Comprehensive Healthcare Simulation

*Series Editors:* Adam I. Levine · Samuel DeMaria Jr.

Dimitrios Stefanidis
James R. Korndorffer Jr.
Robert Sweet *Editors*

# Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties

Springer

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# Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties

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ISSN 2366-4479 ISSN 2366-4487 (electronic)
Comprehensive Healthcare Simulation
ISBN 978-3-319-98275-5 ISBN 978-3-319-98276-2 (eBook)
https://doi.org/10.1007/978-3-319-98276-2

Library of Congress Control Number: 2018967968



This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

*To our wives Evie, Melanie, and Ania for all their support throughout our careers and patience while editing this book.*

# Foreword

It has now been over 25 years ago since, as a young program director, I was approached by the Chief of Urology who complained that his residents were receiving poor basic surgical skills training during their general surgery internship under my direction. This encounter, along with other observations, convinced me that surgical training needed a fresh new approach to instruction in basic surgical skills. Few resources were available at that time to guide a young program director. Now 25 years later, a clerkship director, program director, or other leader in surgical education can find a wealth of outstanding information and guidance in this Surgery and Surgical Subspecialties Edition of *Comprehensive Healthcare Simulation*. The editors, Drs. Stefanidis, Korndorffer, and Sweet, are acknowledged leaders in the field of healthcare simulation and have accumulated a Who's Who list of authors that provide the best expertise available in their respective fields. This edition includes guidance for every step in the process of designing a new surgical skills program or reorganizing a long-standing program, including valuable information in the increasingly important area of simulation for nontechnical skills. Cross-fertilization and peer learning are certain to develop as a result of the comprehensive review of the current state of simulation for the subspecialties of surgery. This textbook should find a home in the library of every surgical educator.

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# Preface

The application of simulation in surgery has seen tremendous growth in the past couple of decades. Our field has transitioned from the stage of justification for the use of simulation in surgery to broad implementation of simulators and skills curricula in many aspects of surgical training and education. Today, most educators and administrators recognize the value of using simulation-based curricula to prepare learners for the demanding environment of the clinic, wards, and operating room. Simulation-based training and assessment have become a part of our training culture. In addition, surgical applications of simulation have disseminated broadly across the surgical disciplines and levels of learners.

Still, several questions exist on how to optimally use simulation-based curricula to maximize the benefit to learners and the institutions they serve across the lifelong learning continuum that defines a surgical career.

We, therefore, present to you this book: *Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties.*

The book is part of *The Comprehensive Textbook of Healthcare Simulation* series and targets those who are involved in the training or assessment of surgeons and their teams using simulators and simulations. It aims to provide the reader with the best available evidence and methods for effective training and assessment using simulators in surgery. Our goal was to generate pragmatic chapters that will provide readers with information easy to adopt and replicate and/or tailor for their respective environment.

We are proud to present to you an international author list comprised of well-known experts and scholars offering their insight and guidance of best simulation practices in their discipline. Unique to this book is its focus on each surgical subspecialty where simulation is used.

Our book is comprised of five parts: Part I, Introduction to Surgical Simulation; Part II, Procedural Simulation; Part III, Simulation for Nontechnical Skills; Part IV, Subspecialties of Surgery: State of the Art; and Part V, Conclusion. In the first part, we start with a historical perspective (Chap. 1) and overview of simulation use in surgery (Chap. 2). We then propose a taxonomy for surgical simulation that aims to clarify some terms that cause confusion in the field (Chap. 3) and discuss principles of validity (Chap. 4). The latter chapter, written by one of the editors, provides the most up-to-date definitions around simulator validity and validation, a much needed reference for this often misunderstood concept in surgical simulation. Chapters 5 and 6 explore the necessary resources and funding models for effectively running your surgical simulation center.

Part II addresses important constructs around procedural simulation, the most common type of simulation used in surgery. The first chapter (Chap. 7) in this part addresses the role of simulation for outcome-based training exploring the concepts of competency/proficiency/mastery training. Best practices for skill maintenance, remediation, and reentry, performance assessment, and optimization are addressed in Chaps. 8, 9, and 10, respectively. This part concludes with the use of simulation for purposes of certification and high-stakes assessments (Chap. 11).

Part III addresses the application of simulation for nontechnical skills training in surgery. It provides best practices for debriefing (Chap. 12), team training in the operating room (Chap. 13), and applications of human factors in surgery (Chap. 14).

Part IV comprises the largest component of this book and addresses the use of simulation in multiple surgical subspecialties, including general surgery, laparoscopic surgery, robotic surgery, surgical endoscopy, surgical oncology and HPB surgery, bariatric surgery, critical care, cardiothoracic surgery, otolaryngology, urology, ophthalmology, vascular surgery, transplant surgery, plastic surgery, orthopedic surgery, and obstetrics and gynecology (Chaps. 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, and 30). These chapters present the state of the art of simulation in each subspecialty and provide best practices and future directions.

Finally, the last part that concludes this book is written by simulation visionary Dr. Richard Satava (Chap. 31) who provides the reader with his thoughts on the future of surgical simulation.

We believe that those who utilize and reference this book will obtain a great overview of how simulation is applied across surgical subspecialties and identify best practices in each discipline. Importantly, our hope is that this book will lead to cross-pollination of best practices among subspecialties, ultimately benefiting the learners and the patients they serve.

Indianapolis, IN, USA — Dimitrios Stefanidis
Stanford, CA, USA — James R. Korndorffer Jr.
Seattle, WA, USA — Robert Sweet

# Acknowledgments

The editors wish to thank Dr. Adam I. Levine, editor of the original book *The Comprehensive Textbook of Healthcare Simulation*, who contacted and encouraged us to create this book and introduced us to the publisher. We also want to thank Victoria Dodge who assisted with the editing of this book and Maureen Alexander, the Developmental Editor of Springer, who effectively guided us throughout the development of the book you have in your hands.

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# Part I

# Introduction to Surgical Simulation

# Historical Perspective

David Marko Hananel

## Preamble

Although for some of us looking back at the last few decades of surgical simulation is a sentimental journey, we must review it as a basis of what is to come. If we look at surgical simulation as an emerging new industry, we can now identify the significance of key technologies and events that have shaped this industry to date.

Although ancient texts, such as the *Sushruta Samhita* from India, written in Sanskrit around 500 CE (origin date unknown but thought to go back to 1000 BCE), mention the use of various models to practice surgical skills for speed and accuracy, we will focus on the recent history of medical simulation and shifts in surgical education [1]. Surgical residency as we know it today in the USA began in the early 1900s at Johns Hopkins under the guidance of William Halsted. During those formative years, we have evidence that dog labs were used to teach both procedural and team-based skills. The animals were used in a similar manner to how patient simulators are used today.

If we consider an integrative model of surgical education and training, focused on patient management we need to consider at least technical skills simulators and human patient simulators. From a historic perspective, how they eventually met to result in a comprehensive model of simulation is just as interesting as how each came to be and evolved over the last 20 plus years.

To those of us who were present at the inception of this industry, this summary may seem like a trip down memory lane, but what is important for the next generation of clinical educators and developers is to be aware of the work that preceded them and build upon it, rather than start over. While researching this chapter, it became evident that it is increasingly more difficult to find pictures, descriptions, and references to work that this industry is built upon.

This chapter is structured to look at technologies that were enablers and then key events and players that followed and cleared the path to arrive at today.

## Building Blocks: Virtual Reality

Like any complex product, the birth of healthcare simulation had to wait for many enabling technologies to evolve until they met a creative spark or transformational event to come to life. Although the medical simulation community is relatively small, it has evolved to a cast of thousands made up of practitioners, educators, technologists, and funders, which can be validated by looking at the growth of communities like American College of Surgeons-Accredited Education Institutes (ACS-AEI) and the Society for Simulation in Healthcare (SSH).

Simulation as a tool to acquire skills has been used in many other industries where the same basic training challenges in the real world exist:

- The cost of experimentation is too high.
- The consequences of experimentation are not acceptable.
- The complexity of what we are studying requires multiple trials and varied approaches.

Thus, we have seen simulation as a core component in training for the nuclear industry, aviation, and of course the military. Medicine presents several challenges that needed to be overcome:

- What we interact with is not a cockpit, dashboard, or control panel designed by us and is well characterized but a patient; thus we need to have an accurate representation of a patient.

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D. Stefanidis et al. (eds.), *Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties*, Comprehensive Healthcare Simulation, https://doi.org/10.1007/978-3-319-98276-2_1

- Unlike machinery which we design and understand by design, we have an infinite number of variations of what a patient is, and our understanding of the human body keeps evolving rapidly.
- We have almost as many different interventions that can be performed on a given patient, with yet many more devices that can be used during those interventions.

The early attempts at simulation based training simplified things by using either animal models or cadavers as the platform to practice on before advancing to patient care, forgoing the challenge of creating an adequate representation of a living patient. Eventually, a set of emerging technologies matured enough around the same time to create the notion of a virtual patient. What initially sparked the imagination of surgical educators was the potential to objectively assess the performance of the surgeon in a simulated environment, which favored virtual reality. As the simulation would take place in the digital domain, supported by mathematical models based on physics, we could track, measure, and quantify everything that would take place in the simulation. It brought together multiple core technologies:

- Real-time interactive graphic simulation, based on finite element modeling concepts, rendering and texturing using powerful graphic processing units (GPU)
- Improved computer displays with higher resolution and color
- Haptic devices to touch objects (collision detection) that exist only as digital representations and eventually manipulate and reshape them (deformation and cutting)

Let's consider each one of these technologies: The early GPUs were not single processors or cards but a computing system with a series of boards and large amounts of memory in cabinets the size of refrigerators, such as those designed, built and sold by Evans & Sutherland in the early 1970s, based on work done at the University of Utah. The early computer screens used for simulation were monochrome vector graphic displays, basically displaying a flickering green line drawing of the objects of interest (Fig. 1).

These early image generators were driven by minicomputers that could fill a room and had to run the mathematical models or what we would consider state engines today that then the image generators could render on a screen (Fig. 2).

**Fig. 1** Evans & Sutherland graphics displays. (Image courtesy of Evans & Sutherland, Salt Lake City, UT. All rights reserved. Used by permission)

**Fig. 2** Early simulation platform. (Image courtesy of Evans & Sutherland, Salt Lake City, UT. All rights reserved. Used by permission)

It took another 20 years for Silicon Graphics Inc. (SGI) (https://en.wikipedia.org/wiki/Silicon_Graphics) to combine those capabilities into smaller packages, based on technology developed at Stanford, and commercialize the technology. Their products dominated the world of computer graphics, animations, and simulation for most of the 1980s and early 1990s. Many of us remember the small refrigerator-sized purple boxes.

Rapid evolution of computing technologies created another major shift, and in 1993 Nvidia (https://en.

wikipedia.org/wiki/Nvidia) created one of the first graphics card, building a complete graphics engine on a single board and then eventually on a chip to bring graphic simulation to off-the-shelf personal computers, completing the journey as we know it today in roughly 20 years and seeing the demise of two generations of graphics computing software and hardware.

Returning to the history of surgical simulation, some early designs were built upon the SGI platform but saw no commercial acceptance until they could be ported to the PC architecture. They were complex to maintain, expensive to acquire, and not very reliable.

The second challenge was the development of better ways to visualize the virtual environment. The earliest surgical simulators still used CRTs (cathode ray tubes) which were bulky and heavy and difficult to place correctly to recreate the proper relationship between the patient, instruments, and surgeon. Going back to the days of Evans & Sutherland (https://en.wikipedia.org/wiki/Evans_%26_Sutherland), they started with monochrome vector graphics monitors that needed at least two people to carry them. Over a few years, they evolved to support multiple colors for the lines representing the objects of interest at a significant premium. Today's LCD panels and 4k displays provide us with acceptable images and based on the targeted application, developers can now consider affordable head-mounted displays and other novel technologies to render the surgical field.

The third challenge that needed to be addressed was the interaction with the patient. The path of least resistance was the emerging field of minimally invasive or laparoscopic surgery: it made the interaction with the patient much more controlled (only 6 degrees of freedom to track per hand) than approaching open surgery with many more degrees of freedom of tracking two hands and ten fingers with almost no limitations.

Two competing approaches framed the initial field. One emerged from work done at MIT in the 1990s by industry pioneers Thomas Massie and Dr. Kenneth Salisbury, to become Sensable, now owned by 3D Systems (https://www.3dsystems.com/scanners-haptics#haptics-devices).

The second approach came out of research done in the 1990s at Stanford by Louis Rosenberg, who founded Immersion Corporation (https://en.wikipedia.org/wiki/Immersion_Corporation), to commercialize his ideas. Both groups used similar components but different kinematic models to accomplish their goal of allowing us to feel and interact with virtual objects. Since then several more competing technologies were created, with varying approaches to the volume we can work in, degrees of freedom, accuracy, and obtrusiveness of the haptic mechanism.

These early technologies enabled several interesting surgical simulators to be directly built upon them: a sinus surgery simulator (Fig. 3) developed jointly between the military (Madigan), academia (UW), and industry (Lockheed Martin) with funding from TATRC [2–4], a vascular anastomosis simulator (Fig. 4) [5, 6] developed by Boston Dynamics with support from DARPA, and an arthroscopy simulator for shoulder procedures (Fig. 5) [7, 8] developed by Prosolvia and University Hospital in Linköping, Sweden, with support from the Swedish government.

What these three examples have in common is that they each demonstrate the challenges of developing an advanced VR surgical simulator, complex hardware for haptic feedback, powerful computers, and graphics cards to keep up with the model calculations and image rendering, yet the end users were not satisfied that the use of these systems could improve surgical performance significantly. The numerous studies performed around these systems, however, pointed the way for future developers and commercial offerings.

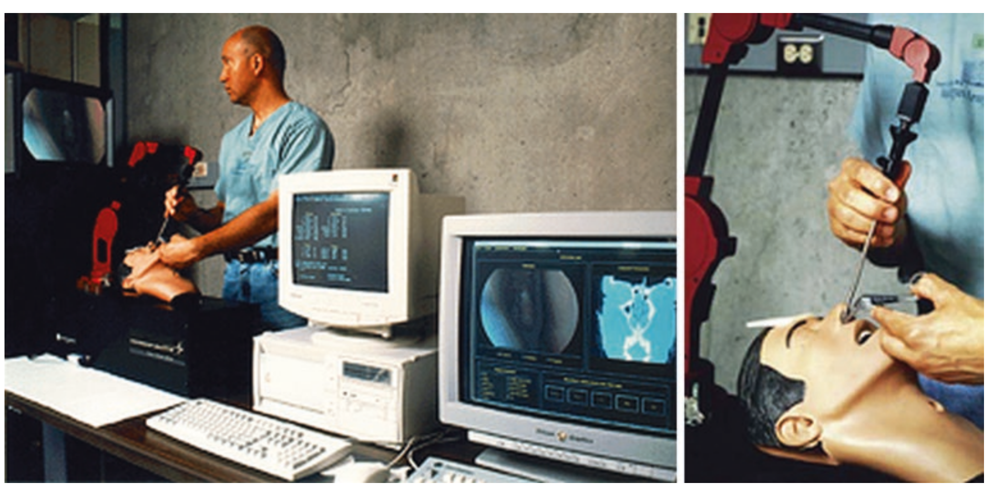

**Fig. 3** Sinus surgery simulator ca. 1995 University of Washington. (Courtesy of Mika N. Sinanan, MD)

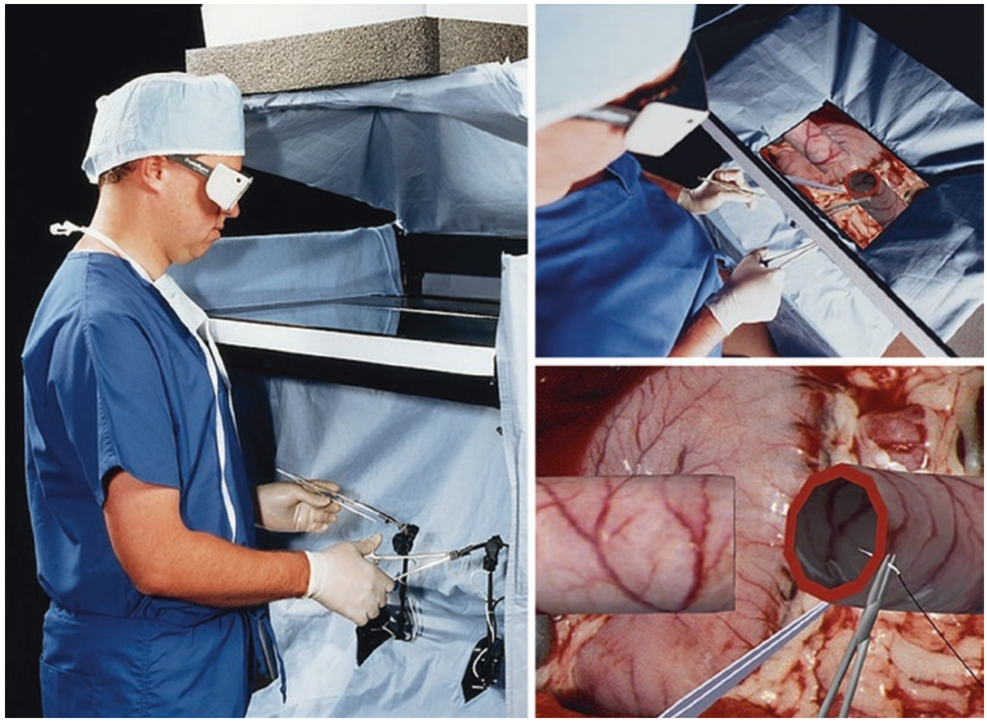

**Fig. 4** Anastomosis simulator ca. 1998 Boston Dynamics. (Used with permission of Boston Dynamics)

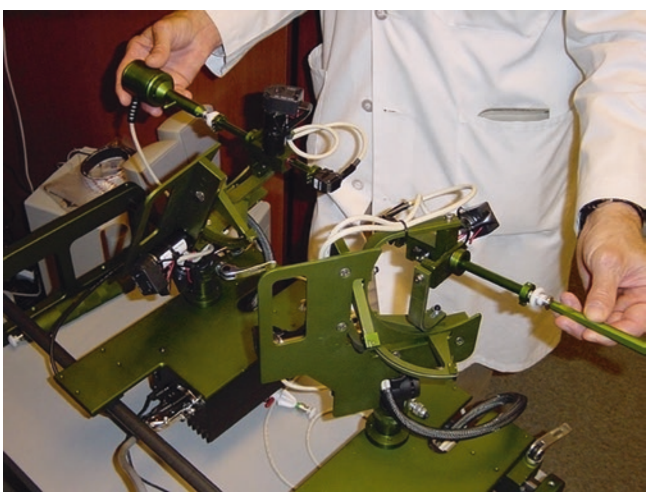

**Fig. 5** Shoulder arthroscopy simulator ca. 1997 Prosolvia

## Building Blocks: Human Patient Simulation

Many of us that were focused on surgical education stayed focused on technical skills acquisition, first basic skills then targeting full procedures. In parallel the field of anesthesia was working on developing their own simulation platforms: full patient mannequins with a physiology engine behind them to teach both physiology and patient management. Although some early work resulted in Harvey that included select aspects of physiology, almost in parallel the University of Florida in Gainesville under Samsun Lampotang, PhD, and Dr. Michael Good [9, 10] and Stanford in California under Dr. David Gaba [11] developed their own versions of a full patient simulator.

Both eventually were commercialized and were used by many healthcare educators before newer generations were developed. Figures 6 and 7 show the CASE 0.5 or the comprehensive anesthesia simulation environment from Dr. Gaba and Stanford. This was the first (used once only – in May of 1986) pre-prototype proof of concept simulator which was put together from some existing devices (e.g., a commercially available noninvasive blood pressure simulator), some components adapted from existing items and some purposely built. Of note in Fig. 6 a COMPAQ portable computer can be seen to the right of Dr. Gaba, a precursor to todays laptops for those that remember the sewing machine sized “portable” computers.

For the patient simulators to become reality, the key enablers were the creation of mathematical models of human physiology (added by the Gaba team in 1991 to CASE 2.0) and the interaction of drugs. Based on those models, one can mathematically solve a complex set of interconnected equations to approximately predict patient progression [10, 12, 13]. Lessons learned from both commercial implementations were invaluable and carry forward to today’s products, specifically the University of Florida design continues to live in the line of patient simulators offered by CAE of Montreal, Canada.

In addition, the fields of cognitive psychology, human factors, and education had to develop models for team-based performance, decision-making under stress, and assessing

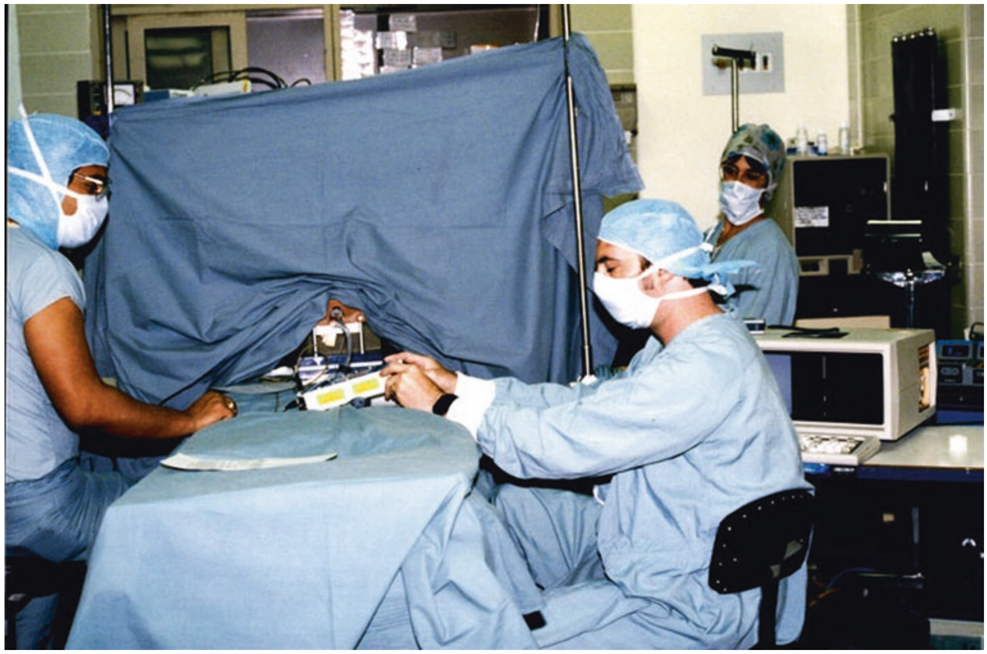
**Fig. 6** CASE 0.5 or the comprehensive anesthesia simulation environment. (Photo credit: David Gaba)

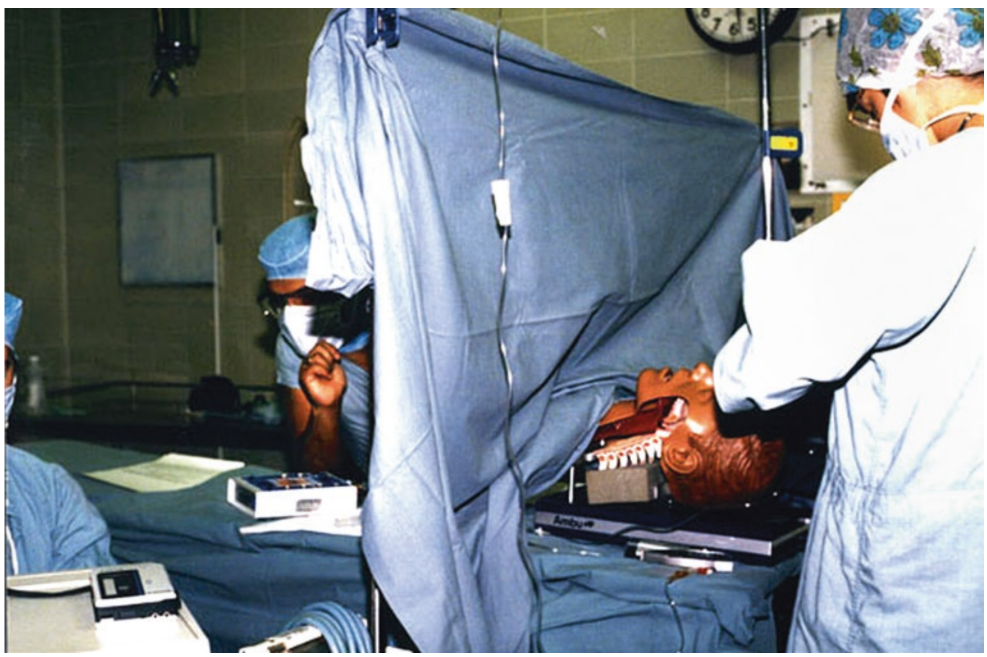
**Fig. 7** CASE 0.5 or the comprehensive anesthesia simulation environment. (Photo credit: David Gaba)

human performance under these conditions to enable team-based training exercises [14].

## Connecting the Dots

A few thought leaders had started to bring the surgical and anesthesia sides together in some of the earliest attempts at team-based training, Penn State University in Hershey under Drs. Thomas Krummel and Bosseau Murray as well as at the University of New Mexico under Dr. David Wilks in Albuquerque being among them. It is important to note that from the very beginning, both these programs worked with the medical school, nursing programs, and the hospital looking for an integrated model to training. However, it took many years for the patient simulators to receive a hearing within the world of surgery.

The first formal appearance of a patient simulator in the world of surgery was at the SAGES Annual Meeting on April 27, 2006, supported by grant W81XWH-06-1-0529 from the US Army Medical Research and Materiel Command (USAMRMC) led by Drs. Satava and Haluck and presented/

demonstrated by Dr. Wilks using a METI Human Patient Simulator or HPS. The patient simulation discussion was triggered looking for a hands-on approach to teach basic anesthesia considerations to surgical residents as covered in a chapter of the *SAGES Manual Basic Laparoscopy and Endoscopy*. A few years later, in the Spring of 2009, Dr. Seymour took a METI Human Patient Simulator to the ABS in Philadelphia with Drs. Lewis, Bell, and Buyske in attendance to demonstrate the concept of a physiology-driven patient simulator and discuss what a surgical version of it would have to be able to do.

Clearly by this time, the concept of simulation in support of improved surgical training had started to gain acceptance as could be seen by the growing number of research articles with the professional journals. The time had come to establish the scientific and professional underpinnings for this new domain.

## First Meeting of the Elders

Dr. Satava had almost single handedly jump-started the notion of using Virtual Reality (VR) based surgical technical skills training [15, 16], and over a few years had moved the needle from let's build it and they will come to let's obtain validity evidence and they will come. He organized a meeting on July 9–10, 2001, named the "Metrics for Objective Assessment of Surgical Skills Workshop" with subject matter experts in objective assessment of surgical technical skills and representatives of relevant official bodies involved in surgical education, evaluation, and certification to create a consensus around appropriate metrics that all could use [17].

The workshop identified the challenges and demonstrated the need to move toward standards in performance metrics so that training effectiveness could be compared across competing design and technologies for the same skill sets [18]. The results of that workshop were published and shared with both industry and academia and were funded by USAMRMC under award DAMD17–02–1-0207.

## Second Meeting of the Elders

Almost concurrently, Dr. Carlos Pellegrini, a pioneer in laparoscopic surgery [19, 20], was questioning the prevalent model of surgical education in light of the rapidly evolving new surgical technologies and interventions and looking for ways to adapt to the changing landscape.

Not even a year later, in June of 2002, the American Surgical Association (ASA) Council in partnership with the American College of Surgeons (ACS), the American Board of Surgery (ABS), and the Residency Review Committee for Surgery (RRC-S) established a Blue Ribbon Committee on Surgical Education based on the ASA Presidential Address by Dr. Debas earlier that year [21]. Their principal concerns were lower numbers of applicants into surgical residency programs and challenges of acquiring laparoscopic surgical skills (interview with Dr. Pellegrini, May 9, 2017). They were charged "with examining the multitude of forces impacting health care and making recommendations regarding the changes needed in surgical education to enhance the training of surgeons to serve all the surgical needs of the nation, and to keep training and research in surgery at the cutting edge in the 21st Century."

Their analysis, resulting report, and recommendations that were published in 2005 have led to many observable changes in surgical education [22]. Among them was the creation of the Surgical Council on Resident Education (SCORE), "a nonprofit consortium formed in 2006 by the principal organizations involved in U.S. surgical education. SCORE's mission is to improve the education of residents in general surgery and related specialties through the development of a national curriculum."

At the same time, with the arrival of Dr. Pellegrini as a regent at the ACS and Dr. Ajit Sachdeva's leadership of the Education Division, the path was laid in 2005 to launch the ACS Accredited Education Institutes (ACS-AEI) to "educate and train practicing surgeons, surgical residents, medical students, and members of the surgical team using simulation-based education." This partnership laid the groundwork to truly bring together the principles of adult education and educational design with the rapidly changing requirements of lifelong learning for our surgeons.

## Slow Growth

Despite the enthusiasm of medical educators, gradual acceptance by the professional societies, publication of many hundred peer-reviewed journal articles, and over a hundred of industry participants with commercial simulators at all price points, the adoption of simulation-based surgical education has been a slow process. Ten or so years ago, we could look at a technology adoption curve, survey programs that had invested in simulators, and clearly recognize the early adopters and the followers and relate that back to individuals. Today that is not possible as almost every residency program has some type of simulation-based training activity that they participate in. In fact simulation is an integral part of the ACGME surgical residency program requirements.

The last few decades have seen surgical educators and simulation technologists with an interest in surgical simulation move from the Medicine Meets Virtual Reality (MMVR) conference, first held in 1992 and driven by futurist, visionaries, innovators, and early adopters to the Society for Simulation in Healthcare (SSH) established in 2004 with membership from physicians, nurses, allied health and paramedical personnel, researchers, educators, and developers from around the globe to finally the ACS-AEI that launched in 2005 with the now (2017) aptly named Annual ACS Surgical Simulation Conference. That clearly demonstrates the readiness of this community to broadly embrace simulation.

At this point we can only hypothesize why growth has been this slow. With so many companies active in this field, from small to large, to subsidiaries of industrial giants, both market size and profitability have been only a fraction of the early forecasts. We have been predicting the inflection point as far back as we can remember, citing various key events, such as those mentioned earlier. We first looked for validation studies and then better technology to lower cost and improved fidelity, as well as acceptance by the professional societies.

There are some aspects that are clear: on the surgical simulation side, although VR simulation has been quite successful from the beginning to train basic skills [23–25], it has not reached the level of sophistication required to train complex surgical procedures, except in some special cases, such as endoscopy, endovascular procedures [26, 27], TURP [28], and laser-based prostate procedures [29]. What these have in common is they are being performed in narrow, tubular structures with minimal, controlled deformations and simple images to render. VR simulators are also quite expensive and time-consuming to develop.

In response, we have seen a return to physical trainers, but now bringing the promise of objective assessments from the VR world by adding sensors and markers of many types into the physical models. Furthermore, long-term research projects underway are collecting tissue properties data to develop more realistic synthetic tissues for such models.

## The Catalyst

Viewed from an economics perspective, any industry that lacks standards is not mature and would not attract large investments as both direction and timing are unknown. Although the years since the second meeting of the elders have seen the introduction of many new products and some companies becoming profitable, in many ways the expectations outpaced development.

Several years back during a discussion with Dr. Richard Reznick in Toronto, he articulated a vision for a full-patient simulator sophisticated enough so that residents theoretically could be able to train their first 2 years without having to treat real patients. His description of needs was very similar to those articulated during the demonstration of the human patient simulator at the ABS. While the technology to get there was probably available, the effort to develop such a platform would require a government agency with vision and a long-term budget of hundreds of million dollars.

The last few years have seen a group of forward thinkers within the DoD developing a long-term vision and funding strategy to change that. This group that cuts across many agencies brings together the healthcare providers, the educators, and scientists. They brought two key elements together: a road map based on experience and a deep understanding of the educational process together with funding opportunities attached to open source, standards based tools, and no associated royalties to create the fundamental building blocks that all simulators could share and thereby also exchange information with each other. The funding opportunities stipulate that the results should not only address the need of the military but also of the civilian side. It seems that our community has now been given this opportunity and of course the associated challenges and is looking at the future of medical education.

It is a vision for distributed, interoperable part-task trainers developed and sold by many different companies that can be combined into a full body patient simulator that brings together decision-making, technical skills, and team-based performance training. It allows for objective assessment and focuses on patient management so that the learners can expand from technical skills to managing a complete medical episode from first encounter with a caregiver until they can return to normal life. The Advanced Modular Manikin™ (AMM™) project (DOD Award # W81XWH-14-C-0101) now in its second phase and being led by the CREST team (Center for Research in Education and Simulation Technologies at the University of Washington) at its core is developing a unified platform to bring researchers, developers, and industry together with guidance from the professional societies and diverse user groups to accelerate the path forward and reduce the initial investment required to create new surgical simulators.

Having a common platform with open standards will allow developers to target specific interventions, training scenarios, or diseases and create specific models without having to build out the complete infrastructure required each time. The common, core building blocks will be published and made available to all interested parties. Having the common platform will allow many individual trainers to connect and exchange data. To accomplish that, the project will also define what it means to be AMM Compliant™ and the process for that claim to be verified. The funders are already looking for means to support the maintenance and growth of the standards and a certification process to assure interoperability. As part of the AMM project, CREST has created a website to disseminate information on the draft standards, reference systems, and developer guides (https://www.advancedmodularmanikin.com).

A second core project is the development of a modular, open-source physiology engine that started somewhat earlier and is now available online. As stated on their website, “BioGears is an open source, comprehensive, extensible human physiology engine released under the Apache 2.0 license that will drive medical education, research, and training technologies. BioGears enables accurate and consistent physiology simulation across the medical community. The engine can be used as a standalone application or integrated with simulators, sensor interfaces, and models of all fidelities.” This program was also funded under the auspices of the DOD contract number: W81XWH-13-2-0068 and can be accessed through a web site (https://www.biogearsengine.com).

## The Future

As we consider the many challenges presented by the development of an integrated training platform for surgery, it is interesting to see that the fields of surgical device development, surgical education, and new paradigms in patient care are moving closer together. This is happening at the level of identifying requirements in each of these domains, in the data models that need to be created and the development workflows themselves.

The first step in any robust simulator development program is the execution of a detailed cognitive task analysis (CTA) [30, 31] that details the critical steps, decisions, and skills required to perform the intervention to be learned. This same CTA can and should be also used in considering new tools and technologies to perform the intervention itself as it clearly identifies the most challenging parts of the intervention that could benefit from better tools.

The data models and standards we need to create, such as to document patient cases, assess performance, and evaluate outcomes, are the same ones that are being considered for electronic medical records (EMR), board exams, credentialing, predictive models of drug interactions, different population studies to understand societal costs of caring for patients, etc. We are still at a stage where different institutions, societies, and agencies have created similar but different, in many cases competing, constructs that make it very difficult to compare results, perform large-scale studies, and easily exchange findings. It is imperative that in the world of healthcare simulation, we move toward universal standards, such that educational content can be shared by all and performance metrics become comparable between sites. Also performance data of learners we collect during simulations need to converge with performance data that is collected in the patient care environment.

Thus, a core effort of developing the AMM platform is to define and vet the initial data models used to create simulated patients, to define findings and trigger events, to build a common model for learner performance assessment, and to document in the language of educators and providers. The next level is to create the data models that will be used for all modules to communicate at the technical level and support interoperability. Finally, the hierarchy of modules and the standard interfaces between them will be designed, tested, and made public.

A major task in creating these standards and the development platform is to share, vet, and update the various designs, make them available to all, and provide the documentation and training required to encourage broad-based adoption.

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# Overview of Simulation in Surgery

Don J. Selzer

Simulation has long played a role in the acquisition of skills in healthcare [1]. Various modalities have been used to prepare the surgeon for the operating theater. Not surprisingly, some of the first simulation occurred with cadavers. However, preservation proved challenging. As a result, carved figures resembling human anatomy were used. Procedures were carried out in a manner similar to that performed in the operating theater of the day. As time passed, interest in realism exceeded that of the carved figures. More complex simulators were developed to recreate actual physiology. However, these rudimentary moveable models did not always appear outwardly consistent with human anatomy. For example, one of the earliest functional devices was an obstetric simulator that consisted of a glass uterus situated in a wooden pelvis with a flexible fetus [1]. Although over the years, multiple simulators were developed for multiple anatomic structures and medical disciplines, Abraham Flexner specifically singled out the importance of obstetric simulation in his landmark report in 1910 [2]. Over the years, detractors of the benefits of simulation have remained. William Osler is famously attributed to say that there is no better place to learn medicine than at the bedside.

The importance of simulation became more evident when the military and airline industry demonstrated the benefit of training pilots prior to actual flight [3]. Anesthesiology and surgical investigators began to evaluate the potential role of structured simulation and its impact on skill acquisition. As the research began to support the importance of simulation, options for training began to multiply. Further, as research began to support the importance of a protected environment in which a medical student or surgical resident can practice his or her skills, regulatory bodies began to expect these venues in medical schools and training programs (Fig. 1) [4]. The Association of American Medical Colleges has stressed the importance of simulation-based education and has invested in confirming its use within current curricula and ongoing curricular reform. Within surgery, there remains concern by some that simulation, although helpful, has yet to demonstrate a clear benefit [5]. However, the direction and standard are clear as suggested by Dietl and Russell who demonstrated that "simulation effectively reduces the surgeon's learning curve, improves communication, and reduces errors while increasing patient safety" [6–8]. Educators now see simulation as an integral part of training. Moreover, the public understands that through the use of simulation, basic skills can be honed prior to a trainee ever touching an actual patient [9, 10].

The use of simulation in surgical education can be divided into two main areas: technical skill/procedural and nontechnical skill/scenario-based. A review of the benefits and drawbacks of each type of simulation will demonstrate that the building blocks for a robust curriculum and eventual assessment of performance are available. The keys to a successful program that maximizes education outcomes based upon the investment of time and money are less clear [11]. Ultimately, there are endless combinations of training options that offer the opportunity to educate, assess, and practice in the lower stake confines of a simulated environment.

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D. Stefanidis et al. (eds.), *Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties*, Comprehensive Healthcare Simulation, https://doi.org/10.1007/978-3-319-98276-2_2

**Fig. 1** Department of Surgery Skills Laboratory at Indiana University School of Medicine

## Validation, Fidelity, and Reliability

Before reviewing the types of simulation, one must consider the goals of simulation and the ways in which one can describe how each form of simulation meets those goals. Ultimately, simulation aims to recreate a scenario that a trainee will encounter in the treatment of actual patients. A measurement of the comparison of these simulated scenarios in reality and their proximity to reality is an assessment of their validity [12]. In other words, a scenario is valid if it approximates real life. Validity can be further defined. For example, an overall assessment of the simulation and how it compares to reality is considered face validity. A comparison of how the simulated environment allows the participant to complete tasks to an accurate level of his or her abilities is construct validity. Finally, it is important to know how performance on a simulator will predict a trainee's performance in reality. This is referred to as criterion-related validity.

Fidelity measures the degree to which a simulated environment more closely provides a picture of reality. As an analogy, compare a low-resolution image to a high-resolution image. Upon evaluation of the low-resolution image closely, one sees rough borders of the items within the image with blocklike configuration. The high-resolution image provides smoother boundaries and a more lifelike appearance. Within simulation, an example may be the difference between using a box trainer with reusable laparoscopic instruments to perform laparoscopic suturing versus a computer-based simulator with a virtual reality (VR) environment in which computer-projected instruments are used to sew computer-generated items together. While the two may allow one to complete the task and therefore are valid, the VR is clearly more complex and with the aid of complex computer software approaches a more realistic picture of what is seen in the operating room. Therefore, this VR simulator is considered high fidelity. Frequently, as in this scenario, higher fidelity generally means higher cost. Controversy remains over the benefits of high-fidelity simulator versus the clear financial implications. Many feel, when used appropriately, low-fidelity simulators provide as effective teaching as high-fidelity devices [13].

Reliability represents the ability of the simulation to be repeated consistently by different users at different times but yield similar results for similar performances [12]. For example, if the simulation is attempting to measure aptitude, an individual observing the simulation must consistently come to the same conclusion regarding a trainee's performance at completion of the simulation. This is referred to as test-retest reliability. Moreover, when two trainees perform the simulation in a similar fashion, the observer should come to the same conclusion with each trainee. This is referred to as internal-consistency reliability. And, two observers watching a similar performance of the simulation should come to the same conclusion regarding the assessment of that performance if completed by the same trainee or by different trainees. This is referred to as inter-rater reliability.

## Types of Simulation

### Technical Skill/Procedural Simulation

In surgical education, the timely acquisition of technical skills remains the focus. Simulation in technical skills training has included both biologic and synthetic models. Some of the first models used for training were biologic in nature. Although initially used to study anatomy, cadavers were then used to prepare for performing the actual procedure. The lack of consistent preservation techniques initially limited the usefulness of cadavers. However, a cadaver naturally provides the most realistic anatomic model, and they remain a consistent component of surgical training [14–17].

Cadavers have generally been used in either a "fresh frozen" format or an "embalmed/preserved" format. The benefits of frozen cadavers are clear. Once adequately thawed, the tissues and the anatomic layers including tissue planes remain lifelike [18]. Unfortunately, natural processes do lead to deterioration of the tissue and a short window of usefulness exists. While the preservation process negatively affects tissue realism, it does significantly increase the timeline for use thereby allowing the cadaver to be used over repeated sessions. Recent trends have provided hybrid preparation techniques that attempt, somewhat successfully, to maximize the realism of fresh cadavers with the usefulness of a preserved one [14, 19]. In addition, some educators have created "live cadavers" connecting the blood vessels of cadaveric specimen to pumps, simulating circulation, and providing an even more realistic educational experience [19–21].

Although the benefits of using cadavers in simulation are clear, the drawbacks may be less obvious. Perhaps more obvious, a lack of flexibility prevents placement in the lithotomy position and limits the use of a cadaver in some procedures (e.g., proctectomy). Although this may be overcome by removal of the legs, some institutions, including the author's, do not support sectioning of cadavers. In addition to inherent issues with a cadaver, there are less obvious environmental issues to address. The use of cadavers requires adequate ventilation and a method of collecting fluids that are commonly associated with the use of cadavers (i.e., intestines remain unprepped). This limits the locations in which cadavers can be used. At some institutions, this requires competing with undergraduate gross anatomy courses for lab space presenting yet another challenge to creating a robust curriculum.

In addition, as the number of medical schools continues to increase, the demand for cadavers has dramatically risen. Fortunately, there remains a continued understanding by the public that donation of one's body to science is a very effective method of providing beneficence to society even after one has passed. Still, the cost of obtaining a cadaver may range from $1500 to more than $3000 depending on the venue and the source. In addition, if one elects to use frozen cadavers, infectious diseases may be transmitted postmortem (e.g., HIV or hepatitis C). So, each frozen cadaver requires these tests and increases costs by more than $500 per cadaver. In the end, the cost to obtain "safe" cadavers in an environment conducive to surgical training may be prohibitive for routine use in a skills curriculum in most programs.

Nevertheless, appropriate simulators for a number of surgical procedures (e.g., open inguinal hernia) are still not available requiring a cadaveric model to provide the best training experience [22]. The limited supply of cadavers and the cost associated with using cadavers have led to some programs using cadaver parts. The use of parts provides a potentially more efficient manner of using this limited resource. However, an interest in returning a collection of cremated ashes to the family members of individuals donating their bodies makes it challenging to offer cadaver parts. The parts must be tracked and returned for cremation. As a result, this option is generally offered at limited sites.

A beating heart and circulating blood with the potential for hemorrhage are helpful in creating a lifelike scenario that creates buy-in by the participant. Naturally, one of the biggest drawbacks for cadavers is the lack of bleeding and movement associated with a living being. Although some centers have overcome these obstacles with circulating pumps attached to sectioned cadaver parts as described above, the expense and regulatory challenges of obtaining cadavers remain major barriers to their use [16, 19]. Therefore, animal models have been identified as another biologic simulated environment for some common surgical procedures. Some of these models were initially identified as efforts to research the surgical treatment of diseases which demonstrated similarities to the human model. For example, canine stomachs have proved very similar to humans while bovine or porcine hearts share a significant resemblance to our own [23]. Animate models do provide actual bleeding, not simulated bleeding, with a beating heart and breathing lungs. This actual living environment clearly sells the benefits of the model. For example, Advanced Trauma Operative Management (ATOM) developed at the University of Connecticut and later adopted by the American College of Surgeons Committee on Trauma has demonstrated the role of the swine model in teaching the skill set necessary to manage traumatic injury [24].

There are also several challenges, however, working with animate models. Acquiring animals for educational sessions is largely dependent on the access to these animals. For the most part, comparative anatomy has helped to identify similarities between human organ systems and several other mammals. Animal size and availability, ease of administering anesthetic, and cost are also determining factors in this decision on which model to use. However, for primarily social reasons, the swine model is most commonly chosen.

In fact, the revolution of laparoscopy was significantly facilitated by the ability for practicing surgeons to practice laparoscopic cholecystectomy with the swine model [25].

Access to an animal holding facility necessary to receive and temporarily house these animals limits this option for some institutions. In addition, for some locations in large metropolitan areas, access to pig farms is quite limited. Therefore, while, in some areas, there is ample access to porcine models for training that are even less expensive than some lifelike synthetic inanimate models currently available for purchase, in some other settings, obtaining pigs can prove even more expensive than considering cadaver models. Over the years, ethical treatment of animals has raised concern regarding the use of animals for educational sessions. For example, bowel preparatory techniques are not used. Limiting the use of live animals in education is considered so important by some that the European Union has pushed to reduce, refine, and replace the use of animals in educational sessions [26]. In fact, the UK has eliminated the use of live animals for surgical training, but some trainees (e.g., military medical trainees) travel outside the UK to neighboring countries like Denmark to participate in trauma surgical training courses [27]. Still, access to pig farms likely offers access to food processing facilities where organs commonly disposed at the completion of processing can be used for training purposes. For example, an ex vivo pig liver has been used in comparison to virtual reality simulators and in the laparoscopic cholecystectomy verification of proficiencies developed at Southern Illinois University [28, 29].

The limited availability of cadavers and the ethical dilemma of using animals have led to a rise in the availability of inanimate synthetic alternatives that range in complexity from a piece of foam to a computer-simulated environment. The prior is an example of a low-fidelity model, while the latter is considered high fidelity. Controversy continues regarding the benefits and drawbacks of low-fidelity versus high-fidelity models. Innovative educators have generated numerous low-fidelity models that commonly represent bedside procedures, simple surgical tasks, or a single component of a much more complex procedure [5, 30]. Moreover, these low-fidelity models have demonstrated success in recreating these tasks or procedures in a low-stress environment during which feedback can be provided without risk to the patient. Examination of the benefit of these low-fidelity models has suggested that skills learned here transfer effectively to the operating room and are even preferred by instructors and learners to other forms of simulation including cadavers and animals [5]. These models are present throughout surgical education. For example, in thoracic and abdominal surgery, basic surgical techniques used in minimally invasive procedures can be practiced in what are commonly called “pelvic trainers” or box trainers (Fig. 2). These trainers are omnipresent and relatively inexpensive with an external hard plastic housing with several holes cut in the top surface that are covered by small thin diaphragms, or some trainers have a rigid plastic endoskeleton that is covered by a sheet of thin pliable material on top. The cut holes or the pliable sheet located on the top surface allows introduction of minimally invasive instrumentation while watched by a small posable camera that sends an image to a contained LCD screen or sends the image to a connected monitor or laptop computer. With availability of electronic materials in most major cities, one can construct a model like this at home [30]. These models have proven very effective, and one is used in the Fundamentals of Laparoscopic Surgery (FLS). FLS is an assessment program developed by the Society of American Endoscopic and Gastrointestinal Surgeons (SAGES) to demonstrate proficiency in basic laparoscopic surgery. It has two components: an assessment of knowledge through a multiple-choice examination and a technical assessment using five basic laparoscopic tasks with efficiency and accuracy benchmarks. In addition to the laparoscopic trainers, similar low-


**Fig. 2** Example of a low-fidelity “box trainer” with camera, ports, and instruments used to practice basic laparoscopic surgical tasks or procedures