prior to randomization, you will take a short written pre-intervention knowledge assessment and be asked to rate your confidence level in completing a fourth-degree repair using a Likert scale. You will also complete a baseline objective structured assessment of technical skills (OSATS) for repair of fourth-degree obstetric laceration on a commercial anatomical replica, the Sultan Anal Sphincter Trainer (Limbs & Things Inc, Savannah, Georgia). The repair will be videotaped and then distributed to evaluators. The time taken for the repair will be recorded.

You will then be randomized into one of two groups. The randomization will be performed using a computer-generated block design so that each group has a balanced number of residents in each postgraduate year training level. One group will be randomized to the modified beef tongue video and one will be randomized to the modified beef tongue instructional workshop. The modified beef tongue video group will be given an instructional video we have created using the modified beef tongue model to show anatomy and proper repair of the laceration which you will be able to watch on a supplied computer. The group randomized to the modified beef tongue instructional workshop will undergo an interactive

workshop using the modified beef tongue model to show anatomy and proper repair of the laceration.

Following the assigned intervention, participants from each group will be given the written knowledge assessment test again and the objective structured assessment of technical skills (OSATS) for repair of fourth-degree laceration on the commercial anatomical replica again. Participants will also be asked to evaluate model realism, ease of use, and satisfaction using a Likert scale. The participants will be asked to assess their confidence again using a Likert scale.

The participants will then be crossed over and those who were initially randomized to the video group will then undergo the instructional workshop and the ones initially in the workshop group will be given the instructional video. Participants will then be asked to rate their overall preference between models on a scale of 1 to 10 with 1 being the video and 10 being the instructional workshop. We expect your participation to take about 2 hours over the course of 1 day.

Risks and Discomforts

There are minimal if any risks associated with this study. You will be performing a repair of a fourth-degree perineal laceration on a model and there may be a risk of a needle stick from handling suture. We expect any risk of needle stick to be rare.

Benefits

You may benefit directly from taking part in this study by increasing your knowledge, confidence, and ability to perform a fourth-degree laceration repair. We hope to gain further knowledge on the best and most efficient way to teach residents.

Alternatives

The alternative is to not participate.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research. The information from the research may be published for scientific purposes; however, your identity will not be given out. Responses will be recorded only by participant ID number. Participants will not be identified in the video recordings and the video recordings will be saved on a secured server. The videos will be deleted following final analysis.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation in Research

You will not be paid for participation in this study.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Joseph Malek. He will be glad to answer any of your questions. Dr. Malek's number is 205-996-5466. Dr. Malek may also be reached after hours by paging him at 205-934-3411 (beeper 2193).

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant

Date

Signature of Person Obtaining Informed Consent

Date