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Approved by the Human Subjects IRB at UAB

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Research Protocol

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

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Background/Rationale:

Obstetric lacerations are a common complication of vaginal deliveries affecting three fourths of all vaginal births [1] with third and fourth degree lacerations, which increase the risk of fecal incontinence, complicating up to 11% of vaginal deliveries [2]. Up to 50% of women experience some degree of fecal incontinence after anal sphincter repair [3]. Anal sphincter gaps detected by ultrasound are prevalent in postpartum primiparous women with a history of sphincter tear and are associated with fecal incontinence severity [4].

In academic centers, lacerations are often repaired by residents. Approximately 60% of obstetrics/gynecology (ob/gyn) residents in residency programs in the United States admitted to not having any didactic teaching on episiotomy repair and no formal teaching on pelvic floor anatomy and when engaged in the repair, were supervised only a third of the time [5]. It has been shown that with the rise in cesarean sections and decline in operative vaginal deliveries, the prevalence of third- and fourth-degree lacerations has been decreasing in recent years and this has resulted in limited exposure to repairs and lack of residents' confidence to properly repair advanced perineal lacerations [6,7]. One study evaluating 40 ob/gyn residents at 13 different residency programs showed an overall pass rate of only 42.5% with many residents missing critical steps of the repair [7].

Surgical models have been increasing in popularity and have been shown to improve surgical skills and knowledge base [3, 6]. It has further been shown that anatomical models and hands-on workshops on how to repair fourth-degree lacerations can improve knowledge and surgical technique [3]. Beef tongue models have been used in the education and assessment of surgical skills for fourth-degree laceration repair [3,6,8]. One study compared a beef tongue

model to sponge model showing all participants preferred the beef tongue model [6]. Siddiqui et al used a beef tongue model to validate a task specific Objective Structured Assessment of Technical Skills (OSATS) for the repair of fourth-degree obstetric lacerations [9]. We recently demonstrated a modified beef tongue model that used beef tripe (small intestine) for the anal mucosa and chicken leg segments for the anal sphincter muscle analogs to create a realistic model [10].

Given the decreasing number of third- and fourth degree lacerations and poor resident confidence and performance demonstrated in these repairs, better and more widely used teaching methods are necessary. The modified beef tongue model serves as a realistic tool to teach and assess fourth-degree laceration anatomy and repair. While workshops have been shown to improve knowledge and technical skills [3], these require significant time, expense, and organization. Instructional videos can be used to serve the same purpose without these limitations and thus could lead to wider use as a didactic intervention for fourth-degree repair. Instructional videos have been evaluated for fourth-degree repair in a limited manner. One study showed an improvement in knowledge after an instructional video but only in residents with no prior experience in repair of lacerations [8] and we could not find any that assess change in outcomes on technical surgical skills.

We believe that an instructional video that utilizes the modified beef tongue model is a valuable educational tool to increase resident knowledge, confidence, and surgical ability to properly repair a fourth degree laceration. The aim of this study is to compare technical skills outcomes with an instructional video using the modified beef tongue model to a modified beef tongue hands-on educational workshop. Our hypothesis is that participants will have similar

improvements in their technical skills for repair of fourth-degree laceration as evaluated by an objective structured assessment of technical skills (OSATS).

Null hypothesis: Participants undergoing the modified beef tongue instructional video will have worse outcomes on an objective structured assessment of technical skills (OSATS) for repair of fourth degree obstetric laceration than those undergoing a modified beef tongue educational workshop.

Significance

There are no studies evaluating the use of an instructional video for fourth-degree laceration repair to assess change in outcomes on technical skills.

Study Design

Inclusion Criteria

PGY1-4 residents in an obstetrics and gynecology training program

Exclusion Criteria

None

Intervention

Instructional video using the modified beef tongue model or instructional workshop using the modified beef tongue model.

Primary outcome

The primary outcome will be change in technical skills score measured as change from baseline in a validated objective structured assessment of technical skills (OSATS) for repair of fourth degree obstetric laceration.

Secondary outcomes

1. Participant preference of model between instructional video and instructional workshop
2. Knowledge assessed by written test performed pre- and post-intervention
3. Participant's confidence in fourth-degree laceration repair as measured by change in confidence score from pre- to post-intervention.
4. Time taken for repair of fourth degree laceration
5. Ease of use of the model as reported by participants
6. Overall satisfaction of the model
7. Model realism
8. Factors associated with higher knowledge scores (e.g. PGY level, number of prior repairs, prior didactics)

Protocol in detail

Institutional Review Board approval and written informed consent will be obtained prior to initiation of the study. All obstetrics and gynecology residents at the University of Alabama will be eligible for the study.

Eligible residents who desire will be enrolled and consented for the trial. Participants will then complete a short pre-intervention knowledge assessment written test and be asked to rate their confidence level in completing a fourth-degree repair based on a Likert scale. The written test is the same as the one used by Patel et al to evaluate residents' knowledge about

fourth-degree laceration repair [8]. The questions are based on Williams's obstetric chapter on episiotomy repair [11] and showed construct validity given a significant difference in scores between postgraduate year (PGY)-1 and PGY-4 residents [8]. Participants will also complete a baseline objective structured assessment of technical skills (OSATS) assessment for repair of fourth-degree obstetric laceration on a commercial anatomical replica, the Sultan Anal Sphincter Trainer (Limbs & Things Inc, Savannah, Georgia). This model comes with a replaceable perineal pad that allows approximately 24 repairs before replacement is necessary. The validated OSATS used will be the assessment described by Siddiqui et al and validated on a surgical model [9]. The repair will be videotaped and then distributed to evaluators who will use the 20 item task specific checklist described by Siddiqui et al [9]. The time taken for the repair will be recorded.

Demographic and baseline data will be collected on the participants 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.

Participants will then be randomized into two groups. 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 created using the modified beef tongue model to show anatomy and proper repair of the laceration. 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.

The modified beef tongue for the video and workshop will be prepared according to the model previously described in the literature [11]. The modified model includes beef tripe (small intestine) used for anal mucosa and chicken leg muscles for anal sphincter muscle analogs. The tripe is tunneled through the body of the trimmed beef tongue and sutured like an ostomy to simulate the anal canal. The tongue is incised toward the tripe “anal canal.” Chicken leg muscles are tunneled from the incision out to the cut edges of the beef tongue to create anal sphincter muscle analogs.

Following the didactic 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. The time taken for the repair will be recorded. Residents will also be asked to evaluate model realism, ease of use, and satisfaction using a Likert scale. The residents 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. They will also complete the written knowledge test again.

The results of this trial may help to inform to a cost- and time-efficient manner of instruction on the repair of 3rd and 4th degree lacerations. A weakness is that it is unclear whether this will translate to effectiveness at the time of an actual third- and fourth-degree repair.

Statistical Analysis Plan

Given the fixed set of residents, a post hoc power analysis will be performed. Categorical variables will be analyzed using chi-squared or Fisher exact tests and continuous variables will be analyzed using student t-tests. The mean scores of knowledge assessment and from the Objective Structured Assessment of Technical Skills (OSATS) as well as the change in scores pre- and post-intervention will be compared using Student t-tests. Differences in improvement scores between the two groups will be further examined using linear regression models, adjusting for baseline score and year of training. Differences in the score improvement between the two study groups and for each resident year will be analyzed using Wilcoxon rank test.

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