Simulation In Surgery: A Proposal For Quality Control In The Use Of Simulators In Surgical Training

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Citation

S Jabir. Simulation In Surgery: A Proposal For Quality Control In The Use Of Simulators In Surgical Training. The Internet Journal of Medical Simulation. 2012 Volume 3 Number 2.

Abstract

Simulation is a concept that has been employed in numerous fields including that of defense, aviation and recently surgery. Simulation seems to hold the answer to several of the challenges faced within the field of surgery. In this study the author reviews the history of simulator use in surgery and then reviews the various applications of simulators in surgery. This will set the foundation to the objective of this study, which is the utility of simulation as a tool in the domain of surgical education (i.e. for training and assessing trainee surgeons). Much of the literature has tended to focus on the design, validity and reliability of simulators, the development of curricula incorporating simulators, and criteria for being regarded as a competent surgeon, in a mutually exclusive manner. [ii][iii][iv] This study will attempt to demonstrate that each of these aspects has an order of inter-relationship to one another. This proposed model of inter-relationship will enable us to gain new insights into how the links between them affect one another. The observation of this order will firstly enable a more effective application of simulators as a tool for training future surgeons. Secondly, it will serve to avoid quality control debacles which may occur with the introduction of new technology, the prime example of this being the laparoscopic cholecystectomy fiasco that resulted in a dramatic rise in bile duct injuries in the 1990s.[v] Finally, the author will also demonstrate how continual feedback within this model enables continuous fine-tuning of the system. Satava RM. Historical review of surgical simulation – a personal perspective. World J Surg 2008; 32: 141-148.[ii] McClusky DA, Smith CD. Design and development of a surgical skills simulation curriculum. World J Surg 2008; 32: 171-181.[iii] Aucar JA, Nicholas RG, Troxel SA et al. A review of surgical simulation with attention to validation methodology. Surg Laparosc endosc percutan tech 2005; 15(2): 82-89.[iv] Sarker SK, Patel B. Simulation and surgical training. Int J Clin Pract 2007; 61(12): 2120-2125.[v] Wanzel KR, Ward M, Reznick RK. Teaching the surgical craft: from selection to certification. Curr Probl Surg 2002; 39: 573-660.

INTRODUCTION

As technology evolves at a rapid pace, the field of surgery which is becoming more reliant on technology, is also having to undergo swift change. This affects the training of surgeons and has implication for the continuous professional development of senior surgeons. In addition, the exponential advancement of technology referred to by some authors as “disruptive technology”1, and its incorporation into almost every aspect of life has meant that even the most ardent conservative will eventually have to cave into the pressure to conform.

Enter the era of simulation, a novel concept that has been employed in numerous fields including that of defense, aviation and recently in surgery. Simulation seems to hold the answer to several of the challenges faced by the field of surgery, especially within surgical training. This paper will first address the concept of simulation and simulators, elucidate some of its applications in the field of surgery and then identify certain benefits and concerns associated with the use of simulators in surgical training. This will set the foundation to the objective of this essay, which is the utility of simulation as a tool in the domain of surgical education (i.e. for training and assessing trainee surgeons). Much of the literature has tended to focus on the design, validity and reliability of simulators, the development of curricula incorporating simulators, and criteria for being regarded as a competent surgeon, in a mutually exclusive manner. This essay will attempt to demonstrate that each of these aspects has an order of inter-relationship to one another. This proposed model of inter-relationship will enable us to gain new insights into how the links between them affect one another. The observation of this order will firstly enable a more effective application of simulators as a tool for training future surgeons. Secondly, it will serve to avoid quality control debacles which may occur with the introduction of
new technology, the prime example of this being the laparoscopic cholecystectomy fiasco that resulted in a dramatic rise in bile duct injuries in the 1990s. Finally, this essay will also examine how continual feedback within this model enables continuous fine-tuning of the system.

THE CONCEPT OF SIMULATION AND SIMULATORS
Simulation has been defined as “the making of working replicas or representations….or the recreation of a situation, environment, etc for demonstration or analysis of problems”. This definition illustrates that simulations are dynamic models that are capable of demonstrating the consequences of different actions upon them. Thus, weather simulations can enable us to predict the pattern of weather over the next few days, and today it can be done in a matter of seconds. A simulator on the other hand is a device that uses simulation to replace a real-world system or apparatus, enabling its users to gain experience and to observe and interact with the simulation via realistic visual, auditory, or tactile cues.

The earliest recorded use of simulators in surgical practice was in 600 BC, when Indian physicians constructed clay and leaf models of the forehead flap that was used for nasal reconstruction. In contemporary practice, simulated surgery involves the use of live animals, cadavers, various bench (i.e. inanimate) models, mannequins and computer simulations. Table 1 shows a classification of the various types of simulators. A point of note is that in the United Kingdom, the Cruelty to Animals Act of 1876 forbids the use of animals to gain proficiency in surgical skills.

Out of the many different varieties of simulators described above, virtual reality (VR), computerized and manikin simulators seem to be the most promising modes of simulation for the future. The foundation for computerized simulation was set by Nicholas Negroponte who introduced the concept of “bits instead of atoms” in his book ‘Being Digital’ to describe how we can represent the real world and the objects within it by a computer or information representation. Negroponte used the example of the facsimile to illustrate his concept. For 4000 years, information was sent from one place to another via actual atoms i.e. on pieces of paper, parchment etc. With the facsimile, however, the same message could be sent instantly by sending bits (of data) over telephone lines rather than ‘atoms’. In 1987, Jaron Lanier introduced “virtual reality” which made interactive image-based simulations a reality. VR is the computer generated representation of an environment that allows sensory interaction, thus giving the impression of actually being present. It requires three components to work: immersion, navigation and interaction.

Less well known is the pioneering work of Gaba et al in the early 1980s with computerized manikin simulators. Today there are a wide range of complicated realistic simulators.
classified as either mechanical, virtual reality or hybrid. Hybrid simulators combine real instruments with physical training models and computer monitoring. Satava has attempted to devise a taxonomy of simulators based upon their functional capabilities as illustrated in Table 2.

**Figure 2**
Table 2: Satava’s proposed taxonomy of simulators based on functional capabilities.

<table>
<thead>
<tr>
<th>Skill</th>
<th>Manual requirement</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision placement</td>
<td>Direct needle/instrument to a point</td>
<td>Intravenous needle placement, spinal anesthetics, needle biopsy</td>
</tr>
<tr>
<td>Simple manipulation</td>
<td>Guide a catheter or endoscope</td>
<td>Coronary angioplasty, endoscopy, ultrasound</td>
</tr>
<tr>
<td>Complex manipulation</td>
<td>Perform a single complex task</td>
<td>Anastomosis, MRI</td>
</tr>
<tr>
<td>Integrated procedure</td>
<td>Perform multiple tasks of entire procedure</td>
<td>Anastomosis, laparoscopy, arthroscopy</td>
</tr>
</tbody>
</table>

**APPLICATIONS OF SIMULATION IN SURGERY**
This section will explore the applications of the new generation of computer and virtual reality simulators. It will not discuss animals, cadavers and simple bench models which also fall under the definition of simulators.

Surgical planning: Prior to surgery, patients often undergo medical imaging (such as an MRI or CT scan). One of the limitations of such imaging is their 2D nature which makes interpretation a challenging task. However, advances in image processing combined with VR technology have enabled the transformation of these 2D images into reliable 3D reconstructions. Nakajima et al reported on their use of such a system to generate 3D images from original CT scans to plan reconstruction in complex craniofacial procedures. An advancement of this technology is what is referred to as patient-specific surgical simulation. This technology enables the surgeon to carry out the surgical procedure on a virtual copy of the patient, allowing evaluation of a surgeon’s ability to perform the procedure. Xia et al have also demonstrated that computer-aided surgical simulation is more cost-effective than the standard methods of surgical planning in cranio-maxillofacial surgery.

Training and education: Due to fiscal restraints, decreasing working hours, the need for objective technical skills assessments and other challenges summarized in Table 3, simulators are rapidly adopting a vital role in the surgical training curriculum. A variety of simulators are available for a range of specialties, the most well known being for minimally invasive and endoscopic procedures. This is probably due to the ease of mimicking reality in such procedures compared to open surgery and also due to the number of complications resulting from the uncontrolled growth of laparoscopic procedures in the early 1990s which created a demand for laparoscopic training tools. The advancements in haptic (force feedback) technology, graphics and tissue modeling have enabled the development of open abdominal and hollow-tube anastomosis simulators.

**Figure 3**
Table 3 A list of factors motivating use of surgical simulators.

- A proliferation of new surgical techniques, technologies and knowledge leading to an ever increasing number of competencies which need to be mastered by the surgeon.
- A recognition of the restrictions on training and gaining competence of the traditional approach of apprenticeship.
- A decrease in the number of trainee working hours imposed by the European working directive in the United Kingdom and recent revisions in the United States.
- An awareness of the ethical implications of practicing on real patients and exposing them to the learning curve of the trainee.
- A desire for new methods of surgical skills training to ensure a level of competence greater than the specific period of time.
- A recognition of the fact that the stressful environment within the operating room (OR) is unlikely to be conducive to learning during.
- A risk that surgical care delivery is a team performance, thus a need for more effective team-based learning methods.

Apart from surgical skills training, simulators have also been used to teach anatomy. Hariri et al compared the use of a VR shoulder arthroscopy simulator in teaching of the anatomy of the shoulder to the use of textbook images. Although the two groups did not display a significant difference in terms of anatomical knowledge, the simulator group rated the simulator significantly higher as a teaching tool than the group in which textbook images were used.

Image guidance: Image guidance systems have been most extensively used in neurosurgery. During neurosurgical procedures it is difficult to locate pathologies in the operating room that have been detected on images taken prior to surgery. For this reason, neurosurgeons have sought methods that allow visualization of underlying brain tissue or relay pre-operative image information to the operating field. Advanced imaging technology, image processing and 3D graphical capabilities have led to the development of surgical navigation systems (SNS) which aid target localization by providing neurosurgeons with pre-operative brain images registered to the patient in the operating room (OR). A further advancement based on augmented reality helps to fuse intraoperative scenes with pre-operatively acquired images. This system permits real-time acquisition of brain images via an open MRI scanner. This provides the surgeon with continuous imaging updates that correct minor
yet critical positional structural shifts of the brain due to craniotomy, cerebrospinal fluid changes and tissue accommodation to the instruments. It also permits data fusion of the video image of the procedure with the MRI image for precision positioning of better than 0.5mm accuracy. \textsuperscript{21}

Telesurgery: This enables a surgeon to carry out a surgical procedure on a patient who is remote from the location of the surgeon. The surgeon relies on a 3D virtual representation of the patient and benefits from dexterity enhancement afforded by the robotic apparatus. \textsuperscript{8}

SIMULATORS IN SURGICAL SKILLS TRAINING: BENEFITS AND CONCERNS

Table 4 summarizes some of the benefits that have been attributed to the use of simulators in surgical training.

![Table 4: Benefits of simulators.](image)

However certain concerns have been expressed with regards to the use of simulators in training and these have been summarized in table 5 with succinct responses to each of them based on current literature.

Concern: Are simulators a reliable and valid method of training and assessment and are simulation based skills transferable to the operative setting?

Response: There is an emerging body of evidence to establish the validity and reliability of simulation techniques for assessing surgical skills. Aucaar et al in a review of surgical simulation with particular attention to validation methodology reviewed 23 studies (incorrectly mentioned as 22 in the body of the article) that contained original comparative data that allowed some assessment of validity of surgical simulation techniques. \textsuperscript{22} The combined data provided evidence of the ability of surgical simulators to serve as objective measures of technical skill level among surgeons thus providing some basis for the use of simulators as training and assessment tools. However due to important inconsistencies between the studies one should temper their acceptance of simulators as training and assessment tools.

Sturm et al on the other hand carried out a systematic review to determine if skills gained in simulation training were transferable to the operative setting. \textsuperscript{22} The study included 10 randomized controlled trials and 1 nonrandomized comparative study. The evidence collated by this team demonstrated that simulation-based training results in skills transfer to the operative setting. However again a note of temperment was called for as the studies included were of variable strength in terms of their evidence.

Concern: Don’t simulators concentrate only on the training of technical tasks of surgery thus overlooking crucial skills such as professionalism and physician-patient communication? \textsuperscript{23}

Response: Kneebone et al have proposed the concept of patient-focused simulator training where simulated patients (i.e. actors pretending to be patients) are used in combination with, for example, an endoscopic simulator. This ensures that the training experience remains rooted in actual practice. The trainee is able to learn the technical skills as well as learning how to communicate with the patient during the procedure. \textsuperscript{24}

Concern: Are more realistic simulators the most crucial factor in determining how well a simulator performs?

Response: Although fidelity (the degree to which a simulator approaches reality) may be desirable in a simulator, it seems that when it comes to skills and procedure training, the more important requirement is for the simulator to mimic the “key constructs” of the task. \textsuperscript{25} However fidelity may be more important when it comes to using simulators in team training and other such practices where the more realistic the environment the more likely it will contribute to effective training.

Concern: How does one incorporate the use of simulators into a surgical training curriculum?

Response: Much has been written about simulators and how they should be incorporated into a surgical curriculum. There is general agreement that simulators should be used as an adjunct to time in the OR rather than the sole mode of training for obvious reasons. There has also been agreement that the curriculum should cover both generic professional and specialty specific areas. Several proposals have been made for curricula which incorporate simulators with Aggarwal et al proposing a simplistic and feasible curriculum for surgical training which incorporates the use of simulators as shown below: \textsuperscript{26}
This section will propose a stepwise mechanism of how simulators should be introduced into surgical training; from the design of simulators to their incorporation into surgical curricula. Figure 2 provides a summary of the model. It is believed that such a model would help to maintain quality-control which at times is circumvented by the sheer enthusiasm to embrace new technology at the hint of some benefit to patient care. This is important if we are to avoid fiascos such as the aforementioned surge of bile duct injuries in laparoscopic cholecystectomies performed in the 1990s. In addition, it will help us to gain an insight into thinking of simulation in surgery in a new perspective. This perspective, where the interlinked nature of surgical training as shown in figure 1 enables feedback loops, will serve to continually improve the system.

**Figure 6**
Figure 1. Proposed theoretical model of interrelationship which helps maintain quality control with feedback loops to help continually improve the system

Design of simulators: The design of simulators is of vital importance as the closer it is to resembling the actual procedure the more useful it will be as a training tool when performing the procedure on a real patient. A vast majority of simulation design and construction is carried out by commercial companies and corporations (e.g. the MIST-VR, a laparoscopic simulator, is a product of Mentice, a Swedish corporation). The problem with this is that companies are
primarily motivated by profit and are not completely in
touch with the skill requirements of surgical procedures.
This means that they are likely to aggressively market their
products prior to adequate validation. They may also
develop sub-optimal simulators holding back the progress of
simulator design. To overcome the first problem cited above,
regulations must be introduced which require validation of a
simulator’s capability prior to its incorporation into a
surgical curriculum. The second problem could be addressed
by introducing surgeons, who are aware of the technical
requirements of a procedure, into the design team. This will
ensure that these companies produce simulators closely
resembling the actual procedure. However it must be borne
in mind that this might give rise to conflicts of interest on
the surgeon’s part.

Validity and reliability: Once the ‘ideal team’ for simulator
design builds the ‘ideal simulator’, it then needs to have its
validity and reliability tested. Validity is a concept that
developed within the field of psychometrics to measure the
extent to which a test measured what it purported to
measure. A number of benchmarks have been developed to
assess validity and they are summarized in table 6.

**Figure 7**
Table 6 Benchmarks to assess validity of a test.

- **Face validity** (reality) — the extent to which the test resembles the situation in the “real world.”
- **Content validity** — the extent to which a measurement reflects the trait or domain it purports to measure. For example, an assessment of a resident who performed a laparoscopic cholecystectomy on an anaesthetized pig has high content validity as a measure of a surgical skill that does a multiple-choice examination on the anatomy of the gall bladder.
- **Construct validity** — describes the agreement between a theoretical and a conceptual assessment tool. For example, to demonstrate that a new simulator has construct validity as a measure of technical performance, more senior surgeons should score higher on its assessment parameters than more junior trainees.
- **Criterion validity** — refers to the extent to which an assessment tool correlates with other measures of performance. There are different types of criterion validity but for our purpose predictive validity is the most useful. Predictive validity is the ability of a tool to predict future performance, for example the ability of performance on the Minimally Invasive Surgical Trainer – Virtual Reality (MIST-VR) to predict future performance as a surgeon.

This concept of validity has to be applied to simulators
before they are incorporated into a surgical training
curriculum. The minimum requirement to be accepted as an
approved simulator for training should be if the device
displays construct validity (i.e. it is able to differentiate
between an experienced senior surgeon and one who is more
junior). Face validity or content validity alone is insufficient.
Table 7 proposes a classification of what is sufficient for
approval and what is not.

**Figure 8**
Table 7: Proposed benchmarks of validity that a simulator
needs to attain to be incorporated into a surgical skills
program.

Another concept that needs to be taken into account is
reliability. Reliability is a measure of a test to generate
similar results when applied at two separate points. When
applied to simulators, it means the ability of a simulator to
give a similar result when two surgeons of a similar level of
experience use it or if the same surgeon uses it twice with no
enhancement of skills in between go’s.

The development of a variety of simulators with a range of
skills testing means that each simulator would have to have
its own validation parameters determined. There have been
significant efforts towards increasing the rigor of the
scientific evaluation of simulation technology by
international workshops aimed at standardizing the
definitions and taxonomy of terms used in surgical
assessment.

Development of a curriculum to incorporate simulators: As
Satava notes: “as important as these first steps are in the
development of surgical simulators, the real fundamental
issue is not the simulator; rather, it is the curriculum. The
simulator is just another tool, and it is the curriculum that
will determine the training of the surgeon”. However prior
to construction of a curriculum that integrates simulators
onto a surgical training program we need to address some
important issues. These issues include:

The American college of surgeons, in a bid to introduce
simulation into general surgical training has already
established 18 basic surgical skills that are required by
general surgery residents in postgraduate training years 1
and 2 which are shown in table 9. This type of criteria,
clarifying what skills should be in the armamentarium of the
trainee at the various stages of training, needs to be
established for the remainder of the program and also for
other surgical specialties.
In terms of the level of technical expertise required, it is now understood that training to reach a defined level of expertise is more important than training for a defined length of time.

The challenge is to provide an objective definition of expertise which enables us to determine that a trainee possesses sufficient expertise to practice independently.

A number of new developments, such as the Imperial College Surgical Assessment Device (ICSAD) and the advanced Dundee Endoscopic Psychomotor Trainer (ADEPT), enable a more objective approach to measurement of competence. A number of other tools to measure competence have also been designed and summarized in Table 8.

Table 8: Recently developed objective methods of measuring competence.

- Checklists
- Global rating scales, such as OSATS (objective structured assessment of technical skills)
- Dichotomous analysis systems, such as ISAM (Imperial College surgical assessment device), ADEPT (advanced Dundee endoscopic psychomotor trainer)
- Virtual reality simulators
- Analysis of final product on bench models
- Error scoring systems

In terms of errors, a system of error scoring has to be developed. A number of proposals for error scoring systems have been put forward by different authors. Error scoring systems with feedback are important as the same error maybe repeatedly performed unless the individual is corrected.

Once these measures have been determined, a curriculum can be developed to incorporate simulators into surgical training. In order to attain optimal benefit, the curriculum needs to be based on one or a combination of the theories of motor skill acquisition, as well as incorporate educational theorists and other professionals who work with the surgeon (i.e. it needs to be a multidisciplinary team).

CONCLUSION

The concept of quality control in this essay adopts the more generalized definition provided by Melia, namely that quality control involves methods used to maintain and enhance quality. This is vital in an era when several new technological products are being introduced into surgical practice without being carefully vetted prior to their introduction. The introduction of laparoscopic cholecystectomy in the 1990s throughout the Western world, in a rapid and uncontrolled fashion leading to a dramatic increase in bile duct injuries, bears important lessons for us to learn. It may be argued that laparoscopic surgery is a patient intervention while simulation has to do with training surgeons and thus bear no resemblance to each other. However simulators can be thought of as indirect interventions on patients, as the surgeons who will be operating on these patients are trained on such systems. If at any point in the chain of quality control proposed above, from simulator design to its incorporation into curricula, standards are not met, it would have a detrimental effect on patients. Thus, there is an onus on the medical and associated disciplines to ensure that any new technology introduced into this discipline meets a set of criteria for acceptance.

The model also provides an insight as to how feedback loops based on outcome measures within the system can lead to continual improvement of simulators and curricula. This allows us to think of simulation within surgical training as a complex adaptive system where feedback loops provide opportunities for change while maintaining a stable environment for training. The complex adaptive system of simulation in surgery is embedded within the field of surgery which is in turn embedded within the healthcare system. This allows us to view simulation in a much wider context. The model proposed above could be expanded to include other systems such as finance, healthcare policy etc. This will enable us to understand the effect of these systems on simulation within surgical training. This holistic view may be the next step to significant progress in the field of simulation in surgical training and surgery as a whole.
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