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HIGHLIGHTS ISSUE, PART 2

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OR safety and efficiency: Measuring and monitoring all factors—including surgical volume

Human, nontechnical, and environmental factors may be as critical as surgeons' experience and skills in OR safety and efficiency. Case volume of the individual surgeon and institution also may play a role.

Oz Harmanli, MD; Kenneth Catchpole, PhD; Teodor Grantcharov, MD, PhD; and Jason D. Wright, MD

The operating room (OR) is a key contributor to a hospital's profitability. It is a complex environment with ever-advancing technology. A successful surgery completed without complications within an optimal time depends not only on the surgeon's experience, skills, and knowledge but also on numerous other structural, human, and nontechnical factors over which the surgeon has limited control.

As in any setting that deals with human life, in the OR, team dynamics, communication, and environment play a major role. Research has indicated the benefits of dedicated teams, reduced handoffs, and innovative modalities that continuously and systematically monitor potential breakdowns and propose solutions for the detected problems.

Finally, who should perform your loved one's hysterectomy? This article also attempts to address the impact of surgeons' and hospitals' volume on operative outcomes with a diminishing number of hysterectomies but an increasing number of approaches.

Human factors in the OR

Human factors research was born as a product of the industrial revolution and mass production. It aims to optimize human experience and improve system performance by studying how humans interact with system. The aviation industry, for example, minimized errors significantly by using methods developed by human factors scientists. As another industry with no tolerance for mistakes, the health care sector followed suit. Ultimately, the goal of human factors research in health care is to improve patient safety, optimize work and environment, reduce costs, and enhance employees' physical and mental health, engagement, comfort, and quality of life (**FIGURE 1**).[1]

Today's OR is so complex that it is hard to understand its dynamics without human factors research. Every new OR technology is first tested in controlled and simulated environments to determine "work as imagined." However, it is necessary to study "work as done" in the real world via direct observation, video recording, questionnaires, and semistructured interviews by an on-site multidisciplinary team. This process not only focuses on surgical skills, process efficiency, and outcomes but also monitors the entire process according to Human Factors and Ergonomics Engineering principles to explore otherwise hidden complexities and latent safety concerns. The Systems Engineering Initiative for Patient Safety (SEIPS) framework is used to study the impact of interactions between people, tasks, technologies, environment, and organization.[1]

Robot-assisted surgery (RAS), an increasingly popular surgical approach among gynecologic surgeons, recently has been the focus of human factors science. A robotic OR poses unique challenges: the surgeon is not scrubbed, is removed from the operating table, and controls a complex highly technologic device in a crowded and

Dr. Grantcharov reports being the founder of Surgical Safety Technologies Inc, an academic startup that commercializes the OR Black Box platform. The other authors report no financial relationships relevant to this article.

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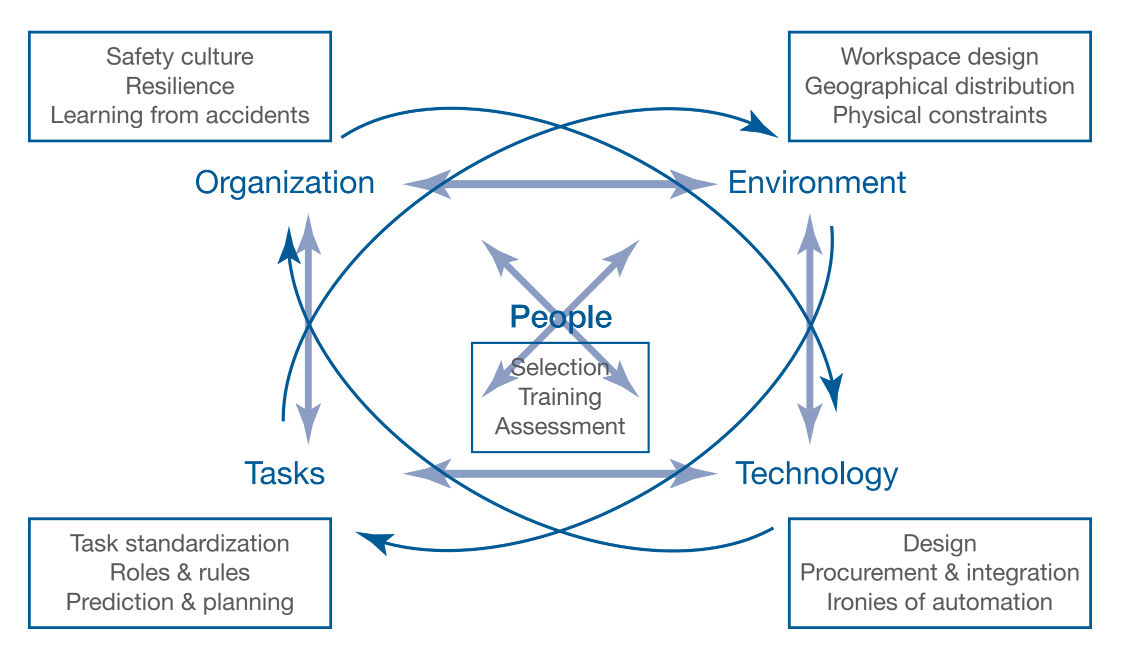
FIGURE 1 Systemic influences on human performance[1]



darkened room. These are ideal conditions waiting to be optimized by human factor experts. To demonstrate the importance of human factors in the OR, we review the evidence for RAS.

Impact of flow disruptions

Flow disruptions (FDs) were found to be more common in RAS. Catchpole and colleagues identified a mean of 9.62 FDs per hour in 89 robotic procedures, including hysterectomies and sacrocolpopexies, from a variety of fields; FDs occurred more often during the docking stage, followed by the console time, and they mostly were caused by communication breakdown and lack of team familiarity.[2]

Surgeon experience significantly reduced FDs. Surgeons who had done more than 700 RAS cases experienced 60% fewer FDs than those who had done less than 250 cases (13 vs 8 per hour).[2] A study focusing on residents' impact on RAS outcomes found that each FD increased the total operative time by an average 2.4 minutes, with the number significantly higher when a resident was involved.[3] About one-quarter of the training-related FDs were procedure-specific instructions, while one-third were related to instrument and robotic instruction. However, pauses to teach residents did not appear to create significant intraoperative delays. Expectedly, experienced surgeons could anticipate and reduce these disruptions by supporting the whole team.

Human ergonomics, turnover time, and robot-specific skills

In a study of human ergonomics in RAS, Yu and colleagues noted that bedside assistants could experience neck posture problems. Surprisingly, the console could constrain the surgeon's neck-shoulder region.[4] Studies that reported on communication problems in a robotic OR suggest that innovative forms of verbal and nonverbal communication may support successful team communication.[5]

On the learning curve for RAS, OR turnover time, a key value metric, has been longer. However, turnover time was reduced almost by half from 99.2 to 53.2 minutes over 3 months after concepts from motor racing pit stops were employed, including briefings, leadership, role definition, task allocation, and task sequencing. Average room-ready time also was lowered from 42.2 to 27.2 minutes.[6] RAS presents new challenges with sterile instrument processing as well. A successful RAS program, therefore, has organizational needs that

Key points

- What factors besides the surgeon's skills influence surgical safety and efficiency?
- Are you ready to have audio, video, and sensor-based recording of everything in the OR?
- Who should perform your loved one's hysterectomy? Do the surgeon's and hospital's volume matter?

include the training of OR and sterile processing staff and appropriate shift management.[1]

In a robotic OR, not only the surgeon but also the whole team requires robot-specific skills. New training approaches to teamwork, communication, and situation awareness skills are necessary. Robotic equipment, with its data and power cables, 2 consoles, and changing movement paths, necessitate larger rooms with a specific layout.[7]

In a review of recordings of RAS that used a multidimensional assessment tool to measure team effectiveness and cognitive load, Sexton and colleagues identified anticipation, active team engagement, and higher familiarity scores as the best predictors of team efficiency.[8] Several studies emphasized the need for a stable team, especially in the learning phase of robotic surgery.[5,9,10] A dedicated robotic team reduced the operative time by 18% during robot-assisted sacrocolpopexy (RASCP).[10] RASCP procedures that extended into the afternoon took significantly longer time.[9] A dedicated anesthesiologist improved the preoperative time.[9] Surgical team handoffs also have reduced OR efficiency.[11,12]

Studying the impact of human factors is paramount for safe and efficient surgery. It is especially necessary in ORs that are equipped with high technologic instruments such as those used in RAS.

Surgical Black Box: Using data for OR safety and efficiency

Surgical procedures account for more than 50% of medical errors in a hospital setting, many of which are preventable. Postevent analysis with traditional methods, such as "Morbidity and Mortality" meetings held many days later, misses many adverse events in the OR.[13] Another challenge with ever-changing and fast-multiplying surgical approaches is the development of effective surgical skill. Reviewing video recording of surgical procedures has been proposed as an instrument for recognizing adverse events and perfecting surgical skills.

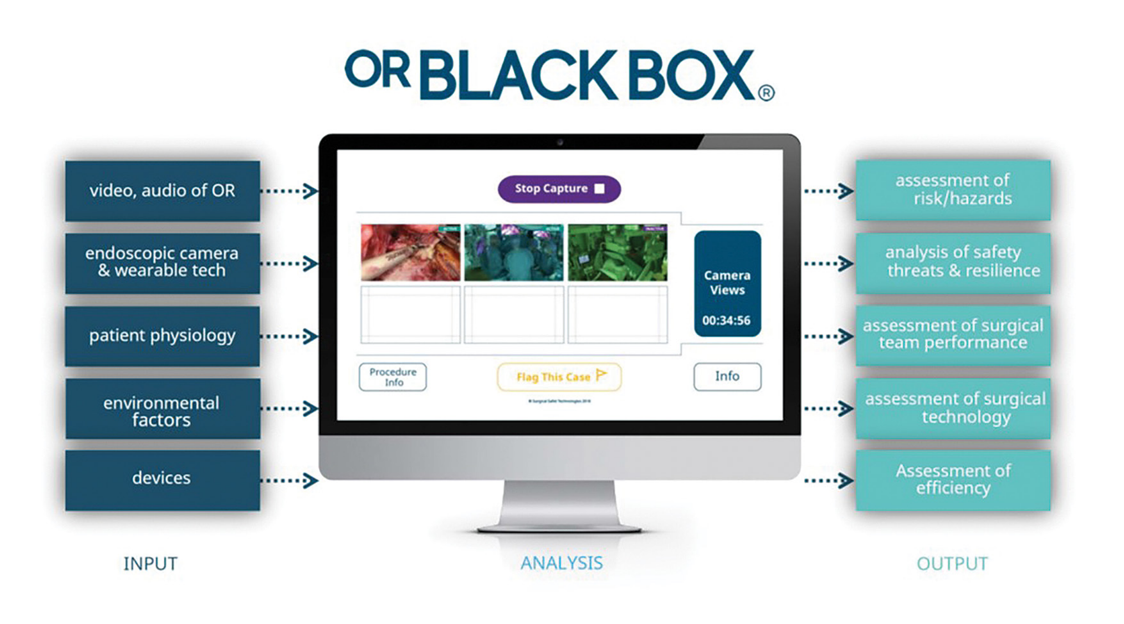
Recently, an innovative data-capture platform called the OR Black Box, developed by Teodor Grantcharov, MD, PhD, and colleagues, went beyond simple audiovisual recording.[14] This high technologic platform not only video records the actual surgical procedure with laparoscopic camera capture (and wearable cameras for open cases) but also monitors the entire OR environment via wide-angle cameras, utilizes sensors, and records both the patient's and the surgeon's physiologic parameters.

The OR Black Box generates a holistic view of the OR after synchronization, encryption, and secure storage of all inputs for further analysis by experts and software-based algorithms (**FIGURE 2**). Computer vision algorithms can recognize improper dissection techniques and complications, such as bleeding. Adverse events are flagged with an automated software on a procedural timeline to facilitate review of procedural steps, disruptive environmental and organizational factors, OR team technical and nontechnical skills, surgeon physiologic stress, and intraoperative errors, events, and rectification processes using validated instruments.

Artificial intelligence built into this platform can automatically extract objective, high-quality, and structured data to generate explainable insights by recognizing adverse events and procedural segments of interest for training and quality improvement and provide a foundation with objective measurements of technical and nontechnical performance for formative and summative assessment. This system, a major step up compared with retrospective review of likely biased medical records and labor-intensive multidisciplinary human observers, has the potential to increase efficiency and reduce costs by studying human factors that include clinical design, technology, and organization. OR efficiency, measured in real time objectively and thoroughly, may save time and resources.

OR Black Box platforms have already started to generate meaningful data. It is not surprising

FIGURE 2 The OR Black Box: A multiport data-capture system



that auditory disruptions—OR doors opening, loud noises, pagers beeping, telephones ringing—were recorded almost every minute during laparoscopic procedures.[15] Most technical errors occurred during dissection, resection, and reconstruction and most commonly were associated with improper estimations of force applied to tissue and distance to the target tissue during operative steps of a laparoscopic procedure.[16] Another study based on this system showed that technical performance was an independent predictor of postoperative outcomes.[17] The OR Black Box identified a device-related interruption in 30% of elective laparoscopic general surgery cases, most commonly in sleeve gastrectomy and oncologic gastrectomy procedures. This sophisticated surgical data recording system also demonstrated a significantly better ability to detect Veress needle injuries (12 vs 3) and near misses (47 vs 0) when compared with traditional chart review.[18]

Data from the OR Black Box also have been applied to better analyze nontechnical performance, including teamwork and interpersonal dynamics.[19] Surgeons most commonly exhibited adept situational awareness and leadership, while the nurse team excelled at task management and situational awareness.[19] Of the total care provider team studied, the surgeon and scrub nurse demonstrated the most favorable nontechnical behavior.[19] Of note, continuous physiologic monitoring of the surgeon with this system revealed that surgeons under stress had 66% higher adverse events.

The OR Black Box is currently utilized at 20 institutions in North America and Europe. The data compiled from all these institutions revealed that there was a 10% decrease in intraoperative adverse events for each 10-point increase in technical skill score on a scale of 0 to 100 (unpublished data). This centralized data indicated that turnover time ranged widely between 7 and 91 minutes, with variation of cleanup time from 1 to 25 minutes and setup time from 22 to 43 minutes. Institutions can learn from each other using this platform. For example, the information about block time utilization (20%–99%) across institutions provides opportunities for system improvements.

With any revolutionary technology, it is imperative to study its effects on outcomes, training, costs, and privacy before it is widely implemented. We, obstetricians and gynecologists, are very familiar with the impact of electronic fetal monitoring, a great example of a technologic advance that did not improve perinatal outcomes but led to unintended consequences, such as higher rates of cesarean deliveries and lawsuits. Such a tool may lead to potential misrepresentation of intraoperative events unless legal aspects are clearly delineated. As exciting as it is, this disruptive technology requires further exploration with scientific vigor.

Surgeon and hospital volume: Surgical outcomes paradigm

A landmark study in 1979 that showed decreased mortality in high-volume centers underscored the need for regionalization for certain surgical procedures.[20] This association was further substantiated by 2 reports on 2.5 million Medicare beneficiaries that demonstrated significantly lower mortality for all 14 cardiovascular and oncologic procedures for hospitals with larger surgical volume (16% vs 4%) and high-volume surgeons for certain procedures, for example, 15% versus 5% for pancreatic resections for cancer.[21,22]

A similar association was found for all routes of hysterectomies performed for benign indications. Boyd and colleagues showed that gynecologists who performed fewer than 10 hysterectomies per year had a higher perioperative morbidity rate (16.5%) compared with those who did more (11.7%).[23] Specific to vaginal hysterectomy, in a study of more than 6,000 women, surgeons who performed 13 procedures per year had 31% less risk of operative injury than those who did 5.5 procedures per year (2.5% vs 1.7%).[24] Overall perioperative complications (5.0% vs 4.0%) and medical complications (5.7% vs 3.9%) were also reduced for higher-volume surgeons. In a cohort of approximately 8,000 women who underwent a laparoscopic hysterectomy, high-volume surgeons had a considerably lower complication rate (4.2% vs 6.2%).[25]

As expected, lower complication rates of high-volume surgeons led to lower resource utilization, including lower transfusion rates, less intensive care unit utilization, and shorter operative times and, in several studies, length of stay.[24,25] Of note, low-volume surgeons were less likely to offer minimally invasive routes and were more likely to convert to laparotomy.[26] In addition, significant cost savings have been associated with high surgical volume, which one study showed was 16% ($6,500 vs $5,600) for high-volume surgeons.[26] With regard to mortality, a study of 7,800 women found that perioperative mortality increased more than 10-fold for surgeons who performed an average 1 case per year compared with all other surgeons (2.5% vs 0.2%).[27]

When gynecologic cancers are concerned, arguably, long-term survival outcomes may be more critical than perioperative morbidity and mortality. Higher surgeon and hospital volume are associated with improved perioperative outcomes for endometrial and cervical cancers.[28] Importantly, minimally invasive hysterectomy was offered for endometrial cancer significantly more often by surgeons with high volume.[28] Survival outcomes were not affected by surgeon or hospital volume, likely due to overall more favorable prognosis for endometrial cancer after treatment.

Although it is intuitive to assume that a surgeon's skills and experience would make the most impact in procedures for ovarian cancer due to the complexity of ovarian cancer surgery, evidence on short-term outcomes has been mixed. Intriguingly, some studies reported that high-volume institutions had higher complication and readmission rates. However, evidence supports that the surgeon's volume, and especially hospital volume, improves long-term survival for ovarian cancer, with a negative impact on immediate postoperative morbidity.[29] This may suggest that a more aggressive surgical effort improves long-term survival but also can cause more perioperative complications. Further, longer survival may result not only from operative skills but also because of better care by a structured multidisciplinary team at more established high-volume cancer centers.

The association of improved outcomes with higher volume led to public reporting of hospital outcomes. Policy efforts toward regionalization have impacted surgical practice. Based on their analysis of 3.2 million Medicare patients who underwent 1 of 8 different cancer surgeries or cardiovascular operations from 1999 to 2008, Finks and colleagues demonstrated that care was concentrated to fewer hospitals over time for many of these procedures.[29] This trend was noted for gynecologic cancer surgery but not for benign gynecologic surgery.

Regionalization of care limits access particularly for minority and underserved communities because of longer travel distances, logistic challenges, and financial strain. An alternative to regionalization of care is targeted quality improvement by rigorous adherence to quality guidelines at low-volume hospitals.

Is there a critical minimum volume that may be used as a requirement for surgeons to maintain their privileges and for hospitals to offer certain procedures? In 2015, minimum volume standards for a number of common procedures were proposed by Johns Hopkins Medicine and Dartmouth-Hitchcock Medical Center, such as 50 hip replacement surgeries per hospital and 25 per physician per year, and 20 pancreatectomies per hospital and 5 per surgeon per year.[30] A modeling study for hysterectomy showed that a volume cut point of >1 procedure in the prior year would restrict privileges for a substantial number of surgeons performing abdominal (17.5%), robot-assisted (12.5%), laparoscopic (16.8%), and vaginal (27.6%) hysterectomies.[27] This study concluded that minimum-volume standards for hysterectomy for even the lowest volume physicians would restrict a significant number of gynecologic surgeons, including many with outcomes that are better than predicted.

Therefore, while there is good evidence that favors better outcomes in the hands of high-volume surgeons in gynecology, the impact of such policies on gynecologic practice clearly warrants careful monitoring and further study. ■

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Challenges and innovations in training gyn surgeons

Educators are responding to the problematic issues involving ObGyn resident surgical training with strategies that encompass tracking and simulation

Mary V. Baker, MD, MBA; Brandy M. Butler, MD; Shivani M. Murarka, MD; Cecile A. Ferrando, MD, MPH; Douglas W. Miyazaki, MD; and Carl W. Zimmerman, MD

Obstetrics and gynecology (ObGyn) is a surgical specialty, yet the training of ObGyn residents differs significantly from that of residents in other surgical specialties. In addition to attaining competency in both the distinct but related fields of obstetrics and gynecology, ObGyn residents have their training condensed into 4 years rather than the 5 years' training of many other surgical specialties. This limits the time dedicated to gynecologic surgery, currently 18 to 20 months in most programs, and has been exacerbated by tighter duty-hour restrictions.[1]

Additionally, with increasing demand for minimally invasive procedures, residents are expected to attain competency in a growing breadth of gynecologic procedures in a patient population with increasing morbidity, and they may have less autonomy to do so in an increasingly litigious environment.[2] Furthermore, annual hysterectomy cases are declining, from about 680,000 in 2002 to 430,000 in 2010,[3] and these declining rates are seen in the low case numbers of recent graduates.[4]

Training time, procedure complexity

With less time to master a growing body of increasingly complex procedures, is the profession adequately training gynecologic surgeons? Many gynecologic surgeons are concerned that the answer is no and that significant shifts in resident training are needed to generate safe and competent gynecologic surgeons. These training deficits represent a deficiency in the quality of care for women specifically, and thus the inattention to training gynecologic surgeons should be considered a health care disparity.

The concern over insufficient attention to gynecologic surgical training is not new, nor are proposed solutions, with many physicians citing the above concerns.[5-9] In 2018, the Accreditation Council for Graduate Medical Education (ACGME) case minimums for hysterectomy increased to 85 from 70 hysterectomies, with a shift toward minimally invasive hysterectomy.[10] Otherwise, minimal national changes have been made in this century to training gynecologic surgeons.

Tracking as an option

Many critics of current ObGyn training argue that obstetrics and gynecology, while related, have significantly different pathologies, surgical approaches, and skill sets and thus warrant the option to track toward obstetrics or gynecology after attaining limited core skill set in residency. In 2010, the Carnegie Foundation for the Advancement of Teaching called for the need for increased individualization opportunities in graduate medical education, citing that minimal changes have been made to medical education since the Flexner Report a century prior.[11]

Notably, **tracking** has been implemented with success at Cleveland Clinic, where residents are given 5 to 10 weeks of time allotted to their specific fields of interest, while still meeting minimum ACGME requirements and, in some cases, exceeding

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hysterectomy minimums by as much as 500%.[12] Tracking is viewed positively by a majority of program directors.[13] See the box below for Dr. Ferrando's experience on tracking at the Cleveland Clinic.

Simulation training

Other educators advocate for maximizing preparedness for the operating room by using high-fidelity **simulation**.[14,15] Simulation allows for the acquisition of basic technical skills needed for surgery as well as for repetition not easily achieved in the current surgical environment. Additionally, it provides lower-level learners the opportunity to acquire basic skills in a safe setting, thereby enhancing the ability to participate meaningfully on arrival in the operating room.[16]

Key takeaways

- Residents and fellows have significant constraints that limit adequate training in gynecologic surgery. In a panel discussion at the 48th annual meeting of the Society of Gynecologic Surgeons, Drs. Zimmerman, Ferrando, and Miyazaki spoke about potential solutions.
- Allowing residents to track toward obstetric or gynecologic subspecialties may improve surgical volume of trainees who aim for a future career in gynecologic surgery.
- Simulation has demonstrated efficacy in enabling residents to prepare and improve their technical skills for specific procedures prior to entering the operating room.

Cleveland Clinic's tracking innovation

Cecile A. Ferrando, MD, MPH

In his 2013 presidential address at the opening ceremony of the 42nd AAGL Global Congress on Minimally Invasive Gynecology, Javier Magrina, MD, asked the audience, "Isn't it time to separate the O from the G?"[7] Since that address, this catchy question has been posed several times, and it continues to be a topic of interest to many ObGyn educators seeking to innovate the curriculum and to better train our next generation's gynecologic surgeons.

Several concerns have been raised about the current traditional 4-year residency training program, which has been impacted by the reduction of training hours due to duty-hour rules in the setting of decreased surgical volume and new technologies used to perform surgery. While other surgical specialties have begun to innovate their pathways for trainees, ObGyn has been a little slower to make a significant transition in its approach to training.

In 2012, Cleveland Clinic decided to lead the way in innovation regarding residency training. At its inception, the curriculum was designed to allow "tracking blocks" through each academic year to allow residents to gain additional experience in their specialty of choice. The program was carefully designed to assure that residents would achieve all 28 of the core obstetrics and gynecology milestones while still allowing for curricular flexibility.

Currently, residents are given autonomy to design their own tracking blocks with an assigned mentor for the rotation. Allowing residents to spend more time in their specialty of choice permits them to fine-tune skills that a standard curriculum may not have afforded the opportunity to home in on. It also allows residents to gain exposure to specialties that are not part of the core program, such as vulvar health, breast health and surgery, and gender affirmation surgery.

The Cleveland Clinic experience has been successful thus far. Importantly, preliminary data show that the tracking program does not interfere with the overall case number necessary for graduation. Residents also have succeeded in their postgraduation pursuits, including those who chose to specialize in general obstetrics and gynecology.

Cleveland Clinic is no longer the only program to incorporate tracking into its curriculum. This innovation is likely to become more standard as medical education in ObGyn evolves. We have not yet "separated the O from the G" completely in our specialty. However, thought leaders in our field are recognizing the need to better prepare our trainees, and this flexibility in mindset is bound to lead to a paradigm that may become the new standard for our specialty.

Acknowledgments: John E. Jelovsek, MD, the first Program Director of the Cleveland Clinic Residency in Obstetrics & Gynecology, who was responsible for creating the tracking program; and Vicki Reed, MD, the current Program Director, who has continued to innovate the program.

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The Miya Model (developer Douglas Miyazaki, MD) supports training in basic and full surgical procedures

The Miya Model (Miyazaki Enterprises LLC) is a multiprocedural vaginal surgery simulator born from the need for standardized, scalable training in response to reductions in the average surgical case volume per resident. The Miya Model supports various basic procedures, such as pelvic exams and dilation and curettage, as well as full surgical procedures, including anterior and posterior colporrhaphy, midurethral and retropubic slings, cystoscopy, and vaginal hysterectomy. Training with the Miya Model moves resident surgical education from the operating room to any simulation lab or office-based setting. With rapidly declining resident surgical case volumes, there is an even stronger need to provide additional training outside of the operating room theater. Creation and development of the Miya Model were fueled by a desire to create a safer and more efficient method to educate residents without the risk of patient harm.

Miyazaki Enterprises has taken the Miya Model from a vision on paper to a standardized, commercially available product to help support resident and physician education. The Miya Model has undergone numerous rounds of waterfall and agile development, validity testing, and the creation of internal and external processes to achieve this vision. It serves as an example that ideas originating from significant demonstrated market need can be successfully created and deployed by a physician.

In 2018, the American Board of Obstetrics and Gynecology added the Fundamentals of Laparoscopic Surgery certification as a new requirement for board certification.[17] Laparoscopic and robotic surgery simulators allow trainees to develop coordination and specific skills, like knot tying and suturing. Additionally, models are available with varying levels of fidelity for vaginal and abdominal hysterectomy.[18-20] See the box above for Dr. Miyazaki's experience in developing the Miya Model trainer for vaginal surgery simulation.

Structured feedback

Finally, if a resident has limited exposure to a specific procedure, maximizing the **preparation and feedback** for each procedure is paramount. However, surgeons receive minimal formal training in teaching trainees, which leads to inconsistent and underutilized feedback.[21] Specific structured feedback models have been implemented with success in the general surgery literature, including the SHARP (Set learning objectives, How did it go, Address concerns, Review learning points, Plan ahead) and BID (Briefing, Intraoperative, Debriefing) models.[22,23]

Reimbursement reform

While surgical **reimbursement** is not directly tied to resident education, decreased reimbursement to women's health pathology and procedures has the downstream effect of decreasing the funds available for ObGyn departments to invest in research and education. Additionally, "suboptimal mastery or maintenance of appropriate surgical skills results in procedural inefficiencies that compound surgical cost."[5] Providers and payors alike should therefore be motivated to improve funding in order to improve adequate training of gynecologic surgeons. Payment reform is necessary to equally value women's health procedures but also can ensure that gynecologic surgeons have the funds needed to train a competent next generation of ObGyn physicians. ■

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Vesicovaginal and rectovaginal fistulas from obstetric-related causes: Diagnosis and management

Fistulas resulting from obstetric causes, although rare in developed countries, create considerable morbidity and psychologic distress, and recovery after surgery often is prolonged. Here, we present an expert review of surgical techniques for VVF and RVF repair.

Saifuddin T. Mama, MD, MPH

Although rare in the United States and more common in low-resource countries, fistulas due to obstructed labor do occur. In developed countries, other obstetric causes for fistula are usually surgery, trauma, or infection related. An abnormal communication between organs—be it the urethra, bladder, ureter, uterus, cervix, or rectum—can develop[1] and lead to vesicovaginal fistula (VVF), urethrovaginal fistula (**FIGURE 1**), vesicocervical fistula, vesicouterine fistula, ureterovaginal fistula (**FIGURE 2**), and rectovaginal fistula (RVF). Other nonobstetric causes include gynecologic surgery, radiation, malignancy, and congenital malformations.

During labor, hypoxia, subsequent ischemia, and pressure necrosis contribute to fistula formation. Injury sustained during a cesarean delivery (CD) or cesarean hysterectomy can lead to fistula formation; at times, however, complications are unavoidable given the nature of the pathologic condition that the patient presents with.

VVF and RVF have a devastating impact on a woman's quality of life as they lead to significant morbidity and short- and long-term psychological distress. The fistula may not be recognized at the time of injury. The presenting signs and symptoms may be intermittent and confusing. Immediate surgical intervention may not be possible due to ongoing inflammation or infection. Recovery often is prolonged. As there is significant concomitant postpartum anxiety and depression, patients with fistula often require psychosocial support and counseling. After repair, there is still a risk for recurrence and voiding dysfunction.

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Fistula signs and symptoms and evaluation

In cases of VVF, patients present with continuing large or small volume urinary incontinence. Depending on the time to diagnosis, patients may have calculi formation, prolapse, scarring, external perineal dermatitis, perineal nerve injury, and even motor weakness. Cyclic hematuria may be seen in vesicouterine fistulas.[2]

Multiple classification systems for diagnosis and staging of VVF have been suggested.[3,4] A classification system for RVF was published by Tsang and colleagues.[5] All these classification systems have attempted to characterize fistulas in terms of level of surgical complexity for repair, providing a guideline for preoperative assessment. These classification systems do not translate into prediction regarding outcomes.

Evaluation of pelvic fistula from the urinary tract starts with a thorough history that includes onset, duration, and description of leakage (continuous, intermittent, or positional) and whether there is concomitant stress and urge incontinence. A detailed obstetric history, including circumstances around the mode of delivery, underlying risk factors, and psychosocial history, should be obtained.

The pelvic examination with a plastic speculum and adequate lighting should assess the

FIGURE 1 Urethrovaginal fistula

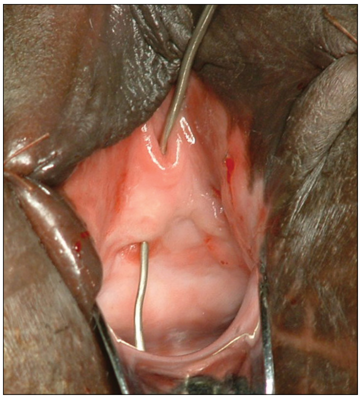


FIGURE 2 Ureterovaginal fistula

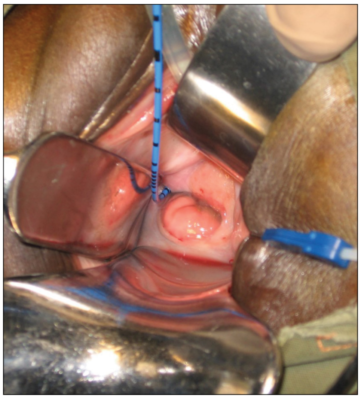
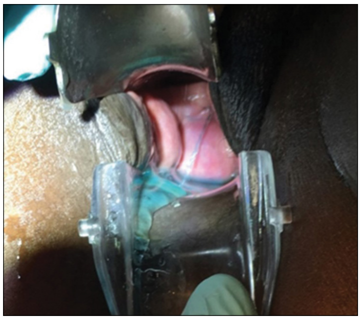


FIGURE 3 Evaluation of vesicovaginal fistula via retrograde filled bladder



external perineum for dermatitis; bulbocavernosus and anal reflexes; and the vagina for length, caliber, level of scarring, and any prolapse. For VVFs, the location, size, and number of the fistula tracts can be visualized and confirmed with a retrograde fill of the bladder via a Foley catheter with saline or water mixed with methylene blue or any other blue dye (**FIGURE 3**). If a ureterovaginal fistula is suspected, the patient can simultaneously be given oral phenazopyridine and a tampon inserted within the vagina; the patient can then ambulate, and re-examination of the end of the tampon can reveal orange staining. The bladder meanwhile is retrograde filled with blue dye, with no blue staining of the tampon.

For RVF, history taking should include the onset, duration, and description of leakage, and the external anal sphincter should be assessed, with careful examination of the distal vagina at the vestibule as this is the most common location for RVF (fistula in ano). Patients may describe vaginal flatus and sometimes only brownish discharge, which can be intermittent, leading to an incorrect diagnosis of vaginitis that is treated repeatedly without success.

There is no consensus regarding optimal imaging for the assessment of VVF. Imaging used for diagnosis of VVF includes a voiding cystogram with opacification of the vagina after filling the bladder with contrast if there is a fistula. A cystoscopy can evaluate for calculi, retained suture, level of inflammation, and location of the ureters in relation to the fistula. Renal ultrasonography is of limited use. Intravenous pyelography can miss lesions by the trigone. In general, a computed tomography (CT) urogram and magnetic resonance imaging (MRI) with bladder contrast are more sensitive.

In the diagnosis of RVF, contrast vaginoscopy, double contrast barium enema, CT scan with contrast, and MRI can be used. MRI is more sensitive.[6] A high index of suspicion is required based on the patient's history as these imaging modalities do not always confirm RVF despite patient's clear history of leakage. When the history is convincing, a thorough rectovaginal exam under anesthesia may be imperative. If rectal trauma is present, endoanal ultrasonography can delineate external and internal anal sphincter defects.

Prolonged Foley catheter placement after obstetric injury can lead to successful closure of a VVF. Prior to surgical intervention, assessing if there is possible ureteral involvement and use of intraoperative ureteral stents is a consideration. The route of surgery can be vaginal, abdominal, combined abdominal-vaginal, laparoscopic, or robotic.[7] The robotic approach is increasingly utilized.[8,9] However, the general consensus among fistula surgeons is that the vaginal approach should be considered first.

Surgical repair

VVF repair. Factors that influence successful repair of VVF include the size and number of fistula, location, degree of scarring, bladder capacity, and urethral length.

Surgical technique requires wide mobilization and adequate exposure. The fistula tract can be delineated and manipulated with a pediatric Foley

FIGURE 4 Visualization of fistula tract with Foley catheter

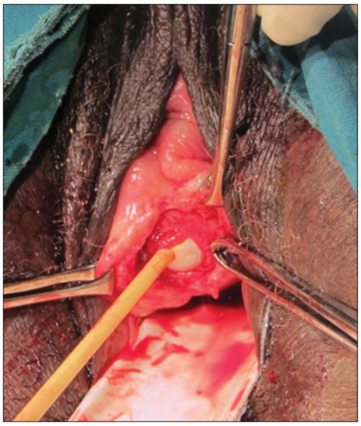
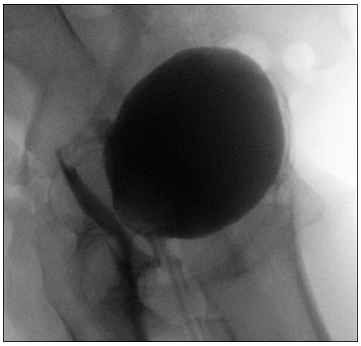


FIGURE 5 Computed tomography cystogram post-repair vesicovaginal fistula



catheter, ureteral stent, or even a ureteral guidewire to aid in dissection (**FIGURE 4**). Intraoperative visualization of the ureters, including stenting, often is needed. The fistulous track is excised depending on the level of scarring. Closure of the bladder uroepithelium for the first layer is with absorbable interrupted 3-0 or 2-0 sutures in a tension-free closure. The bladder is then evaluated with a retrograde fill with saline and methylene blue to ensure a watertight closure for the first layer. If the first layer is not watertight, the second layer closure will not compensate and the fistula will persist. Particular attention is paid to the angles of the fistula at the first layer closure to prevent recurrence of the fistula at the angles. A running second layer with absorbable 2-0 suture is done. At times, a Martius flap or an omental J flap can be used to provide an additional layer for support and to increase vascularity.[10] The patient is sent home with a Foley catheter for drainage for 10 to 14 days.[11] Antibiotics are not needed postoperatively for VVF surgery.[12]

CT cystogram or retrograde cystogram is usually done to evaluate closure of the fistula prior to removal of the Foley catheter; retrograde fill with contrast directly into the bladder with 300 mL is sufficient (**FIGURE 5**). Patients are advised to refrain from sexual activity for a minimum of 6 weeks, but depending on the level of complexity and scarring, this can be up to 12 weeks.

The success rate in general is in the 95% range. Patients with successful closure of VVF are at risk for urge incontinence due to decreased bladder capacity, stress incontinence especially if the continence mechanism or urethra is involved, vaginal scarring, dyspareunia, and infertility.[13] In general, sexual function improves after surgical repair.

RVF repair. Prior to surgical repair of RVF, the integrity of the external anal sphincter must be determined. If it is not involved, a vertical incision is made in the posterior vaginal wall, the vaginal epithelium is separated from the vaginal muscularis, and the fistula tract is identified. After complete wide mobilization of the tissue surrounding the tract, it is excised. The rectal wall is repaired with 3-0 or 4-0 absorbable interrupted sutures; a second layer and if possible even a third layer and finally the vaginal epithelium are all closed with 2-0 absorbable interrupted sutures.

If the sphincter complex is involved, the dissection involves an inverted U incision separating the vaginal wall from the rectum. The fistula tract is excised, the rectal wall is closed, and the internal anal sphincter is identified and reapproximated with interrupted absorbable 2-0 or 0 sutures. The disrupted external sphincter is then reapproximated with 2-0 or 0 sutures, and finally the transverse perineal and bulbocavernosus muscles are brought together with Lembert 0 sutures prior to closure of the external skin. Perioperative antibiotics have been shown to improve success rates in the correction of RVF.[5] In patients with sphincter trauma and known RVF, outcomes with a sphincteroplasty are better, compared with endorectal advancement flaps. The patient is discharged with a bowel regimen and dietary precautions that aim for daily soft bowel movements.

After surgical treatment of fistulas, patients benefit from pelvic floor physical therapy that focuses on pelvic floor strengthening. Incorporating the habit of Kegel exercises after every void, timed (scheduled) bladder voiding, and avoidance of straining with urination or defecation should be emphasized.

CASE 1 Pregnant woman with rectal bleeding

A 37-year-old woman at 36 3/7 weeks' gestation presented with acute rectal bleeding and pain. This was found to result from a catastrophic rupture of a pelvic arteriovenous malformation that caused an 11 x 7 x 9.5 cm size inferior pelvic hematoma and a full-thickness rectal tear at the dentate line. During examination under anesthesia, the baby was delivered by a stat CD due to breech presentation and a prolonged fetal heart rate deceleration. The patient underwent embolization of the right middle rectal artery and right internal iliac artery by a radiologic intervention. Further bleeding required surgical intervention for evacuation of about 1,000 mL of hematoma, repair of the rectal tear, and laparoscopic diverting loop ileostomy. In total, the patient received 8 U of packed red blood cells, 6 U of fresh frozen plasma, 5 L of crystalloid solution, and 2 g of tranexamic acid. The patient reported increased foul-smelling vaginal discharge, bedside exam suggested possible fistulous tract, and on postoperative day 16, an exam under anesthesia by Urogynecology confirmed a rectovaginal fistula in the right mid vagina. After 2 months of observation to allow resolution of inflammation, successful excision of the fistula tract and repair of RVF using the above-mentioned technique was accomplished.

CASE 2 Patient with VVF after cesarean hysterectomy

A 40-year-old (G6P2222) patient underwent cesarean hysterectomy for placenta percreta and uterine rupture at 24 weeks' gestation. Intraoperatively, there were right ureteral ligation and posterior bladder wall cystotomies. The right ureter was reimplanted in the right upper posterior wall and the cystostomies were closed. As the patient had continuous urinary leakage postoperatively, a CT urogram was obtained, which showed left ureteral obstruction and VVF. Urinary incontinence persisted despite bilateral robotic ureteral reimplantation with omental flap by the urology team. Percutaneous nephrostomy tubes were placed bilaterally. The patient underwent additional imaging studies, including MRI, with findings of VVF and possible ureterovaginal fistula.

On referral to Urogynecology, the patient underwent cystoscopy with antegrade pyelogram, and the bilateral ureteroneocystostomy orifices had 5 French open-ended ureteral stents placed. A 10 French pediatric Foley catheter was inserted intravaginally into the bladder through the VVF. Via the vaginal approach, cervical remnant and skin bridges overlying the VVF were excised. The scarred fistula tract was excised with a circumferential incision. Horizontal interrupted Lembert sutures with 3-0 absorbable suture were used to reapproximate the first layer, which was confirmed to be watertight on testing with retrograde fill. Second-layer closure was completed with horizontal mattress 2-0 absorbable sutures, followed by a third-layer closure done in similar fashion. Fibrin glue was then placed. The vaginal epithelium was closed with 2-0 absorbable suture. Percutaneous nephrostomy tubes were removed. Postoperatively, the patient had a CT cystogram with no leak and no incontinence, but she developed urgency, which was controlled with timed voids and oxybutynin. ■

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