Preserving Vaginal Hysterectomy

THANK YOU PLANNING COMMITTEE AND DR. SCOTT WASHBURN

Disclosures

- President/Founder Miyazaki Enterprises
- Affiliations

  Novant Health Pelvic Health Center-retired

  Clinical Faculty, Wake Forest

  Associate Professor Campbell University

Vaginal Hysterectomy : Supporting Information

- ACOG recommends vaginal hysterectomy as the route of choice; vaginal hysterectomy is associated with better outcomes and fewer complications than either laparoscopic or abdominal hysterectomy (Committee Opinion #444, "Choosing the Route of Hysterectomy for Benign Disease," November 2009)

VH- preferred approach

- Cochrane Review
  - vs TAH
    - Shorter duration of hospital stay
    - Faster return to normal activity
    - Few febrile episodes or unspecified infections
  - vs LH
    - Shorter operating time
  - LH vs TAH
    - Faster return to normal activity
    - Shorter duration of hospital stay
    - Smaller drop in Hg
    - Lower EBL
    - Fewer wound infections
    - Longer OR time**
    - Higher GU injury**

•Cochrane. Vol 4, 2006 (27 RCT. 3643 pts)

NYU Langone MEDICAL CENTER

Cost of supplies at Wake Forest - 2015

- TLH: $1400
- LAVH - $1180
- TVH - $300
- *Cost of surgical tech ~ $18/hour*
- OR time is $95/min for basic case

Assessing current trends in resident hysterectomy training

Female Pelvic Med Reconstr Surg. 2011 Sep;17(5):210-4 Burkett D, Horwitz J, Kennedy V, Murphy D, Graziano S, Kenton K

- Only 38.1% of program directors and 27.8% of residents reported graduating residents as being **"*completely prepared*"** to perform a vaginal hysterectomy

...So How do we address this National downward trend???

Need for Improved Training Quality for Residents

- Van der Leeuw et al. "A systematic review of the effects of residency training on patient outcomes", BMC Medicine 2012, 10:65, http://www.biomedcentral.com/1741-7015/10/65

- Resident training is a key factor in developing medical practitioner skills and ensuring successful outcomes. In a review of 97 studies involving the effects of residency training on patient outcomes, the factors identified as influencing positive patient outcomes were:
- Operative exposure and additional operation time
- Attention to and assessment of resident competency
- Adequate supervision

Milestones Project 2008/Next Accreditation System (NAS)

Overarching goal of the Milestone Project is to provide outcomes-based accreditation. Intent of the Project (from Sept 2008 ACGME Bulletin)

"Reassure the public that physicians entering clinical practice have demonstrated the educational outcomes and proved their proficiency in all dimensions of the domains of clinical competency required to graduate from an accredited program."

Milestone

Operational definition of a “milestone” by ACGME is “a notable accomplishment which is measurable and commonly occurs by a certain time.”

Key features:

Notable accomplishment/Skill or knowledge-base development (being able to perform procedure competently and independently)

Measurable (direct observation, global rating scale, etc)

Commonly occurs by a certain time (for these surgical procedures we will presume this time is “by the end of a 4 year Ob/gyn residency”)

ACOG SIMULATION CONSORTIUM WORKING GROUP

- MISSION STATEMENT
- To establish simulation as a pillar in education for women's health through collaboration, advocacy, research, and the development and implementation of multidisciplinary simulations-based educational resources and opportunities for Obstetrics and Gynecology.
- OBJECTIVES
- To develop standardized curricula available to all residency programs.
- To develop standardized teaching and evaluation methods practiced and validated by Working Group members, to ensure the efficacy of simulations education.
- To provide validation of simulations-based education (as a useful teaching strategy) for developing and improving surgical skills, clinical skills, and behavioral skills with a focus on patient safety and the performance of high-quality surgical procedures.

ASSESS COURSE

- Advanced Surgical Simulation and Endoscopic Surgical Simulation
- Laparoscopic hysterectomy
- Laparoscopic ovarian cystectomy
- Vaginal hysterectomy
- Retropubic slings
- ACOG CME cat 1
- ABOG MOC credits towards certification, 2015

Simulations Consortium- Learning Objectives: Vaginal Hysterectomy

- The learner should be able to identify anatomic landmarks:
- Border of vaginal rugae
- Uterosacral ligament, Cardinal ligaments, Uterine vessels
- Location of ureter near cervix: in cardinal ligament
- Uterine arty= level of anterior broad ligament
- Basic knowledge:
- Cystotomy: Incidence: 1.2%
- Location of cystotomy: usually well above trigon, not near ureteral orifices
- Rectocele incidence after vaginal hysterectomy 0.1%-16%
- Uterosacral as primary suspension in vaginal vault
- Most common site for bleeding: between utero-ovarian and uterine artery pedicles, second common is posterior vaginal mucosa
- ii. Simulation Curriculum – Vaginal Hysterectomy
- Preparation:
- Time out
- SCDs/DVT prophylaxis
- Single dose antibiotics prophylaxis
- Position
- Stirrups supporting the entire leg are preferable
- Angles: 90 degrees between thigh and torso, and at the knee
- Exam under anesthesia
- Betadine/Ethanol scrub
- Drape: Self adherent Surgical Drape

ACOG Simulations Consortium- Learning Objectives: Vaginal Hysterectomy

- Procedure:
- Decompress bladder- indwelling catheter optional, consider leaving some urine in bladder to help identify cystotomy
- Inject vasoconstricting agent properly and in appropriate plane
- Initial incision at point of minimal blood loss, point of decreased vaginal rugae
- Incision may be made with energy
- Bladder must be dissected, deflected and protected
- Enter peritoneum anteriorly and posteriorly
- Anterior entry into the peritoneal cavity is not a must for the uterosacral and cardinal ligament ligations.
- Posterior entry should be with sharp dissection
- Identify uterosacral and cardinal ligaments, and uterine vessels
- Tag uterosacrals for use in McCalls
- Clamp placement and Hemostasis: open clamps widely and slide off cervix or lower uterine corpus before clamping down in an effort to include all vascular collaterals. Before any attempt of delivery of uterus or morcellation, abdomen must be entered both anteriorly and posteriorly. Subsequent to peritoneal entry, all clamp placements must include anterior and posterior edges of the peritoneum to ensure closure of all collaterals with vasculature.
- Remove uterus ONLY once all ligaments and vessels are ligated and secured
- Uterus descends after uterine artery dissection is complete
- If uterus is small: deliver fundus through anterior or posterior colpotomy
- If uterus is large: Consider bivalve, Intra-myometrial coring, Morcellation
- The upper pedicles, which include the cornual end of the fallopian tubes, and round and ovarian ligaments' are usually clamped at once. In anticipation of too large pedicles, round ligaments can be clamped and ligated separately. This may also be appropriate to facilitate adnexal removal

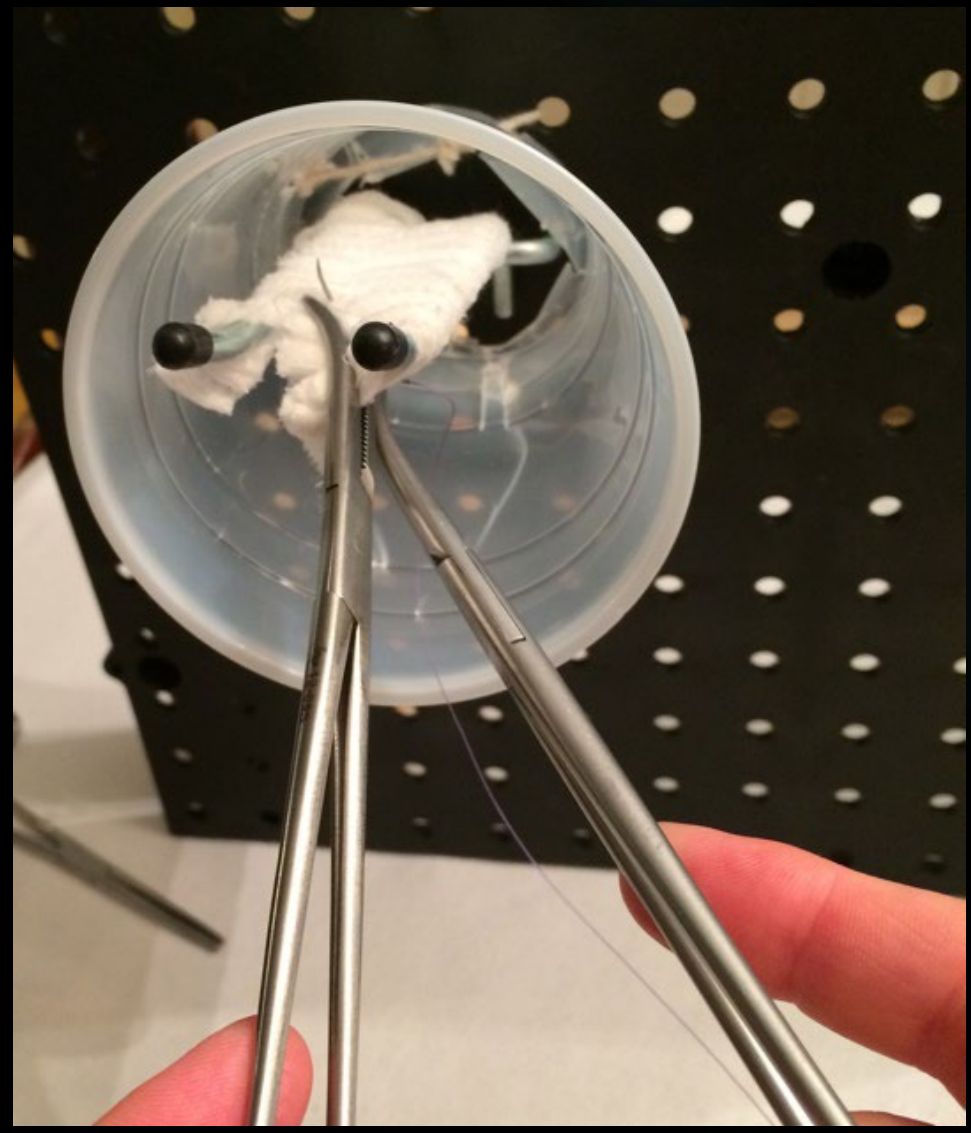
Common examples of vaginal Surgery Trainers

- Task trainers—Peg Board
- Johns Hopkins Flowerpot model (Developed by Dr. Grace Chen's group) build your own
- Mayo Clinic "build your own"
- New York University
- Gaumard "Surgical Chloe
- High Fidelity simulators
- -Gynesim, Uses real animal tissue
- -Miya Model

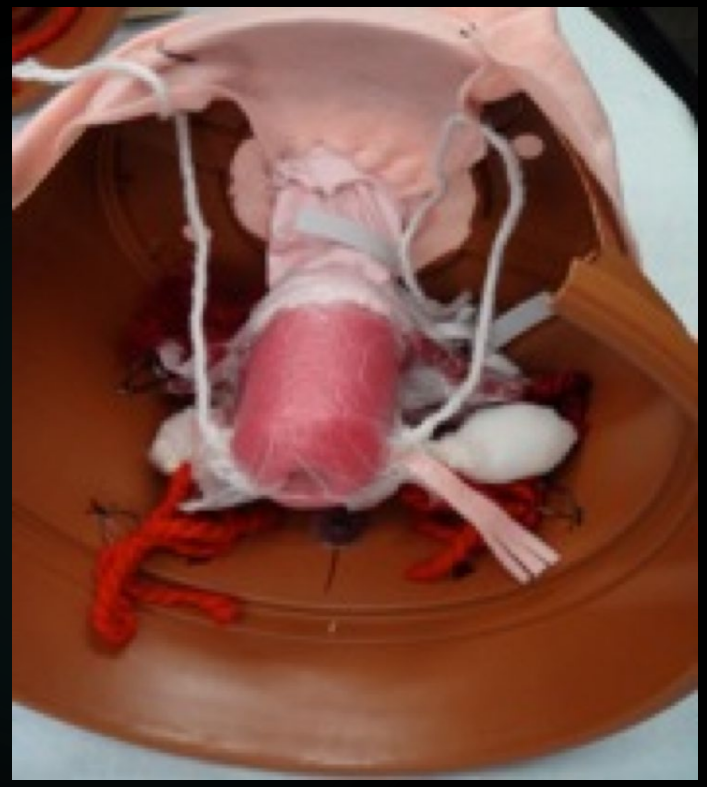
Peg board Task Trainer

Add a cup to
simulate working
in a smaller space – start with
a big cup, then progress to a
smaller narrower one

Developed by Dr. Leslie
Kammire, Wake Forest
Univeristy



Low Fidelity “flower pot” TVH simulator - *Kristiina Altman, MD Johns Hopkins*




X


10
1
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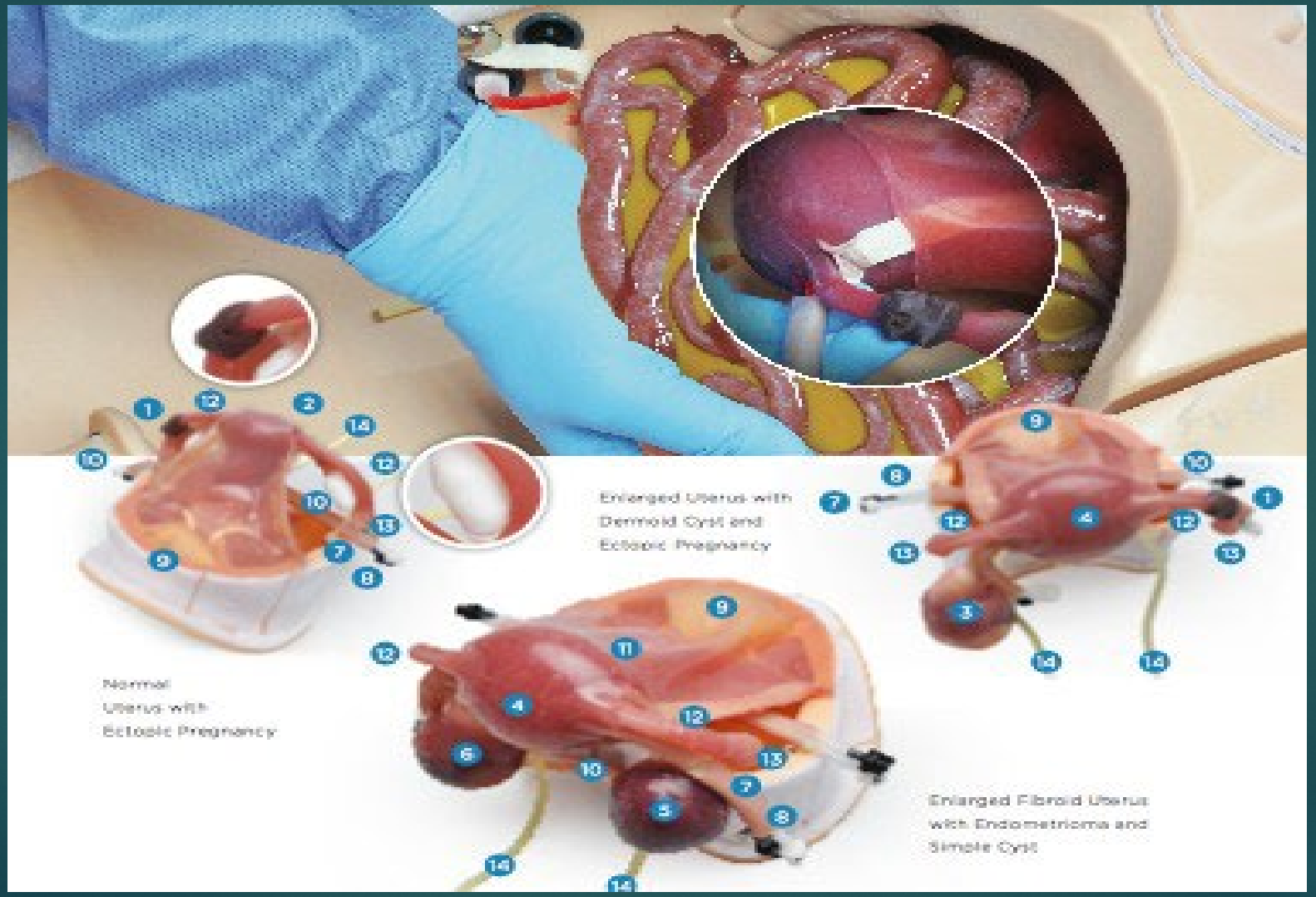
7
9
8
11
GLAD
Press'n Seal

Mayo Clinic-Sym VaHT

ITEMS needed:
PVC piping
Sponge
Adhesive Velcro tape
Alligator clips
Copper wire
Hair elastic
3inch PVC curved
C clamp
Nylon knee highs
Rubberband
Surgical instruments

New York University

Gaumard Surgical Chloe



Gynesim and Miya Model Simulators

Links to simulators

- hMp://2013.iuga.org/handouts/docs/handout24_partdb.pdf

- Video: hMps://vimeo.com/17440577
- hMps://www.ncbi.nlm.nih.gov/pubmed/23211467

- hMp://obgyn.med.umich.edu/contact/news/tovia-smith-sgs
- Video link: hMps://pfrg.smugmug.com/VIDEOS/Vaginal-Hyst-Model/i-TF4bpjd/A

- Video link: hMps://www.youtube.com/watch?v=O2REFAHTUS4
- hMp://www.pharmabo@cs.com/gst100-gynaecological-skills-trainer/

- hMps://www.acog.org/-/media/Departments/Simula@ons-Consor@um/Total-Vaginal- Hysterectomy-Simula@on-Mannequin.pdf?la=en

- hMps://s3.amazonaws.com/gaumard2.0-downloads/products/hifi/S2100/S2100.pdf

Miya Model

Validation of an Educational Simulation Model for Vaginal Hysterectomy (VH) Training

- D. Miyazaki MD, A. Sherif El Haraki MD, N. Miyazaki, C. Mathews MD. Oral Poster, 42nd Annual Scientific Meeting, Society of Gynecologic Surgeons, Palm Springs, Ca. April, 12, 2016
- **Grant Number: 1R43HD084151-01, *SMALL BUSINESS INNOVATION RESEARCH PROGRAM*, Federal Award Date: 05/12/2015**, Department of Health and Human Services, National Institutes of Health, EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Introduction

The Miya Model is a realistic and effective vaginal surgery simulation model

Objective: Determine the construct validity of the Miya Model using the American College of Obstetricians and Gynecologists (ACOG) vaginal hysterectomy competency assessment tool.

Hypothesis: The model would discriminate between novice and expert surgeons.

Metrics: operative times,
blood loss and
overall surgical competency using the ACOG Assessment Tool.

In addition, we sought to determine user satisfaction with the model as a simulation tool for vaginal hysterectomy training.

Study Design:

- A total of 10 novice surgeons, residents (PGY 2-4) and 10 attending surgeons (median 16 years in practice) were included

-Vaginal hysterectomy performed using the steps outlined by the Society of Gynecologic Surgeons and ACOG

-60 minute time limit to complete procedure, each was filmed

-Measured blood loss recorded

-Either the time taken to complete the procedure or the last step completed at 60 min. recorded

-Two independent experienced gynecologic surgeons were blinded to novice and expert groups and evaluated each filmed performance using the ACOG vaginal hysterectomy assessment tool.

-Participants evaluated the model using a post-simulation survey immediately after

Results:

-Time to procedure completion was also significantly faster for the experienced group (40.7 minutes ± 8.87 versus 52.8 ± 8.48 minutes, p= 0.005)

-Blood loss did not differ significantly between groups (152 ml ± 198 for novices versus 95ml ± 155 for experts, 0.48).

-Surgeons in the experienced group received significantly higher scores from both raters in 6/7 domains of the ACOG assessment tool,

categories: time and motion,
knowledge of instruments,
use of assistants,
flow of operation and forward planning, and
knowledge of specific procedure.
Global Rating Scale of Operative Performance

The only parameter that was not different for either rater was respect for tissue.

The variance in scoring range and absence of strong inter-rater reliability prevented us from reporting a combined median score.

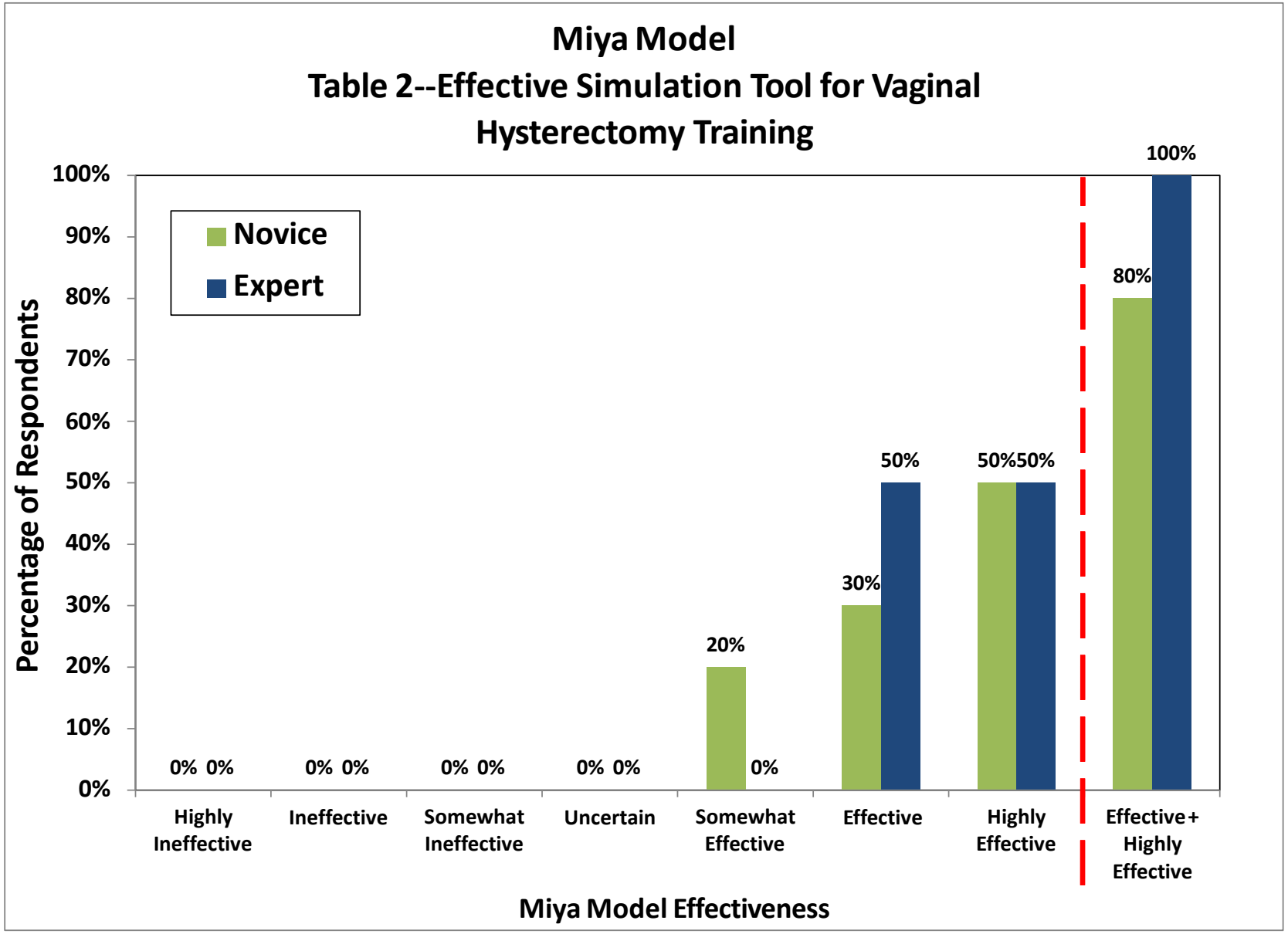
		Rater 1			Rater 2		
	Inter Rater-Reliability Weighted κ (95% CI)	Novice (n=10) Median [A] (IQR)	Expert (n=10) Median [A] (IQR)	P-value[B]	Novice (n=10) Median [A] (IQR)	Expert (n=10) Median [A] (IQR)	P-value[B]
Respect for tissue	0.30 (0.03, 0.58)	3 (3-4)	4 (4-5)	0.06	3 (2-3)	4 (3-5)	0.08
Time and motion	0.47 (0.21, 0.73)	2 (2-3)	4 (4-5)	0.0075	1.5 (1-2)	3.5 (3-4)	0.0108
Instrument handling	0.55 (0.28, 0.81)	2.5 (1-3)	5 (4-5)	0.0058	2 (1-3)	4 (3-5)	0.0092
Knowledge of instruments	0.39 (0.11, 0.67)	3 (3-4)	5 (5-5)	0.0093	4 (3-5)	5 (5-5)	0.0286
Use of assistants	0.42 (0.18, 0.66)	3 (2-4)	5 (4-5)	0.0110	2 (1-3)	3.5 (3-5)	0.0126
Flow of operation and forward planning	0.48 (0.22, 0.75)	2.5 (2-3)	5 (4-5)	0.0171	2.5 (1-3)	5 (3-5)	0.0164
Knowledge of specific procedure	0.33 (0.02, 0.64)	3 (2-3)	5 (5-5)	0.0172	3 (2-4)	5 (5-5)	0.0188
Global Rating Scale of Operative Performance	0.47 (0.19, 0.76)	2.5 (2-4)	6 (6-7)	0.0230	2 (1-3)	6 (5-7)	0.0090

[A] 1=Deficient knowledge. Needed specific instruction at most operative step

3=Knew all important aspects of the operation

5=Demonstrated familiarity with all aspects of the operation

[B]Wilcoxon Rank Sum Test


Miya Model
Table 2--Effective Simulation Tool for Vaginal Hysterectomy Training
Novice
Expert
Percentage of Respondents
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0% 0%
0% 0%
0% 0%
0% 0%
20%
0%
30%
50%
50%50%
80%
100%
Highly Ineffective
Ineffective
Somewhat Ineffective
Uncertain
Somewhat Effective
Effective
Highly Effective
Effective+ Highly Effective
Miya Model Effectiveness

Phase II NIH Grant: Development and Validation of the Miya Model, A Simulator Designed to Train Vaginal Surgery Techniques

- ***SMALL BUSINESS INNOVATION RESEARCH PROGRAM,*** **Federal Award Date: 09/27/16**, Department of Health and Human Services, National Institutes of Health, EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT; P.I. Dr. Douglas Miyazaki,
- Sub P.I: Chi Chiung Grace Chen MD, Christopher Destephano MD, Leslie Kammire MD, Ernest Lockrow MD, Catherine Ann Matthews MD, Mikio Nihira MD, Lisa Landrum MD, Bruce Anderson PhDS, Douglas Miyazaki MD

Results

- A total of 56 surgeons (11 faculty, 39 residents) were assessed 2 videos were excluded due to technical filming issues.
- Four of the participants did not complete demographic information leaving a total of 39 Ob/Gyn residents/fellows and 11 trained gynecologists.
- The average composite score was 24.1, with a standard deviation of 10.4, and range from 1 to 40.
- The composite VSSI score correlated highly with the GRS (Pearson $r = 0.92$, $P < .001$).

Results

- Using a cutoff of 27 as the lowest passing score, agreement is very good with the current pass/fail result.
- Of 112 assessments, 2 failed under the current standard but had a composite score >=27, and 13 passed under the current standard but had a composite score <27, for 88% overall agreement.
- Both scales were able to not only discriminate between novice and expert surgeons but also discriminated between training levels

Conclusions

- This study demonstrates the Miya Model is an effective model when coupled with either the VSSI or GRS to assess vaginal hysterectomy skills. There is sufficient evidence to support the validity of the model for formative assessment of vaginal hysterectomy skills.
- The Miya model fills a significant gap in vaginal surgery skills training and formative assessment by providing a reliable assessment rated highly by faculty and learners that correlates well with training level.

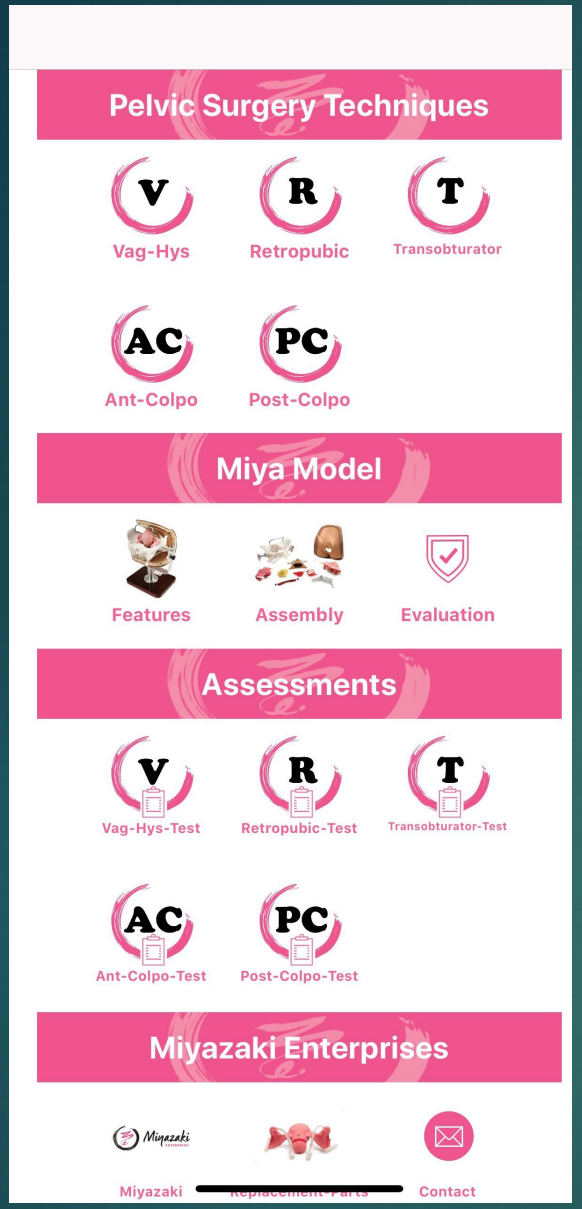
Project Title: Effect of Validated Skills Simulation with the Miya Model on Operating Room Performance of Vaginal Hysterectomy, Phase IIB, Sept.,2020

- Grant Number: 2R44HD084151-04A1, P.I. Dr. Douglas Miyazaki, Sub P.I: Bruce Anderson PHD, Chi Chiung Grace Chen MD, Howard Curlin MD, , Leslie Kammire MD, Roseanne KHO MD, Lisa Landrum MD, , Ernest Lockrow MD, Nicole Mahnert MD, Catherine Ann Matthews MD, Nichole Mahnert MD, Jamal Mourad MD, Mikio Nihira MD, Lichen Quiroz, SMALL BUSINESS INNOVATION RESEARCH PROG Federal Award Date: Department of Health and Human Services National Institutes of Health EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT Notice of Award FAIN# R44HD084151 Federal Award

Goals

- 5 National Training sites:
- Wake Forest University, Vanderbilt University, Walter Reed-Uniformed Health Services Health Sciences, Albert Einstein University and University of Oklahoma
- Compare 2 groups of residents
- -Traditional TVH training
- -Simulation TVH training, must pass the 27 score proficiency x2
- -film and score first live TVH as Primary surgeon and compare arms
- Recordings are with Tobii eye tracking video system which tracks the user's field of view

We hope to share our data next year



Thank You!
Questions?

Email: exec@saaog.org

---Vaginal Surgical Skills Index (VSSI)

The original VSSI is a surgical rating scale used to evaluate trainee performance during live vaginal surgery, specifically vaginal hysterectomies.

- **Total Score Range:** The original VSSI has 13 items and a total score ranging from **0 to 52**.
- **Scoring:** Each item is typically scored on a 5-point Likert scale (0-4), where a higher score indicates better performance.
- **Competency Cutoff:** A cutoff score of around **32** (or 27 for a modified 10-item version) is often used to differentiate between minimally competent and non-competent surgeons.

doi: 10.1016/j.jmig.2020.12.006.

Construct Validation studies

- Validation of the simulated vaginal hysterectomy trainer (SimVaHT) M. H. Vaughan1,2 , S. Kim-Fine3 , K. Hullfish2 , T. M. Smith4 , N. Y. Siddiqui1 , E. R. Trowbridge2
- Validation of Transvaginal Hysterectomy Surgical Model – Modification of the Flowerpot Model to Improve Vesicovaginal Plane Simulation, Linda S Burkett, MD, Jennifer Makin, MD, Mary Ackenbom, MD, MSc, Amanda Artsen, MD, MSc, MF, Megan Bradley, MD, Published:December 23, Published:December 23, 2020, DOI :https://doi.org/10.1016/j.jmig.2020.12.022
- Educational Simulation Model for Vaginal Hysterectomy (VH) Training, Miyazaki D, Matthews CA, Kia MV, El Haraki AS, Miyazaki N, Chen CCG. Int Urogynecol J. 2019 Aug;30(8):1329-1336.
- Validation of an Multi-institutional Validation of a Vaginal Hysterectomy Simulation Model for Resident Training, Dani Zoorob 1, Recia Frenn 2, Melissa Moffitt 3, Adam Kansagor 4, Stephanie Cross 5, Francisco Aguirre 6, Mitchell I Edelson 7, Bronwyn Kenny 8, Erika Banks 9,,2020 Dec 11;S1553-4650(20)31173-0.

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