

Official Title: Effect of Validated Skills Simulation with the Miya Model on Operating Room
Performance of Vaginal Hysterectomy

NCT05418764

IRB Approval Date: 05/06/2025

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Protocol Title: Effect of Validated Surgical Skills Simulation with the Miya Model on Operating Room Performance of Vaginal Hysterectomy

Sponsor: Department of Health and Human Services, National Institutes of Health, EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Consent For Participation in a Research Study

Key Information about this research study

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future. You are being asked to participate in this study because you have expressed an interest in this study. Also, from an in-person interview, you have conveyed that you have met the following eligibility criteria (requirements) for this study: a rising (new) PGY 2 and PGY 3 OB/GYN Residents who are at the point in their Residency program when VH training begins and over the age of 21.

Taking Part in this research is voluntary

You do not have to participate in this study or may choose to leave the study at any time. If you decide not to participate in this study or leave the study later, it will not interfere in any way with your training or bias the grading and evaluation of your performance metrics in the future. Your participation in this research is voluntary. You should be aware that, even if you agree to participate in this evaluation, you are free to withdraw at any time without penalty contacting the PI at phone number, email, address.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information

This information gives you an overview of the study. More detailed information about the study will follow later in the document.

Purpose of this research

The purpose of this Concurrent Validation Study is to determine if Simulation training on the Miya Model™ will ultimately improve performance during Vaginal Hysterectomy (VH) in the OR as compared to the standard training paradigm. Residents will be given a basic didactic curriculum in VH and their skills will be assessed on the Miya Model™. They will then be divided into two groups. One group, the “Control” group, will undergo “Standard” VH training by watching and assisting in surgery.) The other “Experimental or “Simulation” group will undergo simulation training on the Miya Model™. Residents will be evaluated in the OR within two weeks of completing their respective training protocols to minimize degradation of skills. The Resident will sit as the primary surgeon while wearing the Tobii eye tracking glasses so the case can be videotaped just as simulated cases on the Miya Model™. There is no financial reimbursement at this time.

If you participate, how long with the study last?

Your participation in this study may last up to 52 weeks. You will be asked to complete one of two vaginal hysterectomy training protocols until a final assessment in the Operating Room.

Procedure

The purpose of the Concurrent Validation Study is to determine if Simulation training on the Miya Model™ will ultimately improve performance during VH in the OR as compared to the standard training paradigm. Residents will be divided into two groups. The protocol will follow standard human factors study procedures where the participants would first be given time to read, understand and sign this consent form. One group, the “Control” group, will undergo “Standard” VH training by watching and assisting in surgery.) The other “Experimental or “Simulation” group will undergo simulation training on the Miya Model™. They will train on the Miya Model™ until they achieve a modified VSSI score of 27. Miyazaki Enterprises’ previous work demonstrated that this score delineated proficient surgeons from novices. To determine if the experimental simulation curriculum leads to improved performance in VH over the standard training curricula, VH skills must be assessed before either training paradigm is commenced. Since the participants are Residents with little or no background in VH, they must first be given a common didactic curriculum teaching them the basics of the procedure. This is standard protocol in a Concurrent Validation study of this type.

For baseline assessment of VH skill, all residents will perform a VH on the Miya Model after completing the standardized training. The Tobii eye tracking video system will be used on all cases. The initial VH simulation performed on the Miya Model™ for benchmarking will be

scored by both the local Site PI as well as one of her outside expert surgeon from another institution. Residents will then be randomized to

receive either the Standard Curriculum or the Simulation Curriculum, as described and ultimately designed in Specific Aim 1. Videos of simulated VHs performed during the experimental group's simulation training will be scored only by the local Site PI. Approximately 50% of residents at each institution will be randomly assigned to each group. Resident skills need to be assessed in the OR on a live patient to determine if there is an advantage to simulation training on the Miya Model™. Ideally, Residents will be evaluated in the OR within two weeks of completing their respective training protocols so there is no degradation of skills. Faculty will attempt to choose cases without co-morbidities and are not expected to present with undue complications beyond the standard VH. The Resident will sit as the primary surgeon while wearing Tobii eye tracking glasses so the case can be videotaped just as simulated cases on the Miya Model™ were. Videos of the OR cases will be scored by both the local Site PI as well as one other outside expert surgeon from another institution, just as the initial benchmarking simulations were. All patients in the live cases will be consented to allow videotaping of VH and no patient identifiers will be shown or revealed.

Attending physicians will be asked to refrain from assisting or interfering unless patient safety is at risk. If the attending surgeon does intervene, they will be asked to do so by demonstrating with their hands what they are telling the Resident. In this way, proctors reviewing the video at a later date will know the contribution made by the attending surgeon and can score the Resident accordingly. After completion of the case, the video will be scored using the modified VSSI Scoring system and a Global Rating Scale by a local proctor and a proctor at another institution to avoid any bias. Furthermore, proctors will be blinded to whether the Resident being evaluated was in the standard or simulation trained group. During videotaping, the identity of both participating Residents and the patients during OR assessments will be protected. Efforts will be made to not videotape faces or other identifiable features of people. If identifying feature are captured, they will be blurred before any release of videos is made for analysis or presentations.

Potential Risks and Discomforts:

The probability and magnitude of harm anticipated by completion of this research is no greater, in and of itself, than those risks encountered by surgeons in their everyday life. You are being asked to perform a simulated VH on the Miya Model™ similar to what you do in the course of their everyday work in the OR. All equipment will be tested prior to the physicians using it, and if there is any unexpected malfunction, the evaluation will be immediately stopped. Furthermore, you will not be in an immersive environment often presented by Virtual Reality (VR) simulators so there should be no dizziness or confusion sometimes associated with VR.

Participation in this study will not pose any financial, legal, physical, psychological or cultural risks. Furthermore, as described above, measures are in place to

protect your confidentiality. If at any time, for any reason, you wish to end a trial or withdraw from the study, you may do so.

Part of this study will include VH being performed on live patients. Patients will be asked to participate if and only if their physician recommends that VH is an appropriate treatment for their medical condition. During the case, you will be the lead surgeon, but will be under the constant supervision of an attending surgeon. This will present no greater risk than having a VH performed in any teaching hospital. As emphasized above, patients will be briefed on the study and have ample opportunity to review a consent to be videotaped form. Again, their identity will be protected in the video recordings.

Anticipated Benefits

The benefit of this research to the subject will only be for him or her to know that their participation is contributing to the improvement of future development of medical simulators and curriculum that will improve the training of future physicians, nurses and allied health professionals. The true benefit for development and validation of the Miya Model will be for patients who benefit from surgeons who have “learned” in a safer training environment with improved skill. There is no compensation or reimbursement.

Confidentiality:

All or some of your work with the simulator and interviews will be video and audio taped and you will be asked to complete a questionnaire for the purpose of evaluating the simulator and showing the results of our testing. Your name will not appear on any of the test materials; only an assigned code will appear. The subject-code assignment information will be kept on a separate document by Miyazaki Enterprises and will later be destroyed when no longer needed.

Brief quotations of your verbal or written comments may be used for publications and presentations of this work. Video recordings will focus on your hands and arms as you interact with the simulator. If any video recordings or still images from the videos are used for presentations or publications, any random images of your face or other identifying features will be blurred. By signing this form, you give your consent to Miyazaki Enterprises to use the recording data for reporting results of this research, as described in this paragraph.

Representatives of Miyazaki Enterprises are _____ to review research records as part of
authorized their responsibility to protect human _____ h.
subjects in research

If you have any questions regarding your rights as a research subject, you may contact
your local PI _____ or _____

Study Participant

By signing below, you are consenting to participate in this research study. You have
read the information provided above. You have been given an opportunity to ask
questions and all of your questions have been answered to your satisfaction. You have
been given a copy of this form.

Signature _____

Printed Name _____

Date _____

PI or their designee

Signature _____

Printed Name _____

Date _____

